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Health Committee

Patient Safety

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Report, together with formal minutes

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The Health Committee

The Health Committee is appointed by the House of Commons to examine the expenditure, administration, and policy of the Department of Health and its associated bodies.

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Footnotes

In the footnotes of this Report, references to oral evidence are indicated by 'Q' followed by the question number, and these can be found in HC 151-II, Session 2008-09. Written evidence is cited by reference in the form 'Ev' followed by the page number; Ev x for evidence published in HC 1137, Session 2007-08, on 30 October 2008, and PS x for evidence to be published in HC 151-II, Session 2008-09.

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Summary

Every 36 hours, NHS services are used by around a million people; the vast majority receive care which is safe and effective. However, as in every other healthcare system, not all care is as safe as it could be and some patients are harmed, sometimes seriously, even fatally. Reviews of patients' case notes indicates that in the NHS and in other healthcare systems as many as 10% of patients admitted to hospital suffer some form of harm, much of which is avoidable. Tens of thousands of patients suffer unnecessary harm each year and there is a huge cost to the NHS in consequence.

Nearly a decade ago, the Government became one of the first in the world to make it a priority to address patient safety across a whole healthcare system. This put the NHS in England in the vanguard of the emerging international movement to make healthcare safer. Patient safety policy has focused on the creation of a unified national mechanism for reporting and analysing incidents, underpinned by a new culture of openness in the NHS. As a result, staff would feel able to report and discuss incidents without fearing unfair blame. Systems for reporting, and learning from, incidents, were established, centred on the National Reporting and Learning System (NRLS) and the National Patient Safety Agency (NPSA).

Although reporting is useful for learning from incidents, it is not a reliable way of measuring the extent of harm. Judging the overall effectiveness of patient safety policy is made difficult because of the failure by the Department of Health (DH) to collect adequate data. Nevertheless, it is apparent that, for all the policy innovations of the past decade, there has been insufficient progress in making services safer. Underlying Lord Darzi's emphasis in the *Next Stage Review* on safety, there appears to be a tacit admission that not all services are safe enough yet. The perception that this is so is strengthened by the recent cases of disastrously unsafe care that have come to light in a small number of Trusts, such as Mid-Staffordshire NHS Foundation Trust.

Patient safety is a multifaceted issue that touches on many aspects of the NHS and we have examined in some detail what we regard as the most important of these. We have concluded that there are significant deficiencies in current policy. We recommend several changes that need to be made in order for there to be further progress in tackling unsafe care.

Measurement and evaluation

In order to monitor whether or not services are being made safer, data on the incidence of harm must be systematically collected. The best available means of doing this is by reviewing samples of patients' case notes at periodic intervals, in order to calculate a rate of harm. This should be undertaken by all hospitals and data produced in this way should be gathered together by the NPSA.

Harmed patients and their families or carers

Harmed patients and their families or carers are entitled to receive information, an explanation, an apology and an undertaking that the harm will not be repeated. Too often,

however, this does not occur.

Recent changes to the complaints system are unlikely to improve how the NHS treats complainants. Patient Advice and Liaison Services should be provided independently of the NHS organisations to which they relate; and the Independent Review stage of the complaints process should be reinstated.

Harmed patients are currently forced to endure often lengthy and distressing litigation to obtain justice and compensation. At the same time, NHS organisations are obliged to spend considerable sums on legal costs and are encouraged to be defensive when harm occurs. Three years ago, Parliament passed the legislation which enabled the DH to introduce an NHS Redress Scheme, which would change this situation, removing the need for litigation in many cases. However, the DH still has not implemented the Redress Scheme and has no timetable for doing so, which we find appalling.

An open, reporting and learning NHS

The NRLS is now collecting significant amounts of data, which are being used to help make services safer, but there remains significant under-reporting, particularly in respect of incidents in primary care; medication incidents; serious incidents; and reporting by doctors.

A major reason for under-reporting is the persistent failure to eliminate the “blame culture”. Another important factor is fear of litigation or prosecution, underlining the need for the Government to address the medico-legal aspects of patient safety; we particularly recommend the decriminalisation of dispensing errors on the part of pharmacists. The “one size fits all” nature of reporting systems is also a significant cause of under-reporting, for example by GPs.

As much as possible of the data collected by the NRLS should be published. We welcome the decision to start publishing reporting data broken down by individual NHS organisation.

However, there has been too much emphasis on gathering summary data on common types of incident and on less serious incidents. The NRLS should gather more in-depth information on serious and sentinel events (those needing immediate investigation and response, since they involve death or other serious injury, or the risk of those), particularly less common types. There must be much wider, and better, use of root-cause analysis, which is an investigative method that seeks to identify the underlying causes of an incident, with a view to preventing its repetition.

While the Patient Safety Observatory is already collating data from a variety of sources other than reporting data, this must now become a key priority for the NPSA.

Patient safety at the front line

Known patient-safety solutions too often fail to be adopted at the front line in the NHS. Solutions are handed down from on high as diktats (if they are passed on at all) without clinicians being convinced of their effectiveness. Moreover, a culture persists in which various types of easily avoidable harm are seen as inevitable risks of treatment. However,

improvements in safety can be fully integrated into frontline services by engaging and involving clinicians, and other healthcare workers. This has been shown in schemes such as the Safer Patients Initiative and the Productive Ward programme which have been successfully adopted in a number of hospitals.

The NHS lags unacceptably behind other safety-critical industries, such as aviation, in recognising the importance of effective teamworking and other non-technical skills.

Inadequate staffing levels have been major factors in undermining patient safety in a number of notorious cases. This is unacceptable, particularly given the recent huge increases in funding and staffing levels overall.

Technology and patient safety

Several technologies could make significant improvements to care but are being implemented far too slowly. Examples include:

- Automated decision support systems, including electronic prescribing-support systems;
- Automatic Identification and Data Capture technology, such as barcoding; and
- the Electronic Patient Record.

We are alarmed at the lengthy delay in developing spinal needles that cannot be connected to a Luer syringe, which is a simple technical solution to a known, and potentially lethal, problem. It is unacceptable that the NHS does not have a mechanism to ensure that changes such as this, which impact seriously on patient safety, occur in a timely fashion.

Education and training curricula

There are serious deficiencies in the undergraduate medical curriculum, *Tomorrow's Doctors*, which are detrimental to patient safety, in respect of training in:

- clinical pharmacology and therapeutics;
- diagnostic skills;
- non-technical skills; and
- root-cause analysis.

These must be addressed in the next edition of *Tomorrow's Doctors*.

Patient safety must be fully and explicitly integrated into the education and training curricula of all healthcare workers. In addition, there must be more interdisciplinary training: those who work together should train together.

Commissioning, performance management and regulation

A key role for Primary Care Trusts (PCTs) in commissioning services is to ensure the quality and safety of those services. We have grave doubts as to whether all PCTs are actually doing so. We welcome the principle of linking payment by PCTs to the quality of

care, but recommend that it be piloted first. We support the use of “*Never Events*” by PCTs, but have doubts about whether they should involve a financial penalty; we recommend this be piloted too.

The performance-management role of Strategic Health Authorities (SHAs) appears to be ill-defined and to vary between SHAs. We recommend that the DH produce a formal definition of this role.

Regulation has been costly and burdensome. It has been too rule-based, looking at processes and procedures rather than actual outcomes and consequences and professional competence. Consequently, the Annual Health Check has failed to pick up major failings in some cases. The Care Quality Commission’s registration system must focus on the outcomes being achieved by NHS organisations rather than formal governance processes.

The relationship between bodies responsible for commissioning from, performance-managing and regulating NHS service providers is not defined clearly enough. In particular, there is a lack of clarity about the role of Monitor. The DH should produce a succinct statement regarding how commissioning, performance management and regulation are defined, and how they (and the organisations responsible for them) relate to each other.

The role of managers and Boards

There is disturbing evidence of catastrophic failure on the part of some senior managers and Boards in cases such as Mid-Staffordshire NHS Foundation Trust. While other Boards are not failing as comprehensively, there is substantial room for improvement. Boards too often believe that they are discharging their responsibilities in respect of patient safety by addressing governance and regulatory processes, when they should actually be promoting tangible improvements in services. There is a case for providing specialist training in patient safety issues, particularly to non-executive directors, to help them scrutinise and hold to account their executive colleagues. Patient safety must be the top priority of Boards and, to show this, it should without exception be the first item on every agenda of every Board.

We commend to NHS organisations the measures piloted as part of the Safer Patients Initiative, namely:

- implementing tried and tested changes in clinical practice to ensure safe care;
- banishing the blame culture;
- providing the leadership to harness the enthusiasm of staff to improve safety;
- changing the way they identify risks and measure performance, by using information about actual harm done to patients, such as data from sample case note reviews.

We strongly endorse the DH’s view that no Board in the NHS should always be meeting behind closed doors and we urge the Government to legislate as necessary to ensure that Foundation Trust Boards meet regularly in public.

The NHS remains largely unsupportive of whistleblowing, with many staff fearful about the consequences of going outside official channels to bring unsafe care to light. We recommend that the DH bring forward proposals on how to improve this situation.

The role of the DH and Government

The Government is to be praised for being the first in the world to adopt a policy which makes patient safety a priority. However, Government policy has too often given the impression that there are priorities, notably hitting targets (particularly for waiting lists, and Accident and Emergency waiting), achieving financial balance and attaining Foundation Trust status, which are more important than patient safety. This has undoubtedly, in a number of well documented cases, been a contributory factor in making services unsafe.

All Government policy in respect of the NHS must be predicated on the principle that the first priority, always and without exception, is to ensure that patients do not suffer avoidable harm. The key tasks of the Government are to ensure that the NHS:

- develops a culture of openness and “fair blame”;
- strengthens, clarifies and promulgates its whistleblowing policy;
- provides leadership which listens to and acts upon staff suggestions for service changes to improve efficiency and quality and, by the provision of examples and incentives, encourages and enables staff to implement practical and proven improvements in patient safety.

In addition, the Government should examine the contribution of deficiencies in regulation to failures in patient safety.

1 Introduction

As to diseases, make a habit of two things—to help, or at least to do no harm—Hippocrates, *Epidemics* (Book I, Chapter XI), c. 400 BC

[F]or all but the last hundred years, the therapies [medicine] relied on must have done [...] more harm than good. For some two thousand years [...] the main therapy used by doctors was bloodletting [...] which weakened and even killed patients—Professor David Wootton¹

Medicine used to be simple, ineffective and relatively safe. It is now complex, effective and potentially dangerous—Professor Sir Cyril Chantler²

1. Not harming patients has been a key principle of professional medical practice for at least 2,500 years. Even so, a great deal of harm has been done to patients over the centuries. Many a treatment has killed rather than cured.
2. The modern NHS does a great deal of good; in England, for example, it has contact every 36 hours with around a million people³ without significantly harming the vast majority. Nevertheless, patient safety⁴ has remained a concern not just in the NHS but in all healthcare systems.
3. Over the past two decades, notorious cases of harm have come to light in many areas of healthcare, including primary care, acute hospital services, mental health and services for people with learning disabilities. Some of these cases have involved a healthcare worker deliberately causing harm, which is extremely rare—the worst cases being the serial killers Harold Shipman, a GP; and Beverley Allitt, a nurse. Others have involved healthcare workers who were chronically and catastrophically inept, such as the gynaecologists Rodney Ledward and Richard Neale.
4. Other cases have involved failings by individual healthcare workers, but in the context of major systemic failure on the part of the NHS organisation concerned. Examples include heart surgery carried out on very young babies at Bristol Royal Infirmary in the 1980s and 1990s, and the much more recent case of Mid-Staffordshire NHS Foundation Trust. Both of these came to light through public outcry and scrutiny of mortality data, which revealed unacceptably poor clinical outcomes.
5. In the 1990s it was increasingly realised that most harm was not done deliberately, negligently or through serious incompetence but through normally competent clinicians working in inadequate systems. This is the key theme of landmark documents, *To Err is Human* (USA, 2000) and *An organisation with a memory*, the report of the Chief Medical Officer's Expert Group (2000). Whilst there can never be such a thing as entirely harm-free

1 David Wootton, *Bad Medicine: Doctors Doing Harm Since Hippocrates* (Oxford, 2006), p 2

2 Cyril Chantler, "The role and education of doctors in the delivery of health care", *Lancet*, vol 353 (1999), p 1181

3 Q 707

4 "Patient safety" can be defined as freedom, as far as possible, from harm, or risk of harm, caused by medical management (as opposed to harm caused by the natural course of the patient's original illness or condition).

or risk-free medicine, it is now widely agreed that much, and perhaps most, of the harm caused by medical practice is actually avoidable.

6. Despite this recognition, there have continued to be cases of appalling care, including Stoke Mandeville Hospital, and Maidstone and Tunbridge Wells Trust, which involved stark failures in preventing and controlling healthcare-associated infections, and Mid-Staffordshire Trust, where wholly inadequate Accident and Emergency (A&E) care led to unnecessary deaths and harm.

7. These cases are unlikely to be typical of today's NHS as a whole, but they are, nonetheless, deeply dismaying—especially after nearly a decade of policy focus on patient safety. International studies involving reviews of case notes have found that many patients have suffered avoidable harm. Against this background it must be asked how far the Government's policy has succeeded in reducing harm to patients and what more needs to be done. Accordingly, we decided to hold an inquiry into the subject. The terms of reference are given in Annex 1 below.

8. We received memoranda of written evidence from 108 bodies and individuals, and held eight oral evidence sessions. Witnesses included families of harmed patients; Presidents of medical Royal Colleges; nurses; junior and senior clinicians; academics; experts in Human Factors training; a representative of the Health Foundation; representatives of arm's-length bodies, including the Chairman of the National Patient Safety Agency; and the Chairman of the National Institute for Health and Clinical Excellence. We also held evidence sessions with Ben Bradshaw MP, then Minister of State for Health Services at the Department of Health (DH); Ann Keen MP, Parliamentary Under Secretary of State at the DH; Professor the Lord Darzi of Denham KBE, Parliamentary Under Secretary of State at the DH; Professor Sir Liam Donaldson, Chief Medical Officer (CMO) for England; and other officials from the Department.

9. We visited Charing Cross Hospital in London to look at developments in electronic prescribing and barcoding (which we thank Professor Bryony Dean-Franklin for organising), St Thomas' Hospital, London, to look at a patient record system (which we thank Maxine Hoeksma for organising) and Luton and Dunstable Hospital in Bedfordshire to examine the improvements brought about by the Safer Patients Initiative (which we thank the Chief Executive, Mr Stephen Ramsden, for organising). We also saw how patient safety is being addressed in New Zealand, through visiting three hospitals and meeting representatives of the Ministry of Health; the Quality Improvement Committee; the Royal New Zealand College of General Practitioners; the Accident Compensation Corporation; the Health and Disability Commissioner; the New Zealand Medical Association; and several academics. We thank the staff of the British High Commission in Wellington who organised our visit.

10. The voices of frontline healthcare staff are too rarely heard in discussions about patient safety. To ensure that their views were considered, we commissioned the Centre for Patient Safety and Service Quality at Imperial College to interview junior doctors, nurses and therapists, as well as non-clinical frontline staff (porters, cleaners and ward clerks). We thank Susan Burnett and her team for undertaking this work quickly and to a high standard. In addition, we thank the National Audit Office for providing us with the results

of separate research undertaken among junior doctors regarding patient safety, using focus groups and a small sample survey.

11. We are especially grateful to our specialist advisers, Mr Tony Giddings (retired surgeon and Chairman of the Alliance for the Safety of Patients at the Royal College of Surgeons of England); Dr Ike Iheanacho (Editor of *Drug and Therapeutics Bulletin*); and Professor Charles Vincent (Director of Imperial Centre for Patient Safety and Service Quality), for their expertise and assistance.⁵

12. In the report, chapter two summarises the main initiatives to improve patient safety since 2000. Whilst the NHS has undoubtedly been a world pioneer in this field, for which credit is due, there are, however, doubts about how effective patient safety policy has been. In the following chapters, we examine the implementation of patient safety policy since 2000. We evaluate progress and, where policy appears to have failed, discuss barriers to change and other reasons for slow progress, and make recommendations for improvement. While we do refer to particular types of harm done to patients (such as healthcare-associated infections), we have deliberately not looked at these specifically. Instead, we explore the key means of establishing a culture and systems capable of addressing unsafe care whatever form it takes.

5 Mr Giddings declared his interest as Chairman of the Alliance for the Safety of Patients and as an occasional adviser to the Healthcare Commission and the General Medical Council. Dr Iheanacho declared no interests. Professor Vincent declared his interest as Professor of Clinical Safety, Imperial College, London, a consultant to a number of organisations on patient safety and as Director of Safe Quality Care, a company which carries out research on patient safety.

2 Patient safety policy since 2000

13. Since 2000, there have been significant attempts to develop patient safety policy in the NHS. Those efforts are briefly summarised in this chapter and highlighted in Box 1.

Box 1: Key patient safety policy documents and initiatives since 2000

2000	CMO's Expert Group, <i>An Organisation with a memory</i> —sets a new direction for patient safety in the NHS
April 2001	DH, <i>Building a Safer NHS for Patients: implementing An organisation with a memory</i> —makes the NHS the first healthcare system in the world with a patient safety strategy
July 2001	NPSA established
2004	Health Foundation establishes Safer Patients Initiative in four UK hospitals, including Luton and Dunstable in England
2005–6	Series of reports assessing progress: NAO, <i>A Safer Place for Patients</i> PAC, <i>A Safer Place for Patients</i> DH, <i>Safety First: A report for patients, clinicians and healthcare managers</i>
2008	Lord Darzi, <i>High quality care for all: NHS Next Stage Review final report</i>

14. In the late 1990s DH promised a fresh emphasis on the quality of NHS care, including patient safety, to be guaranteed by clinical governance.⁶

15. Subsequently, a more innovative approach to patient safety was developed in line with an international shift in thinking, definitively expressed in the American study *To Err is Human: Building a Safer Health System* (2000).⁷ This argued that events causing or risking harm to patients were far more likely to result from systemic failure than the actions of individual healthcare workers.⁸ Attempts to improve patient safety should not focus on punishing individuals for errors, but on removing “error-provoking” aspects of care-delivery systems. This entails moving away from a “blame culture”, in which incidents are analysed to attribute blame to individuals. Such a culture encourages covering up incidents and fails to identify underlying causes and learn lessons that could prevent repetition of incidents. Instead, individuals should not fear being unfairly made to shoulder the blame

6 Clinical governance is defined as “the system 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 clinical excellence will flourish” (www.dh.gov.uk/en/PublicHealth/Patientsafety/Clinicalgovernance/index.htm).

7 Linda Kohn et al., *To Err is Human: Building a Safer Health System* (Washington DC, 2000)

8 On this basis, terms such as “mistake” or “error” now tend to be avoided in discussing medical harm, as they are perceived to be associated with attributing harm mainly to the “proximal unsafe acts” of individuals, rather than latent “error-provoking” conditions present in the healthcare provider concerned.

for incidents (this has been termed a “fair blame culture”).⁹ Greater openness about, and reporting of, incidents, combined with determined searching for systemic faults, enables lessons to be learned and implemented with tangible improvements in safety. In this respect, healthcare needed to catch up with other safety-critical industries,¹⁰ such as civil aviation, where this approach has become well established.

16. These ideas were readily accepted by an Expert Group on learning from adverse events in the NHS that was chaired by the CMO. The Group’s report, *An organisation with a memory* (2000)¹¹ mirrored the approach of *To Err is Human*, and is similarly regarded as a pioneering document which has helped set the international agenda on patient safety. It highlighted the extent of avoidable harm to NHS patients and advocated both the fostering of an open, reporting and learning culture, and new systems for learning from failure.

17. The Expert Group’s key practical recommendation was for the DH to introduce a mandatory reporting scheme for adverse events and specified “near misses”.¹² This would allow reports of incidents to be collated nationally and used to identify lessons about how harm to patients could be avoided in future.

Box 2: Key conclusions of *An organisation with a memory* (2000)¹³

[T]he NHS needs to develop:

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

18. In April 2001, the DH published *Building a safer NHS for patients: Implementing ‘An organisation with a memory’*, setting out how the Expert Group’s recommendations were to be implemented. This would be done by means of a new national system for learning from error and adverse events, overseen by a new independent body, the National Patient Safety Agency (NPSA), and supported by “an open, no-blame reporting culture”.

9 The term “no blame culture” has been used in this context, but is now widely seen as inaccurate and unhelpful, since in cases of malicious or inept conduct it clearly is appropriate for blame to be attached to individuals.

10 Safety-critical industries are those in which failure can cause serious injury or death. They are also termed “high-reliability” and “high-risk” industries.

11 Department of Health, *An organisation with a memory: Report of an expert group on learning from adverse events in the NHS chaired by the Chief Medical Officer*, June 2000

12 A “near miss” was defined as “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 the result of compensating action, thus preventing injury to a patient” (*ibid.*, p xii).

13 *Ibid.*, para 20, p xi

19. In July 2001, the NPSA was established as a Special Health Authority within the NHS.¹⁴ The Agency began its work in 2003, with a remit covering the NHS in Wales as well as in England.

20. In February 2004 the NPSA published *Seven steps to patient safety*, setting out the steps that NHS organisations needed to take in order to ensure patient safety.¹⁵

21. A key task of the NPSA was to establish the National Reporting and Learning System (NRLS)¹⁶ to receive reports from all NHS organisations of patient safety incidents. These were defined as “any unintended or unexpected incident [due to medical management, rather than the natural course of the patient’s original illness or condition] which could have [led] or did lead to harm for one or more patients receiving NHS-funded healthcare”.¹⁷

22. The NRLS was established in 2004 as a voluntary national reporting system, receiving reports from all local NHS reporting systems in England and Wales, as well as through a parallel, anonymous, electronic reporting system (allowing NHS staff to report incidents without going through their local system). A web-based Patient and Public Reporting e-form, to allow patients and the public to submit reports directly to the NRLS, was developed in 2005–6.

23. Following the Government’s review of arm’s-length bodies, the NPSA acquired several new responsibilities in 2005; these are reflected in its current form, shown in the Box 3 below.

14 A Special Health Authority is a type of arm’s-length body that is independent but can be subject to ministerial direction like other NHS bodies.

15 **Step 1 Build a safety culture:** Create a culture that is open and fair

Step 2 Lead and support your staff: Establish a clear and strong focus on patient safety throughout your organisation

Step 3 Integrate your risk management activity: Develop systems and processes to manage your risks and identify and assess things that could go wrong

Step 4 Promote reporting: Ensure your staff can easily report incidents locally and nationally

Step 5 Involve and communicate with patients and the public: Develop ways to communicate openly with and listen to patients

Step 6 Learn and share safety lessons: Encourage staff to use root cause analysis to learn how and why incidents happen

Step 7 Implement solutions to prevent harm: Embed lessons through changes to practice, processes or systems

16 The NPSA has recently begun using the acronym “RLS” to refer to the Reporting and Learning System, and “NRLS” to refer to the National Reporting and Learning Service division of the Agency. However, “NRLS” is still widely used to refer to the Reporting and Learning System, as it is throughout this report.

17 www.msnpsa.nhs.uk/rcatoolkit/resources/resource_glossary.htm

Box 3: Structure and responsibilities of the NPSA**The three NPSA divisions**

- **National Reporting and Learning Service division**

This aims to reduce risks to patients receiving NHS care, improving safety and care standards through: analysis of incidents that are reported via the NRLS; rapid responses to incidents; and the collaborative development of actions that can be implemented locally.

- **National Clinical Assessment Service division**

This considers the performance of individual doctors, dentists or pharmacists in cases not serious enough to warrant referral to the relevant professional regulatory body (covers the UK and both the NHS and independent healthcare providers).

- **National Research Ethics Service division**

This protects the rights, safety, dignity and well-being of research participants and facilitates ethical research that is of potential benefit to participants, science and society.

The national confidential enquiries

In addition, the NPSA is responsible for commissioning and monitoring the three national confidential enquiries, which are provided independently, often by academics. The enquiries examine fatal healthcare incidents in their respective areas of responsibility, collecting evidence on aspects of healthcare, identifying shortcomings in care and disseminating recommendations based on their findings.¹⁸

24. By the time it became fully operational, the NRLS was considerably behind schedule and over budget. Martin Fletcher, Chief Executive of the NPSA, told us that such teething troubles were down to the pioneering nature of the System:

With hindsight there would be a recognition that an undertaking of this scale was a lot more complex than anybody had perhaps at first realised. You have to remember that when this system was set up five years ago it was the first of its type in the world.¹⁹

25. Following the delays there was an investigation by the NAO in 2005.²⁰ This underpinned the 2006 report by the House of Commons Public Accounts Committee (PAC), *A Safer Place for Patients: Learning to improve patient safety*.²¹ The Committee

18 The three national confidential enquiries are: the National Confidential Enquiry into Patient Outcome and Death; the Confidential Enquiry into Maternal and Child Health; and the National Confidential Inquiry into Suicide and Homicide by People with Mental Illness.

19 Q 825

20 National Audit Office, *A Safer Place for Patients: Learning to improve patient safety*, HC (2005–06) 456

21 Committee of Public Accounts, Fifty-first Report of Session 2005–06, *A safer place for patients: Learning to improve patient safety*, HC 831

criticised the lack of progress and concluded that “there is a question mark over the value for money being achieved by the National Patient Safety Agency”.²² A change of leadership subsequently took place at the NPSA.

26. In December 2006, a report, *Safety First*, which had been commissioned by the CMO, was published.²³ This report:

- found that, while patient safety was gaining a significant national profile, it was “not always given the same priority or status as other major issues such as reducing waiting times, implementing national service frameworks and achieving financial balance”.
- found scant evidence that data collected through the NRLS were “effectively informing patient safety at the local NHS level”. Although the system was now collecting a high volume of reports, too few of these resulted in “actionable learning for local NHS organisations”. Also, “In many cases, an environment has not been created that motivates and inspires clinical and non-clinical staff working at the front line to insist that all care must be as safe as possible.”
- set out 14 recommendations intended to accelerate the pace of change in the NHS in England. These measures, which set a new agenda for the NPSA following its change of leadership, are discussed in the next chapter.

27. It is important to recognise that there have been a number of non-Government projects to improve patient safety over the last decade, including the Safer Patients Initiative (SPI), which was established by the Health Foundation²⁴ on a UK basis in 2004. The first phase of the SPI involved piloting by four NHS acute organisations (one in each of the countries of the UK) during 2004–6. In England, Luton and Dunstable Hospital took part in the SPI to test ways of improving safety on an organisation-wide basis. The Initiative worked on three levels:

- addressing five clinical areas, each containing multiple interventions that have an established and accepted evidence base in the UK (such as better management of patients in intensive care, infection control, preventative antibiotics for surgery and medicines safety);
- teaching methods for quality and safety improvement; and
- establishing a specific role for the Chief Executives and senior executive teams.

28. In 2006, the initiative was expanded to another 20 hospitals (11 of them in England). These hospitals in the second phase aimed to reduce their mortality rates by at least 15% and to reduce adverse events by at least 30% over a two year period. There is evidence of

22 *Ibid.*, p 4

23 Department of Health, *Safety First—A report for patients, clinicians and healthcare managers*, December 2006

24 The Health Foundation is a charity, established in 1998, that works to improve the quality of healthcare.

impressive achievements in some areas but it is not clear whether the wider objective of a sustained reduction in harm has been achieved.²⁵

29. In 2007, Lord Darzi, Parliamentary Under Secretary of State at the DH, published his interim review of the NHS which was followed by his final report, *The Next Stage Review*. This was probably the most important Government initiative in patient safety since *An organisation with a memory*. Lord Darzi's report was a long term vision for the NHS which stressed that the quality of services, including patient safety, should be the top priority for the NHS.

Conclusion

30. **Since 2000, the Department of Health has sought to move the NHS away from a “blame culture”, in which harm to patients is unfairly attributed to individual healthcare workers, to an open, reporting and learning culture, which can identify and address the systemic failings that are responsible for the vast majority of avoidable harm. At the same time, a mechanism (the National Reporting and Learning System) and an organisation (the National Patient Safety Agency) have been created to facilitate systematic reporting of, and learning from, patient safety incidents, and improvement of services. These measures mean the NHS has led the way for healthcare systems throughout the world in the development of patient safety policy and for this credit is due. In his reports in 2007 and 2008 Lord Darzi stressed the importance of safe care in the NHS as part of his *Next Stage Review*.**

31. **In addition, the Health Foundation has established the *Safer Patients Initiative* which seeks to encourage clinicians and other staff to look for the best ways of reducing the harm done to patients.**

32. **We are, however, concerned that Lord Darzi's emphasis on quality and safety is an indication that, for all the policy innovations of the past decade, insufficient progress has been made in making NHS services safer. We note that the report commissioned by the Chief Medical Officer in 2006, *Safety First*, concluded that patient safety was attaining a significant national profile, but was “not always given the same priority or status as other major issues such as reducing waiting times, implementing national service frameworks and achieving financial balance”. This concern is heightened by the recent cases of disastrously unsafe care that have come to light in a small number of Trusts.**

33. Judging what effect policy to date has had on the safety of services across the NHS requires the examination of data regarding the extent, and cost, of harm that has been done to patients. We turn to this in the next chapter.

25 In October 2008, the Health Foundation launched Safer Clinical Systems, a programme to test and demonstrate ways to improve healthcare systems or processes to systematically improve patient safety, which is intended to build on the SPI.

3 Measurement and evaluation

34. The DH's policies for eliminating avoidable harm to patients have to be judged by their effectiveness. The measure of this is the overall amount of harm done to patients, and its cost to the NHS, which diverts resources that could be spent on other care. In this chapter we examine the available evidence.

How much harm is done to patients?

