Healthcare Improvement Scotland is committed to equality. We have assessed the review process for likely impact on equality protected characteristics as defined by age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex, and sexual orientation (Equality Act 2010). You can request a copy of the equality impact assessment report from the Healthcare Improvement Scotland Equality and Diversity Officer on 0141 225 6999 or email contactpublicinvolvement.his@nhs.net
## Contents

Executive summary ........................................... 4

1 Introduction ............................................. 8

2 Scottish Ambulance Service adverse event management policies and procedures .......... 10

3 Detailed review findings ................................. 13

Appendix 1 – Details of review team ...................... 31
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 the Scottish Ambulance Service’s governance arrangements and processes for managing adverse events involved:

- an analysis of evidence provided by the Scottish Ambulance Service, and
- a visit to the Scottish Ambulance Service on Thursday 22 August 2013.

The Scottish Ambulance Service has processes and systems in place for the management of adverse events. This includes the electronic system, Datix, for recording adverse events. The Service has had processes in place to manage adverse events since 2004. However, it recently implemented a new system to manage significant adverse events. The Service reported that it has made significant efforts to improve how it manages significant adverse events. This includes new procedures to support risk-based and transparent decision-making and notification to the family or carers. The Service informed us that its new policy is currently being embedded across all aspects of patient care.

We noted the following areas of good practice within the Scottish Ambulance Service:

- comprehensive policy for managing significant adverse events
- positive culture for reporting adverse events and near misses
- active involvement of the chief executive in the adverse event management process
- regular discussion on significant adverse events at governance meetings, and
- examples of good practice in sharing adverse event cases with relevant NHS bodies.

The review team identified areas which the Scottish Ambulance Service should improve to ensure consistent management of significant adverse events. These include family engagement and feedback to staff, staff input to action plan development, timely investigations and the sharing of wider learning.
We identified aspects of the adverse event process that the Scottish Ambulance Service should improve to help ensure staff follow a consistent process. The recommendations below aim to support this. We encourage the Service to fully embed the new policy (2013) so it can demonstrate that staff consistently apply the policy guidance.

**Recommendations**

We expect the Scottish Ambulance Service 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 Service 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.

The Scottish Ambulance Service’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 and capture their feedback to support investigation reporting and outcomes of adverse events
2. ensure a consistent approach to patient, family and carer involvement where appropriate. If involvement does not take place, the Scottish Ambulance Service should record the rationale for not doing so
3. demonstrate that staff receive appropriate documentation and feedback following an adverse event, including updates on progress and outcomes from the review, and
4. introduce a process to involve staff in the development of action plans, where appropriate.

**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, the Scottish Ambulance Service should:

5. provide support to staff to allow them to access or attend relevant training on adverse event management, and
6. assess the impact of training, to support staff to have the skills and knowledge necessary to appropriately record or review adverse events.
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, the Scottish Ambulance Service should:

7. make sure the appropriate governance groups receive sufficient and timely information on learning outcomes from adverse events, and

8. review the information provided to the Board to ensure it receives an appropriate level of detail on adverse events, which will allow it to fulfil its governance role.

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, the Scottish Ambulance Service should:

9. introduce a process to verify that all significant adverse events are captured on the Datix system

10. introduce a procedure to consistently use version control on investigation documentation, and

11. implement a process to capture thematic learning from adverse events.

Risk-based, informed and transparent decision-making

**Recommendation 22 from the NHS Ayrshire & Arran report**

NHS boards should ensure that the decisions related to the management of significant adverse events are risk based, informed and transparent to allow appropriate level of scrutiny and assurance.

To support a risk-based, informed and transparent approach, the Scottish Ambulance Service should:

12. provide support to adverse event reviewers to allow them to undertake investigations in line with policy deadlines.
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, the Scottish Ambulance Service should:

13 strengthen the process for monitoring adverse event management timescales, review reasons for any delays and ensure timescales are met

14 continue to monitor the completion of action plans, and where an action plan is not necessary, the Scottish Ambulance Service should document the rationale for this, and

15 embed a culture of capturing and sharing lessons learnt across the organisation, supported by a system that provides evidence of discussion at meetings and through feedback mechanisms.

We have asked the Scottish Ambulance Service to develop an improvement plan to address the identified recommendations.

We would like to thank the Scottish Ambulance Service and in particular staff involved in our discussions 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 the Scottish Ambulance Service in advance of the visit. This included:

- policies and procedures for adverse event management
- governance and reporting arrangements
- an assessment of the Scottish Ambulance Service’s current and future planned approach following the recommendations of the NHS Ayrshire & Arran report
- a list of 14 recorded significant adverse events over the past 18 months, and
- details of four specific significant adverse event reviews.
1.1.8 Of the 14 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 22 August 2013. The review team was made up of a number of individuals with relevant specialist knowledge from across Scotland (see Appendix 1 for membership of the review team).

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

1.1.11 We discussed the initial findings of our report with the Scottish Ambulance Service chief executive on Tuesday 17 September 2013.

**Improvement plan**

1.1.12 We expect the Scottish Ambulance Service 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 the Service 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 The Scottish Ambulance Service’s adverse event management policies and procedures

2.1.1 The Scottish Ambulance Service is a special health board providing a national service to all of Scotland. It provides an emergency ambulance and patient transport service for patients in remote, rural and remote communities across Scotland. The Scottish Ambulance Service is split into five regional divisions: north, east central, south east, west central and south west. The national headquarters is based in Edinburgh. The Service has three ambulance control centres. These centres dispatch responses to 999 calls, arrange patient transport services to hospitals and manage air ambulance response.

