

*Involving clinicians
Building local relationships
Safeguarding children and vulnerable adults
Third-party feedback Outcomes for patients
Information-led regulation
A range of regulatory tools
Patients' experience of healthcare
Risk-based approach Protecting patients' safety
Encouraging improvement
Annual health check
Accessible information about healthcare
Investigating serious service failures
Promoting equal citizenship
Reviewing patients' complaints
Measuring what matters
Independent assurance about quality of care
Helping patients make informed decisions
Action to reduce inequalities
Robust and proportionate enforcement
Protecting human rights
Reducing burden of regulation
Whole system approach
Surveillance*

The Healthcare Commission 2004-2009

Regulating healthcare -
experience and lessons

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About the Healthcare Commission

The Healthcare Commission works to promote improvements in the quality of healthcare and public health in England and Wales.

In England, we assess and report on the performance of healthcare organisations in the NHS and independent sector, to ensure that they are providing a high standard of care. We also encourage providers to continually improve their services and the way in which they work.

In Wales, the Healthcare Commission's role is more limited. It relates mainly to national reviews that include Wales and to our yearly report on the state of healthcare in England and Wales.

What we do

Inspecting

To inspect the quality and value for money of healthcare and public health

Informing

To equip patients with the best possible information about the provision of healthcare

Improving

To promote improvements in healthcare and public health

How we work

- We work closely with patients, carers and the public to maintain our focus on improving their experiences of healthcare.
- We promote the rights of everyone to have opportunities to improve their health and to receive good healthcare.
- Our approach to assessing healthcare is based on the best available evidence and aims to encourage improvement.
- We work in partnership to ensure a targeted and proportionate approach to audit and inspection.
- We work locally to build relationships and intelligence about the quality of services throughout England.
- We are independent and fair in our decision-making and report on what we find fairly and impartially.
- We are accountable for our actions and for what we achieve in relation to our costs.

On 1 April 2009, the Care Quality Commission, the new independent regulator of health, mental health and adult social care, takes over the Healthcare Commission's work in England.

Healthcare Commission and Executive Team

Commissioners in office at 31.3.09

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Introduction and background



The Healthcare Commission ceases to exist at the end of March 2009. A new, integrated regulator of health, mental health and adult social care – the Care Quality Commission – takes over on 1 April 2009. In this report, we look at the lessons that have been learned from the work of the Healthcare Commission over the last five years. Our objective is to inform the continuing debate about the place and role of regulation as it relates to health and healthcare in England.

The changing arrangements for regulating health and adult social care come at a time when the role of regulation in different sectors is coming under close scrutiny. In financial services, where globalisation and complex approaches to the packaging and selling on of debt have fundamentally changed the nature of transactions and the assessment of risk, regulators in the UK, EU and US are being asked questions about their role. In health and social care, the case of “Baby P” has raised questions about the role and effectiveness of regulators in safeguarding children.

These developments follow a period when there has been a high level of consensus in terms of policy within government on the approach to regulation in different sectors of public and private activities. The dominant view has been to promote an approach to regulation where the attention that an organisation, service or transaction receives from the regulator is based on an assessment of the risk of poor outcomes (risk-based regulation).

This is, therefore, a good opportunity to take stock of what has been achieved through regulation as part of the design of the healthcare system, drawing on the experience of regulation as conceived by the Healthcare Commission. In doing so, lessons can be identified which can assist in making regulation as effective as possible in safeguarding the public, protecting their rights, promoting better outcomes for people, and supporting those who care for them.

In this report we have:

- Set out the background to the establishment of the Healthcare Commission.
- Summarised the approach to information-led, risk-based regulation taken by the Commission.
- Considered the contribution that regulation of healthcare has made to better outcomes and quality of care for people.

- Reviewed the lessons that have been learned about the approach to regulation, and the implications for future regulatory models.
- Highlighted the lessons from regulation for the healthcare system as a whole.

Background

The Healthcare Commission was established on 1 April 2004. It replaced the Commission for Health Improvement which existed from 2000 to 2004 and took over the regulation of the independent healthcare sector from the National Care Standards Commission. It also took on the responsibility to carry out national studies of the value for money of healthcare services from the Audit Commission.

The development of regulation should be seen in the context of the Government's overall approach to policy on healthcare. The Commission for Health Improvement was established at a time when the Government's stated objective was to provide significant investment in building the capacity of the NHS to meet the demands placed on it, coupled with strong performance management to deliver a set of national targets that focused heavily on improving patients' access to care. The role given to the Commission for Health Improvement focused largely on improving clinical governance (the system through which NHS organisations seek to improve the quality of the care they provide by creating an environment in which clinical excellence can flourish, and in which they are accountable for meeting that objective).

The Health and Social Care Act 2003¹, which established the Healthcare Commission, sat alongside a shift in the Government's stated approach to the NHS towards a more devolved 'self-improving' system with a stronger focus on the commissioning of services, greater choice for patients, a greater focus on public health and tackling health inequalities.* Clearer incentives for organisations providing care through changed financial arrangements, better information on performance, more provision of NHS-funded care by the independent sector, and greater independence for well-managed NHS trusts. The 2003 Act also established NHS foundation trusts, with Monitor as their independent regulator.

The establishment of the Healthcare Commission as the independent regulator was an important component of this overall approach to a more devolved system – with the notion that the regulator would play

* A term which embraces inequality in health status, inequality in access to healthcare, and inequality in the care provided.

an important part in holding more autonomous bodies to account for their performance. There are some parallels in the local accountability of local authorities and the role of the Audit Commission in assessing and reporting on their performance.

The inquiry into the management of the care of children undergoing complex cardiac surgery at Bristol Royal Infirmary was a particular contributing factor behind the legislation and creation of the Healthcare Commission. The inquiry addressed a range of issues, concerned with putting patients at the centre of healthcare, involving patients and their families, leadership in the management and provision of care, a stronger focus on safety, better training of staff, better information and monitoring, agreed national standards and regulation.

The Healthcare Commission was also established at a time when the Government was seeking to reduce significantly the direct costs of regulation (with a commitment in the Budget of 2005 to “reduce the costs of public sector regulation by one third”) and the indirect costs of regulation borne by regulated bodies. As part of this approach, the Hampton report² was commissioned by HM Treasury. It concluded that regulation should be risk-based to make it more effective and to reduce unnecessary burdens on business. This was relevant to the Healthcare Commission as its remit spans both the NHS and the independent sector.

The framework of legislation and policy around the Healthcare Commission

Under the 2003 Act, the Healthcare Commission was established as an independent body with the general responsibility of “encouraging improvement in the provision of health care by and for NHS bodies” in England and Wales.

In exercising its function of encouraging improvement, the Commission must consider such matters as access to healthcare, its quality and effectiveness, and the availability of information provided to the public. In addition, and as a consequence of the Report of the Bristol Inquiry, the Commission is specifically required to be concerned with “the need to safeguard and promote the rights and welfare of children” in the exercise of its functions.

The Commission’s main statutory functions in England are to:

- Review the performance of each NHS organisation and award an annual rating.
- Regulate healthcare provided by the independent sector.
- Investigate serious service failures in the NHS.

- Carry out reviews of the provision of healthcare in the NHS (including reviews of the economy and efficiency of the provision of healthcare).
- Consider complaints about NHS bodies that have not been resolved locally.
- Report annually to Parliament on the state of healthcare in England and Wales.
- Promote the effective coordination of reviews or assessments of the provision of healthcare.

The 2003 Act¹ also stated that public health was to be included as part of healthcare. This, coupled with the fact that one of the seven domains in the Government's *Standards for Better Health*³ which the Commission was required to take account of was public health and that the new national targets largely focused on population health, gave the Healthcare Commission a clear remit to cover the main aspects of public health: protection and improvement of health, tackling health inequalities, preparedness for emergencies and the extent to which agencies at local level work successfully in partnership with each other. This is a unique role in comparison with regulators of health and healthcare in other countries.

To provide the context in which the Healthcare Commission operates, a brief summary of the healthcare sector in England, including levels of activity, expenditure, workforce and numbers of organisations, is set out in Appendix A.

The regulation of organisations is one element of the overall approach developed by the Government to bring about improvements in health and healthcare in England. Other mechanisms, which largely focus on the NHS and the health of the population, include:

- Regulation of professionals, for example through the General Medical Council and the Nursing and Midwifery Council, and improvement of professional standards to be met by professionals, through, among others, the Royal Colleges.
- Development of the workforce and of leadership.
- Development of national standards of care informed, for example, by the National Institute for Health and Clinical Excellence.
- Development and dissemination of good practice, for example, through the Institute for Improvement and Innovation and through the National Patient Safety Agency.
- Stronger focus on the commissioning of services by primary care trusts and practice-based commissioners.

- Performance management by strategic health authorities, or action by Monitor in the case of NHS foundation trusts.
- Greater choice for patients.
- Financial incentives, for example, through tariffs.
- Increased competition from a wider range of providers of care, for example, through the programme of Independent Sector Treatment Centres.
- Auditing of financial management and local value for money, largely through the Audit Commission.
- Improved information for patients and the public, for example, through Connecting for Health and more recently the NHS Choices website.
- Action to reduce the risks of litigation, through the NHS Litigation Authority.

The Government's goals for the healthcare system, as it developed its policies, focused largely on the NHS. They fall into two categories:

- Progress in meeting specific measures of performance set out in successive Public Service Agreements and then in more detail in the Operating Framework for the NHS. These have now evolved into a set of existing commitments that must continue to be met (for example, a maximum of 4 hours waiting time in A&E) and new national targets (for example, rates of mortality in the case of cancer).
- Achievement of the *Standards for Better Health*³ for the NHS set out by the Department of Health in 2004. These provide more general objectives as to the standards of care which the Government expected all providers of NHS care to meet (for example, in the provision of care which enhances the safety of patients; or which ensures that patients, their carers and relatives are treated with dignity and respect). This was the first time such general standards had been established. The Healthcare Commission was given the role of taking account of compliance with these standards in assessing the performance of NHS trusts.

For the independent sector, the National Minimum Standards established under the Care Standards Act 2000⁴, reflected the Government's objective as essentially one of consumer protection – with the regulator providing assurance that independent providers could be registered only if they met the National Minimum Standards set out in regulations.

In considering the Healthcare Commission's statutory remit, and role within the overall Government policy framework, it is worth

highlighting the issues of independence and the responsibility to “encourage improvement”.

Taking independence first, it is clear that if the Department of Health was to step back from its former approach of “hands on” management, devolving responsibility and creating foundation trusts outside the jurisdiction of Strategic Health Authorities, some mechanism was needed, independent of all others, to hold the system to account on behalf of the taxpayer. This need remains, indeed it grows increasingly important, as the public seek information about the NHS and independent healthcare that they feel they can trust and rely on.

The statutory reference to “encouraging improvement” is of the first importance. It explicitly identifies the place of regulation in the overall architecture for the system of healthcare being developed by government. It was the Government’s Better Regulation Task Force (as it then was) that stated that the only purpose of regulation in the public sector was to promote improvement. The significance of this role lies not least in the way that the Healthcare Commission conceived and designed its approach, which is considered below.

The Healthcare Commission’s vision for modern regulation

When the Healthcare Commission was established, there was only a brief history of regulation in healthcare at the level of the organisation (a matter of four years), though regulation of the various professions was well established. The word “regulation” was not commonly used in healthcare – the Commission for Health Improvement and the National Care Standards Commission were seen as inspectorates rather than regulators – and their programme of work was largely seen as being concerned with visiting organisations providing healthcare on a routine, periodic basis.

Born perhaps from experience of the regulation of professionals, regulation was thought of in terms of policing – top-down, potentially oppressive, a stick without any carrot, and burdensome.

This was not the Commission’s view. Instead, the aim was to work with the grain of good practice and to recruit patients and professionals in identifying what was good, rooting out what was poor, and seeking to bring about the changes which would mean that the good would be the norm. To adopt this role of encouraging improvement creates tension, however, not least with those whose job it is to manage the system. Of course, healthy tension is a necessary feature of independent regulation. So, clear lines of accountability and responsibility were

needed, so that the Commission's statutory role in **encouraging** improvement could be coordinated with the role of others in **delivering** whatever produced that improvement. But, whatever the tension, it is fundamental that the regulator has a role, with, of course, others, in improvement. Otherwise, the necessary stimulus for change on behalf of patients, from a position of independence, is lost.

