

• How to Regulate Health Care in England?

AN INTERNATIONAL PERSPECTIVE

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King's **Fund**

Across the world, the appropriate role of government in the planning and delivery of public services has been the subject of intense debate: how should the state control the provision of those services and how far should markets be allowed to determine the provision of those services? One answer to these questions is 'regulation' – ie, the creation of mechanisms that allow governments to influence the behaviour of autonomous service providers. This report compares the regulatory framework in four health systems: the Autonomous Community of Catalonia in Spain, Germany, the Netherlands and New Zealand. This comparison is used to reflect on the future regulation of the NHS in England.

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1

Introduction

The National Health Service (NHS) in England is in a state of transition as the government pushes forward a programme of significant reform. If the government achieves its stated objectives, the NHS will be transformed from a state-owned commissioning and provision system to one in which care is delivered by a diverse range of largely autonomous public and private organisations within a health care market.

With this market now developing rapidly, the question of how best to regulate it becomes ever more pressing. Regulation is intended to guard against various ‘market failures’, such as the development of monopolies or quality deficiencies. So far, the objectives and architecture of NHS regulation are under-developed and the operation of (and importantly the limits to) the market are still being defined. The existing regulatory system is, therefore, unlikely to be fit for purpose as the market matures. A number of important issues remain unresolved – what should be regulated, by whom and how?

The government has been conducting a review of regulation and will shortly produce a consultation document that begins to answer these questions and to describe a new regulatory framework.

This report sets out the findings of a comparative study of regulation in Germany, New Zealand, the Netherlands and the Autonomous Community of Catalonia in Spain. The objectives of the study were to understand how the commissioning, provision and regulation of health care are undertaken and, through comparative analysis, to reflect on the future regulation of the NHS in England. This study does not consider the regulation of health care professionals or other regulatory mechanisms designed to secure basic safety (such as health and safety, licensing of medicines etc). It describes the wider array of governmental instruments of regulation, but maintains a special focus on the use of arm’s length bodies, organisations that are wholly or partially independent of the government, as this question is central to the current debate in England.

The recent reforms of the English NHS are radical but not without international precedent. They represent the evolution of a broader policy of competition and contestability in the supply of public services that stretches back at least to the 1980s. Across the world, the appropriate role of government in the planning and delivery of public services has been the subject of intense debate. Many governments have chosen to withdraw from the direct management of a range of public services (particularly utilities such as telecoms) with the aim of improving quality and efficiency by encouraging choice and provider competition. This withdrawal has been achieved through different strategies such as the outright privatisation of some industries, or by the transfer of responsibility for service delivery from central government to more autonomous organisations within a broadly public sector setting.

The activities and purpose of government have been redefined, a process that has often been labelled ‘new public management’. New public management is founded in the belief that governments should withdraw from direct managerial control of and intervention in public services, restricting themselves instead to setting high-level objectives.

Under new public management, governments primarily ‘steer’ rather than ‘row’ (Osborne and Gaebler 1992). The motivational force for service improvement and continued efficiency is ensured through the application of ‘business disciplines’ to public services, for example through the creation of markets, or quasi-markets, usually allied to a new culture of managerialism (Bovaird and Löffler 2003; Hood 1991).

The partial or complete withdrawal of government from the provision of public services (depending on the sector) has posed a crucial question: to what extent and through what mechanisms should the provision of public services be controlled by the state? Or, in relation to the NHS, to what extent should markets be allowed to determine how health services are provided given that they do not always deliver socially desirable results without a framework of rules?

In answering these questions, governments have turned to ‘regulation’ as an appropriate balance between over-centralised governmental control on the one hand and an unbridled market on the other.

Regulation is a complex concept (and is discussed in depth in Section 2). However, in essence it involves the creation of mechanisms that allow governments, directly or indirectly, to shape the behaviour of providers or funders of goods and services that they do not own to ensure that governmental objectives (such as efficiency and consumer safety) are achieved in the face of potential significant market failures.

Hood and Scott (2000) identify a link between the rise of regulation and the new culture of ‘managerialism’, resulting in a new type of ‘public service bargain’. The terms of this new bargain are that public servants accept direct responsibility for ensuring that services are delivered (even if not publicly provided), while elected politicians avoid hands-on control over operations and focus instead on policy and strategy. This arrangement is underpinned by new types of regulation, in particular additional reporting requirements and rules policed by arm’s length overseers.

However, the new public sector bargain is vulnerable to ‘cheating’ behaviour by either government or management or both. The result can be that politicians exert covert influence over managers while ensuring that they are accountable for any for decisions made. Conversely managers might politicise their own performance by blaming politicians for poor administration (Hood and Scott 2000).

Paradoxically, the new public management desire for the rolling back of the state, and the introduction of markets across the public sector in practice, has led to an increase in certain types of regulation and to new modes of intervention from the centre. Indeed, it has been suggested that we have seen an explosion of new forms of regulation leading to an overload of controls and a high regulatory burden (Hood *et al* 2000).

As Grant (2003, pp 226–27) suggests, despite an apparent retrenchment initially:

... the state starts to expand again, but in a more chameleon-like form, so that the emergence of a regulatory state does not mean that state power necessarily diminishes, but that its form changes... becomes more diffuse... becomes less direct, but also more penetrating. A regulatory state is in many ways a more fragmented state with responsibility divided amongst a host of different regulators or auditors.

Regulation can take many forms. In its everyday usage, the term refers to the creation of and intervention by ‘arm’s length’ bodies. Arm’s length bodies are organisations that are wholly or partially independent of government with powers to scrutinise non-governmental and quasi-autonomous bodies and to intervene if pre-ordained criteria are met.

However, arm’s length regulatory bodies are but one approach that governments adopt in order to exert influence. As we discuss below, a range of new instruments of direct or indirect control are being developed by government (Jordan *et al* 2005). This evolution of regulatory instruments is particularly pertinent to the English NHS where government decentralisation, an increase in the use of independent suppliers and a reliance on market-style incentives, is creating a significantly different organisational environment and presenting new regulatory challenges (Lewis and Dixon 2005).

Since 1997, the NHS has seen an increase in the number of regulatory bodies that oversee care. The creation of the Healthcare Commission, which regulates quality of care, and Monitor, which licenses independent NHS foundation trusts and regulates their financial performance and governance, has transferred significant power away from government.

The formal rules of the emerging market-based NHS are still under construction and the formal and informal relationships between organisations are as yet unclear. The incentives of Payment by Results (the new method of activity-based hospital payment), and enhanced rights for patients to choose from public and private providers, have the potential to introduce radically different dynamics into the NHS. It is in this context that the Department of Health launched a review of the existing regulatory framework of health and social care (Outram 2005).

In this report, we first examine the meaning and evolution of the concept of regulation. We then consider the political context that has shaped the debate about how health care should be regulated. In particular, we look at the development of the new NHS market in England and consider the challenges that this presents. We go on to describe the regulatory approaches adopted in four health systems and identify any lessons for the English NHS. The report concludes with a discussion of options for health care regulation in England in the future.

2

What is meant by regulation?

Defining 'regulation'?

Regulation is a much-contested term. One often-quoted definition of regulation is that of Selznick (1985) who defines regulation as the 'sustained and focused control exercised by a public agency over activities which are valued by a community'. A similarly broad definition is that used by the Better Regulation Task Force, which describes regulation as 'any government measure or intervention that seeks to change the behaviour of individuals or groups' (BRTF 2003).

As Jennifer Dixon points out, regulation in its broadest sense incorporates linked concepts of 'behaviour shaping' and 'overseeing'. Yet such all-encompassing definitions do not allow a distinction to be made in the public sector between the domains of 'performance management' or 'internal regulation' (the control of a public body by a responsible ministry that 'owns' that regulated body) and that of independent or 'external regulation' (where an organisation is controlled by a regulator that is organisationally separate even if in the public domain) (Dixon J 2005).

This is an important distinction as the current regulatory debate has been framed within the wider context of the partial or complete withdrawal of government from the responsibility for operational management of public services. Our interest in regulation lies in understanding the relationship between central government and agencies that are more or less distinct from it (ie 'external regulation') and the balance between external regulation and hierarchical performance management (ie 'internal regulation').

External regulation is largely 'rules based' in that it is associated with a high degree of transparency and regularity with regulators acting predictably in accordance with these rules. Indeed, its 'independence' relies to a degree on the adoption of this approach. This contrasts with internal regulation or 'performance management' where the owner enjoys a high degree of discretion in how it manages its relationship with the business in question.

Other theorists have sought to define regulation with reference to the nature of the institutions that undertake it. Walshe, for example, suggests that regulation must involve a third party or some form of inter-organisational relationship (ie by definition 'external') (Walshe 2003). Hood and Scott suggest that regulation can be defined using three conditions (Hood and Scott 2000):

- one organisation (usually a public one) attempting to shape the behaviour of another organisation
- some form of arm's length separation between the target organisation and that doing the overseeing
- the overseer has some formal authority or mandate to scrutinise and influence the regulated organisation.

While this helps to describe regulation by specially created and independent bodies, and importantly to distinguish their influence from that of pressure groups and other organisations that also seek to oversee and influence without a legislative basis, the definition is rather narrow. Regulation can be seen instead as a set of instruments or strategies that governments use directly or indirectly to exert influence over organisations providing public services. This includes the establishment of arm's length regulatory bodies, but such bodies are not the only means by which government exerts control.

In his earlier writing, Hood describes a range of resources or tools that governments have at their disposal by which they can influence economic or social activity (Hood 1983). These include using force of law, providing financial incentives and informing consumers to influence their behaviour. This demonstrates that 'behaviour shaping' can be multi-faceted.

Baldwin and Cave (1999) have developed this approach and identified a range of different regulatory strategies (ie the means by which government can shape activities of organisations within a given market or sector). These strategies include:

- 'command and control' – the government uses the force of law (backed up by the courts or by regulators) and performance management
- self-regulation – organisations are allowed or required to regulate their own behaviours
- incentive-based regimes – the use of taxes, grants or other financial incentives to shape behaviour
- market-harnessing controls – the use of competition law, government contracts or tradable permits
- disclosure regulation – mandating suppliers to supply information directly to the public or via a regulator
- direct action – working with suppliers to ensure basic standards
- rights and liabilities – conferring rights (such as the right to clean water) which can be enforced through litigation
- public compensation/social insurance schemes – for example, no fault compensation schemes where an organisation's premium depends upon their performance.

The rise of 'governance'

While governments have a range of ways in which they may influence economic or social society which go far beyond 'command and control', the overall power of governments has also been eroded (although this varies by sector). Governments, it has been contended, have lost power upwards (to the European Union), downwards (to devolved regions and communities) and outwards (to non-governmental bodies, private and quasi-private bodies) (Pierre and Peters 2000).

As a consequence, there has been a growth of interest in the concept of 'governance' (rather than 'government'). Governance is founded on the view that a wide range of institutions and interventions are involved in the process of governing, not governments alone. Furthermore, these institutions claim their own rights to participate in the business of government and do not restrict themselves simply to attempting to influence government. In response to this, governments have altered the way in which they seek to achieve their policy goals and have developed a new range of policy instruments.

These include benchmarking, co-regulation, voluntary codes of practice, negotiated agreements and market-based instruments such as taxes, subsidies and traded permits (Jordan *et al* 2005).

While new public management and governance are similar, particularly with respect to the belief that the state is and should be less important in the management of services, there are important differences between these two theoretical approaches. New public management dismisses the role of the state as obsolete, but governance theorists see the state as a vehicle for collective interest, facilitating and co-ordinating overall governance (Bovaird and Löffler 2003).

Therefore, to focus attention simply on one agent of regulation (arm's length regulatory bodies), does not do justice to the variety of ways in which governments seek to shape behaviour of autonomous or quasi-autonomous organisations. Indeed, it is the diversity of strategies and instruments employed that is of interest in comparing the regulatory approaches of different countries.

The functions and means of regulation

Regulation can be divided conceptually into 'economic regulation' and 'quality regulation' (Monitor 2005). Indeed this division underpins the analytical approach discussed further in Section 3. Economic regulation refers to regulating the activities of organisations as they relate to each other or to consumers within a market, for example the management of market entry and exit, anti-competitive behaviour and pricing. Quality regulation relates to controls over the nature of the product offered to the consumer (or controls over the competence of those delivering the product).

Yet despite the different domains of regulation, it is primarily a way of dealing with two types of failure; government failure and 'market failure'. The replacement of direct government management with a mix of markets and independent regulation is intended to improve the delivery of services. It is underpinned by a belief that government is a relatively weak performer in this respect. Therefore, it may be argued that markets are the best way of allocating resources and providing incentives to ensure goods and services are delivered efficiently. In addition, independent regulatory agencies may be better placed to carry out certain functions than government on the grounds of competency, efficiency or impartiality. For example, an independent or quasi-independent agency might be preferred to provide information to the public, where the impartiality of that information is paramount. Similarly, the setting of standards may be devolved to another agency on the grounds that the required expertise lies outside government.

However, the substitution of government by markets also advances the case for regulation in the event of actual or predicted 'market failure' in the sector concerned. There is a wide range of circumstances in which markets may produce undesirable consequences, such as negative 'externalities' (costs that result from the productive process but which do not fall on the consumer), profits that do not reflect a fair rate of return, a lack of competition within the market leading to monopolies and excessive market power or an unequal distribution of benefits (where equity is a public policy goal).

These undesirable outcomes may result from the nature of the market (a natural monopoly will inhibit competition and lead to a supplier dominating consumers), or from the nature of the product (the supplier may have access to information that is unavailable to the consumer giving them an unfair advantage).

These forms of market failure are very pertinent to health care. As a commodity, health care has a number of characteristics that mean market failure is highly likely (Arrow 1963). The ability to access and interpret information is a significant factor with consumers largely unable to judge the appropriateness of the service offered despite being better informed than in the past. The cost of high-technology care means that significant barriers to entry exist in some market sectors, depressing competitive forces. Moreover, public policy goals emphasise the need for health care resources to be allocated fairly. These all establish a *prima facie* case for regulation of health care markets.

Regulation may be *ex ante* or *ex post*:

Ex ante regulation refers to regulatory controls that seek to prevent adverse behaviour or outcomes, for example the licensing of service providers prior to their entry to the market.

Ex post regulation takes action after an offence has been detected, for example the fining of companies for abuse of a dominant market position by the Competition Commission.

Regulators may also adopt different styles of regulation. Two archetypal styles have been developed, although in practice regulators may adopt both at different times according to the context – deterrence and compliance (Walshe 2003).

Deterrence regulators may assume that the organisations that they regulate are motivated solely by self-interest and require careful watching. Organisations are expected to conform to standards of behaviour imposed by the regulator. Deterrence regulators may make extensive use of quality standards and sanctions for non-compliance.

Compliance regulators assume that the regulated organisations are likely to share their objectives and are worthy of trust and support. This style of regulation will offer advice and guidance and will be slow to use sanctions.

The precise institutional form of regulators will differ, as will their autonomy from government and the bodies that they regulate. Regulators can be compared in relation to their constitution, formal remit or mandate, legal powers and authority, governance and reporting or accountability arrangements. (Walshe 2003). For example, a single agency may be charged with both quality and economic regulation (a ‘super-regulator’), or these functions may be institutionally separate. Anna Dixon (2005) applied Preker and Harding’s (2003) taxonomy of autonomy to the field of regulation:

- **Extent of delegation** What powers are delegated to the regulatory institution by the state?
- **Scope of delegation** Over what areas does it have discretion?
- **Governance and accountability** How are the governance arrangements of the regulator organised? To whom is it accountable?

- **Participation rights** What decision-making powers do the governors have? Are the governors to be consulted, do they have voting rights or is there minimal involvement of constituents?
- **Institutional design** How often and in what areas does the state intervene, for example in setting the budget, making or approving appointments, issuing directives or having direct oversight of the regulatory institution?

She comments that different health care systems are arranged along a spectrum of autonomy; the level of autonomy granted to regulators will depend on the political and public interest, the objectives of regulation, the incentives and behaviours of the regulated and the costs of regulatory failure.

Wider regulation policy in the United Kingdom and Europe

There has been significant concern in recent years over the burden that regulation places on producers of regulated goods and services. Attention has been focused on minimising this burden. The government established a Regulatory Impact Unit in 2000 that imposed a process on government departments intended to reduce the scope and extent of regulation to a minimum. Where regulation is proposed (including a wide range of regulatory instruments such as codes of practice and information campaigns) government departments are required to carry out ‘regulatory impact assessments’. These assessments are intended to consider the full range of potential impacts of their policies (ie economic, social and environment) and the range of options available for implementing them.

