
7 Regulation and system management

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As we have seen in previous chapters, the policies introduced into the English National Health Service (NHS) by the Labour government during the early 2000s were intended to develop provider competition on a level playing field and to enable patients to choose any willing provider in a market underpinned by regulation and system management.

These policies included innovations in:

- supply, eg, NHS foundation trusts and independent-sector treatment centres (ISTCs)
- commissioning, eg, world class commissioning and practice-based commissioning
- provider payment (Payment by Results)
- an emphasis on patient choice.

Each was covered by a research programme commissioned by the Department of Health to evaluate the main elements of the government's system reforms, although regulation was not included in this evaluation.

The relationship between regulation and the market-based health policies introduced is complex for two reasons.

First, the Labour government's proposals underwent several dramatic shifts (Stevens 2004; Robinson and Bevan 2005), as demonstrated in its three White Papers on system reform: *The New NHS* (Department of Health 1997), *The NHS Plan* (Department of Health 2000b), and *Delivering the NHS Plan* (Department of Health 2002a). The proposals in the first two White Papers explicitly sought quality improvement from public providers through regulation because provider competition was then deemed to be damaging or ineffective. Only in the third White Paper was it proposed to improve the quality of publicly funded health care through provider competition and patient choice.

Second, developments in the regulatory architecture lagged behind these shifts in policy. The principal role of the successive regulators of the quality of care – the Commission for Health Improvement (CHI), the Healthcare Commission and the Care Quality Commission (CQC) – was to improve quality through regulation.

In 2010, the coalition government redefined CQC's role as quality assurance for a market that is now assumed to be the principal driver of improved performance of publicly funded health care. The objective of quality assurance is therefore to ensure that the organisations providing publicly funded care are of adequate quality. In this light, what is most relevant for the future is evidence of past regulatory failure in the systems of quality assurance used by the CHI and the Healthcare Commission, where failure meant signalling that a provider's quality of care was adequate when it was not.

Drawing on published research that I have contributed to and also on my experience of working for the CHI, this chapter examines the regulation of public providers. First, we examine the shifts in government policies for publicly funded care. Next, we set out the tasks of the successive quality regulators along with those of the Audit Commission and Monitor. The next two sections discuss changes in the systems of assessment used by the CHI and the Healthcare Commission, and the evidence of their effectiveness. The chapter concludes by reflecting on that evidence, and considering its implications for the future design of effective regulation of quality of care in the NHS.

Changing regulatory policies: a third way

The mantra of *The New NHS* was 'what counts is what works' (Department of Health 1997, p 10), along with the idea that New Labour's policies offered a 'third way' (Giddens 1998) of running the NHS, namely by means of a system based on 'partnership and performance' rather than 'the old centralised command and control systems of the 1970s' or 'the divisive internal market system of the 1990s' (Department of Health 1997, p 10).

The government created two new regulators – the CHI and the National Institute for Clinical Excellence (NICE; renamed the National Institute for Health and Clinical Excellence in 2005).

The CHI was created in the wake of a series of scandals over quality of care (Abbasi 1998), particularly the Bristol case (Smith 1998), 'to support and oversee the quality of clinical services at local level, and to tackle shortcomings' (Department of Health 1997, para 3.7). The public inquiry into the management of the care of paediatric cardiac surgery patients at the Bristol Royal Infirmary found that there had been about 30 excess deaths there, along with systemic regulatory failure in that external bodies had been aware of the problem but had failed to take corrective action because of organisational confusion over responsibility for quality assurance (Kennedy 2001 p 2, pp 9–10, pp 186–203).

NICE was created 'to give a strong lead on clinical and cost-effectiveness, drawing up new guidelines and ensuring they reach all parts of the health service' (Secretary of State for Health 1997, para 3.5). One of NICE's functions was to decide what

would and would not be available on the NHS in order to end so-called postcode rationing, the variation among health authorities in the availability of services such as *in vitro* fertilisation.

By 2000, the NHS was perceived to be in crisis, largely as a result of underfunding. The government's ensuing commitment to massive, unprecedented real growth in spending on the NHS resulted in a policy designed to change the traditional system of perverse incentives, described as follows.

The current system penalises success and rewards failure. A hospital which manages to treat all its patients within 9 or 12 months rather than 18 may be told that 'over performance' means it has been getting too much money and can manage with less next year. By contrast, hospitals with long waiting lists and times may be rewarded with extra money to bail them out – even though the root of the problem may be poor ways of working rather than lack of funding. The NHS has to move from a culture where it bails out failure to one where it rewards success. (Department of Health 2000b, p 28)

The new policy was based on developing a regime of star-rating – a system of strong performance management from the centre plus public reporting of the performance of NHS organisations against national targets. Failing (zero-rated) organisations were 'named and shamed', and the jobs of their chief executives were at risk in the first two years (2001 and 2002). So-called three-star organisations were rewarded with what was known as 'earned autonomy', which later became a criterion for being eligible to become a foundation trust (Department of Health 2000b). Initially, the Department of Health was responsible for the star-ratings (Department of Health 2001a, 2002c), but the CHI took over in 2003 (Commission for Health Improvement 2003).