Adverse event definitions

2.1.2 The Scottish Ambulance Service defines a significant adverse event as:

“Any event that resulted in the unexpected death or significant harm (harm includes negative physical and emotional impact) to a patient.”

2.1.3 The Service has identified the top five themes for significant adverse events as:

- clinical assessment
- response related (resource allocation of staff)
- response related (delays)
- ambulance control centre related (categorisation of calls), and
- patient falls.

Policy for managing adverse events

2.1.4 Before May 2013, the Scottish Ambulance Service had a management of health & safety accident and incident reporting procedure (December 2010). This included definitions, responsibilities, guidance on reporting accidents or incidents, accident investigation, and an audit tool. The Service informed us that this guidance related to all incidents. However, the document was more focused on reporting and managing accidents, particularly against the injuries, diseases and dangerous occurrences regulations (RIDDOR) to the Health and Safety Executive. The document did not include guidance on how to support patients, families and staff involved in adverse events, action planning, monitoring and sharing lessons learnt.

2.1.5 Following publication of the NHS Ayrshire & Arran report, the patient safety learn and improve group took forward the recommendations from the report and liaised with other NHS boards to share best practice and learning. The group developed a framework document for the management of significant adverse events: directorate of health professions and nursing care patient safety learn and improve management and review of significant adverse events (May 2013). This document is hereafter referred to as the ‘policy (May 2013)’. Although the document is dated May 2013, the Service did not formally launch the policy to staff until 1 July 2013.

2.1.6 The policy (May 2013) is due for review every 2 years. The policy is a comprehensive document containing the following sections:
• scope and purpose
• commitment to patients and families involved in significant adverse events
• commitment to staff
• supporting staff
• definitions and supplementary definitions
• significant adverse event review process timeline
• procedure
• process flow chart
• review process
• guidance for each level of review
• transfer to disciplinary or conduct process
• monitoring reviews and action plans
• sharing lessons learnt
• document control and retention, and
• roles and responsibilities.

2.1.7 The policy (May 2013) appendices include templates for recording adverse events, forms for particular levels of review, action plan template, chronology form, investigation tools and an incident decision tree flow chart. Appendix 6 of the policy includes comprehensive guidance on being open with patients and families, based on the National Patient Safety Agency guidance: *Being Open: Communicating Patient Safety Incidents with Patients and their Carers* (2009).

2.1.8 The policy (May 2013) includes the following statement:

“Ensuring patients are treated safely is our top priority. Effective reporting and analysis of Significant Adverse Events (SAE) allows the organisation, you and your team to highlight and learn from both strengths and weaknesses in the care we provide. Improving the quality and safety of patient care is a key clinical governance priority in healthcare and SAE reporting has an important role in contributing to this aim. This guidance on identifying, reporting and learning from SAEs will help us to focus on reliable, safe and effective systems of care allowing you and your team to provide the best care every time for patients and their families or loved ones.”

2.1.9 On 1 July 2013, the Scottish Ambulance Service formally launched the policy to staff. Staff we spoke with on the visit were aware of the policy and knew where to find it. While the Service had procedures for managing adverse events in the past, it acknowledged it is in the early stages of implementing a comprehensive management process for significant adverse events, as set out in the policy (May 2013).

2.1.10 The Service is currently working to embed the policy across the organisation. This includes promoting it through the intranet, staff notice boards, divisional management teams and patient safety walkrounds.
Governance arrangements

2.1.11 The policy (May 2013) documents the roles of the governance committees relating to the management of adverse events (see page 18 for detailed information).

2.1.12 Figure 1 below outlines the governance arrangements in place for managing adverse events.

Figure 1: The Scottish Ambulance Service governance structure for adverse events
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 accident and incident reporting procedure (December 2010) did not include any guidance on engaging with patients, family or carers involved in adverse events.

3.1.2 The Scottish Ambulance Service informed us of the unique and complex nature of its operations as a special health board. Service staff usually have a short period of contact with the patient or family before transferring care to the receiving NHS board. If an adverse event is reported and managed by another NHS board which involves the Scottish Ambulance Service, there can be a delay in the Service being notified. Given the short period of time the Scottish Ambulance Service provides care to the patient, it can be challenging to subsequently find family or carer contact details. These details may not have been given to the Service during the period of care.

3.1.3 Following publication of the NHS Ayrshire & Arran report, the Scottish Ambulance Service reviewed how it managed stakeholder involvement. The new policy (May 2013) includes detailed guidance on how staff should engage with patients, families and carers. The policy states that:

“The Scottish Ambulance Service recognises the considerable impact that such an adverse event will have on patients and/or their carers/family. The organisational response to such an event will be compassionate, transparent, honest, timely and consistent with a focus on the needs of the patient and/or carers/family.”

3.1.4 The policy (May 2013) includes details of what patients, families or carers can expect when a significant adverse event occurs:

- “We will keep them informed of our actions from the time that the adverse event happens through to the point when we have identified the learning and improvements to be made
- we will communicate with them respectfully and honestly, in a way that compassionately acknowledges and recognises the emotional impact of the adverse event on the patient and their family
- we will support them by providing a consistent named contact person
- we will work with them to involve them in the review process, taking account of their preferences and providing them with the opportunity to share details of their experiences with staff to support their learning, and
- we will provide them with a sincere and honest apology for identified failings.”

3.1.5 The policy (May 2013) includes a checklist which guides staff to undertake significant adverse event reviews within set timescales. This includes deadlines for staff to notify
the family following the event, to agree who will liaise with the family, and for offering to meet with the family.

3.1.6 The patient safety learn and improve group identifies a suitable member of staff to undertake the family liaison role.

