

Safety

FIRST

A report for patients, clinicians and healthcare managers



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healthcare managers

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Applications across England and Wales.

At present, the National Patient Safety Agency (NPSA) provides support to services in England and Wales.

Whilst *Safety First* discusses the background and proposals for change in the context of the NHS in England, further discussions of the implications for Wales will take place in the weeks after publication.

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Foreword

*Since I published *An Organisation with a Memory* in 2000, important and necessary steps have been taken on the journey to improve patient safety across the NHS.*

There is much greater awareness among clinicians, managers and policymakers that patients are not as safe as they should be. We have seen an unprecedented growth in the number of voluntary reports from healthcare staff about their safety concerns. Much effort and debate has gone into defining the types of intervention necessary to reduce risks and improve safety. At times, within NHS organisations¹ we have seen glimpses of potentially exciting safety projects and initiatives that carry the seeds of the large-scale change that is needed to genuinely put 'safety first'.

However, the pace of change has been too slow. We are still unable to assure NHS patients that all organisations are learning from experience in ways that prevent harm to future patients. This, however, is a challenge for all developed countries – the NHS is not unique in this respect. Indeed, most countries recognise that they have for too long failed to give priority to patient safety compared to other areas of healthcare.

So what do we need to do?

This review provides a comprehensive set of recommendations designed to reaffirm the place of patient safety at the heart of the healthcare agenda.

Let me highlight four major themes.

Firstly, we need to redouble our efforts to implement systems and interventions that actively and continuously reduce risks to patients. Healthcare will always carry risks; human beings are fallible. However, harm to patients should not be viewed as an acceptable part of modern healthcare.

Secondly, when errors occur and risks are identified, we need much better ways to ensure that they are addressed so that their effect on patients and healthcare workers can be quickly mitigated. A quick response is vital. This must not only encompass the specific healthcare organisation where the event occurred but

1. The term NHS organisations is used throughout this report to refer to all organisations providing and commissioning NHS-funded care.



the NHS as a whole. At the moment we are simply too slow to act to ensure that other patients are not harmed by the same sources of risk.

Thirdly, we need to encourage and support competent, conscientious and safety-conscious health workers in frontline services. We need to create an environment that motivates and indeed, inspires them to insist that all care must be as safe as possible.

An overriding message of this report is to restate the importance of strong leadership within NHS organisations. Safety does not have the priority it needs at the top of all our healthcare organisations. This must change if we are really going to put 'safety first'.

Few would disagree that the review sets out a daunting task, especially when we think about change on a national scale. Fortunately, we have much to build upon, both in terms of the work of the National Patient Safety Agency and the significant contribution by many organisations and individuals in this country and internationally. This review is designed to challenge us all to build on these considerable foundations and renew our efforts to ensure the safest possible care as soon as possible for all NHS patients.

Let us not forget that the most important lens for viewing the cost of our lack of progress is the impact on patients and their families. They are the ones who are harmed and sometimes die as a result of unsafe care. They are the stark reality of patient safety and the human face behind the statistics.

The stakes could not be higher nor could our responsibilities to succeed be more important.

Sir Liam Donaldson
Chief Medical Officer

Summary



Improving the safety of patient care is a significant challenge for the NHS, as it is for many health services around the world. Sir Liam Donaldson, Chief Medical Officer, commissioned the patient safety review to reconsider the organisational arrangements currently in place to ensure that patient safety is at the heart of the healthcare agenda. The review explicitly aimed to address issues raised by the National Audit Office in its report *A Safer Place for Patients: Learning to improve patient safety*,² as well as look at the NHS approach to patient safety more widely. The review had a natural focus on the role of the National Patient Safety Agency (NPSA) but also included present and potential contributions from other organisations and agencies working in the field. The review was led by Sir Ian Carruthers OBE and Pauline Philip, programme lead for patient safety at the World Health Organization, and involved a wide range of stakeholders from across the NHS, organisations and interests.

The review findings highlight that championing patient safety at national level has raised its profile. However, while progress has been made, patient safety is not always given the same priority or status as other major issues such as reducing waiting times, implementing national service frameworks and achieving financial balance.

There is little evidence that data collected through the national reporting system are effectively informing patient safety at the local NHS level. Despite the high volume of incident reports collected by the NPSA to date, there are too few examples where these have resulted in actionable learning for local NHS organisations. The National Reporting and Learning System (NRLS) is not yet delivering high-quality, routinely available information on patterns, trends and underlying causes of harm to patients.



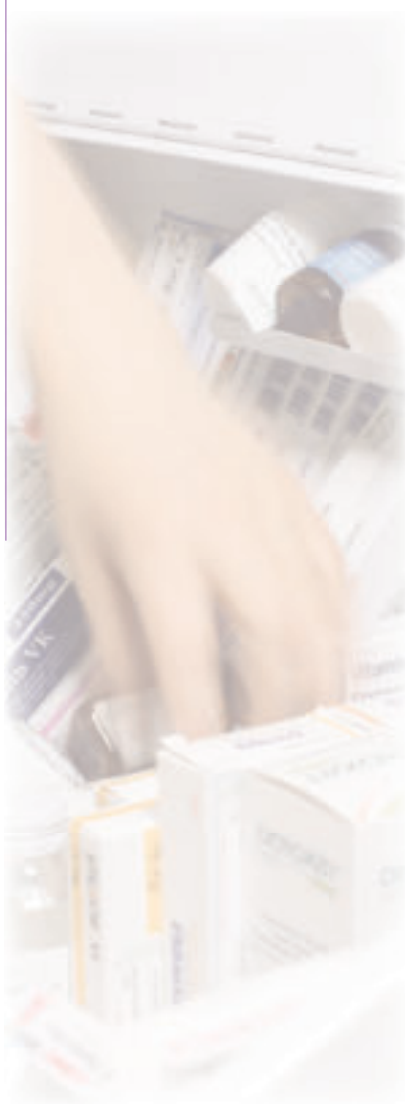
The opportunities available to the NPSA to harness the expertise and commitment of other agencies involved in patient safety have not been realised. In short, not enough has been made of opportunities for achieving real 'on the ground' improvements across the NHS.

