



The Government Response to the
Health Select Committee Report
'Patient Safety'

Presented to Parliament by
the Secretary of State for Health
by Command of Her Majesty
October 2009



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The Government Response to the Health Select Committee Report 'Patient Safety'

Introduction

The House of Commons Health Select Committee published its report on Patient Safety on 3 July 2009. This Command Paper sets out the Government's response to the conclusions and recommendations of that report.

Patient safety is a core domain of quality and demands a system-wide effort. This requires a broad range of actions in organisational leadership, performance improvement, work-place safety, risk management and clinical engagement.

That is why *High Quality Care for All*, the final report of the *NHS Next Stage Review*, published in June 2008, set out a vision of an NHS that has quality of care at its heart and works in partnership with patients and the public, providing people with more information and choice. Quality encompasses patient safety, clinical effectiveness and patient experience.

High Quality Care for All set out the Quality Framework, bringing together a set of policies that will support local delivery of high quality care by:

- bringing clarity to quality – making it easy for clinicians to access evidence about best practice through a single portal, NHS Evidence, and by asking the National Institute for Health and Clinical Excellence (NICE) to develop quality standards;
- supporting clinicians to measure quality to support improvement, including through a menu of assured Indicators for Quality Improvement (IQI);
- requiring information about quality to be published in Quality Accounts;
- rewarding the delivery of high quality care, including through the Commissioning for Quality and Innovation (CQUIN) payment framework, which makes a small proportion of contract value contingent on achieving locally agreed goals around quality improvement and innovation;
- recognising the role of clinicians as leaders at all levels of the system. This includes giving local clinicians the freedom to drive improvements in quality of care and also the establishment of a National Quality Board (NQB) to give strategic leadership and oversight on quality to the NHS;

- safeguarding essential levels of safety and quality through a new independent regulator, the Care Quality Commission (CQC), with tough enforcement powers to assure compliance against care providers' statutory registration requirements;
- staying ahead by ensuring that innovation in medical advances and service design is fostered and promoted.

Securing the safety of patients applies to all healthcare disciplines and it is a challenge faced by healthcare systems all over the world. No country can claim to have solved the problem fully.

The Committee has recognised that we were one of the first countries to give priority to tackling patient safety with a "whole system" approach. Indeed, it is fair to say that the United Kingdom (UK) is one of the pioneers in the field of patient safety. It is one of the first to put in place a comprehensive quality and safety framework, with the establishment of the National Patient Safety Agency (NPSA), a national safety reporting system, clear national standards and inspection.

The 2000 report, *An Organisation with a Memory*, is still regarded internationally as a seminal document, which has galvanized action worldwide, demonstrating the high regard in which our policies are held within the international health policy arena. Since then, the Department of Health, the NPSA and other bodies, have been working closely with the World Health Organisation (WHO) World Alliance for Patient Safety, the European Union Network for Patient Safety (EUNetPaS) and have been playing a leading role in driving forward the Global Safe Surgery Saves Lives initiative in the UK. We are confident that our participation in the international arena gives impetus to our efforts at the domestic level.

Building on *An Organisation with a Memory*, we published *Safety First* in 2006. This set out the Chief Medical Officer (CMO)'s vision on furthering patient safety. Following the publication of *Safety First*, the NPSA has:

- continued developments in work to ensure actionable learning from national reporting, particularly from incidents associated with serious patient harm and death;
- greatly increased the publication of safety data and feedback to NHS Trusts from national reporting, including the publication of organisational safety data summaries;
- strengthened partnerships with Royal Colleges and professional groups to ensure specialty relevant learning and collaboration with regulatory and performance management bodies such as CQC and the Medicines and Healthcare products Regulatory Agency (MHRA);
- completed a major review of the approach across the NHS to ensuring openness with patients and their families especially when things go wrong;

- established Patient Safety Action Teams (PSATs) in partnership with each Strategic Health Authority (SHA) to put patient safety at the heart of the local system management of the NHS;
- led the development and implementation of a national patient safety campaign (Patient Safety First) to better engage frontline staff in safety improvements, in partnership with the NHS Institute for Innovation and Improvement (NHS Ii) and The Health Foundation.

We are pleased that the Health Select Committee has welcomed the creation and work of the NPSA, and the establishment of the National Reporting and Learning System (NRLS) to facilitate systematic reporting and learning from adverse events involving patients. Safety cannot be improved without a range of valid reporting, analytical and investigative tools that identify causes of risk in ways that lead to preventative action and organisation wide learning.

The NRLS is at the centre of the efforts of the NHS to understand risk and opportunities to improve patient safety and provides a unique safety knowledge resource for the NHS. The NRLS is one of the most comprehensive patient safety reporting and learning systems in the world.

The NPSA continues to strengthen its links with the NHS, understanding and supporting its needs and increasing effectiveness. The NPSA works closely with the PSATs that have been jointly established with each SHA to ensure that patient safety is embedded in the local system management of the NHS. NPSA is also increasing its work to engage patients through partnership with the Action against Medical Accidents and WHO to develop a cadre of "Patients for Patient Safety Champions" across England and Wales.

Responses to the Conclusions and Recommendations

The numbering of these responses corresponds to the Conclusions and Recommendations (pages 95 to 104) of the Committee's report.

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)**

We welcome the Committee's support on the Department of Health's work to improve patient safety and recognition of the pioneering work of the NPSA.

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)

We welcome the Committee's views on the Safer Patients Initiative (SPI), The Health Foundation's important work in applying carefully researched methodology for improving safety performance. We also value the contribution The Health Foundation is making as a member of the National Patient Safety Forum and the NQB, and in particular its major contribution with the NPSA and the NHS Ill in supporting the national campaign for improving safety in England.

The Government recognises the importance of encouraging and supporting approaches to spreading best practice in patient safety that are based on sound evidence, and engage and enthuse clinicians and other frontline staff in the provision of safe services. Building the will and desire to lead change directly and at the right level, and providing these key staff with the skills to achieve positive change, are the hallmarks of projects like the Safer Patients Initiative and the Patient Safety First Campaign that are to be encouraged and promoted. Sustainable change in every healthcare organisation – not just some – is only possible if the principles and practices in initiatives such as these are embraced.

The Patient Safety First Campaign is a key initiative of the National Patient Safety Forum and one of the recommendations of the CMO's report, *Safety First*. The Patient Safety First Campaign has used a unique approach to change in the NHS by applying lessons from "social movements". The change is owned and led by local services and healthcare practitioners. It has three main aims:

- to promote and support a specific role for Chief Executives, Boards and senior managers in improving safety;
- to support the implementation of a leadership intervention and four key clinical interventions, each containing others that have an established and accepted evidence base;
- to support and promote improvement methods for quality and patient safety.

The Patient Safety First Campaign is a two-year programme that finishes in March 2010. Evaluation of the campaign includes the impact of the different approach taken. Lessons from this evaluation will be fed into patient safety improvement strategies for the NHS. The NPSA will take forward these lessons and ensure that the campaign's legacy lives on by using the learning to mobilise and support local services and practitioners to drive and implement safer patient care.

- 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)**

We believe that progress has been made to embed patient safety as a priority for all NHS services, but recognise the need for sustained focus and effort. Quality and safety have been key priorities for the NHS over the past decade. Significant improvements in quality have been made, as evidenced by the Healthcare Commission's annual *State of Healthcare* report for 2008. This report concludes that "*the NHS as a whole is getting better at using and managing its resources, and that it is performing better against the wide range of national targets it has to deliver and the core standards it has to meet. Over the last few years, the NHS has made some dramatic progress*".

Lord Darzi's *Next Stage Review* brought renewed vigour and focus to the drive to put quality – covering safety, effectiveness and patient experience – at the heart of the NHS.

The Government shares the Committee's disappointment with the unacceptable safety performance of a very small minority of NHS Trusts within the overall picture of dramatically improved care for patients. We are pleased that the regulatory system we have put in place has allowed such failures to be identified and dealt with, not ignored or suppressed.