From 2002, the government introduced the policies of patient choice and competition among a plurality of providers (*see* Chapters 2, 4 and 6) alongside command and control by means of national targets and standards (Department of Health 2002a). As part of these policies, the Healthcare Commission was created in 2004, with the objective of creating a 'level playing field' with one regulator responsible for public and independent providers of health care. The two different regulators of quality of care – the CHI for the NHS and the National Care Standards Commission for independent providers of health and social care – were abolished. The Healthcare Commission continued to report on the performance of NHS organisations by publication of the star-ratings (Healthcare Commission 2004, 2005a) and, later, by means of the annual health check (Healthcare Commission 2006b, 2007b, 2008d).

In 2009, the Healthcare Commission was replaced by the CQC, which is responsible for regulating the quality of all providers of health and social care. The CQC produced the annual health check for 2009 (Care Quality Commission 2009), but,

as part of the shift in emphasis from national targets to provider competition as the driver of improved performance, in 2010 the coalition government told it to cease carrying out the annual health check (West 2010). Independent providers continue to pay to be licensed, and, whereas regulation by the CHI and the Healthcare Commission of NHS providers was financed by the government, these providers must now also pay a fee to be registered by the CQC.

Five regulatory bodies

The Labour government was notable for creating and then abolishing a number of bodies with regulatory responsibilities for health care (Walshe 2003), and this turbulence has continued with the coalition government. This section outlines the functions of the three successive regulators of quality in the NHS – the CHI, the Healthcare Commission and the CQC – and the two organisations with which they had or have joint responsibilities. The focus is on their responsibilities for England. Some of the CHI's functions originally covered Wales, but the Healthcare Commission and the CQC cover England only. Following devolution in 1999, policies in the two countries increasingly diverged (Greer 2004; Connolly *et al* 2010).

The CHI

The CHI was created in 2000 and abolished in 2004. Box 5, opposite, outlines its initial functions and shows how these were expanded in 2003. As the regulator of the quality of care of NHS providers, the CHI's principal task was to undertake and report on clinical governance reviews (CGRs), which assessed how well NHS providers were implementing the systems and processes of clinical governance (Scally and Donaldson 1998) (*see below*) and the NICE guidelines.

The CHI also undertook:

- investigations of serious or persistent problems of quality caused by systemic failures (Department of Health 1998)
- studies of the implementation of national service frameworks (NSFs), undertaken jointly with the Audit Commission
- and star-ratings (in 2003 only).

The Healthcare Commission

The Healthcare Commission took over from the CHI in 2004, and was abolished in 2009. The Healthcare Commission continued the programme of CGRs, studies of the implementation of NSFs (jointly with the Audit Commission), and publication of star-ratings until 2006, when the Healthcare Commission implemented its own systems for regulating the NHS based on the annual health check (Box 6, opposite).

Box 5 The regulatory functions of the CHI

From April 2000, the CHI was responsible for:

- undertaking and reporting on CGRs for NHS trusts and primary care trust providers
- developing and disseminating clinical governance principles and best practice throughout the NHS
- studying the implementation of NSFs and NICE guidelines
- investigating serious or persistent problems of quality caused by systemic failures.

From April 2003, the CHI was additionally responsible for:

- contracting for annual national surveys of staff and patients
- contracting for national clinical audits
- publishing star-ratings
- publishing an annual report to parliament on national progress on health care.

Sources: Department of Health 1998, pp 51–62; Department of Health 2002c, pp 64–66

Box 6 The regulatory functions of the Healthcare Commission

The Healthcare Commission was responsible for:

- reviewing the performance of each NHS organisation and awarding an annual rating
- regulating health care provided by the independent sector
- investigating serious service failures in the NHS
- carrying out reviews of the provision of health care in the NHS (including reviews of the economy and efficiency of the provision of health care)
- considering complaints about NHS bodies that had not been resolved locally
- reporting annually to parliament on the state of health care in England and Wales
- promoting the effective co-ordination of reviews or assessments of the provision of health care.

Source: Healthcare Commission 2009b, pp 7–8

In addition, the Healthcare Commission had responsibility for:

- licensing independent providers of health care
- undertaking studies of value for money in the NHS (with a transfer of this responsibility and staff from the Audit Commission).

The CQC

The CQC took over the regulation of health care from the Healthcare Commission in 2009, and was given additional responsibilities for:

- regulating adult social care
- monitoring functions by the Mental Health Act Commission on the operation of the Mental Health Act 1983
- registering general medical practices, doctors who work solely within private practice, and all primary dental care providers (whether NHS or private).

The review of arm's-length bodies (Department of Health 2010e) proposed only limited changes to the CQC, the main ones being to transfer responsibility for assessing NHS commissioners from the CQC to the NHS Commissioning Board, and to create HealthWatch England as a new, independent, consumer champion with a distinct identity within the CQC.

Box 7, below, gives CQC's regulatory functions before these proposed changes.

Box 7 The regulatory functions of the CQC

The CQC was to monitor:

- the medical and clinical treatment given to people of all ages, including treatment in hospitals and by the ambulance service and mental health services (eventually to include primary care such as GP and dental practices)
- the care provided in residential homes, in the community, in adult patients' own homes, and in residential care homes for children
- the services provided for people whose rights are restricted under the Mental Health Act
- the care provided by both the NHS and the independent sector.