In many cases, an environment has not been created that motivates and inspires clinical and non-clinical staff working at the front line to insist that all care must be as safe as possible.

This report makes a number of key recommendations which, if implemented, will harness the skills and expertise of the NPSA and all stakeholders' agencies to ensure that the patient safety agenda is owned by clinicians at the front line and the most senior policymakers in the NHS. Patient safety should then be at the very core of policy development and service delivery.

2. National Audit Office (2005) *A Safer Place for Patients: Learning to improve patient safety*, London: The Stationery Office.

Introduction



Improving the safety of patient care is a significant challenge for the NHS, as it is for many health services around the world. In this country, we are fortunate in many ways with our healthcare system. It is affordable and accessible to all; it is staffed by skilled and dedicated professionals; and anybody who falls ill can reasonably expect a high standard of care.

Healthcare relies on a range of complex interactions between people, skills, technologies and drugs. Sometimes things can – and do – go wrong.

Based on the best available research, it is estimated that one in ten patients admitted to hospitals in developed countries will be unintentionally the victim of an error. Around 50% of these events could have been avoided, if lessons from previous incidents had been learned. In short, the same errors and system failures are often repeated. In its review of patient safety, the National Audit Office (NAO) found that NHS Trusts which had evaluated the cost of patient safety incidents had estimated figures ranging from £88,000 to £400,000 per year. The cost of specific patient safety incidents has also been identified. The NAO reported that a fractured neck of femur due to a fall in hospital costs £10,000, and inadequate patient information or clinical details on diagnostic requests costs approximately £1 million per year.

The UK was one of the first countries to give priority to tackling patient safety. The 2000 report, *An Organisation with a Memory* (OWAM),³ is still widely regarded as a seminal document which has galvanised action and commitment to patient safety in the UK. The report set out a blueprint for ensuring that, in future years, healthcare provided by the NHS would be safer. The philosophy and ideas it set out provide an important set of underlying concepts to inform the continued development of the patient safety programme in the NHS. Indeed, OWAM, along



with the Institute of Medicine report, *To Err is Human*,⁴ are recognised internationally as catalysts for the global momentum now being witnessed in patient safety.

Inevitably, pioneers are the first to encounter problems and new challenges. This review is designed to ensure that we learn from our own experience and that of other countries, to ensure that our approach to patient safety continues to be at the forefront of international development.

At its heart, the test of whether a health system is tackling the patient safety agenda will be reflected in the everyday experience of its patients, the practical ways in which frontline staff are supported to implement safer practices and the extent to which organisational managers and leaders can establish patient safety as a genuine priority.

The following questions embody the issues that this review seeks to address through its recommendations for reshaping the national approach to patient safety. The questions reflect the issues raised by patients, clinicians and managers during interviews, visits, etc.

3. Department of Health (2000) *An Organisation with a Memory*, London: The Stationery Office.

4. Institute of Medicine (1999) *To Err is Human: Building a safer health system*, Washington DC: Institute of Medicine.

Patient experience

- » Is my care as safe as it possibly could be?
- » Who is responsible for my safety?
- » Will I be told if a mistake is made?
- » Will my questions be answered honestly and in full?
- » Will somebody say they are sorry?
- » Will somebody support me in dealing with the consequences of a mistake?
- » Will I be invited to help find solutions so that other patients are not harmed?
- » Will somebody help me find my way around the system?
- » Will something be done to prevent this mistake happening to someone else?

Frontline staff

- » If I admit my mistakes or near misses, will I be blamed?
- » How can I easily report errors and near misses?
- » Can I report what might have gone wrong?
- » Will I get feedback?
- » Will we be able to learn locally?
- » Can we share our learning with others?
- » Will somebody support me when I want to talk to my patients and their families about a mistake?
- » Will my organisation be requested to make the changes needed to improve systems of care?

Managers and leaders

- » Is patient safety our top priority or, in reality, do other goals and targets come first in our organisation?
- » Is there support within the wider healthcare system to really make patient safety a top priority?
- » If we pick the three worst errors we have heard of, could they happen here? How would we find out? What would we do?
- » If something serious happened, would we be open and learn from it? How would we ensure that the lessons learned prevent future patients being harmed if faced with similar risks?
- » Do we know the cost of unsafe care in our organisation?
- » How can we ensure that patients and their experiences are at the heart of patient safety within our organisation?
- » Can we measurably demonstrate that the healthcare we provide is becoming safer each year?
- » Can we learn from the experience of other organisations?

T

wo stories of healthcare systems failure

ERROR TRAPS

The example of vincristine

In 1975, Lee Duggins was an eight-year-old boy being treated for leukaemia with chemotherapy. Treatment required the injection of powerful drugs into both his veins (intravenous) and his spine (intrathecal). When Lee had to have both injections, they were done in the operating theatre. His mum was not allowed to be present. Tragically, a drug that should be given intravenously (vincristine) was accidentally given intrathecally. The mistake was not initially realised and Lee went home.

