Management of adverse events

Review Report | NHS National Services Scotland

December 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 National Services Scotland’s (NSS) governance arrangements and processes for managing adverse events involved:

- an analysis of evidence provided by the NHS board, and
- a visit to NSS on 19 September 2013.

NSS has policies and procedures in place to support staff to report and manage adverse events. Governance arrangements are also in place for all strategic business units to report adverse events to the organisation’s clinical governance committee through the clinical leadership forum.

NSS has plans to improve the handling of adverse events across its six strategic business units and has identified the need for an organisation-wide approach. However, NSS reported that its blood, tissues and cells strategic business unit, Scottish National Blood Transfusion Service (SNBTS), combines its pharmaceutical manufacturing activities with direct patient services and blood collection activities from its volunteer donors. SNBTS is therefore subject to the requirements of European law, including the EU Blood, and Tissues and Cells Directives, the Advanced Therapy and Medicinal Product Regulations, the European Pharmaceutical Manufacturing and Distribution Regulations, and in the UK the Blood Safety and Quality Regulations, the Human Tissue (Quality and Safety for Human Use) Act, the Human Fertilisation and Embryology Act and the Consumer Protection Act. The regulations governing the interface between these organisations are not within the scope of this review.

NSS categorises adverse events as being red, amber or green, or high, medium or low severity. The majority of NSS's significant adverse events (defined for this report as category red/high severity) are recorded by SNBTS, with only one of the other strategic business units recording a category red/high severity event in the 18 months before our review. Our review therefore focused on incidents which occurred within SNBTS. However, the majority of our recommendations should have relevance for incident management across the whole of NSS.

None of the four incidents we reviewed resulted in harm being caused to patients by SNBTS. NSS emphasised that it would be extremely rare for such harm to occur.
We noted the following areas of good practice within NSS:

- a formal change management process through which actions identified by incident investigations in SNBTS can be followed up
- use of the QPulse system by SNBTS for incident management and document control, and
- review of risks, complaints and incidents across the whole of NSS by the organisation’s clinical governance committee in a single quarterly report.

We identified a number of challenges in how adverse events are managed by NSS. These related to patient and staff engagement in the incident management process, approach to the definition, recording, support for investigation and management of adverse events, and systems for using learning from significant adverse events to drive improvement.

**Recommendations**

We expect NSS 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**

*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.*

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

1. implement a formal process to consistently engage and support relevant staff, with evidence to demonstrate their involvement in communications, investigations and action plans.
2. consistently document issues raised by staff following an adverse event, and
3. provide guidance to staff on how to consider involving donors, patients and their families or carers in the adverse event review process if they are directly affected by an adverse event within one of NSS’s strategic business units.

**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.*

To support staff knowledge and training, NSS should:
4 ensure staff involved in the management of significant adverse events have training in, and a clear understanding of, investigation methods such as root cause analysis, and apply them to adverse event reviews and action planning.

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, NSS should:

5 continue to document evidence of adverse events being discussed and shared at appropriate meetings, supported by meeting minutes.

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, NSS should:

6 introduce a process to ensure SNBTS staff make full use of QPulse’s functionality to allow separate allocation and tracking of actions

7 ensure consistent document control and cross-referencing of information in QPulse on SNBTS adverse events when additional documents are held in paper files, or actions progress to the change management process, and

8 as far as possible, ensure there is an integrated approach to documentation management across all strategic business units.

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, NSS should:

9 ensure a comprehensive approach to adverse event management - including definitions, recording and support for investigation - is applied across NSS, including, when applicable, working with other NHS boards
as far as possible, implement a standard approach for recording investigations, including checklists and templates, to support staff and ensure consistency across NSS, and

ensure the decision-making and escalation processes, and the level of root cause analysis investigation applied, are consistently documented, to support a transparent and open process.

### 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, NSS should:

12 continue to monitor and improve incident closure throughout NSS to ensure learning is identified and shared in a timely manner

13 ensure there is a comprehensive process for developing and monitoring action plans and outcomes across NSS, and

14 adapt and spread procedures for identifying lessons learned from the review process across all strategic business units, including taking into account feedback from staff.

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

We would like to thank NSS and in particular all staff at Gyle Square, Edinburgh and the Scottish Blood Transfusion Service’s Edinburgh donor centre 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 as outlined in Learning from Adverse Events Through Reporting and Review: a national framework for NHSScotland, which we published in September 2013.

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 NSS in advance of the visit. This included:

- policies and procedures for adverse event management
- governance and reporting arrangements
- an assessment of the organisation’s current and future planned approach following the recommendations of the NHS Ayrshire & Arran report
- a list of 10 recorded significant adverse events (category red/high severity) over the past 18 months, and
- details of four specific significant adverse event (category red/high severity) reviews.
1.1.8 Of the 10 recorded significant adverse events (initially categorised as category red/high severity) we selected four cases for detailed review. We did this by reviewing the high level summary of each case, taking into account the location and specialty of the event and the level of investigation.

1.1.9 Nine of the list of 10 category red/high severity incidents submitted to the review team occurred in SNBTS. The tenth occurred in the National Information Systems Group. As previously noted, we chose to focus on incidents which occurred in SNBTS, due to its patient-facing role.

Review visit

1.1.10 The review visit took place on Thursday 19 September 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).

1.1.11 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.

1.1.12 We discussed the initial findings of our report with NSS’s chief executive on 11 October 2013.

Improvement plan

1.1.13 We expect NSS 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.

1.1.14 We have asked NSS 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 National Services Scotland’s adverse event management policies and procedures

2.1.1 NSS supports Scotland’s health by delivering shared services and expertise to help NHS boards and other organisations work more efficiently and save money. Its services include procurement and logistics, IT consulting and solutions, statistical information and analysis, national payment processing fraud deterrence, and facilities and environmental advice. NSS is also the specialist provider of transfusion medicine in Scotland, supplying high quality blood, tissues, products and services.

