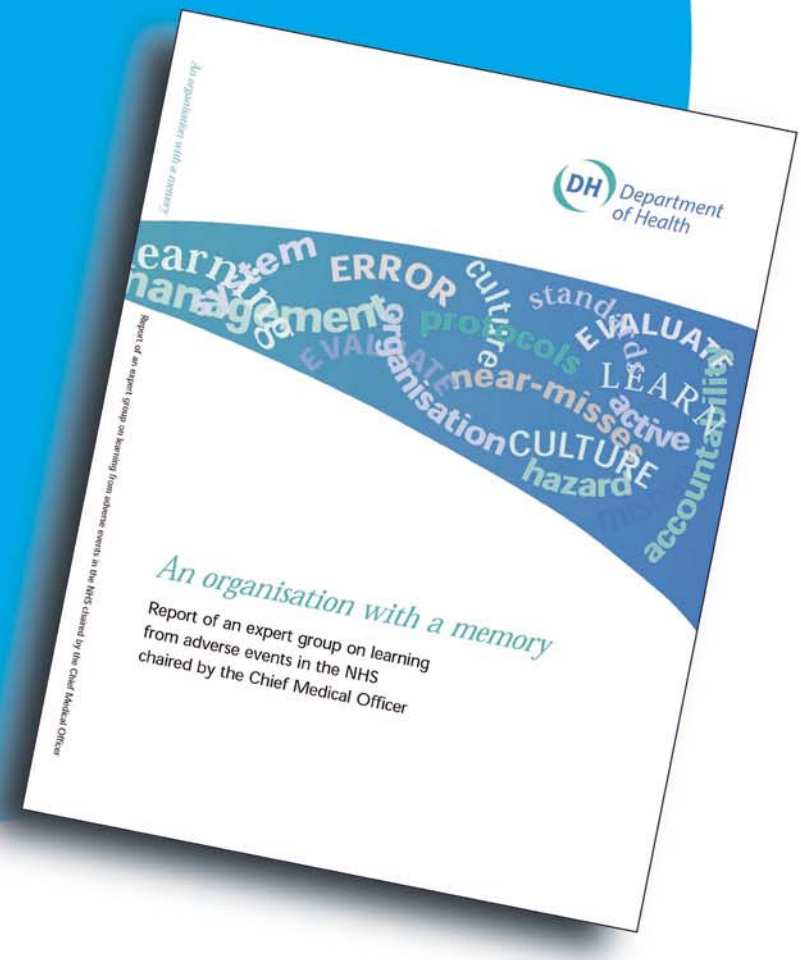
Building a safer NHS for patients

IMPLEMENTING AN ORGANISATION WITH A MEMORY



Contents

Summary of Main Points

- *Building A Safer NHS For Patients* sets out the Government's plans for promoting patient safety following the publication of the report *An Organisation with a Memory* and the commitment to implement it in the NHS Plan. It places patient safety in the context of the Government's NHS quality programme and highlights key linkages to other Government initiatives. Central to the plan is the new mandatory, national reporting scheme for adverse health care events and near misses within the NHS. This will enhance existing mechanisms for improving quality of care and promoting patient safety by harnessing learning throughout the NHS when something goes wrong.

- In the past, most health services around the world have underestimated the scale of unintended harm or injury experienced by patients as a result of medical error and adverse events in hospitals and other health care settings. There has been no real understanding of the approach necessary to reduce risk to patients based on analysing and learning from error and adverse events.

- This is changing. The whole issue of patient safety, medical error and adverse event reporting is becoming a high priority in health care systems in this country and across the world. During the preparation of this programme of implementation extensive contact and discussion has taken place between representatives of the United Kingdom, the United States of America and Australia. This work has shown that:

- health care is a complex and at times high risk activity where adverse events are inevitable; but it is not unique – there are many parallels with other sectors (e.g. aviation);
- capturing and recording information on adverse events, and analysing them in the right way is an essential step to reducing risk to patients, as is creating the right culture within health organisations;
- recognising that it is weak systems that create the conditions for, and the inevitability of, error is vital to achieving higher levels of patient safety.

The new national system for learning from error and adverse events

- The report focuses on action, both nationally and locally ,necessary to establish a system which ensures that lessons from adverse events in one locality are learnt across the NHS as a whole. The system will enable reporting from local to national level. It will introduce a new integrated approach to learning from medical error, adverse events and near misses, and it will capture adverse event information from a wide variety of sources. Local reporting of adverse events and action to reduce risk within the organisation concerned is essential. On a selected basis reports to national level will enable service-wide action where patterns, clusters or trends reveal the scope to reduce risk or prevent recurrence for future patients in other parts of the country.
- The report describes the necessary steps to be taken to set up the linked components of the new system, including:
  - establishing agreed definitions of adverse events and near misses for the purposes of logging and reporting them within the NHS (moving gradually to agreed international standards); detailed guidance for organisations, staff and patients will be issued and pilot sites activated;
  - formalising a minimum data set for adverse events and near misses;
  - producing a standardised format for reporting (initially on paper as well as electronically but gradually moving towards the latter exclusively);
  - building expertise within the NHS in root cause analysis (the more in-depth approach to identifying causal or systems factors in more serious adverse events or near misses);

- ensuring that information from all other major existing adverse event reporting systems (e.g. medical devices, reactions to medicines, complaints to the Health Service Commissioner, serious accidents reported to the Health and Safety Executive) are fed into the new system;

- promoting a culture of reporting and patient safety within NHS organisations, building on the transformation already under way as part of the clinical governance initiative.

The National Patient Safety Agency

- A new independent body, the National Patient Safety Agency, will be established within the NHS. It will implement and operate the system with one core purpose – to improve patient safety by reducing the risk of harm through error.

- The National Patient Safety Agency will:

  - *collect and analyse* information on adverse events from local NHS organisations, NHS staff, and patients and carers;

  - *assimilate* other safety-related information from a variety of existing reporting systems and other sources in this country and abroad;

  - *learn lessons* and ensure that they are fed back into practice, service organisation and delivery;

  - where risks are identified, produce *solutions to prevent harm, specify national goals and establish mechanisms to track progress.*

An improved system for handling investigations and inquiries across the NHS

- Potentially avoidable outcomes of health care arise in a variety of ways and in different patterns. In the past, a wide range of methods – including investigations, reviews, internal and external inquiries – have been used to respond to the problems and concerns raised. Over the years, there has been little consistency in the way these responses have been made.

- The establishment of a new system of adverse event reporting for learning creates an important need to resolve these inconsistencies and clarify the role of existing and new organisations to respond effectively to service failure, both large scale and small.

- The report sets out future procedures for handling situations where there are potential risks to patients of poor outcomes of care or harm or where such events have already taken place. It sets out a new integrated approach, the main features of which are:

  – most adverse events or incidents occurring in local health services, previously dealt with in a wide variety of ways, will in future be dealt with by the new approach to reporting and analysing adverse events and near misses described above;

  – at present, in situations where there has been a failure of a whole service, a seriously dysfunctional service or major systems weakness, a range of approaches is taken (enquiries commissioned by individual NHS Trusts or health authorities, visits by medical Royal Colleges, inquiries commissioned by Regional Offices, Commission for Health Improvement investigations). In future, there will be only two ways of responding: an independent investigation commissioned by either the Department of Health or by the Commission for Health Improvement (the approach to be agreed between the Department and the Commission in each case). There will be no ad hoc external investigations or inquiries commissioned by NHS Trusts or health authorities, but Royal Colleges and their members will continue to play an important role;

  – to cut down on the present practice of multiple investigations into the same problem, full blown internal inquiries will no longer be carried out but be limited to scoping investigations to inform a decision as to whether an independent investigation should be carried out;

  – to reduce the incidents of multiple inspections and accreditation visits, the current system will be rationalised;

  – inquiries into the mental health services (currently dealt with under a separate procedure) will be brought into this integrated approach to investigation;

  – where a service failure results in serious harm to larger numbers of patients, where there is serious national concern, or where a major issue of ethics or policy is raised for the first time by an incident, a public inquiry may be ordered by the Secretary of State for Health using his statutory powers;

- some risks to patients arise from poor performance of an individual practitioner. New procedures described elsewhere and summarised in this report aim to protect patients from such situations. Where the investigation of an individual practitioner's problems reveal wider service dysfunction, the Department of Health and the Commission for Health Improvement will decide whether there should be a follow through investigation of the service concerned;

- complaints by patients will be dealt with under the NHS complaints procedure, which is currently being reviewed, but patients and carers will have a role in the adverse event reporting system;

- staff concerns about standards of care should be addressed by the new adverse event reporting system or as part of clinical governance more generally. For staff who find themselves in an organisation which is dysfunctional or repressive they will continue to be protected by whistleblowing legislation;

- guidance on procedures for the appropriate use of inquiries and investigations will be issued separately.

Specific risks targeted for action

- Within certain fields of medicine and health care regular patterns of error can be recognised which, if selectively targeted, can reduce risks to patients. The report sets out action to reach national targets for four key categories of serious recurring adverse events identified for action in response to the recommendations in *An Organisation with a Memory*:

  - reduce to zero the number of patients dying or being paralysed by maladministered spinal injections by the end of 2001;

  - reduce by 25% the number of instances of harm in the field of obstetrics and gynaecology which result in litigation by 2005;

  - reduce by 40% the number of serious errors in the use of prescribed drugs by 2005;

  - reduce to zero the number of suicides by mental health patients as a result of hanging from non-collapsible bed or shower curtain rails on wards by 2002.

- In addition to the four targets, other areas are being identified where action could provide some early gains in risk reduction. These include:
  - review of care environment to identify environmental changes and changes in care practices that could reduce risk and improve patient safety;
  - reviewing clinical practice with Royal Colleges, professional organisations and specialist associations to identify high risk procedures;
  - building safety into purchasing policy within the NHS;
  - seeking input from the world of design to identify new opportunities for improved safety;
  - examining across the board the potential for computers to reduce the occurrence and impact of error;
  - identifying the scope for formal pre-procedure safety briefings in very high risk situations;
  - enhancing the role of simulation laboratories to expose staff to risk situations with no actual patients involved;
  - creating a clear role for patients in helping to promote and achieve safety goals.

Patient safety research

- Valuable research into patient safety has already been carried out both in the UK and abroad, but it is a young field of research compared to the extensive research literature which has accumulated on safety, risk, accidents and disasters in other non-healthcare fields. The document sets out some key questions for patient safety research and outlines a research strategy. The research will be promoted through direct Department of Health funding and by working with the major medical research funders.

Conclusions

- There has been no systematic focus on patient safety in the NHS so far. In this country we are uniquely placed to build this important strand into a programme of quality assurance and quality improvement which has come into being over the last three years.

- At the heart of the changes described in this document will be a system of identifying, recording, analysing and reporting the things that go wrong in health care and pose risks for patients. Over time, learning from this unique database will be the way in which one patient's bad experience will help hundreds of others and the way in which the NHS will become an even safer service.

- Experience in other sectors also suggests that the reduction of risk to patients and the improvement of safety will be a long-term task which will require sustained effort, commitment and high quality leadership.

1 A New Focus on Patient Safety

This introductory chapter reiterates the case for change, first set out in the report *An Organisation with a Memory*, published last year. It describes how promoting patient safety by reducing error is becoming a key priority of major health services around the world. It sets out the content of the rest of the report, which describes the steps necessary to implement a programme to reduce the impact of error and enhance patient safety within the NHS.

1. In June 2000, the Government accepted all recommendations made in the report of an expert group chaired by the Chief Medical Officer called *An Organisation with a Memory*. The report acknowledged that – as in many other countries – there has been little systematic learning from adverse events and service failure in the NHS in the past.

