Management of adverse events

Review Report | NHS Lanarkshire
June 2014
### Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Executive summary</td>
<td>4</td>
</tr>
<tr>
<td>1  Introduction</td>
<td>7</td>
</tr>
<tr>
<td>2  NHS Lanarkshire’s adverse event management policies and procedures</td>
<td>9</td>
</tr>
<tr>
<td>3  Detailed review findings</td>
<td>13</td>
</tr>
<tr>
<td>Appendix 1 – Details of review team</td>
<td>31</td>
</tr>
</tbody>
</table>
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 Lanarkshire’s governance arrangements and processes for managing adverse events involved:

- an analysis of evidence provided by the NHS board, and
- a visit to NHS Lanarkshire on Tuesday 22 April 2014.

NHS Lanarkshire has guidance documents in place which clearly set out the benefits of incident reporting and promote a positive reporting culture within the NHS board. In response to the recommendations made within *The Management of Significant Adverse Events in NHS Ayrshire & Arran* (2012) report as well as the actions within the *Learning from adverse events through reporting and review: A national framework for NHSScotland* (2013), NHS Lanarkshire has revised its incident management guidance in consultation with staff. The NHS board is planning on launching this in June 2014 with a lead-in time of two months to ensure engagement with the guidance.

Following recommendations made during the *Rapid Review of the Safety and Quality of Care for Acute Adult Patients in NHS Lanarkshire* (December 2013), the NHS board demonstrated that it has been responding and working towards achieving these.

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

- a positive reporting culture
- an open approach to sharing review documentation to support staff learning, and
- the implementation of the joint community health partnership (CHP) critical incident review group.

We identified a number of challenges in how adverse events are managed consistently across the NHS board. We found further improvements could be made in relation to the approach taken to robustly track critical incident review actions through to completion within the governance committees, the definition of when an incident is closed, and the staff-dependent escalation process.
Recommendations

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

1. implement a systematic, consistent approach to involving patients, families and carers throughout the critical incident review process drawing on the good practice seen in mental health, and
2. introduce a consistent process to demonstrate that staff are supported and actively involved through the critical incident review process, including identifying any issues for consideration.

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 Lanarkshire should:

3. demonstrate a robust, systematic and organisation-wide approach to formal incident management training for staff.

Roles and responsibilities

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

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

To ensure clear functions and roles, NHS Lanarkshire should:

4. demonstrate that the governance structure allows clear and transparent oversight and ownership of adverse events management across the whole organisation.
Information management

**Recommendation 21 from the NHS Ayrshire & Arran report**

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

To support its information management processes, NHS Lanarkshire should:

5 continue with current plans to implement a system to monitor all critical incident review actions through to completion to provide assurance to the Board.

Risk-based, informed and transparent decision-making

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

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

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

6 develop formal guidance documentation to outline the process to be followed in the case of a critical incident review not being commissioned, and

7 consider the use of an automatic electronic notification procedure to alert verifiers and senior management of an incident.

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 Lanarkshire should:

8 consider including closure of actions within the timescales set out for closure of a critical incident review, and

9 ensure that discussion and review of critical incident review actions are clearly demonstrated at governance groups.

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

We would like to thank NHS Lanarkshire and in particular all staff at Wishaw General 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 Lanarkshire 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 237 recorded significant adverse events over the past 18 months, and
- details of four specific significant adverse event reviews.
1.1.8 Of the 237 recorded significant adverse events, we selected four cases for detailed review. We did this by firstly randomly selecting 84 cases and then reviewing the high level summary of each case, taking into account the location and specialty of the event and the level of investigation.

**Review visit**

1.1.9 The review visit took place on Tuesday 22 April 2014. 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 Lanarkshire’s chief executive, medical director, corporate risk manager and head of clinical governance and risk on Tuesday 27 May 2014.

**Improvement plan**

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

2.1.1 NHS Lanarkshire is responsible for the healthcare of more than 553,000 people within the council areas of North and South Lanarkshire. Healthcare is provided in three main district general hospitals and various community hospitals by around 12,000 staff:

- District general hospitals:
  - Hairmyres Hospital: 492 inpatient beds
  - Monklands Hospital: 535 inpatient beds, and
  - Wishaw General Hospital: 626 inpatient beds.
- Community hospitals:
  - Airbles Road Centre
  - Caird House
  - Cleland Hospital
  - Coathill Hospital
  - Kello Hospital
  - Kilsyth Victoria Hospital
  - Kirklands Hospital
  - Lady Home Hospital
  - Lockhart Hospital
  - Stonehouse Hospital
  - Udston Hospital, and
  - Wester Moffat Hospital.

