

QQQIP

Quest for  
Quality and  
Improved  
Performance

# Regulation and quality improvement

## A review of the evidence

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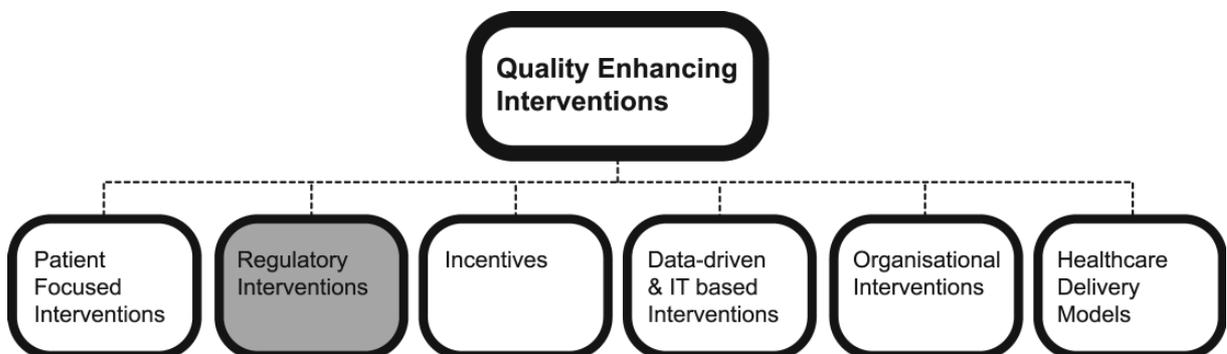




## QQUIP and the Quality Enhancing Interventions project

QQUIP (Quest for Quality and Improved Performance) is a five-year research initiative of The Health Foundation. QQUIP provides independent reports on a wide range of data about the quality of healthcare in the UK. It draws on the international evidence base to produce information on where healthcare resources are currently being spent, whether they provide value for money and how interventions in the UK and around the world have been used to improve healthcare quality.

The Quality Enhancing Interventions component of the QQUIP initiative provides a series of structured evidence-based reviews of the effectiveness of a wide range of interventions designed to improve the quality of healthcare. The six main categories of Quality Enhancing Interventions for which evidence will be reviewed are shown below.



All the information generated through QQUIP will be available at [www.health.org.uk/qquiip](http://www.health.org.uk/qquiip)

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## Executive summary

*We regulate in an empirical void, often addressing anecdotes and hysteria with far-reaching initiatives. (Brennan, 1998, p 725)*

Vast amounts of resources – financial, organisational and human – are expended on regulating healthcare. Regulation has three key purposes:

- to improve performance and quality
- to provide assurance that minimally acceptable standards are achieved
- to provide accountability both for levels of performance and value for money.

It is not possible to achieve optimal performance across all three purposes simultaneously and so trade-offs are required. The Health Foundation's Quality Enhancing Interventions (QEI) project undertook a literature review to address the following question: when trying to improve health through regulation, what works?

## Findings

Overall, the evidence available to answer this question is sparse. Research evidence about the impact of regulatory interventions on quality of healthcare is drawn primarily from observational studies. This means that the links between regulation and improvements in quality are primarily associative rather than causal. The evidence base largely emanates from the US, making the contextual interpretation challenging for other countries. We have reviewed what evidence does exist under the following headings: institutional regulation, professional regulation and market regulation.

### Institutional regulation

There are two main types of institutional regulation:

- those concerned with direction, that is, defining and communicating expected levels of performance
- those concerned with surveillance and enforcement, often referred to as 'external oversight'.

### Evidence in brief

#### *Target setting*

Four studies (Bevan & Hood, 2006; Alvarez-Rosete et al, 2005; Auditor Gen for Wales, 2005; Bevan & Robinson, 2004) drew on routinely available performance data and concluded that targets have been associated in England with reduced waiting times for:

- inpatient care
- urgent ambulance calls
- access to accident and emergency treatment.

Targets have been widely used in public health programmes such as Health for All (WHO, international); Health of the Nation (Department of Health, UK); and Healthy People 2000 (Centers for Disease Control, USA). Case study findings and routine data suggest that these sets have had mixed success (Department of Health, 1998).

### *Standard setting*

Four independent studies found an association between standards – as laid out in the Coronary Heart Disease National Service Framework in England (Department of Health, 2000) – and improvements in quality (Graham et al, 2006; Ramsay et al, 2006; Ramsay et al, 2005; Hippisley-Cox et al, 2005). Progress reports published by government also provide data on generalised improvements in coronary heart disease care (Department of Health, 2005).

Six studies (Sheldon et al, 2004; Abacus International, 2004; National Cancer Director, 2004; Wathen and Dean, 2004; Bloor et al, 2003; Hassan et al, 2005) examined the impact of the National Institute for Health and Clinical Excellence (NICE), a quasi-regulatory body. Overall, these studies found that NICE guidance had a mixed impact on patient care, and was most effective when supported by other levers for change.

### *Accreditation*

Within the US healthcare system (which relies heavily on accreditation), one multistate comparative study found that accredited organisations provided higher quality care for cardiac patients (Chen et al, 2003).

Two studies found a disjuncture between accreditation scores and alternative measures of performance, quality and safety (Miller et al, 2005; Griffith et al, 2002).

One study of a US health plans found that accredited plans had significantly higher quality of care scores across seven out of nine measures (Beaulieu & Epstein, 2002).

One randomised controlled trial conducted in South Africa found improved compliance with standards following the introduction of an accreditation scheme, but little evidence of improvement in quality indicators (Salmon et al, 2003).

### *Inspection*

Three studies (two in the UK and one in the US) found that inspection, or the prospect of formal inspection, was a catalyst for improvement on the part of regulated organisations (Day and Klein, 2004; Benson et al, 2004; Office of Inspector General, 1999).

## **Professional regulation**

Licensure is probably the most widely used intervention in professional regulation. Most countries have a system for controlling entry into the medical professions and an official register of physicians who are licensed to practise. In a growing number of countries, licensing or registration extends to other healthcare professionals such as nurses. The Institute of Medicine (2000) publication, *To Err is Human*, recommended that professional licensing bodies consider continuing qualifications over a lifetime of practice, not just at initial licensure or registration. Despite the international prevalence of physician licensure, there is little evidence available about its impact on quality of care.

## **Evidence in brief**

In the US, certification and recertification are processes that enable physicians to demonstrate achievements and competencies that are beyond the minimum standards required for licensure. We found one systematic review (covering literature published from 1966 to 1999) (Sharp et al, 2002) and four subsequent studies that indicate a positive association between specialty physician certification and higher quality care (Chen et al, 2006; Silber et al, 2002; Prystowsky et al, 2002; Norcini et al, 2002, 2001, 2000). However, evidence is not available to prove that certification has secured improved quality.

## Market regulation

Healthcare markets generally require regulatory interventions for the following reasons:

- manage competition: to ensure a 'level playing field' and allow market forces to deliver efficiency by limiting concentration of power in monopolies or cartels
- protect patients: to assess quality of services, ensure that robust grievance and appeals procedures are in place, protect confidential patient data and ensure financial solvency controls
- provide public accountability: to ensure transparency of performance and information so that consumers can make decisions based on cost, outcomes and quality
- manage supply: to manage conditions of participation and influence the availability of care (addressing both oversupply and undersupply).

## Evidence in brief

### *Managing competition*

One US multistate study (Christianson et al, 1997) covering health maintenance organisation (HMO) mergers from 1985 to 1993 found that regulatory interventions seeking to limit mergers and acquisitions did dampen market consolidation, but that states with stronger anti-takeover regulation had higher HMO failure rates. The regulations may have prevented non-viable units from merging and this could have contributed to their demise, with implications for access to care.

We found nine US studies that examined the impact of conversions from non-profit or public hospitals to for-profit status (Leone et al, 2005; Shen, 2003; Picone et al, 2002; Sloan, 2002; Thorpe et al, 2000; Desai et al, 2000; Young and Desai, 1999; Mark, 1999; Needleman et al, 1999). Regulation can dampen conversion activity; however, none of the studies reported on the role that regulation has played in limiting the undesirable consequences of conversions. Four studies examined provision of uncompensated care for low-income and uninsured patients following hospital conversion. Three of the four found that hospitals that had converted from public to for-profit status provided lower volumes of uncompensated care (Thorpe et al, 2000; Desai et al, 2000; Needleman et al, 1999); the fourth found no impact (Young & Desai, 1999). One study found an association between conversion to for-profit status and higher mortality rates (Picone et al, 2002), while another found an association between conversion and higher rates of pneumonia complications (Sloan, 2002).

### *Accountability*

Of four studies on cardiac surgery in New York, three found that mandatory performance reporting had a positive effect on patient care (Cutler et al, 2004; Petersen et al, 1998; Hannan, et al, 1994) one did not (Dranove, et al 2003). Survey data suggest that mandatory reporting and public disclosure can have unintended consequences, for example, discouraging treatment of high-risk patients (Narins et al, 2005; Weissman et al, 2005).

### *Managing supply*

In the USA, certificate of need (CON) is a permit issued by a governmental body to an individual or organisation proposing to construct, modify, or close a health facility; acquire major new medical equipment; modify a health facility; or offer a new or different health service or discontinue a service. CON regulation as applied to general hospital services has not been successful in curtailing overall expenditure. In respect to impact on quality, one study from the 1980s found that more stringent CON regulations were associated with higher mortality rates across a range of clinical conditions (Shortell and Hughes, 1988). A more recent multistate study found that patients with acute myocardial infarction in states

with CON were less likely to be admitted to hospitals with revascularisation services than patients in states without CON; however, there was no difference in mortality rates (Popescu et al, 2006). As a tool to ensure minimum volumes of cardiac surgery, CON has been associated with lower mortality rates (Vaughan-Sarrazin, et al 2002).

Rate-setting refers to a process of controlling prices, where regulators prospectively define a maximum amount that providers are allowed to charge their customers. Rate setting has been the subject of a number of multistate studies in the US, with mixed findings. In two studies rate regulation did not have an adverse effect on patient mortality or population mortality, despite lower admission rates (Smith et al, 1993; Sloan et al, 1986). However, another study found a statistically significant association between mortality rates and the stringency of rate regulation (Shortell and Hughes, 1988).

In a time series analysis examining outcomes from 1974 to 1983, mortality rates decreased more slowly in states with rate-setting (Gaumer et al, 1989).

Data from New Jersey in 1990-96, indicated that the discontinuation of rate-setting in favour of a price competition model was associated with an increase in relative mortality rates for a number of conditions (Volpp et al, 2005).

In terms of impact on the diffusion of innovations, rate-setting does not appear to hamper the overall availability of cost-increasing technologies, but can temper excessive use and duplication of services (Sloan et al, 1986b; Romeo et al, 1984).

Formularies are lists of preferred drug products that limit the number of options available within a therapeutic class for purposes of drug purchasing, dispensing and/or reimbursement. Drug formularies' influence on quality of care has not been researched robustly. A literature review noted a deleterious effect of formularies on patient outcomes (Lexchin, 2002). However, it also highlighted methodological limitations which bring the results into question. According to a national survey, the formulary introduced by the Department of Veterans Affairs in the US was not perceived by physicians to adversely affect patient care (Glassman et al, 2001).

### **About this study**

We conducted systematic searches of a range of electronic databases: Medline, the King's Fund, Database of Abstracts of Reviews of Effects (DARE), Cochrane Database of Systematic Reviews, Organisation for Economic Co-operation and Development, World Health Organization, Agency for Healthcare Research and Quality and the Commonwealth Fund.

We searched for empirical evidence about the effects of various approaches to regulation on quality of care. The review included different types of research designs: systematic reviews, randomised controlled trials and quasi-experimental and observational studies. We adopted broad inclusion criteria because of the methodological challenges inherent in assessing complex organisational and managerial interventions such as regulation.

## Introduction and methods

There is a vast range of regulatory interventions in use in healthcare systems worldwide. However, whilst there is a huge amount of activity; and extensive description and discussion in health related literature, regulation is not supported by a strong scientific evidence base. There are a number of authoritative reviews of regulation both generally (Ayres & Braithwaite, 1992; Hood et al, 1999) and specifically in health (Walshe, 2003), but no comprehensive, easily accessible overview of the available research evidence to guide policy and decision making.

The empirical evidence regarding healthcare regulation is sparse and where it does exist, is poorly collated and difficult to access. The objective of this study is to address these problems. It is part of a broader initiative, the Quality Enhancing Interventions (QEI) project, which conducts systematic searches of peer reviewed and grey literature in order to assemble available evidence on the impact of interventions designed to improve performance and quality of care.

### Methods

Given the diffuse nature of regulatory interventions and the complex context in which they are implemented, the available evidence is heterogeneous in nature and rarely emanates from randomised control trials. We adopted a stepped approach to data collection, focusing on the most rigorous evidence such as that derived from systematic reviews and randomised control trials where available, but also including less robust evidence such as that from observational studies where empirical data was sparse. Electronic searches were conducted for studies published in English using the following databases: Medline; Cochrane Database of Systematic Reviews; Database of Reviews of Effects (DARE); King's Fund Library. We also searched a number of sources for relevant grey literature including: Agency for Healthcare Research and Quality (AHRQ); World Health Organization (WHO); Organisation for Economic Cooperation and Development (OECD); specialist websites including policy think-tanks and patient organisations. Search terms are listed within each chapter and search strategies are shown in Appendix 1. Abstracts were reviewed for relevance and for reference to empirical data. We retrieved full articles for all studies that included either process or outcome measures of impact of a regulatory intervention. Studies with the following methodologies were included:

- randomised controlled trials
- quasi-experimental studies
- case-controlled studies
- cross over studies
- cohort studies
- before and after studies
- multi-site case studies
- statistical studies such as multivariate analyses

There were no geographical limits placed on the inclusion criteria.

Each study included in the review is summarised and annotated with details of the research design. Annotated summaries of the research studies are also available via our searchable website ([www.health.org/qquip](http://www.health.org/qquip)).

## Format of the report

Scratch the surface of regulation-related literature, and it quickly becomes clear that there are countless interventions that have been adopted in many different contexts. The report uses a series of taxonomies to catalogue the main types of interventions. It focuses particularly on those interventions for which there is empirical evidence about their effectiveness. That evidence is presented in short vignettes that provide details of research design and findings, and is drawn from international literature.

Each set of evidence is prefaced by a brief description that explains the objectives of the intervention, gives examples of where it has been implemented, and compiles insights about specific factors that have been found to influence effectiveness in practice. This narrative fulfils two main purposes:

1. it discusses, as far as is possible, the relevance and application specifically in the NHS
2. it describes for an international audience, the theoretical and empirical justification for the particular intervention.

In pursuing the second purpose, it quickly becomes clear that the overwhelming bulk of published theory development and empirical work comes from the US and so that country features heavily in the descriptions. The preponderance of US-derived data is not a result of geographical limitations placed on the searches; rather it is a reflection of publication patterns that see US research dominating the available literature.

England and the US are also singled out in the provision of supplementary boxes that describe contextual elements of those systems. The justification for this lies in the nature of regulation, where history and context are important features to be considered when making changes. England and the US represent two very different approaches to providing healthcare; with the US historically and culturally relying on market mechanisms, and England traditionally using a centralised, more bureaucratic approach.

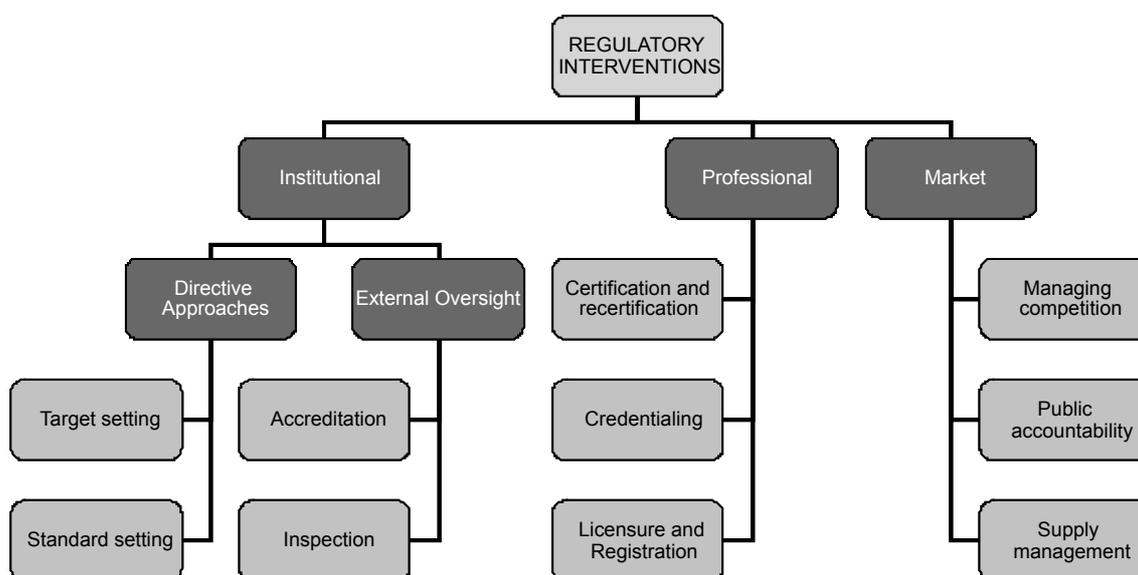
# 1. Background and overview

## Definition and background

Regulation encompasses a wide range of interventions – it has been defined in general terms as “sustained and focused control exercised by a public agency over activities which are valued by a community” (Selznick, 1985: 363) and more specifically in a healthcare context as “any set of influences or rules exterior to the practice or administration of medical care that imposes rules of behaviour” (Brennan & Berwick, 1996: 4).

Regulation is a ubiquitous feature across developed economies<sup>1</sup>. In the public sector particularly, the traditional reliance on centralised command and control has in the last 20 years been largely displaced by regulatory rules, standards, and oversight (Hood et al, 1999).

In conducting this study we developed a taxonomy of regulatory interventions, organised according to the focus of regulatory activity i.e. healthcare delivery institutions; the professions; and healthcare markets (see Figure 1.1).



**Figure 1.1: A taxonomy of quality enhancing regulatory interventions**

### Purpose of regulation

In principle, the purpose of regulation is threefold:

- to **improve** performance and quality
- to provide **assurance** that minimally acceptable standards are achieved
- to provide **accountability** both for levels of performance and value for money.

These three purposes are not necessarily compatible and consideration of the tensions between them is imperative in the development of regulatory programmes (Walshe, 2003). For example, if improvement is the main objective, ambitious standards and targets are

<sup>1</sup> Given their broad application, we have limited our review of regulatory interventions to exclude the use of legislation as well as pharmaceutical and medical device regulation (e.g. Food and Drug Administration [FDA] in the US, or the Medicines and Healthcare Products Regulatory Agency [MHRA] in the England).

used to challenge the status quo and help organisations identify areas for development. If however, the main priority is to provide assurance, standards are set at a minimum acceptable level and there will be little discrimination between organisations as most should be able to comply easily. The third purpose, accountability, requires methods that allow regulators to differentiate and compare performance in an objective and meaningful way.

Regulatory objectives are generally achieved through three distinct types of activity:

1. *Direction*: the communication of expectations and requirements to regulated organisations and other stakeholders. Most often this is achieved through the use of standards, rules or targets. Directive activities are central to regulatory approaches and may significantly overlap with performance management interventions.
2. *Surveillance*: assessment of the level of performance; or extent of compliance with standards, targets or rules; on the part of regulated entities. This can be achieved through data monitoring against explicit published measures, periodic inspection, or formal investigations or enquiries in response to complaints or unsatisfactory levels of performance.
3. *Enforcement*: the use of (or promise/threat of use of) regulatory powers to bring about change. Methods can be both positive (e.g. financial rewards, earned autonomy) or negative (e.g. sanctions, increased scrutiny, curtailed activity) in nature. Most enforcement mechanisms are 'sticks' rather than 'carrots' and these range in severity from informal discussions and advice to formal sanctions, public disclosure and most radically, delicensing or takeover.

Regulation has the potential to be a powerful modifier of behaviour. However there is great diversity in regulatory approaches and little understanding of how they compare in terms of contextual sensitivity, interaction and relative impact. The effects of regulation can be both advantageous and disadvantageous (see Box 1.1), anticipated and non-anticipated. Crucially, these effects are unpredictable and uncertain (Walshe, 2003).

Positive Effects	Negative Effects
<ul style="list-style-type: none"> <li>• Sustain improvements in organisational performance and quality</li> <li>• Encourage critical self-analysis of performance in relation to similar organisations and or standard</li> <li>• Codify policies and procedures</li> <li>• Provide impetus for change</li> </ul>	<ul style="list-style-type: none"> <li>• Temporary improvements timed to coincide with inspections or targets</li> <li>• Reinforcement to strive for minimally acceptable performance rather than aspire towards excellence</li> <li>• Foster gaming</li> <li>• Resource intensive; significant opportunity costs</li> <li>• Focus on centrally defined priorities rather than local needs</li> </ul>

#### **Box 1.1: Positive and negative effects of regulation**

## Costs and benefits of regulation

- *Regulation has been expensive with negligible return on the public's investment (Enthoven & Vorhaus, 1997: 54)*
- *Despite ... huge investment in regulation, it is remarkably difficult to tell what impact [US] hospital regulation has had on the performance of hospitals or on the quality of healthcare (Walshe, 2003: 77).*

Unfortunately, evidence of the impact of regulation on quality is sparse and uneven. At a national level, regulation in the US has been criticised (Kizer, 2001) because despite decades of activity, there remain significant gaps between the healthcare services that people should receive and the care actually provided (McGlynn et al, 2003). This raises important questions about how and in what circumstances regulatory activity can reliably secure improvement in healthcare.

Though robust evidence of impact is wanting in volume and definitiveness, evidence of the cost burden is mounting. In a detailed study of the economic costs and benefits of regulation in the US for 2002, Conover (2004) estimated:

- the total cost of health services regulation exceeded \$339.2 billion. This figure included regulation of healthcare facilities, professionals, insurance, drugs and medical devices, and the medico-legal system (i.e. the tort system)
- the financial benefits of health services regulation to be \$170.1 billion
- the net burden of health services regulation to be \$169.1 billion. This means that the costs of regulation outweigh the benefits by two-to-one, corresponding to over \$1500 per household.

In England, data on the costs of regulation is diffuse and there is little data on benefits. The 2005-06 annual budget for the Healthcare Commission is around £80 million; and for Monitor around £16 million. Regulators administered by professional groups include the General Medical Council (budget around £55 million); the Nursing and Midwifery Council (£21 million); the Health Professions Council (£8 million) the Council for Regulatory Healthcare Excellence (£1.5 million). NICE, which has some regulatory functions inasmuch as NHS Trusts are required to implement its guidance within three months of release, has a budget of around £20 million. Diverse organisations such as the National Audit Office, the Audit Commission, the Parliamentary Ombudsman also play a role in regulating healthcare. It is difficult to unpick the budgets of these organisations to determine specific allocations.

The indirect costs of regulation, that is the costs to those being regulated, are not well demarcated. In the US, the costs of preparing for an accreditation visit are substantial with one study estimating them to be around 1% of a hospital's operating budget (Rockwell et al, 1993). In the UK the Better Regulation Executive has recently carried out an exercise to estimate the costs of regulation falling on the private and voluntary sector – early indications are that cost falling on regulated organisations are at least as large as the costs to regulators.

Despite these significant levels of expenditure, the cost-benefit relationship of regulation is not well understood. The lack of empirical evidence creates a serious dilemma for policymakers who must decide whether the enormous amounts of resource, energy, and goodwill consumed by regulation are sufficiently justified by contributions to quality of care. The budgetary pressures, resource constraints and rising costs that afflict healthcare systems around the world translate into a need to minimise administrative and discretionary spending in order to allocate more money to actual health service delivery.

It must be emphasised, however, that patient outcomes or institutional improvement are not the only rationale for regulation. Accountability and transparency, valued by the public, is not measured by improvement in services or outcomes. Instead, it is reflected in trust, satisfaction and confidence in healthcare organisations, providers of care and the healthcare system generally. Given the growing importance of concerns about accountability in healthcare, some level of investment in regulation is essential.

## Applying the evidence

The following chapters array the available evidence about the effectiveness of a range of regulatory interventions. The translation of the evidence into practice is difficult however, primarily because of methodological challenges that hamper unequivocal evaluations of the effectiveness of social interventions, e.g.

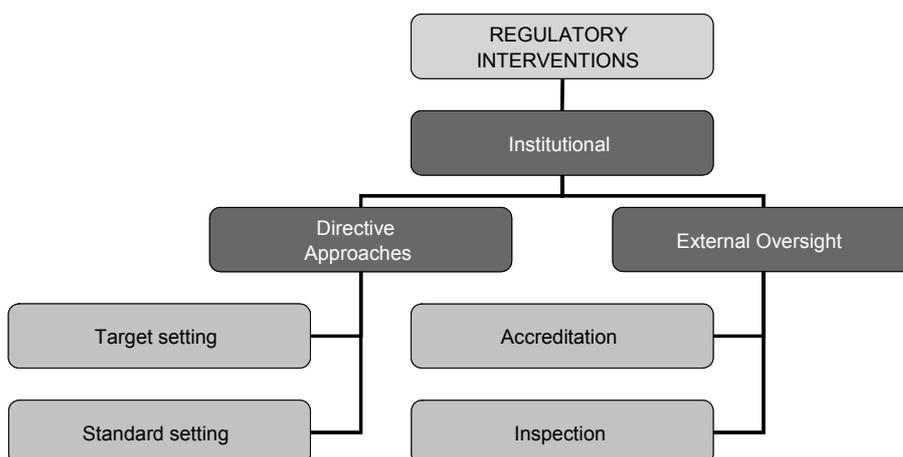
- Regulation refers to a set of disparate interventions and the impact of any discrete intervention is difficult to isolate and measure.
- The combination of regulatory interventions in any healthcare system is a reflection of that system's particular history and organisational context. It is difficult to transfer the findings emanating from research conducted in one system and apply them in another.
- Almost without exception, the evidence on the impact of regulatory interventions is based on observational studies or uncontrolled research designs. Therefore research highlights associations rather than establishes causality.
- There is no counterfactual, we do not know whether healthcare systems would be better or worse without regulation.

Clearly, using the evidence to inform policy and managerial decisions is not a straightforward process. Evidence, even where it has validity and methodological rigour, is not necessarily a sufficient basis on which to make the often complicated value judgements required in policymaking and managing complex systems. The QEI review is forthright in describing the weaknesses of the evidence base, however this should not be interpreted as a widespread condemnation of regulatory interventions. Instead it should be seen as calls for strengthening the evidence base with well designed evaluations of regulatory interventions; and for critical appraisal of existing evidence by those seeking to regulate in order to improve performance and quality.

## 2. Institutional regulation

### Definition and background

Institutional regulation focuses on organisations that provide healthcare. There are two main types of regulatory approaches, those that are predominantly concerned with direction, that is defining and communicating expected levels of performance; and those concerned with surveillance, often referred to generically as external oversight (see Figure 2.1). These approaches are combined, to varying degrees with enforcement functions.



**Figure 2.1: A taxonomy of quality enhancing regulatory interventions aimed at institutions**

### Search terms

Accredit*	Inspect*	Government regulation [MeSH]
NICE OR "National Institute for Clinical Excellence"	Organisational target OR (target AND set*)	External quality assessment
External oversight OR external review OR health care oversight	Health AND target	"National Service Framework"
Social control, formal [MeSH]		

\* truncated search term

Search terms combined with (ratio\* OR outcome\* OR performance OR quality OR data OR mortality OR rate\* OR empirical OR randomised) in Title or Abstract. For detailed search strategy, see Appendix 1.

## Evidence summary: institutional regulation

### *Directive approaches*

- Targets have been associated in England with reduced waiting times for inpatient care, in Accident and Emergency, and for urgent ambulance calls.
- Public health targets, such as the “Health of the Nation” or “Healthy People 2000” targets have had more mixed success.
- Standards have been associated with improvements in quality, particularly in the case of the Coronary Heart Disease National Service Framework in England.
- NICE guidance (considered to be quasi-regulatory as NHS Trusts are required to implement within 3 months) has had a mixed impact on patient care; having most effect when supported by other levers for change.

### *External oversight*

- Within systems that rely heavily on accreditation, accredited organisations generally provide higher quality care. However there is no evidence to suggest that accreditation has secured improved quality.
- Inspection, or the prospect of formal inspection, can catalyse improvement on the part of regulated organisations.

## Directive approaches

### Introduction and background

Directive approaches are manifest in explicit statements of expectations or recommendations for future performance and quality, against which individuals and organisations can be held to account.

There is considerable variation in the terminology applied to directive approaches. For example, the term *standard* has been used variously to mean:

- an indicator to the public of the minimum level of service they can expect from a public body; or that which should be achieved by a service provider (Public Administration Select Committee, 2003)
- A means of describing the level of quality that healthcare organisations are expected to meet (“core standards”) or aspire to (“developmental standards”) (Department of Health, 2004)
- A level of service that has been achieved in response to a previous target. Though the target lapses, monitoring still takes place to ensure that the same standard of provision is maintained. The standard thus operates, in effect, as a minimum requirement for well or acceptably performing services (Social Market Foundation, 2005).
- An optimal achievable level of performance against which organisations are assessed (Joint Commission on Accreditation of Healthcare Organisations, 2005).

Thus standards have been used to denote both minimally acceptable and aspirational levels of performance.

The way in which this report uses the terminology related to directive approaches is shown in Box 2.1.

Directive approach	Definition
Target	A defined level of performance that is aimed for, often with a numerical and time dimension.
Standard	A required level of quality or attainment.
Appraisal	An assessment of the effectiveness and/or cost effectiveness of an intervention produced in order to guide utilisation decisions.
Guideline	A statement that informs and steers decisions about appropriate healthcare on the part of clinicians, managers and increasingly patients
Policy	An exploration of a particular issue that encompasses the definition of goals and objectives; a review of the relevant evidence base; identification of stakeholders and priorities; and development of strategies for securing change.
Performance indicator	A defined measure of performance that can be used to track performance over time (with or without the use of targets or standards to set goals and expectations)

**Box 2.1: Definitions for various instruments used to regulate performance via directive approaches**

This evidence is focused on two main types of directive approaches: target-setting and standard setting. The UK's Blair Government has used directive approaches both for performance management and for regulatory purposes. In England, the Department of Health has adopted three forms of direction: the definition of minimum standards; the promotion of aspirational standards (in the past through performance management but increasingly through "voice and choice" policies); and target setting. It appears however that the policy emphasis is shifting towards the use of choice, together with market-style incentives to improve quality of care, underpinned by less regulation; and performance management only indirectly via commissioners (Dixon, 2005).

## Specific interventions – target setting

### Background

The use of targets in public policy is derived from broader organisational and managerial practice, in particular, the concept of Management by Objectives (MBO). First described by Peter Drucker in *The Practice of Management* (1954), MBO is based on the establishment of specific targets for work activities and emphasises the importance of:

- co-ordinating strategic and operational goals
- specific work objectives
- performance evaluation and individual accountability
- interaction between different levels of an organisation.