In setting out its vision, the Healthcare Commission deliberately sought to take a new and different approach to its regulatory task in ten key ways:

- Reinforcing the accountability of organisations to assure themselves of the standards of care they are commissioning or providing.
- Working with patients in defining what is important in improving health and healthcare and reporting back to them.
- Working with clinicians and clinical bodies to define benchmarks of good performance, and to determine which measures would be of most assistance in their care and treatment of patients.
- Giving particular emphasis to the rights and entitlements of people who find themselves vulnerable, so as to promote equal citizenship.
- Focusing on what the wealth of information in healthcare said about performance and the risk of poor outcomes for people.
- Making information about the quality of care available in relevant and accessible ways, so as to support better informed decisions and to reinforce other ways of promoting improvement.
- Ensuring robust intervention in tackling poor performance.
- Taking a "whole systems" view – looking at commissioners and providers of care, and health as well as healthcare.
- Working in partnership with other bodies to obtain a more comprehensive view of the quality of services, to stimulate improvement and to eliminate duplication of effort and reduce the costs of regulation.
- Establishing a local presence to act as the eyes and ears of the Commission and to build local relationships.

The overall approach was – in 2004 – seen as radical. It required different ways of working to be established and developed. The vision, and lessons learned in seeking to implement it, are considered further below.

The Healthcare Commission's strategic goals

Taking into account its statutory objectives, its vision for modern regulation, and the crowded field of organisations concerned with the improvement of health and healthcare, the Healthcare Commission set itself six goals in its strategic plan in 2004, as a means of defining what it would regard as success in its regulatory role. They were to:

- Promote a better experience of health and healthcare for patients and the public.
- Safeguard the public.
- Provide authoritative, independent, relevant, accessible and fair information.
- Take a lead in coordinating and improving the impact and value for money of assessment and regulation.
- Promote action to reduce inequalities in people's health and increase respect for human dignity.
- Create an organisation delivering world-class assessment and regulation.

Appendix B provides a summary of our progress in meeting these goals.

Regulatory methods and approaches

In translating the vision into a regulatory model that brought together the range of statutory functions in an integrated and coherent approach, the Healthcare Commission developed a range of regulatory methods and approaches as summarised below. This combined the broad assessment of organisations in meeting standards, 'deeper dives' in reviewing particular services and pathways of care as these have most relevance to patients, and targeted intervention, investigations and enforcement. An important part of each method is reporting to the public the Commission's findings in an accessible and relevant form.

Providing independent assurance and information to patients and the public about the quality of care in a sector with over £100 billion of expenditure per year is an enormous task. By taking an information-led, risk-based approach to regulation and pursuing a regulatory approach which was as much about the analysis of information to identify risk as about inspection on the ground, the Commission was able to be a lean organisation – a third of the size of other comparable regulatory bodies while regulating a much larger sector – with a budget which was less than 0.1% of expenditure on the sector. Appendix C provides information on the costs of regulation in different sectors in relation to the size of the sectors, recognising that different

Range of regulatory methods and approaches		
Focus of regulation and assessment	Sector	Method
Organisations	Independent healthcare	Broad assessment of compliance with National Minimum Standards
	NHS	Broad assessment of compliance with core standards and national targets (indicators from government of priorities) through the annual health check
Services or pathways of care	NHS	In-depth national reviews and studies of services; for example, of mental health services and services for people with learning disabilities
Specific areas of concern in individual organisations	Independent healthcare	Inspection and enforcement
	NHS	Intervention and investigation

regulators have different functions in relation to the risks and other matters in their sectors. Appendix D provides a brief summary of some of the key activities carried out based on the overall regulatory approach.

The approach to the assessment of the performance of the NHS in meeting the core standards set out in the Government's *Standards for Better Health*³ was a key part of the regulatory model. This approach reflected the vision for modern regulation described above and is illustrated in Appendix E. In considering any lessons to be gained from the Healthcare Commission's experience, it is worth highlighting the main features of this approach, which were a key part of the annual health check, one of our central activities. They are:

- A formal self-declaration by the board of every NHS trust of the extent to which, in their view, they comply with the core standards, taking account of the guidance provided by the Commission – a crucial starting point since boards are responsible for the services provided.

Introduction

- A commentary by third parties – in particular, Patient and Public Forums (until they were replaced by Local Involvement Networks), other patients' groups, and the Oversight and Scrutiny Committees of local government. The commentary must be included in the trust's self-declaration and made public at the time of submission.
- An analysis by the Commission of the data submitted by trusts in their self-declarations, by reference to the data sets and thousands of items of data, both quantitative and qualitative, that we hold.
- A visit (inspection) on the basis of risk, as identified by the trust or by the Commission; we also visit a certain percentage of trusts on a random basis to provide further evidence that our system is working.
- A qualification of the trust's declaration where there is significant discrepancy between what the trust declared and what the Commission's evidence or visits demonstrate.
- A rating of performance for each trust.

What contribution has the regulation of healthcare made to better outcomes and quality of care for people?



As set out in our 2008 *State of Healthcare* report⁵, significant progress has been made in the last five years and indeed the last decade in improving health, reducing premature deaths, protecting patients' rights and improving the overall quality of care. However, there are also important areas where progress has not been so impressive – for example, in tackling health inequalities, improving the safety of patients, meeting the needs of people who are or are made vulnerable, and the priority given to safeguarding children.

Clearly, huge additional resources for the NHS have played a major part in the improvements in health and healthcare. There have also been extensive reforms of government policy which have sought to improve the performance of the system of healthcare. And, of course, the actual delivery of improvement is about local people responding to the health needs of communities and the interaction between individuals and clinical teams.

Disentangling the contribution of regulation amidst the range of influences on patients and the public, clinicians, commissioners of care and managers is, therefore, extremely challenging. In particular, in the NHS it is clear that independent assessment by the regulator is closely connected to increased local public accountability, and to performance management by the leadership of the NHS and oversight of foundation trusts by Monitor.

Nevertheless, there is a range of robust evidence from evaluation work that supports the view that regulation has made an important contribution as part of the overall system for improving the quality of care. The Healthcare Commission has commissioned an extensive range of external research into, and evaluation of the impact of, different aspects of its work. The report "*Making a difference?*"⁶ summarises the findings of this research up to 2008. This report draws on it and subsequent material which is available on the Commission's website. In particular:

NHS performance on standards and indicators of national priority

The proportion of NHS trusts rated "excellent" or "good" has increased from 46% in 2005/06 to 60% in 2007/08. Some of this may be due to trusts getting better at 'satisfying the regulator'. However, for a number of standards and targets the assessment has got tougher over this period and inspections which are triggered by our

What contribution has regulation of healthcare made to better outcomes and quality of care for people?

identification of risks continue to be more likely to identify non-compliance with standards. This suggests that trusts are not able to 'game' the system against the wealth of intelligence and information that the Commission is able to analyse.

Performance in meeting a range of Government targets has improved significantly since we included these measures in performance assessment; for example, waiting times for treatment for cancer, admission to hospital for treatment (18 weeks target), and care in Accident and Emergency Departments.

Evaluation shows that our assessments of the NHS are fair and contribute to demonstrable improvement and that the benefits outweigh the costs.

- 70% of NHS trusts agreed that the annual health check self-declaration process was a good use of staff's time.*
- 93% of NHS trusts thought that the annual health check had a positive impact on patient care.
- 81% of NHS trusts thought that it focused attention on the safety of patients.
- 25% reported an increase in benefits in the second year; 57% that the benefits were the same – so the impact had been sustained.

Independent healthcare providers' performance

Compliance with National Minimum Standards in the independent sector has also improved – 93% of organisations met or almost met all of the standards in 2007/08 compared to 50% in 2005/06 (though a direct comparison is not straightforward as the Commission changed its methodology for inspection over this period).

Evaluation of our registration and assessments of independent health providers shows that:**

- 99% of providers saw the assessments and inspection as important in promoting and improving the quality of care.
- 97% thought that it improved their reputation with the public.
- 80% thought that the process focused on the safety of patients.

* Evaluation of the second year of the annual health check (performance in 2006/07), interviews with 220 NHS trusts.

** Evaluation of independent health providers, survey of 100 providers 2007.

NHS trusts' performance in reviews of services

Reviews of particular services (such as maternity, inpatient mental health, care of older people, diabetes) have stimulated improvement. These reviews have focused especially on groups who find themselves more vulnerable, and have also provided a useful focus on pathways of care and integration of health and social care (for example in community mental health and learning disabilities).

Evaluation of our reviews showed that:

- 99% of organisations surveyed said that the reviews focused on the right topics.
- Over two-thirds thought that the information generated was useful and worthwhile.
- 70% reported that the reviews had positive impacts for patients.
- 82% reported that the review scores were fair.

Investigations into significant failings

Investigations into “serious service failures” have brought about improvements in individual organisations, and have also had a positive impact across the NHS in improving patients’ safety and the quality of care, for example, following investigations into maternity services, learning disabilities and infection control.

Evaluation of the impact of investigations showed that:⁶

- 35% of trusts reported that they had significant impact on improving standards in their own trust; 55% reported a smaller impact.
- 89% thought that investigations improved patients’ safety and 85% that they improved the quality of care.
- Less than half thought that investigations had improved patients’ confidence, while 15% thought it had worsened.

Working with patients

The patient’s voice has been brought into the system of assessing risks and performance as a matter of course – with local groups providing commentaries on trusts’ declarations; local information, intelligence from the complaints system and quantitative data from surveys being central to the analysis of risk; and people using services being involved in reviews such as the audit of learning disability services. This has encouraged trusts to give more attention to the views of patients and the public. After the first year of assessing compliance with core standards, an independent survey of NHS trusts found that:

What contribution has regulation of healthcare made to better outcomes and quality of care for people?

- 30% of trusts agreed that after the final declaration they had a better relationship with their third parties.
- 37% of trusts thought that they now placed more priority on involving patients, community groups and the public as a result of the assessment.
- Comments by trusts with no opinion or that disagreed were split into two distinct groups: those who thought that their patient and public involvement (PPI) forums had little grasp of the task/capacity to comment at that time and those who thought their relationships were already excellent.

As part of an evaluation of our wider programme of assessment in 2007/08, we brought together 22 representatives from a range of voluntary organisations and the Commission's National Patient Forum Reference Group. The majority of participants agreed that the Commission's process of assessment has had some positive impact, as any process which involves external scrutiny is likely to help to drive up standards and lead to improvement. Several felt that the impact was most apparent in acute trusts where standards and targets have helped focus attention on improving waiting times and cleanliness. Many felt that one of the main benefits of the process was that there had been an increased commitment from trusts to involve patients and the public in decision-making. Several participants were able to recount examples where comments on trusts' self-declarations from PPI forums had directly or indirectly led to improvements in the quality of care at a local level.

Providing accessible and relevant information

- The Commission has also become a reliable source of information on the performance of healthcare organisations and services.
- The Commission publishes the results of its assessments and all of its reports on its website, which receives around 140,000 visitors each month. In 2007, IPSOS Mori conducted a survey with 40 commentators from various backgrounds, including journalists, MPs, healthcare providers, clinicians and regulatory partners. The results revealed that the Commission's information is viewed as its major strength.

There are also areas where the system as a whole, including regulation, does not seem to have been as effective in achieving better outcomes for people. These are picked up in the next section.

*What lessons have been learned
about the approach to regulating
health and healthcare?*



This section sets out the main lessons from the Healthcare Commission's approach to the implementation of its vision for modern regulation of health and healthcare.

The main themes, linking back to the elements of the vision referred to earlier, are:

- The use of a range of regulatory tools and approaches flexibly in relation to the risks in the various sectors providing and commissioning health and healthcare.
- Holding organisations to account for the quality of care they provide and the outcomes for people using services.
- Working with patients and the public.
- Involving clinicians and clinical bodies in measuring what matters.
- Promoting equal citizenship and giving particular emphasis to the rights and entitlements of those who find themselves more vulnerable.
- Making effective use of existing information.
- Improving the information available on the outcomes of care and the experience of patients.
- Providing accessible and relevant information on the quality of care.
- Ensuring robust intervention and investigation in tackling poor performance.
- Taking a 'whole system' view.
- Working in partnership and aligning regulation with other mechanisms for achieving the Government's wider goals in the system.
- Building the capability of the regulator to do its job and respond to requests to take further functions, and establishing a local presence.

