editorial

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The National Patient Safety Agency

To err is human, and mistakes will be made in any human endeavour. Health care is no exception. However, many clinicians are unaware of the extent of suffering and the number of deaths caused by human or system error in health services. A consistent finding, in countries that have examined the problem, is that a significant adverse event happens during the course of about 10% of all hospital admissions. Between 44 000 and 98 000 people die in the USA each year because of mistakes made by health services. In Australia, the equivalent figure is about 10 000 deaths, with a further 50 000 people suffering a permanent disability. It is estimated that 850 000 adverse events happen each year to patients treated in National Health Service (NHS) hospitals in England (Department of Health, 2000). These events cost about £2 billion in additional hospital care alone.

In 2000, an expert group chaired by the Chief Medical Officer for England produced a report entitled *An Organisation with a Memory*, which stated that although

> 'human error may sometimes be the factor that immediately precipitates a serious failure . . . there are usually deeper, systematic factors at work which if addressed would have prevented the error or acted as a safety-net to mitigate its consequences' (Department of Health, 2000, p. 10).

Furthermore, the report criticised the culture of blame in the NHS, which

> 'can encourage people to cover up errors for fear of retribution and acts against the identification of the true causes of failure, because they focus heavily on individual actions and largely ignore the role of the underlying systems' (Department of Health, 2000, p. 10).

An Organisation with a Memory has introduced the technology and language of organisational safety into the mainstream of the NHS in England and Wales. It may also herald a far-reaching change in its culture.

The National Patient Safety Agency

The National Patient Safety Agency (NPSA; www.npsa.nhs.uk) is a Special Health Authority established in July 2001 'to implement and operate [a new national system] for learning from adverse events and near misses with one core purpose – to improve patient safety by reducing the risk of harm through error' (Department of Health, 2001). Its remit includes England and Wales; its budget in 2003/4 was £15 million. The organisation has a core staff team in central London and a patient safety manager in each of the 28 English Strategic Health Authority areas, and three in Wales, to provide a bridge with NHS providers. Strong links have also been established with medical colleges and faculties, and with non-medical professional bodies, through the appointment of 15 part-time clinical specialty advisers who are seconded to the NPSA.

The National Reporting and Learning System

Incident reporting systems have long been established in safety conscious industries such as aviation. The characteristics necessary for success are well understood (Leape, 2002). To be effective, a reporting system must:

- be non-punitive
- be confidential
- be independent of authorities with the power to punish
- incorporate expert analysis
- produce timely reports
- be systems oriented
- be responsive, so that recommendations are widely disseminated.

The NPSA is now introducing a National Reporting and Learning System (NRLS) for adverse events (now termed 'patient safety incidents') across the NHS in England and Wales. The NRLS is based on a simple electronic reporting form (eForm), which collects structured and unstructured data about patient safety incidents. This form is being incorporated into local risk management systems, where these exist, and is also available through the Internet.

It is expected that all NHS staff will have access to the eForm and it is hoped that all care staff will use the system to report patient safety incidents that they have encountered. Whether or not the eForm is integrated into a local risk system, those making reports to the NPSA will be able to do so confidentially and the NPSA will not receive information that will enable it to identify the person making the report or the patient (or patients) involved.

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The pilot and testing phases have demonstrated the willingness of staff to use the NRLS. Over a 10-month period, staff from 28 NHS organisations made nearly 30 000 reports. It is likely that within a year of full implementation, hundreds of thousands of patient safety incidents will have been logged. A sophisticated reporting system will be used to analyse these and to achieve the principal purpose of the NRSL – the identification and, to some extent, quantification of patient safety incidents. The issues that emerge from this analysis will become the focus of the NPSA's future work. The NRLS will be used as a tool for generating hypotheses and identifying fertile areas for further investigation, using observational studies or other research, to define the problem and identify potential solutions.

Root cause analysis

A belief that most adverse events in health care, as in other human industries, are induced by system failures underpins the work of the NPSA. Although the direct and immediate cause of a patient being harmed might be the action of, or an omission by, a clinician, the underlying cause is often that the system within which the clinician works failed to take account of and protect against human fallibility. The expectation is that, by identifying the underlying system failure, the mistake can either be prevented from happening again or, if it does, the seriousness of its adverse consequences can be reduced.