At first, when Lee got home he was okay. However, the next morning he was in considerable pain and was readmitted to hospital. Two days after the initial treatment, Lee and his family were told that something had gone wrong with the initial injection and the wrong drug had been given into his spine by mistake.

Lee was given high-dose steroids to try and suppress the inflammation. This was unsuccessful. Over the next few days, Lee lost the use of all his limbs. He died in hospital six days later.



In 2001, Wayne Jowett was an 18-year-old teenager who lived in Nottingham. He was also being treated for leukaemia. The disease was in remission and his prognosis was good. Wayne and his grandmother had arrived unscheduled for his chemotherapy. To ensure that Wayne got his treatment, the staff squeezed him in to an already busy schedule.

The same mistake, as in the case of Lee Duggins, was repeated. Wayne, like Lee before him, was administered the same intravenous chemotherapy intrathecally. The mistake was realised immediately. He was taken to the operating theatre where the surgeons tried to wash the drug out of his spine. Afterwards he was moved to the intensive care unit. Wayne, like Lee, died in hospital some time later.

Wrong route delivery of vincristine (the chemotherapeutic drug that should never be given intrathecally) is a powerful error trap. Despite a separation in time of over 25 years, similar risks led to these two tragic outcomes. Around the world, there have been reports of approximately 55 such cases over the past 40 years. Almost all of these patients died.

Analysis of the two cases above and cases like them has shown that there are multifactorial system errors that lead to these tragic events. It is too simplistic to assume that the problems lie only with poorly prepared doctors, who do not follow basic protocols and fail to read drug labels. A careful review of cases like these has revealed significant system errors which lead to these tragic mistakes. Lack of adherence to standard operating procedures, lack of ensuring valid training of healthcare staff, multidisciplinary communication

problems and a lack of patient engagement in care, have all been implicated in the chain of events leading to the final mistake. The drug systems themselves have also been implicated as the root cause of error. For example, the delivery to the ward of intravenous and intrathecal drugs from pharmacies should not be simultaneous. Ward refrigerators for sensitive drugs like vincristine should remain locked so that drugs cannot get mixed up. Labelling on the drugs themselves needs to be very clear. The message from cases like these is that the causes of error are complex and are frequently due to weak systems, not individual incompetence. As a result of this incident, rigorous standards were issued to the NHS. A definitive international 'design' solution is being worked on and the UK is taking part in this.

A WEAK SAFETY CULTURE CAN HARM PATIENTS

The story of Paul

Paul was a 23-year-old junior staff nurse working in a busy emergency department. Paul was asked by the sister in charge to give 60mg of oral codeine to the 'abdo pain in bay 6'. He administered the drug without the prescription chart and without checking the patient's name.

Paul came out of the cubicle and the sister informed him: 'The abdo pain has been moved to bay 1, there's a chest pain in there now.' In the time it took Paul to obtain the drug keys and retrieve the drugs from the drug cupboard, the patient in bay 6 had been moved to another bay.

Paul realised he had made a critical error and immediately told the sister in charge. Paul then told the patient his mistake.

The patient informed Paul he had a suspected allergy to codeine. The patient was immediately re-triaged and seen by a doctor. Fortunately, no harm came to the patient.

Incidents such as this illustrate the dangers of a weak safety culture. There was a culture in the department of referring to patients by their presenting complaint and location, rather than their name. Not adhering to basic safety procedures, such as giving a drug without checking the prescription chart and not checking it was the right patient, was prevalent. It was tolerated as 'the cost of doing business' in a busy department.

There was also a lot of peer pressure – especially for junior staff – to conform to this basic deviation from safety procedures to cope with the workload. A prevailing culture of 'helping each other', especially when staff were stretched, had inadvertently increased the risks to patients.

What happened to Paul? Paul was shocked and devastated by what he believed was his personal failure to follow correct procedures. He was informed he was no longer able to administer medicine until he had been reassessed as competent. He was initially isolated following the incident, despite his prompt reporting to his seniors and the patient.

He was the 'second victim' and could have left nursing. His period of reassessment was difficult, but ultimately changed his career. In his own words, he now says that 'fitting in must be less important than doing things right'.



The journey so far



1.1 An Organisation with a Memory

An Organisation with a Memory (OWAM) set out to review what was known about the scale and nature of serious failures in NHS healthcare. Based on a small-scale pilot study of hospital inpatient records, the report estimated that the proportion of inpatient episodes leading to harmful adverse events was around 10%, of which half could have been avoided. It examined the extent to which the NHS has the capacity to learn from such failures and recommended measures to ensure that the likelihood of repeated failures could be minimised in the future. The report concluded that if the NHS was to successfully modernise its approach to learning from failure, four key areas had to be addressed:

- a unified mechanism for reporting and analysis when things went wrong;
- a more open culture, in which errors or service failures could be reported and discussed;
- mechanisms for ensuring that, where lessons were identified, the necessary changes would be put into practice; and
- a much wider appreciation of the value of the system approach in preventing, analysing and learning from errors.

The overall policy objective of OWAM was to provide an independent system to record adverse events and near misses so that the NHS could minimise such incidents in the future by establishing a national, mandatory reporting scheme for adverse healthcare events and specified near misses. A new body, seen to be neutral by healthcare staff, would be established to run the system. By establishing this system and changing organisational culture, it would then be possible to learn lessons from adverse healthcare events or near misses. Together with other available information, the standards and safety of health service delivery for the benefit of all patients and staff would be improved.

