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

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First published April 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 NHS Borders’ governance arrangements and processes for managing adverse events involved:

- an analysis of evidence provided by the NHS board, and
- a visit to NHS Borders on Tuesday 12 March 2013.

In response to the NHS Ayrshire & Arran report and recommendations, NHS Borders has reviewed its processes for the management of significant adverse events. The NHS board agreed a joint incident management policy in January 2013 to ensure a consistent approach to the management of significant adverse events. At the time of our review, this was still in the process of being implemented across the NHS board. Senior management also informed us that they are in the process of creating a suite of documentation for managing adverse events to support this policy.

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

- a good culture for reporting incidents across the NHS board
- comprehensive support provided by the clinical governance and quality team and in particular, the clinical risk facilitator
- good non-executive director engagement, and
- a commitment, in response to the Ayrshire & Arran recommendations, through the development and implementation of an improvement plan to introduce a single system approach to adverse event management.

However, our review identified challenges in the management of significant adverse events. These include patient, family and staff engagement, consistent implementation of methodologies and decision-making, and the sharing of wider learning.
We noted that the NHS board has undertaken work to improve the significant adverse events process. However, this is currently in the development and implementation stages and has not yet been embedded across the NHS board.

The recommendations identified below aim to support the NHS board’s improvement activity to ensure the management of adverse events is reliably and consistently applied across the NHS board.

**Recommendations**

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

1. a systematic approach to consider notifying and engaging with patients, families and carers, throughout the significant adverse events review process. Reasons for not notifying patients, family and carers in specific instances should be documented.

2. developing guidance for staff to ensure consistent involvement with patients, families and carers across the NHS board.

3. developing guidance to ensure appropriate feedback to staff following reporting, and for the involvement of staff in the significant adverse events review process.

**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 Borders should:

4. continue to implement the improvement plans and demonstrate a systematic approach to staff training, ensuring staff are appropriately trained.
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 Borders should:

5 ensure staff roles and responsibilities are clearly defined and staff understand their contribution in the review process across the NHS board

6 consider developing guidance for staff to ensure processes for undertaking a significant adverse event review are consistent across the organisation, and

7 clearly define roles and responsibilities for escalation and decision-making.

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 Borders should:

8 ensure there is a single integrated approach to documentation management, monitoring, scrutiny and assurance across the NHS board, and

9 introduce a process to ensure that staff consistently capture all documentation for each stage of the adverse events review process.

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 Borders should:

10 ensure consistency in the decision-making process to escalate or re-grade incidents, and that this is documented in the incident file.
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 Borders should:

11. ensure the timescales for various stages of the adverse event review process are met in line with the policy

12. ensure there is a consistent process for developing and monitoring action plans and outcomes

13. ensure lessons learned are captured and shared across the organisation, and develop a system to quality assure that learning has been shared and implemented, and

14. ensure the joint policy provides appropriate guidance for staff for all aspects of the process, from reporting through to sharing learning, and demonstrate this policy is consistently implemented across all services within the NHS board.

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

We would like to thank NHS Borders and in particular all staff at Borders 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 Borders 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 118 recorded significant adverse events over the past 18 months, and
- details of four specific significant adverse event reviews.
1.1.8 Of the 118 recorded significant adverse events, we selected four cases for detailed review. We did this by firstly randomly selecting 50 cases and then reviewing the high level summary of each case, taking into the location and specialty of the event and the level of investigation.

Review visit

1.1.9 The review visit took place on Tuesday 12 March 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 NHS Borders’ chief executive on 27 March 2013.

Improvement plan

1.1.12 We expect NHS Borders 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 Borders 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 Borders’ adverse event management policies and procedures

2.1.1 NHS Borders is responsible for providing health services across the Scottish Borders for a population of around 113,000. The NHS board employs around 3,137 staff from a wide range of professional and support occupations.

2.1.2 Borders General Hospital is the main acute hospital for the region. It contains 273 staffed beds and has a range of healthcare specialties and primary care services. There are also four community hospitals, health centres, and a network of mental health and learning disability inpatient, community and day facilities.

2.1.3 Within NHS Borders, incidents have historically been separated into general safety incidents and clinical incidents with corresponding policies on the management of these incidents. The NHS board identified the following documents as key to the management of adverse events:

- guidelines for the management of clinical adverse event recording, and
- conducting a safety incident review guidelines.

2.1.4 Evidence submitted as part of the baseline assessment identified that separate procedures were in place for specialist reporting. For example, suicide reporting, mental health and Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR).

Policy for managing adverse events

2.1.5 The NHS board agreed a joint incident management policy in January 2013 to ensure a consistent approach to the management of significant adverse events. At the time of our review, this was still in the process of being implemented across the NHS board.

