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Saving Lives:
a delivery programme to reduce Healthcare Associated Infection

NHS
National Patient Safety Agency

Patient safety alert 02



Reducing Risk
to keep patients safe in hospital

With your help
we can make
medical equipment
safe!

safe!

Theatre Team Briefing

The Royal Marsden NHS Trust
The Patient
Information, Support
and Advice
Centre



The importance
Many teams experience breakdowns by not understanding the plan (tasks) and how they fit together, roles and responsibilities, where and how others (including fellow team members) are involved.
To help reduce these risks, all team members should understand the plan (tasks) and how they fit together, roles and responsibilities, where and how others (including fellow team members) are involved.
A briefing can be shared under the heading that 'everybody begins their task'.
A briefing session should:
• Enable
• Facilitate
• Reduce
• Develop
• Clear
• Create
• Make

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Doctors, Nurses & Allied Staff—All Grades

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WARNING:
PATIENT AT
RISK OF FALLS



National Audit Office

DEPARTMENT OF HEALTH

A Safer Place for Patients:
Learning to improve patient safety

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National Audit Office

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John Bourn
Comptroller and Auditor General
National Audit Office

31 October 2005

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SUMMARY



1 Every day over one million people are treated successfully by National Health Service (NHS) acute, ambulance and mental health trusts. However, healthcare relies on a range of complex interactions of people, skills, technologies and drugs, and sometimes things do go wrong. For most countries, patient safety is now the key issue in healthcare quality and risk management. The Department of Health (the Department) estimates that one in ten patients admitted to NHS hospitals will be unintentionally harmed, a rate similar to other developed countries. Around 50 per cent of these patient safety

incidents^a could have been avoided, if only lessons from previous incidents had been learned. **Figure 1** details some of the key facts.

“Patient safety incident: any unintended or unexpected event that lead to death, disability, injury, disease or suffering for one or more patients”

“Near miss: any situation that could have resulted in an accident, injury or illness for a patient, but did not, due to chance or timely intervention by another”

1 Key facts and best estimates about the extent and impact of patient safety incidents

- An analysis of 256 (96 per cent) NHS acute, ambulance and mental health trusts’ responses to our main survey showed that in 2003-04 trusts recorded some 885,832 incidents and near misses. Our follow up survey found that for 2004-05 there were around 974,000 reported incidents and near misses. Few trusts included hospital acquired infections which may increase this by around 300,000 incidents (around 30 per cent of which may have been preventable).
- The most common incidents reported were: patient injury (due to falls), followed by medication errors, equipment related incidents, record documentation error and communication failure.
- Whilst reports of near misses have also increased, far fewer are reported than research suggests should be the case.
- Patient safety incidents cost the NHS an estimated £2 billion a year in extra bed days, in addition hospital acquired infections add a further £1 billion to these costs¹.
- The cost of settled clinical negligence claims in 2003-04 was £423 million and provisions for outstanding clinical negligence claims as at end of 2003-04 were in excess of £2 billion.
- A retrospective study of patient records in two English hospitals found 10.8 per cent of patients experienced an adverse incident; of which around half (5.2 per cent) were judged to have been preventable. These adverse incidents caused permanent impairment in six per cent and contributed to death in eight per cent of cases².
- Our analysis of trust surveys found that 169 trusts were able to provide data on the number of deaths as a result of patient safety incidents. This showed that in 2004-05 there were some 2,181 deaths recorded but it is acknowledged that there is significant under reporting of deaths and serious incidents. Other published estimates of death as a result of patient safety incidents range from 840 to 34,000 but in reality the NHS simply does not know.
- An international review of nine retrospective studies of patient records found that the average incidence of adverse events was 8.9 per cent (range from 3.8 -16.6 per cent).

Source: National Audit Office

^a Terminology developed by the National Patient Safety Agency to be used instead of the terms ‘adverse event’ or ‘clinical error’.

2 There are numerous stakeholders with a role in keeping patients safe in the NHS, many of whom require trusts to report details of patient safety incidents and near misses to them (Figure 2). However, a number of previous National Audit Office reports have highlighted concerns that the NHS has limited information on the extent and impact of clinical and non-clinical incidents and trusts need to learn from these incidents and share good practice across the NHS more effectively (Appendix 1).

3 In 2000, the Chief Medical Officer's report *An organisation with a memory*¹, identified that the key barriers to reducing the number of patient safety incidents were an organisational culture that inhibited reporting and the lack of a cohesive national system for identifying and sharing lessons learnt.

4 In response, the Department published *Building a safer NHS for patients*³ detailing plans and a timetable for promoting patient safety. The goal was to encourage improvements in reporting and learning through the development of a new mandatory national reporting scheme for patient safety incidents and near misses. Central to the plan was establishing the National Patient Safety Agency to improve patient safety by reducing the risk of harm through error. The National Patient Safety Agency was expected to: collect and analyse information; assimilate other safety-related information from a variety of existing reporting systems; learn lessons and produce solutions.

5 We therefore examined whether the NHS has been successful in improving the patient safety culture, encouraging reporting and learning from patient safety incidents. Key parts of our approach were a census of 267 NHS acute, ambulance and mental health trusts in Autumn 2004, followed by a re-survey in August 2005 and an omnibus survey of patients (Appendix 2). We also reviewed practices in other industries (Appendix 3) and international healthcare systems (Appendix 4), and the National Patient Safety Agency's progress in developing its National Reporting and Learning System (Appendix 5) and other related activities (Appendix 6).

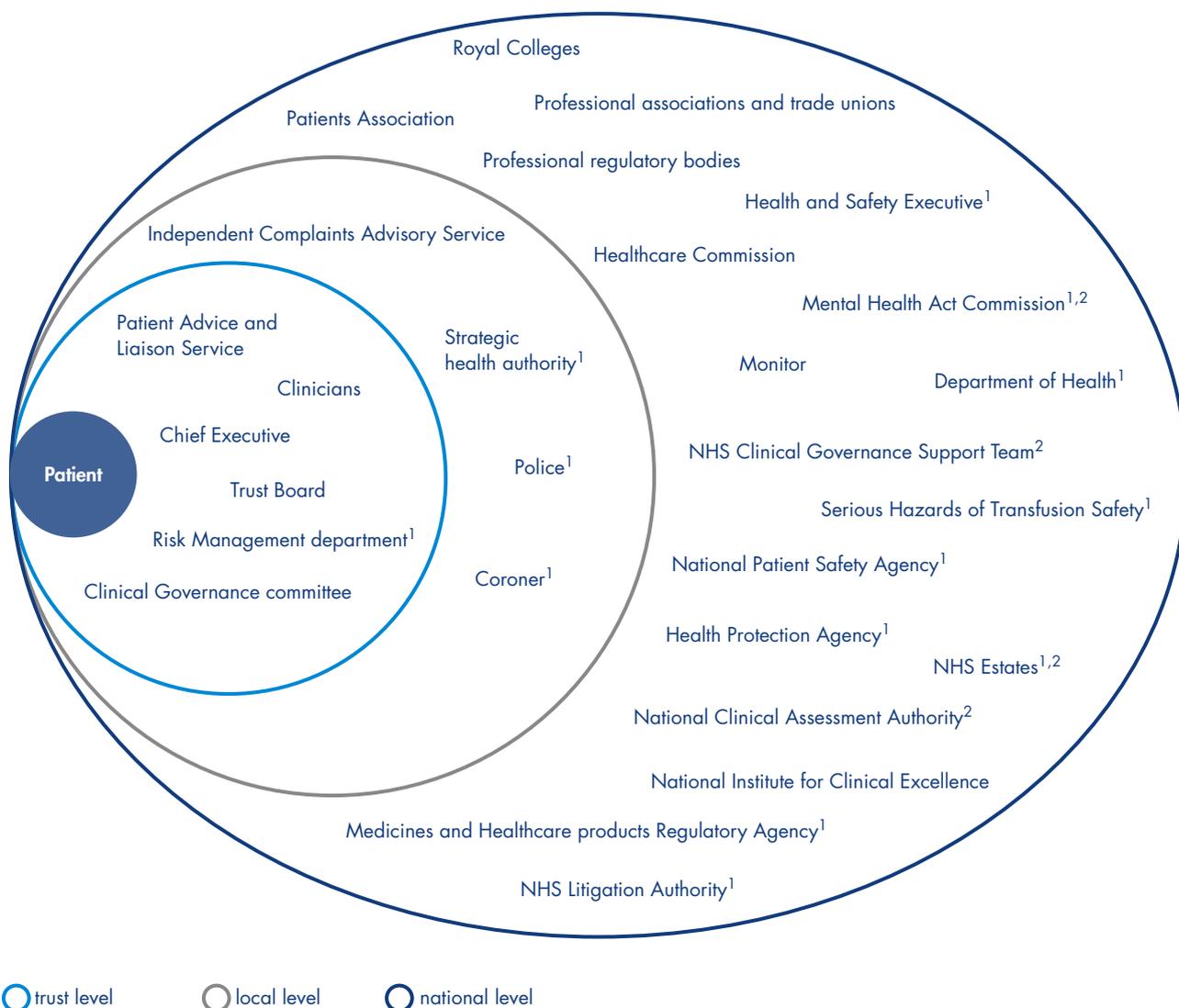
Overall conclusion

6 *An organisation with a memory*¹ was an important milestone in the NHS's patient safety agenda and marked the drive to improve reporting and learning. At the local level the vast majority of trusts have developed a predominantly open and fair reporting culture but with pockets of blame and scope to improve their strategies for sharing good practice. Indeed in our re-survey we found that local performance had continued to improve with more trusts reporting having an open and fair reporting culture, more trusts with open reporting systems and improvements in perceptions of the levels of under-reporting. At the national level, progress on developing the national reporting system for learning has been slower than set out in the Department's strategy of 2001³ and there is a need to improve evaluation and sharing of lessons and solutions by all organisations with a stake in patient safety. There is also no clear system for monitoring that lessons are learned at the local level. Specifically:

- a** The safety culture within trusts is improving, driven largely by the Department's clinical governance initiative⁴ and the development of more effective risk management systems in response to incentives under initiatives such as the NHS Litigation Authority's Clinical Negligence Scheme for Trusts (Appendix 7). However, trusts are still predominantly reactive in their response to patient safety issues and parts of some organisations still operate a blame culture.
- b** All trusts have established effective reporting systems at the local level, although under-reporting remains a problem within some groups of staff, types of incidents and near misses. The National Patient Safety Agency did not develop and roll out the National Reporting and Learning System by December 2002 as originally envisaged. All trusts were linked to the system by 31 December 2004. By August 2005, at least 35 trusts still had not submitted any data to the National Reporting and Learning System.
- c** Most trusts pointed to specific improvements derived from lessons learnt from their local incident reporting systems, but these are still not widely promulgated, either within or between trusts. The National Patient Safety Agency has provided only limited feedback to trusts of evidence-based solutions or actions derived from the national reporting system. It published its first feedback report from the Patient Safety Observatory in July 2005⁵.

2 The stakeholders in patient safety

While the patient is at the centre of the safety agenda, there are many people and a large number of organisations with a role in the management of risk of unintended harm. Several of these organisations may require a report of the same incident at the same time.



Source: National Audit Office

NOTES

- 1 Organisations to which a patient safety incident will be reported, either on a voluntary or statutory basis (see also Figure 14).
- 2 Following the Department of Health's review of Arm's Length Bodies, the functions of these organisations have been or are in the process of being, transferred to other bodies.

The culture within NHS trusts is now more open and fair

7 A just and fair culture is a key requirement if reporting and learning are to be improved. All trusts have continued to build on and develop their clinical governance arrangements, but with varying degrees of success. Most trusts have succeeded in reducing the blame culture. By helping trusts to deal more effectively with poorly performing doctors, the National Clinical Assessment Authority^b is continuing to contribute to the development of a more open and fair culture and, as a result, suspensions have increasingly been avoided. However, the support provided applies only to doctors. In 2004, the National Patient Safety Agency produced guidance aimed at supporting trusts in assessing their safety culture and promulgated a tool to prompt trusts to focus on why the patient safety incident happened, and not who was to blame, and to adopt a systematic approach to decisions about the employee involved (Appendix 6).

8 Within local organisations strong leadership and governance at chief executive and board level is crucial. Virtually all chief executives provided examples of their personal involvement with the patient safety agenda. Since 2001, over 130 trust boards or key members of trust boards have engaged with the Board Development Team at the NHS Clinical Governance Support Team. More recently non-executive trust board members from 113 trusts have undertaken Leadership in Patient Safety Training provided by the NHS Appointments Commission and the National Patient Safety Agency.

9 An organisational top down approach on its own is not sufficient. The regulatory bodies, Royal Colleges and the other professional bodies have all placed greater emphasis on individual responsibility and accountability for patient safety. Although few trusts provided incentives for staff to improve patient safety, 93 per cent involved them in identifying priorities and designing solutions.

10 As nine out of ten NHS employees work in teams⁶, effective communication between staff is important to reduce the risk of unintended harm to patients, yet trusts often cite failure in communication as a reason for an incident. Communicating openly with patients and carers is also essential but only 24 per cent of trusts were routinely informing patients when an incident that they had been involved in was reported to the trust.

^b The National Clinical Assessment Authority was established as a special health authority in 2001 to provide support and expert advice and an assessment service to NHS organisations that are faced with concerns over the performance of individual doctors and dentists (Appendix 2 details our previous work on this issue). Following the Department's Arm's Length Bodies Review, from April 2005, the National Clinical Assessment Authority became part of the National Patient Safety Agency and was renamed the National Clinical Assessment Service.

11 To provide evidence that NHS organisations were doing their reasonable best to manage themselves so as to protect patients, staff and the public against risks of all kinds, the Department established the mandatory Controls Assurance Standards in 1999. Trusts had to undertake a self-assessment against defined criteria. For the Risk Management System standard these criteria included board accountability, adverse incident reporting and complaints and claims handling. Over the five years of its operation average compliance increased from 52 per cent to 87 per cent.

12 In August 2004, the Department announced that key elements of the Controls Assurance Standards would be incorporated in a new performance assessment framework based around a set of core and developmental standards (*Standards for Better Health*), with compliance evaluated by the Healthcare Commission. Safety is the first of seven domains in these standards (Appendix 7).

13 Assessment of trusts' risk management systems undertaken on behalf of the NHS Litigation Authority has also provided a strong incentive for trusts to improve their reporting and learning systems (Appendix 7). Each year since the operation of the Clinical Negligence Scheme for Trusts many trusts have gradually improved their risk management systems and seen their contributions reduced according to the level of compliance achieved (Figure 4 page 19).

Local reporting has improved but there have been delays in establishing an effective national system

14 Unless trusts are confident that their reporting systems identify the main risks to patient safety they cannot target interventions effectively. All trusts had implemented integrated reporting systems as part of risk management. By 2005, the majority of these reporting systems were either confidential (34 per cent) or open (63 per cent) with 38 per cent of these trusts also providing an anonymous reporting route for use by staff who may be fearful of raising their concerns. Reported incidents were analysed at the local level with relevant information passed onto one or more of around 30 organisations.

15 Seventy-eight per cent of trusts told us that their emphasis on encouraging reporting was having a positive impact on the number of incidents reported and the total number of patient safety incidents reported within trusts has risen year on year. Despite the general increase in reporting, trusts acknowledged that a substantial number of incidents still go unreported (trusts on average estimated that 22 per cent of incidents go unreported, mainly medication errors and incidents leading to serious harm). Reporting of near misses was also low, mainly due to different perceptions of what constitutes a near miss. Training can help improve levels of reporting but there has been no evaluation of the efficacy of courses and no system for accrediting those currently in use.

16 Healthcare organisations in other countries, having compared the merits of anonymous and confidential reporting, have generally opted for confidential reporting. The Department proposed a confidential scheme, mandatory for trusts, to record patient safety incidents and near misses across the NHS³, however the National Patient Safety Agency recommended the development of two reporting systems, one which would interface with trusts' incident reporting systems, but with the identity of the patient and person reporting stripped out, and the second, a totally anonymous voluntary e-Form which can be shared with the trust if the person making the report agrees.

17 The roll out of the National Patient Safety Agency's National Reporting and Learning System has taken two years longer than originally envisaged. By 31 December 2004 all trusts had the technology to link to the system but many still had to map details from their local system to the national system. By the end of March 2005, some 170 acute, ambulance and mental health trusts had reported 79,220 incidents (a further 6,122 incidents were reported by primary care trusts making a total of 85,342 patient safety incidents reported to the National Reporting and Learning System up to March 2005).

18 The e-Form was launched in September 2004 and by April 2005, 108 reports had been made using this route. Whilst the National Patient Safety Agency does not know how many staff will make use of the e-Form, it believes this is a rich source of information for learning⁵ and provides a safety net for those who are too frightened to report to their local system. Five trusts told us that they do not want an anonymous system as this undermines local reporting and learning and that they would discourage use of the e-Form. Twenty-nine trusts are actively encouraging the use of the e-Form.

19 *Building a safer NHS for Patients*³ required the NHS to establish agreed definitions of incidents for the purposes of reporting, gradually moving to an international standardised taxonomy (description and classification of incidents). The National Patient Safety Agency developed its taxonomy in consultation with trusts but it is unlike many trusts' taxonomies and, in order to link to the national system, trusts had to map it to their own. At the time of our survey 82 per cent of trusts had had difficulties with the mapping exercise, and 17 per cent of these said that they had experienced major difficulties. Two-thirds of trusts told us that the national taxonomy was not specific enough so were continuing to use their own. It is also different from taxonomies used in other countries. The World Health Organisation is currently developing an international taxonomy which would require the National Patient Safety Agency and trusts to make changes to their taxonomies if they are to comply.

20 The National Patient Safety Agency worked with the Medicines and Healthcare products Regulatory Agency in order to test the feasibility of a single data entry point for reports of errors involving medical devices. However, this did not prove possible due to the statutory responsibilities of the Medicines and Healthcare products Regulatory Agency and the requirements of the National Patient Safety Agency. Indeed there has been no further development in this area and trusts are still required to report the same incident to more than one organisation.

21 Given that the Department's aim was to encourage reporting, no targets were set for reducing the number of reported patient safety incidents. Rather, the Department set targets for reducing the incidence of four specific types of errors (maladministration of spinal injections; serious error in the use of medicines; suicides by mental health inpatients as a result of hanging from non-collapsible rails and harm in obstetrics and gynaecology). Whilst there have been no reports of incidents involving the first type of error, there are limited data to judge whether the target on medication errors has been realised and mixed messages on progress against the targets on suicide as a result of hanging and obstetrics and gynaecology. For example, although negligence claims for obstetrics and gynaecology appear to be reducing, the Healthcare Commission highlighted concerns about the safety of some maternity services^{7, 8}.

A number of local and national systems are in place for analysing and sharing lessons learnt, but most are under-used

22 Most trusts did analyse incident reports and other information. Indeed most had been carrying out in-depth investigations of incidents at the local level for a number of years. Seventy-six per cent of trusts told us that they were now encouraging staff to use the National Patient Safety Agency's root cause analysis tool, with many noting that it had helped to improve the quality and consistency of in-depth investigations. A number of trusts remarked that monitoring and investigating incidents created additional demands on busy senior staff, and consequently they did not always conduct a full root cause analysis of all serious incidents. The quality of reports on investigations was also very variable and recommendations were rarely actioned by organisations outside the trust in which the event had occurred.

23 Dissemination of learning and the development of solutions was patchy and there was also no systematic monitoring to ensure implementation within the trust. Clinical audit can be an effective way to evaluate whether improvements are being implemented but a number of National Audit Office reports have highlighted concerns about the limited extent and coverage of clinical audit (Appendix 1). The Commission for Health Improvement reported in 2004 that this was still under-developed in many trusts⁹.

24 Over half of trusts reported that patients were involved in both identifying safety priorities and developing ways to prevent recurrence. However, only six per cent of patients we surveyed said they were consulted about how the safety incident they experienced could be prevented from happening to someone else.

25 Ninety-nine per cent of trusts identified specific interventions that they had developed to address patient safety issues (some are described in this report). However, few trusts have carried out any cost benefit analysis of interventions/solutions to improve patient safety. Given the estimated £2 billion cost of extra bed days due to incidents and the potential litigation costs, we consider that in many circumstances the cost of intervention is likely to be far less than the cost of failing to prevent the incident.

26 At a regional level, half the strategic health authorities used clinical governance networks to disseminate learning and in some areas they have introduced patient safety learning sets. However, a number told us they were ill-equipped to share lessons and many felt that they did not have the capacity or capability to monitor the implementation of good practice. There is also a risk that as foundation trusts are not required to report to strategic health authorities they will miss out on the sharing of learning. Other sources of learning are organised networks, like those for cancer and coronary heart disease, and ambulance trusts use the Ambulance Service Association. Since summer 2004, the National Patient Safety Agency's 28 Patient Safety Managers have been working with most trusts to help share good practice.

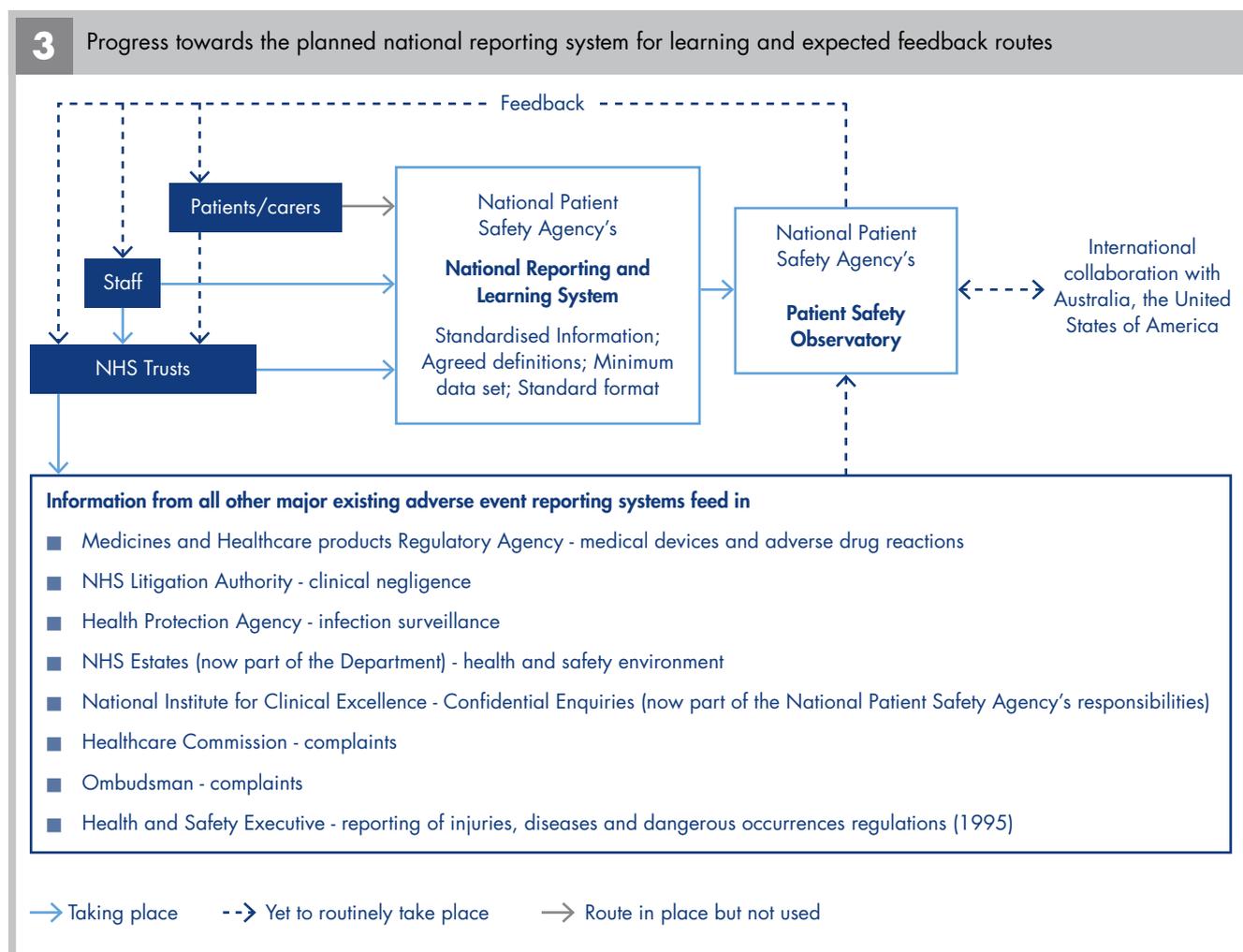
27 One way of disseminating information about necessary changes is the Department's Safety Alert Broadcast System. The Department, the Medicines and Healthcare products Regulatory Agency, NHS Estates^c and the National Patient Safety Agency issue safety alerts to trusts for them to act upon within a defined timescale. During 2004-05, trusts received 93 alerts through the System. Trusts told us that there was a lack of clarity in the rationale for the decision to release information as an alert and some felt that a number of these alerts did not tell them anything new. All wanted better links and communication between the bodies that issue notices via the Safety Alert Broadcast System. The Chief Medical Officer's annual report¹⁰ identified concerns that compliance with alerts was slow and some trusts which reported compliance were subsequently found to be non-compliant.

28 The Department expected that the new national reporting system for learning would bring about changes at trust and national levels, through the analysis of incidents and then subsequently their root causes. As at April 2005, the National Patient Safety Agency had issued limited feedback to trusts of lessons emerging from their reports to the national system. Although the National Reporting and Learning System has the capacity to collect contributory factors, these are not mandatory and the intention is to identify trends that can then be analysed in greater detail. Trusts told us they were concerned that information flow was one-way to the National Patient Safety Agency and the general perception was that the National Reporting and Learning System was simply an information collection system. The July 2005 report from the Patient Safety Observatory should start to address this perception.⁵

^c NHS Estates, responsibilities for health and safety environment alerts are being transferred to the Department as part of the Arm's Length Bodies Review.

29 The Department envisaged that the National Patient Safety Agency would assimilate other safety related information from a variety of existing reporting systems and other sources such as NHS complaints, litigation, National Confidential Enquiries and national audits (**Figure 3**). We found that there has been limited progress on assimilating and disseminating lessons from these different sources of information. Furthermore, the individual organisations responsible for litigation and complaints have until recently not made as much use of the valuable data they collect as they might to help trusts avoid similar incidents.

30 The National Programme for Information Technology in the NHS, being delivered by the Department's agency NHS Connecting for Health, has a crucial role in developing the technology to ensure that relevant information can be stored securely and accessed readily. A key component, the National Care Record, has significant potential to improve safety as lost or poorly completed records are a major contributory factor to patient safety incidents. Technology will also facilitate retrospective audits, improve access to guidance and reduce the risks of incorrect drug prescribing and dosages. In time, trusts' individual reporting systems will be integrated into the National Programme. The National Patient Safety Agency is working with NHS Connecting for Health's patient safety sub-group to take this forward.





CONCLUSIONS AND RECOMMENDATIONS

For the Department:

- a** The Department established a number of arm's length bodies with a role in keeping patients safe. **The Department needs to use its arm's length bodies' performance monitoring system to establish appropriate actions and milestones to:**
- enhance and sustain the development of an effective safety culture within NHS trusts;
 - improve the reliability and completeness of trust incident reporting and for disseminating the results of national reporting back to trusts;
 - provide effective feedback of lessons and solutions to improve safety.
- b** The National Clinical Assessment Authority has played a key role in improving the management of suspensions of doctors but other clinical staff are not covered by the Authority's remit. In the Government's response to the previous Committee of Public Accounts recommendation^d to consider extending the Authority's remit the Department told the Committee that the functions of the National Clinical Assessment Authority were being transferred to the National Patient Safety Agency from 1 April 2005, and that this consideration was therefore on hold. **Given that the transfer is now complete, the Department should now respond fully to the Committee's recommendation to consider extending the role of the National Clinical Assessment Service to other clinical staff.**
- c** It is imperative that patient safety becomes a core part of professional training, including helping clinical staff understand their responsibility for patient safety and the benefits of working in an open and questioning environment. **The Department needs to build on its work with the professional regulatory bodies and Royal Colleges to better embed patient safety training in all pre-registration professional training curricula and to raise the profile of patient safety issues in post-registration training.**
- d** Despite the rationalisation envisaged in *Building a safer NHS for patients*³, trusts are still required to report the same incident to numerous national bodies and revise their data sets to capture new information which those bodies require. **Wherever possible, incidents should only be reported once and, as trusts move to electronic reporting, the Department should explore the possibility of recommending a single entry point, for example via the National Programme for Information Technology in the NHS. As a minimum the Department should consult with NHS Connecting for Health, the NHS Health and Social Care Information Centre, the National Patient Safety Agency, the Medicines and Healthcare products Regulatory Agency and the relevant signatories of the Healthcare Inspection Concordat^e to identify the scope to rationalise the number of data entry points.**

^d The management of suspensions of clinical staff in NHS hospitals and ambulance trusts in England ; Forty-seventh Report of Session 2003-04 (HC 296).

^e A Concordat between the Healthcare Commission and nine other bodies inspecting, regulating and auditing healthcare was launched in June 2004. The aim was to reduce overlap and duplication of inspection, improve co-ordination, support improvements in quality and make inspections proportionate transparent and accountable.