The report set out 10 key recommendations, which were all accepted by the Government. In the process, patient safety became a key component of *The NHS Plan*⁵ and a major strand of the NHS quality and clinical governance agendas.



1.2 Building a Safer NHS for Patients

*Building a Safer NHS for Patients*⁵ set out the Government's plans for promoting patient safety following the publication of OWAM and the commitment to implement it in *The NHS Plan*. The report announced the establishment of the National Patient Safety Agency (NPSA), an independent agency within the NHS, to implement, operate and oversee all aspects of the new national system for learning from adverse events and near misses in all sectors of the NHS.

The report described an integrated approach to responding to risks to patients or adverse events when they occurred, including the establishment of a new, national reporting system for adverse events, which would be analysed and from which lessons could be learned and implemented at the local and national level.

In setting out a plan for such a system, the report described methods for identifying and reporting adverse events, analysis, disseminating lessons and developing models of good practice. The report highlighted that a reporting culture, building local capability and sustaining change through education, learning and performance assessment at local and national level were key to fully embedding patient safety within the NHS.

5. Department of Health (2000) *The NHS Plan*, London: The Stationery Office.

6. Department of Health (2001) *Building a Safer NHS for Patients: Implementing an with a memory*, London: The Stationery Office.



1.3 A Safer Place for Patients

The National Audit Office (NAO) published *A Safer Place for Patients: Learning to improve patient safety* in November 2005. The report followed the NAO's review on the implementation of the Government's policy on patient safety. The review sought to address the following question: 'organisational learning is key to improving patient safety. Is the patient safety agenda proceeding along sensible lines?' It therefore examined:

- whether there was a good strategy for ensuring that the NHS learns lessons at local and national level from all relevant patient safety incidents; and
- whether the NHS was making satisfactory progress in implementing the strategy.

The NAO commenced its review in 2003 and used a number of approaches to gather the information for its report. These included a census of NHS Trusts and strategic health authorities, visits to NHS Trusts, a survey of the public, consultations with stakeholders including a panel of

experts, interviews with Department of Health and NPSA staff, and an analysis of national published data and documents. A further survey of the NHS was conducted in August 2005, which updated the data, although the main findings did not substantially change.

The report revisited the issue of the scale and nature of the problem and showed that there were around 974,000 reported incidents and near misses in England in 2004/05 (excluding hospital-acquired infections), with around 2,180 of these incidents resulting in death.

The report scrutinised progress achieved against the objectives set out in OWAM and *Building a Safer NHS for Patients*. Finally, the NAO highlighted the organisations that had a significant role to play in improving patient safety. These included the NPSA, the National Clinical Assessment Service, the Healthcare Commission and Connecting for Health.

The NAO report acknowledged progress in the following areas:

- The safety culture within NHS Trusts is improving. Most Trusts have established a clear and strong focus on patient safety, driven largely through implementing the clinical governance initiative and the development of more effective risk management systems. The increase in reported incidents to the NPSA's National Reporting and Learning System (NRLS) demonstrates that Trusts are making progress in creating a culture in which staff are prepared to report incidents and near misses.
- The National Clinical Assessment Service is continuing to contribute to the development of a more open and fair culture and, as a

result, suspensions have increasingly been avoided.

- The Department of Health has helped highlight the importance of leadership in delivering the patient safety agenda, by providing support and advice through the NHS Modernisation Agency, Clinical Governance Support Team and Leadership in Patient Safety training, provided by the NHS Appointments Commission and the NPSA.

However, the report acknowledged that much has still to be done. Key challenges identified included:

- renewed strategies to encourage more open reporting of patient safety risks and events by healthcare staff;
- more regular feedback from the NRLS, with regular publications to the NHS, providing examples of learning from the data;
- stronger engagement of patients in identifying patient safety issues and designing solutions;
- drawing more systematically on all available sources of information for the investigation of deaths and serious harm, and to ensure wider learning;
- providing more information to the public on Trusts' compliance with safety alerts and clearer criteria to evaluate how well solutions have been implemented;
- establishing performance monitoring of Trusts' safety culture, incident reporting and dissemination of results of national reporting back to Trusts, and effective feedback of lessons and solutions to improve safety; and
- ensuring patient safety is a core part of professional training.



1.4 Stakeholders

In addition to these reports and reviews, over the past five years a growing number of organisations and stakeholders have played a significant role in patient safety at national level. This is a welcome development as no one can address all of the requirements of a comprehensive patient safety agenda. The figure overleaf illustrates the range of players at different levels of the NHS.⁷ These include:

- the National Patient Safety Agency – set up to improve the safety of NHS patient care by promoting a culture of reporting and learning from patient safety incidents, and by introducing a national reporting and learning system to support this function;
- the National Clinical Assessment Service (currently part of the NPSA) – established to give confidential advice and support to the NHS on how to manage doctors and dentists whose performance gives cause for concern;
- the National Institute for Health and Clinical Excellence (NICE) – its purpose is to provide national guidance on the promotion of good health and the prevention and treatment of ill health;
- the Healthcare Commission – set up to promote improvement in the quality of care and assess the performance of NHS and independent healthcare services;
- Monitor – set up to regulate NHS Foundation Trusts, making sure they are well-managed and financially strong so that they can deliver excellent healthcare for patients;
- the Medicines and Healthcare products Regulatory Agency (MHRA) – established to ensure that medicines and medical devices work and are acceptably safe. As part of its responsibilities, the Agency operates reporting systems for adverse drug reactions and adverse incidents involving medical devices;