Source: Care Quality Commission 2011

The Audit Commission

The Audit Commission was created in 1983 with a focus on local government. Its remit was extended in 1991 to encompass auditing the financial accounts of NHS bodies, and undertaking studies of value for money (Campbell-Smith 2008).

When in opposition, the Labour Party had considered giving the responsibilities of the CHI to the Audit Commission (Day and Klein 2001, p 98), but once in government it decided against this because the Audit Commission enjoyed such independence that it was able set its own priorities.

The Audit Commission undertook studies of NSFs jointly with the CHI and the Healthcare Commission, and, also jointly with the Healthcare Commission, evaluated the government's market-based reforms (Audit Commission and Healthcare Commission 2008). The annual health check assessments of the use of resources by NHS trusts (other than foundation trusts) were conducted by the Audit Commission.

On 13 August 2010, the coalition government announced that the Audit Commission would be abolished by 2012.

Monitor

Monitor was created in 2004 to regulate foundation trusts (*see* Box 8 below). It relied on the Healthcare Commission, and in future will rely on the CQC, for information

Box 8 The regulatory functions of Monitor

Monitor was created to:

- determine whether NHS trusts were ready to become NHS foundation trusts based on the criteria of good governance, financial viability, and being legally constituted, with a membership that was representative of their local community
- assess the governance of NHS foundation trusts, ensuring that they had complied with the conditions they had agreed to, namely that they:
 - were well-led and financially robust enough to operate effectively, efficiently and economically
 - met health care targets and national standards
 - co-operated with other NHS organisations
- support NHS foundation trust development.

Source: Monitor 2011

on the quality of care. The annual health check assessments of the use of resources by foundation trusts were conducted by Monitor.

The review of arm's-length bodies (Department of Health 2010e) proposed that Monitor be transformed into a new economic regulator for the NHS.

Changes in assessment systems

Box 9, below, outlines the seven pillars of clinical governance (as adopted after some development), and Figure 7, opposite, shows how the CHI's CGRs were designed to assess these systems and processes. The government specified key elements in CGRs (Department of Health 1998), but the process was designed by the CHI (Bevan and Cornwell 2006) and influenced by the Baldrige awards for quality in the United States (*see* Baldrige 2011).

The process of CHI's CGRs developed over time, and Box 10, opposite, outlines its final form, including the requirement for trusts to respond by producing an action plan (Bevan and Cornwell 2006). The CHI developed a scoring system for the seven pillars:

I – little or no progress

II – implementation in part

III – substantial progress

IV – excellent.

Box 9 The seven pillars of clinical governance

Processes for quality improvement

- Consultation and patient involvement
- Clinical risk management
- Clinical audit
- Research and effectiveness

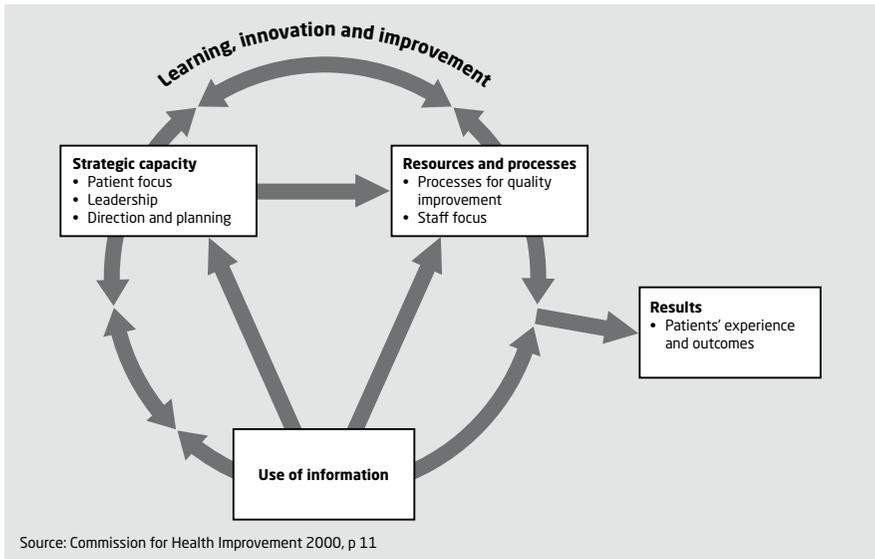
Staff focus

- Staffing and staff management
- Education, training and continuing personal and professional development

Use of information

- Use of information to support clinical governance and health care delivery.

Source: Commission for Health Improvement 2002c, pp xii–xiii

Figure 7 The CHI's model for clinical governance**Box 10** The process of CGRs

- CGRs were based on a rolling programme of visits to every NHS trust responsible for delivering services, mainly selected at random.
- Inspections were by multidisciplinary teams led by the review manager (a staff member of the CHI) and included a nurse, a doctor, an NHS manager, a lay member and another clinical professional (not a doctor or a nurse) recruited through national advertising, carefully selected and trained.
- Before each visit (which lasted a week), data from national datasets, the trust and stakeholders (including patients and carers) were collected and analysed. The purpose of the visit was to interview staff, observe practice, verify information already obtained and gather further information.
- The CHI's reports, drafted by the CHI's review managers and published both in hard copy and on the CHI's website, sought to:
 - identify areas for improvement
 - provide a way of identifying and acknowledging success and good practice, and encouraging its dissemination
 - take account of comments by the trust on factual accuracy.
- The trust was required to develop an action plan in response to the key areas for action outlined in the report.