2.1.6 Senior management told us that they are currently developing standard operating procedures to support implementation of the policy and guide staff on the operational management of events and subsequent investigations. This will include clear instructions for reporting, recording, and reviewing significant adverse events. The standard operating procedure which forms part of the supporting documentation, is intended to be finalised by the end of April 2013 and subsequently distributed throughout the NHS board for consultation.

2.1.7 NHS Borders has advised us that the following will form part of the supporting documentation:

- standard operating procedure to support the incident management policy
- investigation summary report template
- action plan template
- letter request for statements template
- fishbone template
- root cause analysis – contributing factors tool
● guidelines for writing a statement
● guidelines for a fatal accident enquiry
● guidance notes for the use of the investigation summary report, and
● senior charge nurse quality dashboard, containing monthly information on trends in incidents in each ward.

2.1.8 As the new incident management policy is still in the early stages of implementation, we have assessed NHS Borders against its existing policies, which were in place during the cases selected for detailed review. Where possible, we have described the proposed future plans as outlined by the Board in its improvement plan and new joint policy.

Adverse event definitions

2.1.9 The guidelines for the management of clinical adverse event recording (issue date August 2010), hereafter referred to as the clinical policy, defines clinical significant adverse events as follows:

“The incident/accident where a patient suffers very serious injury, major permanent harm or unexpected death, (or the risk of death or serious injury) on health service premises or other premises where health care is provided by NHS Borders staff.”

2.1.10 The conducting a safety incident review guidelines (undated), hereafter referred to as the safety policy, expands this definition with:

“And/or [an incident] is classified as a significant incident by management i.e. a significant event may be an event that has an important effect on other things within the organisation.”

2.1.11 During our review, some staff were not clear about what was categorised as a significant adverse event and should be subject to a significant adverse event review. The NHS board told us in its baseline submission that it was developing a single definition for significant adverse events. The new incident management policy further refines the above definitions, stating that:

“A SAE 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, visitor or member of the public (Healthcare Improvement Scotland, 2012) or an increase in organisational liabilities. These are incidents which have resulted in a major or extreme adverse outcome as defined within the matrix. See Appendix 1.

“This will include any other incident, such as a significant near miss or an identified adverse trend that any member of the Board Executive Team, Clinical Board Executive Teams, Heads of Support Services and Senior Clinical Team, agree warrant review.”

2.1.12 NHS Borders uses the NHSScotland risk matrices to assess and grade incidents and these are subject to the following three levels of review:

● minor – further inquiries will be conducted at a local level
● moderate – local management review
• major or extreme – comprehensive significant adverse event review.

2.1.13 The NHS board told us in its baseline submission that there have been 91 clinical significant adverse events and 27 general safety significant adverse events reported in NHS Borders in the last 18 months.

2.1.14 NHS Borders has identified the top five themes for clinical significant adverse events as:

- slip/trip/falls 24%
- other events 18%
- obstetric events 17%
- investigation, diagnosis and treatment 12%
- access/appointment/admission/transfer/discharge 7%

2.1.15 The NHS board identified that all general safety significant adverse events were categorised as ‘aggression and violence or personal safety’.

2.1.16 The NHS board told us that themes and trends are reported on a regular basis to the clinical governance risk management group which under the new integrated structure is the healthcare governance group.

2.1.17 The baseline submission states that the clinical risk facilitator has reviewed the categories and risk ratings and this may result in changes to the theme data. The NHS board is in the process of reviewing all outstanding incidents on Datix.

2.1.18 On the day of the review, the NHS board told us that the clinical governance and quality team and the risk, health and safety team review all new Datix incidents on a daily basis to ensure appropriate grading and categorisation of events.

**Governance arrangements**

2.1.19 NHS Borders has recently refined its governance reporting structures and simplified arrangements, which supports the implementation of the new incident management policy. NHS Borders’ services are organised within four clinical boards (operating divisions). Previously, each clinical board had a clinical governance group, which reported to the clinical governance risk management group and clinical governance steering group. These groups then reported to the clinical governance committee. Under the revised governance arrangements, each clinical board has a clinical governance group and where appropriate an integrated governance group which reports to the healthcare governance group and finally the committees of the NHS Board.

2.1.20 There are also operational arrangements for the management and governance of general safety and risk. These include occupational health and safety forum and the risk management groups, which report to the Board committees.

2.1.21 The associate medical director (clinical governance) is notified of any clinical adverse events which require review or investigation and they then brief the medical director. General safety adverse events are escalated to the relevant executive directors, who then brief the Board. During our review, senior management told us that this takes the form of verbal and email communication and the decision to escalate to a review is recorded.
in an excel spreadsheet. The NHS board told us that there are plans to record this audit trail on the Datix reporting system.

