

The development of the National Reporting and Learning System in England and Wales, 2001–2005

Susan K Williams and Sue S Osborn

The drive to improve patient safety in the United Kingdom is often attributed to the landmark report in 2000, *An organisation with a memory*,¹ and the government's subsequent response, *Building a safer NHS*,² which established the National Patient Safety Agency (NPSA) in July 2001. However, in effect the drive began with the wider system reforms introduced by the new Labour government in 1997 to promote and assure service quality.

At the centre of these reforms was the introduction of "clinical governance" at the level of individual health care institutions. Clinical governance can be defined as a framework through which National Health Service (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.³ In addition, new national service frameworks were introduced which set out expected quality standards for a range of clinical conditions. New institutions were also established: the National Institute for Clinical Excellence, charged with drawing up guidelines for NHS care, and the Commission for Health Improvement, with powers to inspect health care providers and intervene when necessary.

Action was also prompted by widespread public concern over serious service failures, in particular relating to children's heart surgery at the Bristol Royal Infirmary.^{4,5} High media interest in instances of clinical error and service failure was, and has remained, a feature of life in the United Kingdom.

We describe here the efforts of the NPSA in England and Wales to implement a national system for recording and learning from reported patient safety incidents.

Developing the system

The task for the NPSA was to find a way of capturing information about patient safety incidents — unintended incidents that did result or could have resulted in patient harm — while promoting a culture that would encourage reporting from NHS staff. We called this project the National Reporting and Learning System. Its purpose is to collect incident information so that we can learn from it, alert the health system to potential risks, and use this information to design interventions to make care safer ("safety solutions").

We looked enviously at our American colleagues in the Agency for Healthcare Research and Quality who had set themselves 2 years to achieve an integrated reporting system and who had at their disposal a US\$50 million patient safety research program;⁶ at the Veterans Health Services in the United States who had established a reporting system with freedom from legal disclosure;⁷ and at the Australian Council for Safety and Quality in Health Care (<http://www.safetyandquality.org>) (now the Australian Commission on Safety and Quality in Health Care), which was able to develop stakeholder support and promote cultural change. In contrast, the NPSA had been charged with creating and implementing a comprehensive reporting system, covering all care settings within the NHS, within 18 months.

ABSTRACT

- In 2001, the National Patient Safety Agency (NPSA) was created as part of a wider reform process to improve quality of care for patients in the National Health Services of England and Wales. The NPSA was charged with developing and implementing a national system for collecting and learning from reported patient safety incidents.
- Between 2003 and 2005, 303 447 incidents were reported from a wide range of health care settings. As a result, a range of interventions have been developed to improve safety.
- A number of lessons have been distilled from the experience of England and Wales, including that:
 - clinical risk management system characteristics should be aligned with those of the national reporting system; and
 - safety culture and information dissemination must be addressed at the same time as any new reporting system is implemented.
- These lessons should be of use to other countries implementing similar patient safety strategies.

MJA 2006; 184: S65–S68

After a tendering process by the Department of Health in England, a pilot project was established, based on the Australian reporting system. This ran between October 2001 and March 2002 covering 28, mostly acute, hospital trusts in England.⁸ While on one level the pilot was successful in that 28 000 reports were received from 19 trusts, major difficulties were experienced with data quality and integrating the technical platform with the information technology infrastructure of the wider NHS. It became clear that the undertaking, in terms of both cost and time, had been seriously underestimated and, in February 2003, we embarked on the development of a bespoke reporting system for the NHS for incidents where patients were or could have been harmed.

Between 2003 and December 2004, all the UK-based vendors of risk-management systems worked alongside the NPSA to link NHS trusts to a central database. This involved intricate work to "map" information from multiple systems to a single information architecture. While this proved arduous, it has the significant advantage that clinicians only have to report any patient safety incident once — in our view a prerequisite for comprehensive reporting.

In 2002, there was not a single agreed national taxonomy for collecting and organising patient safety data that covered all care settings anywhere in the world. A number of different taxonomies had been developed independently.^{9,10} The NPSA reviewed what was available and brought together about 300 clinicians and managers to devise a taxonomy suitable for the UK context.¹¹

Overall, the cost of setting up the National Reporting and Learning System has been substantial — in the order of £5 million to date — however, between November 2003 and September 2005, 303 447 reports were received. Of these, most (207 349;