Source: Bevan and Cornwell 2006

The model used by the CHI for star-ratings of NHS acute trusts in England for 2003 employed three different sets of indicators – key targets, CGR scores, and indicators in three domains in a balanced scorecard – to produce a single summary score (see Box 11 below).

Box 11 The CHI's model of star-ratings of NHS acute trusts for 2003

- There were nine key targets, of which six were waiting times with the other three being measures of financial balance, hospital cleanliness, and improving the working lives of staff.
- CGRs were scored against the seven pillars of clinical governance.
- A wider set of about 40 targets and indicators, called the balanced scorecard, was organised into three domains: clinical outcomes, patient experience, and organisational capability and capacity.

Source: Commission for Health Improvement 2011

As CGRs were organised on a four-year rolling programme, the scores in CGR reports became out of date. CHI revised these scores based on reports from strategic health authorities on the progress that trusts had made in implementing their action plans. In outline, a trust with a current CGR:

- was at risk of being zero-rated for failures against more than one key target
- or for failure to make progress (1) in five or more of the pillars of clinical governance
- and was given three stars for good performance against key targets and the balanced scorecard, and reasonable performance in clinical governance (Bevan and Cornwell 2006).

For 2004 and 2005, the Healthcare Commission based star-ratings on key targets and the balanced scorecard only. From 2006, the annual health check was the primary basis of the Healthcare Commission's regulation of the quality of NHS providers, and was based on targets (similar to those of star-ratings) and so-called core and developmental standards.

Table 4, below, details the intended outcomes of the core and developmental standards: core standards were ‘the minimum level of service patients and service users have a right to expect’; and developmental standards signalled the direction of travel for further improvement (Department of Health 2004c, p 3).

Table 4 Core and developmental standards for the annual health check for 2006/7

Standards	Intended outcome
Safety	Patient safety is enhanced by the use of health care processes, working practices and systemic activities that prevent or reduce the risk of harm to patients
Clinical and cost-effectiveness	Patients achieve health care benefits that meet their individual needs through health care decisions and services based on what assessed research evidence has shown provides effective clinical outcomes
Governance	Managerial and clinical leadership and accountability, as well as the organisation’s culture, systems and working practices ensure that probity, quality assurance, quality improvement and patient safety are central components of all the activities of the health care organisation
Patient focus	Health care is provided in partnership with patients, their carers and relatives; it respects their diverse needs, preferences and choices, and is co-ordinated with other organisations (especially social care) whose services impact on patient well-being
Accessible and responsive care	Patients receive services as promptly as possible, have choice in access to services and treatments, and do not experience unnecessary delay at any stage of service delivery or along the care pathway
Care environment and amenities	Care is provided in environments that promote patient and staff well-being and respect for patients’ needs and preferences in that they are designed for the effective and safe delivery of treatment, care or a specific function, provide as much privacy as possible, are well maintained and are cleaned to optimise health outcomes for patients
Public health	Programmes and services are designed and delivered in collaboration with all relevant communities to promote, protect and improve the health of the population served and reduce health inequalities between different population groups and areas

Source: Healthcare Commission 2006c, pp 32–6

Box 12, below, shows the Healthcare Commission's model for the assessment of core standards, which was largely based on self-assurance (*see* below).

The key elements and essential standards for quality and safety of care in the CQC's new system of registration of NHS providers are outlined in Box 13, opposite.

Box 12 The Healthcare Commission's model for assessing core standards for the annual health check

- A formal declaration by the board of every NHS trust of the extent to which, in its view, it had complied with the core standards.
- A commentary by third parties (from groups representing patients and the public and the oversight and scrutiny committees of local government) to be included in the trust's self-declaration and made public at the time of submission.
- An analysis by the Healthcare Commission of the data submitted by trusts in their self-declarations.
- A visit (inspection) on the basis of risk, as identified by the trust or the Healthcare Commission, or (for percentage) on a random basis.
- 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 demonstrated.
- A rating of performance for each trust.

Source: Healthcare Commission 2009b, pp 13–14

Box 13 Elements in the CQC's approach to ensuring that NHS providers have complied with the standards of quality and safety of care

Element	Outline
Quality and risk profile	A tool that gathers all the information CQC know about a provider to assess risk and prompt regulatory activity.
Essential standards of quality and safety of care	<p>These are:</p> <ul style="list-style-type: none"> ■ respecting and involving people who use services; consent to care and treatment ■ care and welfare of people who use services ■ meeting nutritional needs ■ co-operating with other providers ■ safeguarding vulnerable people who use services; cleanliness and infection control ■ management of medicines ■ safety and suitability of premises ■ safety, availability and suitability of equipment; requirements relating to workers ■ staffing ■ supporting workers ■ assessing and monitoring the quality of service provision; complaints; records.
Judgement framework	Provides a framework for assessors when making a judgement about compliance, as well as a guide for providers about the judgements CQC will make.
Setting the bar	Guidance for inspectors and assessors on what regulatory response they should take when concerns are identified.
Review of compliance report	Summarises the findings of a review of compliance including any improvement actions or enforcement activity for publication.
Provider compliance assessment	Tool for providers to evidence their compliance with essential standards.
Outcome evidence	The evidence used to demonstrate the outcomes described in the Guidance about compliance.
Site visit	To gather additional information an assessor may visit a site to carry out observations, interviews and discussions.