The Better Regulation Commission (previously Better Regulation Task Force), an independent body set up by the government to advise on regulation, has established five principles that should underpin government regulation (*see box below*). These principles are to be enshrined in law as a formal duty on all regulators through the Legislative and Regulatory Reform Bill (currently in parliament). This bill also proposes a code of practice for regulators intended to improve the process of regulation.

A further concern has been to simplify the UK regulatory system. Simplification was a key proposal of the Better Regulation Task Force’s publication *Less is More* (BRTF 2005). Government departments have been instructed to take part in a rolling programme of simplification, stimulated by the ‘compensatory simplification’ process. Departments must

PRINCIPLES OF GOOD REGULATION

Proportionate – to the risk

Accountable – to ministers and parliament, to users and the public

Consistent – predictable, so that people know where they stand

Transparent – open, simple and user-friendly

Targeted – focused on the problem, with minimal side effects.

BRTF (2005)

now look for opportunities to simplify or remove existing requirements when they want to introduce new regulations. A Panel for Regulatory Accountability has been established to consider the regulatory impact assessments of all proposals likely to impose a major new burden on business (other than emergency legislation or tax matters). The panel may reject proposals if it determines that there has been insufficient offsetting of old regulation for new.

Simplification has also taken place in relation to the number of regulators. In 2005, the Hampton Review recommended that some national industry regulators should be merged to reduce the total from 31 to 7 by April 2009. Work is currently underway to complete this process. A similar process was undertaken with respect to health services. The arm's length body review resulted in a programme to reduce the number of arm's length bodies (some of which had a regulatory function) from 38 to 20 (DH 2004a).

The role of the European Union (EU) in regulating the English NHS may also be significant in future (Greer 2006). Up to now, the European Court of Justice (ECJ) and the European Commission's competition directorate have played a relatively minor role in relation to publicly financed health services in England. However, it is clear that as EU member states reform their health systems to reduce direct public control over the provision, and to some extent, the financing of health care, they expose their systems to the jurisdiction of the ECJ. Member states retain exclusive authority to organise their own social security and public health care systems, including putting in place state monopolies of finance/insurance and provision, and significant restraints on their citizens seeking care in other EU countries without prior approval. However, if states increasingly organise their systems competitively, with relatively free entry criteria for providers and extensive patient choice within their systems, it will become difficult to prevent insurers and providers from other EU countries entering their health care markets. It will also be harder, as recent cases have shown, to prevent citizens seeking state-funded care in other EU countries when 'undue delay' has occurred in the citizen's own health system (ECJ 16 May 2006, case C-372/04).

By contrast, if a member state retains a national health service mostly vertically integrated between health authorities and providers, with fixed budgets and prior approval for patient choice, it is possible to prevent citizens accessing services in other EU countries, at least for hospital care, under the EC Treaty. It is not, therefore, a matter for ECJ intervention to promote the free movement of goods and services. However, this does not appear to apply to 'non-hospital' services (however defined) or where there has been 'undue delay' in providing treatment to a citizen. In these situations, the ECJ has ruled that prior authorisation cannot be required of patients and they must be reimbursed up to the price of the same treatment in their country of origin.

Thus member states retain the right to choose whether a hierarchical largely non-competitive health care system (like the former NHS) or a more market-driven system is preferable, but their decisions will have different implications in terms of 'internal market' rules and the ECJ's interpretation of its role.

European competition law is also becoming increasingly important for health care systems of EU member states, because where insurers and providers compete and where they are not obliged to ensure universal coverage, they are considered to be 'undertakings'

according to the Treaty. As a result, competition law can be enforced (eg to challenge mergers and prevent vertical integration between providers). However, to date, the European Commission's competition directorate has been relatively restrained in enforcing and/or promoting the application of EU competition law in health care markets.

It is within this context of regulatory review across government and developments in Europe that NHS management is currently considering its own processes for management and regulation. In 2005, the Department of Health began a review of regulation in health and social care (excluding professional regulation). This was overseen by a Regulation Review Panel chaired by David Currie, the chairman of Ofcom (the independent regulator of telecoms). It was intended to, among other things, define objectives for regulation, examine the required regulatory functions and put forward proposals for how these should be implemented. (Outram 2005). As already noted, the results of their review will soon be published in the new Department of Health guidance on NHS regulation.

The following section considers evolving policy for the NHS in England and the regulatory challenges that this presents.

3

The regulatory challenges of NHS reform in England

The trend towards new public management, described in the introduction, has been evident in health policy in England for many years. The decision to reform NHS management in 1982 (Department of Health and Social Security 1983) and, in 1990, to introduce a quasi-market were archetypal of this philosophy. NHS reforms since the 1980s have been informed by the belief that markets with private sector business disciplines and competition between providers would increase quality and efficiency.

The Labour government of 1997 came to power with a rhetoric based more on co-operation than competition. However, it did little to dismantle the new public management foundations of previous governments. Over time, this government has pressed further than any of its predecessors in introducing market competition to the health sector.

The current reform programme consists of four domains (DH 2005; DH 2006):

- demand-side reforms – promoting patient choice of service provider and stronger commissioning by general practices and primary care trusts (PCTs)
- supply-side reforms – creating autonomous foundation trusts, the diversification of providers (including voluntary and private sector providers) and granting them more freedom to innovate and improve services
- transactional reforms – new incentives (such as ‘payment by results’ and better information) intended to reward the best and most efficient providers
- system management and regulation reforms – to include setting standards, licensing of providers, competition policy, performance management and price setting.

This reform programme is as yet incomplete. The NHS is in the process of transition with the remnants of the former system still very much in evidence and new commissioning structures only just bedding in.

The majority of NHS care is still provided by NHS trusts that are accountable, through strategic health authorities, to the Secretary of State for Health. However, 52 NHS foundation trusts have been created and the number is set to increase as all NHS trusts are to have the opportunity to become foundation trusts by 2008 (DH 2006). Foundation trusts are autonomous of the Department of Health, accountable instead to an independent regulator (Monitor), to local members and to commissioners.

In addition, the independent sector is increasing its importance as a provider of NHS care, largely through the national procurement of independent sector treatment centres (privately run centres offering elective surgical care and diagnostic services). The government has recently announced that there is no longer any effective cap to the penetration of private sector providers into the NHS. New providers from the corporate private sector are also entering the market in primary care, through local and national procurement.

Patient choice reforms are also still evolving. From 2006, patients were entitled to choose at the point of GP referral from among four or five alternative providers. This choice menu has recently expanded to incorporate all foundation trusts and independent sector treatment centres. From 2008, patients will be entitled to choose any provider that meets NHS quality standards and agrees to provide services at the NHS tariff price.

Current NHS regulatory arrangements

The pattern of regulation in the English NHS is complex. There are a large number of bodies, some very new, some predating the NHS and there are a number of overlaps in their roles.

Quality of care is regulated by the Department of Health and the Healthcare Commission. The Department of Health sets standards of care (DH 2004b) but delegates monitoring and enforcement to the Healthcare Commission. The Healthcare Commission was originally established as the Commission for Healthcare Improvement in 2000 and transformed to its current role in April 2004 under the legal name Commission for Healthcare Audit and Inspection. It was established under the Health and Social Care (Community Health and Standards) Act 2003 as a non-departmental public body with statutory powers (ie, not exercising delegate powers on behalf of the Secretary of State for Health). In March 2005, it was announced that it will merge with the Commission for Social Care Inspection to form a single organisation by 2008 (the Mental Health Act Commission, responsible for overseeing the use of powers to compulsorily detain people with mental illness will also be merged with this new body).

The Healthcare Commission has a statutory duty to assess the performance of health care institutions in relation to the government's health care standards and targets for the NHS.¹ The results are published under the title 'annual health check' and freely available on the internet at: www.healthcarecommission.org.uk. The Healthcare Commission also provides guidance to the NHS, reviews formal complaints against the NHS, carries out regular patient satisfaction surveys and presents an annual 'state of healthcare' report to parliament. It is also responsible for inspecting and regulating independent health care providers.

Other regulators have responsibility for narrowly defined aspects of service quality and safety. The Medicines and Healthcare Products Regulatory Agency, for example aims to ensure that medicines, health care products and medical equipment are safe for those who use them, and the National Patient Safety Agency collects information on 'adverse incidents' and issues safety alerts to the NHS.

The coverage of and eligibility to NHS benefits is only partially regulated in any formal sense. What patients might expect to receive (or the services that they will be denied) is determined by the decisions of individual PCT commissioners, pronouncements by government and the work of the National Institute for Health and Clinical Excellence (NICE). NICE is an independent body that provides guidance on health care treatments, the

¹ There are 24 'core' standards and 13 'developmental' standards, covering the following areas: safety; care environment and amenities; clinical and cost-effectiveness; governance; patient focus; accessible and responsive care; and public health.

introduction of new technologies, and disease prevention. It considers the economic costs and health benefits of interventions such as new drugs and makes recommendations on whether they should be funded by the NHS and, if so, which patients should have access.

The regulation of foundation trusts is undertaken by an independent regulator (known as Monitor), which was established in January 2004 under the Health and Social Care (Community Health and Standards) Act 2003. Monitor is responsible for licensing new foundation trusts, for monitoring their performance and for intervening in the management of the foundation trust in cases where the trust is significantly breaching the terms of its authorisation. Monitor's statutory powers of intervention include imposing changes to the composition of the trust Board and requiring that they comply with an imposed action plan (Monitor 2006).

It is clear from this brief description of the existing regulatory framework that it is inconsistent and that key regulatory functions are currently incorporated into the management structures of the NHS as 'internal regulation'. For example, while provider authorisation of foundation trusts is carried out by an independent regulator (Monitor), the Department of Health has this function in relation to some independent sector providers (through the national procurement of independent sector treatment centres). Similarly, the intervention and 'failure regime' for NHS trusts is carried out by strategic health authorities under the auspices of the Department of Health, and for primary care contractors, by primary care trusts.

The regulatory challenges facing the NHS

Strong and sophisticated regulation will be needed if key health system objectives such as sustaining equity (equal access to services for people in equal need) and cost control are to be achieved in a market-based health care environment.

Table 1, overleaf, highlights some of the regulatory challenges that are likely to emerge as the NHS reform agenda unfolds.

The government needs to resolve a number of issues when determining the future regulation of the NHS in England. First, does the new market require a broader regulatory scope? If it does, should the current regulatory system be reformed and should a change in the balance between different regulatory instruments be engineered?

As noted above, the wider reform of regulation in the United Kingdom has seen a trend towards simplification and a firm desire to reduce regulatory burden and the number of regulators. In this context, it would appear that a reduction in the number of arm's length regulatory bodies in health services would be a likely first step in the reform process. If this argument were followed, the merger of existing regulators (in particular, the Healthcare Commission and Monitor) into a 'super-regulator' would be a favoured option.

At the same time, government policy is, at a rhetorical level at least, also determined to reduce the direct role of government in managing the supply of health services. More powers, therefore, might be transferred from government to arm's length regulation to 'offset' government command and control. This could include regulatory functions such as price setting or control of market entry. However, new regulatory instruments (beyond

TABLE 1: THE REGULATORY CHALLENGES OF NHS REFORM

<p>Changes to the English NHS since <i>Delivering the NHS Plan (2002)</i></p>	<p>New regulatory challenges/requirements</p>
<p>Increasing diversity of providers (NHS trusts, NHS foundation trusts, private and ‘third sector’ independent providers) – increasingly autonomous and at financial risk in the market</p>	<p>Level of competition/potential for competition will vary depending on the service</p> <p>Challenge to work out how natural monopolies can be made contestable</p> <p>NHS trusts and foundation trusts publicly owned so public investment has to be protected</p> <p>Appointment and remuneration of senior directors needs approval by elected and appointed ‘governors’</p> <p>Need for standards of financial disclosure for all providers</p> <p>‘Failure regime’ necessary to allow exit</p>
<p>Increasingly competitive NHS market with a greater share of activity driven by individual patient choice</p>	<p>Local monopolies will emerge and competition will need to be encouraged or maintained</p> <p>Essential services will have to be provided but difficult to define what is ‘essential’ in which contexts</p> <p>Provider accreditation (especially of new entrants), quality standards and monitoring likely to be needed to protect patients</p> <p>Need for information on quality/outcomes, for patients, practice-based commissioners and primary care trusts (PCTs) to ensure meaningful choice and purchasing</p> <p>Important to minimise externalities (eg, how to pay for training, public health interventions, etc) which may fall on public bodies disproportionately</p>
<p>Increasing proportion of hospital/specialist services paid for by fixed-price health resource groups (HRGs)</p> <p>Other activity-based payments set by a national tariff, Payment by Results (PbR), in which ‘money follows the patient’</p>	<p>Tariff has to be set and increased periodically</p> <p>Effect of fixed prices has to be monitored and disputes resolved</p> <p>Issue of transparency of costs versus prices</p> <p>The tariff can also be a powerful policy tool, eg, for containing costs or by offering higher reimbursement for priority activities</p> <p>Issue of how to protect commissioners (PCTs) from overspending as providers respond to PbR incentives</p>

TABLE 1 *continued*

Changes to the English NHS since <i>Delivering the NHS Plan (2002)</i>	New regulatory challenges/requirements
<p>Complex, hybrid form of commissioning mostly by monopsonistic PCT buyers – but also increasing numbers of practice-based commissioners working under PCT auspices</p> <p>Individual patient choice driving some purchase decisions</p>	<p>Monopsonistic commissioners may ‘over-demand’ although the tariff is some protection against this since increases in activity will hit their budgets</p> <p>Providers may need to provide comparable outcome and quality information (and prices where PbR does not apply)</p>
<p>PCT commissioners continue to provide community health services and have direct responsibility for primary medical services (vertically integrated)</p>	<p>Potential for conflicts of interest and inequity between PCT-owned providers, conventional general practices and other potential entrants</p> <p>Need to ensure competitive neutrality despite vertical integration</p> <p>Need to prevent <i>unnecessary</i> barriers to entry</p>
<p>Department of Health continues to set overarching rules and targets, and strategic health authorities performance manage PCTs as commissioners</p>	<p>Need for rules to determine appropriate ministerial interventions in the NHS market</p> <p>Likely to be interest in some form of separation between the Department of Health and the NHS at national level</p>
<p>English NHS remains publicly financed out of general taxation and subject to continuing political attention</p>	<p>Taxpayers will need comparable data on the performance of different providers and objective information on performance of the system as a whole</p>

arm’s length regulation) might also be considered to deliver the necessary assurance that the new market is delivering the goals of the NHS. This assurance is currently (albeit imperfectly) provided by direct governmental management and accountability but could be delivered through the commissioning process, using contracts as a prime regulatory instrument.

As we discussed in Section 2, governments have an array of regulatory instruments with which to influence the market. The crucial question facing the government and the NHS is, what balance of regulatory instruments is the right one given the challenges faced?

Drawing on the analysis of the regulatory challenge facing the NHS set out in Table 1 above, we have adapted the framework of regulatory functions developed by Monitor (Monitor 2005). For each of these functions or regulatory domains an appropriate regulatory response will need to be developed (*see box overleaf*).

FUNCTIONS OF REGULATION

Quality regulation

- Service coverage and eligibility – to determine what services are available to patients
- Quality assurance and control – to set standards and protect patients from sub-standard providers
- Choice – on the basis of quality (price will also be relevant for choice of services outside of PbR)

Economic regulation

- Prices – accurate and fair to different types of providers
- Entry – to enable new entrants and to maintain local capacity and choice
- Financial monitoring, intervention and exit – failure regime and protection of minimum standard of patient access to essential services in case of failure or poor financial or clinical performance
- Competition – measures to promote or maintain competition in face of natural tendency to monopoly, except in circumstances where this is likely to increase inefficiencies (eg, vertical integration of commissioner and provider or exclusive contracting may be more efficient in relation to some services but not others)

These regulatory functions are used as our main analytical framework for this comparative study. By understanding how each health system has approached the issue of regulation and the strategies that have been adopted, we hope to inform the debate on how an appropriate regulatory system might be developed for the NHS in England.

4

Regulation in four health systems

This section compares the four health systems chosen for study using the analytical framework of quality and economic regulation identified in Section 3.

These case studies were selected to ensure that there was a degree of diversity in the supply side involving public, not-for-profit and for-profit independent providers. However, they also allow a comparison of regulatory approaches with regard to the 'demand side'. In particular, we wanted to explore regulation of purchaser competition (the social insurance models of the Netherlands and Germany) as well as regulation within a single insurer/purchaser environment (Catalonia and New Zealand).

New Zealand was selected to provide a non-European perspective but also because New Zealand has recently introduced health care reforms that move away from the use of health care markets, and towards central planning with vertical integration between purchaser and provider.