> "Accidents hardly ever happen without warning. The combination or sequence of failures and mistakes that causes an accident may indeed be unique, but the individual failures and mistakes rarely are."
>
> *Mike O'Leary (British Airways, UK), Sheryl Chappell (NASA, United States)*

2. *An Organisation with a Memory* drew attention to the scale of the problem of potentially avoidable events that result in unintended harm to patients. The report proposed solutions based on developing a culture of openness, reporting and safety consciousness within NHS organisations. It proposed that a national system should be introduced to identify adverse events in health care including specified

near misses, to gather information on their causes, to synthesise, learn and act to prevent similar events occurring and reduce risk.

ADVERSE EVENTS IN THE NHS: EXAMPLES DEMONSTRATING THE MAGNITUDE AND NATURE OF THE PROBLEM

- Adverse events occur in around 10% of admissions or at a rate of an estimated 850,000 adverse events a year.
- Adverse events cost approximately £2 billion a year in additional hospital stays alone.
- Around 1150 people who have been in recent contact with mental health services commit suicide every year.
- 400 people die or are seriously injured in adverse events involving medical devices every year.
- The NHS pays out every year around £400 million settlement of clinical negligence claims.
- Hospital acquired infections – around 15% of which may be avoidable – are estimated to cost the NHS nearly £1 billion every year.

An Organisation with a Memory, June 2000

3. *An Organisation with a Memory* has attracted a great deal of interest both in this country and internationally. It was described by Don Berwick, one of the world-leaders in the field of quality improvement, as a landmark report that was courageous in labelling the problem of medical errors as pervasive, consequential and pledging progress to address the issue.

"Human beings make mistakes because the systems, tasks and processes they work in are poorly designed."

Dr Lucian Leape, testifying to the President's Commission on Consumer Protection and Quality in Health Care

4. The whole issue of medical error, patient safety and adverse event reporting is rising on the agenda of health care systems around the world. In the last year representatives from the NHS in England have met with their counterparts in Australia and the United States of America. These meetings have clearly demonstrated:

- *Firstly*, that the problems faced are very similar. For example, medication error accounts for around a quarter of the incidents which threaten patient safety in each country. The underlying causes of medication error are similar across health systems.

- *Secondly*, that there is a major need for international standardisation of terminology in the definition of different types of adverse event and in reporting.

- *Thirdly*, that there is enormous scope for collaboration in designing solutions for patient safety and finding effective ways of implementing them.

5. These conclusions have been reinforced by an Anglo/US intergovernmental collaboration on Improving Quality in Health Care. This collaboration has grown out of the Anglo/US Ditchley Park conference series, sponsored by the Commonwealth Fund of New York and the Nuffield Trust in London. Patient safety, medical error and adverse clinical events in health care have become an important strand of this growing collaboration. Both governments recognise that although the UK and the US have very different health care systems, many of the threats to patient safety have similar causes in the two countries – and probably similar solutions.

INTERNATIONAL INITIATIVES ON PATIENT SAFETY: SOME EXAMPLES

- *The Agency for Healthcare Research and Quality* (AHRQ) in the USA is concerned with developing a broader understanding of what the patient safety problems are and where they occur in the delivery of health care. AHRQ-supported research is leading to a rethinking of what does and does not work at the health care systems level (www.ahcpr.gov/qual/errorsix.htm)
- *The Institute for Healthcare Improvement* (IHI) in the USA is an organisation hosting both seminars and a collaborative approach to reducing error in health care. One noted category is their Breakthrough Series Collaborative on reducing adverse drug events and medical errors (www.ihi.org).
- *The Institute for Safe Medication Practices* (ISMP) in the USA is dedicated to making safety the highest performing function in its member organisations to thereby ensure that facilities are as safe as possible for patients and staff. As part of this the Institute produces the ISMP Medication Safety Alert (www.ismp.org).
- *The Joint Commission on the Accreditation of Healthcare Organizations* (JCAHO) is a nationally recognised accreditation agency for hospitals, managed care entities and other types of health care facilities in the USA. JCAHO has an established 'sentinel event' reporting system based on formal root cause analysis (www.jcaho.org).
- *The Australian Patient Safety Foundation's (APSF)* primary functions are to provide leadership in the reduction of patient and consumer injury in all health care delivery systems; to follow a systems approach to patient safety improvement, based on collaboration with clinicians and health unit staff; and to provide a flow of funds to support ongoing research into patient safety (www.apsf.net.au).

6. The early steps of the implementation of *An Organisation with a Memory* and the collaboration with senior health professionals, consumer organisations and researchers in other countries have emphasised:

- health care is not unique, there are many parallels with other sectors (e.g. aviation);
- modern health care is a complex, at times high risk, activity where adverse events are inevitable;
- a successful programme would reduce the chance of error – and hence adverse events – occurring and limit its impact on the patient when it does occur;
- there are few quick fixes;
- systems-thinking is the only route to definitive risk-reduction solutions;
- creating the right culture is essential to successful reporting and learning from errors and adverse events;
- improving patient safety is helped by working with patients so that they are more informed, more involved and more empowered.

> "There is simply no issue more important in health care than ensuring the safety of our patients."
>
> *Dr Ken Kizer, President and Chief Executive Officer, National Forum for Health Care Quality Measurement and Reporting (NQF)*

7. There are many examples of initiatives around the world which have successfully demonstrated that the incidence of medical error can be reduced. None has been translated to a whole health care system. The NHS is uniquely placed to do this.

8. This report sets out next steps towards implementing *An Organisation with a Memory* throughout the NHS. It describes:

- the place of patient safety and risk reduction in the overall NHS quality programme;
- the role of an independent body, which will run and oversee the reporting system, synthesise and analyse the information gathered and initiate action to facilitate learning and produce change;

- the different approaches that will be taken to investigating and enquiring into adverse events and service failure;
- the action that is being taken to address the four specific areas identified in the original report: suicides amongst mental health in-patients; maladministration of spinally injected cancer drugs; harm in the field of obstetrics and gynaecology; and medication errors;
- the proposed research programme into adverse events, medical error and patient safety;
- an action plan outlining the timetable for implementation.

2

When Something Goes Wrong: An Integrated Response from the NHS

Potentially avoidable outcomes of health care arise in a variety of ways and in different patterns. A wide range of methods – including investigations, inquiries, reviews – have been used to respond to the problems and concerns raised. Over the years, there has been little consistency in the way these responses have been made. Past and existing procedures in the NHS are patchy and fragmented. Some are not well understood. There has often been duplication of approaches and ineffective resolution.

The establishment of a new system of adverse event reporting for learning, as recommended in *An Organisation with a Memory*, creates an important need to resolve these inconsistencies and clarify the role of existing and new organisations to respond effectively to service failure both large scale and small. This chapter describes how these different past approaches will in the future work in an integrated way to effect solutions.

1. Improving the quality of public services is essential to justify expenditure of large amounts of public money and to provide the services people need and reasonably expect in an accessible way. It is at the heart of the Government's NHS modernisation agenda.

2. Over the last three years policies have been put in place to establish a clear framework of accountability within the NHS for the assurance and improvement of the quality of health care provided to patients. The need for those policies was

highlighted in the late 1990s, when a number of serious failures in standards of care in local NHS services hit the headlines giving rise to public concern.

3. Lapses in standards of care present in a variety of different ways. For example, sometimes they occur:

- as apparently completely unexpected adverse events which result in harm to, or even the death of, a patient e.g. where the wrong drug or the wrong dose of drug is administered;
- as poor or unsatisfactory outcomes of care from a service performing sub-optimally over a long period of time e.g. where a diabetic service is not achieving good control of the patient's disease;
- when patients are put at risk by a practitioner whose performance is impaired due to inadequate knowledge, skills, ill health or dysfunctional conduct e.g. where patients experience high rates of post-operative bleeding following keyhole surgery.

4. As the result of such failures, the NHS quality programme must incorporate a clearly defined strand, which is directed specifically at protecting patients from harm.

Fragmented approach to failures in standards of care

5. In the past, procedures for dealing with avoidable adverse outcomes of care in the NHS have been unsatisfactory, unclear and inconsistently applied. As a result:

- only a small proportion of adverse events have been properly recognised and documented;
- investigations of problems have been of very variable quality and have not adopted a standardised approach to identifying root causes;
- internal inquiries have often failed to get to the bottom of a problem and some have lacked objectivity;
- the grounds for establishing external inquiries have never been clearly established even though such inquiries are frequently used;
- the format and rules of conduct of inquiries have lacked coherence;
- the same issue has often been investigated or enquired into several times by different bodies;
- uni-disciplinary inquiries have failed to provide recommendations for, or impact upon, multi-disciplinary practice;

- the impact of all the inquiries and investigations carried out on reducing risk and preventing recurrence has been very weak.

6. In designing and implementing the new reporting system for learning from adverse events in the NHS, as set out in *An Organisation with a Memory*, it is important to recognise that it will not deal with all kinds of failure in standards of care. Other mechanisms, in the form of different types of investigations, will still be necessary. The aims of these investigations must be made clear. It is also essential to establish the circumstances in which each type of investigation will be used.

7. This means resolving the lack of clarity and ambiguity, for example over the role of and ground rules for:

- internal inquiries;
- ad hoc independent investigations or inquiries;
- various statutory external inquiries (including public inquiries).

8. It also means setting out clearly the role of two new bodies:

- the National Clinical Assessment Authority;
- the Commission for Health Improvement.

9. The sections of this chapter that follow:

- clarify how patient safety will form part of the overall NHS quality programme;
- distinguish the proposed new adverse event reporting system (described in detail in the next chapter) from the other ways in which failures in standards of care are responded to and investigated;
- describe the way in which in future the identification of failures in standards of care, their investigation and the action resulting from them will be addressed in an integrated way.

Patient safety: an integral part of the NHS quality programme

10. A pre-requisite for achieving a successful approach to reducing risk and enhancing patient safety is to create a health service whose culture and behaviour reflects a strong commitment to providing high and ever improving standards of care and a service that meets the needs and expectations of patients and the public.

11. A set of policies, programmes and structures has been introduced over the last three years which has created in the NHS, for the first time in its history, the conditions for a comprehensive approach to quality assurance and quality improvement.

12. This programme was first set out in the White Paper *The new NHS: modern, dependable*. It was developed further in *A First Class Service* and expanded and strengthened in the *NHS Plan* published in July 2000.

13. The basic elements of the programme are:

- the setting of clear national standards;
- the creation of modern organisational mechanisms for delivering the national standards dependably and safely;
- the monitoring of relevant outcomes.

This framework is underpinned by the Health Act 1999 which placed a statutory duty of quality on all NHS organisations that provide direct patient care.

14. To help fulfil their duty of quality, every hospital, every general practice and every primary and mental health NHS Trust is expected to have introduced a comprehensive programme of clinical governance. Successfully implemented, clinical governance ensures that all the efforts of the organisation and those who work in it are focused and co-ordinated to deliver high standards of care and service.

Definition of clinical governance

Clinical governance can be defined as 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.

A First Class Service: Quality in the new NHS.

15. Clinical governance requires:

- *commitment* from the top of the organisation to put quality of care and patient safety at the top of the agenda;
- the creation of a *culture* in which quality of care and service to patients can flourish. The right culture is characterised by shared passion for quality, by openness and respect, by support and by fairness. It is not a culture in which people are swift to blame, to find scapegoats, or seek retribution;

- *procedures and practices* which mean that people throughout the organisation will know how well care is being provided, understand their contribution to the quality of care, and can identify and act upon opportunities for improving quality and safety.

16. The National Service Frameworks (NSFs) and the National Institute for Clinical Excellence (NICE) have already begun to set clear national standards for important conditions such as coronary heart disease and mental health and for the use of specific treatments (e.g. taxanes for breast cancer). These standards, together with effective clinical governance backed up by new and patient-focused methods of monitoring and performance management, are beginning to raise quality and reduce inequality for those specific conditions and treatments where standards have been set.

17. It is accepted that provision of a quality health care experience includes working with patients to set standards for fundamental aspects of care. Such standards, as presented in the *Essence of Care*, can then be used to structure clinical governance activity with comparison and sharing of good practice that meets individual patient's needs.