More recently, the general concept of MBO has been refined and developed in goal setting theory (see Box 2.2.)

### Goal setting theory

Target-setting as an intervention is rooted in broader organisational and management research, in particular the goal setting theory of motivation. Mitchell and Daniels (2003) estimate that there have been over a thousand articles published on goal setting over 35 years. There is strong evidence to support the theory that for both individuals and groups, the setting of specific and difficult goals leads to higher performance levels than using general non-specific “do your best” encouragement or easily achievable goals (see Erez, 2005; Latham and Pinder, 2005). Goals regulate behaviour through four main mechanisms:

1. *directing* attention and resources towards identified objectives
2. *energising* and intensifying effort
3. *affecting* persistence whereby specific ‘stretch’ goals lead to greater persistence in the face of obstacles than general or easy goals
4. *fostering* strategy development, particularly in highly complex tasks.

*Feedback and goal commitment* have been identified as the factors necessary for goals to impact performance (Locke and Latham, 2002). Challenging or ‘stretch’ goals have been shown to stimulate persistence and foster feelings of self efficacy and self worth, however this is a finite relationship and a significant drop in performance is observed as goal commitment declines in the face of increasingly difficult goals. Participation in goal setting has been shown to be an effective lever for enhancing goal commitment and for stimulating information exchange which also positively affects performance. Monetary incentives can increase goal commitment but can simultaneously inhibit the attainment of complementary goals that are not compensated for (Mitchell and Daniels, 2003).

Setting goals that generate pressure for immediate results can be counterproductive when time is required for planning, strategy development or skill acquisition. In this situation, 'do your best' goals have been shown to be most effective (Latham and Pinder, 2005).

There is a trade-off in performance when multiple goals are set. Empirical research shows that more effort is shifted towards the attainment of difficult goals than general or easy goals; and to those goals supported by feedback (Erez, 2005).

## Box 2.2: A perspective from organisational and management research

### Purpose of target setting

Four distinct purposes for target setting have been identified:

- To *motivate*: galvanising action towards a common goal
- As a *management tool*: targets can:
  - operationalise policy in terms of strategies, timetables, resource allocation thereby helping short and long-term planning
  - act as a vehicle for **consensus building**, opening dialogue about priorities and expectations
  - **facilitate the monitoring** of progress and provide benchmarks
  - provide **basis for performance contracting and incentives**
- To *communicate*: informing stakeholders of the priorities and expectations for the future and providing a common language
- To *hold decision makers accountable*: providing information about the effectiveness of services and the impact of policy decisions.

### Usage

Target-setting is widely used throughout public and private sector organisations. In the healthcare sector, there is a long history of setting discrete and highly focused targets in areas such as efficiency, resource utilisation and eradication of specific communicable diseases (e.g. smallpox). However the last twenty five years have seen the widespread introduction of comprehensive sets of targets, particularly in the field of public health. In 1979, WHO published *Health for All* (World Health Organisation, 1979) which catalysed a series of policies and target-setting programmes around the world. These included:

- In England, *Health of the Nation* (1992) and *Saving Lives: Our Healthier Nation* (1998)
- In Scotland, *Towards a Healthier Scotland* (1999)
- In the US, *Promoting Health/Preventing Disease: objectives for the nation* (1980); *Healthy People 2000* (1990) and *Healthy People 2010* (1998)
- In Australia, *Health for All Australians* (1988) and *Better Health Outcomes for all Australians* (1994)
- In Europe (WHO) *Targets for Health for All* (1985); *Health for All Targets* (1993) & *Health 21: health for all in the 21st century* (1999)

In the UK, the current Labour government has embraced the use of targets across the public sector. In 1998 it published the first set of annual Public Service Agreements (PSAs) which contained wide ranging targets for all departments and agencies across Government (Chief Secretary to the Treasury, 1998). In this document the purpose of PSAs is described:

*Too often in the past it has been hard to identify the effects of extra investment at the sharp end of public services. The lack of objective information has made it almost impossible for the public to make sure services are measuring up to what they want and need. PSAs show the public what they can expect to get for their money (Chief Secretary to the Treasury, 1998: 2).*

According to the Treasury in England, PSA targets seek to focus on “end results”, such as improvements in health and educational achievement and reductions in crime; and “service standards”, such as smaller class sizes and reduced waiting lists for health services. All are said to be specific, measurable, achievable, relevant, and timed (i.e. SMART) targets, and related to outcomes wherever possible (Chief Secretary to the Treasury, 1998: 1). Current PSA targets for health are available at [http://www.hm-treasury.gov.uk/media/70320/sr04\\_psa\\_ch3.pdf](http://www.hm-treasury.gov.uk/media/70320/sr04_psa_ch3.pdf).

### Types of targets

Targets can focus on various types of objectives including outcomes, processes, inputs and outputs, and reductions in inequalities. Box 2.3 provides examples of different types of targets, taken from various sets defined in recent years in England.

#### Different types of targets: examples from England

1. **Outcome targets:**  
To reduce the death rate from cancer amongst people under 65 by at least a fifth (Our Healthier Nation, 1998).
2. **Process targets:**  
Process targets can be used when there is an evidence-based link between the targeted activity and a desired outcome. Process targets may seek to:
  - a. **increase appropriate patient care**  
75% of eligible patients with acute myocardial infarction to receive thrombolysis within 20 minutes of hospital arrival (National Service Framework for Coronary Heart Disease, 2000)
  - b. **decrease inappropriate or unsafe practices**  
To reduce by 40% the number of serious errors in the use of prescribed drugs by the end of 2005 (Building a Safer NHS for Patients, 2001)
3. **Input and output targets:**  
Input and output targets relate to the resources or services that are required if organisational objectives are to be achieved.  
By 2004, there will be 7,500 more consultants; 2,000 more general practitioners; 20,000 more nurses and over 6,500 more therapists and other health professionals (The NHS Plan, 2000).
4. **Inequality targets:**  
Inequality targets relate to differences in process/outcome/input/output measures amongst different socioeconomic groups, ethnic groups, age groups, etc.  
By 2010, to reduce by at least 10% the gap in infant mortality between routine and manual groups and the population as a whole (Public Service Agreement, 2001).

#### Box 2.3: Different types of health targets: examples from England

### What impacts effectiveness?

In 2003, the Audit Commission asserted that targets are invaluable *when used well and as one part of a robust performance management framework* (p 2).

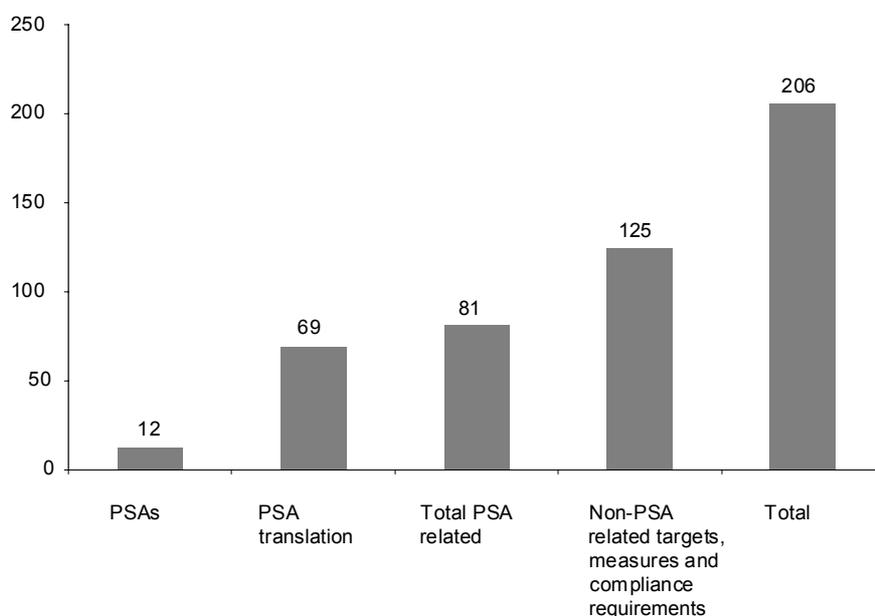
The effectiveness of target setting in enhancing quality and performance is dependent both upon technical issues, regarding the process and levels at which the targets are set; and implementation issues, which influence the ways in which targets secure behaviour change.

In recent years, there has been a number of reviews of, and prescriptions for, target setting programmes (Statistics Commission, 2003; Audit Commission, 2003; Public Administration Select Committee, 2003; Social Market Foundation; 2005), based to varying degrees on evidence. The common themes that emerge from these documents are summarised in Box 2.4.

#### Effective target setting: a summary

1. The level at which a target is set should strike a balance between being realistically achievable and being sufficiently ambitious and challenging within the proposed timescale.
2. The number of targets needs to be modest. When there are too many targets, priorities become meaningless. In practice, parsimony in target setting has proven difficult to achieve as general objectives are translated into specific activities throughout an organisation. Figure 2.3 illustrates how a relatively modest set of 14 Public Service Agreement targets for health in England in 2004 were translated into 206 health targets, measures and compliance requirements for NHS Trusts and PCTs.

Health targets, measures and compliance requirements, 2004



**Figure 2.2: Health targets, measures and compliance requirements (HM Treasury, 2004)**

3. Target setters needs to consider the measurability of key aspects of performance. Areas of performance that are difficult to measure tend not to be subject to targets and can subsequently be perceived as of marginal value.
4. Target programmes have to balance national priorities with local responsiveness. More centralised approaches require stronger incentives and/or sanctions in order to secure change. More localised target setting on the other hand, often requires political support to sustain and protect the local priorities from competing claims to attention (Wismar & Busse, 2002).
5. The alignment of rewards and sanctions with targets also impacts effectiveness. Whilst incentives linked to targets can motivate improvement, they can have serious consequences if set at an inappropriate level. For example, linking targets with harsh sanctions (e.g. so-called “P45 targets” which if missed often result in the dismissal of the organisation’s Chief Executive) can result in inappropriate data manipulation and gaming (Social Market Foundation, 2005). Conversely, when performance failure is not met with significant consequences, it can be seen to give tacit approval for underachievement.
6. There is strong evidence from management research that participation in the process of target setting will strengthen commitment to achieving targets. Involvement in the process is likely to result in greater ownership of, and commitment to, achieving performance targets (Otley, 2005: 89). However participation in setting targets needs to be balanced against the risk of “regulatory capture”. As an instrument of accountability, targets may at times call for uncomfortable yet necessary changes and over-reliance on participation in target-setting can result in difficult issues being sidelined.

#### **Box 2.4: Factors influencing effectiveness of targets: a view from reviews**

##### **Effectiveness issues - in summary**

At first glance target setting appears to be a simple, clear, low cost intervention that can motivate quality improvement and galvanise action towards organisational objectives. However first impressions belie the inherent complexity involved in establishing an effective target-setting approach.

The critical requirements include:

- Robust information systems for: determining base-line performance, tracking changes, and dealing with data distortion and manipulation
- Political support and sufficient resourcing
- Contextual sensitivity, targets aligned with existing social values and ethics
- Vigilance for unanticipated consequences particularly in a resource constrained environment.
- Rigorous evidence about how healthcare organisations can achieve the changes in performance the targets require.
- Need to incorporate measures of user satisfaction.

**Evidence: targets**

There are two perspectives on the evidence base regarding the effectiveness of target setting as a quality enhancing intervention.

The first perspective is provided by comparing a particular target with the corresponding data over the time period in question. On this basis, the final review of the US campaign Healthy People 2000 found that 68 objectives (21%) met the year 2000 targets; 129 (41%) showed movement toward the targets; 35 objectives (11 %) showed mixed results; 7 (2%) showed no change from the baseline and 47 objectives (15%) showed a deterioration. The status of 32 objectives (10%) could not be assessed ([www.cdc.gov/nchs/products/pubs/pubd/hp2k/review/highlightshp2000.htm](http://www.cdc.gov/nchs/products/pubs/pubd/hp2k/review/highlightshp2000.htm)). For such evaluations to be a meaningful guide to the effectiveness of targets however, they must be interpreted in the light of technical and motivational issues such as whether the levels at which the targets were set were over-or under-ambitious, were reasonable in number; or had sufficient support (see Factors Impacting Effectiveness).

The second perspective is provided by comparative studies, which examine the impact of targets across different contexts.

The literature also contains studies on the impact of pay for performance interventions linked to targets (e.g. Rosenthal et al, 2005; Giuffrida et al, 2000) – this research will be collated and summarised in the Incentive QEI (forthcoming).

**Summary**

The natural experiment occurring as a result of political devolution in the UK, suggests that challenging targets, combined with other performance management interventions, have been effective in reducing waiting times for elective surgery; ambulance calls and in Accident & Emergency departments.

**Bevan and Hood, 2006** review the impact of targets on performance in the NHS. Data were drawn from official data sets for 1999-2005. The performance and targets reviewed were:

1. *Target: 90% patients from 2003 (changed to 98% patients from 2005), arriving at Accident and Emergency departments should be seen within 4 hours. In 2002, 23% patients waited longer than four hours; in the first quarter of 2004-05, this had fallen to 5.3%.*
2. *Target: at least 75% of category A ambulance calls (life threatening emergencies) answered within 8 minutes. Target has been in place since 1996; was included in star ratings (public reporting of performance) from 2002. Longitudinal data were available for 17 Trusts. In 2000, only one ambulance trust had response rate above 75% and two trusts had rates lower than 40%. In 2005, 14 trusts had exceeded the target and the worst performer achieved 71%*
3. *Target: maximum wait for elective inpatient admission of 18 months by March 2001; 15 months by 2002; 12 months by 2003; and 9 months by 2004. The numbers of patients waiting more than 12 months and 9 months at the end of March 1998 were reported as 67,000 and 185,000 respectively; at the end of March 2005, only 24 patients were reported to have been waiting longer than 12 months and 41 longer than 9 months.*

The data for inpatient waits were compared to performance in other UK countries (where star ratings have not been used and targets are less stringent). The improvement in England was markedly better than in the other UK countries. The study also summarises evidence of gaming that has occurred in England in response to targets.

*Research design: observational study*

**Alvarez-Rosete et al 2005** in a review of the effect of diverging policy in the UK found striking differences in the reported reductions in waiting times in England between 1996 and 2002. Data were drawn from routine data sets. In 1996, 2.7% of those on the elective inpatient admission waiting list in England had been waiting longer than 12 months; compared to 9.9% in Wales and 17.1% in Northern Ireland. In 2002 these figures had improved in England to 0% waiting longer than 12 months; whilst there had been a deterioration in Wales to 15.9%, and Northern Ireland to 22.0%. These changes in performance are set alongside differences in policy: England's emphasis on targets, increasing capacity and market style incentives; Scotland's drive to build a professionally-led integrated system based on concepts such as managed clinical networks; Wales' focus on improving public health through partnerships with local government, communities and the NHS; and Northern Ireland's stalled devolution process.

*Research design: observational study*

**Auditor General for Wales 2005** in a review of hospital waiting times noted that despite higher levels of spending on health and social care in Wales, waiting times are longer there than in England. The maximum waiting time target for a first outpatient appointment in Wales of 18 months, is contrasted with 17 week target in England (reducing to 13 weeks by December 2005). This divergence is also seen in inpatient waiting time targets: 18 months in Wales; 6 months in England (by December 2005); 6 months in Scotland (by December 2005). Information on health spending per capita and targets is presented alongside performance. In March 2004, inpatient figures showed that in England, 17 patients had been waiting over 12 months (0% of total waiting) compared to 8457 (11%) in Wales and 0 (0%) in Scotland. Figures for patients waiting over 6 months were 79210 patients (9%) in England, 26316 (35%) in Wales and 5729 (5%) in Scotland. Similar divergences were noted in outpatient waits with 18 patients waiting over 6 months in England compared to 68845 in Wales. Despite substantially longer waiting time targets in Wales compared to England and Scotland, few have been achieved.

*Research design: observational study*

**Bevan and Robinson (2004)** provide two examples of the impact that targets have had, when coupled with annual publication of rudimentary league tables known as star ratings, on improving the performance in England's NHS. Data were drawn from routinely collected Department of Health data sources. Since 1996, ambulances have had a target of reaching 75% of immediately life-threatening emergencies (category A calls) within 8 minutes. There were dramatic improvements when this became a key target for Ambulance Trusts in 2002/03. A second key target for acute hospitals in England for 2002/03 was that no patient should wait for more than 12 months. In Wales there is no star rating system. Sixteen percent of patients were waiting more than 12 months in Wales, compared to a negligible number in England.

*Research design: observational study*

**Public Administration Select Committee (2003)** conducted a review of the UK's 1998 Public Service Agreements (PSAs) which had deadlines for 2002. Across all government departments, there were 366 targets, of which 221 (60.4%) were judged as met; 36 (9.8%) were unmet; no judgement could be reached because of a lack of data for 52 (14.2%); and there was no reporting for 38 (10.4%). Whilst supportive of the Government's aspirations for public service targets, the report criticises the target-setting regime for: a lack of clarity about aims and priorities; lack of proportional accountability in cross cutting targets, failures in reporting and monitoring, and confused accountability

*Research design: observational study*

**Robinson et al (2003)** examined the effect of the English government's target for a maximum of 2-week wait for women referred urgently with suspected breast cancer. Audit data from 5750 patients from 19 hospitals (subsequently found to have breast cancer) presenting in two 21 month intervals, before and after the target introduction date in April 1999, was assessed. The research found that there was a significant improvement in waiting times from GP referral to first hospital appointment (proportion of cases seen within 2 weeks rose from 66.0% to 75.2%) following the introduction of the target. Median wait fell from 13.6 to 12.3 days. However, there was a corresponding deterioration in the waiting times between first hospital appointment and treatment (proportion of cases waiting 5 weeks or less fell from 83.8% to 80.3%; median wait for treatment increased from 21.4 to 24.1 days). 86% of women with screen-detected tumours were seen by a consultant within 2 weeks compared to 68% of symptomatic women. The authors concluded that total waiting times remained relatively unchanged.

*Research design: observational study*

**Department of Health (England), 1998** commissioned a review of the Health of the Nation strategy, carried out by the London School of Hygiene and Tropical Medicine and the Universities of Leeds & Glamorgan. The research was based on 16 case studies comprising over 250 interviews and analysis of over 400 documents. It reported that, by and large, the Health of the Nation strategy had been an implementation failure because of an absence of sustained political commitment. Some of the targets were criticised as being set too low, for example those for the incidence of coronary heart disease and stroke could be seen as an extrapolation of an established rate of decline and would have been achieved without the NHS having to do anything at all. Several of the indicators that were subject to targets saw a deterioration rather than improvement (obesity, teenage pregnancies and smoking amongst young people). The research found widespread support for targets as a helpful way of prioritising and focusing efforts. However, the following caveats were stated:

- National targets must be credible – based on sound and convincing evidence
- The development of local targets needs to be encouraged
- Process targets should supplement outcomes locally and nationally

*Research design: observational study*

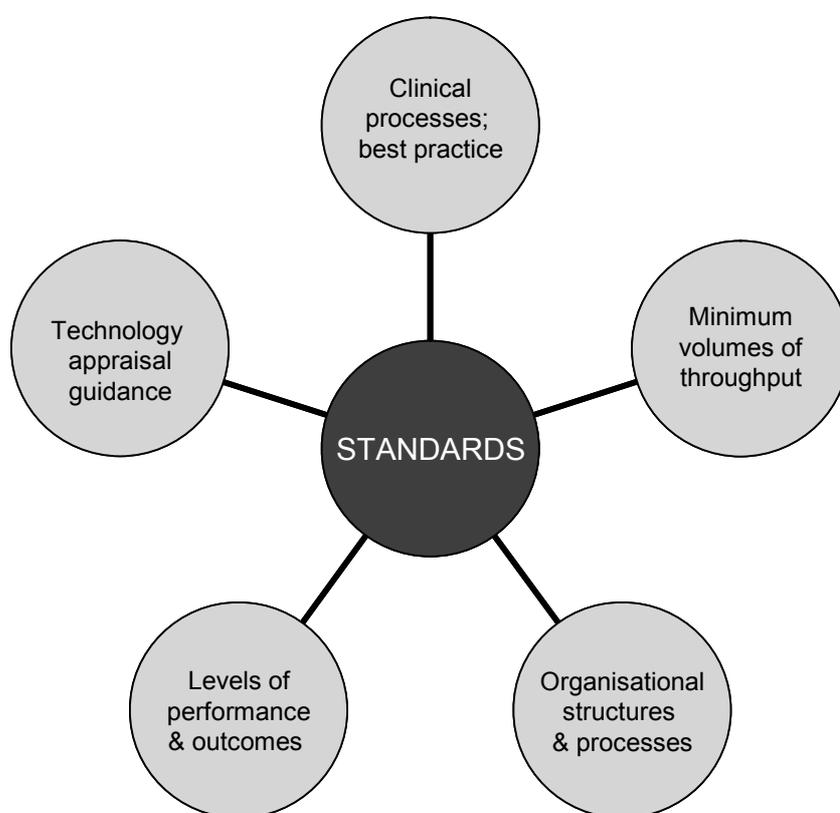
## Specific interventions – standard setting

### Background

Standards communicate the levels of performance that are expected from regulated organisations. In explicitly describing the criteria on which organisations will be judged, standards help ensure that regulatory processes are transparent and fair. Further, they offer an efficient means of encapsulating expertise about optimising performance. Once knowledge and evidence about 'best practice' are translated into standards, assessments are easier to make and are less contestable.

### Purpose

Standards play a central role in a number of regulatory, policy and management functions, guiding decisions and actions throughout a healthcare system. They can focus on a range of performance dimensions (see Figure 2.3).



**Figure 2.3: Types of performance dimensions covered by standards in healthcare systems**

Standards are used widely, often in tandem with other interventions. In various applications they can:

1. translate evidence from clinical research into models of 'best practice' often via guidelines to inform clinical practitioners and patients
2. define minimum levels of throughput or "volumes", based on research regarding the minimum numbers of procedures needed by an unit or individual to maintain expertise and quality of care (see Certificate of Need, p 95)
3. underpin other regulatory interventions, such as accreditation where inspectors

- measure performance against pre-defined standards, particularly for organisational structures and processes (see Accreditation, p 35)
- 4. translate policy and strategy into explicit expectations for organisational outcomes (see Performance Management QEI, forthcoming)
- 5. advise on appropriate adoption of new technologies.

In the following sections, we review the evidence regarding the effectiveness of two applications of standards as implemented in England's NHS: National Service Frameworks (NSFs) and the National Institute for Health and Clinical Excellence (NICE).

It is possible to argue that NICE is not a regulator per se as it is without any enforcement powers. However, since January 2002, the NHS has been obliged to provide funding and resources for medicines and treatments recommended by NICE through its technology appraisals work programme. Local NHS organisations are expected to implement NICE guidance within 3 months of publication and the cost of implementation is covered by their general annual allocations. Further, NICE appraisal guidance is automatically incorporated into the NHS core standards; and NICE clinical guidelines into the developmental standards (DH, 2004). The Healthcare Commission subsequently assesses compliance. The two organisations combine to regulate performance: direction, surveillance and enforcement.

### **National Service Frameworks**

National Service Frameworks (NSFs) were announced in *A New NHS: modern, dependable* (Department of Health, 1997). The role of NSFs at the outset was to:

- set national standards and identify key interventions for a defined service or care group
- develop and enact strategies for implementation
- establish performance measures against which progress within an agreed timescale will be measured.

Over time however the role of NSFs has shifted from these features towards a greater emphasis on principles of good practice and service models.

In developing NSFs, an external reference group (ERG) is convened to bring together health professionals, service users and carers, health service managers, partner agencies and other stakeholders. The Department of Health supports the ERGs and manages the overall process. There is a rolling programme of NSFs and to date the following areas have been covered:

- Mental health (1999)
- Diabetes (1999)
- Paediatric intensive care (1999)
- Coronary Heart Disease (2000)
- Cancer (NHS Cancer Plan 2000)
- Older people (2001)
- Renal services (2004)
- Children's services (2004)
- Long term conditions (2005)

[http://www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/HealthAndSocialCareArticle/fs/en?CONTENT\\_ID=4070951&chk=W3ar/W](http://www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/HealthAndSocialCareArticle/fs/en?CONTENT_ID=4070951&chk=W3ar/W)

*Criticisms of NSFs*

There have been criticisms that the standards set in some of the NSFs are too low. Evans et al (2006) found that in the case of the Coronary Heart Disease NSF, standards for smoking and body mass index (BMI) were achieved by most patients before the start of cardiac rehabilitation.

As the number of NSFs grows, questions of coordination come to the fore, as do questions about clinical areas not covered by NSFs. There are also concerns that NSFs:

- do not sufficiently allow for local differences in terms of the relative importance of care, prevention and promotion (Grimley Evans and Tallis, 2001);
- some of the standards cannot easily be translated into actionable steps (Tyrer, 1999);
- frameworks do not systematically or transparently evaluate the strength of the evidence on which they are based (Harrison, 2000)
- implementation has not been fully funded or subject to cost-benefit analysis (Craft, 2003).

**Evidence: National Service Frameworks**

NSFs have been developed and released at the same time as a number of parallel initiatives designed to improve performance and quality such as the waiting times initiative, increased investment, data handling, and national audits such as MINAP (Myocardial Infarction National Audit Project). It is not possible categorically to establish causality and apportion credit for changes that have occurred. Nevertheless there are some studies that have reviewed changes in quality that have occurred since the introduction of NSFs and provide evidence of some impact.

**Summary**

There is evidence to suggest the Coronary Heart Disease NSF, in particular, has been instrumental in improving quality of care. There are however continuing concerns about age disparities in the provision of CHD care following the release of the NSF.

**Graham et al 2006** evaluated the impact of the Coronary Heart Disease (CHD) NSF on emergency treatment and outcomes in patients with acute coronary syndromes. Data were drawn from a computerised database of patients admitted with acute coronary syndromes in two district general hospitals for 1,993 patients in the 27 months prior to the introduction of the NSF and 1,378 patients in the 24 months afterwards. In-hospital mortality fell after the introduction of the NSF (4.8% before vs 3.2% after ( $p=0.02$ )). There was a reduction in the proportion of patients who developed a Q wave on their ECG (40.6% vs 33.3%;  $p<0.0001$ ). The incidence of Left Ventricular Failure (LVF) fell after the introduction of the NSF (15.9% vs 12.3% patients;  $p=0.003$ ). The underlying mortality trend had been increasing before the NSF (Odds ratio, OR, for the 6 months prior to the introduction of the NSF was 1.22 (95% CI 1.02 – 1.46). Among patients who were eligible for thrombolysis, the proportion who received it increased (69.4% vs 84.7%). After the introduction of the NSF there was a significant stepwise increase (12.1% vs 26.6% patients;  $p<0.0001$ ) in the proportion of patients being thrombolysed within 20 minutes of arrival at the hospital (Door to needle time). The prescription of  $\beta$ -blockers (51.9% vs 65.8%,  $p<0.0001$ ), angiotensin converting enzyme (ACE) inhibitors (37.0% vs 66.4%;  $p<0.0001$ ), and statins (55.2% vs 72.7%;  $p<0.0001$ ) all increased as did the proportion of patients referred for cardiac catheterisation (18.3% vs 27.0%;  $p<0.0001$ ). Trend analysis showed that improvements in mortality and thrombolysis can be attributed to the publication of the NSF whereas improvements in prescriptions rates of statins and  $\beta$ -blockers appear to be a continuation of pre-existing trends.

*Research design: observational study*

**Ramsay et al, 2006** examined the uptake of medication for the secondary prevention of coronary heart disease in people aged 60-79 before (1998-2001) and after (2003) the implementation of the NSF. Data were drawn from broader population based studies of cardiovascular disease focused on 24 British towns, representing all major British regions. Both general practice records and patient survey data were used. The sample included 817 men and 465 women in 1998-2001; and 857 men and 548 women in 2003. Outcome measures were: rates of prescribing antiplatelet medication, statins,  $\beta$ -blockers, and ACE inhibitors and other blood pressure lowering treatments. Between 1998-2001 and 2003 the use of all the secondary prevention medications had increased; the increase was particularly marked in the case of statins post myocardial infarction (increased from 34% to 65% in men; 48% to 67% in women). However in 2003, fewer than half of all patients received  $\beta$ -blockers and ACE inhibitors.

*Research design: observational study*

**Ramsay et al, 2005** examined the use of drugs for secondary prevention of heart disease in men aged 62-85 years. Data were drawn from the British Regional Heart Study (BRHS) which collects data from patients in one general practice in each of 24 towns, representing all the major British regions; and from patient surveys completed by BRHS participants in 1998-2000 and in 2003. Subjects were stratified into two age groups (62-73 years and 74-85 years); social class; and time since diagnosis (<5 years; 5-10 years; >10 years). Data were collected for 807 patients (77% response rate to questionnaire) in 1998-2000 and 857 (80% response rate) in 2003. Prevalence of use of all drugs increased in 2003 and was markedly higher in patients with a history of myocardial infarct than angina. Statins and to a lesser extent  $\beta$ -blockers, were more likely to be received by younger patients. The relative difference were particularly marked for AMI patients: in 2000 older subjects were 60% less likely (95% CI 41-71) to receive statins than younger subjects; and in 2003 39% less likely (95% CI 57-83). Social class appeared to have little association with drug utilisation. Prevalence of use of medication decreased with increasing elapsed time from diagnosis.

*Research design: observational study*

**Hippisley-Cox et al, 2005** examined changes in the uptake of coronary prevention measures 1 year before and 1 year after the implementation of the CHD NSF. Data were drawn from 17 general practices in the Trent region of England and included at baseline two groups of patients. Group A comprised, at baseline, 5193 patients with diagnoses of CHD or stroke and at follow-up, 5784 patients. Group B comprised, at baseline, 7288 patients with diabetes or hypertension and at follow up, 8374 patients. There was a relative 59.5% increase in recording of cardiovascular risk factors for group A and a 40.3% increase for group B. There were also significant improvements in disease control measures: pre NSF, 30.7% of patients in group A were prescribed statins compared to 40.4% post NSF ( $p=0.002$ ). Older patients ( $\geq 75$  years) were less likely than younger patients to have their serum cholesterol levels recorded on the preceding year (group A: adjusted OR 0.23; 95%CI 0.14-0.39). At baseline, older people in group A were less likely to be on statins (adjusted OR 0.17; 95% CI 0.12-0.25); more likely to have a serum cholesterol  $>5\text{mmol/l}$  (adjuster OR 1.66; CI 1.25-2.21); and less likely to have good blood pressure control. At follow up there were no improvements in the discrepancies found and blood pressure control deteriorated further.

