The Management of Significant Adverse Events in NHS Ayrshire & Arran

June 2012
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EXECUTIVE SUMMARY

The Cabinet Secretary for Health, Wellbeing and Cities Strategy instructed Healthcare Improvement Scotland to carry out, as a matter of urgency, a review of the clinical governance systems and processes in NHS Ayrshire & Arran, in particular those that relate to their management of critical incidents, adverse events, action planning and local learning.

This followed a decision by the Scottish Information Commissioner on 21 February 2012 on NHS Ayrshire & Arran’s response to a Freedom of Information (Scotland) Act appeal regarding critical incident reviews and significant adverse event reviews. This document reports on the findings of the Healthcare Improvement Scotland Review Group and makes recommendations for improvement for both NHS Ayrshire & Arran and NHSScotland.

The key findings from the report are summarised below.

- The Review Group found a lack of clarity on the lines of accountability, reporting and ownership of significant adverse event review actions and learning. We found complex and unwieldy clinical governance structures (see section ‘Structure and Accountability’).

- The Review Group found confusion about staff understanding of the scope to share information on significant adverse event reviews and a variation in interpretation of the policy. This hampered learning and improvement (see section ‘Sharing of Information’).

- Although the Review Group found examples of comprehensive Significant Adverse Event Review Reports there was not a robust and systematic approach to implementing action plans and monitoring progress (see section ‘Action Planning’).

- The Review Group found that NHS Ayrshire & Arran had a commitment to involve patients and families and raise awareness of the need to involve families. The system that tracks and responds to issues raised by families was an area of weakness and the Review Group found an inconsistent approach was used to family involvement (see section ‘Involvement of Families’).

- The Review Group did not find evidence of a system to identify thematic learning to allow change and improvements to clinical practice (see section ‘Sharing of learning’).

- There is strength in the potential of AthenA (NHS Ayrshire & Arran’s electronic document management system) to support the management of significant adverse events. However, the Review Group found weaknesses in: the logging and monitoring of significant adverse events; how NHS Ayrshire & Arran connects the information systems it uses; and the level of scrutiny applied to the
information within Datix (NHS Ayrshire & Arran’s electronic risk management system) (see section ‘Identification, Notification and Initial Event Reporting’).

- The Review Group also found that there were weaknesses in the way decisions to undertake significant adverse event reviews were evidenced and documented (see section ‘Escalation of Events’).

- The criteria used to decide between desktop review or full significant adverse event review were not clear and the Review Group has also highlighted the risks associated with single person desktop reviews (see section ‘Types of Significant Adverse Event Reviews’).

- Although there were examples of timely local investigation, the performance management and progress chasing against timeline targets, in general, needs significant improvement (see section ‘Investigation and Reporting Timelines’).

- The Critical Incident Stress Management resource is an area of strength to be sustained and developed. (This resource supports NHS Ayrshire & Arran’s staff and provides intervention designed to prevent potentially harmful psychological reactions often associated with traumatic incidents.)
CONCLUSIONS AND RECOMMENDATIONS FOR NHS AYRSHIRE & ARRAN

NHS Ayrshire & Arran has sought to build a more open and transparent approach to the management of significant adverse events and has made progress in this regard. It has sought to actively involve families in this exercise.

However, and notwithstanding the considerable efforts made to build an improved system, the Review Group identified material weaknesses in the system of significant adverse events review management. Many of these related to document control and systems of governance. However, the Review Group felt that the more substantial shortfalls related to staff involvement, action planning and the dissemination of wider learning. In summary, the Adverse Event Policy and Supporting Procedures was not reliably or consistently applied in NHS Ayrshire & Arran.

The following recommendations are made.

**Recommendation 1:**
NHS Ayrshire & Arran should work, building on AthenA, to establish a single robust database of significant adverse events that allows easier tracking of progress and a verifiable audit trail.

**Recommendation 2:**
NHS Ayrshire & Arran should ensure that whatever system is used, there is clarity of recording of complete and consistent information with appropriate connectivity and audit trails between systems.

**Recommendation 3:**
NHS Ayrshire & Arran should ensure that there is an appropriate level of scrutiny of the information in the Datix system to give assurance to the Board as to the robustness of the identification, management and learning from significant adverse events.

**Recommendation 4:**
NHS Ayrshire & Arran should establish a robust and transparent process for the escalation of adverse events, and ensure decisions therein are well documented.

**Recommendation 5:**
NHS Ayrshire & Arran should undertake a retrospective analysis of the deaths that did not proceed to significant adverse event review, to provide assurance that appropriate investigation and learning was undertaken.

**Recommendation 6:**
NHS Ayrshire & Arran should move to a consistent model for significant adverse event reviews, ensuring the effective involvement of a multidisciplinary team.
Recommendation 7:
NHS Ayrshire & Arran should review the timeline performance targets, ensuring that they are ambitious, but achievable. NHS Ayrshire & Arran should ensure a transparent approach to reporting on progress against such targets with early intervention, to improve performance, as appropriate.

Recommendation 8:
NHS Ayrshire & Arran should build on its approach to involving families in the commitment to ensure greater openness.

Recommendation 9:
NHS Ayrshire & Arran should establish a robust system for tracking and responding to the issues raised by families. This system should be integral to the overall system for the management of significant adverse events.

Recommendation 10:
NHS Ayrshire & Arran should review its approach to the involvement of staff in the investigation of significant adverse events, with the aim of offering consistent opportunities for learning and improvement.

Recommendation 11:
NHS Ayrshire & Arran should build on its approach to the support of staff involved in significant adverse events.

Recommendation 12:
NHS Ayrshire & Arran should make urgent progress in establishing the status of all significant adverse event review action plans since 2009. NHS Ayrshire & Arran should also consider the scope to extend their review to cases pre-dating 2009, within the bounds of the information that is available.

Recommendation 13:
NHS Ayrshire & Arran should ensure an ongoing approach to thematic learning, giving opportunities for those working in NHS Ayrshire & Arran to learn from significant adverse events and to change and adapt clinical practice accordingly.

Recommendation 14:
NHS Ayrshire & Arran should review its clinical governance structure with the focus on delivering a more streamlined and simpler arrangement, giving sharper clarity regarding accountability.

Recommendation 15:
NHS Ayrshire & Arran should ensure a focus on empowering clinical services to develop, own and progress action plans and to share wider learning and to reflect this in a revised flowchart.

Recommendation 16:
NHS Ayrshire & Arran should ensure that Healthcare Directors have explicit objectives related to the effective organisation and learning from significant adverse events, and such objectives are cascaded, appropriately, through their Directorates.
Recommendation 17:
NHS Ayrshire & Arran should undertake a fundamental review of its approach to sharing information arising from significant adverse events. It should ensure that the approach remains within the legislative requirements, but maximises the opportunities for staff to understand the broader context and background regarding specific incidents.
OPPORTUNITIES FOR LEARNING IN NHSSCOTLAND

When reviewing significant adverse event management, NHS boards in Scotland should aim to have in place a clear governance framework for reporting and learning from the most serious incidents. This framework will support preventative measures and will reduce the risk of serious harm to patients.

The importance of learning and sharing of information relating to any aspects of the NHS board’s business, including significant adverse events, is critical to enable the organisation to facilitate any wider local change and improvement. There is widespread acceptance that an effective governance framework will enable a culture for continuous improvement and, in turn, support transparency and accountability. The bullet points below are regarded as headline principles of an effective governance framework.

- Focus on purpose and outcomes.
- Clear functions and roles for organisations and Board members.
- Values of integrity, trust, openness, equality and diversity.
- Informed, transparent decision-making and managing risk.
- Developing the capacity and capability of organisations.
- Engaging stakeholders and making accountability real.

Whilst the findings and recommendations of this review are specific to the systems and processes investigated in NHS Ayrshire & Arran, the wider NHS in Scotland should take this opportunity to review and consider these findings and assess their own significant adverse event management processes and procedures within their wider governance structures.

The recent publications from the National Patient Safety Agency (NPSA) National Framework for Learning from Serious Incidents Requiring Investigation (2010) and the Institute for Healthcare Improvement (IHI) Respectful Management of Serious Clinical Adverse Event (2011) provide a good reference point for NHS boards to undertake any local review of their own arrangements. In addition, to support and facilitate this, Healthcare Improvement Scotland has identified a number of further recommendations for NHS boards and the wider NHSScotland. These are listed below.