The section begins with an overview of the four health systems in general, since this helps explain the pattern of regulation each country has developed.

Health care in Catalonia, Germany, the Netherlands and New Zealand

THE HEALTH CARE SYSTEM IN CATALONIA

General principles and organisation

The public health care system in Catalonia is a national health service, free at the point of use. It provides universal coverage for all citizens of Catalonia. There is a single purchaser of health care services – a 1990 law established the Catalan Health Service (*Servicio Catalán de Salud* – CatSalut) to purchase, finance, co-ordinate and evaluate health services. Despite the apparent arm's length position of CatSalut (it is established as an autonomous body), there is a high degree of integration between the CatSalut and the Catalan Ministry of Health. CatSalut is governed by a council chaired by the health minister and works closely with the Ministry of Health.

Primary and secondary care provision

Unlike the rest of Spain, the Catalonian health service makes use of both public and private providers. Public provision is through the Catalan Health Institute (*Instituto Catalán de Salud* – ICS), which is responsible for 30 per cent of hospital beds and 78 per cent of all primary care units. The ICS receives an annual budget directly from parliament. Independent providers include local elected authorities and private not-for-profit

organisations such as the Catholic Church and the Red Cross. A small number of private for-profit companies also provide health care services through consortiums and agreements with the Catalan administration. In primary care, the ICS manages 346 primary care groups. The remaining suppliers are not-for-profit organisations. Among these are associations of primary care professionals (*Entidades de Base Asociativa*) that contract with CatSalut to provide primary care services.

Finance

The public health care system in Catalonia is funded through general taxation. The purchasing and pricing of hospital services is currently under review. Historical per diem payments for hospital care were replaced in 1997 by a system based on fixed payments for diagnosis-related groups (DRG), plus payments to reimburse hospital overheads. DRG payments are specified in advance based on an average expected cost of a particular clinical condition. Primary care physicians are funded via capitation with 5 per cent of funding linked to quality and service priorities.

Recent policy trends

In an attempt to improve cost control, a pilot is underway to pay groups of providers in geographical regions through capitation rather than on the basis of activity. Under this system, local providers take responsibility for allocating these resources.

Overview of the regulatory system

There are no fully independent regulatory bodies in Catalonia. In the main, regulatory functions are carried out through informal relationships between the Ministry of Health, the quasi-independent CatSalut and a mix of independent and state-owned providers. Quality accreditation of providers is the responsibility of a department within the Ministry of Health.

THE HEALTH CARE SYSTEM IN GERMANY

General principles and organisation

Germany has a statutory health insurance system. For the majority of the population (78 per cent), health care insurance is compulsory; the remainder are voluntary members or have private insurance (Hit Summary 2004). In 2003, 88 per cent of the population had social health insurance (Hit Summary 2004). Citizens have been able to choose their sickness fund since 1997 (under the Health Care Structure Act of 1993) and are allowed to change insurer every year.

Sickness funds are not-for-profit organisations that offer statutory health insurance. They are established in law and governed by boards usually comprising representatives of the insured and employers. In January 2004, there were 292 sickness funds and 49 private health insurance companies.

Primary and secondary care provision

Hospital care is provided by a variety of public, private for-profit and private not-for-profit organisations. The proportion of private for-profit hospitals has grown steadily over recent years (and is now around 12 per cent). Public hospitals are owned by regional governments (the *Länder*).

Ambulatory care equates to UK primary care and outpatient services taken together and is delivered by private, office-based physicians (generalist and specialists), affiliated to the statutory health insurance system (SHI) (Riesberg 2004). Regional associations of SHI physicians have been given a legal mandate to secure ambulatory care to meet their population's health needs.

Finance

The German statutory health insurance system is funded through contributions by employees and employers. Sickness funds set their own rates for member contributions, although the Ministry of Health has powers to regulate the income ceiling under which contributions apply. Co-payments (ie, contributions to the costs of care) by patients are regulated by law.

The government has sought to reduce its role in the provision and financing of health care (for example, some preventive health services became the responsibility of the statutory health insurance system) and increase the use of market forces within the system (Wendt *et al* 2005).

The 1972 Hospital Financing Act introduced a system of 'dual financing' for the acute hospital sector. Investment costs are financed at state and federal level (through taxes), while operating costs are paid by health insurance funds or private patients. The government has introduced a system of hospital payments based on diagnosis-related groups (DRGs), similar to health resource groups (HRGs) in England (Wendt *et al* 2005). The operation of the DRG payment system is now the responsibility of the Institute for the Development of the Hospital Payment System, an organisation run jointly by the federal sickness fund associations and the German Hospital Association.

At regional level, physician and hospital fees are determined by negotiations between regional associations of sickness funds, hospitals and physicians.

Recent policy trends

The German health system has increasingly viewed competition as a tool to improve cost control. For example, in 2004, the Health Care Modernisation Act allowed sickness funds to contract selectively with providers as a means of introducing more competition between both funds and providers (Wendt *et al* 2005).

Overview of the regulatory system

The terms of the statutory health insurance scheme are detailed in legislation known as the Social Code Book V. This sets out the benefits that must be provided and how the system should be regulated. Sickness funds offer insurance policies that cover the basic package of care set down in law.

The German health system is highly corporatist in that it is regulated largely by groups representing health insurers, physicians and hospital providers as well as by the federal and state governments. These self-regulatory organisations have been given the legal status of public bodies.

The Federal Joint Committee (*Gemeinsamer Bundesausschuss* – G-BA), established under the 2004 Statutory Health Insurance Modernisation Act, is the highest decision-making

body in the German self-governing system. The G-BA is responsible for defining the benefits covered under the statutory system and for setting quality standards for care providers. It comprises nine representatives of the federal associations of sickness funds, nine representatives of provider groups (SHI physicians, dentists, hospitals), two neutral members and a neutral chair with a casting vote. There are also nine non-voting representatives of patient organisations. The G-BA is supported in its work by a range of sub-committees.

The G-BA gives directives to the statutory health insurance system that are legally binding, although the government can object to these and overrule them. The government at federal and regional level is not usually involved in the decision-making bodies of the SHI system. However, the Health Care Reform Act of 1989 gave the government greater powers to intervene where necessary.

A system of 'social courts' exists at local, Länder and federal level as a separate regulatory system. Social courts arbitrate in disputes within the system, for example, when a patient complains that sickness funds have disallowed valid claims.

The 1972 Hospital Financing Act also stipulates that each Länd must secure the financial sustainability of all hospitals within its borders, and ensure that hospital care meets the needs of the population at affordable costs, while respecting provider plurality. The Länder, therefore, have a significant role in determining the structure of hospital supply (Wendt *et al* 2005).

THE HEALTH CARE SYSTEM IN THE NETHERLANDS

General principles and organisation

The Netherlands has a statutory insurance-based health care system, funded through social insurance contributions. Under the Health Care Insurance Act 2005 (in operation since 1 January 2006), health care insurance is now compulsory. For people on low incomes, there is a care allowance scheme to subsidise insurance premiums. These reforms have replaced a mixed system of compulsory insurance for lower income groups and voluntary insurance for better-off citizens. They have also converted not-for-profit sickness funds into private insurance companies, some of which are for-profit.

Primary and secondary care provision

Primary health care is provided by family doctors who maintain independent and largely individual practices. Secondary and tertiary care is provided by medical specialists working either in private practice within hospitals, or employed and paid by hospitals. More than 90 per cent of hospitals are private, non-for-profit institutions.

Finance

The health care system is financed by the contributions of citizens, employers and the state. Citizens contribute 45 per cent of the cost via a 'nominal premium' paid directly to the insurer, in return for which care costs are reimbursed. The state's contribution of 5 per cent and the employer's contribution of 50 per cent are paid into an insurance compensation fund. A form of risk equalisation is undertaken to ensure that insurance companies do not suffer from adverse selection and can compete on equal terms.

Hospital care is funded through a mixed system of regulated case payments and free negotiation. The Netherlands has introduced a payment system based on diagnosis treatment combinations (known as DBCs and based on similar principles to DRGs). For most care, the DBC tariff is set centrally (by the Health Care Authority (*Zorgautoriteit*)). However, a growing element of hospital care is to be subject to free negotiation between insurers and hospitals.

Recent policy trends

The government's prime intention is to create competition between insurers to drive up quality and, in particular, to contain health care costs. A number of rules have been established through legislation to achieve this. For example, citizens are allowed to change insurer every year and insurers are obliged to accept everyone for the standard package, irrespective of age, gender or state of health. Moreover, insurance companies must operate nationally (or at least provincially) to avoid local monopolies.

The recent reforms are also intended to stimulate competition among health care providers and to strengthen the power of insurers relative to providers (MINVWS 2006). Insurers must offer a 'basic package' which complies with legislation. However, they are able to offer their customers a choice between policies that reimburse the costs of unrestricted care ('restitution' policies) or, at lower cost, those that stipulate a package of care contracted with selected providers ('managed care' policies). Prior to the reforms, insurers had to enter into contracts with all available providers.

Overview of the regulatory system

Compliance with the insurance benefits package is overseen by the Health Care Insurance Board (*College voor Zorgverzekeringen – CVZ*), an autonomous regulator. Quality of care is overseen by the Health Care Inspectorate (*Inspectie voor de Gezondheidszorg – IGZ*) a quasi-autonomous body within the Ministry of Health. Broader regulation of insurance companies is undertaken by the Pensions and Insurance Supervisory Authority (*Pensioen- en Verzekeringkamer – PVK*). The statutory social insurance and health care provider markets are regulated by a new body, the Health Care Authority. In addition, the Netherlands Competition Authority (*Nederlandse Mededingingsautoriteit – NMa*) monitors and addresses anti-competitive behaviour.

THE HEALTH CARE SYSTEM IN NEW ZEALAND

General principles and organisation

The health system in New Zealand is a national health service where hospital and community services are provided free of charge and funded through general taxation. General practice services are private although many patients receive government subsidies to offset the fees. In addition, a social insurance system exists to cover care required as a result of an accident (the Accident Compensation Corporation).

The health system is 'vertically integrated' in that district health boards (DHBs) are responsible for commissioning health services and providing most hospital care directly through their ownership and management of public hospitals. While New Zealand has introduced direct local elections for the majority of board members (a minority is appointed by the minister of health), the boards themselves are accountable to the minister. Early experience suggests that local autonomy is limited.

Primary and secondary care provision

Most hospital services are provided by public hospitals owned and managed by DHBs, although a small volume of activity is contracted from for-profit independent hospitals, mainly in relation to reducing waiting lists for elective surgery.

Other services are contracted from independent providers of diagnostic and laboratory services. DHBs are also responsible for commissioning residential and non-residential social care. Primary care is provided privately by general practitioners.

Finance

The revenue for public services comes from general taxation and is voted by parliament. Hospital services are funded through a budget agreed by the Ministry of Health, although some use is made of DRGs in agreeing this budget. Prices for other services, which are contracted by DHBs from independent providers, are freely negotiated.

Recent policy trends

The New Zealand health system has undergone significant reform since the 1990s. In 1993, the National (conservative) government introduced a quasi-market by separating purchasing from provision of services. Purchasing was undertaken by four regional health authorities (RHAs) and the previous area health boards were restructured to become 23 crown health enterprises (CHEs) offering mostly hospital and some public health services. These CHEs remained in the public sector but were technically for-profit organisations subject to normal company law (ie, 'crown companies'). Purchasers were able to buy services from both public and private providers and the market penetration of private sector providers increased, though only to a limited extent in relation to acute hospital services. It was also intended that the public be offered health vouchers to enable them to select from competing purchasing plans although this was not implemented (Ashton *et al* 2005).

These reforms had failed to deliver the expected efficiency gains by 1996 and a new coalition government introduced further reforms in 1997. The four RHAs were combined into a single national purchasing agency called the Health Funding Authority (HFA) and the CHEs were reconfigured as not-for-profit, statutory organisations called hospital and health services. The previous adherence to supply-side market competition was softened by a return to the rhetoric of co-operation and a public service ethos, although the purchaser-provider separation remained.

In 1999, a Labour-led coalition government was elected that was opposed on principle to competitive health care markets and, in 2000, the HFA was abolished and replaced by 21 district health boards.

Overview of the regulatory system

Regulation is highly centralised in New Zealand. The minister of health sets a national health strategy together with a series of objectives that must be achieved by the 21 local health agencies, DHBs.

DHBs are required to publish a statement of intent (which demonstrates that they will meet the objectives set by the ministry), a district strategic plan and a district annual plan. These are monitored by the ministry, which reserves powers to intervene where performance is failing.

There is relatively little use made of independent agencies to regulate health care, in part because the current government is not interested in encouraging competition in the publicly financed health sector (although it will tolerate contracting out of specific services such as public hospital laboratories). Inspections of residential service providers and other independent providers against basic quality standards are carried out by a quasi-autonomous branch of the ministry and DHBs also outsource some of their contract monitoring to independent accredited audit agencies.

However, the New Zealand system has created some arm's length bodies with responsibilities for commissioning in defined sectors. Pharmac is an independent body owned by the state responsible for determining which GP pharmaceuticals should receive a public subsidy on the grounds of cost-effectiveness. It also procures these pharmaceuticals on behalf of GPs and, latterly, also on behalf of DHB-owned hospitals. In addition, the Accident Compensation Corporation (ACC) operates a separate social insurance scheme providing income replacement and health and rehabilitation services after accident or injury (accounting for around 8 per cent of total health care spend). This arm's length government-owned agency is separate from the Ministry of Health with its own minister. The ACC displays greater flexibility in the manner in which it purchases and plans health care delivery. For example, because the ACC has no ownership responsibility for any provider organisation, it has traditionally been far more willing than DHBs to enter into preferred-provider relationships.

Comparing regulation in the four health systems

In Section 3 (*see box, p 18*), we set out the key objectives or functions of regulation that were increasingly pertinent to the evolving health market in England. Here we consider the different approaches adopted to fulfil these functions in each of the health systems chosen for study.

QUALITY REGULATION

(*See Table 2, pp 33–35 for summary*)

Service coverage and eligibility

The prescription of compulsory activities of the different health systems (what care must be made available) is determined through a number of different instruments. In all the case studies, the health system is underpinned by a legal obligation established by legislation (for example, the Social Code Book V in Germany and the Health Care Institutions Quality Act 1996 in the Netherlands). Legislation in Germany and the Netherlands means that all insurers offering statutory health insurance must provide at least the same basic package, must accept all applicants and cannot charge individuals according to their risk of ill health.

However, legal requirements are in general brief and lack detail. The Health Care Institutions Quality Act 1996, in the Netherlands, specifies only that 'sound medical care' is available. The Social Code Book V, in Germany, describes the benefits package to be available through the statutory health insurance system but uses broad categories such as 'early detection' and 'curative care'. There is generally little scope within legislation to reflect the range of existing treatments or to take into account future developments. This leaves room for interpretation and disagreement (as is the case in the English NHS).

All the case studies require a way of specifying the health services individuals are eligible to receive. However, the mechanisms adopted for this are different; in particular, the role of government in this process. Governments may:

- set out relatively detailed expectations of service coverage and priorities on an annual basis
- control this implicitly via their control of the commissioning process or through direct line management of providers, or
- pass responsibility for this task to external regulatory agencies.

New Zealand is an example of the first approach. The Ministry of Health constructs a service coverage schedule that sets out standards (such as maximum patient travel times) that are expected to be met by district health boards (DHBs) in their roles of commissioner and provider. Further guidance is published in the form of a ‘letter of expectation’ that details a range of priorities that must be delivered each year, and an operating policy framework.

Catalonia provides an example of the second more implicit approach. Here basic service eligibility is determined at a relatively broad level by the Spanish Ministry of Health (through a ‘*cartera de servicios*’) and approved by the Interterritorial Council (*Consejo Interterritorial*) – a body created by the 1986 Health Act to co-ordinate health policy among the Autonomous Communities (regions with devolved governments). However, the Autonomous Communities can add to the list of services, and detailed service availability is determined in part through the commissioning process. This is undertaken with respect to independent providers through contracts agreed by CatSalut, the single purchaser accountable to the minister of health, and through direct management of the 30 per cent of hospital services and 78 per cent of primary care services delivered by the state-owned Catalan Health Institute (ICS).

The Netherlands and Germany have both adopted the third approach of regulating coverage and eligibility at ‘arm’s length’ from government. In the Netherlands, the Health Care Insurance Board (CVZ) has the responsibility of interpreting what currently constitutes the medical care that must by law be secured by health insurers. The board arbitrates in the case of disputes between insurers and their members over the extent of the benefits package. Its decisions are binding and create precedents that allow the description of entitlements to reflect changes in medical practice (this is a form of ‘case law’ although this is not a judicial process).