2.1.2 NSS completed an internal restructure on 1 April 2013. Before this, services were delivered by 10 divisions. NSS advised that these have been merged to create six strategic business units, as follows:

- Public Health and Intelligence
  - Health Protection Scotland (HPS)
  - Information Services Division (ISD)
- Information Technology
  - National Information Systems Group (NISG)
- Procurement, Commissioning and Facilities
  - National Procurement
  - National Services Division (NSD)
  - Health Facilities Scotland (HFS)
- Blood, Tissues and Cells
  - Scottish National Blood Transfusion Service (SNBTS)
- Practitioner and Counter Fraud
  - Practitioner Services Division (PSD)
  - Counter Fraud Services
- Central Legal Office (CLO)

2.1.3 The incidents under review and the policies in use at the time of our visit on 19 September 2013 relate to the previous divisional structure. This report therefore uses the earlier divisional titles unless the information provided relates specifically to the new strategic business unit structure.

Policies for managing adverse events

2.1.4 NSS advised that staff within all of its strategic business units record, investigate and manage all clinical events where there is a potential or actual, direct or indirect
consequence for the health of individual patients, or for population health. NSS also supports territorial NHS boards in the investigation and management of their own clinical adverse events.

2.1.5 NSS advised that due to the different roles of each strategic business unit and the requirements of regulatory authorities, it does not currently have a common definition for a significant adverse event. Each division has its own reporting and management arrangements. However, NSS advised that all adverse events are assessed and classified as red, amber or green, or high, medium, or low severity. The majority of red/high severity incidents are recorded by SNBTS (now the blood, tissues and cells strategic business unit). NSS advised that many of these are classified as red/high severity due to the requirements of European and UK law. SNBTS is subject to the requirements of EU Blood and Tissues and Cells Directives, ATMP Regulations, European Pharmaceutical Manufacturing and Distribution Regulations, BSQR, the Human Tissues Act, HFE Act and Consumer Protection Act.

2.1.6 NSS provided a copy of the SNBTS standard operating procedure, NATS QAD 038 10, ‘The Reporting of Quality Related Incidents’, effective 4 June 2012. It is hereafter referred to as the SNBTS procedure. NSS also provided a copy of SNBTS’s NATP QUAL 05 004 05, ‘The SNBTS policy for reporting and management of quality related incidents’ (version 5, dated 24 April 2013) hereafter referred to as the SNBTS policy.

2.1.7 NSS advised that other divisions have very low numbers of serious incidents. All nine incidents logged in the 18 months to September 2012 were recorded by SNBTS and it was noted that only one other division had reported a red/high severity incident in the previous five years. When NSS provided updated information in advance of our visit, only one of the 10 significant adverse events which occurred in the 18 months to 31 March 2013 was recorded by a division other than SNBTS.

2.1.8 NISG (now part of the information technology strategic business unit) supports clinical process and efficiency improvements across NHSScotland. NSS provided a copy of the National Information Services Group Clinical and Information Governance Incident Management Process (version 1.0 dated 19 December 2012). It is hereafter referred to as the NISG policy.

2.1.9 NSS noted that clinical governance responsibility for adverse events occurring in national services remains with the service or programme and the host NHS board, not with NSD (now part of the procurement, commissioning and facilities strategic business unit). NSD’s role is described in the National Services Division Adverse Incidents for National Services Policy dated June 2010, hereafter referred to as the NSD policy.

Adverse event definitions

2.1.10 SNBTS staff record “quality incidents” on the electronic QPulse system. SNBTS defines a quality incident as “an event which is a deviation from the normal expectation of a particular part of the SNBTS operations.” Such incidents are scored as red, amber or green based on a combination of their severity and likelihood of recurrence.

2.1.11 SNBTS is required by European and UK law to use the MHRA’s definition of a serious adverse event:

“A serious adverse event (SAE) is defined by UK Blood Safety and Quality Regulations 2005 (BSQR) as ‘Any untoward occurrence associated with the
collection, testing, processing, storage and distribution, of blood or blood components that might lead to death or life-threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity.”

2.1.12 SNBTS is similarly required to use the MHRA’s definition of an adverse reaction:

“A serious adverse reaction (SAR) is defined by BSQR as ‘An unintended response in a donor or in a patient that is associated with the collection, or transfusion of blood or blood component that is fatal, life-threatening, disabling or incapacitating, or which results in or prolongs hospitalisation or morbidity’.”

2.1.13 NSS advised that, although there are also specific HTA and HFEA definitions relating to specific tissues:

“not all incidents meeting these Regulatory Authority definitions would be classified as ‘Red’ and so these SAEs and SARs do not equate to ‘significant adverse events’. In addition failure to adhere to GMP [good manufacturing practice] guidelines may also be reportable to MHRA, and the incident may or may not have a red score, but these types of incidents are not classified as clinical incidents.”

2.1.14 As noted above, the regulations governing the interface between these organisations are outside the scope of this review.

2.1.15 The NISG policy defines an eHealth clinical incident as “an unintended or unexpected incident that could have or did lead to harm for one or more patients receiving NHS care in which eHealth was a factor.”

2.1.16 The NSD policy requires all nationally commissioned services and programmes to notify NSD of significant adverse events, “defined as a matter that has been reported within the host NHS board clinical governance arrangements.”

2.1.17 NSS has identified the top three themes for significant adverse events as:

- equipment related issues
- blood testing/mismatch issues, and
- administration.

Governance arrangements

2.1.18 NSS advised that clinical governance within NSS is overseen by the clinical governance committee, which is a subcommittee of NSS’s Board. The accountable officer for clinical governance and risk management is the chief executive, in partnership with the medical director and nursing director. The clinical governance committee receives quarterly reports on the quality assurance of services, and reports relevant issues to the Board through its minutes. Clinical risks, complaints and incidents are part of the regular reporting templates which strategic business units submit to the clinical governance committee through the clinical leadership forum.
2.1.19 NSS noted that the clinical governance committee reviews both immediate actions and recurring themes in adverse events. Senior staff stressed the value of including both internal NSS incidents occurring in services directly provided by NSS, and incidents where NSS has a role to support NHS boards in reports to this committee.

2.1.20 NSS also advised that a number of divisions had clinical governance committees which reported to their divisional senior management group, chaired by the divisional director, and to the clinical leadership forum. Following restructuring in April 2013, blood, tissues and cells, and public health and intelligence have their own clinical governance committees.