Recommendations for NHS boards

Recommendation 18:
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.
**Recommendation 19:**
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.

**Recommendation 20:**
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.

**Recommendation 21:**
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.

**Recommendation 22:**
NHS boards should ensure that the decisions related to the management of significant adverse events are risk based, informed and transparent to allow an appropriate level of scrutiny and assurance.

**Recommendation 23:**
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.

**Recommendations for NHSScotland**

**Recommendation 24:**
NHSScotland should develop a consistent and agreed approach to the identification, investigation, reporting and learning from significant adverse events.

**Recommendation 25:**
Through appropriate measurement NHSScotland should maximise the opportunities for NHS boards to share and learn from significant adverse event review.

The focus of any significant adverse event review should be on learning and improvement in order to minimise the risk of events recurring. Whilst it is important that within local NHS boards thematic learning is disseminated and acted upon, there may be opportunities for wider national learning and assurance facilitated by appropriate measurement. The implementation of these recommendations seeks to improve the management of significant adverse events in the NHS in Scotland which will, in turn, reduce the risk of serious harm to patients.
1 INTRODUCTION

1.1 Background

A significant 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. The review and management of these events should enable NHS boards to learn from these events in order to minimise the risk of them happening again. This report reviews the management of significant adverse events in NHS Ayrshire & Arran and identifies areas of good practice and issues that need to be addressed.

Other NHS boards will also wish to consider the findings and recommendations in respect of the management of significant adverse events, as they relate to the systems and processes within their own NHS boards.

On 21 February 2012, the Scottish Information Commissioner published a Decision Notice (036/2012) that was highly critical of NHS Ayrshire & Arran’s response to a Freedom of Information (Scotland) Act appeal. This decision focused on a request which Mr Wilson, an employee of NHS Ayrshire & Arran, made on 10 February 2011 for copies of Critical Incident Review Reports and Significant Adverse Event Review Reports completed since January 2005, together with the action plans arising from the reports.

The Cabinet Secretary for Health, Wellbeing and Cities Strategy instructed Healthcare Improvement Scotland to carry out, as a matter of urgency, a review of the approach taken by NHS Ayrshire & Arran in managing significant adverse events. Healthcare Improvement Scotland identified and brought together a Review Group made up of a number of individuals with relevant specialist knowledge from across Scotland. The Terms of Reference for the review are set out in Appendix 1, including the membership of the Review Group. A full description of the events leading to the review are set out in Appendix 2.

1.2 Methodology for the Review

The Review Group has considered the current significant adverse event management system in NHS Ayrshire & Arran in considerable depth. It has drawn on a variety of information sources including documentation related to the process and a number of interviews with staff working in NHS Ayrshire & Arran.

NHS Ayrshire & Arran has publicly acknowledged significant issues related to their significant adverse event management system prior to 2009. The Review Group therefore decided to focus its efforts on significant adverse events since January 2009 to March 2012. This time period covered 57 significant adverse event reviews.

Healthcare Improvement Scotland took into consideration 2,500 separate pieces of documentary information and the Review Group interviewed or met with over 60 individuals who had worked in NHS Ayrshire & Arran over the time period of the review.
The documentary evidence provided by NHS Ayrshire & Arran came from a variety of sources and included policy and procedural documents relating to the significant adverse event process, incident/event reports from the Datix risk management system, sampled Significant Adverse Event Review Reports and related action plans, process monitoring documents, governance group agendas and minutes. The documentary evidence included a recent NHS Ayrshire & Arran Internal Audit Report from PricewaterhouseCoopers (PwC) published in November 2011. Collation and analysis of the material was undertaken by the staff of Healthcare Improvement Scotland.

A visit to NHS Ayrshire & Arran was conducted on 29 and 30 March 2012 and a series of follow-up interviews were held by teleconference in April and May 2012. The interviews that were conducted included a wide range of staff and frontline operational staff, support staff, directors and the Chief Executive. In addition, there were interviews with the former chair of the Clinical Governance Committee and Mr Wilson.

Alongside the overall review of the system for the management of significant adverse events, the Review Group examined, in depth, seven significant adverse events, covering a mix of specialties. The analysis of the sampled cases, the policy and related procedures and also a review of other key reference documents, allowed the Review Group to shape a number of additional requests for information and also the development of a series of questions and prompts for the visit to NHS Ayrshire & Arran on 29 and 30 March 2012. This allowed additional focused questioning of the process to the staff either involved in a particular incident or its review.

The Review Group received considerable support and assistance throughout the review from the staff in NHS Ayrshire & Arran, and is grateful for their time and commitment. The Review Group is particularly appreciative of the openness shown by those they met and interviewed.
2  NHS AYRSHIRE & ARRAN’S DESCRIPTION OF ARRANGEMENTS

12  NHS Ayrshire & Arran has demonstrated an ambition to develop an approach that reflects the key principles of a safer system of care. Over the past several years, it has been apparent that there has been considerable effort in creating a new infrastructure and policies to support the identification, investigation, management and learning from significant adverse events in NHS Ayrshire & Arran. A strong feature of its approach is the involvement of patients and families in the open sharing of information arising from significant adverse events.

13  NHS Ayrshire & Arran employs 10,000 staff and has a revenue budget of around £590m for 2012/13. NHS Ayrshire & Arran’s organisational structure is set out in Figure 1. The Healthcare Directorates are described in this diagram. They are led by a Director accountable to the Chief Executive and are supported by an Associate Medical Director and an Associate Nurse Director.

*Figure 1: Organisational structure*

14  The Chief Executive of NHS Ayrshire & Arran presented to the Review Group on 29 March 2012 the history of the development of the *Adverse Event Policy and Supporting Procedures*. Figure 2 shows the timeline for the development of policy changes. The current policy (Version 4) was the subject of extensive consultation over the course of 2010.
Figure 2: Timeline of development of serious adverse event policy

Figure 3 describes the progress made and key challenges identified by the Chief Executive.

Figure 3: Progress and challenges identified by Chief Executive

The journey and it's challenges

Focus of Experience
- Inclusive agenda
- Consistency and rigour of reporting
- Develop family involvement
- Demonstrate shared learning

Challenges
- Evolve staff mindset
- Develop new ways of working - wider engagement
- Deliver new level of openness, transparency and disclosure
- Clear communication with both family and staff
- Robust scrutiny and governance processes
- Maximise organisational learning
16 In the glossary to its current Adverse Event Policy and Supporting Procedures, NHS Ayrshire & Arran explains that a significant adverse event:

“may also be referred to locally as a ‘critical’ event, ‘significant incident’ or ‘significant adverse incident’ and is an event which has been graded on the ‘consequence’ scale as being ‘major’ or ‘extreme’”.

17 NHS Ayrshire & Arran’s response to significant adverse events sits within the broader context of the duties of NHS boards in relation to clinical governance. The Clinical Governance Committee’s Annual Report for 2010/11 describes clinical governance as the:

“statutory obligation and is a framework through which NHS Ayrshire & Arran is accountable for continuously improving the quality of its services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish.”

18 The Adverse Event Policy and Supporting Procedures states (in paragraph 7.2) that:

“assurance will be provided to the NHS Ayrshire & Arran Clinical Governance Committee by regular reporting on findings and recommendations and subsequently the Board via the minutes of the Local Clinical Governance Groups and Health, Safety and Wellbeing Committee”.

19 The Clinical Governance Committee is chaired by a non-executive director and includes other non-executives as members, and other executives (including the Executive Medical Director and Executive Nurse Director) as ex-officio members. The Committee met seven times throughout 2010/11 and six times in 2011/12.

20 The Clinical Governance Committee receives full reports of significant adverse event reviews and supporting action plans.

21 In addition to the Clinical Governance Committee, there are Healthcare Directorate Clinical Governance Groups and operational clinical governance groups.