2.1.22 The clinical governance committee and Board receive regular reports on NHS Borders incidents and adverse events. The clinical governance committee and audit committee both share minutes of meetings with the Board. Specific reports are also supplied to the various operational groups on request.

2.1.23 The clinical risk facilitator and risk, health and safety manager provide incident monitoring reports to relevant governance groups. These can be taken forward for scrutiny and assurance to the clinical governance committee or the Board or back to the clinical governance groups within the clinical boards for operational management and review. The clinical governance leads for each clinical board are members of the monitoring and governance groups of the Board.

2.1.24 The management of clinical adverse event recording guidelines (August 2010) states that action plans from significant adverse events reviews are reported to the clinical governance group of the appropriate clinical board. These groups are responsible for the monitoring of action plans.

2.1.25 Figure 1 below outlines the governance arrangements in place as of April 2013 for the management of adverse events.

**Figure 1: NHS Borders governance structure**

![NHS Borders governance structure diagram]

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 clinical policy provides guidance on:

- ensuring the immediate safety of patients following an incident, and
- the initial contact with patients, family and carers following an incident as part of good clinical practice.
- It states that the consultant in charge of the patient’s care is responsible for informing the patient or next of kin that the incident has occurred. It also states that the relevant manager should support staff in communications with the patient and the patient’s relative or carer regarding the adverse event. The safety policy does not refer to engaging with patients, carers or families.

3.1.2 The NHS board’s baseline response also identifies engagement with patients across a range of services including mental health, suicide or sudden death and child protection. These outline varying levels of patient, family and carer involvement from initial identification following an event, to ongoing support and involvement during the various stages of the incident and its review, and the outcomes or outputs of these. However, from the evidence submitted by the NHS board, it is clear that there is no consistent, active, planned approach to engaging with patients, families and carers across the NHS board.

3.1.3 The new joint incident management policy states that one of the purposes of the policy is to:

“Ensure an active and planned approach to engaging with key stakeholders particularly patients, family, carers, staff, partner agencies and members of the public affected by any adverse event.”

However, this is not detailed within the main body of the policy and no guidance exists for staff to follow.

3.1.4 As part of the baseline submission, the NHS board reported that its improvement plan reflects the requirement for guideline development, integration and implementation. It focuses on greater family or carer involvement of those affected by a serious adverse event underlined by a clear person-centred focus, values and approach.

3.1.5 During our visit, we received an updated version of the improvement plan. This details plans to develop a leaflet on sharing information with families and carers of patients. This is due to be presented to the information governance committee in March 2013 for approval. However there appears to be no plans to develop guidance for how patients, families and carers should be involved in the actual review process.
3.1.6 Of the four cases selected for detailed review, we saw evidence of clinical staff engaging with patients’ families to varying degrees. In one case selected, this was not applicable. Two cases involved communication with patients and families as part of good clinical practice following an incident, rather than instigated through the review process. In one case, communication with the family during the review was through an external agency. Across the three relevant cases, we did not find any evidence of involving patients, families and carers in the incident investigation.

3.1.7 The NHS board reported that there are robust processes for patient and family support and engagement within mental health services. The clinician is the main point of contact for patient or family support, and the chair of the review contacts the family to ensure their views are fed into the review process.

3.1.8 There was no evidence of a formal process for considering involving patient, families or carers, for documenting any engagement, or for providing a rationale if there was no involvement.

**Staff involvement**

3.1.9 The clinical policy provides some guidance on the involvement of staff in the management of adverse events. Its underlying principles section in the introduction states that:

“Staff who experience trauma as a result of events will be supported and the clinical governance and quality team will work with any professional bodies or partnership representatives and senior managers to provide support and guidance. The organisation will create an environment that enables staff to express concerns and for these to be listened to, discussed and acted on as appropriate.”

3.1.10 It further states that staff should discuss their involvement, provide their assessment of the causes of the clinical significant adverse event and suggest actions to prevent recurrence and reduce risk. It also states that line managers are responsible for ensuring the occupational health and safety service has been made aware if there is any staff injury or staff need extra independent support.

3.1.11 The safety policy also provides guidance on support mechanisms for staff. It states that:

“The people involved with the review may find it very stressful and therefore it is important that they are treated with sensitivity. Any staff involved in reviews will be supported by management and offered access to occupational health support, if appropriate.”

3.1.12 As part of the baseline response, the NHS board provided its occupational health guidance for critical incidents, which details guidelines for staff support.

