Management of adverse events

Review Report | State Hospitals Board for Scotland
March 2013
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Executive summary

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

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

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

What we found

Our review of the State Hospitals Board for Scotland’s governance arrangements and processes for managing adverse events involved:

- an analysis of evidence provided by the NHS board, and
- a visit to the State Hospital on Wednesday 16 January 2013.

The State Hospital, Carstairs, is a high secure forensic psychiatric hospital covering Scotland and Northern Ireland. The State Hospital is part of NHSScotland and is governed by the State Hospitals Board for Scotland. Hereafter, we will refer to the NHS board as the State Hospital.

The State Hospital is unique compared to other NHS boards across NHSScotland. As such, many high graded incidents relate to the likelihood of an incident recurring, with the severity of the incident being low. Within the hospital, these incidents could be well managed, with clinically appropriate care, and they would still be categorised as a high risk incident. Adverse events are also often focused around staff safety, security and information governance, in addition to patient safety.

Our review identified areas of good practice relating to the management of adverse events within the State Hospital, including:

- an effective risk management team co-ordinating risk management activity and supporting adverse event reviews and actions
- a consistent approach in the use of root cause analysis methodologies and involvement of trained staff in the review process
- good access to Datix, with a range of staff recording adverse incidents, and
- good document storage, with a database to track and automatically report critical incident review and significant untoward incident recommendations and actions.
Our review identified a number of challenges in the management of significant adverse events at the State Hospital. These relate to patient, family and staff involvement, the timely management of reviews and disseminating learning.

Our review also identified areas that the NHS board should improve to ensure arrangements in practice match the NHS board’s existing adverse event management policies and procedures. This will help to ensure the policy is consistently applied across the NHS board.

**Recommendations**

We expect the State Hospital 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.

The State Hospital’s active and planned approach to engaging with key stakeholders affected by a significant adverse event should include:

1. a systematic approach to consider engagement with patients and families, with the decision and rationale documented within review documentation
2. ensuring that relevant staff receive documentation and communication on the update of reviews
3. ensuring that relevant staff are involved and supported through the review process and meaningful feedback is consistently provided to staff, and
4. ensuring there is a consistent approach to sharing reports throughout the organisation.

**Staff knowledge and training**

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

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

To support staff knowledge and training, the State Hospital should:

5. continue to maintain an organisation-wide approach to Datix, risk management and investigation training and ensure competencies are kept up to date.
Roles and responsibilities

Recommendation 20 from the NHS Ayrshire & Arran report

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

To ensure clear functions and roles, the State Hospital should:

6  evidence that roles and responsibilities are clearly defined and staff are clear about their involvement in the adverse events process, and

7  consider its approach to including staff when finalising reports and recommendations, and disseminating learning.

Information management

Recommendation 21 from the NHS Ayrshire & Arran report

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

To support its information management processes, the State Hospital should:

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

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

Risk-based, informed and transparent decision-making

Recommendation 22 from the NHS Ayrshire & Arran report

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

To support a risk-based, informed and transparent approach, the State Hospital should:

10  evidence the decision-making process in case documentation to demonstrate the rationale for determining which cases are subject to enhanced review.
Timely management, learning, dissemination and implementation

Recommendation 23 from the NHS Ayrshire & Arran report

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

To improve timely management, learning and dissemination following adverse events, the State Hospital should:

11 ensure that the timescales for various stages of the adverse incident management process are met in line with the policy and that progress against these is monitored regularly

12 ensure actions have both target and actual dates, and

13 spread a culture of capturing and sharing lessons learned across the organisation that results in change and improvements.

The State Hospital provided evidence of an improvement plan that was developed in the 6-month period before the review. This was developed in response to the NHS Ayrshire & Arran report and following a learning session provided by NHS Ayrshire & Arran.

We asked the NHS board to develop an improvement plan to address the identified recommendations detailed in this report.

We would like to thank the State Hospital and all staff 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 In February 2012, the Cabinet Secretary for Health, Wellbeing and Cities Strategy asked us to review NHS Ayrshire & Arran’s processes for managing significant adverse events. This was following the Scottish Information Commissioner’s criticism of how the NHS board had handled Freedom of Information requests for Critical Incident Review Reports and Significant Adverse Event Review Reports.

1.1.3 Following our review, we published a report in June 2012 called: The Management of Significant Adverse Events in NHS Ayrshire & Arran. 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.