22 The Healthcare Quality, Governance and Standards Unit sits at the hub of the significant adverse event process. Section 9.3.3 of the Adverse Event Policy and Supporting Procedures refers to responsibilities of the Healthcare Quality, Governance and Standards Unit. Responsibilities include to:

“co-ordinate, manage and administratively support a significant adverse event review; maintain all records relating to significant adverse events; obtain updates in relation to the action plan and report progress to the Clinical Governance Committee; track timescales, implement, monitor and report upon key performance indicators”.
3 REVIEW FINDINGS AND RECOMMENDATIONS

3.1 Identification, Notification and Initial Event Reporting

Establishing a baseline of information

23 The Review Group agreed at the outset of the review that it was essential to obtain a clear and definitive history of significant adverse events from 1 January 2009 through to the present day. Establishing the baseline was a crucial early step for the Review Group.

24 At the start of the review NHS Ayrshire & Arran identified for the Review Group a range of significant adverse event reviews from January 2010.

25 The Review Group also received summary information on all the significant adverse events documented on the Significant Adverse Event Review Database between 2009 and 2012 on 19 March 2012. Further investigation established that the summary information related to 2009 and 2010 ‘completed’ cases and did not include ‘live’ incidents: the ‘live’ list was received by email the following day. There were a total of 57 significant adverse event reviews recorded between 2009 and 2012 (‘completed’ and ‘live’). The information consisted of an initial summary with a brief description of the cases, but did not include timeline information (for example, date of incident and date reported).

26 Whilst the Review Group received full co-operation from the staff in NHS Ayrshire & Arran, it did encounter substantial difficulties in arriving at a consistent set of significant adverse event reviews between 2009 and 2012 due to conflicting reports and pieces of information. For instance, seven significant adverse event reviews identified in the original set of ‘completed’ and ‘live’ cases failed to be included in subsequent material and clarification was sought on their status. From an email received on 3 April 2012, key pieces of timeline information for some of the 2009 significant adverse event reviews was “not available”.

27 Given the substantial amount of conflicting and incomplete information throughout the review, the Review Group spent a very large amount of time seeking clarification on the information and highlighting inconsistencies and gaps in the documentation.

Information provided in response to Mr Wilson’s FOI

28 The Review Group received the redacted action plans, provided to Mr Wilson, which were placed on the NHS Ayrshire & Arran website. There were 54 redacted action plans provided in response to his FOI request.

29 The Review Group sought clarity as to why a further four cases had not been provided to Mr Wilson, as they appeared to fall within the timeframe of the FOI request. The Review Group was informed by NHS Ayrshire & Arran that the cases – whilst logged on the Significant Adverse Event Review Database – were not actually critical incident reviews or significant adverse event reviews, and did not fall within the terms of Mr Wilson’s FOI request. This example was a good illustration of the substantial
difficulties in reaching a definitive position regarding the status of significant adverse event reviews. A full list of the recorded database cases is provided in Appendix 3 of this report.

**Information from existing systems**

30 NHS Ayrshire & Arran established a Significant Adverse Event Review Database in July 2011 to track and manage cases and supporting action plans. The database is stand alone and separate from the Datix system and the AthenA document management site. Each case is given a ‘DB’ reference number (for example, DB10) as well as an identifier arising from the Datix system. The cases date back to 2006, with a retrospective loading of case information on to the database. As at 19 April 2012, there were 97 cases logged into the database, but several had been mistakenly escalated into the database (for example, complaints) and subsequently “removed”. Also, the numbering of cases in the database did not reflect the chronological order of the incidents. The cases commenced at DB01 and ended at DB97 (as at 12 April 2012). Fifty-seven cases arose from 2009 onwards and a further 32 pre-dated 2009, with the remainder (eight) being removed as mistakenly placed on the database.

31 A shared computer drive holds folders containing information relating to the significant adverse event reviews and is separate from the database.

32 The Review Group had a demonstration of the database on 30 March 2012. The Review Group selected a case from its sample set. It was noted that database fields, describing progress against the review recommendations were largely incomplete. There was no supporting information regarding staff or patient involvement in the significant adverse event contained in the database, but information was available in the separate drive’s folders. The progress report section of the database was blank.

33 The Review Group received a demonstration of the AthenA document management system. The Review Group was impressed by the breadth and depth, and the potential of the system. The system had the potential to be a collaborative tool and allowed for more effective support for the process. However, at present there are only 23 cases on the system.

34 Based on the substantial difficulties in establishing the baseline of significant adverse event reviews, the Review Group considered there were significant weaknesses in logging and monitoring of significant adverse events in NHS Ayrshire & Arran. The Review Group felt that work on the AthenA document management system should be accelerated and a swift move made away from the current separate repositories of information which cause confusion.

**Recommendation 1:**

NHS Ayrshire & Arran should work, building on AthenA, to establish a single robust database of significant adverse events that allows easier tracking of progress and a verifiable audit trail.
35 The Review Group also noted that the quality of the information and recording within the Datix system was variable. Many of the system’s entries lacked detail and failed to give a clear picture of the subsequent management of the incident. **There was often no evidence to allow a clear audit trail, from incident through to investigation and beyond, and a lack of connectivity between systems.**

**Recommendation 2:**
NHS Ayrshire & Arran should ensure that whatever system is used, that there is clarity of recording of complete and consistent information with appropriate connectivity and audit trails between systems.

36 The previous Chair of the Clinical Governance Committee confirmed that there was not an audit of Datix files of the ‘major’ and ‘extreme’ cases to “test” the robustness of the system of management and reporting. **The Review Group concluded that there should be a higher level of scrutiny of the information within the Datix system to ensure that there is an effective system of quality assurance of the management of significant adverse events.**

**Recommendation 3:**
NHS Ayrshire & Arran should ensure that there is an appropriate level of scrutiny of the information in the Datix system to give assurance to the Board as to the robustness of the identification, management and learning from significant adverse events.

### 3.2 Escalation of Events

**Making the decision to escalate**

37 The Review Group was given a recent example of a local investigation into a significant adverse event. The Review Group was advised that it had been decided, at an executive level, not to escalate this case to a full significant adverse event review.

Section 9.3.2 of the *Adverse Event Policy and Supporting Procedures* states that:

“consideration of an event for significant adverse event review should not prevent the initiation of local investigation and is the responsibility of the line manager within the area. Local investigation will then inform any subsequent process, the main benefits are the early corrective action, including statement collection when events remain clear for the staff involved. Local investigation report, with any relevant associated documentation, must be shared with appointed the [sic] Adverse Event Review team lead investigator”.

38 The Review Group sought clarification on this case to understand how this event had been managed through the extant policy. The Review Group noted that the case had not been advanced beyond a local investigation or reported to the Clinical Governance Committee. The Review Group noted that learning appeared to have been largely limited to the specialty involved. The Review Group could find no convincing evidence as to why the decision had been reached to restrict the management of the case to the local level. Moreover, given the serious nature of the incident the Review Group would have reasonably expected reporting to the Clinical Governance Committee and wider learning to have been disseminated throughout NHS Ayrshire & Arran.
The policy states in section 9.3.1 that a:

“decision may be made NOT to proceed in the commissioning of a Significant Adverse Event Review Team following a ‘Major or Extreme’ Event. The decision can only be taken at Executive Medical or Executive Nurse Director level. The rationale for not proceeding must be clearly established and recorded”.

The Review Group established that there was not a well-defined approach to the escalation of significant adverse events. Some staff – as expressed in the minutes of the Healthcare Directorate Clinical Governance Group meetings – indicated their concern regarding the early escalation to more senior management. There was also not a well-defined and transparently documented process for recording decisions to escalate, or not, to the level of significant adverse event review.

Overall, there was a lack of documented evidence regarding the decision to proceed to significant adverse event review. The Review Group concluded that there was not a robust audit trail evidencing decisions not to proceed to significant adverse event reviews.

**Recommendation 4:**
NHS Ayrshire & Arran should establish a robust and transparent process for the escalation of adverse events, and ensure decisions therein are well documented.

**Information from the risk management system**

The Review Group also sought and received all ‘major’ and ‘extreme’ adverse events logged on the Datix system between January 2009 and 2012. There was a total of 1,417 events. Thirty-one of those events could be traced back to the 57 significant adverse events under review by the Review Group. Two of the seven in the sample were registered as ‘major’ or ‘extreme’ in the Datix system. The Review Group noted that 132 of the events in the Datix system were described as resulting in a death and was able to relate 13 of those deaths to the 57 significant adverse event reviews. The Review Group noted the apparently low proportion of ‘major’ and ‘extreme’ events that went on to significant adverse event review.