18. With condition specific, treatment specific, patient experience and patient safety strands, through implementation of the quality programme:

- the NHS will have much clearer standards governing its operation;
- hospitals, primary care organisations and other bodies delivering care to NHS patients will have a culture and approach to care which places the patient at the centre of their work;
- leadership at every level of the service will ensure that the focus of every episode of care is on quality and patient safety;
- other major strategies will underpin the programme so that information and information technology, education and training, and knowledge management support the process of quality improvement.

Adverse events and near misses

19. Adverse events, which usually occur suddenly or unpredictably, or those which 'nearly' happen, will in future be dealt with under the new national reporting system proposed in *An Organisation with a Memory*. No such comprehensive system has existed in the NHS before.

20. As has been explained elsewhere in this document the emphasis will be on: developing a reporting culture, root cause analysis of adverse events, including

specified near misses, thinking about systems and making learning effective so that risk and recurrence are reduced. The steps to implement the new system are set out in Chapter 3.

FUTURE PROCEDURES FOR DEALING WITH ADVERSE EVENTS

In future adverse events, medical errors and near misses will be recognised, analysed and reported through the new system described in the next chapter of this report. Learning and effective action to reduce risk to future patients will take place within the organisation concerned (locally) and at national level (NHS-wide).

A pattern of poor practitioner performance

21. While poor performance by individual practitioners in the NHS is uncommon, when unchecked the results can be catastrophic for the patient and the families concerned.

22. For example, some of the most serious cases in recent years of patients experiencing poor outcomes of care or harm have arisen from the actions of individual doctors such as those of the gynaecologist Rodney Ledward, whose standard of practice and conduct led to him being struck off by the GMC. These have illustrated the difficulties the NHS has had in dealing with poorly performing doctors in the past, even when the behaviour or poor practice has been quite brazen.

23. These medical cases highlighted an unacceptable culture where problems related to medical practice were known about in a hospital but not faced up to or acted upon effectively to protect patients. Senior staff who should have taken action were daunted by the legalistic and inflexible procedures and the absence of any other options for dealing with problems. Often the human resource function was not involved until disciplinary action became unavoidable. There has also been confusion about what should be left to the General Medical Council and what should be dealt with locally. As a result, in the past, risks to patient safety arising from poor individual practitioner performance were not given an absolute priority but were 'traded off' against other considerations.

24. Problems with the practice of a small number of doctors in primary care has also been problematic as this group of doctors have had even less scrutiny in the past. Here too a number of high profile cases have exposed deficiencies in current methods for dealing with poor clinical practice.

25. These weaknesses were addressed with the publication of a consultation paper in November 1999 called *Supporting Doctors, Protecting Patients*. This contained a wide range of measures to ensure that poor clinical performance was prevented, recognised early and resolved more effectively so that patients received a greater degree of protection from poor practitioners than they had in the past. There was also greater emphasis on using educational and training solutions wherever possible in addressing problems in a doctor's practice (rather than disciplinary measures). The proposals are now being put in place as part of NHS Plan implementation.

26. A National Clinical Assessment Authority (NCAA) will provide quick objective assessments on cases that cannot be resolved locally. The NCAA will provide a national focus for dealing with problem cases by providing expert teams to mount investigations. The teams (including lay members) will work to national protocols and aim to identify the underlying causes of clinical failings and devise an appropriate solution to be implemented by the NHS Trust or health authority that employs the doctor.

27. Very serious cases of poor performance amongst doctors must be referred to the General Medical Council (GMC). Last year the Government took action to give the GMC new powers to act quickly and decisively when patients need to be protected whilst the case is being fully investigated.

28. The culture described above has not been so obvious in other health professions. However, here too an over-reliance on the disciplinary system has led to under reporting and often results in unnecessary stress for practitioners. Consequently near misses tend to go unrecorded.

29. To ensure that the highest standards of care are maintained, other health professionals involved in the care of patients need to be covered by similar provisions as the doctors for recognising and acting upon poor clinical performance. Employers must check that all staff are suitably qualified for the tasks which they are expected to undertake and that they are registered with the appropriate body. The regulation of the other health professions is being strengthened and new bodies have been announced for nurses and midwives and for other allied health professions (as a successor to the Council for Professions Supplementary to Medicine). Once the National Clinical Assessment Authority has developed its processes and has gained some operational experience, we will consider how the lessons being learned can be used by local NHS employers to help them in addressing poor clinical performance amongst the much larger group of other health professions.

30. There will be occasions when the investigation of an individual practitioner's performance will reveal wider service problems in the organisation concerned in which case the Commission for Health Improvement would be alerted by the National Clinical Assessment Authority and would consider whether a service-wide investigation would need to be initiated. The new National Patient Safety Agency will be able to monitor standards of patient safety across the NHS. It will ensure that action is taken, where needed, to raise standards to meet the expectations of patients and staff.

FUTURE PROCEDURES FOR DEALING WITH POOR CLINICAL PERFORMANCE

In future consultants, general practitioners and other grades of doctors demonstrating evidence of poor clinical performance will be identified early so that any risks to patients can be reduced. If the problem cannot be evaluated or resolved locally or it is particularly serious, a referral will be made to the new National Clinical Assessment Authority (NCAA), which will make a thorough and objective assessment and give advice to the NHS Trust or health authority. Educational and training solutions will be used where possible to resolve problems with a doctor's practice. Some serious problems will also be referred to the General Medical Council. If the NCAA finds a problematic service it will notify the Commission for Health Improvement which may follow through with its own investigation of the wider service problems that have been revealed. An improved approach to addressing problems of poor clinical performance amongst the other health professions will be developed in conjunction with NHS employers.

Major service failure

31. From time to time it becomes apparent that patients have experienced adverse outcomes of care, have been harmed or have even died because of major weaknesses in the way a service has operated. Sometimes it becomes evident that a service is dysfunctional even though there has been no obvious or overt harm to patients.

32. It is in these circumstances in the past that problems in a local service have not been resolved often until late in the day when damage may have been done.

33. Until recently such events were investigated in a variety of ways:

- an internal inquiry;

- an inquiry or investigation established by the NHS Trust, health authority, or Regional Office of the Department of Health or one of the Department's Chief Officers using a panel pulled together on an ad hoc basis (comprising some or all individuals independent of the local NHS body);

- an inquiry or investigation commissioned by the NHS Trust, health authority or Regional Office of the Department of Health from one of the medical Royal Colleges;

- an inquiry commissioned by the Department of Health established either on an ad hoc basis or under the powers of the NHS Act 1977 (which give powers to subpoena witnesses and documents);

- an internal inquiry followed by an independent inquiry (of one of the types described above);

- a public inquiry established by the Secretary of State for Health under the Tribunals of Inquiry (Evidence) Act 1921 (chaired by a judge and with powers of subpoena).

34. No clear guidance has existed to determine which sort of investigation should be initiated in what circumstances. Moreover, in some high profile situations, more than one investigation has taken place into the same issue. Neither has there been consistency in the methods adopted for carrying out the investigation or inquiry.

35. The range of methods of investigation was added to in 1999 with the establishment of the Commission for Health Improvement. Although the Commission's main role is pro-active inspection of local clinical governance arrangements in the NHS it also has a remit to investigate failing services. On this basis, up to March 2001 the Commission had completed or had in train five investigations of failed services:

- an investigation into the Carmarthenshire NHS Trust, triggered by an incident in which a patient had the wrong kidney removed;

- an investigation into the North Lakeland Healthcare NHS Trust, following an inquiry into the abuse of elderly patients by Trust staff;

- an investigation into the use of locum medical practitioners by the Swindon and Marlborough NHS Trust, the mid-Sussex NHS Trust, Frimley Park Hospital NHS Trust, and the Royal United Hospital, Bath NHS Trust, triggered by concerns about the practice of an elderly locum histopathologist;

- an investigation into the heart and lung transplant activity of the Cardiothoracic Unit at St George's Healthcare NHS Trust between December 1999 and October 2000, to identify the cause of an apparently high mortality rate;

- an investigation into the management, provision and quality of health care for which the Leicestershire Health Authority is responsible, triggered by the conviction of a former Loughborough general practitioner for the indecent assaulted of some of his patients.

36. The Commission for Health Improvement's statutory remit is to investigate the management, provision or quality of health care for which NHS bodies have responsibility. It takes a systems or whole service perspective. It is not the Commission's role to examine conduct of individuals in detail. It is important that the Commission's investigative role is targeted at the right category of problems.

37. In future, a decision will be made on a case-by-case basis on what kind of investigation (if any), independent of the local NHS organisation, should be carried out. NHS Trusts and health authorities will not commission independent investigations as they do at the moment on an ad hoc basis. Instead, they will notify the Regional Office of the Department of Health. The Department and the Commission will agree the approach to be taken.

38. This will avoid the present difficulties caused by multiple investigations of the same issue and inconsistencies of approach in the investigations carried out. It will also enable the issue to be 'plugged in' to the right investigatory machinery (e.g. NCAA, GMC, CHI). The Royal Colleges have played a valuable role in assisting with investigations and they and their Members and Fellows will continue to do so. However, with the advent of the new bodies and the integrated approach to investigation described here, individual NHS Trusts and health authorities will work with Royal Colleges to ensure all investigations are carried out in a co-ordinated manner, making full use of all relevant expertise.

39. To take account of the role of the Commission and all the other types of investigation and inquiry, clear guidance will be provided by the Department of Health on the criteria for establishing particular types of investigations or inquiries.

40. In issuing this guidance, the opportunity will also be taken to rationalise the number of inspection and accreditation visits to local services by a range of external bodies. Some NHS Trusts report as many as twenty different external visits over a six-month period.

41. Cases of homicides by people in contact with mental health services are currently dealt with by independent inquiries carried out under a system established in Health Service Guidance. The current system is adversarial, does not lend itself to

a learning environment and does not meet the needs of victims' families for support and information. A different system that complements the necessary legal process carried out by the police and the courts would lead to the lessons of cases being shared and learnt more effectively. In support of this significant shift these incidents will be handled under the new NHS-wide arrangements as outlined in this chapter. This could in time lead to changes in our mental health systems that reduce the risk to the public whilst improving the treatment of mental health patients. This will enable appropriate action to be taken and lessons learned. Further guidance will be issued to the service that identifies how the changes will operate. They will complement the current development work that is underway to strengthen audits in mental health services and the use of the *Essence of Care* patient focused benchmarks to develop services that make patients with mental health needs feel safe, secure and supported.

FUTURE PROCEDURES FOR DEALING WITH MAJOR SERVICE FAILURE

In future, any serious service failure or major dysfunction will be notified to the Regional Office of the Department of Health by the local service. It will then be the subject of discussion between the Department of Health and the Commission for Health Improvement to decide on the appropriate form of investigation. There will be no full-blown internal inquiries. Internal inquiries will normally be limited to scoping i.e. establishing the facts so that a preliminary report can be made to inform the discussion on what form of independent investigation or inquiry (if any) should be carried out. The Department of Health will approve the format of an independent (i.e. external to the local service concerned) investigation after discussion with the Commission for Health Improvement. In some circumstances, the Commission will investigate. In others the Department of Health (usually through one of its Chief Officers or Regional Offices) will establish an investigation independent of the local service. NHS Trusts and health authorities will not make ad hoc arrangements with medical Royal Colleges or other external bodies. Nominees of Royal Colleges and the Colleges themselves will still, however, play an important role in the new framework described.

Serious public concern

42. From time to time there will be major issues in the NHS which draw attention to a matter of serious public concern either because of the scale of the problem or because it is an issue not previously examined systematically. In these circumstances, the Secretary of State for Health has in the past commissioned

inquiries using specific statutory powers to allow subpoena of witnesses and documents. Most such inquiries have taken evidence in public. In the late 1980's the report of the Inquiry into Child Abuse in Cleveland led to extensive new procedures in the field of child protection. Most recently a public inquiry was commissioned into the standard of care in the Bristol Children's Heart Surgery Service.