*Research design: observational study*

**Department of Health (England), 2005 (The Coronary Heart Disease Progress Report)** catalogued progress on implementing the coronary heart disease NSF. The self-reported achievements were:

Indicators	Then	Now
Adult smoking prevalence	28% (2000)	25% (2003)
# children receiving fruit at school	0 (2000)	Over 2 million (2005)
Estimated number of lives saved with statins	2,900 (2000)	9,000 (2004)
# patients waiting >12 months for heart surgery	1,093 (Mar 2000)	0 (Dec 2002)
# patients waiting > 9 months for heart surgery	2,694 (Mar 2000)	0 (Mar 2003)
# patients waiting > 6 months for heart surgery	2,766 (Apr 2002)	0 (Nov 2004)
% heart attack victims given thrombolysis within 30 minutes of arrival at hospital	38% (2000)	84% (Dec 2004)
Consultant cardiologists	467 (1999)	694 (Jun 2004)
Heart surgeons	182 (1999)	240 (Jun 2004)

*Research design: observational study (government account of official data)*

**Commission for Health Improvement & Audit Commission (2001)** reported on progress made in implementing the Calman-Hine Report (1995) - the equivalent to a NSF on cancer. The report is based on evidence gathered from multiple sources: 15 focus groups (involving 85 patients with cancer); site visits to one randomly selected cancer network from each region in England and one in Wales; structured interviews with 1,100 professionals working across the 9 networks; 9 focus groups with 57 GPs and 9 focus groups with 67 community nurses; bespoke analysis of radiotherapy services and; analysis of centrally collected data (HES) on inpatient and day case activity for patients with a primary diagnosis of five types of cancer (breast, colorectal, genitourinary, gynaecological and lung). The report contains detailed analysis of progress on Calman-Hine principles and recommendations. It asserts that many improvements in cancer services can be attributed to the Calman-Hine Report, including the expansion of multidisciplinary working and increases in staffing and equipment. However, it also found that many key recommendations were not fully implemented. Problem areas included: from the patient point of view there is poor communication and a failure to plan care in a systematic way between the different professional involved; many patients lack access to someone (such as a specialist nurse) who both knows about their cancer and can provide support; patients do not always receive the best treatment or care, and; there were striking variations in provision both across geographical area and between patients with different types of cancer.

*Research design: observational study*

### National Institute for Health and Clinical Excellence

“NICE may prove to be one of Britain’s greatest cultural exports, along with Shakespeare, Newtonian physics, the Beatles, Harry Potter and the Teletubbies” (Smith, R, 2004).

NICE was created in 1999 as a special health authority. It is accountable to the Department of Health and the Welsh Assembly, which provide its funding. NICE was created in order to put an end to unacceptable variations in the quality of care available for patients in different parts of the country (often referred to as ‘postcode prescribing’). In 2005-06 its budget was £20 million.

NICE produces three types of guidance:

- Technology appraisals of new and existing medicines and treatments
- Clinical guidelines for treatment and care of people with specific diseases and conditions
- Guidance on safety and efficacy of interventional procedures used for diagnosis or treatment

NICE has been criticised for concentrating on new technology with little attention on assessing old technologies that may be redundant (Maynard et al, 2004). There are also concerns about the cost and resource allocation implications of NICE decisions. Raftery (2001) reviewed the 22 health technologies on which NICE had issued guidance by March 2001. The net costs of implementing NICE’s guidance was around £200m. However, if NICE’s decisions start to have a big budgetary impact; compulsory implementation may distort resource allocation, shifting priorities towards NICE. Enforcement of NICE decisions could squeeze out effective treatments not considered by NICE, producing inequity between different condition or patient groups (Stevens & Milne, 2004).

NICE does not solve the thorny problem of rationing health care. In England before NICE, the issue of rationing had rarely been addressed explicitly. Historically there have been surreptitious controls on demand for healthcare in the form of the 5Ds: delay, defer, deter, dissuade and decline. Moving towards a health system more firmly founded priority setting or rationing on the basis of available evidence at first glance appears more reasonable and fairer. However, even with the advantages conferred by the presence of a central adjudicator of effectiveness, a strictly evidence-based health service remains contentious in England because of diametric views of rationing. Rationing is variously interpreted as “the equitable distribution of limited resources” or “an arbitrary decision by an anonymous, heartless bureaucrat not to pay for some treatment that has known benefit for a patient, simply to save money and without appropriate consideration of the value of the treatment to the patient” (Eddy, 1999).

There are also concerns about capacity. NICE appraises around 25 technologies per year. This represents a fraction of the needs of the NHS. The NCCHTA which manages the NHS R&D HTA programme on behalf of the DH, receives around a thousand suggestions for assessment per year, of which around 50% are plausible (Stevens & Milne, 2004). In 2005 NICE responded to capacity concerns, announcing a more rapid review process.

A Health Select Committee Inquiry (2002) raised concerns about NICE’s methodology. A WHO review, commissioned by NICE in response to those concerns, (Hill et al, 2003) concluded that in its first four years of operation NICE had developed a well-deserved reputation for innovation and methodological developments. Achievements noted as particularly valuable included: the transparency surrounding the process of technology assessment; the intensive participation of different stakeholders and the inclusiveness of

the approaches taken; the commitment to using the best available evidence for decision-making; the commitment of the technical and management staff; and the dedication of the appraisal team and the Appraisal Committee members.

In July 2004, the Editor of the British Medical Journal reviewed NICE's progress: *Four years ago the BMJ proposed some characteristics for NICE. We can now attach some provisional scores. "Britain", we concluded, "would benefit from a body that admits it is about rationing (2/10), works openly (5/10), uses evidence (8/10), looks right across health care (2/10), incorporates ethical thinking systematically into its judgements (6/10), is more distant from politicians and the pharmaceutical industry (3/10) and is directly accountable to the public (1/10)." "Satisfactory but could do better." (Smith, R, 2004)*

## Evidence: National Institute for Health and Clinical Excellence

### Summary

There is mixed evidence about the effect of NICE guidance on quality of care. NICE guidance can be effective if accompanied by other supportive levers for change such as a strong professional support, a stable and robust evidence base and sufficient resources to fund implementation.

**Hassan et al 2005** examined the impact of NICE head injury guidelines on diagnostic processes. The guidelines recommended that CT head scan should replace skull x-ray (SXR) and observation/admission as the first investigation. Anonymised patient record data for 1130 patients with head injury were collected from two A&E departments (one in a teaching hospital and one in district general hospital), for one month six months prior to implementation of NICE guidance and for one month, subsequent to implementation (NB the timing for implementation differed between the two sites). At the teaching hospital CT scan rate went from 3% to 7% of patients; the SXR declined (37% to 4%) and the admission rate decreased from 9% to 4%. This represented a saving £3381 per 100 head injury patients. The corresponding figures for the DGH were CT scan 1.4% to 9%; SXR 19% to 0.6%; admission rate 7% to 5%; saving of £290 per 100 head injury patients.

*Research design: observational study*

**Sheldon et al 2004** assessed the extent and pattern of implementation of NICE guidance using a multi-method approach with interrupted time series analysis, review of case notes, survey and interviews in acute and primary care Trusts in England and Wales. Assessments were carried out on 50% (n=12) of sets of guidance that had been issued at least 6 months prior to the study's commencement in 2001. They addressed prophylactic removal of wisdom teeth; prostheses for hip replacement; taxanes for treatment of breast and ovarian cancer; hearing aids; implantable cardioverter defibrillators for arrhythmias; zanamivir for influenza; laparoscopic treatment for the treatment of colorectal cancer; laparoscopic surgery for the treatment of inguinal hernia; donazepil, rivastigmine and galantamine for Alzheimer's disease; orlistat for obesity; chemotherapy for non-small cell lung cancer. The evidence on the effect of NICE on quality of care and variations in practice is mixed. Prescribing of some taxanes for cancer (P<0.002), and orlistat for obesity (P<0.001) significantly increased in line with guidance. Prescribing for Alzheimer's and removal of wisdom teeth had trends consistent with, but not obviously a result of, NICE guidance. No change was apparent in the use of hearing aids, hip prostheses, defibrillators, and laparoscopic surgery for colorectal cancer or hernia repair. In the absence of high levels of circulating influenza, prescribing levels of zanamivir could not be used to judge impact. Overall, guidance was found to be more likely to be adopted when there was strong professional support; a stable and convincing evidence base; no increased or unfunded costs associated with compliance; where there are established and effective systems for

tracking implementation; and where professionals are not isolated.

*Research design: observational study*

**Abacus International (2004)** was commissioned by NICE to measure the impact of 28 pieces of NICE guidance. Data for England and Wales was provided by IMS (Intercontinental Marketing Services) for 20 of the topics under review. Where no IMS data was available, alternative sources were used such as manufacturers' sales data and activity data from specialist centres. The report concludes that NICE guidance is driving change but at different rates for different diseases. Of the 28 topics reviewed, 12 were judged to have been reasonably implemented in line with the expectations of the guidance; 12 under-implemented and 4 over-implemented.

*Research design: observational study*

**National Cancer Director, 2004** examined variation in usage of cancer drugs following NICE recommendations. The report considered 16 cancer drugs appraised by NICE and 4 standard cancer drugs as comparators. Data on drug use in NHS Trusts from July - December 2003 was provided by IMS Health and by local cancer networks. The review concluded that overall usage of cancer drugs generally increases after a positive appraisal from NICE; variation in usage exists across the country and cannot be accounted for by case mix or cross boundary flows; variation tends to decrease over time. Reasons for variation in usage were found not to be associated with funding restrictions but were related to constraints in service capacity; differences in individual clinical practice and; variations in the effectiveness of local organisational planning and leadership.

*Research design: observational study*

**Wathen & Dean (2004)** conducted a study into the impact the NICE guidance has on prescribing decisions. The study focused on 102 GPs working within a single PCT (North Devon). Five NICE appraisals were selected: proton pump inhibitors in the treatment of dyspepsia; rosiglitazone in the treatment of type 2 diabetes mellitus; zanamivir in the treatment of influenza; orlistat for the treatment of obesity in adults; and cyclo-oxygenase (Cox) II inhibitors for the treatment of osteoarthritis and rheumatoid arthritis. Data collected included twelve semi-structured interviews; 81 returned postal questionnaires (82.7% response rate); collection of prescribing analysis and cost (PACT) data for the six months before and twelve months after the release of each NICE appraisal. In the cases where NICE guidance resonated with information from other sources or personal experience, there was some evidence that NICE guidance triggered a change in prescribing but this was not always sustained. The authors conclude that NICE guidance, in isolation, had little impact on GP prescribing patterns.

*Research design: observational study*

**Bloor et al, 2003** examined the impact the NICE's guidance on repairing inguinal hernias. In January 2001 NICE recommended that for the repair of primary inguinal hernia, synthetic mesh-open procedures should be preferred over laparoscopic techniques. Data was collected from Hospital Episode Statistics (HES) database. 217,000 cases with a primary procedure code for primary surgery for an inguinal hernia. Of these, 8960 (4.1%) were coded as laparoscopic procedures. An interrupted time series analysis of the rate of laparoscopic repairs as a proportion of the total was performed at 143 time points before publication of the NICE guidance and at 51 time points after. The authors found that the publication of NICE guidance did not reduce the proportion of repairs done laparoscopically.

*Research design: observational study*

## External oversight approaches

### Introduction and background

As discussed in the introduction, regulation of healthcare organisations broadly comprises three key facets:

*Direction:* the communication of expectations and requirements to the regulated organisations and other stakeholders.

*Surveillance:* assessment of the level of performance or extent of compliance on the part of regulated organisations.

*Enforcement:* the use of (or promise/threat of use of) regulatory powers to bring about change.

External oversight refers to the processes of organisational monitoring carried out by bodies constituted at arm's length from those they oversee. However, all three facets of regulation are interconnected, both within and between regulators. External oversight models are often used in tandem with directive approaches such as target and standard setting; as well as enforcement processes via the issuance of informal advice and formal reports, and in extreme cases delicensing or takeover. In this briefing, we particularly focus on accreditation and inspection as representative models of external oversight.

Within the area of external oversight, terminology is somewhat confused with nuanced concepts and approaches often used inconsistently and interchangeably. Box 2.5 arrays the main types of external oversight and outlines their key characteristics and the main methods they draw on to reach their conclusions.

<b>Intervention</b>	<b>Key characteristics</b>	<b>Methods</b>
Accreditation	<ul style="list-style-type: none"> <li>• an authoritative body gives formal recognition that an organisation or person is competent to carry out specific tasks.</li> <li>• participation has traditionally been voluntary; however is increasingly mandatory.</li> </ul>	<ul style="list-style-type: none"> <li>• Compliance with standards</li> <li>• On-site evaluation</li> <li>• Standards usually set at optimal achievable levels to stimulate improvement</li> </ul>
Inspection	<ul style="list-style-type: none"> <li>• experts make periodic visits to a regulated organisation in order to assess its performance</li> </ul>	<ul style="list-style-type: none"> <li>• main focus is the competence of professional staff, compliance with professional standards and outcomes for users</li> </ul>
Audit <sup>2</sup>	<ul style="list-style-type: none"> <li>• primarily concerned with management arrangements, costs and value for money, and accounting for fiscal propriety</li> </ul>	<ul style="list-style-type: none"> <li>• review of financial statements and accounts</li> <li>• often focused on the three Es: economy (minimising costs); efficiency (optimising the input:output ratio); effectiveness (the closeness of intended and actual results)</li> </ul>
Review	<p>Either:</p> <ol style="list-style-type: none"> <li>a. the on-site evaluation component of accreditation schemes</li> <li>b. a one-off study of a particular area of concern</li> </ol>	<p>Either:</p> <ol style="list-style-type: none"> <li>a. on-site assessment against predefined standards</li> <li>b. generally a focused case study</li> </ol>
Licensure	<ul style="list-style-type: none"> <li>• mandatory scheme to ensure a minimum standards</li> <li>• applied to organisations or individuals</li> </ul>	<ul style="list-style-type: none"> <li>• satisfactory performance in either examinations or evaluations required in order to practice/trade</li> </ul>

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2. This does not include clinical audit where individual units' clinical processes and outcomes are collated and fed back to clinicians. The evidence on the impact of clinical audit on quality will be addressed in the organisational branch of QEIs, under professional behaviour change interventions.

Intervention	Key characteristics	Methods
Certification	<ul style="list-style-type: none"> <li>• assurance regarding specific capabilities for a product, service, process or individual</li> <li>• usually beyond basic requirements</li> </ul>	<ul style="list-style-type: none"> <li>• satisfactory performance in either examinations of evaluations</li> <li>• includes ISO 9000 scheme</li> </ul>

**Box 2.5: Types of external regulation interventions (adapted from Audit Commission, 1999; Roa & Rooney, 1999; Shaw, 2000; Boyne et al, 2002)**

The interventions shown in Box 2.5 are generic approaches which regulators often adapt and/or adopt in various combinations. For example a central feature of the Healthcare Commission's current approach to external oversight, the annual health check, uses a combination of self assessment, monitoring of routine indicators, and draws on quality information from a range of sources. The health check subsequently informs the selected use of reviews and inspection visits.

External oversight interventions adopted in any given setting have been found to vary according to differences, in terms of background and training, between regulators and those they regulate. The greater these differences are, the more formal the regulatory process tends to be. Formality in this sense is manifested in autocratic standard setting; strict rules regarding regulatory behaviour; and heavy reliance on formal reporting and sanctioning rather than discretionary regulation reliant upon cooperative methods for collecting and collating information and modifying behaviour (Hood et al, 1998). Similarly, it is recognised that greater use of persuasion is likely to work in highly professionalised contexts when behaviour change is sought (Hughes et al, 1997).

Conceptually, external oversight has been criticised as being at odds with the notion of continuous quality improvement, a notion that remains a central objective in many organisational settings, both within and outside the healthcare sector. Although it is helpful inasmuch as it provides a mirror to an organisation, it is generally descriptive of problems rather than diagnostic of underlying causes and rarely provides solutions (Brennan, 1998) and has been described as stifling the potential for internally led quality improvement (Buetow and Wellingham, 2003).

For external oversight interventions, as for regulation in general, the perennial difficulties of attributing cause and effect hampers conclusive evidence (Pollitt, 1995). The following sections, on accreditation and inspection, illustrate the paucity of rigorous research evidence on the impact of these interventions.

## Specific interventions – accreditation

### Background

Accreditation is a formal process by which an external body, usually a non-governmental organisation (NGO), assesses whether a healthcare organisation meets predetermined and published standards. Accreditation programmes have their roots in independent, voluntary initiatives which assessed structural elements of hospital-based care but over time have developed into multi-disciplinary assessments of healthcare processes, functions, organisations and networks. The concept of accreditation is generally regarded to have been introduced in the US in 1917 when the American College of Surgeons established a set of minimum standards for training posts in surgery.

Accreditation is the most commonly used external mechanism for standards-based quality improvement in health care (World Health Organisation, 2003). Accreditation standards are usually set at a level regarded to be optimal and achievable, and are designed to encourage continuous improvement efforts within participating organisations. An accreditation decision about a specific healthcare organisation is made following a periodic on-site evaluation, conducted by a team of peer reviewers, typically every two to three years. Accreditation is generally described as a voluntary process in which organisations choose to participate, rather than one required by law. This contrasts with licensure which uses minimum standards that must be met to prove fitness to provide healthcare services. However, this distinction has eroded over time and some healthcare systems now use accreditation as a tool of public regulation; as a component in, or substitute for, licensing. Even in settings where accreditation remains voluntary, non-participation often results in substantial financial and organisational consequences and is considered to be a competitive necessity.

Although most widely applied in hospital settings, accreditation schemes also operate in the nursing home sector (e.g. the Aged Care Standards and Accreditation Agency in Australia); ambulatory care (e.g. Accreditation Association for Ambulatory HealthCare in the US) and health plan settings (e.g. the National Committee for Quality Assurance in the US); as well as within specialist functions and services (e.g. Clinical Pathology Accreditation in the UK).

#### *Usage*

A global review of accreditation in health care services conducted by the International Society for Quality in Health Care (ISQuA) for the World Health Organization (WHO) in 2003 documented thirty-six accreditation programmes which were operational at a national level (World Health Organisation, 2003). The Joint Commission on Accreditation of Healthcare Organisations (JCAHO) in the US is the best studied scheme.

#### *Joint Commission on Accreditation of Healthcare Organizations (JCAHO)*

Established in 1951, the Joint Commission is the leading force in accrediting health care organisations in the US. An independent, not-for-profit organisation, it has an annual budget of around \$120 million and accredits more than 15 000 healthcare organisations and programmes. Its stated mission is *to continuously improve the safety and quality of care provided to the public through the provision of health care accreditation and related services that support performance improvement in health care organisations.*

In order for healthcare organisations to receive payment from federally funded Medicare and Medicaid programmes, they must be certified as complying with explicit Conditions of Participation (COPs). JCAHO has 'deeming authority' that is, accreditation by JCAHO confers automatic certification that the Conditions of Participation are being met thereby circumventing the need for additional government inspections. JCAHO accreditation is also used by many states for licensing, certification and contracting purposes. Healthcare organisations often use their participation in accreditation schemes for marketing purposes. These factors are powerful incentives for organisations to take part in JCAHO accreditation. Although in principle participation is voluntary, in practice it is a necessary part of managing a hospital. In 2003, out of a total of 5585 hospitals in the US, 4671 were accredited (over 80% by JCAHO), and 914 were unaccredited (American Hospital Association).

Historically, accreditation focused on structural standards but in recent years there has been greater emphasis on process and quality improvement. As of 2004, surveys included a methodology for evaluating actual care processes, using 'tracer' patients to map out the path from service to service within the hospital. From 2006 there will be a requirement for hospitals to conduct annual self-assessments; and surveys will change from prearranged to unannounced.

For hospital accreditation, there are over 250 standards, organised into 17 focus areas:

<ul style="list-style-type: none"> <li>• Ethics, rights and responsibilities- Assessment of patients</li> <li>• Care of Patients</li> <li>• Education</li> <li>• Continuum of care</li> <li>• Management</li> <li>• Medication management</li> <li>• Surveillance, prevention and control of infection</li> </ul>	<ul style="list-style-type: none"> <li>• Leadership</li> <li>• Management of the environment of care</li> <li>• Management of human resources</li> <li>• Management of information</li> <li>• Governance</li> <li>• Provision of care, treatment and services</li> <li>• Medical staff</li> <li>• Nursing</li> <li>• Improving organisational performance</li> </ul>
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**Source:** <http://www.jcaho.org/htba/hospitals/facts.htm>

There are some concerns about governance and accountability within the JCAHO model. JCAHO derives much of its income from the fees paid by the facilities surveyed, and critics highlight the conflict of interest inherent in this arrangement. Few hospitals are denied accreditation outright.

For the hospitals surveyed in 2003, JCAHO's decisions were as follows:

<b>Decision</b>	<b>No of hospitals</b>
Accreditation	320
Accreditation with requirements for improvement	1191
Conditional accreditation	13
Accreditation denied	0
Total	1524

The accreditation standards are produced by expert consensus and are not evidence-based. They are the result of a trade-off between what performance data suggests is needed and what JCAHO stakeholders are willing to concede. For example, in 2004 JCAHO was accused of "watering down" proposed emergency department overcrowding standards that hospitals found overly demanding (Sprague, 2005).

In addition to hospital accreditation, JCAHO has accreditation programmes for a wide range of entities including nursing homes, home healthcare agencies and health plans. However, JCAHO is only one of the accrediting organisations operating in the US (for details see US Context, p 54).

Although the US has the longest established and largest accreditation programmes in the world, accreditation has been adopted as a regulatory intervention across the world. The International Society of Quality in Health Care (ISQua) launched the Agency for Leadership in Programs in Healthcare Accreditation (ALPHA) in 1999 ([www.isqua.org.au/isquaPages/Alpha.html](http://www.isqua.org.au/isquaPages/Alpha.html)) in order to standardise international accreditation programmes. It aims to make standards-based assessment systems more reliable, valid and compatible within and between countries, assessing and endorsing the standards of national organisations against internationally tested and approved principles.

#### *Costs of accreditation*

A review of national accreditation organisations, conducted by ISQuA on behalf of WHO, estimated that in 2000 survey fees for a 100-bed hospital ranged from US\$1000 to US\$25000 (Shaw and Kalo, 2002). For participating organisations however, the greatest cost is in preparation for accreditation. One estimate set these costs at around four times the cost of the external survey process (World Health Organisation, 2003).

In the US, it has been estimated that the total costs to the healthcare system of JCAHO accreditation are between \$425 and \$850 million per year (Walshe, 2003: 65). However, it is noted that these costs would not disappear entirely if an organisation chose not to participate in an accreditation programme. Much of the preparatory work can be considered to be part of routine management, ensuring that policies, procedures and quality systems are up to commonly accepted standards.

Some experts argue that accreditation is not a good use of resources in low-income developing countries. For example Ovretveit (2002) argues that accreditation in these contexts is often unsustainable, ineffective and inappropriate ... If the money used for the accreditation system was invested in quality methods to improve immunisation programmes or drug supply logistics, many more lives would be saved and the changes would be sustainable. Bukonda et al (2002) describe the implementation of a national hospital accreditation scheme in Zambia which foundered because of insufficient funds. Montagu (2003) asserts that healthcare organisations in developing countries are unlikely to join accreditation schemes unless the costs of participation are subsidised or other external incentives (e.g. vouchers, social marketing, service contracting) are put in place.

#### *Factors influencing effectiveness*

The factors that have been found to influence the effectiveness of accreditation programmes include:

- Clarity of purpose: what is the relative importance of quality improvement, assurance, or accountability in the accreditation programme?
- Methods and approach: does the operationalisation of the accreditation programme accord with its overall objectives?
- Motivation: do stakeholders feel that they are involved in the design and direction of the accreditation programme? What combination and type of sanctions and rewards are applied?
- Perceptions about the accrediting organisation: is it seen as independent, rigorous, fair, transparent?
- Appropriateness and validity of standards: do they capture the drivers of organisational performance; are they reasonable in number; are they reliable?
- Sustainable resourcing: is the accrediting organisation sufficiently staffed and resourced?

- Surveyor capacity: are surveyors well trained with the requisite skills
- Presentation and dissemination of results: are the results presented fairly and used constructively.

(adapted from Shaw, 2003)

### **Evidence: accreditation**

Despite the huge level of resources spent on accreditation, there have been few evaluations that assess the effectiveness of accreditation as a lever to improve quality in healthcare. Evaluations that have been undertaken have tended to focus on perceived benefits for participants rather than objectively assessing impact on outcomes and evidence-based processes (Walshe & Walsh, 2000; Shaw, 2003).

### **Summary**

In the US:

- Although there is some evidence of an association between quality of care and accreditation status, there is no evidence of causality. That is, the accreditation-performance association could be explained by high performing organisations choosing to participate in accreditation, rather than accreditation processes leading to better performance or higher quality healthcare.
- No correlation between JCAHO scores and alternative, evidence-based, measures of healthcare quality and safety.
- No difference in the medical error rates between accredited and non-accredited hospitals.
- No correlation between patient satisfaction scores and JCAHO survey scores
- Disjunction between outcomes measures and JCAHO evaluations.
- JCAHO has acted as a key driver in the development of hospitals' patient-safety initiatives although no evidence of patient impact.

One controlled study in South Africa found evidence of improved compliance with standards following the introduction of accreditation schemes, but little evidence of improvement in quality indicators

**Miller et al (2005)** examined the association between JCAHO accreditation scores and two sets of indicators based on discharge data developed by the Agency for Healthcare Research and Quality (AHRQ): Inpatient Quality Indicators (IQI) and Patient Safety Indicators (PSI). IQIs include inpatient mortality rates for selected conditions; utilisation rates of procedures for which there are concerns regarding overuse, underuse or misuse; and volumes of procedures where there is evidence linking high volumes and lower mortality rates. PSIs include complications of anaesthesia; failure to rescue; decubitus ulcer; foreign bodies left during procedure; iatrogenic pneumothorax; infections due to medical care; postoperative complications; and obstetric trauma. Hospital accreditation and performance data from 2116 hospitals in 24 states for 1997-1999 were analysed. The study found no relationship between JCAHO survey results and evidence-based measures of healthcare quality and safety (IQIs/PHIs).

**Devers et al (2004)** analysed qualitative data emanating from semi-structured interviews with 87 leaders of large hospitals in 12 metropolitan areas in the US; 226 interviews with employees and brokers, health plans and medical groups; a Community Tracking Study (CTS) patient safety survey (n=33); and the Leapfrog Group's publicly reported survey data. Both the interviews and CTS patient survey data show that hospitals' major patient-safety initiatives are a direct result of JCAHO requirements. However the impact on patients is unclear.

*Research design: qualitative study of interview data*

**Heuer (2004)** examined the relationship between accreditation scores and independently measured patient-satisfaction ratings. The study included 41 acute care not-for-profit hospitals with over 200 beds in New Jersey and Pennsylvania. Correlation and multiple-regression statistical methods found no clear overall pattern between summative scores for patient satisfaction and JCAHO survey scores.

*Research design: observational study*

**Government Audit Office (2004):** In a sample of 500 JCAHO accredited hospitals, state agency validation surveys conducted in 2000-2002 identified 157 hospitals with serious deficiencies in Medicare COPs. Of these, JCAHO failed to identify 123 (78%). The report concludes that Centres for Medicare and Medicaid Services (CMS) needs additional authority for adequate oversight of patient safety in hospitals.

*Research design: observational study*

**Chen et al (2003)** examined the association between JCAHO accreditation status, quality of care, and survival of Medicare patients admitted with acute myocardial infarction (AMI). The study consisted of 134,579 patients aged 65 or over who were hospitalised with clinically confirmed AMI. Quality performance data was collected on: use of aspirin or beta-blockers within 48 hours of admission; aspirin or beta-blockers any time during hospitalisation; acute reperfusion therapy (thrombolytic agents or primary angioplasty) within 36 hours of admission; and 30 day mortality rates. Patients admitted to non-surveyed hospitals were less likely to receive aspirin and beta-blockers, both on admission and during hospitalisation; and less likely to receive acute reperfusion therapy. Non-surveyed hospitals had higher 30-day mortality rates than surveyed hospitals after adjustment for patient characteristics (Hazard ratio 1.15;  $p < 0.001$ ). The authors note that accreditation-performance association could be explained by high performing organisations choosing to participate in accreditation, rather than accreditation processes leading to better performance or higher quality health care. The study also assessed hospitals' performance within different JCAHO accreditation levels (accreditation with commendation; accreditation without type I recommendations; accreditation with type I recommendations; conditional accreditation and; not accredited) and found wide heterogeneity within each category suggesting that accreditation levels are of limited value in differentiating quality.

*Research design: observational study*

**Salmon et al (2003)** conducted a randomised control trial of hospital accreditation in KwaZulu-Natal province in South Africa. 20 randomly selected public hospitals, stratified by size took part: 10 entered into the accreditation programme in 1998 and the other 10 (which served as controls) entered approximately 2 years later. Eight indicators of quality were measured: nurse perceptions of quality, client satisfaction, client medication education, accessibility and completeness of medical records, quality of peri-operative notes, hospital sanitation, and labelling of ward stocks. About 2 years after the accreditation of the intervention group began, average compliance with standards had increased in the control group by 1% and by 38% in the intervention group. However with the exception of nurse perceptions of clinical quality, there was little or no effect on the quality indicators in the intervention hospitals.

*Research design: Controlled before-after design*

**Piontek et al (2003)** conducted a retrospective analysis of severity-adjusted discharge data, comparing trauma patient outcomes before and after American College of Surgeons (ACS) Level II verification in a non-profit community hospital setting. Outcomes measured: mortality; length of stay (LOS); total hospitalisation cost; intensive care unit cost; payment and key labour cost; ventilator use; prevalence of complications and; readmissions within 31 days of discharge. The study had both internal (CABG patients) and external (trauma patients at non-ACS hospital) controls. Data was collected on 7811 consecutively admitted patients: 3976 patients before and 3835 after verification was achieved. The two timeframes showed statistically different outcomes in several variables: post-verification LOS was 10% shorter ( $p < 0.000$ ); severity adjusted mortality observed/expected ratios were 0.81 pre-verification and 0.59 post-verification ( $p < 0.000$ ); severity-adjusted ratio of costs were 5% lower post verification ( $p < 0.000$ ). The authors conclude that ACS verification resulted in benefits for injured patients and for the organisation in which they were treated.

*Research design: Controlled before and after design (retrospective comparative study with historical controls). Appropriate design; the comparator used was justified; appropriate statistical analyses of the costs, however there was no pre-verification adjustment of group costs for inflation and this limitation may affect the conclusions reached by the authors (CRD).*

**Barker et al (2003)** conducted a study of medication errors in a stratified random sample of 36 hospitals comprising 12 JCAHO accredited hospitals, 12 non-accredited hospitals and 12 skilled nursing facilities in Georgia and Colorado. Medication errors were witnessed by observation, and verified by a research pharmacist. Clinical significance was judged by an expert panel of physicians. Sample size was 50 doses per nursing unit. Categories of medication error were: unauthorised drug; extra dose; wrong dose; omission; wrong route; wrong formulation; wrong technique; wrong time. In the 36 institutions, 19% (605/3216) were erroneous; 7% of errors were judged to be potential adverse drug events. There was no significant difference between error rates in the three settings ( $p = 0.82$ ).