2.1.21 NSS considered that it was not appropriate for those strategic business units with very few recorded incidents to have their own clinical governance committee. When incidents occur in these strategic business units, the senior management team of that strategic business unit works directly with NSS’s clinical governance and quality team to manage the incident and identify any lessons to be learned.

2.1.22 NSS further advised that operational escalation is through directors of the strategic business units to the chief executive officer, medical director and executive management team. All red corporate risks are health impact assessed before being discussed at the executive management team meeting as part of the routine monitoring of risk.

2.1.23 Figure 1 on page 14 outlines the current governance arrangements in place for the management of adverse events across NSS.

2.1.24 The SNBTS procedure states that a national report of all incidents more than three months old should be prepared and issued monthly. It states that most incidents will be discussed at a local review forum, although green incidents may be closed without the need for discussion, at the discretion of the local quality assurance manager or their deputy. Red and amber incidents may also be discussed at national review forums, depending on their severity, or at other national meetings, if considered necessary. The SNBTS procedure also states that red incidents will be reported to the clinical governance committee and the Board as part of regular quality management system meetings.

2.1.25 The SNBTS policy states that case review normally includes discussion at an appropriate management forum. It notes that there is an overall national incident management forum chaired by the head of quality and regulatory compliance or their depute. The SNBTS policy also states that the functions of the national incident management forum are to:

- “Oversee the development and maintenance of the SNBTS incident report system.
- Review the investigation of all category red incidents.
- Initiate investigations of common, recurring incidents.
- Provide reports for SNBTS Senior Management Team and Clinical Governance Committee.”

2.1.26 Following our review, NSS advised that the audit and incident review forum reports to the clinical governance and safety committee, which provides reports to the senior management team, NSS clinical forum and NSS clinical governance committee.
Figure 1: NHS National Services Scotland clinical governance structure

NSS CLINICAL GOVERNANCE

NSS Board

Chaired by Professor Elizabeth Ireland (Non Executive Director)

NSS Clinical Governance Committee

Chaired by Professor Elizabeth Ireland (Non Executive Director)

NSS Clinical Leadership Forum (CLF)

Chaired by Professor Marion Bain (NSS Medical Director)

Quarterly Report on Clinical Incidents, Risks and Complaints

Prepared by Anne Leigh-Brown Head of Clinical Governance and Quality Improvement

Divisional (now SBU*) Reports

Reports are signed off by Divisional/SBU Clinical Governance Committee or Senior Management Team

NSS Clinical Support Group (Sub-Group of CLF)

Chaired by Professor Marion Bain (Medical Director)

* Strategic Business Unit
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 During our review visit, NSS emphasised the importance of good stakeholder relationships. SNBTS noted that around 85% of blood donors in Scotland are repeat donors. Blood donors have their own organisation, the Scottish Blood Donor Association, which has SNBTS representation on both its national and regional organisations. Donor engagement was seen as crucial for service sustainability. Other strategic business units also engage with stakeholders through a range of forums such as rare disease reference groups and commodity advisory panels.

3.1.2 However, we did not see evidence of guidance being provided to staff on how to involve donors, patients, their families and carers in adverse incident management and investigation. Neither the SNBTS procedure nor the SNBTS policy include guidance on involving donors, patients, or the families of those affected by an incident. The NSD policy and NISG policy also do not contain such guidance. The NSD policy relates to national services and should be used alongside NHS boards’ own adverse incident reporting procedures. NSS advised during our review visit that it saw its role in such situations as supporting NHS boards to improve services, rather than to investigate the incident.

3.1.3 NSS advised:

“NISG do not directly engage with patients, family or carers – where indicated, this would be undertaken by the Board providing the direct service to the patient. For example, if incorrect data in an IT system led to the management of a patient being inappropriate then the person responsible for care such as the GP would engage with the patient/family/carer.”

3.1.4 The review team was given examples of donor incidents such as faints, bruising, and occasionally nerve damage. These occurrences would be recorded as incidents and donor staff will support the donor at the time the incident occurs, or apologise if the incident is brought to their attention later as a complaint. SNBTS staff refer the donor to their GP or a specialist if further clinical care is required.

3.1.5 Occasionally, donors screen positive for disease. Donors with infectious diseases are contacted by phone and asked to attend a donation centre, where they have a consultation with an SNBTS doctor before being referred on to their GP or a specialist.

3.1.6 SNBTS staff noted that most serious incidents in which there was the potential for harm to have been caused to a patient were, in most instances, the responsibility of the NHS board whose staff were caring for that patient. Most incidents recorded by SNBTS are identified by their quality assurance processes and do not result in any harm to patients. Three of the four cases we reviewed did not result in harm occurring to a patient as the incidents were identified during donation testing.
3.1.7 The fourth case was investigated to rule out a potential serious adverse reaction for which SNBTS would have had responsibility. Staff involved in the incident advised that no contact was made with the patient or their family to advise them that an incident had potentially taken place. There were also no documented plans to contact the patient with the outcome of the investigation if the suspected serious adverse reaction was shown to have occurred. SNBTS advised that the incident was reported to MHRA as required by law and an investigation was carried out by SNBTS, including screening the donors whose blood had been transfused to the patient. Following the investigation, it was determined that the suspected serious adverse reaction had not occurred.

3.1.8 The review team considered that NSS should work in partnership with relevant clinical teams from the territorial NHS board when reviewing any incident in which it is believed that harm may have been caused to a patient. This would help to ensure that the most appropriate management of the incident was in place, would support local ‘Being Open’ policies, and would support national sharing of learning from adverse events.

**Staff involvement**

3.1.9 The SNBTS policy notes that all staff are expected to report quality-related incidents when these occur. The SNBTS procedure advises that the report should be made by the person who first observes the incident, or their immediate supervisor. Follow-up is generally co-ordinated locally.

3.1.10 The SNBTS procedures state:

“It is important to note that the purpose of incident reporting is to help SNBTS improve quality and reduce risks to patients. The purpose is not to lead to the disciplining of staff who make genuine errors. However, deliberate failure to report incidents could lead to disciplinary action being taken.”

