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# Regulating quality and safety of health and social care

International experiences

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# Summary

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There is a lack of international consensus on what constitutes ‘effective quality regulation’, given the diversity of governance and financing of healthcare systems within which providers in OECD countries operate. Countries vary with regard to the strategies for healthcare quality that have been adopted, and the extent to which legislative measures ensuring quality of care have been implemented.

In this report, we provide an overview of regulatory strategies and actors that different systems employ to govern safety and quality in health and social care. Specifically, we reviewed the range of regulatory strategies and actors in selected high-income countries aimed at ensuring that essential standards of care are implemented and being adhered to, and consider the range of policy instruments used in those countries to encourage and ensure continuous quality improvement. The evidence presented in this report seeks to inform ongoing policy thinking for the Department of Health and others in developing regulation of safety and quality of health and social care in England.

We selected the following countries: Australia, Finland, Germany, the Netherlands, and the United States of America (USA) and included England for comparison. Data collection involved a review of the published and grey literature, using a structured template, complemented by information provided by key informants in the selected countries.

## **The organisation and governance of health and social care varies across countries**

The countries reviewed provide examples of systems that vary in the way that health and social care services are organised and financed. For example, the health systems in Germany and the Netherlands are funded mainly through statutory health insurance (SHI), while Australia, England and Finland principally operate tax-based systems. The USA is a mixed system, with private sources dominating.

Similarly, the six countries represent different approaches to the governance of health and social care. In Finland, administrative and political responsibility is largely devolved to local authorities, while in the Netherlands responsibility for the health and social care systems is shared by central government and corporatist actors. In Germany, regional and local authorities also play a role. In the USA, healthcare regulation is shared between the federal government and the states, as is the governance of social care systems. This is also the case in Australia. In England, health and social care policy is set nationally while the organisation of care is devolved to local organisations, with clinical commissioning groups replacing primary care trusts from 2013, overseen by a newly established national body, NHS England.

### **The notion of overarching ‘essential standards of quality’ is not commonly used explicitly**

While England has implemented overarching ‘essential standards of quality and safety’ for the provision of health and social care services, this approach is not commonly used explicitly in other system contexts. The setting of standards typically applies to particular sectors or settings (eg nursing homes), rather than an overarching ‘essential’ set that is applied across sectors. In Germany and Australia, recent reforms have begun to examine standards that extend across care boundaries, such as primary and secondary care, although cross-sectoral approaches that cover the entire spectrum of health and social care services are not common.

The sources of standards in the health and social care sectors vary by country and may involve overarching, high-level principles that inform quality regulation such as a country’s constitution, national legislation or frameworks. All systems reviewed here have some form of national (legislative) framework or principle in place, which guide the overall development and implementation of standards. The structure and form of these standards vary in terms of their specificity. Standards can thus be generally embedded within constitutional provisions (Finland) or national framework legislation (England, Germany, the Netherlands), or be developed as standards and frameworks for guiding, although not enforcing, service quality (Australia). The USA has a framework for creating national standards, but the considerable power of state governments and the tendency to rely on private markets to purchase and provide care creates challenges to a unified national quality standard.

### **Countries use a combination of policy instruments to assure quality and safety in the provision of health and social care**

We describe four principal regulatory strategies to ensure quality and safety in the health and social care sectors. These are:

- **Command and control:** implies direct enforcement by government (eg licensing professionals and facilities, enforcing performance standards). Mechanisms to secure standard adherence include criminal or civil penalty; licence revocation or suspension; physician revalidation.
- **Meta-regulation:** describes an approach by which the conduct of self-regulation is monitored by an external third party. There may be sanctions and financial incentives that help ensure adherence. Examples include clinical audits conducted externally; mandated incident reporting systems; and consumer complaints ombudsmen.
- **Self-regulation and voluntarism:** *Self-regulation* describes a system in which organised groups regulate the behaviour of their members; this might involve an industry-level organisation or a professional association which sets rules, standards, and codes of practice relating to the conduct of its members. *Voluntarism* is based on an individual firm, organisation, or individual professional, ‘undertaking to do the right thing without any basis in coercion’. These mechanisms include the use of clinical governance, voluntary hospital accreditation, peer review, clinical protocols, performance indicators/targets and benchmarking.
- **Market mechanisms:** refers to a set of rules and institutions of a market economy as applied to the public sector. Mechanisms to encourage adherence to standards include

elements such as incentive payments, governance by contracting, and performance league tables.