Using a range of regulatory tools and approaches flexibly in relation to risks

It is too simplistic to characterise the regulation of healthcare or of other public sectors as being either about a rolling programme of in-depth inspections **or** the analysis of pre-determined quantitative data to highlight risks. Rather modern regulation needs to be multi-faceted,

What lessons have been learned about the approach to regulating health and healthcare?

using a range of tools and methods to best effect in ensuring that organisations are accountable for the achievement of standards of care and the pursuit of improvement. Effective regulation combines:

- Listening carefully to users of services and staff and taking their concerns seriously.
- Engaging with others (such as local patients' groups) to share intelligence and perspectives.
- Self-assurance by those accountable (such as boards of NHS trusts) by reference to clear standards.
- Measurement and benchmarking by reference to "intelligent" outcome-focused indicators.
- Regular surveillance of performance through the construction of "alerts" – indicators of variation from expected outcomes determined in consultation with clinicians and patients – and early warning of potential concerns.
- Undertaking visits effectively in a risk-based and targeted way.
- Robust and proportionate enforcement.

Overall, the development of a range of appropriate methodologies has been effective in optimising the impact of the Commission. The combination of broad assessments of compliance with standards, 'deeper dives' in the case of particular services and pathways of care, targeted interventions and investigations, and public reporting of findings have allowed the Commission to 'flex' its regulatory approach in relation to the risks of poor outcomes for people. The overall impact of each activity has been enhanced by being part of a wider integrated approach.

Holding organisations to account through regulation for the quality of care they provide and the outcomes for people using services

The Healthcare Commission has reinforced the responsibility of organisations providing services to assure themselves of how well their organisations are performing. The boards of organisations are legally responsible for the performance of their organisations and should therefore render an account of performance and be held accountable. The approach that the Commission took to information-led regulation (see below) followed on from this. Organisations should have sufficient information to know what they are doing and to be held accountable.

The notion of using self-assurance by boards as the starting point for the assessment of compliance with core standards was viewed with concern by some commentators. Some feared that it would be like

most forms of self-regulation – self-serving and unreliable. Others suggested it was only being done to save money. However, it was not decided on lightly and it was not driven by financial pressures. Rather, it was the right thing for the regulator to do, to reinforce the fundamental point that healthcare organisations are, and should be, accountable to the people who use their services and need to be able to describe and explain what they are doing.

Most NHS trusts understood the thinking behind the approach and built the necessary self-assurance into their existing systems of governance (or had already done so). This reinforces the notion that the information that the regulator is asking for is no more than that which a board would want for itself anyway.

Some failed to grasp the approach, or perhaps thought that they could game the system. But, the breadth of the existing data held and analysed by the Commission, and the importance of the commentaries from patients' groups and local authorities, have steadily caused a change in such attitudes. Submitting an accurate picture, warts and all, has come to be seen by boards as the best way forward, not least so that help could be offered where needed. The upshot is that the system is broadly seen to be working. Independent evaluation of the annual health check in 2007/08 found that the overwhelming majority of NHS trusts surveyed believed that the Commission's process of assessment had been an important factor in driving improvement in their own organisation.

One of the key aspects of the system is the setting of the standards (whether Standards for Better Health in the NHS or National Minimum Standards in the independent sector) and ensuring that there is a shared understanding of the levels of performance necessary to meet the standards. Standards are only of any value if they lead to better outcomes for people. Too many of the current standards are not actually ambitious enough in the outcomes that they are seeking. And too much of the attention of the system has been on whether systems and policies are in place, rather than whether people's rights are being consistently safeguarded, better care is being delivered, and crucially, as a consequence, better outcomes for patients are being achieved, as a result of the implementation of those systems and policies. Our view is of course that the delivery of high quality healthcare needs systems and policies, but that the focus of those who provide and commission care and that of the regulator should increasingly be on the outcomes for patients and their experience of care.

What lessons have been learned about the approach to regulating health and healthcare?

Working with patients and the public

The Healthcare Commission, while taking account of the Government's *Standards for Better Health*³ (as required by statute), sought to build regulation from the bottom up, building a consensus with the public and professionals, so that the standards and measures of performance it focused on would reflect and be owned by what patients and those caring for them think is important in improving health and healthcare. The notion was one of co-production rather than top-down imposition in determining what "good" looks like and, thereby, of regulating with the engagement and consent of the regulated. The goal was what could be described as a 'virtuous circle' of regulation – a far cry from the policing stereotype commonly held. The Commission would ask patients, the public and clinicians what promoted improved care. Once identified, the Commission would make it clear that these were the things that it would assess trusts' performance by. Those managing trusts would respond by delivering these things, and trusts would be therefore doing that which patients and clinicians said would lead to improved care – thus completing the virtuous circle.

By working with patients and those caring for them, the Commission sought to ensure that its view on what was meant by quality reflected what mattered to people. Broadly, quality was taken to refer to:

- The safety of care.
- The effectiveness and outcomes of care, including helping people to lead healthier, more independent lives.
- The experience that patients have of care, including fair access to care.

The Healthcare Commission has made significant progress in involving groups of patients and the public in its work, in a variety of ways. It has built relationships with local patients' groups, including Patient and Public Involvement Forums and brought qualitative information from patients, as well as quantitative information from the myriad sources of data, into regulation and assessment in a systematic way. We have also successfully engaged with other groups representing patients with local knowledge, such as Mencap and Age Concern. Patients have been part of the team in some of our reviews of services. The Commission has also conducted major surveys of patients' views which are fed into the annual health check.

We have successfully argued for this involvement of patients and the public to be included in the statutory objectives of the new Care Quality Commission. It must "have regard to" the views expressed by members of the public about health and social care services, the

experiences of people using health and social care services and their families and friends, and the views expressed by local networks for involvement. The Care Quality Commission must also publish and consult on a statement of its involvement of users of services.

However, the Healthcare Commission's national study on the engagement of patients and the public engagement has also highlighted the importance of further action to reinforce the need for commissioners and providers of healthcare to involve people in decisions about local priorities and about their own care and to take account of these views in their plans. NHS trusts declare themselves to be doing well on the relevant core standard relating to involving patients and carers – but shifting to a truly person-centred service will require the standard itself, and the measurement of compliance with it, to be rather more exacting.

Another important issue in working with patients is the handling of complaints about the NHS. The Healthcare Commission has had the function of reviewing complaints which cannot be resolved at a local level. Carrying out this function has provided valuable information to inform the overall assessment of risks of poor outcomes for people. The Care Quality Commission will not have the equivalent function. The Department of Health's objective is to improve the local handling of complaints. As part of this, it is expected that the scheme of registration which the Care Quality Commission will operate will require providers of healthcare to demonstrate that they have an effective system to handle and respond appropriately to complaints and systematically learn from them. It will be vital for this standard to be set at a sufficiently high level to drive significant improvement in the handling of complaints locally. Appendix G sets out the conclusions from our last *Spotlight on Complaints* report.⁷ The report highlights the matters giving rise to the majority of complaints and demonstrates how they remain the same and that trusts, therefore, need to begin to respond effectively.

Involving clinicians and clinical bodies in measuring what matters

The 'virtuous circle' described above is dependent on the premise that the standards and measures of performance are credible and relevant to the public, to patients, and to clinical staff. So, a central part of the vision was to work with clinicians and clinical bodies, as well as patients and the public, to define benchmarks of good performance: in particular, measures that clinicians tell us will be of most assistance in promoting good care and treatment of their patients.

In many areas where the Healthcare Commission has undertaken detailed work, such as in relation to maternity services, we have

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actively sought the assistance of patients' groups and clinical bodies, such as the Royal Colleges, in order to define acceptable standards of care and indicators to measure them. The project that the Commission led on better metrics, working alongside the various national clinical directors appointed by the Department of Health, which produced a range of indicators in 13 major clinical areas, was a significant contribution to the overall approach. But, the system as a whole needs to be doing this as a matter of course, a point recognised by those Royal Colleges that are developing (and, in some cases, already running) schemes to accredit services. These schemes can, *inter alia*, provide further assurance to the regulator about the quality of care being provided to patients.

It is also important to simplify and align the various standards and metrics which are used to define and measure performance, and ensure that they are relevant to patients and to clinical staff. Certainly, the Department of Health's core standards were initially seen as concerned with matters which were more for managers to sort out rather than the clinical staff. The introduction of new requirements for registration under the legislation establishing the Care Quality Commission provides an opportunity to involve and work with clinical staff and patients so that regulation is seen to be relevant and effective by both groups.

Promoting equal citizenship and giving particular emphasis to the rights and entitlements of those who find themselves more vulnerable

The Healthcare Commission's objective was to assess the quality of healthcare from the patient's perspective. However, it sought to go further than this and reflect in its work the rights and entitlements of people who find themselves vulnerable. While groups may differ in their needs, children, older people, people with learning disabilities, people with mental illness, and people from areas of social deprivation, or for whom English is not a first language, may all have particular difficulties in gaining access (or early enough access) to health services and healthcare of the standard that all are entitled to expect. They may also require particular attention in safeguarding their rights. By looking at services through the eyes of those who are often least able to assert their rights, the Commission sought to promote equal citizenship and to contribute to improvements in the overall standards of care.

When setting its priorities, the Commission has drawn on the available evidence on areas of concern in healthcare, and the views of people responding to consultations on its programme of work. The Commission recognised that groups that find themselves more vulnerable may not always get sufficient attention in the overview of

performance at organisational level, or indeed in the Department of Health's national targets. The Commission has sought to improve its guidance on compliance with the Department's core standards so that it promotes equality, diversity and human rights more effectively. We have also undertaken and published extensive analysis of variations in the experience of patients as shown by data drawn from surveys of patients, in relation to age, gender, ethnicity, disability and social deprivation. This has covered inpatient services, mental health and maternity care.

The Commission has also given high priority to work with groups who find themselves more vulnerable in its programme of reviews, including, for example, community and inpatient mental health, an audit of learning disability services, dignity in care for older people, services for children, and race equality.

Looking forward, a shift to focus regulation more at the level of services and pathways of care should also help to ensure that particular groups do not drop through the net.

Making the most effective use of information

The Healthcare Commission has adopted an approach to regulation based on information and what information said about the risk of poor outcomes for people. Information-led, risk-based regulation was at the centre of the Commission's vision. It has combined a 21st century use of information technology, a deep analysis of risk and the consequent establishment of benchmarks for performance, and a lean organisation. We could adopt this approach because of the wealth of data generated by the NHS and others whose work brought them into contact with it. The challenge was to use this information to answer questions about quality which the data had not hitherto been used for in any systematic way.

In adopting this approach the Commission signalled to the NHS that, like any large complex organisation, it ought to know what it is doing. It should be able to assess its own performance and be held accountable on behalf of the public as taxpayer. The data was there and where it was not, it should be collected. To those who complained of a regulatory "burden", the answer was simple. The regulator wants from each organisation, by way of information, no more than the organisation should itself be collecting so that it can know how it is doing and manage its affairs accordingly.

Reliance on information does not mean that visits to trusts (inspections) were no longer undertaken. Far from it. Inspection has been a crucial part of the system – particularly in areas where a

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range of additional sources of information was lacking (such as the quality of services for those with learning disabilities, or the treatment of older people in hospital); where information suggested that questions needed to be asked which could only be answered by visiting; and on a more random basis, and unannounced on occasions, to 'keep the system honest'. Our use of inspection was therefore more deliberate and targeted, informed by an analysis of risks of poor outcomes for people.

The intention was that by pulling together existing information, systematically using quantitative and qualitative data from people using services, and working with patients and clinicians to define acceptable levels of performance, the regulator would steadily build up a picture of what is going on, what good practice should amount to, and enable the gaps in information to be filled where there was not sufficient evidence on the quality and outcomes of care. The collection and analysis of information in 'real time' would also increasingly allow the regulator to highlight concerns about the safety and quality of care and take appropriate action, rather than arrive after the fact.

In implementing this vision, the Healthcare Commission embarked on a programme of investment (amounting to some £16 million) to create its analytical and technological capability. The Commission has used information fundamentally in two ways:

- To provide a view of risks in the system of healthcare and to give early warning which requires some form of action, including intervention.
- To report publicly on the performance of organisations, services and those managing pathways of care, so as to enable people to make better informed decisions.