Evaluations of the Commission for Health Improvement and the Healthcare Commission

This section considers four issues in the evaluation of the CHI's CGRs and the Healthcare Commission's annual health check:

- their objectives
- proportionality
- consistency
- effectiveness in quality improvement and quality assurance.

Objectives

The CHI and the Healthcare Commission had two objectives in regulating the quality of NHS providers:

- quality improvement for all providers
- quality assurance by means of identifying, to ministers and the public, the providers with which there appeared to be problems.

This was difficult as the government required both regulators to use one principal instrument for both objectives (the CHI used CGRs, and the Healthcare Commission the annual health check). There was a crucial shift in what each regulator was required to report:

- the CHI's CGRs reported on the implementation of the *systems and processes of clinical governance* by NHS trusts
- the Healthcare Commission's annual health check reported on the *quality of services directly* (as 'excellent', 'good', 'fair' or 'weak').

Walshe (1999, p 194) presciently asked troubling questions about the CHI's CGRs: would these reports on the systems and processes of clinical governance satisfy the public and politicians, or would they want to know about actual quality of care? Reports on clinical governance would be easier to produce reliably and have the potential to improve quality, but would it be possible for a regulator to report reliably on quality in large and complex acute trusts?

These questions can now be answered with the benefit of hindsight, and pose a serious regulatory dilemma. The public and politicians do prefer the regulator to report directly on the quality of care (as in the annual health check) rather than on systems and processes (as in CGRs), but it is much more difficult to do the former than the latter.

Proportionality

Proportionality entails optimising the costs and benefits of regulation. Walshe (1999) asserted that the CHI's CGRs based on visiting every NHS provider organisation were not targeted and proportionate.

There are two reasons why this assertion was misdirected. First, the CHI's remit was not the single objective of quality assurance, but also to promote good practice, and so the CGRs sought to identify examples of both good and bad practice. Second, with regard to the objective of quality assurance, the CHI's experience was that, for typical acute trusts, the regulatory question was 'not which *organizations* to target, but which *parts of each organization* to target' (Bevan and Cornwell 2006, p 18).

Later, Benson *et al* (2004) rightly criticised the CHI's approach as not being proportionate because it used the same level of resources for each review and did not take account of the scale of organisations.

The CHI's CGRs did impose a regulatory burden on NHS trusts, but the review of inspection and monitoring in health care undertaken jointly by the Cabinet Office's Regulatory Impact Unit Public Sector Team and the Department of Health (Cabinet Office/Department of Health 2003) did not recommend any radical changes, and neither did the evaluation of clinical governance by the National Audit Office (2003).

The Healthcare Commission's regulatory approach aimed to reduce the regulatory burden by being proportionate for both quality assurance and improvement. This approach was based on using a system of self-assurance backed by external scrutiny from local organisations and checks from inspections of 20 per cent of trusts, half of which were chosen at random and half based on their estimated risk. The Office for Public Management's survey of NHS trusts found that they had concerns about gaming (by other trusts) when reporting was based on self-assurance, and that 'those selected at random generally understood why they had been selected but the risk based sample generally did not' (Office for Public Management 2008, p 33).

Consistency

Consistency is tied to the use of explicit standards. There is, however, a trade-off between consistency and effectiveness: limiting regulation to explicit standards is more likely to be consistent, but organisations may respond by focusing on satisfying those standards at the cost of neglecting other processes, which can result in poor quality of care (Bevan and Cornwell 2006).

The CHI was not empowered to specify standards, was unable to wait for the government to do so (Bevan and Cornwell 2006) and, largely as a consequence, its CGRs were criticised for lacking consistency (Benson *et al* 2004; Day and Klein 2004). The Healthcare Commission did use standards for the annual health check, but Shaw (2004) criticised them for not offering a sound basis for regulation because they varied in depth, scope and specificity.

Trusts experienced problems with interpreting what 'compliance' with standards meant and hence there were questions over the consistency with which these would have been reported by different organisations (Scrivens 2007). There were also problems over consistency in the checks on these reports from inspections (Scrivens 2007; Office for Public Management 2008, p 35).

Effectiveness

Ayres and Braithwaite (1992) argued that an effective regulator ought to 'speak softly but carry a big stick' at the top of a hierarchy of sanctions to ensure that the failings identified by the regulator are corrected. Webster (2002) questioned whether the CHI could be effective as its powers were initially limited to reporting (like the previously ineffectual Hospital Advisory Service, later the Health Advisory Service).

Like the Healthcare Commission, the CHI could only recommend that the Secretary of State impose special measures, which 'might include recommendations for practical assistance or organisational support from outside the trust or, in extreme circumstances, suspension of a service' (Healthcare Commission 2008b, p 23). The Healthcare Commission made three such recommendations, which were accepted by the secretary of state.