All of the countries reviewed, or their systems, employ elements of self-regulation and voluntarism, meta-regulation and command and control, with market mechanisms in the form of selective contracting and public reporting. The use of these strategies is highly dependent on, and integrated with, the health system, policy and institutional context within which regulation takes place, although common themes can be identified. For example, the most common elements are self-regulation and voluntarism, involving the accreditation of providers or facilities, the promulgation of voluntary standards of practice, continuing (medical) education or the use of performance indicators or targets (Australia, Germany, Netherlands, Finland, USA). Similarly, meta-regulation is common, through mechanisms such as external clinical audit, mandated incident reporting and ombudsmen. The explicit use of market mechanisms appears to occur less frequently; examples include selective contracting (Netherlands, USA) and incentive payments (England, USA). All of the reviewed countries employ mechanisms of command and control, mostly in relation to professional licences.

While countries use most of these mechanisms, the relative importance placed on these varies. For example, in Australia voluntary regulation and self-regulation play a core role, using frameworks derived from state-led and intergovernmental committees. In Finland, the standards can be traced back to central government and its constitution, but they operate primarily through self-regulation. In the USA, regulation has traditionally relied heavily on professional self-regulation through board certification and peer review. In the Netherlands, the two dominant mechanisms are self-regulation/voluntarism and meta-regulation.

**National-level actors involved in assuring quality and safety in the provision of health and social care vary in the range of enforcement mechanisms they have at their disposal**

Based on each country's approaches to quality regulation in health and social care reviewed, we distinguish three categories of regulatory competencies: supervisory and standard enforcement competencies; monitoring and/or standard setting competencies; and quasi-legislator competencies.

Bodies with competencies for supervision and enforcement of standards monitor the activities of health and social care stakeholders, employing formal or informal mechanisms to ensure standard adherence. Relevant bodies are typically situated at arm's length from government. Examples of bodies with such competencies are present in England, Finland, the Netherlands and the USA. Countries such as Australia and England have also set up bodies that have standard setting and/or monitoring competencies, that develop standards in cooperation with key stakeholders, or that monitor the development of key indicators and report to national governments but these bodies typically do not have enforcement competencies. Conversely, Germany and the USA have established quasi-legislator bodies with wide competences in standard setting. Although these bodies are not involved in actual enforcement, the standards they have developed are mandatory: they are enforceable through other (regulatory) bodies and can be evoked before court.

Given the complexity of the health and social care systems, and the diverse political and cultural contexts within which regulatory mechanisms operate, it is difficult to derive

overarching conclusions of whether one system is more effective than another. Each system is characterised by a particular set of relationships between the different professionals and institutions that deliver care, frequently determined by what has happened in the past. However, certain commonalities can be identified in that the countries appear to have been striving towards a greater centralisation of quality regulation. Moreover, there is a collective move towards greater transparency in the sector through making information available on quality and safety as a means of informing service users and funders.

**The overall evidence of the effectiveness of regulatory strategies towards ensuring care quality and safety at system level is scarce**

Characteristics of effective healthcare regulation and the role of an effective regulator have been defined in the literature. It contends that regulation should, among other things:

- be flexible and adaptive as well as targeted to the content and outcome of each regulatory encounter
- require involvement of stakeholders in both the development and assessment of standards
- employ a range of regulatory strategies and mechanisms, involving both informal and more formal (statutory) approaches to ensure integrity and credibility
- provide for mechanisms ensuring that the regulator is independent and impartial while being accountable for the effects of regulation.

The examples described in this report illustrate that the selected countries principally appear to have implemented regulatory frameworks that exhibit several of these characteristics, although their relative balance varies. However, there is little empirical evidence by which to assess the effectiveness of regulatory strategies for ensuring care quality and safety at system level. The evidence that is available points to the impact of selected mechanisms to enhance standard adherence, such as accreditation, or quality assurance more broadly through, for example, the use of incentive payments or public reporting. However, research has tended to focus on the evidence of impact on provider institutions rather than health systems more generally.

We have identified examples from Australia and the Netherlands that have sought to measure the impact of selected regulatory strategies on standard adherence. These seem to support the notion that regulatory systems need to strike a balance between the use of formal, interventionist instruments and more informal, softer approaches to ensure standard adherence and quality improvement more broadly.

This report has focused primarily on collecting information on existing regulatory mechanisms and actors responsible for ensuring quality of care, rather than comparing levels of patient safety and incidents across the countries examined. In the absence of such information, and of published evidence that examines the effectiveness of existing systems, identifying best practice is not within the remit of this report. What we do provide, however, is a detailed account of the situation in each country, illustrated where available through case studies, about how these regulatory mechanisms are implemented in practice.