7. As outlined in *A Safer Place for Patients*.

- the NHS Litigation Authority – its function is to handle negligence claims made against NHS bodies in England and help raise standards of care in the NHS so as to reduce the number of incidents leading to claims;
- the Health Foundation – founded as an independent charity aiming to improve health and the quality of healthcare in the UK. Over the past two years, the Health Foundation has worked with the Institute for Healthcare Improvement in the United States to implement the Safer Patients Initiative. This aims to develop exemplar patient safety hospitals across the UK and spread the learning on best practice across the NHS; and
- various parts of the former NHS Modernisation Agency, especially the Clinical Governance Team, which have contributed to the patient safety agenda. Its successor, the NHS Institute for Innovation and Improvement, has broadened its remit to include improving health outcomes and raising the quality of delivery in the NHS through innovations in practices and technology. In relation to patient safety, the Institute is working with the NHS to achieve or exceed the Department of Health target to reduce MRSA rates by 50% by 2008. Underpinning this key objective, it is working to spread best practice, including looking at a whole-systems approach to reducing healthcare-associated infections. It is also working with patients and the public to identify ways that should help improve their confidence about the safety and effectiveness of the healthcare environment.





Recent changes

At the Health Select Committee on 20 October 2003, the then Secretary of State for Health, John Reid, announced his intention to carry out a review of the Department of Health's arm's length bodies. The aim of the review was to rationalise these bodies and their remits, in order to deliver:

- appropriate impact for minimal bureaucratic burden for the health and social care system;
- more efficiency in the public sector and a reduction of unnecessary bureaucracy;
- devolution of powers to the front line;
- health and social care organisations working closer together; and
- relocation of arm's length bodies outside London and the South East, where possible.

This resulted in a reduction of the number of arm's length bodies from 38 to 20 and greater devolution of functions to the front line.

The NPSA retained its original functions and, from April 2005, took on additional responsibilities, including:

- the National Clinical Assessment Service;
- the functions of the Central Office for Research Ethics Committees (COREC);
- safety aspects of hospital design, cleanliness and food; and
- management of contracts for three national confidential inquiries.⁸

8. The NPSA is also to manage the contract for a forthcoming national confidential inquiry into the health inequalities and premature death of people with learning disabilities.

Patient safety review



2.1 Terms of reference

This review was commissioned by the Chief Medical Officer to reconsider the organisational arrangements currently in place to support patient safety and explore issues arising from recent review processes (outlined in the previous chapter). The review explicitly aims to build upon the work undertaken through these other review processes and not duplicate their efforts.

This review has a natural focus on the role of the National Patient Safety Agency (NPSA) but also includes present and potential contributions from other organisations and agencies working in the field. It also includes the role that the Department of Health needs to play to support this agenda.

2.2 Methodology

The review was conducted over a period of four months. The review had a number of components:

- semi-structured interviews with approximately 50 stakeholders from an extensive range of organisations;
- a series of service visits conducted by the Chief Medical Officer and the review team;
- a number of meetings with key stakeholder groups (including patients and NPSA patient safety managers);
- submissions made by individual interviewees; and
- expert advice from a number of safety or other specialists.



2.3 Findings and themes

Championing at a national level has raised the profile of patient safety. However, patient safety is too often seen by NHS boards and managers as not having the same priority as achieving financial and access targets. The information collected through the national reporting system is not yet effectively informing patient safety at the local NHS level. Not enough has been made of opportunities for achieving real 'on the ground' improvements across the NHS. The role of the NPSA in harnessing the expertise and commitment of other agencies involved in patient safety is unclear.

The essence of this message is well articulated by Sir Ian Kennedy, chair of the Healthcare Commission:

“... the need to place the safety of patients at the forefront of the agenda in healthcare. Safety cannot be allowed to play second fiddle to other objectives that may emerge from time to time. It is the first objective.”⁹

9. Healthcare Commission (2006) *Investigation into outbreaks of Clostridium difficile at Stoke Mandeville Hospital, Buckinghamshire Hospitals NHS Trust*, London: Commission for Healthcare Audit and Inspection.

Moving from awareness to priority across the NHS

There is greater awareness of the importance of the problems of patient safety. It has become part of the Department of Health's agenda and the principles of *An Organisation with a Memory* (OWAM) are now more widely understood. However, there is a perception that the NHS has not yet fully embraced patient safety as a key organisational priority. This has been compounded at times by inconsistent messages about priorities being given by the Department of Health.

Locally, awareness and commitment to patient safety among NHS healthcare professionals is strong but engagement in the national strategy is weak. Significant confusion appears to exist amongst clinicians and managers with regard to the role of functions of the NPSA and other agencies that might be able to help them tackle safety issues.

Excellent and important projects have often failed to be sustained and incorporated into lasting system improvements.

“ The NHS is not on board. ”

“ Compared to the ambitions of OWAM, we have not come as far as we should have. ”

There does not appear to be a comprehensive and explicit approach to patient safety in the NHS. There is a view that the service either tackles patient safety in terms of narrow and specific targets, eg reduction of MRSA infections, or it exists on the periphery of provider organisations' corporate or clinical governance agenda.

“ Patient safety... is higher up the local agenda than it was, but is still one removed from mainstream business. ”

“ Patient safety has been somewhat overshadowed by other pressures on the service and while the principles are strongly supported, the service seems at a loss on how to bring patient safety concepts to fruition. ”

National coordination and engagement of interested stakeholders essential

Improving patient safety involves multiple players at different levels of the healthcare system. No one group can achieve the required changes on their own. Collaboration and cooperation are clearly important.