The Review Group noted that an attempt had been made in early 2011 to establish an escalation process for incidents logged in the Datix system, but this proposal had not been advanced.

The Review Group examined the available details on the 132 deaths, mentioned previously. It was noted that the deaths logged on the Datix system covered a range of specialties. The Review Group did not make a judgement of the handling of investigation of each of the deaths, but noted that there was an opportunity to ensure a more consistent and systematic approach to the escalation and management of significant adverse events.

The Review Group concluded that there was limited evidence of a systematic and consistent approach to the investigation of the deaths that were recorded within the Datix system, and which did not proceed to significant adverse event review between 2009 and 2012.
Recommendation 5:
NHS Ayrshire & Arran should undertake a retrospective analysis of the deaths that did not proceed to significant adverse event review, to provide assurance that appropriate investigation and learning was undertaken.

3.3 Types of Significant Adverse Event Reviews

Desktop versus a full significant adverse event review

46 NHS Ayrshire & Arran conducts two types of significant adverse event reviews:

- a desktop review, and
- a full significant adverse event review consisting of an investigation review team.

47 The Adverse Event Policy and Supporting Procedures states in section 9.3.2 that:

“the Director will determine the appropriate level of review and will advise accordingly i.e. desktop review or full Significant Adverse Event Review or no further action. A desktop review relates to a trained reviewer conducting an initial review of a significant adverse event. The desktop review will identify whether or not there is a need to recommend full significant adverse event review and will include recommendations from specialists when available e.g. Occupational Health and Safety etc. Even when issues are identified, there may not be a need to move to full review e.g. recommendations already contained within a significant adverse event review report, issues that can be dealt with on a local basis. The Executive Director who requested the desktop review will consider the report and determine future action.”

48 Of the 57 cases since 2009, 14 were desktop reviews (25%) and the remaining 43 (75%) were full significant adverse event reviews.

49 The Review Group heard examples of both types of reviews. The desktop review was a more limited case note review carried out by an individual member of staff, with appropriate specialist input. The desktop review did not appear to extend to the full and more detailed examination of the evidence (for example, conducting interviews) as in the full investigation approach. It was described by one member of staff as a preliminary examination, which may or may not lead to the full significant adverse event review.

50 The full significant adverse event review team was led and populated by individuals external to the service in which the incident happened. The Adverse Event Policy and Supporting Procedures in section 9.3.3 provides a detailed description of the process of undertaking a full significant adverse event review. This includes the composition and attributes of the review team, the roles and responsibilities to support the review team and the responsibilities of the review team members. Within this section, the Adverse Event Policy and Supporting Procedures states:

“At the very outset of the first meeting of the investigation team, the Lead Investigator/Chairperson should make it explicit that the purpose of the investigation is NOT to apportion blame, but to determine the facts, to learn and to make appropriate recommendations that will target the root causes identified.”
The Adverse Event Policy and Supporting Procedures sets out within Flowcharts 1 and 2 the procedure for clinical and non-clinical adverse events. For clinical reviews, the Executive Medical or Executive Nursing Director or on-call Director has the identified responsibility to determine the need for a significant adverse event review. The Review Group noted, through its review of the example cases, that there did not appear to be clear explanation as to which event would merit a ‘desktop’ or ‘full review’ and that the rationale for this decision was not always recorded within the paperwork the Review Group received. In addition, there are clear and detailed procedures and instructions within section 9.3.3 of the Adverse Event Policy and Supporting Procedures which includes defining the attributes of the review team members, the responsibilities of the Healthcare Quality Governance and Standards Unit and the review team’s responsibilities. However, there is not a similar detailed methodology attributed to the desktop review process – which the Review Group witnessed were normally undertaken by the same individual. This risked a level of subjectivity in such reviews.

The Review Group therefore noted the lack of clarity as to the criteria used to decide whether to proceed with a desktop review or commence a full significant adverse event review. It was also a point raised by those the Review Group interviewed that there did not appear to be a transparent and explicit set of criteria governing such decisions. There were emails seeking reviews to be conducted but there was no evidence to support the rationale for one route over the other. This was a point also acknowledged in the PricewaterhouseCoopers (PwC) report.

The Review Group considered that there was a need to adopt a more standardised and consistent approach to deciding whether an event would merit a full significant adverse event review. Initial local investigation and action should continue to be supported to ensure the immediate safety of patients.

The Review Group questioned the lack of documentary evidence underpinning decisions to proceed down one route over the other, and highlighted the risks associated with the single person desktop review, especially regarding the absence of the full engagement with a wider team.

**Recommendation 6:**
NHS Ayrshire & Arran should move to a consistent model for significant adverse event reviews, ensuring the effective involvement of a multidisciplinary team.
3.4 Investigation and Reporting Timelines

The Adverse Event Policy and Supporting Procedures states that any:

“members of staff who have knowledge of or has been directly involved in an adverse event, must complete a report utilising the current risk management system, within 24 hours” (see paragraph 4.10).

In a few instances, substantial delays between the date of incident and reporting reflected the fact that the actual incident had taken place a significant period before the date that the actual incident became known to NHS Ayrshire & Arran (for example, a ‘missed diagnosis’ which goes unnoticed and only comes to light many months later). However, in other instances there are delays which are not accounted for by this reason. Tables 1–6 provide an analysis of investigation reporting timelines.

Table 1: Seven sample cases - performance against 24-hour target (length of time, in days, between the incident occurring and the incident being reported on Datix)

<table>
<thead>
<tr>
<th>Case number</th>
<th>Incident occurring to incident being reported on Datix (days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 (v)</td>
<td>5</td>
</tr>
<tr>
<td>2*</td>
<td>Same/next day</td>
</tr>
<tr>
<td>3*</td>
<td>3</td>
</tr>
<tr>
<td>4 (v)</td>
<td>2</td>
</tr>
<tr>
<td>5*</td>
<td>9</td>
</tr>
<tr>
<td>6*</td>
<td>Same/next day</td>
</tr>
<tr>
<td>7*</td>
<td>522 (misdiagnosis case)</td>
</tr>
</tbody>
</table>

(v) = verified dates against Datix records
*Datix record not provided to verify date and no time information supplied to calculate 24 hour target

Table 2: 57 significant adverse event review cases - performance against 24-hour target (length of time, in days, between the incident occurring and the incident being reported on Datix)

<table>
<thead>
<tr>
<th>Same/Next day</th>
<th>2 to 4 days</th>
<th>5 to 7 Days</th>
<th>8+ days</th>
<th>Missing</th>
<th>Negative days*</th>
</tr>
</thead>
<tbody>
<tr>
<td>17 (29.8%)</td>
<td>12 (21%)</td>
<td>3 (5.3%)</td>
<td>21 (36.8%)</td>
<td>3 (5.3%)</td>
<td>1 (1.8%)</td>
</tr>
</tbody>
</table>

*The reference to ‘negative days’ relates to the incident being presumably mis-recorded as happening after the date of reporting.
Table 3: All 1,417 Datix recorded incidents - performance against 24-hour target (length of time, in days, between the incident occurring and the incident being reported on Datix)

<table>
<thead>
<tr>
<th>Same/Next day</th>
<th>2 to 4 days</th>
<th>5 to 7 Days</th>
<th>8+ days</th>
<th>Missing</th>
</tr>
</thead>
<tbody>
<tr>
<td>865 (61%)</td>
<td>329 (23%)</td>
<td>51 (3.5%)</td>
<td>150 (11%)</td>
<td>22 (1.5%)</td>
</tr>
</tbody>
</table>

The Adverse Event Policy and Supporting Procedures sets out target days for the completion of investigations. Table 4 sets out the target days for each type of incident.

Table 4: Performance targets

<table>
<thead>
<tr>
<th>Type</th>
<th>Days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insignificant/Minor</td>
<td>Initial investigation to be completed within 10 working days</td>
</tr>
<tr>
<td>Moderate</td>
<td>Initial investigation to be completed within 21 working days</td>
</tr>
<tr>
<td>Major</td>
<td>Initial investigation to be completed within 40 working days</td>
</tr>
<tr>
<td>Extreme</td>
<td>Formal investigation to be completed within 45 working days</td>
</tr>
</tbody>
</table>

In Tables 5 and 6, the performance is shown against the 45 working days target for the sampled cases and the 57 significant adverse event reviews. These are based on figures provided by NHS Ayrshire & Arran.