The CVZ is independent of the government but has to agree its programme of work and its budget with the Ministry of Health. A similar approach has been adopted in New Zealand in relation to pharmaceuticals. Pharmac is an arm’s length agency with powers to define, on the basis of cost-effectiveness, the pharmaceutical products that will be subsidised by the public system.

The German system relies to a great extent on self-regulation. The Social Code Book V is the key piece of legislation that describes the public health system and identifies the main features of the basic package of benefits. The responsibility for determining the benefits available under the statutory health insurance is delegated to the Federal Joint Committee (G-BA), made up of representatives of insurers, hospitals and doctors. In addition, a

further level of interpretation is provided by hospital management in deciding whether individuals meet the clinical requirements for that treatment (subject also to regulation by the Medical Review Board, a joint institute of sickness funds).

Citizens have access to 'social courts' to resolve any disputes with their sickness fund or provider over eligibility for treatment. As in the Netherlands, a form of 'case law' is created that sets out what precise services the benefits package must include and its application at the point of treatment.

Under systems of social insurance, it appears that government is more willing (or able) to delegate the responsibility for deciding coverage to non-governmental or quasi-autonomous agencies, albeit within a legal framework established centrally. This reflects the long-standing political and social heritage that favours consensus finding as a means of reconciling the interests of different stakeholders. It may also be the case that such agencies enjoy greater powers to determine eligibility with precision. Indeed, in New Zealand the eligibility for health care following accidents is covered by a separate social insurance system (responsible for 8 per cent of health care expenditure and managed by the Accident Compensation Corporation (ACC)). The ACC enjoys significant discretion in determining through its commissioning what care patients shall receive. This contrasts with the more centralised bureaucracy that manages the rest of the system (funded through general taxation) where entitlements and priorities are established through a more obviously political process.

The introduction (or not) of new technologies is of key interest to all health systems given the potential for increasing costs. All the case studies have established formal mechanisms to assist with the evaluation of the costs and benefits of new technologies.

In New Zealand, the National Health Committee considers evidence and advises the government. The government ultimately decides on inclusion or encourages/discourages local DHBs from providing a particular intervention. In the Netherlands, the CVZ assesses new technologies and advises the minister of health as to whether they should be publicly funded. Again, the minister is responsible for the final decision.

In Catalonia, the Catalan Agency for Health Technology Assessment (*Agència d'Avaluació de Tecnologia i Recerca Mèdiques de Catalunya*) has been created as a public not-for-profit company reporting to CatSalut and is responsible for advising on the adoption of new technologies.

In Germany, with its tradition of self-regulation, a national Institute for Quality and Efficiency (*Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen – IQWiG*) considers scientific evidence concerning new (and existing) technologies and advises the Federal Joint Committee (G-BA). The G-BA then determines whether or not these technologies are to be subject to health insurance funding. The Institute for Quality and Efficiency is commissioned by the G-BA (although it may also initiate its own technology assessments) and any rejection of its advice by the G-BA must be accompanied by a written explanation. The federal minister's agreement is not required to enforce any proposal to extend coverage, but the minister is able to exercise a veto over any given decision.

Quality assurance and control

A wide range of approaches to quality regulation is evident in the study – with a different mix in each health system. These include:

- setting and monitoring of standards
- thematic reviews of quality
- development of guidelines
- encouragement of voluntary accreditation schemes
- assessment of benchmarked performance indicators
- contracts for services
- direct performance management
- use of individual complaints to drive system-wide improvement.

All health systems require a basic operating licence prior to any organisation being eligible to provide publicly funded services.

In New Zealand, a licensing process known as HealthCert is operated by a separate section of the Ministry of Health, although inspection is carried out by independent accredited auditors. HealthCert applies to DHBs and independent providers of residential care. However, such a process of standard setting and inspection is very basic and concerns have been expressed by commissioners that this is insufficient protection for patients. In Catalonia, ‘opening permissions’ are required for new providers and also regulated by the Ministry of Health.

In the Netherlands, licensing of new hospitals has become less restrictive but a certificate is still required from the Ministry of Health. In Germany, the Länder are responsible for planning and partly funding hospital care and therefore control entry and have a ‘hospital plan’. Individual generalists and specialists offering ambulatory care must register with a regional association of social health insurance physicians, which requires them to meet basic criteria (linked to training). Physicians providing certain specialist services in the ambulatory care sector must apply for a licence to do so (Busse and Riesberg 2004).

More substantial mandatory quality assurance systems are also in place in all the health systems, supplemented by a range of voluntary accreditation schemes.

Catalonia maintains a mandatory system of hospital accreditation for public providers based on the European Foundation for Quality Management model. The accrediting body is the Catalan Ministry of Health, which uses standards set by a commission of experts. After an initial self-evaluation, hospitals undergo technical audits for the accreditation committee to make the final decision. The Ministry of Health has recently tendered the services of a number of independent audit agencies to carry out the inspection process. The Catalan accreditation process provides national care standards for all providers.

In New Zealand, the Ministry of Health has also developed a set of health and disability sector standards. However, in this case, the adherence to these standards by DHBs is monitored through the performance management process undertaken by the Ministry, rather than through an independent audit process (although DHBs are also directly accountable to parliamentary select committees).

In the Netherlands, a rather different approach has been adopted. The Health Care Institutions Quality Act 1996 stipulates only that providers funded from social insurance

must offer 'sound care', must have a complaints procedure and a system for quality assurance. Exactly what constitutes 'sound care' is interpreted on an ongoing basis reflecting the evolution of current professional practice, rather than being set down as a set of absolute standards. The interpretation is carried out by the Health Care Inspectorate (IGZ). This is an autonomous body with its own inspector general and acts under the provisions of around twenty different acts of parliament. The IGZ acts to enforce statutory quality requirements through a programme of monitoring, inspection and intervention with regard to individual and institutional health care providers. The organisation has a mandate to develop its own programme of work, but can also be directed by the minister of health, welfare and sport, to whom it is formally accountable.

In determining whether or not sound care is being provided, the IGZ takes advice from professional and patient groups, as well as government and insurance companies. A set of 50 indicators has been developed, against which all hospitals are monitored. These have been agreed with the Dutch Medical Association and the Dutch Hospitals Association and are used to signal areas of concern by comparing individual hospital performance against benchmarks. In addition, the IGZ can take an individual doctor to a disciplinary board where performance is perceived to be weak. This allows a form of case law to determine the parameters of 'sound care'.

In Germany, since 2000, hospitals and ambulatory care providers have been legally required to run internal quality management systems. Hospitals are also required to implement external quality assurance controls. The external system involves assessment against quality indicators (supported by regional offices for quality assurance). Data is analysed at national level by the Federal Institute for Quality Assurance (*Bundesgeschäftsstelle Qualitätssicherung* – BQS), which was established in 2001. Their findings are fed back in the form of reports and recommendations to individual hospitals.

Through an amendment to the Social Code Book V, a corporatist co-ordination committee was created which must develop evidence-based guidelines for at least ten medical conditions annually (Legido-Quigley *et al* forthcoming).

In addition, the introduction of diagnosis-related group payments to hospitals also saw a requirement on the Federal Associations of Sickness Funds, the Association of Private Health Insurers, and the German Federal Association of Hospitals to agree minimum standards for the quality of inpatient services (Wendt *et al* 2005).

However, the multiple reforms to the German health care system, together with the reliance on diffuse self-regulatory mechanisms, have hampered the emergence of a clear strategy to assure quality. 'Overall, the quality initiatives that actually found their way into the Social Law add to the bureaucracy in the German system without delivering visible results to the patients.' (Allen and Riemer Hommel 2006, p 206)

When poor organisational performance is identified, central authorities may intervene.

In New Zealand, the Ministry of Health has powers of intervention through its monitoring and intervention framework, which is described in the economic regulation section below.

In the Netherlands, the IGZ has powers under the Health Care Quality Act to intervene in the case of suspected poor performance. It can issue an order to suspend local provider

management for one week, requesting the Ministry of Health to take over during that time. Where immediate danger is suspected, the IGZ can close any provider of health care. Recently, a cardiac unit was closed following the discovery of high mortality rates (IGZ 2006).

The IGZ in the Netherlands adopts a risk-based approach to inspection, and will visit and inspect providers where performance is out of line with peers or where other causes for concern have arisen (such as reports from ‘whistleblowers’ or high levels of complaints). In Catalonia, routine inspections are carried out as part of the accreditation process.

In Germany, the BQS has no formal powers to apply sanctions, although in cases of concern the institution in question may be visited by a panel of experts. Financial instruments are used to ensure compliance with requirements to provide data (hospitals are paid to complete quality documentation and are fined if they do not comply with their legal obligations to do so). More significantly, where poor performance is unresolved, the G-BA can agree that insurers will no longer contract with the provider in question.

Contracts are a further means of assuring quality in Catalonia and the Netherlands. It is interesting to note that even in systems with long-standing arrangements for contracting between commissioners and providers (such as Germany and Netherlands), non-contractual mechanisms have been developed to strengthen quality regulation.

In all four cases, voluntary schemes for improving quality are increasingly being encouraged as an alternative (or complementary) to government-driven quality mechanisms.

In Catalonia, there is a voluntary scheme for hospitals based on ‘consensus indicators’ run by CatSalut.

In the Netherlands, two voluntary certification schemes are available for health care providers: the Netherlands Institute for Accreditation of Hospitals (*Nederlands Instituut voor Accreditatie van Ziekenhuizen* – NIAZ) and the Harmonisation of Quality Review in Health Care and Welfare (*Harmonisatie Kwaliteitsbeoordeling in de Zorgsector* – HKZ).

In New Zealand, Quality Health New Zealand is an independent body set up by the government to provide voluntary accreditation.

In Germany, there are two major systems for accreditation: ‘Cum Cert’ for religious-based hospitals and the Organisation for Transparency and Quality in the Health Service (*Kooperation für Transparenz und Qualität im Gesundheitswesen* – KTQ) (Busse and Riesberg 2004).

Thematic and system-wide review of quality is also common.

In the Netherlands, the National Institute for Public Health and the Environment publishes reports on the state of the Dutch health system and the IGZ also carries out thematic reviews of particular issues of concern. In New Zealand, the National Health Committee, an independent advisory committee, publishes reports on a wide range of quality issues.

While the committee has authority in what it says, it has no formal powers of direction or intervention.

Legal or quasi-legal rulings on individual cases are an important source of regulation in a number of countries, both as a means by which health care is regulated at the micro level and as a way of setting broader health care policy through ‘case law’.

In the Netherlands, the actions of the CVZ and the IGZ set precedents in interpreting service coverage and quality as discussed above, and ‘social courts’ in Germany arbitrate in disputes within the statutory health insurance system. In New Zealand, the Office of the Health and Disability Commissioner was established, with statutory independence of government, in 1994. It promotes the rights of individuals by dealing with their complaints and also contributes to quality improvement within the health care system by overseeing the implementation of 10 key principles/rights for patients (right 4 is to receive high-quality care). Indirectly, therefore, the commissioner contributes to service coverage and quality expectations.

Enabling Patient Choice

In both the Netherlands and Germany, there is a tradition of patient choice, allowing citizens to choose their general practitioner, specialist and hospital. In New Zealand, experiments with patient choice introduced in the 1990s have recently been reversed. Patient choice of hospital has been abandoned in favour of a planned system where commissioning and the provision of hospital services are combined in a single organisation (DHB). Free choice of general practitioner remains – indeed, in New Zealand general practitioner services are provided privately with public subsidies to reduce costs to patients. In Catalonia, patients are only able to choose whether to go to a GP near home or work. Allocation of specialists is through a GP ‘gatekeeper’, who is encouraged to refer to hospitals within the local catchment area (it is possible, but unusual, to obtain a referral to a different hospital). Historical rationalisation of hospitals has limited the extent to which patients can meaningfully exercise choice in many cases.

Current policy debates in the Netherlands and Germany have emphasised the need to increase competition within the health systems. To this end both have chosen to create (or expand) competition between insurers.

In Germany and the Netherlands, citizens are allowed to change insurer every year. However, in both countries patient choice of hospital is beginning to be restricted by the growth of ‘managed care’ insurance policies. These are based on selective contracting of providers by insurers and are offered at a lower premium to consumers. This initiative has been introduced as a means of containing costs and improving quality, and as part of a deliberate strategy to increase competition in both supply-side and demand-side markets.

Integrated care programmes (ie, spanning the previously separate hospital and ambulatory care sectors) have been encouraged in Germany since 2003, by regulations stipulating that up to 1 per cent of hospital and ambulatory care sector budgets had to be earmarked for integrated care. This is to be achieved through a top-slice of these budgets by sickness funds and is intended to encourage competition among groups of providers (although uptake so far has been relatively slow).

In addition, it is expected that collective contracting will be replaced by selective contracting, further stimulating competition among providers and sickness funds (Greß *et al* 2006). This policy innovation is further advanced in the Netherlands, where the growth of managed-care policies has been encouraged by the removal of the obligation on insurers to contract with all providers, as well as the introduction of free contracting (ie, without price regulation) for a small portion of elective hospital care.

In this respect, there is perhaps a paradox in current Dutch and German health system reforms in that by encouraging competition between insurers and between providers, patients' choice of hospital provider is likely to reduce.

Regulation of choice has primarily been through law (ie, the Health Insurance Act of 2005 in Netherlands and the Healthcare Modernisation Act 2004 in Germany), creating rights for patients and choice-based rules, and through incentive structures such as publicly available information. However, choice has also begun to be regulated by independent bodies in the shape of competition authorities acting to ensure that competitive markets exist. This is discussed in the economic regulation section below.

Patient choice is heavily dependent on improving information available to citizens and patients on the performance of health care purchasers and providers. Good up-to-date information is vital to ensure consumers and patients exercise their right to choose well and commissioners make strategic decisions to contract with providers.

However, there are significant differences between the countries studied in the amount and quality of information provided, and in the organisations responsible for providing it. These do not correlate with the existing level of choice in the system or the way the health care system is funded. Perhaps surprisingly, it is not the case that systems that promote patient choice inevitably offer more information to consumers on the relative performance of providers or insurance companies.

In Germany, relatively comprehensive information on efficiency, patient satisfaction and waiting lists is collected for the purposes of quality assurance and contracting. However, despite free choice for patients of sickness funds and, to a lesser extent, hospitals, there is no regular public comparative reporting on basic organisational performance data by an independent body. Only anonymised data is made available to the public by the BQS (although hospitals themselves may receive feedback and recommendations (Allen and Riemer Hommel 2006). Under a federal regulation of 2004, all hospitals have to produce a biannual quality report (within a framework set by the G-BA) which is available to the public (Legido-Quigley *et al*, forthcoming). Nevertheless, there is a lack of easily comparable information on quality.

In the Netherlands, 'report cards' (on individual providers) are compiled by committees on which providers, patients and insurers are represented, and co-ordinated by the Netherlands Organisation for Health Research and Development (*Nederlandse Organisatie voor Gezondheidsonderzoek en Zorginnovatie* – ZonMw). The cards are still under development, but will ultimately contain indicators of effectiveness, safety and responsiveness to patients. Report cards are already available for insurance companies and are published on the internet by the Ministry of Health. In the past, consumer organisations and a national newspaper have published annual rankings of hospitals.

In New Zealand, the Ministry of Health collects and provides benchmark information to DHBs on their (acute hospital) performance (called hospital benchmarking information). This is available to the wider public through the internet. The Ministry also publishes an annual ‘health and independence’ report. This summarises a wide range of performance and trend data relating to activity, expenditure, quality and outcomes of the public health system. It is possible that the advances in the collection, use and publication of performance information in New Zealand reflect its recent past, where a new public management approach was a strong feature of the 1990s.

The responsibility for providing patient information also differs. In the Netherlands and Germany, information is provided through arm’s length agencies, whereas in New Zealand this is the responsibility of the Ministry of Health.