Box 4: Types of evidence about the scale of harm done to patients, and their respective strengths and weaknesses

Type of Evidence	Strengths	Weaknesses
Reported incidents	Provides a minimum number	Under-reporting
Case note reviews	Provides an adverse event rate	Only provides a snapshot of a particular time and place; methodologies differ (limiting value of comparisons) and may not be applied consistently by reviewers
Patient surveys	Captures the voice of the patient	Under-reporting (patient may not be aware an incident occurred, or may not appreciate what counts as an incident)
Reported data on specific problems (e.g. healthcare-associated infections)	Provides a minimum number	Under-reporting; only captures one facet of safety

35. When we asked Mr Fletcher how much harm the NHS in England does to patients, he referred us to data on reported incidents.²⁶ Of the roughly 850,000 incidents in the NHS in England reported annually through the NRLS, over 65% are “No harm” incidents (including “near misses”, *i.e.* prevented incidents), about 25% are “Low harm” incidents, around 5% involve Moderate harm, less than 1% (about 7,500) involve serious harm and less than 0.5% (around 3,500) involve the death of the patient.²⁷

36. However, as the NPSA itself acknowledges, there is very significant under-reporting of safety incidents (as is discussed further below). So figures for reported incidents are not a reliable indicator of how many incidents actually take place in the NHS.

37. When we asked the Chief Nursing Officer (CNO), Dame Christine Beasley, the same question, she could only refer us to patient survey data collected by the Healthcare Commission (HCC), showing that “92% of people say their care is very good, good or excellent”.²⁸ This answer, however, bypasses the fact that patients may well be unaware of

26 Q 3

27 National Reporting and Learning System quarterly data, Issue 12, May 2009

28 Q 4

failings in their treatment. On the same occasion, the NHS Medical Director, Professor Sir Bruce Keogh, told us only “I have nothing to add”.²⁹

38. We sought to clarify what is known about the harm done to patients. Richard Thomson, Professor of Epidemiology and Public Health at the University of Newcastle, told us that the best available data on the overall extent of harm to NHS patients in England consist of “hospital case note review studies,³⁰ the studies that have looked at medical records of patients”, which “demonstrate that around 10% of admissions to hospital suffer some form of harm”.³¹ These data show that, in between a third and half of admissions associated with harm, that harm was preventable. The DH’s memorandum of written evidence for this inquiry states that these findings are consistent with those of similar studies in other developed countries.³²

39. There have only been two, very limited, such studies in England (relating to admissions in 1998 and 2004, respectively), each covering around 1,000 admissions in one and two hospitals respectively.³³ Other countries in which studies have been conducted include the USA, Australia, Denmark, France, Canada, the Netherlands, Spain and New Zealand; some of these involved up to 50 hospitals and 30,000 admissions (see Annex 2 for a more detailed analysis).

40. All such studies are associated with important methodological problems. Firstly, it can be difficult to decide whether or not an adverse event was avoidable. Making such a judgement carries the danger of “hindsight bias”: not making sufficient allowance for the fact that those involved in the event will not have had the advantage of perceiving the situation with full (retrospective) knowledge or the luxury of time to reflect. (However, it is arguably not “hindsight bias” to regard harm as avoidable when it occurs due to lack of foresight, *i.e.* ignorance of factors that are known to contribute to unsafe care.)

41. Secondly, the criteria used to determine avoidability can vary between studies and consistency can be hard to achieve even among researchers in the same study. One study concluded that “preventability is in the eye of the reviewer”.³⁴ A study of a hospital, oriented towards discovering cases of potential medical negligence, in Massachusetts found an adverse rate of 2.7%; when the same notes were examined using a different approach to assess all forms of harm to patients the rate was put at 11%.

42. Thirdly, as well as the problems in determining preventability, there are particular issues relating to deaths associated with unsafe care. Often, these are the deaths of patients who were very ill with an already poor prognosis regarding their original illness or

29 Q 5

30 Hospital case note review studies are also referred to as “record review” studies. They are usually retrospective, *i.e.* based on a study of records relating to completed treatment episodes.

31 Q 102

32 Ev 2

33 Charles Vincent *et al.*, “Adverse events in British hospitals: preliminary retrospective record review”, *British Medical Journal*, vol 322 (2001), pp 517–519; Ali Baba-Akbari Sari *et al.*, “Extent, nature and consequences of adverse events: results of a retrospective casenote review in a large NHS hospital”, *Quality and Safety in Health Care*, vol 16 (2007), pp 434–439

34 Rodney Hayward and Timothy Hofer, “Estimating hospital deaths due to medical errors: preventability is in the eye of the reviewer”, *Journal of the American Medical Association*, vol 286 (2001), pp 415–420

condition. In such circumstances, determining whether a death counts as an “excess death” (one attributable wholly to the adverse event) is difficult, and sometimes, impossible.³⁵

43. At various times over the past decade, the NPSA, the DH and others have cited estimates of the extent of harm to NHS patients in England, extrapolated either from the case note review studies in England or from similar studies conducted overseas. These extrapolations have suggested that the NHS inadvertently kills tens of thousands of patients each year. Figures generated in this way are questionable given the problems discussed above.

44. Despite the limitations of case note review data, and the Department’s failure to ensure the production of better data, it is clear that a great deal of harm is done to patients in the NHS—as it is in all healthcare systems. The international studies mentioned above put the rate of adverse events in acute care at between 2.7% and 16.6%. Even at the lower end of the range this represents a huge amount of harm given the millions of patients treated.

45. Case note reviews are also an important source of data at the local level. During our visit to Luton and Dunstable NHS Foundation Trust we learned how the Trust had made effective use of case note review data to monitor its progress in improving patient safety. Each month, the Trust scrutinises a random sample of 20 case notes to compute an adverse event rate, which is then reported to the Board and to staff as an indicator of how far care is safe.

46. There are various streams of data on particular aspects of patient safety in acute hospitals, for example, on medication errors and healthcare-associated infections (HCAIs). Cases of MRSA and *Clostridium difficile* are now reported and the Office for National Statistics produces statistics regarding deaths in which these two diseases are recorded causes. These data do not provide a reliable, comprehensive picture of the problem since there is likely to be underreporting of cases and under-registration of deaths; they do, nevertheless, show that HCAIs are a major concern.

47. Regarding harm to NHS patients that occurs outside NHS acute hospitals, Professor Thomson told us that the available evidence is even thinner. There have been no case note review studies in primary care. A review of the international literature on safety incidents in primary care found that studies showed “there might be errors occurring in anywhere between five and 80 in every 100,000 consultations”. But this cannot be taken as a reliable indication of harm to patients in primary care in the NHS in England. According to Professor Thomson:

there are a number of other measures that indicate that there is an issue in primary care. For example, about one in 25 patients admitted to hospital in some studies are shown to have been admitted because of a medication problem. That implies that there are clearly issues around medication safety in primary care that could be addressed. Surveys of patients by the Commonwealth Fund have suggested that maybe as many as six in 100 report that they have experienced some sort of error in medication over the last two years.³⁶

35 PS 80

36 Q 102

However, this information too is inadequate for determining exactly how many patients are harmed and in what ways.

48. In respect of harm to NHS patients from treatment by independent-sector providers, Professor Thomson told us that nothing is known: “That is an area really where there is very little reliable data at all at the moment. I do not think we have anything that could give us an overarching figure for that at all.”³⁷ The HCC told us, regarding data on quality that Independent Sector Treatment Centres were expected to provide, that “the level of returns and data quality were very poor” in 2007 although “there has been some improvement since”. Also, for reports on adverse events, “data quality can be poor and the level of reporting from different providers of the same type varies greatly”.³⁸

What does harm to patients cost the NHS?

49. When we asked about the cost to the NHS in England of harm to patients, the NHS Medical Director referred us to the sum of £633 million³⁹ paid out by the NHS Litigation Authority (NHSLA) in settlement of clinical negligence claims in 2007–8.⁴⁰ It is clear that this figure does not indicate the true cost, since it relates only to litigation over the NHSLA threshold and omits so many of the costs relating to avoidable harm—not least the cost of additional medical treatment.

50. Other figures which attempt to give truer estimates of the cost to the NHS are also incomplete and unreliable but, even so, leave little doubt that the cost is huge. Mr Fletcher of the NPSA referred to work done by the NAO in which Trusts were asked to estimate the cost of unsafe care; this had yielded figures for individual Trusts ranging between £88,000 and £400,000 per year. He also cited work by the NPSA on patient falls, which were estimated to cost the NHS in England and Wales around £15 million per year.⁴¹

51. Alastair Gray, Professor of Health Economics and Director of the Health Economics Research Centre in the University of Oxford, told us that, according to an extrapolation from the first hospital case note review study in England, additional bed-days due to preventable adverse events could be costing “approximately £1bn” per year.⁴² Such data are subject to the limitations relating to case note reviews referred to above, but are at least based on a systematic assessment of medical notes.

52. The CNO informed us that the annual cost of additional bed-days due to healthcare-associated infections was in the region of £1 billion,⁴³ although this is an extrapolation from a single-hospital study that used data from 1994–5.⁴⁴

37 Q 103

38 Ev 196

39 NHS Litigation Authority, Factsheet 2: financial information, November 2008

40 Qq 27–29

41 Q 30. See also Ev 6.

42 PS 81

43 Qq 31–32

44 PS 81; Rosalind Plowman *et al.*, *The Socio-economic Burden of Hospital Acquired Infection: Executive Summary* (Public Health Laboratory Service, 1999)

53. Dr Alison Holmes, the Director of Infection Prevention and Control, and a Consultant in Infectious Diseases, at Imperial College Healthcare NHS Trust, spelt out to us the need for better data on the cost of healthcare-associated infections:

I think we are struggling here. We really do need some very good economic evaluations that are not just about bed days but also the impact in primary care, and I think we really do have to move towards thinking: this is ‘healthcare’ acquired infection, it is across a whole patient journey, and we should be working very closely across primary and acute care. So economic evaluation needs to consider not just what is happening in the hospital but the impact on people’s lives and in primary care. We also have to use data that is useful, that actually comes from the UK and, particularly, that is relevant to whether you are a large teaching hospital or a smaller [District General Hospital]. It would be useful to make economic models based on English or UK data.⁴⁵

54. Another area of cost is that relating to adverse events due to medication errors, which the NPSA has estimated at £774 million per year.⁴⁶ Professor Gray explained that this too is an extrapolated figure the validity of which is far from certain:

That is an estimate which came from two main sources. One is trying to get some handle on how many medication errors occur amongst people already in hospital and the other on what proportion of people are admitted to hospital as a result of medication errors. Based on systematic reviews of literature to get estimates of these rates plus studies of individual hospitals, the figures were attached to these. Also, a small amount are based on litigation costs—I think it was a very small part of that total—and that is how we got the £750 million for medication errors.⁴⁷

Conclusion

55. The evidence, particularly that from case note reviews, both in England and internationally, indicates that the extent of medical harm is substantial, even on a conservative estimate, and that much is avoidable. International studies suggest that about 10% of all patients who are admitted to hospital suffer some form of harm. Judging how far patient safety policy has been successful requires more reliable data regarding how much harm is done to patients. Unfortunately, neither the NPSA nor the DH was able to provide us with that. Government estimates of avoidable harm and the attendant financial costs are extrapolations from old, very limited, data; and no attempt has been made to produce reliable up-to-date figures.

56. We remind the Department of the value of the random case note review that was a part of Royal College inspections for accreditation for training of junior doctors. We commend to all hospitals the practice of conducting regular sample case note reviews, as is done at Luton and Dunstable Hospital, to provide a clear indicator of local performance in making services safer. We recommend that the NPSA monitor progress

45 Q 541

46 National Patient Safety Agency, *Safety in doses: medication safety incidents in the NHS: The fourth report from the Patient Safety Observatory*, March 2007, Appendix 5, p 59

47 Q 148

by the NHS in improving patient safety, using local sample case note peer review data and other sources of information on harm to patients.

4 Harmed patients and their families or carers

57. When a patient is harmed, the NHS organisation responsible has, according to the NPSA, a duty to:

- be totally honest with the patient (or their family or carers) about what has happened;
- give a full explanation;
- apologise unequivocally;
- give an undertaking that all the necessary steps will be taken to avoid the same harm coming to another patient.

58. To fail in any of these duties is to compound the harm done. As Josephine Ocloo, whose daughter's treatment was a matter of serious concern, told us, harmed patients can be “doubly harmed through being unable to get explanations, justice and accountability”.⁴⁸

59. In this chapter we consider whether the NHS is meeting its obligations to harmed patients and their families or carers in respect of being open in this way. We also look at how the NHS handles complaints about services—which are supposed to allow harmed patients and their families or carers to bring unsafe care to light and have it appropriately addressed. We look too at progress towards ensuring redress for harmed patients without the need for litigation—which would both remove medico-legal obstacles to openness about incidents (and to learning from them), and spare harmed patients distressing and lengthy legal proceedings.

Being open

60. During the inquiry we heard harrowing cases of failures in communication from the relatives of harmed patients, who recounted a distressing lack of openness on the part of NHS organisations and staff. Mrs Clare Bowen, for instance, said the following about the circumstances surrounding the death in 2006 of her daughter Bethany during surgery:

Beth was admitted to hospital. Everything was going, so far as we knew, well. She went down to surgery and the next thing we knew the doctors came back up and told us that they had cut a major blood vessel and Bethany had bled to death on the operating table. Subsequently, a lot of information came to light because we fought for it. The hospital were very reluctant to give us any information; we had to ask for everything we were given. Their story changed considerably over time. We found out that the blood vessel they were talking about was her aorta. That they could not have cut through her aorta, that it must have been a problem with her heart—even though she had two cuts in her aorta and cuts to her stomach and her bowel. We found out that a trainee was using a brand new piece of equipment called a morcellator on

Beth. This bit of equipment had never been used in paediatrics in the UK before. It is used widely in gynaecology. They had not received any new training on this. Actually, they decided to use this equipment after the consent form was signed. The additional risks just were not told to us [...]

[O]n the day in the room when they told me Beth had died they told me the truth, I know they did, they were very emotional and they told me the truth. They told me they had cut a blood vessel and she had bled to death. It changed within two days. They came back and they said, I will read it from here: “We cut the aorta in two places, probably the morcellator, but the resulting blood loss not significant. We do not know what killed her.” About six months later: “The aorta was certainly not damaged by the morcellator, the cuts did not have any explanation and the blood loss was insignificant. We do not know how she died.”⁴⁹

61. A series of reports have shown that too many people have had experiences of this kind and have called for more openness. The NAO investigation in 2005 and the following PAC report in 2006 found that there was still too little openness with patients over safety incidents. The NAO found that Trusts “named concerns about the risk of a claim under the NHS clinical negligence scheme⁵⁰ as reasons cited by staff as having discouraged them from apologising or from being open following an incident”.⁵¹ The PAC recommended that all NHS organisations should abide by the NPSA guidance *Being open: communicating patient safety incidents with patients and their carers* (2005) and, as a matter of course, inform patients and their carers if an incident had occurred. The DH agreed and thought that the planned NHS Redress Scheme (to provide an alternative to clinical negligence litigation) would help bring about greater openness⁵²—although, as we discuss below, the Redress Scheme still has yet to be implemented. In December 2006, the CMO’s review group recommended that “All NHS organisations should develop and implement local initiatives to promote greater openness with patients and their families when things go wrong and to provide required support”.⁵³

62. We heard evidence from Dr Susannah Long, a junior doctor, and Sarah Dheansa, a Matron, that some, if limited, progress had been made in recent years:

49 Qq 165, 176. The Committee has received a memorandum from Oxford Radcliffe Hospitals NHS Trust stating that “shortly after Bethany’s death, the surgeon in charge met with her parents and explained (what the surgeon at the time thought to be the case) that the morcellator had caused the damage and that the bleeding from the damage to the aorta had caused the death. However, over the forthcoming days and weeks, and then extending to the inquest, surgeons and investigators and our external expert reviewer questioned whether this explanation made sense. We recognize that giving an initial explanation which is later questioned as different facts emerge can be perceived as becoming defensive.” The memorandum also states that the Trust “values greatly Mrs Bowen’s personal account of her experience, and commends her evidence to the Committee” and has learned important lessons from this case (PS 102).

50 The voluntary Clinical Negligence Scheme for Trusts (CNST) is a form of “risk-pooling”, with NHS organisations paying an annual contribution to belong to the scheme and able to claim from it in the event of litigation. Members of the CNST must undergo a rigorous risk management programme. The core of this is provided by a range of NHSLA standards and assessments. Healthcare organisations are regularly assessed against these risk management standards, which have been specifically developed to reflect issues that arise in the negligence claims reported to the NHSLA.

51 Committee of Public Accounts, *A safer place for patients*, para 6

52 Treasury Minutes on the Forty-seventh to the Fifty-first Reports from the Committee of Public Accounts 2005–2006, Cm 6908, October 2006, paras 20–21

53 Department of Health, *Safety First*, 2006, p 29

Q 435 Sandra Gidley: [...] [I]f a mistake happens, how easy is it to talk to the patient and be open and honest about what has happened?

Dr Long: I personally have no problem with doing that. It tends to start putting things right when something has gone wrong if you can be very clear and explain, “We didn’t mean this to happen, but it has, and this is what we are going to do about it for you” [...]

Ms Dheansa: I would echo that it is a lot more open. There is much fear of litigation and the reputation [damage] to the hospital, et cetera, but from a clinical point of view I would say that we are now able to be very, very open.

63. The lack of training in communicating with patients is a serious matter of concern. Some clinicians had had a good experience. A junior doctor interviewed by Imperial College for this inquiry “recalled having training in medical school about dealing with patient families and breaking bad news”.⁵⁴ Another junior doctor, Dr Simon Kreckler, told us that:

In surgery, complications of surgery are an occurrence that happen all the time, and communication with families and support is usually excellent in my experience. We should flag up here that in medical education [...] there has been a big drive towards training in communication skills. When I was a student, this was coming in, and I certainly think that the doctors coming through now are better equipped to deal with this sort of situation than they once were.⁵⁵

64. However, others thought there was a lack of formal training:

Q 436 Sandra Gidley: [...] Are people trained in [explaining incidents to patients] or do they learn by observation? It is quite a difficult thing to do.

Dr Long: I think I learned by observation, not explicit training.

65. Imperial College asked a nurse whether she had been specifically trained to speak to patients’ families in the event of something going wrong. She replied: “No, I guess not. We are taught that we should talk to patients and families if something does go wrong, but there’s no easy five-step guide on how to do this.”⁵⁶

66. Graham Tanner, one of the Patient Safety Champions for England and Wales, stated that:

progress in this area is extremely slow. Many healthcare workers receive little or no training in skills of communicating with patients. Many are unprepared for the trauma of emotional reaction to adverse events; others fear aggressive confrontation when news is imparted and some are cautious of possible recriminations, disciplinary action and possible litigation [...] There is a school of thought that suggests that specific mandatory provision, with sanctions, should be applied to

54 Centre for Patient Safety and Service Quality, Imperial College, commissioned research

55 Q 439

56 Centre for Patient Safety and Service Quality, Imperial College, commissioned research

“Being Open.” It would, however, be more beneficial if Parliamentarians ensured that the proposed NHS Constitution contained explicit provision for patients (their families and/or carers) to be informed of all information regarding their treatment, including adverse events.⁵⁷

67. According to Action against Medical Accidents (AvMA):

[T]here appears to have been little take up of the training and, given the number of ‘must do’s’ that NHS Boards are faced with, they are unlikely to make this guidance a priority. We think it is fundamentally wrong that something so vital should be relegated to optional guidance.⁵⁸

They recommend that:

- The Chief Medical Officer’s recommendation for a legal ‘duty of candour’ (Making Amends, 2003) is revisited.⁵⁹
- The Healthcare Commission/new Care Quality Commission actively monitor NHS bodies’ implementation of the Being Open guidance/safety alert and uptake of the training.
- Resources are made available for NHS bodies to take up training on ‘Being Open’.
- The principle of ‘Being Open’/patients’ and families’ right to full and unfettered information and explanation [...] is enshrined in the NHS Constitution.⁶⁰

68. AvMA was critical of guidance issued to Trusts by the NHSLA in 2007 on giving apologies and explanations when a patient is harmed:

This circular confused apologies with mere ‘expressions of regret’ or ‘sympathy’ and actually warned NHS bodies that care must be taken on the dissemination of explanations so as to “avoid future litigation risks”.⁶¹

69. However, AvMA welcomed new guidance issued in May 2009 by the NHSLA which states that it is desirable in cases of harm for clinicians “to sympathise with the patient or the patient’s relatives; to express sorrow or regret at the outcome; and to apologise for shortcomings in treatment”. The NHSLA is “keen to encourage both clinicians and NHS bodies to supply appropriate information whether informally, formally or through mediation”. It stressed that these “earlier, more informal, apologies and explanations” were distinct from formal admissions of liability and would be treated as such by the NHSLA. The guidance also explicitly refers Trusts to *Being open*.⁶²

57 Ev 119

58 Ev 221

59 The CMO recommended that there should be a legal obligation (rather than merely a professional or ethical one) on clinicians and managers to inform patients if harm occurred during treatment (Department of Health, *Making Amends: A consultation paper setting out proposals for reforming the approach to clinical negligence in the NHS*, June 2003). The recommendation was not accepted by the Government.

60 Ev 221

61 *Ibid.*

62 www.avma.org.uk/pages/nhs_issues_new_guidance_on_apologies_and_explanations.html

70. Further steps to improve openness are planned following a review of *Being open* by Professor Albert Wu of Johns Hopkins University, in the USA, which was commissioned by the DH and resulted in six options for action being recommended.⁶³

71. Mr Fletcher of the NPSA welcomed the review and, in particular, its recommendations for strengthening implementation through more targeted training of senior clinicians.⁶⁴ Plans to implement the review's recommendations are being finalised.⁶⁵

The role of the coroner

72. Even if the NHS is not open with patients, in the case of fatal incidents, the families of harmed patients rightly expect to obtain frank and comprehensive information through the work of the coroner. However, most unfortunately, this was not the experience of the relatives of harmed patients from whom we took evidence.

73. Following the death of her daughter Krista in circumstances giving significant cause for concern, Ms Ocloo requested a coroner's inquest but was rebuffed:

The coroner basically wrote me quite a terse, dismissive letter saying that he was not inclined to get into any of the issues that I was raising about Krista's care, and eventually the finding was that Krista had died of natural causes.⁶⁶

74. Mrs Bowen was granted an inquest into her daughter's death, but found it unhelpful:

In my case the coroner's inquest wanted to find an answer; that is all they wanted [...] [The coroner] was happy to disregard any evidence that did not fit his line of enquiry [...] We did not have the opportunity to investigate further the evidence that did not fit the big picture. It needs an investigation outside of the coroner [...] The whole coroner process is very, very difficult. It is difficult to find answers [...] I do not believe that enough investigation is done behind coroners' inquests to be able to find the truth.⁶⁷

63 **(1) Patients:** [...] organizations treating NHS patients should have in place visible arrangements to ensure that all NHS patients are made aware about Being Open [...]

(2) Clinicians: [...] organizations treating NHS patients should identify three or more experienced clinicians [...] trained in Being Open to support fellow clinicians in dealing with adverse incidents and Being Open.

(3) Patient Liaison Services: [...] organizations treating NHS patients should have patient liaison services that support patients, including on the spot help to those in hospital, and work with clinicians to promote Being Open, thereby providing an alternative route to expressing concerns [...]

(4) Boards of Directors: The Boards of Directors of local NHS organizations and other organizations treating NHS patients should ensure that Being Open is supported by non-punitive local policy [and] training [...]

(5) NHS Litigation Authority, Medical Defence Union & Medical Protection Society: The NHSLA should review its communications to Trusts to promote Being Open. The MDU and MPS should review current practices to ensure that their staff provide unambiguous advice to health care staff on Being Open.

(6) National Patient Safety Agency: The National Patient Safety Agency should consider a relaunch of Being Open [...]

(National Patient Safety Forum minutes, 14 October 2008)

64 Q 850

65 PS 39B

66 Q 165. See also Q 182 [Ms Ocloo].

67 Q 182

Dealing with complaints

75. The NHS complaints system has undergone a long process of evolution over nearly 40 years; this is summarised in Box 5.

Box 5: Development of the NHS complaints system, 1973–2009

1973	Health Service Ombudsman (Health Service Commissioner) created, with the ability to examine unresolved complaints about NHS services and make recommendations, but no power to enforce compliance.
1974	Community Health Councils (CHCs) created, with a remit that includes assisting complainants.
1996	Creation of three-stage NHS complaints resolution system: <ul style="list-style-type: none"> • Stage One: Local resolution • Stage Two: Independent Review (by Independent Review Panel) • Stage Three: Investigation by the Ombudsman
2001	Patient Advice and Liaison Services (PALS) begin to be introduced into Trusts, with a remit that includes assisting with the speedy resolution of problems and acting as a gateway to the formal complaints process.
2003	CHCs abolished and Independent Complaints Advocacy Services (ICAS) begins operating (commissioned by the DH from the voluntary sector), giving independent advice and support to NHS complainants. Independent Review stage of complaints process handed to Commission for Health Improvement (CHI).
2004	Independent Review stage handed to the HCC, which also regulates the standard of complaints handling and the implementation of learning from complaints by NHS bodies.
2009	NHS and social-care complaints systems are put on the same footing, and new regulations come into force. Independent Review stage is abolished; and Care Quality Commission (CQC) takes on responsibility for regulating NHS bodies' handling of complaints.

76. In her evidence to us, Ann Keen MP, Parliamentary Under Secretary of State at the DH, was in no doubt about the effectiveness of both PALS, which act as the gateway to the complaints system, and ICAS, which assist in seeking local resolution of complaints:

Q 947 Dr Taylor: Coming on to PALS and ICAS, are they up to the job?

Ann Keen: From our experience and from the feedback we get, PALS supply an excellent service to patients. The reporting on the PALS services is excellent [...]

Q 949 Dr Taylor: I have a very high opinion of ICAS. Is that generally shared? Do patients largely find ICAS helpful?

Ann Keen: Very much so [...]

77. Other witnesses were also positive about PALS.⁶⁸ However, Mrs Bowen took a very different view based on her experience following her daughter's death in 2006:

We were made aware of PALS about three months after Beth had died only because a friend who worked in the hospital [...] had said, "Have you not been contacted by the patient liaison person?" [...] I asked to meet someone at the hospital and, to be quite frank, she was worse at hiding things than the doctors. She would sit there and I asked her if we could see Beth's medical records and she would say, "I don't know about that. I will have to check whether you are allowed to." It got to the stage that six months after we originally met this lady the hospital banned her from speaking to us again because she would send me emails with the title "Serious untoward investigation 366" and I would email back saying, "You are not talking about a number, you are talking about my daughter" [...] [T]hey were defensive and unhelpful.⁶⁹

78. She was in no doubt that the problem was that PALS were paid by the Trust that they were dealing with and were not independent:

It was almost like they put up a wall that they were expecting me to take out litigation, they were expecting the litigation route so they wanted to prevent it and defend that point right from the very start.⁷⁰

79. Mrs Bowen's experience reinforces the conclusions of several publications, by the Health Service Ombudsman, HCC and NAO, which have noted the persistence of very serious deficiencies in the NHS complaints system, despite the changes of 2004 (see Box 6).⁷¹

68 Qq 436 [Ms Dheansa], 727

69 Q 185

70 Q 186

71 Health Service Ombudsman for England, *Making things better? A report on reform of the NHS complaints procedure in England*, HC (2004–05) 413; Healthcare Commission, *Is anyone listening? A report on complaints handling in the NHS*, October 2007 and *Spotlight on Complaints: A report on second-stage complaints about the NHS in England*, January 2007, April 2008 and February 2009; National Audit Office, *Feeding back? Learning from complaints handling in health and social care*, HC (2007–08) 853

Box 6: Shortcomings identified in the NHS complaints system

- The system is not centred on the patient's needs.
- There is a lack of public understanding about the complaints process.
- There is confusion about how to complain.
- Complainants have difficulty in navigating the system.
- People feel intimidated and that their complaint will not be taken seriously.
- The complaints system is fragmented.
- The quality of local complaints handling in the NHS is often poor.
- Staff lack the capacity and competence to deliver a quality service.
- The right leadership, culture and governance are not in place.
- Just remedies are not being secured for justified complaints.
- Better use could be made of complaints data to improve services.

80. The DH is confident that the latest changes to the complaints system will resolve these issues once and for all. Lord Darzi told us:

[N]earing 35% to 40% of the complaints that go to the Healthcare Commission go back to the trust to be dealt with. So you had a huge amount of bureaucracy in the system. The trust, because it is going to be moved up, does not deal with it properly; the Healthcare Commission sends it back to them; you have delays of up to six months to a year and what we try to do is get the trust and the board to be accountable for that, to get this right [...] [I]n most complaints patients are purely looking for an apology and have we learned from it. How do we strengthen the dealing of complaint at a local level? The CQC, in their registration purposes, could actually look at the complaint of an organisation and remove their registration if they are not dealing with the complaint. That is much more powerful than it used to be before but we are shifting the responsibility and accountability of dealing with complaints to the NHS provider [...]⁷²

Q 940 Dr Taylor: How are they going to know that the individual trust is not dealing with complaints? Because of the number that are going to the ombudsman?

Professor Lord Darzi of Denham: Yes.

81. The CMO, Professor Sir Liam Donaldson, added that:

I think we do have to weigh into the equation on complaints that the degree of rigour that the ombudsman brings to complaint investigation is much, much higher than

ever was the second stage of the complaints procedure. Maybe you sacrifice fewer people getting that, but when they do get it the rigour, the openness, the public reporting of the outcome is very, very high compared to any other element of the complaints procedure.⁷³

82. However, this confidence in the new arrangements was not shared by the relatives of harmed patients from whom we took evidence, such as Ms Ocloo:

Although I used [the complaints system] in 1998, looking at all of the recent reports, a lot of the criticisms are quite similar, continuing to make the point particularly about this issue of a lack of independence, so there has been some cosmetic tweaking but the system has continued to operate in a similar way. A big complaint that I have and others in my situation have is that we do not want the independent panel review stage to go from the Healthcare Commission. It is so disappointing. I was at a Department of Health conference [...] It was the usual workshop where they will tell you what is happening and they said, “We are telling you this is what is happening,” and the patients were saying, “And we are telling you we do not want that to happen.” Some of us have been fighting for years. We got the [independent review] to the Healthcare Commission stage and we do not want it to go anywhere else. We feel that that has been closest to giving us an opportunity to get an independent investigation and so switching that is very problematic [...] [I]t is scary because it feels as if again after 13 years of review we have gone backwards.⁷⁴

83. In New Zealand we found an apparently successful model for a complaints system, in which the independent Health and Disability Commissioner acts as a strong statutory guarantor of patients’ rights (see Box 7).