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)**

There has now been a number of large-scale record review studies undertaken in countries throughout the world. The results of these studies have been remarkably consistent suggesting that ten percent of all patients admitted to hospital will experience some form of harm associated with their admission. Not all of this harm is preventable and not all of it is serious.

Although the feasibility of these large-scale studies is proven, their high cost and the need for extensive professional expertise prevent them from being repeated at frequent intervals. Any suggestion for a new study would need to give careful consideration to both the benefits in improving patient safety and its cost effectiveness.

- 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)**

This work is underway.

Case note review has been carried out as part of the Safer Patients Initiative and is now a key part of the Patient Safety First Campaign. As part of the campaign, participating organisations review a set of 20 case notes each month using the Global Trigger Tool (GTT) originally developed by the Institute for Healthcare Improvement in the United States.

The NHS III has promoted the use of various GTTs, some of which are speciality specific. They have developed tools for medication triggers, acute care, primary care, General Practitioners (GPs) and paediatrics, working in conjunction with the NPSA.

No one source of data can tell everything we need to know about sources of risk and patient harm. Case note reviews are one aspect of harm indicators – they have to be reviewed together with incident data, complaints and claims for damages.

We welcome the recommendation that the NPSA considers ways in which the learning from case note review, along with other sources of data on patient harm, can be used to monitor progress by the NHS.

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)

We agree that progress has been made, however we recognise that NHS services need to become even more open with harmed patients and their families.

That is why the NHS Constitution for England pledges that the NHS commits to the principle that:

"...when mistakes happen, to acknowledge them, apologise, explain what went wrong and put things right quickly and effectively..."

The NHS Constitution for England includes the staff responsibility as follows:

"...to be open with patients, their families, carers or representatives, including if anything goes wrong; welcoming and listening to feedback and addressing concerns promptly and in a spirit of co-operation. You should contribute to a climate where the truth can be heard and the reporting of, and learning from, errors is encouraged..."

The report *Safety First* 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. In response to this recommendation a review of *Being Open* practice was carried out by Professor Albert Wu of the WHO in late 2008.

The NPSA is leading on the implementation of the findings of the review. The first step in doing this will be re-launching revitalised *Being Open* guidance, implementation tools and educational support for NHS Trusts by autumn 2009.

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)

As noted above (recommendation 6), it is right that harmed patients should get a prompt apology and explanation. The NHS Constitution for England includes this as a specific responsibility for staff.

The NHS Litigation Authority's guidance supports staff in meeting this responsibility and sits alongside and complements other activities on *NHS Complaints*, *Safety First*, and *Being Open*.

A legal duty of candour already exists in the codes of practice of professions' regulatory bodies. Members of the medical, nursing and midwifery professions already have a duty of candour, required by their respective regulatory bodies, the General Medical Council (GMC) and the Nursing and Midwifery Council (NMC).

From April 2010, NHS providers will register with the CQC against a set of registration requirements, which set out the essential levels of safety and quality of care and treatment. Independent sector healthcare and adult social care providers will register from October 2010. The registration requirements will support a culture of openness, and require registered providers to give service users appropriate information and support in relation to their care and treatment. There is ongoing work to consider other ways that the registration requirements could be used to further clarify the requirement for information to be made available to service users when things go wrong.

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)

Coroners are independent judicial office holders. Operational issues such as the scope of their investigations and inquests are solely for them. It would not be appropriate to comment on individual cases.

The outcome of an inquest can be challenged in the courts. However, the system is in the process of reform – through the Coroners and Justice Bill, which is currently before Parliament.

The Bill provides for a bespoke appeal system, for families and for others with an interest in coroners' investigations, which will enable them to appeal against the outcome of inquests. The Bill also provides for a Charter for Bereaved People, which sets out the services that they can expect coroners to deliver – this will lead to more opportunities for participation in a coroner's investigation so that families can make their views better known on the questions they would like the investigation to answer.

NPSA receives a growing number of Rule 43 letters from coroners. As well as information on incidents, these letters provide valuable contextual and causal information that NPSA use, together with other sources of information, as part of their weekly reviews of serious incidents and in the development of risk-reducing interventions.

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)

The reformed arrangements for complaints handling were introduced on 1 April 2009, following numerous external criticisms of the three-stage complaints model. Complainants did not have confidence in the previous arrangements, which placed more emphasis on responding to complaints within set timescales than on providing a quality response that met the needs of the person making the complaint. The previous system also placed little emphasis on organisational learning, which in turn devalued the important need for organisations to learn from their mistakes in order to improve future service delivery.

The new arrangements were introduced following two years of consultation (in the form of roadshows, conferences and written documents) with the public, health and social care frontline and senior staff, and other key stakeholders. The principle of an independent review of complaints is at the heart of the reforms. There is an expanded role for the Health Service Ombudsman, who is entirely independent, and there is scope for truly independent investigation at local level, when appropriate. The secondary legislation has been drafted specifically to allow organisations to work flexibly within a general framework based on good complaints handling, and to deliver a robust and personalised response to a complainant that is proportionate to the complexity and sensitivity of the case. There will be a greater emphasis on involving the complainant throughout the process – identifying at the outset why the complaint has been made, and what redress the complainant is seeking in making the complaint.

The Local Government and Health Service Ombudsmen and the CQC do not consider that complaints handling is an appropriate role for any regulator. In a February 2009 CQC press release welcoming the Healthcare Commission's report, *Spotlight on Complaints*, Cynthia Bower, Chief Executive of the CQC, said:

"Effective systems for managing complaints will be one of the requirements for registration ... So while we will not have a direct role in handling complaints, we will be making sure that [registered care providers] are dealing with complaints properly. CQC will have the interests of patients at the heart of what we do and we will want to make sure that complaints are being effectively managed".

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)

The Patient Advice and Liaison Service (PALS) provide information and on-the-spot help and advice for patients, their families and carers. They are also a focal point for user feedback and a powerful lever for change and improvement in the NHS. By operating in locally flexible ways, PALS help patients and the public successfully negotiate the NHS. In gathering local feedback, PALS are able to influence service improvement. An external provider would be less effective.

PALS staff have a long track record of working with patients to find a satisfactory resolution to their issues and concerns.

It is in the interest of NHS Trusts that PALS and/or other staff work constructively with patients who are raising concerns, and we are confident that the vast majority do so. Working on-the-spot and from within Trusts, PALS are well placed to liaise effectively with staff and services within the Trust to resolve issues rapidly for patients. It is doubtful that they could be as effective if they were based outside the Trust.

There is no statutory requirement for Trusts to maintain a Patient Advice and Liaison Service. It is for Trusts to determine how to organise services locally, and we understand, for example, that some Trusts have merged the PALS function with complaints work to form a "customer service team", whilst others have kept the two roles distinct. It would therefore be inappropriate for the Department of Health to survey staffing levels or make judgements about the adequacy of PALS staffing.

The Government has now required the establishment of new independent community-wide bodies known as Local Involvement Networks (LINKs). While LINKs have no specific role in the handling of individual complaints, they are there to find out what people want and need from their local health and social care services and to act to strengthen the patient voice in the planning, design, delivery and scrutiny of those services.

The recommendation also quotes a witness as finding PALS defensive and unhelpful, in a case when harm appears to have been alleged. Clearly this has been an upsetting experience, however it should not be taken as failure of PALS as a whole. A 2008 national evaluation of PALS, undertaken by the University of the South West, was positive in its assessment of PALS.

- 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)

The Government does not agree that a reversion to the three-stage model for the NHS complaints system is necessary, desirable or beneficial to complainants or to health and adult social care organisations. We believe that complaints are best dealt with locally. The rationale for reformed arrangements that have been introduced is expanded under recommendation 9 above.

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)

The recommendation regarding the Independent Review was addressed under recommendation 9 above. As the Ombudsman is independent of Government, it would be inappropriate for us to seek to comment on a revised role on her behalf.