For the National Patient Safety Agency:

- e Many trusts and organisations involved in collecting data on patient safety incidents consider that the taxonomy developed by the National Patient Safety Agency is not specific enough for their purposes. **The National Patient Safety Agency should work to adopt a taxonomy that ideally corresponds to the international taxonomy being developed by the World Health Organisation, but as a minimum should gain buy-in from all trusts and other bodies requiring reports on incidents to a mandatory minimum data set to ensure that there is consistency in the data collected at local and national levels.**
- f Many trusts are questioning the value of sending data to the National Reporting and Learning System given the lack of feedback and would like to see more of an emphasis on solutions. **The National Patient Safety Agency needs to agree with the Department a regular publication timetable, so that opportunities to sensationalise the data are reduced, and provide examples of how the NHS is learning from the data. One option is to produce quarterly updates so that it becomes standard. The National Patient Safety Agency needs to expedite its evaluation and feedback programme and focus on developing solutions to nationwide problems to mitigate the risk that trusts will stop sending data to the National Reporting and Learning System. These solutions should be accompanied by a sample business case which trusts can then customise.**
- g There is little dissemination of learning between most trusts. **The National Patient Safety Agency's Patient Safety Managers should establish formal systems to capture learning in specialties and share learning across other teams and trusts at both local and national level. In addition they should investigate the possibility of establishing local networks similar to those for cancer, which will have the potential to improve the delivery of patient-centred care by disseminating learning about the whole patient journey.**
- h There is currently no scheme for accreditation or benchmarking of patient safety training; thus trusts have no assurance that the training they commission is a good product. **The National Patient Safety Agency should look to other industries and together with the NHS Institute for Learning, Skills and Innovation, develop an accreditation scheme for all patient safety training supplied by external providers. It should also evaluate training programmes operated by trusts to build up a library of good practice to enable trusts to customise their training to best effect.**
- i NHS Connecting for Health has asked the National Patient Safety Agency to help assure the specification for the National Programme for Information Technology in the NHS to ensure that patient safety is inherent throughout the system. **In taking this forward the National Patient Safety Agency should ensure that Connecting for Health fully understands and builds on the lessons from the development and roll out of the National Reporting and Learning System.**

For the Healthcare Commission

- j** Safety alerts are an important mechanism for implementing solutions and we support the conclusions in the Chief Medical Officer's recent report¹⁰. **Information on compliance should be made public and the Healthcare Commission should place special focus on verification of NHS trusts' compliance when assessing performance against the *Standards for Better Health*.**
- k** No single NHS organisation is responsible for auditing implementation of best practice solutions for patient safety issues. **The Healthcare Commission should ensure that in assessing the safety domain it builds in assessment criteria that evaluate how well solutions have been implemented.**
- l** Information from complaints and litigation is still greatly under-exploited as a learning resource. **The Healthcare Commission needs to expedite its in-depth analysis of information from the NHS Complaints system and share lessons on a regular basis. The Healthcare Commission needs to work with the NHS Litigation Authority and the National Patient Safety Agency to agree how best to share the data and where the responsibility lies for identifying key lessons and providing trusts with feedback from these analyses.**

For NHS acute, mental health and ambulance trusts

- m** Despite improvements in safety culture many NHS employees still fear blame or unequal treatment if they report incidents and this remains a major barrier to increasing accurate and honest reporting. There is a need for trusts to re-enforce their commitment to an open and fair reporting culture and to support staffing initiatives to improve. **Trusts should assess their safety culture using one of the established tools, such as those listed in the *Seven steps to patient safety*¹¹, and implement an action plan to address the identified issues.**
- n** Financial problems and staff shortages can push patient safety down the list of trusts' priorities. Although the potential avoidable costs of patient safety incidents is estimated to be as much as

£1 billion¹, some areas of investment are likely to have a bigger pay back than others. **Trusts should ensure that funding for managing and improving patient safety reflects the organisation's risk register, and require their patient safety leads to develop annual business cases that demonstrate the opportunity costs of the improvements they plan to make, where relevant these should build on the solutions and accompanying business cases developed by the National Patient Safety Agency.**

- o** Patients have little involvement in the identification of patient safety priorities and in the design of solutions in most trusts. **Trusts need to engage patients more in identifying important patient safety issues and designing solutions and make better use of information gained through contacts with Patient Advice and Liaison Services. Trusts should ensure that they fully investigate complaints and litigation claims and analyse trends in both so as to learn from them.**
- p** Under-reporting is a problem in some staff groups more than others and there is a perception amongst staff that not all employees take responsibility for patient safety reporting. **Trusts should target specific training and feedback on those groups of staff that are less likely to report. They should liaise with the National Patient Safety Agency to identify and learn lessons from trusts which have achieved high reporting rates and also to build on the lessons from national initiatives to encourage reporting such as the work being done by the Agency on encouraging junior doctors to report.**
- q** Near misses are generally under-reported and information on outcomes, particularly death and serious harm is poor. **Trusts should ensure that their reporting policies clearly define a 'near miss' and should develop strategies to encourage more staff to report them to make sure potential serious incidents that were prevented are not overlooked. Trusts should also triangulate information from various data sources such as complaints, claims, coroners reports etc to ensure that all deaths and serious harm as a result of a patient safety incident are recorded on their incident reporting system.**



PART ONE

The safety culture within NHS trusts is now more open and fair



1.1 Although the great majority of patient care in the NHS is of a high standard, the number and complexity of patient interventions means that patients can sometimes suffer unintended harm. In 1997, the Government introduced a ten year programme to continuously improve the overall standard of clinical care; central to this was the clinical governance initiative. By 2000, the NHS was still failing to learn from things that went wrong and had limited systems in place to put things right. *An organisation with a memory*¹ therefore identified the conditions needed to improve people's confidence in the NHS. It advocated a change in the safety culture, from one that was essentially based on fear and blame, to an open and fair reporting culture to transform the NHS into an effective learning organisation.

1.2 In June 2000, the Department accepted all the recommendations of *An organisation with a memory*¹ and made a commitment to implement them in *The NHS Plan*¹². The 2001 policy document, *Building a safer NHS for patients*³, set out how the Department planned to take forward the patient safety agenda and the timetable for implementing the identified changes. It advocated that patient safety and risk reduction should be at the heart of the framework for improving quality of care, including protection against poorly performing clinicians. A key action was the establishment of the National Patient Safety

Agency in July 2001. This Part of the report examines the progress in developing an NHS safety culture. In particular whether:

- trusts had created an environment in which staff could report concerns without fear;
- communication with staff and patients was two-way and effective team-working predominated;
- there was a high profile lead on the issue; and
- there was integrated risk management.

Progress has been made both locally and nationally in encouraging an open and fair culture

1.3 To establish a safety culture an organisation must build a climate where staff feel they can report concerns without fear and they understand that they are accountable for unacceptable behaviours. Eighty per cent of the senior clinical and non-clinical managers in a YouGov poll¹³ said creating a culture that encourages reporting and avoids blame was one of the most beneficial ways of improving patient safety. We found that 97 per cent of trusts had made a clear statement of support for an open and fair culture, and around three-quarters of them disseminated it to staff by management cascade and/or through written communication.

1.4 Almost all trusts reported that they had made progress in reducing the culture of blame. Our analysis of the specific actions that trusts had taken to improve their patient safety culture showed that the most common were: the introduction or increased provision of training on patient safety (35 per cent); and the employment or re-deployment of staff to improve risk management (22 per cent). By July 2005, 31 per cent of trusts felt that they had an open and fair culture throughout the organisation (compared with 23 per cent in 2004) and 65 per cent that they had a predominantly open and fair culture (72 per cent in 2004).

1.5 We also asked trusts to rate their position in 2005 compared with 2004 on a scale of 1-7 (where 1 is predominantly a blame culture, 4 is moving towards an open and fair culture but pockets of blame exist in some major areas of the trust and 7 is predominantly an open and fair culture throughout the trust). The average score in 2005 was 5.66 compared with 4.73 in 2004. Overall, 68 per cent of trusts reported that they had improved, 28 per cent that they had stayed the same but two per cent felt that they got worse. Executive directors of patient safety may be under-estimating the prevalence of the blame culture as only half (51 per cent) of trusts had actually evaluated their safety culture (mostly commonly through their staff survey and external audits or assessments).

1.6 In 2001, because of trusts over-reliance on disciplinary measures, the Department set up the National Clinical Assessment Authority to provide quick objective assessments on doctors' performance and to place a greater emphasis on using education and training to address problems. Our report on the management of suspensions of clinical staff¹⁴ highlighted trusts' difficulties in managing poor performance and that referring a case to the National Clinical Assessment Authority, at an early stage, helped to reduce the perception that the trust operated a blame culture. Other clinical staff such as nurses were not given the same level of support and we recommended that the work of the National Clinical Assessment Authority should be extended to cover all clinical staff. Since 2003, the National Clinical Assessment Authority^f has continued to contribute to the development of a more open and fair culture and through its work suspensions have been avoided in a growing number of cases.

1.7 Surveys of nurses and other non-medical staff highlighted that they perceived that the blame culture continues to exist in the NHS. Whilst 25 per cent of respondents to a Unison survey¹⁵ (2003) said that the culture within their trust had improved since 2000, a third of respondents still believed that their trust would not want to know about a serious problem affecting services. The Royal College of Nursing¹⁶ found a perception remained that there was significant disparity between the treatment of doctors and nurses, by both their employer and the regulatory body, following a serious patient safety incident. The National NHS Staff Survey 2004⁶ showed that only 47 per cent of ambulance personnel felt their employers treated those involved in an error, near miss or incident fairly and 26 per cent said their employers blamed or punished staff when they made errors. **Case example 1** shows how one ambulance service has taken steps to address these perceptions and begun to embed an open and fair culture in the Trust.

1.8 One of the key targets for the National Patient Safety Agency was to support an NHS culture that is open and fair. Its *Seven steps to patient safety*¹¹ (February 2004) provides a checklist and references a number of available tools to help trusts assess their safety culture (Appendix 6). Forty-five per cent of trusts had actively disseminated this guidance to staff in some form. *Seven steps to patient safety*¹¹ also drew attention to the Incident Decision Tree, an interactive web-based tool aimed at helping trusts focus on possible system failures and trust-wide weaknesses rather than who was to blame. Trusts told us the tool had helped ensure there was fairer and consistent management of staff involved in reported patient safety incidents or near misses.

Trusts are now more likely to be fostering open and questioning communication between staff in teams

1.9 High performing teams with collective responsibility for their actions are important if trusts are to deliver safe and effective care. Nine out of ten NHS staff work as part of a team⁶ but most trusts identified that a lack of communication within teams was one of the root causes of patient safety incidents. Some had therefore concentrated on making communication in multi-disciplinary teams more open and questioning to reduce the risk of

^f Under the Arm's Length Bodies Review, the National Clinical Assessment Authority became part of the National Patient Safety Agency from April 2005 and was renamed the National Clinical Assessment Service.

CASE EXAMPLE 1

North East Ambulance Service NHS Trust

Situation: Prior to the merger of the Northumbria and Durham Ambulance Services in 1999, the Trusts' approach to the management of staff involved in patient safety incidents had been confrontational, often involving suspension from duty.

Action: Following the merger, the North East Ambulance Service NHS Trust has moved towards a non-disciplinary approach to investigating such incidents. In response to our 2002 census for the *Management of suspensions of clinical staff in NHS hospital and ambulance trusts in England*¹⁴, the Trust indicated that it was moving towards a fair-blame culture and had introduced a panel system to minimise the need to take final action. Two years on, the system is well embedded in the Trust.

Outcome: In the event of an incident requiring an investigation, staff are called to a 'variation to clinical practice' panel meeting. The panel includes the ambulance crew involved in the incident under investigation, a union representative and representatives from Trust management. The trade union was closely involved in the development of the panel, and the opportunity to have a union representative at panel meetings was an important factor in staff acceptance of the process. If the panel finds that a staff member has committed an error, the Trust ensures that the individual takes responsibility and the Trust would take further action, such as providing re-training, if required.

This panel process, combined with continuing professional development training, works to ensure staff are aware of their professional responsibilities. The development of this more collaborative approach has had promising results and has been a key step in embedding an open and fair culture within the Trust. Staff are now much more confident that they can report incidents that occur without fear of disproportionate repercussion or punishment.

Source: National Audit Office

unintentional harm (**Case example 2 overleaf**). Indeed, teams from 83 trusts have attended the Team Resource Management and Patient Safety Programme run by the NHS Clinical Governance Support Team. The programme develops capacity for team working by drawing on experiences from other industries, particularly aviation, and examining the impact of personality and behaviour on co-operative working.

There is still more to do to achieve a fully open and fair culture with regard to communicating with patients

1.10 Good practice guidance¹⁷ encourages trusts to inform patients when they are involved in an incident and clinical staff need to be trained to develop an open approach to communicating with patients. In our survey, 69 per cent of trusts had criteria for staff to follow but only 24 per cent routinely informed patients when they were involved in a reported incident; 6 per cent did not inform patients at all. A YouGov poll¹³ found most senior clinical managers believed patients and their families should be told if patients suffered harm, and most non-clinical managers believed that patients should be told when there has been a problem, even if they suffered no harm.

1.11 Patients' perceptions of the practice of informing them differed from those of the trusts. Fifty-one per cent of patients in our survey said that when their treatment had gone wrong, the hospital had informed them and 56 per cent were completely satisfied with the explanations given following the incident. Those patients who were provided with an explanation of risks and how to minimise them were less likely to complain or make a claim, with only 13 per cent going on to take further action.

1.12 Patients are also being encouraged to take greater responsibility for their safety. Seventy-three per cent of trusts reported that they provided information to patients to help them to maintain their own safety. (Most common were written materials to take away (48 per cent) or posters in public areas (38 per cent) and 42 per cent of trusts stated that they provided oral information as a matter of course). In contrast, 56 per cent of patients in our survey said that they had been informed about maintaining their own safety and how to minimise their risk of harm.

CASE EXAMPLE 2

Royal Cornwall Hospitals NHS Trust

Situation: The work of theatre teams at the Royal Cornwall Hospitals NHS Trust requires a high degree of co-ordination and communication to maintain effectiveness and safety. A typical theatre team does not come together in its entirety until the first surgical operation is underway and will often disperse as the last patient leaves theatre.

Action: Two anaesthetists at the Trust were interested in human factors research in other industries and its application to healthcare. They therefore asked a medical educationalist to conduct ethnographic observation of theatre teams. The NHS Clinical Governance Support Team provided the educational resources for induction to human factors for an entire operating theatre complex. Following this, the National Patient Safety Agency agreed to fund work to identify a routine formal approach to team briefing and debriefing to improve communication and enhance teamwork. QinetiQ (the former Defence Evaluation and Research Agency) were engaged to work with the Trust to develop a team self-review process (a form of structured debriefing that assists surgical teams in collective reflection on their performance). The process aims to improve teamwork behaviours which then translates to improved team performance and risk reduction for the patient. Acknowledging positive behaviour encourages teams to explore solutions internal to the team.

Outcome: Initially, personnel were self-conscious during the briefings, though overall they have reacted positively to the self-review concept. The team discusses issues around team management, safe practice and shared situational understanding at the self-review meetings. In the first week of using team self-review in the theatres, over 80 learning points emerged. A number of these were 'actioned', particularly those which were minor and cost-free. For example, identification that there should be a laminated MRSA policy placed on the theatre door when an MRSA patient is in theatre.

Source: National Audit Office

Preliminary research undertaken by the Theatre Team Resource Management Team at the Royal Cornwall Hospital found that staff in the theatre complex exposed to team self-review showed statistically significant improvement in teamwork climate and some improvement in the safety climate (using the Safety Attitude Questionnaire, a reliable and formally validated research tool used in over 350 hospitals worldwide) than staff who were not offered debriefs or did not attend. Other domains of stress recognition, working conditions, management perceptions and job satisfaction showed little or no change, possibly explained by the fact that the Trust was going through extensive reorganisation at the time.

We funded further research by the Trust to evaluate the long term impacts and benefits of team self-review. The Staff Attitude Questionnaire data identified that:

- briefing and debriefing had a positive impact on non-technical skills and patient safety;
- pre-session briefing was important for safety and effective team management (those interviewed reported that the process improved teambuilding and communication, and enhanced preparation and anticipation of potential problems for theatre lists); and
- debriefing was valued as a process by which the teams could learn from problems encountered during lists and plan how care could be improved in the future.

Although time restrictions and additional pressing commitments have limited universal uptake, theatre staff have endorsed the concept of briefing and debriefing and extension of the team self-review process.

Most trusts have established a clear and strong focus on patient safety

Many trusts are building a safer culture through the development of leadership

1.13 All but three trusts gave us examples of how the chief executive had personally been involved in promoting and driving forward the patient safety agenda (**Illustrative examples 1**). All trusts had a board director responsible for leading on patient safety – commonly the director of nursing (47 per cent), the medical director (32 per cent) or the chief executive (eleven per cent). A YouGov poll¹³ of senior managers in the NHS found that most agreed that patient safety was a high priority for their organisation, though not top priority.

1.14 The Commission for Health Improvement's clinical governance reviews conducted between December 2000 and March 2004 revealed a lack of good quality clinical leadership in acute, ambulance and mental health trusts.⁹ During the last four years the Department has provided assistance and advice on developing effective leadership through the NHS Clinical Governance Support Team. In particular, it provided a number of board development programmes and supported challenged organisations to make sustainable improvements. By April 2005, trust boards or key members of trust boards from over 130 acute, ambulance and mental health trusts had engaged with the Board Development Team. Between November 2004 and March 2005 the NHS Appointments Commission and the National Patient Safety Agency also provided training on Leadership in Patient Safety to 154 non-executive trust board members from 113 trusts.

ILLUSTRATIVE EXAMPLES 1

Chief executives involvement in patient safety

The Chief Executive and most of the executive management team at Staffordshire Ambulance Service NHS Trust consider that the best way of demonstrating leadership and involvement in the patient safety agenda is to “walk the walk”. They therefore go out on call with their paramedics. Staff that we interviewed felt positively about this direct involvement. The Chief Executive personally writes to members of staff when they save lives and meets with families affected by a serious patient safety incident occurring whilst their relative was in the care of the Trust.

At Wirral Hospital NHS Trust the Chief Executive has re-defined the Trust's arrangements for patient safety and invested in the infrastructure. He personally chairs the Clinical Governance Council which has agreed new standards and the Trust has a rolling programme to audit nursing standards. He performance managed the Trust's achievement of Level 3 for the Clinical Negligence Scheme for Trusts.

The Chief Executive at South Staffordshire Healthcare NHS Trust has engaged Aston University to conduct team health checks against patient safety research evidence. He also established robust structures and processes for patient safety and improved access to training.

Source: National Audit Office Survey of NHS acute, ambulance and mental health trusts 2004

1.15 In our 2003 report on achieving improvements through clinical governance⁴ we noted that clinical governance had improved the way that trusts dealt with quality of care issues and trust boards had started to become more involved in clinical concerns. Most trusts have continued to develop the quality agenda through the implementation of clinical governance arrangements and our 2004 survey revealed that 42 per cent of chief executives ranked the Commission for Health Improvement's Clinical Governance reviews as the most significant driver for the board to improve patient safety. Where trust boards had become more engaged with patient safety, improvements had also been driven by the need to gain assurance to sign off the Statement on Internal Control and their self-assessment for the Controls Assurance Standards or to secure lower contributions to the NHS Litigation Authority to cover negligence claims.

1.16 The National Patient Safety Agency has identified the need to be seen as a leader in its field and has employed well-respected clinical staff to lead on key areas and specialties. Most trusts' contact with the National Patient Safety Agency has been through the Patient Safety Managers assigned to the 28 strategic health authorities.

However, in a survey¹⁸ 77 per cent of junior doctors said they needed more information about the National Patient Safety Agency and 60 per cent did not know of, or were unsure of an organisation with a specific remit to improve patient safety. The National Patient Safety Agency launched a webcast campaign to combat this, fronted by Professor Sir John Lilleyman, former President of the Royal College of Pathologists and vice-chairman of the Academy of Medical Royal Colleges. The follow-up survey showed that 70 per cent of respondents still needed to know more about the National Patient Safety Agency and 18 per cent were unaware of its existence.

Staff are now more involved in improving patient safety

1.17 Staff were generally positive about the priority given to patient-focused care by their employer⁶ but vision and leadership alone are insufficient. Hippocrates' golden rule that healers should “first, do no harm” remains a central tenet of NHS healthcare. Individual staff need therefore to take responsibility for patient safety and be accountable for their actions. The professional bodies and Royal Colleges were concerned that once staff had filled in an incident report they were abrogating further responsibility for the patient safety incident to the recipient of the report. As a result the Royal Colleges have begun to place greater emphasis on patient safety in their curricula, for example the new Modernising Medical Careers initiative gives much greater prominence to behaviours that are intended to improve patient safety. In future junior doctors will have to demonstrate their competence in communication and consultation skills, clinical governance and team working. And a number of universities are currently piloting patient safety modules in their medical undergraduate degree courses. The professional regulatory bodies have also been strongly emphasising the individual responsibility of clinicians for patient safety through their Fitness to Practise schemes.

1.18 This emphasis may be paying dividends as 93 per cent of directors of patient safety reported that relevant staff groups played a role in identifying patient safety priorities and in the design and development of solutions in their trusts. However, few trusts provide incentives for staff to improve patient safety; only 16 per cent told us they used incentives for managers and 15 per cent for clinical staff. Most trusts agreed that detailed job descriptions, staff appraisal and 360 degree feedback exercises were the key tools for focusing staff on improving patient safety.

1.19 The National Patient Safety Agency has been collaborating with organisations representing NHS staff and produced tools to promote awareness and understanding of patient safety (Appendix 6). Some trusts are using the National Patient Safety Agency's induction video and there are e-learning projects in the pipeline (**Case example 3**).

Most trusts have improved their patient safety environment in response to risk management requirements

1.20 For the NHS to be safety conscious the Department advocated that trusts become, and remain, aware of potential risks so that they were in a position to take action to mitigate them before patient safety incidents occur. We developed an objective measure to assess trusts' relative performance with regards to reporting and learning from patient safety incidents based on responses to key questions in our survey (Appendix 2).

1.21 Our results showed that the majority of trusts have made substantial progress in introducing a patient safety focused environment. No trust obtained a perfect score. Three trusts achieved a score of over 90 per cent, while two trusts achieved a score of just 33 per cent. The average score was 67 per cent. Most trusts are reactive in their approach to patient safety, only taking action following an incident or near miss. A few trusts have achieved the stage where managing risk is an integral part of everything the organisation does (**Case example 4 overleaf**).

1.22 These findings are backed up by the results of trusts' self-assessment against the Risk Management System Controls Assurance Standard (one of 22 standards that formed part of the NHS Controls Assurance project). Ten per cent of chief executives ranked this as the biggest driver for their board to improve patient safety. Trusts had to undertake self-assessment against criteria such as board accountability, adverse incident reporting and complaints and claims handling. During the years it was in operation the assurance scores for acute, ambulance and mental health trusts rose from an average compliance of 52 per cent in 1999-2000 to 87 per cent in 2003-04, showing that trusts are gradually moving towards a comprehensive risk management process.

CASE EXAMPLE 3

Involving Doctors with the Patient Safety Agenda

Situation: Doctors.net.uk was set up in 1998 to facilitate communication between doctors and to provide links to policies and guidance for all specialties. Eighty per cent of all registered doctors in the United Kingdom, from all specialties within the health sector, are members. Doctors.net.uk offers online learning modules which can count towards doctors' personal development plans and it identified that junior doctors starting hospital placements could benefit greatly from additional training to reduce the risks to the safety of their patients.

Action: It commissioned 24 modules, under the title of the Clinical Foundation Programme, directly related to specific areas of junior doctors' responsibilities, such as *Abnormal blood results (and what to do)*, *Drugs dosage and administration*, *Good medical records* and *Is your hospital safe?* The Medical Protection Society sponsored the programme, offering a 50 per cent discount on joining fees for those junior doctors who passed ten of the modules. Although mainly aimed at house officers it is available for senior house officers as well. The programme commenced in August 2003, with two modules launched each month and all accredited modules were available by July 2004.

Outcome: There has been a high uptake of the programme by junior doctors. Between August 2003 and July 2004, 4,671 doctors passed 10,780 modules and almost 3,000 others began at least one module. The most popular topics were *Work life balance* and *Basic blood gas analysis*. Given the positive response, there will be further modules offered relating to patient safety incidents and reporting and learning lessons from them. The National Patient Safety Agency commissioned this work and it will revolve around a patient safety incident scenario.

Source: National Audit Office

1.23 From inception in 2000, the eight criteria contained in the Risk Management System standard were the same as those used by the NHS Litigation Authority for the purposes of the Risk Pooling Schemes for Trusts. Independent assessors, working on behalf of the NHS Litigation Authority to evaluate clinical and non-clinical risk management under the Clinical Negligence Scheme for Trusts and Risk Pooling Schemes for Trusts, found that year on year trusts have continued to improve their compliance with the assessment criteria. Twenty-six per cent of chief executives ranked NHS Litigation Authority standards and evaluations as the chief driver for their board to improve patient safety because the higher their effectiveness rating and level of compliance with the standards, the greater the discount on their contributions to the Schemes (one trust has managed to reduce its contributions by £750,000).

Figure 4 shows the ratings for acute and mental health trusts for 2004-05 as compared with 2003-04 (a specific ambulance assessment was introduced in 2004-05 and so comparatives have not been included) and Appendix 7 gives details of the assessment criteria.

1.24 From April 2005, all trusts and other providers of NHS healthcare were expected to comply with a new performance framework. *Standards for Better Health* provides a common set of requirements to ensure that health services are safe and of acceptable quality; and a framework for continuous improvement in the overall quality of care that people receive. The Healthcare Commission has responsibility for assessing trusts' performance against seven domains with both core (where compliance is not optional) and developmental standards. The first domain is Safety (Appendix 7).

1.25 As with Controls Assurance, the onus is on healthcare organisations to ensure that they are meeting the expected standards of performance. On 31 October 2005, trust boards will make a draft declaration on the extent to which they are meeting the core standards; identifying areas where they are at risk of not meeting them; and any action they propose to take to address the risks. They will supplement this with comments from their patient and public involvement forum, local overview and scrutiny committee and strategic health authority. The Healthcare Commission will check these declarations against a wide range of surveillance information and follow up where there are concerns. In subsequent years trusts will be expected to make a declaration on performance against both the core and developmental standards.