3.1.7 Appendix 6 of the policy includes a detailed ‘Being Open’ policy and procedure based on the guiding principles recommended by the National Patient Safety Agency. The being open guidance refers to the Scottish Ambulance Service having a cross section of family liaison officers to communicate with patients, families and carers.

3.1.8 The Service informed us that its complaints and commendations system, Viewpoint, is used to capture patient complaints and feedback. The Service is also one of seven NHS boards piloting the online patient opinion portal. The portal is a dedicated website that patients can use to provide feedback.

3.1.9 The Service informed us that it has a system for tracking contact made by patients, families or carers and responding to issues they raise.

3.1.10 Three of the cases we reviewed occurred before the policy (May 2013) was introduced. Two out of these cases had no evidence of patient or family engagement. On the visit, staff told us that they had not considered involving the family at the time of the incident, as the adverse event had no impact on the patient’s condition. However, if similar incidents were to happen again, they would now engage with the patient and family in line with the policy (May 2013) guidance.

3.1.11 The third case included a meeting with the patient and family and a follow-up letter. The patient and family agreed that the Service would forward their concerns to the clinical department to allow a review to be carried out to identify lessons learnt. The letter also noted that the family did not require any further action to be taken.

3.1.12 The fourth case occurred at the time the new policy (May 2013) had been drafted. Staff involved followed the new policy guidance when undertaking the adverse event review. The Service contacted the family involved. The case documentation records that the family did not want any further contact and did not want to receive feedback following the investigation.

3.1.13 The Service reported that it is working to improve how it engages patients, family and carers involved throughout the adverse event management process. The Service would normally send a letter offering to meet with the family and ask if they would like feedback on the outcomes of the investigation. Under the Service’s complaints procedure, the family is offered a copy of the investigation report within the letter. However, it is not standard practice for families involved in adverse events to be offered a copy of the report, unless they request it. For a recent case, the Service informed us it offered the family the opportunity to include questions they would like asked within the investigation.
**Staff involvement**

3.1.14 The accident and incident reporting procedure (December 2010) did not include any guidance on support for staff involved in adverse events. However, the Service has an employee assistance policy in place to provide confidential advice and support for staff. Counselling is also available for staff where required. On the visit, staff confirmed that counselling was offered to them following an adverse event.

3.1.15 The policy (May 2013) states:

“Current thinking suggests that the causes of incidents cannot simply be linked to the actions of individual people, but are usually the result of system-wide issues. The Scottish Ambulance Service wants to encourage and support staff to do the right thing, first time and every time. The process is not designed to apportion blame, indeed no-one should be disciplined for making an honest mistake. But it is important for both individuals and organisations to learn from these mistakes, especially so when they are significant in nature.”

3.1.16 The policy (May 2013) further states:

“The Scottish Ambulance Service recognises the importance of staff governance as a feature of high performance which ensures that all staff have a positive employment experience in which they are fully engaged with both their job, their team, and their organisation. Achieving such an outcome will not only have a positive impact on organisational performance (and therefore on the quality of the services we provide), it is also an important component in providing all employees with dignity at work. For staff, the Staff Governance Standard, together with existing staff Codes of Conduct, sets out the responsibilities, standards of performance and behaviours expected. Our approach to supporting staff through significant adverse events will reflect these aims and has been agreed in partnership with staff through the National Partnership Forum.”

3.1.17 The policy outlines the Scottish Ambulance Service’s commitments to staff when a significant adverse event occurs:

- “We will ensure that you are safe and fully supported throughout the process
- we will communicate with you respectfully and honestly, in a way that compassionately acknowledges and recognises the emotional impact the event may have had on you. This communication will be provided by a named contact person
- we will involve you in the review process, listening to your experience and ensuring this informs the process and the resultant learning
- we will ensure that the review is completed thoroughly, openly, non-judgementally and as quickly as possible
- we will keep you informed of progress of the significant adverse event review, through your named contact, from the time that the event happens through to the point when we have identified the learning and improvements to be made, and
- we will ensure you receive feedback on the findings, recommendations and wider learning.”
3.1.18 The being open section of the policy states that: “The Service encourages staff to seek support from their relevant regulatory / professional body such as the Healthcare Professions Council of Paramedics.”

3.1.19 The Service has a serious incident escalation procedure (dated November 2010). This procedure is linked to the policy (May 2013) and continues to be applied across the NHS board. The procedure advises that the situation, background, assessment and recommendations format be used for staff briefings. It also states that: “a structured debrief will follow the incident as soon as practicable.”

3.1.20 The Service reported that structured debriefs for staff following adverse events have been in place for several years. A number of staff have been trained to deliver these debriefs. The evidence provided by the Service did not include staff debrief documentation.

3.1.21 All four cases we reviewed had evidence of staff involvement, although the degree of engagement was limited to initial meetings and staff statements.

3.1.22 In general, staff we spoke with felt they were supported during the adverse event process. However, some staff did not receive formal feedback or a copy of the final report following the adverse event investigation.

3.1.23 In one of the cases, staff who reported the adverse event were not aware of what happened after they recorded the event. They told us they would like to be kept informed of the progress of investigations and alerted to possible actions and improvements arising from the event.

3.1.24 At the time of the visit, the south east division was carrying out a pilot to improve communication to staff following an adverse event or near miss. This includes training team leaders to review adverse events.

3.1.25 None of the cases we reviewed had evidence of operational staff input to investigation reports or action plan development. This was confirmed through discussions with staff on the visit. Operational staff told us that they would find it useful to be involved in developing and agreeing actions following adverse event reviews.