Currently, the coordination of agencies involved in patient safety, including their respective roles and responsibilities, is not clear. There is a view that there are too many organisations involved, and it is not clear how each is contributing to embedding patient safety within the NHS. There are other stakeholders who have the potential to play an important role but whose expertise and interest have not been well harnessed.

“ The current set-up does not reflect the significance of the patient safety area and the fragmentation of the agenda undermines its impact. ”

“ The arrangements are fragmented and far too many bodies exist, all dealing with patient safety. ”



More effective learning from error is needed

Patient safety encompasses a range of errors and system failures associated with the delivery of patient care. This can include situations such as mistakes and delays in diagnosis, medication and treatment errors, problems with equipment, infections acquired in hospitals and accidents such as slips and falls. Each event is unique. However, there are often similarities and patterns in the sources of risk, which may otherwise go unnoticed if they are not reported and analysed.

Building well-targeted safety initiatives requires careful understanding of the safety problems occurring and their contributing factors, usually through the voluntary reporting of such situations. This should be a source of learning for change rather than a reason to blame and punish.

At national level, the NRLS is receiving around 60,000 incident reports each month. Despite the volume of reports, it has been very difficult to establish a timely, complete and accurate picture of the major safety problems faced by the NHS and to derive the required learning. As highlighted by other review processes, key barriers to progress include:

- the poor data quality of incident reports, many of which contain inaccurate or incomplete information about the patient harm that has occurred;
- in many cases, poor engagement from senior clinicians to use the reporting system;
- insufficient involvement of local NHS organisations in reviewing and acting upon analysis of their own incident reports; and
- slow rate of feedback of identified trends and patterns in incident reports to local NHS organisations, compounded by difficulties in effectively managing a large national database of incident reports.



safety alert

Establishing a standard crash call telephone number in hospitals

Put simply, the power of information to increase understanding of patient safety at local NHS level is not being well used.

“ There is clearly no national reporting and learning system and the NPSA does not tell the NHS anything it does not already know. ”

“ Quantity of data moving forward – still outstanding qualitative issues; challenge is to get learning from the data. ”

There is a view that the national reporting system has become too complex and bureaucratic, potentially to the detriment of fully embedding patient safety in actual practice:

“ Hospitals are trying to take the weight of the National Reporting and Learning System off the clinicians by getting them to report to risk managers – this means [the NRLS] is not truly embedded. ”

There is criticism of the lack of feedback to the NHS on what staff have been reporting:

“ Output is not commensurate with input. ”

How this information is presented and used is often questioned. The relationship between patient safety solutions and analysis of NRLS data is not well understood:

“ Not sure of the benefit of widespread analysis, especially as this doesn't appear to have changed anything. ”

More broadly, the development of national solutions was perceived as too slow and not drawing enough on existing expertise and work already undertaken both within local NHS organisations and internationally.

Interestingly, the issue of ensuring that national data are anonymous in order to promote reporting did not emerge as a major issue. Indeed, the view of a number of stakeholders was that anonymity has been a barrier to national learning rather than an enabler. This is because it has constrained timely follow-up of specific incident reports, which may have important lessons for the NHS as a whole.



Overall, there was a view that, although much has been achieved in developing a national reporting system, the focus now needs to shift to ensuring the response system works. This needs to involve all levels of the NHS and Department of Health. One view is that issues emerging from patient safety data should be more directly linked to establishing national goals and targets.

A variation of this is that NHS Trusts should be identifying potential patient safety issues locally and using feedback from the NRLS to facilitate local learning. Either way, there appears to be a call for clearer and stronger messages that the identification of risk to patients and the ability to respond appropriately needs to be reinforced at both national and local level, with particular emphasis on securing local ownership. A particular theme was a call for greater engagement by strategic health authorities and primary care trusts in improving patient safety, through, for example, performance management arrangements.

“ It must be legitimate to say that we have to prioritise one issue over another, even within patient safety. Ask the local institutions for their top three patient safety issues and what changes they have seen as a result of tackling these. ”

Safety monitoring systems must have teeth

Many stakeholders welcomed the progress that has been made in developing core and developmental standards, and associated criteria, by which the safety performance of local NHS organisations can be more systematically assessed. However, there was a sense that the standards lacked 'teeth' and a 'stretch factor' for local NHS organisations genuinely trying to improve patient safety. There appears to be a lack of confidence that the current standards and monitoring process can effectively identify NHS organisations whose safety performance may be of concern.

Accelerating the pace of change

A new national approach

The review highlighted the need to build on the progress that has been achieved in addressing the patient safety agenda to refocus efforts to enable clinicians and healthcare organisations to deliver safe healthcare. This approach will need strong Government and Department of Health support to ensure that patient safety is at the top of the healthcare agenda.

Recommendation 1

As the next round of national goals, priorities and targets are being established from the period from 2008, it is important that the NHS takes steps to ensure that patient safety is further deeply embedded as a core principle that underpins those priorities.

→ Rationale

Patient safety needs to be a core, non-discretionary part of the agenda for 21st-century healthcare in this country. The setting of national priorities should explicitly take this into consideration and be informed by overall analysis of NRLS data linked to existing safety-related targets and drawing on other relevant national information sources through the National Patient Safety Observatory.

Recommendation 2

The Department of Health should establish a National Patient Safety Forum, jointly chaired by the Chief Executive of the NHS and the Chief Medical Officer, to harness the skills and expertise of a number of organisations, agencies and stakeholders which are making a significant contribution to patient safety.

