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
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3
Executive summary

In June 2012, Healthcare Improvement Scotland published a report called: *The Management of Significant Adverse Events in NHS Ayrshire & Arran* (2012). The report provides an in-depth analysis of NHS Ayrshire & Arran’s adverse event management system and outlines a number of recommendations and issues that the NHS board should act on. The report also contains recommendations for other NHS boards in Scotland and learning points for NHSScotland as a whole.

Immediately following the publication of our report, the Cabinet Secretary for Health, Wellbeing and Cities Strategy asked Healthcare Improvement Scotland to carry out a rolling programme of reviews across NHS boards starting in autumn 2012.

Our reviews focus on the six key recommendations for NHS boards (numbers 18–23) from the NHS Ayrshire & Arran report. The purpose of the reviews is to assess how investigation of adverse events is being used by NHS boards to drive learning and improvement in order to reduce the risk of these events occurring again.

What we found

Our review of NHS Forth Valley’s governance arrangements and processes for managing adverse events involved:

- an analysis of evidence provided by the NHS board, and
- a visit to NHS Forth Valley on Wednesday 28 November 2012.

NHS Forth Valley has conducted a significant amount of work following the recommendations from *The Management of Significant Adverse Events in NHS Ayrshire & Arran* (2012). In particular, they are in the process of developing a significant adverse event policy and significant adverse event toolkit. This is due to be completed by December 2012. There are plans to improve the management of significant incidents, including a focus on the reporting and recording of review processes, the monitoring of actions and how learning is shared throughout the organisation.

The current NHS Forth Valley incident management policy states that it is:

“committed to the health, safety and well being of its staff, patients, visitors and all users of its premises and services by being proactive in its approach to prevent, reduce, control and manage the number of incidents that occur within and connected to our organisation.”

Our review identified many areas of good practice relating to the management of adverse events within NHS Forth Valley, including:

- wide-ranging staff engagement, particularly in reporting and feedback
- a rolling programme of staff training for incident reporting
- a recently simplified governance structure which has resulted in improved Board assurance and executive oversight of serious incidents, and
- an incident management system which has been adapted in response to staff feedback.
We saw a commitment to a culture that supports learning and continuous improvement to increase the quality and safety of healthcare across the NHS board.

In summary, our review showed that NHS Forth Valley’s incident management policy is reliably applied across the NHS board. Further improvements could be made in relation to patient, family and staff involvement, the grading of incidents, monitoring of action plans and how this relates to organisational learning. These areas have already been identified by NHS Forth Valley and improvement activity is under way. The recommendations below aim to support this activity.

Recommendations

We expect NHS Forth Valley to continue to implement recommendations 18–23 from the NHS Ayrshire & Arran report. We have also identified the following associated recommendations to improve how the NHS board manages adverse events.

Engaging with stakeholders

**Recommendation 18 from the NHS Ayrshire & Arran report**

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

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

1. always consider the involvement of patients, families and carers in investigations and analysis of the event,
2. demonstrate a consistent process of documenting the involvement of patients, families and carers in the incident investigation, and
3. consistently provide meaningful feedback to staff to encourage a reporting culture.

Staff knowledge and training

**Recommendation 19 from the NHS Ayrshire & Arran report**

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

To support staff knowledge and training, NHS Forth Valley should:

4. demonstrate a systematic approach to staff training.
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 organisations governance structure.

To ensure clear functions and roles, following the recent organisational re-structuring, NHS Forth Valley should:

5 evidence that roles and responsibilities are clear and adhered to by staff.

Information management

Recommendation 21 from the NHS Ayrshire & Arran report
NHS boards should ensure that their document control and related information systems are suitably integrated and robust to provide a complete audit trail of significant adverse event management from the incident occurring to evidencing change and improvement. These systems should also allow NHS boards to undertake ongoing thematic learning from significant adverse events.

To support its information management processes, NHS Forth Valley should:

6 demonstrate that all incident reporting systems are integrated and provide a robust audit trail, and

7 continue to demonstrate that the system allows thematic learning to take place.