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)

The proposed NHS Redress Scheme was not envisaged primarily to be an application scheme. Through internal governance processes, organisations would identify cases where financial compensation may be warranted. It relies upon a more open, less defensive culture within the NHS. The recent reforms to the NHS complaints arrangements apply the principles underpinning the NHS Redress Act across a wider range of cases (and provider organisations). It is a more effective way to seek to facilitate culture change.

In itself, the NHS Redress Act is unlikely to remove defensiveness within the NHS. It is this culture, not the failure to implement the Act, which works against the settling of appropriate cases without the need to go to court.

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)

“No fault” compensation was considered as part of the *Making Amends* (2003) consultation and more recently during the passage of the NHS Redress Act 2006. The Department rejected the introduction of a “no fault” scheme for a number of reasons, including:

- overall costs are expected to be higher than the current tort system because more claims would fall within the scheme;
- there is no clear definition of “no fault”, and we would argue that none of the schemes we examined are genuinely “no fault”;
- a high minimum level of injury or hospitalisation that a patient has to meet to qualify may be necessary to make a scheme cost-effective;
- there is still a need to establish causation, leading to arguments about “fault” being replaced by ones about “cause”;
- explanations and apologies are not necessarily provided in a system which focuses on financial recompense alone;
- a “no fault” scheme, in itself, does not improve accountability or ensure learning from adverse events.

Ministers in Scotland have already announced that they are going to consider the benefits to patients of introducing a “no fault” compensation scheme in Scotland. We maintain an interest in the review and, rather than duplicating, we will await its outcome in order to inform further thinking.

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)

We welcome the Committee’s recognition that clear progress has been made in incident reporting.

There is always scope to improve the NRLS, but very real and steady progress has been made. This includes:

- NHS services have worked closely with the NPSA to improve the consistency and quality of reporting for local and national learning. There has been a consistent upward trend in the reporting of data and improvements in the completeness and accuracy of reports;
- the NRLS has focused on ensuring rapid, national learning from significant incidents resulting in deaths and serious harm;
- a vastly increased amount of feedback to the NHS and publication of safety data is now well established. This includes organisational level data, which is searchable on the NPSA website.

There is close partnership working with the Royal Colleges and professional associations to analyse and set safety priorities on the basis of reported data. For example, the NPSA has established a Clinical Safety Board led by the Royal College of Surgeons.

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)

Whilst reporting trends in each of the areas referred to are positive, the NPSA recognise the areas of under-reporting mentioned and is working closely with the NHS and other key stakeholders to implement a number of initiatives that will improve matters further. Examples of these initiatives are as follows:

- development of a specialty specific e-form for GPs which will be rolled out as part of the Patient Safety Direct programme. The NPSA has worked with the Royal College of General Practitioners and other primary care stakeholders to develop national guidance which supports the use of Significant Event Audit (SEA) within general practice and is undertaking a pilot for collating the results of local SEAs for national learning;
- special reporting system for anaesthesia. The NPSA has worked in partnership with the Royal College of Anaesthetists and the Association of Anaesthetists Great Britain and Ireland to pilot the use of a special reporting system for anaesthesia across 12 Trusts. This is being rolled out across all Trusts as part of Patient Safety Direct;
- the NPSA is working with junior doctors to promote reporting and learning, led by a small cadre of junior doctors who now work as part of the NPSA through the CMO clinical advisor programme;
- in relation to medicines and medical devices incidents, NPSA has recently concluded a detailed data sharing protocol with MHRA to improve the comprehensiveness of national learning and action on significant risks.

The further development and implementation of Patient Safety Direct will allow the NPSA to build on the existing NRLS to address these issues further. Patient Safety Direct is a three-year programme of development work being led by the NPSA, which will:

- improve healthcare practitioner engagement with patient safety improvement initiatives and approaches;
- strengthen arrangements for reporting and learning from the most serious healthcare-related incidents;
- increase the incident reporting, particularly by doctors.

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)

Addressing under-reporting is a priority for the NPSA as outlined under recommendation 16.

Blame is a major barrier to reporting and learning. Although progress has been made, for example, as evidenced by the NHS Staff Survey, building an open and fair environment requires long-term focus.

The Government recognises the serious concerns that have been raised about dispensing errors. The Medicines and Healthcare products Regulatory Agency (MHRA) is currently reviewing existing medicines legislation and the representations received on this subject will help to inform our plans to develop a medicines legislative framework, which is comprehensive, comprehensible and fit for current purpose.

MHRA and the Department of Health are also working with the Royal Pharmaceutical Society of Great Britain and Crown Prosecution Service to consider a common approach to future prosecutions concerning dispensing errors, what future changes to the law may be needed and what interim position should prevail until any revised medicines legislation is enacted.

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)

We support this recommendation.

The NPSA is already publishing more and more NRLS data and this will continue.

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)

The Government shares some of the Committee's concerns about the current arrangements for investigation of serious events. Although some of these arrangements have developed well over recent years, we cannot be complacent about the opportunities to learn quickly and effectively about how to strengthen the systems designed to protect patients. We intend to study this area further.

The Government supports the general approach currently taken by the NPSA and rejects the assertion that information on less serious patient safety incidents is of doubtful usefulness. In reaching this view we have considered that:

- the current data in the system enables the NPSA to review trends, and track changes over time. This means the NPSA can provide a safety overview for the NHS;
- reports of "low harm" and "no harm" events and "near misses" can be usefully analysed to establish whether a particular incident is "one-off" or suggestive of a more generalised pattern of risk;
- the current data also allows focus on risks that are still common, for example falls. Failing to report incidents and to collect information could make it more likely that real risks would be ignored.

The NPSA invests substantial effort in reviewing and acting on serious incidents. Since April 2008, a new systematic process has been developed to scrutinise the most serious incidents and identify issues for urgent alerts to the service. Around 1500 serious incident reports are received every month.

Each patient safety incident, resulting in a serious harm or death and reported to the NRLS by doctors, nurses and others in the NHS are now reviewed individually by clinical and safety experts in the NPSA. These are screened to identify and prioritise the incidents that suggest wider system problems that could affect a number of Trusts.

Issues which meet set criteria are developed as Rapid Response Reports (RRRs). To ensure consultation and involvement of key clinical and NHS stakeholders, these are usually produced within two to four months although some are produced in a matter of weeks when faster action is needed. As at August 2009, 20 RRRs had issued.

The NPSA continues to work to improve the use of Root Cause Analysis (RCA) following patient safety incidents. It has worked with NHS services and Patient Safety Action Teams (PSATs) to develop a wide range of standardised tools (for local use with regional and national benefit) for conducting RCA investigations and writing investigation reports. These have been warmly accepted by the service. PSATs within each SHA have a key role in improving the quality of safety investigations and promoting learning.

The NPSA is also developing a data capture system from which learning from RCA findings can be identified and shared. The aim is for this to be in place by mid 2010. The ultimate aim is to include RCA investigation findings in the data being made available to users via web access and specialty based search facilities.

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)

The Government agrees that multiple sources of data need to be considered to gain a full understanding of sources of risk and potential solutions.

The NPSA set up a Patient Safety Observatory in 2005 to collate data from other sources such as the litigation database held by the NHS Litigation Authority. This has been built on the current work of the NPSA, particularly in the approach to analysing and learning from serious events. For example, other data sources considered include Serious Untoward Incident (SUI) reporting and coroners' inquiries.

NPSA continues to work with other agencies to improve data sharing (CQC, MHRA) and to make better use of information available through the Agency's clinical teams. This is a major ongoing priority for the Agency.

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)

Ensuring and supporting reliable implementation of safer practices by frontline clinicians is a central focus for current work on patient safety. A multi-faceted approach is needed using both "top down" and "bottom up" levers. Some of these solutions can be found locally, but national processes also have an important role to play.