FUTURE PROCEDURES FOR DEALING WITH LARGE SCALE PROBLEMS OR MATTERS OF SERIOUS PUBLIC CONCERN

There will continue to be a small number of very serious situations involving health services which raise major public concern, important ethical questions or fundamental issues of health policy. In such circumstances the Secretary of State for Health may decide to establish an inquiry under one of a number of statutory powers which enable witnesses or evidence to be subpoenaed.

Complaints by patients

43. A clear and accessible process through which patients can complain or comment on the quality of care they have received is an essential part of any modern health system.

44. Complaints are also another way of ensuring that poor or unsatisfactory outcomes of care are recognised and that improvements can be made to secure a better service for future patients.

45. Complaints can be a way through which adverse events are first recognised but more often they throw light not just on clinical outcomes of care but also the process of care. Delay, poor communication, inefficient delivery of care are all common features of complaints that are made.

46. The NHS last revised its complaints procedure in 1996 but it has been recently reviewed because of concerns expressed that it was still not responsive enough to patients or their families who made complaints. Proposals will be set out on a new procedure in due course.

47. In addition to the NHS complaints, procedure which will contribute some information on adverse events, it is planned that there will be a role for patients and carers in the adverse event reporting system (discussed more fully in the next chapter).

FUTURE PROCEDURES FOR RESPONDING TO COMPLAINTS OR CONCERNS OF PATIENTS

Currently patients can raise a concern about the quality of their care through the NHS complaints procedure, which has a number of steps that must be followed. Although the NHS complaints procedure was last revised in 1996 there have been continuing concerns about its operation – complainants feel that it is still not responsive, accessible or independent enough. The current NHS procedure has been evaluated and the Government will be setting out proposals for a new procedure. Aside from being able to make a complaint, patients will also play a part in the adverse event reporting system. They will be entitled to report an incident that they see in their own care or in the care of another patient. If they believe they have witnessed a near miss they will also be encouraged to report this. The role of patients in reporting is described in the next chapter.

48. The NHS Plan sets out new proposals for patient and public involvement in the running of the NHS. Patient Advocacy Liaison Services (PALS) will provide advice and support to patients who have concerns about the service. There are also proposals to commission a new independent advocacy service to provide support to those who wish to make a complaint.

Concerns expressed by staff

49. Past examples of services which posed risks to patients but which continued unchecked in the face of concerns by staff led to discussion of the need for mechanisms to enable staff to sound the alarm. Even more worrying were examples of staff that had voiced concerns then being discriminated against, marginalised or disadvantaged in career terms. All this led to the creation of the Public Interest Disclosure Act 1998 (PIDA). With it the Government has introduced one of the most far-reaching whistleblower protection laws in the world to ensure that any member of NHS staff can speak out against poor standards without fear of victimisation. Every NHS Trust and health authority is now expected to have in place local policies and procedures which comply with the provisions of the Act.

50. The core of the new adverse event system will be reports made by NHS staff. The success will depend on creating an open culture within all NHS organisations where staff feel that they can draw attention to errors or mistakes (so that learning can take place) without fear of disciplinary action. A confidential channel will also be created for reporting. Experience elsewhere (e.g. in the aviation industry) has

found that this is necessary, at least initially, until some staff feel that they can have the confidence to report using the main 'open' channel.

51. The need for extensive use of whistleblowing would be a sign of an unhealthy local organisation which could not create the kind of culture where reporting was taking place openly and non-judgementally.

FUTURE PROCEDURES INVOLVING NHS STAFF CONCERNS ABOUT STANDARDS OF CARE

NHS staff will be the main way in which adverse events and near misses are reported (under the new arrangements described in the next chapter). As proposed in *An Organisation with a Memory*, the reporting arrangements will also include a confidential reporting channel for staff who do not have confidence in making a report openly. Experience of other sectors (e.g. aviation) suggests that this is necessary at least initially, until a blame-free reporting culture can be fully developed. Whistleblowing legislation has been implemented within the NHS and will remain in place. It will be a failsafe for staff in health organisations which are so dysfunctional that this last resort approach to drawing attention to poor standards of care is necessary.

Monitoring service performance

52. Some poor outcomes of care are not just the result of adverse events. A whole service can perform sub-optimally over a period of time. The NHS does not have a systematic way of monitoring the occurrence of poor clinical outcomes of care unless they are manifest as serious events. For example, patients dying after complications of major surgery is likely to focus attention on the performance of a service whereas a relatively high rate of foot ulcers or failing vision amongst patients being treated by a diabetic clinic may not. Indeed much of what is known about the outcomes of care produced by a service has been derived from one-off research studies, rather than routinely available surveillance data. Some disciplines (e.g. cardiothoracic surgeons and intensive care specialists) have developed clinical audits that collect and analyse information to support improvement in the quality of care.

53. Benchmarking activity is also providing comparative data to support the identification and sharing of structures and processes that support good patient outcomes. This approach originally focused upon quantitative outcomes but has recently been developed by nurses in the *Essence of Care* to support the comparison and sharing of best practice in achieving a quality patient experience.

54. In future, the NHS will work with stakeholders to explore how these examples of national audits and benchmarking can be developed and used to best effect.

Conclusions

55. In future the handling of situations where there are potential risks to patients of poor outcomes of care or harm, or where such events have already taken place, will be as follows:

- under the new national reporting system, *adverse events, including specified near misses* will be identified, recorded, analysed, reported and lessons learnt will be shared to effect change at local and national level (details are described in the next chapter). Investigation at local level will focus on analysis of systems to identify underlying or root causes;

- actual or potential risks to patients from *poorly performing doctors* which cannot be resolved locally will be referred to the National Clinical Assessment Authority (NCAA) for assessment and advice. The emphasis will be on intervening early to protect patients and where possible finding solutions to the doctor's problems by retraining or education. Serious cases will continue to be referred to the General Medical Council;

- the *regulation of the other health professions* is being strengthened and new bodies announced for nurses and midwives and allied health professions. Once the NCAA has developed its processes and has gained some operational experience this will be used to inform local NHS employers' approach to dealing with poor clinical performance amongst other health professions;

- where there has been a *failure of a whole service, or it is seriously dysfunctional, or there are major systems weaknesses*, the Department of Health and the Commission for Health Improvement will discuss what sort of investigation independent of the local service should be carried out. Depending on the circumstances, this will either be an investigation by the Commission using its statutory powers or an investigation independent of the local NHS organisation concerned constituted by the Department of Health (through one of its Chief Officers or Regional Offices). Internal inquiries in future will be limited to 'scoping' investigations prior to a decision on whether an independent investigation should take place; NHS Trusts and health authorities will not commission independent investigations directly on an ad hoc basis outside the framework described in this chapter;

- inquiries into serious incidents in the mental health services are currently dealt with under an entirely separate procedure; in future they will be integrated in to the Department of Health/Commission for Health Improvement procedures described in this chapter;

- where the new adverse event reporting system reveals a *major problem in the operation of the service* concerned, or the NCAA (in assessing a doctor) discovers *major service problems,* the Commission for Health Improvement will be asked to consider whether to follow on with its own investigation;

- where a *service failure results in serious harm to larger numbers of patients*, where there is serious national concern, or where a major issue of ethics or policy is raised for the first time by an incident, a public inquiry may be ordered by the Secretary of State for Health using his statutory powers;

- *complaints by patients* will be dealt with under NHS complaints procedure, which is currently being reviewed but patients and carers will have a role in the adverse event reporting system;

- *staff concerns* about standards of care should be addressed by the new adverse event reporting system or as part of clinical governance more generally. For staff who find themselves in an organisation which is dysfunctional or repressive they, and patients, will continue to be protected by whistleblowing legislation.

3

A Blueprint for the New National System for Learning from Adverse Events and Near Misses

This chapter sets out action to establish a new national system to report and learn from adverse events and near misses resulting from medical and other errors occurring in the delivery of care and treatment to NHS patients. The system will ensure that lessons learnt in one part of the NHS are properly fed back to improve practice and service organisation and delivery across the whole of the health service. Everyone involved in providing care and treatment to NHS patients will be included. So will patients and carers. By establishing this system of reporting from local to national levels, by linking existing systems of adverse event reporting and by taking account of other available information from the United Kingdom and abroad it will be possible to take an integrated approach to learning. A new independent body, the National Patient Safety Agency, will unite the functions, skills and experience needed to implement and operate the system with one core purpose – to improve patient safety by reducing the risk of harm through error.

1. The planned system of adverse event reporting for learning in the NHS is based on the principles and proposals set out in *An Organisation with a Memory*. They were founded on a thorough review of the evidence and experience of patient safety, adverse events and near misses resulting from medical error, their analysis and reporting, and mechanisms for learning from error in health care and in other sectors.

"Individuals by the very nature of being human are vulnerable to error. Although individuals are the focus of the error, errors also happen because of the systems in which people work. More often than not, a single error has multiple sources. Reducing errors also will require us to design and implement more error-resistant systems."

Gordon Sprenger, President and CEO American Hospital Association.

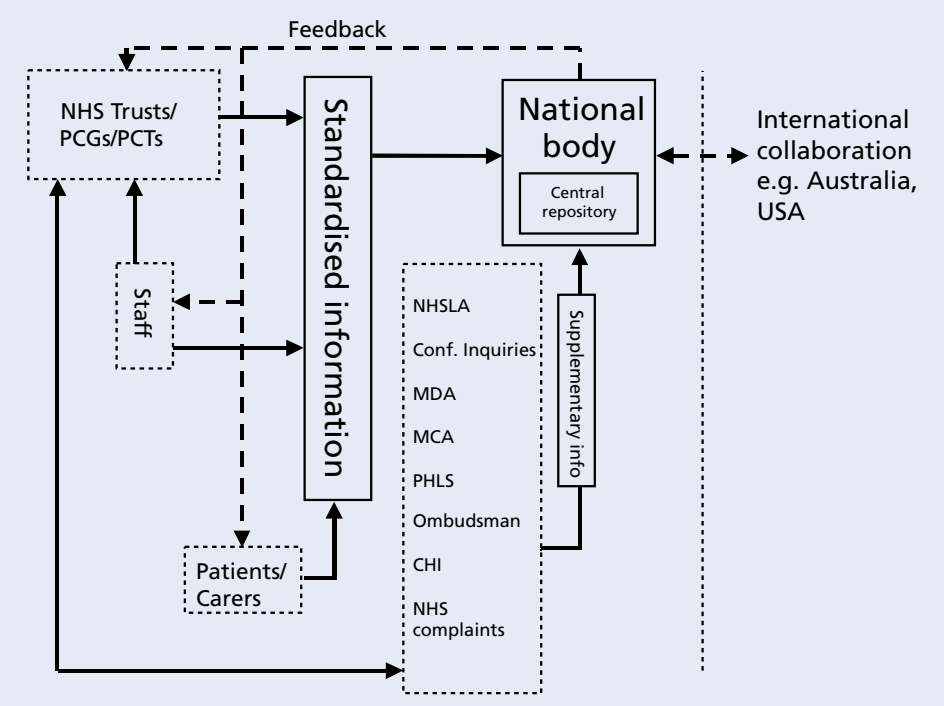
2. The new system, which is represented schematically at Figure 3.1, provides a unique opportunity for the NHS to address the question of patient safety comprehensively and decisively by:

- establishing a clear and strong focus on patient safety within the overall NHS quality programme;
- creating an effective system of identifying, recording, reporting and analysing adverse events and near misses in all NHS clinical services;
- ensuring that information from the analysis of such events is synthesised with information from other systems in this country and abroad to learn lessons;
- enabling lessons learnt to be available at local, national and international level so that risk can be reduced and recurrence prevented through changes in practice and in service organisation and delivery;
- developing further the cultural change in NHS organisations already occurring through clinical governance so as to promote a culture of openness that is generally free of blame, with a commitment to reporting and learning from medical error and failure based on systems awareness;
- establishing the new independent body to implement and operate the system and to improve patient safety across the NHS.