→ Rationale

The National Patient Safety Forum should bring together key organisations, agencies and stakeholders at national level, as well as other key players with responsibilities for patient safety. The Forum should influence the development of the patient safety agenda and facilitate its delivery. The Forum should become the national conscience of patient safety by constantly addressing the question 'Are we saving lives?'

Recommendation 3

The National Patient Safety Forum should oversee the design and implementation of a national patient safety campaign-focused initiative. The objective of this initiative should be to engage, inform and motivate clinical staff and healthcare providers to address the challenge of providing safer healthcare.

→ Rationale

A high-profile initiative should be designed and implemented to ensure that clinical and non-clinical staff responsible for patient care understand that patient safety must become their first priority. The programme is likely to be campaign-focused and should be in keeping with the approach already successfully used by organisations such as the Health Foundation and the Institute for Healthcare Improvement. The programme should be specifically designed to engage and inform frontline staff and should enable staff to take ownership and harness the opportunity to influence the national patient safety agenda.

The engagement initiative should provide an opportunity for NHS organisations and their most senior staff to demonstrate a commitment to patient safety. This could be done by allowing organisations to pledge their commitment in a publicly accountable way, undertake a number of important actions that would demonstrate top management attention, and measure and publish their results.

Recommendation 4

The role of the National Patient Safety Agency (NPSA) should be refocused on its core objective of collecting and analysing patient safety data to inform rapid patient safety learning, priority setting and coordinated activity across the NHS. A number of current functions, for example the development of technical solutions to improve patient safety, presently delivered by the organisation should in future be commissioned from other expert organisations with the requisite expertise.

→ Rationale

The objectives, functions and accountabilities of the NPSA need to be recast as part of a renewed national strategy for patient safety. This is particularly marked in relation to reporting and learning. Despite the high volume of incident reports collected by the NPSA to date, there is little evidence that these have resulted in actionable learning for local NHS organisations.

The NRLS is not yet delivering high-quality, routinely available information on patterns, trends and underlying causes of harm to patients. The process of gathering, analysing and learning from data on adverse events and near misses needs to be fundamentally addressed. The NPSA should work in partnership with agencies and activities that gather different sources of data, such as complaints, claims and coroners' reports, as part of its National Patient Safety Observatory to ensure that all deaths and serious harm associated with adverse events are identified.

Key relationships should include the NHS Litigation Authority and the confidential inquiries.

As part of this refocusing process, additional programmes that have been developed and delivered by the NPSA should be commissioned from other expert agencies. These functions include patient involvement, awareness raising, technical solution development and education.

Recommendation 5

The core purpose of the National Reporting and Learning System (NRLS) should be to identify sources of risk and harm to patients which can be acted upon at local and national level. The present NRLS should be redesigned to make it more effective in this respect, including simplifying and encouraging reporting as well as including a new category of analysing risk prone situations and anticipating adverse events. PCTs should take account of the information and learning available locally from the NRLS in commissioning services.

→ Rationale

The reporting of adverse events should be simplified. NHS organisations should be required to develop local strategies to encourage reporting. Near misses and a new category of ‘adverse events that could happen’ should also be reported. The NRLS should be redesigned to make it easier for clinical staff to report on a confidential basis without fear of retribution.

Simplifying reporting is important if we want to engage with busy frontline staff. The experience of other high-risk industries which have well established reporting systems highlights the importance of all staff having immediate access to easy mechanisms for simple reporting such as a computer or paper reporting box. To promote more rapid and effective learning, reports should be confidential but not anonymous. In particular, rules on confidentiality of data should not block the identification of very serious adverse events, recognising the need to ensure that reporters are free from retribution. The opportunity should be taken to ensure that local reporting mechanisms cover both the NPSA reporting and learning system and the adverse incident reports required by the MHRA.

Recommendation 6

The Patient Safety Management function currently delivered by the NPSA should be hosted by strategic health authorities (SHAs), and recast as ‘Patient Safety Action Teams’ to support the delivery of the national patient safety agenda by local NHS organisations. The team should consist of experts with skills in data analysis, incident investigation and solution development.

→ Rationale

The involvement of strategic health authorities in patient safety needs to be completely redesigned to ensure that patient safety is mainstreamed. In part, this could be achieved by appointing Patient Safety Action Teams, which would be established from existing NPSA resources and be accountable locally to the SHA Director of Public Health (or other). Staff employed in these teams would include experts with skills in data analysis, incident investigation and solution development, who would work to support local provider organisations.

Patient Safety Action Teams should work together with national organisations and agencies to provide a coordinated, vibrant, national network across the service.

Recommendation 7

Prime responsibility for incident investigations should reside with local NHS organisations. Every NHS organisation should have access to a specialist investigator based within the Patient Safety Action Team. All reports should be considered locally within 24 hours of being reported. The NPSA should be notified of events that involve serious patient harm and death within 36 hours of the initial report.

→ Rationale

All reports should be considered locally within 24 hours. This should allow quicker identification of serious adverse events or potential problems that could lead to death or serious injury for future patients. It should be a significant move towards successfully fulfilling the 'orange-wire test'.¹⁰

NHS organisations should also be encouraged to draw on different sources of data, such as complaints, claims and coroners' reports, to ensure that all deaths and serious harm associated with adverse events are identified.

Experts within Patient Safety Action Teams should play an important part in deciding what should and should not be investigated and at what level. They should help clinicians and healthcare managers understand why mistakes have occurred and should play an active role in ensuring that learning is shared across the NHS as quickly as possible.