3.1.11 Neither the SNBTS procedure nor the SNBTS policy include any guidance on involving staff in investigations, or providing support to those involved in an incident. Of the four SNBTS cases we reviewed, three noted that interviews had taken place with staff directly involved in the incident. Although no record of these discussions was provided, case records included points made during these discussions.

3.1.12 Paperwork for one of these three incident investigations included a formal root cause analysis which took place around three and a half months after the incident occurred. This highlighted:

“A formal investigation with the staff involved in this incident was commissioned by senior blood collection staff with the support of HR. It is apparent that this incident was not discussed with staff involved until the formal investigation was organised. This delay may have had an impact on the recollection of events by staff involved.”

The root cause analysis recorded issues highlighted by staff in the team in which the incident occurred. Following the root cause analysis, a workshop was held to discuss this topic with relevant staff and to attempt to determine further root causes of the incident.

3.1.13 Paperwork for another of the cases we reviewed included a presentation which had been used to help staff understand the potential consequences of not following standard operating procedures, which had been identified as the root cause of that incident.
3.1.14 No evidence was provided to demonstrate a standardised approach to involving staff directly involved in an adverse incident in its investigation. Interviews had taken place in three of the four cases we reviewed, but no record of these was stored electronically with case investigations. SNBTS advised that this would be due to the sensitive nature of such documents, since documents stored on QPulse are fully visible to all staff with access to the system. Sensitive documents are instead stored in hard copy in paper files retained by the quality assurance department. However, copies of any such interview documentation were not provided to the review team.

3.1.15 Staff directly involved in the four incidents we reviewed were not available to discuss these cases on the day of our review. Donor centre staff whom we spoke with as part of our review had confidence in the incident review process. Those with access to QPulse knew how to report incidents when these occurred, and were able to access the system both for incident reporting and to see progress against actions.

3.1.16 Donor carers were not trained on how to use QPulse and did not have access to the system. Donor centre staff advised us that donor carers report incidents by passing completed paper forms to their line managers, who then enter details of the incident on QPulse. This differed from the procedure described in the SNBTS procedure in which staff reporting incidents on paper forms should send these to the quality assurance department so they can be entered on the system. Those members of staff we spoke with advised that they received feedback from their managers when incidents they reported were closed, although they sometimes had to request this rather than receiving it automatically.

3.1.17 Donor centre staff advised that they had seen improvements following adverse events as standard operating procedures had been changed through the change control procedure. They felt that suggestions they made were heard and also reported that they were supported by their line managers, with access to occupational health and counselling if required. SNBTS also advised that staff had access to additional training if this was required.

**Recommendations**

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

1. implement a formal process to consistently engage and support relevant staff, with evidence to demonstrate their involvement in communications, investigations and action plans
2. consistently document issues raised by staff following an adverse incident, and
3. provide guidance to staff on how to consider involving donors, patients and their families or carers in the adverse event review process if they are directly affected by an adverse event within one of NSS’s strategic business units.
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 SNBTS policy and the NISG policy both note that all staff are responsible for reporting incidents. SNBTS staff we spoke with during our review advised that they had received training on how to report incidents and were familiar with reporting arrangements.

3.2.2 The SNBTS procedure states:

“As soon as an incident is detected, it must be recorded appropriately. This initial report will be made using the wizard in QPulse 5 for those with access to QPulse and who have been trained appropriately. For those without access to QPulse, the initial details will be recorded on Section 1 of the incident report form (NATF 119).”

3.2.3 The SNBTS procedure includes a description of the process to be followed by staff when making the initial report using the wizard in QPulse 5, including how to access the wizard. It also refers staff to the standard operating procedure for using the wizard, which is available as a separate document.

3.2.4 The SNBTS procedure also describes the process to be followed when reporting using the paper incident form, which should be forwarded to quality assurance staff to be entered on QPulse. This form does not include references to other documents. It was not clear from the paperwork provided for our review how the four cases we reviewed had initially been recorded. NSS advised that most staff had access to QPulse. However, as noted in Section 3.1 on Engaging with Stakeholders, donor carers do not have access to QPulse and advised that they record incidents on paper forms, which are entered by their line managers.

3.2.5 The SNBTS procedure notes:

“Follow-up will generally be co-ordinated locally. This will normally be managed by the relevant local manager. However, incident management may involve a wide range of inputs, including relevant Directors and relevant Incident Review forums as specified in the SNBTS Policy for incident management and in this SOP.

“The decision on whether there is satisfactory documented evidence for incident closure will be taken by the relevant local quality manager. The incident report file will be held by the Quality Directorate until it is archived in an approved manner.”

3.2.6 The standard operating procedure for using the wizard includes references to other SNBTS documents. However, it does not refer to the SNBTS guideline document SNGD 002, ‘Methodology for Use of Root Cause Analysis in SNBTS’. Quality assurance staff reported that they had received training in root cause analysis and supported local staff where necessary. However, it was not clear from the cases we reviewed how fully these methods were used to support local investigations.
3.2.7 SNBTS’ policies and procedures require formal root cause analysis to be carried out for all category red and selected recurring category amber incidents. We reviewed three category red incidents and one category amber incident. The methodology document suggested that red incidents should have root cause analysis carried out in a meeting consisting of at least three people. However, there was variation in the root cause analysis documentation which was available for these cases.

3.2.8 One red incident recorded a root cause which stated that the incident was not the serious adverse reaction initially suspected. Staff who carried out the investigation told us that it was felt there was a low chance that a serious adverse reaction had taken place. Nevertheless, the incident was reported to Serious Adverse Blood Reactions and Events (SABRE) and investigated to rule out the possible serious adverse reaction, as required by law.

3.2.9 In another red incident, the root cause was specified as staff not following the appropriate standard operating procedure. This was included in the incident investigation report, but no evidence was available to show how this root cause had been identified. There was no evidence of whether consideration had been given to factors causing this omission. The presentation shared with staff in response to this incident emphasised the importance of following standard operating procedures and the potential consequences of not doing so, but did not appear to consider factors which may have influenced that behaviour.

3.2.10 Another similar red incident investigation took failure to follow standard operating procedures as a starting point, but identified root causes of this failure. It included full root cause documentation demonstrating discussion by a meeting of several members of staff.