3.1.26 Staff informed us that the culture for reporting and managing adverse events has been improving. We noted that all staff we spoke with had a positive attitude towards reporting adverse events.

**Recommendations**

The Scottish Ambulance Service’s active and planned approach to engaging with key stakeholders, particularly the patients, family and carers affected by a significant adverse event, should:

1. always consider involving patients and family in the review process and capture their feedback to support investigation reporting and outcomes of adverse events
2. ensure a consistent approach to patient, family and carer involvement where appropriate. If involvement does not take place, the Scottish Ambulance Service should record the rationale for not doing so
3. demonstrate that staff receive appropriate documentation and feedback following an
adverse event, including updates on progress and outcomes from the review; and

4 introduce a process to involve staff in the development of action plans, where appropriate.

3.2 Staff knowledge and training

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

3.2.1 The policy (May 2013) has limited reference to staff training and does not mention specific training courses or learning mechanisms available to staff. The accident and incident reporting procedure (December 2010) had no reference to staff training. The Scottish Ambulance Service informed us that a training course prospectus is available to staff through the intranet site. This includes application forms for various risk management and Datix courses.

3.2.2 The Service informed us that staff have access to e-learning packages, which guide them on how to report adverse events using Datix. Training on Datix is not mandatory. Staff can access training on request or can speak to the Datix administrator if they need support. Staff may request face-to-face training if they prefer this format. Managers who review adverse events can also access specific face-to-face training. Managers are expected to cascade training to their staff as required.

3.2.3 The Service has a training academy for ambulance staff located within Glasgow Caledonian University’s campus. The academy provides a realistic training environment and the opportunity for students to simulate the types of situations that they may encounter in practice. All students attending the academy receive training on Datix and risk management. The university’s undergraduate programme also features training for clinical students on how to report adverse events. The Service reported that all newly qualified clinicians receive training in reflective practice to support them to learn from previous experience.

3.2.4 The majority of staff we spoke with had received training in the use of Datix either through e-learning, induction or through training in other organisations. We noted that while staff were aware of how to record adverse events, they were not always aware of the appropriate use of Datix and what events should or should not be recorded.

3.2.5 The policy (May 2013) states:

“The PSL&I co-ordinator will agree with the reviewing officer who should conduct the patient safety event analysis, this person will have had formal training to enable them to conduct this.”

3.2.6 In April and May 2013, the Service provided training on root cause analysis, which included training on being open, to approximately 50 additional managers. It plans to deliver another course in December 2013 to a further 30 staff. On the visit, staff who attended the training provided positive feedback on the quality and comprehensiveness of the course. The majority of adverse event reviewers we spoke with on the visit had attended the training.”
3.2.7 The Service also reported that it has trained a group of managers to fulfil the role of family liaison. This is supported by a standard operational procedure for family liaison.

3.2.8 The risk manager maintains a database which records staff access to e-learning packages and training courses. The clinical incident and clinical risk report to the clinical governance committee features an update on risk management training for staff, as a standing agenda item.

3.2.9 Staff informed us that they sometimes find it difficult to find the time to access training due to ongoing work commitments. We noted that staff might benefit from dedicated time to undertake training.

**Recommendations**

To support staff knowledge and training, the Scottish Ambulance Service should:

5 provide support to staff to allow them to access or attend relevant training on adverse event management, and

6 assess the impact of training, to support staff to have the skills and knowledge necessary to appropriately record or review adverse events.

### 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.**

**Roles and Responsibilities**

3.3.1 The policy (May 2013) states that:

“All staff have a responsibility to report incidents and take appropriate remedial action where necessary.”

3.3.2 The Service also asks staff to “ensure that you seek to fully understand the revised process and support its implementation within your area of work.”

3.3.3 Where staff are required to participate in a review process, the policy (May 2013) expects staff to:

- “Fully and actively engage throughout the process from initial review to developing and delivering improvement plans and identifying learning
- communicate openly, respectfully and honestly with everyone involved
- operate within all relevant professional code of conducts as well as the Service’s code of confidentiality
- fully implement any learning and education relevant to your role or sphere of practice, and
- identify if you need help and support and accept this when it is offered.”
3.3.4 The policy (May 2013) includes specific roles and responsibilities of staff broken down by job function. Our discussions with staff on the visit confirmed that staff were aware of their roles within the adverse event review process.

**Governance groups**

3.3.5 The policy (May 2013) documents the roles of the various governance committees relating to the management of adverse events.

3.3.6 In early 2012, the patient safety learn and improve group was established to: “ensure lessons learnt from incidents, complaints, claims and comments are captured, reported and learnt from as part of Service policy and procedures.” The group is chaired by the director of health professions and nursing care, and reports into the risk management steering group. The patient safety learn and improve group is responsible for overseeing the significant adverse event process to provide assurance to the Board. The group compiles 3-monthly statistical reports for governance committees detailing the status of all reviews and their subsequent action plans. It also provides an executive summary for all completed reviews to staff and clinical governance committees.

3.3.7 The risk management steering group analyses all high and very high incidents, risk logs, corporate risk register, clinical and non-clinical incidents. It also reviews key performance indicators, performance management of Datix, safety and risk alerts, infection control, and complaints and claims.

3.3.8 The clinical governance committee reviews the 3-monthly statistical reports (clinical incident and clinical risk reports) to assure the Board that appropriate investigations are taking place. The committee also reviews the clinical risk register, complaints, compliments, concerns and comments, and the clinical performance report. The clinical performance report includes divisional operational reports with information on individual critical incident reviews, actions taken in response and any lessons learnt. The report also includes updates on key clinical risks, objectives and operational delivery against them. For example, patient falls, cardiac arrest and major trauma. The audit committee also receives the 3-monthly statistical report.