TABLE 2: COMPARISON OF QUALITY REGULATION

Functions	Catalonia	Germany	Netherlands	New Zealand
Service coverage and eligibility	<p>The Spanish Ministry of Health and the Interterritorial Council determine the level of service across the whole of Spain.</p> <p>The Catalan Ministry of Health can add to the list of services, and detailed service availability is determined in part through the commissioning process.</p> <p>The Catalan Agency for Health Quality Assessment advises on adoption of new technologies.</p>	<p>The Social Code Book V regulates the statutory health insurance schemes. It prescribes the health care benefits to be provided and the system of self-regulation that manages the statutory health insurance system (SHI).</p> <p>However, the Social Code Book V only provides a generic list of benefits, so residual regulations relating to all sectors of care are decided by the Federal Joint Committee (G-BA).</p> <p>The National Institute of Quality and Efficiency advises the G-BA on new technology.</p>	<p>The Health Insurance Act 2005 sets out characteristics of the basic benefits package that must be provided under statutory health insurance.</p> <p>The Health Care Insurance Board (CVZ) is responsible for interpreting what is in the benefits package and manages disputes between insurers and members, where its decisions are binding.</p> <p>The CVZ assesses new technologies and advises minister for health whether they should be adopted within the publicly funded system.</p>	<p>A service coverage schedule sets out standards that are expected to be met by district health boards (DHBs).</p> <p>The Ministry of Health issues an annual ‘letter of expectation’ setting out service priorities.</p> <p>The National Health Committee advises government on the adoption of new technologies.</p>

continued overleaf

TABLE 2 *continued*

Functions	Catalonia	Germany	Netherlands	New Zealand
Quality assurance and control	<p>‘Opening permissions’ (that cover basic quality and safety issues such as fire safety and staffing levels) are required for all providers and are regulated by the Ministry of Health.</p> <p>There is a mandatory system of accreditation for public providers run by the Ministry of Health. The scheme sets national care standards for all providers.</p> <p>CatSalut runs a voluntary quality assurance scheme for hospitals based on ‘consensus indicators’.</p>	<p>The Länder are responsible for planning and partly funding hospital care and so control entry.</p> <p>SHI physicians who provide ambulatory care must belong to a self-governing regional physicians association.</p> <p>Hospitals and ambulatory care providers are legally required to have internal quality systems. Hospitals must also have external quality assurance controls and these are monitored by the Federal Institute for Quality Assurance (BQS).</p> <p>There are two major voluntary accreditation schemes for hospitals including ‘Cum Cert’ for religious-based hospitals and the Organisation for Transparency and Quality in the Health Service (KTQ).</p>	<p>Providers are licensed but this process has recently been made less restrictive.</p> <p>Any provider funded by social insurance must offer ‘sound care’, and have a complaints procedure and a system for quality assurance. These statutory quality requirements are monitored by the Health Care Inspectorate (IGZ).</p> <p>The IGZ monitors hospitals using 50 indicators for signs of poor quality, carries out investigations on selected themes and publishes results (eg, recently, the use of bed bars in hospitals), and can intervene in cases of reported incidents, complaints, etc.</p> <p>Two voluntary schemes for quality accreditation of hospitals are the Netherlands Institute for Accreditation of Hospitals and the Harmonisation of Quality Review in Health Care and Welfare.</p>	<p>Licensing is required for all DHBs and independent providers of residential health and disability services. This is overseen by Health Cert, a section of the Ministry of Health, but inspectors are independent.</p> <p>The Ministry of Health has established a set of health and disability sector standards. These set out in some detail the quality of care expected.</p> <p>The health and disability commissioner contributes to quality improvement by overseeing 10 key principles/rights for patients. Right 4 is to receive high quality care.</p> <p>Health Quality New Zealand is a voluntary accreditation scheme that most DHBs take part in. This accredits hospital services but not community-based services.</p>

TABLE 2 *continued*

Functions	Catalonia	Germany	Netherlands	New Zealand
Enabling patient choice	<p>Patients are only able to choose whether to go to a GP near home or work and not usually their specialist.</p> <p>Information on efficiency, patient satisfaction or waiting lists for individual hospitals is not made public.</p>	<p>Citizens can choose their sickness fund annually. Also patients have the right to choose the hospital where they want to be treated – but, except in emergency conditions, they require a referral from an ambulatory physician (GP or specialist).</p> <p>There is no regular public comparative reporting on basic organisational performance data by an independent body.</p>	<p>Citizens can choose their health care insurer every year. People may chose between insurance policies that offer a ‘managed care’ approach (ie, restricted to services from preferred providers) or open choice.</p> <p>Health insurers are obliged to accept everyone for the ‘standard package’, irrespective of age, gender or state of health. Health care insurers no longer have to enter into a contract with every provider, but can choose to selectively contract.</p> <p>The Health Care Authority produces ‘report cards’ on hospital performance that are available online. Consumer organisations and a national newspaper publish annual rankings of hospitals.</p>	<p>GP services are provided privately with public subsidies to reduce cost to patients, so there is free choice.</p> <p>There is no longer free choice of hospital – it is now a planned system with structural integration between commissioner and hospital provision.</p> <p>The Ministry of Health collects and provides benchmark information to DHBs on their (acute hospital) performance. This is available to the public through the internet. It also publishes an annual report that summarises a wide range of information (eg, expenditure, quality and outcomes of the public health system).</p>

ECONOMIC REGULATION

(See Table 3, pp 43–45, for summary)

Prices – accurate and fair to different types of providers

Pricing policy has been the subject of considerable review in all the health systems that we selected as case studies. All have sought to use pricing policy to improve efficiency, specifically by removing per diem payments (where hospitals receive a payment per day of treatment regardless of their overall efficiency in managing the care process).

All the case studies have introduced diagnosis-related group (DRG)-based systems in part or in whole. However, the objectives of these systems, and how they are constructed and regulated differ considerably. In particular, the degree of governmental control over price setting and the extent to which contracts between commissioners and providers reflect price negotiation varies widely.

In New Zealand, the government controls pricing of hospital services indirectly through setting population-based budgets for district health boards (DHBs) via a weighted capitation formula. DHBs are expected to meet the needs of their residents within these budgets. In this context, DRG prices are used mainly to allow patients to be treated outside their district (ie, compensating one DHB for treating another's patients) and in providing information against which to benchmark costs. Given that movement of patients between districts is relatively minimal, the pricing of hospital services is of limited importance (except in cases where DHBs are affected significantly).

By contrast, the prices of community-based diagnostic and laboratory services (often provided by independent sector providers) are determined through contracts following market tenders. Similarly, general practice services are essentially privately provided and fees set by individual general practitioners. Recent government policy has been to use financial policy instruments to influence rather than direct prices. This has taken the shape of markedly increased subsidies available for patients seeking general practice services. However, the absence of formal price regulation has meant that the government has struggled to ensure that these subsidies have not been offset by supplier price rises.

New Zealand therefore provides an example of contrasting styles of price setting in different domains of the health care system. Hospital services are highly regulated by government (and prices, in effect, are mostly agreed locally through the funding agreement between the Ministry and DHBs) whereas the price of out-of-hospital services is largely unregulated by government or any other body.

In the Netherlands, this variable approach is also evident. The Netherlands has historically regulated prices of hospital services through the Board for Health Care Tariffs (*College Tarieven Gezondheidszorg* – CTG). This is an independent body with responsibility for setting prices under the 1980 Health Care Tariffs Act and 1999 and 2000 Amendments. However, the lack of price competition between providers was deemed to put at risk the development of greater competitive forces, which were intended to result from the wider reforms to the health insurance system. It was feared that with fixed prices, health insurers would be largely restricted to competing over the efficiency of their business administration rather than by driving down overall costs of health care provision. This is a different logic to that used in setting fixed prices in England, where it was believed that this would focus providers' attention on quality rather than cost reduction.

As a result, the CTG is to be abolished and residual price setting functions incorporated into the new Health Care Authority (*Zorgautoriteit*). Significantly, a new pricing policy has been introduced so that a modest 8 per cent of hospital revenue is determined through direct and unregulated negotiation between providers and commissioners in relation to elective care. Ministers have recently announced this will be extended to all elective care (which is 70 per cent of all hospital revenue) by 1 January 2008.

Prices for general practice were historically set by negotiation between the National Association of Insurance Funds and the National Association of General Practitioners. However, GPs are now obliged to enter into individual contracts (or as small groups of 8–10 GPs).

In Germany, prices are agreed without government intervention in a highly corporatist style. The prices charged by physicians providing ambulatory care are negotiated through a two-stage process. A budget for these services is agreed between the Regional Physicians' Association (*Kassenärztliche Vereinigung – KV*) and the Regional Association of Health Insurers. This sets the total quantum of resources. The distribution of these resources is governed by a calculation of the relative value of the different services provided by the physician body (the uniform value scale). This scale awards point values to different activities and the regional budget is allocated according to the number of points earned by individual physicians. The scale is set by the federal valuation committee, part of the corporatist structure of self-regulation.

While the government allows the self-regulation apparatus to set prices, it does intervene in determining the overall pricing framework. Indeed, the decision to move to a DRG-based payment system was imposed by the federal government, although it was left to the corporatist interest groups to develop the system. The government also regulates co-payments made by patients, in particular, to introduce incentive structures designed to contain costs.²

Funding for hospitals is more complex. Fixed costs are met through funding from the local *Länder* and running costs from the health insurance funds. Budgets for running costs are agreed in negotiations between individual hospitals and regional associations of health insurance funds. However, like in the Netherlands, German health policy is founded on a desire to increase competition between providers and between sickness funds. New integrated care contracts were introduced in 2000 (under section 140 of the Social Code Book V) which limit choice through preferred-provider contracts.

As in Germany, hospital care in the Catalonian health system is funded by a combination of remuneration for fixed costs (65 per cent of funding) and payments made for activity using DRGs (adjusted by a complexity index). Activity is regulated by contract and once the activity levels have been reached, only 35 per cent of the DRG tariff is paid. Additional payments at a single national tariff may also be made for specific initiatives to reduce waiting lists.

The funding of hospitals and the setting of prices is undertaken by a single purchaser, CatSalut. This organisation is formally autonomous but has a significant relationship with the minister and the Ministry of Health. Indeed, the minister of health is the president of the council of CatSalut. Price regulation is, therefore, significantly a politically influenced process.

² Patients have to pay €10 to visit a general practitioner or specialist, but are charged only once per quarter with other contacts free if they get a referral from a general practitioner. This provides patients with an incentive to appoint a general practitioner as a 'gate-keeper' and not to 'doctor hop'.

CatSalut operates by agreeing contracts, and therefore prices, with independent health care providers. Prior to this there is an attempt to reach consensus over prices through discussion with the employers' associations (the *Unión Catalana de Hospitales* and the *Consortio Hospitalario de Cataluña*). As in many health systems, there is a significant variation in costs between hospitals (estimated to be as much as a 40–50 per cent difference). In order to reduce this variation financial benchmarking information is collected on the costs of all providers. Payments to providers significantly above the benchmark are reduced over a period of years. In addition, financial penalties (1–2 per cent of contract value) may be levied if quality standards are not met.

Public providers within the Catalan Health Institute (ICS) (which covers the majority of primary care) receive an operating budget directly from the Ministry of Health. However, this budget is not linked to activity and therefore there are no inbuilt financial incentives to increase service provision.

Entry – to enable new entrants and to maintain local capacity and choice

In the tax-funded systems of Catalonia and New Zealand, entry to the public health service market is heavily regulated by central government. In Catalonia, a network of public and private providers of care has been created called the Network of Providers of Public Hospital Care (*Red Hospitalaria de Utilización Pública (Xarxa Hospitalària d'utilització Pública)* – XHUP). This incorporates 52 hospitals, 8 public hospitals and primary care. The network appears very stable with few recent exits and little or no scope for willing providers to enter the market. Entry to XHUP is controlled by CatSalut and therefore central government.

A similar largely closed hospital market exists in New Zealand, with the overwhelming majority of hospital providers existing within the public sector, integrated with the commissioning function within DHBs. DHBs are able to (and do) tender for new or alternative providers in the domain of diagnostics and laboratory services, however this is generally a marginal activity. The current government is looking at the historical use of private sector providers, a policy encouraged by the previous government, and a protocol has been developed in order to regulate in this area. Under this protocol, private sector providers may be involved if this is the only way in which public patients can benefit (ie through the shared purchase of expensive equipment such as a CT scanner).

Primary care in New Zealand is privately provided so market entry is not regulated other than on grounds of professional competence. However, in areas where the Ministry of Health considers there to be sufficient GPs, doctors who set up new practices are ineligible for public funding for their patients.

The growth in hospital supply is largely regulated by regional government in Germany through the use of legislative and market-based regulatory instruments. The *Länder* are responsible for funding the fixed-cost element of hospital care and this provides them with leverage over market entry. In addition, the *Länder* each develop their own hospital legislation – a hospital plan (this will specify the number of hospitals to be reimbursed through the public system and some *Länder* even specify the precise number of hospital beds). The Medical Review Board, which represents sickness funds, also has rights to monitor hospital beds in order that an over-supply is avoided (Wendt, Rothgang and Helmert 2005).

Entry of ambulatory care physicians is under the control of regional associations of statutory health insurance system (SHI) physicians. They must register any physician who wishes to be reimbursed for patient care via statutory health insurance funds. These organisations are state-licensed monopolies. Federal law stipulates that associations of SHI physicians, in consultation with the regional health insurance fund associations and the relevant Länder authorities, must develop plans that regulate the number of SHI-affiliated ambulatory care physicians in the region ('specialisation-group general quotas' define a local physician to population ratio by specialty, with quotas informed by directives issued by the Federal Joint Committee (G-BA).

It is only in the Netherlands that a significant weakening of central control over market entry is evident. Historically, the development of hospital capacity was highly planned by the Netherlands Board for Hospital Facilities, based on estimates of regional health care needs and the likely availability of funding. Now, although hospitals need a permit from the Ministry of Health, this is relatively easy to obtain. Entry to the general practice market is also comparatively unregulated (other than on professional grounds). It remains to be seen what effect this will have on the ability of the system to control expenditure in line with its income. There is also free entry to the health insurance market. However, a consistent trend of mergers has seen numbers of insurers drop from around 80 in the 1980s to around 15 in 2006.

It is notable that market entry in each of the four health systems is generally weak and that relatively stable supply-side dynamics predominate. While this may be expected in countries such as New Zealand, where hospital services are largely and very deliberately, state owned, it is also the case where there is a mixed economy of providers.

Financial monitoring, intervention and exit

The extent that health care providers are monitored and regulated with regard to financial performance varies significantly.

Predictably, the closest monitoring and intervention in relation to financial performance (particularly financial distress) is found in New Zealand. Here, due to the wholly public nature of hospitals and their integration with commissioners, the Ministry of Health has developed a five-stage 'monitoring and intervention framework'. This framework allows for ever-increasing levels of monitoring and ultimately the minister can appoint a commissioner to take over the running of the district health board. This framework is underpinned by a hospital benchmarking information system that has recently seen financial indicators augmented by service performance measures.

The ability of government to directly intervene in the management of health care providers is not restricted to publicly owned systems. In Catalonia, while the majority of hospitals are independent of government, the power of CatSalut as the sole purchaser is significant and has allowed informal powers of intervention to emerge. This is underpinned by the fact that following a hospital rationalisation programme in the 1980s there is mutual dependence between commissioner and provider. As one interviewee within the Ministry of Health presented it: 'if a hospital is about to fail, the hospital has a problem. However, we [the Ministry of Health] have a big problem.'

CatSalut receives detailed information on hospital costs and monitors these against benchmarks. The mechanism is called the *Central de Balances* – a system for financial

information set up by the Spanish national government within the Bank of Spain. It benchmarks individual hospitals against a range of different indicators (eg discharges divided by budget). This information is used in negotiation with providers but they only receive their own position relative to benchmark (ie there is no general publication of benchmarks at hospital level). Where significant and sustained managerial problems exist at provider level, CatSalut will expect to be involved in developing appropriate solutions and can even demand a change of management. Where independent hospitals have links to local elected members, the handling of financial problems may become highly political.

Hospital failures with the potential for market exit are, of course, potentially politically sensitive in most countries. However, in the Netherlands and Germany greater separation exists between commissioner and provider. Moreover, the largely independent nature of most hospital providers means that there is no automatic assumption that commissioners have responsibility or indeed authority to monitor or intervene in the financial affairs of providers.

In the Netherlands, providers have become bankrupt, although this is rare. Again, mutual dependency between insurers and providers may exist and could prompt action in the case of provider insolvency. One interviewee told us about two hospitals that were close to bankruptcy. This situation led to joint financial intervention by insurers and government and the replacement of the management. However, the Ministry of Health is now developing a bankruptcy process which is likely to include arrangements for temporary management and the auctioning off of 'necessary care' to other providers (ie that element of the bankrupt business that is deemed essential to local services).

In the social insurance systems of the Netherlands and Germany, insurance providers are regulated by a range of independent regulators such as the Dutch Central Bank, the Dutch Pensions and Insurance Supervisory Authority and the German Federal Insurance Office. These regulators ensure that insurance law is met and that companies are appropriately solvent (as they do for insurance companies in all sectors). In the Netherlands, the Health Care Authority checks the policies provided by the insurance companies to ensure that the requirements of the Health Care Institutions Quality Act 1996 are met and, in particular, that the basic package of services is offered. They are advised in this role by the Health Care Insurance Board (CVZ).