*Research design: observational study*

**Beaulieu & Epstein (2002)** explored the relationship between NCQA accreditation status of US health plans and measures of health plan quality. Analysis was based on HEDIS quality of care scores; and patient-reported quality and satisfaction data from a survey of federal employees. Accredited plans ( $n = 170$ ) had significantly higher HEDIS scores than non-accredited plans ( $n = 69$ ) for seven out of nine measures: childhood immunisation ( $p < 0.05$ ); adolescent immunisation ( $p < 0.10$ ); breast cancer screening ( $p < 0.05$ ); cervical cancer screening ( $p < 0.05$ ); prenatal care ( $p < 0.05$ ); diabetic eye examination ( $p < 0.05$ ); follow-up after mental health hospitalisation ( $p < 0.10$ ). For the remaining two measures, check up after delivery and beta-blocker treatment after myocardial infarction, accredited plans had higher HEDIS scores but the differences were not statistically significant. Patient-reported quality and satisfaction data showed that accredited plans ( $n = 148$ ) significantly outperformed non-accredited plans ( $n = 83$ ) on overall satisfaction scores ( $p < 0.05$ ) however non-accredited plans outperformed accredited on quality of care rating ( $p < 0.05$ ) and on choice of specialist ( $p < 0.1$ ).

*Research design: observational study*

**Griffith, Knutzen & Alexander (2002)** compared JCAHO overall evaluation scores (OES) to seven performance measures derived from Medicare: cash flow margin; asset turnover; mortality index; complications index; cost per case; length of stay; and outpatient activity. Data from 742 non-federal general hospitals was analysed. The study found the

only statistically significant associations between the OES and the specific performance measures were in mortality ( $R=-0.085$ ;  $p=0.21$ ) and % outpatient revenue ( $R=-0.089$ ;  $p=0.15$ ). The authors conclude that there is a disjuncture between outcomes measures and Joint Commission evaluations of performance.

*Research design: observational study*

**Simons et al (2002)** studied data from three designated trauma centres, one of which was subsequently accredited, in British Columbia, Canada. The study population included all trauma patients 1992-1999. The main outcome measure was actual versus predicted mortality; some Length of Stay (LOS) data is also presented. Over the 7 years of the study, the hospital which had a trauma programme consistent with the Canadian accreditation criteria was statistically better than at the other two centres ( $p<0.001$ ). Its odds ratios were 2.06 and 1.47 versus the other two centres. LOS for blunt trauma (non-hip fracture) improved over time at all centres however the accreditation candidate bettered the other 2 centres on average by  $>2$  days.

*Research design: observational study*

**Office of Inspector General (1999)** concluded that Joint Commission surveys play an important role in reducing risk and fostering improvement in hospitals. The study found that Joint Commission surveys focus attention on minimum protections that are important to patients and promote projects aimed at improvement. However, it recognised that “Joint Commission surveys are unlikely to detect substandard patterns of care or individual practitioners with questionable skills ... [They] afford little opportunity for in-depth probing of hospital conditions or practices”.

*Research design: observational study*

**McGurrin and Hadley, 1991** examined the effects of accreditation status on performance indicators in psychiatric hospitals. Data from all state psychiatric hospitals in the US were collected for 1984 and 1986 and analysis was conducted on 216 hospitals. Hospitals were classified into four groups: neither JCAHO nor HCFA approval ( $n= 38$  in 1984; 33 in 1986); only JCAHO approval ( $n= 14$  in 1984; 14 in 1986); only HCFA approval ( $n=41$  in 1984; 37 in 1986); or both JCAHO and HCFA approval ( $n=123$  in 1984; 133 in 1986). The outcome measures were: average cost per patient; per diem bed cost; number of staff hours per patient; percentage of staff hours by physicians; patient turnover per bed; percentage of beds occupied. Median scores for each accreditation category were calculated. Hospitals with neither JCAHO nor HCFA had slightly lower median scores across all of the indicators than hospitals in the other categories. The study hypothesised that hospitals strive to maintain their accreditation status; and that unaccredited hospitals are motivated to improve quality of care to achieve such status. The authors conclude that their results support, albeit weakly, both hypotheses.

*Research design: observational study*

**Hadley and McGurrin, 1988** analysed data from 1983 for 216 state psychiatric hospitals to determine whether JCAHO accreditation or HCFA certification were related to seven indicators of hospital performance: average cost per patient; per diem bed cost; total staff hours per patient; clinical staff hours per patient; percentage of staff hours provided by medical staff; bed turnover; percentage of beds occupied. Hospitals were classified into four groups: neither JCAHO nor HCFA approval ( $n= 38$ ); only JCAHO approval ( $n= 14$ ); only HCFA approval ( $n=41$ ); or both JCAHO and HCFA approval ( $n=123$ ). Median values for the

indicators were compared across the four categories. Differences in median values were too small to substantiate any claim to overall superior performance or quality. The authors concluded that the relationship between accreditation status and characteristics that are often asserted to reflect quality care is weak.

*Research design: observational study*

## Specific interventions – inspection

### Background

Inspection is a mechanism of external oversight whereby teams of experts make periodic visits to a regulated organisation in order to assess its performance.

Many countries have a range of specialised inspectorates for issues such as health and safety, fire, hygiene and so on. Satisfactory inspections often result in certification or registration. This briefing focuses on those inspectorates concerned with organisational performance or quality more broadly.

Inspectorates that are focused upon such broad issues as quality and performance may vary in terms of:

- The qualification and background of inspectorial teams, i.e. professional inspectors or peer assessors on secondment from their normal job
- The pattern of inspections, i.e. routine rounds where all organisations are visited or selective visiting based on desktop monitoring; patterns of announced and/or unannounced visits
- The use of standards i.e. explicit standards to structure the visit or reliance on the judgement of inspectorial teams
- The level of analysis i.e. focus on the organisations' control systems (process) or test how that control system works in practice (outcomes)
- Relative reliance on deterrence or compliance models of regulation, where:
  - **Deterrence** models assume that regulated organisations have an overriding self interest which may lead to unacceptable behaviour. Hence regulators need to monitor them carefully and prescribe and enforce appropriate conduct. Deterrence regulators rely heavily on formal standards and inspections, and impose penalties and sanctions for non-compliance.
  - **Compliance** models on the other hand, assume that the regulated organisations are trustworthy and share the regulator's goals and objectives. Compliance regulators respond to poor performance with additional support and guidance and use sanctions and penalties only as a last resort.

(adapted from Walshe, 2003; Day & Klein, 2004)

The early years of the current UK Government saw a great deal of emphasis placed on inspection as an intervention to improve public services generally. However more recently there has been a shift towards more proportionate use of external assessment and increasing pressure to reduce the burden of regulation. A turning point in this change in approach was the release of a wide-ranging review of inspection practices by the Office of Public Services Reform (OPSR) which developed a set of principles for inspection and external review that are now used to guide policy and practice in the UK (see Box 2.6).

### The principles of inspection

1. The **purpose of improvement**. There should be an explicit concern of the part of inspectors to contribute to the improvement of the service being inspected. This should guide the focus, method, reporting and follow-up of inspection. In framing recommendations, an inspector should recognise good performance and address any failure appropriately. Inspection should aim to generate data and intelligence that enable departments more quickly to calibrate the progress of reform in their sectors and make appropriate adjustments.
2. A **focus on outcomes**, which means considering service delivery to the end users of the services rather than concentrating on internal management arrangements.
3. A **user perspective**. Inspection should be delivered with a clear focus on the experience for whom the service is provided, as well as on internal management arrangements. Inspection should encourage innovation and diversity and not be solely compliance-based.
4. **Proportionate to risk**. Over time, inspectors should modify the extent of future inspection according to the quality of performance by the service provider. For example, good performers should undergo less inspection, so that resources are concentrated on areas of greatest risk.
5. Inspectors should encourage rigorous **self-assessment** by managers. Inspectors should challenge the outcomes of managers' self-assessments, take them into account in the inspection process, and provide a comparative benchmark.
6. Inspectors should use **impartial evidence**. Evidence, whether quantitative or qualitative, should be validated and credible.
7. Inspectors should disclose the **criteria** they use to form judgements.
8. Inspectors should be **open** about their processes, willing to take any complaints seriously, and able to demonstrate a robust quality assurance process.
9. Inspectors should have regard for **value for money**, their own included:
  - Inspection looks to see that there are arrangements in place to deliver the service efficiently and effectively.
  - Inspection itself should be able to demonstrate it delivers benefits commensurate with cost, including the cost to those inspected.
  - Inspectorates should ensure that they have the capacity to work together on cross-cutting issues, in the interests of greater cost effectiveness and reducing the burden on those inspected.
10. Inspectors should **continually learn** from experience, in order to become increasingly effective. This can be done by assessing their own impact on the service provider's ability to improve and by sharing best practice with other inspectors.

#### Box 2.6: The principles of Inspection: a policy statement (OPSR, 2003)

##### What impacts effectiveness?

The impact of regulatory interventions, in general, is shaped by the interplay between factors such as: the consistency of approach adopted by individual regulators and inter-rater reliability; the perceived accuracy and robustness of regulatory decisions; the specificity and level of detail of regulatory interventions; the capacity for differential responsive regulation with different levels of performance attracting stepped levels of scrutiny and intervention; the frequency and mechanisms of interaction between regulators and those they regulate; and the enforcement mechanisms available to ensure that problematic issues are addressed.

Inevitably, there are trade-offs both between and within many of these issues. For example in the case of specificity, greater detail can increase consistency but can result in rigid and unwieldy processes. Some aspects of organisational performance are difficult to capture and codify and high specificity may compromise sensitivity. The way these trade-offs are resolved is, to a large extent, a function of the overall regulatory approach. A deterrence type inspector is more likely to have highly specific standards and favour unannounced visits or spot checks. A compliance type inspector will be more concerned with responsiveness and favour pre-arranged visits as they provide a mechanism for organisations to review and improve their own performance, thereby triggering a valuable learning process, in preparation for external review.

Focusing on inspections more specifically, there is general agreement about factors that contribute to effectiveness. They are:

- *Expertise of inspectors*: both costs and benefits are widely acknowledged to be contingent upon the technical and managerial expertise of inspectors
- *Clear goals for inspection regime*: explicit articulation of the role of the inspectorate and the methods for, and interrelationship between, direction, detection and enforcement elements
- *Balance local flexibility with national standards*: the assurance element of inspection seeks to establish a “safety net” or minimally acceptable levels .often in the form of national standards which must be reconciled with local flexibility to set meaningful improvement priorities
- *Clear goals for inspected organisations*: explicit criteria and clear standards to guide the work of inspectors
- *Proportionality* in terms of costs and risks. Are the costs of inspection providing value for money e.g. is there less scrutiny of high performing organisations where the added value of inspection may be outweighed by its costs? Are the risks of the system such as duplication of effort; excessive bureaucratic burdens and other barriers (see below) adequately managed?

(Byatt and Lyons, 2001; Boyne et al, 2002; Day and Klein, 2004)

Additionally, there are a number of factors which have been identified as being barriers to effective inspection. They include:

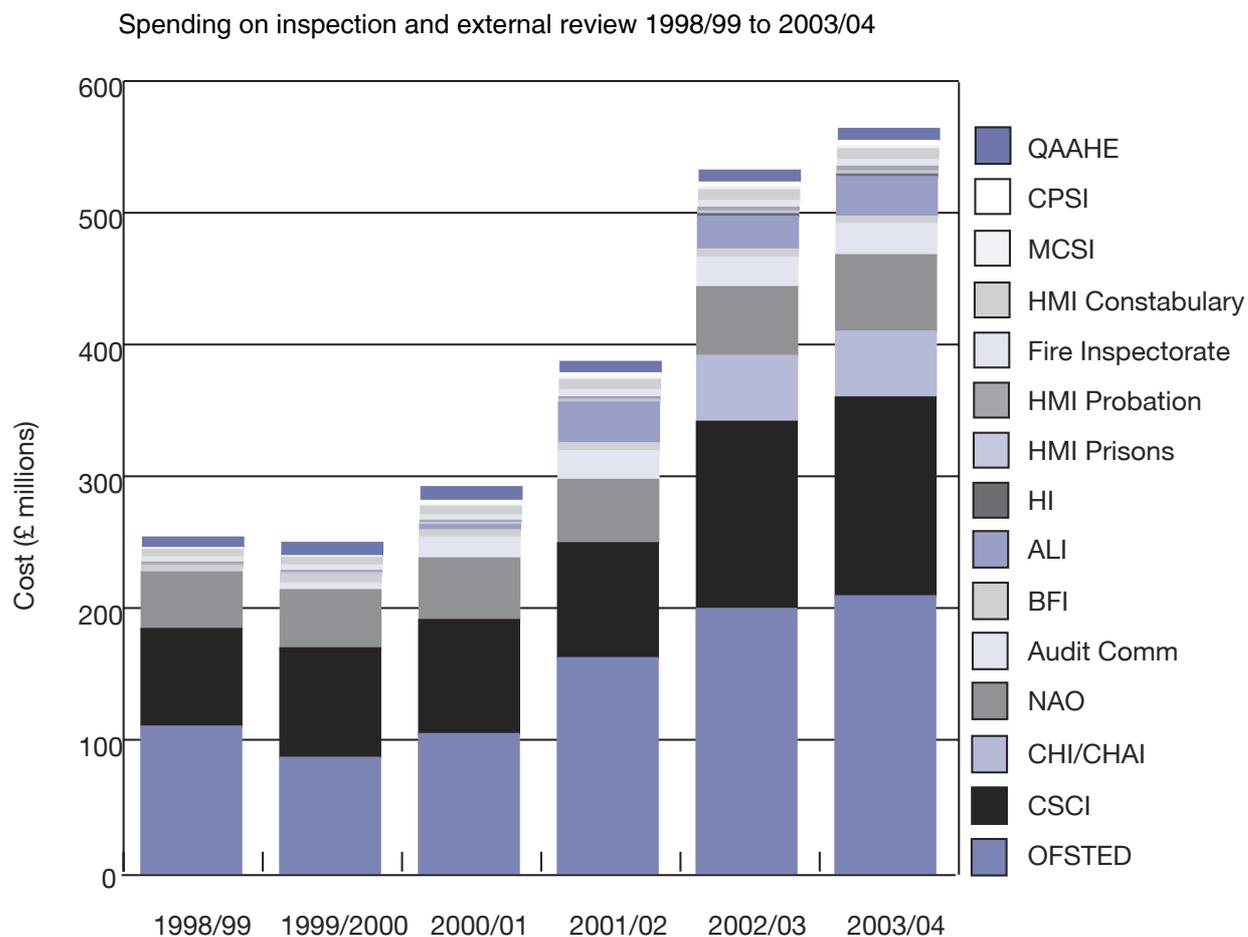
- **Resistance** – those being inspected undermine the inspection process in order to protect their autonomy.
- **Ritualistic compliance** – inspected organisations pay lip service to compliance and cooperation.
- **Regulatory capture** – inspectors identify and sympathise too closely with those they are inspecting and the capacity for independent judgement is compromised.
- **Performance ambiguity** – because concepts of quality and performance are multifaceted and contested, it may be difficult to define and measure meaningful standards, processes and outcomes.
- **Data problems** – it can be difficult for inspectors to obtain relevant and accurate information. Indeed inspected organisations may themselves lack the information.

(Power, 1997; Boyne et al, 2002)

#### Costs

There are three key dimensions to be considered in estimating costs of inspection regimes. Firstly, direct costs or the resources allocated to inspectorates themselves. As Figure 2.4 shows, spending on inspection and external review in the UK has seen a marked increase

over the last five years. External inspection across UK public services cost £550million in 2002/03, compared to £250million in 1997/98 (Martin, 2004).



Source: HM Treasury

**Figure 2.4: Spending on inspection and external review (Source: OPSM, 2003)**

Secondly, there are the indirect costs of compliance incurred by regulated organisations. There are no robust estimates for these costs however in 1999 were estimated to be at least as high as the direct costs (Hood et al, 1999). The third category of cost is that of goal displacement which occurs as inspected bodies aim to please the inspectors rather than other stakeholders – in effect refers to the opportunity cost of focusing on inspectors' concerns rather than those of other constituencies (Boyne et al, 2002).

### Evidence: inspection

There is little evidence on the impact of inspection as a generic intervention. There have been specific studies into the impact of CHI in England and the impact of external oversight in the US.

## Summary

There is some evidence to suggest that the prospect of inspection catalyses organisational efforts to measure and improve performance. Inspections rarely uncover issues that are unknown to managers, however are able to focus attention and galvanise action to address problems.

**Day & Klein 2004** conducted a three year study into the methodologies, activities and impact of England's Commission for Health Improvement which operated between 1999 and 2004. The study drew on interviews with policy-makers and CHI executives and staff; analysis of CHI reports; interviews with inspectors and trust staff; observation of meetings of the CHI and its boards (in all, 60 individual interviews and 10 group interviews – distribution not supplied). The authors are critical of CHI's inspection methodologies and describe the lack of consistency across review teams as problematic: reports varied in terms of the issues identified, presentation of evidence and in the analysis, or lack of analysis, of data. CHI's impact on the public's consciousness was judged to be minimal however interviews with trust staff indicated that CHI's main impact was in changing institutional dynamics. The prospect of an inspection prompted organisational self-examination and focused management effort on clinical governance. CHI sought to secure demonstrable improvements in the quality of care provided by trusts. Methodological problems such as the difficulties of measuring quality and attributing impact have hampered the evaluation of whether they have achieved that aim.

*Research design: observational study*

**Benson, Boyd and Walshe, 2004** examined the impact of CHI's clinical governance reviews on patient care in the NHS. The research was conducted in 30 NHS trusts which underwent CHI clinical governance reviews in 2001 or 2002, and with subsequent progress reviews in mid-2003. The authors found that CHI review reports varied greatly in structure, presentation, and specificity of their recommendations and they suggest that this reflects variation in the quality, rigour and effectiveness of the reviews and proficiency and skills of different review teams. The study revealed widespread acceptance of CHI analysis across NHS trusts although many of the issues raised by the review were known locally prior to the visit. Most of CHI's recommendations focused on systems, processes and management and very few addressed issues of quality or the nature of patient care. NHS Trust action plans which responded to CHI findings were variable in structure, presentation and level of detail. The study found that most of CHI's recommendations had been acted upon, albeit with different rates of progress. Changes that have occurred are attributed by many stakeholders to CHI's intervention. The authors suggest that external reviews are more likely to result in change and improvement if: recommendations are clearly defined and are focused on measurable and deliverable issues; if the NHS trust's action plans address the recommendations effectively and in some detail; if a relatively short timescale for action to be completed is set and; if the NHS trust has the internal capacity and capability to monitor and implement change itself. Recommendations for future policy and practice are: select organisations for

### England context: institutional regulation

The National Health Service (NHS) was established in 1948 and since that time has played a central role in British life, providing a broadly comprehensive service that is based on clinical need rather than ability to pay. The NHS serves over 50 million people in England and in year 2004-05, its total net expenditure was £69bn. The healthcare system in England is influenced by a complex regulatory environment with a number of key players including:

- *The Healthcare Commission*: is the key quality regulator in England's NHS. It has a statutory duty to assess the performance of healthcare organisations, award annual performance ratings for the NHS and coordinate reviews of healthcare by others (see below for further details).
- *Monitor*: is the financial regulator of NHS Foundation Trusts (FTs). The Healthcare Commission assesses the quality of care provided by FTs whilst Monitor assesses applicants for Foundation Trust status and, in the event of failings in standards or financial position, has the power to intervene in the running of a FT (for further details, see p 108).
- *National Institute for Health and Clinical Excellence (NICE)*: is responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health. NICE produces guidance in three areas of health:
  - public health- guidance on the promotion of good health and the prevention of ill health for those working in the NHS, local authorities and the wider public and voluntary sector
  - health technologies - guidance on the use of new and existing medicines, treatments and procedures within the NHS
  - clinical practice - guidance on the appropriate treatment and care of people with specific diseases and conditions within the NHS (for further details, see p 33).

Other organisations that have a regulatory influence on healthcare organisations include:

- National Audit Office (NAO): scrutinises public spending on behalf of Parliament. It is independent of Government.
- Audit Commission: an independent public body responsible for ensuring that public money is spent economically, efficiently, and effectively in local government, housing, health, criminal justice and fire and rescue services. It seeks to promote good practice and help those responsible for public services to achieve better outcomes for citizens.

There are also more generic regulators, e.g. those concerned with health and safety; data protection; equal opportunities; etc. across the economy.

*Healthcare Commission (HCC)*

The Healthcare Commission was launched in April 2004 with a wide ranging mandate to assess the quality and value for money of healthcare across the NHS and the independent sector, and to promote improvement for patients and the public. Its budget for 2005-06 was £80 million. Statutory functions include:

- Carrying out reviews and investigations of the provision of healthcare and the arrangements to promote and protect public health, including studies aimed at improving economy, efficiency, and effectiveness in the NHS
- Promoting the co-ordination of reviews and assessments undertaken by other bodies
- Publishing information about the state of healthcare across the NHS and the independent sector, including the results of national clinical audits
- Reviewing the quality of data relating to health and healthcare

Additional functions applied only to England include:

- Reviewing the performance of each local NHS organisation and awarding an annual rating of that organisation's performance
- Regulating the independent healthcare sector through annual registration and inspection
- Considering complaints about NHS bodies that they have not been able to resolve through their own complaints processes
- Publishing surveys of the views of patients and staff

**Box 2.7: An overview of the Healthcare Commission**

The Healthcare Commission's Corporate Plan 2004-2008 states that one of the organisation's strategic goals is to be an inspectorate that sets world-class standards (p13). It will seek to achieve this by:

- Creating an organisation in which quality assurance and improvement is central through the use of explicit and challenging targets, rigorous evaluation of organisational impact and maximisation of learning opportunities
- Researching best practice and adapting to evidence of "what works"
- Engaging patients, the public and providers of healthcare• Demonstrating commitment to equality and diversity
- Managing and using information effectively
- Demonstrating exemplary governance, ensuring that decision making is characterised by openness and accountability
- Continuously improving the organisation's value for money through rigorous financial management
- Building a workforce of skilled, motivated and committed people, supported and able to give of their best through inspiring leadership and management.

The Healthcare Commission assesses the performance of NHS organisations against a number of standards. The current Labour government has used standards and targets extensively in articulating policy. This has resulted in criticisms of over-regulation, intrusiveness and excessive micro-management of local services (Leatherman and Sutherland, 2003).

Acknowledging the problem of standard overload, the Department of Health released *National Standards, Local Action* in July 2004. It seeks to rationalise the plethora of existing standards and presents a range of core and developmental standards. Core standards define a minimally acceptable level of care whilst developmental standards are more aspirational. The document contains 24 core standards and 13 developmental standards which fall into 7 domains:

- Safety
- Clinical and cost effectiveness
- Governance
- Patient focus
- Accessible and responsive care
- Care environment and amenities
- Public Health

Box 2.8 shows an example of the NHS standards – those for clinical and cost-effectiveness.

### **NHS standards for clinical and cost effectiveness**

#### *Core standards*

- Health care organisations ensure that
  - They conform to NICE technology appraisals and, where it is available, take into account nationally agreed guidance when planning and delivering treatment and care;
  - Clinical care and treatment are carried out under supervision and leadership;
  - Clinicians continuously update skills and techniques relevant to their clinical work
  - Clinicians participate in regular clinical audit and reviews of clinical services
- Health care organisations co-operate with each other and social care organisations to ensure that patients' individual needs are properly managed and met

#### *Developmental standard*

- Patients receive effective treatment and care that:
  - Conforms to nationally agreed best practice, particularly as defined in NSFs, NICE guidance, national plans and agreed national guidance on service delivery
  - Takes into account their individual requirements and meets their physical, cultural, spiritual and psychological needs and preferences
  - Is well co-ordinated to provide a seamless service across all organisations that need to be involved, especially social care organisations
  - Is delivered by health care professionals who make clinical decisions based on evidence-based practice.

**Box 2.8: an example of NHS core and developmental standards (from Department of Health, 2004)**

**US context: institutional regulation**

Healthcare in the US exists in a highly complex regulatory environment, populated by both state and federal regulation. Compared to most other healthcare systems there is the added complexity that comes with a market based system; regulators in markets need to ensure fair trading and level playing field, and protect consumer's rights.

The US healthcare system is huge: annual health expenditure in 2003 was around \$1.6 trillion or \$5,635 per capita, more than double the OECD average (OECD Health Data, 2005). Around 44% of health spending is funded via government revenues –primarily through Medicare (for those aged ≥65 years) and Medicaid (for low income groups). In 2004 there were around 46 million people without health insurance

([http://www.census.gov/Press-Release/www/releases/archives/income\\_wealth/005647.html](http://www.census.gov/Press-Release/www/releases/archives/income_wealth/005647.html)).

The centrepiece of institutional regulation in the US is accreditation. The JCAHO model, implemented in hospitals is the best studied. The process is based on standards, an example of which is provided below.

*JCAHO Standard*

**PI.3.1.1** The organisation collects data to monitor the performance of processes that involve risks or may result in sentinel events.

*Intent of PI.3.1.1*

Organisations select processes that are known to be high-risk, high-volume, problem-prone areas related to the care and services provided. This information is correlated with the listing of frequently occurring sentinel events published by the Joint Commission, the organisation's risk-management data, or information about problem-prone processes generated by field-specific or professional organisations.

Organisations select performance measures for processes that are known to jeopardise the safety of the individuals served or associated with sentinel events in similar health care organisations. At a minimum, the organization identifies performance measures related to the following processes, as appropriate to the care and services provided:

- Medication use
- Operative and other procedures that place patients at risk
- Use of blood and blood components
- Restraint use
- Seclusion when it is part of the care or services provided
- Care or services provided to high-risk population
- Outcomes related to resuscitation
- Staffing effectiveness.

The detail and frequency of data collection have been determined and are appropriate for monitoring high-risk, problem-prone processes. Data are collected at the frequency and with the detail identified by the organisation.

The performance measure data are used to evaluate outcomes or performance of problem-prone processes. <http://www.jcrinc.com/subscribers/perspectives.asp?durki=3116&site=10&return=2897>

Although JCAHO is perhaps the best known accrediting organisation in the US, there are a number of accrediting organisations in operation (see Box 2.9)

<b>Accrediting body</b>	<b>Target areas for accreditation</b>
Joint Commission on Accreditation of Healthcare Organisations (JCAHO)	Hospitals, home health, long term care, behavioural healthcare, clinical laboratories, ambulatory care, health networks
National Committee for Quality Assurance (NCQA)	Participation is voluntary and around half of all health maintenance organisations (HMOs) (and most of the larger ones) participate in the accreditation scheme. Almost 90% of all health plans measure their performance using standardised set of quality measures (HEDIS).
American Medical Accreditation Programme (AMAP)	Physician credentials and office practices
American Accreditation HealthCare Commission/ Utilisation Review Accreditation Commission (AAHC/URAC)	Managed care organisations with an emphasis on preferred provider organisations and workers' compensation programmes)
Accreditation Association for Ambulatory HealthCare (AAAHC)	Ambulatory surgery, birthing centres, urgent care, community health centres

**Box 2.9: The main accrediting organisations in the US health care sector (adapted from Viswanathan & Salmon, 2000)**

The regulation of nursing homes in the US has been reviewed by Walshe (2001) (see Box 2.10).

### **Nursing home regulation in the US**

- In 1999, the US spent \$90 billion on nursing home care (approximately \$55,900 per resident); 60% of cost borne by states and federal government through Medicaid and Medicare programmes
- Historically, standards in nursing home care have varied widely
- Institute of Medicine released a report Improving the Quality of Long Term Care (1986), proposing radical reform of regulatory arrangements including:
  - More detailed and comprehensive standards, focusing on quality of care and rights of residents
  - Reform of inspection and survey processes, shifting emphasis to direct observation and patient feedback rather than paper records and structures
  - Introduction of broader enforcement mechanisms e.g. financial penalties, exclusion from Medicare/Medicaid
- Current regulatory framework consists of:
  - CMS (Centers for Medicare and Medicaid Services - formerly HCFA) develops federal regulations defining terms for participating in Medicaid and Medicare and oversees state agencies
  - State survey, licensing and certification agencies check compliance with regulations, investigate complaints and report to CMS
  - Problems identified are dealt with by CMS regional offices and state agencies
  - States may also have separate licensing requirements which all homes (not just Medicaid/Medicare participants) must comply with
- Evidence for improved quality since IOM report:
  - Inappropriate use of physical and chemical restraints has declined
  - Rates of urinary incontinence and catheterisation have fallen
  - Decrease in hospitalisation rates
- However, no change in pressure sore rates; malnutrition, dehydration and other feeding problems remain relatively common; and rates of bowel incontinence have risen slightly
- CMS and states spent \$382.2 million in 2000 on nursing home regulation; costs to regulated organisations are unquantified but thought to be even greater
- It is unclear whether the benefits of regulatory reform justify the costs

**Box 2.10: A brief overview of nursing home regulation in the US (adapted from Walshe, 2001)**

## 3. Professional regulation

### Definition and background

Historically, medical professionals have enjoyed significant autonomy and freedom from external control. This autonomy is based on three key features:

- Extensive and highly specialised knowledge and skills that are difficult for outsiders to comprehend or assess
- Presumptions that a strong value system is inculcated into new entrants to the profession, and promulgates appropriate behaviour
- Existence of adequate systems for the identification and rectification of aberrant performance

As a result of this autonomy, professional regulation has primarily been the preserve of an elite subset of the professions, manifested in various mechanisms of self regulation.

With the rise of better informed patients, increasing complexity in medicine, and high profile reports of poor performance – both at a routine (e.g. safety concerns raised by Institute of Medicine report *To Err is Human*) and exceptional (e.g. paediatric surgery at Bristol Royal Infirmary) level of analysis - the ability and willingness of healthcare professions to regulate themselves is no longer taken on faith. Increasingly, stakeholders outside the professions are seeking more detailed reassurance and explanation about the delivery of healthcare services. In many countries, there is movement towards more rigorous and transparent regulation, in effect reducing reliance on the professions to monitor their own quality of care and remediate cases of poor performance.

### Purpose

Professional regulation serves five key objectives:

- to improve quality of patient care
- to set standards of clinical competence for practice
- to foster continuing education and development required for professional excellence over a lifetime of practice
- to identify the competence of the individual practitioner
- to reassure patients and the public about the competence of those belonging to the healthcare professions.

### Manifestations

A range of mechanisms that have been used to regulate the healthcare professions including:

Licensure:	The granting of legal permits to practise to individuals who demonstrate appropriate levels of knowledge, skill and competence. Mandatory licensure assures minimum acceptable levels of competence.
Registration:	The compilation of a list of individuals who have satisfied an authority that they are qualified to practise. In most countries a medical register is maintained, either by state governmental departments (e.g. in Australia, the US and Canada) or professional organisations (e.g. the General Medical Council in the UK). Different registers have varying admission requirements. In the US and Canada medical school graduates take a formal licensing examination in order to

achieve registration whilst in the UK, doctors are admitted to the register upon qualification from medical school (or upon assessment if they qualified outside the UK).