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

- develop a national framework for managing adverse events, and
- carry out a rolling programme of reviews across NHS boards starting in autumn 2012.

The review process

1.1.5 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.

1.1.6 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.

1.1.7 The review process has two key phases:

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

Pre-visit analysis

1.1.8 We reviewed information provided by the State Hospital 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 13 recorded significant adverse events over the past 18 months, and
• details of four specific significant adverse event reviews.

Review visit
1.1.9 The review visit took place on Wednesday 16 January 2013. The review team was made up of a number of individuals with relevant specialist knowledge from across Scotland (see Appendix 1 for membership of the review team).

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

1.1.11 We discussed the initial findings of our report with the State Hospital’s deputy chief executive and director of finance and performance on Thursday 7 February 2013. The chief executive was unavailable at this time due to sickness absence.

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

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

2.1.1 The State Hospital, Carstairs, is a high secure forensic psychiatric hospital covering Scotland and Northern Ireland. The State Hospital is part of NHSScotland and is governed by The State Hospitals Board for Scotland. The hospital has 140 beds and provides care for male patients requiring high secure care.

2.1.2 In its incident reporting and review policy, the State Hospital sets out its commitment to an open and fair culture, encouraging employees to report incidents and to continuously learn and improve from them.

Adverse event definitions

2.1.3 The incident reporting and review policy (issue 3, August 2011) hereafter referred to as the policy, defines an adverse event as:

“Any event which causes unexpected or unintended harm, loss or damage. Adverse events can include errors, accidents, emergency situations, incidences of violence or aggression, and equipment malfunctions. Local incidents may have implications for other healthcare services and it is essential that all adverse events are reported.”

2.1.4 The policy also describes a critical incident as an adverse event which has a major impact on patient care, service provision, or the State Hospital’s reputation.

2.1.5 The State Hospital uses the NHSScotland risk matrices to assess and grade incidents and these are subject to the following two levels of review.

- Local (standard) review – The NHS board undertakes a local review for all incidents reported on Datix. This is led by the line manager or person responsible for the area where the incident occurred, or by a nominated expert.
- Enhanced review – Following local review and grading of an incident, further review may be necessary to establish the root cause of the incident and ensure organisational learning. This enhanced review can take the form of either a critical incident review, or a serious untoward incident review.

2.1.6 Any incident graded as very high is automatically subject to a critical incident review. This is the fullest form of review. Any incident graded as high can be subject to review either at the request of the senior management team or the clinical team.

2.1.7 The NHS board reported that there are occasions when a full critical incident review is not required, but local investigation is not sufficient to ensure learning across the organisation and minimise the risk of the incident recurring. In these cases, an abridged version of the process may be appropriate and the senior management team would commission a serious untoward incident review.

2.1.8 Between 2010 and 2012, the State Hospital recorded a total of 3,440 reported incidents. The NHS board assessed none of these as very high and 137 of these as high. The NHS board informed us that due to the context of the hospital, many of the high graded incidents relate to the likelihood of the incident recurring, rather than severity. As a result, 13 of these incidents have been subject to critical incident review or serious untoward
Incident review.

2.1.9 The State Hospital has identified the top three themes for significant adverse events as:

- assault
- security, and
- information governance.

2.1.10 The State Hospital uses the Datix incident management software system.

**Governance arrangements**

2.1.11 The State Hospital has a flat governance structure of accountability for adverse event management. The risk management team oversees the day-to-day workings of the system, led by the head of clinical and risk governance. The team is part of the finance and performance directorate, ultimately accountable to the chief executive.

2.1.12 The policy states that the chief executive is accountable to the Board for the effective management of risks. Reporting structures demonstrate that incident reporting information is presented at all levels of the organisation.

2.1.13 The clinical governance and risk and governance committees receive regular information on the management of adverse events. The clinical governance committee receives reports on incident monitoring and critical incident reviews. The risk and governance committee monitors critical incident and serious untoward incident reviews every 3 months, and reports to the audit committee. The reports include specific and aggregated data on new incidents, information on current incident reviews, and progress on the action plans of previous reviews. The risk and governance committee is the central monitoring group for actions arising from the adverse event review processes. A monthly progress update on adverse events is also discussed at the senior management team.