Competition

The extent to which supply-side and, where there are multiple commissioners, demand-side competition is regulated varies considerably in the health systems studied.

In the state-dominated system of New Zealand, competition is not a policy aim for hospital services, therefore it is unsurprising that there is little formal regulatory activity and no independent agencies dedicated to this task. For non-hospital services, rules exist to ensure that fair tendering arrangements are followed when letting contracts, but neither DHBs nor the Ministry of Health now take into account, or seek to maximise, competition for service provision. This contrasts markedly with the 1990s when the creation of supply-side competition was pursued vigorously, if not very successfully.

While Catalonia has a diverse supply side in that there are many different types of hospital owner, the majority of which are independent of the Ministry of Health, as we have

described above, there is little competition between them. Competition management is through entry to the XHUP network, which has historically been stable. Indeed, a pilot is underway to promote greater collaboration between existing providers within a region. In this pilot CatSalut is devolving a capitation-based budget to a co-operative organisation of local providers with the involvement of local elected officials. It is expected that this organisation will plan and allocate resources among existing providers. This represents a shift towards the use of financial regulatory instruments (in that providers face shared financial incentives to minimise care costs).

By contrast, the stimulation of both supply-side and demand-side competition is a policy goal in the Netherlands and Germany. This has been created and regulated by law, new financial incentives and by the establishment of independent regulators charged with encouraging and managing competition.

As we described above, in the Netherlands, the 2005 Act has abolished the requirement of insurance companies to contract with all providers. The stimulation of 'managed care' policies based on selective contracting with providers (in the Netherlands called 'in nature' contracts) is designed to increase competitive forces among providers. Indeed, there are signs that competition between hospitals exists – in major cities such as Rotterdam and The Hague, hospital advertisements aimed at patients are widespread.

A similar but less pronounced desire to encourage more competition is evident in Germany. However, the highly corporatist German approach to health system management can act as an inhibitor to competition, notwithstanding the diversity of the supply side. For example, hospital fees are negotiated between the regional associations of insurers and providers.

Competition between insurers for patients has been a key goal of the recent health insurance reforms in both the Netherlands and Germany. Citizens can change their health insurer every year and health insurers compete on the level of premium that they charge (premiums are effectively unregulated). Unlike in Germany, where co-payments are regulated by law, insurers in the Netherlands can offer policies with personal excess payments for patients of up to €500. Dutch insurers are obliged to accept all applicants for the standard health benefits package and must operate nationally to prevent local monopolies.

A potentially significant phenomenon that has begun to emerge in both the Netherlands and New Zealand is the role of generic competition authorities. The Commerce Commission in New Zealand has recently become involved in the health care market using powers granted by the Commerce Act of 1984. Actions are generally restricted to the private sector and the commission has intervened in tender exercises by DHBs in relation to laboratory services (rejecting one tender exercise). The commission will also rule on the acceptability of mergers in the private health sector where this serves the interests of the public system (for example, recent mergers of laboratory services). In primary care, the commission has issued guidance to general practitioners warning them against collective price fixing and stipulating that they should negotiate individually with primary health care organisations (these are the organisations established and funded by DHBs to contract with and develop general practices and primary health care more generally).

The Commerce Commission does not intervene in main public hospital services as these are wholly within the public sector. However, in a landmark case it fined a number of specialist ophthalmologists (NZ\$130,000), and the Ophthalmological Society (NZ\$467,000), when it found that they had colluded to prevent Australian ophthalmologists being brought in to a public hospital to provide cataract operations under a government waiting list initiative.

In the Netherlands, the Generic and Independent Competition Authority (NMa) takes an active role in the regulation of competition and enforces the Competition Act. The act applies to 'undertakings', which includes all providers of health care and, since 2006 when sickness funds were transformed into insurance companies, companies offering health insurance policies (in Germany sickness funds remain as such and are not therefore subject to competition law).

This regulatory role is both *ex post* and *ex ante* in that the NMa acts to detect cartels and undertakings entering into agreements that restrict competition or abuse a dominant position in the market place.³ The NMa can fine those found transgressing the Competition Act. The NMa undertakes *ex ante* regulation in its role of examining proposed mergers of undertakings. This has been applied to insurance companies where there has been a strong trend towards mergers, and at least one of these has been prevented.

A more overt attempt to ensure competition through regulation is also evident in the Netherlands where the Health Care Authority has been created specifically to regulate competition within the health system. The authority monitors the health market place and advises the NMa on mergers of insurers and providers and whether these are considered detrimental to public values such as efficiency, quality and access.⁴ The Health Care Authority can carry out *ex ante* regulation of companies with 'considerable market power' (equivalent to 'dominant position') and ensure that providers maintain access to 'essential facilities'.

In late 2006, the Health Care Authority expects to be granted *ex ante* powers to regulate prices that are negotiated between insurers and providers by setting maximum tariffs to prevent market abuse and to facilitate market entry. The authority has already enforced rulings in the home care and health insurance markets to ensure that prices are more transparent to consumers. In addition, rules have been developed to prevent predatory or excessive prices,⁵ although there has so far been no trigger to bring these rules into use. The current restriction of free price negotiation between insurer and provider to only 8 per cent of care means that competition has not yet developed sufficiently for price regulation to be necessary.

³ Abuse of a 'dominant position' occurs where an enterprise holds a significant power within a market and uses this power to impose unfair selling or purchase prices, to limit production to the disadvantage of consumers or to impose obligations on contractors that are unrelated to the contract.

⁴ Those proposing mergers may counter with a 'failing firm' defence, ie without such a merger their business cannot survive commercially.

⁵ Predatory pricing is where providers set prices below an economic level to prevent the entry of competitors to a market. Excessive pricing is where providers exploit their dominant position in the market to set prices above an economic level.

TABLE 3: COMPARISON OF ECONOMIC REGULATION

Functions	Catalonia	Germany	Netherlands	New Zealand
Prices	<p>CatSalut agrees contracts and, therefore, sets prices with independent health care providers.</p> <p>Payments are made based on a combination of remuneration for fixed costs (65%) and payments made on a diagnosis-related group (DRG) basis (adjusted for complexity).</p> <p>Hospitals are each paid a different amount and this changes every year.</p> <p>Once contracts have reached agreed activity levels, payments reduce to 35% of the tariff, ie marginal cost only.</p> <p>There are also specific contracts at a national tariff for waiting list procedures.</p> <p>Up to 2% of contract is at risk if quality standards are not met.</p>	<p>Prices are set without government intervention.</p> <p>Sickness funds are free to set their own contribution rates although these have to be approved by Länder government or by the Federal Insurance Office.</p> <p>Prices for ambulatory care are negotiated in 2 stages. A budget is agreed by the regional representatives of insurance physicians and health insurers. The resources are then allocated to physicians via a calculation of the relative value of the different services provided.</p> <p>Hospital investments are funded by Länder. Operational costs are negotiated between hospitals and regional associations of sickness funds using DRG prices.</p>	<p>Under a new system to be introduced, the tariff for hospital care is to be regulated by the Health Care Authority.</p> <p>However, to introduce provider competition, free negotiation of prices (between insurer and provider) has been introduced for 8% of elective care rising to 100% by 2008.</p>	<p>Hospital treatment prices are set by the Ministry of Health via a weighted capitation formula.</p> <p>DRG prices are mainly used to compensate district health boards (DHBs) for treating patients from another district.</p> <p>Prices for services not provided directly by DHBs are set by contract negotiation and are unregulated.</p>

continued overleaf

TABLE 3 *continued*

Functions	Catalonia	Germany	Netherlands	New Zealand
Entry	<p>There is little competition between providers for contracts and only contestability at the margins (eg, CatSalut could reduce activity in poorly performing hospitals but this is limited by lack of geographical overlap).</p> <p>Acceptance into the network of public and independent providers (the XHUP) is a decision made by the commissioner, CatSalut, based on whether there is a need for additional capacity. The membership of the XHUP is very stable.</p>	<p>Entry in to the hospital market is largely regulated by regional government.</p> <p>The Medical Review Board, which represents sickness funds, has rights to monitor bed numbers to avoid over-supply.</p> <p>Entry of ambulatory care physicians is regulated by regional associations of statutory health insurance system (SHI) physicians to meet quotas set by the Federal Joint Committee.</p>	<p>Central control of market entry has been significantly weakened.</p> <p>New hospitals need a licence from the Ministry of Health but this is relatively easy to obtain.</p> <p>There is free entry into the insurance market though the trend is towards mergers – there are now 15 companies compared to around 80 in the 1980s.</p>	<p>There is a largely closed hospital market.</p> <p>Promotion of new market entrants is the responsibility of DHBs as local purchasers.</p> <p>This usually involves disability services and community diagnostics that are mainly private sector as DHBs have no incentive to set up services in competition with the hospital services they are responsible for providing.</p>
Financial monitoring, intervention and exit	<p>CatSalut monitors providers to ensure service delivery is not threatened but there is no clear process for graded intervention.</p> <p>Financial monitoring is through a system set up by the national government. It uses detailed financial information provided by hospitals and benchmarks individual hospitals against a range of different indicators.</p> <p>There is no clear distress/failure regime, although financial grants may be made in the case of financial difficulty.</p>	<p>Sickness funds are supervised nationally by the Federal Insurance Office to ensure companies are solvent.</p> <p>No assumption that commissioners have rights of financial monitoring or intervention in relation to providers.</p> <p>There is no specific financial distress regime for independent providers.</p>	<p>The Pensions and Insurance Supervisory Authority oversees the financial position of insurance companies.</p> <p>The relative independence of hospital providers means commissioners do not have automatic rights to monitor finances or intervene – but it is rare for providers to go bankrupt and exit the market.</p> <p>Hospital closures become political problems, especially at local level, so may result in political pressure on insurance companies to intervene.</p>	<p>Closest monitoring and intervention regime.</p> <p>The Ministry of Health has established a ‘monitoring and intervention framework’ allowing five stages of increasing monitoring and intervention. This is mainly triggered by financial problems at DHB or hospital levels.</p> <p>No distress/failure regime (other than general insolvency) exists for independent providers.</p>

TABLE 3 *continued*

Functions	Catalonia	Germany	Netherlands	New Zealand
Financial monitoring, intervention and exit <i>continued</i>	The commissioner may intervene informally to change management practices (or management) in independent providers.		The Ministry of Health is developing a new bankruptcy regime to ensure essential services are maintained.	
Competition	<p>There is very little competition between providers.</p> <p>Hospital contract values are all different and there is variation in the expenditure per activity that is financed by CatSalut.</p> <p>A new pilot scheme to offer capitation payments to geographical groups of providers is likely to decrease provider competition further.</p>	<p>Competition between insurers and between providers is encouraged. A number of initiatives have been introduced including selective contracting between insurers and providers and financial incentives for ‘integrated care’ policies.</p>	<p>Providers are largely independent and subject to contracts rather than direction from the government.</p> <p>New rules have outlawed negotiations between the national associations representing GPs and insurance funds. Now sickness funds must enter into individual contracts with GPs (or groups of up to 10).</p> <p>Legislation has encouraged competition between insurers by ending the requirement for them to contract with all providers.</p> <p>The Health Care Authority regulates the provider and insurer markets to ensure no abuse of ‘dominant position’.</p> <p>A generic competition authority (the NMa) has primacy in <i>ex post</i> regulation.</p>	<p>Competition is not a policy aim for hospital services so there is little formal regulation.</p> <p>Outside hospital services, there are rules to ensure fair tendering when letting contracts but no attempt to encourage competition.</p> <p>Recent involvement of a generic competition authority in the health care market has generally been restricted to the private sector.</p> <p>Competition between DHBs is rare except in the case of tertiary services. DHBs expect to use their own hospital services in the first instance.</p>

DISCUSSION

What is notable from our study is the sheer diversity and range of ways in which health system performance is shaped. Many different regulatory instruments have been adopted and the mix of these differs in each case (see Table 4, opposite). In addition, governments vary widely in their faith in competition as a means to improve quality, efficiency and responsiveness, which explains the requirement for different types of regulation.

It seems that all the systems studied have identified the need to regulate the provision of health care and insurance against health risks in order to manage the equity–efficiency balance in their systems. However, the ways in which they do this are embedded in their wider welfare state regimes and governmental traditions (eg reliance on corporatist self-regulation in Germany). This is hardly surprising given the vast differences between their histories and cultures.

Regulation by independent regulators is by no means extensively used in our case studies, notwithstanding the existence of some form of health care market in all of them (albeit sometimes very limited markets). Independent regulatory bodies are a significant feature only in the Netherlands (which is the country most explicitly and extensively focused on increasing and sustaining competition). In Catalonia and New Zealand, quasi-independent agencies are preferred, with strong links to or incorporation into the Ministry of Health. Germany, however, has adopted an avowedly self-regulatory approach.

Also, there is no evidence of any ‘super-regulators’, bringing together a range of different economic and quality regulatory functions in a single agency. Instead, the regulatory systems are mostly complex and dispersed.

In addition to whatever formal independent or self-regulatory framework exists, more subtle relationships are also often at work –especially between purchasers and providers. Formal contracts are an important regulatory instrument, particularly in relation to providers independent of the state (performance management relations often replace contracts as the means by which governments or their agents influence state providers). That is, the quality, level and price of services are often established through contracts, although some elements of pricing may well have been set nationally.

Notwithstanding the use of contracts by purchasers, the more direct role of national and local government is also important in shaping provider behaviour. This can often be informal and reflects the high visibility of health services in local and national political debates. The future of hospitals and other health services remains a significant public issue in all systems, leading to intervention by state agencies where this is threatened. As one of our interviewees in Catalonia reflected, the closure of an independent hospital is a problem for both that provider and the public commissioner.

In this sense, contracts between purchasers (both state and non-state) and providers do not replace government regulation but provide a further opportunity for it because governments influence the contracts that exist between purchasers and providers. However, the utility of contracts to shape provider behaviour is also constrained, in some cases, by the mutual dependence between provider and purchaser following a historical process of rationalisation (for example, in New Zealand and Catalonia). Competition and purchaser power require the ability to choose between alternative providers.

TABLE 4: SUMMARY OF REGULATORY INSTRUMENTS

	Independent regulation	Self-regulation	Law and legal rights	Performance management	Purchaser– provider contracts	Financial incentives	Information provision
Catalonia	<p>Quasi-independent regulators used only in field of quality inspection</p> <p>A public not-for-profit agency established to carry out health technology assessment and advise CatSalut</p>	<p>New pilots to allocate health care resources on geographical basis (via capitation formula) rely on self-regulation by providers</p>	<p>Little use made of law in health care regulation</p>	<p>Mutual dependence between single purchaser and independent providers means significant levels of informal performance management</p>	<p>Prices set using contracts (fixed cost element) for independent providers</p>	<p>New pilots to allocate health care resources on geographical basis provide financial incentives to contain costs through the use of capitation payments</p>	<p>Information collected by Ministry of Health but not made public at level of individual provider</p>
Germany	<p>Little use made of independent regulation</p>	<p>High use made of self-regulation</p> <p>System regulated by groups representing health insurers, doctors and hospital providers as well as federal and state governments</p>	<p>Many aspects of the health system defined in law, eg, Social Code Book V sets out benefits to be provided and how the system should be regulated</p>	<p>Little use made of performance management – the government sets the framework within which it expects self-regulation to operate</p>	<p>Growth in preferred-provider relationships between hospitals and sickness funds has increased the importance of contracting as a regulatory instrument</p>	<p>Länder make available funding for fixed costs of hospital care</p>	<p>Information collected by Institute for Quality and Efficiency but not made public</p>

continued overleaf

TABLE 4 continued

	Independent regulation	Self-regulation	Law and legal rights	Performance management	Purchaser– provider contracts	Financial incentives	Information provision
Netherlands	High use of independent regulation of social insurance and provider markets	No use made of self-regulation	Law stipulates how insurance market should operate and quality requirements	Only informal intervention by government in cases where providers may be unviable	Contracts between insurers and providers determine quality and activity Insurers are no longer required to contract with all providers making contracting a more important regulatory instrument	Introduction of free contracting as an incentive for cost control	Information collected by the Health Care Inspectorate and made public on internet
New Zealand	Mainly quasi-independent regulators operating as departments within Ministry of Health with independent audit agencies	No use made of self-regulatory mechanisms	Legal right to appeal to health and disability rights commissioner	High use made of direct performance management, eg, to set expected standards, to agree funding of district health boards (DHBs)	Autonomous contracts between purchasers and independent providers of diagnostic, laboratory and general practice services	Restrictions on government financial support for patients of GPs in areas with sufficient doctors	Information collected by Ministry of Health and made public through annual 'health and independence report'

It is also clear that the Netherlands, Germany and Catalonia (and in some sectors New Zealand) all have a diverse supply side. However, while this diversity might be a necessary condition for competition it is not a sufficient condition. Competition between providers and between health insurers is relatively limited, sometimes deliberately so. In the Netherlands, especially, and Germany to a lesser extent, this has led governments to create competitive forces. New Zealand and Catalonia have moved in the opposite direction to encourage collaboration within the publicly financed system.