3.2.11 The category amber incident which we investigated occurred around a year before our review and had a target date for root cause analysis around seven months after it occurred. Although documentation was provided showing discussion of the case in meetings, no root cause had been allocated in the documentation which we were sent. The case was later logged as closed on the system a week before our review. NSS advised that actions resulting from the investigation had been completed within the expected timeframe. The delay in closing the incident was due to a delay in producing the summary report which they advised would be filed with the incident for later ease of inspection.

**Recommendation**

To support staff knowledge and training, NSS should:

1. ensure staff involved in the management of significant adverse events have training in, and a clear understanding of, investigation methods such as root cause analysis, and apply them to adverse event reviews and action planning.
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 SNBTS procedure sets out staff responsibilities and accountability when an incident is identified. It specifies that incidents should initially be reported by the first person to identify them, or their immediate supervisor. The procedure explains that incidents are followed up locally and managed by the relevant local manager. The decision on whether there is satisfactory documented evidence for incident closure is taken by the relevant local quality manager. The incident report file is held by the quality directorate until it is archived.

3.3.2 The SNBTS policy states that incident reports must be initiated and passed to quality assurance within one working day of the incident being detected. Quality assurance must record each incident and score for risk within three days of receiving the report form. Management and incident follow-up depends on the risk level assigned at that stage.

3.3.3 If the wizard is used to enter information on the QPulse system, the system automatically emails notification to the relevant manager and local quality staff. If the individual reporting the incident does not have access to QPulse, they must use a paper form instead. The SNBTS procedure states that this form:  

“should be photocopied to relevant personnel judged to need to know of the incident”.

3.3.4 It suggests this may include:

- relevant director(s)
- relevant local manager(s)
- relevant Head(s) of Department, and
- any other relevant personnel.

3.3.5 Incidents reported on a paper form are registered on QPulse by quality assurance staff. For all incidents, quality assurance are responsible for:

- scoring the incident
- escalating red incidents to the quality director or their deputy on the day of scoring
- reporting incidents relating to defective goods or services, and initiating component or product recall, using relevant standard operating procedures
- deciding whether an incident requires to be reported to SABRE, Serious Hazards of Transfusion (SHOT), the HTA or HFEA using the relevant standard operating procedures, and
identifying the elements to be included in incident investigations for laboratory assays and clinical examinations.

3.3.6 Quality assurance staff we spoke with during our review highlighted that they are also responsible for producing a summary report on the incident before it is closed.

3.3.7 The SNBTS procedure lists the actions required for all incidents. It notes that incident follow-up is carried out by the relevant senior manager within the area in which the incident occurred, or their deputy. Follow-up may be documented either using an electronic template or using Section 2 of the incident reporting form.

3.3.8 It was not clear in three of the four cases we reviewed if follow-up had been recorded in this way, although it was described in the corrective actions field of each case. In the fourth case, a copy of the NATF 300 01 form was provided. This had been completed on paper by quality assurance staff following the incident review. All actions were dated as complete on the same date, nearly eight months after the incident occurred.

3.3.9 The SNBTS procedure states that the manager is expected to return details of their investigation to the quality assurance department, either on paper or electronically using QPulse. It notes:

“In general, all incidents will be discussed at a review forum, but simple green incidents may be closed without need for discussion, at discretion of local QA Manager (or deputy).”

3.3.10 The local quality assurance manager, local or national review forum may also specify that further review is required, such as referral to other parts of the organisation or the relevant national manager.

3.3.11 The line manager is responsible for informing the person who reported the incident that it has been closed on QPulse, and providing feedback to staff members without QPulse access.

3.3.12 We reviewed one category amber incident which had been downgraded from its initial categorisation of category red, and three category red incidents. NSS provided minutes showing that a series of meetings had taken place to discuss the category amber incident and a meeting had taken place to discuss one of the three category red incidents. One of the other category red incidents included a list of actions agreed by the national review forum in January 2012. NSS provided minutes showing that these category red incidents had been discussed by the national review forum, and the delayed closure of the category amber incident had also been considered. No evidence of discussion of the other category red incident was provided.

**Recommendation**

To ensure clear functions and roles, NSS should:

5 continue to document evidence of adverse events being discussed and shared at appropriate meetings, supported by meeting minutes.
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 Information governance incidents across NSS are recorded, investigated and managed using an online reporting tool.

3.4.2 NSS advised that arrangements in strategic business units recording small numbers of clinical adverse events were similar. Incidents are recorded as required on the NSS standard incident reporting template and stored on the NSS corporate filing system.

3.4.3 NISG reported plans to begin using Microsoft Sharepoint to improve integration of information and provide an overview of incident status.

3.4.4 Due to regulatory requirements related to the manufacture of blood products, SNBTS requires a quality management system, and the blood, tissues and cells strategic business unit uses QPulse. NSS advised that QPulse is an electronic quality management system which includes an incident management module and is designed to meet the legal and other requirements of interested parties including the MHRA and HTA.

3.4.5 At the time of our visit, NSS was considering how to achieve greater consistency in incident management across the whole organisation while retaining QPulse in order to meet regulatory requirements.

3.4.6 Most documentation relating to incidents in SNBTS is uploaded to the incident record in QPulse. Sensitive documents such as interviews relating to staff performance are not uploaded. This information is instead retained in a paper incident file by the quality assurance team. Quality assurance staff advised that in these circumstances they would make a note on the incident in QPulse that this documentation was available, providing an audit trail for the incident.

3.4.7 Staff with access to QPulse are able to view incidents and attached documentation across all areas of SNBTS. Quality assurance staff receive email notification when incidents are recorded, and incident and action owners receive email notification of actions, with reminders for approaching deadlines. NSS reported that staff without access to QPulse should be provided with feedback on incident progress by their line managers.

3.4.8 An analysis module built into QPulse allows quality assurance staff to generate reports and analyse trends. Each of the five blood transfusion centres generates monthly reports, and SNBTS also generates national reports on closure rates and fault categories. At the time of our review, SNBTS was considering introducing more regular reporting to better track issues and analyse trends, in response to feedback received from MHRA.