2.1.14 As part of our review, the State Hospital provided minutes of their clinical governance committee, risk and clinical governance committee, senior management team and management team meetings. In the last 18 months, there have been six meetings of the clinical governance committee, with five critical incident reviews presented. Also during this time period, one non-clinical critical incident review was presented to the risk and governance committee.

2.1.15 The NHS board also reported that:

- there is a daily reconciliation between Datix and the local 24-hour security report
- the risk management team reviews all incidents locally investigated by staff, and
- there is a monthly meeting to review all incidents with members of the senior management team to ensure consistency of incident grading.
2.1.16 Figure 1 outlines the current management arrangements and Figure 2 outlines the current governance arrangements in place for the management of adverse events.

**Figure 1: The State Hospital management arrangements for adverse events**

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Chief Executive

Director of Finance and Performance

Head of Clinical & Risk Governance

Risk Management Team
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**Figure 2: The State Hospital governance arrangements for adverse events**

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Clinical Governance Committee

Risk and Governance Committee

Senior Management Team

Staff Governance / Audit Committees
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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 provides information on involving staff in the process of the review, ensuring the immediate safety of people and the environment, and the need to identify support for all groups involved. However, it does not provide guidance for involving patients, family and carers in adverse event reviews.

3.1.2 Appendix 7 of the policy, Guidelines for Undertaking an Investigation, states that:

“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 NHS board baseline submission stated that:

“The approach taken is highly dependent on both the type of incident, and the patient involved, and is tailored to individual circumstances. A copy of each report is provided to the relevant clinical team whenever the incident involved a patient.” However, there is no policy guidance around the involvement of patients, family and carers in the analysis of the event, or for tracking and responding to concerns raised by families.

3.1.4 Of the four cases selected by the review team for detailed review, there were two cases with evidence of involving patients and families in the incident review process. In one case, the patient was interviewed as part of the investigation. Review details for this case were not subsequently shared with the patient or family and the rationale for this was documented. In another case, communication with the patient was evident following the incident and the patient was interviewed as part of the investigation.

3.1.5 During our review, we found examples of clinical staff engaging with families (where appropriate) as part of good clinical practice. However, there was no consistent approach for engaging with patients, family and carers as part of management of adverse events, including:

- involving patients and family in the incident review process
- documenting when this happens, or
- providing a rationale if there is no involvement.
Staff involvement

3.1.6 Staff report incidents through the Datix risk management system. The policy sets out clear guidance for engagement of staff in reporting incidents. It states that the hospital is:

“Committed to developing a learning culture which encourages employees to report incidents and near misses. The organisation’s continuing commitment to a ‘fair blame’ culture will positively encourage the reporting of errors, incidents, accidents and near misses.”

3.1.7 During our review, it was clear that staff were aware of the processes to report incidents and every member of staff has access to the Datix reporting software. However, some staff spoken with expressed dissatisfaction with their involvement in the review process and voiced concerns about the perception that a critical incident review could be linked to disciplinary action. The NHS board policy states that the purpose of incident review is not to apportion blame, and disciplinary action will not normally be taken as a result of incident reporting. The policy lists exceptions to this including criminal activities and acts of gross misconduct. During our review, senior management reported that in practice, the adverse event and disciplinary processes are separate and staff concerns were perception rather than reality. The NHS board reported that if disciplinary actions are identified, the critical incident review process stops and the relevant HR policy is implemented. The NHS board improvement action plan details plans to include the National Patient Safety Agency decision tree in its policy to ensure appropriate consideration of disciplinary action.

3.1.8 Appendix 7 of the policy outlines how staff should be involved in the review process. However, the guidance is unclear on how feedback should be provided to the member of staff who reports the incident, or to staff involved in the review process and how the reports, recommendations and action plans are shared more widely.

3.1.9 Of the four cases selected by the review team for detailed review, all showed evidence of varying levels of staff involvement in the review process. In two of these cases, the NHS board reported that information was fed back to staff through team debrief or formal presentation. However, there was no evidence of staff involvement in compiling recommendations and action plans from the reviews. This is in line with the policy which states that the draft report is taken to the clinical team, where appropriate, for review of factual accuracy. After this, the final report is submitted to the commissioning executive director and taken to the next senior management team meeting where actions are identified and agreed. Historically, clinical teams had the opportunity to comment on draft reports. However, the Board perceived this as ineffective and wanted to secure the independence of the critical incident review.