Box 7: The role of the New Zealand Health and Disability Commissioner in resolving complaints

The Office of the Health and Disability Commissioner (HDC) is a New Zealand crown entity responsible for promoting and protecting the rights of health and disability service consumers; and facilitating the fair, simple, speedy, and efficient resolution of complaints.

Providers are required to respond in a timely and appropriate way to any complaints made to them. Complaints can also be made directly to one of HDC’s Health and Disability Consumer Advocates, who can assist in trying to resolve the complaint locally.

Anyone can make a complaint to HDC, orally or in writing. This includes not only consumers, but also their families and carers, and other third parties—including staff members in a health or disability service. HDC does not have to receive a complaint in order to take action. The Commissioner can also undertake an inquiry on his own initiative, and may do this where serious public concerns have been raised about the safety of a service.

The Commissioner may take an educational approach, ask for an apology or recommend action, which is followed up in the same way as recommendations arising from

73 Q 951

74 Qq 189–190

investigations. He may formally refer the complaint to the provider, or to advocacy or formal mediation for resolution between the parties.

At any time, the Commissioner has the discretion to refer matters to another person or authority where he considers it in the public interest to do so. He must refer matters to the appropriate person or authority when an investigation has revealed a significant breach of duty or misconduct; and at any point during the complaint handling process when he has reason to believe that the practice of a health practitioner may pose a risk of harm to the public.

All complaints made directly to professional registration bodies must be referred by them to HDC. Once referred to HDC, no disciplinary action can be taken by the professional body until HDC has dealt with the matter and decided to take no further action. Only at this point can the professional body take up the matter itself.

84. The Commissioner effectively combines the Independent Review and Ombudsman stages of the NHS complaints system in England as it existed until recently—and with greater authority and resources.

Compensation and redress

85. Many harmed patients and their families or carers are obliged to bring clinical negligence cases to obtain financial compensation and redress from the NHS and, in some cases, to obtain full information, an explanation and an apology. There is widespread agreement that litigation is an extremely unsatisfactory means of achieving these ends. It can be distressing, unfair, slow and costly, with the NHS paying substantial legal costs in each case. It also tends to encourage NHS organisations to be defensive towards harmed patients and their families or carers, and inhibits the development of a safety culture.

86. In 2003, the CMO proposed a new system for patients harmed by NHS care, as an alternative to litigation in a large proportion of cases—the NHS Redress Scheme.⁷⁵ This was accepted by the Government and plans for the Scheme were worked out (see Box 8).

Box 8: Key principles of the planned NHS Redress Scheme

- obtaining redress to be a consensual process, as opposed to the adversarial process involved in litigation;
- proceeding under the Scheme to be voluntary;
- patients to be eligible for redress for serious harm during NHS care, provided it was avoidable and not the result of the natural course of the patient's initial illness or condition;
- the right to litigate to remain, but with a presumption that litigants have first

⁷⁵ Department of Health, *Making Amends: A consultation paper setting out proposals for reforming the approach to clinical negligence in the NHS: A report by the Chief Medical Officer*, June 2003

applied to the Scheme;

- those accepting redress under the Scheme to be required to waive their right to go to court on the same case;
- the same tests for negligence to be applied as under current tort law in clinical negligence cases;⁷⁶
- the upper limit for compensation to be set at £20,000 initially;
- the Scheme to be a risk-pooling membership scheme for NHS service-providers in England, with NHS commissioners providing cover in the case of independent-sector providers of NHS care.

87. Enabling legislation (the NHS Redress Act) was passed in 2006, providing the legislative framework to allow the Secretary of State to establish the NHS Redress Scheme. It was expected that the Scheme would begin operating in 2008, but this has not happened. There is widespread support for the principle of a Redress Scheme and the lengthy delay in its introduction has caused consternation. Mr Tanner, one of the Patient Safety Champions, told us:

The NHS Redress Act (2006) contained many of the remedies sought by patients,—apology, explanation of error and details of actions to prevent reoccurrence. Prolonged delay in enacting this legislation has led many patients to use litigation to obtain explanation and reason of adverse events and error. Government should move swiftly to rectify its own error in not supporting openness and honesty within our NHS system.⁷⁷

88. We discovered that the Government still has no definite plans to establish the Scheme. Ann Keen MP, told us:

[W]e believe that initially focussing on complaints reform, rather than the introduction of the NHS Redress Scheme, will be of wider immediate benefit to users of all NHS services, and will also be more effective in embedding the general principles of redress across the NHS. When the reformed complaints arrangements are embedded, we can consider further the matter of financial redress.⁷⁸

89. In New Zealand, we examined a form of redress scheme, which is much bolder in scope than the planned NHS Redress Scheme (see Box 9). The New Zealand scheme has existed since the 1970s and is considered successful and popular in that country. We were told that the elimination of litigation over clinical negligence in this way worked well for patients and healthcare providers; and that it had significantly reduced medico-legal barriers to developing a safety culture. We have received evidence commending this system as a

76 The criteria for proving clinical negligence under tort law include the “Bolam Test”. Under this, care is deemed negligent if it runs counter to “responsible”, “reasonable” or “respectable” clinical opinion.

77 Ev 119

78 PS 01B

model.⁷⁹ On the other hand, we also heard some concerns. Steve Walker, Chief Executive of the NHSLA, informed us that the New Zealand scheme “has been constrained at least twice since inception, because initially it was seen to be too wide”.⁸⁰

Box 9: The role of the New Zealand Accident Compensation Corporation in compensating for medical harm

The New Zealand Accident Compensation Corporation (ACC) is a statutory body operating a universal compensation scheme in lieu of all forms of litigation over personal injury, including in cases of medical harm (“treatment injury”).

The system is funded from levies and taxation, and funds medical treatment arising from treatment injury, as well as compensating victims of harm.

There is no need to prove negligence, as would be required under tort law. This has led some to term this a “no fault” system, but the ACC does have a set of “exclusionary criteria”, whereby harm is not compensable if it is the necessary or ordinary consequence of treatment.

Conclusion

90. Harmed patients and their families or carers must receive honest information, a full explanation, an unequivocal apology and an undertaking that the harm done will not be repeated. While, the NHS has made progress in this regard, there is still too often a lack of frankness on all these counts.

91. The new NHS Litigation Authority guidance on giving apologies and explanations is welcome and we urge its implementation. We also recommend further consideration be given to the CMO’s proposal for a statutory duty of candour in respect of harm to patients.

92. Relatives have a right to expect that coroner’s inquiries will provide information about the reasons for deaths. We are disappointed that some harmed patients’ families do not believe that coroners provide the objective inquiry and independent review that is needed. We believe coroners are too narrowly focused on the immediate cause of injury rather than underlying causes, as evidenced by the case of Bethany Bowen.

93. The NHS continues too often to deal poorly with complainants and fails to use complaints as a means of improving services. We are sceptical that there will be a major improvement following the latest in a protracted series of changes to the complaints system.

94. We are concerned that Patient Advice and Liaison Services, which are effectively the gateway to the NHS complaints system, are provided by NHS organisations themselves. While many PALS services undoubtedly do a good job for patients, their lack of independence makes it more likely that some at least will be “defensive and unhelpful”,

79 PS (BP 02)

80 Q 783

as a witness found them to be, when a patient has been harmed. PALS should not be hosted by individual NHS organisations and must be independent. We recommend that the Department report on the adequacy of PALS staffing by publishing the number of staff dedicated to PALS affairs by whole-time equivalents for each Primary Care Trust, acute Trust and Foundation Trust.

95. We are very concerned about the loss of the Independent Review stage of the complaints process, which we regard as a retrograde step. There is no guarantee that the new regulations will improve the handling of complaints at local level. Moreover, we doubt the Ombudsman has sufficient resources to be able to act as an adequate “backstop” for the many people whose complaints are not adequately addressed locally. We recommend a reversion to the three-stage model for the NHS complaints system as soon as possible, with the Care Quality Commission, or another appropriate body, taking on the Independent Review stage.

96. In addition, we recommend that the DH consider the possible application in England of the model provided by the independent Health and Disability Commissioner in New Zealand, to encompass both the Independent Review and Ombudsman roles.

97. The failure to be open and to satisfactorily address complaints is in large part due to the fear of litigation. We are appalled at the failure of the DH to implement the NHS Redress Scheme three years after Parliament passed the necessary legislation. The DH has explained that it wishes to focus on complaints reform and will consider the matter of redress “When the reformed complaints arrangements are embedded”. We find this wholly unsatisfactory. By dragging its heels over implementing the NHS Redress Scheme, the DH is forcing harmed patients and their families or carers to endure often lengthy and distressing litigation to obtain justice and compensation. It is also obliging the NHS to spend considerable sums on legal costs, and encouraging defensiveness by NHS organisations. In addition, it is hindering the development of a safety culture in the NHS, which cannot flourish in the midst of powerful tensions between the desire to be open and medico-legal concerns. We recommend that the Redress Scheme be implemented immediately.

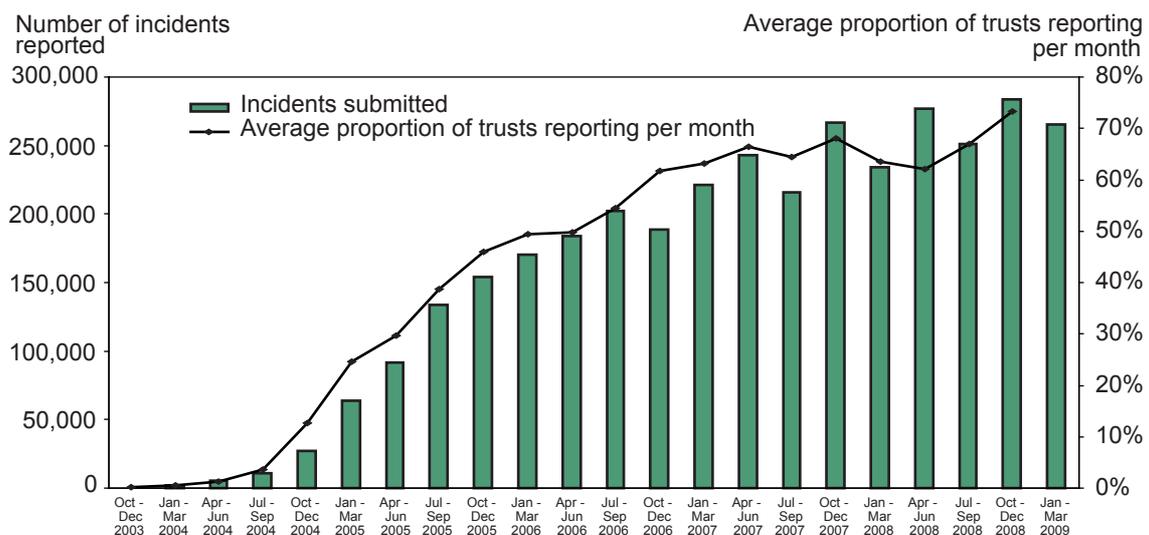
98. If anything, the Government should be considering more radical measures in this direction, rather than shying away from the limited changes for which it has already legislated. We urge consideration of a scheme like that in New Zealand, where litigation over clinical negligence has been entirely replaced by a statutory right to compensation for “treatment injury” from an independent fund, without the need to prove negligence as required under tort law.

5 An open, reporting and learning NHS

99. As we have noted, the NHS has sought for a decade to emulate other safety-critical industries by creating unified mechanisms for reporting and analysing incidents, underpinned by a “fair blame” culture that encourages staff to be open about incidents and report them.

100. After a faltering start, the NHS has succeeded in establishing an incident-reporting system (comprising both local systems and the NRLS) that is unique in the world in its scale and comprehensiveness. As Figure 1 shows, there have been substantial increases in the number of incidents reported, and of organisations reporting regularly, via the NRLS since it began operating in October 2003. Over 850,000 incidents per year are now reported in the NHS in England through the NRLS; and a total of 3.3 million incidents have been reported since the NRLS was set up. Of the 392 NHS organisations in England, 370 (94%) reported at least once during the first quarter of 2009, with 55% of organisations reporting at least once every month.⁸¹

Figure 1: NPSA chart showing numbers of incidents reported and Trusts reporting by quarter, October 2003–March 2009 (England and Wales)⁸²



101. The NPSA now publishes a substantial quantity of statistical data and other forms of output, derived from the NRLS and other sources, in order to assist NHS organisations in making their services safer. (The various types of published output produced by the NPSA since its inception are listed in Box 10.)

81 National Reporting and Learning System quarterly data, Issue 12, May 2009

82 *Ibid.*

Box 10: Types of NPSA published output

- **NPSA Newslines** (a monthly newsletter);
- **Organisation Feedback Reports** (confidential NRLS statistical reports, showing individual NHS organisations how their incident-reporting rates compare with a “benchmark” for a “cluster” of similar organisations);
- **Organisation Patient Safety Incident Reports** (public NRLS statistical reports, containing data broken down to the level of individual NHS organisations);
- **Patient Safety Alerts** (urgent information for immediate action);⁸³
- **Patient Safety Bulletin** (a review of learning from incidents);
- **Patient Safety Guidance** (advice and information);
- **Patient Safety Information** (good practice guidance against which to review current practice—generally reminders of existing guidance);
- **Patient Safety Notices** (good practice guidance, to be implemented over time);
- **Quarterly Data Summaries** (statistical breakdowns of NRLS data by care setting, incident type and degree of harm, for England and Wales);
- **Rapid Response Reports** (advice on patient safety issues that need immediate local attention);
- **Reports, tools and resources** (discussion documents; Patient Safety Observatory reports; toolkits and eLearning, for local education and training);
- **Safer Practice Notices** (guidance on patient safety issues).

102. However, despite the great strides made in incident reporting, its effectiveness is restricted by:

- the significant extent of under-reporting, which is caused by several factors (particularly the continued absence of a “fair blame” culture in much of the NHS);
- the lack of focus in the NRLS; and
- the inherent limitations of data from reporting systems as a means of generating information about patient safety issues and solutions.

These issues, and how they might be addressed, are discussed in this chapter.

⁸³ Patient Safety Alerts carry a deadline for implementation, at which Trusts must report whether they are fully, partially or not compliant. Alerts were distributed initially through the Safety Alert Broadcast System and subsequently through the electronic Central Alerting System, managed by the DH, to which every Trust is connected.

Under-reporting

103. Although many incidents are being reported through local NHS systems and the NRLS, there is substantial under-reporting, for several reasons.

The extent of under-reporting

104. Under-reporting is apparent as follows:

- **Under-reporting in acute care**

According to an NAO survey, “Trusts estimated that on average around 22% of incidents and 39% of near misses go un-reported”.⁸⁴ The two hospital case note review studies conducted in England suggest under-reporting is even greater than this. One of them found that a local incident-reporting system had detected only 17% of all incidents detected by both the review and reporting—and just 5% of all identified incidents leading to harm.⁸⁵

- **Under-reporting in primary care**

General practice accounts for about 0.25% of reports each year (around 2,000 incidents)—yet up to 95% of NHS patient contacts occur in primary care, most of them in general practice, where there are some 750,000 consultations per day. A large proportion of complaints in the NHS are about primary care, particularly regarding delayed or inaccurate diagnosis in general practice,⁸⁶ which is the commonest cause of litigation against GPs.⁸⁷ There are likely to be many more medication incidents in general practice than are reported, as discussed below. NRLS data show that reporting from other primary care settings (community pharmacy; community and general dental services; and community optometry / optician services) is also extremely low.

- **Under-reporting of medication incidents**

Around 80,000 incidents involving medication are reported each year through the NRLS, the vast majority of them from the acute hospital setting. Professor Thomson told us that survey data “suggested that maybe as many as six in 100 [patients] report that they have experienced some sort of error in medication over the last two years”.⁸⁸ Less than 1% of reported medication incidents come directly from general practice. Yet around 1.8 million prescriptions per day are dispensed in that setting; and “about one in 25 patients admitted to hospital in some studies are shown to have been admitted because of a medication problem”, implying significant problems with medication safety in primary care.⁸⁹

84 Committee of Public Accounts, *A safer place for patients*, p 5

85 Q 119; Ali Baba-Akbari Sari *et al.*, “Extent, nature and consequences of adverse events: results of a retrospective casenote review in a large NHS hospital”, *Quality and Safety in Health Care*, vol 16 (2007), pp 434–439

86 Ev 205

87 Ev 22–23; Q 623 [Dr Kostopoulou]

88 Q 102

89 *Ibid.*

- **Under-reporting of serious incidents**

The PAC found in 2006 that incidents leading to serious harm were among the least likely to be reported.⁹⁰ As we have noted, around 11,000 incident reports per year involve serious harm or death;⁹¹ but extrapolations from the case note review studies indicate that substantially more such incidents occur (one extrapolation, by the NPSA in 2004, put the figure for deaths at 72,000 deaths per year).⁹²

- **Under-reporting by doctors**

The PAC found in 2006 that “Doctors are less likely to report an incident than other staff groups”.⁹³ The NPSA recognises the need to get “doctors reporting as much as we see nurses reporting”;⁹⁴ the NAO research undertaken for this inquiry found that “many doctors simply do not report events”;⁹⁵ and the Royal College of Ophthalmologists told us “under reporting by medical staff [...] is commonplace”.⁹⁶

- **Under-reporting of “near misses”**

An organisation with a memory (2000) stated that “systematic reporting of ‘near misses’ (seen as an important early warning of serious problems) is almost non-existent across the NHS”.⁹⁷ In 2004, the NPSA noted “research has shown that near misses are rarely reported”.⁹⁸ And Dr Kreckler, one of our junior-doctor witnesses, told us: “near misses, on the whole, are not reported as much as the incidents themselves”.⁹⁹

Reasons for under-reporting

105. The following reasons for under-reporting are apparent:

- **Persistence of the “blame culture”**

The PAC reported in 2006 that “the perception amongst nursing and other non-medical staff is that they risk suspicion if they report a serious incident”; and that “Trusts said that fear of retribution undermines staff’s willingness to report”.¹⁰⁰ The NAO reported, following its research for this inquiry, that: “Junior Doctors told us that they believed that the current formal incident reporting systems were still focused on apportioning blame and are not confidential.”¹⁰¹ The Imperial College researchers

90 Committee of Public Accounts, *A safer place for patients*, p 5

91 Ev 5, 141

92 Qq 15–19

93 Committee of Public Accounts, *A safer place for patients*, p 5

94 Q 829

95 National Audit Office, commissioned research

96 Ev 85. See also Ev 87.

97 Department of Health, *An organisation with a memory*, 2000, para 15, p x

98 National Patient Safety Agency, *Seven Steps to Patient Safety—Step 4: Promote reporting*, August 2004, p 97

99 Q 433

100 Committee of Public Accounts, *A safer place for patients*, p 5

101 National Audit Office, commissioned research

found likewise that some interviewees “thought that in principle reporting a patient safety incident was worthwhile but in practice they were less likely to do so because of fear of being blamed.”¹⁰² We also heard from the Royal College of Nursing that:

The blame culture still exists in some environments and this may contribute to under reporting of staff or patient related incidents [...] Anecdotal evidence leads us to understand that it is not uncommon for a trust to discipline staff following incidents [...] ¹⁰³

- **Fear of litigation or prosecution**

The Royal College of GPs told us that “Perceived legal risk in [GPs] engaging in this process, that could result in an adverse outcome” was a factor in lack of reporting.¹⁰⁴ We also heard from an academic researcher that “there is an increase in the rate of litigation against GPs so it might be that they are becoming more reluctant to discuss their errors.”¹⁰⁵ Fear of criminal prosecution is a particular issue among pharmacists, since they are criminally liable, under the Medicines Act 1968, for any errors in the dispensing of medicines.¹⁰⁶

- **Lack of response to reports**

The Imperial College researchers found that: “Some individuals clearly felt that their voices would be unheard [...] and some reported that they never had any feedback from reporting and therefore it was pointless.”¹⁰⁷ Likewise, the Royal College of GPs referred to a “Perception that reports are stored and not used”.¹⁰⁸ And Dr Kreckler, one of our junior-doctor witnesses, said that “really there is very limited feedback that comes back down the front line which also further reinforces to some extent the pointlessness of incident reporting”.¹⁰⁹

- **Lack of appropriate reporting systems**

Dr Aneez Esmail, Professor of General Practice at Manchester University, told us his research indicated that GPs were willing to report patient safety incidents; but systems could not take the same form as they had done in the acute sector.¹¹⁰ The Royal College of GPs also referred to the fact that “Reporting systems have not been adequately designed” as a reason for low levels of reporting.¹¹¹ Mr Fletcher informed us that the NPSA was working with the Royal College to: build on the established tradition of

102 Centre for Patient Safety and Service Quality, Imperial College, commissioned research

103 Ev 169

104 Ev 187

105 Q 654

106 PS 78A

107 Centre for Patient Safety and Service Quality, Imperial College, commissioned research

108 Ev 187

109 Q 433

110 Q 537

111 Ev 187

Significant Event Audit¹¹² in general practice; develop an electronic reporting form for general practice; and provide more feedback on reports for general practice.¹¹³ Similar work is being undertaken with the College of Anaesthetists to design with a specialty reporting system for anaesthesia.¹¹⁴ The NPSA used to have Clinical Specialty Advisors, but these were done away with in 2006, as the Royal College of Ophthalmologists noted. They also told us that “More work could be done on extracting specialty specific data from [the NRLS] if funding was made available and if the quality of data on the NRLS was improved upon by better reporting”.¹¹⁵

- **Lack of contractual incentive**

The Royal College of GPs drew attention to “Lack of a contractual incentive” for GPs to report incidents.¹¹⁶ This may be relevant to other independent practitioners, such as dentists and pharmacists, who are contracted to provide NHS services.

- **Poor understanding of what to report**

In 2004, the NPSA cited research indicating that prevented incidents (“near misses”) are “rarely reported because [NHS] staff do not understand what they are”.¹¹⁷ There also appears to be a tendency not to report “No harm” incidents (both completed incidents and near misses) in the mistaken belief that, since no harm occurred, there is no point in reporting. Dr Kreckler said there was an attitude that “‘We’ve got away with it this time’ or ‘No harm came, so why bother reporting it’”.¹¹⁸

- **Lack of knowledge about how to report**

The Imperial College researchers reported that:

We had mixed views on whether staff knew how to fill in an incident report and what happens with them afterwards. Those that had not reported an incident knew very little about how to report one.¹¹⁹

The Royal College of GPs suggested that lack of reporting could be due to clinical teams being “Unaware of the communication channels”.¹²⁰

- **Lengthy and complicated reporting processes**

The NAO reported:

112 Significant Event Audit is a process through which individual episodes in which there has been a significant occurrence (either beneficial or deleterious) are analysed in a systematic and detailed way to ascertain what can be learnt about the overall quality of care and to indicate changes that might lead to future improvements.

113 Qq 21, 828–829

114 Q 827. See also Ev 246.

115 Ev 88

116 Ev 187

117 National Patient Safety Agency, *Seven Steps to Patient Safety—Step 4: Promote reporting*, August 2004, p 97

118 Q 433

119 Centre for Patient Safety and Service Quality, Imperial College, commissioned research

120 Ev 187

Our survey responses suggested that the main reason Junior Doctors did not report adverse events was due to “lengthy and complicated reporting processes”. This, coupled with the heavy workloads of Junior Doctors, means that many doctors simply do not report events [...]¹²¹

Mr Fletcher acknowledged that reporting was less likely “if it is hard for people to report”, and one of the NPSA’s tasks was “making it simple” to report.¹²² One way of achieving this appears to be through Patient Safety Direct, which “will build on the National Reporting and Learning System and create a single portal nationally for reporting and learning”.¹²³

- **Fear of adverse publicity**

Fear of hostile media coverage of patient safety issues seems to be a factor discouraging openness and reporting. Ms Dheansa, the Matron from whom we took evidence, told us “The media can very much destroy morale on the ground floor [...] when you are working extremely hard in the interests of the patient and when it is spun round”.¹²⁴ Whilst the NHS itself sees increased reporting of patient safety incidents as a positive thing, indicating a better safety culture,¹²⁵ sections of the media assume that increased reporting must mean that more incidents are actually occurring and services are becoming less safe.¹²⁶ Such coverage in the local media, referring to reporting data for particular NHS organisations, could be particularly damaging, especially if it influences patients’ choice of service provider.

Lack of focus in the National Reporting and Learning System

106. The NRLS has been set up as an overarching, catch-all system that draws in summary data on all reported incidents, whether they are common or uncommon in type; and regardless of the extent of harm associated with them. Thus, it has accumulated outline information on many incidents of common types that are already well understood, such as slips, trips and falls by patients, which account for around one-third of all reports—around 280,000 per year.¹²⁷ And it has similarly accumulated basic information on many less serious (“No harm” and “Low harm”) events, of various types, to which 93% of reports relate—around 800,000 per year.¹²⁸

121 National Audit Office, commissioned research

122 Q 827

123 Q 829. In his interim report for the NHS *Next Stage Review*, Lord Darzi announced that the NPSA would be “establishing a single point of access for frontline workers to report incidents: Patient Safety Direct” (Department of Health, *Our NHS, our future: NHS Next Stage Review interim report*, October 2007, para 4, p 7).

124 Qq 447, 448

125 Q 822

126 See, for instance: “Mothers at risk on NHS blunder wards: ‘Substandard’ care claim as safety incidents double”, *Daily Mail*, 8 October 2008; “Deaths from hospital blunders soar 60% in two years as NHS staff ‘abandon quality of care to chase targets’”, *Daily Mail*, 6 January 2009.

127 Learning on this subject is summarised in National Patient Safety Agency, *Slips, trips and falls in hospital: The third report from the Patient Safety Observatory*, February 2007.

128 National Reporting and Learning System quarterly data, Issue 12, May 2009

107. It is a significant criticism of the NRLS that its approach to data collection is “wide and shallow”, whereas it should be “narrow and deep”. The latter approach, would entail focusing on gathering in-depth analysis of reported incidents that are less common in type and more serious in the degree of actual or potential harm associated with them. Such an approach is typical of safety-critical industries with well-established safety cultures, such as civil aviation and of patient safety reporting systems in other countries, such as New Zealand.¹²⁹ In both cases, root-cause analysis¹³⁰ is routinely deployed to provide in-depth analysis of serious and sentinel events.¹³¹ The NRLS only gathers data on “contributory factors” in incidents, and is not geared up to deal with the sort of detailed information generated by root-cause analysis. The NPSA has been actively promoting the use of root-cause analysis in the local investigation of incidents in the NHS, but there are doubts about how widely, and how well, it is used.

108. The apparent paucity of effective root-cause analysis in the NHS, along with other potential drawbacks of self-investigation by NHS organisations, raises the question of whether there ought to be something akin to the Air Accident Investigation Branch for healthcare. Mr Bromiley, the widower of a harmed patient who works in the airline industry, made a good case for such a body:

Health care is technically very complex and it requires proper investigation, for the sake of the clinicians let alone the patients. A clinician needs to know and have peace of mind that whatever they did there is no political influence from their bosses, somebody independent who is an expert will review their work and will look on it in a proper light and lessons can be learned and an independent investigative process is the best way forward.¹³²

109. When we asked Lord Patel about this, he seemed to stop short of endorsing the idea of a new independent investigation body, but he did agree that “The principle of having an independent inquiry for serious untoward incidents, particularly that might lead to serious harm or death, is important”. He pointed out that 10,000 such incidents were reported each year and it would require substantial resources to investigate them all. But he suggested this might be got round by setting clear criteria for in-depth investigation of incidents—for instance, those where there were likely to be particular lessons to learn and those involving “a never event—things that should not happen”. If necessary, those screening criteria could be set aside to allow other cases to be independently investigated. It was particularly important to “have the right people with the right skills carrying out these investigations”.¹³³

129 In New Zealand, we learned that the Ministry of Health’s Quality Improvement Committee has begun publishing, on an annual basis, detailed information on all serious and sentinel events (with details of patients and staff anonymised), broken down by local District Health Board.

130 Root-cause analysis is an investigative method that seeks to identify the underlying causes of an incident, with a view to preventing repetition.

131 Sentinel events are defined as those incidents that signal the need for immediate investigation and response, since they involve death or other serious injury, or the risk thereof.

132 Q 184

133 Q 815

Inherent limitations of reporting data

110. However good a reporting system is, it will never on its own capture all the data needed to identify the full range of patient safety issues and their solutions. Professor Thomson told us:

It is clear that whatever source of identification of patient safety incidents one uses, it is likely to provide a different profile of incidents [...] Several studies have demonstrated that the overlap between different sources is relatively small [...] This emphasises the need for systems of surveillance and monitoring that recognise the strengths and weaknesses of different sources of data and brings them together to capture a fuller picture of safety.¹³⁴

111. The Patient Safety Observatory (PSO) was created by the NPSA in 2004 as a “virtual observatory”, to “draw together information from different sources in new ways to quantify, characterise and prioritise patient safety issues”.¹³⁵ Professor Thomson, who was one of the architects of the PSO, explained to us that:

it had three components to it. Part of it was conceptual—you know, this is a public health approach and a way of thinking about data and information in a sensible way—part of it was about collaboration—it was bringing together people across organisations that had information, so getting people from the [Medicines and Healthcare products Regulatory Agency] and other organisations around the table to discuss common issues—and part of it was about a structure to deliver that. I think those three components are important. From a public health perspective, that is the way we should be taking it.¹³⁶

112. There are numerous sources of data and intelligence that need to be collated through the PSO to get as full a picture as possible of patient safety issues and solutions. These sources include the Yellow Card reporting scheme on adverse drug reactions, the Serious Adverse Blood Reactions and Events reporting scheme, the three national confidential enquiries, Hospital Episode Statistics, litigation data and complaints data.