3.4.9 Staff outwith quality assurance are unable to run reports, but can carry out keyword searches of the incidents held within QPulse across all five centres. Incident numbers start with a three letter code which indicates the centre where the incident was identified.
3.4.10 We reviewed four cases, including documents stored in QPulse under these records. Two of these cases had supporting documentation stored on QPulse which referred to staff interviews. These interviews were not available on QPulse due to their sensitivity. However, none of these cases noted in the QPulse records that staff interview documentation was available in hard copy. No interview documentation was provided to the review team when requested.

3.4.11 QPulse includes the facility to list separately numbered actions with their own target and completion date, which can be assigned to different action owners. One of the four cases we reviewed used this functionality. The other three cases did not and the owners of these cases did not close off the list of completed actions until all actions had been completed or transferred across to the change management process. This could potentially be confusing to anyone wishing to determine what progress had been made in responding to these incidents.

3.4.12 The SNBTS procedure provides staff with the following guidance on incident closure:

“The principal criterion for closure of an incident is that all corrective actions have been completed. In addition, preventive actions which are readily implemented will also have been completed. However, in some instances, significant projects will be necessary to complete planned preventive actions. Where this is the case, it is possible to close incidents, provided the necessary actions have been identified in another part of the QMS [quality management system] (eg by initiation of change control), or documented in a suitable SNBTS management process (eg Business Plan).”

3.4.13 SNBTS aims to close incidents within 42 days. Quality assurance staff whom we spoke with during our review advised that the relevant change management system or business plan would be referenced on QPulse if an incident was closed with outstanding, longer term preventive actions still outstanding.

3.4.14 Of the four cases we reviewed, one QPulse record made reference to work under way as part of the ‘Transforming the Donor Experience’ project. Another case referred to this project in associated documentation, but not in the incident record. A third case made reference to the change management process. A change reference number for this change was recorded on the incident record in QPulse.

Recommendations

To support its information management processes, NSS should:

6 introduce a process to ensure SNBTS staff make full use of QPulse’s functionality to allow separate allocation and tracking of actions

7 ensure consistent document control and cross-referencing of information in QPulse on SNBTS adverse events when additional documents are held in paper files, or actions progress to the change management process, and

8 as far as possible, ensure there is an integrated approach to documentation management across all strategic business units.
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 SNBTS defines an incident as: “An event which is a deviation from the normal expectation of a particular part of the SNBTS operations”. To meet regulatory requirements, SNBTS also requires staff to report incidents specified by the MHRA.

3.5.2 SNBTS has two parallel routes for reporting incidents. Most members of staff have access to QPulse and are able to enter incidents into the system using a wizard, which guides the user through the process.

3.5.3 Donor carers do not have access to QPulse. A separate, paper-based procedure exists to allow staff without access to QPulse to record incidents using a form which they send to the quality assurance department to allow the relevant information to be entered on QPulse. However, when we spoke with some of these staff as part of our review, they advised that they would normally forward their paper form to their line manager, who would record the incident on QPulse on their behalf.

3.5.4 The SNBTS procedure notes that a local manager, “likely to be the relevant Senior manager within [the] area or Deputy” is responsible for incident follow-up. Follow-up may be documented electronically or using Section two of the incident reporting form. The extent of the review depends on the type of incident and its severity.

3.5.5 Regardless of severity, the SNBTS procedure states that the local manager is expected to:

- “Provide detail of any relevant information which has come to light during the local investigation.
- Summarise any remedial action taken in response to the incident and to prevent a recurrence of the incident.
- Provide details of any review meetings held to discuss the incident.
- Identify root cause(s) of the incident. (Note: A formal meeting must be convened for all category red incidents during which root cause will be assigned. For complex incidents, this will involve formal root cause analysis).
- Propose any further action necessary to prevent a recurrence, and which will take time to introduce, or which requires resources or inputs from other Departments or Directorate.
- Provide relevant supporting information on the incident or on the corrective or preventive action taken.”

3.5.6 The SNBTS policy states that, for category red incidents:

- “Local follow-up must be initiated within 24 hours.
• A formal review meeting must be held within 1 month. This review meeting will ensure that an action plan is initiated and that a formal meeting to examine root cause is scheduled.

• All category red incidents must be reviewed for the effectiveness of remedial action. This will involve a quality audit where appropriate, and review by the National Review Forum.

• All category red incidents will be reported to the SNBTS Management Team.”

3.5.7 The SNBTS procedure contains a table of actions to be carried out for all category amber incidents. The SNBTS policy includes two of these points:

• the local manager should initiate the review, including considering root cause assessment, and

• the incident is discussed at a local review forum, possibly with further root cause analysis carried out, and at the National Review Forum, if necessary.

3.5.8 The ‘Methodology for use of root cause analysis in SNBTS’ document states:

“It is SNBTS policy that an assessment of root cause should be undertaken for all Category Amber incidents… the root cause will be identified by the judicious use of RCA analysis principles and will be recorded in the incident review documentation.”

3.5.9 The amber incident we reviewed was still open at the time we received incident documentation, 11 months after it occurred. A root cause had not yet been allocated.

3.5.10 Responsibility for root cause analysis of incidents in SNBTS appeared to be somewhat unclear. The senior manager in the local area where the incident occurs is responsible for investigation and follow-up of the incident. However, SNBTS reported that senior quality assurance department staff have training and expertise in root cause analysis, not local managers.

3.5.11 Evidence of formal root cause analysis was provided for one of the category red cases we reviewed. The root cause analysis was carried out around three and a half months after the incident occurred, in a meeting which was recorded by a member of quality assurance staff.

3.5.12 Quality assurance staff advised that no root cause analysis took place for the category amber case which we reviewed because staff followed a standard operating procedure specific to that type of incident, which described how all potential points of failure should be considered.

Escalation of events

3.5.13 When an SNBTS incident is entered on QPulse, the system generates an automatic email notification to the relevant manager and local quality staff, recording:

• details of the incident
• immediate action taken
• source centre
• key dates, and
• incident owner.

3.5.14 If paper incident report forms are completed, the SNBTS procedure states that Section one of the incident reporting form: “should be photocopied to relevant personnel judged to need to know of the incident” which it suggests may include:

• relevant director(s)
• relevant local manager(s)
• relevant head(s) of department, and
• any other relevant personnel.