3.1.10 In each of the four cases, relevant staff were interviewed as part of the investigation. However, with the exception of the social work department, there were variations of staff involvement in the three other cases with updating staff on the progress of the review and always providing staff with a copy of the final report and action plan.

3.1.11 Staff spoken with from the social work department reported that they felt well informed and had received both verbal and written feedback. Staff spoken with about two cases expressed frustration and disengagement with the process of not being involved in the drafting of reports or development of action plans. This has had an impact on the ownership of the findings, implementation of action plans and ultimately learning.
3.1.12 During our review, all staff spoken with reported that they received support from their peers and managers at a local level following an incident. However, they reported that they do not recognise this support as part of the formal NHS board-wide approach within the management of the incident review process. The NHS board reported that in addition to peer and line management support, occupational health support is available and there is a specific hospital policy for this. The NHS board improvement plan details development of a staff information leaflet to explain the critical incident review and serious untoward incident review processes.

3.1.13 The NHS board stated that it intends to provide all interviewed staff with a copy of the anonymised report and further develop a staff bulletin style publication to highlight learning from the review process. The NHS board improvement plan details actions to give staff the opportunity to provide feedback throughout the process. The existing policy and action plan set out the level of staff involvement. However, the review team notes that these arrangements do not encourage an appropriate level of engagement with staff, particularly those directly involved in the incidents. This results in a lack of ownership of the findings and implementation of action plans. This was evidenced in at least two of the cases reviewed.

**Recommendations**

The State Hospital's active and planned approach to engaging with key stakeholders, particularly the patients, family and carers affected by a significant adverse event, should include:

1. a systematic approach to consider engagement with patients and families, with the decision and rationale documented within review documentation
2. ensuring that relevant staff receive documentation and communication on the update of reviews
3. ensuring that relevant staff are involved and supported through the review process and meaningful feedback is consistently provided to staff, and
4. ensuring there is a consistent approach to sharing reports throughout the organisation.

**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 states that staff have a responsibility to participate in risk management training and education. During our review, the NHS board reported that all staff receive training on Datix and incident entry, risk management, health and safety, complaints and business continuity, as part of the induction process.

3.2.2 Line managers undertake further training in Datix and risk grading to ensure that incidents are recorded, graded and managed appropriately. The risk management team reported that it reviews all Datix entries and risk gradings to ensure consistency.

3.2.3 Section 7 of the policy includes clear guidelines for undertaking an investigation (based
on the six steps of root cause analysis). The policy explains that staff who undertake critical incident reviews are trained and competent to do so. It states that at least one member of the review team should have completed appropriate investigation training (root cause analysis). We confirmed this with staff during our review.

3.2.4 The NHS board stated that all reviews are facilitated by the risk management department who have undertaken root cause analysis training. The risk management team is a valued central resource for the organisation with knowledge of all aspects of incident reporting and review. All four cases selected for detailed review had risk management team involvement in the review process and root cause analysis methodologies were used to support the review process. Where appropriate, external experts may also be involved to ensure that a level of independence is maintained.

3.2.5 The NHS board reported that the senior management team discusses all report recommendations and agrees an action plan. The risk and clinical governance committee reviews any outstanding actions every 3 months.

Recommendation
To support staff knowledge and training, the State Hospital should:

5 continue to maintain an organisation-wide approach to Datix, risk management and investigation training and ensure competencies are kept up to date.

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 5 of the policy clearly sets out the roles and responsibilities of staff, managers and committees. During our review, staff involved in the review team confirmed that they were clear about roles, remit and reporting procedures of the review team. However, we noted that the review team would benefit from identifying a lead reviewer.

3.3.2 Section 7 of the policy outlines the reporting requirements and responsibilities for each stage of the review process, within each level of review.

3.3.3 Local reviews are short investigations undertaken by the ward or department manager, in partnership with the risk management department. These are undertaken within 7 days of an incident occurring, and the investigation and actions are recorded on Datix.

3.3.4 The senior management team may commission a sudden untoward incident review, either during or following a local review. This is facilitated by the risk management department. Following a short report, the senior management team decides whether a full critical incident review is required.

3.3.5 The policy also states that the general manager oversees the process for a full critical incident review. The commissioning executive director and the senior management team
agree the terms of reference, and the final report is submitted to them to ensure the remit of the review has been fulfilled. The senior management team agrees an action plan with identified leads appointed for implementation.