Policy for managing adverse events

2.1.2 NHS Lanarkshire has policies and procedures in place to manage adverse events. These are outlined in the incident management guidance document which was implemented in the NHS board in March 2009, refreshed in August 2011 and again in August 2013. This document sets out the benefits of developing and maintaining effective incident management for the individual, management and the NHS board. It also provides guidance on reporting and recording an incident, commissioning and undertaking a critical incident review, and sharing the outcome of the review. This document is used across all NHS Lanarkshire sites including primary care, and also covers non-clinical incidents.

2.1.3 NHS Lanarkshire has recently revised the incident management guidance document, now titled “adverse event/incident management policy”. This was developed in consultation with all NHS Lanarkshire staff and will be launched in June 2014 to allow time for staff to fully engage and familiarise themselves with the updated document and processes.
Adverse event definitions

2.1.4 NHS Lanarkshire uses the electronic reporting system, Datix, to record and categorise adverse events. The incident reviewer estimates the severity of the incident by selecting one of four gradings on the Datix system:

1. Low
2. Medium
3. High
4. Very high/“never event”

2.1.5 Within the new adverse event/incident management policy, NHS Lanarkshire has replaced the above grading system with that set out in the Healthcare Improvement Scotland national framework to learning from adverse events:

- Category 1: events contributing to or resulting in permanent harm
- Category 2: events contributing to or resulting in temporary harm
- Category 3: events that had the potential to cause harm, but
  - an error did not result
  - an error did not reach the person
  - an error reached the person, but did not result in harm.

2.1.6 NHS Lanarkshire defines a significant adverse event, or critical incident, as

“Any situation, or omission that had or could have had significant or catastrophic impact on the patient and may adversely affect NHSL and its staff.

“Within NHSL, these are normally categorised as incidents/accidents/near miss with the outcome graded as High or Very High and/or a ‘Never-Event’.”

2.1.7 As with the incident grading categories, NHS Lanarkshire has redefined the definition of a significant adverse event in the adverse event/incident management policy due to be implemented June 2014:

“An event that has contributed to or resulted in permanent harm, for example death, intervention required to sustain life, or ongoing national adverse publicity.”

2.1.8 NHS Lanarkshire has identified the top five themes for significant adverse events as:

1. Patient dies: 50 incidents (21.1%)
2. Self harm: 28 incidents (11.8%)
3. Treatment problems: 21 incidents (8.9%)
4. Maternal/delivery: 16 incidents (6.8%), and
5. Staffing issue: 13 incidents (5.5%).
2.1.9 The NHS board noted that the percentage of significant adverse events within the total number of all adverse events recorded for this period is 0.95%.

**Governance arrangements**

2.1.10 Figure 1 below outlines the governance arrangements in place for the management of adverse events which were in place within NHS Lanarkshire until 31 March 2014.

2.1.11 Following recommendations made during the Healthcare Improvement Scotland Rapid Review of NHS Lanarkshire (December 2013), a review of the clinical governance structure within the NHS board has been undertaken. One such recommendation set out:

“NHS Lanarkshire should review the number of internal groups and bodies with a view to ensuring a sharper and clearer line of accountability through the corporate management team and to the Board for delivery.”

2.1.12 This has resulted in a change to the clinical governance structure which was implemented on 1 April 2014 and is depicted in Figure 2 on page 12. The review team were conscious that the revised governance structure will take time to embed itself within the adverse events management process.

**Figure 1: NHS Lanarkshire clinical governance structure (in place until 31 March 2014)**
Figure 2: NHS Lanarkshire clinical governance structure (implementation date 1 April 2014)
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 NHS Lanarkshire’s incident management guidance document sets out from the outset that one of the benefits of developing and maintaining effective incident management is to promote a safe environment for patients.

3.1.2 The incident management guidance document states that staff should follow the National Patient Safety Agency guidance Being Open: Communicating Patient Safety Incidents with Patients and their Carers (2009). A link to this is provided in this guidance document. This document outlines that communication with patients and carers following an incident should not differ from that of during the patient’s care. Throughout the document, it states that being open involves:

- “Acknowledging, apologising and explaining when things go wrong
- Conducting a thorough investigation into the incident and reassuring patients and/or their carers that lessons learned will help prevent the incident recurring
- Providing support for those involved to cope with the physical and psychological consequences of what happened.”

3.1.3 It also notes within the guiding principles for critical incident reviews to include discussions with patient, relatives and carers. The guidance continues that a member of the team will be assigned as the point of contact for the patient and family during the review and will ensure they are kept updated as well as feeding their questions and needs into the review. As part of this role, the contact person will ensure that the method of contact is adapted to that of the individual case.

3.1.4 Guidance on the format of the critical incident review report is provided; one section to be included is titled “involvement and support of the patient and/or families affected by the incident.” The incident management guidance document outlines the steps which are to be taken to ensure engagement with the patient, family and carers:

- Provide an accurate, open, timely and clear explanation of what has happened, ensuring sensitivity to the distressing nature of the incident.
- Ensure that an apology in the form of a sincere expression of apology for the harm that has resulted from the incident has been given.
- Share plans regarding what can be done medically to repair or redress the harm done.
- Provide a clear explanation of the critical incident review process and the expected report.
• Allow the opportunity to outline questions to be taken into consideration by the review team.