4 NHS Litigation Authority Year End Assessment Results for 2003-04 and 2004-05

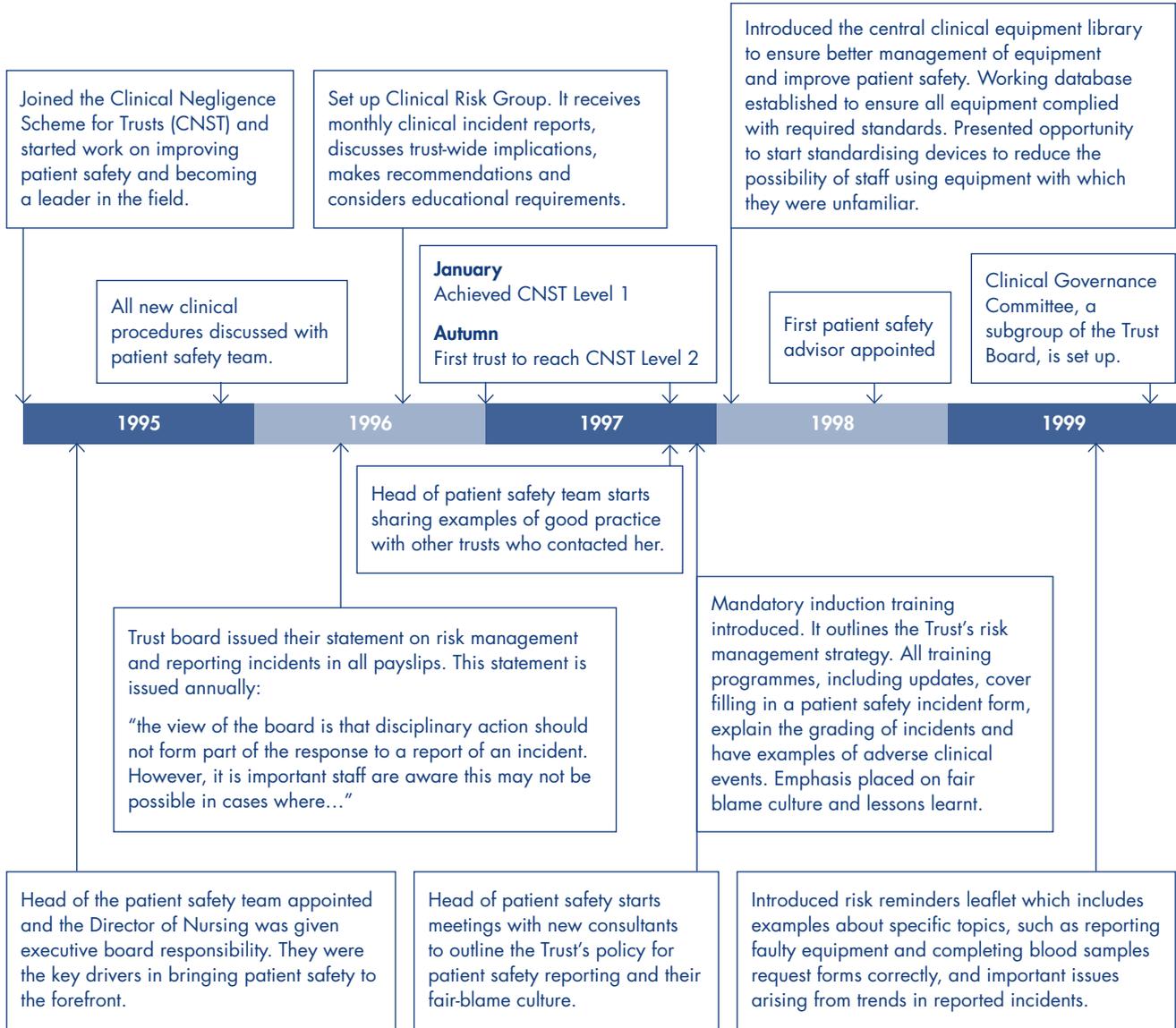
For the first time since inception of the Scheme, all 239 NHS hospital (acute and mental health) trusts have achieved at least Level 1 of the Clinical Negligence Scheme for Trusts general assessment and only one had yet to reach Level 1 for the Risk Pooling Schemes for Trusts.

| Hospital Trusts | Clinical Negligence Scheme for Trusts General | | | | Risk Pooling Scheme for Trusts | |
|-----------------|---|---------|---------|---------|--------------------------------|---------|
| | Level 0 | Level 1 | Level 2 | Level 3 | Level 0 | Level 1 |
| End of 2004-05 | 0% | 74% | 22% | 4% | 0.4% | 99.6% |
| End of 2003-04 | 5% | 74% | 19% | 2% | 15% | 85% |

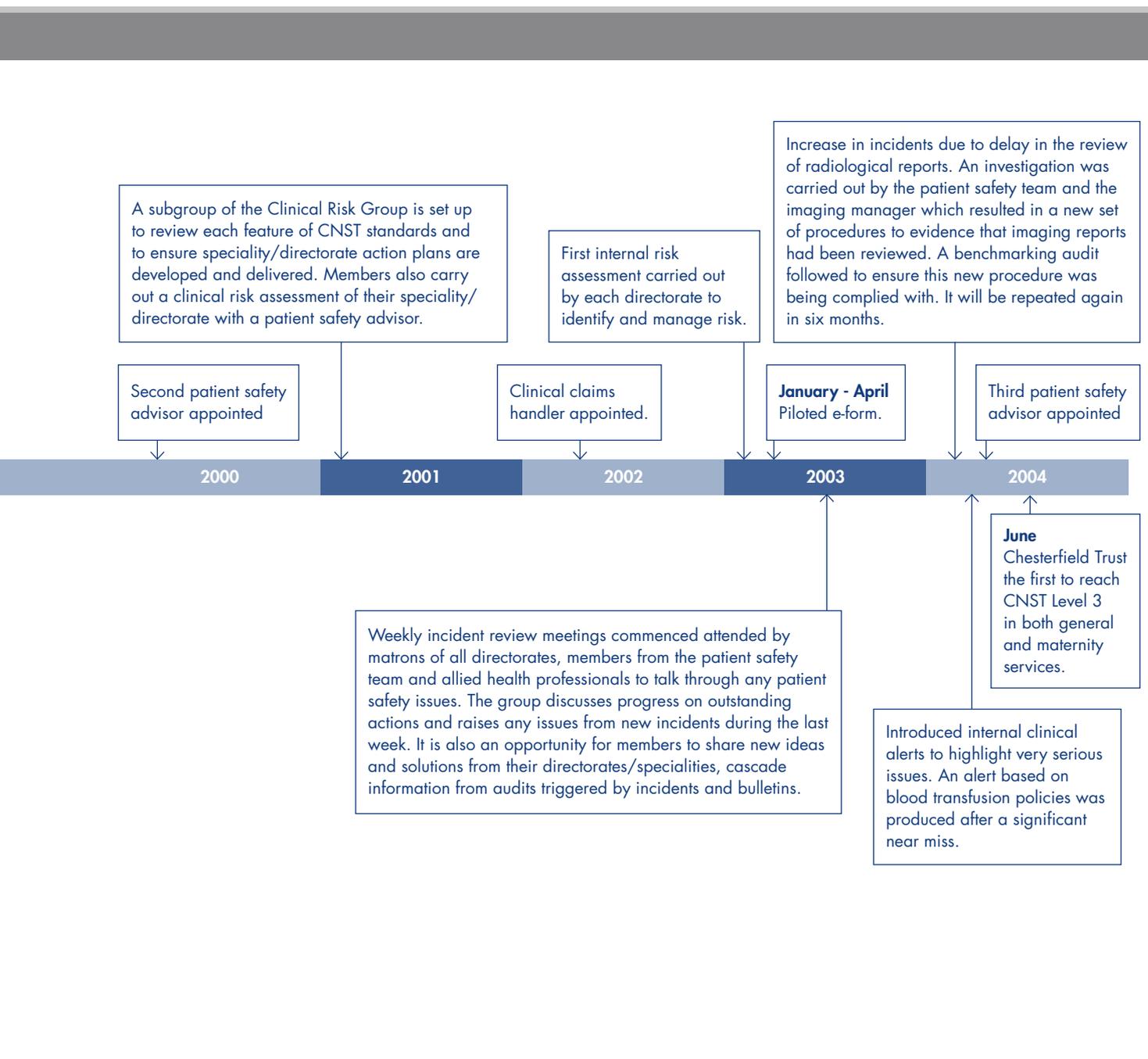
Source: NHS Litigation Authority

CASE EXAMPLE 4

Timeline for Chesterfield Royal Hospital NHS Foundation Trust



Source: National Audit Office



PART TWO

Local reporting has improved but there have been delays in establishing an effective national system



2.1 “If you can’t measure it, you can’t manage it” is a key message for patient safety. *An organisation with a memory*¹ identified a lack of robust comprehensive information as the reason why the NHS was failing to learn the lessons of past events. It presented the first national estimates of the number of incidents of unintended harm, estimating that one in ten admitted patients experienced some form of harm, costing the NHS £2 billion. To this must be added approximately £430 million paid out each year in settlement of clinical negligence claims and the £1 billion cost of hospital acquired infection¹⁹. Estimates suggest around half of these incidents could have been prevented². The Department’s response, *Building a safer NHS for patients*³, detailed plans to establish unified mechanisms for reporting and analysing information on errors and the need to agree definitions.

2.2 This Part of the report examines the capacity of trusts to collect information locally on patient safety incidents and their ability to identify patterns and trends. We also assessed the NHS’s progress against the objectives and targets set out in *Building a safer NHS for patients*³, including the implementation of a national reporting system for learning and the progress against the targets to reduce four specific high risk or frequently occurring types of incidents.

All trusts have organisation-wide patient safety reporting systems

2.3 Research on the characteristics of effective local incident reporting systems suggests that they should ideally be integrated, confidential and collect information on incident severity and risk. Our survey showed that 97 per cent of trusts operate a reporting system that records both clinical and non-clinical incidents. In 2004, 63 per cent of trusts had a confidential incident reporting system and 36 per cent had an open reporting system. By 2005, many more trusts had moved to open reporting systems (34 per cent had a confidential system and 63 per cent an open system). In addition 38 per cent of trusts had facilities to enable staff to report concerns through an anonymous reporting route, such as a whistle-blowing hotline, or for specific incidents such as medication errors.

The total number of incidents reported has risen year on year

2.4 Fifty-six per cent of trusts told us that reporting of incidents was much more common amongst their staff, following a slow and steady development of a patient safety culture. A few trusts had made the reporting of incidents mandatory with a disciplinary procedure if a member of staff had witnessed an incident but not reported it. In the National NHS Staff Survey 2004⁶, 85 per cent of staff said their employer encouraged reporting of errors, near misses and incidents.

2.5 As expected, the number of incidents reported annually to trusts' incident reporting systems has increased, which suggests that most trusts have made progress in creating a culture in which staff are prepared to report (78 per cent of trusts told us that their encouragement of staff to report had had a positive impact on the number of incidents reported).

2.6 In response to our 2004 survey, trusts reported that in 2003-04 they had recorded some 885,832 incidents and near misses (data provided by 256 trusts). In our 2005 re-survey, data from 212 trusts indicated that for 2004-05, 758,528 incidents and near misses were recorded (the average (median) increase reported by trusts was four per cent suggesting that the total number of reported incidents and near misses in 2004-05 is likely to be around 973,560). A year on year comparison of incidents is difficult as many trusts have changed their systems and therefore were only able to provide full data for the last two years. Nevertheless, an analysis of the average number of incidents per 1,000 staff shows that since 2001-02 the number of reported incidents and nears misses has increased by 24 per cent (Figure 5). The Department told us that it welcomed this increase in numbers as it showed a more complete coverage of reports from across the NHS.

2.7 The increase in reported incidents across the NHS is also demonstrated by comparing the median number of reported incidents per trust over the last three years (1,954 in 2001-02, 2,511 in 2002-03, 2,946 in 2003-04 and 3,184 in 2004-05). Nevertheless, there are still wide variations in the number of reported incidents per type of trust (Figure 6).

5 Number of reported incidents and near misses per 1,000 members of staff in each reporting year by type of trust

The number of incidents reported per 1,000 members of staff has increased year on year in all types of NHS trust.

| Trust type | 2001-02 | 2002-03 | 2003-04 | 2004-05 |
|--|--|--|--|--|
| Acute | 950 | 1,099 | 1,165 | 1,216 |
| Ambulance | * | * | 128 | 114 |
| Mental Health | * | 1,629 | 1,744 | 1,610 |
| All trusts | 1,000 | 1,148 | 1,190 | 1,201 |
| Percentage increase since 2001-2002 | - | 15 | 19 | 24 |
| Total number of incidents reported | 447,228 incidents (175 trusts) | 707,509 incidents (225 trusts) | 885,832 incidents (256 trusts) | 758,528 incidents (212) or 973,560 if extrapolated to 256 trusts |

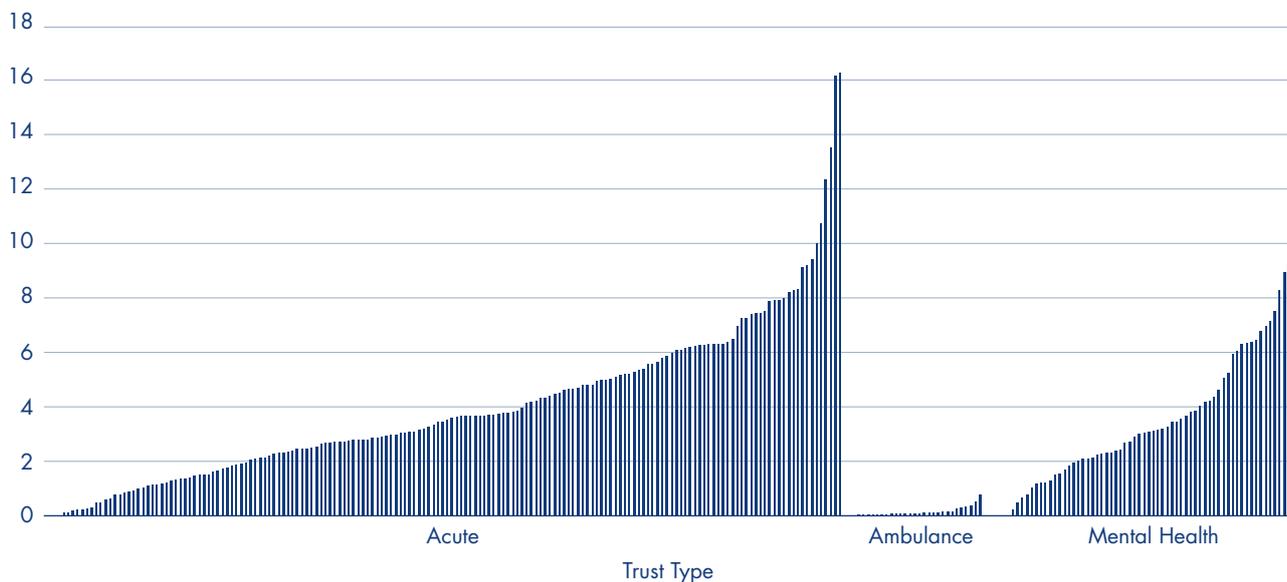
Source: National Audit Office survey of 267 NHS acute, ambulance and mental health trusts 2004 and National Audit Office update survey of 211 acute, ambulance and mental health trusts 2005 with results extrapolated to the same trust that responded in 2004

NOTE
* indicates insufficient responses to make comparisons.

6 Number of incidents and near-misses reported 2003-04

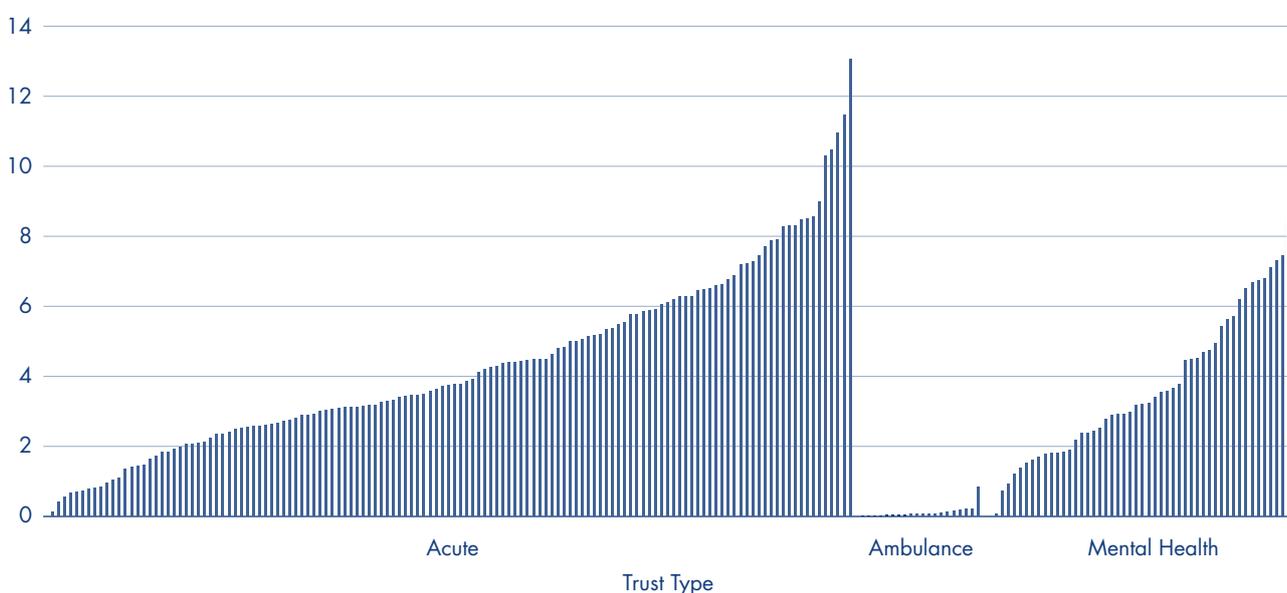
There is a wide variation in reported incidents and near misses both between similar NHS trusts and the different types of trusts. Ambulance trusts, given the nature of their role, have significantly fewer incidents reported than either mental health or acute trusts.

Number of incidents (2003-04¹) (000s)



Source: National Audit Office survey of NHS acute, ambulance and mental health trusts 2004 (responses from 256 trusts)

Number of incidents (2004-05²) (000s)



Source: National Audit Office re-survey of NHS acute, ambulance and mental health trusts 2005 (responses from 212 trusts)

NOTES

- 1 2003-04: Reported incidents in acute trusts ranged from 94 to 16,186; in ambulance trusts from 6 to 770 and mental health trusts 4 to 9,196.
- 2 2004-05: Reported incidents in acute trusts ranged from 134 to 13,056; in ambulance trusts from 15 to 825 and mental health trusts 81 to 8,472.

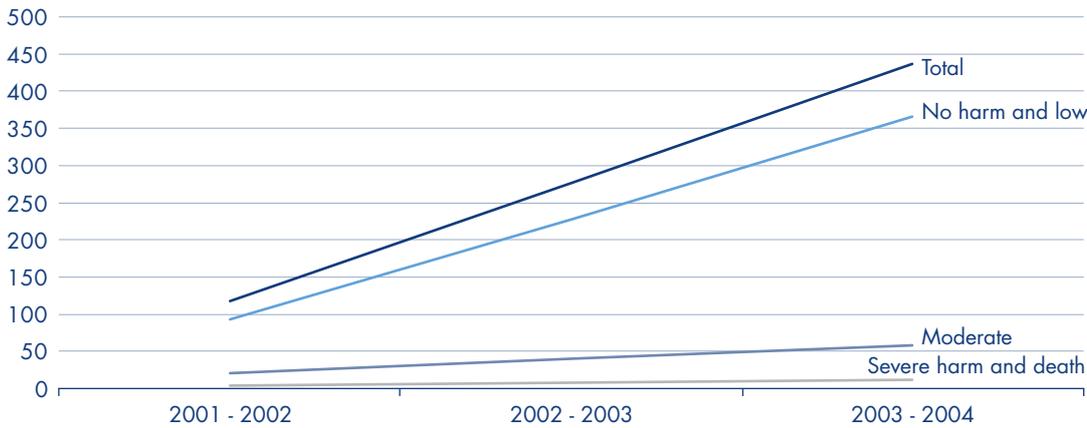
2.8 The National Patient Safety Agency suggests that over time it would expect the total number of reported incidents to increase to facilitate learning but the number of severe incidents should decline. Most trusts began to use the National Patient Safety Agency definitions of severity in 2004-05. In our 2004 survey, only 22 per cent of trusts were able to provide us with information on severity for all their reported incidents whereas in our 2005 re-survey of incidents in 2004-05, this had increased to 35 per cent of trusts. Given the emphasis on encouraging reporting, to date the numbers of all types of reported incidents are increasing (**Figure 7**). In our survey those trusts that graded incidents reported that they had records of 2,181 death incidents for the year ended March 2005 (90 per cent of trusts graded incidents by severity and 58 per cent of trusts graded incidents using severity, likelihood of recurrence and likely consequences of recurrence).

2.9 Retrospective studies of hospital case records in countries such as the United States and Australia have shown a substantial rate of adverse events (Appendix 4). In England, there is limited national information on the severity and outcome of adverse patient safety incidents and published estimates vary widely. In 1999 a retrospective review² of 1,014 medical and nursing records from two acute hospitals in London found that 110 (10.8 per cent) of patients experienced an adverse event, about half of which were judged to have been preventable with ordinary standards of care. A third of these events were judged to have led to moderate impairment (19 per cent) or permanent impairment (6 per cent) or death (8 per cent). These adverse incidents resulted in some 999 extra bed days of which 460 were judged to be preventable, and which would have saved the two trusts £290,268 in direct costs.

7 Number of incidents reported compared to severity

To date reported incidents in all categories are increasing.

Total number reported (000s)



NOTE

Based on responses from the 58 trusts that were able to provide us with data on numbers of incident by grade for each year.

Source: National Audit Office survey of NHS acute, ambulance and mental health trusts 2004

2.10 The above pilot study is widely quoted as providing the best information currently available on patient outcomes as a result of adverse patient safety events. Since then various publications on patient safety have applied the findings to derive a national figure for deaths and permanent disabilities. For example in 2001, the Department's draft guidance *Doing Less Harm* suggested that patient safety incidents may have contributed to as many as 25,000 permanent disabilities and 34,000 deaths each year and, in *Seven steps to patient safety*¹¹, which superseded *Doing Less Harm*, the National Patient Safety Agency estimated that there may be as many as 72,000 incidents which may have contributed to the death of patients, although it was unclear what proportion of this number would die as a direct result of the incident.

2.11 Improvements in trusts' reporting systems means that more exact figures of the number of actual reported deaths due to patient safety incidents is now beginning to emerge. The National Patient Safety Agency's first Patient Safety Observatory report in July 2005⁵ reported that between December 2004 and March 2005, the National Patient Safety Agency received some 79,220 reports of patient safety incidents from acute, ambulance and mental health trusts⁸ (a further 6,122 incidents were reported by primary care trusts making a total of 85,342 patient safety incidents reported to the National Reporting and Learning System up to March 2005), of which 68 per cent resulted in no harm to patients. It estimated, based on 46 deaths reported by 18 trusts over a three months period, that there would have been some 840 deaths as a result of a patient safety incident in acute hospitals in England. We found that deaths and serious harm are likely to be under reported, suggesting that further work is needed to arrive at a more precise figure.

The extent of the reporting of near misses is much lower than expected

2.12 Some trusts did not distinguish between near misses and incidents but our survey results revealed that although the reporting of near misses had increased annually, there are still far fewer near misses reported than incidents (the total number in 2004-05 was 115,820). In 2001-02, only 52 per cent of trusts reported more than 100 near misses; this had increased to 73 per cent (out of 161 who did distinguish between incidents and near misses) in 2004-05.

2.13 The ratio of incidents to near misses reported is useful in assessing how far an organisation has developed a robust reporting culture. There is a lot of variation between trusts, with between four and ten times more incidents reported than near misses; for acute trusts the ratio is 5:1, for ambulance trusts 1.5:1 and for mental health trusts 11:1. *An organisation with a memory*¹ stated that the health of a reporting system can be judged by the proportion of minor incidents reported to more serious incidents reported; suggesting that for every serious accident there will be 29 minor accidents and 300 occasions when the accident could have happened but for some reason was averted^h. Statistical analysis also showed that the more that staff believe that their incident reporting system is fair, the closer the ratio of incidents to near misses.

2.14 Some trusts have developed a Close-Call reporting system, separate from the main incident reporting system, to capture information on situations that could have resulted in an accident, injury or illness but did not, due to chance or timely intervention. All reporters are guaranteed anonymity and forms typically take fewer than five minutes to complete. Although this has maximised the trusts' opportunities for learning from near misses to improve patient safety, it does mean that these incidents may not be fully recorded in the trusts' incident reporting system and consequently in the national collation of incidents.

Under-reporting persists to varying degrees between staff groups and trusts

2.15 Thirty-five per cent of executive directors of patient safety told us that under-reporting of patient safety incidents was a moderate problem, with two per cent stating it was a major problem for their trust. Most (93 per cent) trusts had attempted to estimate the proportion of incidents and near misses reported and they told us that on average around 22 per cent of incidents went unreported and 39 per cent of near misses (Figure 8). Similarly, in the National NHS Staff Survey 2004⁶, healthcare workers said of those patient safety incidents they had witnessed, someone reported it in 83 per cent of cases.

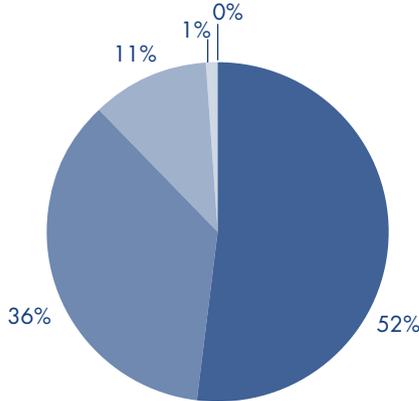
g The total should increase as the number of organisations that report increases, as staff send reports direct to the National Reporting and Learning System and more importantly, as an open culture becomes more wide spread within organisations so that more staff feel able to report incidents.

h Heinrich, when investigating factory accidents in the 1940s identified this 1:29: 300 ratio.

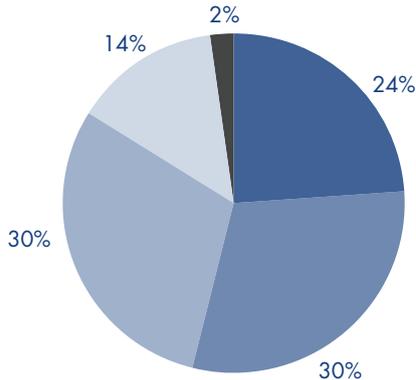
8 NHS trusts' best estimates of the proportion of actual incidents and near misses which go unreported

Staff are more likely to report actual incidents than near misses.

Actual incidents¹ that go unreported



Near misses² that go unreported



Key: estimated proportion of incidents and near misses that go unreported

- 0-20%
- 21-40%
- 41-60%
- 61-80%
- 81-100%

Source: National Audit Office survey of NHS acute, ambulance and mental health Trusts 2005

NOTES

- 1 Based on 201 trusts.
- 2 Based on 198 trusts.

2.16 Research indicates that certain types of incident are more likely to be under-reported. In our visits to trusts, managers pointed out that staff were less fearful about reporting a patient fall, as in many cases the attributed cause was not direct staff action. In contrast, medication errors and adverse drug reactions were under-reported due to fears of repercussions and these incidents were often complex and multi-factorial in nature (a fact that is supported by research findings). Also staff on wards suggested that, as under-reporting of medication errors was an acknowledged problem, one solution might be to have an anonymous reporting system for drug related incidents. Indeed, in a number of trusts staff can report direct to the pharmacy or there is anonymous reporting for drug related incidents in addition to the trust-wide incident reporting system (**Illustrative example 2**). Whilst this goes against the premise of an open reporting culture, it does allow managers to respond to recurrent problems.

2.17 Seventy-seven per cent of trusts told us that under-reporting by medical staff was a problem, whereas only eleven per cent believed under-reporting was a problem amongst nurses. Executive directors of patient safety considered that this was partly due to doctors expecting the nurse to report the error.

2.18 In a Doctors.net.uk survey of 3,314 doctors working in secondary care²⁰, 78 per cent acknowledged that they had made a mistake which had an impact on patient care, but only 19 per cent said that they had reported an error through the trust or the General Medical Council. Just 17 per cent stated that most often they would report through those systems. Ninety-seven per cent of respondents agreed that a system, which was not operated by either trusts or a Departmental organisation, as for example happens in the rail and aviation industries (Appendix 3), which allowed them to report electronically and receive feedback anonymously, would encourage reporting. However, this would segregate a key staff group and undermine moves towards an open and fair reporting culture. Some trusts we visited had achieved high levels of incident reporting amongst doctors by allowing them to report in different ways, (with the information being fed into the main reporting system at a later date); providing feedback on every report and promoting awareness of the open and fair culture. **Case example 5** illustrates a national initiative to improve reporting by doctors.

ILLUSTRATIVE EXAMPLE 2

Using anonymous reporting systems for medication errors

In 1993 King's College Hospital established an anonymous medication error reporting scheme called Sure-Med. Prior to this Pharmacy had little knowledge of the types or numbers of medication errors occurring in the trust. Errors identified were reported to Pharmacy via a specific telephone line in the Medicines Information Department. Reports were reviewed by a multidisciplinary group who issued alerts and newsletters highlighting problem drugs or practices. During the first year the reporting rate averaged between 30 and 50 errors per quarter. By 2001 Pharmacy had reviewed over 600 reported medication errors allowing themes and trends to be identified and information to prevent recurrence of common errors to be disseminated to staff.

Source: National Audit Office survey of acute, ambulance and mental health trusts 2004

2.19 Staff often cite fear of reprisal as a barrier to reporting but there are many other factors which discourage healthcare workers from reporting patient safety incidents. Our findings in our report on clinical governance⁴ identified that some of the most significant barriers to incident reporting were culture (56 per cent), lack of resources (23 per cent) and problems with information (14 per cent trusts). These were very similar to the responses to our survey in 2004 (**Figure 9 overleaf**).

Almost all new staff receive training on incident reporting, but it is less likely to be given to existing employees, temporary staff and contractors

2.20 Most trusts maintained staff awareness of the need to report through at least one method such as update training and staff communication and appraisal systems. Education and training is essential if staff are to be encouraged to report and we found that 97 per cent of trusts trained new employees on what, when and how to report. However, there were less comprehensive methods for making temporary staff and contractors aware of patient safety reporting requirements (**Figure 10**). Trusts identified a number of barriers to training together with solutions aimed at improving matters (**Figure 11**).

CASE EXAMPLE 5

The National Patient Safety Agency and Doctors.net.uk

Situation: There is a perception within the Health Service that doctors are less likely to report a patient safety incident than, for example, a nurse.

Action: The National Patient Safety Agency has tried to target awareness of the patient safety agenda and it commissioned Doctors.net.uk. to communicate electronically with their members. For example, anaesthetists and surgeons received a link to the Correct Site Surgery safety alert and further information on the National Patient Safety Agency website.

Doctors.net.uk also conducted a survey of junior doctors regarding the reasons why they might not report a patient safety incident and to assess their knowledge and awareness of the National Patient Safety Agency. Two hundred and ninety-two junior doctors replied and the main reasons given for choosing not to report a patient safety incident were: 'don't have time'; 'don't think it will make a difference'; and 'don't believe I will get any feedback'. Also 72 per cent were undecided as to whether the National Patient Safety Agency would improve patient safety.

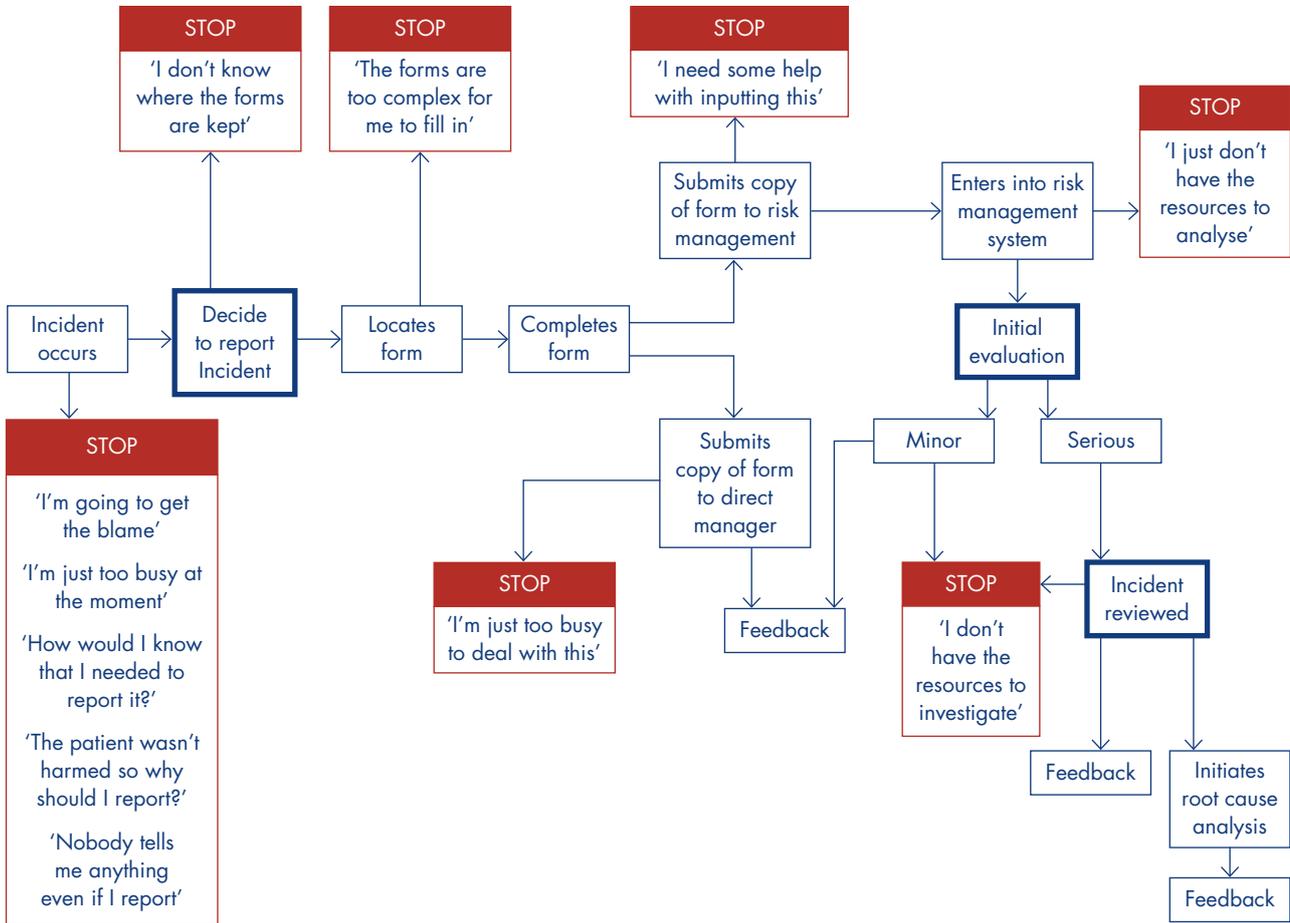
Outcome: The National Patient Safety Agency planned a campaign to address the issues identified and Professor John Lilleyman asked for junior doctors' assistance with reporting. Doctors.net.uk found in a follow-up survey of 189 doctors that the percentage of junior doctors who thought that the National Patient Safety Agency would improve patient safety had increased from 13 per cent to 34 per cent as a result of the online information campaign. The percentage of doctors indicating that they would definitely or be likely to use the National Patient Safety Agency's anonymous online reporting form increased from 36 per cent to 48 per cent of the sample.