"Improvement strategies that punish individual clinicians are misguided and do not work. Fixing dysfunctional systems on the other hand is the work that needs to be done."

Saul Weingart, Harvard Executive, Session on Medical Error and Patient Safety.

Figure 3.1 The new national reporting system for learning from adverse events and near misses in the NHS



KEY REPORTING CHANNELS FOR ADVERSE EVENTS AND NEAR MISSES

- reports by individual members or teams of staff to management for action;
- reports by organisations to the new national body and, where appropriate, other agencies responsible for specific reporting schemes;
- reports by individual members of staff or teams of staff directly to the new national body in some circumstances (including a confidential channel of reporting);
- reports by patients and carers to the new national body.

Establishing the new national reporting system for learning – an overview

3. Extensive discussions have taken place in this country and also with national and international experts. Key organisations and systems have been examined in the United Kingdom, Australia and the United States of America to ensure that the

new system, including the new national body, is built on national and international best practice and experience.

4. To help promote effective use of the system, it needs to be embedded in an open, no-blame reporting culture, designed and built in a way that addresses potential barriers to reporting. The system is being designed around and built upon the following linked elements:

- *identifying, gathering information on, recording* and *reporting* adverse events and near misses;
- applying standardised *root cause analysis* methodologies to provide causal information to facilitate learning from serious adverse events and near misses and to produce an action plan to prevent recurrence where possible and reduce risks to future patients;
- *analysing* patterns and trends across all reported adverse events and near misses to identify further opportunities for improving patient safety;
- *reporting* of standardised information on specified adverse events and near misses by organisations and individuals both locally and to a new independent national body, with concurrent reporting to relevant systems operated by other agencies;
- *learning and disseminating lessons* from analysis of adverse event and near miss information from all major sources, as well as from research, international collaboration and other sources of information;
- *implementing effective change* to prevent recurrence where possible and reduce risks to future patients.

SOME KEY QUESTIONS ON SYSTEMS FOR REPORTING ADVERSE EVENTS AND NEAR MISSES IN HEALTH CARE

- What makes reporting systems successful?
- What data and other information should be collected and how?
- How should data be categorised and aggregated to enable patterns of events and trends to be recognised?
- How can confidentiality and discoverability be balanced with the need to inform in order to prevent harm to future patients?
- What organisational cultures and leadership factors promote reporting as a means to improve patient safety?

The key components of the new national reporting system

5. The remainder of this chapter sets out the steps being taken to implement the new system, including the new national body, together with relevant context.

Identifying, gathering information on and recording adverse events and near misses

6. Health care organisations and staff working within them need to know what constitutes an adverse event or near miss and how information on these should be gathered and recorded for the purposes of reporting locally and to national reporting systems.

7. Fundamental to these processes is development of agreed definitions of terms relating to error, adverse events and patient safety. A variety of terms are in common usage in the patient safety and quality literature. Some of these have specific meanings in particular studies or contexts, and some are used to mean different things in different contexts.

8. As a starting point *An Organisation with a Memory* proposed the following definitions of adverse health care event and health care near miss:

- 'an adverse health care event (AHCE) is an event or omission arising during clinical care and causing physical or psychological injury to a patient';
- 'a health care near miss (HCNM) is a situation in which an event or omission, or a sequence of events or omissions, arising during clinical care fails to develop further, whether or not as a result of compensating action, thus preventing injury to a patient'.

9. Since publication of *An Organisation with a Memory* in June 2000, the Department of Health has been taking part in an international initiative to develop agreed definitions for patient safety. This work will conclude during 2001 and will provide a glossary of key terms with associated definitions. To aid the identification of adverse events, in addition to clear definitions, a range of exemplars is being devised.

10. Gathering information on, and recording adverse events and near misses needs to be a straightforward process, with the record being structured to capture adequate detail. Most NHS Trusts already have standardised forms or other mechanisms, including electronic data capture, for recording adverse events and near misses. There has been much less development work in health authorities to cover the important sector of primary care.

11. Exemplar forms for recording adverse events, applicable to primary and secondary care and patient or carer reporting will be developed. Whilst ideally information should be provided on a standard document or form, and in an electronic format, emphasis will be placed initially on obtaining the necessary standardised information by whatever appropriate means. During 2001 detailed guidance will be issued, developed through piloting, on identifying, gathering information about, and recording adverse events and near misses.

Reporting adverse event and near miss information

12. Information on adverse events and near misses, once identified and recorded, will be reported both locally within the NHS organisation and on a defined basis to the new independent body described later in this chapter. It is important that the creation of a national body does not detract from the important element of reporting and using adverse event information within NHS Trusts, health authorities and Primary Care Groups and Trusts. This local element is essential to assuring and improving quality throughout the NHS as well as promoting patient safety. However, one of the serious deficits in the NHS of the past has been an inability to recognise that the causes of failures in standards of care in one local NHS organisation may be the way in which risk can be reduced for hundreds of future patients elsewhere.

13. Good work has already been carried out within the NHS to encourage local level NHS reporting. The Clinical Negligence Scheme for Trusts (CNST) run by the NHS Litigation Authority has ensured that a proportion of NHS Trusts have in place a basic system for risk management including clinical incident reporting. The Department of Health, through its NHS Controls Assurance project, has set down minimum standards for incident reporting and analysis, including underlying, or root cause analysis, as part of its generic Risk Management System Standard.

14. However, these developments are not integrated, systematic nor comprehensive across all NHS organisations – in particular primary care is not covered. There is no local to national element in the reporting. The CNST incident reporting requirements apply only to NHS Trusts and Primary Care Trusts and are voluntary. The Controls Assurance standards for incident reporting and analysis, whilst mandatory for all NHS organisations, require development of additional guidance to clarify applicability of the standards to adverse events resulting from medical error. The Controls Assurance standards currently do not apply to independent contractors and private organisations providing care and treatment to NHS patients.

15. By learning and building on existing systems, a coherent, standardised approach to reporting adverse event and near miss information will be introduced locally and nationally. A 'minimum data set' of reportable information is being defined. Reporting requirements will be piloted during 2001 and detailed guidance on reporting will be issued.

A MINIMUM DATA SET FOR ADVERSE EVENT AND NEAR MISS REPORTING

- What happened? (event/near miss description, severity of actual or potential harm, people and equipment involved)
- Where did it happen? (location/speciality)
- When did it happen? (date and time)
- How did it happen? (immediate, or proximate cause(s))
- Why did it happen? (underlying, or root causes(s))
- What action was taken or proposed? (immediate and longer term)
- What impact did the event have? (harm to the organisation, the patient, others)
- What factors did, or could have, minimised the impact of the event?

16. Initially, it is anticipated that information on adverse events and near misses will be reported using paper-based forms in most instances. However, use of NHSnet and the Internet is increasing and both systems offer potentially significant opportunities for electronic reporting both by NHS organisations and staff, and patients and carers. As part of the system design, development and testing the use of Internet-based adverse event reporting and feedback is being investigated.

17. Within the NHS there has been interest in local *software* for adverse event and near miss reporting and analysis. It is recognised that there are a number of established software systems available from commercial organisations. Some NHS organisations have developed their own. For many NHS organisations, the software they use is a key component of their local reporting system. It often has capabilities that exceed those that would be required for the national system, and works for them. NHS organisations will have the flexibility to choose software that meets their needs. The primary consideration for the national system will be that all organisations, irrespective of local software systems in use, can provide standardised information in accordance with the minimum data set. We are investigating as part of pilot activities throughout 2001 how standardised

information from a range of commonly used software packages could be communicated to the new national body.

Using information provided by patients and carers

18. Patients and carers are a potentially valuable source of information on adverse events and near misses outwith the complaints procedure which will continue as a strong feature of the NHS. As a first step, current work is focusing on devising reporting routes that patients and carers find accessible with a view to piloting detailed and comprehensive information. Distinguishing these routes from the complaints process outlined in Chapter 2 is very important. Work to establish the routes for patient and carer reporting will:

- raise patient and carer awareness about safety, error and the benefits of learning from adverse events and near misses;
- provide information or 'tips' for patients on what to look for so as to specifically engage them in promoting patient safety;
- involve the new Patient Advocacy Liaison Schemes (PALS), introduced under the NHS Plan, as a reporting vehicle that will also offer patients and carers assistance with the reporting process.

Applying standardised root cause analysis methodologies

19. The key to successful learning from adverse events is meaningful analysis at both local and national levels to establish patterns, trends and causal factors. Determining the underlying, or root causes of events and near misses is critical. The philosophy of *root cause analysis*, which aims to provide answers to why something happened, will underpin the gathering of data on all adverse events and near misses. The methodology of root cause analysis will be applied more formally to investigate a defined range of more serious events and near misses.

20. There are many approaches to root cause analysis used in healthcare and in other industries. The Department of Health is participating in an Australian initiative to review a range of approaches from different countries and produce guidance on alternative methodologies that are directly relevant to healthcare. We will pilot the results of this work during 2001 and issue guidance on root cause analysis to complement the guidance on identifying, recording and reporting adverse events.

KEY FEATURES OF A THOROUGH ROOT CAUSE ANALYSIS

- Determination of the human and other factors most directly associated with the event, and the processes and systems related to its occurrence;
- Analysis of the underlying systems and processes through a series of 'why' questions to determine where redesign might reduce risk;
- Identification of risk points and their potential contributions to the event;
- Determination of potential improvements in processes or systems that would tend to decrease the likelihood of such events in the future, or a determination, after analysis, that no such improvement opportunities exist.

Joint Commission on the Accreditation of Healthcare Organisations, USA

Integrating information from other agencies

21. Success of the new system for adverse events and near misses will depend crucially on gathering and integrating valuable information from other reporting systems operated by various agencies such as those listed below. It is not the intention to subsume or replace these systems but to ensure that reporting and standards of reporting are enhanced across the board and that there is a single integrated system to synthesise and learn lessons. For example, it would be dysfunctional if the NHS local systems for recording medication error were not co-ordinated with the Medicines Control Agency yellow card system for recording adverse effects of medicines, so that there is a single integrated way to synthesise and learn lessons.

22. The same information on any particular adverse event will need to be received separately by different bodies. Clear guidance on reporting of various information to the different bodies will feature prominently in local reporting arrangements. The guidance on reporting will include a summary of requirements for those key reporting systems listed below:

- Clinical negligence (NHS Litigation Authority);
- Medical devices (Medical Devices Agency);
- Adverse Drug Reactions (Medicines Control Agency);
- Mental Health Act Incident Notification;
- Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (Health and Safety Executive);

- NHS complaints system;
- Confidential inquiries (National Institute for Clinical Excellence);
- Infection surveillance (Public Health Laboratory Service);
- Serious Hazards of Transfusion (SHOT).

Creating a reporting culture within the NHS and building local capability

23. The key to the success of the new national system will be ensuring the presence of a *reporting culture* in local NHS organisations. Strong and effective clinical and managerial leadership will be essential. This will mean continuing to create an environment in which all NHS staff will be able to report adverse events and near misses. *An Organisation with a Memory* identified fear of retribution as a potential barrier to local reporting by staff of adverse events. The need to develop a blame-free culture to promote non-punitive local reporting of adverse events, errors and near misses is an important step to improving patient safety. This approach is already part of the implementation of the clinical governance initiative but work will need to continue into the medium-term to achieve the cultural change required.

24. NHS staff will be able to report adverse events and near misses in confidence to the national body if they wish to do so. Other incentives for reporting by organisations and individuals are being investigated.

REPORTING OF ADVERSE EVENTS AND NEAR MISSES: SOME BARRIERS THAT NEED TO BE OVERCOME

- lack of awareness of the need to report, what to report, and why;
- lack of understanding of how to report;
- staff feel they are too busy to make a report;
- too much paperwork involved in reporting;
- the patient recovers from the adverse event and the urgency goes out of the situation;
- fear of 'point-scoring' by colleagues, retribution by line management, disciplinary action or litigation;
- an assumption that someone else will make the report;
- no evidence of timely feedback and/or corrective action being taken resulting from making a report.