68.3%) related to incidents where no actual harm occurred to the patient. However, 2185 (0.7%) incidents resulted in severe harm to the patient, and 1297 (0.4%) resulted in the patient's death. Most reported incidents where a location was recorded occurred within an acute hospital (226 002; 74.7%), while 41 809 (13.8%) occurred within mental health services. The remaining incidents occurred within a range of community-based services, such as general practice and ambulance services.¹² We have used these incident reports to publish regular alerts and bulletins on safety issues through our newly created Patient Safety Observatory.¹³

Lessons learned

Lesson 1: *Each reporting system needs to be developed in the context of the risk-management history, information technology environment, financial and other incentives that are applied to institutions and individuals, and formal decision-making framework of the country or state in which it is developed. It needs realistic funding, availability of skills and clarity of purpose.*

The difficulty of obtaining each of these prerequisites should not be underestimated; the National Reporting and Learning System took 2 years longer to implement than originally expected, but it is now connected electronically to over 600 organisations in England and Wales.

Lesson 2: *A national risk management specification should be mandatory and integrated within a national approach to managing clinical care records and wider information collection protocols for the health system. It must also be compatible with national information technology standards (it proved more difficult than expected to align the development of our system with that of wider information systems for the NHS).*

In 2002, not only was there no mandatory dataset for patient safety, there was no national program for information technology development with which we could integrate. Just as importantly, there was no wish to disturb the relationship with the commercial vendors of risk management systems. Indeed, government policy for the National Reporting and Learning System was that it must work alongside any existing risk management system used by local NHS organisations.² While this stipulation was intended to ensure a diverse market place, this lack of central direction made the collection of uniform safety data more complex to achieve. There may be benefit in a more prescriptive and standardised approach to the data requirements of local health care organisations.

Lesson 3: *Implement incident reporting and learning systems alongside the development of several supporting tools, techniques and incentives that promote a "safety culture" within which clinicians feel it is safe to report.*

During the development of the National Reporting and Learning System, the NPSA prepared the NHS for the discipline of a "root cause analysis" approach to incident investigation. We drew heavily on the experience of the Veterans Health Services in the US and developed an e-based tool kit and training package in root cause analysis (http://www.npsa.nhs.uk/health/resources/root_cause_analysis). A choice of training in five types of root cause analysis was offered so that local discretion could be applied. Our "patient safety managers" have so far trained 8000 staff in more than 600 organisations in England and Wales, providing a qualitative jump forward in the capacity of the NHS in this important investigative technique. However, we set no hard and fast rules about when a root cause analysis should be undertaken. Local discretion was preferred.

The challenge we now face is how to systematically capture and share the learning from the rapidly increasing number of root cause analyses. The launch of a new website (<http://www.safer-healthcare.org.uk/ihl>), developed by a partnership between the NPSA, the Institute of Health Improvement and the *British Medical Journal*, will go some way to providing a vehicle for sharing learning.

Lesson 4: *A learning and dissemination strategy should be developed at the same time as a reporting system. Users of the information at the local level should be involved in designing the feedback products.*

The scale of the data collection exercise, with thousands of reports arriving each week, has presented challenges for data analysis and feedback. Some observers have questioned why the NPSA does not limit the data to more manageable volumes by using sampling techniques or restricting the range of incident types (as does, for example, the Joint Commission on Accreditation of Healthcare Organizations in the US). Our view is that, in the initial stages of national reporting, all types of incidents should be reported. This view is based on research showing that:

- different professional groups have different perceptions of what constitutes an incident;¹⁴
- there is significant learning to be had from "near misses";¹⁵
- reporting must be encouraged from all sectors;¹⁴
- there is no consensus in different care settings on what an incident is; and
- events that are rare at the level of the institution may be identified as significant when captured at the national level.¹⁶

Given the high volume of data that our strategy has created, some experimental analytical techniques are being developed.¹⁷ Three approaches to data analysis have been adopted. Firstly, standard statistical analyses of incident data are undertaken across a range of domains, such as medical specialty, severity of harm, and location. Secondly, all incident reports involving death or severe harm to patients are read by clinicians, providing a narrative analysis. Thirdly, "data mining" tools are used to group reports and identify issues using sophisticated keyword searches. This technique can potentially identify unfamiliar issues, find previously unsuspected connections between incidents, or confirm what was only suspected.

The National Reporting and Learning System acts as a mirror back to the NHS, but can also raise issues that might otherwise remain buried at a local level where they would be considered one-off events. The data can be used to inform educational curricula development, performance assessment and standards development, risk assessments at both national and local level and, perhaps most importantly, focus the health service on tackling the quality of care.