3.3.6 During our review, staff spoken with expressed frustrations with the adverse events review process. Some staff reported that local assessment of the incident and the identification and implementation of actions is undertaken by those involved soon after the incident, and often before the formal review process has begun. Staff were unclear how their informal review feeds into the critical incident review process. Staff were also unclear of the added benefit of in-depth investigations, as improvements have often been made locally by the time the review findings are disseminated. As part of its improvement plan, the NHS board is developing an information leaflet to inform staff about critical incident review and serious untoward incident processes.

3.3.7 The risk management team has a structured approach to providing incident information and monitoring the progress of actions and reports to the following groups as appropriate:

- senior management team
- health and safety committee
- hospital management team
- risk and governance committee
- clinical governance committee, and
- staff governance committee.

3.3.8 The risk management team also provides reports for clinical teams when needed. The policy states that operational managers are responsible for communicating key messages to staff within their areas.

3.3.9 The documentation provided for each of the four selected cases evidences that incidents are reported and fed back through governance structures. We saw evidence that cases are discussed at clinical governance committees. However, there is a lack of evidence to show assurance around the overall effectiveness of the review process.

3.3.10 There was also no evidence to demonstrate that the NHS board consistently documented how a decision was made to escalate each incident to a serious untoward incident or critical incident review, or the rationale for that decision.

3.3.11 Discussions with staff during our review highlighted that staff did not feel appropriately included in the finalisation of reports, the development of action plans and implementation of learning. We also found that staff involved in the incident were not clear about their role throughout the process.

3.3.12 The governance arrangements are well defined at the State Hospital, with clear senior management and executive team engagement. However, we found a continued disconnect with frontline staff throughout the process.
### Recommendations

To ensure clear functions and roles, the State Hospital should:

6. evidence that roles and responsibilities are clearly defined and staff are clear about their involvement in the adverse events process, and

7. consider their approach to including staff when finalising reports and recommendations, and disseminating learning.

### 3.4 Information management

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

3.4.1 The State Hospital uses the Datix risk management system to report incidents. Staff from all disciplines report adverse events and near misses. The policy states that the NHS board uses the system as a central source for capturing information relating to the incident and the subsequent review, actions, and learning.

3.4.2 Appendix 7 of the policy lists the types of documentation that should be gathered throughout the review process. The State Hospital provided comprehensive documentation for each of the four cases selected by the review team.

3.4.3 The risk management team stores all review information in a central repository, on a secure shared drive, which all members of the risk management team can access. Critical incident review and serious untoward incident reports are also stored in this central repository. The NHS board has recently started attaching final (anonymised) reports to the Datix entry. The NHS board improvement plan also details the development of procedures for the retention and disposal of information relating to critical incident reviews and significant untoward incidents.

3.4.4 The risk management team is the central co-ordinator for all associated documentation for a serious untoward incident or critical incident review. However, on reviewing the evidence provided, we noted there was no document or version control on the majority of the paperwork submitted. This makes it difficult for external viewers to track progress, to identify what stage each review is at, and to demonstrate whether the process outlined in the policy had been followed.

3.4.5 The NHS board has a database to track critical incident review and serious untoward incident recommendations and actions, and monitor their implementation. This local database is referenced to the Datix entry using the incident number and all members of the risk management team can access it.

3.4.6 The risk management team presents reports on incident trends to the hospital management team and the clinical governance committee for action. The NHS board also reported that incident data can be collated for individual patient case reviews and care planning purposes.
3.4.7 The policy is clear how information should be shared within the governance structure. However, there was no evidence of a robust and consistent mechanism to share information from adverse events more widely throughout the organisation.

3.4.8 Of the four cases selected for detailed review, we found a lack of consistency in the sharing of information and dissemination of findings of adverse event reviews. Staff spoken with told us that in one case, they had not received transcripts of interviews to review for factual accuracy or any other documentation associated with the review or its outcomes. However, in another case, staff reported that they received all documentation associated with the review and were satisfied with the information management processes.

3.4.9 During our review, we noted that staff did not understand the process for sharing reports. Staff spoken with told us that they believed that if they requested a serious untoward incident or critical incident review report, it would not be shared. Senior management reported that anonymised reports are available on request and would not be withheld from a member of staff who asked to see it. The NHS board improvement plan details actions to update the current policy to clearly set out the process for sharing reports.