3.1.13 The new joint incident management policy states that staff are entitled to support throughout the review process. The occupational health and safety service, professional specialist advisers, chaplaincy service and staff side organisations can provide this.

3.1.14 The clinical and safety policies set out different definitions for disciplinary action resulting from an incident. The new joint incident management policy sets out a single definition that is to be used across the NHS board. It outlines that NHS Borders is committed to a Just Culture, whereby the NHS board has a non-punitive approach to
human error and aims to learn from mistakes. However, the disciplinary system may apply where gross negligence of duty has occurred.

3.1.15 Every staff member of NHS Borders can report incidents through the Datix risk management system, accessed on the NHS board intranet website. Staff spoken with during our review knew how to access the system and the majority felt comfortable reporting incidents. We found a good culture for reporting incidents across the NHS board. During our review, staff told us that they felt there was value in reporting incidents and they were confident incidents were being progressed. However, staff did express frustration at the lack of feedback they received after reporting an incident.

3.1.16 There are no guidelines for the involvement of staff following initial reporting. The new joint incident management policy details that line managers are responsible for ensuring staff who have been involved in an incident are informed, engaged and supported. During our review, staff told us that they were not always updated or informed of progress of reported incidents. The majority of staff do not have access to login or view an incident once it has been reported through Datix. If a staff member needs an update on an incident they have been involved in, this can be requested through the staff members line manager, the clinical risk facilitator or the risk, health and safety manager.

3.1.17 Of the four cases selected for detailed review, there was no evidence of a consistent process for involving staff in the significant adverse event review process. In one case, the staff involved in the incident were not involved in the local review. Two cases showed staff involvement in review meetings, staff meetings, and email and verbal communication through line management. In the fourth case, staff reported that the clinical governance department kept them updated and provided them with a copy of the formal report. In two of the cases, the case documentation included detailed communication records with staff.

3.1.18 Staff spoken with were complimentary and spoke highly of the support provided by the clinical governance and quality team and in particular, the clinical risk facilitator. This included both staff involved in the initial incident and those involved in the subsequent significant adverse event review.

Recommendations

NHS Borders’ 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 notifying and engaging with patients, families and carers throughout the significant adverse events review process. Reasons for not notifying patients, family and carers in specific instances should be documented.

2. developing guidance for staff to ensure consistent involvement with patients, families and carers across the NHS board.

3. developing guidance to ensure appropriate feedback to staff following reporting, and for the involvement of staff in the significant adverse events review process.
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 Borders introduced Datix in April 2011. Senior management told us that full training was delivered to staff on the system at that time. The NHS board’s baseline response provided by the NHS board also states that an introduction to the risk management system is given to all new employees as part of their formal induction. This emphasises the importance of reporting, learning and improving from incidents, risk assessment, risk management and patient experience. All trainee medical staff receive a similar induction including training on the Datix system, policies and guidelines.

3.2.2 The baseline response states that the clinical governance and quality, and risk, health and safety teams have delivered a rolling training programme for incident reporters and incident approvers in Datix. During our review, senior management told us of a new e-learning guide for Datix reporting that is being rolled out. Staff spoken with during the case reviews also referred to this new training package.

3.2.3 The NHS board reported that it issues the following documentation to support staff after completing of training:

- Datix reporter quick reference guide
- Datix reporter full guidance
- Datix approver quick reference guidance, and
- Datix approver full guidance.

3.2.4 The NHS board reported that training is an ongoing process delivered as and when required. The baseline response outlines a variety of training that is also undertaken with individual teams across the NHS board, including:

- health and safety risk assessment and management training for managers
- root cause analysis and incident investigation training
- child protection training for significant adverse events
- occupational health risk assessment
- prevention and management of aggression and violence incident training, and
- adult protection significant and critical incident review training.

3.2.5 The baseline response states that significant adverse event reviews are supported and led by the clinical governance and quality team, where appropriate. This team is trained in root cause analysis and investigation skills. During investigations, staff are also supported through action learning to gain knowledge and skills to carry out investigations.
3.2.6 The NHS board reported that departmental training plans have been embedded throughout NHS Borders. These identify training requirements based on local need and risk assessment.

3.2.7 Staff spoken with during the review told us they had received mixed levels of training. Some staff told us that they had received no training on Datix, while others told us that they had received initial training in 2011. The majority of staff spoken with were aware of the new e-learning module for Datix reporting. Line managers told us that they had received first or final approver training.

3.2.8 Of the four cases selected for detailed review, none of the staff spoken with had undertaken root cause analysis or investigation training. However, staff spoke highly of the support provided by the clinical governance and quality team and in particular, the clinical risk facilitator. The NHS board told us that some members of the clinical governance and quality team have undertaken root cause analysis and investigation training.