The NPSA has adopted an approach known as root cause analysis to investigate patient safety incidents and identify the underlying system failures. During 2004, staff from every English and Welsh NHS trust will be trained in how to apply root cause analysis to local incidents. The success of this approach will depend on it gaining the confidence and trust of staff involved in patient safety incidents.

Developing and implementing patient safety solutions

The NPSA will disseminate its work through formal guidance, 'patient safety alerts' and direct feedback of the results of the reporting system. Being a new organisation, it has yet to develop the full range of mechanisms for supporting implementation of patient safety solutions. These are likely to include sharing (anonymous) information with agencies responsible for performance management and regulation, and working with industry to develop new products based on safety-enhanced design and with NHS Estates to improve building design.

Creating a safety culture

An Organisation with a Memory (Department of Health, 2000) summarised the features of an organisation's culture that promote safety:

- people are prepared to report errors or 'near misses';
- there is an atmosphere of trust;
- there is respect for the skills and abilities of front-line staff;
- there is an ability and willingness to learn and to implement improvements

The experience of those who work in the NHS can be far from these ideals. In some places staff tell us that the leadership style is one of top-down, target-driven performance management backed by punitive sanctions. Powerful new regulatory bodies have been established to inspect services and to 'name and shame' organisations that are inadequate or unsafe. The media focuses on 'blunders' and 'errors', and courts have recently imprisoned doctors whose mistakes have resulted in loss of life. Not surprisingly, the prevailing culture within the NHS is one of secrecy, underpinned by fear of litigation or blame. This is not consistent with a safety-oriented approach to health care delivery.

The challenge for the NPSA is how to transform this culture to one that is 'open and fair', necessary to promote patient safety, while maintaining public confidence and support from politicians. The Chief Medical Officer for England is backing the NPSA in this task. The Department of Health is consulting on potentially far-reaching changes to the legal framework within which health care safety operates (Chief Medical Officer for England, 2003). Three important proposals for statutory changes have been made:

(a) a 'duty of candour' on clinicians and health care managers to inform patients of any harm;
(b) exemption from disciplinary action for those reporting adverse events (except where criminal acts have taken place, or where professionals are not safe to continue to treat patients);
(c) legal privilege for reports and information on adverse events, except where this information is not part of the medical record.

A first step to promoting this new culture has been the publication by the NPSA of an 'incident decision tree' (National Patient Safety Agency, 2004) to help NHS managers adopt a fairer and more consistent approach to dealing with staff involved in adverse events. The hope is that this will discourage the practice of suspending staff while an investigation is conducted.

The NPSA and mental health care

The NPSA has appointed an assistant director with responsibility for mental health and another for learning disability. There are also two part-time specialty advisers: one is a psychiatrist and the other a director of social services. A mental health external reference group represents a wide range of other interests; a third of its members are patients and carers.

A number of mental health trusts participated in the piloting and testing phase of the NRLS. The majority of their reports related to incidents on psychiatric wards – assaults and threats, absconsions and self-harm. Although it might be partly an artefact of how the NRLS was tested, with an emphasis on hospital-based services,

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this does support the NPSA's decision that its first priority in mental health will be an initiative to improve safety on acute psychiatric wards.

Mental health services have been particularly affected by the culture of blame that pervades the NHS. Although inquiries into widely publicised adverse events in mental health, such as homicides and suicides, invariably identify system failures, the process of investigation is often perceived to be adversarial and leaves staff feeling that they have been held culpable. Also, judging by the fact that inquiry after inquiry flags up the same types of failure, the current approach does not seem to be leading to the introduction of safer systems. The Department of Health has approved that root cause analysis is the acceptable method to be used in future to examine all adverse events in mental health care, including homicides.

Mental health services need the cultural change advocated by the NPSA if they are to recruit and retain staff, maintain morale and improve patient care and safety. However, the NPSA cannot do this alone. The process of inspection and performance management must reflect the same values, and – crucially – the Government and the Department of Health must hold their nerve when faced with a hostile media response to adverse events in the NHS.

Declaration of interest

The author is seconded part-time to the NPSA as a mental health clinical specialty adviser.

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