The first area has been very important. Given that the Commission was conceived out of the Report on the Bristol Inquiry, one of the abiding challenges has been for the regulator to identify and head off dangers before they materialise into some awful occurrence, harming patients and those caring for them. Initially, given the Commission's need to create an informatics system from scratch, and given the statutory duty to publish an annual rating of organisations' performance, we began by producing what could be described as a post hoc audit of performance. This approach, the annual health check, involving the overall analysis of existing data – including the views of patients and the public – to provide an assessment of the extent to which there are risks that a provider of services may not be able to deliver good outcomes, has been developed over the years. The analysis was backed up by targeted visits. The visits, which are triggered on the basis of the risks that the Commission has identified,

have consistently proven to be more likely to lead to the self-declarations made by trusts being “qualified” than visits carried out on a random basis (up to three times more effective in the second year). Trusts visited on the basis of risk assessment are also more likely to have their declarations qualified on a higher number of standards. So the system is working. The next stage is to get better information in areas which are important to patients, but where there is currently very limited data.

While the annual health check has been a significant development, in that it has moved away from a crude allocation of one, two or three stars to an organisation in order to provide a richer picture of performance, it has still been backward-looking. What patients want, and the regulator needs to provide, is a more up-to-date picture. It should not merely describe the performance of an entity called a trust, but seek to disaggregate the information down through the trust to the hospital and the unit, and across hospitals and trusts, so as to describe services. Patients want to know whether their treatment will be managed well in this or that unit or through this particular pathway of care, and they want to know the current position.

Gradually, the Commission has developed the capacity to engage in ‘real time’ surveillance of performance. This is an extremely important step. It begins to refine the information available, so as to tell patients what they want to know. And, it also provides an early warning system when things are going wrong so that action can be taken. From the perspective of the regulator, it means that less emphasis need be placed on lengthy investigations of things that have gone badly wrong and more on collaborative working between the regulator and others to identify problems early and work to resolve them. Some may think that this is a role that is properly for, and can safely be left to, management. Certainly, management has a part to play. But, in a system of healthcare that attracts so much of taxpayers’ money and where things can and do go wrong, an independent, authoritative and rigorous regulator, acting on behalf of all, is essential.

An example of the progress that the Commission has made in this area of surveillance, early warning, and following up when the analysis of data suggested possible problems, can be found in our report on ‘mortality’ outliers⁸. Appendix F provides a brief summary of real time surveillance in following up data which indicates some possible concerns. To date, the Commission has concentrated on mortality outliers. Such outliers raise questions; concerns arise when no satisfactory answers can be found. The investigation into Mid Staffordshire NHS Foundation Trust fell into this category. This system is, of course, a more precise regulatory tool where the data is

stronger. But, nevertheless, it is bedding in effectively and needs to be built on by, for instance, extending the approach next to emergency re-admissions of patients into hospitals.

Improving the information available on the outcomes of care and the experience of patients

In seeking to encourage improvement in the quality of care, the Commission has been effective in making good use of existing data. But, it is also very clear that there are serious gaps in the information available. Key issues include:

- Information on the provision of safe care. Information on hospital-associated infection is now improving, but there is a wide range of other risks to the safety of patients where there is a dearth of good data – such as about falls, management of medicines, surgical errors, and the preventable deterioration of patients' health.
- The reporting of incidents when safe care has been compromised remains poor in large parts of the system. In particular, there needs to be a much more robust and consistent approach to the reporting of serious untoward incidents and sharing such reports nationally so that lessons can be learned and improved practice implemented. This is an urgent priority for the new system of registration.
- There is little or no data on risks to the safety of patients which are not incidents (and therefore not captured in any system entirely dedicated to reporting incidents). This is a major challenge both philosophically and practically. The risks include the failure to diagnose, or the late diagnosis of, a condition. They relate particularly to primary care and care in the community, where about 90% of contacts between patients and professionals take place. If safety is only conceived of as involving some action (or near-miss), the equally important cases of inaction will continue to go unanalysed and patients will continue to be put at risk as a consequence. The capturing of such data is no easy task, but initial work has been carried out by the Commission. The work involved analysing already available data at the level of individual GPs' practices to identify the reasons for variation in performance. The purpose was to identify where better preventative care could have been provided. This data covered the main long term conditions including diabetes, chronic obstructive pulmonary disease, heart failure and hypertension, as well as stroke. As the sources of data in primary care continue to improve, with the ability to construct longitudinal data for every practice in England from 2011/12, then this ground-breaking work needs to be built upon.
- Too many services still have limited data available on outcomes. This applies to clinical outcomes and also to information on the

extent to which people using services are able to live healthier, more independent and better lives as a result of the care they receive. The agenda outlined by Lord Darzi, including the phased approach to “quality metrics” and the complementary roles of the regulator and NICE, places considerable emphasis on greater activity at all levels of the system. Without better information on outcomes, those providing, commissioning and receiving services are unlikely to know how they are performing and how good and safe care actually is.

- The mandatory requirements for information placed on the independent healthcare sector fall well short of what is required for people using services to make informed decisions and for the regulator to be able to assess risk. We are some way from a level playing field between public and independent providers.
- The Department of Health has given high priority to certain indicators of desired performance in its guidance to the NHS – what it chooses to call the “vital signs”. But the lack of attention to areas such as mental health, learning disabilities, equality, and the integration of health and social care in this set of ‘national priorities’ poses significant risks. Primary care trusts are seen by the Department as the engine for promoting improved care, through their role as the commissioners of care. There is a danger, however, that they will be caught between their responsibility to understand the needs of their local communities, commissioning care accordingly in a fair and equitable manner, and the political imperative of responding to “vital signs”. Experience suggests that national priorities become the dominant issue, to the detriment of pursuing other goals. Of course national priorities are inevitable in a tax-payer funded system for which government is accountable and which government rightly seeks to lay down goals. What is important is, first, that these priorities are sufficiently comprehensive and, secondly, they are managed alongside, not in competition with, other goals.

Providing accessible and relevant information on the quality of care

The regulator should bring together and analyse information from a wide range of sources, both to identify areas of risk and to report publicly on progress in meeting the relevant benchmarks of performance, with judgements being made on the basis of the evidence. The regulator should be a reliable, independent source of information on what is going on in the commissioning and provision of health and healthcare, so as to provide accountability to the public for NHS-funded care and to enable people using both publicly and privately funded healthcare to make better informed decisions about their care. The Healthcare Commission has invested significant effort

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in making the information on its website understandable to patients. The information provided by the regulator should, therefore, help to reinforce and strengthen some of the other mechanisms for improving care in the system.

The statutory arrangements under which the Commission operated required it to focus on “NHS organisations” (NHS trusts). But, patients may not know what a trust is, and, in any event, are more interested in what happens to them as they navigate their way through a complex set of organisational arrangements, captured in the phrase “the patient’s journey”. In part, the Commission could assess how well patients are cared for on this journey by examining not only what happens to them while in a particular organisation, but how they arrive there and what happens when they leave, in other words how well the journey is managed. Therefore, as regulation develops, benchmarks of performance specifically related to the performance of services and pathways, locally and nationally, and of individual units, need to be developed. Ways of measuring the extent to which the benchmarks are met are then required, followed by the reporting in public of what the measurement shows. The Commission has broken some new ground in this regard with its reviews of services on, for example, maternity care, the care of children in hospital, and – working with the Commission for Social Care Inspection – community mental health services and commissioning services for people with learning disabilities.

Ensuring robust intervention and investigation in tackling poor performance

The Healthcare Commission has developed a graduated and proportionate approach to tackling poor performance in healthcare. This ranges from:

- Requiring action plans from NHS trusts that do not meet core standards.
- Placing specific requirements on independent sector providers to improve.
- Investigating “serious service failure” in the NHS, including making recommendations to the Secretary of State for Health and Monitor to remedy failures (“special measures”).
- Taking action by way of enforcement which can lead to de-registration of those providing care in the independent sector.

In the NHS, while overall performance in meeting core standards has improved, the attention given by the system to getting core standards in place, and then, since they are **core** standards, moving

performance along a trajectory of improvement, has not been adequate. The overall performance of the NHS in relation to the safety of care has not changed in the last three years of the annual health check: the proportion of trusts declaring compliance with all standards relating to safety being stuck at around 50% (though it should be recognised that for some standards there is now much greater clarity on what is involved in meeting the standard, for example, on decontamination). This is for a set of standards that the Department of Health said should be met everywhere in 2004. But, this inadequate level of performance does not even get a mention in the Operating Framework for the NHS for 2009/10. It may be that the political pressures in the system are more concerned with certain specific targets which are readily measured than with the less easy to document, but fundamentally more important, general achievement of a set of standards for everyone.

As regards the NHS, one of the most significant activities carried out by the Commission has been its various investigations into what the 2003 Act¹ calls “significant failings” and what the Commission describes as “serious service failures”, emphasising both seriousness and that the concern is with the service provided to patients.

The power to investigate has been used with care. The Commission has developed a graduated approach, ranging from a telephone call to a chief executive to a full-scale investigation using experts, taking evidence and lasting months. Indeed, of the 320 requests that the Commission carry out an investigation, only 17 have resulted in a full-scale investigation. The decision whether to do so has been based not only on the apparent seriousness of the circumstances, but also on the extent to which lessons could be learned across the whole of the NHS (rather than its being a relatively parochial matter), and whether the investigation would allow the Commission to draw attention to an area of care which has been historically neglected or which, from other sources of information, is a cause of concern. Examples of investigations which have had a major impact in promoting improvements in care nationally include those concerned with the management of hospital-associated infections (Maidstone and Tunbridge Wells NHS Trust) and of maternity care (Northwick Park, part of North West London Hospitals NHS Trust).

There can be no doubt that the Commission’s response to significant failure has had a major effect in improving the performance of individual trusts and in having a wider impact on the overall system of care. For example, independent evaluation shows that 89% of the trusts surveyed thought that investigations carried out by the Commission had improved the safety of the care provided to patients.

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The actions taken by the Commission have come to be regarded as thorough, authoritative and independent. Indeed, the Commission's reputation has meant that healthcare providers and senior officials have even, on occasions, chosen to seek the regulator's intervention through, for example, asking it to carry out an independent analysis of potential problems (such as the engagement over two weeks with Papworth Hospital after surgeons reported an abnormal incidence of deaths after heart transplants).

In its investigations, the Commission has routinely found that a consistent feature of poor performance is poor leadership. In this context, a key lesson for the regulator is the importance of the local relationship it develops with regulated organisations. This allows the regulator to have a regular and close view of the capability of the leadership in an organisation to tackle emerging problems. As part of this approach, the Commission has developed a local mechanism for recognising and responding to increased risk, meeting regularly with other local agencies to pool their knowledge through monthly "risk summits".

What the Commission currently lacks, however, is any effective standards or benchmarks by which to measure the quality of leadership. To some, leadership is entirely a matter of management for management. Our view, however, is that benchmarks of performance can and should be developed and that an independent regulator has a role in measuring the quality of leadership on behalf of patients, clinicians and the wider public. Moreover, it is clear that the issues are wider than any particular organisation. The healthcare system as a whole needs to attract, develop, and retain sufficient numbers of high quality leaders, if performance is to continue to improve. Given what we have said about the central importance of boards of trusts, this imperative begins with boards, but then must be carried forward by them into every corner of the system.

Taking a "whole system" view

In encouraging improvement in and the provision of healthcare, the Healthcare Commission appropriately has a remit to consider both the commissioning and provision of care. It is important to review whether the services that are provided are of the right standard, but also whether the right services are being provided to improve outcomes for diverse local communities. Where there are problems in meeting standards in the case of a particular provider, the commissioners are also a central part of the process of getting to a sustainable solution.

The 2003 Act¹ included the promotion and protection of public health

within the definition of “healthcare”. The inclusion of public health and health inequalities within regulation and the assessment of performance was then reinforced by the standards on public health in the *Standards for Better Health*³ and the strong focus on outcomes for population health in the national targets. Systematically collected feedback from primary care trusts and provider trusts shows that this focus has had a significant and positive impact on performance in relation to public health. The Department of Health’s consultation document on the topics for requirements for registration places a much weaker emphasis on population health than the core standards on public health. As a consequence, there are concerns that in the new regulatory system the emphasis on prevention of ill health and on the role of providers of care in tackling health inequalities will be more limited.

In taking forward its remit with respect to commissioners, the Healthcare Commission has now separated the assessment of primary care trusts as commissioners from their assessment as providers of care. Further work is needed to ensure that the assessment effectively reinforces the accountability of primary care trusts to their local communities in addressing their diverse health needs, tackling health inequalities and securing good value for society from the investment in healthcare.