3.3.9 Divisional clinical governance and quality groups analyse clinical incidents every 2 months. Local and national health and safety committees discuss non-clinical incidents every 3 months. The national clinical governance group reviews signed-off investigations and action plans to confirm the investigation has identified root causes and appropriate learning.

3.3.10 The Board receives reports on significant adverse event reviews including themes and trends.

3.3.11 We saw evidence of individual significant adverse event cases being discussed at various governance meetings across the Scottish Ambulance Service. This includes the clinical governance committee, risk management steering group and audit committee. However, we noted that the information provided on learning outcomes may not be sufficient to provide assurance to these governance groups.

3.3.12 The Board receives information on risk management updates and adverse event trends. However, the Scottish Ambulance Service acknowledged that the Board would like to see more information on adverse events. At the time of the visit, the Service was
considering the level of detail required to assure the Board that adverse events are appropriately managed.

3.3.13 The medical director has overall responsibility for clinical governance. The Scottish Ambulance Service should monitor the adverse events management process to ensure there is a balanced approach between medical and nursing leadership.

3.3.14 The chief executive signs off complaint response letters. The policy (May 2013) includes a process for the chief executive to also sign off significant adverse event reviews. The review team noted good practice with the chief executive being actively involved in the adverse event management process.

Recommendations
To ensure clear functions and roles, the Scottish Ambulance Service should:

7 make sure the appropriate governance groups receive sufficient and timely information on learning outcomes from adverse events, and

8 review the information provided to the Board to ensure it receives an appropriate level of detail on adverse events, which will allow it to fulfil its governance role.

3.4 Information management

NHS boards should ensure that their document control and related information systems are suitably integrated and robust to provide a complete audit trail of significant adverse event management from the incident occurring to evidencing change and improvement. These systems should also allow NHS boards to undertake ongoing thematic learning from significant adverse events.

3.4.1 In 2004, the Scottish Ambulance Service introduced the electronic reporting system, Datix to record adverse events. The system included the incidents, risks, complaints and claims modules. In February 2008, the Service rolled out a web-based version of Datix.

3.4.2 Over the years, the Service has made a number of upgrades to the system. This includes changes made in response to staff feedback. In early 2012, the Service distributed a staff survey to gather feedback on the use of Datix. An improvement plan was developed in response to the survey results. Improvements included streamlining the recording form to remove duplicate questions and to focus on relevant information.

3.4.3 The Service recently upgraded to version 12.1 of Datix to improve the functionality of the actions module.

3.4.4 Staff can access Datix through the intranet site. Our discussions with staff confirmed that various levels of staff use Datix to record adverse events, including paramedics. The Service informed us that first responders use a paper-based version of the record form to report adverse events or near misses. Their line manager then records the event on Datix.

3.4.5 The Scottish Ambulance Service has a separate system, Viewpoint, for capturing complaints and patient feedback. The two systems are not electronically linked. Staff use a specific code within the complaint name on Viewpoint, to show that it is also recorded.
as an adverse event on Datix. Three of the four cases we reviewed were recorded on Datix, while the fourth was only recorded on Viewpoint.

3.4.6 The Service informed us that if a significant adverse event is initially recorded on Viewpoint, the risk department would usually be made aware of this and would record it separately on Datix. The significant adverse event process would then run in parallel to the complaints process.

3.4.7 We identified the need for a process to verify that all significant adverse events are consistently captured on the Datix system. This should include adverse events which are initially identified through the complaints process. This will help ensure identification of learning and trends and help reduce the likelihood of the event happening again.

3.4.8 The accident and incident reporting procedure (December 2010) stated that: “All relevant documents (statements, photographs, RIDDOR forms, etc) must be uploaded onto the DATIX system as electronic documents.”

3.4.9 The policy (May 2013) states that:

“The PSL&I group will be responsible for maintaining a records database recording all significant decision points. In addition to this the PSL&I group shall maintain all records associated with this process in a secure environment appropriate for patient records.”

3.4.10 The Service informed us it has a dedicated work area on the intranet which reviewers use as a central repository during the review process. The policy (May 2013) requires that all significant adverse event review information: “is documented and stored within the work area site and once complete all uploaded to Datix.” The risk manager uploads the final adverse event report to Datix after removing any patient identifiable information.

3.4.11 The being open guidance states:

“Throughout the Being Open process it is important to record discussions with the patient, their family and carers as well as the incident review process.” The policy includes examples of what information should be formally recorded following discussions with the patient, family and carers.”

3.4.12 All four cases we reviewed had evidence of documents appended to the Datix or Viewpoint record.

3.4.13 The policy (May 2013) does not include guidance on version control. For example, the need to include the date, author and version number on adverse event documentation.

3.4.14 Only one of the cases showed evidence of version control in use on all relevant documentation. In two other cases, some of the documents had version control. The fourth case had dates on the documents, but no evidence of document author or version number.

3.4.15 The Service informed us that staff who are not involved in the adverse event would usually only get access to the final report if there is good reason for them to see it. This is to protect patient or staff confidentiality.
Thematic learning

3.4.16 The policy (May 2013) does not detail how thematic learning is identified.

3.4.17 The Datix record template includes a linked records section which “allows you to link other incidents or risks to this incident to help identify trends (e.g. same patient, category, time of day/week).”

3.4.18 The Scottish Ambulance Service informed us that it recently added a question to Datix to record whether the adverse event was significant to help identify trends and themes.

3.4.19 The sharing lessons learnt section of the policy (May 2013) states that:

“A review executive summary should be published and circulated for each incident containing learning points which should be grouped and themed to help readers identify points applicable to their team, service, speciality or division or wider organisation.”