3.1.5 When sharing the outcome of a review, the incident management guidance document provides guidance and templates as to how the information is to be shared.

• Patients: “Letter the patient or person affected by the incident using the template in Appendix 3 and attaching an unredacted, watermarked copy of the CIR Report with evaluation request.”

• Family of deceased patients: “Letter the NOK [Next of Kin] (and the agreed family contacts – no more than 3 contacts) using the template in Appendix 4 and attaching a redacted, watermarked copy of the CIR Report and evaluation request.”

3.1.6 The appendices mentioned in the above statements are included within the same document and includes:

• Apology
• Reasons for undertaking a critical incident review
• Copy of the report
• Contact details for any further information/support.

3.1.7 A “patient and family checklist” is included within the appendices and provides guidance as to who is responsible for ensuring engagement of this group. This checklist features three check points:

• Notification of patient/family to the incident
• A senior manager has been appointed as the point of contact for the patient/family.
• The point of contact senior manager has feedback to and debriefed the patient/family and shared the critical incident review.

3.1.8 From December 2013, NHS Lanarkshire has provided an information leaflet on the critical incident review process for patients and families. This leaflet includes a brief overview of the process in terms of expectations, confidentiality and notes the assigned point of contact.

3.1.9 Within information provided by NHS Lanarkshire in advance of the review visit, the NHS board stated that it analysed critical incident reviews completed in 2012 and 50% of these demonstrated patient, family and carer involvement. This involvement included commenting on the draft and final report, commenting on action plans and being sent the full/redacted final report.

3.1.10 The senior management team reported that engagement with patients, family and carers is a key area they would like to continue to improve on.

3.1.11 Across the four cases reviewed, the engagement with patients, family and carer varied. Within one case, which originated in mental health, the family were fully involved within the review to the extent that they attended some review meetings to allow them to fully input into the process. Separate meetings were also held to ensure that their needs were met during the review process. In two
cases, one of which was also based in mental health, staff contacted patients, families and carers to liaise with them to address any questions that they may have had throughout the review. However, the final stages of sharing the outcomes or final report were not met to the satisfaction of the patient, family or carers due to delay or external circumstances. The final incident was a complaint made by the family which was then reported into the adverse event system. Evidence shows that the review team was in contact with the family to address their concerns and answer any questions that they had. However, correspondence shows that the family do not yet feel that the issue has been resolved.

3.1.12 The review team noted the good practice within mental health and learning disability services which was undertaken by staff involved in the cases reviewed.

Staff involvement

3.1.13 As with patient, family and carer engagement, the incident management guidance document outlines that NHS Lanarkshire seeks to promote a safe working environment for staff. The NHS board also promotes a culture of reporting incidents and near misses in order to review and learn from these incidents to prevent recurrence.

3.1.14 Within the patient and family checklist featured in the incident management guidance document, one step outlines that a debrief and feedback should be provided to staff members, and the critical incident review report shared with them.

3.1.15 The incident management guidance document notes that the designated operational manager is to ensure that the staff involved in the incident are offered various types of support including:

- de-briefing
- clinical supervision
- occupational health referral, and
- emotional support.

3.1.16 To ensure the involvement of staff within the review process, the incident management guidance document states that interviews are to be set up with the staff involved and statements taken which will be analysed as part of the report writing process.

3.1.17 During discussions with staff, they reported mixed levels of involvement throughout the critical incident review process. Within two of the cases, staff reported that they felt that they had been adequately involved and “kept-in-the-loop” during the process. However, staff involved in the other two cases said that they were aware of the review, but had minimal input into it.

3.1.18 During the visit, staff across all four cases told us that they had not actively participated in the critical incident reviews and had no input into identifying improvements or developing the report or action plans.
3.1.19 Staff spoken with during the review also reported a mix of support during the critical incident review process. Some staff reported that they had been provided with formal support by immediate debrief and occupational health support, whereas other staff reported no formal support was made available. However, all staff reported that they had experienced peer support which they said was extremely beneficial to them throughout the review process.

3.1.20 When sharing outcomes from a review, the incident management guidance document provides guidance as to how the information is to be shared with staff members involved in the incident. A letter template is provided in the guidance document for this purpose which outlines the aim of the review and contact member of staff who will be able to provide a copy of the report. During discussions with NHS Lanarkshire senior management and staff it was widely reported that the critical incident review report, in a redacted form, would be shared with any staff member requesting a copy. Many senior staff further reported that they would go through the report to highlight key points with staff if this was the preferred option by staff.

