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EDITORIAL

Modernising medical regulation: where are we now?

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Abstract

Purpose – This paper aims to outline and comment on the changes to medical regulation in the UK that provide the background to a special issue of the *Journal of Health Organization and Management* on regulating doctors.

Design/methodology/approach – This paper takes the form of a review.

Findings – Although the UK medical profession enjoyed a remarkably stable regulatory structure for most of the first 150 years of its existence, it has undergone a striking transformation in the last decade. Its regulatory form has mutated from one of state-sanctioned collegial self-regulation to one of state-directed bureaucratic regulation. The erosion of medical self-regulation can be attributed to: the pressures of market liberalisation and new public management reforms; changing ideologies and public attitudes towards expertise and risk; and high profile public failures involving doctors. The "new" UK medical regulation converts the General Medical Council into a modern regulator charged with implementing policy, and alters the mechanisms for controlling and directing the conduct and performance of doctors. It establishes a new set of relationships between the medical profession and the state (including its agencies), the public, and patients.

Originality/value – This paper adds to the literature by identifying the main features of the reforms affecting the medical profession and offering an analysis of why they have taken place.

Keywords Regulation, Doctors, Medical sciences, Public administration, Transition management

Paper type General review

1. Introduction

One of the striking features of the framework regulating doctors in the UK, until recently, was its remarkable stability and resilience: it survived relatively unscathed for the best part of 150 years since its establishment under the Medical Act of 1858. Although the self-regulatory model then established endured dramatic social and political transformations, including the creation of the National Health Service (NHS) in 1948, the last decade has seen a radical renegotiation of the so-called "regulatory bargain" originally struck between the state, the profession and the public. The sweeping changes that have occurred mean that the current regulatory model can no longer be fairly described as self-regulatory in character; there has been wholesale transformation of the regulatory architecture of medicine.

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These reforms demand sustained attention and analysis. The Economic and Social Research Council's Public Services Programme's call for research on medical regulation and performance, issued in January 2007, was therefore very timely. Recognising that medical regulation involves complex multi-player structures in a dense interactive system, and that regulatory interventions in complex systems can have unintended effects, the Programme sought to explore links between performance and regulation of doctors. In this special issue, we present a selection of reports from the projects commissioned under the Programme's call. The four papers presented here represent novel insights into the changing landscape of medical regulation. Each addresses key developments in, and implications for, the way in which doctors' performance is monitored, supported and improved. In this introductory paper, we outline the self-regulatory model that previously applied to the British medical profession and the pressures that led to its demise, and we provide an overview, with some commentary, of some of the key reforms that have been introduced.

2. Medical self-regulation and the preservation of professional autonomy

Before exploring the contours of UK medical regulation and its trajectory, it is helpful to consider what we mean by the term "regulation". While regulation has entered both political and academic debate in ways almost unimaginable several decades ago, the term continues to be used in quite different ways. In political and popular debate, the meaning of regulation is often seen as simplistic and narrow, treated as some form of state intervention, and portrayed in opposition to free markets (Prosser, 2010). In academic discourse, however, the term is sometimes given a breathtakingly wide interpretation, referring to all forms of social control, whether intentional or not, and whether imposed by the state or other social institutions (Morgan and Yeung, 2007, p. 4). For purposes of this paper, we adopt a middle path. We understand regulation as the sustained and focused attempt to alter the behaviour of others according to defined standards or purposes with the intention of producing a broadly identified outcome or outcomes, which may involve mechanisms of standard-setting, information-gathering and behaviour modification (Black, 2001).

In the UK, the legal basis for the regulation of the medical profession was marked by the enactment of the Medical Act in 1858, which established the Medical Register and the predecessor to the General Medical Council (GMC (then known as the General Council on Medical Education and Registration)). The Act granted the medical profession both a monopoly on the supply of medical services and considerable autonomy. While the statutory foundation for the regulatory regime established its legal legitimacy, the state's legislative imprimatur served mainly to stabilise and reinforce the profession's authority to govern itself, rather than establishing a scheme of extensive state oversight and involvement. The original legislation was thus based firmly on the principle of self-regulation (Stacey, 1992), a characterisation which becomes evident once attention is paid to the substantive practice of regulation within the framework thereby established rather than its legal form.

In labelling a regulatory scheme as "self-regulatory", it is important to recognise that the term is used throughout academic literature to encompass a broad array of regulatory arrangements that may vary along a number of dimensions, including the character and level of state involvement, the degree of formality with which those arrangements are established and enforced, the extent to which the relevant regulatory

authority exerts exclusive or monopoly control over the regulated activity, and the level at which social behaviour is regulated (Ogus, 1995). Nonetheless, all such arrangements connote some degree of collective constraint, other than that directly emanating from government, to engender outcomes that would not be reached by market behaviour alone. It is also typically taken to imply "a fairly well established and generally recognised set of rules, whether customary or reduced to writing, in accordance with which the activity is regulated" (Ogus, 2000).