3.5.15 The SNBTS procedure advises that the original form should be forwarded to quality assurance staff in order to be entered on QPulse.

3.5.16 We were unable to determine if the cases we reviewed had initially been recorded on paper forms or using QPulse. SNBTS staff advised that the vast majority of incidents were recorded on QPulse. Staff we spoke with during our review advised that donor centre staff without access to QPulse usually forwarded their paper forms to their line managers for entry on QPulse.

3.5.17 The SNBTS procedure describes how quality staff will:

• score the incident for severity and recurrence, resulting in a classification level of red, amber or green
• escalate red incidents to the quality director or their deputy on the day of scoring
• report incidents relating to defective goods or services, and initiate component or product recall using relevant standard operating procedures
• decide whether an incident requires to be reported to SABRE, SHOT, HTA or HFEA, and
• identify the elements to be included in incident investigations for laboratory assays and clinical examinations.

3.5.18 The SNBTS procedure notes that the quality director or their deputy is responsible for notifying category red incidents to the national director, NISD (SNBTS national information services directorate), and relevant senior managers. Immediate actions are agreed by the quality director following discussion with the senior manager responsible for incident investigation and follow-up.

3.5.19 The SNBTS procedure also states:

“In general, all incidents will be discussed at a review forum, but simple green incidents may be closed without need for discussion, at discretion of local QA Manager (or deputy).”

3.5.20 The SNBTS procedure notes that the quality assurance manager is involved in discussion of category amber incidents at the local review forum.

3.5.21 As noted in Section 3.3 above on Roles and Responsibilities, minutes of discussions were provided for two of the four incidents we reviewed. A third case included action points resulting from discussion of the case at the national review forum. There was no
evidence of discussion of the fourth incident taking place, but that incident was shown by laboratory investigation not to be the serious adverse reaction which had initially been suspected.

3.5.22 Once follow-up is complete, the local manager who carried out the review is expected to return details of their investigation to the quality assurance department, either in hard copy or using QPulse. The local quality assurance manager, and the local or national review forum, may specify that further review is required.

3.5.23 Once all actions have been completed by the local manager and information has been returned to quality assurance, quality assurance is responsible for closing the incident. The quality manager or their deputy decides whether further action is required, which may involve:

- “Requesting further information from any relevant personnel.
- Organising a wrap up meeting with relevant personnel to discuss the follow-up to amber or red incidents.
- Receiving feedback from relevant review forum.”

3.5.24 The SNBTS procedure states that the quality manager or their deputy should complete form NATF 300 when they are satisfied that the follow-up investigations are complete. The quality manager then closes the incident on QPulse. It also states that this form should be used to record incident progress. Paperwork provided for one of the cases we reviewed included this form. Each item had been completed on the same date, almost eight months after the incident occurred.

3.5.25 The NISG policy includes a clinical risk assessment matrix and descriptions similar to those used in grading severity and occurrence in the SNBTS policy, which results in incidents being classified as high, medium or low severity. This clinical risk assessment matrix is the same as the matrix included in the NSS integrated risk management approach (version 1.2, October 2011) which describes how risk should be assessed across the whole organisation.

3.5.26 The NISG policy also includes a template on which NISG clinical/information governance, service clinical governance and system suppliers’ assessments of risk can be recorded and calculated, along with the resulting joint risk score. This template form includes space for up to three dated assessments by each of these groups, and includes justifying reasons for the scoring. A separate table is used to calculate and record the joint risk score, produced by combining the scores assigned by each of these groups.

3.5.27 The NSD policy does not include a risk classification or recurrence score. However, it describes how the local service should ensure NSD is notified of adverse incidents affecting national services, in addition to local reporting and investigation arrangements. The level of information to be provided to NSD by the local service is based on the severity of the incident, classified as having either:

- minimal impact, no significant service disruption, easily resolved locally
- significant or major impact on patients and the service, or
- major problem/discrepancy.
3.5.28 The NISG policy describes how NISG responds to incidents. It notes that reporting to the relevant IT service governance groups should occur as required. It states that the incident review team should be in weekly dialogue with senior managers. High level monthly reports are provided to the senior management team and any concerns are also raised monthly. The incident review team formally review all incidents every three months, alongside reporting to the NSS clinical governance committee.

3.5.29 As noted previously, NSS reported that staff within all of its strategic business units record, investigate and manage all clinical events where there is a potential or actual, direct or indirect consequence for the health of individual patients, or for population health. NSS also supports territorial NHS boards in the investigation and management of their own clinical adverse events. However, NSS provided limited information about how other strategic business units manage or escalate incidents. All strategic business units are expected to report their incidents to the NSS clinical governance committee, through the clinical leadership forum, every three months.

Recommendations

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

9 ensure a comprehensive approach to adverse event management – including definitions, recording and support for investigation – is applied across NSS, including, when applicable, working with other NHS boards

10 as far as possible, implement a standard approach for recording investigations, including checklists and templates, to support staff and ensure consistency across NSS, and

11 ensure the decision-making and escalation processes, and the level of root cause analysis investigation applied, are consistently documented, to support a transparent and open process.

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 Within SNBTS, the quality assurance department is responsible for closing incidents within the target 42 days and aim to achieve this in 75% of incidents. Unless an extension is agreed with quality assurance in advance, all incidents should be closed within three months. The SNBTS procedure does not specify who is responsible for requesting an extension, or the process for doing so. SNBTS also has a duty to report certain incidents to regulators within 24 hours of their occurrence.

3.6.2 We reviewed four cases, which included five QPulse incident records. These were all closed later than the 42-day target. Only one of the five incident records was closed within three months; it was linked to another incident record which was not closed within this timescale. Case closure took between three months nine days to just under one year. Only one case recorded an extension agreement.
3.6.3 NSS advised that the commissioning manager who initiated the incident report was responsible for ensuring actions were completed on time. The SNBTS quality assurance department used QPulse to produce monthly reports on incidents which had not been closed on time. Quality assurance staff advised that they would normally raise overdue incidents at their local monthly quality meetings at which they discuss incidents. NSS’s Head of Clinical Governance and Quality Improvement would also follow-up on any incidents which were significantly overdue.