The CHI was not empowered to set deadlines for trusts to produce action plans in response to CGRs, and the key responsibility for putting pressure on trusts to do so lay with regional bodies, which were being reorganised. The CHI did, however, carry 'a big stick' when its CGRs fed into star-ratings, as lack of progress in the seven pillars of clinical governance could result in a zero-rating, or denial of three stars, along with the sanctions associated with those outcomes (Bevan and Cornwell 2006).

In assessing the effectiveness of both the CHI and the Healthcare Commission as independent regulators, it is vital to recognise that this is also an assessment of the way the government designed their regulatory instruments and powers. This section first considers the evidence for quality improvement, which comes from a positive impact of regulation. It then considers the evidence for quality assurance, which is negative, and of regulatory failure: did the regulator signal to ministers and the public that a provider's care was adequate when it was poor?

Quality improvement

Three instruments of quality improvement were used by the CHI and the Healthcare Commission:

- CGRs
- star-ratings
- the annual health check.

CGRs

The National Audit Office (2003) found that more than 90 per cent of members and senior managers of trusts reported that they had taken action in response to the CHI's CGRs, and that this had had the biggest impact on them of the various national initiatives (including star-ratings).

Benson *et al* (2004, pp 29–37) also found that the great majority of CHI's recommendations had resulted in action, with much of this attributed to CHI's intervention.

Star-ratings

The period between 2000 and 2005 offered the basis for evaluation of a so-called natural experiment between the NHS in England and that in the devolved countries in the United Kingdom (Scotland, Wales and Northern Ireland). Over this period:

- each country's NHS experienced sustained and unprecedented increases in funding (with England having the lowest per capita spending throughout)
- the governments in each country had common policy objectives, with targets to reduce hospital waiting times and improve the speed of responses by ambulances to life-threatening emergency calls
- no country had a system of provider competition in place
- only in England was there a regime of performance management and public reporting that applied sanctions for failure to hit targets and rewards for success; in Scotland and Wales there was the perception that failure was still capable of being rewarded (Bevan 2010).

Evaluations of this natural experiment found that the star-ratings regime resulted in a transformation in the reported performance of the NHS in England – particularly in bringing down waiting times for hospitals (Auditor General for Wales 2005; Bevan and Hood 2006a; Hauck and Street 2007; Propper *et al* 2008b; Besley *et al* 2009; Bevan 2009, 2010; Connolly *et al* 2010; Propper *et al* 2010a) and ambulance response times to potentially life-threatening emergencies (Auditor General for Wales 2006; Bevan and Hamblin 2009) – but not in the other three UK countries. Although the systems of regulation were not designed to counter gaming (Bevan and Hood 2006b), this appears to have been limited (Bevan and Hamblin 2009; Connolly *et al* 2010; Propper *et al* 2010a).

Examinations of the scoring system of star-ratings raised questions about the selection and aggregation of indicators into a single score (Commission for Health Improvement 2004a; Jacobs and Smith 2004; Bevan 2006; Jacobs *et al* 2006) and the transparency of the scoring system (Spiegelhalter 2005). Qualitative research has shown that when a trust was zero-rated, it had a devastating effect on staff morale (Mannion *et al* 2005).

The annual health check

The survey by the Office for Public Management (2008) of NHS trusts with regard to the three components of the annual health check for 2006/7 found that 90 per cent thought that targets and the core standards had been effective in driving improvement (p 22), fewer than 50 per cent thought that the developmental standards were effective (p 23), and there was criticism of targets: 'We work in pathways but the system measures us in bits' (p 23). More than 90 per cent saw self-assessment and inspections as triggers for change (p 40).

The Healthcare Commission's summary of external evaluations reported improvements over time in the self-assessments of the quality of services of NHS trusts from 2005/6 to 2006/7, but identified problems with primary care trusts following their reorganisation. They were 'the poorest performing sector and the only sector for which performance *deteriorated* as a whole' in 2006/7 (Healthcare Commission 2008c, p 36, original emphasis).

Quality assurance

There were two principal instruments of quality assurance: the CHI's CGRs, over which there were no public concerns; and the Healthcare Commission's annual health check, about which the House of Commons Health Committee observed: 'Doubts about the effectiveness of regulation have been raised by the fact that none of the recent appalling cases of lethally unsafe care in the NHS was brought to light by the annual health check' (House of Commons Health Committee 2009, p 75). These 'cases of appalling care' included 'Stoke Mandeville Hospital, and Maidstone & Tunbridge Wells NHS Trust, which involved stark failures in preventing and controlling healthcare-associated infections, and Mid-Staffordshire Trust, where wholly inadequate Accident and Emergency (A&E) care led to unnecessary deaths and harm' (p 10).

Table 5, opposite, gives the scores for each of the seven pillars of clinical governance for these three trusts following their CGRs in 2002. None did well on any pillar, and each had made no progress on two or more.