**Recommendations**
To support its information management processes, the State Hospital should:

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

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

3.5 Risk-based, informed and transparent decision-making

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

**Identification, notification and initial event reporting**

3.5.1 The policy outlines that staff must report all incidents and near misses through the Datix system as soon as possible after an adverse event has occurred.

3.5.2 During our review, we observed a demonstration of the Datix reporting system. Once an incident has been entered onto Datix, key members of staff are automatically notified by email depending on the nature of the incident and the fields entered on the original form. The reporting member of staff’s line manager then takes responsibility for the initial review of the incident.

3.5.3 The policy uses the NHSScotland Risk Matrix to grade and quantify individual incidents. The severity of the incident determines the level of investigation and reporting. The policy states that the risk management team can provide support for grading incidents, if required.
3.5.4 The risk management team provides training on the grading of incidents and members of the team are available should staff require support. A member of the risk management team reviews Datix forms and gives final approval to all incidents. The team can review the final grading and take appropriate action if the original grade is deemed inappropriate. This is undertaken in conjunction with the relevant line manager.

3.5.5 The policy also provides information on additional reporting duties, for example the submission of the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 reports to the Health and Safety Executive.

Escalation of events

3.5.6 The policy outlines the various levels of investigation undertaken and what is included for each level of incident:

- low risk incidents – no further action, patterns of incident monitored
- medium risk incidents – no further action, patterns of incident monitored
- high risk incidents – local review undertaken, the senior management team can approve requests for enhanced review if appropriate, and
- very high risk incidents – enhanced review.

3.5.7 The NHS board told us that the context in which the hospital operates means that a number of incidents are graded as high or very high based on the likelihood of an event occurring, rather than severity. As such, the majority of the incidents assessed as high are not subject to a full critical incident review.

3.5.8 The NHS board told us that all very high risk incidents are automatically reviewed and high risks are considered by the general manager, security director, and (where appropriate) clinical team members. A serious untoward incident or critical incident review can be commissioned as a result of these discussions or at the request of the clinical team. The NHS board reported that while there are a number of routes for initiating a serious untoward incident or critical incident review, the risk management team ensures that the processes are consistently applied. However, during our review, we were not assured that decisions concerning the level of review required were always appropriately documented.

3.5.9 Of the four cases selected for detailed review, the following levels of investigation were applied.

- Two cases were graded as high and a full critical incident review was undertaken. The decision to proceed to a critical incident review was not documented.
- One case was graded as both high and medium on two Datix forms and a serious untoward incident review was undertaken. Following this review, no further follow-up was required. The decision was not documented.
- One case was initially identified as a complaint, therefore there was no Datix grading. The decision to proceed to a critical incident review is filed in the case documentation.
3.5.10 Data submitted by the State Hospital indicate that the NHS board has classified 137 incidents as high over the past 18 months. Thirteen of these incidents were subject to a form of enhanced review. However, we were not assured that the rationale behind the decision-making process to determine which cases undergo enhanced review is well documented. The NHS board recognises that the process for documenting escalation of an incident to a serious untoward incident or critical incident review needs to be strengthened.

3.5.11 The NHS board also noted that where there is concern over a number of similar incidents, further investigation would be undertaken. The relevant line manager is responsible for actioning this with support from the risk management team if required.

**Recommendation**

To support a risk-based, informed and transparent approach, the State Hospital should:

10 evidence the decision-making process in case documentation to demonstrate the rationale for determining which cases are subject to enhanced review.

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 states that staff should complete a Datix form as soon as possible after an incident occurs, 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 selected for detailed review, three were reported through Datix; two within 24 hours and one within 48 hours.

3.6.3 Appendix 8 of the policy provides timescales for completion of the enhanced review process. A serious untoward incident review should be completed within 6 weeks of an incident occurring and a critical incident review should be completed within 12 weeks of an incident occurring.

3.6.4 The NHS board acknowledges that the timely completion of significant event reviews is a challenge. One of the four cases selected for detailed review, was a serious untoward incident review and was completed within 3 weeks of the incident reporting date. The three cases that led to critical incident reviews were completed, on average, within 32 weeks of the incident reporting date. The NHS board stated that it has tried various efforts to address these timescales in recent years, most notably through the introduction of the serious untoward incident process.