**Action planning**

3.6.4 SNBTS staff advised us that the MHRA has suggested that ideally all incidents should be closed within 30 days rather than the current target of closing 75% of incidents within 42 days and the remainder within three months. The review team was conscious of the challenges associated with carrying out thorough incident investigations using root cause analysis to identify learning and actions for improvement within this timescale. However, we felt that NSS should continue to monitor and improve compliance with incident closure timescales to ensure learning is shared in a timely manner.

3.6.5 SNBTS staff described how the QPulse system sends reminder emails to action owners shortly before the target date for closing each action. Quality assurance staff are also able to run reports to identify cases which have not been completed on time. We felt that these were strengths of the system. However, as described above, actions were not consistently closed by their target dates. In addition, only one of the four cases reviewed appeared to make use of the system’s capacity to record actions in separate numbered fields, assigning different owners, target and completion dates. This could potentially limit the usefulness of sending automated reminder emails to action owners.

3.6.6 We saw evidence that one of the four cases we reviewed, which included actions which could not be completed as part of the incident investigation, was escalated to the change management system. The change reference number was stated on QPulse and this change was discussed by the change management committee the day after the incident was closed. Changes were subsequently made to the standard operating procedure to address one of the causes of the incident. We considered the ability to track outstanding actions resulting from incident investigations after these investigations were complete to be another strength.

**Sharing of learning**

3.6.7 The SNBTS procedure recognises the importance of learning from adverse incidents. It states:

“The reporting of incidents has several benefits. Firstly, to prevent defective components or product from being issued and placing patients at risk. Secondly, to ensure that faults in clinical test methods are identified and corrected. Thirdly, through the identification of a root cause, to permit remedial action to be taken to prevent a repetition of the incident. Fourthly, to provide data that can be used as a basis for continual quality improvement.”

3.6.8 The SNBTS policy adds:

“The SNBTS will use the data available in databases to analyse for recurring incidents. This trend analysis data will be presented to relevant Management
forums where action will be taken to understand the root cause of these incidents and to initiate strategies for preventive action. Where relevant, this will involve the creation of appropriate project teams.”

3.6.9 NSS gave examples of improvements which had been made in response to category red incidents within SNBTS. These included:

- issuing a national controlled memo to remind all staff to follow correct approved procedure
- national and local procedures clarification or revision
- staff retraining, and
- implementation of additional checks.

3.6.10 SNBTS staff noted that cases are managed in the first instance by the local team. Following completion, the management team reports up to the clinical directorate management team, which allows learning to be shared across all blood banks. In parallel with this, there is a quality line of reporting which goes through functional quality management to the SNBTS national reporting group and the SNBTS clinical governance and safety group.

3.6.11 SNBTS staff advised that all category red and amber incidents are reviewed by the national review forum, which meets every two months and allows learning to be shared between centres. We spoke with donor centre staff who advised that they also participate in a best practice group which includes donor centre staff from across all Scottish regions, which they considered to be a good forum for sharing issues and challenges, and spreading good practice.

3.6.12 Information about incidents is also shared with the NSS clinical governance committee in quarterly reports, having first passed through the clinical leadership forum. We saw evidence that all four cases we reviewed had been reported to the clinical governance committee. Clinical governance committee reports do not include details of when the incident occurred or the length of time it is expected will be required to complete actions arising from the incident.

3.6.13 SNBTS staff advised that feedback is provided to incident owners when cases are closed by the quality assurance department. Incident owners are usually the line manager or senior manager of the individual who identified the incident. When the person who originally reported the incident does not have access to QPulse, this feedback is shared with them in person by their line manager.

3.6.14 Paperwork for one category red incident included a PowerPoint presentation. This had been used to discuss the incident with relevant staff. It emphasised the importance of following standard operating procedures. Following another category red incident, a workshop was held with staff to discuss possible root causes of the incident, and a further meeting was held to discuss changes to the standard operating procedure. Both of these incidents resulted in staff involved in the incident receiving retraining. The first also resulted in a national control memo being issued to staff involved in blood donation. The second case led to the standard operating procedure being changed through the SNBTS change management process.
3.6.15 The category amber incident we reviewed included discussion at a series of three teleconferences, which included managers from other centres. Quality assurance staff advised that this incident had also been discussed by the national review forum.

3.6.16 We noted that the root cause identified for the cases we reviewed did not always demonstrate that consideration had been given to possible contributory factors. As noted in Section 3.5 on Risk-based, Informed and Transparent Decision-making, making full use of root cause analysis or other appropriate methodologies could provide the NHS board with further opportunities to learn from these events.

3.6.17 The NISG policy states that incident investigations by clinical/information governance management within NISG should include a lessons learned review, conducted by clinical/information governance management, in consultation with all other parties involved in the investigation. This review is intended to identify good practice, areas for improvement and wider learning, including learning relating to the management and investigation of the incident. A “lessons learned” template is included in the NISG policy.

3.6.18 The NSD policy notes that NSD may choose to hold a meeting of all relevant NHS boards to agree consistent action across Scotland if it is felt that an incident identified in one NHS board has the potential to occur elsewhere.

**Recommendations**

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

12 continue to monitor and improve incident closure throughout NSS to ensure learning is identified and shared in a timely manner

13 ensure there is a comprehensive process for developing and monitoring actions plans and outcomes across NSS, and

14 adapt and spread procedures for identifying lessons learned from the review process, across all strategic business units, including taking into account feedback from staff.
Appendix 1 – Details of review team

The review of NHS National Services Scotland was conducted on Thursday 19 September 2013.

Review team members:

**Mark Aggleton**
Senior Programme Manager, Healthcare Improvement Scotland  
(Not present on day of review visit)

**Gordon Birnie**
Medical Director, NHS Fife

**Yvonne Bronsky**
LSAMO, South East and West of Scotland Region

**Robin Creelman**
Public Partner

**Nanisa Feilden**
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**Tammy Nicol Fenton**
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**Edel Sheridan**
Project Officer, Healthcare Improvement Scotland

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- by email
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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.