3.1.21 Across all cases, staff confirmed that feedback information was shared with them following the completion of the review. This took various forms:

- specific review feedback meetings
- feedback at team meetings
- provided with a copy of the critical incident review report, or
- guided through the highlights by a line manager, or other senior member of staff.

3.1.22 Senior management echoed the information outlined within the incident management guidance document and added that a confidential email system had been set up for NHS Lanarkshire employees to raise any issues they may have. This email system is directly managed by the HR director.

**Recommendations**

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

1. implement a systematic, consistent approach to involving patients, families and carers throughout the critical incident review process drawing on the good practice seen in mental health, and

2. introduce a consistent process to demonstrate that staff are supported and actively involved throughout the critical incident review process, including identifying any issues for consideration.
3.2 Staff knowledge and training

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

3.2.1 NHS Lanarkshire’s incident management guidance document highlights that effective incident management will inform and identify training needs for all those in contact with the organisation.

3.2.2 In order to support staff throughout the incident review process, various templates are provided within the incident management guidance document for:

- SBAR (Situation, Background, Assessment/Action and Recommendation) used to summarise and escalate an incident
- contacting patients
- contacting family
- sharing critical incident review report with staff, and
- contacting external partners.

3.2.3 The incident management guidance document also sets out how the critical incident review report should be developed and explicitly describes the information to be included in each section of the report.

3.2.4 Information provided by NHS Lanarkshire outlines the various methods of training that the NHS board provides to its employees:

- root cause analysis
- NHS Lanarkshire-specific web-based training modules on LearnPro including:
  - how to record incidents
  - verification of incidents, implemented December 2013
  - root cause analysis module, due to be implemented following the implementation of the revised adverse events/incident management policy.
- general introduction to risk and incident management which is used at all staff induction sessions.

3.2.5 The NHS board also uses a document titled “Critical Incident Review Using Root Cause Analysis”. This lists various root cause analysis tools and sets out which would be used to fulfil a particular requirement within a review.

3.2.6 During discussions with senior management, they reported that staff who have been trained in investigation skills are encouraged to guide other non-trained staff through the tools that they were provided with during training as part of a buddy-system in order to spread skills across the NHS board. Furthermore, the review team were told that a database of root cause analysis-trained staff members is kept in order to ensure that there is always a member of the team, generally the chair, trained in investigation skills.
3.2.7 Senior management also reported that over a three-year period of monitoring that they became aware that many incidents were being graded incorrectly with a disproportionate number of incidents being graded as high or very high. As a result, a standard operating procedure was developed to inform and refresh the incident reporter of the correct grading criteria to be used.

3.2.8 During discussions with staff, all reported that they had been trained to report incidents on the Datix incident management system. Those staff responsible for verifying incidents on the system also reported that they had received appropriate training.

3.2.9 Formal training on carrying out critical incident review was described as mixed during discussions with staff. Many members of staff who were part of a review team stated that they “learned on the job”. It was also frequently stated that they were supported by the clinical governance lead during the process of the review and would feel comfortable in contacting the clinical governance team if more support or guidance is required.

**Recommendation**
To support staff knowledge and training, NHS Lanarkshire should:

3. Demonstrate a robust, systematic and organisation-wide approach to formal incident management training for staff.

### 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 NHS Lanarkshire’s incident management guidance document provides information as to the roles and responsibilities of staff and notes that it is the responsibility of all staff to record incidents and highlight risks. This is shown in the “notification of significant adverse events to the Chief Executive and Board members” flowchart which is included within the incident management guidance document.

3.3.2 During discussions with senior management and staff, they reported that they were all aware of their responsibility in relation to reporting incidents within NHS Lanarkshire.

3.3.3 More information about roles and responsibilities is set out in relation to the review process within the incident management guidance:

- Critical incident review commissioner: oversees the overall critical incident review process. For clinical incidents, this is the divisional medical/nurse director and for non-clinical it is a general manager.
• Critical incident review team lead: ensures that the critical incident review process is followed during the review process at an operational level.

• Designated operational manager: oversees a particular/assigned critical incident review.

3.3.4 NHS Lanarkshire provided an incident management flowchart, “critical incident review pathway” which explicitly outlines the process to be followed once it has been decided that a critical incident review will take place. It also outlines, the timescales in which the report is to be drafted and finalised following the critical incident review team meeting.

3.3.5 During discussions with staff, all those within the critical incident review teams reported that they were clear on their role within the team and were aware of what was expected of them.

3.3.6 During discussions with senior management, they told the review team about plans to introduce designated risk managers at operational levels to be able to support the critical incident review process further.

3.3.7 NHS Lanarkshire set up a joint CHP critical incident review group in March 2013, which is a subgroup of the joint CHP clinical governance group. The role of this group is to review all completed critical incidents within the CHP area with a view to ensuring that the joint CHP clinical governance group can be assured about the following:

• Critical incident reviews are being taken forward and completed in line with NHS Lanarkshire protocols and existing guidance.