Risk-based, informed and transparent decision-making

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

To support a risk-based, informed and transparent approach, NHS Forth Valley should continue to:

8 assess if grading processes ensure consistency of response and appropriate management of incident reporting, and

9 develop robust and consistent mechanisms for escalation of events to clinical governance groups.
Timely management, learning, dissemination and implementation

**Recommendation 23 from the NHS Ayrshire & Arran report**

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

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

10. demonstrate that the timescales for various stages of the adverse incident management process are met in line with the policy

11. ensure systematic and formal monitoring of action plans throughout the organisation, and

12. continue to improve the sharing of information and application of learning across the organisation.

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

We would like to thank NHS Forth Valley and in particular all staff at Forth Valley Royal Hospital, Larbert, and Stirling Community Hospital for their assistance during the review.
1 Introduction

1.1.1 An adverse event can be described as an unexpected or avoidable event that could have resulted, or did result in, unnecessary serious harm or death of a patient, staff, visitors or members of the public. Reviewing and managing these events should help NHS boards learn how to reduce the risk of them happening again.

1.1.2 We published a report in June 2012 called: The Management of Significant Adverse Events in NHS Ayrshire & Arran. The report focuses on NHS Ayrshire & Arran’s adverse event management system but also contains recommendations for other NHS boards in Scotland and learning points for NHSScotland as a whole.

1.1.3 Immediately following the publication of our report, the Cabinet Secretary for Health, Wellbeing and Cities Strategy asked us to:

- develop a national approach to learning from adverse events, and
- carry out a rolling programme of reviews across NHS boards starting in autumn 2012.

The review process

1.1.4 Reviewing NHS boards’ governance arrangements and processes for managing adverse events helps us to identify whether appropriate learning and improvement is taking place to reduce the risk of events happening again.

1.1.5 Our reviews focus on the six key recommendations (18–23) for NHS boards from the NHS Ayrshire & Arran report (2012) to provide assurance that NHS boards are effectively managing adverse events. We measure NHS boards against the recommendations within the NHS Ayrshire & Arran report and against their own policies.

1.1.6 The review process has two key phases:

- pre-visit analysis, and
- the review visit.

Pre-visit analysis

1.1.7 We reviewed information provided by NHS Forth Valley in advance of the visit. This included:

- policies and procedures for adverse event management
- governance and reporting arrangements
- an assessment of the NHS board’s current and future planned approach following the recommendations of the NHS Ayrshire & Arran report
- a list of 299 recorded significant adverse events identified between February 2011 and June 2012, and
- details of four specific significant adverse event reviews.
1.1.8 Of the 299 recorded significant adverse events, we selected four cases for detailed review. Firstly, we randomly selected 50 cases and then reviewed in further detail 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 Wednesday 28 November 2012. The review team was made up of a number of individuals with relevant specialist knowledge from across Scotland (see Appendix 1 for membership of the review team).

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

1.1.11 We discussed the initial findings of our report with NHS Forth Valley’s chief executive on 20 December 2012.

**Improvement plan**

1.1.12 We expect NHS Forth Valley to continue to implement recommendations 18-23 from the NHS Ayrshire & Arran report and to implement the specific recommendations within this report. It is important that the recommendations are carefully considered and a detailed improvement plan developed, with appropriate timescales, ownership, accountability and measures incorporated.

1.1.13 We have asked NHS Forth Valley to keep us updated as the improvement plan progresses and to notify us when it has been agreed by local governance structures. This will inform the development of the national approach to learning from adverse events.
2 NHS Forth Valley’s adverse event management policies and procedures

2.1 NHS Forth Valley provides health services for a population of around 300,000 people across Clackmannanshire, Falkirk and Stirling. The NHS board has one acute hospital, six community hospitals and 56 health centres throughout the region. Forth Valley Royal Hospital undertakes all acute services and became fully operational in July 2011. The NHS board also works with NHS 24, the Scottish Ambulance Service and the voluntary sector services to deliver healthcare services to the residents in the Forth Valley area.

2.1.2 NHS Forth Valley sets out a commitment to an open and fair culture in their incident management policy, and to developing a learning culture, within which employees are encouraged to report incidents.

Adverse event definitions

2.1.3 The incident management policy (version 3, issue date 30 March 2011) hereafter referred to as the policy, defines an incident as:

“anything which gives rise to unwanted and/or unexpected outcomes (actual) involving:

- The safety or well being of any person either on NHS FV Premises, employed by NHS FV or who is being treated by a person employed by NHS FV.
- Loss or damage to property, records, data or equipment on NHS FV premises or owned by NHS FV.
- Any incident causing injury or ill health, specific “clinical” type incidents, security breaches, episodes of violence and any other categories such as failure of medical or other equipment which resulted in harm or loss.