It is important to note that the regulatory reach of the Commission extends only to NHS organisations. One consequence is that the whole of primary care at the level of GPs’ practices falls outside the Commission’s remit. The primary care trust, as the relevant NHS organisation providing primary care, is therefore, the Commission’s only entry into the regulation of primary care. This is a shortcoming which is now recognised. The Government plans to address it through the process of registering GPs’ practices.

Working in partnership and aligning regulation with other mechanisms in the system

The Healthcare Commission sought to work in partnership with other regulators, auditors and oversight bodies, both to use their findings to obtain a more comprehensive view of the quality of services and to eliminate duplication of effort and reduce the costs of regulation. The Commission aimed to draw on and analyse data from a wide range of sources in its work, and to streamline collection of data where possible.

The Commission has established, over time, effective working relationships with Strategic Health Authorities and Monitor as the oversight bodies for NHS organisations. The respective roles of performance assessment and performance management have been

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clarified. However, the number of trusts that are still struggling to demonstrate that they meet the Department of Health's core standards is unacceptable. Management in the NHS has focused rather more on the performance indicators in national targets than on the broad standards of care in *Standards for Better Health*³. The evidence on the improvement in performance over time suggests that the things which are easier to measure are taken more seriously than issues which matter just as much or more to patients, such as being treated with dignity and respect.

Overall, the attention to improving the performance of the NHS trusts that have been weaker on the quality of care has not been as vigorous – or effective – as the turnaround support given to NHS trusts that were struggling to achieve financial balance. The Department of Health's new regime for performance may help to address this – it will be important that the regulator's assessment of the quality of care is a key component of the approach.

In relation to the Healthcare Commission's statutory function to coordinate the regulation of healthcare, there remains a large number of oversight, audit, regulatory and associated bodies with overlapping statutory and non-statutory remits on aspects of quality. The Healthcare Commission has made some progress in reducing collections of data, for example, the number of special collections of data to measure progress in meeting Government priorities has decreased by over 50% since 2005/06.

We have also made increasing use of others' findings in our assessment of risks and improved the sharing of information and proposed actions among these bodies – particularly through a programme of risk summits with other regulatory and audit bodies, Strategic Health Authorities and Monitor.

However, there is a need for a more fundamental examination of the controls on the information being collected, including that from visits. The starting point is the information that organisations should be collecting about themselves, so that they can know how they are doing and manage themselves accordingly.

Building the capability of the regulator and establishing a local presence

It will be clear from what has gone before that modern regulation calls for a variety of skills. Historically, inspection was the term used. It called for particular skills, not least long experience in the relevant area from which grows, in some, the ability to identify good and less good practice. With the move to information-led, risk-based regulation,

inspectors remain important. But others are needed. Indeed, the emphasis has shifted to analysis and analysts, and to those who coordinate the regulator's links with organisations and agencies at a regional and local level. Equally important are those who translate the Commission's work into accessible information. This last function is crucial, since not only does it serve to hold the Commission to account, but it also seeks to empower patients and the public through authoritative, accessible and fair information about their health service.

The Commission has established effectively what was dubbed a "local presence". It set up a network of local offices so that staff could liaise closely with NHS trusts and independent sector providers, local agencies, patients, and members of the community. These offices have been the eyes and ears of the Commission, advising of concerns, feeding back comment and generally keeping a regulatory eye on things in their patch.

*What are the lessons from regulation
for the healthcare system as a whole?*



The Healthcare Commission has sought to give proper emphasis to the many examples of excellent services in the NHS and the independent sector. The staff providing these services rightly deserve credit and recognition. That said, the work of the regulator in assessing performance, highlighting concerns about standards, investigating serious service failure and providing information about the quality of care has raised some important common themes for the healthcare system as a whole to address:

- While overall levels of satisfaction are high, further progress is needed to ensure that patients really are at the centre of care. Too many concerns about the standards of care arise because the culture of the organisation providing care does not consistently treat people with dignity and respect, protect them from harm and abuse, and promote their rights. Patients tell us that they want to be able to make meaningful choices, be fully involved in decisions about their care, and have the information that they need, when they need it. Further attention needs to be paid to training staff, to rewarding the right behaviour, to ensuring that feedback from patients and carers is sought and acted on (including the feedback that comes from complaints), to measuring, benchmarking and reporting on performance (across all sectors of care, including primary and community care) and to ensuring that requirements for registration are patient-focused.
- Many of the concerns about poor performance and investigations into serious service failures have highlighted poor leadership and governance, particularly in relation to the safety of care. Management has not been effective “from board to ward”, and information on outcomes of care has not been routinely reported to the board, analysed and acted upon.
- More attention needs to be given to a wider range of matters relating to the safety of patients: a better understanding and description of what constitutes “good care”; better identification of early “alerts” and other related information, before harm occurs; better reporting of incidents (which should have a wide definition to embrace failure to act which puts a patient at risk), more systematic learning and implementation of lessons; and better information to compare performance.
- There have been repeated concerns about the need to ensure that staff are appropriately trained and that their skills maintained.

What are the lessons from regulation for the healthcare system as a whole?

- In all of the Commission's major investigations, the boards of the organisations were not receiving adequate information about the quality of care that their organisations were providing. No organisation of the size and complexity of the NHS, particularly if it exists to provide a service, can function properly without such information.
- In many cases, there has been a lack of clarity on what "good" looks like in delivering care – for example regarding the safe care of patients, safeguarding children, maternity care, and services for people with learning disabilities. Too many of the standards that are set concentrate more on processes than outcomes.
- There has been a lack of attention to areas such as mental health, learning disabilities, equalities and the integration of health and social care in the national priorities set by government (the 'vital signs'). Many of the concerns about the quality of care that the Commission has had to focus on relate to these areas.

Many of these themes – being patient-centred, stronger professional leadership, a more rigorous approach to education and training, improving information about the quality of care, a clearer approach in setting standards – are recognised in the Department of Health's Next Stage Review. The challenge now is to ensure sufficiently vigorous and urgent action in implementing the policies set out in that review to make a difference for people.

Conclusions



Regulation has now been established in the healthcare system. Independent evaluation has produced robust and positive evidence on the impact that the Healthcare Commission has had.

In taking stock of the lessons learned from regulation of healthcare, it is important to recognise that the establishment of an independent regulator was an important step for Government. The independence of the regulator can be uncomfortable for Government in a partially devolved system, as the regulator will inevitably highlight concerns about aspects of services that Ministers are politically accountable for. However, it is also a necessary component of such a system. Indeed, effective regulation can help to support a more devolved system by providing strong guidance to people using services about the quality of care they are entitled to receive, and as a trusted source of information to support decision-making and accountability.

Regulation of healthcare has played an important part as one lever in a broad programme of reform. Clearly, the task of building the regulatory system is far from complete. This report has highlighted the main lessons about what has worked well and less well on the journey so far. As such it is intended to help those taking the next steps in the journey.

The creation of the new regulator of both health and adult social care provides an opportunity to build on what has been achieved. It is also an opportunity to take some new directions, by using registration to provide **stronger** guidance to the public about the standards of care they should expect, ensuring better information on performance across the health and social care sectors, and promoting a more integrated approach to health and social care in meeting the needs of people using services.

Appendices



Appendix A

Analysis of the healthcare sector in England

Characteristic	NHS	Independent healthcare
People provided with care	<p>300 million GP and community consultations</p> <p>NHS Direct 4.9 million calls, 30 million visits to website</p> <p>19 million A&E attendances, 4.5 million emergency hospital admissions</p> <p>7 million elective inpatients</p> <p>14 million first outpatient attendances</p> <p>308,000 caseload of community mental health services</p>	1.2 million independent sector health procedures
Annual expenditure	£90 billion NHS 2007/08 (7.3% GDP in 2007/08 up from 5.4% in 1997/98)	<p>£5 billion self-pay and insured healthcare</p> <p>£ 2.5 billion NHS funding</p>
Number of providers	<p>152 primary care trusts</p> <p>169 acute and specialist acute hospitals</p> <p>11 ambulance trusts</p> <p>59 mental health and/or learning disability trusts</p> <p>8,300 GP practices</p> <p>9,000 dental practices</p>	<p>2,108 establishments of which:</p> <ul style="list-style-type: none"> - 310 acute hospitals - 178 mental health/learning disability providers - 180 hospices - 372 private doctors
Workforce	1.3 million in NHS	150,000 in independent healthcare

Appendix B

Summary of the Healthcare Commission's progress against its strategic goals

Strategic goal	Evidence of achievement
1. Promote a better experience of health and healthcare for patients and the public	<ul style="list-style-type: none">• While it is not possible to isolate the Healthcare Commission's impact from that of other potential influences, our surveys of patient experience across England continue to show steady overall improvement with 92% of hospital inpatients describing their care as excellent, very good or good in 2007.• The Commission is keen to ensure that the views of patients are an integral part of our assessment process. For example, our programme of surveys of patients and NHS staff is the single biggest source of data we use for the annual health check. The Commission also encourages direct patient feedback through its <i>SpeakOut</i> network and through running focused engagement events. As part of the annual health check, we invite council overview and scrutiny committees, lay members of the boards of governors of NHS foundation trusts, and from 2008/09, the new local involvement networks (LINKs), to comment on how well each trust is meeting the national core standards. We then publish these commentaries. Some patient forum members (the predecessors of LINKs) have said this gave their views added leverage for improvement with local healthcare organisations. We also invite views from organisations representing specific groups of patients – for example, Mencap and Age Concern.• There has been a marked improvement in the proportion of NHS trusts that meet national standards and targets for the quality of their services. Overall, the Commission rated one-quarter (100) of NHS trusts as having excellent quality of services in 2007/08 compared to just 4% two years earlier. Over the same period, the number of trusts scoring weak for their quality of services has declined from 52 (9%) in 2005/06 to 20 (5%) in 2007/08.• The Commission and relevant strategic health authorities have jointly followed up the 20 trusts that were scored as weak this year for their quality of services and are actively encouraging improvement for patients in these areas.

Strategic goal

Evidence of achievement

- Our assessment of the compliance of independent healthcare organisations with core minimum standards has suggested overall improvement in compliance rates. In 2007/08, 93% of organisations met or almost met the standards, compared to 50% in 2005/06. However, a direct comparison between the two years is not straightforward due to changes in the Commission's inspection methodology over time.
- The Commission has carried out more than 30 national reviews of individual healthcare services and engaged with patients and clinicians to ensure that we measure what matters as part of each review. All our service reviews have generated recommendations for improvement and triggered an action planning process in those trusts where performance was found to be comparatively weak. Where we have undertaken follow-up reviews, we have found that healthcare organisations are generally acting on our recommendations. Our regional assessment staff also monitor concerns identified through the reviews with the trusts and independent healthcare providers concerned.
- Independent evaluation of the annual health check in 2007/08 found that the overwhelming majority of NHS trusts and independent healthcare organisations surveyed for the evaluation believed the Commission's assessment process to have been an important driver of improvement in their own organisation.
- In our most recent annual staff survey in 2008, 86% of our staff believed that the Commission was improving patient care. This was an increase of 13 percentage points since the 2006 survey.

2. Safeguard the public by acting swiftly on complaints, concerns and significant failings

- The Commission takes enforcement action or investigation where this is warranted to protect the safety of patients. In 2008/09, the number of enforcement notices served on independent healthcare organisations doubled over the previous year, with 39 cases being investigated, the successful prosecution of an establishment operating in breach of its registration conditions and with several more cases in preparation for prosecution.