25. There is a need to provide NHS staff with the skills required to identify, gather information on, record and report events and near misses, undertake formal root cause analysis, and generally analyse reported events and near misses to establish patterns and trends. This will be addressed in a number of ways including:

- embedding consideration of adverse event and near miss reporting and analysis into existing and planned training and development activities of the Modernisation Agency, NHS Clinical Governance Support Team, the NHS Controls Assurance Support Unit, and the NHS Litigation Authority;
- ensuring that sufficient staff in each NHS organisation are skilled in the analysis of adverse events and near misses;
- providing Intranet/Internet and CD-based 'e-learning' tools;
- establishing a dedicated training programme;
- ensuring consideration of patient safety, medical error, adverse event reporting and analysis is reflected by training and education programmes provided by Universities and other institutions educating students in the health care professions.

Learning lessons, disseminating them and implementing effective change strategies

26. Whilst it is essential to gather and analyse information, disseminate lessons and develop models of good practice, experience within and outside the NHS clearly demonstrates that this alone is unlikely to embed lessons in practice or bring about and sustain changes in individual or organisational practice. Implementing and sustaining change will require ongoing education, learning and performance assessment at local and national levels. The continuing development of the clinical governance initiative will be critical to success. So too will be the role of the Modernisation Agency, Learning Networks, collaboratives, the way in which we train and continue to develop NHS staff, and the mainstream performance management structure.

27. The identification of trends and patterns of avoidable adverse events will allow targeted action to avoid risk. In some cases this will be achieved by safety alerts to the NHS followed up through the Regional Office performance management system. In other cases it will involve specific action agreed with a number of local NHS organisations. In some circumstances action will be taken directly with manufacturers of medical equipment or pharmaceutical companies (through the Medicines Control Agency or Medical Devices Agency) to design safer products. Safety is an important element of the duty of quality placed on NHS organisations

in the 1999 Health Act, and this overall duty and accountability in quality (including safety) will be reinforced with local NHS organisations.

THE NEW NATIONAL SYSTEM FOR LEARNING FROM ADVERSE EVENTS AND NEAR MISSES: PRINCIPLES AND COMPONENTS

The new national reporting system is founded on the following principles:

- 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;
- systems learning and change at local level and national levels.

The system comprises five linked key components:

- *identifying and recording* reportable adverse events;
- *reporting* by individuals to local sites and to the national system, and by institutions to the national system;
- *analysing* incidents, including *root cause analysis*, and trends;
- *learning lessons*, from analysis, research and other sources of information, and *disseminating them*;
- *implementing change* at local level and national level.

The new national body

28. A new national body, the *National Patient Safety Agency*, will be established as an independent agency within the NHS. It will have its own purpose and constitution with its functions set out in regulations. The primary purpose of the body will be 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. Its detailed functions will include:

- *setting and maintaining* the standards and requirements for reporting in conjunction with the Department of Health;
- *collecting, collating, categorising and coding* adverse event information from local NHS organisations, other bodies providing care to NHS patients, directly from NHS staff, and from patients and carers;

- *assimilating* other safety-related information from a variety of existing reporting systems and other sources: for example, the NHS Litigation Authority claims database, Confidential Inquiries, Medical Devices Agency, Medicines Control Agency, Public Health Laboratory Service, the Health Service Commissioner, the Commission for Health Improvement, and the NHS complaints procedure;
- *analysing* information on adverse events and maintenance of a publicly available *central repository* of de-identified information for learning;
- examining and tracking *patterns and trends* and acting on their findings where risks are identified;
- providing *feedback* to organisations and individuals, including issue of 'patient safety alerts' to improve safety and quality;
- producing *solutions* to reduce risk and prevent harm to future patients and specifying national *goals and targets*;
- promoting *research* on patient safety;
- promoting a reporting *culture* within the NHS;
- *collaborating* with relevant bodies nationally and internationally.

THE NEW INDEPENDENT BODY

The National Patient Safety Agency will unite the functions, skills and experience needed to implement and operate the reporting 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. It will identify patterns and trends in avoidable adverse events so that the NHS can introduce changes to reduce the risk of recurrence.

Conclusions

29. The new national system for reporting and learning from adverse events and near misses is being designed based on international experience and best practice.

30. It will provide the basis for something that the NHS has never had before – the opportunity to ensure that the adverse experience of a patient in one part of the country is used to reduce the risk of something similar happening to future patients elsewhere.

31. Experience around the world and in other sectors (e.g. aviation) strongly indicates that a successful approach will need: rigour in the design of the new reporting system, clear standardised definitions of adverse events and unambiguous reporting criteria, skill in the systems approach to identifying and analysing underlying causes and the development of positive reporting cultures within NHS organisations.

32. Experience in other sectors also suggests that the reduction of risk to patients and the improvement of safety will be a long-term task which will require sustained effort, commitment and high quality leadership.

33. The preparatory work for the new system is already underway and will be picked up and taken forward by the National Patient Safety Agency when it is established.

4

Specific Risks Targeted for Action

Within certain fields of health care, regular patterns of error can be recognised which, if selectively targeted, can reduce risks to patients. *An Organisation with a Memory* highlighted four such areas and recommended targets for the reduction of risk associated with them. Subsequently, work has started to identify high-risk procedures in other areas. This chapter describes plans which have been formulated to target adverse events in specific fields of health care.

1. In its final recommendation *An Organisation with a Memory* identified four areas for action and set targets for improvement. The timescale for addressing them was agreed after considering the targets recommended in the report and is as follows:

i. to reduce to zero the number of patients dying or being paralysed by maladministered spinal injections by the end of 2001;

ii. to reduce by 25% the number of instances of harm in the field of obstetrics and gynaecology which result in litigation by the end of 2005;

iii. to reduce by 40% the number of serious errors in the use of prescribed drugs by the end of 2005;

iv. to reduce to zero the number of suicides by mental health patients as a result of hanging from non-collapsible bed or shower curtain rails on wards by March 2002.

2. It was always recognised that a new system of reporting and learning from adverse events and near misses would have to be comprehensive in its coverage and not focussed solely on a small number of problems. However, the expert group which produced *An Organisation with a Memory* also considered it important to challenge the health service to really see what it could do to reduce risk and promote safety in a way which was visible and unambiguous.

3. The targeted areas were carefully chosen because they reflected different facets of the problem of medical error:

- the problem of maladministration of drugs through spinal injection is a rare but catastrophic event – the 'aeroplane crash' in health. Cases have been recognised since 1978 – many of the circumstances behind the incidents have been very similar. The problem has occurred in other countries. Efforts made to prevent their recurrence in the past have not succeeded. The challenge is to find a definitive solution that has not been found before;

- the complications arising from some areas of obstetric practice can have devastating consequences for children and families. Analysis of litigation data has suggested that a small number of avoidable factors are involved. The challenge in addressing the second target area is to see whether by modifying these very specific factors the risks (and associated costs of litigation) can be significantly reduced;

- in many countries of the world medication errors account for about a quarter of all patient safety issues. The causation is complex and there is no simple solution. The challenge here is to bring about a sustained reduction in risk where multiple interrelated factors are involved;

- tragically, suicides amongst people who are in hospital with mental illness has occurred all too regularly in the past. Despite the fact that many people kill themselves by hanging from non-collapsible bed or shower curtain rails the NHS has been unable significantly to cut this death rate. The challenge is to create a focus on a simple, single solution so that it is implemented properly everywhere. This has not been achieved previously and as a result lives have continued to be lost.

4. In each of the four target areas an expert in the field has been identified and asked to look quickly at ways of achieving the required reductions in risk.

5. During the course of implementing *An Organisation with a Memory* a number of other specific high-risk areas of clinical practice are also being identified and amongst these further targeted action will be taken.

Spinal Injections

6. Since 1975 there have been at least 14 incidents in Britain of cases of which the drug Vincristine – used in the treatment of some forms of cancer – has been given intrathecally (spinally) when it should have been injected intravenously (into a vein). In almost all cases, the patient (usually a child or teenager) has eventually died.

7. In addition to the reported cases in medical journals other cases may have occurred, but the true size of the problem is not known because no central records are kept. However, as recently as February 2001 another teenager in Nottingham died following the spinal injection of Vincristine as part of treatment of leukaemia. The drug should have been injected intravenously whilst another drug should have been injected intrathecally. This tragedy is the subject of an independent investigation which will report to the Chief Medical Officer. It is being undertaken by an experienced accident investigator to provide a different insight to the usual health perspective. It is believed to be the first time in this country that a non-health accident investigator has examined a health catastrophe.

8. Previous attempts to eradicate this source of risk to patients have used a wide range of measures but none have provided the solution. The catastrophe has continued to occur, albeit rarely. It is also important to remember Heinrich's ratio, quoted *An Organisation with a Memory*. Heinrich showed in 1941 that for every serious accident there were approximately 300 occasions when the accident could have happened but for some reason was averted. This is the concept of a 'near miss'. The potential for there being 300 intrathecal treatments which resulted in some degree of error but did not actually result in the wrong drug being injected adds impetus to finding the definitive solution.

MALADMINISTRATION OF INTRATHECAL DRUGS: STEPS TAKEN PREVIOUSLY TO ATTEMPT TO ERADICATE RISK

- Emphasis on education and training of clinical staff to warn of the dangers of intrathecal administration of Vincristine.
- A requirement for a registrar or consultant and one other practitioner (doctor or nurse) to check and administer intrathecal chemotherapy.
- Policies established in some hospitals that cancer patients requiring intravenous and intrathecal injections should not receive the two sorts of injection on the same day.
- Special prescription forms for intrathecal therapy. Or pre-printed prescription forms for the entire chemotherapy course which includes intrathecal chemotherapy.
- In paediatrics where intrathecal injections are administered under general anaesthetic, there are separate lists for intrathecal therapy. Intravenous therapy is not allowed in the room where the intrathecal therapy is being used.
- Hospital pharmacies label Vincristine syringes with "For Intravenous Use Only". There is a consensus among hospital pharmacy practitioners that there are additional dangers in using the warning "Not for Intrathecal Use". The inclusion of intrathecal on the syringe could prompt the administration by the route being warned against.
- Pharmaceutical company labelling of Vincristine packaging and vial with the words "not for intrathecal use".

9. Professor Kent Woods, Director of Health Technology Assessment Programme, has been asked to find a definitive solution to this longstanding and tragic problem. Whilst no options have been ruled out, at this stage, most attention is being given to finding a design solution which would make it impossible for drugs which should not be administered intrathecally to be given in this way, even if a doctor mistakenly tried to do so.

10. Further action will be taken and the Chief Medical Officer and the Chief Pharmaceutical Officer will issue guidance to the NHS once Professor Woods' recommendations have been received.

Obstetrics, Gynaecology and Midwifery Care

11. Adverse events affecting the newborn are always tragic and can lead to a lifetime of care and support. Reducing the number of adverse events will improve the quality of life of many children and their families. It will also free up significant amounts of resource within the NHS for direct patient care. Every year approximately 50% of the NHS litigation bill relates to claims arising from brain damaged babies. It has been estimated that when the target set within *An Organisation with a Memory* is met (a 25% reduction in the number of instances of negligent harm, resulting in litigation by 2005) that this could save as much as £50 million a year, as well as reducing great distress and suffering for children and families.

12. Evidence from the 1990s suggests that substantial reductions in risk could be achieved by focusing on improving staff supervision, proper use of equipment to monitor labour, the introduction of better techniques and application of higher levels of diagnostic skill at delivery. The Report on Confidential Inquiries into Maternal Deaths in the United Kingdom (1994-1996) highlighted areas of substandard care that had contributed to deaths. These are failures in diagnosis and referral (these include ectopic pregnancy, pre-eclampsia and pulmonary embolism), failures of consultants to attend in emergencies or to delegate appropriately, inappropriate treatment, lack of protocols and lack of teamwork.

