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Quality improvement science

Regulation in primary care

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ABSTRACT

Professional bodies have long overseen the maintenance of standards of training and practice within the different healthcare professions. Organisational regulation of healthcare in England comprises two main elements: regulation of the quality and safety of care offered by healthcare providers, currently undertaken by the Care Quality Commission (CQC); and regulation of the market in healthcare services, currently the responsibility of Monitor and the Department of Health. The eighth in the series, this article considers the expanding roles of newer bodies, particularly in relation to primary care. The cost-effectiveness of these new arrangements is unknown – and possibly unknowable.

Keywords: general practice, health systems, primary care, quality control, quality improvement, regulation

Introduction

All health professionals work in healthcare systems that are regulated by professional bodies and government organisations. With 1.7 million employees and an annual budget of £104 billion, the National Health Service (NHS) is one of the largest organisations in the world and there are complex regulatory structures in place which aim to ensure that patients receive high-quality care. Despite these structures, adverse events can (and do) occur. Government-led investigations such as the Mid-Staffs Inquiry and Shipman Inquiry have sadly served to remind us that organisational failings and the actions of individuals can place patients at risk. A challenge for successive governments has been to develop systems that regulate healthcare professionals and the organisations in which they work, to ensure that patient care is safe and effective. In this article, we examine these systems in more detail and consider their effectiveness.

Professional regulators

Currently, regulation in healthcare occurs on many different levels. Individual healthcare practitioners such as doctors are required by law to apply for licences to practice from their professional regulators (e.g. the General Medical Council), of which there are nine in the UK (see Box 1). Over 1.3 million professionals carrying out 32 different roles hold such licences and the performance of their regulators is overseen by the Professional Standards Authority for Health and Social Care, which reports to parliament.

The General Medical Council

The General Medical Council (GMC) was created 'to protect, promote and maintain the health and safety of the public by ensuring proper standards in the practice of medicine' and is currently adapting to a new environment in which greater levels of public accountability are required. As set out in the Medical Act of 1983, its main role is to keep a register of qualified doctors and erase from the register those who are deemed unfit to practise. This role has, however, evolved over the past decade or so. The GMC is now also responsible for setting standards in medical education and professional conduct, and for revalidation.

Box 1 The nine UK regulators and the professions they regulate

- General Chiropractic Council (GCC) – regulates chiropractors.
- General Dental Council (GDC) – regulates dentists, dental nurses, dental technicians, dental hygienists, dental therapists, clinical dental technicians and orthodontic therapists.
- General Medical Council (GMC) – regulates doctors.
- General Optical Council (GOC) – regulates optometrists and dispensing opticians.
- General Osteopathic Council (GOsC) – regulates osteopaths.
- General Pharmaceutical Council (GPhC) – regulates pharmacists and pharmacy technicians.
- Health and Care Professions Council (HCPC) – regulates art therapists, biomedical scientists, chiropodists/podiatrists, clinical scientists, dieticians, hearing aid dispensers, occupational therapists, operating department practitioners, orthoptists, paramedics, physiotherapists, practitioner psychologists, prosthetists/orthotists, radiographers, social workers, speech and language therapists.
- Nursing and Midwifery Council (NMC) – regulates nurses and midwives.
- Pharmaceutical Society of Northern Ireland (PSNI) – regulates pharmacists.

Revalidation is the process by which all licensed doctors are required to demonstrate on a five-yearly basis that they are up-to-date and fit to practise. It aims to give extra confidence to patients that their doctor's professional knowledge is up-to-date, and doctors are assessed using their annual appraisals and supporting portfolios. The GMC expects to revalidate the majority of licensed doctors in the UK for the first time by March 2016.

Nursing and Midwifery Council

Established in 2002, the Nursing and Midwifery Council (NMC) is the UK regulator for nursing and midwifery professions. The NMC maintains a register of all nurses, midwives and specialist community public health nurses eligible to practice within the UK. It sets and reviews standards for their education, training, conduct and performance. The NMC also investigates allegations of impaired fitness to practise where these standards are not met. Nurses should be appraised annually via their employers though a comparable system of revalidation is not yet compulsory. Indeed, little is known of the extent to which primary care nurses are effectively appraised.

Organisational regulators

Responsibilities for regulating 'organisational' rather than 'individual' aspects of healthcare delivery in England, Scotland and Wales are split across many different bodies (see Box 2) with different powers, roles and remits.

Box 2 Healthcare regulators in the UK

England:
- Care Quality Commission
- Monitor

Scotland:
- Healthcare Improvement Scotland
- Care Inspectorate

Wales:
- Care and Social Services Inspectorate Wales

Regulating quality and safety

In 1997, there was no national policy covering all aspects of safety and quality of healthcare provision. The new Labour government concluded that the quality of care provided by the NHS had been 'variable' and that the service had been slow to respond to 'serious lapses in quality', notably at the Bristol Royal Infirmary.[1] The Commission for Healthcare Improvement (CHI) was established in 1999 to offer guidance to NHS providers on clinical governance.