Source: National Audit Office



9 Most frequently reported barriers to incident reporting

The top five reasons given by trusts for under-reporting by staff were fear (19 per cent), poorly designed forms (15 per cent), lack of understanding about what to report (13 per cent), failure to recognise that an incident needed reporting (eleven per cent) and being too busy and lack of feedback after a report (both ten per cent).



Source: National Audit Office

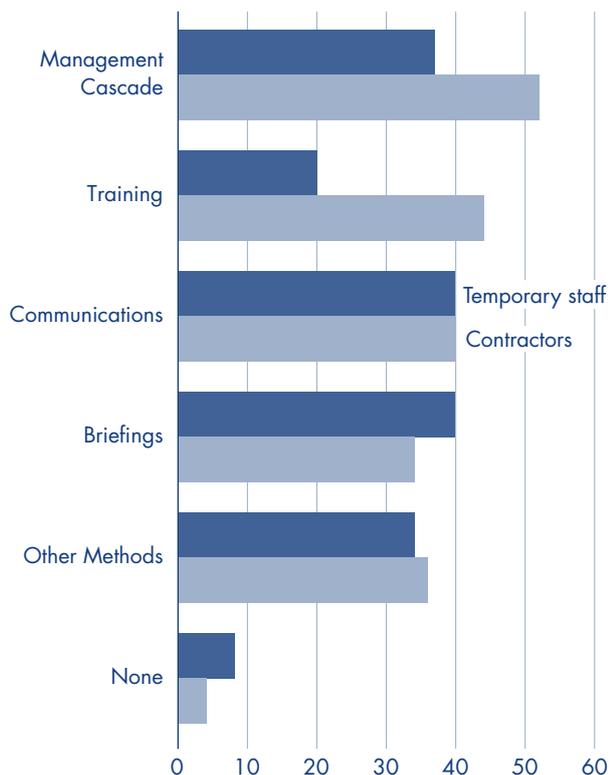
Feedback on extent and subsequent action is important

2.21 Ninety-nine per cent of trusts produced formal summarised patient safety incident reports for review and action, with 80 per cent on either a monthly or quarterly basis. Most contained analysis of incidents by category (91 per cent), trends (88 per cent) and directorate (81 per cent), though few analysed by frequency (63 per cent), ward (57 per cent) or speciality (52 per cent) and even fewer analysed by underlying causes (34 per cent). **Illustrative example 3** shows how one trust's system for analysing incidents has evolved. Although some trusts log patient complaints, claims and incidents onto the same risk management system, few actually analysed the inter-relationships of these data sources to identify unreported incidents.

2.22 Management feedback to staff who report patient safety incidents is also crucial in encouraging subsequent reporting, but from our survey we found no consistency of practice between trusts, even allowing for the different levels of maturity in safety culture. Half told staff how they would deal with their initial report and 83 per cent of trusts provided feedback after an investigation of the incident had taken place. As a reporting system and culture matures, providing individual feedback can become a substantial administrative burden and trusts need to target feedback at areas where there are the greatest risks.

10 Making temporary and contract staff aware of reporting requirements

There are a wide range of methods for ensuring that temporary and contract staff are aware of their reporting requirements for patient safety incidents in use, but many trusts relied on just one method.



Source: National Audit Office survey of NHS acute, ambulance and mental health trusts 2004

NOTE

58 trusts used only one method for temporary staff; 70 trusts used only one method for contract staff.

11 Trusts have taken a variety of actions to overcome barriers to training

Barriers to training

Releasing staff

Common actions to address barriers

- Review of requirements and timing and delivery of training
- Mandatory training days
- CDRom/e-learning

Not enough trainers

- Review of training capacity, capability and delivery
- Additional resources made available
- Business case for resources

Time

- Review of training requirements, shift patterns and delivery
- CDRom/Intranet/e-learning
- Mandatory training
- Training in the ward/department

Source: National Audit Office survey of NHS acute, ambulance and mental health trusts 2004

ILLUSTRATIVE EXAMPLE 3

Trend analysis of underlying causes

West Middlesex University Hospital NHS Trust has been operating a common trust-wide incident reporting system that, for the past seven years, has included the reporting of 'patient safety incidents'. Staff reported the details and underlying causes of the incidents confidentially using the Trust IR1 form. However, in respect of clinical/patient safety incidents, nursing management and clinical leads felt that the standard periodic reports (generated using the computerised incident recording system), whilst producing statistical information, gave insufficient insight into the nature of the patient safety incidents or the ways in which patient outcomes might be improved.

In 2002, the Risk Facilitator set up a database linked to the incident recording system. This simplified and automated the production of quarterly reports, detailing clinical categories (as defined by the Clinical Negligence Scheme for Trusts) against the reported underlying causes. The Trust's Senior Management and the Directorates received these standard reports, with the Directorate Quality and Risk Committees being responsible for discussing the trends and underlying causes in detail. Members of the Risk Management Department team attended these Committees to give advice and monitor the responses to these reports. The Quality and Risk Committees also had to present at the bi-monthly Trust Governance Committee, and more recently, to provide a summary of actions taken for the quarterly "Incidents Update" bulletin so that learning was disseminated across the Trust.

Source: National Audit Office

Patient falls are more routinely reported than medication errors or adverse drug reactions

2.23 All trusts have a customised taxonomy for classifying incidents and there was a broad consensus amongst the different types of trusts that we surveyed as to the types of incidents most frequently reported. Patient injury, such as slips, trips and falls being most common (**Figure 12**).

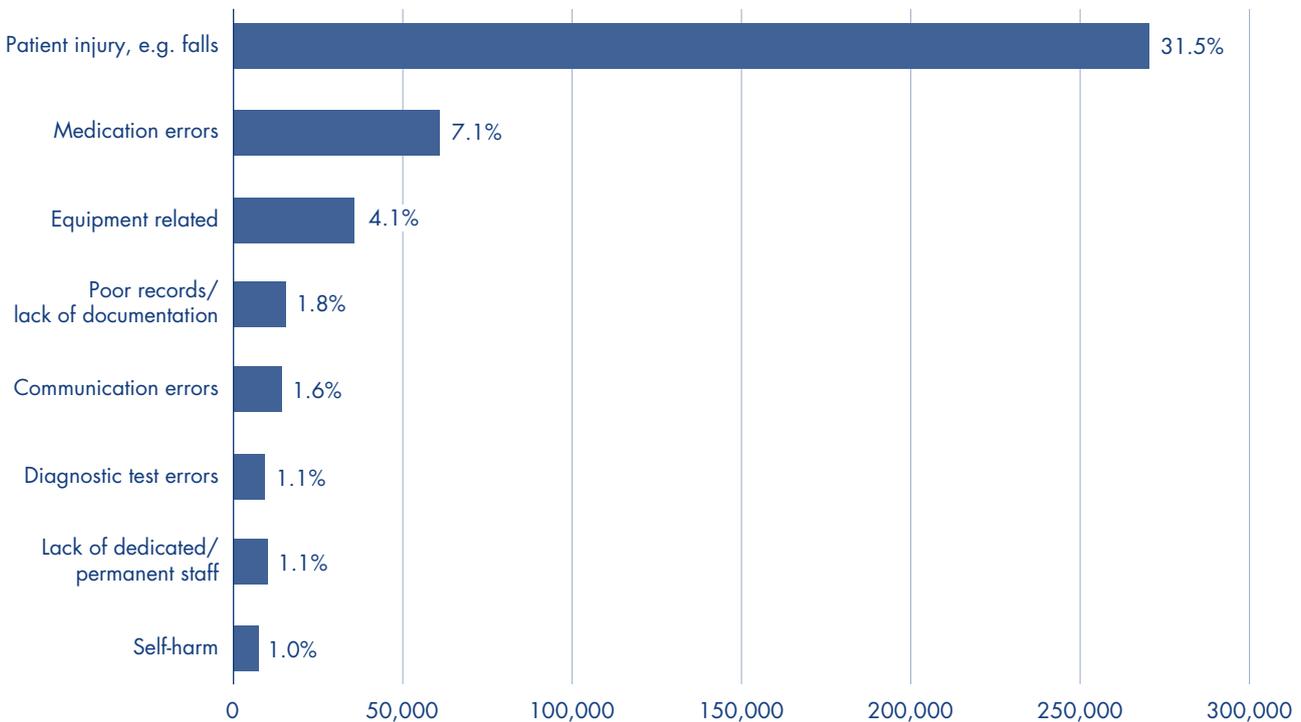
2.24 Trusts can take steps to minimise risks, but some errors can never be fully eliminated from healthcare (**Figure 13**). For example, on wards where rehabilitation is an important part of recovery for elderly and vulnerable patients, it is difficult to eliminate all risk of them falling. In contrast, evidence indicates that automated processes reduce errors, for example computerised prescribing systems remove opportunities for documentation error (**Illustrative example 4**).

In 2000 *An organisation with a memory* identified weaknesses in the plethora of incident reporting systems used in the NHS

2.25 Traditionally external regulators, such as clinicians' regulatory bodies and the Royal Colleges, and professional bodies have inspected and investigated when there were concerns about the safety of patients. For many years there have been National Confidential Enquiries into maternal death, perioperative death, stillbirths and infant death, and suicides and homicide by people with mental illness. There are also a number of long standing, voluntary reporting systems to collect data and encourage learning on specific types of patient safety incidents. For example, the Adverse Incident Reporting System for medical devices and the Yellow Card Scheme for routine monitoring of medicines safety.

12 Frequency of incidents by type

Patient injuries are the most frequent types of reported patient safety incident.



Source: National Audit Office survey of acute, ambulance and mental health trusts 2004

NOTE

Based on NHS data for 2003-2004. Accident and emergency attendances: 16.5 million; Finished consultant episodes: 13 million; Patient journeys by ambulances: 18 million.

13 Perceived preventability of patient safety incidents

Staff perceive it is easier to reduce some types of patient safety incidents, especially if resources are limited.

| | | | | |
|------------------------------|---|------------------------|--|------------------------------|
| | | High frequency | | |
| | | Patient falls | Medication errors | |
| Perceived low preventability | Use of temporary staff/operating below complement | | Communication failure Missing records | Perceived low preventability |
| | | Adverse drug reactions | | |
| | | Self harm | | |
| | | Low frequency | | |

Source: National Audit Office literature review and visits to acute, ambulance and mental health trusts 2005

ILLUSTRATIVE EXAMPLES 4

Using automated processes to reduce errors

Aintree Hospitals NHS Trust has piloted and will be rolling out an automated patient identification system to reduce prescribing errors based on incorrect patient identification. The system uses a bar-coded wrist band, with the same bar code attached to all test results and observation notes. The pilot proved it was a cost-saving measure for the trust.

Dartford and Gravesham NHS Trust installed an automated dispensing robot in July 2004 as a risk reduction initiative. The automated dispenser has helped reduce dispensing picking errors and so has enhanced patient safety. The robot has also decreased dispensing turnaround times, improving patient throughput. As a result of the change, the pharmacy department has observed a reduction in picking errors, as well as an improvement in the working environment for dispensing staff.

Other industries successful use of simulators to teach skills that are difficult to acquire by traditional educational methods encouraged Barts and the London NHS Trust to use a clinical medicine simulator for training. The Trust has developed a one-day multidisciplinary emergency obstetric training course in which anaesthetists, obstetricians and midwives use a lifelike manikin that artificially duplicates conditions without risk to patients.

Source: National Audit Office survey of acute, ambulance and mental health trusts 2004

2.26 From 1996 under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (1995), trusts have been statutorily obliged to report to the Health and Safety Executive any accidents resulting in the death, serious injury or incapacitation for more than three days. Also in 1996 the four United Kingdom blood services funded a scheme, established by a professionally led group known as SHOT, to collect information on serious hazards of transfusion. Since 1997, the Department has established other arm's length organisations to monitor and review trusts performance on various aspects of patient safety. For example, NHS Estates operated a defects and failures reporting system (in April 2005 responsibility transferred to the Department).

2.27 By the time of the Chief Medical Officer's review¹ a wide range of reporting systems were in use, but they were fragmented and compliance with reporting was still patchy. His report concluded that there were several systematic weaknesses in data collection including:

- no consensus of what to report;
- different and potentially conflicting views on the purpose of patient safety incident reporting systems; and
- no proper linkages between reporting systems.

An organisation with a memory proposed a single focal point for information on patient safety incidents but this has not been achieved

2.28 *An organisation with a memory*¹ recommended that a direct, confidential, but not anonymous, national reporting scheme be introduced. *Building a safer NHS for patients*³ acknowledged the good work that the NHS had done to encourage local reporting, but identified a need for a mandatory, national reporting system for patient safety incidents and near misses which would be implemented and operated by a new independent body, the National Patient Safety Agency.

2.29 The aim was that the system would “capture information from a wide variety of sources in order to detect national patterns, clusters or trends that could reduce risk or prevent the recurrence of incidents in the future”. The Department recognised that in establishing the National Patient Safety Agency to implement and operate the system, the same information on particular patient safety incidents would still need to be reported to a number of organisations. And since then other reporting mechanisms have also been introduced.

2.30 Given this complex reporting environment and the different maturity of systems, the National Patient Safety Agency aimed to reduce the administrative burden on front line staff by exploring whether it could integrate reporting of medical device incidents to the Medicines and Healthcare products Regulatory Agency with its own National Reporting and Learning System. However, during the testing and development phase of the project, it became clear the National Reporting and Learning System could not capture the detailed statutory data required by the Medicines and Healthcare products Regulatory Agency. As there has been no integration of reporting forms, the National Reporting and Learning System added to the list of organisations to which trusts were already required to report and trusts still face an extremely complex system of reporting and investigation.

Figure 14 overleaf shows the main national reporting systems, but around 30 routes still remain.

The national reporting scheme was rolled out two years later than originally planned

2.31 *Building a safer NHS for patients*³ proposed a new national reporting system for learning and envisaged that by December 2001, 60 per cent of trusts would be able to provide information to the system and that by the end of 2002 all NHS trusts, and a significant proportion of primary care trusts, would be providing information to the system. The system was envisaged as being:

- mandatory for individuals and organisations;
- confidential, but open and accessible;
- generally blame free and independent;
- simple to use but comprehensive in coverage and data collection; and
- allow systems learning and change at local and national levels.

Healthcare organisations in other countries, having compared the merits of anonymous and confidential reporting, have generally opted for confidential reporting (Appendix 4). Other industries have also opted for confidential and not anonymous reporting systems (Appendix 3). Over time, as the aviation industry and some hospitals in the United States of America have embedded their systems, they have moved towards an open system of reporting.

2.32 Following publication of *Building a safer NHS for patients*³ (and prior to the formation of the National Patient Safety Agency in July 2001) the Department conducted an Official Journal of the European Communities procurement exercise to establish a pilot project for the national reporting system for learning. This resulted in the Australian Patient Safety Foundation being awarded a contract to develop software for a central repository and Safecode (United Kingdom supplier of risk management systems to trusts) being engaged to work with the Australian Patient Safety Foundation to develop software to allow patient safety incident data (both the details of the incident and root cause analysis) to be extracted from local reporting systems. The pilot commenced in September 2001 in 28 trusts; an interim report was published in April 2002 and a final report in June 2002.

2.33 The report on the pilot concluded that it had been successful in identifying implications for the implementation of a national reporting system for learning across the NHS, although trusts had some difficulties capturing the root cause analysis data. The National Patient Safety Agency considered that the roll out of the pilot would be neither optimal nor cost effective due to the complexity of data extraction and data mapping problems. It therefore developed a Business Case with options ranging from “Do Nothing” to an in-house developed computerised national reporting and learning system. This latter option, with a revised, phased, implementation timetable between summer 2003 and December 2004, was subsequently agreed by the Department and approved by the Treasury in February 2003 (subject to close scrutiny of the e-Form integration with local risk management systems and the carrying out of peer reviews as suggested by the Office of Government Commerce).ⁱ

2.34 The approved option was to collect comprehensive data on patient safety incidents in NHS trusts and identify national trends in incidents, from which the National Patient Safety Agency could develop practical solutions for application across all local organisations. The National Reporting and Learning System either extracts information directly from trusts’ own incident reporting systems, which is then de-identified, or collects information from an anonymous electronic reporting form (e-Form). The cost in the business case was £9.4 million over seven years. As at March 2005, £5.5 million had been spent from a revised lifetime budget of £10.4 million (June 2004).

2.35 The National Patient Safety Agency’s decision to devise an anonymous reporting e-Form was based on the belief that assurances of confidentiality would not be enough to encourage clinicians too frightened to report and that there was a need for a safety net. Experience, at trusts where both anonymous and confidential systems work in parallel, has showed that less than ten per cent of all reported incidents are submitted anonymously. Some trusts told us that the potential for incidents to by-pass their own reporting systems would in their view undermine the progress they had made in establishing an open and fair culture.

2.36 The National Patient Safety Agency believe the initial indications are that the e-reporting system will be a rich source of information for learning. Ninety-four per cent of the 108 reports received between September 2004 and March 2005 had the agreement of the reporter to share the information with the trust involved. Although still early, 13 per cent of reports are from medical staff who generally may be less likely to report incidents locally.

2.37 *Building a safer NHS for patients*³ stated that the data requirements at local and national levels are different. Trusts need to know who reported the incident, to ensure no misinterpretation and to validate the information. In contrast, national reporting systems gather information about what, where, when, how and why things are likely to go wrong, what action is taken, the impact of the incident and what could have been done to prevent it, rather than identify the people involved. The majority of the data captured by the National Reporting and Learning System has come from local incident reporting systems and all trusts told us that it had already been analysed to identify learning. Ninety-nine per cent provided examples of such learning. Therefore the National Patient Safety Agency could have collected aggregate information on commonly occurring incidents that trusts knew about and used it to promulgate learning nationally, whilst focusing on the collection of information on less frequent incidents.

2.38 *An organisation with a memory*¹ envisaged the national collection of certain categories of data and *Building a safer NHS for patients*³ that definitions of incidents should gradually move to internationally agreed standards. To meet its objective of identifying and disseminating patient safety learning the National Patient Safety Agency decided not to limit its dataset and consequently the National Reporting and Learning System receives data on all incidents, regardless of their potential for national learning. And despite the existence of well developed international incident classification, the National Patient Safety Agency decided to define its own taxonomy for national reporting and produce tailored versions for use in nine different healthcare settings. However, reporting fields, which identify the contributory factors to the incident, are optional, and compliance is variable, even though the learning of lessons is most likely to come from this information.

ⁱ As the focus of study is on reporting and learning to improve patient safety an audit of the procurement and implementation of the National Reporting and Learning System was out-with the scope of this study – the references herein are used to demonstrate the reason for the changes to the implementation timetable and the delay in the opportunity for national reporting and learning.

14 Organisations involved in collecting reports on patient safety incidents and near misses and encouraging learning from these incidents

There is duplication in the reporting and investigation of patient safety incidents.

| | Trust incident reporting system (plus close-call) | Medicines and Healthcare products Regulatory Agency | Health Protection Agency | NHS Litigation Authority | NHS Estates ¹ | National Patient Safety Agency | Health and Safety Executive |
|----------------------------------|---|---|--------------------------|--------------------------|--------------------------|--------------------------------|-----------------------------|
| | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| | ? | ? | ? | ? | ? | | ? |
| | G | G | G | G | G | G | G |
| | ! | ! | | ! | ! | ! | |
| Patient injury | ● | ● | | 3 | ● | ● | ● |
| Adverse drug reactions | ● | ● | | 3 | | ● | |
| Equipment failure or malfunction | ● | ● | | | | ● | |
| Blood transfusion errors | ● | 4 | | 3 | | ● | |
| Communicable disease outbreaks | ● | ● | ● | 3 | | ● | ● |
| Suicides | ● | 5 | | | | ● | |
| Violence and aggression | ● | ● | | | | ● | ● |
| Absconson | ● | | | | | ● | |
| Unexpected death | ● | ● | | 3 | | ● | |
| Key | ✓ Receive reports | ? | | G | | ! | |
| | ● Required to be reported | ● Depends on underlying cause and severity | | | | | |

Source: National Audit Office

NOTES

- 1 The Department has now taken over NHS Estates responsibilities for the health and safety and environmental reporting.
- 2 Only for patients detained under the Mental Health Act.
- 3 Will only receive reports, conduct investigations, issue guidelines and alerts if there is significant risk or a claim has been received.
- 4 From November 2005 the Medicines and Healthcare products Regulatory Agency assumes responsibility for Haemovigilance. The new system will provide a single data entry point for Medicines and Healthcare products Regulatory Agency and Serious Hazards Of Transfusion reports.
- 5 Data on those incidents involving licensed medicines or where a medical device is involved and a device fault needs to be ruled out.

| Serious Hazards of Transfusion | Mental Health Act Commissioners ² | Police | Coroner |
|--------------------------------|--|------------------|---------|
| ✓ | ✓ ? | ✓ ? | ✓ ? |
| ● | | ● ● | |
| | ● ● | ● ● ● ● | ● ● |



2.39 The full roll out of the National Reporting and Learning System commenced in September 2004, nearly two years later than the headline target in *Building a safer NHS for patients*³ (see paragraph 2.28). By end of December 2004, all trusts had the technology to link to the National Reporting and Learning System but not all had finished mapping their data sets. The revised target for all trusts to begin sending their data to the System was June 2005. By August 2005, at least 35 trusts still had not submitted any data to the National Reporting and Learning System.

2.40 Trusts have invested considerable time and resources to develop individual data mapping schemes in order to comply with, and to send data to, the National Reporting and Learning System (Appendix 5). Our survey in 2005 showed that 12 per cent of trusts had no problems in linking to the National Reporting and Learning System. Eighty-two per cent of trusts reported problems, of which 36 trusts said these were major, and these were due to time and resource issues (64 per cent and 46 per cent respectively) and software compatibility issues (39 per cent). We found that there was a significant relationship^j between the manufacturer of the trust's incident reporting system and the ease with which the local and national data sets were integrated.

The Department focused on improving levels of reporting and learning but evidence on progress against the specified high risk areas is patchy

2.41 The Department identified target reductions for four specific high risk areas which, despite a body of evidence on them, had not been addressed satisfactorily (Figure 15).

j Using a Chi-Squared test ($\chi^2 = 43.09$, $df=22$, $p= 0.05$).

15 Progress on the four specific targets identified in *An organisation with a memory*

| Risk | Target | Date | Position at July 2005 | Position at August 2005 (Report from NHS Trusts) |
|--|---|---|--|--|
| Fatal incidents occur if drugs are incorrectly administered | Reduce to zero the number of patients dying or being paralysed by mal-administered spinal injections | end 2001  | In April 2001, the Department published a report on the prevention of intrathecal medication errors ²¹ and a report on the adverse incident at Queen's Medical Centre ²² which identified serious systems failures. As a result all trusts that administered this form of chemotherapy were required to review their procedures and make sure that they were fully compliant with the National Guidance on the Safe Administration of Intrathecal Chemotherapy by 31st December 2001. Trusts did not achieve full compliance until summer 2003 after interventions by the regional Directors of Public Health, the Chief Medical Officer and a health minister. The Department issued revised guidance in October 2003, which trusts finally self-reported compliance by January 2005. Although no further cases of mal-administered vincristine have been reported in England since 2000, a national cancer peer review programme, which started in November 2004, found nine out of 19 trusts reviewed by April 2005 were not satisfactorily compliant, and three of them had reported compliance. This peer review is to continue over the next 18 months and the Department is working with strategic health authorities to help ensure that full implementation of guidance is maintained. In collaboration with the NHS Purchasing and Supplies Agency, the National Patient Safety Agency, and the Medicines and Healthcare products Regulatory Agency, the Department has set up a parallel project to identify design solutions to help prevent cross connection errors during spinal injection procedures. | Only acute NHS trusts administer spinal injections. All trusts stated that there had been no incidents of fatalities from mal-administered injections. Thirteen stated that they had put new policies and procedures into place, and other trusts had improved training and guidance. |
| High volume and cost of clinical negligence claims against the NHS | Reduce by 25 per cent the number of instances of negligent harm in the field of obstetrics and gynaecology which result in litigation | end 2005  | Around 50 per cent of the NHS litigation bill relates to claims arising from childbirth and achieving the target reduction of 25 per cent by 2005 could save as much as £50 million a year. Evidence from the NHS Litigation Authority suggests that the number of claims notified (by year of formal notification) have reduced by around 13 per cent from 1,210 in 2001-02 to 1,051 in 2003-04. Projecting the trend across three years, to 2004-05, suggests a 20 per cent reduction compared to the 25 per cent target. Despite this improvement in relation to claims other research suggest that there are some concerns about maternity services which remain. For example, the Healthcare Commission's investigations into maternity services have revealed serious failings in a number of common risk areas: risk management, working relationships, training and supervision, the environment and staff shortages. ^{7,8} The National Patient Safety Agency's analysis of reports to the National Reporting and Learning System shows treatment incidents are most common in obstetrics and gynaecology. It will be developing solutions for women known to be at risk of maternal death or serious maternal morbidity where appropriate. Additionally, it will be reviewing system factors leading to operative complications during gynaecological surgery. | This target predominantly applied to acute NHS trusts. Out of the acute trusts that answered this question, just over half (55 per cent) could not state that they had achieved this target. However, the main reason cited was that previous under-reporting of incidents and the often substantial delay between incidents and the onset of litigation made progress towards this target impossible to assess. |

15 Progress on the four specific targets identified in *An organisation with a memory* (continued)

| Risk | Target | Date | Position at July 2005 | Position at August 2005 (Report from NHS Trusts) |
|---|--|---|--|---|
| Mistaken administration, prescribing or dispensing of drugs | Reduce by 40 per cent the number of serious errors in the use of prescribed drugs | end 2005  | Prescribing medicine is the most frequent treatment provided for patients in the NHS (200 million a year in hospitals alone) but incidents of medication error are still seriously under-reported (paragraph 2.12). The Medicines and Healthcare products Regulatory Agency only receives reports on drug error as the result of adverse reactions to the medication and because of low reporting rates and the many barriers to reporting medication errors, the true extent of serious errors in the use of prescribed drugs is unknown. The Chief Pharmaceutical Officer's 2004 report ²³ highlighted drugs and clinical settings that carry particular risks and identified models of good practice to reduce risk in the NHS. The National Patient Safety Agency has a programme of improving medication safety that has included patient safety alerts on potassium chloride and methotrexate. The Department and the Design Council jointly commissioned a report ²⁴ to produce practical recommendations for the NHS to improve patient safety through better procurement and design of packaging for medicines and medical devices. The National Patient Safety Agency and the Medicines and Healthcare products Regulatory Agency have been working with drugs manufacturers in the United Kingdom to improve labelling. | Action regarding this target was mainly taken by acute and mental health trusts, with over 77 per cent of ambulance trusts stating that it did not apply to them. Of those trusts that stated that this target was applicable to them, only 20 per cent answered that they had met this target. Many trusts stated that this target was difficult to assess, often due to a lack of baseline data. The most common responses after this were that trusts were currently in the process of putting action plans into place, or that there were very few errors in the first place, making a 40 per cent reduction difficult. |
| Fatalities occur if environmental risks have not been removed from mental health services | Reduce to zero the number of suicides by mental health inpatients as a result of hanging from non-collapsible bed or shower curtain rails on wards | March 2002  | Six trusts failed to meet the deadline but by the end of May 2002 all trusts were reporting compliance. Overall, there has been a substantial fall in the number of inpatient suicides from 195 in 2000 to 156 in 2002 (20 per cent reduction). However, the National Confidential Inquiry into Suicide and Homicide by People with Mental Illness subsequently identified that suicides by hanging from non-collapsible rails had not been completely eliminated (two cases may have occurred since 2002 but investigations are still ongoing). NHS Estates issued a further alert in November 2004 but four trusts are still working towards the replacement of these fittings. ¹⁰ | All trusts that responded that they had had no suicides as a result of hanging from non-collapsible rails. Ten trusts stated that they currently have work underway to comply. |

 Not achieved  Progress made, but unclear if target will be met  Achieved

Source: National Audit Office

PART THREE

Systems for analysing and sharing lessons learned are in place but are largely under-used



3.1 *An organisation with a memory*¹ recognised that little systematic learning from patient safety incidents and service failures had taken place in the NHS and in most other countries. Designers, builders and those responsible for developing clinical procedures and protocols can unintentionally embed pre-conditions in the NHS which can cause harm to patients. While human error is often the most easily identifiable element in many serious patient safety incidents, it is only part of the explanation. More often than not the central issue is systemic: not who made the error but how and why the safety mechanisms failed and what helped to create the conditions in which the mistake occurred. *Building a safer NHS for patients*³ therefore focused on the action, both nationally and locally, necessary to establish a system that ensures lessons from adverse events in one locality are learned across the whole NHS.