Self-regulation can emerge for multiple reasons, but it has been particularly prominent as the model for regulating the so-called elite professions (Ogus, 1995). At the core of the professional self-regulatory project is the identification and elaboration of a body of expert knowledge, mastered through education and training, that is uniquely suited to address a specific class of human problems (Rostain, 2010). But there is little inherent in mastery of a body of expert knowledge that means that those with the expert knowledge should be due the right to self-regulate. In this context, a well-developed literature has focused specifically on the socio-political processes that led to formation of the "regulatory bargain" struck between the medical profession and the state. This work has portrayed the emergence of the profession as the result of determined efforts by a distinct occupational and social group to establish ownership over the expanding market for healthcare (e.g. Larson, 1978). Much of this work characterises the creation of the profession as the emergence of rule by oligarchy and the institutionalisation of collegiality, with the state devolving responsibility to the profession for assuring the quality of its members and its services. In part, this delegation of power was based on the assumption that medical expertise was far beyond the ability of unqualified people to understand, evaluate or pass judgement upon. This assumption was nurtured by and within the UK medical profession and largely accepted by both the state and the public, and it proved remarkably enduring. The Merrison Inquiry, reporting over a century after the Medical Act, for example, concluded that:

> It is the essence of a professional skill that it deals with matters unfamiliar to the lay man, and it follows that only those in the profession are in a position to judge many of the matters of professional competence and conduct which will be involved (Merrison, 1975).

In another sense, it has been argued that the devolution of responsibility to the profession reflected a dependence on *laissez-faire* "club government", a term that Moran (2004) employs to describe the prevailing orthodoxy underpinning the system of regulatory governance that applied to huge swathes of social activity in mid-Victorian Britain.

Whatever the reasons for the adoption of the self-regulatory model for the medical profession, it is useful to understand it as what Salter (2000) describes as a triangular regulatory "bargain" that, in its ideal type, provided benefits to civil society through offering some assurance as to the standards of healthcare, benefits to the state in the form of enhanced legitimacy from civil society, and benefits to the profession in the form of trust and the privilege of self-regulation. Its practical effect was that the medical profession was allowed to monitor the conduct and performance of members, for the most part free of external scrutiny.

For much of its existence, the profession was largely self-regulatory both formally and informally, in the sense that individual doctors, peer groups and the GMC were, to varying degrees and formality, responsible for assuring and "safeguarding" the quality of medical performance and conduct. The GMC represented the formal, statutory body

for regulatory doctors. Through its various roles in education, setting standards, licensing doctors and investigating poor performance, it was largely concerned with professional "entry" and "exit" (Allsop and Mulcahy, 1996). However, within this formal national framework, for much of the lifetime of the profession, collegial structures and practices were the primary means of control.

Within the collegium, doctors themselves were the guardians of professional conduct and performance (Allsop and Mulcahy, 1996; Dent, 1995). Informal practices and collegial rituals – what Lessig (1999) terms "social norms" – directed at the control of medical peers were (and are) extensive. An especially strongly enforced norm was that concerns about a doctor's conduct or performance should be dealt with "in house" and peer-to-peer rather than, unless especially egregious, being escalated to formal authorities. Rosenthal's (1995) empirical work highlighted a number of informal and quasi-formal practices that colleagues used to deal with professional deviance long before more formal procedures were triggered, starting with "little stick" talks that conveyed friendly concern about work quality. Social control practices also included case conferences, ward rounds, "death rounds", clinical audit meetings and complaints procedures that can be best characterised as collegial approaches (Allsop and Mulcahy, 1996; Arluke, 1977; Dent, 1995; Freidson, 1970). The "big stick" was wielded by the GMC itself, but concern was repeatedly expressed increasingly loudly from the 1980s onwards that it was not applied often enough, hard enough or sufficiently consistently to those who failed to live up to the standards that the profession had set itself.

The concept of "self-regulation", as applied to the medical profession for most of the twentieth century, can thus be understood as one of state-sanctioned collegial self-regulation. Such a conceptualisation highlights how the legislative basis for the regulatory scheme contributed to its perceived legitimacy. It provided state endorsement of a system of regulation that devolved the *locus* of responsibility back to the profession, with individual doctors and peer groups, largely on the basis of collegial norms, ultimately responsible for undertaking regulatory tasks and responsibilities. Although this framework of medical regulation matured, gradually acquiring new features over time, pressures arising from the growing political and economic ambitions associated with state modernisation, public sector reform and the renewal of civil society, have now ushered in a new era that has substantially eroded the self-regulatory model in British medicine.

3. The pressures of modernisation on the regulatory landscape

Attempts to reform the framework of UK medical regulation occurred throughout the twentieth century, in part as a result of evolving relationships between the profession and the state (Allsop and Mulcahy, 1996; Stacey, 1992). Over the last 25 years the government appetite and capacity for change has been significant, culminating in the last decade of landmark reforms of the regulatory structure for doctors. In elaborating the reasons for these regulatory shifts, three related sources of pressure can be identified that profoundly destabilised the institutional and ideological foundations that had historically provided the basis for the legitimacy of medical self-regulation:

(1) market liberalisation and the accompanying pressures on public services and its delivery;

(2) shifting social and political attitudes that reflected a declining trust in expertise (and those claiming expertise) in favour of a rise in risk management ideology; and

(3) high-profile instances of regulatory failure in medicine.