Current elements of the approach include:

- proportionate and focused national guidance on significant risks to patient safety with tools to aid local implementation. For example, the Rapid Response Reports of the NPSA;
- involvement of frontline clinicians in the design of solutions and safety interventions. The NPSA has worked closely with frontline doctors, nurses, pharmacists and others (including patients) when developing solutions and issuing alerts;
- supporting local implementation of proven safety interventions through initiatives such as the Patient Safety First Campaign. Its whole ethos, philosophy and way of working is to engage clinicians and frontline managers to work together for a shared purpose of improving patient safety. The peer-to-peer and opinion leader approach is very successful at engaging staff to adopt changes to their practice;
- building improvement capability in teams of doctors, nurses and pharmacists on the Leading Improvement in Patient Safety programme (LIPS). The focus is to equip frontline clinicians with the skills to lead safety improvement. The programme is taught by a faculty of NHS clinicians;
- engaging and equipping Boards to scrutinise and assure local implementation of safer practices;
- partnership work with regulators, for example the CQC, to follow-up implementation of key safety practices. For example, implementation of guidance associated with high-risk medicines has been one focus of the Annual Health Check.

The NPSA, working with others, has shown that some issues, that may in the past have been regarded as inevitable complications, are in fact patient safety incidents. For instance, recent safety alerts have included areas such as perforations of organs following chest drains or deaths on the operating table following hip fracture repair, which may have been seen as unavoidable surgical complications. The NPSA continues to promote awareness of these incidents as avoidable.

The vision of the Patient Safety First Campaign is of an NHS with “*no avoidable harm and no avoidable death*”.

The aim of the LIPS programme is to build capability and capacity in staff to eliminate harm to patients. This starts with an understanding that this can be achieved.

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)

The Government fully supports the importance of involving clinicians and other healthcare workers in making tangible improvements to health. The NHS already engages and involves clinicians and healthcare workers and recognises their importance in the implementation of improvements to health. The report *High Quality Care for All* emphasises the importance of clinical leadership in delivering high quality healthcare, and sets out a series of policies to support this. The Government agrees that a focus on improvements that are tangible is a positive way to engage clinicians and other healthcare workers.

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)

The Government welcomes the Committee’s views on the Productive Ward programme and the Safer Patients Initiative, both of which are linked with the Patient Safety First Campaign and its approach. The Patient Safety First Campaign promotes the reliable delivery of clinical practice in four high-risk areas: critical care, peri-operative care, high-risk medicines and the deteriorating patient.

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)

The Government fully accepts the importance of “non-technical skills” for improving patient safety. Skills such as communications, team dynamics, effective team working, understanding and managing change and skills for conflict management are all important. We agree that the NHS can usefully learn from some of the innovations adopted by the civil aviation and other safety-critical industries to develop understanding of the impact of human factors, behavioural attitudes, systems and processes upon patient safety and outcomes.

The NHS has already made considerable progress in recent years in building the development of non-technical skills into its educational and governance processes. For instance, guidance and training provided by the NPSA and the NHS Ill stresses the importance of team-working and other human factor skills as does the 2006 edition of the General Medical Council’s *Good Medical Practice* and the September 2009 edition of *Tomorrow’s Doctors*.

The Government will draw the specific recommendation on undergraduate and postgraduate education to the attention of the professional regulators, as discussed in more detail under recommendations 34 and 35 below.

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)

The Government agrees that the use of appropriate checklists and routines can play an important part in ensuring patient safety. We welcome the support of the Committee for the WHO Safe Surgery Checklist, which is currently being implemented across the NHS with support from the NPSA, in particular the work of the Patient Safety First Campaign.

We recognise the need for local adaptation of tools such as checklists to unique local circumstances. Our approach to implementation of the WHO Safe Surgery Checklist supports this. The NPSA has worked with professional groups to adapt the WHO Safe Surgery Checklist for use across NHS services and within specialities. Through the Patient Safety First Campaign, and in partnership with the relevant colleges and professional associations, a team of consultant surgeons and peri-operative nursing staff are supporting the implementation in England of the surgical checklist, and has provided face-to-face training, online advice and numerous presentations to support local implementation.

Of course, protocols may not be appropriate in every case, although standardisation and simplification are important building blocks for improving patient safety. Clinicians should be able to demonstrate the patient specific, professional or organisational issues that led them to depart from the agreed

protocol in specific instances. If a clinician persistently ignores a locally-agreed protocol we would expect that to be taken up through local clinical governance processes, if necessary through the head of profession. The aim should be not to perpetuate the “blame culture” but to understand the barriers to acceptance. Retraining may not be the appropriate solution if the clinician does not accept the validity of the protocol.

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)

The NHS has seen significant levels of investment in recent years and there has been an unprecedented period of expansion in the workforce since 1997. This has resulted in reduced waiting times, improved access to services and high quality treatment and care.

Local NHS organisations are best placed to assess the health needs of their local health community and plan the workforce they need. Workforce planning should be locally led, driven by service needs and integrated with service and financial planning, with strong national assurance engagement with clinicians. This will require more focus on the skills and quality of the workforce rather than the quantity.

High quality local decision making is essential in order to deliver first class patient care. *High Quality Care for All* set out a vision for the NHS with quality at the heart of everything that it does, based around the following aspects: patient safety, patient experience and effectiveness of care.

Recent high profile instances of failure within the NHS, such as the case of Mid-Staffordshire NHS Foundation Trust, highlight that poor local decision making and a failure to integrate fully workforce planning with service planning and financial planning can seriously compromise patient safety and the patient experience.

To address this we are developing a system that will see:

- workforce planning being clinically driven and based on a clear clinical vision built around patient pathways;
- regional and national professional advisory bodies, offering coherent evidence-based clinical input, particularly on long-term developments and the effect on future workforce requirements;
- a Centre for Workforce Intelligence providing strategic oversight and leadership on the quality of workforce planning across the healthcare system including that which is delivered by social care.

All of this will be underpinned by an SHA assurance process that will provide a robust system health check at a regional level. This will help ensure that the NHS is delivering services appropriate to the needs of its local populations.

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)

The overriding principle is patient safety and high quality care. This is paramount to all that we do in the NHS. This is health and safety legislation with the overall aim of the NHS achieving full implementation and compliance for junior doctors in training to the European Working Time Directive (EWTD) consistent with improving patient safety, providing high quality care and treatment, protecting the quality of training, providing a good work/life balance and improved patient experience.

The Directive enables a good work/life balance of doctors in training and all NHS staff. No one wants to be treated by tired staff.

Significant progress has been made in implementing the Directive and the 48-hour working week. Implementation began over ten years ago. The remaining cohort to become fully compliant is the junior doctors in training whose hours have been reducing in incremental stages since 2004.

Partnership work has been key with good collaboration. We have listened and acted upon the concerns of the clinicians and medical professionals.

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)

The Department of Health endorses the conclusions that technology can make a major contribution to patient safety and significantly reduce errors in providing healthcare, but also that it can carry potential for harm if not well implemented and carefully risk assessed.

The NPSA, NHS Connecting for Health (NHS CfH) and Improving Healthcare in Wales meet quarterly to share information and lessons learnt on the use of technologies in healthcare, developments in information systems, and their contribution to an understanding of risk in the NHS and the prevention of adverse incidents.

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)

High Quality Care for All recognised the importance of providing NHS staff with simple access to quality-assured information and evidence on health services and included a commitment to launch NHS Evidence; a single web-based portal providing access to authoritative clinical and non-clinical evidence and best practice. NHS Evidence was launched in April 2009 and will support the use of an evidence-based approach in decision making. NHS Evidence will also quality assess key producers of evidence-based information to allow users to recognise trusted sources and to drive up standards of evidence.

NICE makes considerable efforts to publicise and implement its guidance across the NHS and its Electronic Guidance Accessibility Project (EGAP) will increase the accessibility of NICE guidance by making it available in a form that is more appropriate to the end-user, including suppliers of GP decision-support systems and users of NHS Evidence.

NICE will be publishing its existing technology appraisals in the revised format this autumn and its future technology appraisal guidance will be routinely published using the EGAP template to the same timetable. NICE's clinical guidelines and public health guidance will be published in the enhanced form in early 2010. NHS CfH will explore further with suppliers of GP decision-support systems the potential to incorporate NICE's guidance.