3.2 This Part of the report examines the action taken by NHS trusts, the Department and other NHS organisations to improve patient safety through organisational learning. In particular through the use of information on patient safety incidents from investigations and other sources of data.

Good foundations have been laid for improving the quality and relevance of local incident investigations

All trusts now undertake in-depth analysis of incidents but capacity problems have limited the number conducted

3.3 We found 59 per cent of trusts had been undertaking in-depth analysis of incidents to learn lesson for at least two years, with eight per cent of those having conducted analysis for more than seven years. We found that there was no systematic pattern as to how trusts determined what incidents required a detailed investigation. Eighty per cent told us that they based their decisions on a number of factors, including the severity of impact on the patient, frequency of incident type and potential risk to the trust or the patient. Our visits revealed the idiosyncratic ways some trusts decide which incidents require analysis. One trust told us that they assess the 'ooo-er factor' of an incident – that is, whether an incident is serious, potentially serious or unusual and therefore may warrant further investigation.

3.4 Forty per cent of trusts were following the guidance on the need to carry out full analysis of all severe harm and death category incidents. Nine trusts told us that staff reported 50 or more of this type of incident during 2003-04 and all but two trusts had investigated more than five per cent of these incidents. One of the reasons given for the lower number of investigations was that incidents were mis-graded to draw attention to a minor incident – one trust with a serious incident hotline told us it was used to report a doctor was missing, when he was not answering his bleep. Whilst most trusts raised the cost of in-depth investigations as a deterrent, few knew the actual cost.

3.5 There are wide variations in the way that trusts have developed their capacity to conduct these investigations. Whilst some trusts have as many as 17 trained staff per hundred staff members, others have no-one trained to do in-depth analysis. One explanation for this variability is that in some trusts, a small number of staff act as facilitators for others to conduct the investigation, while in other trusts a large number of staff are trained to carry out investigations but will rarely be called upon to do so.

The National Patient Safety Agency's tools have contributed to the improvement in the quality of investigations but more needs to be done to embed the concept and the lessons

3.6 The National Patient Safety Agency introduced the root cause analysis toolkit to strengthen in-depth investigations and aid consistency. Trusts uptake of the toolkit was high, with 76 per cent of trusts in our 2004 survey having actively encouraged its use. Sixty per cent of trusts changed their approach to in-depth investigations as a result of the work of the National Patient Safety Agency and of those, 23 per cent considered that they now have a better quality of investigation and 17 per cent had a more structured or consistent approach to an investigation. However, its use was limited in 37 per cent of trusts owing to time constraints.

3.7 Improving trusts' patient safety standards depends on the quality of the recommendations arising from the root cause analysis. Strategic health authorities told us that the quality of recommendations made by trusts was still very variable. In North East London they are addressing this through further programmes of training for preparation of reports from in-depth investigations. Staff also reported difficulties in getting recommendations actioned by organisations outside their own trust.

3.8 As yet the National Patient Safety Agency does not collect information from trusts' root cause analyses. The National Patient Safety Agency is scoping the possible options for collecting information on trusts' root cause analysis which will enable it to identify national issues and promulgate lessons learned.

3.9 Since 2002, the National Patient Safety Agency and the Royal Colleges have jointly appointed eleven national Clinical Specialty Advisors, representing most medical specialties. These clinicians support its work in identifying key patient safety priorities within and across the specialties and provide feedback to the colleges and other organisations, creating a two-way flow of information. Some Clinical Specialty Advisors have established External Multi-Professional Reference Groups, to validate work and recommendations, and to undertake a holistic analysis of the root causes of key patient safety incidents. Their intention is to help develop workable solutions for these incidents (**Illustrative example 5**).

ILLUSTRATIVE EXAMPLE 5

In September 2003, the Clinical Specialty Advisor in Anaesthesia took up post on a one-day per week secondment to contribute and co-ordinate input to the National Patient Safety Agency about anaesthetic related issues.

The Clinical Specialty Advisor recognises that there is no shortage of issues to be pursued, even within a specialty acknowledged to be a leader in aspects of safe practice. He has facilitated a risk assessment exercise of the whole anaesthetic process to look at the journey of an adult patient undergoing elective general surgery, from referral by general practitioner to the conclusion of anaesthesia. From this work, key areas of potential risk and patient harm have been identified, and these will form part of the initial agenda for the specialty reference group.

Other projects of note involving the National Patient Safety Agency in anaesthesia are:

- the production of a report on Blocked Anaesthetic Tubing and the subsequent revision of the Association of Anaesthetists' anaesthetic machine checklist, following the tragic accidental death of a child when an anaesthetic circuit became blocked;
- efforts to design out the risks of inadvertent spinal injections; and
- work with manufacturers and clinicians to reduce the mis-administration of drugs through colour-coded labelling of ampoules and their boxes.

Source: National Audit Office

Trusts have identified and implemented lessons from incidents but few knew of the cost-effectiveness of the interventions

3.10 In their responses to our survey, all but three trusts provided at least one example of a lesson learnt or a change in practice introduced following a patient safety incident. The lessons or changes were mostly derived from incident reports or an analysis of underlying causes of an incident. In some trusts, complaints and claims were logged on the same system as patient safety incidents which enabled them to obtain a more complete picture of errors and enhanced their capacity to learn (**Figure 16 overleaf**).

3.11 We found trusts do not routinely produce cost data on the impact of incidents or evaluations of the changes made to processes or the environment. Only three trusts had evaluated the costs incurred as a result of all incidents. The figures estimated range from £88,000 to £400,000 per year. Six trusts calculated the cost of specific patient safety incidents (for example, a fractured neck of femur due to a hospital-based fall costs £10,000 and inadequate patient information or clinical details on diagnostic requests costs approximately £1 million per year). Fourteen trusts have undertaken analysis of savings made by changes to improve patient safety, though only three included the investment costs (**Case examples 6 below and 7 on page 46**).

CASE EXAMPLE 6

The Royal Marsden NHS Foundation Trust

Situation: Many patients at the Royal Marsden require irradiated blood and blood products to prevent Transfusion Associated Graft Versus Host Disease, a serious and often fatal disease that occurs when there are histocompatibility differences between donated cells and the recipients cells, usually associated with bone marrow transplant. Transfusion Associated Graft Versus Host Disease has a high mortality rate (90-100 per cent). To ensure quality control, the National Blood Service irradiates blood products for healthcare providers using dedicated equipment. There is a premium charge for each bag of blood, platelets or white cells irradiated (currently £6.39 per bag).

Until 2001, the Trust ordered both irradiated and non-irradiated blood and blood products and the following checks were in place to ensure that patients who required irradiated blood were given it:

- training in safe blood transfusion practice was given to all new nurses and doctors coming to the Trust;
- the Blood Transfusion policy was posted on the hospital intranet and available to all nurses, doctors and clinical staff;
- a quick reference guide for the busy clinician detailing which patients must receive irradiated blood products was printed on the back of the blood cross match;
- the Royal Marsden Manual of Clinical Nursing procedures contained evidence and information on Transfusion Associated Graft Versus Host Disease; and
- 'Radsure' labels that change colour following irradiation were used on blood products.

Despite these checks, in 2001, a patient in the Intensive Therapy Unit who had recently had a bone marrow transplant received a transfusion with non-irradiated platelets, and died a few weeks later.

Action: An in-depth investigation into this serious incident found the causes were multi-factorial. At the National Blood Service, a new technician was preparing the platelets and a power-cut occurred interrupting the processing, causing non-irradiated blood to be sent to the Royal Marsden. At the Royal Marsden, a new technician in the laboratory was under considerable time-pressure and instead of putting the platelets to one side when they arrived, she placed them in the agitator and carried on with another task. In the Intensive Therapy Unit the staff nurse was very busy so the sister on call for the hospital offered to get the platelets for her. Although the sister had had some blood transfusion training and would have been familiar of irradiated products, she worked in a non-haematology area. Seeing the blood technician was busy, the sister verified that the platelets were for the correct patient and took them up to the Intensive Therapy Unit. After checking with the staff nurse, the patient was given the transfusion.

The patient in question was expected to have died despite the incident, however it was decided during the investigation that as so many patients at the Sutton site of the Trust require transfusions, risks of further incidents should be reduced by the purchase of only irradiated blood products. A business case to justify the extra costs involved was put to the Trust Board (with the support of the Clinical Governance Executive Committee). Though the reasons behind the proposal were to ensure patient safety, the business case also put forward an economic argument for the purchasing of only irradiated blood products. Transfusion Associated Graft Versus Host Disease does not cause immediate death but a slow (up to three weeks), painful and therefore costly one as the patient will have to be cared for in an Intensive Therapy Unit bed, costing around £52,000. Hence, the Trust Board deemed that the extra costs of the Sutton site purchasing all irradiated blood was good value, as well as an essential patient safety measure, and thus approved the proposal.

Outcome: The Trust has been purchasing only irradiated blood and blood products for the Sutton site for over three years and there have been no further incidents of Transfusion Associated Graft Versus Host Disease.

Source: National Audit Office

16 Trusts' examples of lessons learnt as a result of in-depth investigations of patient safety incidents, trend analysis, complaints and claims and national recommendations

The top five areas for trusts to focus improvements on were problems with equipment (87 examples); medication errors (65 examples), patient falls (48 examples), poor records and lack of documentation (36 examples) and self-harm (34 examples).

The Royal Liverpool and 
Broadgreen University Hospitals
NHS Trust

The Royal Liverpool and Broadgreen University Hospitals

Issue: The quality of the hospital case notes was having an impact on the delivery of care due to poor presentation, content and maintenance of files.

Identified via: Poor availability of case notes during patient consultation was identified through reported incidents and patient complaints and claims.

Action: The Trust formed a case note committee with representatives from a wide range of occupations. A new case-note folder with 4 sections and a see-through plastic document slot on the front was introduced:

- front – tracking reminder and instructions
- section 1 – orange: all correspondence, including interim discharge notes and summaries, with the most recent letter uppermost
- section 2 – green: referral letter and clinical medical notes in chronological order, divided into specialties, and pink: consent forms and do not attempt resuscitation cards
- section 3 – blue: results of all investigations, divided according to specialty
- section 4 – grey: the remaining notes and yellow: therapy records.

The outer-cover was designed to have colour coded margins for the benefit of staff filing the records. The Medical Records Managers made presentations to Trust staff to educate them about the new system. The Trust financed the introduction of computer scanning to replace the microfiling of case notes. A three month supply was ordered and following the launch of the system the committee continued to gather comments from staff so that the system can be adjusted as necessary. The hospital is also improving the quality of existing records by refurbishing and replacing old case note folders.

Outcome: Staff feel case notes easier to use as the presentation of information has improved and there has been a reduction in the number of bulky records. Retrieval has been improved through the use of scanned notes. The case note committee will be looking at filing and re-housing case notes in the future.

Moorfields Eye Hospital 
NHS Foundation Trust

Moorfields Eye Hospital NHS Foundation Trust

Description of the problem – Staff reported falls by patients in outpatient clinics. Trend analysis revealed that there was a high level of low consequence incidents.

How the problem was addressed – Staff were made aware of how to minimise the potential for slips and falls by elderly patients. The Board made a one-off investment of £15,000 to replace all patient stools in waiting areas with chairs with arms and back support.

Outcome of actions taken – The risk of recurrence has been significantly reduced. There were no patient falls from stools within outpatient clinics in the eight months after the chairs were introduced. A cost benefit analysis of the replacement furniture revealed long term savings on the cost of claims as the result of patient falls.

Source: National Audit Office Survey of Acute, Ambulance and MH Trusts, 2004

NOTE

Two hundred and sixty-four trusts submitted a total of 749 examples of lessons learned.



Westcountry Ambulance Services

Description of the problem: An adverse incident involving the incorrect use of a First Response Emergency Defibrillator was reported in accordance with the Trust's policy. There was no adverse effect on the outcome for the patient.

How the problem was found: Following submission of an adverse incident a thorough and in depth investigation took place and the findings presented to a Serious Untoward Incident Panel. The investigation identified that, although the employee had received training in the use of defibrillators, he had not been trained in the use of the specific defibrillator in question. The Panel considered the Trust's strategies, systems, processes, procedures, standards and working arrangements; the sufficiency of resources; the adequacy of risk assessments and control systems; and competency issues. It recommended that the Trust undertake significant actions to manage risk of recurrence.

Actions taken:

- 1 The supplier of the defibrillator delivered training covering topics such as controls and visuals, manual operation and safety notices and maintenance. The Trust then assigned a fully trained and competent 'device expert' to each Assistant Divisional Officer zone. Area Training Officers were also trained.
- 2 The Trust provided training leads to facilitate instruction for all staff in accordance with the formal programme and support to the 'experts' to ensure that the training was completed. The Director of Operations tasked each Assistant Divisional Officer with ensuring compliance.
- 3 The Trust introduced a formal process for individual members of staff to raise competency issues and identify training needs.

Outcome of actions taken: Competent staff now use the defibrillator which means the device is used correctly and safely. The Trust expects that this will lead to improved patient outcomes. Learning from the incident has been shared with other ambulance trusts via a national forum and to date over 30 staff have used the procedure to access additional training, information, instruction regarding medical devices. A full evaluation of the system is due to take place next year.



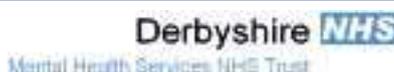
Liverpool Women's hospital

Situation – Lack of robust multi-disciplinary training and development in the management of obstetric emergencies and the interpretation of cardiocographs.

How it was identified – The gaps were highlighted through the Trust system of formal review and root cause analysis for serious patient safety incidents. The recommendations from the Confidential Enquiries into Maternal Deaths and Stillbirths and Deaths in Infancy (4th and 7th annual reports) drew attention to the need for robust forward planning. Additionally the guidance and requirements from the Clinical Negligence Scheme for Trusts informed the Trust.

Action – In partnership with medical staff and midwives, the Trust developed a robust twelve month training plan. All staff were informed of the plan and this enabled training places to be booked in advance to ensure operational areas were not depleted of essential staff. All information is recorded onto the training database, which enables managers to flag up when staff are due training updates.

Outcome: Training and development skills for dealing with obstetric emergencies and interpretation of cardiocographs is now part of the culture of the Trust. This is reflected in the Trust achieving Clinical Negligence Scheme for Trusts Maternity Standard Level 3 in January 2005. Staff also feel that there is greater cohesion in working relations within the multi-disciplinary team. The Trust will be auditing the training to determine the impact it has had on practice within the maternity unit.



Problem: Numerous ligature points on acute wards resulting in a high risk of patients attempting to hang themselves.

How it was identified: A serious patient safety incident occurred and NHS Estates issued a directive shortly afterwards.

Action taken: Ligature points steering group set up which developed an action plan and secured annual capital funding to progress work on reducing the number of ligature points in the wards.

Outcome of actions taken: Analysis of incidents reported shows that there are few occasions when in-patients have been able to use a ligature point. When they have tried to harm themselves, the safety solutions planned by the steering group have worked, resulting no injury or minor injury to the patient.

CASE EXAMPLE 7

Isle of Wight Healthcare NHS Trust

Situation: Research shows that people diagnosed with borderline personality disorder take up an unduly high percentage of resources, often because they drop out and re-engage or stay with treatment services for years. High rates of self-harm and suicidal behaviour can result in frequent ambulance call-outs and attendances at accident and emergency and admissions to medical and acute psychiatric services.

The Isle of Wight Healthcare NHS Trust noticed an increasing trend in the number of their service users diagnosed with borderline personality disorder. The majority of patients remained on the island with support from community and in-patient services, as placements in specialist units on the mainland were expensive, difficult to secure and required the patient to leave behind his or her social network. However, staff felt local services were not necessarily well equipped to help this client group.

Action: In order to address clinical and financial concerns the Trust explored options for a specialist personality disorder service. Preliminary research shows that treatment combining cognitive and behavioural strategies with validation and acceptance strategies to enhance clients' commitment to therapy, increase adaptive coping and reduce self-harm and suicidal behaviours is effective.

The Trust therefore developed the Dialectical Behaviour Therapy service. It used staff from existing social work, mental health and occupational therapy services. Therapists attended a commitment day to build motivation and they and their managers signed up to making time available for training as well as delivering the service. The Trust initially invested in training for ten therapists. Each therapist works part-time on weekly individual and group sessions for between one and three clients for a year and is available to be contacted on the telephone. Eighteen months after the project began an audit methodology to quantify the outcomes of the Dialectical Behaviour Therapy was developed.

Outcome: Managers prioritised achievements for the service as: reduced in-patient bed use, reductions in suicide and self-harm and positive effects on the trained therapists' colleagues. The therapists added improved mental health and quality of life for clients.

- In-patient bed use and accident and emergency attendance: Psychiatric in-patient bed use decreased by more than half, attendance at accident and emergency by 26 per cent and the use of the Medical Assessment Unit beds by 94 per cent. (see table below)
- Incidents of self-harm and suicidal behaviour: Clients' diary cards showed a decrease in reported self-harm (a full sample was not available). The modified Self-Harm Inventory scores revealed a similar trend, but one client who dropped out of the therapy did commit suicide a year later. Other professionals working with this client group also reported decreased incidents of self-harm and suicidal behaviour.
- Views on the impact of the service: Colleagues were generally positive about the programme and reported that the therapists were sharing useful skills. All clients agreed that the service was useful and the majority felt that the Dialectical Behaviour Therapy had helped them to change negative thought patterns or handle relationships better. However, they were concerned that there were gaps between treatment sessions and these needed to cover weekends.
- Improvements in mental health and quality of life: Results of psychometric assessment and patient surveys showed some reductions in clinical symptoms, such as depression, anxiety and dependent personality features. However, there was an increase on the hostility and borderline personality sub-scales.

| | Accident and Emergency | Medical Beds | Psychiatric Beds | Total | Average cost per patient |
|---|------------------------|----------------|------------------|-----------------|--------------------------|
| Year before Dialectical Behaviour Therapy | £3,318 ¹ | £38,602 | £248,193 | £290,113 | £20,722 |
| Year after Dialectical Behaviour Therapy | £2,449 ¹ | £2,270 | £117,916 | £122,635 | £8,760 |
| Savings | £869 | £36,332 | £130,277 | £167,478 | |

NOTES

1 does not include ambulance call-outs

2 based on ten clients who received the full therapy package and four service users who participated in the skills group

3 based on bed days and does not include treatments or community resources needed by clients

4 savings must be off-set against the initial cost of £20,000 and £30,000 in the second year. The Trust estimate that on-going costs will be £10,000 per year for training

Source: National Audit Office

3.12 Although researchers have quantified the frequency of medical errors and patient safety incidents, particularly in the United States of America, there has been little work on identifying and evaluating solutions and even less on cost-effectiveness²⁵. The estimates of the costs of patient safety incidents included in *An organisation with a memory*¹ alone suggest that most interventions and solutions would have a positive cost-benefit ratio. However few trusts have used a business case model to argue for investment in prevention. Whilst the National Patient Safety Agency plans to develop template business cases to accompany solutions, by April 2005 only one, on infusion pumps, was available to trusts.

Trusts do learn from complaints but more use could be made of this source of information

3.13 We found 91 per cent of trusts had taken steps to inform patients about how they might raise their concerns about safety, though 20 trusts did so only if the patient had already experienced a patient safety incident. All trusts had at least one route through which patients could raise issues, with four trusts operating an on-line reporting system for them.

3.14 Formal patient complaints can also be an important way of ensuring that poor or unsatisfactory outcomes of care are recognised and improvements made and they can also be the way that adverse events are first identified. Between 2001 and 2004, the Commission for Health Improvement's clinical governance reviews⁹ identified that many barriers existed to patients making complaints, and that it was rare to find formal systems that ensured that complaints would be reviewed, acted upon and the lessons disseminated across the organisation.

3.15 From July 2004 responsibility for dealing with complaints that could not be resolved satisfactorily at the local level passed to the Healthcare Commission. Since this responsibility for second stage complaints was transferred the numbers made have increased significantly (expected around 3,000 per annum, but nearly 7,000 requests to review complaints have been received in the first ten months to May 2005). As a result the Healthcare Commission has focused on handling the complaints and has not had the time or resources to promulgate wider lessons. The Healthcare Commission is expected to analyse and identify common issues and early findings indicate²⁶:

- 60 per cent of referrals in a month are from the acute sector, with around four per cent about mental health services and one per cent about ambulance trusts; and
- complaints are mainly about: poor communication with patients and relatives, poor clinical practice, unsatisfactory patient experience, poor staff attitude and poor complaints handling.

3.16 Sixty-eight per cent of trusts reported that they had involved patients in identifying priorities and 58 per cent in developing solutions through patient forums, representation on trust boards and via complaints and claims. This was in contrast to the YouGov poll¹³ where just 30 per cent of senior managers reported that patients were actively involved in activities to improve patient safety. And in our survey of patients, six per cent said they were consulted about how the safety incident should be prevented from happening to someone else and nine per cent were told what the hospital was going to do to prevent a similar incident.

3.17 A third of trusts stated their Patient Advice and Liaison Service was the most effective way patients could raise their concerns about patient safety issues, while a quarter felt that complaint forms were most effective. In the trusts we visited the Patient Advice and Liaison Service had facilitated open communication about concerns between patients and staff and in many cases prevented these issues from escalating into a formal complaint or a patient safety incident (**Case example 8**). In most cases the Patient Advice and Liaison Service manager made a report to the committee responsible for patient safety which was followed by a review by the trust board.

Clinical audit is still under utilised as a learning tool

3.18 Clinical audit is an important component of clinical governance which helps to identify deviations from standard care practices, including clinical incidents, and has many opportunities for learning. The Commission for Health Improvement concluded in 2004 that NHS trusts were beginning to establish clinical audit strategies based on the National Institute of Clinical Excellence guidance and National Service Frameworks. In addition, there were positive trends in the understanding and development of clinical audit in some trusts but multi-disciplinary approaches to audit were rare and there was limited dissemination of learning⁹.

CASE EXAMPLE 8

Norfolk and Waveney Mental Health Partnership NHS Trust

Situation: *The Saving Lives: Our Healthier Nation* target has been to reduce the suicide rate by at least one fifth by 2010 and in 2002 the Trust prioritised the reduction of suicide risks. In developing an action plan, the Trust wanted to incorporate the views of the relatives of patients who had taken their own lives regarding the potential risks within the Trust's policies and procedures. The Trust organised meetings for relatives and two representatives from the Trust to talk through some of the issues surrounding the risks for service users. A group of relatives were then supported to make recommendations to the Trust aimed at reducing suicide risks.

Action: During the two meetings, the relatives proposed recommendations involving:

- patients' access to belts and shoelaces;
- availability of information for relatives/carers;
- training of unqualified staff;
- a named contact for the relatives if a patient dies; and
- a single point of entry to each ward.

These recommendations were put to the Trust Board, which agreed with them in principle but also stressed that the privacy and dignity of patients should be considered at all times.

Outcome: All these points were actioned. The Trust revised its clinical standards on Additional Observation of Patients at Risk, including the need for the documentation of the rationale for the removal/ or not of potential risks of self-harm and involving the patient and carer/relative in the decisions for the care plan. Guidance was issued to staff about involving relatives in risk assessments. The Communications of Clinical Risk policy was agreed which details when the Trust may be obliged to breach confidentiality. Unregistered staff now have training regarding physical health monitoring, in addition to the same mandatory training in basic life support as registered staff. The Trust now includes a named contact in its incident file if a patient dies. All acute in-patient wards were re-designed to ensure only one point of entry and exit and the nurses stations were moved next to the entrance for better observation. The Trust have also recently introduced a swipe card system for staff and patients in one area. This system is planned for the remaining adult acute in-patient wards. The Trust has seen a reduction in the number of in-patient deaths as a result of suicide.

Source: National Audit Office

3.19 A number of the Royal Colleges have worked with specialties, such as cardiothoracic surgery and intensive care, to implement standardised clinical audits in all relevant trusts. These provide an evidence base for evaluating clinical care and in the last two years the Royal Colleges have published the outcome for individual trusts; highlighting lessons and raising performance. From April 2004, the Healthcare Commission assumed responsibility for developing a national programme of clinical audit and for evaluating compliance.

Case example 9, illustrates the approach of one ambulance trust in using clinical audit to improve outcomes for its patients.

Trust-wide application of lessons and embedding of learning is patchy

3.20 To ensure effective organisational learning following patient safety incidents it is essential to cascade lessons learnt to the relevant staff groups and monitor their compliance with this new information. Trusts shared the examples of lessons learnt through clinical governance reports, internal risk management reports and trust-wide and departmental newsletters, but most used a combination of methods to disseminate learning, increasing the chance that the message gets through (**Figure 17 overleaf**).

3.21 The National NHS Staff Survey 2004⁶ showed that only 29 per cent of respondents felt that the different parts of their trust communicated effectively with one another. We found there were other barriers to implementing lessons learnt, though many trusts had taken action to overcome these (**Figure 18 overleaf**). There were also wide variations in the systems for embedding organisational learning. Where monitoring of lessons identified a lack of implementation, many trusts placed the issue on the risk register, facilitated discussion of the issues between the management and staff, or gave responsibility for close monitoring to a specific committee or group.

3.22 The National NHS Staff Survey⁶ also found that only 43 per cent of staff felt that their trust built strong co-operative links with other organisations. Our results also showed that sharing of best practice with external organisations was very patchy, with 63 per cent of trusts surveyed sharing learning with other local trusts, often through organised networks or the Ambulance Service Association.

CASE EXAMPLE 9

Staffordshire Ambulance Service NHS Trust

Situation: Coronary Heart Disease is the single most common cause of premature death in the United Kingdom and ambulance services deal with a significant number of patients with this disease. During cardiac arrest a lack of oxygen causes brain injury within four minutes and death will occur within twelve if no therapy is given. Therefore optimal survival depends primarily on early access to emergency medical services, early cardiopulmonary resuscitation, early defibrillation and early advanced life support.

In Staffordshire approximately 3,000 people die prematurely each year as a result of cardiac arrest and Staffordshire Ambulance Service NHS Trust has adopted a number of procedures to improve its performance in treating these patients. There is clear evidence that appropriate intervention leads to increased chances of survival and the Trust uses the Advanced Medical Priority Dispatch System, which has a high sensitivity for identifying cardiac arrest cases and allows the call-taker to give pre-arrival instructions, to maximise the assistance offered to the patient before paramedics attend the scene. Although the Department's minimum response time is eight minutes the Trust expects the first paramedic to arrive on the scene within 4 minutes and 59 seconds. The Trust has also purchased

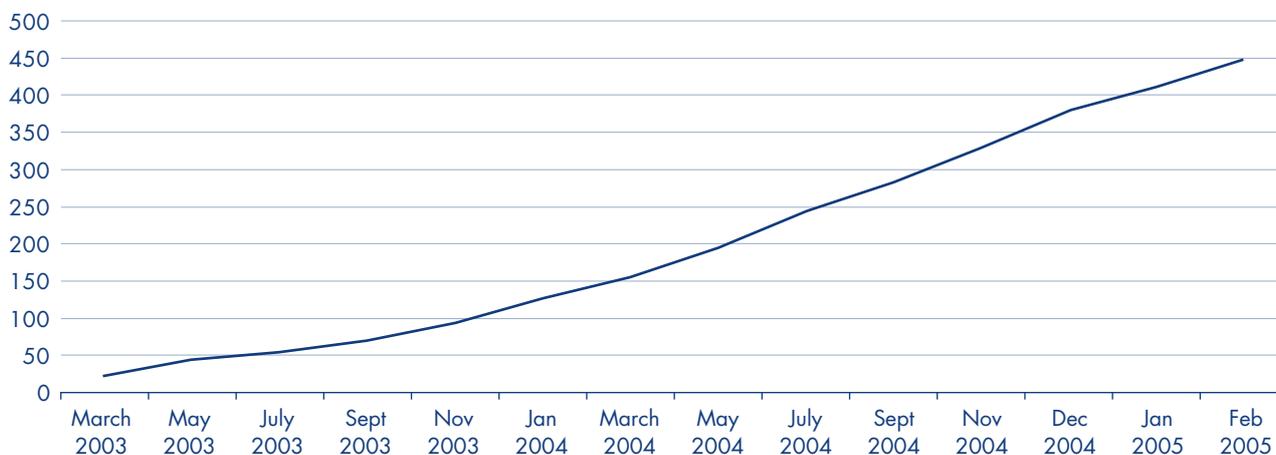
12 lead Electrocardiograms to allow pre-hospital thrombolysis to be administered and Zoll defibrillators which store clinical performance data.

Action: The Clinical Audit Department measure and audit each individual case of cardiac arrest and acute myocardial infarction attended by the Trust, using paper and electronic patient report forms. It matches the dispatch system records with the electrocardiogram and defibrillator data, such as cardiac waveforms, blood pressures, pulse oxymetry and an audio recording of the event.

Outcome: Ambulance crews reached 50 per cent of calls within 4 minutes and 59 seconds. Return of spontaneous circulation has increased from 22.99 per cent in 2002-03 to 25.69 per cent in 2003-04. The results of the audit and anonymous reporting of concerns about poor execution of chest compressions led to the Trust purchasing equipment to provide mechanical chest compression/heart massage for community paramedics to use during cardiopulmonary resuscitation. The Trust is now introducing these devices into the ambulance fleet. To ensure that patients receive the most effective treatments the Trust hopes to collaborate with acute trusts to facilitate the audit of the complete care pathway.