3.6.5 Staff spoken with during our review reported frustrations with the length of time taken to complete significant event reviews. We noted that a significant factor in these delays was the difficulty in arranging interviews with staff.
3.6.6 The NHS board reported that it has plans to review the serious untoward incident process to streamline investigation times. The NHS board is aware of the reasons for delays and is developing actions to address these. This is detailed in the NHS board improvement plan.

**Action planning**

3.6.7 The policy outlines that the senior management team generates action plans from the findings of a critical incident review. The policy states that timescales for action will be directed by the level of risk posed with an expectation that:

- high priority issues are addressed within 3 months
- medium priority issues within 6 months, and
- low priority issues within a year.

3.6.8 During our review, staff spoken with expressed concerns that they are not involved in the action planning process. The NHS board explained that the senior management team discusses recommendations for all reports and compiles an action plan to address these. However, during our review we noted that this contributes to staff disengagement with the adverse events review process.

3.6.9 The risk management team uses a database to track critical incident review and serious untoward incident recommendations and actions, and monitors their implementation. The team reports to the senior management team and the risk and governance committee. A monthly monitoring system reminds responsible officers of the outstanding actions, and unresolved issues are escalated to the chief executive’s office as required. During our review, we were assured that action plans are reported to the clinical governance committee and risk and governance committee.

3.6.10 The NHS board provided action plans for all four cases selected for review. These follow a standard format with an owner identified, a completed box and a comments field. We noted that the action plans submitted as evidence did not include completion dates for actions or version control dates. The NHS board recognised that actions would benefit from including an expected completion date in order to drive and monitor implementation timescales.

**Sharing of learning**

3.6.11 The policy states that the key objective of reporting incidents and near misses is to facilitate organisational learning and improvement. It also refers to sharing of information throughout the document and outlines the responsibilities of line managers and the senior management team to share learning across the organisation.

3.6.12 Section 8 of the policy specifies the method for disseminating shared learning as a result of adverse events review analysis. An executive summary of all critical incident reviews is discussed at the hospital management team meeting. The team generates an action plan to take forward agreed recommendations; the general manager is responsible for overseeing this process. The risk management department monitors the progress of any completed or outstanding actions and reports regularly to the hospital management team and the risk and governance committee.
3.6.13 Documentation from clinical governance groups and committees demonstrates that themes are presented from adverse events. However, there was no evidence to suggest that an overarching approach is in place to present these themes.

3.6.14 Staff spoken with during our review reported that informal sharing of learning is undertaken within teams. However, there is no formal or consistent process to share this throughout the organisation.

3.6.15 The NHS board did not provide information on how thematic learning from all incidents (high, medium and low) has been identified and changes that have been implemented as a result. Staff spoken with during our review told us that changes in policy and procedure were communicated with staff. However, it was not clear whether this was as a result of an incident or other drivers.

3.6.16 Of the four cases selected for detailed review, we did not see evidence of a consistent approach for disseminating learning both with staff involved in the incident and across the wider organisation. Within the social work case, staff reported that the learning from this review was shared within the clinical team, social work team and across other relevant agencies. Staff spoke enthusiastically of the changes implemented as a result. However, this approach was not evident within the other cases selected for review.

**Recommendations**

To improve timely management, learning and dissemination following adverse events, the State Hospital should:

11 ensure that the timescales for various stages of the adverse incident management process are met in line with the policy and that progress against these is monitored regularly

12 ensure actions have both target and actual dates, and

13 spread a culture of capturing and sharing lessons learned across the organisation that results in change and improvements.
Appendix 1 – Details of review team

The review of The State Hospital was conducted on Wednesday 16 January 2013.

Review team members

Mark Aggleton
Senior Business Manager, Healthcare Improvement Scotland

Gordon Birnie
Medical Director, Operational Division, NHS Fife

Robin Creelman
Public Partner

Leanne Hamilton
Clinical Governance Support Officer, Healthcare Improvement Scotland

Susan Lowes
Project Officer, Healthcare Improvement Scotland

Lorna Ramsay
Clinical Lead for eHealth, NHS National Services Scotland

Lesley Anne Smith
Quality Improvement Programme Director, NHS Education for Scotland

Observed by:

Claire Scrim
Project Officer, Healthcare Improvement Scotland
We can also provide this information:

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

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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.