3.2.9 As part of the baseline response, the NHS board reported that it was planning to undertake an educational training needs analysis which identifies additional training requirements and timescales. The updated improvement plan provided by NHS Borders indicates that this work was under way at the time of our visit.

3.2.10 The improvement plan details plans to:

- develop an e-learning module for root cause analysis and investigation training, and
- deliver training on the wider review process through an external training company.
- Specialised training will also be delivered to a group of chairs and lead investigators for significant adverse event reviews to help ensure a consistent approach to managing and undertaking reviews.

**Recommendations**

To support staff knowledge and training, NHS Borders should:

4 continue to implement the improvement plans and demonstrate a systematic approach to staff training, ensuring staff are appropriately trained.

### 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 The clinical policy provides details of roles and responsibilities for the management of clinical significant adverse events. This includes the process for dealing with events with a major or extreme outcome and highlights specific staff group responsibilities. However, the policy does not detail the roles and responsibilities of the significant adverse events review team. This detail is described in the safety policy for the management of general adverse events.
3.3.2 The baseline response outlines the differing expectations, roles, responsibilities and accountability for reviews across a range of services including child protection, pharmacy, infection control and occupational health.

3.3.3 The NHS board reported in the baseline submission that the new joint incident management policy would contain appropriate information to ensure all NHS Borders staff members are fully aware of roles & responsibilities and accountability in:

- reporting
- managing
- improving
- learning, and
- assurance.

3.3.4 The NHS board reported that this would provide clarity and ensure consistency throughout the management of incidents and complement the ambitions of safe, effective and person-centred care within the Healthcare Quality Strategy for NHSScotland.

3.3.5 The new joint policy outlines the responsibilities of staff, line managers and the chief executive for the management of an initial incident and specialist reporting to external agencies. It also highlights the role of the clinical board and operational governance groups in the development of action plans and sharing learning. However, it does not set out the roles and responsibilities of the significant adverse event review teams or offer guidance on how to conduct a review.

3.3.6 Staff spoken with during our review were clear about their responsibilities for reporting incidents and knew where to access support if necessary. However, staff were less clear about the process and their role and responsibilities for carrying out a review. In two of the four cases selected for detailed review, staff were unclear of the difference between their local investigation of an incident and the significant adverse events review process, and what would trigger such a review. These case reviews appear to have been undertaken within the local setting, as part of good practice, rather than being triggered through the formal significant adverse event review process. One case was undertaken with the clinical governance and quality team and appears to follow a formal significant adverse event review process, and one case was not progressed to a full review and the incident classification downgraded following review.

3.3.7 The NHS Borders risk management strategy sets out the management structures for risk and how risk management fits within the governance systems. Risk and significant adverse events are monitored locally by clinical boards through the clinical board clinical governance and integrated governance groups, and at a higher level by the risk management group. This includes ensuring actions contained within improvement plans are completed, analysing trends and identifying learning opportunities.

3.3.8 As part of our review, we received copies of minutes from the following governance groups:
- Board clinical governance committee
- Borders General Hospital integrated clinical governance group
- clinical risk management group
- joint learning disability service clinical governance and quality group
- mental health clinical governance group
- primary and community services clinical governance group, and
- information governance committee.

All the minutes evidenced presentation and discussion of adverse events at the meetings, relevant only to that area of work.

3.3.9 However, we are not assured that the overview of the full adverse event management process is considered, or that the Board is assured a consistent process is used and learning shared across the NHS board. The minutes from the Board clinical governance committee suggest that the presentation of adverse event management information is variable. The committee is provided with copies of meeting minutes from the clinical governance and risk management group. At two meetings in 2012, the committee received a report from the clinical governance and quality team.

3.3.10 Non-executive directors spoken with during our review spoke of being well engaged and being clear on their role within the governance arrangements. They reported that they were satisfied with the reports they received and were confident to ask for more information if required.

3.3.11 Of the four cases selected for detailed review, we did not see a consistent process for the escalation of the incident to a full significant adverse event review. One case was reviewed by line managers and then downgraded. Two cases were undertaken as local investigations with no documented senior management discussion or decision-making. Following completion, one of these cases was reported through a national reporting structure and the other through a directorate steering group. The final case was discussed at a clinical governance group as expected.

**Recommendations**

To ensure clear functions and roles, NHS Borders should:

5 ensure staff roles and responsibilities are clearly defined and staff understand their contribution in the review process across the NHS board

6 consider developing guidance for staff to ensure processes for undertaking a significant adverse event review are consistent across the organisation, and

7 clearly define roles and responsibilities for escalation and decision-making.
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 Borders installed the Datix incident reporting software for the management of adverse events in 2011. Before this, the NHS board relied on paper-based systems and electronic scanning of records.