The Healthcare Commission was established in 2003 to bring together the work of the CHI, the National Standards Commission (the independent regulatory body responsible for inspecting and regulating residential and domiciliary care) and also the efficiency work relating to the NHS that was carried out by the Audit Commission.

The Care Quality Commission (CQC)

Pressure to reduce the number of regulators led to the establishment of the CQC in 2009. This brought together the Healthcare Commission, the Commission for Social Care Inspection and the Mental Health Act Commission. The CQC regulates and inspects the quality and safety of all providers of healthcare and adult

social care services. It registers and scrutinises hospitals, ambulance services, clinics, community services, care homes, mental health services, dental practices and, since April 2012, GP practices. Registration requirements cover areas such as the management and training of staff, the state of premises and provision of information. Using information from a wide range of sources, the CQC focuses on outcomes for service users and has a wide range of enforcement powers, including closure and deregistration of services, if essential standards are not met.

Recent scandals, notably at Mid-Staffordshire, highlighted major deficiencies in the CQC's hospital inspection regime, but wholesale reorganisation has been favourably received.[2] How successfully it has addressed deficiencies in general practice is as yet unknown.

Other statutory bodies

The Medicines and Healthcare Products Regulatory Agency (MHRA) was established in 2003 as an agency of the Department of Health to protect the public through the regulation of medicines and medical devices and equipment used in healthcare. Any product used for the diagnosis, prevention, monitoring or treatment of illness or disability is classed as a medical device so the MHRA monitors the many thousands of items used every day by professionals and patients, ranging from contact lenses and walking sticks to heart valves, CT scanners and defibrillators.

NHS organisations are also subject to oversight by many other regulators with a specific health remit such as the Health and Safety Executive (HSE), responsible for employee health and safety, or the Human Fertilisation and Embryology Authority (HFEA) which licenses fertility clinics and human embryo research.

Market regulation

Some NHS services have always been provided by private sector bodies – most GPs are in fact independent contractors. The previous government, however, actively promoted an expansion of private provision of hospital and community services, with the aim of creating a mixed economy in which any willing – and licensed – provider could offer services to NHS patients. Patients, or commissioners on their behalf, were free to choose between them.

This led to the need for a new form of regulation to ensure that market forces worked to the benefit of patients. Allowing patients to choose where they received hospital treatment required a new hospital payment system that reimbursed hospitals for the number of patients treated and the types of treatment given. The Department of Health set a national tariff for most hospital activity, to encourage competition on the basis of quality of service, rather than cost. The Co-operation and Competition Panel was established to offer advice to ministers on mergers of NHS bodies – as these could reduce the extent of competition – and to monitor how commissioners adhered to rules on when to tender for services. Private sector providers can appeal to the panel if they feel they have not been given a fair opportunity to compete.

Monitor

To strengthen the ability of NHS providers to respond to market opportunities, the government introduced a new form of NHS organisation, the foundation trust. These enjoyed greater financial freedoms than traditional NHS trusts, as well as freedom from the direct control of the Secretary of State. A new regulator, Monitor, was established in 2004 to vet applications for foundation trust status and to oversee their financial performance once they were in operation.

The coalition government's Health and Social Care Act 2012 made significant changes to Monitor's role. Since April 2013 it has become *the* sector regulator for healthcare, with responsibility for regulating and licensing all providers of NHS-funded services. Monitor's stated aim is to 'protect and promote the interests of people who use healthcare services by promoting the provision of services which are economic, efficient and effective, and to maintain or improve the quality of the services'. Monitor will set the tariff for NHS-funded services and will work together with the NHS England – the new organisation set up to carry out some national commissioning functions – in developing tariffs and prices. The Co-operation and Competition Panel has been absorbed into Monitor, but eventually the NHS will come within the remit of the Office of Fair Trading and general UK, as well as EU, competition law. The coalition government proposed greater freedom for foundation trusts, for example, in respect of their governance arrangements, their ability to raise capital and their ability to raise income from private patients. Monitor has responsibility for continuity of essential trust services, for example in the event of financial failure.

The coalition government proposals are thus designed to take the development of a mixed economy further, and to extend the role of the independent regulators and reduce that of the Department of Health.

Does regulation 'work'?

There is little evidence to draw on to appraise the latest developments. International comparisons are of limited value. The King's Fund reviewed regulation in four healthcare systems – New Zealand, Catalonia, Germany and the Netherlands – all of which have similarities with the English NHS. All five countries have to regulate a healthcare system comprising public, for-profit and not-for-profit independent providers. Even though those health systems share many objectives with the NHS, there is no agreement on the best way to regulate healthcare systems, and regulation must be appropriate to the particular structure of each system.[3]

The regulatory framework of healthcare in England is still developing – the government's proposals leave a number of questions unanswered. The boundaries between the different regulators, NHS England and the Secretary of State need clarification. What should be the objectives of the economic regulator and who should set them? If prices are to be set, who should do this? Should price competition be allowed? How should the tension between promoting co-operation, networking and integration, and maintaining competition be resolved? How effectively will clinical commissioning groups be regulated?