Mainstream competition authorities have played a relatively small part in each health care system. The limited but evolving role of formal competition authorities in the Netherlands and New Zealand has focused on enabling market entry, encouraging competition and ensuring a level playing field when tendering for services occurs. As such, it is a potentially important development. However, the role of competition law is controversial and subject to evolving European case law (ECJ July 2006). It has not as yet featured prominently in Germany or Catalonia.

These differences between the four health systems may reflect different interpretations of the risks associated with both competition and its absence in health care markets. For example, exclusive contracts or periodic selective contracting may be seen by some regulators as anti-competitive and automatically a bad thing because they establish some providers as dominant. However, they can also promote efficiency – vertical integration in health care can reduce transaction costs and ensure better quality monitoring. A reduction in provider uncertainty (eg, through a longer-term contract) may also enable highly specific investments to be made. As a result of such arguments, there is a case, in theory, for competition rules to be justifiably less stringent in health care than other industries. However, this argument is not universally accepted leading to variation across regulators.

In the Netherlands, the new Health Care Authority has taken a strongly pro-competitive stance in all situations, arguably failing to recognise the complexities of the health care market. It is too soon to know what the consequences of its interventions to reduce barriers to competition will be.

Another notable difference between the case studies is the degree of choice of provider for patients. Choice of general practitioner exists in them all; however, choice of hospital provider is variable. In Catalonia, choice of hospital is simply unavailable and in New Zealand, the policy is not favoured by the government. Where high choice has historically existed, in Germany and the Netherlands, the desire for greater efficiency through competition between purchasers and among providers is likely to reduce patient choice through the development of selective contracting. The paradox appears to be that certain competitive mechanisms can reduce patient choice as in the UK in the 1990s when the internal market was introduced.

The regulation of quality of care has elicited broadly similar approaches across the four case studies, although they use different agents and mechanisms. The independent monitoring of service standards or performance indicators at the level of provider, with central powers to intervene in the case of quality deficiencies, is widespread. However, not all of them make information on which central quality assurance is based available to the public.

One area in which regulation is well developed in countries with statutory social insurance systems is in relation to the benefits package. Here the use of individual cases to develop a non-judicial form of ‘case law’ has proved important. In tax-funded Catalonia, the benefits package has been less clearly defined. In New Zealand, the government has attempted to define benefits and service priorities; however, it relies on commissioners to put this into practice.

The benefits package in the tax-funded systems has ultimately been controlled by political decisions. For example, ministers’ acceptance (or otherwise) of the recommendations of those responsible for health technology assessment, or the formal and informal instructions sent by governments to state purchasing and providing agencies. However, as we discuss in the following section, the decision to make explicit the benefits package is not solely a consideration for systems based on statutory health insurance. Indeed, as tax-funded systems devolve responsibility for planning, commissioning and providing care to independent state and non-state agencies, the case for setting out the NHS benefit package more explicitly becomes compelling.

5

Implications for regulating the English NHS

The study of the four health systems shows that while they share many objectives, particularly the promotion of universal access to good-quality services, there is no single model of regulation that could appropriately be imported to England. At one level, of course, this is not surprising; health systems develop in the context of wider state and social structures and culture, and are bound to differ. Their pattern of health care regulation has developed in the context of different institutional constraints from those that exist in England.

This diversity of regulatory approach, and of current regulatory policy (both towards and away from competition and towards and away from government control), is also likely to reflect the fact that economic theory and research on health care markets has been unable to identify an unequivocally superior solution to the complex problem of allocating health care resources. There is no strong basis in theory for preferring to organise competitive markets in health care with a strong separation of providers from funders/purchasers, over a system based on vertical integration between the two, in terms of their likely impact on costs or outcomes (Rice 1998).

However, notwithstanding their diversity, the health systems we have selected bear some important similarities to each other and to the English NHS. In particular, they all have to regulate the actions of a diverse set of providers that includes public, for-profit and not-for-profit independent providers. Moreover, each of them faces the same global pressures on health care, particularly a rise in demand and cost, and the desire for greater efficiency and cost control. In this context, the lack of congruity between their regulatory strategies may offer an important high-level message – there is no agreement on the best way to regulate health systems and regulation must be appropriate to the wider institutional structure of each system.

The Department of Health’s review of regulation will seek to define regulatory objectives and functions as well as the changes to the current structures that will be required to best deliver these objectives. In this section, we consider what broad implications might be drawn from our comparative study about the way in which these regulatory functions could be discharged in the new NHS market.

As we have already noted, ‘regulation’ is much broader than simply the establishment and use of arm’s length regulatory bodies backed by statutory powers to inspect and intervene. Governments can draw on a wide range of regulatory instruments as illustrated by the study of the four health systems (see Section 4, pp 19–50).

Complexity of regulation

A key question faced by the government is whether or not to simplify the existing regulatory system. In part, such a strategy has already begun with the ongoing merger between the Healthcare Commission, the Commission for Social Care Inspection and the Mental Health Act Commission.

However, such a merger brings together organisations with similar functions (quality regulation) from different environments (health and social care). Arguments have been advanced that this simplification should extend to different regulatory functions (HCC 2005a). Most obviously, this would involve the creation of a ‘super-regulator’ combining for example the functions of both Monitor (licensing and financial regulation) and the Healthcare Commission (quality regulation). The strengths and weaknesses of such an option have been considered in depth by both of these organisations (HCC 2005a; Monitor 2005).

It is significant, however, that we found no examples of independent super-regulators spanning economic and quality regulation. Where these functions were brought together (for example, in New Zealand) the functions were exercised by the Ministry of Health. In Germany, some quality assurance and economic regulatory functions were combined in the system of self-regulation under the aegis of the Federal Joint Committee and regional joint structures. Nevertheless, the direction of policy in Germany is away from all-encompassing self-regulatory structures. In addition, the state is becoming a more rather than less powerful regulatory actor (Wendt *et al* 2005).

Safeguarding public interest

A key feature of the current regulatory framework in England is that different regulatory systems apply to state-owned and independent providers. Independent providers are subject to annual inspection by the Healthcare Commission against a set of national standards and are subject to the Competition Act 1998. State-owned providers divide into two groups: those directly accountable to the Secretary of State for Health through the Department of Health (NHS trusts and primary care trusts (PCTs)); and foundation trusts. The former are subject to direct performance management by the Department of Health (with discretionary powers to intervene); the latter are regulated by Monitor with clearly defined powers for monitoring and intervention. Both sets of providers are subject to inspection by the Healthcare Commission.

This variation in regulatory approach is problematic in an evolving market-based NHS. One crucial component of a well-functioning market is ensuring there is a ‘level playing field’ between all competing providers. Clearly, the regulatory burden is different on each of the three categories of provider identified. If government policy is successful and all NHS trusts achieve foundation trust status, in time a degree of convergence of regulatory regimes will occur naturally (albeit with a potentially extended period of transition).

However, this convergence will not be complete. NHS foundation trusts and independent providers will still face different regulatory requirements. This poses the question as to whether or not the regulation of independent and public providers can and should ever be fully aligned. One option would be to give a regulator statutory powers to monitor and intervene in all providers of health care whether public or private. With regard to quality

regulation, this is in fact stated policy – all providers of NHS-funded care are to be subject to the standards set by the Healthcare Commission with continued compliance a condition of entry.

Such an option with respect to economic regulation, however, would be counter to the trend towards less, rather than more, regulation of business. For example, the monitoring and regulation of the finances of independent providers would place an additional burden on them and involve the government where previously it has had no role. For example, the suggestion that the government should routinely monitor the finances of independent providers was generally treated as a curious proposal by some interviewees in Spain, the Netherlands and Germany. After all, are these providers not separate from the state and responsible for their own finances?

In fact, as we discussed above, the reality is that the mutual dependence between commissioners and providers and the high political visibility of health services means that such a detachment is difficult to maintain. This was recognised by some of our informants who gave examples of government involvement where independent providers were in difficulties. In this situation, governments find it difficult to remain detached and instances of central intervention (such as additional funding or replacement of management) were cited. However, such intervention is generally covert and based on well-understood rules of engagement.

Any extension of economic regulation, for example monitoring internal financial viability beyond existing generic insolvency regulation to independent providers, would be a significant development. However, as (and if) the NHS market matures, with greater penetration of independent providers and therefore more mutual dependence, such a proposition may become more credible. Importantly, it is not without precedent in other countries. On the other hand, it is equally likely that this economic regulation of public and independent providers will be designed to remove the financial guarantees enjoyed by public providers to produce a more level playing field.

The difference in economic regulatory regimes between foundation trusts and independent providers also stems from their very different stakeholders. Currently, Monitor is responsible both for ensuring the viability of autonomous public providers (through financial monitoring and intervention) and for ensuring the appropriate supply of public services to a given population (through awarding licences and managing market exit).

These are very different types of function. Ensuring financial viability is, in part at least, designed to protect public assets (it is also designed to ensure continuous supply of appropriate services). In this role, Monitor is acting as guardian of public assets and as a form of public ‘shareholder’. If regulatory regimes were to be harmonised between public and independent providers, an economic regulator would want to take on the role of ensuring appropriate supply across all providers (this is currently carried out by the Department of Health with respect to independent hospital providers through a process of central procurement and PCT procurement of other services). That is to say an NHS economic regulator would determine market entry and the scope of operation.

However, the NHS economic regulator would have no obvious role in protecting stakeholder interests in non-state providers – this is the role of shareholders or other

governance arrangements where shareholders do not exist (for example, regulation by the Financial Services Authority or Community Interest Company Regulator). European law might come into play if it were shown that any difficulties among private providers were due to the preferential treatment of public providers.

This highlights a tension that must be managed as economic regulatory structures are developed. A single regulator responsible for economic regulatory functions (such as market entry and exit) across public and independent providers would offer simplification of the system. However, such a regulator might also have duties with regard to protecting the public's interest in foundation trust assets. This could create conflicts of interest within the regulator where market entry of independent providers might threaten the financial viability of foundation trusts. This potential for conflict of interest may then suggest that Monitor should remain to act as the public shareholder in relation to foundation trusts, separate from any new economic regulator responsible for regulating all providers of NHS services.

Of course, foundation trusts already have elaborate governance arrangements designed to create community accountability. These arrangements are currently relatively weak (Healthcare Commission 2005b; Lewis 2005). However, as they mature the need for additional regulatory assurance might be questioned. Should local foundation trust boards, together with their community governors, be left to protect the interests of their stakeholders in the same way as shareholders do for private independent providers? If so, the monitoring of financial performance and intervention in the case of financial distress would be replaced by a regulatory regime designed to ensure that appropriate governance procedures were in place – as Companies House does for limited companies.

How should the regulatory functions be discharged?

In Section 3 (see pp 15–17) we set out what we believed to be the key regulatory challenges for the emergent NHS market under the headings of quality and economic regulation. Here we present options as to how these regulatory challenges might be met, drawing on the information gained from our comparative study.

QUALITY REGULATION

Currently, only foundation trusts are licensed (by Monitor and largely on grounds of their financial viability rather than quality). NHS trusts, foundation trusts and independent providers are required to meet minimum quality standards (independent providers face different standards although these are due to be harmonised).

The creation of a single 'licensing' process for all providers of NHS-funded care offers the potential to establish a clear acceptable threshold for market entry based on organisational competence to deliver care of the appropriate quality. This could incorporate the harmonised minimum standards and be implemented by a single regulator.

Licensing in the health systems we studied tended to incorporate only minimal quality standards. In themselves these standards were unlikely to offer anything further than a basic assurance of quality and safety. The current developmental standards issued by the

Healthcare Commission are more ambitious, and are intended to stretch performance and stimulate ongoing quality improvement. Arguably, the contracting process and patient choice could fulfil this role of quality improvement rather than regulation. However, doubts remain over the current capacity of commissioning to achieve sufficient leverage. Similarly, there is as yet no substantive evidence that patient choice will drive quality improvement. Indeed, some international evidence suggests that patients are unlikely to use quality information to inform their choices (Schneider and Lieberman 2001).

This suggests that a combination of contracts, licensing and state and voluntary independent accreditation might be the appropriate mix of regulatory instruments to assure quality across a diverse supplier base. This is in fact similar to the approach taken in Catalonia and in the ambulatory care sector in New Zealand. The provision of high-quality information to guide commissioners and patients is vital. Here it would appear that the NHS in England is already at least as advanced as any country we studied.

In systems where contestable commissioning exists, the regulation of the benefits package (exactly what health care must be provided by law) is a significant function within the overall regulatory architecture. It is tempting to see this as a regulatory feature of social insurance systems rather than publicly funded health services such as that in England. Given that there is no current policy to provide patients with a choice of primary care trust (PCT), these regulatory questions may be seen as purely theoretical and of little practical concern.

However, such a view may be short-sighted. The NHS in England is already moving to a diversified commissioning base through practice-based commissioning. This introduces the potential for patients to select their commissioner as part of their decision to select a general practitioner (of course in practice the growth of practice-based commissioning clusters will reduce the extent of this choice). Moreover, there has been a growth in NHS and independent providers willing to manage particular services and the financial risk for those services. An example of this is entry of (and expected rise in the number of) 'third party disease management' providers, already prevalent in the United States. These providers offer 'managed care' where financial and clinical risk is transferred in return for a budget set in advance. Lastly, there has been increasing discussion about the possibility and desirability of 'outsourcing' the commissioning function to non-PCT parties and a national procurement exercise for such services is underway.

In these circumstances, commissioners will face conflicts of interest as any extension to the scope of services will increase their financial risk or reduce the value of financial incentives, such as budget underspends for practice-based commissioners (ie commissioners will face incentives to provide less care than they should). Consequently, there may be a case for more overt regulation of commissioning to ensure that patients receive an agreed package of benefits regardless of the identity of the commissioner (or delegated agent).

In the case of practice-based commissioners, PCTs hold them to account for their performance. This will include the 'regulation' of the health care package that they offer patients. PCTs, in turn, are performance managed by strategic health authorities (SHAs) that, in theory at least, are responsible for ensuring that commissioners offer

comprehensive services and, for example, comply with guidance from the National Institute for Health and Clinical Excellence. However, both PCTs and SHAs may appear partial from the public viewpoint if asked to adjudicate on benefits coverage – any financial distress resulting from an expanded benefits package impacts adversely on the performance of PCTs and SHAs.

As commissioning develops and diversifies, there may be a case to look at alternative means of regulating (and defining) the NHS ‘benefits package’. This could be through an independent regulator or through quasi-legal regulation in the form of a system of administrative justice like German ‘social courts’ or the New Zealand Health and Disability Rights Commissioner. Such regulation may be thrust on the NHS in any case as the European Court becomes increasingly active in this field. Already, European Court judgments have begun to establish norms regarding quality of care such as maximum waiting times for treatment (ECJ 16 May 2006, case C-372/04).

ECONOMIC REGULATION

A key facet of economic regulation is that of market entry. Currently, entry of non-NHS providers is managed by a combination of national and local procurement. Such a process could be argued to be potentially anti-competitive and inefficient. Local commissioners may be subject to ‘provider capture’, that is, unwilling to challenge or change long-standing providers. National procurement of additional capacity may be inefficient in that the desire to establish competition could result in procurement that is independent of local market requirements (the recent experience of independent sector treatment centres suggests that capacity may in some cases have been badly allocated as a result).

Market entry could be managed through independent regulation (although an increase in the number of suppliers may lead to financial pressure on PCT commissioners, especially in an environment of free patient choice). Indeed, it would be possible to align the economic regulation of market entry with that of quality regulation (‘licensing’) discussed above. Of course, a further option is to leave market entry unregulated and open the market to ‘any willing provider’. In this scenario, there would be no capacity planning and the allocation of NHS resources would be left to commissioners and patients. This places a significant expectation on PCT and general practice commissioners to ‘manage demand’ and there is a clear risk of ‘supplier induced demand’.

Competition regulation is currently applied differentially across public and independent sectors. This is generally also a feature of our case studies. However, given that independent sector providers are predominant in the Netherlands and Germany, this disparity is of less significance (we found little evidence of overt competition management in Catalonia).