• Key learning points are identified and disseminated appropriately throughout the organisation and its partner agencies including an overview of issues that could potentially have an impact on or link to disciplines outwith the scope of the review.

• Recommendations and any resulting actions are fully implemented - this will involve tracking of longer term actions to completion date.

• A continuous review of the critical incident review process is undertaken to address issues and suggest improvements.

• An analysis of emerging trends is undertaken and key themes fed back to relevant governance groups and external agencies if required.

3.3.8 Senior management told the review team that this group was set up due to the number of critical incidents that the joint CHP clinical governance group was required to review. These incidents are now delegated to the joint CHP critical incident review group to allow detailed discussion. Senior management reported that the acute clinical governance committee does not have a similar sub-group as the number of critical incidents discussed at the acute clinical governance group allows a similar level of detailed discussion to that held at the joint CHP critical incident review group. The NHS board also stated that it considered that it would be more productive to have multidisciplinary discussion at the main acute clinical governance committee. The review team was unable to assess the extent of discussion at the acute clinical governance committee meetings as the minutes were not as detailed as those outlining the discussions held at the joint CHP critical incident review group meetings.
3.3.9 The risk management team standard operating procedure details the process to be followed when an incident has been graded as high or very high. It includes the dates by which information of incidents from a specified time period is to be reported to the corporate risk manager. The critical incident review using root cause analysis guidance provides a pathway for sending signed-off critical incident review reports to the relevant governance committees as outlined in the flowchart in Figure 3 below.

Figure 3: Sharing outcomes from review flowchart

![Flowchart Diagram]

3.3.10 The 2011-14 Quality and Clinical Governance Strategy sets out the terms of reference for various groups and committees within NHS Lanarkshire in relation to the management of adverse events:

- Clinical Governance Committee: “responsible for ensuring corporate accountability for the quality of clinical care provided.” This committee reports directly to NHS Lanarkshire’s Board.

- Clinical Governance Steering Group: “to ensure co-ordination of clinical governance activities across NHS Lanarkshire by agreeing the clinical governance work programme for NHS Lanarkshire, monitoring activity, reassuring the organisation on clinical governance and prioritising activity.”

- Risk Management Steering Group: “develop, refine, review and oversee the implementation of the NHS Lanarkshire risk management strategy, in support of the Board and in collaboration with the Governance Committees as outlined below:
  - Clinical Governance Committee
  - Staff Governance Committee
- Audit Committee”

- Joint CHP Clinical Governance and Risk Management Committee: “executive group for the Community Health Partnerships (CHPs), agreeing the clinical governance work programme for the CHPs, monitoring activity, reassuring the organisation on clinical governance and risk management and prioritising activity. This group will be supported by a range of groups which will ensure actions in relation to clinical governance and risk management standards are progressed and practice is reviewed across primary care.”

- Acute Clinical Governance and Risk Management Committee: “executive group for the Acute Division, agreeing the clinical governance work schedule for the acute division, monitoring activity, reassuring the organisation on clinical governance and risk management and prioritising activity.”

3.3.11 NHS Lanarkshire’s Board is provided with assurance on the significant clinical incidents from the clinical governance committee by way of the clinical governance steering group. This steering group is provided with highlight reports from the joint CHP clinical governance and risk management committee as well as the acute clinical governance and risk management committee. These committees review all critical incidents within the specific area. The joint CHP clinical governance and risk management committee is also supported by the joint CHP critical incident review group due to the number of incidents that are reported within its remit.

3.3.12 Following recommendations made during Rapid Review of the Safety and Quality of Care for Acute Adult Patients in NHS Lanarkshire (December 2013), modifications were made to the clinical governance structure. The clinical governance committee, chaired by a non-executive Director, agreed to change the name of the committee to the healthcare quality assurance and improvement committee, and continues to be chaired by a non-executive director.

3.3.13 Across the four cases reviewed, there appeared to be a mix within the information provided to evidence discussion at the relevant governance groups. Discussion of incidents occurring within a mental health or CHP setting was evidenced at the governance groups appropriate to the specialty. However, discussions related to an incident occurring in an acute setting were less apparent and did not feature as strongly within the meetings.

3.3.14 Information provided by NHS Lanarkshire further states that reports on high and very high incidents are routinely considered at:

- the Board (through quality dashboard key performance indicators and quarterly report on risk management)
- divisional management teams
- partnership groups
- risk management steering group, and
- clinical governance and risk management operational groups.
Recommendation
To ensure clear functions and roles, NHS Lanarkshire should:

4 demonstrate that the governance structure allows clear and transparent oversight and ownership of adverse event management across the whole 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 Lanarkshire uses Datix to report and record incidents. Review documentation is also attached to the system, for example:

- final report
- staff statements
- review team discussions and notes
- action plan, and
- SBAR.