Conclusion

113. After the expenditure of much effort and funding on the National Reporting and Learning System, clear progress has been made in incident reporting; but we are concerned that the NRLS is nevertheless still limited in its effectiveness.

114. We welcome the fact that the NRLS is now collecting significant amounts of data, which are being used to generate statistical and other output to help make services safer. However, we are concerned that there remains significant under-reporting, particularly in respect of incidents in primary care; medication incidents; serious incidents; and reporting by doctors.

134 PS 80

135 National Patient Safety Agency Fact Sheet—Patient Safety Observatory

136 Q 120

115. A major reason for under-reporting is the persistent failure to eliminate the “blame culture” in much of the NHS. Another important factor is fear of litigation or prosecution, underlining the need for the Government to address the medico-legal aspects of patient safety; we particularly recommend the decriminalisation of dispensing errors on the part of pharmacists. The “one size fits all” nature of reporting systems is also a significant problem. We welcome the NPSA’s recognition of the need to address this by developing reporting systems that are appropriate to different specialties (such as general practice and anaesthesia). We recommend that work on this be treated as a major priority by the Agency.

116. We believe that as much as possible of the data collected by the NRLS on reported incidents should be published, in the interests of openness and learning about patient safety. We, therefore, welcome the decision to start publishing this data broken down by individual NHS organisation.

117. While acknowledging the importance of incident reporting for patient safety, we question whether the NRLS, as presently constituted, is as useful and as cost-effective as it should be. The System currently amasses a good deal of summary data of doubtful usefulness, particularly on: common types of incident that are already well understood, such as slips, trips and falls; and less serious (“Low harm” and “No harm”) events, of various types. However, unlike reporting systems in other safety-critical industries, and in other healthcare systems, it does not systematically gather in-depth (root-cause analysis) data on serious and sentinel events. We recommend that consideration be given to rebalancing the NRLS accordingly. We also recommend that root-cause analysis be undertaken much more widely, and better, in the NHS in respect of serious and sentinel events in general and less common types of these in particular. We believe this might be facilitated by the establishment of a body along the lines of the Department for Transport’s Accident Investigation Branches, which could undertake independent root-cause analysis of serious and sentinel events in cases where there are likely to be significant new lessons to learn. In cases involving a patient’s death, this could have the additional benefit of providing their family with the full explanation that coroners do not seem always to provide. We recommend that the DH look into the feasibility of this.

118. No reporting system, however well it functions, can capture all the information about patient safety issues and solutions that is needed to help make services safer. Data must be collated from as wide a range of sources as possible. We acknowledge the work that the NPSA has already done in this regard, particularly through the Patient Safety Observatory, and we recommend that this should be made a major priority for the Agency.

6 Patient safety at the front line

119. In this chapter we consider some of the major factors in determining whether or not safety becomes deeply rooted in frontline services. In many cases, the measures needed to resolve specific safety issues have been identified and proven by research to work. However, all too often these measures are not implemented at the front line in the NHS as the PAC noted in 2006: “Patient safety alerts and other solutions are not always complied with though trusts self-certify that they have implemented them.”¹³⁷ Professor Sir Ian Kennedy, then Chairman of the HCC, told us:

If I could draw a distinction between what I would call structural responses, which have been quite significant, the creation of the NPSA, the National Patient Safety Forum¹³⁸ and other such exercises, Darzi’s review, and so on, contrast that with cultural changes and behavioural changes and I think they lag behind in translating ideas into reality.¹³⁹

120. There are, however, NHS organisations which have made significant and lasting improvements in safety, as we discuss below. We also look at proven solutions in the field of non-technical skills that have yet to be widely adopted in the NHS. We also consider how the safety of services can be undermined by a sheer lack of adequate staff numbers.

Empowerment and improvement

121. At Luton and Dunstable Hospital, we were most impressed by pioneering work that has demonstrated how frontline staff can be empowered to redesign services, making them both more efficient and safer. This hospital has made “clinical leadership” and “clinical engagement” into a reality, rather than just slogans. We were impressed by the recognition that improvement happens when staff see what needs to be done and seek to do it. The major barrier to improvement is the sense that change is being imposed, probably to advance the careers of those who seek to impose it.

122. We heard about the “transformational approach” at Luton and Dunstable Hospital, whereby ambitious goals have been set for the improvement of services, which are being achieved, not by diktat, but by motivating staff to take the lead in a process of “continuous improvement”. Data on deficiencies in services (derived from a case note review) were presented to staff, and volunteers came forward to participate in a patient safety improvement project. The hospital then became the exemplar site in England for the Health Foundation’s SPI programme.

137 Committee of Public Accounts, *A safer place for patients*, p 6

138 *Safety First* (2006) recommended the establishment of a National Patient Safety Forum to “harness the skills and expertise of a number of organisations, agencies and stakeholders which are making a significant contribution to patient safety” and run a “national patient safety campaign-focused initiative” (pp 24 and 25). The Forum began meeting in February 2007. The Patient Safety First Campaign for England began in September 2008, but the Forum does not appear to be running this.

123. SPI is a structured process for identifying and addressing patient safety and quality problems, drawing on the industrial management strategy of “lean” thinking.¹⁴⁰ This is also the basis for the “Productive Ward” programme,¹⁴¹ which was piloted at Luton and Dunstable Hospital, as we heard from frontline staff who had found it very worthwhile. This is being used in New Zealand, at Middlemore Hospital in Auckland, where it is known as the *Whai Manaaki* (“More time, Better care”) programme. We found this too very impressive. At Middlemore we spoke to nurses who had created significantly more time which could be devoted to better care for patients by thinking how they could reorganise their ward more sensibly. Much time was saved just by moving equipment to better locations.

124. At Luton and Dunstable Hospital, several “workstreams” were set in train, involving frontline staff in achieving a series of specific, measurable goals. An overall goal was set of reducing adverse events (as measured using case note review) by 50% and creating “a culture that puts patients at the centre of everything we do”.

125. In the Intensive Treatment Unit, we heard how goals had been set of a 50% reduction in central venous line infections¹⁴² and 95% compliance with the Central Line Bundle—a group of evidence-based interventions that, when implemented together, result in better outcomes than if they were implemented individually. This has resulted in a significant improvement, such that central line infections are now very rare and seen as exceptional occurrences, rather than a normal risk associated with this procedure, as senior clinicians had tended to see them at the beginning of the process.¹⁴³

126. Research into the application of “lean” thinking to the improvement of patient safety is currently being undertaken by the Quality, Reliability, Safety and Teamwork Unit at Oxford University. The Unit is looking at ways of bring about lasting improvements in safety on surgical wards by reducing recognised preventable complications, such as deep venous thrombosis,¹⁴⁴ which can be addressed by the thorough application of well-established standard prophylactic (preventative) measures. Although the research has yet to be completed, early results apparently show sustained improvement in deep vein thrombosis prophylaxis.¹⁴⁵

140 “Lean” thinking was developed by the Toyota motor company. It entails empowering and motivating shop-floor staff to streamline and improve processes, reduce waste, improve quality, and deliver products and services in a more timely way.

141 The “Productive Ward” was developed by the NHS Institute for Innovation and Improvement. It entails involving shop-floor staff in designing and implementing more efficient ways of working, bypassing conventional management chains of command.

142 A central venous line (or catheter) is a tube placed into a large vein in the neck, chest or groin to provide long-term access to the vein, for treatment and diagnostic purposes. Poor management of a central line can lead to a bacteraemia (bloodstream infection), prolonging length of hospital stay and, in some cases, causing the death of the patient.

143 A national initiative around this issue, starting in April 2009, was announced by Lord Darzi in his final report for the NHS *Next Stage Review* (Department of Health, *High Quality Care For All: NHS Next Stage Review Final Report*, Cm 7432, June 2008, para 55, p 45). This initiative (now called “Matching Michigan”) involves emulating a successful project in Michigan, in the USA; the NPSA has been working with Johns Hopkins Hospital on it (Ev 152 [National Patient Safety Agency]).

144 Deep venous thrombosis is the formation of a blood clot in a deep vein, which can be fatal; admission to hospital for some medical illnesses as well as for surgery is a risk factor for this condition. Risk assessment for all patients admitted to hospital would lead to appropriate preventative measures being taken for every patient.

145 Ev 123. See also Ev 93.

Teamwork and other non-technical skills

127. Safety science also encompasses the realm of “non-technical skills”, which have been shown to have a significant impact on patient safety. Non-technical skills are the cognitive and social skills (complementing technical skills—such as clinical skills in healthcare) that allow people working in safety-critical industries to function effectively and safely. (They are also often referred to as “Human Factors”).¹⁴⁶ Some examples of such skills are given in Box 11.

Box 11: Examples of non-technical skills

- teamwork / team coordination;
- communication;
- leadership;
- decision making;
- conflict resolution;
- assertiveness;
- coping with stress and fatigue;
- workload management;
- prioritisation of tasks;
- situation awareness.

128. Many people will use non-technical skills intuitively alongside their technical skills. However, others (who may be highly competent in technical terms) will need to be taught non-technical skills. They may assume that advanced technical skills are sufficient for safe practice and not see the need to learn another set of skills for which they have little or no natural aptitude.

129. The importance of non-technical skills has long been recognised in other safety-critical industries, such as civil aviation. Healthcare, however, is seen as lagging behind in this regard, despite the fact that analysis of adverse events and psychological research both show that proficiency in non-technical skills contributes significantly to enhanced technical performance, reduced error and improved safety.¹⁴⁷

130. Non-technical skills have become increasingly important in medicine in recent decades as healthcare has become much more complex and dependent upon invasive

¹⁴⁶ Strictly speaking, the term “Human Factors” has a much broader definition than non-technical skills. The Health and Safety Executive defines Human Factors as “environmental, organisational and job factors, and human and individual characteristics which influence behaviour at work in a way which can affect health and safety” (www.hse.gov.uk/humanfactors).

¹⁴⁷ Q 666

technology with greater scope for things to go wrong and cause harm. The growing complexity of medicine has been accompanied by increasing specialisation among clinicians and greater devolution of knowledge, skills and responsibilities within clinical teams. These developments make effective teamwork in healthcare all the more crucial to safety and effectiveness. Rigid and narrow professional hierarchies, once the norm in clinical practice, need to give way to new modes of working, characterised by a “flat hierarchy”. Safe and effective healthcare depends increasingly on close interdisciplinary teamwork between a range of clinicians and other healthcare workers.¹⁴⁸

131. The evidence we received from two trainers in non-technical skills illustrates how far the NHS has yet to go in this respect:

We have established a collection of case studies from our own observations with distinct and discrete details of specific behaviour of hospital professionals. Some of these are highly effective and contribute to patient safety, some do not. These include distraction of surgical team during a complex operation with loud rock music in theatre by a senior consultant surgeon; rudely ignoring safety-related inputs from junior team members; absence from theatre of critical team members without announcing the fact; refusal to discuss surgical accidents with other team members and many more.¹⁴⁹

132. The trainers, Trevor Dale and Guy Hirst, are both retired airline Captains who have been involved since 1990 in non-technical skills training, using the civil-aviation “crew resource management” model. They state in their evidence that “Despite the many overtures by those responsible for Healthcare in the United Kingdom the understanding of the importance of Human Factors is negligible”. They point out that, while Human Factors training has become mandatory in the aviation industry, this is not the case in healthcare. They particularly recommend the use of “briefing and debriefing” of teams engaged in safety-critical tasks.¹⁵⁰

133. As previously mentioned, the Quality, Reliability, Safety and Teamwork Unit at Oxford University is currently conducting research on the effectiveness of interventions to improve patient safety. As part of this research, the Unit studied a surgical team before and after its members had participated in a training programme based on civil-aviation principles (Crew Resource Management). This showed an improvement in teamwork and a reduction in technical errors by addressing deficiencies in non-technical skills—but strong cultural resistance to the new way of working meant change was not sustained.¹⁵¹

134. The memorandum submitted by the Clinical Human Factors Group cites further evidence of the connection between teamwork skills and error rates:

Studies in paediatric cardiac surgery at Great Ormond Street [Hospital for Children] showed a clear correlation between the quality of teamwork and the frequency of technical and procedural errors in operations [...] and this has been confirmed by

148 Ev 121

149 Ev 95 [Guy Hirst and Trevor Dale]

150 Ev 94, 95

151 Ev 122

the [Quality, Reliability, Safety and Teamwork Unit] in Oxford [...] Not surprisingly, operations where there are a large number of minor technical errors are more likely to result in a serious major problem.

135. The Group refers to the case of Elaine Bromiley, who died while receiving treatment in the private sector. Her death was attributable to “Failings in leadership, decision-making, prioritisation, situational awareness, communication and teamwork” among clinicians:

These same “human factors” are the direct cause of 75% of aviation accidents. Many safety critical industries refer to these [non-technical skills] yet no member of this team, and virtually no clinician in the UK receives any training in these vital skills. There is a clear correlation between [Human Factors] skills and the frequency of error in operations. Minor errors are frequently tolerated but they are significant as they accumulate to cause major hazards. Minor errors must be recognized and reduced by [Human Factors] training.¹⁵²

136. Mrs Bromiley’s widower, Martin Bromiley, a commercial pilot who chairs the Group, told us about his wife’s case and explained how it illustrated the difference between healthcare and the airline industry. Mrs Bromiley died of a recognised anaesthetic emergency (“can’t intubate, can’t ventilate”), for which established guidelines exist. The team were technically competent to respond, but lacked the situation awareness, and the personal and team organization, needed to deploy their undoubted technical skills to do what was required.¹⁵³

137. Another issue raised by the Group was the importance for patient safety of routine checking in the context of surgery:

Routine surgical and anaesthetic checks are not carried out, equipment problems are frequent and adherence to basic procedures is variable [...] In the absence of pre-operative checks, crucial equipment and prostheses are missing in many operating theatres.¹⁵⁴

We heard that checklists have long been used in civil aviation, and are an important part of the Human Factors approach to safety that has become so well-embedded in that industry.¹⁵⁵

138. In light of the evidence of widespread failure to use checking processes in surgery, the World Health Organization (WHO) has developed a Surgical Safety checklist, for use at three points during an operation:

- before the patient is offered anaesthesia (“Sign In”);
- before any skin incision is made (“Time Out”); and

152 Ev 91

153 Q 165 ff.

154 Ev 92

155 Qq 78, 684

- before the patient leaves the operating theatre (“Sign Out”).

At each of these points, a checklist coordinator must be permitted to confirm that the team has completed its tasks before it proceeds any further. The primary aim of using the list is to target the three biggest cause of mortality in surgery:

- preventable infections;
- preventable complications from bleeding; and
- lack of safety in anesthesia.

139. The checklist was launched in June 2008 as part of the WHO World Alliance for Patient Safety “Safe Surgery Saves Lives” initiative. It was trialled in eight pilot sites across the world (one of which was St Mary’s Hospital, London) during 2007–8; and the results of the trials were published in the *New England Journal of Medicine* in January 2009. The NPSA subsequently issued a Patient Safety Alert, requiring “healthcare organisations in England and Wales to implement the WHO Surgical Safety Checklist (adapted for England and Wales) for every patient undergoing a surgical procedure” by February 2010.¹⁵⁶

140. We were told by John Black, President of the Royal College of Surgeons of England, that:

Lots and lots of hospitals have had safety check lists for a long, long time and when the original WHO 15-point one came up with the College council, most people said, “But we have got far more rigorous ones in use in our hospital at the moment.” For example, in my own hospital in Worcester you would not have got through the theatre door on that check list; it is far more rigorous. Clearly, remember, this is designed for international use, but it is a good thing because you cannot be too careful on the real basics. Of course it will be accepted by surgeons, and it does not take much time to do, and we have given it our full support.¹⁵⁷

141. However, we heard from National Concern for Healthcare Infections that:

Unfortunately some surgical staff oppose the use of such checklist as denigrating their professional expertise and have drawn comparison with motor mechanic worksheets.¹⁵⁸

142. We were also informed by Dr Kreckler about adherence to the NPSA’s 2005 Patient Safety Alert on Correct Site Surgery, which mandated a form of checklist.¹⁵⁹ He stressed the importance of empowering and involving staff in ensuring uptake of patient safety solutions:

Q 503 Sandra Gidley: In your experience are [checklists] always used?

¹⁵⁶ www.npsa.nhs.uk/nrls/alerts-and-directives/alerts/safer-surgery-alert/

¹⁵⁷ Q 354

¹⁵⁸ Ev 33

¹⁵⁹ The Correct Site Surgery Alert (March 2005) mandates measures to ensure that operations are carried out on the correct site in the patient’s body. It was superseded in February 2009 by the Alert mandating use of the WHO checklist.

Dr Kreckler: [...] The short answer to that is no. The reason for that really depends on the way in which this initiative is implemented locally. It depends on those who require to use it to understand the purpose of it, if they are adequately trained and educated and the fact that we have evidence behind this [...] They were required by the NPSA towards the end of 2005. This requires that you sign a box when the patient is first consented, when they leave the ward, when they arrive in the anaesthetic room, and just before the operation starts, to confirm that you have the right patient, the right operation, and that it is the right side. I certainly know of situations where I have seen the scrub nurse bring a form down to the coffee room, to be signed by a surgeon in the coffee room rather than the surgeon going to check the patient in the room. These are not bad surgeons, these are not people who are flippantly ignoring safety protocols, they simply do not appreciate the purpose of the form because they have not been adequately trained. [...]

Q 505 [...] Dr Kreckler: [...] [U]nfortunately, it is the way these things are implemented [...] It is not going to happen with a big stick and a diktat because you automatically get resistance to that. Certainly, the way the Saves Lives surgery was implemented in my experience, was that it was done one day: “This is what you’re going to do from tomorrow” and everyone was, “Oh, another box-ticking exercise.” There was no explanation, nothing to back it up. If it is done properly, I think everyone will do it and will embrace it. I think that, with time, it will become part of the culture and will be done anyway.

We heard a similar view from Captain Hirst:

It is no good saying “use a checklist”, people have to understand it has to be sympathetically introduced with the right sort of training to know why you are using it, how you are using it. I do not think just saying, “Use that, everything will be okay”, will work. I am concerned that in some hospitals we go to they are bringing in sensible programmes to introduce it and in others it is almost by email, “From next week you will use a checklist” and I do not think that will work. That is my concern, that a “from on high” downwards diktat is not the way to really get serious change.¹⁶⁰

Staffing levels

Shortages of staff

143. Despite the huge increase in the number of staff in the NHS, there is evidence that inadequate staffing levels in some cases have been a significant factor in undermining the safety of care. The HCC stated that:

Having the right number of competent staff is key to safety. A number of commission reviews have looked at this area. For example our recent review of maternity services found that levels of staffing were well below the average, indicating that they may have been inadequate [...] Our 2007 review of children’s hospital services found that in a small number of hospitals (12%), there was

insufficient cover during the day to ensure that effective paediatric life support was available in serious emergencies. At night, this figure rose to 18%. Our review of day surgery found it was common that a child trained nurse was not always available when children were being treated.¹⁶¹

144. In investigating the major lapses in safety at Stoke Mandeville Hospital, Maidstone and Tunbridge Wells Trust, and Mid-Staffordshire Trust, the HCC found that understaffing had been a key factor (see Box 12).

Box 12: Illustrative extracts from HCC investigation findings on understaffing

Stoke Mandeville Hospital, Buckinghamshire Hospitals NHS Trust

Low levels of staffing made it particularly difficult for nurses to find time to practise good hand hygiene, to answer call bells and empty commodes promptly, to clean mattresses thoroughly, to use new or properly cleaned equipment for each patient, to wake patients to give them their antibiotics, to complete fluid balance charts and to supervise confused patients who wandered in and out of isolation areas.¹⁶²

Maidstone and Tunbridge Wells NHS Trust

The medical and surgical wards at the trust had a history over at least three years of low staffing levels and a relatively low proportion of qualified nurses [...] Staff across several professions commented that shortages of nurses contributed to the spread of infection because they were too rushed to communicate with their colleagues, wash their hands, wear aprons and gloves consistently, empty and clean commodes and clean mattresses and equipment properly.¹⁶³

Mid-Staffordshire NHS Foundation Trust

Receptionists were responsible for assessing any patients who did not arrive by ambulance. This was as a consequence of having too few trained nurses to maintain consistent triage [...] [Staff] described the EAU [Emergency Admissions Unit] as “dreadfully understaffed” [...] Patients and relatives of patients who had been treated on the EAU had a general impression that the unit was short-staffed [...] [P]atients reported not getting basic care, such as washing and being escorted to the toilet. There was a lack of support noted for patients needing help to eat [...] One patient told us that EAU was generally chaotic, filthy and there was a lack of basic hygiene control; for example he did not see any hand washing.¹⁶⁴

161 Ev 205

162 Healthcare Commission, *Investigation into outbreaks of Clostridium difficile at Stoke Mandeville Hospital, Buckinghamshire Hospitals NHS Trust*, July 2006, p 9

163 Healthcare Commission, *Investigation into outbreaks of Clostridium difficile at Maidstone and Tunbridge Wells NHS Trust*, October 2007, p 108

164 Healthcare Commission, *Investigation into Mid Staffordshire NHS Foundation Trust*, March 2009, pp 43 and 58

145. Other cases where staffing levels have been an issue are referred to in the Commission's document *Learning from Investigations* (2008), to which we were referred by Professor Kennedy.

European Working Time Directive

146. An additional issue regarding staffing levels is posed by the likely impact on safety of new European Working Time Directive (EWTD) rules, due to be introduced from 1 August 2009, under which junior doctors will not be allowed to average more than 48 hours per week on call except in certain limited circumstances. We heard from the Royal College of Surgeons of England that this will lead to inadequate cover at evenings and weekends, and multiple handovers of patients, which will be detrimental to patient safety. In addition, it will take longer for a surgeon to obtain the experience needed to become fully trained. Mr Black, President of the Royal College, told us this was:

the biggest threat to patient safety and, not only that, to delivery of service for a long, long time [...] [W]e anticipate significant service failures [...] Next summer, if this is implemented, there are many hospitals and units that will not be able to provide a service and will be closing [...]¹⁶⁵

The Royal College argued that the Government should opt out of the EWTD to allow junior doctors to work a 65-hour week on-call with adequate rest breaks.

147. Lord Darzi responded that the EWTD was in fact a means of protecting patients from being harmed by overtired surgeons.¹⁶⁶ The Minister of State for Health Services, Ben Bradshaw MP, told us that “tired doctors are not only dangerous for patients but they are dangerous for doctors”. He was “confident that the health service would be in a position to implement this. It will require the re-organisation of services in some hospitals”.¹⁶⁷ Professor Keogh, the NHS Medical Director, did not agree that there would be “a disaster” on 1 August, but he did think “it is going to be very challenging”. He reported that a working group on derogation from the Directive was considering 220 applications from services to derogate on grounds of “physical reorganisation of plant or services” or “difficulties of recruitment into some specific specialities”. Regarding the impact on training, the Postgraduate Medical Education and Training Board was being commissioned to look at this.¹⁶⁸

Conclusion

148. Too often known patient-safety solutions fail to be adopted in the NHS even when they are disseminated by means such as Patient Safety Alerts. They are handed down from on high as diktats (if they are passed on at all) without frontline clinicians being convinced of their effectiveness. Moreover, a culture persists in which various types of

165 Q 373

166 Q 894

167 Q 1108

168 *Ibid.*

harm to patients are seen as inevitable when in fact they are avoidable if the right steps are taken.

149. Some organisations, however, have shown that it is possible for improvements to be fully integrated in frontline services by engaging and involving clinicians, and other healthcare workers. The focus needs to be on tangible improvements to health, drawing on staff's own initiative.

150. "Lean" thinking, using the initiative of frontline staff to increase efficiency and use time more effectively, is beginning to be introduced into the NHS through schemes such as the Productive Ward programme and the Safer Patients Initiative. This approach has much to commend it. If less efficient ways of working can be eliminated then more can be achieved and standards of care raised.

151. Lack of non-technical skills can have lethal consequences for patients. However, the NHS lags unacceptably behind other safety-critical industries, such as aviation, in this respect. Human Factors training must be fully integrated into undergraduate and postgraduate education, as we discuss more fully below.

152. Routines and, in particular, checklists are an important aspect of safety in healthcare as in other activities. We welcome the implementation of the World Health Organization Safe Surgery checklist. While similar measures are already used in NHS hospitals, we are concerned that such checklists are not always followed because clinicians regard them as diktats and do not always see the point of them. We recommend that clinicians who persistently disregard these checklists should undergo retraining.

153. Despite the massive increase in the numbers of NHS staff in recent years, inadequate staffing levels have been major factors in undermining patient safety in a number of notorious cases. It is clearly unacceptable for care to be compromised in this way. NHS organisations must ensure services have sufficient staff with the right clinical and other skills.

154. Regarding the new European Working Time Directive rules, we are not convinced by the more alarmist claims being made that these will seriously jeopardise patient safety when they are introduced on 1 August 2009. But we do seek assurance from the DH that everything possible is being done to ensure that safety is not compromised. Professor Sir Bruce Keogh, the NHS Medical Director, did agree that 1 August "is going to be very challenging" and he told the Committee that derogation for some services and the impact on training were being looked into further.

7 Technology and patient safety

155. All forms of healthcare involve the extensive use of technology; and medicine continues to change dramatically as a result of both the refinement of existing types of technology and the development of new forms. Innovative clinical techniques (in diagnosis, medication and surgery alike) have transformed many aspects of clinical practice, reducing the risks and increasing the benefits of almost all types of medical intervention.

156. However, the complexity and power of modern, high-technology healthcare brings with it increased scope for things to go wrong, and for adverse events to have very harmful consequences. Moreover, the introduction of new clinical techniques can pose a risk to patients when their introduction is not accompanied by appropriate training or they are not properly integrated into clinical pathways. Professor Bryony Dean-Franklin, Director of the Centre for Medication Safety and Service Quality at Imperial College Healthcare NHS Trust, outlined in her evidence some of the main potential drawbacks associated with technology.

- Over-reliance on the technology to check for errors, and assuming that the technology is more effective than it actually is, and so decreasing personal vigilance
- Development by staff of work-arounds to avoid safety features
- New types of error introduced, eg errors when selecting from pull-down menus
- Introduction of additional steps into work processes
- Failure of the computer system
- Deskillling [of healthcare professionals]
- Assumption that the technology is more advanced than it is—eg assuming that a computer system includes decision support where none exists.¹⁶⁹

157. Nevertheless, properly used, technology can greatly improve patient safety. Some new technologies are less invasive and reduce the potential for harming patients. Other forms of technology might reduce the types of error classified as “slips and lapses” or “failure to carry out a planned action as intended”. The automation of various processes in healthcare could reduce, or perhaps even eliminate, a number of errors that are attributable to causes such as failures in memory and lapses of attention on the part of both clinical and non-clinical healthcare workers. This could apply to areas where the accurate carrying out of tasks such as checking and measuring is crucial to patient safety.

158. A number of such innovations have been successfully piloted in parts of the NHS, but witnesses were concerned that their adoption throughout the service was unnecessarily delayed.

Automated decision-support

159. We heard from Dr Olga Kostopoulou, of the Medical Decision Making Research Group at Birmingham University, that a possible solution to the problem of diagnostic error in general practice was greater use of automated decision-support systems, which can help GPs ensure that they do not miss less common diagnoses.¹⁷⁰ We also heard that automated prescribing-support systems, such as drug interaction programmes, offer great potential for making prescribing safer and are already being successfully used by many GPs. As we saw during our visit to Charing Cross Hospital, such systems also have an application in the acute setting, although we were concerned to find in this particular case that the alerts had been switched off.

160. Automated decision-support systems would be even more useful if National Institute for Health and Clinical Excellence (NICE) guidance could be integrated into them. The Chairman of NICE, Professor Sir Michael Rawlins, gave us an encouraging account of the development of NHS Evidence for this purpose—although the system does not yet allow for the automatic interaction of NICE guidance with patients' records.¹⁷¹

Automatic Identification and Data Capture

161. Automatic Identification and Data Capture (AIDC), including barcoding, has the potential to reduce errors during routine tasks requiring accuracy, such as checking and measuring.¹⁷² The benefits of AIDC technology were outlined in 2007 in the DH's *Coding for Success: Simple technology for safer patient care* (see Box 13). During the inquiry we looked at a number of areas where barcoding could bring such benefits.

Box 13: Potential benefits of Automatic Identification and Data Capture technology, such as barcoding

Verification – a major application of AIDC is to verify the identity of an item, person or procedure and link this with the member of staff involved in patient care. A hand-held computer with a built-in scanner can be programmed with protocols for procedures such as blood transfusion [...]

Data capture – there are many situations where serial numbers or reference numbers need to be entered into electronic records. Using AIDC to enter the information eliminates the risk of manual keystroke errors [...]

Supply chain issues – effective track and trace of goods improves stock control so the right supplies are available in the right place at the right time. Unique product codes can be used on individual high-value items as an anti-counterfeit measure. Linking patients to the supply chain—by recording product information on patient records—can help to identify batches where a patient or patients have had an adverse reaction.¹⁷³

170 Q 647

171 Qq 857–858

172 AIDC technology encompasses the use of barcodes, radio frequency identification and other machine-readable codes to identify quickly and accurately an item or process.

173 Department of Health, *Coding for Success: Simple technology for safer patient care*, February 2007, para. 2.4, p 7

162. A number of schemes in New Zealand have shown the benefits of AIDC. The New Zealand Medication Safety Project has produced benefits by introducing bedside verification of prescriptions using barcodes.

163. In Auckland we met Professor Alan Merry, who has developed the use of barcoding technology for double-checking anaesthetic drugs in operating theatres with considerable success. This is now being piloted in the UK, as the DH told us:

The NPSA, in collaboration with the Royal College of Anaesthetists is currently undertaking a qualitative study into the feasibility of introducing double checking procedures to improve the safety of the administration of injectable anaesthetic drugs. As part of this study bar coding technology that has been developed by Professor Alan Merry in New Zealand is being piloted in two hospitals in the UK.¹⁷⁴

164. During our visit to Charing Cross Hospital, we saw how barcodes could be used to automate drug dispensing and administration. The hospital uses a pharmacy-based dispensing robot, which is essentially an automated picking mechanism in a closed cupboard, handling medicines by means of barcodes. Use of the dispensing robot avoids picking errors (*e.g.* picking the wrong drug because of identical packaging or similar drug names)¹⁷⁵ and allows for better use of space (as the robot requires less room to move around than a person does). While there is still some scope for errors to occur and it remains essential that staff continue to check and do not assume that the robot makes any error impossible, use of the robot has been proven to reduce the level of errors overall.