13. Initiatives by service providers and professionals to introduce measures designed to reduce risk in the field of obstetric care have been disjointed, patchy and have never led to real service-wide change being adopted. Initiatives such as those of the NHS Clinical Governance Support Team and other multi-professional initiatives as well as research and other evidence bases must be drawn into and inform work nationally. Mr Nick Naftalin, Consultant Obstetrician and Medical Director at Leicester Royal Infirmary has been asked to take this work forward and make recommendations. He will build on existing evidence, identify where further work is required and provide a coherent and comprehensive programme designed to reduce risk and hit the stated target of a 25% reduction in the occurrence of avoidable harm in this field by 2005.

NHS CLINICAL GOVERNANCE SUPPORT TEAM INITIATIVE ON SAFETY IN MATERNITY CARE

The NHS Clinical Governance Support Team, working in partnership with the Royal College of Obstetrics and Gynaecology, Royal College of Midwifery and the NHS Litigation Authority, is developing a targeted, multi-disciplinary, task orientated programme involving 12 maternity units. They will produce a working model for safe and high quality care. This work will start in May 2001.

These pilots are designed to deliver local risk management systems that will reduce the instances of avoidable harm. Subsequently, regional maternity service networks will spread a wider understanding and implementation of the identified risk management model, which will significantly contribute to meeting the target in *An Organisation with a Memory*.

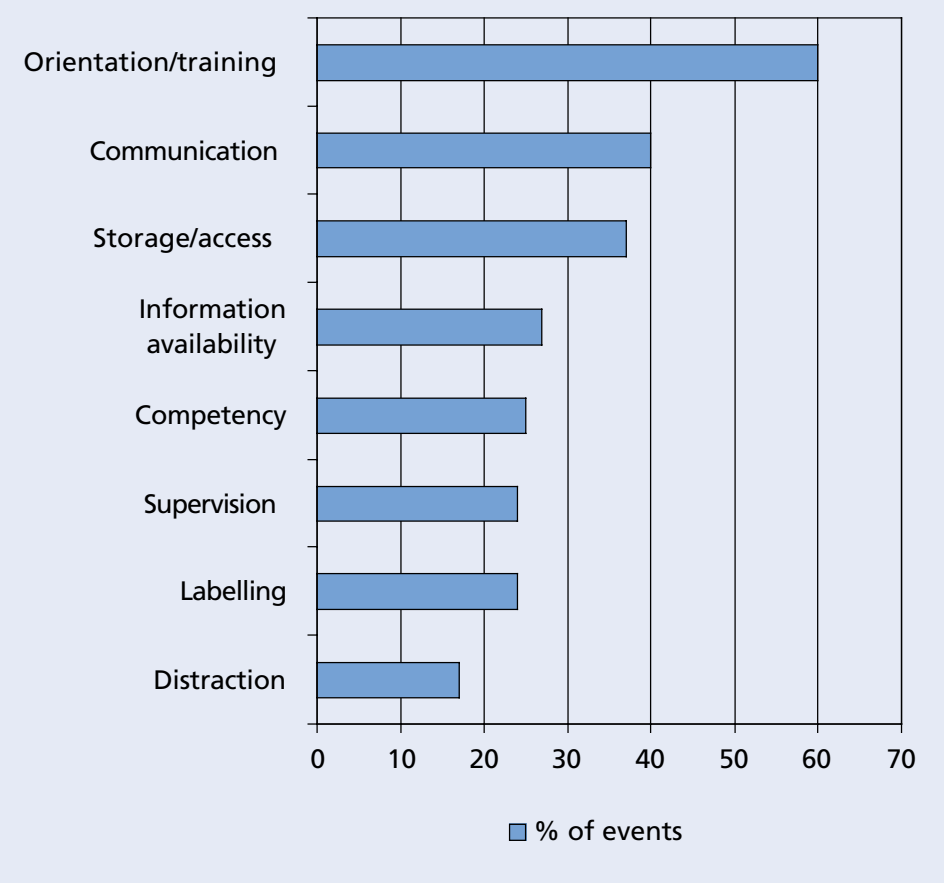
Medication errors

14. Various forms of medication error comprise a large category of events posing a threat to patient safety. This is the case not just in the NHS but in health care systems in other countries.

15. About 1.5 million prescriptions are written by general practitioners in England every day and a further 0.5 million in hospitals daily. The standard of prescribing of drugs is generally high but it is inevitable that errors will occur. When this happens, patients can be harmed, sometimes seriously.

16. When errors occur they rarely happen because of one failure only (see Figure 4.1). It would be a mistake to assume that all medication error was prescribing error. Review of prescriptions by a pharmacist in hospital or the community can detect and prevent many prescribing errors but prescribing is only one aspect of the process of medication use. There is usually multiple breakdown in the system, with some of the other parts of the overall process – such as review, ordering, dispensing, administration and monitoring – also affected.

Figure 4.1 Root Causes of Medication Errors



Source: (c) Joint Commission: Preventing Adverse Events in Behavioural Health Care: A Systems Approach to Sentinel Events. Oakbrook Terrace, IL: Joint Commission on Accreditation of Healthcare Organizations. Used with permission.

17. Some of the most serious incidents occur as a result of the mistaken administration of the wrong drugs. One of the causes of these errors is that very different medications are presented to clinicians in almost identical packaging – see Figure 4.2. These errors are avoidable and medicines should be packaged in such a way that this confusion is removed. Work has started on identifying these cases and steps will be taken, in conjunction with the industry, to reduce risks from this source of medication error.

Figure 4.2

A: Packaging of lignocaine. *Source:* BMJ Vol 322; p.549. Used with permission

B: Packaging of sodium chloride, water and lignocaine. *Source:* BMJ, Vol 322; p 308. Used with permission.

18. There is already much good practice in prescribing, dispensing and administering medicines in the NHS. Areas where action is already under way or is planned include:

- many hospitals have already made considerable progress to meet the NHS Executive Controls Assurance Standard "Safe and secure handling of medicines";
- hospitals providing chemotherapy treatment have to meet the standards required by the NHS Cancer Centre Accreditation process;
- NHS Hospital Trusts are currently undertaking a self assessment exercise for the performance management of medicines management in NHS Hospitals;
- pharmacists in many hospitals are undertaking work to improve the quality and completeness of medication history-taking when patients are admitted to hospital;
- systematic monitoring of drug charts for all hospital inpatients is taking place, undertaken by a pharmacist or, increasingly, by suitably trained pharmacy technicians;
- the Guild of Healthcare Pharmacists has recently published a valuable position statement on strong potassium chloride injections, one of a number of hazardous drugs where serious harm has resulted from error;
- there is active consideration by the Department of Health's Medicines Control Agency of how labelling of medicines can be improved within the regulatory framework;
- introduction of repeat dispensing schemes in community pharmacy, and of medicines management programmes in primary care groups and trusts, as set out in the Government's *Programme for Pharmacy in the NHS*;
- principles for safe practice in the management and the administration of medicines by nurses, midwives and health visitors is provided by the UKCC (2000), which is now providing guidance to support registrants in protecting the public.

SureMED – King's College Hospital NHS Trust

SureMED is a reporting scheme for actual and potential medical errors. It is an anonymous system that focuses on change and not on identifying people to blame. It has been running for seven years and is about to be extended to include community pharmacists. Action is taken on the reports to change systems, ensuring that risk of a similar event happening again is reduced.

19. Increased awareness of these issues and the attention focussed on them by *An Organisation with a Memory* combined with the improvements in error and event monitoring is resulting in some nominal increases in error rates, in the short term. The Chief Pharmacist in the Department of Health is drawing up a plan to hit the medication error target. He will consult widely and draw on national and international expertise and best practice.

SOME USEFUL WEBSITES ON MEDICATION ERROR

The Institute for Safe Medication Practices: http://www.ismp.org

ECRI: http://www.ecri.org

Patient Safety Centre, American Society of Health-System Pharmacists: http://www.ashp.org/patient_safety/index.html

European Foundation for the Advancement of Healthcare Practitioners: http://www.efahp.org

Suicides by Mental Health Patients

20. For a number of years it has been recognised that a major means of suicide in acute psychiatric units has been hanging from curtain or shower rails. The report of the National Confidential Inquiry into Suicide and Homicide by People with Mental Illness concluded that hanging from non-collapsible structures such as bed, shower and curtain rails, is still the commonest method among mental health in-patients. This is despite the fact that collapsible rails are now readily available.

21. A total of 81 mental health inpatients committed suicide on the ward by hanging in the two years to April 1998 – two thirds of all suicides, which took place on the ward. These are avoidable deaths.

22. Each Regional Office of the Department of Health has been asked by the National Director for Mental Health, Professor Louis Appleby, to put in place programmes to ensure that immediate action is taken to remove all non-collapsible structures

such as bed, shower and curtain rails in acute psychiatric wards. An implementation date of 31 March 2002 has been set.

Other risk areas and further initiatives

23. In addition to the four targets described above, other high-risk areas of clinical practice are being identified so that further early targeted action can be considered where appropriate.

24. Other 'cross-cutting' initiatives are being identified where introducing a focus on safety could lead to risk reduction. So far these include:

- *reviewing the safety environment* – identifying changes in care practices that could reduce risk and improve patient safety;
- *reviewing clinical practice* – in conjunction with Royal Colleges, professional organisations and specialist associations to identify high risk procedures;
- *purchasing for safety* – addressing safety as part of buying policy throughout the NHS;
- *design for safety* – seeking input from the world of design to identify previously unrecognised opportunities for improved safety;
- *computers to reduce error* – examining across a broad field the potential for computers to reduce the occurrence and impact of error;
- *safety briefings* – identifying the scope for formal 'pre-procedure' safety briefings in a selected number of high risk clinical situations;
- *risk simulation* – enhancing the capacity for staff to be exposed to and handle risk in simulation laboratories;
- *patients' role in safety* – examining comprehensively the potential for patients themselves to help to promote and achieve safety goals.

Conclusions

25. Within the overall programme of learning from adverse events, a number of specific areas and high-risk procedures provide the basis for early action to reduce risk. These are being targeted alongside the work to develop the reporting system.

5

Key Questions in the Developing Patient Safety Research Agenda

Research is needed to: understand the human and system factors which cause unintended harm to patients; develop patient-focused solutions that are embedded in practice across the NHS; and underpin and promote a patient safety culture. *An Organisation with a Memory* highlighted the need for patient safety research. This chapter sets out the research strategy and how it will be implemented.

1. The need for research to improve patient safety by reducing the impact of medical error and adverse events is internationally recognised. For example, in the USA the report of the Institute of Medicine *To Err is Human*, and in Australia the report *Iatrogenic Injury* call for increased research and national research agendas. Patient safety research funding of £50 million over three years and £20 million over five years has recently been announced in the USA and Australia respectively.

2. In the UK, *An Organisation with a Memory* highlighted the need for patient safety research. A patient safety research agenda has now been identified and is set out in the remainder of this chapter.

"From past work in Human Factors a single standard emerges for judging success in research on error and safety. Research is successful to the degree that it helps recognise, anticipate and defend against paths to failure that arise as organisations and technology change, before any patient is injured."

David Woods, Past President Human Factors and Ergonomic Society

Research context

3. Whilst the area of medical error, adverse events and patient safety research is a young field, there is a rich tradition of research in other fields – such as aviation, engineering and disaster prevention – that can help inform patient safety research questions and research themes.

4. There are two key themes of research in the non-health fields:

- research to understand the causes of failure;
- research to understand the factors that influence learning from failure.

5. Extensive study in the non-health field has shown that with most unintended failures there is usually no single explanatory cause for the event. Rather there is a complex interaction between a varied set of elements, including human behaviour, technological aspects of the system, socio-cultural factors and a range of organisational and procedural weaknesses. Systematic study of these issues in the health care field is sparse, but available evidence suggests a similarly complex pattern of cause and effect relationship.