Specialist investigators, working within Patient Safety Action Teams, should have access to specialist support and resources for those investigations deemed as having national significance. Links should be made to specialist safety investigative skills and resources in other high-risk industries, such as aviation.

Recommendation 8

Accountability for patient safety rests with the Chair and Board of each NHS organisation. Each Board should therefore be expected to outline how it intends to discharge this responsibility. Importantly, each Board should also make clear how it intends to ensure that patients and carers play an integral part in all initiatives to introduce a patient safety culture change within the NHS.

→ Rationale

Senior management of NHS organisations need to demonstrate that patient safety is a top priority. Without strong and committed leadership, patient safety will not improve. Feedback and discussion of the risks of care should be an integral part of the work of every local NHS organisation.

10. Donaldson L (2004) When will healthcare pass the orange-wire test? *The Lancet* 364: 1567-8.

Recommendation 9

The approach of the Healthcare Commission in monitoring progress in patient safety should be further developed into a high-profile programme which comprehensively monitors and assesses progress against national and local standards and indicators of performance. PCTs should be accountable for ensuring that all providers used by their patients have effective patient safety reporting systems and are implementing technical solutions satisfactorily.

→ Rationale

Monitoring programmes should draw on the experience of leading organisations internationally including the work of the World Health Organization's World Alliance for Patient Safety. The programmes should enable the tracking of progress against national and local safety standards and indicators of performance. They should also monitor the implementation of national alerts and other guidance, the reliability of incident reporting, the development of a stronger safety culture within NHS organisations and the overall effectiveness of solutions and safety interventions. The Healthcare Commission programme results should be publicly reported. PCTs should be responsible for ensuring that patients are aware of safety issues as part of the patient choice pathway.

Recommendation 10

A pilot should be established to examine the option of the National Institute for Health and Clinical Excellence (NICE) developing technical patient safety solutions.

→ Rationale

NICE is an independent organisation with an established track record of success in providing national guidance on the promotion of good health and the prevention and treatment of ill health. NICE guidance is developed using the expertise of the NHS and the wider healthcare community including NHS staff, healthcare professionals, patients and carers, industry and the academic world. There may be opportunities to harness this expertise to streamline the production and dissemination of safety solutions across the NHS.

During the pilot, NICE should work with provider organisations, Patient Safety Action Teams, the NPSA, the Department of Health and the NHS Institute for Innovation and Improvement to develop a process and method statement, which should be used to develop a technical solution. In undertaking the pilot, NICE should take advantage of the experience of international patient safety partners and WHO World Alliance for Patient Safety in order to ensure that duplication of effort is minimised. The Department of Health should develop the success criteria against which the pilot will be assessed.

Recommendation 11

The NHS Institute for Innovation and Improvement should be asked to work with the medical Royal Colleges and other educational providers to ensure that advances are made in education and training to support patient safety.

→ Rationale

The mission of the NHS Institute for Innovation and Improvement is to support the NHS and its workforce in accelerating the delivery of world-class health and healthcare for patients and the public by encouraging innovation and capacity at the front line. Building on its existing work and relationships, patient safety is an area that fits well within the goal of building improved capacity and capability in the NHS, and is indeed already incorporated in existing streams of work. The organisation is, therefore, in an excellent position to facilitate the development of education and training in a short timescale.

It is important that a patient safety curriculum is developed and widely implemented in undergraduate, postgraduate and continuing education, in order to promote the knowledge, skills, behaviours and attitudes required of clinical and non-clinical staff to provide the safest possible care to patients.

Recommendation 12

All NHS organisations should develop and implement local initiatives to promote greater openness with patients and their families when things go wrong and to provide required support.

→ Rationale

Communicating openly and honestly with patients and their families when things go wrong is a vital part of patient safety. However, it is often very difficult for frontline staff to do this. More needs to be done to help healthcare staff with this difficult task. National guidance and experience to date in this area will be reviewed by Professor Lucian Leape from the Harvard School of Public Health and refined in light of international experience.

Recommendation 13

The active involvement of patients and their families should be promoted by establishing a national network of patient champions who will work in partnership with NHS organisations and other key players to improve patient safety; the network should also have strong links with WHO World Alliance for Patient Safety's 'Patients for Patient Safety' initiative.

→ Rationale

Consumers of healthcare are at the heart of patient safety. When things go wrong, they and their families suffer from the harm caused. Such harm is often made worse by the defensive and secretive way that many healthcare organisations respond in the aftermath of a serious event.

Around the world, healthcare organisations that are most successful in improving patient safety are those that encourage close cooperation with patients and their families. Patients and their families have a unique perspective on their experience of healthcare and may provide information and insights that healthcare workers may not otherwise have known.

Partnership must be a key theme: patients, health professionals, policymakers and healthcare leaders should be working together to prevent avoidable harm in healthcare. A particular focus is to challenge the current culture of denial.

Recommendation 14

- The development of an overall project plan to ensure the delivery of all key recommendations – this should be discussed at the first meeting of the National Patient Safety Forum.
- An inaugural meeting of the National Patient Safety Forum is to take place in early 2007.
- With expert input, redesigning the National Reporting and Learning System in order to have a re-engineered system launched in 2007.
- An early pilot to determine if NICE can effectively deliver technical solutions with a decision in early 2007.
- Immediate action to establish Patient Safety Action Teams.
- There is a need to clarify roles and responsibilities both within the Department and in the NHS for the delivery of the Patient Safety Agenda.
- The imperative to improve patient safety will need to be taken into account as a central component of the Health Reform Agenda. It is therefore important that an ongoing dialogue takes place with the Healthcare Commission, Monitor and other regulators.





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