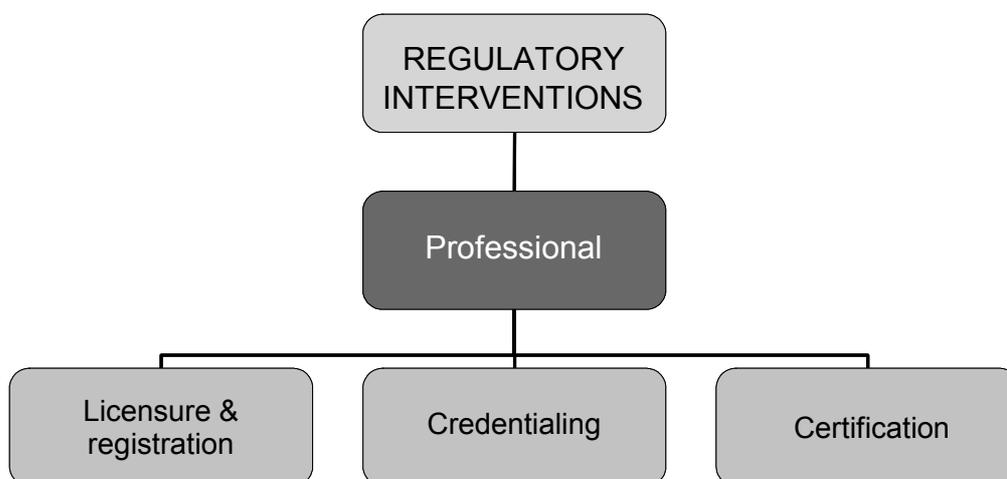
**Certification:** An acknowledgement of a pre-determined level of achievement or performance, generally recognising achievements exceeding those set as minimum acceptable standards (such as those set for licensing purposes).

**Revalidation and recertification:** Processes that require individual practitioners to maintain/collect appropriate evidence to attest to the standards of their practice and to demonstrate their continuing competence. The use of these interventions is increasing as it is acknowledged that the validity of certificates and qualifications erodes over time and that skills, knowledge and competence require periodic reaffirmation

**Credentialing:** The systematic collection, review and verification of a practitioner's professional qualifications. Often includes using patient data to attest to the clinical competence of an individual in a particular activity (e.g. specific surgical procedures). Most widely used in the US, individuals are often credentialed by their affiliated hospital(s) or clinic(s), health plans or payers.

**Privileging:** The granting of permission to perform specific professional activities under the jurisdiction of an organisation's (usually a hospital's) authority.

The available evidence focuses on three main areas: licensure and registration; credentialing; and certification (see Figure 3.1).



**Figure 3.1: A taxonomy of regulatory interventions focused on professionals**

## Search terms

“Professional regulation”	Regist*	Licen*
Credential*	Revalidation	Privileg*
Certif*	Recertif*	“Scope of practice”
“external peer review” OR visitatie	National Practitioner Data Bank	

\* truncated search term

Search terms combined with (ratio\* OR outcome\* OR performance OR quality OR data OR mortality OR empirical OR rate\*) AND (profession\* OR nurs\* OR specialty OR staff OR physician OR doctor); in Title/Abstract. For detailed search strategy, see Appendix 1.

### Evidence summary: professional regulation

There is a substantial body of evidence that indicates a positive association between specialty physician certification (as implemented in the US) and higher quality of care.

Two studies have found wide variation in the characteristics of credentialing in practice, one of which found that increased stringency in credentialing requirements was not associated with higher quality care.

Taken together, these findings suggest that professionally-led, publicly reported regulation is more effective than employer-driven regulation.

Licensure and registration, probably the mostly widely used interventions in professional regulation, have little evidence to support their effectiveness amongst the medical profession (NB no evidence does not equate with no effect). There is however strong evidence to show that within healthcare organisations, a higher proportion of registered nurses is associated with improved quality of care.

## Specific interventions – licensure and registration

### Background

Licensure is probably the most widely used intervention in professional regulation. Almost all countries have a system for controlling entry into the medical profession and have in place an official register of physicians who are licensed to practise. In a growing number of countries, licensing or registration extends to other healthcare professionals such as nurses.

The Institute of Medicine publication *To Err is Human* (2000) recommended that professional licensing bodies consider continuing qualifications over a lifetime of practice, not just at initial licensure or registration. In the UK, the General Medical Council (GMC) proposed revalidation as a mechanism to assure continued competency in medical practice. However, the revalidation process proposed by the GMC adopted a peer appraisal process as its core feature and was strongly criticised by Dame Janet Smith in the Fifth Report of the Shipman Inquiry (2004) as lacking sufficient rigour. Subsequent to those criticisms, the Department of Health undertook a wide ranging review of professional regulation in the UK and the CMO's report, *Good doctors, safer patients* (2006) lays out its current position.

A recent review of medical regulation in seven countries, Australia, Canada, Finland, France, Netherlands, New Zealand, and the US; (Allsop and Jones, 2006) found that professional

regulation generally is moving from a model dominated by pure self-regulation to one based on a partnership between state and professional bodies, with an associated increase in the transparency of regulatory processes. This shift has increased the accountability of regulatory bodies; and has encouraged lay involvement in oversight functions. Concurrently, there are discernible moves towards ongoing assessments of competence. The authors note however that there is little information on costs and on whom they fall.

Despite the international prevalence of physician licensure, there is little evidence about its impact on quality of care Brennan (1998) asserts that there is no evidence that the US boards of registration affect quality of care. He states that in 1995, fewer than 300 disciplinary actions were taken in response to poor quality care (from 600,000 qualified doctors; or 0.05%).

Although it is difficult to assess the number of licensed physicians who provide poor quality care, some broad indication can be gleaned from incidence of serious error (98,000 deaths caused by medical error annually) or litigation activity (around a million cases filed annually). These figures should be interpreted with care however as isolated errors do not equate with consistently substandard performance; and adverse events are often grounded in system rather than individual shortcomings.

There are a number of studies focusing on nursing staff that indicate a correlation between a higher proportion of licensed or registered nurses and higher quality of care. This area is complex however, as licensed or registered nursing staff receive higher levels of training and are not direct substitutes for unlicensed or unregistered staff. The issue may be seen more as one of skill mix rather than regulation of quality.

### **Evidence: licensure and registration**

#### **Summary**

Available research is dominated by the association between quality of care and the concentration of nursing care provided by registered nurses. There is a considerable body of evidence to suggest that a higher proportion of registered nurses is associated with improved patient outcomes although there are diminishing marginal returns to increased registered nurse levels.

**Lankshear et al 2005** conducted a systematic review of research evidence, published between 1990 and 2004, on the relationship between nursing workforce and patient outcomes in the acute healthcare sector. Only studies that made adjustments for case mix were included, resulting in 22 studies. Research designs were predominantly cross sectional analysis of large administrative data sets. A higher proportion of registered nurses was associated with improved patient outcomes although the improvement tailed off at higher RN levels (absolute and percentages) indicating diminishing marginal returns to increased registered nurse levels.

*Research design: systematic review*

**Tourangeau et al 2006** conducted a review of studies concerned with the impact of nursing on patient mortality. One focus area was the nursing staff mix, defined as the proportion of nursing care provided by registered nurses within all nursing care provided. Ten relevant studies were reviewed; seven of which found that a higher registered nurse staff mix was related to lower patient mortality.

*Research design: literature synthesis*

**Needleman et al 2006** in a simulation study found that increasing the proportion of nursing hours provided by registered nurses reduces length of stay, adverse outcomes and patient deaths. Data was drawn from an earlier regression analysis (see Needleman, 2002 below) investigating the association between nursing staff and various quality measures. The study simulated the effect of three options:

1. raise the proportion of hours provided by registered nurses to the 75th percentile
2. raise the number of licensed (i.e. registered nurses and licensed practical/vocational nurses) nursing hours per day to the 75th percentile
3. raise staffing to both these levels.

The study found that all options would improve the quality of care and that the first option, raising the proportion of care provided by registered nurses without increasing total nursing hours, would be associated with a net reduction in costs and better outcomes of care.

*Research design: simulation study based on observational data*

**Needleman, et al 2002** investigated the relationship between the proportion of hours of nursing care provided by registered nurses and patient outcomes. Data on hospital discharges and staffing levels were collected from 799 hospitals in 11 states for 1997. (Represents records for 5,075,969 medical patients and 1,104,659 surgical patients). Patient outcomes included: length of stay; urinary tract infections (UTIs); pressure ulcers; hospital-acquired pneumonia; shock or cardiac arrest; upper gastrointestinal (GI) bleed; hospital-acquired sepsis; deep venous thrombosis; central nervous system complications; in-hospital death; failure to rescue; wound infection; pulmonary failure; and metabolic derangement. Among medical patients, a higher proportion of hours of care per day provided by registered nurses and a greater absolute number of hours provided by registered nurses were associated with a shorter length of stay ( $P=0.01$  and  $P<0.001$ , respectively) and lower rates of both UTIs ( $P<0.001$  and  $P=0.003$ ) and upper GI bleeding ( $P=0.03$  and  $P=0.007$ ). A higher proportion of hours of care provided by registered nurses was also associated with lower rates of pneumonia ( $P=0.001$ ), shock or cardiac arrest ( $P=0.007$ ), and failure to rescue ( $P=0.05$ ). Among surgical patients, a higher proportion of care provided by registered nurses was associated with lower rates of UTI ( $P=0.04$ ), and a greater number of hours of care per day provided by registered nurses was associated with lower rates of failure to rescue ( $P=0.008$ ).

*(study included in Lankshear's systematic review but is listed here as context for Needleman et al, 2006)*

*Research design: observational study*

## Specific interventions – credentialing

### Background

*Credentialing is the systematic approach to the collection, review and verification of a practitioner's professional qualifications* (Freed et al, 2006: 913). It is carried out by employing organisations, most commonly hospitals or health plans, in the US to select and retain competent clinicians who will deliver high quality care. Credentialing is often used alongside privileging, which is a process conducted by healthcare providers, whereby clinicians are granted permission to undertake specific procedures and activities. Both credentialing and privileging frequently draw on a clinician's certification status as part of their assessment (Cassel & Holmboe, 2006).

In the US, the National Practitioner Data Bank (NPDB) was established in 1990 to receive, store and disseminate information on malpractice payments and disciplinary sanctions against healthcare practitioners. Hospitals are required to report all sanctions to the NPDB, and to query it when credentialing or recredentialing physicians. However, an evaluation of the NPDB between 1991 and 1995 found a "low and diminishing level" of hospital privileging action reported to NPDB (Baldwin et al, 1999); and a more recent study found that between 60 – 75% of reportable actions were not reported to the NPDB (Waters et al, 2006), undermining the utility and validity of the data bank.

### Evidence: credentialing

#### Summary

Credentialing is a process performed by employing organisations and is subject to considerable variability in its implementation. There are few studies that examine its effectiveness in improving quality of care. One available study suggests that the stringency of credentialing is not related to surgical outcomes.

**Sharma et al 2005** conducted a postal survey of credentialing practices in Gastrointestinal Endoscopy Centres in the US in 2000. Completed surveys were received from 479 respondents in 46 states (response rate not calculated due to lack of denominator – no registry or database of GI endoscopy centres). Sixty percent of respondents reported that their organisation had no requirement for a minimum number of supervised procedures for initial credentialing and only 10% met American Society for Gastrointestinal Endoscopy (ASGE) criteria; more than two thirds of centres had no minimum requirements for maintenance of credentials. 20% of centres reported denying endoscopic privileges.

*Research design: observational study*

**Sloan, Conover and Provenzale (2000)** assessed whether there was an association between hospital credentialing practices and surgical outcomes in North Carolina hospitals in 1996. Credentialing practices were collected by postal survey from 85 hospitals and corresponding outcome data collected for laparoscopic cholecystectomy, open cholecystectomy, hysterectomy, intestinal operations, stomach operations and total hip replacement. Outcome measures were: death; surgical and medical complications; and elevated length of stay. A series of credentialing procedures were analysed individually and as a composite "stringency" rating (developed by summing the number of requirements at each hospital).

They were:

- board eligibility or certification or equivalent experience required for appointment
- investigation of complaints to Medical Board when considering appointing a physician
- whether any of the following were sometimes imposed for granting clinical privileging:
  - consultation before procedure can be done
  - assistants used for certain procedures
  - supervision of certain procedures
- review of measures of clinical competence such as complication rates prior to reappointment of the physician
- routine system to alert administrators of frequent adverse outcomes (e.g. hospital acquired infection, post operative mortality, high readmission rates) AND the hospital employed dedicated staff to monitor these indicators
- mortality and morbidity requirements for surgical staff
- external chart reviews
- length of time taken to initiate a formal investigation of an individual report
- business plan contains operationalised quality of care objectives. The multivariate analysis controlled for patient demographics, type of admission, severity of illness and hospital characteristics. Teaching hospitals adopted more stringent credentialing practices. Surgical outcomes typically were not related to stringency of the hospital credentialing environment. The effect of specific practices was inconsistent or counterintuitive.

*Research design: observational study*

## Specific interventions – certification

### Background

Certification is most widely used in the US. It is a process where physicians can demonstrate achievements and competencies that are beyond the minimum acceptable standards that are required for licensing purposes.

The American Board of Medical Specialties (ABMS) is the umbrella organisation for the 24 approved specialty boards which manage certification and recertification (known as Maintenance of Certification or MOC) processes. In 2002 more than 85% of licensed physicians held a valid certificate (Horowitz et al, 2004). Requirements for initial certification are:

- 3-6 years (depending on specialty) of training in an accredited training programme
- Passing score on rigorous cognitive examination
- Various combinations of
  - Satisfactory programme director evaluations on six competencies (patient care, medical knowledge, practice-based learning and improvement, interpersonal and communications skills, professionalism, and systems-based practice)
  - Oral examinations
  - Audits of medical records
  - Review of case logs
  - Observed performance on real or standardised patients (Brennan et al, 2004)

### *Maintenance of certification*

There is a significant body of evidence to suggest that over time, the skills and knowledge of medical professionals erode with potentially serious consequences for quality of care (Choudhry et al, 2005; Cassel and Holmboe, 2006). In response, the ABMS developed the MOC programme. MOC requires specialists to demonstrate evidence of:

1. professional standing
2. commitment to lifelong learning and involvement in periodic self-assessment
3. cognitive expertise (e.g. performance in a standardised examination)
4. evaluation of performance in clinical practice.

### **Evidence: certification**

The literature has two main bodies of evidence about the interplay between certification and performance:

1. Correlation of certification status with patient outcomes
2. Correlation of certification status with other measures of quality (particularly disciplinary action)

## Summary

A substantial amount of evidence links certification status with improved quality of care. Multiple studies have found: an association between certification status of physicians and better patient outcomes and; an association between a lack of certification and the receipt of disciplinary action.

### 1. Correlation of certification status with patient outcomes

Numerous observational studies, conducted over a considerable period of time and in a range of contexts, have found an association between certification and improved performance.

**Sharp et al (2002)** conducted a systematic review of evidence regarding the link between specialty board certification and clinical outcomes. It included literature published between 1966 and 1999. Overall, the methodological quality of studies was poor with only 5% of studies adjudged satisfactory. Of those with robust methodology (29 findings in 11 papers), over half (16) demonstrated positive and statistically significant associations between certification status and superior outcomes.

*Research design: systematic review, no independent assessment found*

Sharp et al's systematic review covered publications up until 1999. Since then, there have been a number of studies which have corroborated the association between certification and performance.

**Chen et al, 2006** evaluated whether care provided by board-certified physicians was associated with greater compliance with clinical guideline recommended therapies and lower 30-day mortality in the treatment of patients with AMI (acute myocardial infarction or heart attack). The study drew on data from 101,251 patients hospitalised between January 1994 and February 1996 as part of the Cooperative Cardiovascular Project (CCP) which comprised a national cohort of elderly patients ( $\geq 65$  yrs) hospitalised with AMI. Quality of care measures were aspirin at admission, aspirin at discharge,  $\beta$ -blockers at admission,  $\beta$ -blockers at discharge (for patients without documented contra-indications); and 30 day mortality. Physicians who were board-certified in family practice, internal medicine, or cardiology provided better quality of care and were modestly more likely to prescribe aspirin and  $\beta$ -blockers than non-certified physicians:

	Board certified	Non-certified	P value
<b>FAMILY PRACTITIONERS</b>			
Aspirin at admission	51.1%	46.0%	<0.001
Aspirin at discharge	72.2%	63.9%	<0.001
$\beta$ -blockers at admission	44.1%	37.1%	<0.001
$\beta$ -blockers at discharge	46.2%	38.7%	0.001
30 day mortality	19.9%	21.8%	0.02
<b>INTERNISTS</b>			
Aspirin at admission	53.7%	49.6%	<0.001
Aspirin at discharge	78.2%	68.8%	<0.001
$\beta$ -blockers at admission	48.9%	44.1%	<0.001

	Board certified	Non-certified	P value
β-blockers at discharge	51.2%	47.1%	0.001
30 day mortality	19.4%	19.8%	0.46
CARDIOLOGISTS			
Aspirin at admission	61.3%	52.1%	<0.001
Aspirin at discharge	82.2%	71.5%	<0.001
β-blockers at admission	52.9%	41.5%	<0.001
β-blockers at discharge	54.7%	42.5%	<0.001
30 day mortality	16.2%	17.9%	0.001

Multivariate analyses adjusting for patient, hospital and physician characteristics found no significant difference between certified and non-certified family practitioners. However, patients of board certified internists continued to be more likely to receive aspirin at admission (risk ratio RR= 1.04; CI 1.01-1.07); aspirin at discharge (RR= 1.05; CI 1.06-1.11); β-blockers at admission (RR= 1.06; CI 1.02-1.10). Board certification was not associated with significant differences in 30-day mortality.

*Research design: observational study*

**Lipner et al 2006** report the results of a postal survey that sought to ascertain the profile of physicians who maintain certification in internal medicine, and the motivating factors for doing so. The Maintenance of Certification (MOC) participation rates for the American Board of Internal Medicine (ABIM) indicate that 23% of general internists and 14% of subspecialists choose not to renew their respective certificates. A representative sample of 3500 physicians initially certified in internal medicine, a subspecialty or an area of added qualifications in 1990, 1991 or 1992 was surveyed. There were 1799 respondents, a 51% response rate. Of those still working in internal medicine, around half reported that they are required to maintain their certificate by at least one employer. Over half of those participating in the MOC programme indicated that they did so in order to maintain or improve their professional image or to update knowledge; slightly fewer than half indicated that their participation was motivated by a desire to improve the quality of patient care or quality; and around 10% reported participating for direct monetary benefits. Of those not participating in the MOC programme, the most common reasons given were that it required too great a commitment of time (~30%); was too expensive (~30%); and the lack of employer requirements (~30%).

*Research design: observational study*

**Miller et al 2004** examined whether certification of general practitioners in Australia was associated with clinical performance. The study was conducted in 2000-2002, following the mandatory requirement of certification before entry into general practice in 1995. Subjects consisted of a random sample of 1982 GPs. Of 1975 GPs who indicated certification status, 659 (33.4%) were certified. Data was drawn from an Australian cross sectional patient encounter survey (Bettering the Evaluation and Care of Health - BEACH) and included 65,900 encounters with certified and 131,600 encounters with non-certified GPs. Comparisons were made using 34 indicators of care; 5 were significantly better in certified GPs after adjustment for GP/practice, patient and morbidity differences. Certified GPs had longer consultations (15.3 vs 14.9 minutes), performed more therapeutic procedures,

prescribed less overall and, more specifically, fewer antibiotics for upper respiratory tract infections and fewer NSAIDs in the elderly. However, certified GPs were less likely to detect and manage depression than non-certified GPs. Certified GPs were more likely to be: female, younger, Australian graduates, working fewer sessions, in larger practices, in accredited practices and using computers for clinical purposes.

*Research design: observational study*

**Silber et al (2002)** compared the outcomes of patients in Pennsylvania who underwent surgical procedures under the care of certified and non-certified anaesthesiologists. Data was collected from Medicare claims records for 144,883 patients aged  $\geq 65$  years who underwent general surgical or orthopaedic procedures between 1991 and 1994. The outcome measures were mortality within 30 days of admission, and failure-to-rescue rate (death after an in-hospital complication). Data were adjusted to account for case mix, patient severity and hospital characteristics. Outcomes from 8,894 cases involving midcareer anaesthesiologists (11-25 yr from medical school graduation) who lacked board certification were compared with all other cases. Non-certified mid career anaesthesiologists had higher mortality rates (OR 1.13; 95% CI 1.00-1.26;  $P < 0.04$ ) and failure to rescue rates (OR 1.13, 95% CI, 1.01-1.27;  $P < 0.04$ ) than other anaesthesiologists. The mortality effect in the non-certified mid career group was estimated to be up to 3.8 excess deaths per 1000 cases. However it was not possible to determine whether the poor performance of non-certified anaesthesiologists was a result of the type of hospital in which they practised.

*Research design: observational study*

**Prystowsky et al 2002** examined patient outcomes for colon resection to determine whether they varied according to certification status of the surgeon. Research design was a retrospective study of 15,247 patients from Illinois, with a primary operation of segmental colon resection performed by one of 514 surgeons between 1994 and 1997 at 76 non-federal hospitals. Main outcome measures were inpatient mortality, complication rate and length of stay. Data were risk adjusted. American Board of Surgery (ABS) certification was associated with reduced mortality and morbidity (non-ABS certified vs certified: mortality OR 1.4; 95% CI 1.1-1.9; complications OR 1.2, 95% CI 1.0-1.4.  $p < 0.05$  for both). Increasing years of experience was associated with reduced mortality; sub-specialty certification in colorectal surgery did not significantly affect outcomes.

*Research design: observational study*

**Tamblin et al (2002)** conducted a study of family physicians in Quebec to investigate whether:

- a. there was a sustained relationship (4-7 years) between certification examination scores and performance
- b. licensing examinations taken at the end of medical school are predictive of future performance

Subjects were 912 practising physicians who passed the Quebec family medicine certification examination (QLEX) between 1990 and 1993. QLEX is a mandatory requirement for practice. For each physician, claims files derived from health administration databases were used to identify all patients seen between licensure date and the end of 1996. Indicators of practice performance were mammography screening rate; continuity of care; differences between disease-specific and symptom-relief prescribing (as measure of diagnostic competence); contraindicated prescribing rate; and consultation rate. Data were

case-mix adjusted. Physicians with higher scores in certification examinations had higher rates of mammography screening ( $\beta = 16.8$ ; 95% CI, 8.7-24.9) and consultation rates ( $\beta = 4.9$ ; 95% CI, 2.1-7.8). Higher subscores in diagnosis were predictive of greater differences between disease specific and symptom-relief prescribing ( $\beta = 3.9$ , 95% CI, 0.9 – 7.0). For the licensing examinations, physicians with higher scores had higher rates of mammography screening ( $\beta = 17.4$ ; 95% CI, 10.6 – 24.1) and consultation rates ( $\beta = 2.9$ ; 95% CI, 0.4-5.4); higher subscores in diagnosis were predictive of greater differences between disease specific and symptom-relief prescribing ( $\beta = 3.8$ , 95% CI, 0.3 – 7.3); and higher scores for drug knowledge were predictive of a lower rate of contraindicated prescribing (Relative risk 0.88; 95% CI 0.77 – 1.00). Relationships between examination scores and practice performance were sustained through the first 4 to 7 years in practice.

*Research design: observational study*

**Norcini et al 2002** investigated whether certification of doctors was associated with patient mortality and length of stay following acute myocardial infarct (AMI or heart attack). The study drew on administrative and clinical data from Pennsylvania in 1993 and included data from 16,629 hospitalisations and 2277 doctors. A linear regression model was applied to mortality data using generalised estimating equations methodology (GEE). Holding other variables constant, certification in internal medicine or cardiology was associated with a 19% reduction in mortality. There was no association between shorter stays and certification.

*Research design: observational study*

**Norcini et al 2001** examined whether the certification status of generalist physicians affected the mortality rates of acute myocardial infarct (AMI or heart attack) patients. The study drew on administrative and clinical data from Pennsylvania in 1993 and included data from 18,943 patients and 3,760 doctors. A linear regression model using generalised estimating equations (GEE) methodology found that physician certification was associated with a 15% reduction in mortality.

*Research design: observational study*

**Norcini et al, 2000** studied outcomes from acute myocardial infarct (AMI or heart attack) for an association with certification status, comparing cardiologists, internists and family practitioners. The study drew on administrative and clinical data from Pennsylvania in 1993 and included data from 28,756 patients and 4,546 doctors. A regression model was applied using mortality as the dependent variable with probability of death, hospital characteristics (location and availability of advanced cardiac care) and physician characteristics (patient volume, years since graduation, specialty and certification status) as the dependent variables. Holding all other variables constant, treatment by a certified physician was associated with a 15% reduction in mortality. Lower mortality was associated with cardiologist-provided care, higher volumes, and fewer years since graduation from medical school.

*Research design: observational study*

## 2. Correlation of certification with disciplinary action

Within the UK (Donaldson, 1994) and internationally (Lens and van der Wal, 1997) studies have found the prevalence of problem doctors (defined as physicians with recurrent problems in functioning) to be around 5-6%. Four studies in three US states have found an association between lack of certification and disciplinary action. Khaliq et al, (2005) examined the characteristics of disciplined doctors in Oklahoma using publicly available

data issued by the Oklahoma Board of Medical Licensure and Supervision. Of 14,314 currently or previously licensed physicians, 396 (2.8%) had been disciplined. Using univariate proportional hazard analysis non board certified physicians were at greater risk of being disciplined (hazard ratio 3.3;  $P < 0.001$ ).

*Research design: observational study*

**Kohatsu et al, 2004** conducted an unmatched case controlled study of 890 physicians disciplined by the Medical Board of California between 1998 and 2001, compared with 2981 randomly selected, non-disciplined controls. The study found that lack of certification was associated with an increased risk of disciplinary action (OR, 2.22;  $P < 0.001$ ). Other characteristics were also found to be associated with physician discipline.

*Research design: observational study (case control)*

**Clay & Conatser, 2003** investigated the characteristics of physicians disciplined by the State Medical Board of Ohio between January 1997 and June 1999. There were 308 physicians publicly disciplined and these were matched by two groups of control physicians, one matched by location only and the second matched for location, gender, practice type, and self designated specialty. Compared with the second group of controls, offenders were significantly less likely to be board certified (OR 0.65, 95% CI 0.46-0.92;  $P < 0.05$ ).

*Research design: observational study (case control)*

**Morrison & Wickersham, 1998** studied the characteristics of physicians disciplined by the California State Medical Board between 1995 and 1997. The study drew on data collected by the board on disciplined physicians, matching 375 disciplined physicians with two groups of control physicians (one matched by location and a second matched for sex, type of practice and locale). The study found that when controlling for sex, type of practice and locale, disciplinary action was negatively associated with specialty board certification (i.e. certified physicians were less likely to be disciplined OR 0.42; 95% CI, 0.29-0.60).

*Research design: observational study (case control)*

### **England context – professional regulation**

In England, concerns re quality of care and the reliability of professional self-regulation came to the fore with a series of highly publicised cases of poor performance (e.g. Bristol paediatric cardiac surgery, the case of Rodney Ledward) and criminal behaviour (e.g. the case of Harold Shipman).

Historically doctors were admitted to the medical register, administered by the General Medical Council (GMC), on qualification (or on assessment if they qualified from outside the UK). No further checks were made unless the doctor's performance gave cause for concern that led to a referral to "fitness to practise" procedures.

In the face of growing unease about the profession's regulatory procedures, the GMC introduced new performance procedures in tandem with the publication of Good Medical Practice in 1998. These procedures meant that for the first time it was possible for the registration of a doctor to be restricted or removed not only on the grounds of poor conduct or ill health but also because of poor performance. Said to have signalled a revolution in the regulation of British medical practice (McManus et al, 2000), Good Medical Practice

defines what constitutes quality medical care against which the performance of a doctor can be judged. The soon to be updated 2001 edition of Good Medical Practice specifies sixty standards of required behaviour

Alongside the definition of good practice, the GMC developed the idea of revalidation. The objective of revalidation was to reassure the public that doctors continued to practise medicine to a high standard throughout their careers and was touted as a “MOT for doctors” – a claim that has since been challenged. Whilst the aims of revalidation were widely supported, the GMC proposals for implementation – i.e. revalidation based on a formative appraisal process - were not (Smith, J, 2004). The Department of Health subsequently undertook a review of medical regulation, and released a report, *Good doctors, safer patients* in July 2006.

*Good doctors, safer patients* (DH, 2006) outlined proposals to strengthen the system of medical regulation and makes 44 recommendations, including:

- the development of a clear, unambiguous set of standards for generic medical practice, and for each area of specialist medical practice, providing an operational definition of a “good doctor”
- the adoption of a two-component model of revalidation, the renewal of a doctor’s license to practise (or relicensure); and for those on specialist registers a recertification process. The emphasis in both elements should be a positive affirmation of the doctor’s entitlement to practise, not the absence of concerns.
- Specialist certification should be renewed at regular intervals of no longer than five years

#### *Wider health professions regulation*

Across the healthcare system, the domain of professional regulation is densely populated both with interventions (licensing, re-licensing, registration, appraisal, qualification and revalidation) and organisations, with the attendant problems of duplication of effort and conflict between different approaches. In an attempt to address such concerns the Council for the Regulation of Healthcare Professionals was created.

The Council for Healthcare Regulatory Excellence (formerly Council for the Regulation of Healthcare Professionals) was established in April 2003 as a response to concerns about the adequacy of self regulation by the health professions. It is a statutory body, covering all of the UK and aims to promote best practice and consistency in the regulation of healthcare professionals. It oversees nine regulatory bodies:

- General Medical Council
- General Dental Council
- General Optical Council
- General Osteopathic Council
- General Chiropractic Council
- Health Professions Council
- Nursing and Midwifery Council
- Royal Pharmaceutical Society of Great Britain
- Pharmaceutical Society of Northern Ireland

Its functions are to:

- Promote the interests of patients and the public in the regulation of health professionals
- Promote best practice in professionally-led regulation
- Report annually to Parliament on its work
- Promote co-operation and consistency across the health professional regulation arena
- Develop principles of good regulation
- Advise Ministers on professional regulation issues

It may also:

- Refer a regulator's final decision on a "fitness to practise" case to the High Court (or its equivalent) for the protection of the public
- Order a regulator to change its rules (although this requires the permission of both Houses of Parliament)

In 2006b, the Department of Health released *The regulation of the non-medical healthcare professions*. It concluded that:

- an integrated and consistent framework of regulation across the different professions should be adopted
- a revalidation system that is both formative (an aid to development) and summative (a check that a required standard is met) is necessary for all professionals.

### **US context – professional regulation**

In the US, in order to practise medicine, doctors must be licensed by their State Medical Board (see Box 3.1). The States use licensure and "scope-of-practice" acts to ensure that all practising physicians have appropriate education and training, to specify the type of care that a particular professional can provide, and to maintain standards of professional conduct. Applicants must submit proof of prior education and training and provide details about their work history. Candidates for licensure must also complete a rigorous examination, designed to assess a physician's ability to apply knowledge, concepts and principles that are important in health and disease and that constitute the basis of safe and effective patient care. The applicant must reveal information regarding past medical history (including the use of habit-forming drugs, emotional or mental illness), arrests and convictions.