3.4.2 During discussions with staff, the review team noted a positive approach to reporting incidents on Datix since its implementation in the NHS board in 2006. However, staff often mentioned that once they had submitted an incident report, they did not receive feedback about the actions taken to address the report.

3.4.3 During the review, the review team was given a demonstration of how the Datix system is used within NHS Lanarkshire. The initial reporting form was shown to the team which is available to all staff across NHS Lanarkshire and is accessible from the NHS board intranet page. The form is made up of various drop-down menus which narrows subsequent available reporting categories in order for available options to be specific to that of the incident to increase the ease of reporting. Various prompts are also included within the form that support the reporter to complete the form. The review team was also guided through the steps used to link other members of staff to an incident, attach documents and add general notes to the incident report.

3.4.4 Once a report is submitted, the risk management team told us that an alert is sent from the system to a trained verifier who then has five working days to approve the report. During this time, the incident report sits in a holding area monitored by the clinical governance and risk management team.

3.4.5 The NHS board noted that it had implemented a performance target that a maximum of 8% of the operating division’s incidents can be waiting for
verification at any one time. If this percentage is exceeded, then an SBAR must be submitted to the director.

3.4.6 The risk management team also showed us the access restricted section of Datix which is used to verify incidents. During this step, the verifier will check the report for accuracy as well as completing lessons learned and any immediate action taken.

3.4.7 Senior management also reported that they are currently working towards the development of a new module on Datix called “hotspot”. This will allow early identification of pre-defined categories and themes of incidents. For example, this will be used to automatically notify if any “never events” or very high graded incidents are reported.

3.4.8 In order to monitor the progress of critical incident review actions, the NHS Lanarkshire risk management team logs all actions developed during a review on to an Excel spreadsheet which is updated centrally. The operational designated lead facilitators audit these actions and incident reports every month.

3.4.9 During discussions with senior management, they reported that the use of Datix as an archive system has proven to be limited in functionality with no ability to monitor overall performance for the management of actions arising from critical incident reviews. In order to address this, the risk management team consulted with NHS Ayrshire & Arran to review their Sharepoint-based documentation system. This system logs all steps within the critical incident review process and enables all agreed actions from critical incident reviews to be recorded on a dedicated system. The risk management steering group supported a business case in October 2013 to procure such a system and a project team has been working towards implementation of this system.

3.4.10 During discussions with staff involved in the four cases being reviewed, there appeared to be a consistent awareness of the requirement for attaching all appropriate documentation to the Datix incident report following the closure of the review.

3.4.11 Within the incident management guidance document, the process for sharing a critical incident review report is depicted in a flowchart (Figure 3, see page 20). This outlines the process to be followed when sharing the final critical incident review report with patients, staff, family and external stakeholders.

3.4.12 During discussions with staff, all those met with reported that the process had been followed. They also stated that depending on specific critical incident review circumstances, these steps would be individualised to suit the recipient. For example, staff reported extra meetings were held with families and staff to go through and explain the critical incident review report.

3.4.13 Senior management also reported that if a report was requested by a member of staff who was not involved in the incident, they would be more than happy to share a redacted version of the report with them.

3.4.14 The incident management guidance document makes reference to the redaction of reports. It states that patients and staff members should not be identifiable
within the critical incident review report and provides guidance on how to minimise the risk of identification.

3.4.15 During discussions with staff, they reported that redaction of the reports was common practice. Risk management staff added that three versions of the final critical incident review report are stored and attached to the Datix record:

- final version with all information included
- version with all information marked for redaction, and
- fully redacted version.

3.4.16 Although all staff reported that they were aware of the processes of effective version control, there did not appear to be full version control across the critical incident review reports. Within case evidence submitted before the review visit, there was a mix across the file names and watermarks indicating whether the version was in draft or finalised.

**Recommendation**

To support its information management processes, NHS Lanarkshire should:

5. continue with current plans to implement a system to monitor all critical incident review actions through to completion to provide assurance to the Board.

### 3.5 Risk-based, informed and transparent decision-making

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

#### Identification, notification and initial event reporting

3.5.1 The NHS Lanarkshire incident management guidance document clearly states that staff are required to inform their line manager and report any incident or near miss as soon as possible or within 24 hours. These steps are outlined within the “grading pathway and escalation process” diagram in the incident management guidance. Staff are also required to grade the incident which is based on the NHSScotland Risk Matrix.

3.5.2 The incident management guidance document also states that a report can be completed on paper if approved by the risk management team.