The number of patients receiving pre-hospital thrombolysis in Staffordshire has increased from 137 in 2003-04 to 288 in 2004-05

Cumulative number of patients thrombolysed

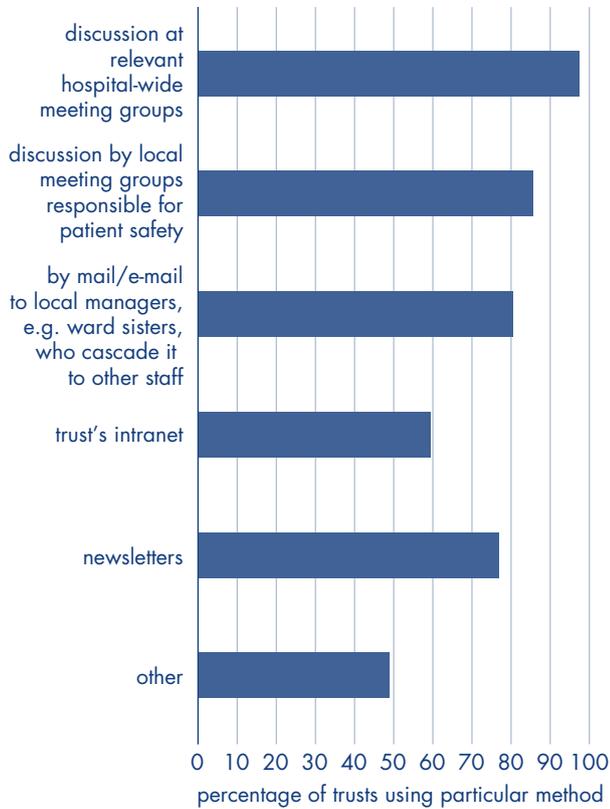


Source: National Audit Office

17 How trusts disseminate lessons learnt

All trusts use at least one method to disseminate lessons learnt.

Method of dissemination



Source: National Audit Office survey of NHS acute, ambulance and mental health trusts 2004

18 Barriers to lessons learnt

| Barriers | Actions to address barriers |
|-----------------------------|--|
| Difficulty in communication | ■ Improvement of distribution and communication system |
| | ■ Introduction of newsletters |
| | ■ Intranet |
| Finance and resources | ■ Prioritising actions |
| | ■ Risk assessments and risk registers |
| Cultural difficulties | ■ Education and training to increase awareness |
| | ■ Fair-blame culture |

Source: National Audit Office survey of NHS acute, ambulance and mental health trusts 2004

3.23 Ninety-one per cent of trusts stated that they shared lessons with their strategic health authorities, but the trusts we visited felt that they were not receiving sufficient feedback. In contrast, although half of strategic health authorities used clinical governance networks as an opportunity to disseminate learning and good practice, they reported that trusts were often reluctant to share their lessons. NHS organisations were concerned that as foundation trusts are not required to report to strategic health authorities that they could miss out on information.

3.24 Since summer 2004, the National Patient Safety Agency's 28 Patient Safety Managers have been working with most trusts to help share good practice and develop local solutions. Patient Safety Managers are well placed to improve the links between trusts and their strategic health authority and to share learning locally (**Case example 10**). However, just 19 per cent of trusts had shared lessons with the National Patient Safety Agency and there was a perception that it was not interested in disseminating learning from individual trusts nationally. Three-quarters of trusts did say that they were planning to increase the extent to which they shared lessons learnt with other organisations.

Nationally the focus has been on processes and systems rather than organisational learning

Safety alerts can be an effective way of ensuring solutions are implemented, but compliance must be audited

3.25 A number of NHS organisations used safety alerts as a key tool for sharing lessons learnt but there was little monitoring or information as to whether trusts were acting on them. In 2003, the Department piloted a system to follow-up on these alerts. After a successful six month pilot, the Department introduced an electronic system (Safety Alert Broadcast System) in which a nominated responsible person from each trust (generally the Medical Device Liaison Officer) was required to acknowledge the receipt of the alert and record the actions the trust had taken, in relation to the deadline for completing action on the alert. Strategic health authorities are responsible for monitoring the responses.

CASE EXAMPLE 10

Northumberland and Tyne and Wear Strategic Health Authority

Situation: The Strategic Health Authority identified patient safety and clinical governance as key priorities and that more work needed to be done to ensure trusts across the patch learned from each other to improve their service.

Action: It undertook a three month programme of informal visits to each NHS organisation to gain an understanding of the various approaches to clinical governance and subsequently established a Clinical Governance Forum in November 2002. This included all acute, ambulance, mental health and primary care trusts and has recently been extended to include representatives from the Independent Sector. NHS Direct and the National Patient Safety Agency's Patient Safety Manager were also active participants. All stakeholders, contributed to the terms of reference. The Forum meets quarterly and focuses on:

- organisational culture and structure in relation to clinical governance;
- specific clinical governance topics and priorities on the trust-led agenda;
- the sharing of good practice; and
- networking between colleagues across organisational boundaries.

A clinical governance network, structured around the Clinical Governance Forum, has evolved based upon streams of work covering all clinical governance areas and incorporating relevant issues raised by other networks (for example the senior nurse group). Underpinning this network is the theme that clinical governance is everybody's business and it operates with the Clinical Governance Forum at its hub. It encourages active stakeholder participation and a series of targeted educational events supports its development. The annual Clinical Governance Conference is central and it engages up to 300 health professionals, support staff, clinical governance leads, delegates from staff organisations and patient representatives, through a high quality programme delivered by national speakers.

The network also provides a framework through which the National Patient Safety Agency can engage in the local clinical governance agenda, meeting the needs of the local health economy and national programme priorities. This convergence

of agendas between the Strategic Health Authority and National Patient Safety Agency allows closer working on clinical governance issues and helps maximise the potential for the spreading of good practice and the dissemination of lessons learned from serious untoward incidents. One such example of this synergy was the "Mind the Gap" regional workshop held on 12 July 2004 in which the strategic health authorities and trusts in the north of England met to clarify the roles and responsibilities of organisations in the sharing of learning and good practice.

The National Patient Safety Agency's Patient Safety Manager has also participated in the review of the Strategic Health Authority serious untoward incident policy and maintains a regular office presence as an important stakeholder in the output of the clinical governance team. In addition, the National Patient Safety Agency has delivered Root Cause Analysis training across all trusts within the Strategic Health Authority, driven the "cleanyourhands" campaign aimed at preventing the spread of infection, and has been working to develop trust readiness for Clinical Negligence Scheme for Trusts assessment.

The Strategic Health Authority has worked with local trusts to include local priorities into the framework of clinical governance plans, for instance hospital acquired infections and suicide and child protection, and broadened its engagement on clinical governance issues through the secondment of a risk manager from a local acute trust for one day a week over a period of 18 months. The secondee has developed local "learning lessons" bulletins, each based around a particular theme, with input from the National Patient Safety Agency's Patient Safety Manager. The Strategic Health Authority is building on it to produce technical bulletins and a newsletter incorporating a regular feature from the National Patient Safety Agency.

Outcome: Trusts are very positive about the efforts made by the Strategic Health Authority to share learning and the involvement of the Patient Safety Manager. The annual Clinical Governance Conference is highly rated. The Patient Safety Manager is actively identifying lessons learnt locally and asking for more information about these issues. The Strategic Health Authority has promoted a proactive safety culture emphasising that risk management should be an integral part of all trusts' operations through its network and bulletins.

Source: National Audit Office

3.26 Between April 2004 and April 2005, trusts received 93 alerts and acknowledged them in 99.7 per cent of cases. The alert issuing organisations do not have the remit or funds to investigate how the advice was used and during our visits we found examples where trusts had signed up to undertake specific actions but when resources were not forthcoming, a similar incident occurred. The Chief Medical Officer, in his annual report for 2004¹⁰, highlighted the fact that some self-reports of compliance with the removal of non-collapsible rails in mental health services proved unreliable, and only 54 per cent of organisations had fully completed the actions required to reduce harm from oral methotrexate 50 days beyond the deadline. Although he questioned whether some deadlines were realistic, the Chief Medical Officer suggested that the general problem with implementing alerts is at least partly due to the current safety culture in the NHS, rather than the method of dissemination of information about risks to patients and how to reduce those risks. For the year 2005-06 the Healthcare Commission, in assessing trust performance against the *Standards for Better Health*, will be checking on trusts' self-assessments asserting that they have implemented all relevant alerts at a sample of trusts.

3.27 Not all national organisations that issue healthcare alerts currently participate in the Safety Alert Broadcast System. The most notable omission is the drug alerts from the Medicines and Healthcare products Regulatory Agency (it issues these by an alternative system that operates all hours). During 2004-05, the Medicines and Healthcare products Regulatory Agency issued 63 medical device safety alerts which required action from trusts and some also provided advice on environmental and usage factors. The trusts we visited told us that the medical device safety alerts they received were very useful to maintain patient safety.

3.28 In total the National Patient Safety Agency has issued six patient safety alerts and six other notices since it was established (Appendix 6). Although the National Patient Safety Agency alerts helped raised the profile of the particular issue concerned, trusts told us that they rarely provided any new information. There was also a perception that the alerts were too acute-trust focused, contradicted other guidance, and did not apply across trusts and that the National Patient Safety Agency had not considered the cost implications for implementing them. For example, to comply with an alert advising acute trusts to use alcohol gel trusts were required to identify significant resources out of their existing budget. Trusts told us that they wanted the National Patient Safety

Agency to develop more innovative lessons and real solutions to on-going patient safety issues rather than issue safety alerts on subjects of which they were already aware.

There are opportunities to improve learning at regional and national level

3.29 The present system for analysing and disseminating lessons learnt is dependent upon trusts reporting a patient safety incident. If trusts devise and implement strategies to design out risks before an incident occurs then this learning remains at the local level. In addition, improvements after patient safety incidents are dependent upon trusts carrying out their planned actions and embedding the learning in their own practice.

3.30 At a regional level, strategic health authorities are well placed to facilitate learning but we found that generally learning came from trusts' own experiences. Following the report of a serious untoward incident, trusts are required to record the actions taken and lessons learnt. Many strategic health authorities told us that at present they lack the resources to fully monitor all these reports or disseminate the learning from them. At best they reviewed the investigation reports and resultant action plans and ran trend analysis on untoward incidents to identify high risk areas (**Illustrative examples 6**).

3.31 Only eight strategic health authorities gave examples of interventions following a serious untoward incident, usually where the competence of a health professional was in question. We found that strategic health authorities did not have integrated systems to learn from serious untoward incidents, complaints and litigation cases, mainly because different parts of the organisation dealt with complaints and litigation. There was also no evidence of monitoring of these latter areas for learning points. Although most strategic health authorities provided feedback to trusts following their monitoring of clinical governance development plans, they did not monitor trusts' implementation of recognised good practice and the lessons learnt.

3.32 Trusts we visited told us that they had sent incident reports to the National Patient Safety Agency via the National Reporting and Learning System but had received nothing back. Our survey showed trusts wanted the National Patient Safety Agency to provide feedback on trends in incident reporting so that they could assess their position and track their improvements relative to similar organisations. In July 2005, the first report⁵ of the Patient Safety Observatory was published. Whilst this mainly

ILLUSTRATIVE EXAMPLES 6

Map to show action taken in strategic health authorities to improve patient safety

Cumbria and Lancashire

The clinical governance team inform all executive directors, communication and governance leads regarding all serious untoward incident reports to ensure the executive directors are briefed if they are on call, the appropriate cross office links are made and SHA action co-ordinated.

Dorset and Somerset

After the Willis review against the Risk Pooling Scheme for Trusts and the Clinical Negligence Scheme for Trusts in 2002-03, the Strategic Health Authority organised a seminar for local trusts. This was an opportunity to learn from the expertise of the Willis team, to de-mystify the trusts' perceptions of reporting requirements for both schemes and to obtain answers to queries, facilitating the sharing of good practice. Breakout sessions were organised as part of the event which enabled trusts to work together on how to present themselves in assessment. All trusts now have been assessed as meeting Level 1 or above.

Thames Valley

In November 2004 the Clinical Governance Manager organised a Thames Valley Safety Event which was a one day free workshop organised in partnership with the National Patient Safety Agency for all staff with responsibility for risk management, health and safety or any other member of staff in an appropriate role. This was an opportunity to raise awareness of safety issues for both staff and patients and to share learning from specific incidents. It included an update on linking to the National Reporting and Learning System and a presentation on the National Patient Safety Agency's Seven steps guidance to support implementation across Thames Valley.

North and East Yorkshire and North Lincolnshire

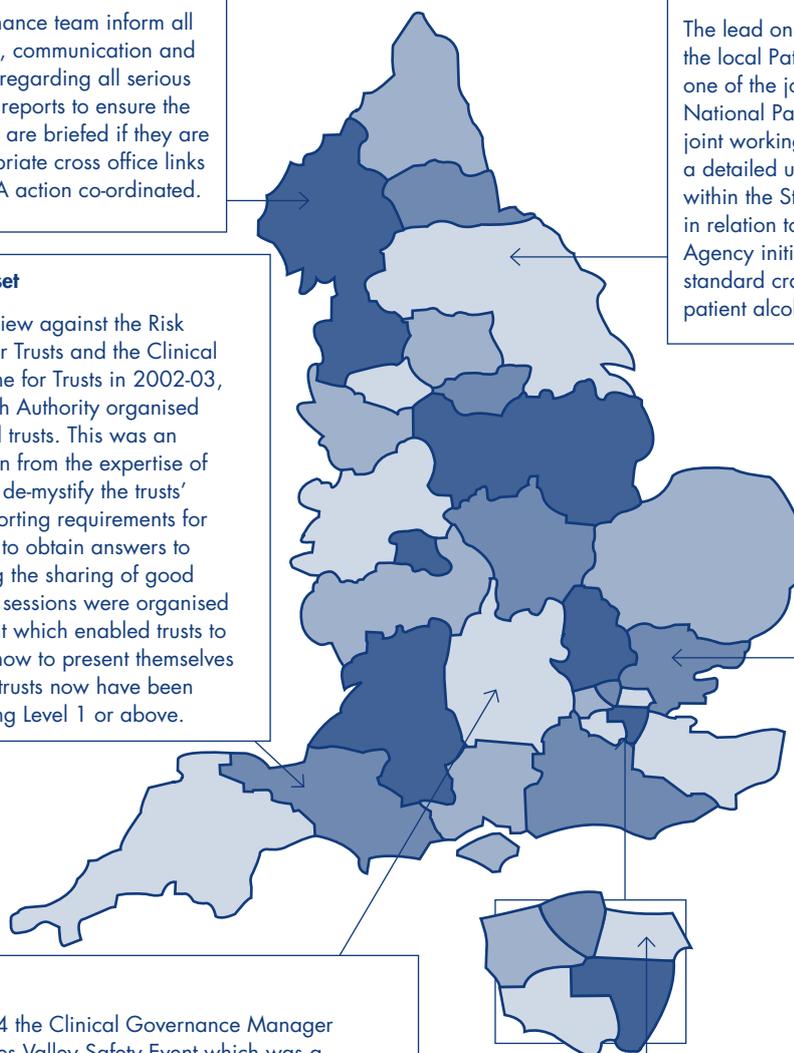
The lead on Patient Safety has met with the local Patient Safety Manager and one of the joint Chief Executives of the National Patient Safety Agency to review joint working arrangements. This included a detailed update of where all 17 trusts within the Strategic Health Authority are in relation to the National Patient Safety Agency initiatives on potassium chloride, standard crash calls, methotrexate, near patient alcohol gel and infusion devices.

Essex

At the bi-monthly Clinical Governance and Risk Management "members' exchange" incidents are discussed and good practice or areas for improvement are identified. Minutes are circulated to all trusts to facilitate further learning. The local National Patient Safety Agency's Patient Safety Manager sits on all the committees and feeds in the national perspective. In addition, the Risk Management Committee of the Strategic Health Authority (SHA) receives information and intelligence from the Patient Safety Manager and from other sources from which it distils learning and good practice.

North East London

The Strategic Health Authority disseminated learning and good practice through presentations at sector specific groups, Clinical Governance networks and a quarterly newsletter that includes an incident summary and an outline of actions.



Source: National Audit Office survey of strategic health authorities 2004

focused on an analysis of the incidents reported to the National Reporting and Learning System, it also provided illustrative examples of how these reports were being used:

- the National Reporting and Learning System received reports of 311 incidents linked to anticoagulant medicine, including two deaths. The National Patient Safety Agency obtained information from medical defence and negligence bodies, where in 600 cases between 1990 and 2002, one in five (120) reports were of the death of a patient, and solutions are now being developed in collaboration with the British Society for Haematology;
- 493 reports from 45 trusts with problems with patient identification, including one in eight incidents involving wristbands. Analysis showed a lack of systematic and standardised processes to support identification and the National Patient Safety Agency expects to promulgate advice in the autumn of 2005; and
- a review of reported deaths revealed some cardiac arrest incidents were the result of equipment problems on the crash call trolley. The National Patient Safety Agency is collaborating with the Helen Hamlyn Trust to fund the design of a crash call trolley that eliminates risks around missing equipment.

There is scope to improve evaluation and dissemination of learning by other NHS organisations

3.33 In 2001, the Department proposed³ that there should be a single system to share lessons on patient safety that would draw on information, research and analysis from a variety of sources. However, we found that a number of organisations have continued to share lessons through their own systems (**Illustrative examples 7**). These lessons were often identified from the organisation's own data sources so there is the potential for duplication and contradictory advice.

3.34 The Healthcare Commission has archived the evidence base collected during the Commission for Health Improvement's clinical governance reviews at individual trusts. Whilst three national reports⁹ were published, covering a wide number of issues, the Healthcare Commission have not interrogated the remaining body of evidence to promulgate learning about patient safety and related issues.

ILLUSTRATIVE EXAMPLES 7

The work of the NHS Litigation Authority

In the last two years, the NHS Litigation Authority has begun to establish itself as more of a learning organisation. It has built on its established network of contacts in trusts to publicise high-risk areas and provide risk education activities for clinicians. It has produced a variety of risk management publications, including the long established *NHSLA Review*, and held two conferences and other training events. Since October 2003, trusts and researchers have been able to request analyses of claims data from the Clinical Negligence Scheme for Trusts and the Risk Pooling Schemes for Trusts to assist in risk management. In 2004 the NHS Litigation Authority formalised a system for the sharing of notable practice identified during its risk management assessments under which trusts can request assistance on a particular issue and be put in touch with other trusts that have devised practical solutions. A study²⁷ of NHS Litigation Authority data identified those procedures and specialties at most risk of litigation. This information could help trusts in developing their risk registers.

The work of the Medicines and Healthcare products Regulatory Agency

The Medicines and Healthcare products Regulatory Agency draws on information obtained through longstanding national reporting systems and other data sources, such as the GP Research Database, to minimise the risks from the manufacture of medical devices and medicines to patients. One report is sufficient to trigger investigation and if the Medicines and Healthcare products Regulatory Agency receives notification of serious incidents or early indications of problems, it is able to use its resources to identify corrective action. For example every medical device incident reported through its Adverse Incident Reporting System is risk assessed to identify areas that require investigation. In over 50 per cent of cases investigators found the incident was due to a problem with the use of the device in the hospital, primarily around poor training, learning and management issues.

The Medical Device Liaison Officer in each trust can access dedicated pages on the Medicines and Healthcare products Regulatory Agency's website and they and other staff such as the Pharmacy Leads attend study days and conferences on important safety issues. The Medicines and Healthcare products Regulatory Agency also disseminates learning through publications such as *Current Problems in Pharmacovigilance* and *One liners* and has been working with other NHS bodies, such as the National Patient Safety Agency, to develop training programmes to assist in changing healthcare professionals' practices.

Source: National Audit Office

The strategy for the Patient Safety Research Programme has yet to have an impact on frontline healthcare delivery

3.35 *Building a safer NHS for patients*³ identified the key role that research can play in understanding the human factors that cause unintended harm and in developing patient-focused solutions to embed in practice across the NHS. Compared to other industries, research on learning from errors in healthcare was relatively under-developed. In 2001, the Department proposed a programme of research, with specific foci for the work, and the Programme Director made a commitment to concentrate on prescribing errors and patient safety during labour.

3.36 To date the Patient Safety Research Programme in England and Wales has published reports from ten of the projects it commissioned, at a cost of around £400,000, and there are a further 18 studies in progress (there are 46 projects in the pipeline with a total value of £8.9 million). The reports have provided a background on reporting systems and confirmed the approaches needed to improve patient safety. Key findings are:

- reporting systems and disciplinary arrangements need to be separate and feedback from any reporting system is vital to maintain clinicians interest;
- the prevailing legal system does not encourage health professionals to be open after an adverse patient safety incident and they need to be equipped with skills to deal with discussions where errors are disclosed;
- clinical inexperience; lack of supervision and training; heavy workloads and staff shortages; lack of equipment and poor communication are the root causes of errors in maternity care;
- firm central direction is needed if patient safety systems are to be effectively implemented;
- evaluation of the effectiveness of educational interventions or incentives is needed; and
- engineering and psychology could be used together to design systems which may be more resistant to error when humans use medical technology.

*Building a safer NHS for patients*³ made a case for research to underpin how best to utilise experts, learn lessons and disseminate them. The programme has yet to deliver on these.

Developments in information technology should help improve patient safety

3.37 Preventing errors by the appropriate use of information technology is well established. The Institute of Medicine in the United States of America advised that moving from a paper to an electronic based patient record system would be the single step that would most improve patient safety²⁸. The National Programme for Information Technology in the NHS being delivered by the Department's agency, NHS Connecting for Health, has begun to roll out its National Care Record system and expects it to have full functionality by 2010. Most trusts foresee that this will help them in ensuring that patient records are no longer lost and there are better controls over prescribing (both issues have led to significant numbers of patient safety incidents).



3.38 One of the most robust methods for identifying unreported incidents is through retrospective audits of patient records. Electronic patient records will enable trusts to quickly identify unreported incidents, monitor trends and promote learning through clinical audit. However clinicians will still have an important role to play in improving patient safety. For example, although there will be automatic identification of adverse drug reactions, the Medicines and Healthcare products Regulatory Agency will still need detailed reports of clinicians' suspicions as an early warning and to be able link them to reactions which emerge at a later date.

3.39 Knowledge management is a key element of successful healthcare delivery. Our report on clinical governance⁴ highlighted that knowledge management

was one of the least developed components. In our visits to trusts we found ward staff had problems accessing guidance and information on good practice. The Commission for Health Improvement reviews highlighted similar concerns⁹. Although the Department has already established the National Electronic Library for Health, it plans to make full use of the new NHS information technology system to improve access to learning from patient safety incidents and near misses.

3.40 NHS Connecting for Health is working to optimise the management of risk in the health service and in partnership with the National Patient Safety Agency, is developing a range of interventions to reduce such risks as the incorrect identification of a patient or the prescribing of the wrong drug or dose (**Illustrative example 8**).

ILLUSTRATIVE EXAMPLE 8

Connecting for Health and Patient Safety

A compelling case for investment in information technology to improve patient safety was made in the Audit Commission report: *A Spoonful of Sugar*, (December 2001):

"Complications arising from medicines treatment are the most common cause of adverse events in hospital patients...Most errors are caused by the prescriber not having immediate access to accurate information about either the medicine (its indications, contra-indications, interactions, therapeutic dose, or side effects); or the patient (allergies, other medical conditions, or the latest laboratory results)... Computerised prescribing linked with electronic health records will radically alter the way in which care is provided and will deliver significant improvements in the quality of patient care."

The Connecting for Health Business Plan re-iterates the NHS National Programme for Information Technology's commitment to patient safety:

"Critically, all the new systems will contribute to ensuring safety and quality of care while helping to improve efficiency... Our cluster teams coordinate the implementation of many thousands of IT installations designed to improve the safety, efficiency and quality of patient care."

Action: The Electronic Transmission of Prescriptions

Research has highlighted both the potentially fatal consequences of adverse drug reactions and the avoidable nature of many such events. The Electronic Prescription Service will contribute to patient safety in two ways:

- It will provide both prescribers and dispensers with more information about what medication a patient is taking. This will be achieved by populating the patient's medication record on the NHS Care Records Service with information about what has been prescribed and dispensed for the patient. This will allow those healthcare professionals with approved access and within appropriate care settings to view a patient's medication history, supporting the decision on what further or alternative treatment should be provided in the light of what the patient has already received.
- By using electronic systems and communication, patients' demographic and medication details will not have to be interpreted from hand writing, or re-keyed, reducing labelling errors and the times when medication information, such as dosage or strength, is missing.

Connecting for Health Service Implementation seeks to ensure that the potential of this technology is achieved in the Service:

Its stated aim is to connect with the people who will, in their day to day work, use the technology to improve patient safety and clinical governance - for example through the electronic transmission of prescriptions and the NHS Care Record.

Connecting for Health aims to provide the Department and the NHS, with support, based on best practice, to enable all local health communities to produce robust service improvement plans that include evidence-based projections of the quality, safety and productive time benefits to be realised from the deployment of the National Programme, by the March 2006 deadline.

APPENDIX 1

References to patient safety in previous National Audit Office and Committee of Public Accounts' reports

Health and Safety in NHS Acute Hospital Trusts in England (HC 82, Session 1996-97)

Key NAO findings: As many as 450,000 accidents take place each year in acute hospitals, three-quarters of which involved patients, costing some £6 million. Accidents will always happen but many are preventable, and hospitals should aim to develop a more proactive approach to managing safety issues. Senior trust management should lead on actions taken to ensure safety is of the highest priority.

PAC conclusion and recommendations: Treating preventable accidents diverts money from other patients. Many hospitals did not have accident recording systems to provide accurate and timely information, and there were wide variations in the number of incidents reported. Trusts were encouraged to routinely collect and publish information on incidents to promote accountability. Staff should be encouraged to report incidents.

Response from the Department: Hospitals are dangerous due to the nature of their work but risk must be better managed. The Chief Executive of the NHS wrote to all trusts asking them to make safety a priority area. The Department supported trusts in developing and sharing good practice in safety management.

The Management and Control of Hospital Acquired Infection in Acute NHS Trusts in England (HC 230, Session 1999-2000)

Key NAO findings: Nine per cent of patients will acquire an infection during their stay in hospital leading to a cost of £1 billion annually. Fifteen per cent of infections are preventable. Chief Executives may be unaware of the extent of infection in their hospitals. A lack of basic information about rates of infection restricts the prioritisation of resources.

PAC conclusion and recommendations: The Department has taken actions to address this issue, though tangible results were not expected until 2003. Infection rate surveillance should be mandatory for all trusts. Appropriate funding will be required to support trusts in reducing rates of infection.

Response from the Department: The Department accepted that incidents could be reduced, leading to cost savings of as much as £150 million annually. Surveillance of infections became compulsory from April 2001, with results published from April 2002. The Department made funds available for infection control training as well as other additional resources to improve systems for preventing and controlling infection.

Hip Replacements: Getting it Right the First Time (HC 254, Session 1999-2000)

Key NAO findings: Trusts are generally unclear about what to report to the Medical Devices Agency (now the Medicines and Healthcare products Regulatory Agency) and half do not have data on infection rates for hip replacements. Infection rates of one to two per cent are acceptable.

PAC conclusion and recommendations: Tightened controls over the introduction of hip prostheses from 1995 have not led to uniform compliance from manufacturers, trusts or clinicians so implementation needs close monitoring by the Department and the National Institute for Clinical Excellence. There is a case for a national register of hip replacements. There is a lack of key information on infection rates.

Response from the Department: The Medical Devices Agency has taken steps to improve reporting arrangements for adverse incidents concerning medical devices. The Department accepted the advantages of a registry. Enhanced processes for determining the safety and efficacy of interventions were being considered.

Safety, Quality and Efficacy: Regulating Medicines in the UK (HC 255, Session 2002-03)

Key NAO findings: There were 19,000 adverse drug reactions reported in 2001-02, of which three per cent were fatal. There was less than one adverse reaction for every 10,000 medicines prescribed. Only a small proportion of adverse reactions are subject to a report, and only a third of patients read the information leaflet supplied with prescribed medicines. The Medicines Control Agency, (now the Medicines and Healthcare products Regulatory Agency), does not routinely monitor the effectiveness of advice to prescribers and pharmacists.

PAC conclusion and recommendations: There is a low level of participation by health professionals in the Yellow Card reporting scheme. The Medicines Control Agency needs to do more to measure the effectiveness of safety alerts and warnings and should make use of prescribing information to provide feedback to doctors. The Department should facilitate the transfer of information between the Agency and the National Patient Safety Agency.

Response from the Department: The Agency agreed to expand its measurement of the effectiveness of safety alerts and warnings. It had taken actions to improve adverse drug reaction reporting rates, including introducing a direct system of reporting for patients. It agreed that more effective use could be made of information collected, though direct feedback to doctors is not within its remit.

A Safer Place To Work: Protecting NHS Hospital and Ambulance Staff from Violence and Aggression (HC 527, Session 2002-03) and A Safer Place to Work: Improving the Management of Health and Safety Risks to Staff in NHS Trusts (HC 623, Session 2002-03)

Key NAO findings: Staff do not report incidents because forms are too complex, there is little feedback and they fear no action will be taken. Most incidents stem from systemic issues, and there are lessons for the health service from other industries. All trusts offer training to reduce risk, but there is little evidence as to its effectiveness. Most trusts record incidents involving patients, staff and visitors on integrated reporting systems, though there are significant variations in definitions between trusts, and significant under-reporting. The National Patient Safety Agency is undertaking work to see where improvements can be made.

PAC conclusion and recommendations: The Department and the Counter Fraud and Security Management Service should introduce a reporting system to address problems of under-reporting and inconsistency in the definitions of the type and severity of an incident. Healthcare workers need to be aware of violence and aggression risks early in their careers, to ensure reporting becomes second nature. The Department should take steps to address the inconsistency in identifying and reporting incidents, and encourage trusts to adopt systems that give complete information on the type and nature of the incident. The Department should remind trusts of the need to manage health and safety risks.