After physicians are licensed in a given state, they must re-register periodically to continue their active status. During this re-registration process, physicians are required to demonstrate that they have maintained acceptable standards of ethics and medical practice, and have not engaged in improper conduct. In some states, physicians must also show they have participated in a programme of continuing medical education (Institute of Medicine, 2001).

**State Medical Boards**

US medical practice in the early twentieth century was largely unregulated, with multiple efforts underway to manage physician examining and licensing. In 1912, the National Confederation of State Medical Examining and Licensing Boards and the American Confederation of Reciprocating Examining and Licensing Boards merged to form the Federation of State Medical Boards of the United States, Inc. (FSMB). The FSMB sought to define the scope of medical practice and improve licensure methods. In the early 1950's, the FSMB established grievance committees to address consumer complaints. The FSMB's primary aim is "to protect consumers of health care through proper licensing and regulation of physicians and, in some jurisdictions, other health care professionals." The FSMB has 70 member boards (in the 50 states and the territories, and 13 state boards of osteopathic medicine), composed of volunteer physicians and non-physician citizens. All boards have licensing authority, but they vary in degree of autonomy, ranging from full independence to control licensure matters, to interdependence with other entities, such as State Departments of Health. They also determine whether it is necessary to modify, suspend, or revoke the license to practice medicine. The boards review consumer complaints, malpractice data, government reports, and hospital/health care institution information.

**Box 3.1: State Medical Boards in the US**

## 4. Market regulation

### Definition and background

It is widely accepted that there is a positive relationship between competition and performance in the production and distribution of goods and services. That relationship is founded on the premise that competition promotes efficiency, innovation and consumer responsiveness. However the efficiency of markets is compromised by a number of factors, including:

- *Asymmetric information* which occurs when one party to a transaction has more or better information than the other party
- *Externalities* or the costs or benefits arising from an economic activity that affect somebody other than those directly engaged in the activity that are not fully reflected in prices e.g. costs to society of failing to treat communicable disease.

In health, there are added complexities such as the inequitable outcomes that may result. These outcomes may be morally unacceptable to society, e.g. high mortality rates amongst those who cannot afford healthcare.

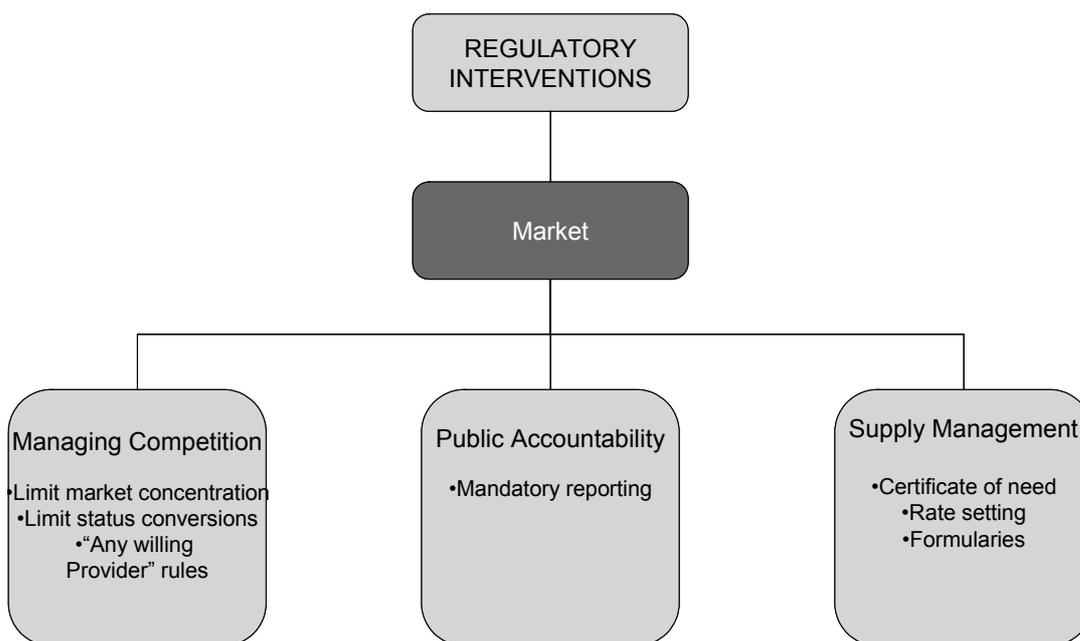
### Purpose

Where there are market imperfections, regulation is required. Public policy is acknowledged to be a major force that influences local healthcare markets (Solomon, 1998; Katz and Thompson, 1996; Robinson and Luft, 1988). In practice regulatory interventions in healthcare markets are used to address a range of issues including choice, quality, and supplier-induced demand; and to protect, as far as is possible, fair competition and assure a “level playing field” for providers.

### Manifestations

- |                        |   |
|------------------------|---|
| Managing competition:  | regulators act to ensure a “level playing field”; and to allow market forces to deliver efficiency by limiting concentration of power in monopolies or cartels  |
| Patient protection:    | regulators protect the patient or consumer in assessing quality of services; ensuring that robust grievance and appeals procedures are in place; protecting confidential patient data; financial solvency requirements  |
| Public accountability: | regulators ensure that consumers are able to choose from among the healthcare options available in accordance with their expectations concerning cost, outcomes, and quality. In order to make such choices, consumers require accurate information is about healthcare services. For such choices to be the organising principle of the healthcare system, providers must be held accountable for the services they deliver.                         |
| Supply management:     | Asymmetric information means that providers of healthcare often better informed about the prognosis and effective treatments than patients. A consequence of this situation is that there are incentives for providers to give unnecessary care, escalating healthcare expenditures. Regulatory mechanisms that seek to address this situation include: Certificate of need; Pharmacy formularies; Reimbursement policies, particularly rate-setting. |

The available evidence is focused in three of these areas (see Figure 4.1).



**Figure 4.1: The evidence on the impact of market regulation on quality: a typology**

**Format**

Our review of interventions focused on regulating markets follows the model used in earlier sections where the research evidence detailing impact on quality of care is placed in context with an introductory background description. In the case of market regulation, much of the available empirical research is concerned with either: the financial consequences of regulation rather than its impact on quality; or with making a case for regulation (e.g. quality consequences of mergers and acquisitions) rather than examining the effects of regulatory interventions themselves. The introductory sections preceding the evidence review for each intervention briefly reviews both the evidence available on financial consequences and that collated to argue for regulation.

**Search terms**

Market AND regulat*	Rate-setting	“Length of stay requirement”
Antitrust	Market entry	Supply AND market
Merger	Market exit	Data protection
Price control	Gag rules	Mandated benefits
Reserve requirement	Safety net	Conversion AND (hospital OR profit OR ownership)
Grievance OR appeal	Financial reporting	Subsid*
governance	formulary	“Any willing provider”
(Compulsory OR mandatory) AND reporting	Certificate of need	

\* truncated search term Search terms combined with (ratio\* OR outcome\* OR performance OR quality OR data OR mortality OR empirical OR rate\*). For detailed search strategy, see Appendix 1.

### **Evidence summary: market regulation**

There is a substantial body of literature on various regulatory interventions in healthcare markets. However the evidence on the impact of market regulation is relatively sparse. Much of the available empirical research is concerned with why regulation is required, rather than evaluating the impact of regulation post implementation. In terms of the effect of regulatory interventions on quality, the findings are summarised below.

#### *Managing competition*

- One study found that regulatory interventions seeking to limit mergers and acquisitions did dampen market consolidation but this may have prevented non-viable units from merging and contributed to their demise, with implications for access to care.
- Conversions from non-profit or public hospitals to for-profit in the US have had consequences for quality. There is some evidence that regulation can dampen conversion activity however the role that regulation has played in limiting undesirable consequences of conversions is unknown. A number of studies examine provision of uncompensated care for low income and uninsured patients following hospital conversion. Results predominantly show that hospitals that have converted from public to for-profit status provide lower levels of uncompensated care. Conversions to for-profit status were associated with higher mortality rates by one study; and with higher rates of pneumonia complications by another.
- “Any willing provider” laws, ensure access to the healthcare market for all providers. One study suggests that greater diversity in pharmacy markets resulting from AWP laws, may improve prescription compliance and reduce inpatient admissions.

#### *Accountability*

- Evidence emanating from New York suggests that mandatory reporting of performance in the field of cardiac surgery can have a positive effect on quality of care. There are survey data to suggest that mandatory reporting and public disclosure can have unintended consequences, e.g. discouraging treatment of high risk patients; and meets with some resistance from hospital executives and clinicians.

#### *Managing Supply*

- Certificate of need regulation as applied to general hospital services has not been successful in curtailing overall expenditure. One study found that more stringent CON regulations were associated with higher mortality rates although this has not been replicated. Used as a tool to ensure minimum volumes of cardiac surgery, CON has been associated with lower mortality rates in a multistate study.
- The evidence on the impact of rate-setting on mortality rates is mixed: two studies found that rate regulation did not have an adverse effect on patient mortality or population mortality, despite lower admission rates; one found a statistically significant, although small, association between mortality rates and the stringency of rate regulation; whilst another found mortality rates decreased more slowly in states with rate setting but found no correlation between mortality rates and level of cost savings. The discontinuation of rate setting, in favour of a price competition model, has been associated with an increase in relative mortality rates for some conditions. In terms of impact on the diffusion of innovations, rate-setting does not appear to hamper the adoption of cost increasing technologies but can temper excessive use and duplication of services.
- There is little robust evidence available on the impact of formularies on quality

of care. A literature review noted a deleterious effect of formularies on patient outcomes but highlighted methodological limitations which bring the results into question. According to a national survey, the formulary introduced by the Department of Veterans Affairs (VA) was not perceived by physicians to adversely affect patient care.

## Specific interventions – antitrust and merger and acquisition regulation

### Background

In markets with limited or single providers, there are few incentives to improve either efficiency or quality. Seeking to limit excessive market concentration, and to foster competitiveness, regulators may intervene in merger and acquisition activity.

Antitrust laws legislate against trade practices that undermine competition or are considered to be unfair. The term antitrust derives from the US law that was originally formulated to combat “business trusts” - now commonly known as cartels. Antitrust law is a means to prevent excessive concentration of market power in the form of oligopolies, cartels and monopolies.

Competitive pressures have led to mergers among different types of providers in the healthcare industry, including hospitals, HMOs, nursing homes and diagnostic laboratories. In the US, there were 310 hospital mergers and acquisitions in 1997; 132 in 2000 and 101 in 2002 (Cuellar & Gertler, 2005). System consolidation or mergers can be seen two ways:

- *positively*, leading to improved efficiency and quality as a result of economies of scale and concentrated expertise; or
- *negatively*, where market dominance results in decreased competition; unbridled pricing power; excessive influence on the availability of choice and access; and a lack of incentives to maintain or improve quality.

The literature reveals a complex picture of the interrelationship between size, outcomes, and costs, making it difficult to determine categorically the costs and benefits of market consolidation. There is a substantial body of work that shows for a number of select procedures, higher volumes of throughput are associated with better outcomes (see e.g. Luft et al, 1979; Halm et al, 2002) although there are concerns that many of the available studies have not adequately handled differences in case mix. In terms of organisational economies of scale a rigorous systematic review concluded that *there is no evidence that cost saving can be secured merely by increasing scale in acute hospitals beyond 200 beds and it is likely that large hospitals (> 600 beds) display diseconomies of scale* (NHS Centre for Reviews and Dissemination, 1996: 1).

From a quality point of view, the impact of market concentration is an unresolved issue. Findings on the effects of competition on mortality rates are mixed, with some studies finding that competitive markets are associated with higher mortality rates (Shortell & Hughes, 1988); whilst others have concluded that competition is associated with lower mortality (Kessler & McClellan, 2000). There is multistate research to suggest that higher market concentration (i.e. less competition) is associated with higher inpatient complication rates (Sari, 2002).

Antitrust regulation is applied unevenly in the US healthcare market. Federal and state approaches vary and different criteria are used to challenge and regulate merger and acquisition activity (Kassirer, 1996). More fundamentally, there is considerable controversy

about the extent to which regulation is required (Ho and Hamilton, 2000; Greaney, 2002). Competition law courts have in recent times ruled against state and federal antitrust suits (Hammer and Sage, 2003) contributing to the argument that antitrust enforcement should be curtailed (Cuellar & Gertler, 2005). The long running controversy has fuelled the development of a significant body of evidence that examines the impact of mergers and acquisitions on various financial and quality outcomes. The principal question for these studies is “is regulation required?” This question is subtly but importantly different to the question that underpins the QEI project, namely “what is the impact of a particular regulatory intervention?” Box 4.1 summarises key studies that have examined the first question, and provides an overview of the impact of mergers and acquisitions in healthcare organisations. It shows that there is some evidence of modest cost reductions, particularly in areas where there are more competitive markets; little in the way of price reductions; and either no improvement or deterioration in quality. As per the format used throughout this document, evidence pertinent to the second question is provided in the subsequent section (p 65).

Study	Outcomes	Context	Data and findings
Cuellar and Gertler, 2005	Efficiency; Quality; Prices; Volume; Charity benefits	Four US states; acquisitions 1995-2000	Longitudinal data from hospitals joining a hospital system (with non-system controls). <ul style="list-style-type: none"> <li>• 2.8% higher spending per admission in hospitals joining system</li> <li>• no change in inpatient mortality or rate of adverse safety events</li> <li>• 1.2% decrease in overused procedures for managed care patients (no change for indemnity patients)</li> <li>• 7.7% increase in prices for managed care patients; 4.1% increase for indemnity patients</li> <li>• 14% increase in inpatient admissions for managed care patients (no change for indemnity patients)</li> <li>• No change in charity care admissions</li> </ul>

Study	Outcomes	Context	Data and findings
Capps and Dranove, 2004	Prices paid to hospitals by insurers	Five geographic areas in the US (includes one Midwest, one Southwest state; three metropolitan areas – two smallest areas combined for regression); 1997-2001	Before and after pricing comparisons of 25 hospitals involved in consolidations (cross section and time series analysis).  Consolidating hospitals generally increased prices by more than median increase. Consolidations enabled hospitals to increase prices in 3 of the 4 markets studied.
Fulop et al, 2002	Perceptions and Costs	England; merger activity 1998-1999	Qualitative and cost data collected on 11 merged NHS Trusts. Mergers had a negative effect on delivery of services; two years after merger, average cost savings in management costs were £178 700 in the first year and £346,800 in the second (this fell short of their objective £500,000 p.a.).
Dranove and Lindrooth, 2003	Costs	US; merger activity between 1988-1996	Performance data collected between 2 years prior and 4 years after merger. No savings from hospital consolidation
Spang et al, 2001	Costs and prices	US; merger activity 1989-1997	Analysed costs for 1767 short term general hospitals (including 204 merged hospitals; 653 rivals to merged hospitals; 910 non-merging, non-rival hospitals). Modest merger related cost and price savings exist but vary according to market and hospital conditions. Savings were greater in more competitive markets.
Ho and Hamilton, 2000	Mortality and 90-day readmission rates for stroke and acute myocardial infarct patients; discharge within 48h for newborns.	California; merger activity 1992-1995	Performance data collected between 1991 and 1996. No measurable impact on mortality rates. Readmission rates and early discharge increased in some cases.

Study	Outcomes	Context	Data and findings
Connor et al, 1997	Costs	US; merger activity 1986-1994	Analysed costs for >3500 short term general hospitals (including 244 merged hospitals). Mergers generally financially beneficial to consumers with average price reductions of 7%. Price reductions were smaller in areas with higher market concentration.

#### Box 4.1: The impact of mergers and acquisitions on financial and quality outcomes

##### Evidence: antitrust and merger and acquisition regulation

###### Summary

The evidence regarding the quality consequences of regulation in market consolidation processes is extremely thin. There is evidence available on the consequences of merger and acquisition activity and is provided for reference in the narrative (p 65). One study was available on the impact of regulation and found that regulatory interventions did dampen market consolidation but this may have prevented non-viable units from merging and contributed to their demise, with possible consequences for access to care.

Some US states regulate mergers of Health Maintenance Organisations (HMOs), requiring reports of changes in ownership and control, or plans to acquire a medical facility.

**Christianson et al (1997)** analysed data on HMO mergers that occurred between 1985 and 1993. Using econometric models, the study examined whether HMO mergers increased premiums for private enrollees and whether the impact of mergers on premiums differed according to HMO market structure. The research concluded that mergers historically have had little effect on market structure and HMO premiums. In terms of the effects of regulation, states with more anti-takeover regulations had far fewer mergers and more HMO failures. Adoption of additional anti-takeover regulation decreased the probability of an HMO's merging and surviving by 34%; the probability of merging into another plan decreased by 24%; and the probability of failure increased by 11%. The authors concluded that since mergers do not raise HMO premiums (on average), state laws that make mergers more difficult to consummate may not be necessary or may be counterproductive; increasing HMO failures, thereby reducing both the number of competitors and the public's access to HMO services.

*Research design: observational study*

## Specific interventions – hospital status conversions

### Background

Between 1985 and 1999 about 700 hospitals in the US changed their ownership status (Shen, 2003), encompassing various permutations to and from for-profit, non-profit and public (i.e. government) status (Needleman et al, 1997).

Most regulatory attention has been paid to conversion from public or non-profit to for-profit status – a process which is often a precursor to merger with, or acquisition by, another for-profit company. Advocates of conversions argue that they can result in new sources of capital, more efficient management, and greater negotiating power (Mark, 1999) and can save troubled organisations from demise.

There are a number of regulatory controls in the process of converting from non-profit to for-profit status. Once a Board of Directors decides to pursue a conversion, the proposal must be submitted for regulators' approval. States in the US have different arrangements but usually jurisdiction is shared between the attorney general, who focuses on the effects the proposed transaction will have on the charitable trust; and the insurance commissioner, who focuses on the broader ramifications for the non-profit insurance company—particularly, how it will meet its obligations to policyholders and the public and remain a solvent, viable company (Bell et al, 1997).

Between 1996 and 1998, 24 states passed laws regulating non-profit hospital conversions, supplementing attorney general oversight (Leone et al, 2005). The regulations typically require that when charitable assets are sold and converted to for-profit status, the price paid must reflect the fair market value and proceeds must go to another charity. The structure, purpose, governance and community accountability of that charity is also considered by the regulators (Miller, 1997; Leone et al, 2005).

Stakeholders often have concerns regarding the level of services provided to vulnerable and indigent populations after conversion from public or non-profit status. There are perceived risks of increased prices, decreased access to care, and fewer resources for medical education and research. To assure that a community's healthcare needs are addressed by the for-profit entity, regulators can insist that the transaction between the non-profit and the for-profit organisation encompasses an adequate and continuing level of community service.

In England, the conversion of hospital status, and the regulation that controls that process, has an entirely different complexion to that in the more market-based healthcare system of the US (see Box 4.2). However the lessons learned from converting US hospitals from public to non-profit have some resonance and may provide lessons for the creation of Foundation Trusts.

### Conversions in England's NHS

Until recently most secondary care in England was supplied by NHS Trusts which are public corporations, subject to borrowing constraints and to direction from the Department of Health. There is a rolling programme to convert NHS Trusts to Foundation Trusts over the next five years. According to the Department of Health (2005), NHS Foundation Trusts are a new type of NHS organisation, established as independent "public benefit corporations", free from central government control and from strategic health authority performance management. There are three core parameters for Foundation Trusts:

- their mission continues to be aligned with core NHS principles – free care, based on need and not ability to pay
- they must be financially viable; although subject to the risk of insolvency, service provision will be protected
- they are required to present annual reports and accounts to Parliament.

The benefits and constraints of Foundation Trusts are:

Key benefits	Key constraints
<ul style="list-style-type: none"> <li>• accountable to local people, who can become members or governors;</li> <li>• free to retain and build up surpluses that they generate;</li> <li>• able to borrow from commercial sources within limits set by the regulator;</li> <li>• able to restructure and modernise in order to increase service capacity and efficiency.</li> </ul>	<ul style="list-style-type: none"> <li>• not able to withdraw from providing services that are unprofitable without ensuring alternative provision</li> <li>• services required by Primary Care Trusts (PCTs) must be provided unless clinical reasons why not</li> <li>• not able to prioritise private patients and neglect responsibilities to the NHS.</li> <li>• must comply with national targets and standards</li> <li>• subject to regulator's terms of compliance</li> </ul>

#### Box 4.2: Conversions in the NHS

##### Evidence: hospital status conversions

All the research evidence emanates from the US and it focuses primarily on the impact of conversions on performance and quality. It is difficult to discern the impact that regulation has had on those conversions (or subsequent outcomes) as studies do not indicate the extent to which the conversions were subject to regulatory control. In England, where conversions are regulated by Monitor, the process has only recently been established and there is no evaluative research available.

##### Summary:

Conversions from non-profit or public hospitals to for-profit in the US have had consequences for quality. A number of studies examine provision of uncompensated care for low income and uninsured patients following hospital conversion. Results predominantly show that hospitals that have converted from public to for-profit status provide lower levels of uncompensated care. Conversions to for-profit status were associated with higher mortality rates by two studies; and with higher rates of pneumonia complications by another. Conversions were associated with improved financial performance; one study found that this association held for both profit to non-profit and non-profit to profit conversions (suggesting

a “new broom” effect). There is some evidence that regulation can dampen conversion activity however the role that regulation has played in limiting undesirable consequences of conversions is unknown.

**Leone et al 2005** tested for fair market pricing before and after the introduction of state regulation on conversions and sales of non-profit hospitals. Their data were drawn from reports of merger and acquisition activity; and financial and operating information on publicly traded hospital companies from 1990 to 2001. Arguing that abnormally high returns from acquisitions of non-profit hospitals would provide evidence of below market pricing, the study found no abnormal returns and no evidence that non-profit hospitals were systematically under-priced. The authors claim their results are consistent with the view that investor owned chains paid “fair market value” for non-profit hospital assets, even before the passage of state regulations. After 1997, they found that acquirer abnormal returns became significantly negative in states that adopted regulations but remained close to zero in states that did not adopt regulations. Investor owned chains’ acquisitions of non-profit hospitals also declined in regulated states but continued at the same rate in unregulated states. The study suggests that regulation reduced expected synergies and/or increased the costs of acquiring non-profit hospitals, dampening conversion activity.

*Research design: observational study*

**Farsi 2004** examines the effects of conversions between for-profit (FP) and not-for-profit (NFP) status and quality of care in California hospitals. Data were drawn from patients aged 65 or over admitted with acute myocardial infarction (AMI) or congestive (chronic) heart failure (CHF) between 1990 and 1998 and statistical regressions performed. Outcomes were risk adjusted in-hospital mortality for AMI and CHF and readmission rates for AMI. Hospitals that converted to FP showed an increase in AMI mortality rates, while those converting to NFP had an increase in CHF mortality. Converted hospitals experienced quality changes prior to the status change and this may be a source of bias in studies into the effects of conversion.

*Research design: observational study*

**Shen 2003** examined how ownership conversions affected hospital performance between 1987 and 1998 in terms of financial performance, staffing, capacity, and unprofitable care (e.g. emergency and trauma care provision). Data were drawn from the American Hospital Association annual surveys and Medicare hospital cost reports. A control group of hospitals was selected on the basis of similar covariates to those in converting hospitals so that observed characteristics in the pre-conversion period are indistinguishable in the control and conversion groups. Total profit margin increased by an average of 2.2% after non-profit/public conversions to for-profit status; and by an average of 5% in private hospitals that converted to public status (due to rising revenue, and to reduced operating costs and rising revenue, respectively). Converted hospitals all experienced a reduction in staffing ratios after the change of ownership: hospitals that converted to for-profit ownership had the greatest reduction (an average 14.8% reduction in staff to bed ratio) relative to other converted hospitals (conversion to non-profit 3.1% reduction; conversion to government 3.2% reduction in staff to bed ratio). There was little change in bed capacity after conversion to for-profit status, but some reductions in bed capacity in specialty units after conversion to government (8.9% reduction) or non-profit status (3.4% reduction). No conversion of any kind led to a reduced amount of unprofitable care, but conversion to private ownership (non-profit and for-profit) increased the probability of trauma centre closures.

*Research design: observational study*

**Picone 2002** et al examined how changes in hospital ownership to and from for-profit status affected quality and Medicare payments per hospital stay. Data were drawn from the National Long Term Care Survey in 1982, 1984, 1989, and 1994 and the American Hospital Association. Overall 35, 845 Medicare beneficiaries were included in the dataset. Mortality data were collected at 1 month, 6 months and 1 year post discharge. The study found that within 2 years of conversion to for-profit status, mortality of patients increased while hospital profitability rose markedly and staffing decreased. Thereafter, the decline in quality was much lower. A similar decline in quality was not observed after hospitals converted from for-profit to government or private non-profit status.

*Research design: observational study*

**Sloan, 2002** examined whether hospital conversions, especially those to for-profit status, lead to increased barriers to care, diminished quality of care, and profit seeking billing practices designed to maximise revenue. The study drew on hospital discharge data from 1988-1996 from 21 states. The rate of pneumonia complications rose in hospitals converting from public or non-profit to for-profit status (from 3.8 to 5.0%;  $P=0.001$ ); there was no change in the non-converting sample. Mortality rates fell from 8.2% to 7.6% following conversion however this difference was not statistically significant. Amongst non-converting hospitals the fall was larger from 8.7% to 7.5% ( $p<0.0001$ ). Rates of extended stays and length of stay declined more in hospitals that converted than in controls. No systematic upcoding was found in for-profit conversions.

*Research design: observational study*

**Thorpe et al 2000** examined associations between community hospital conversions and the provision of uncompensated care (which includes charity care and bad debt; and is used as an indicator of care to low income and uninsured patients), total adjusted admissions, total margin, total revenue, and costs per adjusted admission. Data were drawn from the American Hospital Association survey of hospitals 1990-1997. Multivariate analysis measured the association between conversions and outcomes. The results show that the proportion of total expenses spent on uncompensated care was 0.6% lower in those hospitals converting from non-profit to for-profit compared to non-converting non-profit hospitals (4.7% vs 5.3%). Among hospitals converting from public to for-profit status, uncompensated care accounted for 2.5% of total expenses compared to 5.2% if the hospital had not converted. The volume of uncompensated care increased by 2.3% when for-profit hospitals converted to public status (from 5.2% to 7.5% of total expenses). Total margins increased by 4% when non-profit converted to for-profit status.

*Research design: observational study*

**Desai et al, 2000** examined whether privatisation of public hospitals affected the amount of uncompensated care provided by those organisations and; whether there is a difference, in terms of levels of uncompensated care, between conversions from public to non-profit or for-profit status. The study drew on hospital cost reports for 52 hospitals that were privatised between 1980-1997 in California, Florida and Texas ( $n=37$  non-profit and 15 for-profit). It used a time series design and used a control group of non-converting public hospitals. Before privatisation, the hospitals had an average of 157 beds; an average occupancy rate of 53% and; provided an average of 8.9% of their gross patient revenue as uncompensated care (where uncompensated care includes charity care and bad debt). Before privatisation hospitals provided on average less uncompensated care than the control group (8.9% vs 11.5%;  $P<0.05$ ). Following privatisation (3-6 years) those differences were (8.7% vs 11.9%;  $P<0.05$ ). More detailed analysis revealed considerable variation: almost two thirds of for-profit privatisations and almost a quarter of non-profit conversions resulted in at least a 15%

decrease in the level of uncompensated care. However, around one-tenth of for-profit and a third of non-profit conversions resulted in at least a 15% increase in uncompensated care. For conversions to for-profit, the provision of uncompensated care declined significantly (-2.12%;  $P=0.02$ ) relative to that of comparison hospitals. Uncompensated care in low-income areas declined significantly (-2.02%) relative to high income areas ( $P<0.01$ ).

*Research design: observational study*

**Young & Desai, 1999** examined the short and long term community impacts of non-profit hospital conversions. The study focused on 43 conversions that occurred between 1981 and 1995 in California, Florida and Texas and drew on data from state-level cost reports, using 129 non-converting hospitals as controls. Four indicators of community benefit were used: uncompensated care (which); net prices; unprofitable/non-reimbursable services (e.g. emergency/trauma care, burns units, substance abuse care, disease screening and prevention); and community representation on the board. Conversions did not have an effect on uncompensated care, prices or availability of non-reimbursable/unprofitable services. They were followed by substantial shifts in governing board composition with a shift away from community representation towards greater participation by senior management and medical staff.

*Research design: observational study*

**Mark, 1999** examined precursors to private hospitals conversion, both from non-profit status to for-profit status and from for-profit to non-profit status; and the effect of hospital conversions on hospital profitability, efficiency, staffing, and the probability of closure. Data were drawn from Health Care Financing Administration's Medicare Cost Reports and the American Hospital Association's Annual Survey of Hospitals. Bivariate and multivariate analyses comparing conversion hospitals to non-conversion hospitals over time were conducted. The study sample consisted of all private acute care hospital conversions that occurred between 1989 and 1992 (non-profit to for-profit  $n=33$ ; for-profit to non-profit  $n=50$ ). Performance data were collected for 1987-1995 from the Medicare Cost Report database and the American Hospital Association. Hospitals that converted had significantly lower profit margins prior to converting than non-conversion hospitals. This was particularly true for non-profit to for-profit conversions. After converting, both non-profit and for-profit hospitals significantly improved their profitability. Non-profit to for-profit hospital conversions were associated with a decrease in the ratio of staff to patients. No association was found between for-profit to non-profit conversion and staff-to-patient ratios. The difference may reflect higher staff ratios (prior to conversion) in non-profit hospitals that converted. For-profit to non-profit conversions were associated with an increase in the ratio of registered nurses to patients, and administrators to patients, although in general non-profit and for-profit hospitals did not differ in these ratios.

*Research design: observational study*

**Needleman et al 1999** examined the effect of Florida hospital conversions on the rate of uncompensated care. The research used a pooled time series analysis to compare two groups of converted hospitals, non-profit ( $n=15$ ) and public ( $n=4$ ), to three reference groups: an always for-profit group ( $n=75$ ), and non-converting controls, both non-profit ( $n=66$ ) and public ( $n=26$ ). Data were drawn from administrative and state financial reports from 1981-1996. Converting hospitals were smaller, less likely to have a medical school affiliation and more likely to be non-metropolitan. Converting non-profit hospitals had lower levels of uncompensated care prior to conversion than non-converting hospitals (3.9% vs 6.1% of all care); the pre-conversion rates of uncompensated care for non-profit hospitals were similar

to those in for-profit hospitals (3.9% vs 4.0% of all care) and rates remained steady post-conversion (pre :3.9%; post : 4.1%); public hospitals reduced their rates of uncompensated care following conversion (pre : 9.1%; post : 6.8%).

*Research design: observational study*

## Specific interventions – ‘any willing provider’ regulation

### Background

In the US any willing provider laws require health plans to be ready and willing at all times to enter into service contracts with all healthcare providers who are qualified under state law, who practise within the general geographic area served by the insurance company, and who are willing to meet the terms and the conditions set by the insurer. Almost half the states in the US have laws prohibiting health insurers from excluding participation of willing and qualified health care providers in their geographic coverage areas (MacEachern, 2003). Although most provisions are limited to pharmacies or pharmacists, several states have adopted broad provisions applying to hospitals, physicians, chiropractors, pharmacists, podiatrists, therapists and nurses (<http://www.ncsl.org/statefed/health/AWP.htm>).