3.5.3 The incident management guidance document outlines other immediate actions that are to be taken following the incident:

- immediate management of the event
- inform any other departments that will require an early alert
- inform any non-NHS employees, for example contractors, and
- record the incident if on behalf of a member of the public.
3.5.4 The risk management team told the review team that following this initial report on Datix, trained verifiers are responsible for confirming the accuracy of the incident report as well as completing lessons learned and any immediate action taken. The verifier is alerted to the incident report when the incident reporter assigns the report to their particular verifier. These verifiers are generally the department or ward team leader, or senior charge nurse.

Escalation of events

3.5.5 The “grading pathway and escalation process” mentioned above which is included within the incident management guidance document clearly sets out the steps to be followed following an incident being reported depending on the grading:

- **Low:** learning points/improvement measures to be communicated and monitored. Close the Datix record at time of verification or within 10 working days (after attaching documentation).

- **Medium:** Individual to consider support services. Ensure actions are in place to minimise recurrence. Discuss these actions/further actions with senior management and feedback at team meeting. Close the Datix record within 20 working days (after attaching documentation).

- **High:** Inform site senior nurse/manager/head of function. SBAR to be forwarded to divisional nurse or medical director/site unit general manager/head of department. Validate the report grading when deciding whether to commission a critical incident review. Close the Datix record within 45 working days (after attaching documentation).

- **Very high and “never events”:** Inform site senior nurse/manager/head of function. SBAR to be forwarded to divisional nurse or medical director/site unit general manager/head of department. Validate the report grading when deciding whether to commission a critical incident review. Escalate to divisional directors and Board. Close the Datix record within 45 working days (after attaching documentation).

3.5.6 Information provided by the NHS board before the review visit stated that the escalation of serious events or incidents, listed in the bullet points above, was integrated into the revised incident management guidance to ensure communication, transparency and assurance for non-executives and Board members in how the organisation responds and learns from these incidents.

3.5.7 In terms of notifying and alerting individuals within the NHS board, the “notification of significant adverse events to the Chief Executive and Board Members” flowchart (see Figure 4, p26) defines the steps that are to be taken. The review team noted that the steps taken were dependent on NHS Lanarkshire staff, and although these steps did appear to be followed in the cases that were reviewed, there was no automatic system in place, for example through Datix, which could also be used to provide further assurance of the escalation process.

3.5.8 Following an incident being graded as high/high very or “never event”, an SBAR is developed by either the site senior nurse, manager or head of function and sent to the divisional director, nurse director, site general manager, unit general manager or head of department. Support for completing this is included
within the incident management guidance document. The rationale and final decision as to whether to commission a critical incident review is recorded on the SBAR template. This decision-making is based on criteria outlined in the incident management guidance and this is carried out by the critical incident review commissioner.

3.5.9 Across the four cases reviewed on the day, one case was escalated to a critical incident review following a complaint. The NHS board provided evidence of the three remaining cases all having been escalated though the SBAR process.

3.5.10 In cases where a critical incident review is not commissioned following the recommendations recorded on the SBAR, previous to the incident management guidance document refresh in August 2013, a concise review was undertaken. This review was a scaled-down version of the full critical incident review process. During the refresh of the incident management guidance document in August 2013, the option of a concise review was removed. The local department manager would now consider the need for an alternative understanding of the incident through such methods as peer review or a case note review.

Figure 4: notification of significant adverse events to the Chief Executive and Board members

[Diagram showing notification process]
Recommendations
To support a risk-based, informed and transparent approach, NHS Lanarkshire should:

6 develop formal guidance documentation to outline the process to be followed in the case of a critical incident review not being commissioned, and
7 consider the use of an automatic electronic notification procedure to alert verifiers and senior management of an incident.

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 NHS Lanarkshire incident management guidance document states that incidents are to be reported as soon as possible after occurrence, and within 24 hours.

3.6.2 Across the four cases reviewed, one was highlighted to the NHS board by way of a complaint. The other three cases were evidenced to be reported within the 24-hour timescale.

3.6.3 The incident management guidance document further sets out that incidents graded high and very high/never event are to be escalated to Board members within 24 hours, and closed within 45 days. During discussions with senior management, they stated that a critical incident review is defined as closed when the report is signed off by the critical incident review team and attached to the Datix record. Completion of the actions included within the critical incident review action plans is not required within the 45-day timescale and there are no timescales set out as to when actions are to be completed. Timescales for the completion of actions are set out in the individual action plans. The NHS board noted that the timescales assigned to each action will vary.

3.6.4 These timescales are reported as part of the NHS board’s monthly quality dashboard on risk management which is discussed at the board, healthcare quality, assurance improvement committee and steering group, as well as divisional partnership groups and the risk management steering group.

3.6.5 Of the four cases reviewed, none of these met the timescale for closure set out in the incident management guidance document. During discussions with staff, they reported that the reason for delay in one of the cases was due to the involvement of the Procurator Fiscal.