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

NHS CfH has worked with and consulted NHS clinicians to identify the types of decision-support that should be provided within ePrescribing systems procured by the NHS. Details are contained within the ePrescribing functional specification published in 2007. A report outlining the "top 10" areas of decision-support to reduce patient harm has also been published and forms a core part of the strategy to moving forward¹.

¹ www.connectingforhealth.nhs.uk/eprescribing

More detailed work is now being progressed to identify appropriate levels of alert configuration and standardisation for support systems. A consultation on dose range checking functionality closed on 10 July 2009. A final consensus on this and other related support areas is due to be published later on this year.

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)

The Department accepts that a review of progress of the implementation of the recommendations of *Coding for Success* would be appropriate. A brief internal review took place at the end of November 2008. At that time, it was felt that significant progress was being made (albeit after initial slow progress), including some significant developments not envisaged when *Coding for Success* was produced, including, for example, the development work of the NHS Procurement e-Enablement Programme. Other organisations, such as Global Standards 1 UK (GS1 UK) and NHS CfH were also beginning to build momentum through their individual work programmes. We said then that we would continue to work with the agencies and other organisations involved to ensure that the policy was reviewed and updated in a timely fashion.

The Government recognises that automation and modern information management in hospital pharmacies can increase productivity, reduce waiting times and improve patient safety by reducing dispensing errors, and a lot of the work arising from *Coding for Success* has had a focus in this area.

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)

It is important to understand that many of the National Programme for Information Technology (NPfIT) systems and services that together make up the electronic patient record have been (or are being) delivered successfully. These include the N3 broadband network for the NHS, GP2GP record transfers, the Electronic Prescription Service and Picture Archiving and Communications Systems (PACS) which makes X-ray and other images readily available to clinicians. In addition, good progress is now being made in delivering the Summary Care Record.

Whilst deployment of information technology systems to support acute hospitals through the NHS Care Records Service is taking longer than anticipated, it is important that the roll-out of such complex systems is undertaken at a safe and steady pace, and that systems are not rolled out until they are thoroughly tested and fit for purpose. To do otherwise would be reckless and potentially dangerous to patients.

Progress is being made and NHS CfH continues to work closely with suppliers to ensure that software is fit for purpose before deployment. This approach ensures that quality takes priority over target dates before go-live and ensures that Trusts are fully involved in the testing and sign-off of products. The taxpayer is protected as suppliers are only paid upon delivery of fully tested, working systems.

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)

While progress has been slower than we would have liked, the identification and implementation of a technical solution is a priority.

There are two main reasons for the delay:

- the way the medical devices market operates. The demand for such devices is low as wrong-route administration of drugs is relatively uncommon. As a result, manufacturers have been reluctant to develop the product;
- in response to this reluctance of the market to respond, the Department of Health has sponsored the development of possible products which have been going through clinical simulation and clinical trials. This has taken time but it is important to ensure that the proposed solution does not introduce any new risk or unintended consequence into the system and that it is clinically usable.

Nevertheless, solid progress is being made:

- working prototypes have been developed and a system that addresses Professor Toft's recommendation is CE-marked and on the European market. The MHRA is participating in the drafting of an international standard for connectors through the International Standards Organisation (ISO);

- in summer 2008, the Department of Health asked the NPSA to lead this work. Work on the non-Luer connector is now being taken forward in the context of a programme of work on implementing safer neuraxial (spinal and epidural) devices. The NPSA has consulted on a proposed draft patient safety alert, which promotes a “purchasing for safety initiative” and the introduction of neuraxial medical devices with safer connectors within the next two years. An External Reference Group has been set up for this initiative with Professor Toft as the Chairman.

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)**

The Department of Health is discussing this recommendation with the organisations that have legal responsibility for the content of medical education curricula – the General Medical Council (GMC) for undergraduates and the Postgraduate Medical Education and Training Board (PMETB) for postgraduates.

This is timely as:

- the GMC launched in September 2009, following widespread consultation, a new edition of *Tomorrow's Doctors*. Medical schools will be required to incorporate changes to curricula by 2011-2012;
- PMETB is reviewing all specialty training curricula in 2009 and 2010.

Patient safety is at the heart of the revised version of *Tomorrow's Doctors*, which makes clear that it is a fundamental element of medical undergraduate education. *Tomorrow's Doctors* sets out the GMC's requirements for the knowledge, skills and behaviours that undergraduate medical students should learn and for the delivery of teaching, learning and assessment. These requirements provide the framework that UK medical schools use to design their own detailed curricula and schemes of assessment. The quality of undergraduate teaching and assessments is tested against these requirements by the GMC's Quality Assurance of Basic Medical Education (QABME) programme.

The Department of Health will liaise with the GMC over the monitoring of the quality of new medical graduates' use of these skills.

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)

The Department of Health agrees completely that patient safety should be an integral part of the training of all health professionals. We believe that the bodies responsible for professional regulation are equally committed to the patient safety agenda, but will explore with these bodies and with the NPSA how the focus on patient safety in educational and training curricula could be further strengthened. This would include training in human factors, as already noted in our response to recommendation 24.

We also agree with the principle of interdisciplinary training. There is evidence that the principle is being increasingly adopted, with for example the creation of multidisciplinary schools in higher education organisations.

The Department of Health funded a three-year project, Creating an Interprofessional Workforce (CIPW), which worked with leading edge sites to develop good practice and recommendations on interprofessional training. That project reported in September 2007 and embedded the excellent practice in areas including Southampton, Sheffield, South London and Newcastle.

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)

World Class Commissioning (WCC) is not a tick box exercise, but a ground-breaking and ambitious programme that will deliver better health and well-being for the population. It builds on best practice from this country, and from health systems around the world, to transform the way Primary Care Trusts (PCTs) commission. It will help PCTs deliver better services, more closely matched to local needs, resulting in better quality of care, improved health and well-being and a reduction in health inequalities across the community.

The programme is already creating a step-change in the way the Department and the NHS, including commissioners themselves, view commissioning.

The first year of the commissioning assurance system has been a success. It has been judged as rigorous, stretching but fair, and valuable.

In year one of the assurance process all PCTs have identified a clear path to help them become world-class organisations. The scores for competencies were, as expected, between levels 1 and 2 (of a four point scale), with a few at level 3.

Feedback from the NHS and local Government has been very positive. Nearly 90% of participants in the process agreed that World Class Commissioning will lead to an improvement in commissioning capability and governance.

From here onwards, we expect the pace of development in PCT commissioning capability to be impressive. We anticipate improvements in commissioning competencies in the next two to three years, and effects on locally identified health outcomes to become visible in the next three to five years.

Incentives and interventions will apply to commissioners based on performance in the assurance system. At the upper end of performance, PCTs will be rewarded for improvement and achievement. This will focus on celebrating success and enhanced reputation at national level. PCTs performing at the top level of success will achieve status as a world-class PCT and a package of complementary incentives.

We will also hold PCTs to account if they fail to deliver improved commissioning. Commissioners will be subject to the NHS Performance Framework once the WCC agenda has been fully embedded. In advance of that, SHAs should be applying the principles of the Performance Framework, intervening appropriately to tackle underperformance.

We welcome the support for Never Events and note the Committee's concerns on how these events are linked to funding and the suggestion that this should be piloted.

All commissioning should be about quality, not just the 0.5% associated with the Commissioning for Quality and Innovation (CQUIN) payment framework. However, making part of a hospital's money directly conditional on quality as well as volume through the CQUIN framework is intended to help embed quality within commissioner-provider discussions at Board level, both during contract negotiations and throughout the year. Patient safety is one of the key dimensions in the provision of the high quality service. The CQUIN framework is also intended to promote quality developments over and above the existing contractual commitments of provider organisations.