Any willing provider regulations resulted from the growth of managed care which sought to control costs and limit choice of provider, purportedly to manage costs while protecting quality. As a result, some physicians and hospitals were deliberately excluded from some managed care plans. Any willing provider laws prohibit such actions.

Hellinger (1995) reviewed the effect of any willing provider and similar “freedom of choice” laws (ensure that health plan members can use providers outside the defined panel) and found that they: result in an increase in the number of providers in a network, leading to greater processing and administrative costs and; limit managed care plans’ ability to obtain volume discounts. The curtailment of selective contracting has been calculated to increase the total costs of operating a managed care plan by 1.3% (Atkinson, 1994; cited by Hellinger, 1995).

The impact of any willing provider laws has been investigated in terms of financial and market impact but there has been almost no research on their effect on quality of care. The financial studies are summarised in Box 4.3, for reference. The single study that addresses (albeit cursorily), access to care - a key component of quality - is summarised on p 87.

Study	Setting and Design	Findings
Morrisey and Ohsfeldt, 2003	Pooled cross section time series. Data from CMS and compendium of state laws 1989-1995	High regulatory intensity is associated with a 4.7% reduction in HMO market share. Freedom of choice laws had a greater impact on market share than any willing provider laws. Laws limiting selective contracting with physicians are more effective in reducing HMO market share than laws covering hospitals or pharmacies.

Study	Setting and Design	Findings
Vita, 2001	State-level health spending data 1983-1997	States with a high regulatory intensity had ~\$50 higher per capita total health spend than states with low intensity regulation.

### Box 4.3: Financial and market impact of any willing provider and freedom of choice laws

#### Evidence: any willing provider

##### Summary

The evidence on the impact of any willing provider (AWP) laws focuses on market and financial outcomes (see p 74) rather than on quality or clinical outcomes. However, one study suggests that greater diversity in pharmacy markets resulting from AWP laws may improve prescription compliance.

**Carroll and Ambrose, 2003** investigated the impact of any willing provider laws on HMO performance. The study used cross-sectional time-series data for 1992-1995. Data were drawn from a range of sources: American Association of Health Plans, American Hospital Association, American Medical Association, US Bureau of Statistics, US Bureau of Census, Health Insurance Association of America. Any willing provider laws had a limited effect on HMO financial performance and did not affect overall profitability. HMO inpatient expense ratios were around 4% lower in states with “pharmacy” any willing provider laws; suggesting that additional admissions were prevented through better access to pharmacies, and therefore to required medication.

*Research design: observational study*

## Specific interventions – mandatory reporting

### Background

Accountability refers to the principle that individuals or organisations are responsible for their actions and may reasonably be required to act in a transparent manner and provide relevant data in the public domain.

Within the context of our review of regulatory interventions, we focus upon mandatory reporting as a means of public accountability within healthcare markets. Before examining the evidence on mandatory reporting, we review briefly the current state of knowledge regarding the impact of public disclosure of performance data (both voluntary and mandatory) as this is relevant to policymakers in their decisions whether to require public reporting.

An entire QEI report will focus on the use of data-based and IT-based interventions. Scheduled for release in 2007, it will feature a full review of public reporting (including voluntary and quasi-voluntary participation in benchmarking ) and its effect on quality and performance.

Public reporting of comparative information about performance is an increasingly popular intervention that aims to improve accountability and quality of healthcare (Marshall et al,

2003). It has two primary goals:

- to provide information to patients, payers, and purchasers to guide their decisions, both in terms of individual treatments and collective health policy decisions
- to catalyse improvements by both individual and institutional healthcare providers

In the US, quality report cards have been in wide use for more than a decade whilst in England “star ratings” and “health checks” have been a central feature of the Blair Government’s health system reform.

The potential advantages and disadvantages of publicly reporting clinical performance are summarised in Box 4.4.

Advantages*	Disadvantages
Informs physicians about relative levels of performance and areas for improvement	A risk that providers will avoid high-risk patients
Focus organisational attention on areas of suboptimal performance	Data can be used to unfairly or inaccurately compare performance
Guides decisions by payers and purchasers	Can confuse by an oversimplified account of a complex situation (e.g. failure to appreciate statistical significance)
Informs patients for selection of providers	
Alerts healthcare organisations to poor performing professionals	

(\*assumes valid data and methodology)

**Box 4.4: Advantages and disadvantages of publicly reporting clinical performance data (adapted from Chassin et al, 1996; Marshall et al, 2000; Werner and Asch, 2005)**

The US has been at the forefront of the public disclosure movement (Marshall et al, 2003). Some of the key schemes that have been developed are summarised in Box 4.5.

<b>Organisations engaged in public disclosure activities</b>	<b>Scope and application</b>
National Committee for Quality Assurance (NCQA)	A non-profit organisation that evaluates healthcare quality, primarily within health maintenance organisations. The Health Plan Employer Data and Information Set (HEDIS) is a set of standardised performance measures related to a range of public health issues such as cancer, heart disease, asthma and diabetes. HEDIS also includes a standardised survey of consumer experiences that evaluates plan performance in areas such as access to care and claims processing. Health plans participate on a voluntary basis.
Hospital Quality Alliance	A public-private collaboration to improve the quality of care provided by the nation's hospitals by measuring and publicly reporting on that care. The alliance includes the Centers for Medicare & Medicaid Services (CMS), the American Hospital Association, the Federation of American Hospitals, and the Association of American Medical Colleges, and is supported by numerous other organisations. The goal of the programme is to identify a robust set of standardised and easy-to-understand hospital quality measures. An important element of the collaboration is Hospital Compare, a web site developed to publicly report credible and user-friendly information about the quality of care delivered in the nation's hospitals.
Agency for Healthcare Research and Quality (AHRQ)	A federal agency charged with improving the quality, safety, efficiency, and effectiveness of healthcare, AHRQ publishes the National Healthcare Quality Report, a compendium of 150 quality measures.
Pacific Business Group on Health (PBGH)	A consortium of large employers that use public reporting of providers' self reports and patient surveys to improve quality and cost effectiveness.
Healthgrades	A for-profit company that provides healthcare ratings and information on hospitals, nursing homes and home health agencies.

Organisations engaged in public disclosure activities	Scope and application
QualityCounts	An Employer Health Care Alliance initiative that provides consumers information on quality and safety in Wisconsin. QualityCounts releases published reports about the performance of health care providers. Hibbard et al (2003; 2005) provide evidence to show its effectiveness in improving quality.
Consumer Reports	The public release of healthcare quality data into formalised consumer health report cards is intended to educate consumers, improve quality of care, and increase competition in the marketplace. Evidence about their effectiveness is mixed (Schauffler and Mordavsky, 2001; Longo et al, 1997).

#### Box 4.5: A selection of public reporting initiatives in the US

In the UK, there has been an increasing trend towards reporting performance, both in public organisations such as the star ratings scheme and patient surveys produced by the Healthcare Commission; and in private organisations such as Dr Foster which makes performance data available via their website and various publications.

It is widely acknowledged that in order for public reporting to be fully effective, it should be mandatory (McCormick et al, 2002; Marshall et al, 2003). Otherwise, providers can simply withdraw from a reporting scheme when it is not in their best interest, consequently compromising that scheme's usefulness.

##### *Mandatory reporting*

Recently the US has enacted a law (the Medicare Prescription Drug, Improvement, and Modernization Act of 2003) which stipulates that hospitals that fail to submit performance data for ten designated quality measures will receive a 0.4% reduction in its annual payment update from the Centers for Medicare and Medicaid Services (CMS) for 2005, 2006, and 2007. Many states also have requirements for safety-related reporting, such as adverse incidents and hospital acquired infection rates (e.g. Coldiron, 2002; Tuttle et al, 2002; McKibben et al, 2005). States differ in the extent to which they report these data publicly.

Mello (2005) describes mandatory reporting of adverse events in the US as a case of "uncoordinated pluralism". Adverse event reports are required by a large number of organisations and oversight bodies, including the hospital's insurer, the hospital's peer review committee, the state department of health, the state board of medicine, the JCAHO, the Food and Drug Administration (FDA), and privately run reporting systems in which the hospital participates. The definitions of reportable events vary among these systems, as do the degree of protection reports receive from legal discovery and public scrutiny.

Despite all this activity, there is little evidence that assesses the impact of mandatory reporting schemes broadly on quality of care. The evidence summary which follows includes studies that focus on the impact of New York's cardiac surgery reporting programme. Although it is not embodied in any regulation, this programme was introduced

in the context of a state-wide regulatory environment (Chassin, 2002); is administered by a regulatory body (the State Department of Health); and has 100% participation across the state's hospitals. Therefore it largely conforms to the characteristics of a regulatory intervention. Evidence of its impact may provide insights into the use of mandatory reporting as a regulatory tool to improve quality.

New York has recently introduced a mandatory electronic reporting scheme for diabetes patients whereby laboratories are required to report glycaemic control indicators to the city's Department of Health (Steinbrook, 2006).

## **Evidence: mandatory reporting**

### **Summary**

Evidence emanating from New York suggests that publicly reporting of performance in cardiac surgery can have a positive effect on quality of care. There are survey data to suggest that mandatory reporting and public disclosure can have unintended consequences, e.g. discouraging treatment of high risk patients; and meets with some resistance from hospital executives and clinicians.

**Narins et al 2005** investigated the perceptions of cardiologists regarding the public release of risk-adjusted patient mortality rates. Data were drawn from a questionnaire sent to all interventional cardiologists practising coronary angioplasty in New York (n=186), to which 120 responded (65% response rate). The majority (79%) of respondents agreed or strongly agreed that the publication of mortality statistics has, in certain instances, influenced their decision regarding whether to perform angioplasty on individual patients. Physicians expressed an increased reluctance to intervene in critically ill patients with high expected mortality rates: 83% agreed or strongly agreed that patients who might benefit from angioplasty may not receive the procedure as a result of public reporting of physician-specific patients' mortality rates. Further, 85% believed that the risk-adjustment model used was not sufficient to avoid punishing physicians who perform higher-risk interventions.

*Research design: observational study*

**Weissman et al 2005** surveyed the views of chief executive and chief operating officers (CEOs/COOs) about mandatory error reporting systems. Respondents were drawn from randomly selected hospitals in two states with mandatory reporting and public disclosure (Massachusetts, Colorado), two states with mandatory reporting without public disclosure (Pennsylvania, Florida), and two states without mandatory systems (Georgia, Texas) in 2002-2003. Responses were received from 203 of 320 hospitals approached (63% response rate). Respondents were asked about their perceptions about the effects of mandatory systems on error reporting, likelihood of lawsuits, and overall patient safety; attitudes regarding release of incident reports to the public; and likelihood of reporting incidents to the state or to the affected patient based on hypothetical clinical vignettes that varied the type and severity of patient injury. Most CEOs/COOs thought that a mandatory, non-confidential system would discourage reporting of patient safety incidents to their hospital's own internal reporting system (69%) and encourage lawsuits (79%) while having no effect or a negative effect on patient safety (73%). More than 80% felt that the names of both the hospital and the involved professionals should be kept confidential, although respondents from states with mandatory public disclosure systems were more willing than respondents from the other states to release the hospital name (22% vs 4%-6%,  $P = 0.005$ ). Based on the vignettes, more than 90% of respondents said their hospital would report incidents involving serious injury to the state, but far fewer would report moderate or minor injuries, even when the incident was of sufficient consequence that they would tell the affected patient or family.

*Research design: observational study*

**Werner et al, 2005** investigated the impact of New York's Coronary Artery Bypass Graft surgery (CABG) reporting programme on racial and ethnic disparities in cardiac care. The study explored whether intervention rates might be influenced by perceptions that black and Hispanic patients represented higher risk, and be reduced as a result of public reporting of outcomes. The study drew on state inpatient data and hospital discharge files for New York and 12 control states for the period 1988-1995, encompassing 310 412 patients in New York and 618 139 patients in control states. Black and Hispanic patients were significantly less likely to receive CABG than white patients in New York after the programme to release data was instigated (Before: 3.6% white patients, 0.9% black, 2.9% Hispanic; After: 8.0% white, 3.0% black, 4.8% Hispanic). In comparison states, the change in the difference in CABG use by race and ethnicity was not significant. The net effect of the release of data in New York was an overall increase in racial and ethnic disparities in CABG use by 2.0% (95% CI 0.7-3.4) in white versus black patients and by 3.4% (95% CI 0.8-5.9) in white versus Hispanic patients. The increase in disparities was however transient - increasing initially after the programme's introduction and then decreasing over time to levels similar to those before the reporting programme. There was no differential change in racial and ethnic disparities between New York and comparison states in the use of alternative procedures (cardiac catheterisation or PTCA) after the CABG report was released.

*Research design: observational study*

**Cutler et al 2004** examined the impact of the cardiac surgery outcomes reporting scheme in New York in terms of mortality rates and allocation of patients for individual providers of care. The study used a cross sectional time series over the period 1991-1999. Risk adjusted mortality fell significantly across the state during the first decade of the reporting programme. The range between the hospitals at the 25th and 75th percentiles narrowed during the early years of the programme, suggesting improved performance on the part of initial poor performers. Being identified as a high-mortality hospital was associated with a decline of approximately 4.9 bypass surgery patients per month during the 12 months following that designation (average hospital volume is 50 operations per month). Reports of low mortality rates are not associated with a significant increase in future volume. Identification as a high mortality hospital is associated with improved future performance. Hospitals that were publicly identified as being of low quality, experienced in the subsequent 12 months, a 1.2% decrease in mortality rates ( $p < 0.01$ ). The average risk adjusted mortality rate is 2.55% for the entire sample. For those hospitals receiving a high-mortality report, the average risk-adjusted mortality prior to receiving that report is 3.82%. Those hospitals receiving a low mortality report showed no evidence of significant mortality changes.

**Dranove et al, 2003** examine the net consequences of mandatory cardiac surgery reporting for health care expenditures and health outcomes in New York and Pennsylvania from 1987 to 1994, relative to control states that did not have reporting schemes. Data were drawn from a Medicare claims database and the American Hospital Association database. Outcomes were complications or readmission with AMI or heart failure within 1 year of the initial admission. The study found that the reporting scheme improved matching of patients with hospitals (i.e. sicker patients went to high quality hospitals); increased the quantity of CABG surgery; and changed its incidence from sicker to healthier patients.

*Research design: observational study*

**Burack et al 1999** surveyed New York cardiac surgeons in 1997 regarding the perceived impact of the State Department of Health Cardiac Surgery Reporting System. Of 150

cardiac surgeons in New York, 104 responded (69.3% response rate). Surgeons were queried about the number of high risk patients they turned down for treatment primarily because of public reporting. Most surgeons (62%) reported that they refused to operate on at least one high-risk patient over the prior year, primarily because of public reporting of outcomes data. Refusal was more common in surgeons in practice less than 10 years, those with less than 100 cases per year, and those with a mixed cardiothoracic practice ( $p < 0.05$ , Pearson's  $\chi^2$  test).

*Research design: observational study*

**Petersen et al 1998** examined the impact on access to, and outcomes of, coronary artery bypass graft (CABG) surgery in New York (NY) following the 1989 introduction of a programme that released risk adjusted mortality rates for the procedure. National Medicare data for 1987-1992 (i.e. before and after programme initiation) were used to examine:

- in-state procedure use among elderly myocardial infarction patients
- trends in the percentages of NY residents  $\geq 65$  years of age receiving out-of-state bypass surgery
- trends in surgical outcomes in NY Medicare patients in comparison to those for the rest of the nation

Between 1987 and 1992, an elderly patient's likelihood for bypass following myocardial infarction in NY increased significantly; the percentage of NY residents receiving bypass out-of-state declined (from 12.5% to 11.3%,  $p < 0.01$  for trend) and; unadjusted 30-day mortality rates following bypass declined by 33% in NY Medicare patients compared with a 19% decline nationwide ( $p < 0.001$ ). NY had the lowest risk-adjusted bypass mortality rate of any state in 1992.

*Research design: observational study*

**Omoigui et al, 1996** examined referral patterns following the introduction of the cardiac surgery outcomes reporting scheme in New York, in order to investigate whether high risk patients migrated out of state for surgery. The study was a retrospective analysis of 9442 coronary artery bypass (CABG) operations undertaken at the Cleveland Clinic in Ohio (110 miles from the western border of New York). Data were drawn from the Cleveland Clinic's information registry for 1989-1993. Average annual volume of New York referrals increased from 61.4 to 96.2 cases, whereas referrals from Ohio and other states decreased from 1285.3 to 1208.4 and 882.1 to 388.2 respectively. Relative to patients from Ohio, patients from New York had an odds ratio for death of 1.7 (95% CI 1.1-2.7). The observed mortality rate was 5.2% for New York referrals; 2.9% for patients from Ohio; 3.1% for referrals from other states and 1.4% for referrals from other countries.

*Research design: observational study*

**Hannan et al (1994)** assessed changes in outcomes of coronary artery bypass graft (CABG) surgery in New York between 1989 and 1992, following introduction of a state initiative that collected, analysed, and disseminated information regarding risk factors, mortality, and complications of CABG surgery. Data were drawn from all hospitals ( $n=30$ ) performing CABG procedures on 57,187 patients. A clinical database was used to identify significant independent risk factors and to assess risk-adjusted provider mortality rates. The volume of CABG operations increased by 30.6%; from 12 269 in 1989 to 16 028 in 1992. Main outcomes were actual, expected (from a logistic regression model), and risk-adjusted in-hospital mortality. Actual mortality decreased from 3.52% in 1989 to 2.78% in

1992. Average patient severity of illness increased over the study period, and risk-adjusted mortality decreased from 4.17% in 1989 to 2.45% in 1992.

*Research design: observational study*

## Specific interventions – certificate of need

### Background

Certificate of need (CON) is a permit issued by a governmental body to an individual or organisation proposing to construct, modify, or close a health facility; acquire major new medical equipment; modify a health facility; or offer a new or different health service or discontinue a service. Such issuance recognises that a facility or service, when available, will meet the needs of those for whom it is intended. ([www.dph.state.ct.us/OPPE/sha99/glossary.htm](http://www.dph.state.ct.us/OPPE/sha99/glossary.htm)). The rationale behind CON requirements is that they balance supply and demand, control costs, improve quality, and promote access to healthcare services.

Federally mandated in 1974, every state in the US was required to have a certificate of need programme. Prior to the introduction of CON, competition was on the basis of service expansion, there was a proliferation of new technology, retrospective payments guaranteed reimbursement, and almost complete insurance coverage for hospitals meant that competition was on a non-price basis. Expenditure on healthcare grew alarmingly. In striving to curtail growth of expenditure states pursued two strategies – capital investment controls through CON and hospital price controls through rate setting. The process was intended to keep down costs associated with the construction of new health facilities, and prevent over-development. Because the federal requirement was for states to establish CON programmes under state statutes and to administer the programmes through state and local health planning agencies, great variation existed in terms of expenditure thresholds and types of services covered (Feder & Scanlon, 1980; Harrington et al, 2004).

A substantial amount of empirical evidence accumulated in the 1980s indicating that CON regulation was ineffective at containing costs (Schwartz, 1981; Lanning et al, 1991; Conover and Sloan, 1998). Specific factors that have been identified as limiting the effectiveness of CON programmes in controlling expenditure include:

- Difficulties in developing objective standards and criteria for the review of projects (Feder & Scanlon, 1980; Joskow 1981; Colby & Begley, 1983)
- Absence of robust procedures to secure compliance with CON decisions (Colby & Begley, 1983)
- Difficulties coordinating with other regulatory interventions such as prospective rate setting or budget review programmes (Mahler, 1981)
- Politicisation of the review process (Consedine et al, 1980; Colby & Begley, 1983)
- Perception of limited federal legislative authority and power (Sloan, 1988)
- Perception that CON established entry barriers to protect the income of existing providers (Schwartz, 1981; Solomon, 1998)

The federal requirement for CON was lifted in 1986, and a number of states subsequently abolished their programmes although some later restored them in a modified form. The most prominent uses for CON today are in long term care and nursing home provision; and in ensuring minimum volumes of throughput for specialist services, particularly in cardiac surgery.

CON regulations more recently have had multiple goals. Alongside cost containment,

secondary objectives of CON regulation were to promote access and improve quality (Conover and Sloan, 1998). Box 4.6 depicts survey data drawn from interviews with state officials on the reasons and justifications for CON regulation in the long term care environment.

Reason	Nursing home/ hospital bed conversions (n=42)	ICF-MR <sup>e</sup> (n=30)	Residential care/ assisted living (n= 14)	Home health/ hospice (n=25)
To reduce the growth of supply	30	21	10	13
To control Medicaid utilisation of expenditures	30	20	10	11
Shift long term care to home and community-based services	21	15	7	6
To prevent growth in areas of oversupply and promote growth in undersupplied areas	33	23	12	18
To plan for the appropriate amount of services, taking into account current and future needs for long-term care services as the population ages.	32	25	12	19
Deny facilities with poor quality records	22	19	8	13
Other	9	3	1	3

\*ICF-MR: intermediate care facilities for the mentally retarded/developmentally disabled

**Box 4.6: Reasons for using CON and/or moratoria for long-term care organisations (n=43 states) [from Harrington et al, 2004]**

*Nursing home sector CON*

CON remains in extensive use in the US nursing home sector. The CON programme, established nationally in 1974 to control the number of nursing home beds and expenditures, requires State CON approval for new construction or expansion of health care facilities, including nursing homes. Some States removed their CON requirements after the Federal legislation was repealed, but in 2002, 43 states had a CON and or moratoria (MOR) (i.e. restrictions on applications for new facilities, beds or agencies) policies in place (Harrington et al, 2004 – see Box 4.7 below). Moratoria are applied and then rescinded over periods of time in many states

	None	CON only	MOR only	CON and MOR
1985	5	37	2	7
2002	8	21	6	16

**Box 4.7: State profiles of CON and moratoria in US Nursing Homes (Harrington, et al, 2004).**

In the US, nursing homes have a mixed population of private and Medicaid/Medicare patients (funded by state and federal governments). Around 40% of nursing home residents are covered by Medicaid at the time of admission (US National Center for Health Statistics, 2002) and many residents “spend down” to Medicaid eligibility as they use up their resources (Harrington et al, 2004). State Medicaid programmes pay, on average around 70% of private rates (Grabowski et al, 2003). Of the total \$103 billion spent on nursing home care in 2002, public payments account for 64%, and Medicaid alone for 49% (Levit et al, 2004).

CON/MOR policies may be designed primarily to control costs to Medicaid and/or to assist in planning efforts to redistribute beds. Some States, such as Oregon, have made conscious decisions to direct new investments in long-term care to areas that provide alternatives to nursing homes, such as residential care, assisted living, and home care. CON legislation provides a mechanism for review and approval of the growth and replacement of nursing homes. It can have a positive, negative or neutral effect on bed supply and can influence the type of beds built, the location of new capacity; and which companies are permitted to participate in the market.

CON regulations are sometimes used in conjunction with rate setting to control supply and costs of nursing home beds. Theoretically a state can set a rate, independent of the costs of an individual home, that will attract the construction of the number of beds the state is willing to support. Unless rates are related to a patient’s condition however, problems of discrimination against those who require extra care arise if rates or CON restrictions create a shortage of beds. With free entry into the market however (i.e. no CON), nursing homes will compete for patients. The result, some argue, will be both higher quality and greater efficiency in the delivery of care.

Box 4.8 summarises the evidence about the impact of CON on expenditure.

Study	Setting and design	Findings
Grabowski et al, 2003	Examined the effects of repealing CON and moratorium laws; all US states except Arizona; 1981 - 1998	<p>Sixteen states repealed their CON nursing home laws for some period; 25 imposed moratoria on new nursing homes and 10 states repealed their CON programmes without imposing a moratorium. Elimination of nursing home CON had no statistically significant effect on Medicaid nursing home or long term care expenditures. Explanations for no effect of CON repeal on Medicaid expenditures:</p> <ul style="list-style-type: none"> <li>• Changes in the long term care markets with a declining occupancy rate in nursing homes and increased assisted living facilities, respite care, adult day care and home health care.</li> <li>• Private pay residents have increased options for non-nursing home options (e.g. home care)</li> </ul>
Harrington et al, 1997	Telephone surveys of US state officials; 1983, 1986, 1989, 1992, and 1994	<p>Total number of nursing home beds in the US increased 24% from 1.39 million to 1.72 million between 1981 and 1993. The bed supply varied from state to state, ranging in 1993 from 23 beds per 1,000 population ≥65 years in Nevada to 85 beds per 1,000 population ≥65 years in Nebraska. States with CON or MOR policies had less growth in nursing home beds than States without these policies. Reimbursement rates were not related to changes in bed supply. The number of nursing home beds per 1000 aged ≥65 years in the previous year was also a significant negative predictor of change in bed stock (i.e. those states with high levels of supply are less likely to have rates of growth).</p>
Feder & Scanlon, 1980	Qualitative interviews with state officials, industry representatives in 8 states (California, Colorado, Georgia, Massachusetts, New Jersey, New York, Tennessee and Washington) in 1978.	<p>CON restrictions meant that patients were poorly served; and the state lost in efficiency but gained in budgetary control. The impact on quality was unclear.</p>

#### Box 4.8: CON in the nursing home sector of the US

The literature that examines the influence of CON regulation on quality of care focuses on two main areas:

- The impact of CON on hospital services
- The use of CON to encourage high hospital volumes in specialist care, particularly cardiac surgery.

## Evidence: certificate of need

### Summary

CON as applied to general hospital services has not been successful in curtailing expenditure. One study found that more stringent CON regulations were associated with higher mortality rates although this has not been replicated.

As a tool to ensure minimum volumes of cardiac surgery, CON has been associated with lower rates of coronary revascularisation in one national study (although there was no impact on mortality); and lower mortality rates in a multistate study which focused on coronary artery bypass surgery. It is important to note that in the case of coronary revascularisation, despite strong evidence from randomised controlled trials that revascularisation is the most effective treatment for myocardial infarction, observatory data suggest that emergency revascularisations are not necessarily associated with better outcomes (Van de Werf, 2005). Therefore CON may have limited the diffusion of emergency revascularisation facilities, but this had no impact on mortality.

### *Hospital CON*

**Conover and Sloan 1998** assessed the impact of certificate of need (CON) regulation for hospitals on costs, supply, technology diffusion, and industry organization, whilst controlling for area characteristics, the presence of other forms of regulation, such as hospital rate-setting, and competition. Data were collected from the US Health Care Financing Administration (HCFA), Centers for Medicare and Medicaid Services (CMS), the American Hospital Association (AHA), SMG Marketing Group, and the National Directory of HMOs to conduct a time series cross sectional study. The study found that mature CON programs were associated with a modest (5%) long-term reduction in acute care spending per capita, but not with a significant reduction in total per capita spending (probably due to offsetting expenditures onto other services). There was no evidence of a surge in acquisition of facilities or in costs following removal of CON regulations. Mature CON programs also resulted in a slight (2%) reduction in bed supply but higher costs per day and per admission, along with higher hospital profits. CON regulations generally had no detectable effect on diffusion of various hospital-based technologies. The article identifies a paucity of evidence regarding the impact of CON on access to acute care services and asserts that "it is doubtful that CON regulations have had much effect on quality of care, positive or negative".

### *Research design: observational study*

**Campbell and Fournier, 1993** investigated the way in which regulators have used CON powers to achieve objectives other than cost containment. The study draws on 1983-1989 CON application data from Florida. Using a least squares regression and probit models, the study found that CON regulation was used to create an incentive to hospitals to provide high levels of care to the indigent population. Approval rates for CON applications were 79% where facilities offered high levels ( $\geq 12\%$  uncompensated care as a percentage of total revenues) of indigent care; 60% approval rates for those offering medium levels ( $< 12\%$  and  $> 4\%$ ) of indigent care; and 49% for those offering low levels ( $\leq 4\%$ ) of indigent care. Multivariate regression analysis found that a hospital's success with CON applications increased strongly with its performance in indigent care.

### *Research design: observational study*

**Shortell and Hughes 1988** examined the effects of regulation, competition and hospital ownership on in-hospital mortality rates. Mortality rates among Medicare patients for 16

clinical conditions were calculated for 981 US hospitals in 45 states. Data for the regression model were collected from the Health Care Financing Administration's Medical Provider Analysis and Review (MEDPAR) dataset for July 1983 to June 1984 and were case mix adjusted. Regulatory constraints and constraints on payment were measured in terms of the stringency of each state's CON and rate setting programmes and its Medicaid payment level. The stringency of programmes to review applications for CON was calculated as a composite variable which included: the number and types of facilities covered; the threshold limits (\$) for the review of capital expenditures, purchases of major equipment, and new programmes or services; the degree of enforcement in terms of review criteria and penalties for violation; and the length of time the programmes had been operational. The stringency of CON programmes was positively and significantly associated with higher mortality rates ( $\beta = 0.008$   $P \leq 0.01$ ). The ratio of actual to predicted deaths in states with stringent CON programmes was 1.06. The association of higher mortality rates with more stringent CON programmes was stronger for the five most critical conditions (acute myocardial infarct, acute tubular necrosis, congestive heart failure, coronary bypass surgery and hip replacement) ( $\beta = 0.01$ ;  $P \leq 0.002$ ), suggesting that CON regulation may hamper innovation and development of services.

*Research design: observational study*

#### *CON and cardiac surgery*

The volume of cardiac procedures has been associated with outcomes of care, particularly reduced mortality. Hospitals and surgeons with higher throughput tend to have lower mortality rates (Luft et al, 1979; Hannan et al 1991; Jollis et al, 1994; Kimmel et al, 1995; Hannan, 1999; Canto et al, 2000). CON regulations have been used to ensure that providers achieve minimum throughput necessary to maintain quality of care.

**Popescu et al 2006** compared the rates of coronary revascularisation and mortality after acute myocardial infarction (AMI) in states with and without CON. The study was a retrospective cohort study 1,139,792 Medicare beneficiaries aged 68 or over who were admitted to 4587 hospitals over the period 2000-2003. Outcomes were 30-day risk-adjusted rates of coronary revascularisation with either coronary artery bypass graft surgery (CABG) or percutaneous coronary intervention (PCI); and 30-day all cause mortality. Patients in states with CON (n=624,421) were less likely to be admitted to hospitals with revascularisation facilities than those in states with no CON (n= 515,371) 51.5% vs 62.8%;  $p < 0.001$ . Adjusting for demographic and clinical risk factors, patients in states with highly and moderately stringent CON regulations, were less likely to undergo revascularisation within the first 2 days (high stringency: adjusted hazard ratio 0.68; 95%CI 0.54-0.87; moderate stringency adjusted hazard ratio 0.80; 95% CI 0.71-0.90) relative to patients in states without CON. Unadjusted 30-day mortality was similar in states with and without CON (17.5% vs 17.5%) as was adjusted mortality (OR 1.00; 95% CI 0.97-1.03).