Response from the Department: The Department will strengthen the reporting system and investigate why staff do not report. The Counter Fraud and Security Management Service will take steps to prevent incidents from occurring. The Department will work to ensure that appropriate health and safety training is available to all staff as part of their induction. Guidance was to be issued to remind trusts and staff of mandatory reporting obligations.

Achieving Improvements through Clinical Governance: A Progress Report on Implementation by NHS Trusts (HC 1055, Session 2002-03)

Key NAO findings: High quality leadership and committed staff are key to improving performance. Clinical audit remains underdeveloped in trusts. There has been progress in changing the professional culture towards open and transparent ways of working and in developing risk management systems. There has been less progress in involving patients and the public and a failure to share learning across and between organisations.

There was no Committee of Public Accounts hearing on this report.

The Management of Suspensions of Clinical Staff in NHS Hospitals and Ambulance Trusts in England (HC 1143, Session 2002-03)

Key NAO findings: In a small number of cases, patient safety incident reporting identified poorly performing clinicians. The National Patient Safety Agency has developed an incident decision tool to support managers in their actions following a patient safety incident. The Department has a key role in encouraging trusts to establish an open and fair culture that will lead to reporting clinical incidents and promote learning.

PAC conclusion and recommendations: Trusts are failing to undertake specified employment checks when hiring staff, potentially putting patients at risk. There are also weaknesses in communicating potential concerns to future employers where staff were suspended, and many trusts fail to complete investigations if suspended clinicians leave.

Response from the Department: The Department reminded trusts that pre-appointment checks are mandatory.

Improving Patient Care by Reducing the Risk of Hospital Acquired Infection: A Progress Report (HC 876, Session 2003-04)

Key NAO findings: Higher priority has been given to preventing hospital acquired infections at the national level. Improvements are constrained by limited progress in developing a national mandatory surveillance programme and the pursuit of other key policies and priorities. Staff must accept personal responsibility for preventing infections.

Tackling Cancer: Improving the Patient Journey (HC 288, Session 2004-05)

Key NAO findings: Most patients were not told how to make a complaint, and in those cases where they did make a complaint, some had trouble in obtaining a satisfactory result. Improvements were made from 2000 in communicating with patients about their condition, though some patients wished to know more about the side effects of treatment.

APPENDIX 2

Methodology

We have used a number of approaches to gather the information in this report. These included a census of NHS trusts and strategic health authorities, visits to NHS trusts, a survey of the public, consultations with the numerous stakeholders including a panel of experts, interviews with Department of Health and the National Patient Safety Agency staff and analysis of national published data and documents.

a) Census of NHS trusts

Key among our methodologies was a census of acute, ambulance and mental health trusts and a telephone survey of all 28 strategic health authorities. Details of the surveys are set out below. Key findings and copies of the questionnaires used may be found at <http://www.nao.org.uk>.

1 Acute, ambulance and mental health trusts

Taylor Nelson Sofres undertook a census of 171 acute trusts, 30 ambulance trusts, 66 mental health trusts and one trust providing all three services on our behalf. All three types of trust received the same questionnaire. Only one acute trust did not respond our survey, the Buckinghamshire Hospitals NHS Trust. We aimed to obtain evidence on the progress trusts had made in implementing recording systems that provide reliable and timely information on patient safety incidents and to gather information about existing systems, progress, innovation and successes in organisational learning for patient safety. The questionnaire was divided into sections focusing on the management of patient safety,

patient safety incident reporting, analysis of incidents and organisational learning from incidents and other sources. There was also a section for the chief executive of each trust to provide their views on patient safety in their trust.

*An organisation with a memory*¹ highlighted the need for trusts to have a culture that encourages staff to report incidents and robust systems for incident reporting and learning from patient safety incidents. We used these criteria to develop an objective way of assessing trusts' performance in regards to reporting and learning from patient safety incidents. Scores were allocated on the basis of trust responses to a selection of questions regarded as key performance indicators (listed in Figure 19). The scores presented in Figure 20 are a relative indicator of performance and are not an attempt to assign an absolute score to trusts. The full model can be found on our website.

Summer 2005 – Re-survey of trusts to update key pieces of information

In August 2005, we sent out an update survey to obtain data on the number of patient safety incidents and near misses reported to trusts by staff during 2004-05 and to gauge the amount of progress made in a rapidly changing arena. We found trust performance had generally improved, for example: more trusts reported having an open and fair culture; more trusts had introduced open reporting systems; fewer numbers of incidents were going un-reported; and classification of incidents had improved. A full analysis of the re-survey is available on our website.

19 Questions from our survey and the scoring system used to assess trusts' progress towards establishing a reporting and learning culture

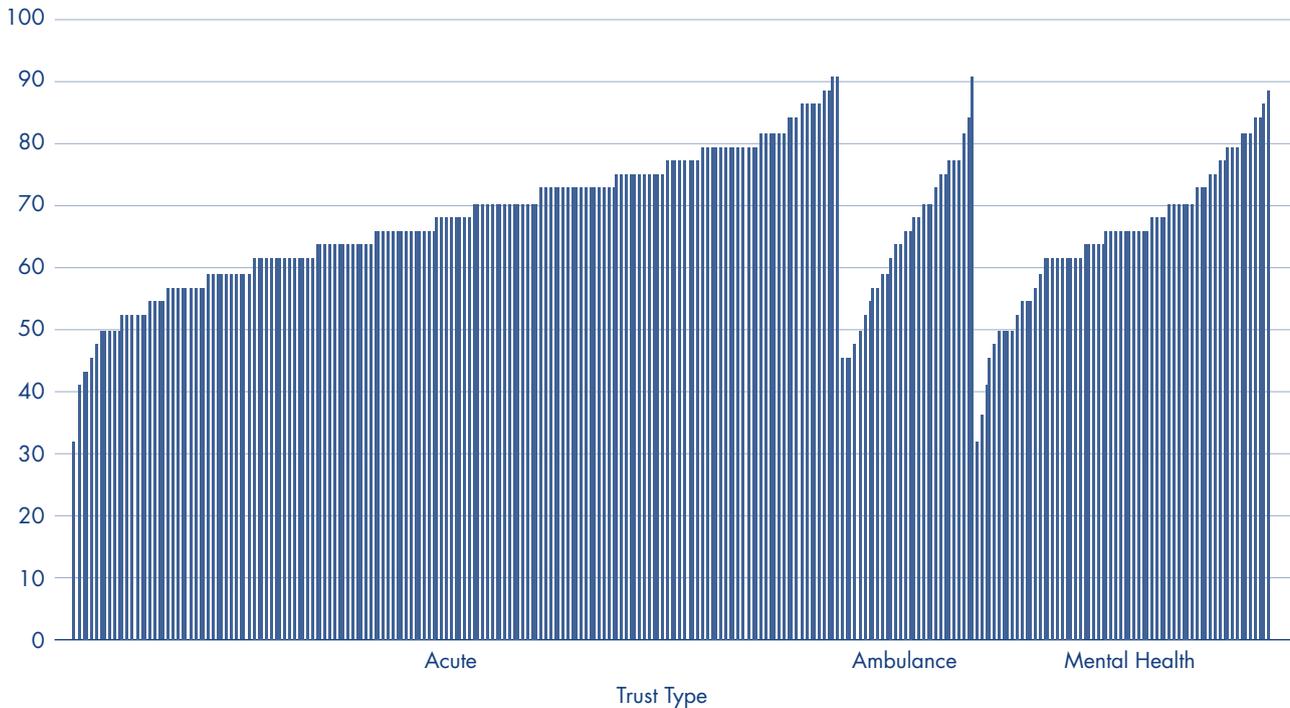
| Question | Score for comprehensive response |
|--|----------------------------------|
| ■ A2: Who has lead board level executive responsibility for patient safety? | 1 |
| ■ A10: How would your organisation describe its safety culture? | 3 |
| ■ B1: How long has your organisation been operating a trust-wide patient safety incident reporting system? | 3 |
| ■ B9: What steps does the trust take to inform patients of the ways in which they can raise their concerns about patient safety? | 3 |
| ■ B10a: To what extent does your organisation perceive under-reporting of actual patient safety incident (those that have an impact on patients) to be a problem? | 3 |
| ■ B10b: To what extent does your organisation perceive under-reporting of near misses to be a problem? | 3 |
| ■ B16: How does your organisation ensure existing staff are continually made aware of the trust's patient safety reporting requirements? | 3 |
| ■ B17: How does your organisation ensure temporary staff (such as locums and agency nurses) are continually made aware of the trust's patient safety reporting requirements? | 3 |
| ■ B18: How does your organisation ensure contractors are continually made aware of the trust's patient safety reporting requirements? | 3 |
| ■ C17a: When staff report patients safety incidents or near misses, is it the trust's practice to provide the following feedback? | 3 |
| ■ C17b: When patients or the public report patient safety incidents or near misses, is it the trust's practice to provide the following feedback? | 3 |
| ■ D2: Do all relevant staff groups play a role in the identification of patient safety priorities for action within the trust? | 1 |
| ■ D3: Do patients and the public play any role in the identification of patient safety priorities for action within the trust? | 1 |
| ■ D4: Do all relevant staff groups play a role in the design and development of patient safety solutions within the trust? | 1 |
| ■ D5: Do patients and the public play a role in the design and development of patient safety solutions within the trust? | 1 |
| ■ D6: How does your organisation disseminate lessons learnt across the trust? | 3 |
| ■ D7: Does your organisation share lessons learnt with external organisations? | 3 |
| ■ E1: What actions has the chief executive taken to improve patient safety? | 1 |
| ■ E4: To what extent does the system your trust currently has in place enable it to meet the Patient Safety Domain in the new Standards for Better Health? | 2 |
| Maximum | 44 |

Source: National Audit Office survey of Acute, Ambulance and Mental Health Trusts, 2004

20 Trusts' scores

There is wide variation in trusts' performance but the majority have made substantial progress in introducing a patient safety focused environment.

Percentage score



Source: National Audit Office survey of Acute, Ambulance and Mental Health Trusts, 2004

2 Strategic health authorities

We conducted semi-structured interviews by telephone with the individual responsible for patient safety in each strategic health authority. All but one (Shropshire and Staffordshire) of the strategic health authorities responded. We asked about how they monitor trusts' performance regarding patient safety, what information they gather from trusts and the feedback they provide, what training they organise and how their work fits in with that of the National Patient Safety Agency.

b) Visits to trusts

We carried out a series of visits to selected NHS trusts throughout February and March 2005. We selected trusts to visit based on responses they provided in their survey return. Key questions we looked at included D13 (trusts that felt they had extremely effective systems for learning from patient safety incidents) and E4, (trusts that considered themselves to have a system to learn from patient safety incidents which would meet the requirements of the *Standards for Better Health*). Alongside these questions we identified some trusts where a unique or innovative approach to the management of patient safety was in practice.

During our visits we conducted semi-structured interviews with a range of staff involved in managing and learning from patient safety incidents, for example senior managers, clinical staff and patient representatives. The visits also provided us with a more detailed understanding how NHS organisations treat patient safety issues and the systems they use to learn from patient safety incidents. We are grateful to the staff of the organisations we visited for their time and assistance. The trusts we visited were:

- Chesterfield Royal Hospital NHS Foundation Trust
- Isle of Wight Healthcare NHS Trust
- Norfolk and Waveney Mental Health Partnership NHS Trust
- North East Ambulance Service NHS Trust
- Royal Cornwall Hospitals NHS Trust
- Staffordshire Ambulance Service NHS Trust
- The Newcastle upon Tyne Hospitals NHS Trust
- The Royal Marsden NHS Foundation Trust

c) Case examples

In the course of our visits to trusts we sought to identify examples of good practice from which other trusts and organisations may be able to learn lessons and improve their own performance. We have included a number of case examples in the report. These are used as a means of identifying and recognising the diverse and often innovative techniques trusts have implemented in their efforts to improve their record in patient safety and to improve their ability to learn from patient safety incidents.

d) Public survey

We commissioned from Ipsos UK a survey of patients who had recently undergone hospital treatment, to learn:

- whether the risks of treatment had been explained to them;
- whether they had been involved in a patient safety incident;
- whether the hospital informed them if they had been involved in such an incident; and
- if they were satisfied with any actions taken by the hospital as the result of the incident.

A sample of 2061 adults were interviewed, of which 881 had been a patient in an NHS hospital in the previous two years. Respondents were aged 15 and over, and the results were weighted across sex, age, social grade and working status to achieve a nationally representative sample. Interviews took place between 29 October and 4th November 2004. Key findings and a copy of the questionnaire used can be found at <http://www.nao.org.uk>.

e) Research papers

1 International Comparisons

Stuart Emslie, an Independent Healthcare Consultant, facilitated two one-week study tours to visit key individuals and organisations in Australia and the United States of America and a visit to Hong Kong to understand how hospitals manage and control patient safety. We then commissioned Mr Emslie to produce a report on a selection of notable patient safety programmes, initiatives and practices in place outside the United Kingdom. A summary of these findings is at Appendix 4.

2 Analysis of patient safety databases and learning systems

We commissioned ECRI Europe to compare the data fields used in England on patient safety incidents with information other established systems elsewhere collect and examine the operation of incident reporting in some trusts in England (Appendix 5).

f) Wider consultations

We consulted with the Royal Colleges (receiving replies from the Anaesthetists, Nursing, Pathologists, Psychiatrists, Radiologists and Surgeons), the regulatory bodies (General Medical Council and the Nursing and Midwifery Council), the Royal Pharmaceutical Society of Great Britain, the Society of Radiographers, the Ambulance Service Association and Doctors.net.uk.

Expert advisory panel

We invited a panel of individuals with a range of experience and expertise in patient safety and organisational learning to advise on the scope of our study, methodologies and emerging findings. There were two formal meetings of the panel (March and September 2004) and we approached the panel members throughout the study period for advice. We are grateful to the following panel members for the time and assistance they provided:

| | | |
|----------------------------|--|---|
| Professor Peter Hutton | Then Chairman Council Member | Academy of Medical Royal Colleges General Medical Council |
| Jeff McIlwain | Consultant, Clinical Risk Management | St. Helens and Knowsley NHS Trust |
| Bob Nicholls | Council Member Former Chairman | General Medical Council National Clinical Assessment Authority |
| Jan Norman | Project Manager Director of Governance | Commission for Health Improvement Dartford and Gravesham NHS Trust |
| Professor James Reason | Professor of Psychology | University of Manchester |
| Representative | (Various) | Nursing and Midwifery Council |
| Ken Smart | Chief Inspector of Air Accidents | Air Accidents Investigation Branch |
| Chris Taylor | Principal Inspector, Health Services Unit | Health and Safety Executive |
| Steve Walker | Chief Executive | NHS Litigation Authority |
| Peter Walsh | Chief Executive Officer | Action Against Medical Accidents |
| Dr Alexander Yule | Registrant Member – Radiography Clinical Governance Manager | Health Professions Council Cardiff and Vale NHS Trust |
| David Knight | Project Lead, Patient Safety | Department of Health |
| Dianne Parker | Patient Safety Strategy Developer | Department of Health |
| Sue Osborn Sue Williams | Joint Chief Executives | National Patient Safety Agency |

APPENDIX 3

Other industries

Most research on patient safety has recognised that lessons from other industries can be instructive.

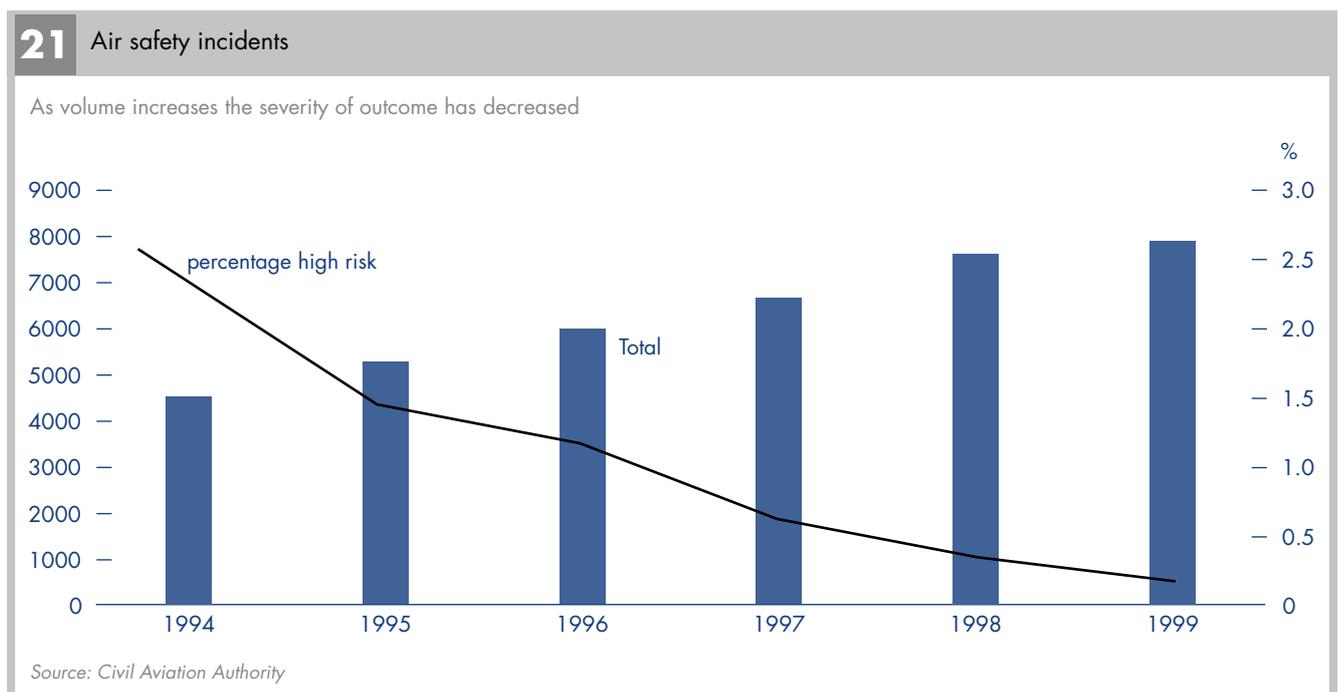
The Aviation Industry

Airlines have made considerable improvements to their safety records by developing an open and fair culture, introducing a high degree of standardisation and employing a constant process of reviewing the implications of incidents and the outcomes of changes in procedure (Figure 21). To develop an open and fair culture where individuals report incidents when required, airlines train their staff to give them the confidence to speak up. While standardisation curtails the autonomy of the individual it does not reduce their authority to take action to break the chain of events where necessary. Staff view the system as more transparent and this has reduced the threshold for reporting untoward incidents. As a result airlines have been able to move away from confidential reporting to a system of open reporting of potential incidents.

While commercial firms are ultimately accountable to customers through the market for their services, there are regulatory bodies that oversee their systems, audit trails and training. The Civil Aviation Authority is the independent organisation with the remit to promote aviation safety and consequently the safety of passengers, staff and the public. Whilst safety is at the heart of everything, the means by which aircraft, crew and passengers are protected in terms of safety and health is multi-faceted.

The Rail Industry

Staff working in the railway industry in the United Kingdom can use the independent Confidential Incident Reporting and Analysis System as an alternative way to report safety concerns that they feel unable to report through their employers' safety channels. An independent organisation, which is external to the rail industry and regulators, manages and administers the Confidential Incident Reporting and Analysis System. The System is complementary to company reporting systems and is not designed to replace these.



It captures information that otherwise may not be identified. Since becoming compulsory for all United Kingdom rail companies in 2000, it has received over 3,000 reports.

Individuals can submit reports in writing or by phone but must provide their name and details. Confidential Incident Reporting and Analysis System staff conduct a short interview with the individual to ensure they have understood the issue and to check that it can be sent to the company without identifying those involved. The appropriate company will then receive a report for its response. The contact details of the individual are destroyed and only a number identifies the report. Commonly reported issues include signalling problems, near misses and fatigue related errors (**Illustrative example 9**).

Reports and responses are entered into a national database where they can be analysed for trends. This information can be used alongside other safety performance data to identify any trends in safety and help companies to target resources to address problems. A suite of summary reports are produced – the number of concerns reported, the type of issue raised and why it was reported. In addition, the Confidential Incident Reporting and Analysis System

staff can carry out data searches on behalf of companies, for example the number of reports made by employees compared with other companies in the sector or more detailed analysis of specific issues reported.

The Recreational Diving Industry

The British Sub-Aqua Club represents the recreational diving industry and membership for divers is voluntary. Its National Diving Committee Incidents Advisor gathers, collates and reports on diving incidents and liaises with the Coastguard, Royal National Lifeboat Institution and British Hyperbaric Association, advising on emerging trends in diving safety, making recommendations on future changes. The National Diving Committee then issue advice or alerts as required.

Hundreds of incidents are reported and entered on the British Sub-Aqua Club database each year; in 2003, 409 incidents were reported, and 392 of these were investigated (**Figure 22**). Information for the database is drawn from incident report forms that have been submitted, as well as the Coastguard, the Royal National Lifeboat Institution and news reports.

The British Sub-Aqua Club does not investigate incidents at a national level. If a branch is involved an incident it will often conduct its own investigation and report the findings to the national body. In the event of a fatality there is usually a coroner's inquest and report. Occasionally regional representatives are asked to investigate if a serious event has occurred and it is felt that follow up is required. The British Sub-Aqua Club does not have the resources to investigate all the 400 to 500 incidents that are reported to it each year.

Most incidents are a result of human error and the organisation is careful to protect individuals' identities and to avoid pointing a finger, as this would likely cause the flow of information to dry up. It believes blame would be inappropriate in a situation where people have had the courage and candour to admit to a mistake, thereby giving others the opportunity to learn from it.

ILLUSTRATIVE EXAMPLE 9

Report made to the Confidential Incident Reporting and Analysis System

A driver was concerned that the warning boards and associated Advanced Warning System magnets were incorrectly placed at a level crossing. Despite having raised this concern with his manager nothing had been done to rectify the situation.

Company response: After the Confidential Incident Reporting and Analysis System report was received the company acknowledged that there were a number of irregularities with the positioning of Advanced Warning System magnets and signs on the line. A full survey of the entire line, including all crossings, was commissioned. Once complete the company undertook to develop a 'scheme plan' to specify the work required to remove the anomalies and bring the crossing up to the current required standard.

22 Incidents reported to the British Sub-Aqua Club

Most incidents reported to the organisation are investigated.

| | 1994 | 1995 | 1996 | 1997 | 1998 | 1999 | 2000 | 2001 | 2002 | 2003 |
|--------------------|------|------|------|------|------|------|------|------|------|------|
| Incidents Reported | 385 | 351 | 315 | 397 | 452 | 397 | 439 | 465 | 453 | 409 |
| Incidents Analysed | 385 | 351 | 315 | 370 | 431 | 382 | 417 | 458 | 432 | 392 |

Source: British Sub-Aqua Club

APPENDIX 4

International comparisons of organisational learning for patient safety

As in England, the patient safety movement has galvanised itself in recent years in many developed countries, and globally through the World Health Organisation. The rate of development of patient safety programmes and initiatives is increasing to the point that patient safety appears to be the most important common issue in health care internationally. For example, an internet search for “patient safety” in February 2004 revealed just over 500,000 results, the same search in March 2005 revealed 2,680,000 results – a five fold increase. Whilst many less tangible quality issues can be open to debate, improving patient safety through reducing the incidence of potentially preventable harm appears to have become difficult to argue against.

The following are the five elements of patient safety that most developed countries have identified in their strategies for improving patient safety:

- A ‘just’ or ‘fair’ culture that encourages a reporting and questioning culture;
- Systems for reporting and analysing incidents both locally and nationally;

- A good in-depth analysis process to establish root causes for selected individual incidents and aggregate incident reviews, thus enabling learning;
- A process to ensure that actions are implemented and corresponding improvements in patient safety and quality of care can be demonstrated; and
- Effective processes for sharing information at various levels – nationally, organisationally and clinically – for learning and improvement.

In order to improve understanding of the extent and impact of patient safety incidents a number of research projects have been carried out in various countries. As a result patterns and trends are starting to emerge. Indeed, Neale et al collated information on international studies involving retrospective reviews of patient records to determine the incidence of patient safety incidents (**Figure 23**). This found that the average incidence was 8.9 per cent and the average incidence of potentially avoidable adverse events was 3.4 per cent. The variation in data can in part be explained by differences in the underlying methodologies for screening records to determine patient safety incidents.

23 Results of retrospective case record reviews

| Study | Year | Number of hospitals | Number case records | Percentage incidence of adverse events | Percentage incidence of preventable adverse events |
|------------------------|------|---------------------|---------------------|--|--|
| California | 1975 | 24 | 20,864 | 4.6 | 0.78 |
| NY State | 1984 | 51 | 30,121 | 3.8 | 0.95 |
| Utah-Colorado | 1992 | 28 | 14,700 | 2.9 | 0.93 |
| Australia (Victoria) | 1993 | 31 | 14,179 | 16.6 | 8.4 |
| England (London) | 1999 | 2 | 1,014 | 10.8 | 5.2 |
| Denmark | 2000 | 17 | 1,097 | 9.0 | 3.6 |
| New Zealand (Auckland) | 2000 | 3 | 1,326 | 10.7 | 4.3 |
| Canada (Ottawa) | 2002 | 20 | 3,745 | 7.5 | 2.8 |
| France (Aquitaine) | 2002 | 7 | 778 | 14.5 | 4.0 |
| Average | | 20 | 9,758 | 8.9 | 3.4 |

Source: Presentation made by Graham Neale at Making Health Care Safer 2004, Royal College of Physicians, London, 21-22 October 2004

Figures 24 and 25 overleaf presents summary information on aspects of patient safety programmes and initiatives in selected countries. Given that tremendous differences in health care provision can exist within individual countries, this information needs to be interpreted with caution.

Case examples 11 and 12 provide details of some of the more advanced reporting and learning systems used in Australia and the United States of America. A full report on the international comparisons work that we commissioned, which details the developments in a number of comparative countries, can be found at <http://www.nao.org.uk>.

CASE EXAMPLE 11

The Advanced Incident Monitoring System, New South Wales, Australia – www.health.nsw.gov.au

The Australian Patient Safety Foundation was initially formed by a group of anaesthetists, who continue to provide anonymous information to a centralised database, and has been researching patient safety since 1988. It developed a computerised incident management system with its commercial company, Patient Safety International. The Advanced Incident Management System provides a mechanism for any adverse event or near miss in health care to be reported, coded and analysed to identify the underlying causes and to help prevent the error from recurring. The system was released to the acute hospital sector in Australia in 1998 and since that time it has been enhanced significantly. It now allows for the capture of any type of incident and has been taken up by over 54 per cent of Australian public health organisations. The latest installation is in New South Wales, a state of around 7 million people, where over 100,000 healthcare users access the system to report incidents. The system went 'live' in December 2004 and has since captured over 30,000 incidents. This information is immediately available for follow-up, classification and analysis by health managers at the local level through to state level. New South Wales conducted an extensive pilot to ascertain the different types of service delivery models and how the software managed the differences, the incident management processes and the training requirements. The New South Wales Health Department had previously introduced a version of the Department of Veterans' Affairs (United States of America) Root Cause Analysis methodology across its entire health care system and released its first report on learning from patient safety incidents in January 2005.

Prepared by Stuart Emslie, Independent Healthcare Consultant under contract to the National Audit Office

CASE EXAMPLE 12

Pennsylvania Patient Safety Authority, United States of America – www.psa.state.pa.us

The Pennsylvania Patient Safety Authority is an independent state agency established under Act 13 of 2002, the Medical Care Availability and Reduction of Error Act. It is charged with taking steps to reduce and eliminate medical errors by identifying problems and recommending solutions that promote patient safety. Under Act 13, all Pennsylvania-licensed hospitals, birthing centers and ambulatory surgical facilities are required to report what the Act defines as "serious events" and "incidents" to the Pennsylvania Patient Safety Authority. In turn, the Authority analyses the collected data to identify trends or systems failures that can be corrected to prevent future serious events and incidents.

In July 2003, the Emergency Care Research Institute and partners, EDS (an international information technology firm) and the Institute of Safe Medication Practices, were appointed to implement a state-wide web-based patient safety reporting system. By mid-November 2003, 22 facilities, representing a cross-section of Pennsylvania's healthcare institutions, were voluntarily participating in a test phase of the reporting system prior to state-wide roll out. From March 2004, the Emergency Care Research Institute produced a comprehensive quarterly newsletter containing wide-ranging feedback from the Pennsylvania Patient Safety Authority. State-wide roll out of the reporting system, involving over 400 healthcare facilities, commenced from June 2004.