Strategic goal	Evidence of achievement
	<ul style="list-style-type: none"> • The Commission conducts investigations into significant failings in the NHS. To date we have received hundreds of concerns around patient safety and have completed 17 full investigations as well as a range of other interventions. Independent evaluation shows that our investigations helped to bring about change by raising the profile of the poorly performing service within the trust as a whole, acting as a catalyst for greater investment in the service, acting as a catalyst for the reorganisation of the service, and enabling individuals to draw attention to issues that they previously felt were ignored. In the two trusts that had been placed under special measures, it was felt that this had helped to raise priority within the trust and galvanise support from partners. Trusts had also found additional support provided as part of special measures, such as external change teams, to be helpful. • Infection rates and hygiene are issues of particular concern to the public. Rates of MRSA bloodstream infections and <i>Clostridium difficile</i> infections are continuing to fall across the NHS as a whole. The MRSA rate fell by 33% for the third quarter of 2008 compared to the corresponding quarter in 2007, to 837 reported cases across England. The rate for <i>Clostridium difficile</i> fell by 35% over the same period, to 8,696 reported cases. • The Commission's investigation into the outbreaks of <i>Clostridium difficile</i> at Maidstone and Tunbridge Wells NHS Trust highlighted the stark consequences for patient safety of poor infection prevention and control. Independent evaluation showed that our investigation not only resulted in wholesale change at the trust concerned but had the biggest impact of all our investigations nationally – with other trusts reviewing their infection control procedures in the light of our recommendations. • The Commission inspects all hospital trusts to assess local compliance with the hygiene code and to date has served five improvement notices on NHS trusts for breaching the hygiene code. The Commission actively monitors such cases and these trusts have now improved their systems of infection prevention and control.

Strategic goal

Evidence of achievement

- NHS trusts are getting better at handling complaints although standards remain variable. We reviewed 8,949 in the year to 31 July 2008, making recommendations to the providers on steps they should take to improve services. The Commission has published three annual reports highlighting general lessons for the NHS. We have also produced a toolkit for trusts which has been positively received by NHS complaints managers.
- The Commission initially struggled with the high volume of complaints it received for review but has subsequently redesigned its processes (for example, to ensure that clinical advice is sought early on). The average time it takes to close a complaint has fallen from 23 weeks in September 2007 to just nine weeks by September 2008.

3. Provide authoritative, independent, relevant and accessible information

- On average we have published two reports a month, as well as making the detailed results of the annual health check for each NHS trust, and inspection reports for independent healthcare organisations available on our website.
- Our service reviews frequently provide NHS organisations with benchmarked scores on elements of performance. There is a good body of research evidence showing that publication of such data leads to improvements. Clinicians and healthcare staff also tell us that they find it useful.
- In 2007, we commissioned a survey of 40 key stakeholders from various fields: journalism, MPs, healthcare providers, clinicians, patient representative groups and the Department of Health. The Commission's information is viewed by all these groups as our major strength and is seen as independent and credible.
- The Commission's website is a vital tool in our mission to make information about healthcare accessible to as many people as possible and is visited by 140,000 visitors each month. In 2008 we focused both on extending the range of information we provide online, and on making sure that it is easy to find and understand.

Strategic goal	Evidence of achievement
	<p>In 2007, we introduced a new facility whereby users could type in their postcodes and be taken to Google maps displaying our ratings of all their local NHS organisations, with more detailed information just one click away. At the end of March 2008, we extended the site to include searchable information about more than 2,000 independent healthcare organisations.</p> <ul style="list-style-type: none"> • The Commission has piloted an early-warning programme identifying potential risks to the safety of patients by monitoring death rates in hospitals. We are now expanding the system to include other indicators of outcomes for patients, for example, monitoring how many patients are readmitted to hospital for the same problem and how many stay in hospital for shorter or longer periods than expected. • The Commission and the Society for Cardiothoracic Surgery in Great Britain and Ireland have produced detailed information on cardiac surgery outcomes for patients on a dedicated website – including at the level of the individual surgeon. Feedback from patients has been very positive.
<p>4. Promote action to reduce inequalities in people’s health and greater respect for human rights and diversity</p>	<ul style="list-style-type: none"> • The Healthcare Commission has a role in seeking to improve health and reduce inequalities. As part of the annual health check we assess healthcare organisations on the public health national standards and targets, and carry out national studies and reviews in this area. The Commission has undertaken surveys of public health professionals and provider chief executives. These show that the Commission’s assessment methods are perceived by these groups to have been influential in raising health inequalities up the agenda of individual NHS trusts. • It is clear from our programme of reviews and engagement with patients, carers and their representatives, that some patients have needs that tend to be missed or poorly met by healthcare services, for example, children and adolescents with mental health problems. Identifying such issues is a crucial step in ensuring that inequities in provision are systematically addressed in future.

Strategic goal

Evidence of achievement

- The Commission has consistently encouraged equality, diversity and the protection of human rights. For example, our national surveys of NHS patients and staff in England, our census of mental health inpatients with the Mental Health Act Commission and our national study of dignity have all highlighted that action is required in these areas.
- Together with other regulatory bodies and the Department of Health, the Commission has successfully pursued more comprehensive monitoring of the ethnicity of patients in the NHS.
- The Commission will publish a national review of race equality in healthcare in March 2009. The findings show that in September 2008, 94% of trusts reported that they had published a race equality scheme and 96% had produced at least one of the workforce statistics required by legislation. This represents marked improvement since the Commission began looking at how well trusts were meeting their publication requirements. However there is still some way to go before trusts meet all of the minimum requirements.

5. Take a lead in coordinating and improving the impact and value for money of assessment and regulation in healthcare

- The Concordat has been able to reduce the number of data collections which are now coordinated by the NHS Information Centre. The Information Centre also manages the 'ROCR-Lite' gateway process for proposed regulatory data collections.
- Survey evidence and feedback from NHS and independent healthcare providers, however, suggests that the Concordat is viewed as a good idea in principle but which has yielded little in the way of obvious impact. In 2008, the Provider Advisory Group (PAG) was established to advise on areas where the Concordat might make a difference from the provider perspective. A recent workshop event to assess the experience of the Concordat found that the PAG was regarded by Concordat members as a highly effective source of constructive challenge.
- Between November 2008 and February 2009, the Commission has overseen the roll-out of a series of collaborative risk summit

Strategic goal	Evidence of achievement
	<p>meetings – one in each strategic health authority area. For the first time, these meetings involved the principal healthcare regulators and inspectorates, along with strategy health authority representatives, who discussed concerns about local healthcare organisations and agree collective action. More than 250 people attended them.</p> <ul style="list-style-type: none"> • Early evaluation suggests that these meetings have the potential to reduce duplication, improve the reputation of regulators with trusts and enrich the intelligence that we can use to inform future activities such as registration of NHS trusts.
<p>6. Create an organisation delivering world class assessment and regulation</p>	<ul style="list-style-type: none"> • The Commission has an international reputation for being at the forefront of modern regulation. Delegations from over 30 countries have undertaken fact-finding visits to learn more about our information-led and risk-based approach. • The Commission has been innovative and keen to learn from others, by, for example, participating in the Comprehensive Area Assessment pilot sites and trials, commissioning and publishing evaluation of its own work, participating in academic research on the accountability of audit and review as a case study, hosting the annual conference of the International Society for Quality in Healthcare (ISQUA) in 2007 and piloting initiatives with partner regulators.

Appendix C

Comparative costs of regulation by sector for 2007/08

The following table summarises the costs of regulation (the costs of the regulator) compared to budget or market size as a measure for the size of the sector that is regulated.

Sector	Expenditure on services in 2007/08	Regulator(s) annual budget 2007/08	Cost of regulator(s) % sector spend	Sources
Healthcare	£98.7 billion of which: NHS £91 billion, Independent healthcare £7.7 billion	£160.8 million of which: Healthcare Commission £76 million, Monitor £13.5 million, NPSA £30.6 million, NICE £35.1 million, MHAC £5.6 million	0.16 (0.08 Healthcare Commission)	DH Annual Report 2007, Healthcare Commission Annual Report & Accounts 2007/08 Gross Operating Costs, MHAC Annual Report and Operating Accounts 2006/07, Monitor Business Plan 2007/08, NPSA Business Plan 2007/08, NICE Annual Report 2006/07
Social care	Social care £21.5 billion	CSCI £125.4 million	0.58	The State of Social Care 2006/07 – part 1 published Jan 2008. CSCI spend from CSCI annual report 2007/08.

Appendix C

Sector	Expenditure on services in 2007/08	Regulator(s) annual budget 2007/08	Cost of regulator(s) % sector spend	Sources
Children and learners	£71.5 billion of which: DfES spending £60.1 billion ^I , Private childcare spending £11.4 billion ^{II}	Ofsted £216 million ^{III}	0.30	DfES Departmental Report 2008, DfES Children's Services The Childcare Market, Ofsted
Local services	£51.8 billion ^{IV}	Audit Commission £220 million ^V	0.42	Public Expenditure Statistical analysis 2007 Table 7.7
Justice and community safety	Home Office expenditure £14.8 billion	£57 million by six inspectorates ^{VI}	0.39	Departmental reports of six regulators ^{VII} .

I Total education spending in England in 2007/08, DfES departmental annual report 2008, page 111.

II We have calculated the overall spending on childcare by multiplying the average weekly fees of £140 (private sector) and £120 (public and third sector) with the number of weeks and the total number of Ofsted registered places (1.5 million of which – roughly 20% – were in the public or third sector).

III 2007/08 estimated outturn, Ofsted Departmental Report 2007/08 Financial Tables Annex C page 57.

IV Overall current expenditure of local authorities was £105 billion in 2007/08, less £38 billion on education regulated by Ofsted and £15.2 billion on adult social care funded by councils regulated by CSCI (£14.2 billion council-funded social care in 2006/07 with cost uplift of 7%).

V Audit Commission Annual Report and Accounts April 2007 to March 2008.

VI Cost of CJS regulators in 2006/07 was HMI Constabulary £12.3 million, HMI Prisons £3.4 million, HMI Probation £3.6 million, HMI Court Administration (includes CAF/CASS in England) £2.4 million, HM Crown Prosecution Service Inspectorate £3.3 million (in 2004/05), Independent Police Complaints Authority £32 million in 2007/08. Assume cost uplift between 2006/07 and 2007/08 of 5 per cent.

VII Departmental Report 2007, HM Chief Inspector of Constabulary Annual Report 2005-07, HM Chief Inspector of Prisons Annual Report 2006/07, HM Inspectorate of Probation Annual Report 2006/2007, annual report of HM Chief Inspector of Court Administration 2006-2007, HM Crown Prosecution Service Inspectorate Annual Report 2004/05, Independent Police Complaints Authority 2007/08.

Sector	Expenditure on services in 2007/08	Regulator(s) annual budget 2007/08	Cost of regulator(s) % sector spend	Sources
Energy	£110 billion ^I	Ofgem £35.1 million ^{II}	0.032	BERR Digest of UK Energy statistics 2007
Telecoms	£51 billion	Ofcom £126.7 million ^{III}	0.25	Ofcom The Communications Market
Water	£9 billion ^{IV}	Ofwat £13.2 million ^V	0.14	Ofwat forward programme 2007-08 to 2009-10
Food	£33.1 billion	Food Standards Agency £144 million ^{VI}	0.43	United Kingdom National Accounts The Blue Book 2007

I The overall market grew by 14% from 2005 to 2006 due to the strong increase in prices. We have assumed a further 10% rise from 2006 to 2007.

II Ofgem Corporate Strategy and Plan 2008-2013.

III 2007 Ofcom Annual Plan 2007/08.

IV Base on a 4% increase compared to 2006/07 which was the average of previous years. £11 billion industry size quoted in Ofwat Annual Report 2007/08 page 1.

V Ofwat annual report 2007/08 page Appendix 3 table of costs.

VI Food Standards Agency Annual Report 2006/07.

Appendix D

Implementing our regulatory model: key activities

Involving patients, the public and staff in our work

- The views of patients are central to our assessment of NHS performance.
- Our programme of surveys of patients and NHS staff is the single biggest source of data we use for the annual health check.
- Over 8,000 comments from patients and members of the public have been coded into our screening system.
- We invite comment on how well every trust is meeting the national core standards from council overview and scrutiny committees, lay members of the boards of governors of NHS foundation trusts, the former patient and public involvement forums and in 2008/09 for the first time, the new local involvement networks (LINKs).
- We supported LINKs by running awareness events across the country in 2008/09 and developing a website so that they can submit patient experiences throughout the year.
- We involve patients, carers, users of services and clinicians and their representatives in the design of our national reviews of healthcare services, to make sure we measure what matters and produce information that can be used to improve services
- Our review visits to learning disability services have included a person with learning disabilities or a carer as a member of every review team. Evaluation of the national audit of specialist learning disability health services conducted in 2007 found that this was considered by staff in these services as central to the integrity of the review.
- We have continued to support and consult our *SpeakOut* network of community and voluntary groups including groups representing homeless people, travellers and minority ethnic groups. We have provided the network with training to help them capture patient experiences that can be fed into our assessments.
- We continue to assess healthcare organisations against their statutory duty to involve patients and the public. In 2008/09, following a review of what forms of public engagement work well and why, we have developed a new framework that we will be recommending for the future assessment of public involvement in healthcare.