165. The hospital also uses CII Safe, an automated dispensing system utilising barcodes for the administration, documenting, storage and ordering of controlled drugs, such as morphine.

166. We also saw at Charing Cross Hospital a pilot project for electronic prescribing, automated dispensing on the ward and barcode verification of patient identity (the ServeRx closed-loop system). There is still scope for error to occur; for example, in the USA problems have occurred where these systems have been used by an unskilled workforce, accustomed to assuming that the system is always right. Nevertheless, by almost completely doing away with handwritten prescriptions, the Charing Cross Hospital system helps eliminate illegible prescriptions, lack of information from the prescriber, and nonsense prescriptions—dramatically reducing drug administration errors.

167. Professor Mike Murphy heads a team at the Oxford Radcliffe Hospitals NHS Trust that has used barcoding to transform how blood for transfusion is handled. He explained that this project had been a proven success, in terms of both safety and saving money—yet it still had not been implemented throughout the NHS. His team had been funded by Connecting for Health to write a national specification, but this was still being trialled (at the Mayday Hospital in Croydon). Professor Murphy told us that “we have all been

174 PS 01A. See also Ev 269.

175 We heard from Professor Brian Toft about look-alike medicines (where different drugs or dosages are similarly packaged) and sound-alike medicines (drugs with similar sounding names) and the apparent reluctance of manufacturers to change their packaging (Qq 221, 266).

incredibly frustrated about how slow [the pilot] has been”.¹⁷⁶ He identified underlying causes of delay as follows:

[T]here are huge financial barriers [...] Finance for the equipment is one; finance for the training is another. There are IT connectivity problems within hospitals, between patient administration systems and laboratory systems and other systems within hospitals. We would like to use the NHS number [for patient identification purposes], but we have problems with that [...]¹⁷⁷

168. We questioned the DH about the failure to make more progress. The Department has recommended that the GS1 system¹⁷⁸ should be adopted as the universal standard for AIDC technology throughout the NHS in England, both for manufactured products and for coding systems used within healthcare settings, such as patient identification codes on wristbands.

169. The DH had promised to review progress in the implementation of *Coding for Success* by the end of 2008. However, we were told by Ann Keen MP, Parliamentary Under Secretary of State at the DH, that the NHS Procurement e-Enablement Programme, which had not been envisaged when *Coding for Success* was published, was “starting to drive uptake of coding” and so the Department had “decided that it was no longer appropriate to undertake a review in 2008”.¹⁷⁹

Electronic Patient Record

170. As we noted in a previous report:

Storing and transferring patient information electronically has the potential to significantly reduce clinical errors and improve patient safety as well as allowing clinicians to communicate more quickly and accurately and to identify relevant information more easily.¹⁸⁰

171. During that inquiry we saw how the successful implementation of the Millennium Patient Administration System at Homerton Hospital in London had made services safer for patients. More recently, when we visited St Thomas’ Hospital in London, we saw the application of electronic records in the A&E care setting, where the Symphony system (specifically designed for emergency care) is in use. In both these cases, however, their systems are free-standing and not yet networked with the rest of the NHS, not even with local general practices—at St Thomas’ we heard that the only way for patients’ GPs to see the records is for them to be printed off in “hard copy” and put in the post. Networking of records between all care settings is vital if computerisation is to facilitate better continuity of care between acute and primary care sectors to address acknowledged risks such as poor medicines reconciliation.

176 Q 302

177 Q 308

178 “GS1 is a neutral, not-for-profit standards organisation developing global supply chain standards and facilitating the adoption and implementation of such standards” (Ev 181 [GS1]).

179 PS 01B

180 Health Committee, Sixth Report of Session 2006–07, *The Electronic Patient Record*, HC 422-I, para 1

172. The creation of an Electronic Patient Record (comprising a Summary Care Record and a Detailed Care Record) that is universally accessible throughout the NHS has been the objective of the Care Records Service element of the NHS National Programme for IT. We noted in our report on the Electronic Patient Record that implementation of the Care Records Service had fallen significantly behind schedule, for a number of reasons. And the NAO has since reported that:

Current indications are that it is likely to take some four years more than planned—until 2014–15—before every NHS Trust has fully deployed the care records systems.¹⁸¹

Technical solutions to preventing catastrophic disasters

173. We heard from Professor Brian Toft about his inquiry (on behalf of the CMO) into the death of Wayne Jowett, a patient who died in 2001 when an anti-cancer drug (Vincristine) was mistakenly injected into his spine instead of into a vein. In summarising his findings, Professor Toft explained that there was a simple solution to this problem:

You can connect any Luer¹⁸² syringe to a spinal needle, which meant that Vincristine could be put into his back. Once they got to that stage, that was it, finished. One of my recommendations was they should change the technology and design a spinal needle to which a Luer syringe could not be connected. That seemed to me to be a reasonable way to progress. Since that point in 2001, and we are now in 2009, we still have not got that connector. There has been a lot of reasons for this. In the first instance, although I have had no close supervision of it, there is the commercial interest—who will be the manufacturer who would be prepared to put money into creating such a syringe—and, then, will the medical profession buy it? The next thing, of course, would be the designing of the syringe—how would we design it—and then a whole range of other issues surrounding whether professionals will be prepared to use it when they are used to using their own methodologies. Would the needle work in the way it is supposed to do? What about the law of unintended consequences? In systemic terms, will the creation of this create another problem in another area and lead to a patient death for another reason? And so forth. It has been those kinds of things. I did ring the Department of Health yesterday and ask them how we were doing, as the saying goes, and they said they had some prototypes that they were working on now and they hoped, within the not too distant future, they would have a suitable solution to that problem. Of course, I cannot say how long the future is.¹⁸³

174. The NPSA has been consulting on a draft “purchasing for safety initiative”, requiring healthcare organisations to use neuraxial (spinal) syringes / needles and infusion systems with connectors that will not connect with intravenous devices. It is intended that NHS bodies will be required to act on this by 2011. The intention is apparently to stimulate both

181 National Audit Office, *The National Programme for IT in the NHS: Progress since 2006*, HC (2007–2008) 484–I, para 13

182 Luer connection systems are the standard way of making leak-proof connections for devices such as syringes, catheters and intravenous tubes.

183 Q 219

the medical devices and pharmaceutical industries to produce this type of connector, possibly ahead of the new International Organization for Standardization Industry Standard (ISO) for small-bore (non-Luer) connectors for neuraxial and other medical devices.

175. Unfortunately, no manufacturer has to date begun production of such a simple yet life-saving gadget.¹⁸⁴ This may be in part because the ISO standard has still yet to appear nearly a decade after a European Standards Agency Task Force recommended in 2000 that Luer connectors be restricted to intravenous and hypodermic devices.

Conclusion

176. While the potency and complexity of modern technology mean that it carries great potential for harm, it can also make a major contribution to patient safety. During the inquiry we took evidence about a number of technologies which could make significant improvements to care but which were being implemented far too slowly.

177. Automated decision-support systems can help improve patient safety, notably in primary care. We note the slow progress made in integrating National Institute for Health and Clinical Excellence guidance into such systems and recommend that a timetable be set for achieving this.

178. Electronic prescribing-support systems should be introduced throughout the NHS and set up with the alerts feature appropriately configured.

179. Automatic Identification and Data Capture technology, such as barcoding, has the potential to reduce significantly certain types of error. Impressive pioneering advances, such as those in relation to blood transfusion at Oxford Radcliffe Hospitals NHS Trust and to medication at the Charing Cross Hospital, have been made in this respect, but we have grave concerns about their slow uptake across the NHS. We are concerned at the DH's decision not to review progress on *Coding for Success*. Its reasons for not doing so are unacceptable in view of the slow progress to date.

180. The continued delay in the Electronic Patient Record also represents a huge missed opportunity to improve patient safety by improving the communication of clinical data (particularly between care settings), which would reduce administrative errors and facilitate better continuity of care.

181. We are alarmed at the lengthy delay in implementing Professor Toft's 2001 recommendation regarding the development of spinal needles that cannot be connected to a Luer syringe. It is totally unacceptable that an identified and simple technical solution to a catastrophic problem should take so long to be put into practical use. The Chief Executive of the NHS must explain why this delay has taken place and ensure that such delays never occur again. It is unacceptable that the NHS does not have a mechanism to ensure that changes such as this, which impact seriously on patient safety, occur in a timely fashion.

¹⁸⁴ Since giving evidence, Professor Toft has informed us that one company may soon be able to begin production (PS 83B).

8 Education and training curricula

182. Our inquiry revealed that there are obvious deficiencies in medical curricula in several specific respects that are to the detriment of patient safety. In this chapter we discuss these; and we look at the broader question of the place that patient safety occupies in the education and training curricula of healthcare workers.

Non-technical skills

183. We have already noted that deficiencies in non-technical skills are a significant patient safety issue in the NHS. Education and training clearly have a big part to play in addressing this, as the Clinical Human Factors Group told us:

Training in [Human Factors] skills such as teamwork and communication is virtually absent in healthcare. It should be mandated by regulation, taught and examined. The appropriate professional bodies should be active partners in examining and assessing competencies in non-technical skills (NTS) and [Human Factors] for both trainees and qualified staff. Those who work together should train together. Research has shown that teamwork training may reduce technical errors by 30–50% [...] Effective education must be supported by regulation, an appropriate curriculum, time, and money. It also requires a workforce of trainers who have been selected and trained to teach. It must also be quality-assured, assessed and examined. In the generic and critically important field of [Human Factors] none of this has taken place.¹⁸⁵

184. Captain Hirst and Captain Dale likewise advocated that “training of non-technical (teamworking) skills should be introduced immediately at all stages of medical education and across all disciplines”.¹⁸⁶

Clinical pharmacology and therapeutics

185. As we have mentioned, there is significant evidence that adverse drug events are widespread. Although errors can occur in the dispensing and administration of drugs, research indicates that there is a particular problem with prescribing. For some time, clinical pharmacology experts have been arguing that the undergraduate medical curriculum does not offer sufficient teaching in prescribing and appropriate use of medicines. The consequence is said to be significant potential for error and harm to patients. We heard from David Webb, Professor of Therapeutics at the University of Edinburgh, that, although there were now many more drugs available for doctors to prescribe, medical students were receiving less training than they once did in prescribing. This was partly due to the undergraduate curriculum (*Tomorrow's Doctors*, introduced in 1993) excluding the study of clinical pharmacology and therapeutics, and partly due to the

185 Ev 90, 93

186 Ev 95

lack of a practical element in the curriculum (which would allow students to prescribe under supervision).¹⁸⁷

186. Professor Webb also told us that the General Medical Council (GMC) had now acknowledged this was an issue. However, Finlay Scott, the Chief Executive of the GMC, indicated that it had not yet been decided how to address the problem in the revised version of *Tomorrow's Doctors*. He cautioned against “rush[ing] to the conclusion that the solution to the perceived problem lies in more teaching of pharmacology per se”.¹⁸⁸

Diagnosis in general practice

187. We have already noted that delayed or missed diagnosis in general practice is a significant problem, generating many complaints and claims against GPs. Dr Kostopoulou, who has been researching this topic, told us that “prompt and accurate diagnosis of serious conditions in primary care [...] is a very difficult job and sometimes it is not done well”.¹⁸⁹ Experienced GPs tend to diagnose in an intuitive way, based on the types of case that they see most often. Whilst this is an effective and productive way of diagnosing in the great majority of cases, it can lead to delayed or mistaken diagnosis when a patient presents with a condition that is “slightly less common but more serious”.¹⁹⁰

188. According to Dr Kostopoulou, one solution to this is better medical education and training: “There are ways of getting them to become more aware of those situations, possibly through education and training, so we can ‘de-bias’ the way people think.”¹⁹¹ This would include simulation of clinical situations, using “computerised scenarios” (analogous to the use of flight simulators in aviation); and teaching “how to diagnose formally, how to form differential diagnoses, how to test diagnoses”.¹⁹²

Root-cause analysis

189. We have already noted the limited extent to which root-cause analysis is used in investigating patient safety incidents in the NHS. Professor Toft, who is developing a postgraduate course in root-cause analysis at Coventry University, told us that skills in this regard were widely lacking and advocated that:

It should be in medical student training. Right from the very beginning that they start their training there should be a gradual build up of notions of error, how human error is created, how the whole system works together, how it leads to the creation of errors but, most importantly, everybody should be told directly that nobody is perfect—nobody.¹⁹³

187 Q 392

188 Q 747

189 Q 623

190 Q 644

191 *Ibid.*

192 Q 648

193 Q 226

Patient safety in education and training curricula

190. The Quality, Reliability, Safety and Teamwork Unit at Oxford University have concluded from their research that the conventional model of medical training actually ingrains in healthcare workers a culture that is inimical to safer ways of working:

Repeated experience [...] reports strong negative staff reactions and resistance to practice change [...] the problem appears to be rooted in the professional ethos of healthcare workers. The professional model for patient care assumes that individuals have a moral duty to ensure that no harm befalls each individual patient. It follows from this that the direct carers for a patient are individually and completely responsible for all aspects of their care, and that they are expected to be alert, vigilant and in full possession of all the relevant information at all times. How to achieve this is taught through an apprenticeship learning system, following the practices of respected and experienced practitioners.¹⁹⁴

191. Reverend Dr Pauline Pearson, Deputy Director of CETLAHealthNE: Centre for Excellence in Healthcare Professional Education at Newcastle University, told us about *Patient safety in health care professional educational curricula: examining the learning experience*. This was a major research project, involving five universities, which examined the pre-registration education curricula of doctors, nurses, physiotherapists and pharmacists.

192. Dr Pearson stressed the importance of: clinical educators as role models; encouraging students to challenge unsafe practice; appropriate clinical placements for students; and interdisciplinary education, with different clinical groups training together, to help facilitate good teamworking.¹⁹⁵ She told us patient safety was:

taken seriously by people providing courses for all the health professions that we have looked at, but it is often implicit rather than explicit, so it is there in the curriculum but it is not always made clear or clearly assessed.¹⁹⁶

193. The junior doctors and nurses from whom we took oral evidence were agreed that patient safety as such had not been a formal part of their education:

Q 410 [...] Dr Long: I can only talk for my training, obviously. I qualified in 2002, so I started my training in 1994, in the old-style system, I think. Although I knew safety was of crucial importance, that everything I was learning was so that I could treat my patients safely, it was never really made explicit. I never really heard the expression “patient safety”. The only thing I can vaguely remember is a talk given to us as undergraduates by one of the defence unions about prescribing safely and trying to avoid complaints. When I qualified, I was always very worried about making mistakes, but I never really stepped back and thought about why mistakes might occur or what the consequences might be or anything like that [...]

194 Ev 121

195 Q 333 ff. See also PS 90 and PS (BP 01).

196 Q 331

Dr Kreckler: I can certainly echo those views. In [Dr Pearson's evidence] it was said that it was very much implicit rather than explicit and that has certainly been my experience. There is a lot of activity going on now, particularly in the last couple of years, trying to bring patient safety to the undergraduate curriculum. I have been personally involved in training not only undergraduates but foundation year doctors, and when you start teaching about patient safety, they are completely unaware of safety as a concept in its own right.

194. The Imperial College researchers reported that:

Interviewees were asked if they had any training or education about patient safety. It seems that some of the interviewees seemed confused about what actually constituted as 'patient safety training'. Some spoke about fire safety training, risk management or perhaps training in reporting incidents but few actually specified they had patient safety training. Nurses reported training in manual handling, cardiac arrest training, communication and listening skills, handling complaints, transferring patients, infection control and yearly health and safety training. Doctors recalled training on medico-legal issues, communication skills and risk management.¹⁹⁷

Conclusion

195. **There are serious deficiencies in the undergraduate medical curriculum, which are detrimental to patient safety, in respect of training in: clinical pharmacology and therapeutics; diagnostic skills; non-technical skills; and root-cause analysis. These must be addressed in the next edition of *Tomorrow's Doctors*. The DH and GMC must monitor the quality of new medical graduates' use of the skills listed above. Elements of patient safety are taught, but this tends to be done implicitly rather than explicitly; this should also be addressed in the curriculum, which must make clear that patient safety is the first priority of medical practice. Patient safety must also be fully integrated into postgraduate medical education and training as a core element, not an optional extra.**

196. **Patient safety, including Human Factors, has yet to be fully and explicitly integrated into the education and training curricula of healthcare workers in general. This training should include the recognition that errors will inevitably occur in certain circumstances. There are convincing arguments for interdisciplinary training to foster good teamwork skills across professional boundaries: those who work together should train together.**

9 Commissioning, performance management and regulation

197. Various bodies, both within the NHS and outside it, are responsible for deciding how well services are provided in the NHS and for taking action when services are poor. These bodies can be categorised as:

- commissioners (which act as “purchasers” of services provided for NHS patients);
- performance managers (which monitor how well NHS organisations commission and provide services); and
- regulators (which ensure that appropriate standards are met).

In this chapter we look at how effective those bodies and their respective roles are at identifying and addressing unsafe care in the NHS.

Commissioning

Failings in commissioning

198. Commissioning in the NHS is defined as “using the available resources to achieve the best outcomes by securing the best possible health and care services for local people”.¹⁹⁸ It is supposed to be undertaken through a continuous “Commissioning Cycle”, involving strategic planning, procuring services and monitoring and evaluation.¹⁹⁹

199. Since 2002, Primary Care Trusts (PCTs), which were reorganised in 2006, have acted as the commissioners of NHS services in each locality of England.²⁰⁰ In our report on Lord Darzi’s *Next Stage Review*, we stated:

We have noted on numerous occasions, and the Government has accepted, that PCT commissioning is poor. In particular, PCTs lack analytical and planning skills and the quality of their management is very variable. This reflects on the whole of the NHS: as one witness told us, “the NHS does not afford PCT commissioning sufficient status”. We consider this to be striking and depressing.²⁰¹

200. The perception that many PCTs have failed to assess adequately the quality of services they have purchased is reinforced by the fact that in none of the cases of disastrously unsafe care that have recently come to light had commissioners detected and addressed that unsafe care. The Mid-Staffordshire Trust case provides a powerful example of commissioning that was wholly inadequate in regard to quality and safety. The HCC found that South Staffordshire PCT:

198 Department of Health, *Health reform in England: update and commissioning framework*, July 2006, para. 1.2, p 3

199 www.ic.nhs.uk/commissioning

200 Under the Practice-based Commissioning initiative, some aspects of commissioning are supposed to be delegated by PCTs to GP practices.

201 Health Committee, First Report of Session 2008–09, *NHS Next Stage Review*, HC 53-I, para 55

- “inherited a chaotic situation” from its predecessors in 2006, “with no detailed handover”;
- “Commissioning had not inquired in any depth into specific aspects of the quality of care being provided” by the Trust; and
- the PCT relied on regulatory processes to guarantee standards, “gain[ing] assurance from the trust’s performance in the annual health check of NHS trusts”.²⁰²

201. Professor Sir George Alberti, the NHS National Director for Emergency Access, in his report on emergency admissions at Mid-Staffordshire Trust, said he found it:

unfortunate that the main PCT commissioning services (South Staffordshire Primary Care Trust) did not pay more attention to standards and quality of clinical care and comments from patients but focused more on throughput and targets.²⁰³

Dr David Colin-Thomé, the NHS National Director for Primary Care, notes likewise in his report on lessons for commissioners and performance managers from Mid-Staffordshire Trust that:

The focus of the PCT was not on commissioning for outcomes, but rather a reliance on pre-determined process [...] In addition, there was not the expertise, particularly in the PCT to interpret data that was available.²⁰⁴

202. Dr Colin-Thomé does, though, conclude that:

On balance, there is nothing within the Healthcare Commission Report to suggest that the Primary Care Trust (PCT) [...] [and its] predecessors contributed to the problems at Mid Staffordshire NHS Foundation Trust or missed signs in the nationally recognised approaches to managing performance which operated in the NHS at that time. My review has confirmed that while the national approaches were being followed, local signs were missed.²⁰⁵

203. For his part, the Minister of State for Health Services reiterated this and argued that “The system has changed and the system changed before Mid-Staffordshire came to light”.²⁰⁶

204. The DH sought to assure us that inadequate commissioning is being driven out of the NHS by a series of initiatives. Foremost among these is the “World-Class Commissioning”

202 Healthcare Commission, *Investigation into Mid Staffordshire NHS Foundation Trust*, 2009, pp 118

203 Professor Sir George Alberti, “Mid Staffordshire NHS Foundation Trust: A review of the procedures for emergency admissions and treatment, and progress against the recommendation of the March Healthcare Commission report” 29 April 2009, p 4

204 Dr David Colin-Thomé, “Mid Staffordshire NHS Foundation Trust: A review of lessons learnt for commissioners and performance managers following the Healthcare Commission investigation”, 29 April 2009, pp 19–20

205 *Ibid.*, p 5

206 Q 1043

programme, which aims to build capacity for commissioning and involves PCTs being evaluated through the Commissioning Assurance System.²⁰⁷

205. At the same time PCTs are being given two new mechanisms through which to influence the quality of services: the Commissioning for Quality and Innovation (CQUIN) payment framework, which entails giving financial incentives for better quality care; and “*Never Events*”, which may entail imposing financial penalties for harming patients.

Commissioning for Quality and Innovation

206. CQUIN was announced by Lord Darzi in his final report for the NHS *Next Stage Review*.²⁰⁸ It allows PCTs to make part of the payment to a provider conditional on the quality of care (comprising safety, effectiveness and patient experience) and on innovation in care.²⁰⁹ One means of measuring quality will be “patient-reported outcome measures” (PROMs) which involve using patient-completed questionnaires to judge how much patients have benefited from their treatment.²¹⁰

207. In 2009–10, the first year of operation, PCTs must have local CQUIN schemes in place for all acute services on standard national contracts; and in all non-acute services (community, mental health, ambulance and specialised services) there must be either a CQUIN scheme or an agreed Quality Improvement Plan. Many schemes are expected in the first year to focus on data collection, to establish a baseline. The size of the incentive, which is decided nationally, is set at only 0.5% of the contract value in 2009–10; but we heard from Lord Darzi that the DH hopes to increase this figure in subsequent years.²¹¹

208. The Health Foundation told us that “If applied appropriately such financial incentives could be beneficial”.²¹² When we considered the *Next Stage Review*, we strongly supported using financial incentives to improve the quality of care, but we did set out several concerns and recommended that the DH “proceed with caution”, piloting and rigorously evaluating all such schemes before their adoption by the wider NHS.²¹³

Never Events

209. *Never Events* (the principle of which was also announced by Lord Darzi in *High Quality Care for All*) are adverse events that are both serious and largely, or entirely, preventable. The NPSA was asked to draw up a list of eight of these, which it did using the following criteria:

207 The Commissioning Assurance System involves an annual assessment cycle, covering outcomes, competencies and governance, overseen by the Strategic Health Authorities.

208 Department of Health, *High Quality Care For All*, Cm 7432, 2008, paras 40–41, pp 41–42; para 21, p 52

209 Hitherto, the amount paid under Payment by Results has been determined by the volume of care alone.

210 From April 2009, all licensed providers of hip replacements, knee replacements, groin hernia surgery and varicose vein surgery have been expected to invite patients undergoing one of these procedures to complete a pre- and post-operative PROMs questionnaire.

211 Q 872

212 Ev 77

213 HC (2008–09) 53–I, para 86

- the event may result in severe harm or death;
- it has occurred in the past;
- existing guidance describes how it can be avoided; and
- its occurrence can be monitored.

The eight *Never Events* chosen are listed in Box 14.

Box 14: The eight *Never Events* chosen by the NPSA

- Wrong site surgery;
- Retained instrument post-operation;
- Wrong route administration of chemotherapy;
- Misplaced nasogastric or orogastric tube not detected prior to use;
- Inpatient suicide using non-collapsible rails or whilst under one-to-one observation;
- Absconding of transferred prisoners from medium- or high-secure mental health services;
- In-hospital maternal death from post-partum haemorrhage after elective Caesarean Section;
- Intravenous administration of concentrated potassium chloride.

210. *Never Events* derive from a system used in the USA, under which some private insurers and government-funded schemes have a policy of not paying providers for costs attributable to *Never Events*. Lord Darzi's report mentioned that *Never Events* were linked to payment in the USA, but did not state that this aspect of the policy would be introduced in the NHS. He indicated only that, starting in 2009–10, PCTs would choose priorities from the *Never Events* list in their annual operating plans.

211. By contrast, when the Chief Executive of the NPSA, Mr Fletcher, and the NHS Medical Director, Professor Keogh, gave evidence to us, it was clearly stated that *Never Events* would be linked to payment, beginning in the second year of the scheme's operation (2010–11). According to Professor Keogh:

The eight *Never Events* which have been articulated, PCTs will not be expected to pay for that. For the first year [2009–10] the *Never Events* they will be expected to report on and, thereafter, it is anticipated that they will not pay. That is the key lever in the *Never Events*.²¹⁴

212. However, when the DH subsequently wrote to us about this, it was more equivocal:

Building on the experience gained during the first year, and emerging international experience, the NHS and Department of Health will work to define whether linkages to payment regimes would be appropriate and effective. Moving to this second phase of Never Events would be a possibility from the financial year 2010/11 onward.²¹⁵

This was echoed by Lord Darzi:

After a year I think we should have this debate about whether payments should be withheld or not. It depends who you ask really. There are those who are likely to suggest that it may suppress people reporting, in other words it will disincentivise them from reporting. There are those who think penalties are appropriate. I think we should wait and see what the [first] year [2009–10] gives.²¹⁶

213. A further concern about attaching financial penalties to *Never Events* is the practical difficulty of disentangling costs associated with an adverse event from those relating to the treatment of the patient's original illness or condition. This could be done through a calculation of additional time spent in hospital (counted in bed days)—but such calculations are not necessarily straightforward; and in some cases a bed-day calculation clearly will not be appropriate, as Mr Fletcher admitted.²¹⁷

214. Further arguments against the idea of fines for harming patients were given to us by the Health Foundation, which contrasted with the Foundation's support, noted above, for incentive payments for better quality care:

The Foundation opposes the imposition of financial sanctions on hospitals which have unintentionally harmed a patient. Fining publicly-funded institutions penalises the population and can lead to the manipulation of performance data and the demoralisation of staff.²¹⁸

Performance management

215. The function of performance management in the NHS, which might be described as monitoring how well organisations commission and provide services, is clearly an important one, but there appears to be some confusion as to which bodies are responsible for it—and what exactly it entails.

216. Some DH pronouncements have indicated that PCTs have a role in performance management. Dr Colin-Thomé's report on Mid-Staffordshire Trust refers several times to the PCT having failed to play such a role. He states that this "is an area where expectations have now changed considerably and PCTs have greater responsibility for performance management of the quality of care provided".²¹⁹ Professor Alberti refers likewise to the PCT

215 PS 01A

216 Q 874

217 Q 58

218 Ev 77

219 Colin-Thomé, "Mid Staffordshire NHS Foundation Trust", 2009, pp 12, 16 and 23

performance managing providers.²²⁰ The Minister of State for Health Services also spoke of “the performance management responsibilities of [...] PCTs”.²²¹

217. However, performance management most often seems to be regarded as one of the responsibilities of Strategic Health Authorities (SHAs). These were created in 2002 (and reorganised in 2006) and effectively act as both regional headquarters of the NHS and regional offices of the DH. Their performance management role extends both to Trusts as service providers (but not Foundation Trusts)²²² and to PCTs as commissioners.

218. Dr Colin-Thomé notes that, in the case of Mid-Staffordshire Trust, West Midlands SHA and its predecessors failed to detect unsafe care, as did the PCT—although he adds that the SHA, like the PCT, did nothing wrong in terms of “nationally recognised approaches to managing performance which operated in the NHS at that time”.²²³

219. This is perhaps unsurprising given that the performance management role of SHAs has seemed ill-defined, and when we asked the DH for a note on this, it was unable to give a concise definition of what the role entails.²²⁴

220. However, according to Dr Colin-Thomé:

The SHA role, has also recently been strengthened with an overall system management responsibility including all the providers (but not directly Foundation Trusts), and commissioners in their area.²²⁵

This was also the view of the Minister of State for Health Services, who referred to the “evolving improvement of performance management across the NHS”.²²⁶

221. One means of performance management by SHAs in respect of the safety of services appears to be through reports of Serious Untoward Incidents (SUIs). There is no standard definition of an SUI but they are usually defined along the lines of the following:

something out of the ordinary or unexpected, with the potential to cause serious harm, and/or likely to attract public and media interest that occurs on NHS premises or in the provision of an NHS or a commissioned service.²²⁷

222. All SUIs should be reported by non-Foundation Trusts to SHAs, typically via the Strategic Executive Information System (STEIS),²²⁸ although it is unclear what exactly SHAs do with the resulting data. There are doubts about the justification for having this

220 Alberti, “Mid Staffordshire NHS Foundation Trust”, 2009, p 7

221 Q 1043

222 Foundation Trusts are part of the “NHS family”, but free from the control of the Secretary of State for Health and so not accountable to their local SHA.