The CQUIN framework was launched in April 2009. Although it is not being formally piloted, the first year is very much regarded as developmental and the Department is working closely with NHS partners to share learning and to inform how the framework develops in future. In this first year, PCTs and acute providers have agreed a CQUIN scheme within their contracts. Many mental

health, ambulance and community providers have also agreed CQUIN schemes, although they had the option of agreeing a local quality improvement plan as an alternative in 2009/10.

The CQUIN framework will be subject to independent evaluation to ensure it improves as it matures and continues to support the wider agenda around commissioning and quality.

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)

SHAs are accountable to the Secretary of State for Health through the NHS Chief Executive. Their performance management role within that is to hold their local PCTs to account in delivering their obligation to provide for the populations they serve, the best care for the best value, through the contracts they hold with providers of NHS care. In the case of NHS Trusts, SHAs are able to have a direct performance management role, which they carry out in conjunction with the local PCT. Underpinning this, the Department's new performance framework sets out a rule-based system for intervention by PCTs, SHAs and finally the Department of Health in underperforming NHS Trusts.

SHAs do not have a direct performance management relationship with NHS Foundation Trusts (FTs) as they have earned a level of autonomy from central government. NHS FTs are performance managed through the contracts they hold with their PCT, who are held to account for their ability to do this well, by the SHA. In addition, Monitor, the FT regulator, is able to intervene if FTs breach the terms of their authorisation.

The main functions of SHAs, including their performance management function, were originally set out in *Commissioning a Patient Led NHS*, published in 2005. Following the mergers of 2006, there are currently ten SHAs. They have a strong record of performance management and in the latest performance year all delivered, across their geographical areas, financial balance (with a small surplus in all ten) and key commitments on: reducing MRSA and *Clostridium difficile*, reducing waiting times and improving primary care access. To help clarify and strengthen the accountability of SHAs, the Department is currently developing an SHA assurance framework. The assurance framework will support SHAs in their roles as leaders of the local NHS by helping to build their capacity and capability to drive improvements in quality across the system. The framework is being implemented from September 2009.

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)

The Annual Health Check was just one of many mechanisms available to the Healthcare Commission to detect failures in care. Approaches including systems for investigations into serious concerns, mortality outlier programmes and requests from the Secretary of State for Health were used to identify the three major failings referenced in the report. Additional mechanisms used to identify and act on instances of poor care included collaborative risk summits, screening and surveillance, surveys of staff and patients, and service reviews.

Regulation has already undergone considerable change in the last few years, both in response to the report into Mid-Staffordshire in March 2009, and in the longer term. One of the biggest recent changes in the system has been the creation of the CQC as part of the new regulatory framework set out in the Health and Social Care Act 2008. CQC took over the regulation of health and adult social care in April 2009.

In addition to its periodic review functions (akin to the Annual Health Check), the CQC has a core regulatory function of registering care providers.

For the first time, NHS organisations will be required to register with the regulator in order to be able to deliver regulated services and will be subject to the CQC's enhanced range of tough, independent enforcement powers – powers unavailable to the former regulator, the Healthcare Commission. These enforcement powers are designed to bring providers into compliance if they fail to meet the essential levels of safety and quality set out in their registration requirements.

As part of the response to the events at Mid-Staffordshire, the former Secretary of State for Health asked the new National Quality Board (NQB) 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 will review key issues relating to alignment and co-ordination at a system level and is expected to publish its report by the end of 2009.

The CQC has reviewed the effectiveness of the Annual Health Check in the light of the Mid-Staffordshire investigation and has identified areas for improvement that will be reflected in the design of new systems of regulation.

As part of its work, the CQC has been developing an approach to how mortality outlier data can be used to raise alerts and take action where data suggests there may be serious concerns about the safety of patients. This process involves analysing data that suggests concerning trends in the death rate for specific conditions or operations, and was the primary method used to identify the problems in Mid-Staffordshire. All such alerts go through an investigative process, involving the Trust concerned and other key stakeholders, such as the SHA or Monitor and the host PCT. The results of closed cases will be made publicly available on a quarterly basis.

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)

The importance of outcomes and the views of patients and service users is enshrined in the Health and Social Care Act 2008 that established the CQC. The CQC is charged with *“performing its functions for the purpose of encouraging the provision of health and social care services in a way that focuses on the needs and experiences of people who use services”*². In particular it must have regard to the *“experiences of people who use health and social care services and their families and friends, and the views expressed by local involvement networks about the provision of health and social care services in their areas”*³.

From April 2010, all NHS organisations will need to comply with registration requirements that will set the essential levels of safety and quality in the provision of both healthcare and adult social care. The registration requirements will be focused on outcomes for patients and will not be prescriptive about how providers should go about achieving these outcomes. The CQC is currently consulting on its guidance about compliance with these registration requirements. This guidance emphasises the central importance of outcomes for patients in the CQC’s approach to regulation. The CQC has also consulted on how users of services can get involved in regulation as published in *Voices into Action* statement.

Importantly, the registration requirements will be a legal requirement, and the CQC will have a range of enforcement actions that it can take against providers that fail to meet essential levels of safety and quality.

² Section 3(2)(a), of the Health and Social Care Act 2008.

³ Section 4(1)(b), of the Health and Social Care Act 2008.

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)

The regulation of healthcare services was introduced in 2000 with the establishment of the Commission for Health Improvement, which soon evolved into the Commission for Healthcare Audit and Inspection (the Healthcare Commission). From its inception the Healthcare Commission's approach to scrutiny was evidence and risk-based. Organisations were asked to self-assess against both qualitative and quantitative standards. In the independent sector this was confirmed by inspection to support a registration process, and in the NHS it was backed by commentary from local organisations. For both sectors local assessors subsequently considered evidence from a variety of sources before determining where and how often to target inspection activities and sector-specific reviews.

The Healthcare Commission approach to determining risk was not entirely rules-based. Local assessment staff were involved in considering levels of risk, using quantitative and qualitative information, and making judgements based on inspection findings.

The above mentioned (response under recommendation 39) arrangements for legal registration requirements for all NHS organisations, will put in place an outcomes-based framework for assuring that all NHS care meets the level that patients have a right to expect, overseen by a regulator with the powers to take action where these levels are not achieved. The CQC will be developing an approach to the effective use of qualitative as well as quantitative information and will use this approach to reach a judgement on the level of risk posed to patients.

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

The Government agrees that the new system of registration could usefully take account of previous experience in related fields, including the Royal Colleges' inspections of hospital training posts. We will draw this recommendation to the attention of the CQC.

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)

There are clearly defined roles within the system. We have consulted on, and outlined our reasons for, introducing a new approach to regulating health and adult social care in previous publications⁴.

Whilst previous systems have served their purpose well, as services have developed and become more integrated it makes sense to move to a single aligned regulatory framework.

From April 2010, all providers of regulated services, including NHS FTs, will be required to comply with a full set of registration requirements that will establish essential levels of safety and quality. (From April 2009, all NHS bodies, including NHS FTs have been required to register with the CQC against a single registration requirement relating to healthcare associated infections.)

The CQC will have the same range of enforcement powers in regulating NHS FTs as any other provider. The CQC makes no distinction between NHS FTs and any other registered service providers.

We are clear that Monitor and the CQC each have specific, different and complementary roles in relation to regulating NHS FTs. Registration of NHS providers is separate from the authorisation process to obtain FT status. Registration with the CQC will offer independent assurance of safety and service quality by assuring that providers meet their registration requirements, and will be a requirement for providers (including NHS FTs) wishing to offer regulated activities. Continued compliance with registration requirements will be part of the terms of authorisation of NHS FTs. Monitor will intervene if the Trust is in breach of its terms of authorisation. Monitor and the CQC must co-operate with each other in the exercise of their respective functions (Section 70 of the Health and Social Care Act 2008).

The NPSA will be consulting on a new national framework for the reporting of and learning from Serious Untoward Incidents during autumn 2009. This consultation will help determine how reporting of incidents will inform CQC's risk assessments of NHS providers.