Table 5: Seven sampled cases - performance within 45 working days target for completion of investigation

<table>
<thead>
<tr>
<th>Case number</th>
<th>Within 45 working days, 20 for desktop</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>57</td>
</tr>
<tr>
<td>2</td>
<td>82</td>
</tr>
<tr>
<td>3</td>
<td>51</td>
</tr>
<tr>
<td>4</td>
<td>118</td>
</tr>
<tr>
<td>5</td>
<td>desktop -14</td>
</tr>
<tr>
<td>6</td>
<td>105</td>
</tr>
<tr>
<td>7</td>
<td>desktop -7</td>
</tr>
</tbody>
</table>

Table 6: 57 significant adverse event review cases - performance within 45 working days target for completion of investigation

<table>
<thead>
<tr>
<th>Within 45 working days target</th>
<th>46-90 days</th>
<th>91-135 days</th>
<th>136+days</th>
<th>Ongoing</th>
<th>Missing data</th>
</tr>
</thead>
<tbody>
<tr>
<td>7 (12%)</td>
<td>16 (28%)</td>
<td>6 (11%)</td>
<td>11 (19%)</td>
<td>6 (11%)</td>
<td>11 (19%)</td>
</tr>
</tbody>
</table>
59 It was widely accepted, based on the interviews with staff, that the performance targets were not routinely monitored or reported upon. The Review Group concluded that there was not a rigorous process for performance management and progress chasing to ensure targets were met and to address outliers.

**Recommendation 7:**
NHS Ayrshire & Arran should review the timeline performance targets, ensuring that they are ambitious, but achievable. NHS Ayrshire & Arran should ensure a transparent approach to reporting on progress against such targets with early intervention, to improve performance, as appropriate.

### 3.5 Involvement of Families

60 The Review Group was made aware of NHS Ayrshire & Arran’s commitment to involve patients and their families in the identification of learning from significant adverse event reviews, and efforts had been made to draw families into the process. This was accepted as being a difficult process.

**Recording family involvement**

61 The Review Group sought evidence to confirm the number of cases that had been shared with the families since 2009. NHS Ayrshire & Arran supplied a spreadsheet on 17 April 2012, with cases that had been monitored. There were 20 cases in the spreadsheet pertaining to 2011 and 2012 with records of meetings and telephone contacts with families. The oldest contact was February 2011, and the most recent February 2012. The reference numbers of the cases did not relate to the Significant Adverse Event Review Database DB numbering system. The reference in the spreadsheet would indicate that the recording of family contact commenced around February 2011 (for example, the statement ‘one call made prior to recording’ in ‘Case A’). There is no record of who made the entries into the spreadsheet, but initials are used throughout relating to other staff members.

62 Many of the cases in the spreadsheet ended without further formal recording of the actions to progress outstanding issues. It was subsequently identified that the information had been transferred to the Significant Adverse Event Review Database.

63 There may also be additional information contained, for instance, in AthenA but that would call into question the purpose and robustness of the spreadsheet that was supplied. The documentary evidence in the spreadsheet, and the failure to reconcile to the DB numbering system, reinforced the perception of poor record management and documentation within the system.

64 The Review Group also noted that there did not seem to be a consistent way in which the significant adverse event review team involved and/or communicated with the patients/families throughout the process. Whilst there were examples of patient/family involvement, this was not consistently applied across the organisation.

65 The Review Group noted that whilst there would be instances where the involvement of wider stakeholders, for example staff or patients/families, may not be
appropriate, the paperwork and responses to questions of senior management and operational staff did not explain why this may be the case.

66 NHS Ayrshire & Arran submitted evidence that identified that 23 of the 57 cases under review (40%) had some level of family involvement in the incident review. This covered a period from 2010 to 2012.

67 **Whilst NHS Ayrshire & Arran had clear ambitions to raise awareness of the need to involve relatives in the significant adverse event review process, the Review Group was unable to obtain a complete picture of the level of family involvement over the 57 cases since 2009.**

<table>
<thead>
<tr>
<th>Recommendation 8:</th>
</tr>
</thead>
<tbody>
<tr>
<td>NHS Ayrshire &amp; Arran should build on its approach to involving families in the commitment to ensure greater openness.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Recommendation 9:</th>
</tr>
</thead>
<tbody>
<tr>
<td>NHS Ayrshire &amp; Arran should establish a robust system for tracking and responding to the issues raised by families. This system should be integral to the overall system for the management of significant adverse events.</td>
</tr>
</tbody>
</table>

### 3.6 Staff Involvement

68 NHS Ayrshire & Arran has adopted a model for full significant adverse event reviews that is led and populated by members of staff outside the area in which the incident takes place.

69 The process allows a level of involvement and contribution in the construction of report recommendations and its subsequent action plans. However, again the Review Group witnessed variation in the involvement and contribution made by staff to these documents. The Review Group heard that it had led, in some cases, to a distrust of the process which then did not support the improvement culture that the *Adverse Event Policy and Supporting Procedures* ultimately sets out to achieve.

70 The PwC report acknowledged that:

> “in practice, however, from review of available documentation for recent reviews and from discussion with staff, this [staff feedback] is not performed consistently and consequently, this could result in staff disengagement at the action [sic] implementation stage or low morale within the Service being subject to the SAER”.

71 The Review Group heard about a number of examples of robust local investigation. However, in the majority of significant adverse event review cases looked at by the Review Group, the use of the local investigation knowledge and information was limited to the initial written statements. This created a level of frustration in the local operational staff, evident through the operational team interviews undertaken on 29 and 30 March 2012, who had not been involved or able to contribute to any part of the significant adverse event review process.
72 The model, adopted in NHS Ayrshire & Arran, of an independent scrutiny team to lead significant adverse event reviews, excludes staff directly involved in the incidents and runs the risk of failing to obtain ownership of the action plans and improvements. Operational staff also felt, in some instances, that they had important insight and knowledge that could have been shared and used throughout the process, but the process did not allow their voice to be heard.

73 The Review Group concluded that the general approach to the management of significant adverse event reviews did not encourage an appropriate level of engagement with staff, particularly those directly involved in the incidents, with a resultant impact on the ownership of the findings, implementation of action plans and ultimately learning.

**Recommendation 10:**
NHS Ayrshire & Arran should review its approach to the involvement of staff in the investigation of significant adverse events, with the aim of offering consistent opportunities for learning and improvement.

74 The Review Group did hear positive feedback regarding the contribution of the Critical Incident Stress Management resource. It was viewed as being very supportive of staff and offered a “structured system of care” as set out in paragraph 5.3 of the *Adverse Event Policy and Supporting Procedures*. **NHS Ayrshire & Arran should seek to sustain and develop this.**

**Recommendation 11:**
NHS Ayrshire & Arran should build on its approach to the support of staff involved in significant adverse events.

### 3.7 Action Planning

75 During the time period studied by the Review Group, the Clinical Governance Committee received full Significant Adverse Event Review Reports and associated action plans and discussed them at their meetings. The minutes recorded varying levels of detail in respect of the consideration of the Significant Adverse Event Review Reports.

76 The Clinical Governance Annual Report for 2010/11 notes in paragraph 8 that:

“Eighteen significant adverse events were reported to the Committee. These took the form of an independent review of the incident, identifying contributory factors and a set of conclusions and recommendations. These reports were discussed in detail by the Clinical Governance Committee and were then reviewed (or plan to be reviewed), typically after 6 months to check on progress. A review of all cases was done to identify causal trends and actions undertaken.”

77 The PwC report commented that:
“upon conclusion of an SAER, the final report will contain an ‘action plan’ which includes measures to be implemented as a result of the conclusions of the review, to minimise the risk of a similar occurrence in the future and to improve the arrangements in place which gave rise to the event. From the review of a sample of these action plans from 2006 to present attached to the final reports, we found these to be thorough, targeted and a significant degree of consultation had taken place to agree the relevant actions, for example, draft action plans are discussed at Clinical Governance Committee meetings prior to these being finalised in the final report”. 4

78 The Review Group considered the extent of understanding, ownership and feedback relating to the action plans within and beyond the Clinical Governance Committee.