3.4.2 NHS Borders uses Datix to report incidents. Every member of staff can report incidents, training is provided at induction and guidelines are available on the NHS board intranet. The NHS board also told us that it is in the process of developing an incident recording and management operational procedure, which will act as a guide for staff to help them decide when, how and what to report.

3.4.3 The NHS board reported that all finally approved clinical significant adverse events are recorded in an excel spreadsheet to track the review progress and provide an audit trail for documentation and decision-making. The NHS board also told us that each case is given a unique investigation identifier and linked to the relevant investigation folder in the clinical governance and quality secure shared drive. All review information is stored in this central repository, which all members of the clinical governance and quality team can access. The NHS board reported that it is currently developing Datix to allow documentation to be electronically stored in the incident management system.

3.4.4 The baseline response identifies a range of processes for information management across the NHS board. It highlights that information on the drug death review group, child protection reviews, information governance reviews and occupational health reviews are held within secure files in their respective departments. The NHS board reported that there is no current integration between information systems used for the management of all significant adverse events.

3.4.5 The NHS board reported that it is planning to use Datix more fully to ensure a single integrated approach to documentation management, monitoring, scrutiny and assurance. It is also planning to integrate the current groups of reporting, governance, scrutiny and assurance to attain more clarity and transparency.

3.4.6 Of the four cases selected for detailed review, two had documentation uploaded to the Datix record. All staff spoken with during our case review told us that, where the information was not in the Datix record, the clinical risk facilitator would hold this in a separate file.

3.4.7 There was no evidence of review documentation being shared with staff involved in the incident or investigation, or across the organisation for all of the four cases. Staff told us that while all staff have access to report incidents on Datix, only managers can access the information stored on Datix following the initial report. Only managers and approvers can login to the system. However, the majority of staff spoken with knew how to request information from the clinical risk facilitator and felt comfortable to do so.
Recommendations

To support its information management processes, NHS Borders should:

8. ensure there is a single integrated approach to documentation management, monitoring, scrutiny and assurance across the NHS board, and

9. introduce a process to ensure that staff consistently capture all documentation for each stage of the adverse event review process.

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 clinical policy states that the purpose of clinical adverse event recording is to assess and analyse adverse events and near misses, manage the events and minimise the chance of the incident happening again. It goes on to explain the use of the NHSScotland risk matrix when reporting incidents, using the initial grading of the incident, likelihood of the incident happening and the consequence should the incident happen again.

3.5.2 All employees involved in, or witness, an incident have a responsibility to report this on Datix and they are also responsible for applying an initial risk grading. Upon submission, the Datix system sends an automatic notification to the reporting staff member’s line manager as the first approver. The first and a final approver review the incidents to ensure an appropriate risk grading is applied.

3.5.3 The baseline response states that if an incident is identified as a high or very high risk, staff are encouraged to escalate the problem and/or record it within the JCAD risk register. JCAD is a management information system application which enables recording and control overview of risks reported within the organisation. The NHS board further reported that it intends to use the risk register function in Datix, which would reduce the need for a separate system.

3.5.4 The safety policy outlines that review teams should develop actions to address the contributory factors identified. A risk assessment is required as standard when action plans are developed. This then feeds into the JCAD risk register process to ensure resulting decisions will be informed and risk based.

3.5.5 The joint incident management policy also contains information on the reactive and proactive management of incidents.

3.5.6 All of the four cases selected for detailed review were reported on Datix and automatic notifications sent.

3.5.7 Staff spoken with who are involved as approvers on the Datix system reported a challenge in managing the day to day volume of incident reports and reviewing these. Some staff stated that they can be required to look at 30 incidents a day. Senior management stated that they actively encourage the reporting of incidents, and with implementation of the new policy, they expect reporting rates to increase. The NHS
board will need to ensure it has adequate capacity to manage such an increase within the current arrangements.

**Escalation of events**

3.5.8 The clinical policy and the new joint incident management policy both outline the level of response that is required depending on the grading of the incident. Incidents are subject to the following three levels of review:

- minor – further inquiries will be conducted at a local level
- moderate – local management review
- major or extreme – comprehensive significant adverse event review.

3.5.9 The joint incident management policy states that there may be exceptions to this grading and, in such cases, independent judgement will be applied. It states that these must be authorised by the:

- “medical director/director of nursing and midwifery (or deputy)
- chief operating officer/general manager (or deputy), and
- director/head of support service.”

The Board executive team may also decide to commission an independent review if required.