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)

The system has undergone considerable change in the last few years and with renewed urgency in our response to the report into Mid-Staffordshire NHS FT in March 2009. One of the biggest recent changes in the system has been the creation of the CQC as part of the new regulatory framework set out in

⁴ *The future regulation of health and adult social care in England* (Department of Health, November 2006), available at: www.dh.gov.uk/en/Consultations/Closedconsultations/DH_063286 *The future regulation of health and adult social care in England: response to consultation* (Department of Health, October 2007), available at: www.dh.gov.uk/en/Consultations/Responsestoconsultations/DH_078227

the Health and Social Care Act 2008 as mentioned earlier (response under recommendation 39).

The CQC will therefore make decisions as to whether providers should be granted registration, and be allowed to provide services. The CQC will undertake ongoing monitoring and surveillance to assess whether providers continue to comply with its registration requirements. The CQC has a range of enforcement powers it can use to bring about improvements when a provider has breached its requirements. In severe cases, the CQC has the power to shut down services to protect patients, or suspend or cancel a provider's registration altogether so that it can no longer provide services.

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)

Monitor has assured the Government that it has improved its assessment process since it authorised Mid-Staffordshire to become an NHS FT. As part of the response to the Healthcare Commission's report, Dr David Colin-Thomé conducted a rapid review to learn lessons about how the PCT and the SHA, within the commissioning and performance management systems that they operate, failed to expose what was happening in this hospital. Dr Colin-Thomé's report identifies that parts of the healthcare and regulatory system need to work more closely together to ensure that cases such as Mid-Staffordshire NHS FT do not happen again. Dialogue between Monitor and the CQC and with commissioners has been increased and formalised in order to identify risks related to quality of care.

The former Secretary of State for Health also asked the NQB to review, in the context of the Healthcare Commission's investigation into high mortality rates at Mid-Staffordshire, the national systems and processes in place for the early identification of potential serious failings in patient care and the subsequent response. This review will specifically consider the alignment of the systems and processes in place across the different national bodies responsible for ensuring that patients receive high quality care, as well as examining the relationships between regulation, commissioning and system management. The final report of the review, including any recommendations, is expected to be published by the end of 2009.

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)

NHS FTs are operationally independent organisations. The Board of an FT is accountable to the local community for the delivery of high quality healthcare through their Board or Council of Governors. Monitor is responsible for ensuring that FTs meet their terms of authorisation, including the requirement that Trusts meet healthcare targets and national standards. Monitor does not replicate the performance management role played by SHAs but has adopted a proportionate approach to regulating NHS FTs, detailed in its *Compliance Framework*. Where NHS FTs are experiencing major financial or service problems, oversight will be intensive and Monitor will intervene to ensure that services and patients are safeguarded.

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)

We are clear that Monitor and the CQC each have specific, different and complementary roles in relation to regulating NHS FTs.

Registration of NHS providers is separate from the authorisation process to obtain FT status. Registration with the CQC offers independent assurance of safety, service quality and governance by assuring providers meet the essential levels of care as set out in their registration requirements, and will be a requirement for providers (including NHS FTs) wishing to offer regulated activities.

As such, registration with CQC is a prerequisite for FT authorisation rather than a substitute or subsequent requirement. Registration requirements will be part of the terms of authorisation of the NHS FTs.

The CQC and Monitor have agreed respective roles for FTs and how these roles fit together, including appropriate exchange of information.

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)

The CQC and NHS Litigation Authority (NHSLA) have very distinct roles.

The CQC regulates care and provides independent assurance that providers are meeting the essential levels of safety and quality set out in their statutory registration requirements. The CQC will use a modern data-driven approach, using information and intelligence – drawing on information already available elsewhere whenever possible, for example from the NHSLA – to target its finite resources to the areas of greatest risk.

The NHSLA's *Risk Management Standards* are used to assess the systems and processes that are in place to manage risk and specifically relate to factors of relevance to negligence claims, although there will be some read across to safe care and safety culture. However, these are not a proxy for measuring how safe health services may be.

Results and findings from NHSLA assessments are used in a variety of ways by other bodies. These include the Health and Safety Executive, Monitor, NICE and the NHS Security Management Service. The CQC (as did the Healthcare Commission before it) already makes use of the NHSLA inspection findings in its risk assessment of providers, thereby reducing the burden of regulation.

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 next NHS Operating Framework will include a succinct statement on how commissioning, performance management and regulation contribute to a coherent healthcare system.

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)

We do not accept the suggestion that NHS Boards in general have neglected their duty to “promote tangible improvements in services”. During much of the past decade, Boards of NHS organisations have focussed attention on the clinical priorities first enunciated, after wide public consultation, in the *NHS Plan* of 2000. As a result there have been major improvements in many aspects of clinical quality, which are highly relevant to the patient safety agenda, for instance in vastly improved access to diagnosis and life-saving treatment, and in the reliable use of evidence-based interventions for people suffering myocardial infarction. Clinical governance, first introduced in *A First Class Service* in 1999, supported this agenda by establishing the processes, structures, metrics and culture needed to focus the whole organisation on quality improvement. We are not aware of any evidence that healthcare organisations in general have pursued the structures and processes of clinical governance as an end in themselves.

It is fair to say that a minority of Boards, in their focus on national priorities, may have overlooked some other aspects of quality, which required local attention. That is why *High Quality Care for All*, the final report of the *NHS Next Stages Review*, put in place a Quality Framework designed to enable local quality improvement. The approach set out as part of the Quality Framework gives flexibility to commissioners and providers to focus on local priorities for quality improvement based on local needs and on analysis of the quality of current services. The recently published *Indicators for Quality Improvement* provide a validated and nationally available set of quality indicators, covering safety, effectiveness and patient experience, which Boards can use to help them understand the quality of their own services. The requirement, from 2010, that all Trusts and FTs publish Quality Accounts will also ensure that Boards focus directly on understanding the quality of care and the quality improvement work taking place within their organisations.

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)

The initial induction programme provided by the Appointments Commission for new Board chairman and non-executive directors already includes a strong emphasis on quality and patient safety issues. This includes a presentation by the NPSA and a patient safety case study, held at the end of the first year after appointment, to enable participants to reflect on their experience and consider how they can use their role on the Board to improve patient safety. A number of supporting tools have also been developed and disseminated.

While we recognise the potential value of a designated non-executive member having a deeper understanding of patient safety issues, we believe that all non-executive directors should be involved in patient safety issues. We think it inappropriate for the Government to prescribe any particular organisational model, but we welcome innovation in this area such as the model adopted by Luton and Dunstable Hospital.

The work of programmes such as the Patient Safety First Campaign and the LIPS programme both put a major emphasis on equipping Boards with the skills and knowledge to oversee effectively patient safety in their organisation.

The LIPS programme works with Board members as well as frontline staff to teach the concepts of safety improvement and to develop a clear strategy for Boards to ensure the organisation has the competence in safety improvement with the right supporting structures and processes in place. This is a two-day Executive Quality and Safety Academy (EQSA) course for the Chief Executive and four directors.

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)

The Government agrees completely that the quality of NHS services, of which patient safety is a key component, should be the top priority of all NHS Boards.

The Patient Safety First Campaign’s leadership intervention suggests that every NHS Board agenda should devote around 25% of its time to patient safety and quality.

We do not think it is sensible for the Department of Health to lay down centrally exactly how each NHS Board should structure its agenda. However, we do emphasise that quality and safety issues should be the central focus of every NHS organisation.

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)

Further to our response under recommendation 52, the Government fully supports the recommendation and would highlight that the Patient Safety First Campaign and related initiatives such as LIPS offers organisations across the NHS an opportunity to learn how to implement these recommendations.

For example, the Patient Safety First Campaign through LIPS works at Board level and with a team of frontline staff to develop the systems and improvement skills required to ensure effective implementation of change, coaching in how to do case note reviews, access to a portal to record rates of harm and the development of an implementation plan to achieve system level improvements in harm rates.

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)

There are a number of tools in healthcare, which are both qualitative and quantitative to assess safety climate within organisations and teams.