*Research design: observational study*

**Vaughan-Sarrazin et al, 2002** compared risk-adjusted mortality and hospital volumes for coronary artery bypass graft (CABG) surgery in US states with and without CON regulation directed at open heart surgery. The study was a retrospective cohort study of 911,407 Medicare beneficiaries aged 65 years or over, who underwent CABG surgery between 1994 and 1999 in 1063 hospitals. The analysis used Medicare claims data from all 50 states. Data were collected on mortality rates, both in-hospital and within 30 days of CABG surgery, and mean annual hospital volumes for CABG. After adjustment for demographic and clinical factors, mortality was higher in states without CON compared with states with continuous CON (OR 1.22; 95% CI 1.15-1.28,  $p < 0.001$ ). The mean annual hospital volume for CABG was 104 in states without CON, compared to 191 in those with continuous

CON ( $P < 0.001$ ). In states without CON 30% of patients underwent CABG in low volume hospitals (<100 procedures annually) compared to 10% in states with continuous CON ( $P < 0.0001$ ). Following the repeal of CON regulations in states with intermittent application, the percentage of patients undergoing CABG surgery in low volume hospitals tripled.

*Research design: observational study*

**Robinson et al 2001** examined volumes and outcomes of Coronary Artery Bypass Graft (CABG) surgery in all hospitals in Pennsylvania in the 3 years prior to, and the 3 years following, termination of CON in 1996. The CON programme was terminated after a review found that whilst regulation had moderately controlled the expansion of cardiac services, it had not controlled costs. Data was drawn from a state-wide inpatient reporting system. Mortality rate data were risk adjusted and were calculated on a sample of 19,961 patients operated on between July 1998 and June 1999. In the 3 years prior to the termination of CON, the number of open-heart surgery centres increased 2% (from 43 to 44); in the 3 years post termination, the number increased 25% (from 44 to 55). There was no significant increase in the number of CABG procedures performed in the state and only a slight increase in PTCA procedures. Over the 6-year period of the study, the crude mortality rate for all CABG surgeries declined. Risk adjusted mortality rates for non-valve CABG were similar for CON and post-CON centres.

*Research design: observational study*

**Ho 2004** compared hospital volumes (or throughput) for percutaneous transluminal coronary angioplasty (PTCA) in Florida, which uses CON regulations to ensure high volumes, and California where there are no CON-mediated restrictions. In 1988 the mean hospital PTCA volumes in Florida (237) were not significantly different from those in California (218;  $P = 0.44$ ). By 1998, Florida volumes were significantly greater (724 vs 389;  $P < 0.001$ ). Data were collected from discharge databases for 292,832 Florida admissions and 393,754 California admissions between 1988 and 1998 for which a procedure code for coronary angioplasty was recorded. Between 1988 and 1998, the inpatient mortality rate fell from 1.9% to 1.6% in Florida and from 1.7% to 1.3% in California. Over the same period, rates of urgent bypass graft surgery (a complication of PTCA) decreased from 3.1% to 1.8% in Florida and from 6.0% to 1.9% in California.

*Research design: observational study*

## Specific interventions – rate setting

### Background

Rate setting refers to a process of controlling prices, where regulators prospectively define a maximum amount that providers are allowed to charge their customers. The evidence may have particular relevance in the context of the introduction of Payment by Results (a form of rate setting) in England. Rate setting was instituted by some states in the US in the 1970s in an attempt to curtail spiralling costs (Mitchell, 1982). Rate regulation may be used to set the rate per service; the rate per case (as in DRGs); or the total revenue of the hospital (Smith et al, 1993). Two key factors are generally identified as triggering rate-setting programmes: rising premiums for private health insurance and financial crises caused by public expenditures exceeding budget.

Rate-setting was a controversial intervention and was implemented to various degrees by different states (Eby and Cohodes, 1985; Mitchell, 1982; Wallack et al, 1996). A summary of

the polarised positions that underpin the controversy is provided in Box 4.9.

The case for rate-setting	The case against rate-setting
<ul style="list-style-type: none"> <li>• Hospital expenditures exceed corresponding benefits</li> <li>• Society and government cannot afford to finance the excess</li> <li>• Government reimbursement on the basis of costs makes hospitals inefficient</li> <li>• When rate-setting replaces cost-based reimbursement, large cuts in expenditure growth can be achieved without sacrifice of quality or access; hospitals will absorb a lower rate of payment increases by improving efficiency</li> <li>• Relying on market forces in healthcare is neither feasible nor equitable</li> </ul>	<ul style="list-style-type: none"> <li>• Rate-setting programmes may control the rate of spending growth, but cannot properly control for efficiency and quality</li> <li>• Regulators have insufficient data for cost-benefit decisions so quality of care may be compromised</li> <li>• Rate setting limits supply, leaving demand unchecked</li> <li>• Better value may be secured through other approaches including making physicians, patients and employers more cost conscious; eliminating unnecessary barriers to market entry and improving comparative performance data</li> </ul>

**Box 4.9: Arguments for and against rate setting (adapted from Mitchell, 1982)**

Two models of rate setting were used initially: the formula method and the budget-review method.

- The formula method compares the costs of a unit of service in a given hospital with the costs in a group of similar hospitals. Any hospital in a particular cluster is reimbursed up to the mean cost in the group (normally making allowances for teaching and inflation and disallowing charges for above average length of stay).
- The budget review method requires hospitals to construct a budget for the coming year and the rate-setting agency appraises it and can reduce or eliminate any expenditure it considers to be excessive.

The two approaches were sometimes used in tandem with an initial rate set through the budget method and reimbursement limits set through the use of a formula.

Over time, it became clear that prospective reimbursement based on hospital characteristics did not adequately reflect the costs of case mix in a particular institution. As a result of this the Diagnostic Related Grouping (DRG) system developed. The DRG system (analogous to the HRG system in England) consists of several hundred categories that group patients according to primary diagnosis, secondary diagnosis, age and procedures (e.g. surgery). Criticisms of the DRG system include:

- A single DRG contains patients whose illnesses vary widely in severity and require very different levels of care, and hospitals may be less willing to provide care to those with severe illness
- The system encourages the use of interventions, by attracting additional DRG payments
- Provides an incentive to hospitals to manipulate DRG classification (e.g. by a sequence of diagnoses) in order to maximise revenue (known as “upcoding”)
- Imposes heavy costs of data collection and processing that yield no medical benefit (Schwartz, 1981)

A full review of the evidence pertaining to the impact of rate setting on quality of care is given on the following page. There has also been a significant volume of research into the financial impact of rate setting programmes. Key financial studies are summarised in Box 4.10.

Study	Setting and design	Findings
Lanning et al, 1991	Statistical regression 1966, 1969, 1972, 1976-1982.	Mature rate setting programmes are associated with lower per capita healthcare expenditures, both hospital and non-hospital. Rate setting constrained hospital expenditures in the long run by 4.8%. When rate setting regulation is treated as an endogenous variable; and rate setting and expenditures are determined simultaneously, rate setting has a more pronounced effect (~15.9% reduction).
Robinson and Luft, 1988	Data from 5490 short-term general hospitals 1982 and 1986	All-payer rate-regulation programs reduced inflation rates by 16.3% in Massachusetts, 15.4% in Maryland, and 6.3% in New York, compared with the control hospitals in 43 states with neither all-payer rate regulation nor an aggressive market-oriented strategy. New Jersey hospitals experienced a rate of cost inflation similar to the control hospitals.

Study	Setting and design	Findings
Eby and Cohodes, 1985	Evidence review 1979 - 1984	Mature rate-setting programmes constrained hospital expenditures. An association between rate-setting and cost constraints were found in four studies of per diem and per admission costs; two studies of per capita costs; and one study of state-wide aggregate hospital costs. The magnitude of the effect was estimated to be 2-3% reduction in annual rate of change in hospital expenditures per day and per admission; with a long run reduction in expenditures of around 10-20%.
Schwartz, 1981	Evidence review Pre 1980	Rate setting through mandatory prospective reimbursement was found to slow the growth of hospital expenditures by around 3-5%.

#### Box 4.10: Studies on financial impact of rate setting

From a financial viewpoint, there is strong evidence that rate setting can constrain the growth of expenditure on healthcare. However, the potential consequences of severe constraints on expenditure were illustrated in New York State where rate setting has been imposed most rigorously. In a review of the New York Prospective Hospital Reimbursement Methodology (NYPHRM), Fraser (1995) describes how in the late 1980s, when cost containment was pursued vigorously, hospitals suffered a significant drop in revenue and in margins. Losses for the states hospitals almost doubled between 1987 and 1990, from ~\$500m to ~\$1 billion; and operating margin deficits also doubled, from ~ \$700m to ~ \$1.4 billion.

#### Evidence: rate setting

The literature on the impact of rate-setting on quality of healthcare contains two key themes: – the effect on patient outcomes, particularly mortality rates; and the effect on the diffusion of innovations.

#### Summary

The evidence on the impact of rate-setting on mortality rates is mixed: studies by Sloan et al (1986a) and Smith et al (1993) found that rate regulation did not have an adverse effect on patient mortality or population mortality, despite lower admission rates; Shortell and Hughes (1988) found a statistically significant, although small, association between mortality rates and the stringency of rate regulation; Gaumer et al (1989) found mortality rates decreased more slowly in states with rate setting but found no correlation between mortality rates and level of cost savings. A more recent study found that discontinuation of rate setting, in favour

of a price competition model, was associated with an increase in relative mortality rates for some conditions (Volpp et al, 2003; 2005)

In terms of impact on the diffusion of innovations, rate-setting does not appear to hamper the adoption of cost increasing technologies but can temper excessive use and duplication of services.

#### *1. The effect of rate setting on outcomes*

**Volpp et al 2005** examined whether mortality rates for insured and uninsured patients in New Jersey hospitals changed after discontinuation of state rate-setting in 1993. Subsequent to discontinuing rate-setting, a model based on price competition with reduced subsidies for uncompensated care was adopted. Hospital discharge data for New Jersey 1990-1996 were used, with data from New York used as a control (n=469,629 discharges). Mortality rates (30-day; in-hospital; non-Medicare patients <65years) for seven conditions were collected: hip fracture, stroke, AMI, gastrointestinal bleeding, congestive heart failure, pneumonia, and pulmonary embolism. There were substantial decreases in risk adjusted mortality rates between 1994 and 1996 (1.0-1.7% per year for uninsured patients; 1.7-2.6% per year for insured). Following discontinuation of rate setting, mortality in New Jersey decreased less than in New York by 0.4% (p = 0.07). There was a relative increase in mortality for patients with AMI, congestive heart failure, and stroke; and especially for uninsured patients with these conditions.

*Research design: observational study*

**Volpp et al, 2003** examined whether acute myocardial infarction (AMI) mortality rates changed in New Jersey following the discontinuation of rate setting regulation and introduction of reforms based on price competition and reduced subsidies for uninsured care. A multiple time series research design was used, with New York as a control. Hospital discharge data were collected from 286,640 AMI patient records from 1990-1996. The principal outcome measure was death during the initial hospitalisation (provided length of stay was  $\leq 30$  days). Mortality rates declined steadily over the period 1990-1996 for insured patients in New York. The rate of decline was similar in New Jersey preceding reform (1990-1992) but following discontinuation of rate setting (1994-96), there was a levelling off of mortality rates. For uninsured patients, mortality rates decreased between the pre-reform and post-reform periods in New York whereas for New Jersey there was a 3.7 – 5.2% increase in mortality relative to New York.

*Research design: observational study*

**Smith et al 1993** examined whether there was an association between state rate setting and mortality rates. Data from Medicare patients ( $\geq 65$  years) from all US states in 1986 were included (6,046,518 Medicare inpatients; 29,179,000 population  $\geq 65$  years). Mortality rates did not differ between regulated and non-regulated states. For regulated states, the population mortality rate was 5.05%, with a standardised mortality rate (SMR) of 0.987 (99% CI: 0.983-0.991). For unregulated states, the mortality rate was 5.12% with an SMR of 1.006 (99% CI: 1.003-1.008). Hospitalisation rates were significantly different: in regulated states 20%; in unregulated states 22% (P<0.00005).

**Gaumer et al 1989** investigated the effect of state prospective reimbursement (rate-setting) on hospital mortality rates. The study compared standardised mortality rates in hospitals subject to rate setting (n = 1248) with those in a random sample of hospitals in the same region that were not subject to rate setting (n = 844). Data was drawn from Medicare records from 1974 to 1983 and were collected from four groups of patients: 5% random sample of

all Medicare recipients discharged from study hospitals; an aggregated sample of patients from 59 urgent care categories; a sample of patients with acute myocardial infarction; and a sample of patients with congestive heart failure. Hospital mortality rates generally fell over the period 1974-1983; however the introduction of rate-setting was associated with higher relative mortality in all patient groups studied. For the random sample of all Medicare patients, the effect of rate setting on mortality rates was 1-4 additional deaths per 1000 admissions; among patients receiving urgent care the effect was 2-3 additional deaths per 1000 admissions. There was no indication that the level of cost saving in states under rate setting was correlated with patterns of mortality rates.

*Research design: quasi-experiment*

**Sloan et al 1986a** analysed data on patients that underwent seven surgical procedures in 521 hospitals between 1972 and 1981. The procedures studied were hip arthroplasty, coronary artery bypass graft (CABG), morbid obesity surgery, hysterectomy, mastectomy, nephrectomy and spinal fusion and data for regression analysis consisted of discharge abstracts from the Commission of Professional and Hospital Activities. The study found that volume explained, at most, 10% of the variation amongst hospitals in 1981 mortality rates. State rate-setting programmes had no effect on mortality rates associated with the procedures studied.

**Shortell and Hughes 1988** examined the effects of regulation, competition and hospital ownership on in-hospital mortality rates. Mortality rates among Medicare patients for 16 clinical conditions were calculated for 981 US hospitals in 45 states. Data for the regression model were collected from the Health Care Financing Administration's Medical Provider Analysis and Review (MEDPAR) dataset for July 1983 to June 1984 and were case mix adjusted. The stringency of rate-setting was measured as a composite variable, including whether the programme was mandatory or advisory; whether hospitals were required to pay back excessive revenue; the extent to which rate-setting formulae were used; the extent to which cross subsidisation by departments and payers was allowed; and whether adjustments were made for patient volume. The stringency of rate setting programmes was positively and significantly associated with higher mortality rates ( $\beta = 0.003$   $P \leq 0.05$ ). The ratio of actual to predicted deaths in states with stringent rate-setting programmes was 1.04.

*Research design: observational study*

## 2. The effect of rate setting on the diffusion of innovations

**Robinson et al, 1987** analysed 1983 data from 3720 non-federal short-term hospitals from, in order to explore the influence of local market competition and state regulatory programs on the availability of percutaneous transluminal coronary angioplasty (PTCA) and coronary-artery bypass surgery (CABG). The degree of competition for patients with heart disease was measured in terms of the number of hospitals in the local market area that maintained a cardiac catheterisation laboratory or facility for open-heart surgery. When the patient case mix and the hospital's teaching role were controlled for, institutions with more than 20 competitors in the local area were 166% more likely to offer coronary angioplasty ( $P < 0.0001$ ) and 147% more likely to offer bypass surgery ( $P < 0.0001$ ) than hospitals with no competitors in the local market. Four fifths of the hospitals performing bypass surgery whose annual volume was less than 200 had one or more neighbouring hospitals with a facility for open-heart surgery. State rate-regulation programs in New York, New Jersey, Connecticut, Massachusetts, and Maryland significantly reduced the availability of both procedures, with the greatest regulatory effects being observed in the most competitive hospital markets. The authors concluded that in the period under consideration, competition encouraged and regulation discouraged the proliferation of these cardiac services.

*Research design: observational study*

**Sloan et al, 1986b** examined the diffusion patterns of five surgical procedures, focusing on a number of factors including regulatory policies. Data for regression analysis was drawn from discharge abstracts from 521 hospitals between 1971 and 1981. The procedures were: hip arthroplasty (total hip replacement), coronary artery bypass surgery (CABG), morbid obesity surgery, retina repairs and cataract surgery. The study found that whilst mandatory rate-setting showed little effect on the diffusion of the surgical technologies studied, they did appear to reduce slightly the use of CABG. Certificate of need programmes did not retard diffusion.

*Research design: observational study*

**Romeo et al 1984** examined the effects of rate-setting on diffusion of five technologies in six states; three with rate setting (Maryland, New York and Indiana) and three without (Pennsylvania, Missouri and Ohio). The innovations were electronic foetal monitoring, volumetric infusion pumps; upper gastrointestinal fibre-optic endoscopes; automated bacterial susceptibility testing; and centralised energy management systems. Data were drawn from American Hospital Association's annual survey for 469 hospitals. Among the states included in the study, mandatory rate-setting had no effect on the diffusion of five technologies in Maryland. The New York programme, which is the most restrictive, had no discernible effect on the decision to introduce cost increasing technologies but it did reduce the number of units of equipment hospitals acquired.

*Research design: observational study*

**Cromwell and Kanak, 1982** examined the effects of rate setting on the adoption of innovations and service sharing. The study drew on data from a sample of over 2,500 hospitals in 15 rate-setting and other states between 1969 and 1978. Rate setting in New York, where the oldest and most stringent model is in place, had a consistent, retarding effect on all services for New York. Several other States, notably Minnesota, Maryland, New Jersey, Washington, and Wisconsin showed retarding effects on costly rapidly diffusing services such as open heart surgery, intensive care units (ICUs), and social work, as well as accelerating the phasing-out of redundant services, such as the premature nursery. The study found no consistent, significant effects on service sharing.

*Research design: observational study*

## Specific interventions – formularies

### Background

Formularies are lists of preferred drug products that limit the number of options available within a therapeutic class for purposes of drug purchasing, dispensing and/or reimbursement. A government body, third-party insurer or health plan, or an institution may compile a formulary.

There are three main types of formularies:

1. open formularies: the least restrictive, open formularies list all drugs and drug products and rank which products are preferable
2. managed formularies: similar in breadth to open formularies, managed formularies use interventions and financial incentives to encourage the use of preferred products
3. closed or restrictive formularies: only those drug products listed can be dispensed in that institution or reimbursed by the health plan/insurer

Formularies are an increasingly important tool in supply management because of burgeoning drug costs across all healthcare systems. Recent trends in the US are towards the use of restrictive formularies, however a number of health plans now include a wider array of drugs in their formularies but stratify the drug choices by the amount of co-payments patients incur, i.e. if patients choose the more expensive option, they will pay a higher co-payment. In either design, formularies are instruments that can act to temper supply within healthcare markets.

Widely used in systems dominated by public provision, social insurance, private insurance and healthcare markets alike, formularies increasingly seek to balance concerns of quality and effectiveness with affordability and cost effectiveness (Aspinall et al, 2005). Restrictive formularies however have been criticised as over constraining of physician practice and potential barriers to optimal patient care (De Lissovoy, 2003); and stifling of innovation (Goodwin, 2003).

### Evidence: formularies

#### Summary

There is little robust evidence available on the impact of formularies on quality of care. A literature review noted a deleterious effect of formularies on patient outcomes but highlighted methodological limitations which bring the results into question. Conversely, according to a national survey, the formulary introduced by the Department of Veterans Affairs (VA) was not perceived by physicians to adversely affect patient care.

**Pearson et al 2003** undertook a systematic review of the effectiveness of strategies to improve the quality and efficiency of medication use in managed care organisations (MCOs). Their searches identified 105 studies, 70 of which were reported since 1996. Overall, 48 of the studies met the minimum criteria for methodological adequacy. Consistently effective interventions included dissemination of educational materials with drug samples, participatory clinical guideline development, group or one-to-one educational outreach, and enhanced patient-specific feedback. Disease management (primarily for depression and diabetes) showed promise in improving short-term outcomes. Dissemination of educational materials and aggregated feedback alone were ineffective. The review notes that there is a *glaring lack of evidence concerning the effects of financial and formulary-related interventions* (p 730).

*Research design: systematic review*

**Huskamp et al 2003** investigated the impact of incentive-based formularies by US health plans. The study drew on 1999-2001 claims data to compare the utilisation of, and spending on, drugs in two employer-sponsored health plans that introduced three-tier formularies (i.e. differential co-payments) with those in comparison groups covered by the same insurers. One employer switched from a single-tier to a three-tier formulary and an across the board increase in co-payments. For ACE inhibitors; 42% of patients changed to less expensive tier 1 or 2 drugs; for proton pump inhibitors 35% changed; and for statins 49% changed. However a sizeable proportion of enrollees stopped taking medications altogether: ACE inhibitors 16%; proton pump inhibitors 32%; and statins 21% (compared to 6.4%, 18.9% and 10.6% respectively for the control group). The second employer switched from a two-tier to a three-tier formulary with no increase in cost sharing for drugs in tiers 2 and 2. These changes had little effect on the probability of using a drug, or the likelihood of discontinuation of use.

*Research design: systematic review*

**Lexchin, 2002** examined the literature for studies that evaluated the consequences of restrictive formularies in the ambulatory care setting. The review focused on four areas: overall drug expenditures, overall healthcare spending, changes in the quality of prescribing, and health outcomes. A Medline search was conducted for English and French language articles, published between 1977 and 1999. Poor methodological quality made definitive conclusions difficult to draw. Studies which examined the impact of restrictive formularies on health outcomes show a deleterious effect, although the studies had methodological limitations. The study found that both desirable and undesirable therapeutic substitutions take place when drugs are removed from formulary list. Prior authorisation may be effective in controlling drug costs without increasing other costs.

*Research design: literature review*

**Glassman et al 2001** used a cross-sectional survey to ascertain the perceptions of US Department of Veterans Affairs (VA) physicians about the effects of a National Formulary (NF) on patient care, access to drugs, physician workload, and resident training approximately 1 year after it was implemented in 1996. A questionnaire was sent to attending physicians working within the VA healthcare system (n = 4536) and 2052 responses were received (45.2% response rate). Respondents included general internists (n = 1278), neurologists (n = 95), psychiatrists (n = 468), general surgeons (n = 147), and urologists (n = 70). Most respondents (63%) thought that they could prescribe needed drugs; 65% agreed that patients could obtain needed non-formulary drugs when medically justified. One third disagreed that access to prescription drugs at their facility had increased with the introduction of the national formulary; 29% disagreed that the formulary enhances their ability to provide quality care. Thirty eight percent of physicians perceived the NF to be more restrictive than private sector formularies; 16% thought that the NF diminished the ability to train residents for managed care; 34% indicated that the NF added to workload.

*Research design: observational study*

**Avery et al 1997** examined whether the introduction of prescribing formularies helped general practitioners (GPs) to prescribe from a narrower range of non-steroidal anti-inflammatory drugs (NSAIDs). Data were drawn from 10 practices in Lincolnshire between April and June 1992 (before the development of the formularies) and April and June 1993 (after development) and compared to data from 10 matched controls. Those practices that introduced a formulary for NSAIDs reduced the mean number of different drugs used (14.3

vs 13.1;  $p=0.04$ ) and increased the percentage of defined daily doses coming from the three most commonly used drugs (70.1% vs 74.8%;  $p=0.02$ ). Similar changes were not seen in control practices.

*Research design: observational study*

### England context: market regulation

The government in England has in recent years has increasingly turned to market mechanisms as a lever to improve performance in the healthcare system. Policies have focused on four main areas:

1. developing locally based 'commissioners' or purchasers of care;
2. providing incentives to secure improvement;
3. extending patient choice;
4. encouraging a mixed economy of providers of care.

Such significant change has important implications for regulation. At the moment, the key regulators are the Healthcare Commission (responsible for regulating quality across all NHS organisations) and Monitor (responsible for regulating the "market" populated by Foundation Trusts).

Monitor's functions are shown in Box 4.11.

Function	Key activities
Monitor financial performance	<ul style="list-style-type: none"> <li>• Gather and synthesise financial performance data (e.g. income and expenditure, cash flow)</li> <li>• Compare provider performance to benchmark (financial risk rating system)</li> </ul>
Enforce the "rules of the game"	<ul style="list-style-type: none"> <li>• Monitor and address violations (e.g. illegitimate tariff splitting, caps, conflicts of interest between payer and provider)</li> </ul>
Intervene to address financial instability, failure and insolvency	<ul style="list-style-type: none"> <li>• Set criteria for when intervention will occur (e.g. below a certain financial risk rating)</li> <li>• Develop and implement framework for intervention</li> <li>• Define when market exit can occur (e.g. provider is financially unviable and other providers are able to provide all essential services)</li> </ul>
Set conditions for market entry	<ul style="list-style-type: none"> <li>• Set entry criteria for suppliers/providers</li> <li>• Assess applicants against the criteria</li> </ul>

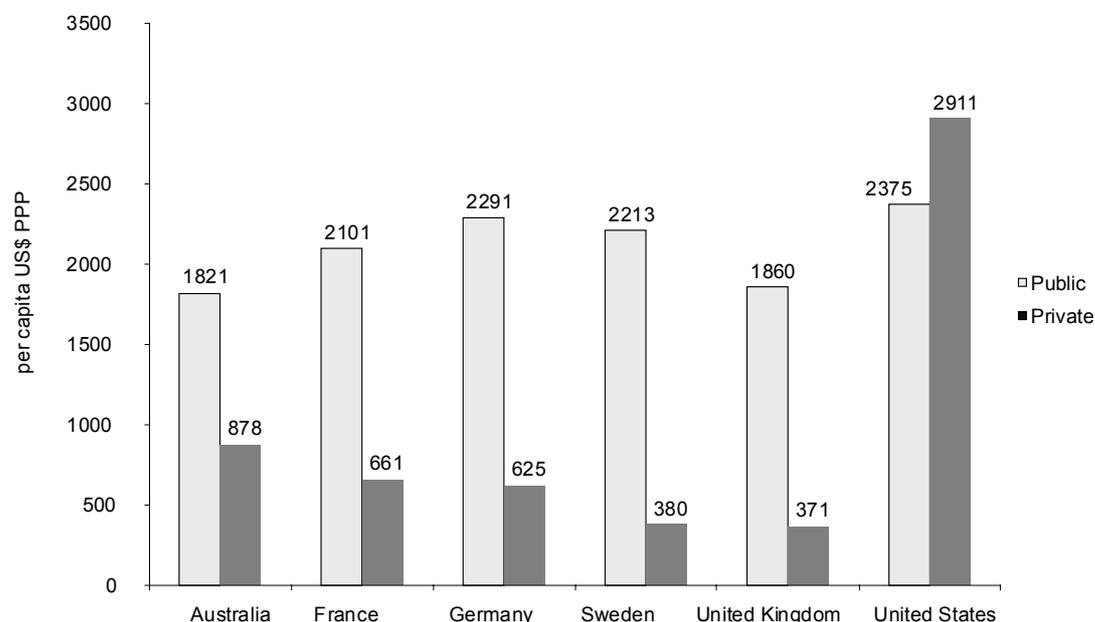
Function	Key activities
Facilitate competition across all providers	<ul style="list-style-type: none"> <li>• Monitor anti-competitive behaviour (e.g. by expanding financial monitoring to assess market penetration)</li> <li>• Assess mergers and acquisitions for the view point of financial viability, governance, essential services, and impact on competition (including feasibility of vertical integration between primary and secondary care)</li> </ul>
Develop tariffs	<ul style="list-style-type: none"> <li>• Gather information on industry cost base</li> <li>• Agree incentives with other stakeholders</li> <li>• Consider overall system affordability</li> </ul>

#### Box 4.11: Monitor's function in regulating Foundation Trusts

#### US context: market regulation

Almost all the available evidence on the impact of regulatory interventions on healthcare markets emanates from the US.

The healthcare market in the US is huge. Figure 4.2 shows the relative public and private spending on healthcare, illustrating how private expenditure on health in the US dwarfs that in comparator countries.



**Figure 4.2: Public and private expenditure on health in 2002 (Source: OECD Health Data, 2005)**

Any review of the evidence pertaining to the US healthcare market highlights the heterogeneity of approaches adopted across the various states. Whilst this variation provides some insights from the resulting “natural experiments” that allow us to make comparisons between different interventions adopted by different states, it also complicates interpretation of results. Each state has its own historical and cultural context which makes for a unique environment for regulation.

The historical reliance on market-based mechanisms to deliver accountability and performance improvement in the US is increasingly coming under scrutiny (Nichols et al, 2004; Cogan et al 2005). The high administrative costs of regulating the market are seen to be a contributory factor in the high health spending figures.

## Appendix

### Exemplar search strategies

The following three tables illustrate the search strategies used in our main Medline searches. As noted in the methods section (p 11), searches were run across multiple electronic bibliographic databases and it was necessary to vary the search strategies slightly in order to accommodate characteristics particular to different databases.

### Institutional regulation

#### Medline search – final run July 2006

#1.	accredit* [ti]	3213
#2.	inspect [ti]	2757
#3.	“external review”[ti]	27
#4.	“external oversight”[ti]	2
#5.	target AND set* [ti]	77
#6.	health AND target [ti]	405
#7.	standard AND set* [ti]	338
#8.	“national institute for clinical excellence” OR NICE [ti]	857
#9.	“national service framework” OR NSF [ti]	486
#10.	#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9	7861
#11.	outcome* OR data OR ratio* OR rate* OR randomi* OR empirical OR mortality OR quality OR performance [ti/ab] [human]	3167473
#12.	#10 AND #11	1400

### Professional regulation

#### Medline search – final run July 2006

#1.	“professional regulation”[ti]	30
#2.	licen* [ti]	1929
#3.	regist* NOT registry [ti]	8081
#4.	credential* [ti]	490
#5.	“external peer review” [ti]	13
#6.	revalid* [ti]	92
#7.	certif.* [ti]	3570
#8.	privileg* [ti]	943
#9.	visitatie [ti]	4
#10.	“scope of practice”	212
#11.	national practitioner data bank” [ti]	156
#12.	#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11	15300
#13.	nurse* OR doctor* OR special* OR profession* OR physician* OR staff OR employee*[ti/ab]	491533
#14.	. outcome* OR data OR ratio* OR	rate* OR randomi* OR empirical
#12 AND #13 AND #14		1319

**Market Regulation**  
**Medline Search – final run May 2006**

#1.	rate setting [ti]	172
#2.	antitrust [ti]	1025
#3.	“market entry” [ti]	5
#4.	“market exit” [ti]	2
#5.	supply AND market [ti]	25
#6.	merger* [ti]	1556
#7.	“data protection” [ti]	172
#8.	“price control” [ti]	26
#9.	“gag rules” [ti]	9
#10.	“mandated benefits” [ti]	50
#11.	“reserve requirement” [ti]	2
#12.	“safety net” [ti]	310
#13.	conversion AND (hospital OR profit OR ownership) [ti]	88
#14.	grievance OR appeal [ti]	1025
#15.	“financial reporting” [ti]	16
#16.	727 subsid* [ti]	
#17.	governance [ti]	1179
#18.	formulary [ti]	705
#19.	“any willing provider” [ti]	53
#20.	(compulsory OR mandatory) AND report* [ti]	199
#21.	“certificate of need” [ti]	154
#22.	market AND regulat* [ti]	96
#23.	#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22	6553
#24.	outcome* OR data OR ratio* OR	rate* OR randomi* OR empirical
#23 AND #24		1360

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