3.5.10 A first and final approver reviews the incidents to ensure an appropriate risk grading is applied. The NHS board told us that the clinical governance and quality and risk, health and safety teams review all incidents on a daily basis. These teams also offers on-site support on how to use the risk matrix. All finally approved clinical significant adverse events are recorded in the excel spreadsheet.

3.5.11 While the categorisation of incident was recorded in Datix for each of the four cases selected for detailed review, the decision to escalate incidents to a full significant adverse event review was not detailed in the case documentation for any case. The NHS board reported that where an investigation has not been carried out, a rationale for this decision is entered against the event in the excel spreadsheet. This was not evidenced in the documentation for the case that was downgraded.

3.5.12 The associate medical director (clinical governance) is notified of any clinical adverse events which require review or investigation and they then brief the medical director. General safety adverse events are escalated to the relevant executive directors, who then brief the Board. The management and escalation of significant adverse events is undertaken within each clinical board’s clinical governance group or where appropriate their integrated governance group.

3.5.13 Investigations for general safety incidents are presented to the occupational health and safety forum for monitoring and scrutiny. This forum comprises employee health and safety representatives from the staff side organisations, senior managers and specialist advisors. The minutes from the forum are passed to the risk management group (healthcare governance group under new structure).
3.5.14 The baseline submission states that incidents can also be reviewed, discussed and shared through multidisciplinary team meetings, case reviews, case conferences, morbidity and mortality meetings and directorate incident review meetings.

3.5.15 The clinical risk facilitator submits a report to the monthly clinical risk management group as an update on types and quantities of incidents reported, illustrating any trends or themes which have been identified. Details of any clinical significant adverse events, identified risks and clinical significant adverse event investigations are also provided within this report.

3.5.16 The NHS board reported in its baseline response that it is expected that all significant adverse events are reported and investigated following an incident. A root cause analysis is undertaken identifying contributing factors and then an improvement plan is produced to reduce or eliminate future risks to patients.

3.5.17 Of the cases selected for detailed review, one case was graded as high and subsequently downgraded to moderate following first approver review. The remaining cases were graded as major or extreme. However, during our review, we noted that only one case had been through a full consistent significant adverse events review. The other case reviews appear to have been initiated through a local process, rather than triggered through the organisation’s significant adverse event review process. Subsequently, support was provided to these reviews from the clinical risk facilitator.

**Recommendations**

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

10. Ensure consistency in the decision-making process to escalate or re-grade incidents, and that this is documented in the incident file.

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 clinical policy states incidents should be recorded within 72 hours. With the implementation of Datix in April 2011, this was reduced to 48 hours. The joint incident management policy confirms this amended timescale and further states that:

“Staff are therefore required to ensure all incidents are reported within 48 hours, if the incident is a significant adverse event it should be reported within 24 hours.”

3.6.2 The conduct of critical incident reviews April 2009 documentation states that:

“The initial review meeting will be conducted as soon after the critical incident as possible but within 72 hours, and the formal review meeting to consider its content will be completed within 14 weeks.”
3.6.3 The NHS board reported in its baseline response that where critical incident reviews are supported by the clinical governance and quality team, there is an internal 8-week timescale. The safety policy does not detail the timescales necessary for reporting an incident or for the root cause analysis or subsequent finalisation of general safety incidents.

3.6.4 The joint incident management policy clarifies and formalises the timescales required for all levels of reviews as follows.

- Minor incidents – incident approved within 10 working days of being reported. Where local management review is required this should be commenced within 10 working days. Closed within 5 weeks.
- Moderate incidents - commence formal local review within 10 working days. Closed within 5 weeks.
- Major or extreme incidents – commence comprehensive review within 3 working days. Complete within 8 weeks.

3.6.5 The baseline response highlights that the clinical governance and quality team investigation tracker monitors the timescales for reviews and these are reported against clinical governance and quality key performance indicators monitored by the Board.

3.6.6 Of the four cases selected for detailed review, the time taken between the incident notification date and the date the incidents were finally approved in the Datix record varied.

- One case that was subsequently downgraded to a moderate incident took 22 months to be finally approved. This case took 13 days from initial reporting to be reviewed by an approver and the incident was downgraded 17 months after the incident occurred.
- One case took 14 days to be reported on Datix and another 21 days to be reviewed by an approver. The incident was finally approved 8 months after the incident was identified.
- The remaining cases were finally approved within the 8 weeks allocated for major or extreme incidents. However, initial reporting varied from 1 day to 12 days.

Action planning

3.6.7 The clinical policy identifies the need for action plans that improve practice to be produced and implemented where appropriate. The safety policy mentions the creation of action plans, and that these should reflect the recommendations made by the review team. The joint incident management policy details responsibilities for ensuring that improvements identified are undertaken. However, none of these policies offers any guidance on the creation of action plans.