The problems of regulatory failure

The CHI's CGR of Stoke Mandeville Hospital for 2002 identified improving the control of infection as a key area for action. In 2004 and 2005, 'over 30 people died there as a consequence of two outbreaks of infection caused by the bacterium *Clostridium difficile*' (Healthcare Commission 2006a, p 2). This occurred before the annual health check, when the only current public information on quality of care was from star-ratings, which gave Buckinghamshire Hospitals NHS Trust (responsible for Stoke Mandeville) two stars (with a low score on the indicators of quality of care in the balanced scorecard) (Healthcare Commission 2005a, p 31).

In his foreword to the Healthcare Commission's investigation into the outbreaks of *Clostridium difficile* infection there, chairman Professor Sir Ian Kennedy

Table 5 Scores for the seven pillars of clinical governance for three NHS trusts in 2002

Pillars of clinical governance	Mid Staffordshire General Hospitals NHS Trust	Stoke Mandeville Hospital	Maidstone & Tunbridge Wells NHS Trust
Clinical audit	II	I	II
Clinical risk management	II	II	I
Continuing personal and professional development	II	II	II
Education and training	II	II	II
Research and effectiveness	II	I	I
Staffing and staff management	I	I	II
Use of information to support clinical governance and health care delivery	I	I	I

Source: Commission for Health Improvement 2002a, 2002b, 2002c

noted: ‘what happened at Stoke Mandeville reflects many of the organisational failings identified in the Bristol report’. He went on to acknowledge regulatory failure from reporting after the event, but intended to correct this by developing the Healthcare Commission’s ‘capacity to identify when things are going wrong, before they end in tragedy... by using our techniques of surveillance, examining data on the performance of organisations providing healthcare on a regular basis, and by working with others’ (Healthcare Commission 2006a, p 2).

The CHI’s CGR of Maidstone & Tunbridge Wells NHS Trust for 2002 also identified improving the control of infection as a key area for action. There were serious outbreaks of *Clostridium difficile* there in the autumn of 2005 and in early 2006, but the Healthcare Commission’s new system failed to detect it: the annual health check for 2005/6 reported that the trust was compliant with the core national standard for control of infection (Bevan 2008).

The CHI’s CGR of Mid Staffordshire (which is used here to encompass Mid Staffordshire NHS Foundation Trust and its former status as Mid Staffordshire General Hospitals NHS Trust) for 2003 highlighted problems with:

- staff shortages among senior nurses, doctors and middle management
- poor quality of clinical data
- weaknesses in handling informal complaints and involving patients
- and the trust giving more attention to improving its financial position and performance on waiting times at the expense of a focus on quality of patient care (Commission for Health Improvement 2003).

The trust was rated on quality of services in successive annual health checks as:

- 'fair' in 2005/6 and 2006/7
- as one of the four '*most improved* acute and specialist trusts' in 2006/7 (Healthcare Commission 2007b, p 33, emphasis added)
- and provisionally as 'good' in 2007/8 (Healthcare Commission 2008d, p 93).

The Healthcare Commission's investigation into Mid Staffordshire identified all the problems that the CHI had highlighted six years previously, but exacerbated by pressure on the trust in 2006/7 'to stabilise its finances, and become an NHS foundation trust', requiring it to save £10 million (Healthcare Commission 2009a, p 9).

The report of the investigation was criticised by Bird (2009) for its inadequate documentation of mortality statistics. One of these inadequacies was the omission of an estimate of the number of excess deaths at the hospital, which was widely reported in the media as 400 (compared with 30 excess deaths at Bristol in the 1990s).

The problems at Mid Staffordshire were so grave that subsequently there have been official reports by Colin Thomé (2009) and Alberti (2009), an independent inquiry (Francis 2010), and a public inquiry (still in progress at the time of writing). The published reports depict an organisation failing in clinical governance with shocking accounts of indignity and suffering inflicted on patients. What also emerges is that there was such organisational turmoil and confusion that, as at Bristol in the 1990s, there was no effective system for assuring and monitoring the quality of care at Mid Staffordshire.

The reason the Healthcare Commission classified Mid Staffordshire's quality of services as 'good' in the annual health check assessment for 2007/8 was that it was then under investigation (Healthcare Commission 2008d, p 93) because the Healthcare Commission did not accept the trust's explanation that its high standardised mortality ratios were an artefact of coding. Monitor, however, did accept that explanation, and therefore granted the trust foundation trust status. The House of Commons Health Committee reported that 'the two organisations were not in communication about the Trust, and the [Healthcare Commission] only found out by accident that Monitor had decided to grant it Foundation Trust status' (House of Commons Health Committee 2009, para 244, p 79).

None of the external organisations that the Healthcare Commission relied on for checks on the trust's reports for the annual health check based on its self-assurance – the primary care trust, the strategic health authority, or local oversight and scrutiny committees – detected anything wrong with the trust's performance until after the Healthcare Commission investigation (Colin Thomé 2009). Colin Thomé points out that Monitor looked to the primary care trusts and strategic health

authorities to raise concerns about the trust's quality of care when it applied for foundation status, but that these organisations 'assumed that regulation of quality would be fulfilled by the Healthcare Commission and Monitor' (Colin Thomé 2009, p 22).

Lessons for the future of regulation

This chapter concludes by seeking to draw lessons from the past to inform the future, drawing on the review of the three regulatory instruments used by the CHI and the Healthcare Commission: star-ratings, CGRs and the annual health check.