79 The previous Chair of the Clinical Governance Committee indicated in his interview that he had believed that all significant adverse event reviews had been presented to the Committee. As at 3 May 2012, the position – shared with NHS Ayrshire & Arran – is shown for the 57 cases in Table 7 below.

Table 7: Review of the status of the 57 significant adverse events and progression to Clinical Governance Committee (CGC)

<table>
<thead>
<tr>
<th>Status</th>
<th>Number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cases discussed at CGC</td>
<td>38</td>
<td>66.7</td>
</tr>
<tr>
<td>Cases scheduled to be discussed at CGC</td>
<td>2</td>
<td>3.5</td>
</tr>
<tr>
<td>Not yet reached CGC stage - ongoing/pending</td>
<td>12</td>
<td>21.0</td>
</tr>
<tr>
<td>Did not proceed to CGC</td>
<td>5</td>
<td>8.8</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>57</td>
<td>100.0</td>
</tr>
</tbody>
</table>

80 A major objective for the Review Group was to confirm that the detailed sample of seven significant adverse events had action plans that were produced within the same time period as the conclusion of their reviews and development of the review reports. Evidence was gathered and analysed to confirm that action plans were in existence within these time frames, following the Freedom of Information (Scotland) Act request by Mr Wilson. The Review Group confirmed that for the seven cases, under more detailed review, that the action plans were developed at the same time as the preparation of the full review reports.

**Final reports and action plans**

81 The Adverse Event Policy and Supporting Procedures describes the process by which reports are finalized, and identifies the various roles and responsibilities of certain staff, groups and committees in this process. Section 9.3.4 details the reporting process for ‘extreme’ events. The Review Group witnessed, through the senior management and operational team session on 29 and 30 March 2012, a degree of
uncertainty as to the flow and presentation of information that culminates in the final report.

82 The full and final Significant Adverse Event Review Reports tended to be comprehensive, but of variable quality. There was evidence of careful consideration and appraisal of issues in reaching conclusions. However, in some instances, the recommendations were sometimes numerous, and without prioritisation. The Review Group questioned the consistency of the quality of the Root Cause Analysis (RCA) through the investigations.

83 The Review Group noted that there was a degree of uncertainty in relation to the ownership of the various aspects of the reporting process. An example of this included variation in parts of reports going to various groups and committees. In one instance, the Review Group noted that an action plan had been reported to the Clinical Governance Committee, with the majority of actions described as complete. One year later, many of the actions previously recorded as complete were recorded as ‘ongoing’.

84 The material from NHS Ayrshire & Arran contained a summary report of information relating to Significant Adverse Event Review Reports and action plans discussed at the Clinical Governance Committee between September 2006 and November 2011. It contains a short summary such as ‘all actions complete’ or ‘discussions around the report’. The Review Group noted that ‘Date Completed’ column was blank from February 2009 until the last entry in November 2011. The ‘Follow-up Completed’ column refers to some actions that are beyond their due date (for example, July 2011).

85 NHS Ayrshire & Arran explained that the failure to complete the ‘Date Completed’ column related to the difficulties in obtaining robust information from the clinical services as to evidence of progress against action plans. The Clinical Governance Committee on 22 September 2010, stated that:

“the actions [sic] plans tabled in this report are historic action plans. Evidence is able to be provided to show that the recommendations has [sic] been implemented but there is no systematic collation of evidence that the recommendation has been effective. The Committee require that this be carried out. [The Assistant Director, Healthcare Quality] confirmed that this was being actioned within the existing SAER work and that he would ensure that actions that were tabled today were considered in relation to measures of effectiveness”.

86 The Review Group reviewed the minutes of the Clinical Governance Committee between 2009 and 2012. The Review Group found only limited examples of follow-up to chase progress from the full Significant Adverse Event Review Reports and action plans. There was not a systematic approach to assurance on progress. This was reinforced by the gaps in the evidence presented by NHS Ayrshire & Arran in their report covering significant adverse events between September 2006 and November 2011. The PwC report highlighted the fact that:
“for more recent reviews, there is some evidence of actions being implemented, however, this is inconsistent across Services and does not always appear to be given an appropriate priority for the operational management of clinical services upon close-out of the review”.

87 It was noted that work had been advanced to establish progress against the action plans against the background of the Scottish Information Commissioner’s investigation. However, the Review Group noted that attempts made in November 2011 and subsequently in March 2012 to establish progress against the action plans, had met with limited success.

88 On 20 April 2012, the Review Group requested documentary evidence to confirm the successful implementation of ‘completed’ action plans since 2009 that had also been signed off by the NHS Ayrshire & Arran Clinical Governance Committee/Group.

89 Based on information received from NHS Ayrshire & Arran, the analysis indicated that only nine cases had achieved ‘completed’ status: five were from within the cohort of 57 cases, with the remaining four cases prior to 2009. It was only possible in one case of the five to confirm that the action plan was complete. The Review Group concluded therefore that there was not a robust and systematic approach to the implementation of action plans and their monitoring.

Recommendation 12:
NHS Ayrshire & Arran should make urgent progress in establishing the status of all significant adverse events review action plans since 2009. NHS Ayrshire & Arran should also consider the scope to extend their review to cases pre-dating 2009, within the bounds of the information that is available.

3.8 Sharing of Learning

Information presented to the Clinical Governance Committee

90 The Clinical Governance Committee has also received Trend Reports and overall reports on significant adverse events. In September 2010, the Committee received a report on significant adverse event action plans between April 2009 and March 2010. The report covered 14 significant adverse events over that year and reported on progress against the action plan for each one. Five of the 14 significant adverse event action plans are described as ‘incomplete’ at that stage. The Review Group noted that at its meeting on 14 September 2011, the Clinical Governance Committee considered the position in respect of 18 significant adverse events that were ‘live and ongoing’. The Committee received a verbal report on the 18 events.

91 In February 2012, the Clinical Governance Committee received a report entitled Trend Analysis Adverse Events and Complaints, 1 July to 31 December 2011. The Trend Analysis identified high-level themes as well as categories of adverse events and complaints over the time period. The report by the Good Governance Institute (2010) notes that “Boards focus too much on individual serious untoward incidents…and should systematically consider lower level but often more revealing patterns of adverse events and near misses”. The Trend Analysis report did not go into any detail in respect of significant adverse events. This is not a deficiency, so long as there were alternative arrangements to ensure thematic learning from the significant adverse events.
The Management of Significant Adverse Events in NHS Ayrshire & Arran – June 2012

92 The Review Group concluded that it could not find convincing evidence of a system to identify thematic learning from significant adverse events to allow change and improvement to clinical practice.

**Recommendation 13:**
NHS Ayrshire & Arran should ensure an ongoing approach to thematic learning, giving opportunities for those working in NHS Ayrshire & Arran to learn from significant adverse events and to change and adapt clinical practice accordingly.

3.9 Structure and Accountability

93 The Review Group noted that there was a general lack of clarity regarding the accountability lines in the NHS Ayrshire & Arran system. At times, there was a level of ambiguity between operational and professional lines of accountability as expressed in decisions regarding significant adverse event reviews.

94 Paragraph 7.1 of the *Adverse Event Policy and Supporting Procedures* states that:

> “each Healthcare Directorate has arrangements in place to implement continuous clinical improvements and to ensure effective reporting and assurance regarding clinical governance. In relation to all adverse events that are not called for significant adverse event review, it is the responsibility of the Lead Investigator to produce summary reports for the appropriate Clinical Governance Group. It is the responsibility of the Chairperson of the Clinical Governance Group to ensure that for all local reviews of adverse events, actions plans are developed and implemented. In addition, the Chairperson is responsible for ensuring that action plans arising from significant adverse event reviews are implemented. This can be delegated as appropriate”.

95 Paragraph 7.3 of the policy states that:

> “it is the responsibility of the Healthcare Director to ensure that learning points are disseminated”.

**Managing significant adverse events across the clinical governance groups**

96 The Review Group noted that there were around a further 60 operational clinical governance groups covering individual specialties and services.

97 The Review Group received a sample of papers relating to the clinical governance groups, within the Healthcare Directorates. The Review Group noted that there was an inconsistent approach to the receipt and management of action plans across the groups.