3.4.20 The clinical governance committee receives the clinical incident and clinic risk report as a standing agenda item. The report includes graphs of all clinical incidents reported on Datix since 2006, by grading, and top 10 categories for the latest 3 months. The minutes of the September 2012 national clinical governance committee meeting showed complaints and commendations, including lessons learnt, being discussed.

3.4.21 In November 2012, the clinical governance committee was provided with an update on a review of complaints undertaken by corporate affairs. The review identified no particular trends in complaints in terms of area, station or patient group involved. Overall, delayed response was a key issue and the meeting minutes referred to ongoing monitoring and staff awareness-raising.

3.4.22 We did not see evidence of a similar trend analysis exercise for adverse events. Information on adverse events is co-ordinated and shared through the patient safety learn and improve group to support thematic learning. At the time of the visit, the group was developing adverse event theme analysis to help identify thematic learning.

3.4.23 Our review of the cases demonstrated some examples of changes made in response to adverse events, including the introduction of standard operating procedures and reviews of existing practice.

3.4.24 In general, staff were aware of improvements introduced by the Scottish Ambulance Service as a result of adverse events. On the visit, staff told us that issues arising from adverse events, such as patient transport issues, are regularly discussed at team meetings and on training courses. However, staff acknowledged that this is not standard practice across all areas of the organisation.

3.4.25 The Scottish Ambulance Service has an arrangement in place to share an adverse event Datix record with the National Waiting Times Centre where it concerns both organisations. The National Waiting Times Centre also has a link on its intranet site to allow staff to record relevant adverse events directly onto the Scottish Ambulance Service Datix system. The Service is currently working to create similar sharing arrangements with other NHS boards. We identified this as good practice.
Recommendations
To support its information management processes, the Scottish Ambulance Service should:

9 introduce a process to verify that all significant adverse events are captured on the Datix system
10 introduce a procedure to consistently use version control on investigation documentation, and
11 implement a process to capture thematic learning from adverse events.

3.5 Risk-based, informed and transparent decision-making

**NHS boards should ensure that the decisions related to the management of significant adverse events are risk based, informed and transparent to allow appropriate level of scrutiny and assurance.**

**Identification, notification and initial event reporting**

3.5.1 The policy (May 2013) dictates that staff should inform their line manager or duty manager when an adverse event occurs. The line manager or duty manager is responsible for informing the general manager (in-hours) or on-call general manager (out-of-hours).

3.5.2 The policy (May 2013) states:

“It is assumed that any event involving death or serious harm will always be treated as a Significant Adverse Event Review (SAER) incident. All others will be considered by the Patient Safety Learn and Improve (PSL&I) Group.”

3.5.3 The patient safety learn and improve group uses a formal initial incident review form, contained in Appendix 1 of the policy (May 2013), to determine whether an adverse event is significant. If the adverse event is significant, the group informs the executive team and seeks approval to instigate a significant adverse event review. The Service informed us that when an adverse event is not considered to be significant, the decision is formally documented.

3.5.4 The policy (May 2013) does not include guidance on risk grading and how staff initially identify risk. The Service informed us that staff grade the incident using drop down boxes on Datix which include guidance on definitions. The grading is then reviewed centrally by the risk manager using a risk matrix. The Service informed us that root cause analysis training for staff also includes guidance on how to grade adverse events. Our discussions with staff confirmed that they were generally comfortable with risk grading.

3.5.5 Adverse events recorded as major or extreme on Datix are automatically notified to the patient safety learn and improve group. Automatic emails are also sent to relevant groups, such as infection control or health and safety.

3.5.6 All four cases selected for review had evidence of notification to managers. On the visit, staff confirmed that relevant managers, including the chief executive, are made aware of adverse events.
Escalation of events

3.5.7 The timeline section of the policy (May 2013) states that relevant internal stakeholders should be notified of adverse events. This includes executive directors, health and safety, and risk management. Health and safety, risk management or corporate affairs must notify and liaise with relevant external stakeholders such as other NHS bodies, the police, Health and Safety Executive and the Medical Devices Agency.

3.5.8 The serious incident escalation procedure (November 2010) includes a useful escalation protocol flow chart to help guide staff.

3.5.9 The area service manager or head of service is required to review the situation, background, assessment and recommendations document and DATIX report and to seek advice from the on-call clinical lead or the patient safety learn and improve group. They are also responsible for ensuring the situation, background, assessment and recommendations document is submitted to the general manager and on-call executive lead. The area service manager or head of service makes a recommendation to the medical director and director of health professions and nursing care whether a significant adverse event review is required.

3.5.10 The chief executive is notified of all significant adverse events and takes an active role in the adverse event management process. Staff on the visit also informed us that the chief executive can be contacted at any time, in the event of emergencies.

Investigations

3.5.11 The policy (May 2013) refers to the investigation process being divided into three levels:

- Patient Safety Reflective meetings
- Patient Safety Review meetings, and
- Patient Safety Event Analysis.

3.5.12 The divisional clinical governance manager conducts patient safety review meetings. The nominated reviewers undertake patient safety event analysis and patient safety reflections.

3.5.13 The timeline section of the policy (May 2013) states that the:

“Lead Reviewer will work with PSL&I to identify subject matter experts to assist with the significant adverse event review. The whole process will be overseen by the PSL&I Group who will mobilise virtually to ensure actions are progressed timeously. Consider involvement of territorial Health Board if appropriate.”

3.5.14 The Service informed us that a member of the patient safety learn and improve group attends each significant adverse event review to help co-ordinate the process and ensure a consistent approach to undertaking investigations.