3.6.6 However, during discussions with senior management, they reported that the 2013 target for the closure of incidents within the set timescale was 65%. The NHS board noted that the incident closure rate reported in October 2013
exceeded this and the actual average rate was 75% which was broken down by each incident grading:

- Low: 79%
- Medium: 75%
- High: 88%
- Very high: 100%

3.6.7 The risk management steering group is now considering whether to increase this target to 75%.

**Action planning**

3.6.8 The NHS Lanarkshire incident management guidance states:

“Solutions should be identified when there is agreement about the contributory factors and causes of the incident. Solutions will be converted into recommendations within the report and must be considered with a level of reasonableness as what is achievable”.

3.6.9 During the process of a critical incident review, lessons learned will be collated from the notes recorded by the critical incident review team lead throughout the course of the review and should be addressed by the recommendations within the report. Development of these recommendations is the responsibility of the critical incident review commissioner and team lead.

3.6.10 The incident management guidance document notes that the action plan is to be attached to the Datix incident report and will be owned by the named operational manager listed on the action plan. This is to outline how each of the recommendations will be operationally implemented. Each item on the action plan will be assigned to an appropriate member of staff with reasonable timescales based on the individual action and resultant impact. The action plan is attached to the executive summary for internal critical incident review circulation and approval. When approved, the action plan is attached to the Datix record.

3.6.11 Following approval of the action plan, the critical incident review commissioner is responsible for the dissemination of the critical incident review executive summary and action plan through the appropriate governance and operational structures.

3.6.12 Actions resulting from critical incident reviews are logged by each directorate on separate Excel spreadsheets. These are updated and monitored by designated lead facilitators in each directorate. Actions that are nearing their completion date are tracked by the designated lead facilitators who will contact the individual assigned to the action.

3.6.13 Senior management reported that the overall responsibility for critical incident review action plans is with the general managers and directors. They should ensure that the completed action plans are provided to the clinical governance committee or audit committee to provide the assurance that any actions or recommendations have been implemented.
3.6.14 During review of the governance meeting notes, the review team was unable to track all individual actions included within the action plans through to completion. This was mainly noted in acute-based incidents, actions developed following CHP-based incidents appeared to be discussed and tracked throughout the meeting notes. The review team was not assured as to whether the action tracking process used in NHS Lanarkshire was sufficiently robust to assure the Board and all staff that actions were fully addressed and subsequently implemented.

3.6.15 This issue was recognised by senior management who told the review team about their plan to implement the Sharepoint-based system similar to that of NHS Ayrshire & Arran. This system would allow the NHS board to manage and monitor all actions made following a critical incident review through to completion. The system also has the functionality for each action to be assigned to a member of staff and sends out a reminder alert when the date for completion is nearing.

3.6.16 Staff also raised this issue during one session. Staff noted that they were not aware of any arrangements in place to address the root cause of the incident. They also reported that they were unaware of how these plans were moving forward or how to address similar issues during current working practice. The review team raised these issues with the NHS Lanarkshire chief executive and medical director to seek assurance on them.

Sharing of learning

3.6.17 The incident management guidance document outlines that one of the aims of undertaking a critical incident review is to determine whether there are any learning points for:

- the area where the incident occurred
- the staff involved
- the service, and
- NHS Lanarkshire to minimise the risk of recurrence.

3.6.18 Senior management reported that lessons learned are shared and discussed at various clinical governance and risk management groups. Staff confirmed this and noted that staff attending these meetings routinely report back to departments and wards.

3.6.19 During discussions, with staff and following review of information provided by NHS Lanarkshire, there were reports of various different methods of sharing learning.

- A learning outcomes newsletter is used within the mental health and learning disabilities directorate.
- Critical incident review lessons identified briefs have been distributed and used throughout the NHS board, including within the patient safety briefing process. These briefings were developed in an SBAR format, and set out recommendations for NHS Lanarkshire staff. They included an overall view of lessons learned within existing
critical incident reviews. The main themes that emerged from the lessons learned analysis were:
- record keeping
- communication
- did-not-attend alerts
- working practices
- gaps in knowledge, and
- patient participation.

• The quality hub identifies and monitors themes emerging critical incident reviews from across NHS Lanarkshire. A quality improvement approach is taken to address these themes and a quality improvement work programme is developed annually. The mental health and learning disabilities team noted that this is also done at a local level within their directorate.

3.6.20 During discussions with staff, they reported that they are made aware of actions being taken forward following an incident and any subsequent improvement plans. However, they often find it difficult to attribute a particular improvement to a specific incident and to understand the context behind the change.

**Recommendations**

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

8 consider including closure of actions within the timescales set out for closure of a critical incident review, and

9 ensure that discussion and review of critical incident review actions are clearly demonstrated at governance groups.
Appendix 1 – Details of review team

The review of NHS Lanarkshire was conducted on Tuesday 22 April 2014.

Review team members

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We can also provide this information:

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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.