98 In more recent minutes of the clinical governance groups, the Review Group noted confusion regarding the responsibility for progressing action plans. One member of staff advised in a meeting that:

> “summary reports are circulated and she brings them to the meeting. She advised that she is happy to go through those for her area for shared learning but is unclear as to how to
communicate information on other SAERs...also advised that there are FAIs and advised that it is difficult to use all the reports.”

99 Paragraph 7.1 of the policy sets out clearly the responsibility of the Chair of the Clinical Governance Group but paragraph 7.3 also highlights the role of the Healthcare Director in ensuring the dissemination of learning points. There is the risk of overlap and confusion in these roles, leading to a potential lack of clarity about responsibilities and accountabilities between the Clinical Governance Group Chair and the Healthcare Director. The evidence from the Clinical Governance Group material highlighted the absence of a systematic approach to the sharing of action plans and the development of a robust approach to wider organisational learning. There was also insufficient evidence to indicate a consistent approach to follow-up of individual actions plans, or ownership at Directorate level. It was also noted that the full Significant Adverse Event Review Reports were not generally shared at clinical governance group level.

100 The Review Group considered that the three tier structure for clinical governance in NHS Ayrshire & Arran: the Clinical Governance Committee; the Healthcare Directorate clinical governance groups; and the specialty and service-level clinical governance groups was complex and unwieldy. The large number of groups (60+) and different layers runs the risk of confusion regarding accountability and diluting ownership of action plans.

Recommendation 1
NHS Ayrshire & Arran should review its clinical governance structure with the focus on delivering a more streamlined and simpler arrangement, giving sharper clarity regarding accountability.

101 The Adverse Event Policy and Supporting Procedures sets out on page 26 a Flowchart of the review of adverse events (Flowchart 3). The Flowchart guides staff through the steps from adverse event being reported through to action plans. The Flowchart paints an ambiguous and unclear diagram of how to handle the most significant adverse events.

Recommendation 15:
NHS Ayrshire & Arran should ensure a focus on empowering clinical services to develop, own and progress action plans and to share wider learning and to reflect this in a revised flowchart.

102 The Healthcare Directors are key senior operational directors in the NHS Ayrshire & Arran system. They lead and manage complex operating units and report directly to the Board Chief Executive as effectively ‘chief operating officers’ of their Directorates. However, they appeared to be absent from the ownership of the process, in practice and as expressed to varying degrees in the Adverse Event Policy and Supporting Procedures. In the considerable volume of emails sent to the Review Group, they were also largely absent from the correspondence regarding the handling and learning from significant adverse event reviews. This is a potentially significant gap in the governance and accountability arrangements.
The Review Group heard that the new Chief Executive had taken firm action to define more explicitly the responsibilities and accountabilities of the Healthcare Directors for all aspects of the performance of their Directorates, and he had written to them to this effect.

**Recommendation 16:**
NHS Ayrshire & Arran should ensure that Healthcare Directors have explicit objectives related to the effective organisation and learning from significant adverse events, and such objectives are cascaded, appropriately, through their Directorates.

### 3.10 Sharing of Information

**NHS Ayrshire & Arran’s policy for sharing information**

104 A core issue shared by those the Review Group interviewed was the interpretation of the restrictions placed on NHS Ayrshire & Arran to protect patient confidentiality and the privacy of employees. Chiefly, this related to the interpretation of the Data Protection Act, the requirement to comply with the Caldicott principles and the Freedom of Information (Scotland) Act.

105 The Review Group heard that the full Significant Adverse Event Review Reports were considered to be confidential and restricted in their circulation. An email of 15 May 2010, reminded directors that the attached full reports – due to be considered by the Clinical Governance Committee – were confidential:

> “the reports are not for general distribution and no copies can be given to staff without explicit Executive Medical Director or Executive Nurse Director approval”.

106 The minutes of the Clinical Governance Committee meeting on 5 May 2010 note that the:

> “Committee discussed the possibility of patients being identified in the reports. It was agreed that these documents are treated as confidential clinical information and are not available under Freedom of Information (Scotland) Act provisions.”

107 The *Adverse Event Policy and Supporting Procedures* makes it clear in section 9.3.4 that:

> “a full copy of the report will not be issued to any individual, either patients, relatives or staff members, without the explicit authorisation of either the Executive Medical or Executive Nurse Director”.

108 The policy gives the opportunity for staff to identify: “potential inaccuracies within the report”. However, given the restrictions on the circulation of the full report, there are extremely limited opportunities, in the current policy, for staff to correct material inaccuracies in the report before it is finalised and presented to the Clinical Governance Committee. This risks inhibiting staff contributing to reviews in an open way, and which ultimately promotes improvement and learning.
109 The Review Group noted that, through the desktop review exercise, a similar scenario existed, where final reports are written with limited or no involvement or contribution from those involved in the incident. In one of the cases reviewed, this created resentment from operational staff who were unaware of the content of the report, recommendations or actions until they were provided with it 10 minutes before the Review Group began their questions, at the visit on 29 March 2012.

**Wider learning**

110 The Review Group heard evidence from a range of staff that they felt that the policy was unnecessarily restricting the sharing of information and wider learning within NHS Ayrshire & Arran. For some, this required individuals to work around the policy in order to overcome the perceived obstacles created by the policy. In one instance, the Lead Investigator showed the full Significant Adverse Event Review Report to some (but not all) members of staff involved in the incident. However, in that instance it was restricted to allowing staff to read it in the Lead Investigator’s office and not to take a copy of the report away with them. The Lead Investigator took the initiative to promote wider learning outside the terms of the policy, but the Lead Investigator was also clear that in a future similar event the current policy would not permit such a step.

111 One member of staff referred to the fact that staff involved in incidents were not permitted to see the full Significant Adverse Event Review Report. In their view, this was at risk of “disenfranchising” frontline clinical services. A more general theme identified by the Review Group was that the significant adverse event review process was “done to them” rather than “with them”. It was noted that in one instance staff referred to a case when a local investigation report was over-turned by a subsequent significant adverse event review by another team. For those involved in the original review, this led to lack of ownership and disagreement regarding the conclusions and the action plan.

112 It was noted that the Healthcare Directorates were now being supported in populating the action plans themselves rather than reports being written in isolation. This was seen to be an important step forward in promoting ownership. However, based on the evidence presented, there remained considerable confusion about the scope to share information and the variation in interpretation of the policy, as well as the legislation.

113 Throughout the review, it was clear to the Review Group that there was not an open approach to the sharing of Significant Adverse Event Review Reports. This hindered the provision of contextual information and wider learning opportunities for NHS Ayrshire & Arran staff. In one Clinical Governance Group minute of October 2011, it was acknowledged that it “would be very interesting to have visibility of all SAERs across A&A”.

33
In the view of the Review Group, the approach taken by NHS Ayrshire & Arran hampered the delivery of the primary objectives of the Adverse Event Policy and Supporting Procedures to learn from significant adverse events and to promote wider learning and improvement.

**Recommendation 17:**
NHS Ayrshire & Arran should undertake a fundamental review of its approach to sharing information arising from significant adverse events. It should ensure that the approach remains within the legislative requirements, but maximises the opportunities for staff to understand the broader context and background regarding specific incidents.
APPENDIX 1: TERMS OF REFERENCE

Healthcare Improvement Scotland: Review of NHS Ayrshire & Arran Significant Adverse Event Systems and Processes

Focus on the Management of Critical Incidents/Adverse Events, Action Planning and Learning

March 2012

Background
Concerns have been raised about the NHS Ayrshire & Arran’s arrangement for managing, reviewing and acting on critical incidents and adverse events. The Cabinet Secretary for Health, Wellbeing and Cities Strategies has now formally asked Healthcare Improvement Scotland to undertake an urgent review of the clinical governance systems and processes in NHS Ayrshire & Arran, in particular those that relate to their management of critical incidents, adverse events, action planning and local learning.

Healthcare Improvement Scotland has carried out a number of similar reviews and the focus is on ‘diagnosing’ the key issues and supporting the relevant NHS board(s) in developing and implementing improvement plans. More generally, the focus is on shared learning across the NHS in Scotland and healthcare providers generally.

The specific request for the review has arisen following a report by the Scottish Information Commissioner (Decision 036/2012) – Mr Rab Wilson and NHS Ayrshire & Arran.