3.5.15 The policy (May 2013) states:

“Weekly updates will be produced from the significant adverse event review team to provide information to the PSL&I. If at any time during the review
process there are concerns that any issues about conduct are being identified, a 48 hour (maximum) pause will be called to allow the relevant operational management and HR colleagues to discuss actions necessary.”

3.5.16 The Service has investigation form templates for each of the three investigation levels. The templates are included as appendices to the policy (May 2013). On the visit, staff provided positive feedback on the investigation templates which help formalise the process and encourage consistency across the organisation.

3.5.17 The policy (May 2013) includes the following appendices to support the investigation process:

- information mapping form to detail the chronology of the adverse event and construct a tabular timeline
- fish bone, contributory factors diagram and template form
- five whys tool and Glasgow grid to examine all of the evidence gathered to identify the root cause, and
- incident decision tree featuring harm, incapacity, foresight and substitution test sections to help highlight any system failures.

3.5.18 All four cases had evidence of an investigation, although the level and format of each investigation varied. Only one case, which was investigated under the current policy (May 2013), had reference to root cause analysis and investigation tools being used. Another case had evidence of reflective practice being used as part of the investigation.

3.5.19 On the visit, staff told us that they found it challenging to undertake investigations in line with policy deadlines on top of their day-to-day duties. It could also be difficult to arrange staff interviews given tight work schedules.

**Recommendation**

To support a risk-based, informed and transparent approach, the Scottish Ambulance Service should:

12 provide support to adverse event reviewers to allow them to undertake investigations in line with policy deadlines.

### 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 accident and incident reporting procedure (December 2010) does not include guidance on timescales and only has reference to deadlines for RIDDOR reportable incidents.
3.6.2 The policy (May 2013) includes a detailed significant adverse event review timeline. This outlines what activities should be undertaken within a set number of days from the date a significant adverse event is recorded:

- “Within 0 working days, a Datix report should be completed for significant adverse events and the executive lead on-call and general manager informed
- within 2 working days, an initial review should be conducted, decision whether to progress to a significant adverse event review communicated to all concerned, and significant adverse event review initiated where required
- within 30 working days, complete the significant adverse event review, and
- within 10 working days of completion of the significant adverse event review, PSL&I to meet and agree draft report and recommendations.”

3.6.3 The Datix administrator sends reminders to relevant staff when deadline dates are due.

3.6.4 The Scottish Ambulance Service reported that while significant adverse event reviews should be completed within 30 days of notification, the timescale can be difficult to achieve in practice. Delays can happen when external stakeholders need to be involved in the investigation, such as GPs or other NHS boards.

3.6.5 The risk manager notifies the chief executive and risk management steering group of adverse events which have exceeded the set timescale. The chief executive and senior management team can then take action to help prevent further delay. We identified this as good practice.

3.6.6 In three of the four cases we reviewed, the adverse event was recorded on Datix within one day. The fourth case was a complaint. The patient registered the complaint at another NHS board and there was a delay in the complaint being forwarded to the Scottish Ambulance Service. The complaint was added to the Viewpoint system a month after the patient first registered the complaint.

3.6.7 Each of the four cases we reviewed had evidence of a review or initial investigation being commenced within 5 working days of the incident being recorded on Datix or Viewpoint.

3.6.8 In all four cases, the final investigation or significant adverse event review was completed 2–3 months after the incident was recorded. This is outwith the policy (May 2013) guidance to complete within 30 working days.

3.6.9 At the time of the visit, the Service was considering a process to audit its performance against the policy (May 2013) timescales.

3.6.10 We saw evidence of a quality scorecard 2013–2014 which goes to the Board. The scorecard shows percentage achievement of selected key performance indicators by month. The scorecard includes indicators for responding to calls, dispatching resources, treating patients on scene and working with partner organisations. However, there is no specific indicator for adverse events. The only related indicator is for “Compliant RIDDOR Incidents Reported.” We suggest that specific indicators for significant adverse events are included within the scorecard.
**Action planning**

3.6.11 The policy (May 2013) includes an action plan template for each level of review. The template can be used to document what actions are to be taken forward, by whom, when and whether actions have been completed. The template also prompts staff to record:

- “What could be done differently next time?

- is there any wider organisational learning that can be taken from this event? How will this be shared?”

3.6.12 The action plan template includes a note that:

“All action plans will be monitored for completion by the Risk Team. The Risk and Safety Team will request evidence of all completed actions, 3 months after the final completion date.”

3.6.13 The accident and incident reporting procedure (December 2010) stated:

“On completion (as soon as possible after the event) of the investigation the area supervisor or manager shall ensure that appropriate corrective actions are taken to prevent reoccurrence, they shall record these actions on the investigation report.”

3.6.14 The new policy (May 2013) states:

“Whilst a review process is ongoing the review co-ordinator shall maintain an overview of the review and action planning process. Once completed reviews and action plans are passed to the review co-ordinator by the reviewing officer. The review co-ordinator shall enter all appropriate information into the PSL&I database. The reviewing officer is responsible for ensuring the review co-ordinator is provided with the completed copy of each stage of the process when they become available. Within 10 working days of receipt of completed documents the PSL&I will formally review the review to identify if the review appears complete. If it does then a record will be made within the PSL&I database and the documents forwarded to the National Clinical Governance Group for formal sign off. On a quarterly basis the Reviewing Officer shall forward to the PSL&I details of ongoing review processes and action plans.”