Prepared by Stuart Emslie, Independent Healthcare Consultant under contract to the National Audit Office

24 Summary of international patient safety programmes and initiatives

| | Australia | Canada | Hong Kong | Ireland | New Zealand | Singapore | United States of America | England ¹ |
|---|------------------|--------------|-----------|---------|-------------|-----------|--------------------------|----------------------|
| Truly national approach to patient safety? | No | Yes | Yes | Yes | Yes | Yes | No | Yes |
| National patient safety body? | Yes ² | Yes | No | No | No | No | Yes | Yes |
| Confidential national reporting scheme(s)? | Yes ³ | ⁴ | Yes | Yes | Yes | Yes | No | Yes |
| Mandatory national reporting of sentinel adverse events? | No | ⁴ | Yes | Yes | Yes | Yes | Yes ⁵ | ⁷ |
| Mandatory State or Territory reporting of sentinel adverse events? | Yes | No | Yes | N/A | N/A | N/A | Yes ⁶ | Not Applicable |
| Web-based reporting system? | Yes | ⁴ | Yes | Yes | No | No | | Yes |
| Progress in encouraging a reporting and questioning culture? | Yes | ⁴ | Yes | ? | ? | ? | Yes | Yes |
| Root Cause Analysis for learning? | Yes | ⁴ | Yes | No | Yes | Yes | Yes | Yes |
| Evidence of systematic local learning? | Yes | ⁴ | Yes | Yes | Yes | Yes | Yes | Yes |
| Evidence of systematic national learning using existing sources of information? | Yes | ⁴ | Yes | No | ? | Yes | Yes | ? |
| System(s) for disseminating lessons? | Yes | ⁴ | Yes | Yes | Yes | No | Yes | Yes ⁸ |
| Patient safety research programme | Yes | ⁴ | No | No | No | No | Yes | Yes |
| Specific categories of recurring adverse incident? | No | ⁴ | Yes | No | No | No | Yes | Yes |
| Specific efforts towards 'organisational learning'? | No | No | Yes | No | No | No | Patchy | Yes |

Prepared by Stuart Emslie, Independent Healthcare Consultant under contract to the National Audit Office

NOTES

- For comparative purposes we have included a summary of the findings from our own analysis.
- Australian Council for Safety and Quality in Healthcare oversees national patient safety issues.
- The Advanced Incident Management System operated by Australian Patient Safety Foundation.
- Canadian Patient Safety Institute will be covering these issues in implementing its strategic business plan, 2004-2007.
- To the accreditation body, the Joint Commission on Accreditation of Healthcare Organizations.
- Most states have established, or are establishing patient safety bodies, e.g. Pennsylvania Patient Safety Authority.
- Not all strategic health authorities or trusts use the Strategic Executive Information System.
- The first report of the Patient Safety Observatory was published in July 2005.

Devolved Nations

25 Summary of the approach adopted in the Devolved Nations

| | Northern Ireland | Scotland | Wales |
|-------------------------------------|---|--|---|
| Strategy document | Consultation paper <i>Best Practice – Best Care 2001</i> | Consultation paper <i>Learning from experience: How to improve safety for patients in Scotland 2003</i> | <i>Improving Health in Wales (the NHS Plan) 2001</i> |
| Priorities | <ul style="list-style-type: none"> a evaluation of current systems to identify and manage adverse incidents b open reporting and balanced analysis of patient safety incidents c development of a Service Level Agreement with National Patient Safety Agency d standardisation of adverse incident reporting | <ul style="list-style-type: none"> a review of current local and national reporting systems b developing an open culture c implementing the Australian/New Zealand Risk Management Standard 4360: 2004 | <ul style="list-style-type: none"> a developing an open culture b sharing of learning from patient safety incidents c monitoring compliance with National Patient Safety Agency alerts/guidance d development of revised S41 agreement with National Patient Safety Agency following the Arm's Length Bodies review |
| Body responsible for patient safety | Safety in Health and Social Care Steering Group, chaired by the Deputy Chief Medical Officer | The Scottish Executive Health Department has delegated this role to NHS Quality Improvement Scotland, a special health board | <ul style="list-style-type: none"> 1 Welsh Assembly Government through its Quality, Standards and Safety Improvement Directorate 2 All-Wales Advisory Group to the National Patient Safety Agency |
| National Reporting system | <ul style="list-style-type: none"> 1 Northern Ireland Adverse Incident Centre, part of Health Estates, records and investigates adverse incidents concerning medical devices and equipment and issues warnings and guidance to prevent recurrence. 2 Serious adverse incidents that warrant regional action to improve safety or care; are of public concern; or require an independent review are reported to the Department of Health, Social Services and Public Protection. | <ul style="list-style-type: none"> 1 Scottish Healthcare Supplies issues safety action and hazard notices on non-clinical issues and has an electronic reporting system for devices and estates incidents and near misses. 2 NHS Quality Improvement Scotland has responsibility for investigating serious service failures. 3 NHS Quality Improvement Scotland is currently developing a national approach for incident reporting across NHS Scotland. | <ul style="list-style-type: none"> 1 Serious patient safety incidents are reported to Welsh Assembly Government through its Regional Offices. Anonymised incidents are logged centrally and reviewed by its Clinical Risk Committee to determine those which require independent review and to determine any shared learning across Wales. 2 All NHS Wales organisations connected and expected to report to National Patient Safety Agency's National Reporting and Learning system. |

Source: National Audit Office

APPENDIX 5

Integrating trusts' reporting systems with the National Reporting and Learning System

We commissioned ECRI Europe to review and report on the implementation of the National Reporting and Learning System. The review focused on four trusts' experiences in introducing the new system and how well it could be integrated with their existing risk management systems. The key findings were as follows:

- the National Reporting and Learning System is an extremely sophisticated data collection tool;
- mapping of local datasets with the national system was considered to be complicated;
- the bespoke systems in use in other countries record particular types of incident information collectively and have a natural hierarchy. The structure and approach of the National Reporting and Learning System appears entirely different with similar pieces of information (categories) being scattered throughout making the mapping even more time consuming;
- two software packages that were procured to produce statistical information and enable free text searching have not yet delivered feedback for trusts; feedback which had been received was mostly limited to comments on data quality during submission to the national system; and
- trusts that were visited felt that the local systems were more important for learning lessons.

The experience of one of the acute trusts reviewed is described in **Illustrative example 10** and **Figure 26** provides details of some of the explanations about the problems of integrating with the National Reporting and Learning System given to us by trusts via our survey.

ILLUSTRATIVE EXAMPLE 10

Integrating a trust's risk management system with the National Reporting and Learning System

The Royal United Hospital Bath NHS Trust have used the Prism Risk Management System to record patient safety incidents for four years. In November 2003 the National Patient Safety Agency launched its second trial to collect local reports of patient safety incidents and Prism Risk Management Limited asked the Trust to be the pilot site for the establishment of the electronic link between its 'Incident Manager' and the National Reporting and Learning System.

Prism Risk Management Limited wrote a piece of software which allowed data interface between the two systems. Then staff from the Royal United had to map the details and categories of information recorded on their adverse incident and medication adverse incident forms to the dataset defined by the National Patient Safety Agency. Staff reported that they found it extremely difficult to match the descriptions to those of the National Reporting and Learning System. It took between 50 to 60 hours and it was hard for Risk Management staff to devote time to concentrate on the mapping exercise whilst they had to carry out their normal duties. Also without the staff's detailed knowledge and experience of the 'Incident Manager' database the process may well have taken longer.

Source: ECRI report to National Audit Office

26 Quotes given by trusts in response to our survey question "How readily has the trust integrated the National Patient Safety Agency's reporting system into its own reporting system?"

“There has been an underestimation of the time and energy required on the part of the trust to gear up for compliance.”

“We had problems with mapping the data but got support and assistance from the patient safety manager for Greater Manchester to solve this.”

“The number of categories and detail required means that the current simple form used for incident reporting, which the Trust feels encourages a high level of reporting, needs to be changed.”

“Our own Access data base did not comply.”

“There are many categories which had to be marked as ‘other’ because the National Reporting and Learning system could not accommodate the incident type we had defined.”

“On several occasions the administrators of the National Reporting and Learning System challenged the categorisation reports we submitted. After we had explained the definition they had to agree that we had in fact mapped the incident to the correct place.”

“The two years it took the National Patient Safety Agency to organise the whole process and the limited information it shared on the process of the programme until a very late stage, held our Trust back in developing our reporting system because we were uncertain of the minimum data sets that would be applied.”

“Contact with the National Patient Safety Agency helped to clarify things.”

“Our previous electronic system used for reporting patient safety incidents was not compatible with the National Reporting and Learning System. So we could not report automatically and were required to complete e-Forms that proved to be very time-consuming.”

“We required investment for a system and so had to produce a business case.”

“We had discussions with the local National Patient Safety Agency's patient safety manager to agree compromises on data mapping.”

“There were delays in obtaining an upgrade of our risk system.”

“The National Patient Safety Agency's mapping toolkit is too acute-focused and has caused difficulties with appropriate mapping.”

“Staff attended the National Patient Safety Agency's process mapping event in Leeds on 17 August 2004 to learn how to integrate coding systems.”

“We had problems linking the community hospitals - the National Reporting and Learning system seems to reject data from outside the main hospital environment.”

Source: National Audit Office survey of acute, ambulance and mental health trusts, 2004

APPENDIX 6

Outputs from the National Patient Safety Agency

Alerts

- July 2002 **Potassium Chloride Alert** – Research identified a risk to patients from errors occurring during intravenous administration of potassium solutions. Actions required: policies for the storage and handling of potassium chloride concentrate and other strong potassium solutions; the preparation of dilute solutions containing potassium, the prescription of solutions containing potassium and checking the use of strong potassium solutions in clinical areas.
- February 2004 **Crash Call Alert** – NHS hospitals in England use 27 different crash call numbers. Actions required: trusts should review standardising the crash call number to 2222 to reduce the risk that temporary staff are unaware of the crash call number, causing a delay in treating the patient.
- July 2004 **Oral Methotrexate Alert** – 137 patient safety incidents over the last ten years in England alone were due to problems with taking this medication. Actions required: provide patient information before and during treatment, update prescribing and dispensing software programmes and review purchasing.
- September 2004 **Hospital Infections Alert** – Issued in preparation for the ‘cleanyourhands’ campaign. Actions required: install alcohol-based hand rub at point of care across the NHS organisation by April 2005 and assess and manage risks associated with its use and storage.
- March 2005 **Reducing the harm caused by the misplacement of nasogastric feeding tubes** – At least 11 patients have died as a result of misplaced nasogastric feeding tubes between December 2002-04. A further 13 incidents where patients were harmed were reported to the National Reporting and Learning System. Actions required: provide staff, carers and patients in the community with information on correct and incorrect testing methods, carry out individual risk assessment prior to nasogastric tube feeding and report misplacement incidents via local risk management reporting systems.
- March 2005 **Correct site surgery** – The pilot of the national reporting system for learning recorded 44 incidents related to wrong site surgery. Actions required: use a robust system for marking the correct site for surgery; use a verification checklist; review integrated care plans and provide information to staff.

Notices

- May 2004 **Improving Infusion Device Safety** – At least 700 unsafe incidents are reported each year related to infusions, of which 19 per cent are attributed to user error. Actions recommended: review how purchasing decisions are made; evaluate the necessity for an infusion device prior to purchase; reduce the range of infusion device types in use and have agreed default configurations; and investigate the benefits of a centralised equipment library. Include a toolkit to help trusts review their existing device management systems and assess the potential for significant cost-benefits and improved patient safety.
- April 2005 **Ensuring safer practice with Repevax and Revaxis vaccines** – Reported incidents where staff have given children the wrong vaccine. Actions recommended: develop procedures to check for correct vaccine; display pictures of packaging to reduce chances of wrong vaccine being selected and review risk assessment procedures for new vaccines.

Information

- September 2004 **Spinal Cords Injury Information** – Some people with an established spinal cord lesion are dependent on manual removal of faeces and without it they risk developing autonomic dysreflexia. Actions recommended: developing a policy for manual bowel evacuation based on guidelines such as the *Royal College of Nursing's Digital Rectal Examination and Manual Removal of Faeces: Guidance for Nurses* (April 2004); ensuring nursing staff are aware of the risks associated with these patients, the potential harmful outcomes of developing autonomic dysreflexia and how to access staff able to undertake a manual evacuation; ensuring experienced staff are available at all times to undertake and teach the procedure; and recognising that these patients are experts in managing their bowel care.
- November 2004 **Update on producing patient information on methotrexate usage**
- November 2004 **Update on the implementation of recommended safety controls for potassium chloride in the NHS**
- April 2005 **Improving emergency care for patients who breathe through their neck** – Patients who have had a laryngectomy or have a long-term tracheotomy may be at risk when receiving emergency care if staff are not aware of how to manage their ventilation needs. Actions recommended: ambulance and acute trusts include airways management for patients with stomas in relevant local training courses for all staff; ensure that all emergency response vehicles and resuscitation trolleys include appropriate equipment to administer oxygen effectively and manage the airway of a neck breather and make appropriate training equipment available for trainers.

Newsletters

- August 2003 **Newsline** – First quarterly newsletter for the NHS to keep abreast of developments at the National Patient Safety Agency

Guidance/Learning

- 2003 **Root cause analysis toolkit** – Root cause analysis, is a retrospective review of a patient safety incident undertaken in order to identify what, how, and why it happened. The analysis is then used to identify areas for change, recommendations and sustainable solutions, to help minimise the re-occurrence of the incident type in the future. Alongside the introduction of the root cause analysis training and a CD ROM, a modular online training programme with support material was available for NHS staff unable to attend the training workshops.
- June 2003 **Patient safety induction video** – Provides a practical introduction to patient safety and an insight into how each staff member responsible for delivering care can contribute to a safer environment. Intended for incorporation into staff induction programmes.
- November 2003 **Seven Steps for Patient Safety** – To help NHS organisations to improve patient safety: 1) Build a safety culture, 2) Lead and support your staff, 3) Integrate your risk management system, 4) Promote reporting, 5) Involve and communicate with patients and the public, 6) Learn and share safety lessons and 7) Implement solutions to prevent harm. Accompanied by a checklist for chief executives to enable them to plan their activities and measure performance in patient safety.

- May 2004 **Incident Decision Tree** – A framework for human resource and NHS managers to determine the course of action to take with staff who have been involved in a patient safety incident in order to encourage a consistent and fair approach to staff issues across the NHS.
- June/July 2004 **Patient safety e-learning** – An introduction to the National Patient Safety Agency's work and the factors that effect patient safety. The modules are: introduction to patient safety; guidance and support; reporting; patient safety reporting; team working; infusion devices and misidentification.
- July 2004 **Safer Handover** – Provides guidance to doctors on best practice and examples of good models for safer patient handover.
- March 2005 **Hospital at Night – Patient Safety Risk Assessment Guide** – Provides an approach to risk assess Hospital at Night solutions to ensure their design and implementation leads to safer patient care.

Reports

- February 2004 **Listening to people with Learning Disabilities** – Five key risks identified from the experiences of people with learning disabilities and their carers across England and Wales, feedback from health and social care professionals and a literature review around existing work: 1) control and restraint, 2) vulnerability of people with learning disability in general hospitals, 3) swallowing difficulties, 4) lack of accessible information and 5) illness or diseases being mis- or un-diagnosed.
- December 2004 **Right patient, right care** – Patients can receive healthcare which is not intended for them or be matched with specimens other than their own. Proposed a way forward with the NHS, industry and patients working together to devise and introduce systems which will help to reduce mismatching significantly and make patient care safer.

Reporting Mechanisms

- September 2004 **Online incident reporting form (e-Form)** – For all NHS staff who want to report (anonymously) to the National Patient Safety Agency, rather than through their trust. Fully functional January 2005.
- December 2004 **National Reporting and Learning System** – System designed to link to local incident reporting systems to receive patient safety incident reports. All trusts were to begin sending data in June 2005 (at least 35 have not yet submitted data).

APPENDIX 7

Measuring Risk Management and Performance

Clinical Negligence Scheme for Trusts

The Clinical Negligence Scheme for Trusts is a risk pooling scheme in respect of clinical claims administered by the NHS Litigation Authority. Contained within the scheme are a number of clinical risk management standards to encourage trusts to promote good risk management practices and reduce the number and value of clinical claims.

General Clinical Risk Management Standards: Standard one, learning from experience (April 2004)

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| Level 1 | 1 | Patient adverse incidents and near misses reported in 50 per cent of all specialties |
| | 2 | Summarised patient incident reports are provided regularly to relevant bodies for review and action |
| Level 2 | 1 | Clinically related events are reported as they occur and before claims are made |
| | 2 | There is evidence of management action arising from patient safety incident reporting |
| | 3 | Patient adverse incidents and near misses are reported in 100 per cent of all specialties |
| | 4 | In the interest of patient safety, openness and constructive criticism of clinical care is actively encouraged |
| | 5 | Examples of two changes which reduce risk as a consequence of complaints can be demonstrated |
| | 6 | The Trust applies the advice in the National Confidential Enquiries |
| Level 3 | 1 | All clinical staff receive training in patient adverse incident reporting |
| | 2 | Examples of five changes which reduce risk as a consequence of complaints can be demonstrated |

Maternity Clinical Risk Management Standards: Standard two, learning from experience (April 2004)

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| Level 1 | 1 | A system is in place for reporting adverse incidents and near misses in all areas of service |
| | 2 | The incident report form gathers significant data about the event |
| | 3 | The incident report form contains clear guidance on its completion and any subsequent action required |

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| | 4 | Summarised adverse incident reports are provided regularly to the Maternity Services Risk Management Group for review and action |
| | 5 | The service implements the trust policy on the relationship between incident reporting and disciplinary action |
| Level 2 | 1 | The service has a strategic approach to the management of adverse incidents that might lead to a claim or litigation |
| | 2 | There is evidence of lessons learned and action arising from adverse incident reporting |
| | 3 | The service applies the board approved trust policy for managing serious untoward incidents |
| | 4 | The service can demonstrate changes in practice which reduce risk, in response to complaints |
| | 5 | All professional staff receive guidance and training in adverse incident reporting |
| | 6 | The service considers and applies the recommendations made in the National Confidential Enquiries |
| Level 3 | 1 | The service audits its practice against the advice in the National Confidential Enquiries, and implements changes accordingly |

Risk Pooling Schemes for Trusts

The Liabilities to Third Parties Scheme was established in 1999, to provide a means for NHS trusts to fund the cost of non-clinical legal liabilities to third parties and to encourage and support the effective management of risk and claims. The Risk Pooling Schemes for Trusts which supported the non-clinical risk pooling scheme and assessed NHS bodies' general approach to risk management was withdrawn at the end of March 2005, but key elements of the Standard will be incorporated into the revised approach to NHS Litigation Authority standards and assessments.

Criterion four:

Incident reporting and management (all to achieve Level one) (April 2004)

- 1 There is a Board approved policy/procedure for recording, reporting and managing incidents
- 2 The policy/procedure is based upon a standard definition of incidents
- 3 The policy/procedure promotes a positive and fair blame approach towards incident reporting
- 4 All reported incidents and causal factors are classified and categorised in accordance with a standardised classification scheme
- 5 The policy/procedure states that all incidents must be reported promptly and an incident form completed
- 6 The policy/procedure states that management actions and preventative measures taken must be recorded
- 7 All reported incidents are graded according to severity of outcome and potential future risk to patients and/or the organisation

- 8 A policy/procedure on incident investigation and root cause analysis is in place that contains a clear protocol to be followed
- 9 For serious adverse incidents that could have an impact upon staff, patients or the public the policy/procedure requires them to be advised
- 10 All incidents are reported on standard forms, which may be paper-based or electronic, and which captures a minimum dataset of information in accordance, where relevant with NHS guidance

Standards for Better Health

Core standard – Safety

Patient safety is enhanced by the use of health care processes, working practices and systemic activities that prevent or reduce the risk of harm to patients

- C1 Health care organisations protect patients through systems that prevent or reduce the risk of harm to patients.
 - a) identify and learn from all patient safety incidents and other reportable incidents, and make improvements in practice based on local and national experience and information derived from the analysis of incidents; and
 - b) ensure that patient safety notices, alerts and other communications concerning patient safety which require action are acted upon within required timescales
- C2 Health care organisations protect children by following national child protection guidance within their own activities and in their dealings with other organisations
- C3 Health care organisations protect patients by following National Institute for Clinical Effectiveness interventional procedures guidance
- C4 Health care organisations keep patients, staff and visitors safe by having systems to ensure that:
 - a) the risk of health care acquired infection to patients is reduced, with particular emphasis on high standards of hygiene and cleanliness, achieving year-on-year reductions in MRSA;
 - b) all risks associated with the acquisition and use of medical devices are minimised;
 - c) all reusable medical devices are properly decontaminated prior to use and that the risks associated with decontamination facilities and processes are well managed;
 - d) medicines are handled safely and securely; and
 - e) the prevention, segregation, handling, transport and disposal of waste is properly managed so as to minimise the risks to the health and safety of staff, patients, the public and the safety of the environment

Developmental standard

- D1 Health care organisations continuously and systematically review and improve all aspects of their activities that directly affect patient safety and apply best practice in assessing and managing risks to patients, staff and others, particularly when patients move from the care of one organisation to another

Components of a safety culture have been defined as:

- Commitment to safety articulated at the highest level
- Safety is perceived to be the highest priority
- Financial investment is made in safety practice
- Incentives are aligned to promote safe practice
- Open communication around safety issues is encouraged
- Unsafe acts are rare
- Commitment to organisational learning rather than blame
- Organisations are proactive not reactive

GLOSSARY

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| Acute NHS Trust | Hospitals, which are managed by their own Boards and which provide beds on the following wards: intensive care, terminally ill/palliative care, surgical, medical and paediatric, acute maternity and acute elderly and young physically disabled. |
| Adverse drug event | Harm resulting from medical intervention related to a drug. |
| Adverse event | Unintended injuries caused by medical management rather than the disease process. |
| Arm's Length Bodies Review | A review by the Department of the work undertaken by the stand alone national organisations it sponsors to undertake its executive functions, carried out in 2004. |
| Blame culture | An organisational culture which inhibits openness regarding reporting incidents as staff are fearful of being personally penalised for making errors. |
| Clinical audit | Organised review of current clinical procedures compared with pre-determined standards. Action is then taken to rectify any identified deficiencies in current practices. The review is repeated to see if the standards are being met. |
| Clinical governance | A framework through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish. |
| Clinical governance reviews | Reviews carried out by the Commission for Health Improvement to evaluate trust structures that assess the quality of their services and safeguard high standards of care. |
| Clinical incident | Incidents in a health care setting caused by clinical procedures that resulted, or could have resulted, in unexpected harm to the patient. |
| Contract staff | Staff who work for a company which is employed by an NHS trust to carry out work for them, for example contract cleaners. They take instructions from a manager who also works for the contractor, not from trust employees themselves. |
| Controls Assurance | The system of management which informs NHS boards about identified risks and help determine unacceptable levels of risk. Chief executives and boards can then decide where best to direct resources to eliminate or reduce those significant risks within their organisation. |
| Foundation Trusts | Trusts that are responsible for their own financial management and are performance managed by primary care trusts . |
| General Medical Council | All practising doctors must be registered with the General Medical Council. It protects the interests of patients via legal powers designed to maintain the standards the public have a right to expect of doctors. |
| Harm | Death, disease, injury, suffering and/or disability experienced by a person. |

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| Health and Safety Executive | A statutory body, which reports to the Health and Safety Commission, with day-to-day responsibility for making arrangements for the enforcement of safety legislation to ensure that risks to health and safety due to work activities are properly controlled. |
| Health Protection Agency | Independent body that protects the health and well-being of the population of the United Kingdom, particularly with regard to infectious diseases, chemical hazards, poisons and radiation. |
| Healthcare Commission | Promotes improvement in the quality of the NHS and independent healthcare. Has a statutory duty to assess performance of healthcare organisations, awarding annual ratings for the NHS, and co-ordinate inspections and reviews of healthcare. |
| Hospital acquired infection | An infection that was neither present nor incubating at the time of a patient's admission which normally manifests itself more than three nights after the patient's admission to hospital. |
| In-depth investigation | A full investigation into the causes of a patient safety incident, though not necessarily using root cause analysis techniques. |
| Inspection | A visit carried out as part of a review, investigation or study to inspect premises or documents, or to require explanation. |
| Integrated risk management | The process of identification, assessment, analysis and management of all risks and incidents for every level of the organisation, and aggregating the results at a corporate level, which facilitates priority-setting and improved decision-making to reach optimal balance of risk, benefit and cost. |
| Local risk management system | A trust's own system for the reporting and logging of patient safety incidents and near misses . |
| Management cascade | The path by which important corporate messages are communicated from trust board level down to the operational staff. |
| Medical device | Any instrument, apparatus, appliance, material or health care product, excluding drugs, used for a patient or client for the purpose of: <ul style="list-style-type: none"> ■ diagnosis, prevention, monitoring, treatment or alleviation of disease or an injury or handicap ■ investigation, replacement or modification of the anatomy or of a physiological process ■ control of conception. |
| Medical error | An adverse event or near miss that is preventable with the current state of medical knowledge. |
| Medical Protection Society | A mutual medical protection organisation to assist doctors with the legal problems that arise from their professional practice. |
| Medication error | Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient or customer. |

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| Medicines and Healthcare products Regulatory Agency | Executive agency of the Department of Health and Competent Authority that ensures medicines and medical equipment meet appropriate standards of safety, quality, performance and effectiveness. The legislation covers neither the prescribing or administration of drugs nor the user of the device or the environment in which it is used. |
| Mental Health Act Commission | Body to protect the rights of mentally ill patients detained under the Mental Health Act 1983. Receives notification of the deaths of detained patients and reviews all deaths from unnatural causes and provides expert advice and guidance to the Department, providers and professionals. |
| Morbidity | The state of having a disease, or reduced state of health. |
| Mortality | Death. |
| National Clinical Assessment Authority | A special health authority to provide a support service to health authorities, primary care trusts and hospital and community trusts that are faced with concerns over the performance of an individual doctor. Following the Arm's Length Bodies Review , it became part of the National Patient Safety Agency and was renamed the National Clinical Assessment Service. |
| NHS Estates | Produces estates and facilities alerts and guidance on land, property, equipment and facilities issues. Following the Arm's Length Bodies Review this responsibility has transferred to the Department. |
| NHS Litigation Authority | Special health authority responsible for handling negligence claims made against NHS bodies in England. In addition to dealing with claims when they arise, it has an active risk management programme to help raise standards of care in the NHS. |
| NHS Clinical Governance Support Team | Provides practical support to help trusts implement clinical governance through development programmes, disseminating lessons from development work across the country and answering trusts' clinical governance questions. |
| National Institute for Clinical Excellence | <p>An independent organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health. On 1st April 2005, it joined with the Health Development Agency to become the new National Institute for Health and Clinical Excellence. Produces three kinds of guidance:</p> <ul style="list-style-type: none">■ technology appraisals – the use of new and existing medicines and treatments within the NHS in England and Wales■ clinical guidelines – appropriate treatment and care of people with specific diseases and conditions within the NHS in England and Wales■ interventional procedures – whether those used for diagnosis or treatment are safe enough and work well enough for routine use in England, Wales and Scotland. |
| National NHS Staff Survey 2004 | Between October and December 2004, over 217,000 staff in 572 NHS trusts and 26 strategic health authorities in England took part in the second National NHS Staff Survey, conducted by the Healthcare Commission . |

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| National Programme for Information Technology in the NHS | From 1 April 2005, after the Arm's Length Bodies Review , the Department's agency, NHS Connecting for Health is delivering the National Programme. Over the next ten years, over 30,000 general practitioners in England are expected to connect to almost 300 hospitals and give patients access to their personal health and care information. New systems, such as Electronic Patient Record, Choose and Book electronic appointment booking, and Prescription Transmission, will be implemented to improve patient experience of the NHS. |
| National Service Frameworks | One of a range of measures to raise quality and decrease variations in service. They are long term strategies which: <ul style="list-style-type: none"> ■ set national standards and identify key interventions for a defined service or care group ■ put in place strategies to support implementation ■ establish ways to ensure progress within an agreed time scale. |
| Near miss | Unexpected or unplanned events in the provision of care that could have, but did not, lead to harm , loss or damage. |
| Non-clinical incident | Incidents in a health care setting not caused by clinical procedures that resulted, or could have resulted, in unexpected harm to the patient, for example a patient fall. |
| Patient Advice and Liaison Service | Available in every trust to provide: <ul style="list-style-type: none"> ■ confidential advice and support to patients, families and their carers ■ information on the NHS and health related matters ■ confidential assistance in resolving problems and concerns quickly ■ information on and explanations of NHS complaints procedures. |
| Patient Safety Observatory | Its staff draw together information from different sources in new ways to quantify, characterise and prioritise patient safety issues and thus drive the work programme of the National Patient Safety Agency. |
| Patient safety incident | Defined by the National Patient Agency as: any unintended or unexpected incident that could have or did lead to harm for one or more patients receiving NHS-funded healthcare. |
| Patient safety incident (prevented) | The National Patient Safety Agency's term to describe a near miss . |
| Primary care trust | Receives a budget directly from the Department to provide primary care (general practitioner and local community services) and to commission secondary and tertiary care services. |
| Risk | The chance of something happening that will have an impact on individuals and/or organisations. It is measured in terms of likelihood and consequence. |
| Risk assessment | The process that helps organisations understand the range of risks they face – both internally and externally, the level of ability to control these risks, their likelihood of recurrence and their potential impacts. It involves a mixture of quantifying risks and using judgement, assessing and balancing of risks and their benefits and weighing them, for example, against the cost. |

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| Risk register | A database where results of all an organisation's risk assessments are collated. |
| Root cause analysis | Systematic process whereby factors that contributed to an incident are identified. |
| Safety | A state in which risk has been reduced to an acceptable level. |
| Serious Hazards of Transfusion | Information on serious patient safety incidents involving transfusion of blood or blood components from participating bodies is collected to: improve the safety of the transfusion process; inform policy within the Transfusion Services; improve standards of hospital transfusion practice; aid production of clinical guidelines for the use of blood components. Participation in the scheme is voluntary, but it covers both NHS and private hospitals in the United Kingdom and Ireland. |
| Serious Untoward Incident | No single definition but in general it is an event that causes or has the potential to cause serious injury, mental trauma, and unexpected death or where there could be police involvement, major litigation and/or media interest. Reported to the local strategic health authority via the Strategic Executive Information System. |
| Strategic health authorities | Responsible for the performance of the local NHS and for setting strategies within which the national framework set out by the Department can be achieved. |
| Statement of Internal Control | A confirmation that the effectiveness of the system of internal control has been reviewed and that the Accounting Officer, the Board and the Audit Committee of the organisation have discussed the results. Produced with a high-level summary of the processes to identify, evaluate and control risk and training for staff to manage risk. |
| Taxonomy | System for naming and organising items into groups that share similar characteristics. |
| Temporary staff | Staff who are employed by an agency or by the trust directly to work for it for a limited period of time. When at the trust they take instructions from trust employees, for example agency nurses and locum doctors. |

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