- The Commission has steadily expanded its work with a wide range of clinicians and their representative bodies. We have recently focused on understanding how clinicians define quality, through a series of workshops. The Commission is also participating in work to develop a systematic approach to the accreditation of services with the professional colleges and bodies.
- The Commission sends out a regular e-bulletin about its work to 18,000 subscribers. It also produces a specialist quarterly e-bulletin with items of particular interest to clinical staff.

Making intelligent use of information and communicating the results of assessment and regulation

- The Healthcare Commission has pioneered the use of information for targeting regulatory resources to areas of greatest risk to patients and local communities.
- The Commission's screening and surveillance system uses over 2,000 items of national data on NHS performance.
- We are developing the capacity to monitor key indicators such as mortality rates in real time. This means that potential problems can be detected early and followed-up speedily by the Commission and local trusts. We are looking at extending this work to encompass a range of indicators of potentially poor outcomes – for example, readmission rates.
- There are some areas of healthcare where information is not readily available or is of poor or variable quality. The Commission has responded by visiting and inspecting such services first hand, for example, conducting ward-based observations for the review of dignity in care.
- Where appropriate we have used information to reflect the quality of care across organisational boundaries. For example, in our review of heart failure, NHS trusts and primary care trusts were scored collectively for the quality of local services in over 300 local areas.
- The Healthcare Commission is a producer of information, publishing on average two reports each month about healthcare performance.
- Our website is used heavily, receiving around 140,000 visitors each month. We have worked with patient groups and clinicians to improve our information. Our website was redesigned in 2007 and 2008 after consultation with patients and members of the public.

- Over time, the Commission has gained substantial and increased news coverage of its reports, reviews and investigations. A media audit undertaken in January 2007 showed that coverage in the national media had risen by over 30% in one year.
- The Commission has worked with the Society for Cardiothoracic Surgery in Great Britain and Ireland and patients to produce detailed information on cardiac surgery outcomes for patients – including at the level of the individual surgeon. This has been very well received and is the type of detailed service-level information that patients tell us they find valuable.
- The Commission has been increasingly keen to celebrate success as well as highlighting where problems exist. We published case studies of good practice from the annual health check in 2007/08 and publicly report on progress following investigations to highlight improvements made.

Assessing against standards and national priorities

- The Commission assesses the overall performance of every NHS trust each year as part of its annual health check, publishing separate ratings for trusts' quality of services and use of resources.
- Overall performance in the NHS has improved each year since the annual health check was established in 2005.
- An independent evaluation of the first year of the core standards assessment found that improved board level accountability was the most widely reported early benefit of the new assessment system (in a survey of 128 trusts).
- The Commission has a statutory duty to provide an annual performance rating for all NHS trusts in England. These are intended to provide public assurance and are widely reported in national and local media. There has been concern, however, that the ratings can be misleading – a trust that has been rated as 'weak' for example, is likely to be providing many instances of excellent care at the individual patient and service level. Great care is needed in the way assessment results are presented.
- Some standards are easier to assess and evidence than others. More work needs to be done, for example, on methods of assessing how well primary care trusts are commissioning healthcare services on behalf of their populations, and how well trusts are working in partnership to meet the needs of local people. The Commission has welcomed the development of the new comprehensive area assessment and has participated fully in early trials of this methodology with other agencies.

- Over 1,000 independent healthcare establishments have been registered since the Care Standards Act 2000⁴ came into force. The Commission inspects all establishments currently registered over a five year period.
- The Commission is actively following up NHS trusts that were scored as 'weak' in the 2007/08 annual health check with joint visits with strategic health authority staff. We will publish a report in 2009 summarising the learning from these visits.
- In 2008/09 the Commission is inspecting every acute trust against the hygiene code. These visits are unannounced. To date we have issued improvement notices to trusts over breaches of the code and more widely have made many recommendations for improvement as a result of the inspection programme. We have commissioned an independent evaluation of the impact of this inspection programme.
- The Commission has supported the development of the Care Quality Commission's methodology for registering NHS organisations that are compliant with the hygiene code by 1 April 2009.

In-depth reviews and studies

- The Commission has carried out more than 30 in-depth reviews and studies of healthcare services. Topics include services for children in hospital, the quality of commissioning of learning disability services, dignity in care, admissions management, an audit of services for people with learning disabilities, maternity services, older people's mental health, medicines management after discharge, race equality in health care, urgent care, adult inpatient mental health, diabetes, heart disease, tobacco control and sexual health (see Appendix H).
- In the course of conducting these reviews, we have conducted over 100 targeted follow-up visits to trusts to encourage improvement.
- The Commission has prioritised areas for in-depth review where:
 - patients may be more vulnerable, for example, children, people using mental health services and people with learning difficulties
 - where good information on performance is lacking
 - our investigations in individual trusts reveal issues that may be more systemic. Our reviews of maternity services and learning difficulties were triggered by such concerns.
- Findings from the reviews are fed back into our screening and surveillance system to ensure that we have a holistic picture of performance in each trust.
- The evaluation of the annual health check in 2006/07 identified substantial support for the topics selected for reviews, with 79% of

respondents strongly agreeing with the selection. Evaluation of the impact of three of our early reviews (with a sample of 100 NHS service managers and clinicians) found that 70% thought that the reviews had positive impacts for patients.

- Focused evaluation of the audit of learning disabilities in 2007 found that the review was having a major impact on practice. In this case, the audit resulted in a wide range of recommendations to improve aspects of care and the Commission has continued to work with services, strategic health authorities and Monitor to ensure recommendations are implemented.

Intervention and investigations

- The Commission has statutory duties to investigate serious concerns in the NHS and enforce registration requirements and standards in the independent healthcare sector.
- The Commission has received 320 referrals about concerns in the NHS, completed 17 full investigations and published a range of interventions and progress reports.
- An independent evaluation of the inspection programme has found that our investigations are respected as robust and have a major impact on the individual trusts concerned.
- In extreme cases, where the Commission has little confidence that either an NHS trust or its partners have the capacity to rectify problems, it has recommended that the Secretary of State for Health put in place special measures. While this is rare, evaluation suggests that it is highly effective in promoting change in these cases.
- The Commission has increased the number of enforcement actions pursued against independent healthcare organisations in the last year.
- Evaluation and media analysis shows that our investigations work has a strong impact not only on the trust under the spotlight but also nationally. The more cross-cutting the issue under investigation (for example, infection control) the greater the impact has tended to be across the NHS. Service-specific investigations, for example, into maternity services, have similarly had a demonstrable impact across the specialty.
- The Commission has responded to concerns about the length of time taken to conduct full investigations by successfully conducting more rapid interventions with trusts where this is warranted.

Patients' unresolved complaints about the NHS

- Each year the NHS delivers 380 million treatments and receives around 135,000 complaints. The Commission reviews cases where the patient is unhappy with the response from the trust. The Commission reviewed 8,949 complaints in the year to 31 July 2008.
- The Commission upheld 30% of the cases reviewed during this period, up from almost 20% last year. In a further 17% of cases (down from 26% in 2006/07), the Commission found that the trust's response to the complainant was not sufficient and it was sent back to the trust for further work. This means almost half of complaints reviewed required further work by the trust.
- Twenty-seven per cent were out of the Commission's jurisdiction, mostly because the complainant had not raised their concerns locally first. This suggests that some trusts are not making the complaints procedure clear enough for patients and the public or that people do not have faith in the independence of the local procedure.
- Eighteen per cent of cases were found in favour of the trust because the NHS had handled them appropriately.
- We have annually published a report highlighting the lessons for trusts emerging from our reviews.
- We have brought down the time taken to close complaints to an average of just nine weeks. This is a major improvement on our earlier performance.

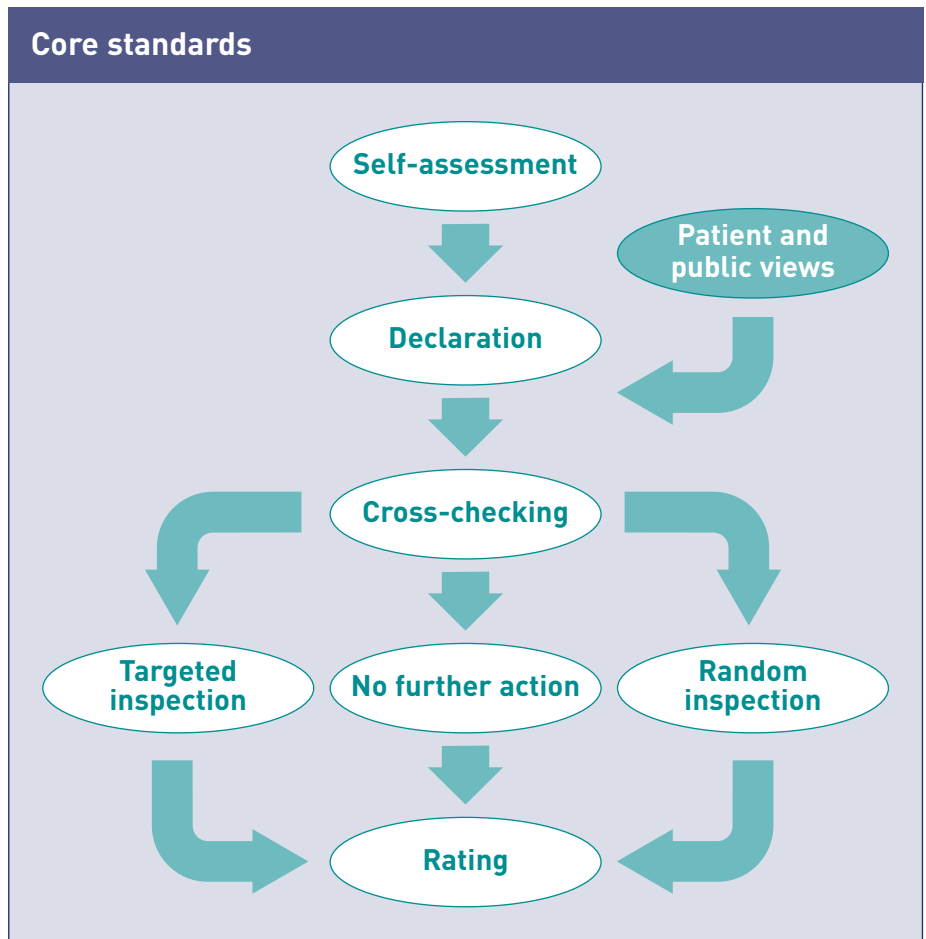
Working with others

- The Commission has a role in coordinating regulation and inspection across healthcare to reduce unnecessary administrative costs and duplication. It has set up the Concordat – a voluntary agreement between organisations that regulate, audit, inspect or review elements of health and healthcare in England. The Concordat was launched in June 2004 by 10 organisations, led by the Healthcare Commission. There are now 20 signatories working together to coordinate their activities such as audits, reviews and inspections. By streamlining their activities, these signatories are supporting the improvement of health services for the public.
- The Concordat has been responsible for various initiatives such as, a dedicated website and web-based scheduling tool for regulators and inspectorates.
- Concordat members have mapped the information they hold to identify areas of duplication.

- We have designed a regulatory impact assessment that is used across the concordat group to assess the costs and benefit of regulatory actions in advance of implementation in line with good regulatory practice.
- The NHS Information Centre now approves and monitors new data collections from regulators and operates a formal gateway process. Two data collections have been entirely discontinued as a result.
- The Healthcare Commission itself has conducted joint reviews of services with the Audit Commission, National Audit Office, CSCI, the Mental Health Act Commission, Ofsted and others.
- The Commission has reduced the number of criteria it uses to assess core standards in the NHS and since 2006/07 uses the judgements of other bodies as sufficient evidence of compliance for relevant core standards. We have introduced targeted inspection of the independent healthcare sectors – inspecting all organisations over a five-year cycle rather than annually.
- From November 2008, the Commission led the roll-out of a new way of working together at local level – the collaborative risk summit meetings. Local regulatory staff meet to share intelligence and information about risks in local healthcare organisations with strategic health authority colleagues. The aim of the meetings is to agree collectively on appropriate action. Early evaluation suggests this approach has real potential to reduce unnecessary duplication.