223 Colin-Thomé, “Mid Staffordshire NHS Foundation Trust”, 2009, p 5

224 PS 01A

225 Colin-Thomé, “Mid Staffordshire NHS Foundation Trust”, 2009, p 14

226 Q 1043

227 www.london.nhs.uk/webfiles/tools%20and%20resources/NHSL_SUI_Guidance.pdf

228 Ev 210, 211. Foundation Trusts are apparently supposed to report SUIs to Monitor and PCTs.

reporting route alongside the NRLS, and we understand the NPSA is working to integrate STEIS reports into the NRLS.²²⁹

223. *Safety First* (2006) was clearly concerned about the role of SHAs and recommended that “The involvement of strategic health authorities in patient safety needs to be completely redesigned to ensure that patient safety is mainstreamed”. This was to be partly accomplished as follows:

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

Prime responsibility for incident investigations should reside with local NHS organisations. Every NHS organisation should have access to a specialist investigator based within the Patient Safety Action Team. All reports should be considered locally within 24 hours of being reported. The NPSA should be notified of events that involve serious patient harm and death within 36 hours of the initial report.²³⁰

224. Accordingly, the NPSA transferred its 28 Patient Safety Managers to SHAs to be core members of the new PSATs on 1 April 2009; and the Agency provides a national network of events and communications, as well as policy support for patient safety leads in the SHAs. It also provides policy support for the SHA leads in patient safety. In addition, it has developed refined tools and techniques to help PSATs support local organisations with their incident investigations.²³¹

Regulation

225. Several bodies are involved in the regulation, inspection, audit and review of health and social care in England. Their efforts are coordinated through a voluntary agreement called the Concordat, which was launched in 2004 by 10 organisations, led by the HCC. Signatories work together to coordinate their activities, including inspections, audits and reviews.²³²

226. Regulation of NHS bodies by independent, formal structures and processes dates back to 1999. The history of regulation in the NHS is very briefly summarised in Box 15.

Box 15: Brief history of NHS regulation

229 Ev 13

230 Department of Health, *Safety First*, 2006, pp 26 and 27

231 Ev 150–151

232 The full signatories to the Concordat are: the Audit Commission; the Care Quality Commission; the Conference of Postgraduate Medical Deans; the General Medical Council; the Health and Safety Executive; the Human Fertilisation and Embryology Authority; the National Audit Office; the NHS Counter Fraud and Security Management Service; the NHS Litigation Authority; the Postgraduate Medical Education and Training Board; and Skills for Health. The associate signatories are: the Academy of Medical Royal Colleges; the Council for Healthcare Regulatory Excellence; the Department of Health; the Health and Social Care Information Centre; the Healthcare Inspectorate Wales; the NHS Confederation; the Quality Assurance Agency for Higher Education; and the United Kingdom Accreditation Forum.

Formal structures for the regulation of NHS organisations as service providers were introduced in 1999, with the creation of CHI. From 2000–01, Trusts were given star ratings by the DH; responsibility for these passed to CHI in 2003 and in 2004 to the HCC, which replaced CHI.

From 2006, the HCC was responsible for the Annual Health Check system, which replaced star ratings, and was later extended to cover regulation of NHS bodies as commissioners of services, as well as providers. On 1 April 2009, the HCC (along with several other bodies) was replaced by the CQC. From 1 April 2010, the CQC will register all providers of health and social care, including the independent sector, in a unified system. At some point after 2010, the CQC will also register independent practitioners in primary care (such as GP practices), which have not hitherto been subject to such regulation.

The year 2009–10 is a transitional one, during which the CQC is conducting “periodic reviews” of health and social care providers and commissioners (in the NHS this will be similar to the Annual Health Check). From 1 April 2009, there is a legal requirement for all NHS Trusts that provide services for patients to register with the CQC in respect of requirements regarding the prevention and control of healthcare-associated infections. All NHS organisations will need to be fully registered with the CQC by the time the requirements come into force on 1 April 2010.

Annual Health Check

227. The heart of the regulatory process has been the Annual Health Check operated by the HCC until 1 April 2009. Under this system, trusts were rated in respect of the quality of their services partly on performance against targets set by the Government (and latterly also by commissioners) and partly on performance against a series of Core Standards, in respect of which Trusts assessed themselves.²³³ Self-assessment declarations were cross-checked against “commentaries” from “third parties” (SHAs; patient and public representatives;²³⁴ and local-authority Overview and Scrutiny Committees), with any significant discrepancies triggering “risk-based” inspections by the HCC. (In addition, a proportion of Trusts were randomly selected for inspection.) The HCC reported that in 2008 it received 1,930 comments from third parties, from which 8,779 items of intelligence were extracted and used. Across all the third parties, 9% of commentaries were given a high data-quality rating, 35% a medium rating, and 36% a low rating; 20% fell into the “no comment” category.²³⁵

228. The Annual Health Check was described as a form of “light touch” regulation; instead of there being an army of inspectors, Trusts assessed themselves. The process might also be described as “rules-based” in that Trusts had to show they had certain policies in place and followed certain processes.

233 Under the first Core Standards domain (“Safety”), Trusts had to self-certify compliance in areas including the implementation of NPSA Patient Safety Alerts.

234 This role was initially fulfilled by Patient and Public Involvement Forums (which took on part of the remit of CHCs when they were abolished in 2003) and then passed to Local Involvement Networks, which replaced the Forums in 2008.

235 Healthcare Commission, Core Standards Assessment 2007/2008, Third party feedback

229. Although described as “light touch”, such regulation still clearly imposes a significant financial and administrative burden on the NHS. Professor Kennedy assured us that regulation justified its cost:

Regulation is a lever: it is neutral. It is available to government to do a job. It is neither burdensome, nor the other. It has to be efficient in so far as it has to be cost-effective, the benefits outweigh the costs—and, in my view, in the Healthcare Commission case they do—and it has to be effective in so far as delivering what you have asked us to deliver, which is to promote improvement. In my case it has done that.²³⁶

230. However, while Professor Kennedy was able to tell us the cost to the NHS of his own organisation, he could not quantify the costs that it imposed on the organisations it regulated:

Q 698 Sandra Gidley: [...] Regulation is quite expensive. How much does it cost NHS organisations to meet all the requirements that your respective organisations put upon them? Have you made an estimate of that? [...]

Q 699 [...] Professor Sir Ian Kennedy: Nought point one [percent] of the total cost of public funding allocated to the sector, or, if you want to put it another way, 94p for every thousand pounds spent [...]

Q 700 Sandra Gidley: The question I did ask was about cost. I was not clear whether that was the cost for each organisation that has to provide information or that was your cost of the total budget?

Professor Sir Ian Kennedy: That is the cost to the public purse of what the Healthcare Commission does. As regards the cost to each individual trust, I do not have that data. It may well be that it is discoverable, but I would have thought it is quite difficult to calculate, because, of course, it depends on lots of things, namely the energy put into it.

231. Doubts about the effectiveness of regulation have been raised by the fact that none of the recent appalling cases of lethally unsafe care in the NHS was brought to light by the Annual Health Check. Mid-Staffordshire Trust, for instance, was rated “Fair” on Quality of Services in 2005–06 and 2006–07; and provisionally “Good” in 2007–08.

232. The *Cure the NHS* group asked whether “this method of ‘self-assessment’ [the Annual Health Check] has not been seriously discredited by the failures at Stafford Hospital?”²³⁷ This view was echoed by the Patients Association, which stated that the case of Mid-Staffordshire Trust “raises serious concerns over the assessments made by the [HCC] since its inception in 2004”.²³⁸

233. In respect of this case, Professor Kennedy told us that the Annual Health Check “will not always spot every area of inadequacy” and problems could be “masked by the bigger

236 Q 703

237 PS 101

238 PS 50A

picture”. He stressed that the “Fair” ratings for the Trust had indicated that services were “barely adequate and in need of improvement”; and that the “Good” rating for 2007–8 had been provisional, pending the outcome of the HCC’s investigation of the Trust.²³⁹

234. The HCC was alerted to unsafe care at Mid-Staffordshire Trust by data showing a high hospital standardised mortality ratio (HSMR).²⁴⁰ When the Trust gave an unsatisfactory explanation of the data (arguing that it was the result of administrative issues rather than a genuine indication of unsafe services), a long and thorough investigation by the HCC was triggered. In consequence, the HCC brought issues to the Trust’s attention as they were uncovered and published its findings in full (in March 2009), leading to a change of leadership at the Trust and action to improve services. The HCC also downgraded the Trust’s 2008–09 Annual Health Check rating for Quality of Services from “Good” to “Weak”.

235. The Minister of State for Health Services argued, on this basis, that regulation could not be said to have failed:

I think it is [...] fair to say that the procedures of the Healthcare Commission [...] have been constantly evolving, they have been constantly improving and they have constantly been becoming more sophisticated. It was indeed the growing sophistication of the Healthcare Commission’s procedures with use of HSMRs and other alert systems that finally alerted them to the potential problems that were there at the hospital.²⁴¹

A similar point was made by the CNO regarding one of the other such cases:

I would say one of the reasons that Maidstone and Tunbridge Wells came to the fore was because we had some of these systems in place that were beginning to bite, the Healthcare Commission doing inspections and all those sorts of things, so that whilst it was a very sad event for Maidstone and Tunbridge Wells it was showing that our systems were beginning to work.²⁴²

However, the fact remains that annual assessment failed in each of these instances, so that abysmal standards of care continued for some time before finally being detected by other means, and then investigated and addressed.

236. The DH maintained that it was possible to say confidently that these cases of very unsafe care are isolated instances. Regarding Maidstone and Tunbridge Wells, the CNO told us: “No, I do not think it is widespread”.²⁴³ In respect of Mid-Staffordshire Trust, the Minister of State for Health Services told us:

239 PS 52B. See also Q 707.

240 The HSMR compares the actual number of deaths in a hospital with the average national experience, after adjusting for several factors that may affect in-hospital mortality rates, such as the age, sex, diagnoses and admission status of patients. The ratio provides a starting point to assess mortality rates and identify areas for improvement, which may help to reduce hospital deaths from avoidable adverse events.

241 Q 1035

242 Q 80

243 *Ibid.*

This issue of whether Mid-Staffordshire was an isolated incident was dealt with by the Healthcare Commission itself, by the independent regulator, who made clear both in the report and subsequently to it that they went back and did a very careful check of other trusts that had similar high levels of hospital standardised mortality rates and other indicators that may be a cause for concern and they satisfied themselves (Anna Walker [the Chief Executive] is on the record as having said this [...]) that there were not any other trusts that gave rise to similar concerns.²⁴⁴

However, the Annual Health Check is clearly not a sound basis for such assumptions; and absence of HSMR data giving cause for concern is no guarantee that there are not further undetected instances of things going badly wrong.

237. Understandably, scepticism has been expressed about the assurances of the type given by the CNO and the Minister. *Cure the NHS* told us they had:

been contacted by people from a number of other places. Performance will be like most other things in human affairs, ‘distributed’ roughly in the shape of the ‘bell’ curve, the ‘normal’ or ‘Gauss’ distribution. Stafford Hospital is probably at the very end of the tail of the poor performers but the big question is, how many more poor performers have been missed?²⁴⁵

Care Quality Commission

238. The year 2008–09 is a transitional one in the regulation of NHS care. On 1 April 2009, the CQC took over from the HCC and from 1 April 2010 a new system, based on “registration”, will be implemented.

239. We asked Baroness Young of Old Scone, the Chairman of the CQC, how she would ensure the organisation maximised effectiveness while minimising the burden and cost of regulation:

Q 704 [...] Baroness Young of Old Scone: We have made a commitment to be what I call a modern regulator.

Q 705 Sandra Gidley: Yes; I wish I knew what that meant. It is one of those phrases that is bandied around endlessly and means zilch.

Baroness Young of Old Scone: For me it is risk-based, it is proportionate, it is working with providers on issues that they ought to be focused on because they are important issues and also with a strong focus, and, indeed, we have introduced into our structure and our processes a strong focus on looking at the administrative burden particularly of changes in regulation that we make. So we will be doing impact assessments of all of the regulatory changes that we make to ensure that they are not putting disproportionate burdens on the folk we are regulating. But I think the point that [Professor] Ian [Kennedy] made is absolutely the case, and that is that, if the regulator is asking questions about things that the governance structure or the

244 Q 1041

245 PS 101

commissioners or the performance managers are not asking questions about, somebody is on the wrong page. So we have got to explore, if people are saying, “We do not want to look at this because we do not think it is important”, why there is a difference of view as to the importance of a particular issue [...]

Q 706 [...]It will vary with the issue and it will vary with the organisation. For some organisations a ticking off behind the bike sheds is just as effective as doing any formal enforcement mechanism. In some cases there will be issues that are best resolved, for example, through a professional process rather than a regulatory process or through a managerial process or a commissioning process, and I think we have got to be flexible and alert about that, but in terms of our regulatory mechanisms, we have built into our structure a way of making sure that, before we make any change, before we lay any new requirement on the people we regulate, that we are assessing whether that is truly a justifiable additional or changed requirement and whether there are ways we can do it that will reduce the cost.

240. The CQC will span all of health and social care, both public and private, allowing it to take an all-encompassing view and deal with interconnections between services; after 2010 the CQC will have power to address safety issues within primary care. Registration will be the central plank of the CQC’s regulation of providers. Details of the registration compliance criteria are still being worked out, but Baroness Young assured us that “about 75% of the registration requirements are directly about issues of safety, so there is safety threaded right through the registration requirements”.²⁴⁶ The CQC will publish periodic assessments of both providers and commissioners (equivalent to the Annual Health Check) and it will also have the power to carry out “special reviews”. Formal enforcement powers will include warning notices, prosecution and a fine of up to £4,000 (in lieu of prosecution). The CQC will also be able to impose conditions on, temporarily suspend, or cancel, a provider’s registration; cancellation will be the ultimate sanction, as it will effectively close down the provider.²⁴⁷

241. The Minister of State for Health Services assured us that the CQC would have the same power as the HCC to conduct a thorough investigation where there were serious concerns about the performance of a Trust.²⁴⁸

Coordination and cooperation

242. Effective regulation, commissioning and performance management requires the maximum possible clarity about the roles of all the bodies concerned, coordination of their respective efforts, avoidance of duplicated roles and efficient use of resources. However, there is worrying evidence that these are all to an extent lacking, as Dr Colin-Thomé noted in respect of Mid-Staffordshire Trust:

A key lesson has been about the need for clarity of role and responsibility to ensure that each organisation understands where it fits and what accountability it has. This

246 Q 733

247 Ev 157–160; PS 41A

248 Q 1037

was not clear in Mid Staffordshire and there were cases of issues falling between organisations.²⁴⁹

The role of Monitor

243. Monitor (the Office of the Independent Regulator) is an independent statutory corporate body that grants authorisation for Trusts to become Foundation Trusts and ensures that they comply with their terms of authorisation—effectively a licence to operate.²⁵⁰ Monitor is supposed to ensure that Foundation Trusts have maximum freedom in their operations while safeguarding the interests of NHS service-users, using a system of regulation that should identify actual and potential problems, both financial and non-financial. In a case of significant failure by a Foundation Trust, Monitor has substantial formal powers of intervention. According to the DH:

While Monitor does not play a direct role in defining patient safety, it does have an important part to play in ensuring that Foundation Trusts are effectively governed, including meeting the required standards in relation to clinical quality and patient safety.²⁵¹

However, serious doubts about Monitor’s effectiveness in performing this role have been raised by the case of Mid-Staffordshire Trust.

244. Dr Bill Moyes, the Executive Chairman of Monitor, told us his organisation had accepted the Trust’s explanation that its poor HSMR figures were an artefact of how cases were coded (classified), rather than evidence of actual lapses in care standards. Consequently, Monitor did not pursue the matter when considering whether to grant Foundation status.²⁵² At the same time, the HCC was, as noted above, exploring this further. Incredibly, it transpires that the two organisations were not in communication about the Trust, and the HCC only found out by accident that Monitor had decided to grant it Foundation Trust status.²⁵³ Monitor, according to Dr Colin-Thomé, “emphasise[d] that prior to the foundation trust application process, both the SHA and PCT had an opportunity to comment on a hospital’s suitability”.²⁵⁴ The HCC investigation, however, found that “The PCT [...] considered that the trust and its activities were the subject of scrutiny as part of its application for foundation trust status”, and was thus reassured about the quality of services.²⁵⁵

245. Dr Moyes informed us that Monitor had changed its approach since the Mid-Staffordshire Trust case came to light:

249 Colin-Thomé, “Mid Staffordshire NHS Foundation Trust” 2009, p 22

250 Access to Foundation Trust status is supposed to be based on the principle of “earned autonomy”—in theory, only high-performing Trusts are permitted to apply for Foundation Trust status. Trusts must also show a financial surplus before they are permitted to become Foundation Trusts.

251 PS 01A

252 Qq 721–5

253 “Mid Staffordshire crisis: quality of care sacrificed in Foundation Trust bid”, *Health Service Journal*, 19 March 2009

254 Colin-Thomé, “Mid Staffordshire NHS Foundation Trust”, 2009, p 22

255 Healthcare Commission, *Investigation into Mid Staffordshire NHS Foundation Trust*, 2009, p 6

Since Mid Staffs, we have expanded our assessment process, so we do take a look at local press cuttings, for example, we do ask the Healthcare Commission, not just at local level, but at national level, “Is there anything you want to tell us?”²⁵⁶

246. The case of Mid-Staffordshire Trust also raises questions regarding the arrangements for overseeing authorised Foundation Trusts. Dr Colin-Thomé notes:

There was [...] lack of clarity over the respective roles of the SHA, PCT and Monitor once Mid Staffordshire hospital trust achieved foundation trust status. The SHA and PCT, in particular, were unsure of their ongoing management relationship with the Foundation Trust, in relation to the independent regulation role taken on by Monitor.²⁵⁷

247. Foundation Trusts, unlike ordinary Trusts, have Boards, or Councils, of Governors,²⁵⁸ through which they are supposed to be accountable to their local communities rather than to SHAs, the DH and the Secretary of State (“looking outwards, not upwards”). However, it seems unclear whether these governance structures involve any equivalent of the performance-management role played by SHAs on behalf of the Secretary of State. The DH informed us that “Monitor cannot replicate [SHAs’] powers [exercised on behalf of the Secretary of State] or have any role in performance managing Foundation Trusts.”²⁵⁹ Yet this was directly contradicted by the Minister of State for Health Services:

Q 1080 Dr Stoute: [...] [W]hy do we need Monitor [as well as the CQC]?

Mr Bradshaw: Their roles are slightly different. Monitor also has what I would describe as a performance management role [...]; Monitor has the power ultimately to deal with personnel issues, deal with boards for failing, failed management and so forth. The independent regulator – I think this is a very important distinction not least in terms of public confidence – has to be completely independent from the performance management and from the financial management role that Monitor has [...]

248. Monitor has expressed misgivings about the impact that the creation of the CQC will have on Foundation Trusts and the role of Monitor itself. In evidence to the Public Bill Committee on the Health and Social Care Bill in 2008, Monitor stated:

The creation of a new regulator, the Care Quality Commission, with statutory powers over NHS foundation trusts puts [the success of the Foundation Trust regulatory regime] at risk. Giving two regulators powers of intervention over the same bodies risks confusion, duplication and loss of accountability.²⁶⁰

256 Q 722

257 Colin-Thomé, “Mid Staffordshire NHS Foundation Trust”, 2009, p 22

258 Governors are partly elected by Trust Members, who are drawn from the public, patients and staff; and partly appointed by local partner organisations, such as PCTs and local authorities. Governors play an advisory, guardianship and strategic role. They are not involved in the day-to-day running of the Foundation Trust and so do not deal with matters such as budget-setting and performance-management. They also directly appoint the non-executive directors of the Foundation Trust, including the Chair.

259 PS 01A

260 www.publications.parliament.uk/pa/cm200708/cmpublic/health/memos/ucm1202.htm

Dr Moyes was less outspoken when we asked him about this, but he did indicate that this issue still had yet to be resolved:

It is still an area I am anxious about. Monitor has been consistent throughout, quite openly saying that we believe that the strength of the system is that we have the responsibility to intervene in circumstances of failure where other mechanisms such as the Commission's pressure, and so on, has not had an effect [...] [T]he Care Quality Commission has a power to register and, therefore, to deregister and, therefore, to vary the registration conditions, and I think we both recognise that that is an area where, once the CQC comes into being properly, we are going to have to work quite carefully together to identify who does what in what circumstances. But it is an obvious issue that has to be sorted. We both recognise it has to be sorted. We are developing a memorandum of understanding between our two organisations which tries to make sure that we can describe to the world in language the world can understand, how our compliance system and the CQC's registration system will bolt together. It is not an insuperable problem [...]²⁶¹

The role of the NHS Litigation Authority

249. A significant complicating factor in regulation is the involvement of the NHSLA, through setting standards in respect of the Clinical Negligence Scheme for Trusts, an issue that we raised with Steve Walker, the Agency's Chief Executive:

[T]he background is that the Clinical Negligence Scheme is a risk-pooling scheme. It began during what used to be called the internal market, when trusts were first exploring autonomy and the idea was that risks would be pooled, claims would be settled from the pool, and the rather wise people, I think, who were putting that together recognised that if it were a mutual insurer, for example, that insurer would want to instigate some risk management activity to protect the pool. That is how standards were initially devised [...]

No one has volunteered to take it on historically, I should say, and what has happened is that people like the Healthcare Commission, for example, have used our assessment outcomes and fed them into their own data to produce things like the annual health check. I think that what we do, we do very well, but I am not saying that we are the only people who could do it, nor am I saying that it is not possible that someone could do it better, but lots of people take our data on the basis of what we do now and make use of it.²⁶²

250. For the DH, Ann Keen MP, Parliamentary Under Secretary of State, told us: "The Department is satisfied by the work undertaken by the NHSLA on standard setting [...] We see no compelling case for asking [the CQC] to take on an additional role at this stage".²⁶³

251. However, we heard as follows from AvMA:

261 Q 741

262 Qq 769, 771

263 PS 01B

We believe the NHSLA is the wrong body to be responsible for developing and monitoring safety standards. Currently, they are, in the form of their “risk management standards”. Whilst it is important that lessons from NHSLA’s work inform standards for improving safety, we believe it is wrong to have responsibility for standards underpinning patient safety with what is essentially an organisation with an insurance industry approach. This work would more appropriately be handled by another agency/agencies such as the NPSA and Care Quality Commission, so that standards are informed by other areas of their work.²⁶⁴

General concerns

252. There seemed to be a general concern that there were too many organisations involved in regulation, commissioning and performance management, but uncertainty about how to change the situation.

253. Baroness Young told us:

[T]here are a lot of players on the pitch, but I think there is an opportunity for us to make sure that all of that effort is aligned because there are distinctive contributions that each of the players are making. Clearly, the bodies that particularly are important in the safety area are ourselves, the National Patient Safety Agency, NICE, the Litigation Authority, the PCTs the SHAs, Monitor, probably a good few others besides, the providers themselves, of course. Our role is as the regulator of quality in which safety is our first principle of quality [...] Safety will be a fundamental part of that and we will enrich that risk profile with information, not just from stuff that we collect ourselves through our regulatory processes, but from a whole variety of other players, including Monitor, including the SHAs and the performance management system, including the commissioners, including the Litigation Authority and also from things like professional quality assurance processes and accreditation. So it will be a very rich and increasing profile for each provider, and safety will be a fundamental element of that.²⁶⁵

Lord Darzi’s views were as follows:

How do we align all of these people together with the ultimate aim of improving safety and quality? If I could bring you back to accountability—I think Liam [Donaldson] said this earlier—someone needs to be out there accountable for core standards of safety and quality. That should be just one, and that will be the CQC and only the CQC. Anything above core standards, everyone who wants to be on the pitch, they should start talking about quality improvements whether it is Monitor, whether it is commissioners, whether it is the SHA and that is the culture we need to move to. The only way to do that is to go back to the teams in A&E who are providing that care to look at themselves and what they are doing. From an accountability perspective it is very important to know who is doing it exclusively.

264 Ev 222

265 Q 694

Then you come up and ask how we do it at a national level. I have tremendous expectations from the National Quality Board which was launched last week.²⁶⁶

254. The CQC will reportedly be convening routine “risk summits” in respect of NHS organisations, involving all bodies with relevant information, allowing swift intervention where problems in care standards are brought to light.

255. The Government response to the Alberti and Colin-Thomé reports states:

In the case of Mid Staffordshire Trust, it is clear that there was not enough cooperation and communication between the different management and regulatory bodies. Various warning signs were known by different organisations, but they did not pool their knowledge to expose the Trust’s failures.

As the regulatory system evolves, all parties are determined to ensure that cannot happen again. On 1 April 2009, a new statutory duty came into force under the Health and Social Care Act 2008 for the CQC and Monitor to cooperate with each other in the best interests of patients.

The Secretary of State has also asked the new National Quality Board to look at how we can ensure that any early signs that something is going wrong in the NHS are picked up immediately, that the right organisations are alerted and that action is taken quickly. The NQB [National Quality Board] will review key issues relating to alignment and co-ordination at a system level and will report by the end of 2009.

Linked to the NQB’s review, we will work with the CQC and other key partners to organise a programme of local clinical risk summits, which would bring together a range of organisations to assess and address the risks across a particular health community.²⁶⁷

Conclusion

256. **As we have argued elsewhere, we have grave doubts about Primary Care Trusts’ performance in their commissioning role. The DH’s hope is that World Class Commissioning will transform PCTs, but there is a danger that it will be another tick box exercise. As we stated in our report on the *Next Stage Review* we welcome the principle of linking payment to the quality of care, but recommend that it be tested first in a pilot project. We support the use of *Never Events* by PCTs, but have doubts about whether they should involve a financial penalty; we recommend this be the subject of a pilot project.**

257. **The performance-management role of Strategic Health Authorities appears to be ill-defined and to vary between SHAs. We are not convinced that this function is being effectively discharged throughout the NHS. There seems to be no definition of it laid down by the DH; and the Department was unable to supply this when we asked. We**

266 Q 928

267 Government response to Alberti and Colin-Thomé Reports, 2009, pp 7–8

recommend that the DH produce a formal definition of the performance-management role of SHAs.

258. Regulation has been burdensome and costly and its main mechanism, the Annual Health Check, has failed to pick up major failings in healthcare, although the HCC did through other means identify the problems in cases such as Mid-Staffordshire Trust and things would have been even worse without regulation. We do not, of course, know how much poor care the Annual Health Check failed to identify.

259. Regulation in the past decade has been characterized by an expansion in rule-based mechanisms, looking at processes and procedures rather than actual outcomes and consequences and professional competence. Too often the rule-based approach has been unable to capture the complexities of frontline care. Worse, it may fail to engage professionals, who are quick to recognize opportunities to work around rules. Inappropriate rules will foster ingenuity in compliance but detachment from the more demanding role of asserting and fulfilling the needs of patients. Sustained improvement depends on releasing the potential of staff to see, develop and own solutions.

260. The new Care Quality Commission's registration system must focus on the outcomes being achieved by NHS organisations rather than formal governance processes; it must ensure that organisations only collect information which they should be collecting for their own purposes.

261. We recommend the DH consider how to reinstate the best aspects of the Royal Colleges' inspections in the new system.

262. The relationship between commissioning, performance-managing and regulating bodies is not defined clearly enough. There are, as Baroness Young put it, "a lot of players on the pitch" and we are concerned that too often they are not an effective team. There is evidence of overlapping functions and multiple submission of information to different regulators. Most disturbing of all is that Foundation Trusts appear to be operating in an entirely different regulatory framework from non-Foundation Trusts.

263. What all the complex panoply of organisations has actually achieved is called into question by the fact that these systems have been shown recently to have failed in several instances promptly to expose and address major instances of unsafe care.

264. The case of Mid-Staffordshire Trust has also exposed serious shortcomings in Monitor's assessment process when granting authorisation. Not only did Monitor fail to detect unsafe care—it effectively allowed the Trust to compromise patient safety in premature pursuit of Foundation status. We note the Healthcare Commission found that achieving Foundation status was one of the factors that distracted the Trust from patient safety issues. Monitor's acceptance at face value of the Trust's excuse that its poor mortality figures were a statistical anomaly is wholly unacceptable.

265. We are also concerned about Monitor's role in regulating Foundation Trusts following authorisation. We are told that Monitor does not replicate the performance management role played by SHAs in respect of Trusts, but it is unclear by exactly which means Foundation Trusts are intended to be performance managed—or whether they

are supposed to be performance managed at all. In Monitor's defence it could be said that too many SHAs have also done no effective performance management.

266. There appears to be considerable potential for confusion, and possibly conflict, regarding the respective roles of Monitor and the CQC, as Monitor itself has indicated. The DH must clarify exactly what these two organisations' regulatory roles are in respect of Foundation Trusts and how those roles fit together.

267. While the NHS Litigation Authority has performed an important role in setting standards, its involvement in scrutiny of NHS bodies leads to burdensome and wasteful duplication of time and effort for both Trusts and regulators. Moreover, the role of indemnifying Trusts against litigation over clinical negligence is quite distinct from the role of setting standards on safe care and safety culture—and there is potential for tension between the two, notably regarding openness about unsafe care. We recommend that the inspection process currently undertaken by the NHS Litigation Authority should be subsumed within the work of the Care Quality Commission.

268. The DH should produce a succinct statement regarding how commissioning, performance management and regulation are defined, and how they (and the organisations responsible for them) relate to each other.

10 The role of managers and Boards

269. The day-to-day running of NHS organisations rests in the hands of managers and Boards. These include both executive and non-executive directors, the latter being tasked with holding the former to account. In this chapter we consider how well they are discharging their responsibilities in respect of patient safety.

270. The first point in the *Code of Conduct for NHS Managers* (2002) reads “As an NHS manager, I will [...] make the care and safety of patients my first concern and act to protect them from risk”. *Governing the NHS: A guide for NHS Boards* (2003) states:

The duty of an NHS Board is to add value to the organisation, enabling it to deliver healthcare and health improvement within the law and without causing harm [...] It is the duty of the Board to ensure through Clinical Governance that the quality and safety of patient care is not pushed from the agenda by immediate operational issues.²⁶⁸

271. Two regulatory bodies, Monitor and the HCC, were keen to emphasise that ultimate responsibility for standards of care in each NHS organisation rests with squarely its Board:

Q 693 [...] Dr Moyes: [...] The other thing I think is quite important is the emphasis that we have placed on the role of the board, because the other thing that I think has been lacking in the past has been absolute clarity about who is accountable for the delivery of services in the round, and we are quite clear in foundation trusts that that is the board. It is not the medical director, it is the board. Therefore, saying to the board, “You are accountable and you have to give an account of yourself and, therefore, you have to know what is going on in your hospital and you have to have ways of spotting the areas of problem and intervening”, I think also would be very powerful [...]