The Scottish Information Commissioner investigation and a recent (November 2011) NHS Ayrshire & Arran Internal Audit report from PricewaterhouseCoopers (PwC) – Significant Adverse Events Review – highlighted a number of governance issues in relation to the effectiveness of the clinical incident review/significant adverse event process within NHS Ayrshire & Arran between 2006 and 2011.

Remit and scope of review
Healthcare Improvement Scotland will review and report on NHS Ayrshire & Arran’s significant adverse event policy and supporting procedures. The aim is to ensure there is systematic, comprehensive and transparent approach to management and follow-up of significant adverse events. The review will ensure that the approach maximises the opportunities for learning, and explicit action for service change and improvement is embedded throughout the organisation. Learning opportunities will also be shared more widely across all healthcare providers.

The Healthcare Improvement Scotland review will focus on the:

- systems related to the identification, investigation, reporting, documentation and learning from significant adverse events in NHS Ayrshire & Arran
- relationship between clinical governance support and operational (including management and human resources/clinical services in the management of significant adverse events, and
opportunities for the wider improvement of the management of significant adverse events in NHSScotland and healthcare providers in general with a particular emphasis on openness, transparency and shared learning.

**Proposed method**

The review will be undertaken using a group made up of individuals with specialist knowledge from across NHSScotland, including the Director of Scrutiny & Assurance at Healthcare Improvement Scotland, and will include the following methods.

- Review of NHS Ayrshire & Arran's serious adverse events policy, procedures and related documentation in the context of their clinical governance and risk management arrangements.
- Draw from/ensure, appropriate linkages with recent related Healthcare Improvement Scotland clinical governance and assurance work.
- Review of information systems to support the management of significant adverse events within NHS Ayrshire & Arran.
- Interviews with key staff to ascertain typical process adherence and understanding throughout the organisation. This will take account of the views of operational staff at the frontline, the Executive Team, clinical governance and any other involved staff. A number of key controls will be tested and cover, in the first instance, the following:
  - a consistent and robust approach to reviewing and updating the organisational understanding, compliance and capability of the systems and process associated with significant adverse events, specifically:
    - identification of significant adverse events
    - assessment of significant adverse events, including consistent triggers
    - reporting (including document storage and consistency) and escalation of serious adverse events
    - key roles and responsibilities following a significant adverse event, including organisational relationships and partnerships across the organisation
    - associated training and staff capability
    - key learning, sharing, improvement and action planning, and
    - staff engagement and follow-up to reporting.

The review will be completed with the presentation of a report with associated risk-based recommendations and may include any appropriate Learning and Improvement Briefings. This report will be sent to the Scottish Government Health & Social Care Directorates on completion.
Assumptions

Through the Healthcare Improvement Scotland review, we will use data, where possible, from recent related Healthcare Improvement Scotland clinical governance and assurance work findings

Through the Healthcare Improvement Scotland review, the findings of the Scottish Information Commissioners report will be cited as evidence of identified failings and where available we will use any additional external sources of information.

Through the Healthcare Improvement Scotland review, the PwC report findings will be used as baseline information and as such the level of risk to the organisation will be subject to ongoing assessment where appropriate.

The main purpose of the Healthcare Improvement Scotland review is to support NHS Ayrshire & Arran to further identify potential [and then resolve] key deficiencies within their systems and processes in relation to significant adverse events. We will share the wider learning to support wider improvements across the NHS in Scotland.

Initial key reference documentation


• Scottish Information Commissioner Report 036/2012 Rab Wilson and Ayrshire & Arran NHS Board.

• NHS Ayrshire & Arran Board & Clinical Governance Committee papers 2006-2012.

• Documentation held within the clinical governance function relating to serious adverse events.

• NHS Ayrshire & Arran self-assessment for the clinical governance and risk management standards: section on serious adverse events.
## Review Group membership

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<tr>
<th>Name</th>
<th>Position</th>
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<tr>
<td>Robbie Pearson (Chair)</td>
<td>Director of Scrutiny &amp; Assurance, Healthcare Improvement Scotland</td>
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<tr>
<td>Dr Gordon Birnie</td>
<td>Medical Director, Operating Division, NHS Fife</td>
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<tr>
<td>Professor Kevin Rooney</td>
<td>University of the West of Scotland, and Consultant in Intensive Care, NHS Greater Glasgow and Clyde</td>
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<td>Dr Mags McGuire</td>
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<td>Robin Creelman</td>
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<td>Dr Lorna Ramsay</td>
<td>Clinical e-Health Lead and Divisional Caldicott Guardian, NHS National Services Scotland</td>
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<td>Dr Lesley Anne Smith</td>
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<tr>
<td>Mark Aggleton</td>
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Project management support will be provided by the Directorate of Scrutiny & Assurance team at Healthcare Improvement Scotland.
APPENDIX 2: EVENTS LEADING TO THE REVIEW

From 2006 onwards, Mr Wilson made a number of requests to see a Critical Incident Review Report and action plan. This was followed up by requests for further information regarding Critical Incident Review Reports held by NHS Ayrshire & Arran, culminating in a request in February 2011 for all Critical Incident Review Reports and Significant Adverse Event Review Reports (and the action plans derived from these) from January 2005.

Mr Wilson was unhappy with the response from NHS Ayrshire & Arran and appealed to the Scottish Information Commissioner. The Scottish Information Commissioner set out his conclusions in Decision Notice 036/2012.

NHS Ayrshire & Arran, in direct response to the concerns expressed regarding the management of significant adverse events, also commissioned PricewaterhouseCoopers (PwC) to carry out an investigation. The results of that investigation were reported to the Clinical Governance Committee of NHS Ayrshire & Arran in December 2011, followed by an action plan presented to the Clinical Governance Committee in February 2012.

The PwC report made 13 recommendations for improvement but noted that “since 2006, particularly since 2009, there have been substantial improvements, with strong leadership support in respect of significant adverse event reviews, and with a clear strategy to make this process effective and consistent across all services within NHS Ayrshire & Arran”. The cover report to the Clinical Governance Committee acknowledged that “recommendations were also made in order to support ongoing improvements particularly around report sharing and lessons learned, it was highlighted that these are not critical risks to the organisation, and do not have a significant impact on patient safety”.

NHS Ayrshire & Arran issued press statements in response to the conclusions of the Scottish Information Commissioner on 22 February 2012 and stated that:

“In his request, Mr Wilson asked for copies of Critical Incident Reviews (CIRs) and Significant Adverse Event Reviews (SAERs) which had been completed since January 2005, along with action plans relating to the reports.

We acknowledge that the Commissioner’s criticism of NHS Ayrshire & Arran’s records management system prior to 2009 is justified, and apologise that Mr Wilson has had to go to significant lengths to receive the information he requested.

I would like to reassure the public that there has never been any intention to deliberately withhold information from Mr Wilson to which we thought he should have been entitled. Where we applied the Act to exempt information from disclosure, again we did so in good faith.

We identified failings in our system for conducting and recording CIRs back in 2009. As a result we took steps to improve the way in which we as an organisation conduct incident investigations. A vital part of this process is how learning is applied to improve patient
care and safety and reduce risk. This is the process now referred to as the Significant Adverse Event Review.

Indeed, a recent independent audit report by Price Waterhouse Cooper, while critical of the former process, finds little fault with the new SAER process for investigating adverse events and publicising the learning points from them.”

A further statement on the same day said that:

“Prior to the introduction of the Significant Adverse Review Process (SAER) in 2009 the Board did not have an established system for capturing actions taken as a result of reports into critical incidents. This meant the Board could not ensure and report that all necessary changes to practice, identified from reports, were implemented. The Commissioner was rightfully very critical of this and the Board accepts these comments, which relate to the period before 2009.

Since the introduction of SAERs the necessary audit trails and assurance systems have been in place. This has been confirmed to the Board by both an external PwC audit that it commissioned in 2011, and now also by the Commissioner’s findings.”

The review by Healthcare Improvement Scotland has sought to give external scrutiny and assurance to the process of the management of significant adverse events in NHS Ayrshire & Arran.
APPENDIX 3: LIST OF ADVERSE EVENTS ON NHS AYRSHIRE & ARRAN
SIGNIFICANT ADVERSE EVENT REVIEW DATABASE (in chronological order)

Key: x = not included/outwith remit

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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 key components of our organisation.