3.6.8 The baseline submission details that clinical boards monitor risk and significant adverse events locally. The baseline submission details that each clinical board and director must develop an occupational health and safety intervention plan. This should be based on feedback from the occupational health and safety services on training, incident recording, risk assessment and policy implementation.
3.6.9 The joint incident management policy states that the clinical board governance groups, and where appropriate their integrated governance group, will ensure that improvement action plans are implemented and monitored. The NHS board also reported that the relevant manager will be responsible for liaising with the persons identified in the action plan to ensure that the actions have been taken forward and will feedback to the healthcare governance group.

3.6.10 Of the four cases selected for detailed review, two contained action plans. Staff reported that, as part of their local review of the incident, they would normally develop an action plan and share this with staff in their area. Neither of the action plans provided had version control on the documentation, and only one of these contained action completion dates and responsibilities assigned.

3.6.11 The Board reported that the Board clinical governance committee is presented with an aggregated action plan providing an overview of the significant adverse event action plans that are in place within the four clinical boards. The committee can request to see individual action plans should they wish.

3.6.12 The NHS board reported that it is currently developing an action plan template. It intends that this will form part of a suite of documentation that will accompany the new policy.

**Sharing of learning**

3.6.13 The clinical policy states that learning points will be shared through the clinical risk management group, local review groups and senior management meetings for dissemination to staff by managers, and through quarterly reports and the annual report.

3.6.14 The safety policy states that the review lead should discuss findings of reviews with managers and appropriate staff members. It also states that the report should be shared with relevant stakeholders, clinical boards, groups, forums and teams to allow others to learn from the incident.

3.6.15 In the case of general safety significant adverse events, the baseline response highlights that investigations are submitted to the occupational health and safety forum and are disseminated to the various members of the forum. This includes staff side organisations, health and safety representatives and senior managers from the clinical boards. The risk management strategy details that the sharing of investigations at the occupational health and safety forum and risk management groups allows other clinical boards to learn from general safety significant adverse events. The baseline response also states that the reports of clinical incidents presented to the clinical risk management group facilitate cross-system awareness and shared learning.

3.6.16 The new joint incident management policy outlines the responsibilities of the chief executive, occupational health and safety forum, and clinical board healthcare governance group for ensuring learning is shared across the organisation. This includes sharing learning plans and identifying learning opportunities within the relevant clinical board and across other clinical boards.

3.6.17 The baseline response identifies examples of learning in a range of services. This includes:

- mental health meetings specifically scheduled for learning every 2 weeks
- a journal club, where doctors usually present a paper which has been published in a journal
- psychiatric education meetings where case presentations, outside speakers and various topics are discussed
- grand round sessions, which can be used as discussion and learning opportunities for clinical significant adverse events
- monthly formal child health business meetings to discuss significant adverse events, and
- learning from medication events presented at the medication safety action committee.

3.6.18 There was no consistent approach to sharing learning in the four cases selected for detailed review. In one case there was no evidence of sharing of learning either with staff involved in the incident or across the wider organisation. In two cases, there was evidence of learning within the clinical area, but not the wider organisation. In another case, a memo was sent to all relevant staff, with an invitation to an all staff meeting to discuss and training sessions were held with relevant staff. In this case, staff reported that improvements in practice as a result of this significant adverse event review have led to safer processes and a reduction in the likelihood of such an incident recurring.

3.6.19 While it is evident that learning as a result of significant adverse event reviews does take place, there is no evidence of a strategic and planned approach to sharing the learning of significant adverse events reviews across the organisation. The Board acknowledged that there is work to be done on sharing thematic learning from all adverse events across the NHS board.

3.6.20 During our review, senior management told us that there are plans to hold an event to share learning from significant adverse events in 2013. The NHS Borders improvement plan also details that the NHS board is in the process of reviewing its systems and processes for learning from significant adverse events. As part of this, the NHS board is in the process of producing an organisation-wide learning and improvement report to help embed learning and improvements from all incidents to date.

**Recommendations**

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

11 ensure the timescales for various stages of the adverse event review are met in line with the policy

12 ensure there is a consistent process for developing and monitoring action plans and outcomes

13 ensure lessons learned are captured and shared across the organisation, and develop a system to quality assure that learning has been shared and implemented, and

14 ensure the joint policy and supporting suite of documentation provide appropriate guidance for staff for all aspects of the process, from reporting through to sharing learning. Demonstrate this policy is consistently implemented across all services within the NHS board.
Appendix 1 – Details of review team

The review of NHS Borders was conducted on Tuesday 12 March 2013.

Review team members

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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.