Lesson 5: *Develop a strategy alongside the reporting system to promote new safety interventions. This will help to prove the worth of the reporting system locally and thereby help to sustain reporting levels.*

While developing a range of "safety solutions", we focused particularly on the issue of effective implementation of any intervention. In our experience, guidance usually already existed on how to solve most of the problems we identified, but was not being followed, or was not known. Where possible, we attempted to "design out" safety risks rather than present clinicians with further guidelines.¹⁸

We are beginning to see some early successes. For example, we issued an alert to standardise the cardiac arrest telephone number used in acute trusts to 2222. Before this, 27 different numbers

were in use in England and Wales; now all trusts have standardised to a single number.¹⁹

We have worked with general medical practice computer systems to integrate an improved medication alert hierarchy,²⁰ and with pharmaceutical companies on packaging and labelling.²¹

Lesson 6: Consider how to secure compliance from the “front line” at the same time as developing solutions.

It is often said that a safer health service relies on the culture of the organisation. Our approach has been to provide practical tools that in themselves will alter traditional thought and working patterns. We have worked with the University of Manchester to customise a tool primarily used by the Shell Group. This tool can be used to assess progress in developing a good safety culture in a wide range of health care settings.²²

We are now using training in safety awareness to empower clinicians at the front line to reduce risk. This includes work to reform undergraduate and foundation year education in medical schools, together with the development of techniques such as teamwork assessment.

Lesson 7: Encourage candour between clinicians and patients while seeking to maintain anonymity in the reporting of incident data nationally. Attempt to manage political ramifications and media interest proactively.

Of all the issues that have been debated over the past 4 years the question of communicating unintended harm through error to patients and the public has been the most vexing. At the level of the individual patient who has experienced unintended harm, we learnt from Australian work on “open disclosure” and developed our own version of this approach called *Being open*. This comprised a policy promoting honest disclosure, together with training and support tools for clinicians and managers.²³

We have found that a range of tactics can be effective in shaping the public debate about safety. These include:

- media background briefings;
- an open and fast response to safety-related media stories;
- regular reports giving feedback;
- linking problems to a solution endorsed by professional bodies and patient groups; and
- putting NHS problems in the context of international comparisons.

Developments in the wider NHS policy environment have also proved important to our work.²⁴ The promotion of patient choice of provider has provided a new context for the public provision of information on the performance of health care providers, including information about safety.²⁵ Some NHS trusts already publish anonymised aggregated reports of incidents and actions taken in their public board meetings. New laws — under the *Freedom of Information Act 2000* and the *Data Protection Act 1998* — support greater openness.

On the other hand, fear of blame, retribution, disciplinary and legal action combine to act as a barrier to clinicians’ speaking up about either their own or colleagues’ mistakes. Under-reporting of incidents among clinicians is generally acknowledged. For this reason the NPSA has ensured that national data reporting from the National Reporting and Learning System is, as far as is reasonably practical, anonymous. In September 2004, we opened an anonymous and confidential web-based reporting route for staff who did not want to report via their host organisations. Interestingly, although only a small number of reports have so far been received, a higher proportion came from doctors compared with health care

organisations. Changing medical culture with regard to incident reporting remains a key challenge, and we have recently undertaken a campaign to promote reporting among junior doctors.

Political nervousness surrounding public debate of safety has also proved challenging. A civil service culture highly averse to risk has resulted in delay or a lack of agreement to the public reporting of our data. This underlines a dilemma for any reporting system. Lucian Leape of the Harvard School of Public Health has suggested that reporting systems should be seen to be independent.²⁶ However, being inside the NHS has given us the distinct advantages of, firstly, being able to enlist the support of ministers and the Department of Health and their mandate where necessary; and, secondly, of securing considerable resources and being able to influence national policy. The downside at times has been the level of attendant bureaucracy and the degree of media scrutiny that has discomfited politicians. On balance our preference is to remain within the NHS.

Conclusions

We believe we have started to develop a new way of looking at old problems that yields benefits in terms of safer health care. Of course, there is much more to do and we face new challenges as we move beyond our infancy to sustain and build on our early successes. Our efforts have been greatly assisted by learning from other countries’ experiences in this field and by the support and encouragement that has been freely offered by our international colleagues. We hope that our work, too, will help others as they develop their own strategies for patient safety.

Competing interests

None identified.

Author details

Susan K Williams, BA(Hons), IHM, Joint Chief Executive
Sue S Osborn, BA(Hons), IHM, Joint Chief Executive
National Patient Safety Agency, London, UK.

Correspondence: JCE@npsa.nhs.uk

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(Received 29 Jan 2006, accepted 3 Apr 2006)

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