Q 697 [...] Professor Sir Ian Kennedy: [...] [T]he emphasis on the board that Bill [Moyle] laid earlier is critical, it is a view we share, but [...] if I were the Chairman of a board I would not be entirely sure who I am obliged to please, as it were, and that requirement for clarity will now depend upon the working together of these two agencies [Monitor and the CQC]. The structures, because they have grown, they have grown a bit like Topsy, and they do need very powerful and insightful leadership, otherwise, as I say, if I was the Chairman of a local trust I would not know quite what the tune is we are playing, or I might not.

272. Several recent HCC investigations have shown in detail how senior managers and Boards have failed in their most basic duties as regards patient safety, with disastrous consequences. In each of these cases, patient safety was found to have been crowded out by other priorities, including the meeting of targets, financial issues, service reconfigurations and achieving Foundation status. As we have already noted, in these cases inadequate

²⁶⁸ Department of Health and NHS Appointments Commission, *Governing the NHS: A guide for NHS Boards*, June 2003, pp 9 and 11

staffing levels have been a particular factor in compromising patient safety—despite the enormous increase in funding and staffing across the NHS as a whole.

273. The DH has been keen to present these as highly exceptional cases of rogue managers and dysfunctional Boards. However, there is evidence of widespread shortcomings in the way that Boards approach patient safety. In March 2009, the HCC published a study of how NHS Boards address patient safety as regards: making safety a priority; placing items on agendas; and drawing on information. The study involved 30 to 35 Trusts and was conducted by means of focus groups and interviews with key people (there were no visits or inspections). The key findings were as follows:

- Boards are paying more attention to safe care, largely driven by concern for such matters as infection control, and the aftermath of high-profile investigations.
- Control of healthcare-associated infection is given a lot of attention by boards, and rightly so, but this is disproportionate to the priority afforded to other areas of safety.
- Most boards receive reports on serious untoward incidents, healthcare-associated infections and complaints, but immediate targets or finances still tend to dominate their priorities, and boards do not regularly receive a range of information on different areas of safety (eg medicine management, suicides) or of safety culture.
- Many of those consulted felt strongly that more could and should be done to hear on a regular basis at board level the direct experiences of patients.
- Most non-executive directors described themselves as passive recipients of information on safety, with limited understanding to challenge it effectively.
- Restructuring of services or the application for foundation trust status tended to diminish the priority afforded to safe care. However, such changes often prompted a review of governance and reporting, with positive outcomes.²⁶⁹

Means of improving Boards' approach to safety

274. There are a number of measures with the potential to improve the approach of Boards to safety. Lord Patel, Chairman of the NPSA, told us he thought steps needed to be taken to help non-executive directors do better in holding their executive colleagues to account:

I personally believe there ought to be a non-executive director who gets appropriate training on what quality and safety means in healthcare and that would be the person who takes the role of governance in every trust, focussing on safety and quality.²⁷⁰

275. The *Next Stage Review* puts in place several mechanisms intended to focus the attention of managers and Boards on quality and safety, including the regular publication of “Quality Accounts” and the use of “Clinical Dashboards”. At Luton and Dunstable Hospital we heard that the Board routinely looks at “dashboard” data at its meetings.

269 PS 52A

270 Q 854

276. The culture of an organisation may well be harder to measure than other aspects of performance. We were informed that several means exist of promoting a safety culture and assessing progress in doing so. These include “tools” produced by the Royal College of Nursing;²⁷¹ and the Manchester Patient Safety Framework (MaPSaF).²⁷² However, it is unclear how widely such tools are used or how appropriate they are as a means of quantifying progress. At Luton and Dunstable Hospital we heard that the Trust there uses the Safety Climate Survey, developed by the Center of Excellence for Patient Safety Research and Practice at the University of Texas.

277. In discussing the Health Foundation’s SPI project, Dr Jo Bibby mentioned some ways in which Boards could better discharge their duties in respect of patient safety:

One of the approaches that the hospitals that we worked with used was called Leadership WalkRounds. The idea of that would be that usually two members of the board would visit an area in the hospital on a weekly basis, different members of the board. These were not spot checks, so it was not about trying to find things that were wrong, it would be planned ahead, the team would know they were coming. The idea of that would be to start to have a conversation about issues around patient safety in this organisation, the directors might say, “What was the last safety issue that happened? Tell us about it so we can understand how we would prevent that again. What could be the risk that it could happen next?” When you go into the organisations where they have been doing this, you get a real sense of recognition that patient safety is something that the senior leadership are paying attention to and that they are willing to act on system practice to improve patient safety.²⁷³

278. Dr Bibby also told us about the example of Torbay Hospital, whose Board:

will start every board meeting with an item on patient safety, so it is sending some very visible signals there that this is something that is a priority for the leadership of the organisation.²⁷⁴

At Luton and Dunstable Hospital, we learned that a quarter of Board meetings were specifically concerned with safety and quality, and that these routinely began with the stories of harmed patients told either in person or through recorded interviews. This served powerfully to focus Board members’ attention on the consequences of providing unsafe care.

Closed Board meetings

279. Another area of concern is the tendency for a significant number of Boards to transact all, or a substantial part, of their business behind closed doors—with the public and press barred from their meetings and Board papers not freely available. At Mid-Staffordshire Trust, the Board conducted a lot of its business in private before it became a Foundation

271 Ev 209

272 MaPSaF was described to us by the NPSA as “a tool to help NHS organisations (bespoke guides for acute, ambulance, mental health and primary care) assess progress in developing a safety culture” (Ev 149).

273 Q 633

274 Q 635

Trust and thereafter held all of its meetings in private. It has been reported that at least two-thirds of Foundation Trust Boards meet in private.²⁷⁵ We were told by Eric Morton, interim Chief Executive at Mid-Staffordshire Trust, that Foundation Trusts can discharge their duty in respect of public accountability through public meetings of Governors²⁷⁶ (we heard the same argument from the Chief Executive at Luton and Dunstable Hospital). Mr Morton told us that at Mid-Staffordshire Trust, which lacked developed Foundation Trust governance arrangements, the Board had begun meeting in public again since the publication of the HCC's report.

280. The Minister of State for Health Services told us that the DH deplored Boards meeting in private and had written to them stating that this should not be happening. He explained that the Department had no power to force Foundation Trusts to heed this, but the Government was considering legislating to give the DH more power to intervene in Foundation Trusts over this and other matters.²⁷⁷

Whistleblowing

281. An important measure of an organisation's safety culture is how it treats "whistleblowing", *i.e.* "Spontaneous reporting outside normal channels by individual members of staff"²⁷⁸ as a last resort in order to draw attention to unsafe care. Managers and Boards in NHS bodies have a duty to heed whistleblowers and to afford them protection from victimisation for raising genuine matters of concern. In theory, such protection exists under the Public Interest Disclosure Act 1998; and is reinforced in the NHS by executive guidance, issued in 1999, requiring appropriate local policies and procedures.²⁷⁹ And this protection is also reiterated in the draft NHS Constitution. Yet, in practice, it seems that many NHS staff fear the consequences of whistleblowing.

282. This has been a contentious issue in respect of the poor safety standards uncovered at Mid-Staffordshire Trust. The Secretary of State for Health has referred to "the mystery of Stafford being the absence of any whistleblower" despite the existence of adequate legal protection for whistleblowers. He has insisted that "I do not accept that nurses, and least of all consultants or doctors—I have yet to meet a shy consultant—would not come forward on such a serious issue because they were somehow terrified, despite the protection of the law".²⁸⁰ However, fear of victimisation may well have been a factor inhibiting staff from whistleblowing at the Trust.

283. Ms Ocloo, the mother of a harmed patient and a WHO Patient Safety Champion, told us:

275 "Private board meeting risks spelled out", *Health Service Journal*, 2 April 2009

276 Qq 96–100

277 Qq 1056–1059

278 Department of Health, *An organisation with a memory*, 2000, p 50. The document notes that: "In one sense, 'whistleblowing' can be seen as evidence of a failure to learn—people are far more likely to pursue channels outside their own organisation if there has been a failure to act on or even acknowledge concerns raised internally. To many a perceived need for external whistleblowing is in itself a sign that organisational culture is seriously awry" (para 4.47, p 64).

279 NHS Executive, HSC 1999/198 The Public Interest Disclosure Act 1998—Whistleblowing in the NHS, August 1999

280 HC Deb, 12 May 2009, col 672

I think there is still quite a lot of stigma attached to doctors who speak up or so-called whistle-blow. Doctors should have an obligation to speak up and tell the truth. I think we should do something more about trying to get rid of that stigma. Those doctors get quite badly labelled and stigmatised. If we get rid of some of that, then we might get more of a flow of doctors who could come through who would not feel that their reputation might be tarnished.²⁸¹

284. The Royal College of Nursing told us about the results of a survey of its members according to which:

- 78% of respondents said they would be concerned about victimisation, personal reprisals or a negative effect on their career if they were to report concerns to their employers;
- 21% had been discouraged or told directly not to report concerns at their workplace;
- 64% did not feel confident their employer would protect them if they spoke up;
- 99% of registered nurses understood their professional responsibility to report worries about patient safety but fears about personal reprisals meant that only 43% would be confident to report concerns without thinking twice;
- 71% said their employers had not taken immediate action to resolve the situation after concerns had been reported;
- 35% said no action was ever taken by employers after concerns had been reported;
- 45% did not know if their employer had a whistleblowing policy.²⁸²

285. The Royal Pharmaceutical Society of Great Britain indicated that the law on whistleblowing is not adequate:

In Denmark the law has been changed so that it is now an offence not to speak up when things go wrong, but measures to encourage whistleblowing need to be accompanied by strong measures to protect whistleblowers from dismissal and blacklisting. We recommend that the Committee considers whether the UK's Public Interest Disclosure Act (1998) has been successful in encouraging and supporting whistleblowing, and whether additional measures are needed in this area.²⁸³

286. Dr Peter Daggett asked the Committee “to codify the way that consultants and nurses can actually contact the next layer up, the PCT or the SHA, because at present there is no defined route of doing that”.²⁸⁴

287. We found that in New Zealand a statutory body, the office of the Health and Disability Commissioner, has the power to investigate and act on complaints from health-service

281 Q 193

282 PS 44A

283 PS 78

284 Q 967

staff (as well as from patients and members of the public, as we have noted) where they are not satisfactorily resolved locally.

Conclusion

288. There is disturbing evidence of catastrophic failure on the part of some Boards in cases such as Maidstone and Tunbridge Wells Trust and Mid-Staffordshire Trust. While other Boards are not failing as comprehensively, there is substantial room for improvement.

289. Boards too often address governance and regulatory issues, believing that they are thereby discharging their responsibilities in respect of patient safety—when what they should actually be doing is promoting tangible improvements in services. The concept of clinical governance may be to blame for spawning a structural approach, focused on processes rather than on the actual state of frontline services.

290. Many managers and non-executive members of Boards with responsibility for patient safety seem to have little or no grounding in the subject. There is a case for providing specialist training in patient safety issues, particularly to non-executives, to help them scrutinise and hold to account their executive colleagues. We agree with Lord Patel's suggestion about giving one non-executive member of each Board specialist training, to allow them to take particular responsibility for it. The example of Luton and Dunstable Hospital in having committees of the Board of Directors to look specifically at patient safety and patient experience should be recommended to all Trust boards.

291. Patient safety must be the top priority of Boards. In order to fulfil their duty to ensure “that the quality and safety of patient care is not pushed from the agenda by immediate operational issues”, patient safety should without exception be the first item on every agenda of every Board.

292. We commend to NHS organisations the measures piloted as part of the Safer Patients Initiative to ensure that Boards maintain safety as their foremost priority, namely

- implementing tried and tested changes in clinical practice to ensure safe care;
- banishing the blame culture;
- Providing the leadership to harness the enthusiasm of staff to improve safety;
- changing the way they identify risks and measure performance, by using information about actual harm done to patients, such as data from sample case note reviews.

We strongly urge the adoption of these throughout the NHS.

293. In addressing the blame culture, we recommend that Trusts use means such as the Texas Safety Climate Survey to measure and monitor how far staff feel confident about being open and reporting incidents.

294. We strongly endorse the DH's view that no Board in the NHS should always be meeting behind closed doors. We urge the Government to legislate as necessary to ensure Foundation Trust Boards meet regularly in public; the public should only exceptionally be excluded.

295. Many healthcare workers remain fearful that if they are open about harm to patients they will be unfairly blamed for causing it; and that if they whistleblow they will be victimised. Where information is available about incidents, it is too often not used to make lasting improvements to services. We have insufficient evidence to comment on the adequacy of statutory protection for whistleblowers. However, the information we have received indicates that the NHS remains largely unsupportive of whistleblowing. We recommend that the DH bring forward proposals on how to improve this situation and that it give consideration to the model operated in New Zealand, where whistleblowers can complain to an independent statutory body. We recommend that Annex 1 of the Health Service Circular, HSC 1999/198, "The Public Interest Disclosure Act 1998—Whistleblowing in the NHS" be re-circulated to all Trusts for dissemination to all their staff as a matter of urgency.

296. Regarding Mid-Staffordshire Trust, we are unconvinced of the case for a full public inquiry into the Trust, given the work that has already been done by the HCC, Professor Sir George Alberti and Dr David Colin-Thomé, and the likely further disruption to the Trust. However, we do see merit in the idea, recommended to us by the Royal College of Nursing, of holding hearings in private to allow members of staff to give evidence confidentially to discover how the state of affairs progressed so far without detection by the Trust Board. As this would look at the past and involve those in post in previous years, it would not impede the process of improvement and the rebuilding of confidence in the hospital. Although held in private its findings should be made public with protection of individual witnesses as appropriate.

11 The role of the DH and Government

297. Patient safety policy since *An organisation with a memory* (2000) has been mainly focused on the creation of reporting and learning mechanisms together with an open safety culture. As we have seen, a formidable, and pioneering, reporting and learning system has been created; yet a safety culture apparently remains elusive in much of the NHS. As Professor Kennedy, then Chairman of the HCC, told us, “cultural changes and behavioural changes” in respect of safety “lag behind in translating ideas into reality” compared to “structural responses”.²⁸⁵

298. A major factor in this seems to have been that, as *Safety First* (2006) noted, safety is “not always given the same priority or status as other major issues such as reducing waiting times, implementing national service frameworks and achieving financial balance”.²⁸⁶ As we have noted, in several cases of major lapses in patient safety, an important factor was that safety was pushed aside in the deliberations of Boards by other priorities—particularly waiting-time targets, the need to achieve financial balance and the achievement of Foundation status. Although patient safety has theoretically been among the major priorities of the NHS for the past decade, in practice the message coming from the DH, as several witnesses told us, appears to have been that all these other matters were actually greater priorities. In respect of targets in particular, the quantity of services provided has appeared to be much more important than their quality.

299. Ministers and DH officials told us rightly that many Trusts have managed to respond to targets and other imperatives from the centre, whilst also providing safe services. They accept that some Trusts have not done so, but insist that these are exceptional cases, with dysfunctional managers and Boards who must take the blame for their failure to provide safe care.

300. Two points can be made in response to this. Firstly, the Government’s overwhelming emphasis on hitting targets (particularly waiting-list and A&E waiting), achieving financial balance and attaining Foundation status, clearly did not help to improve failing Trusts—rather it compounded their failure. The failing Trusts, like Mid-Staffordshire and Maidstone and Tunbridge Wells, clearly thought the Government was telling them that patient safety was a second-order priority. Secondly, the failure of the systems for commissioning, performance management and regulation to detect in a timely fashion the failings of these Trusts’ managers and Boards, which we have already noted, must at least in part be laid at the door of the Government, which is responsible for those systems. Likewise, the failure of the NHS systems for handling complaints, and for patient and public involvement to bring to light those failings can also ultimately be seen as a failure of the Government policy underlying those systems.

285 Q 691

286 Department of Health, *Safety First*, 2006, p 6

Conclusion

301. The Government is to be praised for being the first in the world to adopt a policy which makes patient safety a priority. However, Government policy has too often given the impression that there are other priorities, notably hitting targets (particularly for waiting lists, and Accident and Emergency waiting times), achieving financial balance and attaining Foundation Trust status, which are more important than patient safety. This has undoubtedly, in a number of well documented cases, been a contributory factor in making services unsafe. We welcome Lord Darzi's statement in the *Next Stage Review* of the importance of quality and safety. From now on, all Government policy in respect of the NHS must be predicated on the principle that the Service's first priority, always and without exception, is to ensure that patients in its care do not suffer avoidable harm. The Government should state clearly that safety is the overriding priority of the NHS and that, if necessary, other targets should be missed where patient safety is being jeopardised; for example, A&E patients should not be moved to unsuitable wards just to meet the four-hour maximum waiting target.

302. The key tasks of the Government are to ensure that the NHS:

- develops a culture of openness and “fair blame”;
- strengthens, clarifies and promulgates its whistleblowing policy; and
- provides leadership which listens to and acts upon staff suggestions for service changes to improve efficiency and quality and, by the provision of examples and incentives, encourages and enables staff to implement practical and proven improvements in patient safety.

In addition, the Government should examine the contribution of deficiencies in regulation to failures in patient safety.

Conclusions and recommendations

Patient safety policy since 2000

1. Since 2000, the Department of Health has sought to move the NHS away from a “blame culture”, in which harm to patients is unfairly attributed to individual healthcare workers, to an open, reporting and learning culture, which can identify and address the systemic failings that are responsible for the vast majority of avoidable harm. At the same time, a mechanism (the National Reporting and Learning System) and an organisation (the National Patient Safety Agency) have been created to facilitate systematic reporting of, and learning from, patient safety incidents, and improvement of services. These measures mean the NHS has led the way for healthcare systems throughout the world in the development of patient safety policy and for this credit is due. In his reports in 2007 and 2008 Lord Darzi stressed the importance of safe care in the NHS as part of his Next Stage Review. (Paragraph 30)
2. In addition, the Health Foundation has established the Safer Patients Initiative which seeks to encourage clinicians and other staff to look for the best ways of reducing the harm done to patients. (Paragraph 31)
3. We are, however, concerned that Lord Darzi’s emphasis on quality and safety is an indication that, for all the policy innovations of the past decade, insufficient progress has been made in making NHS services safer. We note that the report commissioned by the Chief Medical Officer in 2006, *Safety First*, concluded that patient safety was attaining a significant national profile, but was “not always given the same priority or status as other major issues such as reducing waiting times, implementing national service frameworks and achieving financial balance”. This concern is heightened by the recent cases of disastrously unsafe care that have come to light in a small number of Trusts. (Paragraph 32)

Measurement and evaluation

4. The evidence, particularly that from case note reviews, both in England and internationally, indicates that the extent of medical harm is substantial, even on a conservative estimate, and that much is avoidable. International studies suggest that about 10% of all patients who are admitted to hospital suffer some form of harm. Judging how far patient safety policy has been successful requires more reliable data regarding how much harm is done to patients. Unfortunately, neither the NPSA nor the DH was able to provide us with that. Government estimates of avoidable harm and the attendant financial costs are extrapolations from old, very limited, data; and no attempt has been made to produce reliable up-to-date figures. (Paragraph 55)
5. We remind the Department of the value of the random case note review that was a part of Royal College inspections for accreditation for training of junior doctors. We commend to all hospitals the practice of conducting regular sample case note reviews, as is done at Luton and Dunstable Hospital, to provide a clear indicator of local performance in making services safer. We recommend that the NPSA monitor

progress by the NHS in improving patient safety, using local sample case note peer review data and other sources of information on harm to patients. (Paragraph 56)

Harmed patients and their families or carers

6. Harmed patients and their families or carers must receive honest information, a full explanation, an unequivocal apology and an undertaking that the harm done will not be repeated. While, the NHS has made progress in this regard, there is still too often a lack of frankness on all these counts. (Paragraph 90)
7. The new NHS Litigation Authority guidance on giving apologies and explanations is welcome and we urge its implementation. We also recommend further consideration be given to the CMO's proposal for a statutory duty of candour in respect of harm to patients. (Paragraph 91)
8. Relatives have a right to expect that coroner's inquiries will provide information about the reasons for deaths. We are disappointed that some harmed patients' families do not believe that coroners provide the objective inquiry and independent review that is needed. We believe coroners are too narrowly focused on the immediate cause of injury rather than underlying causes, as evidenced by the case of Bethany Bowen. (Paragraph 92)
9. The NHS continues too often to deal poorly with complainants and fails to use complaints as a means of improving services. We are sceptical that there will be a major improvement following the latest in a protracted series of changes to the complaints system. (Paragraph 93)
10. We are concerned that Patient Advice and Liaison Services, which are effectively the gateway to the NHS complaints system, are provided by NHS organisations themselves. While many PALS services undoubtedly do a good job for patients, their lack of independence makes it more likely that some at least will be "defensive and unhelpful", as a witness found them to be, when a patient has been harmed. PALS should not be hosted by individual NHS organisations and must be independent. We recommend that the Department report on the adequacy of PALS staffing by publishing the number of staff dedicated to PALS affairs by whole-time equivalents for each Primary Care Trust, acute Trust and Foundation Trust. (Paragraph 94)
11. We are very concerned about the loss of the Independent Review stage of the complaints process, which we regard as a retrograde step. There is no guarantee that the new regulations will improve the handling of complaints at local level. Moreover, we doubt the Ombudsman has sufficient resources to be able to act as an adequate "backstop" for the many people whose complaints are not adequately addressed locally. We recommend a reversion to the three-stage model for the NHS complaints system as soon as possible, with the Care Quality Commission, or another appropriate body, taking on the Independent Review stage. (Paragraph 95)
12. In addition, we recommend that the DH consider the possible application in England of the model provided by the independent Health and Disability Commissioner in New Zealand, to encompass both the Independent Review and Ombudsman roles. (Paragraph 96)

13. The failure to be open and to satisfactorily address complaints is in large part due to the fear of litigation. We are appalled at the failure of the DH to implement the NHS Redress Scheme three years after Parliament passed the necessary legislation. The DH has explained that it wishes to focus on complaints reform and will consider the matter of redress “When the reformed complaints arrangements are embedded”. We find this wholly unsatisfactory. By dragging its heels over implementing the NHS Redress Scheme, the DH is forcing harmed patients and their families or carers to endure often lengthy and distressing litigation to obtain justice and compensation. It is also obliging the NHS to spend considerable sums on legal costs, and encouraging defensiveness by NHS organisations. In addition, it is hindering the development of a safety culture in the NHS, which cannot flourish in the midst of powerful tensions between the desire to be open and medico-legal concerns. We recommend that the Redress Scheme be implemented immediately. (Paragraph 97)
14. If anything, the Government should be considering more radical measures in this direction, rather than shying away from the limited changes for which it has already legislated. We urge consideration of a scheme like that in New Zealand, where litigation over clinical negligence has been entirely replaced by a statutory right to compensation for “treatment injury” from an independent fund, without the need to prove negligence as required under tort law. (Paragraph 98)

An open, reporting and learning NHS

15. After the expenditure of much effort and funding on the National Reporting and Learning System, clear progress has been made in incident reporting; but we are concerned that the NRLS is nevertheless still limited in its effectiveness. (Paragraph 113)
16. We welcome the fact that the NRLS is now collecting significant amounts of data, which are being used to generate statistical and other output to help make services safer. However, we are concerned that there remains significant under-reporting, particularly in respect of incidents in primary care; medication incidents; serious incidents; and reporting by doctors. (Paragraph 114)
17. A major reason for under-reporting is the persistent failure to eliminate the “blame culture” in much of the NHS. Another important factor is fear of litigation or prosecution, underlining the need for the Government to address the medico-legal aspects of patient safety; we particularly recommend the decriminalisation of dispensing errors on the part of pharmacists. The “one size fits all” nature of reporting systems is also a significant problem. We welcome the NPSA’s recognition of the need to address this by developing reporting systems that are appropriate to different specialties (such as general practice and anaesthesia). We recommend that work on this be treated as a major priority by the Agency. (Paragraph 115)
18. We believe that as much as possible of the data collected by the NRLS on reported incidents should be published, in the interests of openness and learning about patient safety. We, therefore, welcome the decision to start publishing this data broken down by individual NHS organisation. (Paragraph 116)

19. While acknowledging the importance of incident reporting for patient safety, we question whether the NRLS, as presently constituted, is as useful and as cost-effective as it should be. The System currently amasses a good deal of summary data of doubtful usefulness, particularly on: common types of incident that are already well understood, such as slips, trips and falls; and less serious (“Low harm” and “No harm”) events, of various types. However, unlike reporting systems in other safety-critical industries, and in other healthcare systems, it does not systematically gather in-depth (root-cause analysis) data on serious and sentinel events. We recommend that consideration be given to rebalancing the NRLS accordingly. We also recommend that root-cause analysis be undertaken much more widely, and better, in the NHS in respect of serious and sentinel events in general and less common types of these in particular. We believe this might be facilitated by the establishment of a body along the lines of the Department for Transport’s Accident Investigation Branches, which could undertake independent root-cause analysis of serious and sentinel events in cases where there are likely to be significant new lessons to learn. In cases involving a patient’s death, this could have the additional benefit of providing their family with the full explanation that coroners do not seem always to provide. We recommend that the DH look into the feasibility of this. (Paragraph 117)
20. No reporting system, however well it functions, can capture all the information about patient safety issues and solutions that is needed to help make services safer. Data must be collated from as wide a range of sources as possible. We acknowledge the work that the NPSA has already done in this regard, particularly through the Patient Safety Observatory, and we recommend that this should be made a major priority for the Agency. (Paragraph 118)

Patient safety at the front line

21. Too often known patient-safety solutions fail to be adopted in the NHS even when they are disseminated by means such as Patient Safety Alerts. They are handed down from on high as diktats (if they are passed on at all) without frontline clinicians being convinced of their effectiveness. Moreover, a culture persists in which various types of harm to patients are seen as inevitable when in fact they are avoidable if the right steps are taken. (Paragraph 148)
22. Some organisations, however, have shown that it is possible for improvements to be fully integrated in frontline services by engaging and involving clinicians, and other healthcare workers. The focus needs to be on tangible improvements to health, drawing on staff’s own initiative. (Paragraph 149)
23. “Lean” thinking, using the initiative of frontline staff to increase efficiency and use time more effectively, is beginning to be introduced into the NHS through schemes such as the Productive Ward programme and the Safer Patients Initiative. This approach has much to commend it. If less efficient ways of working can be eliminated then more can be achieved and standards of care raised. (Paragraph 150)
24. Lack of non-technical skills can have lethal consequences for patients. However, the NHS lags unacceptably behind other safety-critical industries, such as aviation, in

this respect. Human Factors training must be fully integrated into undergraduate and postgraduate education, as we discuss more fully below. (Paragraph 151)

25. Routines and, in particular, checklists are an important aspect of safety in healthcare as in other activities. We welcome the implementation of the World Health Organization Safe Surgery checklist. While similar measures are already used in NHS hospitals, we are concerned that such checklists are not always followed because clinicians regard them as diktats and do not always see the point of them. We recommend that clinicians who persistently disregard these checklists should undergo retraining. (Paragraph 152)
26. Despite the massive increase in the numbers of NHS staff in recent years, inadequate staffing levels have been major factors in undermining patient safety in a number of notorious cases. It is clearly unacceptable for care to be compromised in this way. NHS organisations must ensure services have sufficient staff with the right clinical and other skills. (Paragraph 153)
27. Regarding the new European Working Time Directive rules, we are not convinced by the more alarmist claims being made that these will seriously jeopardise patient safety when they are introduced on 1 August 2009. But we do seek assurance from the DH that everything possible is being done to ensure that safety is not compromised. Professor Sir Bruce Keogh, the NHS Medical Director, did agree that 1 August “is going to be very challenging” and he told the Committee that derogation for some services and the impact on training were being looked into further. (Paragraph 154)

Technology and patient safety

28. While the potency and complexity of modern technology mean that it carries great potential for harm, it can also make a major contribution to patient safety. During the inquiry we took evidence about a number of technologies which could make significant improvements to care but which were being implemented far too slowly. (Paragraph 176)
29. Automated decision-support systems can help improve patient safety, notably in primary care. We note the slow progress made in integrating National Institute for Health and Clinical Excellence guidance into such systems and recommend that a timetable be set for achieving this. (Paragraph 177)
30. Electronic prescribing-support systems should be introduced throughout the NHS and set up with the alerts feature appropriately configured. (Paragraph 178)
31. Automatic Identification and Data Capture technology, such as barcoding, has the potential to reduce significantly certain types of error. Impressive pioneering advances, such as those in relation to blood transfusion at Oxford Radcliffe Hospitals NHS Trust and to medication at the Charing Cross Hospital, have been made in this respect, but we have grave concerns about their slow uptake across the NHS. We are concerned at the DH’s decision not to review progress on Coding for Success. Its reasons for not doing so are unacceptable in view of the slow progress to date. (Paragraph 179)

32. The continued delay in the Electronic Patient Record also represents a huge missed opportunity to improve patient safety by improving the communication of clinical data (particularly between care settings), which would reduce administrative errors and facilitate better continuity of care. (Paragraph 180)
33. We are alarmed at the lengthy delay in implementing Professor Toft's 2001 recommendation regarding the development of spinal needles that cannot be connected to a Luer syringe. It is totally unacceptable that an identified and simple technical solution to a catastrophic problem should take so long to be put into practical use. The Chief Executive of the NHS must explain why this delay has taken place and ensure that such delays never occur again. It is unacceptable that the NHS does not have a mechanism to ensure that changes such as this, which impact seriously on patient safety, occur in a timely fashion. (Paragraph 181)