There is strong evidence from the evaluations of the star-rating regime that this had a direct and powerful effect in improving the reported performance of the English NHS in terms of shorter hospital waiting times and ambulance response times, both over time, and as compared with the performance of the NHS in the other three countries of the United Kingdom. With apologies to Winston Churchill (who was commenting on democracy), New Labour's target regime was described by Bevan (2009) as 'the worst system ever invented except for all the others', and needed development to take account of local circumstances, which the CHI would have sought to do if it had not been abolished.

The evidence on quality improvement from CGRs and the annual health check is less strong than that for star-ratings. Both have been assessed by means of surveys of those who were subjected to CGRs and the annual health check. The impact of the annual health check has also been assessed in terms of the improvement in scores based on self-assurance.

Patient choice and competition are seen as the policy instruments that will drive future improvements. With that in mind, what can be learned from the CHI's CGRs and the Healthcare Commission's annual health check that might enhance the CQC's role in quality assurance and ensure that the public can have confidence in the quality of care provided by registered and licensed suppliers?

The main feature of the CHI's CGRs was a rolling programme of visits to all NHS trusts by teams that undertook peer review and involved patients and carers in agreeing scores for performance under the seven pillars of clinical governance, which then fed into the star-ratings. The drawbacks of continuing this process would have been four-year gaps between visits, limits to the breadth and depth of scrutiny of each visit, and issues of consistency in scoring.

The main features of the Healthcare Commission's annual health check were that trusts determined their scores from self-assurance and there was a risk-based approach to inspections founded on routinely available data. The Healthcare Commission's method offered wide coverage of each trust with annual assessments, but raised concerns about the reliability of those assessments.

Although independent, both the CHI and the Healthcare Commission had only limited leverage over providers as the power to impose sanctions was reserved for the Secretary of State for Health. The recent review by the Department of Health of arm's-length bodies for health and social care concluded that the CQC 'will continue to inspect providers against essential levels of safety and quality in a targeted and risk-based way, taking into account information it receives about a provider...[from]... a range of sources' (Department of Health 2010e, p 17). This is, in effect, continuing to develop the Healthcare Commission's method of self-assurance and its risk-based approach to inspections, which has notable flaws (Bevan and Cornwell 2006; Bevan 2008).

Self-assurance relies on trust boards prioritising issues of clinical quality and safety. The CHI's review of acute services found that boards tended to be well informed on performance with regard to waiting times and finance, but needed better access to information on quality of services and the factors that affect quality (Commission for Health Improvement 2004b, p 18).

At Mid Staffordshire, the board's failure to engage with issues of clinical quality and safety was at the heart of its problems:

There were many complaints from patients and relatives about the quality of nursing care. These primarily related to patients not being fed, call bells not being answered, patients left in soiled bedding, medication not being administered, charts not being completed, poor hygiene and general disregard for privacy and dignity. Worryingly, the trust's board appeared to be largely unaware of these. (Healthcare Commission 2009a, p 8)

Furthermore, a risk-based approach to inspections is handicapped by inadequacies in the data that are routinely available.

Despite its regulatory failures, the Healthcare Commission remained convinced that its system, based on self-assurance with local scrutiny and risk-based and random inspections, was 'the right thing for the regulator to do' (Healthcare Commission 2009b, p 25) and that although some 'thought that they could game the system', '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' (Healthcare Commission 2009b, p 25).

Sadly, these assertions were unfounded with regard to Mid Staffordshire: information on what was going wrong was contained within the trust. If a four-yearly rolling programme of CGRs had continued, Mid Staffordshire would have been expecting a review team to visit in 2006/7, the period when so much damage was done.

One strength of CGRs was that this process enabled patients and their relatives to express concerns, and created a safe environment for 'whistleblowing', allowing doctors, nurses and other professionals to report their concerns in confidence to their

peers on the review team. It seems inconceivable that under these circumstances the problems at Mid Staffordshire could have been kept from such a team.

Effective regulation of the quality of care of publicly owned providers, which will continue to dominate supply even with pluralism of delivery, requires a rolling programme of inspections based on visits (Bevan and Cornwell 2006; Bevan 2008). The system of CGRs could offer a model, but would require development to learn from evaluations of that process: the seven pillars would need to be reworked; inspections would need to be proportionate; and the system of surveillance would continue to need development (Bardsley *et al* 2009).

The coalition government rejected that model and planned to regulate providers by continuing with self-assurance and risk-based inspections (Department of Health 2010a). As this chapter was going to press, however, Cynthia Bower, the Chief Executive of CQC, announced that CQC plans to abandon this form of 'light touch' regulation for a system of unannounced inspections based on visits. She argued that 'there's no substitute for getting on to the wards and seeing what's going on, talking to patients, talking to clinical staff' (Santry 2011). This change from the government's plan requires extra funding and will be much more difficult for CQC to do than for CHI, because of the scope and scale of CQC's regulatory functions.

Publicly funded health services in England now face the combination of severe fiscal pressures, organisational turmoil, and the challenges of regulating quality with pluralism in delivery. The English NHS of the 2000s, where performance was driven by 'star ratings' and regulation of quality of care by CGRs, will look like a golden age in comparison.