Incidents also include near misses. These are defined as any situation that could have resulted in harm or loss but did not (potential), due to either chance or intervention. Near misses include the examples above.”

2.1.4 Between February 2011 and the end of June 2012, NHS Forth Valley recorded a total of 12,513 reported incidents. The NHS board assessed 239 of these as high or very high; nine incidents were rated as very high; and 228 were rated as high. Before the review, the NHS board identified issues surrounding the grading of incidents using the NHSScotland Risk Matrix. The NHS board provided a further 60 incidents that had occurred in this period that they had re-graded as high or very high. NHS Forth Valley uses the Safeguard Incident Management Software system.

2.1.5 NHS Forth Valley has identified the top five themes for high and very high incidents as:

- inappropriate behaviour
- violence, aggression and harassment
- equipment
- slip, trip, fall, and
- medication.
Governance arrangements

2.1.6 NHS Forth Valley undertook a review of governance arrangements in early 2012 to ensure ongoing effective systems of assurance. Alongside this, a management restructure was completed bringing strategy and operations closer together and streamlining a number of processes, including those for risk management, clinical governance and incident reporting.

2.1.7 NHS Forth Valley is currently updating its clinical governance and risk management strategies to reflect the new arrangements and the recommendations from the NHS Ayrshire & Arran review. NHS Forth Valley’s new governance framework for the management of adverse events is provided at Figure 1.

Figure 1: NHS Forth Valley governance structure (implemented during 2012)

A new significant adverse event policy and significant adverse event toolkit are also currently being developed as part of NHS Forth Valley’s risk management arrangements and are due to be completed by December 2012.
3 Detailed review findings

3.1 Engaging with stakeholders

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

Patient, family and carers involvement

3.1.1 The policy outlines guidance to ensure the immediate safety of patients and family following an incident and highlights the need to identify support for all groups involved.

3.1.2 Appendix 4 of the policy states:

“All key members of staff/ visitors/ contractors/ patients (if possible/ appropriate) must be identified and advised that an incident review is going to take place and that their support in collecting relevant information is required.”

3.1.3 The policy does not provide guidance on the process for involving patients, families and carers in investigations or the analysis of the event. However, NHS Forth Valley also provided the critical incident/suicide review guidance issued in August 2011 which includes letter templates for contacting families asking for their input into the suicide review and an accompanying information leaflet for families explaining the review process.

3.1.4 We reviewed evidence provided by NHS Forth Valley for four incident cases. In all cases, staff told us that communication with patients and families had taken place or been attempted. We were told there were also processes for tracking and responding to concerns raised by families. However, there was no consistent approach for involving patients, families and carers in the incident investigation, or a systematic process for documenting these events. Staff confirmed that none of the four cases reviewed involved family or carers in the investigation or action plan process.

3.1.5 NHS Forth Valley is in the process of developing a new significant adverse event policy and intends to clearly define communication involving patients and families within this.

Staff involvement

3.1.6 The policy contains guidance for engagement of staff in reporting incidents. Appendix 3 of the policy indicates that NHS Forth Valley promotes an open and fair culture and states:

“Incidents will be investigated for the purposes of learning and improvement and all staff are required to engage as active participants in this process. Line managers and supervisors have a responsibility to ensure that all staff involved are appraised of outcomes. Unless there is clear evidence of flagrant malpractice, a complete disregard for the safety of others, maliciousness, intent to harm, or theft or fraud, the disciplinary process will not be used for investigation purposes.”

3.1.7 Every staff member of NHS Forth Valley can report incidents through the Safeguard reporting system. The policy contains links to guidance notes and user guides which are
available via the intranet. Staff spoken with at the time of the review were knowledgeable about incident reporting and felt supported during the incident management process. Staff told us that disciplinary processes are distinct from the incident management process. However, this separation was not clear from the documentation submitted.

3.1.8 Systems are in place to provide confidential support and counselling for all staff involved in major incidents. If there are occasions when the employee does not feel comfortable or confident reporting an incident, they can report an incident through the Safe Haven confidential answer phone service. The incident is then pursued anonymously on their behalf.