Appendix E

Assessment of the performance of the NHS in meeting core standards



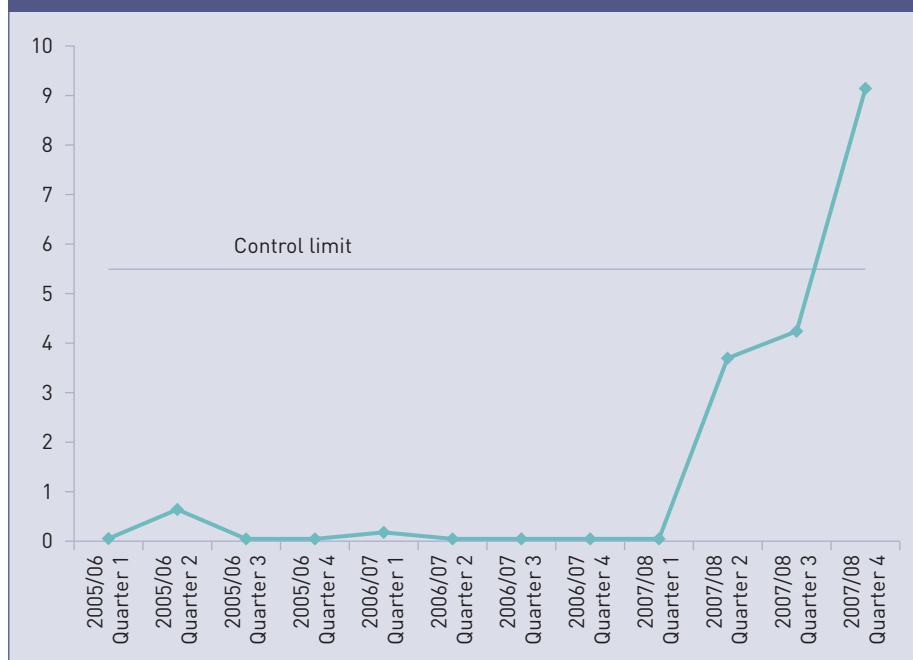
Appendix F

Real time surveillance – following up outliers

An outlier arises from the analysis of information that is routinely available. It identifies where, within an organisation, the numbers of patients who have suffered an adverse outcome (notably, but not always, death) is significantly higher than we would expect. There are many reasons why this might be, and we cannot and do not assume that there is a problem in the quality of care. However, these outliers cannot be ignored and we have developed a process for rigorously following them up.

The basic technique used to identify outliers is called CUSUM (cumulative sum) which detects significant deviations from expected outcomes, derived either from standardised mortality rates or the underlying risk associated with each patient. If the plotting of data crosses a fixed “control limit”, then a significant run of poor outcomes is detected and an alert is signalled. Figure 1 gives an example of a CUSUM chart.

Figure 1: CUSUM of in-hospital mortality for patients admitted as emergencies with non-transient stroke or cerebrovascular accident, age > 69 or with complications or co-morbidities at Mid Staffordshire Hospitals NHS Trust



While it is important to follow up outliers brought to our attention by other bodies (for example, Royal Colleges, and the Dr Foster Unit at Imperial College London). We also think it essential for the regulator actively to identify outliers, on the basis that any may represent a risk to the safety of patients. We, therefore, created a programme of work to use our experience and the wealth of data available to us actively to search for and follow up statistical outliers with the aim of identifying potential failures in care at the earliest possible stage. This requires a particularly thoughtful and sensitive approach, as data alone is unlikely to provide a complete insight into the complexities of healthcare.

The process of following up outliers, therefore is crucial. Our process includes:

- Preliminary analysis to identify inaccuracy or artefact in the data.
- Advice from internal and external clinical and other experts.
- A multi-disciplinary panel for decisions.
- Communication with the organisations involved to establish the accuracy of the data used in our analysis and to understand whether there may be known problems with the quality of data in the organisation.
- Intervention where no clear and well-evidenced explanation for an outlier is available.

Appendix G

Conclusions from *Spotlight on Complaints 2009* (the Healthcare Commission's third annual report on reviewing second-stage complaints about the NHS)

Since we assumed responsibility for the second stage of the NHS process for handling complaints in July 2004, we have reviewed 30,268 complaints about the NHS made by patients and their relatives, and made 16,500 recommendations to resolve complaints and improve services.

Over this period, we have seen some improvements in the way that the NHS responds to complaints but, as the outcomes of our reviews from this year show, there is some way to go before the NHS can confidently say that there are robust arrangements for handling complaints across England. This will be a big challenge for trusts under the new arrangements, which are due to come into force in April this year.

The types of complaints that we have seen have not changed substantially over the last four and a half years. They have mostly related to the fundamentals of good healthcare: communication, the attitude of staff, record keeping, and privacy and dignity.

Many complaints have also been about a poor standard of handling complaints by the organisation concerned – this was the issue that complainants were most concerned about this year. For example:

- Letters which do not seek to understand the circumstances of the complaint, or are full of clinical or other technical terminology.
- Concerns raised by the complainant not addressed in the response.
- A failure to interview or take statements from members of staff involved in the complaint.
- A lack of flexibility in the trust's approach, for instance, not offering the complainant the opportunity to meet representatives of the trust to discuss their concerns.

We have also seen cases this year where trusts have apologised for things that have gone wrong, but have expressed this in equivocal terms. For example, chief executives who say to complainants: 'I am sorry if you feel that way'. We strongly recommend that trusts provide a full and unequivocal apology when shortcomings in care and treatment have been identified.

As we emphasised in last year's report, it is crucial that NHS organisations get the aspects of a complaint which involve providing appropriate service to the complainant right at the first time of asking. Complaints and feedback from patients are likely to play an increasingly important role as a mechanism to improve patients' care in the NHS. The framework set out in the final report of the NHS Next Stage Review, *High Quality Care for All*⁹, sees far greater choice for patients and more personalised services. Advances in technology mean that there are now more ways for the public to provide feedback to NHS organisations. In this context, it will be even more important for NHS organisations to listen to and learn from complaints to ensure that the quality of services meets the increasing expectations of patients and the public.

We have always believed, and this is reflected in our previous reports on NHS complaints, that complaints are best resolved by the local provider without the need for involvement of an outside agency. Improving the way that complaints are responded to locally has always been the focus of our work. We call on NHS organisations to use all the guidance on good practice available to improve their handling of complaints, including our Spotlight reports, our Complaints Toolkit and the Ombudsman's *Principles of Good Administration*¹⁰, *Principles for Remedy*¹¹ and *Principles of Good Complaints Handling*.¹²

We know that patients and their representatives make complaints to healthcare organisations for three major reasons:

- They want an explanation of the events leading to their complaint.
- They want an apology.
- They want an assurance that the same mistakes will not be made in the future.¹³

We urge NHS organisations to ensure that they give active consideration to these three crucial components when responding to a complaint.

The key finding of this report is that there is still much that the NHS can do to improve the way that it deals with complaints. It is essential that there is a change of thinking throughout healthcare organisations – that they view complaints positively as a learning experience, rather than adopting a defensive approach. This is even more important with the increased emphasis on providers getting their responses to

complaints ‘right first time’ under the new arrangements. We have done a great deal of good work on complaints and we are proud of our achievements as the independent reviewer. We call on NHS organisations to build on our legacy of learning to continuously drive improvements in complaints handling.

Next steps

We have provided a successful independent service, which has identified key themes in complaints and has disseminated these to the NHS. As a result of a number of reports, including previous publications of Spotlight on Complaints, the NHS system for handling complaints is being reformed, together with the system for handling complaints about social care. From 1 April 2009, a single, simpler process will be introduced for all health and social care services in England. Under this new system, complaints should be made first to the provider of NHS or social care and, if the complainant remains unhappy with the outcome, to the Parliamentary Health Service Ombudsman (or Local Government Ombudsman where that is appropriate). The Health Service and Local Government Ombudsmen will work together in a coordinated way on complaints that cross the boundaries between health and social care. Our focus has always been on improving local resolution of complaints – so we welcome these reforms, which put much greater emphasis on resolving complaints locally.

We trust that NHS organisations will draw on the lessons that we have learned from complaints as they move into the new system. As this report shows, there are considerable challenges facing the NHS to bring the standards of local responses for complaints up to one where patients are much less likely to seek a second, independent view on their concerns. It is vital that trusts’ boards show clear leadership on complaints and challenge some of the areas of poor practice that we have highlighted. Poor handling of complaints can cause damage to the reputation of NHS providers so it is essential, in a more commercially competitive environment of healthcare, that boards listen to and learn from, complaints. Those commissioning services also need to make clear that they will follow up any failings in handling complaints with vigour.

This report shows that, although much progress has been made on NHS complaints, there is much work to be done to achieve these aims and that there are many challenges in doing so for NHS organisations and the Ombudsman. However, we trust that the new arrangements will meet these aims. An NHS that is locally responsive to patient concerns and that continuously improves as a result of complaints is something that would be universally welcomed.

Appendix H

In-depth reviews and studies

Published reports

- *Commissioning services and support for people with learning disabilities and complex needs*, March 2009
- *A review of the clinical governance of the Defence Medical Services in the UK and overseas*, March 2009
- *Actions speak louder: A second review of healthcare in the community for young people who offend*, February 2009
- *Spotlight on complaints 2009: A report on second stage complaints about the NHS in England*, February 2009
- *Commissioning healthcare in prisons*, February 2009
- *Not just a matter of time: A review of urgent and emergency care services in England*, February 2009
- *Improving services for substance misuse 2007/08*, January 2009
- *The safer management of controlled drugs: Annual report 2007*, September 2008
- *Audit of services for people with learning difficulties: Services for young people and adolescents*, August 2008
- *Towards better births: A review of maternity services in England*, July 2008
- *The pathway to recovery: A review of NHS acute inpatient mental health services*, July 2008
- *Safeguarding children: The third joint chief inspectors' report on arrangements to safeguard children*, July 2008
- *Is the treatment working? Progress with the NHS system reform programme*, June 2008
- *Improving services for substance misuse 2006/2007: Commissioning drug treatment and harm reduction services*, May 2008
- *Ionising radiation (medical exposure) regulations 2000: A report on regulation activity from 1 November 2006 – 31 December 2007*, March 2008

- *A life like no other: A national audit of specialist inpatient healthcare services for people with learning difficulties in England*, December 2007
- *Audit of equalities publications 2007*, November 2007
- *Is anyone listening? A report on complaints handling in the NHS*, October 2007
- *Caring for dignity: A national report on dignity in care for older people while in hospital*, September 2007
- *No voice, no choice: A joint review of adult specialist community mental health services in England*, July 2007
- *Managing diabetes: Improving services for people with diabetes*, July 2007
- *Healthcare associated infection: What else can the NHS do?*, July 2007
- *Pushing the boundaries: Improving services for patients with heart failure*, July 2007
- *Independent sector treatment centres: A review of the quality of care*, July 2007
- *Performing better? A focus on sexual health services in England*, July 2007
- *Getting results: Pathology services in acute and specialist trusts*, April 2007
- *Taking a closer look: Endoscopy services in acute trusts*, March 2007
- *An improving picture: Imaging services in acute and specialist trusts*, March 2007
- *Better safe than sorry: Preventing unintended injury to children*, February 2007
- *No ifs, no buts: Improving services for tobacco control*, January 2007
- *The best medicine: The management of medicines in acute and specialist trusts*, January 2007
- *Talking about medicines: The management of medicines in trusts providing mental health services*, January 2007
- *Spotlight on complaints: A report on second-stage complaints about the NHS in England*, January 2007

- *Improving services for substance misuse: A joint report*, December 2006
- *Management of admissions*, October 2006
- *Let's talk about it: A review of healthcare in the community for young people who offend*, October 2006
- *Race equality audit*, August 2006
- *Clearing the air: A national study of chronic obstructive pulmonary disease*, June 2006
- *Living well in later life: A report of progress against the National Service Framework for Older People*, March 2006
- *Tackling child obesity – first steps*, February 2006
- *A snapshot of hospital cleanliness in England*, December 2005
- *Accident and emergency*, August 2005
- *Day surgery*, July 2005
- *Ward staffing*, June 2005
- *The Healthcare Commission's review of NHS Foundation Trusts*, July 2005

Reports for publication March/April 2009

- National study of patient and public engagement
- Race equality review
- Follow-up review of children's services in hospital
- Follow-up review of community mental health services
- Older people's mental health services
- Health inequalities report
- Review of management of medicines after discharge from hospital

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