Ultimately we want to ensure that the benefits accruing from the vast bureaucracies involved outweigh their costs. The US provides a ghastly reminder of the potential burdens of this 'hidden tax'. Healthcare regulation may cost in excess of $500 billion and yield one third as much in benefit.[4]

Regulation in (general) practice

CQC registration is an arduous process – bureaucratic but systems-focused. The new Chief Inspector of General Practice is responsible for developing a framework for monitoring practices that will further stretch administrative and clinical resources.[5] It is easy to see these encroachments in entirely negative terms.[6] The key for health professionals – as with their individual appraisals – is to make the process work for you and your organisation. This means using inspections to identify and 'fix' areas for improvement. If what's measured is what matters, teams will 'buy in' to procedures and help routinise data collection. Practice teams without strong leadership or a clear vision of where they are going will struggle to adapt. Against a backdrop of labour shortages, the next few years are likely to be testing for many general practices.

Conclusion

A robust regulatory framework is important for assuring a basic standard of healthcare. The regulation of medical professionals and healthcare providers is a central component of quality improvement in most countries. The NHS faces the challenges of an ageing population, an increase in long-term conditions, costly scientific and technological advances, and an unsustainable growth in healthcare spending, together with rising public expectations. The recent restructuring of the health service and legislative changes give regulatory organisations such as the CQC and Monitor

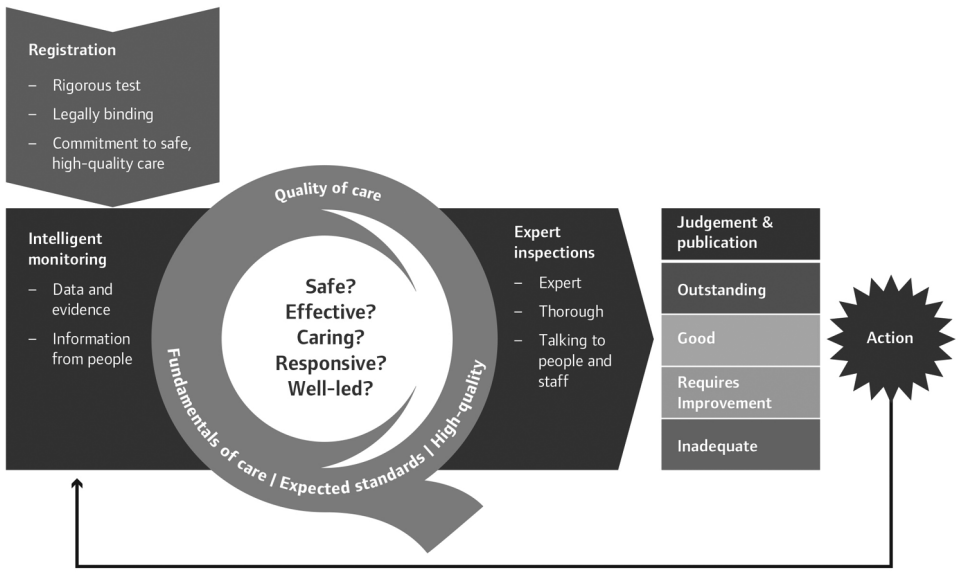

Figure 1 CQC infographic of proposed operating model. Provided courtesy of CQC.

greatly increased powers over general practices. In addition, individual health professionals can expect their professional practice to come under closer scrutiny as the process of revalidation is rolled out.

REFERENCES

1 Department of Health. *The New NHS: modern, dependable*. London: Stationery Office, 1997.
2 Dyer C. After period of failure, CQC is fit for purpose, say MPs. *BMJ* 2014;348:g434.
3 Lewis R, Alvarez-Rosete A, Mays N. *How to Regulate Health Care in England, an international perspective*. The King's Fund: London, 2006.
4 Conover C. Health care regulation: a $169 billion hidden tax. *Policy Analysis 527*. Cato Institute: Washington, DC, 2004.
5 Care Quality Commission. *A Fresh Start for the Regulation and Inspection of GP Practices and GP Out-of-Hours Services*. CQC: London, 2013.
6 Mathews-King, A. CQC threatens to send 'OFSTED-style' letters to patients in poor practices as Field unveils findings from first 1,000 inspections. *Pulse* 12 December, 2013. www.pulsetoday.co.uk/your-practice/practice-topics/regulation/cqc/cqc-threatens-to-send-ofsted-style-letters-to-patients-in-poor-practices-as-field-unveils-findings-from-first-1000-inspections/20005321.article (accessed 30/01/14).

PEER REVIEW

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CONFLICTS OF INTEREST

None declared.

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