3.6.15 The risk manager maintains a log of action plans following adverse event reviews and records the actions on Datix. The Datix system sends automatic reminders to staff informing them of due dates for completion of actions. The risk manager liaises with action plan owners when timescales are over due to chase the progress of the action plan. The patient safety learn and improve group compiles 3-monthly reports for governance committees showing the status of all reviews and their subsequent action plans.

3.6.16 Two out of four cases we reviewed had evidence of an action plan. We identified good practice in one of the cases where actions were recorded on Datix, including due dates for completion and dates when actions were implemented. In another case, an action plan was not considered necessary at the time as no learning had been identified during the review. However, since the event happened the Service has reviewed its procedures to help prevent a similar situation happening again.
**Sharing of learning**

3.6.17  The policy (May 2013) states that:

“Timely and appropriate dissemination of learning following a significant adverse event is core to reducing the risk of reoccurrence, both within the Service and also elsewhere in NHSScotland. Learning from a patient safety incident is a collaborative, decentralised and reflective process that draws on experience, knowledge and evidence from a variety of sources. This will lead to co-production and national sharing of safety solutions and improvements, increased visibility to lessons learnt and participation in the learning process leading to enhanced patient safety.”

3.6.18  The policy (May 2013) also lists the responsibilities of specific job roles to identify and share learning from adverse events and to provide updates to the senior management team and Board.

3.6.19  The policy (May 2013) lists examples of appropriate learning, including:

- “solutions to address incident root causes that may be relevant to other teams, services and provider organisations
- identification of the components of good practice that reduced the potential impact of the incident, and how they were developed and supported
- potential impact of the incident
- lessons from conducting the review that may improve the management of reviews in future
- documentation of identification of the risks, the extent to which they have been reduced, and how this is measured and monitored, and
- a review executive summary should be published and circulated for each incident containing learning points which should be grouped and themed to help readers identify points applicable to their team, service, speciality or division or wider organisation.”

3.6.20  The being open section of the policy (May 2013) states that:

“Being open is supported through the Service’s Patient Safety Learn and Improve Group, with accountability to the Executive Team to ensure required changes are implemented and their effectiveness reviewed. Findings will be disseminated to staff so that they can learn from patient safety incidents. Continuous learning programmes and audits will be developed to allow the Service to learn from the patient’s experience of the policy of being open. The information used to share learning will be treated appropriately, which may mean the incident and/or findings will be anonymised before being disseminated.”

3.6.21  We saw evidence of the governance committees receiving updates through divisional operations reports on action taken following individual adverse incidents. The clinical incident and clinical risk report submitted to the November 2012 clinical governance committee included lessons implemented from incidents. Subsequent reports contained...
some information on lessons learnt following adverse incidents. However, this does not appear as standard within all these reports.

3.6.22 We also saw evidence of the clinical governance committee receiving updates on lessons learnt following a review of complaints.

3.6.23 The patient safety learn and improve group sets aside a couple of days each year to undertake a detailed review of processes. In August 2012, the group reviewed the NHS Ayrshire & Arran report. This resulted in the development of the new policy (May 2013).

3.6.24 The Service informed us that it sometimes holds multi-agency de-briefs with external organisations to discuss and capture lessons learnt.

3.6.25 In two of the cases we reviewed, lessons learnt were captured in the case documentation, although one of the cases referred to ‘recommendations’ rather than lessons learnt. Another case recorded that there was no lessons to be learnt from the incident. The fourth case had no reference to lessons learnt.

3.6.26 Staff we spoke with agreed that learning could be improved by engaging with staff throughout the process.

3.6.27 The Service informed us of several routes through which learning can be shared with staff across the organisation, including:

- patient safety highlight reports (currently being rolled out)
- patient safety learn and improve group
- local and national groups
- senior management team, and
- clinical governance committee.

3.6.28 The Service reported that learning from adverse events is included within education and training sessions and conferences. This includes ‘flying lessons’ workshops to discuss organisational culture and feedback from adverse events.

3.6.29 None of the cases we reviewed had evidence of learning outcomes from adverse events being shared with staff who had not been involved in the event.

3.6.30 The Service acknowledged that it does not yet have a consistent approach to sharing thematic learning from adverse events across the organisation. The Service informed us that the clinical governance committee is discussing options for sharing learning at its August 2013 meeting.

3.6.31 The Service informed us that it is working on a staff bulletin as a way to provide feedback and to share lessons learnt following adverse events.
Recommendations

To improve timely management, learning and dissemination following adverse events, the Scottish Ambulance Service should:

13 strengthen the process for monitoring adverse event management timescales, review reasons for any delays and ensure timescales are met

14 continue to monitor the completion of action plans and where an action plan is not necessary, the Scottish Ambulance Service should document the rationale for this, and

15 embed a culture of capturing and sharing lessons learnt across the organisation, supported by a system that provides evidence of discussion at meetings and through feedback mechanisms.
Appendix 1 – Details of review team

The review of the Scottish Ambulance Service was conducted on Thursday 22 August 2013.

Review team members

Mark Aggleton
Senior Business Manager, Healthcare Improvement Scotland

Melinda Cuthbert
Lead Pharmacist, Lothian Medicines Information Service, NHS Lothian

Jamie Malcolm
Clinical Advisor

Marguerite Robertson
Public Partner

Kevin Rooney
Consultant in Anaesthesia & Intensive Care Medicine, NHS Greater Glasgow and Clyde

Edel Sheridan
Project Officer, Healthcare Improvement Scotland

Anna Wimberley
Programme Manager, Healthcare Improvement Scotland

Observed by:

Anne Hanley
Operations Manager, Healthcare Improvement Scotland
We can also provide this information:

- by email
- in large print
- on audio tape or CD
- in Braille (English only), and
- in community languages.

---

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.