3.1.9 The policy details that investigations should be led by staff who are trained and competent to do so, undertaken by more than one person, and the lead should be impartial and remote from the incident or service involved. Staff spoken with during the review confirmed that investigations are conducted by staff separate to the incident and those staff had received appropriate training.

3.1.10 NHS Forth Valley demonstrated that the incident reporting system allows feedback to be sent directly to the individual reporting the incident. The NHS board has also worked to promote the provision of timely and meaningful feedback to staff to encourage a reporting culture. However, we did not see evidence that this was consistent throughout the organisation.

**Recommendations**

The 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 the involvement of patients, families and carers in investigations and analysis of the event
2. demonstrate a consistent process of documenting the involvement of patients, families and carers in the incident investigation, and
3. consistently provide meaningful feedback to staff to encourage a reporting culture.

**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 provides information on incident management training that is available in NHS Forth Valley. It contains links to the National Patient Safety Agency root cause analysis toolkit and other resources provided by National Patient Safety Agency. At the time of the review, the NHS board reported that they were in the process of developing a ‘significant adverse event toolkit’ due for completion in December 2012 as a source of additional support for staff.

3.2.2 The risk management team provides regular staff training on incident reporting and risk assessment with guidance available on the intranet. The NHS board reported that work is currently under way to create an e-learning module for incident management and
investigation. All staff spoken with during the review had received training on the incident reporting system and we were informed that update training was also regularly provided.

3.2.3 NHS Forth Valley reported that 54 staff have also recently been trained in complaints investigation (Scottish Public Services Ombudsman investigation training). This provides staff with generic skills that can also be used to investigate clinical incidents.

3.2.4 NHS Forth Valley told us that they are developing a pool of trained staff with skills specific to adverse event investigations that can be used across the organisation. NHS Forth Valley has taken an organisation-wide approach to ensure individuals use their training to maintain competency, and is considering how to provide support to individual teams.

3.2.5 All staff spoken with during the review, who were involved in the investigation process, had undertaken specialist training and felt supported throughout the process.

3.2.6 The policy indicates that an external review can be commissioned if it is decided that either specialist skills external to the organisation are required, or if it is felt that the review should be independent of the organisation.

3.2.7 At the time of the review, NHS Forth Valley was in the process of upgrading the incident reporting system to allow automatic generation of a root cause analysis through the incident reporting form. The NHS board has also planned the following additional actions:

- undertaking a training needs analysis that takes account of roles, responsibilities and the impact of recent organisational change and improvements to the current policy
- implementing a wider availability of investigation training for complaints
- designing and implementing a training plan for all identified individuals
- developing specific guidance for the investigation of significant adverse events, and
- acknowledging recent organisational re-structuring, roles and responsibilities will be re-defined to ensure clarity and consistency.

Recommendation
To support staff knowledge and training, NHS Forth Valley should:

4 demonstrate a systematic approach to staff training.

3.3 Roles and responsibilities

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

3.3.1 Section 4 of the policy clearly sets out the roles and responsibilities of staff, relevant departments and committees in NHS Forth Valley. Appendices 1 and 3 of the policy also outline reporting arrangements and associated roles and responsibilities for each category.
of incident (low, medium, high and very high risk). Appendix 5, the incident summary report form, provides a checklist for the internal reporting requirements which reflect the lines of accountability.

3.3.2 The documentation provided for each of the four selected cases demonstrates that incidents are reported and escalated as appropriate. Staff spoken with during the review were all aware of the policy and where to find it. They were also knowledgeable about their level of involvement in the process.

3.3.3 In line with the policy, staff reported that managers, designated by specialty, undertake investigations resulting from the incident reporting process. Staff reported that these were then discussed at the appropriate clinical review groups and staff are supported to create and manage action plans.

3.3.4 The policy does not explicitly mention the role of the Board or non-executives in the management of adverse events. However, one of the actions from the February 2012 Board development event was to:

“Review our Serious Adverse Event Policy to ensure that it clearly defines process, roles, communication involving patients and families and how non-execs are informed, particularly through Clinical Governance Committee.” We note that a first draft of this is due to be developed by December 2012.

3.3.5 The policy states that:

“The NHS Forth Valley Clinical Governance Committee, Health and Safety Committee and Risk Network group will review all incident information and statistics and monitor trends as they play an integral part in the process of incident minimisation.”