6. Learning from adverse events is also a complex phenomenon. Yet research suggests that it is possible to identify some of the barriers to prevent organisations from learning from adverse events, and to put in place measures to help overcome them. Particular industries – for example aviation and nuclear power generation – have been conspicuous in implementing improvements based on systematic learning from accidents and incidents. Others have studied the conduct of inquiries into disasters and identified the factors that appear to determine whether their findings will be implemented.

Key questions in the developing patient safety research agenda

7. Current world literature on patient safety research suggests that it has been funded and carried out in a piecemeal way. Published areas of research concerned with patient safety represent a broad spectrum of subjects including work to:

- *identify the nature and magnitude of system failure and medical error:* that hospitals are a dangerous place to be has been demonstrated through the groundbreaking work of Schimmel in the 1960s to the seminal independent work of Brennan, Leape, and Wilson in the 1990s, and most recently by Vincent in the United Kingdom;

- *understand the causes of system failure, medical error and adverse events:* many investigators are now drawing on the disciplines of epidemiology, industrial quality management, accident and human error assessment, organisational sociology, medicolegal and regulatory theory. The airline industry is seen as a good model outside health care, and anaesthesia within;

- *reduce harm in perceived problem areas:* informing health care delivery systems so that the risk of a problem recurring is reduced e.g. in Australia, research on adverse events in hospital emergency rooms showed a 50% reduction, maintained over five years, through the implementation of a number of systems involved in the delivery of care which involve:

  – better understanding of how problems progress or manifest themselves;

  – better detection of problems;

  – better crisis management once they have occurred.

8. Work in this country and abroad suggests that some of the research questions which need to be answered are quite fundamental. They span a continuum: from establishing the size and nature of the problem, to understanding the root causes of system and individual failure, through early detection of evolving problems and developing interventions to mitigate failure, to assessing the effect of implementation of error reduction approaches, to developing mechanisms that ensure sustained change in the behaviour and practice of individuals and organisations. A research agenda to improve patient safety needs to develop themes that help focus effort at key points along this continuum.

EXAMPLES OF RESEARCH QUESTIONS

- What are the main types of error and adverse event in different health care settings?
- What methodologies would ensure effective patient and consumer involvement to enhance patient safety?
- What strategies would ensure early detection of new risks before they result in a rare but catastrophic event?
- How can organisational cultures be achieved that are safety conscious, 'reporting-friendly' and free of blame?
- What methods can reduce error in particular specialist fields of healthcare (e.g. drug therapy)?
- How can equipment acquisition and management policies reduce risk?
- What automated methods of data capture could be developed to reduce reliance on human reporting?
- How can data collation, classification and analysis be enhanced to allow patterns of causation, presentation, detection and amelioration to be elucidated?
- What are the characteristics of good leadership of clinical teams, that have a good performance on patient safety?
- Why does change to improve patient safety so often fail to be implemented despite widespread dissemination of strategies which have been shown to work?

A research strategy

9. Key themes in the developing strategy of research to be commissioned by the Department of Health, in conjunction with other key funders, are set out below. They are intended to point the direction of work needed to provide evidence to support the patient safety programme as it develops.

Establishing the size and nature of the problem

10. Research in this country and abroad on the scale of medical error, adverse events and near misses in health care has tended to focus on secondary care. Some of these studies have been carried out using standardised definitions and have

provided valuable preliminary data on the problem of unintended harm to patients. However, in this country, basic epidemiological research is now needed to establish the size, pattern and nature of medical error, adverse events and near misses in different kinds of health care settings. Information is needed about the size and nature of the problem at boundaries between health care settings, for example between primary and secondary care specialities, disciplines and organisations. Methodologies will have to transcend such boundaries.

Understanding the factors which cause harm and assessing the efficacy of intervention strategies

11. Research is needed to identify and understand the human and system factors, which cause unintended harm to patients. Such work needs to be informed by the sort of basic epidemiological research outlined above. Research is needed to develop risk- and cost-effective interventions, and develop and test the efficacy of those interventions, for both the common problems, and the rare, dangerous but potentially preventable problems which make up the bulk of unintended harm. Such work might be used to identify recurring error where national action is needed and to inform methodologies needed to systematically set realistic national goals and targets.

Developing and designing reporting systems to help ensure their good use

12. Reporting systems need to be developed and designed in a way that encourages reporting and ensures their full and effective use. To do this, research is needed to identify and understand the factors unique to health care which act as barriers to reporting. Work will be needed to find ways to remove them by a variety of strategies. Research will need to evaluate, for example, techniques to enhance reporting, reporting system design and development (especially by sectors of the healthcare workforce that have traditionally not been involved in systematic reporting), the development of reporting cultures within NHS organisations, and the approach to be taken in primary and ambulatory care settings.

Learning lessons and disseminating them

13. There is considerable need for research to underpin how best to learn lessons. Work is needed to help develop methodologies to interrogate information collected at the national level in ways which link to other key sources of data. This might be achieved by developing and improving information technology that can deal with large amounts of data, that use powerful search engines to search world literature and to link relevant data bases, and feed into decision aids for clinicians which can be tailored to conditions at particular institutions as well as to the needs of individual patients. How experts are best utilised to help learn lessons is yet another part of this research area.

14. How best to disseminate lessons, tools and techniques in ways which embed them in practice is also a key research area. Research has shown that passive information swapping does not work. Work is needed to identify other mechanisms for achieving effective learning which results in sustained reduction in risk and improved patient safety.

Changing individual and organisational behaviour

15. This key area of research is critical for success. In the first instance, it will need some scoping or development work to learn about strategies already used in health care in this country and abroad, as well as in other sectors. This will help identify the strands of work needed to change individual and organisational behaviour. For example, a key question might be how best to involve leadership and clinical governance.

Involving patients

16. Moving towards a patient-centred NHS means that patients need to be involved in enhancing patient safety, as they are in fact our greatest untapped resource. Research needs to establish methodologies to release that knowledge e.g. through retrospective analysis of complaints and litigation records; by using network study populations and the clinicians involved to help define common and clinically important problems, and their solutions. Methodologies need to be developed and evaluated to ensure effective patient involvement in future.

17. When something does go wrong, we need to understand what information should be given to the patients who are harmed or their family members, tailored to their particular problems, treatments and interventions, and to develop and test the best ways of imparting this information. This may involve checklists, courses and advanced guidelines for those involved.

Supporting patient safety research – working together to ensure a coherent national research effort

18. The Department of Health is committed to helping drive forward the development of a coherent national patient safety research agenda:

- *directly*, by funding a programme of patient safety research through its Research and Development Directorate. The Department of Health has already funded research in the patient safety field. However, to signal the Department's recognition of the importance and need for patient safety research, it is committed to funding a programme of work. A call for proposals will shortly be issued;

- *indirectly*, by working with other key funders of medical and health services research, together with users of the research, the research community, and representatives of patient interests.

19. Patient safety research needs to be supported in the short, medium and long term through:

- existing generic research programmes, training research staff etc. for example through the Department of Health's Research and Development Directorate;

and by

- targeting funding to:
  - build research infrastructure e.g. by helping to establish centres of excellence, and/or networks of centres and research units;
  - build capability e.g. by promoting research that is multi-disciplinary, by investing in postgraduate training and/or research programmes;
  - establish themed programmes of related projects.

20. Representatives of funding bodies need to decide who does what to support patient safety research. This might best be achieved through:

- existing forums for research in health care quality;
- existing research mechanisms;
- the creation of a new forum for funders.

21. The existing forums and mechanisms provide routes to take this forward. However, a new forum for funders provides an opportunity to bring together:

- funders of patient safety research including the Department of Health, Research Councils and relevant Research Charities;
- users of patient safety research including the Department of Health (which uses research to inform policy development), professional bodies (e.g. the Royal Colleges who might use research to inform their training and quality assurance programmes), and NHS clinicians, managers (who use research to inform practice and underpin clinical governance);
- key stakeholders representing the patient safety research community;
- key stakeholders representing patient interests.

22. A workshop is shortly to be held to bring together all these stakeholders to add extra dimensions and impetus to the national strategy for patient safety research.

Role of the new National Patient Safety Agency

23. The Department envisages that, once established, the independent body charged with running the new adverse event reporting system will wish to identify research needs and requirements.

24. It is envisaged that the National Patient Safety Agency will take the lead in strengthening the relationship between funders, users and providers of research and patient interests by providing focus on the common goal of promoting patient safety.

6 Implementation Timetable

Realising the vision set out in *An Organisation with a Memory* and taken forward in the NHS Plan will require the combined efforts of the Department of Health, the NHS, major professional bodies, patients and their representatives and the research community.

Much of the groundwork is done. Now the task of implemention begins. By December 2001, 60% of NHS Trusts will be in a position to provide information to the national adverse event reporting system. These Trusts will join the national system by the end of the year. All other NHS Trusts will be working towards this goal. By the end of 2002, we expect 100% of NHS Trusts and a significant proportion of primary care to be providing information to the national system. We anticipate that current levels of NHS Trust reporting will double in this time period.

This chapter sets out the implementation plan to introduce an operational system by the end of 2001. The key targets and milestones described here provide a timetable for action to: establish the new national reporting system, including the independent body, for learning from adverse events and near misses; introduce an improved system for the handling of investigations and inquiries across the NHS; identify and implement solutions to address specific categories of serious recurring adverse events; agree and begin a programme of patient safety research. The challenge of reducing risk, limiting the impact of medical error and promoting patient safety is a long-term task which will require sustained commitment beyond even the milestones identified in this report.

Implementation deadlines	Date
Headline Targets	
60% of NHS Trusts in a position to provide information to the national system; all NHS Trusts will be working towards this goal	December 2001
All NHS Trusts and significant proportion of primary care providing information to the national system	December 2002
Levels of reporting in NHS doubled	December 2002
Supporting Targets	
Establish the National Patient Safety Agency	July 2001
Develop and issue guidance:	
• on identifying and recording adverse events and near misses, including a glossary of standardised terms and associated definitions	August 2001
• to all organisations providing care to NHS patients on the reporting of adverse events and near misses, including potential for use of IT	August 2001
• on reporting by staff to the new national body	August 2001
• to patients and carers on adverse events and how to report them	November 2001
• on root cause analysis for individual events and analysis of patterns and trends across clusters of events and near misses	November 2001
• on procedure and criteria for establishing independent investigations and inquiries in the NHS	July 2001
Test the reporting system through selective pilots and other evaluations	from August 2001
Work closely with other national reporting agencies	from April 2001
Produce a strategy on building local capability	October 2001
Develop a strategy for learning lessons, disseminating them and implementing effective change strategies	December 2001
Implement the system progressively	from December 2001

Implementation deadlines	Date
Work with key partners to establish methods for implementing solutions from investigations and inquiries across the NHS	from March 2001
Deliver the four specific targets identified in *An Organisation with a Memory*:	
• maladministered spinal injections	end 2001
• harm in obstetrics, gynaecology and midwifery care	end 2005
• serious error in the use of medicines	end 2005
• suicides by mental health patients as a result of hanging from non-collapsible bed or shower curtain rails	March 2002
Progress work to take early action to reduce risk in specific areas and by influencing specific processes	April 2001 onwards
Liaise with key stakeholders to progress patient safety research agenda	April 2001
Fund a programme of patient safety research – issue a call for proposals	May 2001
Link with education and training bodies to increase content of curricula and training programmes in relation to understanding error, systems thinking and patient safety.	September 2001

This document can be found on the internet at www.doh.gov.uk/buildsafenhs

The NHS Plan itself can be found on the internet at www.nhs.uk/nhsplan

Further copies of this document and copies of a Summary of the NHS Plan are available free of charge from:

Department of Health
PO Box 777.
London SE1 6XH
Fax: 01623 724524
E-mail: doh@prolog.uk.com

Produced by Department of Health

23720 1P 2K Apr 01 (TSO)