The NPSA worked with Manchester University to design a specific safety culture tool for the NHS that covers all care settings from primary to acute. This is called MaPSaF – it has been promoted throughout the NHS and training has been provided. The MaPSaF is a tool for assessing safety culture, part of which is around openness and reporting. The Texas Safety Climate tool is similar. It is therefore encouraging that the results from the 2008 annual NHS staff survey suggest that nearly all staff (96%) reported the most recent error, near miss or incident they had witnessed, which is one percentage point higher than in 2007 and three percentage points higher than in 2006.

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)

The Government is considering what legislative or other changes may be necessary or desirable in the light of recent events in Mid-Staffordshire.

The reviews by Dr Colin-Thomé and Professor Sir George Alberti were highly critical of the closed culture and non-involvement of patients and the public that operated at Stafford Hospital. In its response, the Government stated that all NHS organisations must ensure they are operating in accordance with current guidance, which promotes openness, transparency and accountability to their local populations, including Boards holding meetings in public. Both David Nicholson, the Chief Executive of the NHS, and Dr William Moyes, the Executive Chair of Monitor, have written to all Trusts/FTs telling them to make sure they have read the reports and addressed all issues.

The NHS FT *Code of Governance*, published by Monitor, states that the Board of directors of an NHS FT should *"follow a policy of openness and transparency in its proceedings and decision making unless this conflicts with a need to protect the wider interests of the public or the NHS FT (including commercial-in-confidence matters) and make clear how potential conflicts of interests are dealt with"*.

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)

We accept that proposals should be brought forward as recommended to improve protection for whistleblowers. We will consider the practicalities of establishing a model whereby whistleblowers can complain to an independent statutory body.

The legal protection afforded by the Public Interest Disclosure Act (PIDA), together with Government guidance requiring every NHS organisation to have policies and procedures in place to support whistleblowing, means that NHS staff should feel confident that they can raise concerns locally without fear of recrimination. In addition, the right for staff who report wrongdoing to be protected has been specifically recognised recently in the new NHS Constitution.

We realise however that in practice there may be situations where a member of staff does not feel comfortable raising concerns locally with their employer, and for this reason the Department of Health has commissioned a charity, Public Concern at Work (PCaW), to provide an independent helpline available to all health workers to which they can turn for confidential advice.

We are working with PCaW and with NHS Employers, the organisation which represents the majority of NHS employing organisations in England, to ensure that the guidance we issued on whistleblowing is kept up to date and that access to PCaW's helpline is well publicised through bulletins and events. We are determined that where poor practice still exists, healthcare staff will have ways in which they can speak up for patients. Listening to and acting on the concerns of those who work on the frontline is a vital way to drive up standards and guard against poor or unacceptable quality care.

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)

On 21 July 2009, the Secretary of State for Health, Andy Burnham, announced the establishment of an Independent Inquiry into Mid-Staffordshire, to be chaired by Robert Francis QC. The Inquiry's focus will be on ensuring that patients or their families have an opportunity to air their experiences so that any further lessons can be learned. We too are unconvinced of the case for a full Public Inquiry and that is why the Inquiry is not being established under the Inquiries Act 2005. The Chairman will decide the precise details of how the inquiry will be conducted. The Inquiry is planned to report by the end of 2009. The Terms of Reference are published on the Department's website⁵.

⁵ http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_098660

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)

As the Healthcare Commission recognised in their 2008 report, *Learning from Investigations*, "targets or outcome measures are an integral feature of a modern 21st century healthcare system, and have resulted in measurable improvements for patients in some important areas. NHS managers have always had to deal with conflicting priorities. The vast majority do it successfully".

The Government has always been clear that no achievement of targets or FT status should be done at the expense of patient safety. These are not ends in themselves – they are a means towards improving services for patients. Improving access to services and providing these in a financially sustainable manner is vitally important to improving the quality of care provided to patients.

The Department of Health continues to work with the SHAs and the regulators to ensure this is what happens in practice. Specific actions that have been taken forward include:

- setting a minimum quality threshold that has to be achieved before Trusts can apply to be an FT (CQC, performance framework, etc);
- providing high-level advice on the service quality of FT applicants;
- reminding Monitor of its requirement to take into account any reports by CQC;
- promoting a duty of co-operation between the relevant regulators.

Guidance available to the NHS in relation to the reporting of information for the Accident and Emergency (A&E) four-hour standard makes clear that the total time measurement can "stop" once a patient is moved to a ward-like environment, which is described in terms of privacy, access to washing facilities,

availability of hot food, etc. Assessment units can be classed as “ward-like environments” if they are compatible with these terms, but any move should be part of a planned outcome to improve patient care, and not simply as a place to “hold” patients or to avoid breaching the four-hour A&E standard.

We make no apologies for setting targets; they have driven improvements for millions of people. It is wrong to say that targets have nothing to do with quality and safety. Waiting 18 weeks rather than 18 months for an operation, spending four hours or less to be seen and treated in A&E, a markedly reduced chance of catching a Healthcare Associated Infection – these are all about improving quality and safety. Of course we know we need to do more and Lord Darzi’s *High Quality Care for All*:

- makes it easier for clinicians to access evidence about best practice through a single portal, called NHS Evidence, and through NICE’s development of quality standards;
- supports clinicians to measure quality to support local improvements;
- requires quality information to be published in Quality Accounts;
- rewards the delivery of high quality care through a new payment framework;
- establishes an NQB to provide strategic oversight and leadership on quality in the NHS.

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)

High Quality Care for All promotes quality – covering safety, effectiveness and patient experience – at the heart of the NHS. It sets out a Quality Framework, which outlines a series of policies to support staff in delivering high quality care locally. For this to happen, clinicians must be clear what high quality care looks like, they must measure the care they deliver across the three domains of quality and use this measurement to drive improvement. They should report the quality of the care they deliver publicly and use the levers and incentives available to them to improve the quality of care. All this requires local leadership, particularly from clinicians themselves.

The Department of Health recognises that removing the “blame culture” around making mistakes is essential to improving NHS patient safety. We are supporting the NPSA, which has the key national leadership role to promote an open and fair safety culture in all NHS organisations.

The NHS Constitution for England includes the following staff responsibilities:

“...to be open with patients, their families, carers or representatives, including if anything goes wrong; welcoming and listening to feedback and addressing concerns promptly and in a spirit of co-operation. You should contribute to a climate where the truth can be heard and the reporting of, and learning from, errors is encouraged...”

The NPSA will be re-launching revitalised *Being Open* guidance to NHS Trusts by autumn 2009, including promoting ways of further embedding non-punitive local policy. At an organisational level, Boards and senior managers and clinicians have an important leadership role.

Following a period of consultation and Parliamentary scrutiny during the passage of the Health and Social Care Act 2008, regulation has already undergone considerable change in the last few years, both in response to the report into Mid-Staffordshire in March 2009, and in the longer term.

One of the biggest recent changes in the system has been through the creation of the CQC. The CQC took over the regulation of health and adult social care in April 2009. For the first time, NHS organisations will be required to register with the regulator to be able to deliver regulated services and will be subject to the CQC's enhanced range of tough, independent enforcement powers – powers unavailable to the former regulator, the Healthcare Commission – designed to bring providers into compliance if they breach their registration requirements.

The Healthcare Commission's March 2009 report revealed a catalogue of poor patient care and systemic failings at Mid-Staffordshire that was totally unacceptable. Former Secretary of State for Health, Alan Johnson, has apologised on behalf of the Government and the NHS to the patients and families who suffered as a result of the appalling standards of care.

As part of the subsequent programme of action, and as further scrutiny of how regulation and other mechanisms within the system can help improve patient safety, the Secretary of State for Health asked the new NQB 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 will review key issues relating to alignment and co-ordination at a system level and is expected to publish its report by the end of 2009.

The CQC is reviewing its systems of monitoring and assessment to ensure it is best placed to identify and act swiftly on risks posed to people who use services, so that in the future it can work with providers and commissioners to nip poor performance in the bud, rather than having to tackle failures of care afterwards.



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