Education and training curricula

34. There are serious deficiencies in the undergraduate medical curriculum, which are detrimental to patient safety, in respect of training in: clinical pharmacology and therapeutics; diagnostic skills; non-technical skills; and root-cause analysis. These must be addressed in the next edition of Tomorrow's Doctors. The DH and GMC must monitor the quality of new medical graduates' use of the skills listed above. Elements of patient safety are taught, but this tends to be done implicitly rather than explicitly; this should also be addressed in the curriculum, which must make clear that patient safety is the first priority of medical practice. Patient safety must also be fully integrated into postgraduate medical education and training as a core element, not an optional extra. (Paragraph 195)
35. Patient safety, including Human Factors, has yet to be fully and explicitly integrated into the education and training curricula of healthcare workers in general. This training should include the recognition that errors will inevitably occur in certain circumstances. There are convincing arguments for interdisciplinary training to foster good teamwork skills across professional boundaries: those who work together should train together. (Paragraph 196)

Commissioning, performance management and regulation

36. As we have argued elsewhere, we have grave doubts about Primary Care Trusts' performance in their commissioning role. The DH's hope is that World Class Commissioning will transform PCTs, but there is a danger that it will be another tick box exercise. As we stated in our report on the Next Stage Review we welcome the principle of linking payment to the quality of care, but recommend that it be tested first in a pilot project. We support the use of Never Events by PCTs, but have doubts about whether they should involve a financial penalty; we recommend this be the subject of a pilot project. (Paragraph 256)
37. The performance-management role of Strategic Health Authorities appears to be ill-defined and to vary between SHAs. We are not convinced that this function is being effectively discharged throughout the NHS. There seems to be no definition of it laid down by the DH; and the Department was unable to supply this when we asked. We

recommend that the DH produce a formal definition of the performance-management role of SHAs. (Paragraph 257)

38. Regulation has been burdensome and costly and its main mechanism, the Annual Health Check, has failed to pick up major failings in healthcare, although the HCC did through other means identify the problems in cases such as Mid-Staffordshire Trust and things would have been even worse without regulation. We do not, of course, know how much poor care the Annual Health Check failed to identify. (Paragraph 258)
39. Regulation in the past decade has been characterized by an expansion in rule-based mechanisms, looking at processes and procedures rather than actual outcomes and consequences and professional competence. Too often the rule-based approach has been unable to capture the complexities of frontline care. Worse, it may fail to engage professionals, who are quick to recognize opportunities to work around rules. Inappropriate rules will foster ingenuity in compliance but detachment from the more demanding role of asserting and fulfilling the needs of patients. Sustained improvement depends on releasing the potential of staff to see, develop and own solutions. (Paragraph 259)
40. The new Care Quality Commission's registration system must focus on the outcomes being achieved by NHS organisations rather than formal governance processes; it must ensure that organisations only collect information which they should be collecting for their own purposes. (Paragraph 260)
41. We recommend the DH consider how to reinstate the best aspects of the Royal Colleges' inspections in the new system. (Paragraph 261)
42. The relationship between commissioning, performance-managing and regulating bodies is not defined clearly enough. There are, as Baroness Young put it, "a lot of players on the pitch" and we are concerned that too often they are not an effective team. There is evidence of overlapping functions and multiple submission of information to different regulators. Most disturbing of all is that Foundation Trusts appear to be operating in an entirely different regulatory framework from non-Foundation Trusts. (Paragraph 262)
43. What all the complex panoply of organisations has actually achieved is called into question by the fact that these systems have been shown recently to have failed in several instances promptly to expose and address major instances of unsafe care. (Paragraph 263)
44. The case of Mid-Staffordshire Trust has also exposed serious shortcomings in Monitor's assessment process when granting authorisation. Not only did Monitor fail to detect unsafe care—it effectively allowed the Trust to compromise patient safety in premature pursuit of Foundation status. We note the Healthcare Commission found that achieving Foundation status was one of the factors that distracted the Trust from patient safety issues. Monitor's acceptance at face value of the Trust's excuse that its poor mortality figures were a statistical anomaly is wholly unacceptable. (Paragraph 264)

45. We are also concerned about Monitor's role in regulating Foundation Trusts following authorisation. We are told that Monitor does not replicate the performance management role played by SHAs in respect of Trusts, but it is unclear by exactly which means Foundation Trusts are intended to be performance managed—or whether they are supposed to be performance managed at all. In Monitor's defence it could be said that too many SHAs have also done no effective performance management. (Paragraph 265)
46. There appears to be considerable potential for confusion, and possibly conflict, regarding the respective roles of Monitor and the CQC, as Monitor itself has indicated. The DH must clarify exactly what these two organisations' regulatory roles are in respect of Foundation Trusts and how those roles fit together. (Paragraph 266)
47. While the NHS Litigation Authority has performed an important role in setting standards, its involvement in scrutiny of NHS bodies leads to burdensome and wasteful duplication of time and effort for both Trusts and regulators. Moreover, the role of indemnifying Trusts against litigation over clinical negligence is quite distinct from the role of setting standards on safe care and safety culture—and there is potential for tension between the two, notably regarding openness about unsafe care. We recommend that the inspection process currently undertaken by the NHS Litigation Authority should be subsumed within the work of the Care Quality Commission. (Paragraph 267)
48. The DH should produce a succinct statement regarding how commissioning, performance management and regulation are defined, and how they (and the organisations responsible for them) relate to each other. (Paragraph 268)

The role of managers and Boards

49. There is disturbing evidence of catastrophic failure on the part of some Boards in cases such as Maidstone and Tunbridge Wells Trust and Mid-Staffordshire Trust. While other Boards are not failing as comprehensively, there is substantial room for improvement. (Paragraph 288)
50. Boards too often address governance and regulatory issues, believing that they are thereby discharging their responsibilities in respect of patient safety—when what they should actually be doing is promoting tangible improvements in services. The concept of clinical governance may be to blame for spawning a structural approach, focused on processes rather than on the actual state of frontline services. (Paragraph 289)
51. Many managers and non-executive members of Boards with responsibility for patient safety seem to have little or no grounding in the subject. There is a case for providing specialist training in patient safety issues, particularly to non-executives, to help them scrutinise and hold to account their executive colleagues. We agree with Lord Patel's suggestion about giving one non-executive member of each Board specialist training, to allow them to take particular responsibility for it. The example of Luton and Dunstable Hospital in having committees of the Board of Directors to

look specifically at patient safety and patient experience should be recommended to all Trust boards. (Paragraph 290)

52. Patient safety must be the top priority of Boards. In order to fulfil their duty to ensure “that the quality and safety of patient care is not pushed from the agenda by immediate operational issues”, patient safety should without exception be the first item on every agenda of every Board. (Paragraph 291)
53. We commend to NHS organisations the measures piloted as part of the Safer Patients Initiative to ensure that Boards maintain safety as their foremost priority, namely
 - implementing tried and tested changes in clinical practice to ensure safe care;
 - banishing the blame culture;
 - Providing the leadership to harness the enthusiasm of staff to improve safety;
 - changing the way they identify risks and measure performance, by using information about actual harm done to patients, such as data from sample case note reviews.

We strongly urge the adoption of these throughout the NHS. (Paragraph 292)

54. In addressing the blame culture, we recommend that Trusts use means such as the Texas Safety Climate Survey to measure and monitor how far staff feel confident about being open and reporting incidents. (Paragraph 293)
55. We strongly endorse the DH’s view that no Board in the NHS should always be meeting behind closed doors. We urge the Government to legislate as necessary to ensure Foundation Trust Boards meet regularly in public; the public should only exceptionally be excluded. (Paragraph 294)
56. Many healthcare workers remain fearful that if they are open about harm to patients they will be unfairly blamed for causing it; and that if they whistleblow they will be victimised. Where information is available about incidents, it is too often not used to make lasting improvements to services. We have insufficient evidence to comment on the adequacy of statutory protection for whistleblowers. However, the information we have received indicates that the NHS remains largely unsupportive of whistleblowing. We recommend that the DH bring forward proposals on how to improve this situation and that it give consideration to the model operated in New Zealand, where whistleblowers can complain to an independent statutory body. We recommend that Annex 1 of the Health Service Circular, HSC 1999/198, “The Public Interest Disclosure Act 1998—Whistleblowing in the NHS” be re-circulated to all Trusts for dissemination to all their staff as a matter of urgency. (Paragraph 295)
57. Regarding Mid-Staffordshire Trust, we are unconvinced of the case for a full public inquiry into the Trust, given the work that has already been done by the HCC, Professor Sir George Alberti and Dr David Colin-Thomé, and the likely further

disruption to the Trust. However, we do see merit in the idea, recommended to us by the Royal College of Nursing, of holding hearings in private to allow members of staff to give evidence confidentially to discover how the state of affairs progressed so far without detection by the Trust Board. As this would look at the past and involve those in post in previous years, it would not impede the process of improvement and the rebuilding of confidence in the hospital. Although held in private its findings should be made public with protection of individual witnesses as appropriate. (Paragraph 296)

The role of the DH and Government

58. The Government is to be praised for being the first in the world to adopt a policy which makes patient safety a priority. However, Government policy has too often given the impression that there are other priorities, notably hitting targets (particularly for waiting lists, and Accident and Emergency waiting times), achieving financial balance and attaining Foundation Trust status, which are more important than patient safety. This has undoubtedly, in a number of well documented cases, been a contributory factor in making services unsafe. We welcome Lord Darzi's statement in the Next Stage Review of the importance of quality and safety. From now on, all Government policy in respect of the NHS must be predicated on the principle that the Service's first priority, always and without exception, is to ensure that patients in its care do not suffer avoidable harm. The Government should state clearly that safety is the overriding priority of the NHS and that, if necessary, other targets should be missed where patient safety is being jeopardised; for example, A&E patients should not be moved to unsuitable wards just to meet the four-hour maximum waiting target. (Paragraph 301)

59. The key tasks of the Government are to ensure that the NHS:

- develops a culture of openness and "fair blame";
- strengthens, clarifies and promulgates its whistleblowing policy; and
- provides leadership which listens to and acts upon staff suggestions for service changes to improve efficiency and quality and, by the provision of examples and incentives, encourages and enables staff to implement practical and proven improvements in patient safety.

In addition, the Government should examine the contribution of deficiencies in regulation to failures in patient safety. (Paragraph 302)

Glossary

A&E	Accident and Emergency
ACC	Accident Compensation Corporation (New Zealand)
AIDC	Automatic Identification and Data Capture
AvMA	Action against Medical Accidents
CHCs	Community Health Councils (1974–2003)
CHI	Commission for Health Improvement (2000–4)
CMO	Chief Medical Officer
CNO	Chief Nursing Officer
CNST	Clinical Negligence Scheme for Trusts
CQC	Care Quality Commission
CQUIN	Commissioning for Quality and Innovation
DH	Department of Health
HCAIs	Healthcare Associated Infections
HCC	Healthcare Commission (2004–9)
HDC	Health and Disability Commissioner (New Zealand)
ICAS	Independent Complaints Advocacy Services
MaPSaF	Manchester Patient Safety Framework
NAO	National Audit Office
NHSLA	NHS Litigation Authority
NPSA	National Patient Safety Agency
NQB	National Quality Board
NRLS	National Reporting and Learning System
PAC	House of Commons Committee of Public Affairs
PALS	Patient Advice and Liaison Services
PCT	Primary Care Trust
PROMs	Patient-reported outcome measures
PSAT	Patient Safety Action Team

PSO	Patient Safety Observatory
SHA	Strategic Health Authority
SPI	Safer Patients Initiative
STEIS	Strategic Executive Information System
SUI	Serious Untoward Incident
WHO	World Health Organization

Adverse event: An incident in which a patient is harmed.

Clinical governance: The system 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 clinical excellence will flourish.

Fair blame culture: A culture in which healthcare workers feel able to report and discuss harm to patients in which they have been involved without fearing that they will be unfairly blamed.

Human Factors: Environmental, organisational and job factors, and human and individual characteristics which influence behaviour at work in a way which can affect health and safety. Often used as a synonym for non-technical skills (see below).

“Lean” thinking: The philosophy of empowering and motivating shop-floor staff to streamline and improve processes, reduce waste, improve quality, and deliver products and services in a more timely way.

Near miss: 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 the result of compensating action, thus preventing injury to a patient.

Non-technical skills: The cognitive and social skills (complementing technical skill, such as clinical skills in healthcare) that allow people working in safety-critical industries to function effectively and safely.

Patient safety: Freedom, as far as possible, from harm, or risk of harm, caused by medical management, as opposed to harm caused by the natural course of the patient’s original illness or condition.

Patient safety incident: Any unintended or unexpected incident due to medical management, rather than the natural course of the patient’s original illness or condition, which could have led or did lead to harm for one or more patients receiving NHS-funded healthcare.

Productive Ward: A scheme for involving frontline staff in designing and implementing more efficient ways of working, bypassing conventional management chains of command.

Root-cause analysis: An investigative method that seeks to identify the underlying causes of an incident, with a view to preventing repetition.

Safer Patients Initiative: A UK-wide project, established by the Health Foundation (an independent charity), to test and implement ways of improving patient safety in acute hospitals.

Safety-critical industries: Those industries in which failure can cause serious injury or death.

Sentinel event: An incident that signals the need for immediate investigation and response, since it involves death or other serious injury, or the risk of these.

Serious Untoward Incident: Something out of the ordinary or unexpected, with the potential to cause serious harm, and / or likely to attract public and media interest that occurs on NHS premises or in the provision of an NHS or a commissioned service.

Significant Event Audit: A process through which individual episodes in which there has been a significant occurrence, either beneficial or deleterious, are analysed in a systematic and detailed way to ascertain what can be learnt about the overall quality of care and to indicate changes that might lead to future improvements.

Annex 1: Terms of reference of the inquiry

1. What the risks to patient safety are and to what extent they are avoidable, including:

- Role of human error and poor clinical judgement
- Systems failures
- How far clinical practice can be risk-free; the definition of “avoidable” risk; whether the “precautionary principle” can be applied to healthcare
- The role of public perceptions of risk in determining NHS policy

2. What the current effectiveness is of the following in ensuring patient safety:

a) local and regional NHS bodies, and other organisations providing NHS services (including primary and community care, and mental health services)

- How far the Boards of NHS bodies have established a safety culture

b) systems for incident reporting, risk management and safety improvement

- Whether adequate measurement and assessment is undertaken and acted upon
- The impact of the changing public-private mix in provision

c) national policy

- The appropriateness of the objectives set out in national policy statements, including Safety First and High Quality Care for All, and what progress has been made in meeting them
- Whether past spending on patient safety has been sufficient and cost effective, and what future spending should be
- The appropriateness of national targets

d) the National Patient Safety Agency and other bodies, including:

- Healthcare Commission / Care Quality Commission
- NHS Litigation Authority

e) education for health professionals

3. What the NHS should do next regarding patient safety

- Whether the measures taken to improve patient safety are supported by adequate evidence regarding their clinical effectiveness and cost effectiveness
- How to determine best practice and ensure it is spread throughout the whole NHS
- How to ensure that learning is implemented

- What should be measured and assessed; and what data should be published
- What incentives there should be to improve patient safety
- How patients and the public can be involved in ensuring that services are safe

Annex 2: International case note review studies

Country	Number of hospitals	Number of admissions	Year of admissions	Adverse event rate (%) ⁱ
USA (California)	23	20,864	1974	4.65 ⁱⁱ
USA (New York State)	51	30,121	1984	3.7
USA (Massachusetts)	1	3,141	1990–1	2.7 ⁱⁱⁱ
Australia (New South Wales and South Australia)	28	14,179	1992	16.6 ^{iv}
USA (Utah and Colorado)	28	14,732	1992	2.9
UK (London)	2	1,014	1998	10.8
Denmark	17	1,097	1998	9.0
New Zealand (Auckland)	3	1,326	1995	10.7
New Zealand	13	6,579	1998	12.9 ^v
France (Aquitaine)	7	778	Unknown	14.5
Canada (Ottawa)	1	502	Unknown	12.7
Canada	20	3,745	2000	7.5
UK (England)	1	1,006	2004	10.9 ^{vi}
Spain	24	5,624	2005	9.3
Netherlands	21	7,926	2004	5.7

ⁱ Proportion of admissions associated with adverse events (*i.e.* incidents in which patients were harmed).

ⁱⁱ Data relate to numbers of “potentially compensable events”.

ⁱⁱⁱ Study oriented towards discovering cases of potential medical negligence. When the same notes were examined using a different approach to assess all forms of harm to patients, the rate was put at 11%.

^{iv} Applying a different methodology to the same data has given a figure of 10.6%.

^v Prevalence rate, *i.e.* rate over period 1998–2000 in a population of patients admitted in 1998.

^{vi} Applying a different methodology to the same data has given a figure of 7.2%.

Formal Minutes

Thursday 18 June 2009

Members present:

Mr Kevin Barron, in the Chair

Jim Dowd
Sandra Gidley
Dr Doug Naysmith

Mr Lee Scott
Dr Howard Stoate
Dr Richard Taylor

Draft Report (*Patient Safety*), proposed by the Chairman, brought up and read.

Ordered, That the Chairman's draft Report be read a second time, paragraph by paragraph.

Paragraphs 1 to 302 read and agreed to.

Annexes and Summary agreed to.

Resolved, That the Report be the Sixth Report of the Committee to the House.

Ordered, That the Chairman make the Report to the House.

Ordered, That embargoed copies of the Report be made available, in accordance with the provisions of Standing Order No. 134.

Written evidence was ordered to be reported to the House for printing with the Report.

Written evidence was ordered to be reported to the House for placing in the Library and Parliamentary Archives.

[Adjourned till Thursday 25 June at 9.30 am

Witnesses

Thursday 30 October 2008

Professor Sir Bruce Keogh, NHS Medical Director, **Professor Dame Christine Beasley**, Chief Nursing Officer, Department of Health, and **Mr Martin Fletcher**, Chief Executive, National Patient Safety Agency

Thursday 20 November 2008

Professor Richard Thomson, Professor of Epidemiology and Public Health, University of Newcastle, and **Professor Alastair Gray**, Professor of Health Economics and Director of the Health Economics Research Centre, University of Oxford

Mr Martin Bromiley, Chairman, Clinical Human Factors Group, **Ms Josephine Ocloo**, Patients for Patient Safety Champion, England, WHO, World Alliance for Patient Safety, and **Mrs Clare Bowen**

Thursday 15 January 2009

Professor Andy Adam, President, Royal College of Radiologists, **Dr David Whitaker**, Immediate Past President, Association of Anaesthetists of Great Britain and Ireland, and **Professor Brian Toft**, Professor of Patient Safety, Coventry University

Professor Mike Murphy, Consultant Haematologist, John Radcliffe Hospital, and **Professor Bryony Dean Franklin**, Centre for Medication Safety and Service Quality, Imperial College Healthcare NHS Trust, and **Mr Roger Lamb**, Healthcare Manager, GS1 UK

Thursday 22 January 2009

Mr John Black, President, Royal College of Surgeons of England, **Rev Dr Pauline Pearson**, Deputy Director, CETL4HealthNE: Centre for Excellence in Healthcare Professional Education, Newcastle University, and **Professor David Webb**, Professor of Therapeutics and Clinical Pharmacology, The University of Edinburgh

Ms Kathryn Fawkes, Senior Theatre Nurse, Great Ormond Street Hospital, London, **Dr Susannah Long**, Clinical Research Fellow, Clinical Safety Research Unit, Imperial College London, **Mr Simon Kreckler**, Clinical Research Fellow, Nuffield Department of Surgery, and **Ms Sarah Dheansa**, Matron for Surgical Care, Queen Victoria Hospital, East Grinstead

Thursday 5 February 2009

Dr Alison Holmes, Director of Infection Prevention and Control, and Consultant in Infectious Diseases, Imperial College Healthcare NHS Trust, **Professor Matt Griffiths**, Visiting Professor of Prescribing and Medicines Management, Northampton University, and **Professor Aneez Esmail**, Professor of General Practice, The University of Manchester

Dr Jo Bibby, Director of Improvement Programmes, The Health Foundation, **Dr Olga Kostopoulou**, Medical Decision Making Research Group, The University of Birmingham, and **Captain Guy Hirst**, retired airline pilot, human factors trainer

Thursday 5 March 2009

Professor Sir Ian Kennedy, Chairman, Healthcare Commission, **Baroness Young of Old Scone**, Chair, Care Quality Commission, and **Dr Bill Moyes**, Executive Chairman, Monitor

Mr Finlay Scott, Chief Executive, General Medical Council, and **Mr Steve Walker**, Chief Executive, NHS Litigation Authority

Mr Geoffrey Podger, Chief Executive, Health and Safety Executive, and **Professor Kent Woods**, Chief Executive, Medicines and Healthcare Products Regulatory Agency

Thursday 19 March 2009

Professor Sir Michael Rawlins, Chairman, National Institute for Health and Clinical Excellence, **Lord Patel**, Chairman, and **Mr Martin Fletcher**, Chief Executive, National Patient Safety Agency

Professor the Lord Darzi of Denham KBE, Parliamentary Under Secretary of State, **Ann Keen MP**, Parliamentary Under Secretary of State for Health Services, and **Sir Liam Donaldson KB**, Chief Medical Officer, Department of Health

Wednesday 3 June 2009

Dr Peter Daggett FRCP, Consultant Physician, Stafford Hospital, and **Mr Howard Catton**, Head of Policy and Implementation, Royal College of Nursing

Mr Ben Bradshaw MP, Minister of State for Health Services, **Professor Sir Bruce Keogh**, NHS Medical Director, and **Mr David Flory**, Director General, NHS Performance and Operations, Department of Health

Mr Eric Morton, Interim Chief Executive, Mid Staffordshire NHS Foundation Trust

List of written evidence

The following memoranda were published as *Patient Safety: Written evidence*, HC 1137, Session 2007–08

PS

- 1 Department of Health
- 2 Dr Jeffrey C McLwain
- 3 Professor Matt Griffiths
- 4 Medical Decision Making Research Group, The University of Birmingham
- 5 Infant and Dietetic Foods Association
- 6 Patient Concern
- 7 Health and Safety Executive
- 8 National Concern for Healthcare Infections
- 9 Medical Protection Society (MPS)
- 10 Patient Opinion
- 11 Health Service Ombudsman for England
- 12 Royal College of Radiologists
- 13 Mencap
- 14 General Dental Council
- 15 Lifeblood: The Thrombosis Charity
- 16 Association of British Healthcare Industries
- 17 Brian Capstick
- 18 Bayer Schering Pharma
- 19 Confidential Enquiry into Maternal and Child Health (CEMACH)
- 20 British In Vitro Diagnostics Association (BIVDA)
- 21 The Health Foundation
- 22 Mr Arthur Briggs
- 23 Royal College of Ophthalmologists
- 24 Clinical Human Factors Group (CHFG)
- 25 Guy Hirst and Trevor Dale
- 26 Patient Liaison Group: Royal College of Surgeons England
- 27 Dr Richard FitzGerald
- 28 Christopher Wiltsher
- 29 MRSA Action UK
- 30 Faculty of Pharmaceutical Medicine
- 31 The Medical Technology Group
- 32 NHS Litigation Authority (NHSLA)
- 33 Graham Tanner
- 34 Quality, Reliability, Safety and Teamwork Unit, Oxford University (QRSTU)
- 35 Diabetes UK
- 36 Hospedia UK
- 37 PatientPak Ltd
- 38 Dartex Coatings Ltd

- 39 National Patient Safety Agency (NPSA)
- 40 Mind (National Association for Mental Health)
- 41 Care Quality Commission
- 42 UNISON
- 43 Medical Defence Union
- 44 Royal College of Nursing
- 45 ARHAI
- 46 British Institute of Radiology
- 47 Dr Liam O'Hara
- 48 GS1
- 49 Royal College of General Practitioners
- 50 Patients Association
- 51 Hepatitis C Trust
- 52 Healthcare Commission
- 53 Adrian Delemore
- 54 Patient Involvement in Patient Safety Team, University of York
- 55 Royal College of Midwives
- 56 Action against Medical Accidents
- 57 National Institute for Health and Clinical Excellence
- 58 Nursing & Midwifery Council
- 59 IDIS
- 60 Baxter Healthcare
- 61 Independent Healthcare Advisory Services (IHAS)
- 62 British Medical Association
- 63 Association of Anaesthetists of Great Britain and Ireland (AAGBI)
- 64 Bristol-Myers Squibb and sanofi-aventis
- 65 Monitor
- 66 Royal College of Pathologists
- 67 NHS Confederation
- 68 Royal College of Psychiatrists
- 69 Royal College of Surgeons of England
- 70 Royal College of Anaesthetists
- 71 Stuart Emslie and John Step
- 72 Council for Healthcare Regulatory Excellence
- 73 David Ringwood
- 74 Royal College of Physicians
- 75 Faculty of Occupational Medicine

List of further written evidence

The following written submissions were received after the publication of *Patient Safety: Written evidence*, HC 1137, Session 2007–08. They are reproduced with the Oral evidence in Volume II of this Report.

- 1 Department of Health (PS 01A, 01B, 01C and 01D)
- 2 The Health Foundation (PS 21A and 21B)
- 3 National Patient Safety Agency (NPSA) (PS 39A and 39B)
- 4 Care Quality Commission (PS 41A)
- 5 Royal College of Nursing (PS 44A and 44B)
- 6 Royal College of Physicians (PS 47A)
- 7 Patients Association (PS 50A)
- 8 Healthcare Commission (PS 52A and 52B)
- 9 Action against Medical Accidents (AvMA) (PS 56A)
- 10 Royal College of Psychiatrists (PS 68A)
- 11 Orde Levinson (PS 76)
- 12 BASICS (British Association of Immediate Care) (PS 77)
- 13 Royal Pharmaceutical Society of Great Britain (PS 78)
- 14 Royal Pharmaceutical Society of Great Britain (PS 78A)
- 15 Mrs Clare Bowen (PS 79)
- 16 Professor Richard Thomson (PS 80)
- 17 Professor Alastair Gray (PS 81)
- 18 Ms Josephine Ocloo (PS 82)
- 19 Professor Brian Toft (PS 83)
- 20 Professor Brian Toft (PS 83A and 83B)
- 21 CORESS (Confidential Reporting System in Surgery) (PS 84)
- 22 CORESS (Confidential Reporting System in Surgery) (PS 84A)
- 23 National Association of Laryngectomees Clubs (PS 85)
- 24 Professor Bryony Dean Franklin and Nick Barber (PS 86)
- 25 Professor Mike Murphy (PS 87)
- 26 Dr Susannah Long (PS 88)
- 27 Professor David Webb (PS 89)
- 28 Revd Dr Pauline Pearson, Amanda Howe, Aziz Sheikh, Darren Ashcroft, Pam Smith, Alison Steven on behalf of The Patient Safety Education Study Group (PS 90)
- 29 Medicines and Healthcare Products Regulatory Agency (PS 91)
- 30 General Medical Council (PS 92)
- 31 General Medical Council (PS 92A)
- 32 Dr Peter Greengross, Medical Director, The Learning Clinic (PS 93)
- 33 Joint Epilepsy Council (JEC) (PS 94)
- 34 Astellas Pharma Ltd (PS 95)
- 35 Dr Helen Hogan (PS 96)
- 36 Isabel Healthcare Ltd (PS 97)
- 37 Dr Tony Wright MP (PS 98)

- 38 David Kidney MP (PS 99)
- 39 Mid Staffordshire NHS Foundation Trust (PS 100)
- 40 Cure the NHS (PS 101)
- 41 Oxford Radcliffe Hospitals NHS Trust (PS 102)
- 42 William Cash MP (PS 103)
- 43 Dr Peter Daggett (PS 104)
- 44 Andrew Lansley CBE MP (PS 105)
- 45 Academy of Medical Royal Colleges (PS 106)
- 46 Dr Pradip Singh (PS 107)
- 47 Richard Stein (PS 108)

List of unprinted evidence

The following memoranda have been reported to the House, but they have not been printed and copies have been placed in the House of Commons Library, where they may be inspected by Members. Other copies are in the Parliamentary Archives, and are available to the public for inspection. Requests for inspection should be addressed to The Parliamentary Archives, Houses of Parliament, London SW1A 0PW (tel. 020 7219 3074). Opening hours are from 9.30 am to 5.00 pm on Mondays to Fridays.

Patients Association (PS 50B)

Orde Levinson (PS 76 (Exhibits 1–5A and Appendices 1–3a))

Cure the NHS (PS 101A)

Dr Pradip Singh (PS 107 Annexes A to F)

List of Reports from the Committee during the current Parliament

The following reports have been produced by the Committee in this Parliament. The reference number of the Government's response to the Report is printed in brackets after the HC printing number.

Session 2008–09

First Report	NHS Next Stage Review	HC 53 (Cm 7558)
Second Report	Work of the Committee 2007–08	HC 193
Third Report	Health Inequalities	HC 286 (Cm 7621)
Fourth Report	Top-up fees	HC 194
Fifth Report	The use of management consultants by the NHS and the Department of Health	HC 28

Session 2007–08

First Report	National Institute for Health and Clinical Excellence	HC 27 (Cm 7331)
Second Report	Work of the Committee 2007	HC 337
Third Report	Modernising Medical Careers	HC 25 (Cm 7338)
Fourth Report	Appointment of the Chair of the Care Quality Commission	HC 545
Fifth Report	Dental Services	HC 289 (Cm 7470)
Sixth Report	Foundation trusts and Monitor	HC 833 (Cm 7528)
First Special Report	National Institute for Health and Clinical Excellence: NICE Response to the Committee's First Report	HC 550

Session 2006–07

First Report	NHS Deficits	HC 73 (Cm 7028)
Second Report	Work of the Committee 2005–06	HC 297
Third Report	Patient and Public Involvement in the NHS	HC 278 (Cm 7128)
Fourth Report	Workforce Planning	HC 171 (Cm 7085)
Fifth Report	Audiology Services	HC 392 (Cm 7140)
Sixth Report	The Electronic Patient Record	HC 422 (Cm 7264)

Session 2005–06

First Report	Smoking in Public Places	HC 436 (Cm 6769)
Second Report	Changes to Primary Care Trusts	HC 646 (Cm 6760)
Third Report	NHS Charges	HC 815 (Cm 6922)
Fourth Report	Independent Sector Treatment Centres	HC 934 (Cm 6930)