3.3.6 We looked at meeting minutes of the clinical governance committee, acute clinical governance working group, Community Healthcare Partnership clinical governance working group and joint clinical governance working group. These minutes detail the numerous other groups that report into the clinical governance committee.

3.3.7 From the documentation provided it was unclear how these groups worked together. However, NHS Forth Valley has recently simplified its governance structure which has resulted in improved Board assurance and executive oversight of serious incidents (see Figure 1 on page 11).

3.3.8 The minutes provided demonstrate that there is a focus on improving reporting, reviewing and learning from adverse events. This was reinforced through discussions with staff at the time of the review.

3.3.9 Responsibility for escalating adverse events and taking forward actions following the recording of adverse events was clear throughout discussions with staff. Demonstration of the Safeguard system highlighted that all actions are assigned owners, and the system automatically provides alerts and monitors timescales.

3.3.10 We were also assured that there is clear ownership at a strategic level, with the director of pharmacy formally responsible for providing a strategic overview of all risk within the organisation.
3.4 Information management

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

3.4.1 NHS Forth Valley uses Safeguard as an integrated risk management system. The Safeguard Incident module is used as the incident reporting system. Safeguard Incident can collect and report trends on all types of incidents and can track investigations and other actions or events with target and completion dates.

3.4.2 It is standard procedure within NHS Forth Valley that staff from all disciplines report adverse events on Safeguard. The Safeguard system times and date stamps all communication in and out of the system.

3.4.3 We were shown that a defined list is used to classify incidents on the Safeguard system. Staff are consulted on the contents of this list and categories are updated according to need.

3.4.4 NHS Forth Valley informed us that the ability to attach documents to Safeguard is currently being rolled out across the NHS board. Documents such as action plans, staff statements and incident reports can now be attached to the Safeguard record. From the cases reviewed, it is evident that not all related documentation has been stored on Safeguard, although we recognise this is a new function of the system.

3.4.5 NHS Forth Valley told us that a number of actions have been identified following a review of the current system. This includes the development and implementation of a robust document control system to ensure reporting, investigation, completion and follow-up of all serious adverse event reviews. At the time of the review, the NHS board further reported that the process had been streamlined to ensure that:

- immediate action is taken
- incidents are graded appropriately
- effective escalation and additional reporting, for example the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations, is in place, and
- the appropriate process is followed, including the correct level of investigation.

3.4.6 NHS Forth Valley demonstrated that it adapts Safeguard following staff consultation, for example staff highlighted issues regarding feedback following the reporting of an incident. Safeguard now has the ability to produce feedback directly to the staff member reporting the incident.
3.4.7 Safeguard generates reports for wards, units and various groups and committees, and also alerts to ensure that the NHS board notifies external bodies when appropriate.

3.4.8 During the review, we also saw evidence that thematic learning, change and improvement was taking place which is supported by reports produced from Safeguard. The policy states:

“The findings of all investigations should be shared with those directly involved and where there are lessons to be learned, the wider management of NHS Forth Valley. A range of groups and committees within the units and CHPs will review the content and findings of these investigations to ensure appropriate actions are taken and information effectively disseminated.”

3.4.9 The policy is clear that learning outcomes should be shared and the minutes of the clinical governance committee and groups provided evidence to demonstrate that discussions occur at these forums. Staff spoken with confirmed that learning was shared through the circulation of minutes, operational meetings, safety briefs and informal networks. NHS Forth Valley also highlighted the risk network as a mechanism for sharing information and risk assessments across the NHS board.

3.4.10 Appendix 4 of the policy provides guidance on protecting patient confidentiality throughout the incident reporting process. This should allow reports to be shared throughout the NHS board without jeopardising patient confidentiality.

3.4.11 NHS Forth Valley also demonstrated an anonymous reporting system that medical staff have developed. This has proven to be powerful in engaging medical staff with reporting and formally documenting the management of adverse events, and as a learning tool. However, care needs to be taken that all information systems are integrated and that a consistent adverse event management process is adhered to across the organisation.

**Recommendations**

To support its information management processes, NHS Forth Valley should:

6 demonstrate that all incident reporting systems are integrated and provide a robust audit trail, and

7 continue to demonstrate that the system enables thematic learning to take place.

### 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 an appropriate level of scrutiny and assurance.**

**Identification, notification and initial event reporting**

3.5.1 The policy provides guidance that each individual member of staff must record incidents through the IR1 form and maintain the record of action taken. The individual must also contact the appropriate line manager or deputy. A member of designated senior staff then reviews the IR1 form to ensure that the risk impact is appropriately graded.