The role of formal competition law and independent competition agencies such as the Office of Fair Trading and the Competition Commission look set to become more important in the health market. Although publicly owned providers are currently exempt from the provision of the 1998 Competition Act, independent sector providers of NHS services are not. The experience of the Netherlands and, to a lesser extent, New Zealand suggests that formal competition management can have a significant effect, either positive or negative.

It will be important to apply similar disciplines to public sector providers if a level playing field is to be established. This suggests that a new economic regulatory role will need to be established to monitor and enforce appropriate competition. This will include *ex post* monitoring of apparent abuse of dominant position and *ex ante* consideration of proposed mergers with respect to their impact on choice and competition within the market. Such a regulator would be expected to build up expertise in the whole market place, including public providers over which it had a regulatory remit and private providers where it did not. In the case of private providers, the regulator could have powers to warn and advise existing competition authorities, which may have less experience of the dynamics of health care markets. This would mirror the role of the Health Care Authority in the Netherlands.

However, it is important to recognise that competition driven by patient choice ('competition in the market') is likely to be limited to certain sectors of the health care market. It is unlikely, if not undesirable, that competition will emerge for highly specialist services or those requiring significant infrastructure (such as full accident and emergency services). Indeed, a significant recent policy theme has been to create collaborative provider networks to improve the quality of care (eg cancer networks).

The regulator will therefore have to determine whether the public interest is served by applying competition rules to any given service or in specific circumstances. If competition was considered desirable for services where patient choice is unlikely to be significant, the regulator could oversee 'competition for the market'. The regulator would have to ensure that PCTs or other commissioners tendered appropriately for the right to manage monopoly services, as happens in other public utilities. This is currently a role undertaken by the Commerce Commission in New Zealand.

At other times, certain forms of vertical integration and/or local monopoly may be judged more efficient in providing a high-quality service than attempting to co-ordinate the actions of competing providers for the benefit of patients. For example, contractual stability may be required in technology-intensive health care services to encourage providers to make the required investment in costly, highly specialised equipment. As we discussed in Section 3, the regulation of competition within the NHS in England is also likely to be influenced by developments in Europe.

Another important facet of economic regulation is that of price setting. The NHS hospital market is a fixed-price market as a matter of policy. Indeed, the extent to which prices are fixed is far greater than in our case studies.

The Department of Health currently sets the tariff, but should it continue to do so in future? One option would be to pass tariff regulation to an independent regulator, in the same way as the Bank of England is responsible for setting interest rates (this is discussed further below). The tariff is itself a powerful financial regulatory instrument capable of achieving a number of policy objectives (eg targeted improvements in efficiency at the level of the provider, incentives to deliver particular types of service, transfer of resources from secondary to primary care). It would be possible for the government to establish objectives for the tariff, but to leave its calculation to an independent regulator.

This degree of independence may foster a perception of impartiality among public and independent providers. However, this degree of regulatory devolution is not common among our four case studies (in Germany price setting is in part devolved to national and regional self-regulatory groups).

Financial monitoring, intervention and market exit is the final category of economic regulation that needs to be considered. As we discussed above, financial monitoring and intervention in relation to independent providers would result in a significant increase in regulation. However, an economic regulator with a remit to ensure continuity of services would require financial information from all providers in the market place. Where a risk of market failure emerges, the regulator could have powers to intervene, in particular to ensure continuity of essential patient services (ie those for which there is no readily available alternative). Ultimately, the regulator could have the power to remove the licence to trade where financial or quality thresholds were crossed.

For independent sector providers, there are already authorities responsible for managing insolvency (under the 2002 Enterprise Act). However, current insolvency laws are designed to maximise the value of the business to shareholders, and do not take into account any broader public values, or the needs of service users. Such an approach would not be sufficient if and when privately owned providers become more integrated into the NHS. If private sector providers delivered essential services, then regulatory powers would need to be developed to ensure that these services were maintained in the event of insolvency. Some assurance could be available through contractual provisions between commissioners and providers (such as the posting of financial bonds by the supplier). However, it may also be appropriate to give powers to a regulator to intervene directly in the management of a private business that is at risk of failure, and perhaps include powers to compulsorily purchase private assets. This would be similar to the provisions made for sector regulators to impose 'special administration' in relation to failure among privatised utility companies. The Health Care Authority in the Netherlands is currently developing such a bankruptcy regime and one is urgently required for the NHS.

Similar powers must be developed for public providers – including the disposal of assets, responsibility to maintain supply of essential services and securing new providers as required. While Monitor currently has powers to intervene prior to the financial failure of a foundation trust, there are insufficient provisions in place to handle actual failure should remedial action be unsuccessful (Palmer 2005).

6

Conclusions

How the evolving NHS in England should be regulated is a key issue in current health policy. In determining an appropriate regulatory framework, the government will essentially be setting out its future vision for the health care market. Serious consideration will have to be given to the following questions:

- What limits, if any, will be placed on market incentives?
- How seriously will competition be pursued and in what sectors?
- What powers will the government devolve to independent agencies?

Our study of four health systems demonstrates that there is no single approach to regulation, nor even any basic agreement over what should be regulated and how. We found little sign of ‘super-regulation’ in the four health systems; regulation was instead something of a ‘patchwork quilt’.

The appropriate balance of regulatory instruments for the NHS in England rests on the answers to a number of fundamental questions:

How great is the government’s confidence in competition as a driver for quality improvement and greater efficiency?

If confidence is high, then there may be a case for strengthening economic regulation particularly in relation to market entry, competition management and financial distress regimes. The use of independent regulators may be preferred, particularly if there is to be greater penetration of the NHS by independent sector providers. However, if competition is to remain at the margins, then a wholly new regulatory regime may simply add more complexity with only limited value. In these circumstances a more incremental approach, such as tweaking the powers of existing regulators, might be preferred.

How much faith can be placed in NHS commissioning?

Strong commissioning could be a key regulatory instrument in the drive for improved quality. If quality can be assured and developed through primary care trust (PCT) contracts, there may be little need for substantive external quality regulation. This might mean that the Healthcare Commission (or any other regulator) would only need to set basic quality standards as part of a licensing arrangement. However, evidence to date suggests that commissioning has largely failed to make a significant impact, particularly on the hospital sector (Smith *et al* 2004). Therefore, a high reliance on commissioning, at least in the short term, might appear something of a risk.

What role will there be for strategic health authorities (SHAs)?

A fundamental review of regulation must call their role into question. SHAs currently have responsibility for managing local health markets as well as holding PCTs to account. There would appear to be a conflict between any shift towards independent regulation of

suppliers of care and a continued role in market management for SHAs. One option would be for SHAs to focus entirely on the ‘demand side’ once all NHS trusts have converted to foundation trust status. The government, through SHAs, would therefore only enjoy direct control over commissioning.

While this is perhaps one logical conclusion of the market-based reforms, it may feel like a sudden and risky loss of control by the centre (not least due to the currently undeveloped nature of commissioning, as well as the challenging programme of hospital reconfiguration that lies ahead). A less radical approach would be for SHAs to retain, on behalf of government, a ‘market management’ role alongside one or more new independent bodies responsible for economic and quality regulation. While some role conflict would appear to be inevitable, this might be justified on the grounds that competition is only applicable to some care sectors. For those sectors not within the competition mode, SHAs would act as a focus for engineering appropriate collaboration between providers.

How much confidence can be placed in local governance of foundation trusts?

Strong local governance, particularly which closely and meaningfully involves local people, might be sufficient to protect the public shareholder’s interest. However, weak governance suggests that the public shareholder’s interest must be protected through external regulation and that Monitor (or some other body) should continue to oversee foundation trusts with powers of intervention as necessary.

Can the NHS tolerate yet more organisational change?

The development of a new regulatory system inevitably involves transaction costs and those associated with a loss of focus while all NHS organisations adjust to new arrangements. If such costs are to be borne, it is important that a clear assessment of the expected benefits is made. As we have already noted, the argument that competition will deliver significant benefits in the shape of higher quality and lower cost is highly contested. It is notable that no general trend towards greater competition was found in the study.

This discussion of regulation is at the heart of a bigger concern – what is the fundamental role of central government in managing the health service? It is perhaps timely that this question has been highlighted recently with informal proposals from the government that the NHS should be subject to a ‘constitution’ or even managed by an arm’s length ‘agency’ (the latter concept is also promoted enthusiastically by the Conservative party).

This underlines the desire of the current government and the Conservative opposition to step back from operational responsibility for the NHS in England, in line with the creed of new public management that was discussed earlier in the report. However, it also underlines the need for a clear regulatory framework that sets out, among other things, the role of ministers and departmental administration, mechanisms for public accountability, the application of and limits to market-based incentives and the architecture of arm’s length regulation.

If the idea of an NHS agency were to be pursued, it would pose significant questions about the need for, and appropriate level of, public accountability. Under such an arrangement, the government would be likely to retain responsibility for the overall strategy for the NHS and for setting budgets while the implementation of the strategy would be devolved to the Agency Board.

Such a notion is often compared to the decision of the 1997 Labour government to devolve responsibility for setting interest rates to the Monetary Policy Committee of the Bank of England – almost universally perceived to be a success. Whether such a parallel is appropriate might be questioned. The Bank of England has only one target (inflation) and one regulatory instrument (interest rates). An NHS board would be likely to face numerous objectives such as improved equity, choice and efficiency. These may well be in tension with one another. Finding the appropriate balance between them could be regarded as an essentially political decision for which the government, rather than an arm's length agency, should be responsible.

Arm's length regulation implies a rules-based regime, where rules are applied uniformly with predictable outcomes. Were governments to look to regulators to resolve difficult tensions between competing priorities, the regulators may face loss of legitimacy (in so far as their legitimacy is derived from perceived independence and a rules-based operation) and perhaps political capture. Our study showed that even in those countries where governments have no direct ownership of health care providers or insurers, they retain an ongoing interest in the operation of the health service. Covert government influence may be a worse outcome than the current arrangements, however imperfect they may be considered.

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Appendix 1: Methodology of the comparative study

Our analysis was based on a combination of desk research and face-to-face and telephone interviews with key informants and academics in each country. Official websites and both grey and academic literature provided a basic understanding of the health system and the regulatory structures. Interviews were used to validate the findings from the literature, to clarify points of fact and to gain further insights into how regulation operates in each country. Much of the literature was out of date, given the constant evolution of health systems, or failed to adequately describe the formal and informal relationships that existed within the system.

Interviews were semi-structured and based on the analytical framework of quality and economic regulation set out in Section 3. Most interviews were conducted by two members of the research team and notes taken from the interviews were compared.

We believe that we have captured the main characteristics of the regulatory systems in place at the time of writing, however, any errors are the authors' own.

Appendix 2: List of interviewees

Catalonia

Dr Enric Agustí i Fabré

Director, Services and Quality
CatSalut

Dr Marc Soler

Director, Corporative Section

Mr Berenguer Camp

Responsible Professions Section
Colegio Oficial de Médicos de Barcelona (COMB)

Dr Rafael Manzanera López

Director, General Directorate of HealthCare Resources

Dr Luisa López

Departamento de Sanidad y Seguridad Social de la Generalidad de Cataluña

Dr Rosa Suñol

Director
Fundación Avedis Donabedian

Dr Mateu Huguet

Director, Department of Hospital Care
Instituto Catalán de Salud (ICS)

Germany

Dr Peter T Sawicki

Director
Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

Dr Ellen Nolte

London School of Hygiene and Tropical Medicine

Dr Peter Kotzian

Project Director and Researcher
Technische Universität Darmstadt

The Netherlands

Dr Lydia de Heij

Senior Policy Adviser

Dr Floor Rikken

Senior Policy Adviser
CVZ College Voor Zorgverzekeringen

Jan Vesseur

Chief inspector for patient safety, health information technology and international affairs
IGZ Inspectie voor de Gezondheidszorg

Brenda Schouten

Responsible Area of Economic Regulation

Rob Verrips

Responsible Area of Quality Regulation

NVZ Vereniging van Ziekenhuizen

Prof Dr Niek Klazinga

Department of Social Medicine, Academic Medical Centre, University of Amsterdam

Misja Mikkers

Director, Unit of Economic Analysis

Zorgautoriteit

New Zealand

Bob Henare

Chair

Capital and Coast District Health Board

Bridget Allen

Director of Planning and Funding

Chai Chuah

Chief Executive Officer

Peter Glensor

Chair

Dr Robert Logan

Medical Director

Hutt Valley District Health Board

John Foley

Manager, System Performance, Sector Policy Directorate

Keith Walton

Senior Adviser, District Health Boards Funding and Performance Directorate

Ministry of Health

Mary Slater

Senior Analyst, Social Policy Branch

Bronwyn Croxson

Senior Analyst, Social Policy Branch

New Zealand Treasury

Joy Cooper

Director of Planning and Funding

Wairarapa District Health Board

Jackie Cumming

Director of Health Services Research Centre

Victoria University of Wellington

Appendix 3: Glossary of health care organisations

Catalonia

English name	Spanish (Catalan) name	Abbreviation
Catalan Agency for Health Technology Assessment	<i>Agencia de Evaluación de Tecnología e Investigación Médicas de Cataluña (Agència d'Avaluació de Tecnologia i Recerca Mèdiques de Catalunya)</i>	AATRM
Catalan Health Institute	<i>Instituto Catalán de Salud (Institut Català de la Salut)</i>	ICS
Catalan Health Service	<i>Servicio Catalán de Salud (Servei Català de la Salut)</i>	CatSalut
Catalan Ministry of Health	<i>Departamento de Sanidad y Seguridad Social de la Generalidad de Cataluña (Department de Salut)</i>	[No abrv]
Central Balance Sheet Data Office	<i>Central de Balances</i>	[No abrv]
Interterritorial Council	<i>Consejo Interterritorial</i>	CI
Network of Providers of Public Hospital Care	<i>Red Hospitalaria de Utilización Pública (Xarxa Hospitalària d'utilització Pública)</i>	XHUP

Germany

English name	German name	Abbreviation
Federal Association of SHI Physicians	<i>Kassenärztliche Bundesvereinigung</i>	KBV
Federal Institute for Quality Assurance	<i>Bundesgeschäftsstelle Qualitätssicherung</i>	BQS
Federal Insurance Authority	<i>Bundesversicherungsamt</i>	BVA
Federal Joint Committee	<i>Gemeinsamer Bundesausschuss</i>	G-BA
Federal Ministry of Health	<i>Bundesministerium für Gesundheit und Soziale Sicherung</i>	BMG
Federal Valuation Committee	<i>Bewertungsausschuss</i>	[No abrv]
German Hospital Organisation	<i>Deutsche Krankenhaus-Gesellschaft</i>	DKGEV
Institute for Quality and Efficiency	<i>Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen</i>	IQWiG
Organisation for Transparency and Quality in the Health Service	<i>Kooperation für Transparenz und Qualität im Gesundheitswesen</i>	KTQ
Regional Physicians' Association	<i>Kassenärztliche Vereinigung</i>	KV

The Netherlands

English name	Dutch name	Abbreviation
Board for Health Care Tariffs	<i>College Tarieven Gezondheidszorg</i>	CTG
Dutch Hospitals Association	<i>Vereniging van Ziekenhuizen</i>	NVZ
Harmonisation of Quality Review in Health Care and Welfare	<i>Harmonisatie Kwaliteitsbeoordeling in de Zorgsector</i>	HKZ
Health Care Authority	<i>Zorgautoriteit</i>	[No abrv]
Health Care Inspectorate	<i>Inspectie voor de Gezondeidszorg</i>	IGZ
Health Care Insurance Board	<i>College voor Zorgverzekeringen</i>	CVZ
Ministry of Health, Welfare and Sport	<i>Ministerie van Volksgezondheid, Welzijn en Sport</i>	MINVWS
Netherlands Board for Hospital Facilities	<i>Bouwcollege</i>	[No abrv]
Netherlands Competition Authority	<i>Nederlandse Mededingingsautoriteit</i>	NMa
Netherlands Institute for Accreditation of Hospitals	<i>Nederlands Instituut voor Accreditatie van Ziekenhuizen</i>	NIAZ
Netherlands Organisation for Health Research and Development	<i>Nederlandse Organisatie voor Gezondheidsonderzoek en Zorginnovatie</i>	ZonMw
Pensions and Insurance Supervisory Authority	<i>Pensioen- en Verzekeringskamer</i>	PVK
Supervisory Board for Health Care Insurance	<i>College van toezicht op de zorgverzekeringen</i>	CTZ

Linked publications

NHS Reform

Getting back on track

Keith Palmer

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