3.5.2 The policy also provides guidance on what staff should or should not report as an
incident and provides examples of each category. The guidance aims to promote a reporting culture, whilst ensuring the aim of reporting is to increase patient safety and share learning.

3.5.3 NHS Forth Valley uses the NHSScotland Risk Matrix to grade individual incidents and the policy outlines this process. The severity of the incident determines the level of investigation and reporting. NHS Forth Valley told us that the use of the grading system was a current challenge as the likelihood of the event impacted on the level of investigation. At the time of the review the NHS board had already changed the IR1 form so that likelihood was not determined during the incident reporting process, but actual consequence or harm is used to grade incident severity.

3.5.4 At the time of the review, staff reported that NHS Forth Valley has a separate risk register, which is recorded within another Safeguard module. When a member of staff completes a risk assessment, the risk register is populated automatically. This risk assessment can then be attached to an IR1 form electronically.

Escalation of events

3.5.5 The policy outlines the various levels of investigation undertaken:

- low risk incidents (green) – investigation considered
- medium risk incidents (yellow) – local investigation and action plan required
- high risk incidents (orange) – escalated to the general manager to confirm the incident level, major investigation and action plan required, and
- very high risk incidents (red) - escalated to the senior manager to confirm the level of risk before notifying the chief operating officer, head of risk management and other relevant directors, major investigation and action plan required.

3.5.6 All staff spoken with during the review were aware of these levels of investigation.

3.5.7 It is clear from the minutes of the clinical governance groups and committees that we received that incidents are escalated for discussion. However, there was no evidence of a robust and consistent mechanism for escalation of events to these groups and committees.

3.5.8 The minutes of the acute clinical governance working group show that the group regularly receives reports on clinical incident trend data and summaries of significant incidents. We also saw evidence that learning from other NHS boards takes place, for example, an audit within NHS Forth Valley was undertaken around the use of intravenous paracetamol following the outcome of a fatal incident enquiry in another NHS board. However, from the minutes, there was limited evidence of how agreed actions are implemented and monitored across the organisation.

3.5.9 NHS Forth Valley are taking forward the following actions as part of their ongoing improvement activity.

- The development of formal reports on significant adverse events for the clinical governance committee.
• Systematic and formal monitoring of action plans in relation to significant adverse events by Unit and CHP management teams with formal reporting through the clinical governance working group (now chaired by the medical director).
• The development of metrics in key areas including the timeliness of investigations.
• Within the new unit structure, management teams will be subject to formal executive performance reviews three times a year. The management of adverse events will form part of this agenda.

3.5.10 One of the cases examined during the review had resulted in a complaint from a member of the patient’s family. This was documented within the existing Safeguard incident report and an investigation was initiated in response to this complaint. We did not discuss the complaints process at the time of the review, but it is clear that there are links between the complaints and incident reporting processes, as evidenced by this case.

Recommendations
To support a risk-based, informed and transparent approach, NHS Forth Valley should continue to:

8 assess if grading processes ensure consistency of response and appropriate management of incident reporting, and
9 develop robust and consistent mechanisms for escalation of events to clinical governance groups.

3.6 Timely management, learning, dissemination and implementation

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

Investigation and reporting timelines
3.6.1 The policy details that staff should complete the incident report form as soon as practical after the incident occurs. It should be completed before the personnel finish their shift or working day and at the latest within 48 hours of the incident occurring.

3.6.2 Of the four cases examined during the review, three were reported to Safeguard within 48 hours of the incident occurring. The fourth case was reported within 3 days of identification of the incident.

3.6.3 Appendix 3 of the policy provides timescales for completion of investigations for incidents graded high or very high as follows.

• For incidents rated as high, the report, risk assessment (where required) and action plan is sent to the general manager within 10 days of the incident occurring.
• For incidents rated as very high, the report, risk assessment (where required) and action plan is sent to the general manager within 7 days of the incident occurring.

3.6.4 The evidence we saw provided only limited assurance that timescales set out in the policy
are being met. The NHS board told us that indicators are currently being developed.

3.6.5 NHS Forth Valley told us that the culture for reporting and the effectiveness of systems for processing significant incidents has improved. During the review, we saw significant staff engagement in the reporting of incidents and all staff spoken with were aware of the processes involved.

**Action planning**

3.6.6 The policy states that action plans are required for all incidents graded as medium, high and very high risk. Action plans were available for three of the four cases examined as part of the review. No action plan was available for the fourth case.

3.6.7 The policy states that the staff member designated to lead the investigation generates an action plan (where appropriate) following the initial investigation. The report is then sent to the senior unit manager and added to the risk register to enable the sharing of learning throughout the NHS board.

3.6.8 The demonstration of the Safeguard system during the visit highlighted that staff enter actions directly on to the incident reporting system. NHS Forth Valley uses a system prompt on Safeguard to alert staff to outstanding items on the system to ensure that actions are implemented.

3.6.9 We saw evidence that some action plans are presented to clinical governance groups or committees. However, there was no evidence of consistent application across all incidents. NHS Forth Valley told us that it is developing a systematic and formal monitoring of action plans for significant adverse events with formal reporting through the clinical governance working group.

**Sharing of learning**

3.6.10 The policy states that:

“The NHS Forth Valley Clinical Governance Committee, Health and Safety Committee and Risk Network Group will review all accident information and statistics and monitor trends as they play an integral part in the process of incident minimisation. They will also ensure full liaison with staff side representation, professional groups and staff associations prior to and during the implementation of safety initiatives.”

3.6.11 The policy also states learning outcomes should be shared and reported at appropriate meetings to identify actions for future incidents to prevent or better manage an occurrence. Section 4 of the policy details that it is the responsibility of general managers, heads of service, charge nurses, line managers and supervisory staff to share learning outcomes.

3.6.12 During the review, staff told us that learning outcomes are shared through safety alerts from the risk management team, safety briefs, Scottish Patient Safety Programme walkrounds and other staff meetings. Reports with recommendations are discussed at clinical review groups, clinical governance committee and risk network meetings to share learning.

3.6.13 NHS Forth Valley also told us that the medical director, nurse director and head of clinical governance meet regularly to consider significant incidents identified though the
incident reporting system and complaints process. This allows for close senior management oversight.

3.6.14 The minutes of the clinical governance groups and committees demonstrate that thematic learning from incidents does occur. For example, one case examined as part of this review, was discussed with other similar incidents at the acute clinical governance working group and action plans were produced and monitored. In this particular case, changes were made to an electronic system to prevent the same human error from happening again.

3.6.15 The documentation provided for another case examined as part of the review, included the terms of reference of the clinical review group within the women and children's department. Established in December 2009, this group aims to increase the involvement of clinical staff in clinical risk management and clinical governance, with particular emphasis on review of clinical incidents. The group facilitates feedback of findings to clinical staff not personally involved by displaying learning points on posters in communal areas and holding themed staff meetings.

3.6.16 NHS Forth Valley told us it has identified areas for future action, including the ongoing use of the risk network, which identifies themes and disseminate learning across the organisation. It has also identified greater engagement with clinicians, which will identify themes and build on existing good practice.

3.6.17 The NHS board explained that the anaesthetic department has developed a system to theme learning from a range of sources including IR1s and morbidity and mortality reviews. We were provided with the report, *The Patient Safety Update, A Summary of Critical Incident Reporting relating to Anaesthesia 2009–2011*, which shares key learning points from incident reports and highlights actions which have been taken following incident reports. For example, the introduction of a protocol for peri-operative blood glucose management of diabetics.

3.6.18 Additionally, the NHS board has developed specialty specific and themed improvement programmes. Draft copies of the medicines safety strategy 2012–2015 and the Falls Prevention Programme were submitted. Falls and medication are two of the top five themed reported incidents, which demonstrates an active approach to improving these areas.

**Recommendations**

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

10 demonstrate that the timescales for various stages of the adverse incident management process are met in line with the policy

11 evidence systematic and formal monitoring of action plans throughout the organisation, and

12 continue to improve the sharing of information and application of learning across the organisation.
Appendix 1 – Details of review team

The review of **NHS Forth Valley** was conducted on **Wednesday 28 November 2012**.

**Review team members**

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**Susan Lowes**  
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The Healthcare Environment Inspectorate, the Scottish Health Council, the Scottish Health Technologies Group and the Scottish Intercollegiate Guidelines Network (SIGN) are part of our organisation.