3.1 Market liberalisation and public sector reform

Although self-regulation in medicine survived the establishment of the National Health Service in 1948, it was unable to insulate itself from the fiscal pressures that bore down on Britain and much of the industrialised world from the mid-1970s onwards, as states were confronted with rising inflation, increasing levels of unemployment and burgeoning national debt. It was in this context that significant changes began to take place in the way in which modern industrialised states, including Britain, conceived their role, organisational structure, and the way in which states sought to discharge their functions (Yeung, 2010). Throughout the 1980s, many industrialised states embarked upon extensive programmes seeking to privatise state-owned assets, transferring the ownership of key industries to the private sector (Foster, 1992). At the same time, many governments introduced a systematic programme of restructuring the provision of public services, based on a belief that public-policy making functions could be separated from operational service delivery functions (Harlow and Rawlings, 1999). These so-called "New Public Management" (NPM) reforms were intended either to shift the role of service delivery out of the public sector and into the hands of the private or voluntary sector (by contracting out), or at least to make service delivery more responsive to competitive market forces (for example, through the introduction of compulsory competitive tendering) (Hood, 1991; Freedland, 1994).

These changes are claimed to have resulted in the "hollowing out" of the state, which was no longer a single, monolithic entity, but an allegedly trimmer, policy-focused core executive supplemented by a series of discrete units, with varying degrees of autonomy from the central core (Rhodes, 1994) underpinned by the ideology of the New Public Management. Several scholars have observed that the reforms wrought under the Thatcher and Reagan governments on both sides of the Atlantic throughout the 1980s generated apparently contradictory tendencies. On the one hand, the market liberalisation and "de-regulation" agenda sought to lift the burdens of state regulation from industry, which was perceived as stifling the entrepreneurial impulses of the private sector, but within the public sector itself, the state engaged in much more extensive, intrusive control, including the introduction of a raft of institutional mechanisms intended to wring greater productivity from state-funded services and to monitor and enforce compliance with state-imposed standards (Moran and Woods, 1993; Hood and Scott, 1996).

Having been incorporated with the NHS, the services provided by the medical profession provision were far from immune to wide-ranging reforms to the public sector that ensued, the full force of which was brought to bear upon the provision of publicly-funded healthcare in Britain. These reforms have accelerated in recent years. Thus, for example, market-like incentives have been introduced in several areas, including the Quality and Outcomes Framework, which in 2003 began to provide financial rewards to GPs for meeting a range of indicators. These incentives have a direct impact on doctors' behaviour (Campbell *et al.*, 2008). Targets and their measurement have also proliferated. They act not only as economic incentives but also

as reputational incentives, steering organisations and individuals to avoid being bottom of the pile.

At the same time, a range of other regulatory agencies and regulatory tools – including the National Institute for Clinical Excellence, the National Patient Safety Agency, the National Service Frameworks, and others – have been established in the last decade or so, reflecting enhanced state control over aspects of medical quality, professional decision making, and surveillance of professional activity and performance. The Commission for Healthcare Audit and Improvement (now the Care Quality Commission), established as a regulator of the quality and safety of healthcare, perhaps most decisively underlines the loss of deference to professional opinion and controls. This and other agencies have colonised large tracts of regulatory responsibility that were previously under the control of the profession itself. Referral and remediation services for doctors, including the National Clinical Assessment Service, have, for example, been introduced to assist in the assessment and rehabilitation of doctors whose clinical performance gave cause for concern, thus clearly fulfilling a role that might once have been filled by the profession itself.

Such transitions in public policy and management have been widely interpreted as transforming and challenging the UK medical profession. Early commentators talked of an erosion of clinical autonomy in the face of new managerial powers to transform services (Light, 1995; Harrison and Pollitt, 1995). There has been great interest in the threats to the profession's influence on policy-making, service organisation and care delivery. Although a body of evidence also points to the limits of management and the capacity of doctors to negotiate reform (Ackroyd, 1996; Harrison and Pollitt, 1995; Waring and Currie, 2009), it is nonetheless clear that the medical profession has not escaped the effects of the NPM and associated reforms. Doctors' work is increasingly shaped through organisational and policy pressures that have direct bearing on what they do and how they do it. Taken together, the rise of new regulatory institutions engaged in specifying the content of medical work and supervising its performance illustrate the ascendance of a new approach to regulating doctors.

3.2 Changing ideologies and public attitudes towards expertise and risk

A second significant, albeit related, pressure for regulatory change relates to wider developments in contemporary society, especially related to public and political expectations. Three relevant features of these developments can be identified (Harrison, 2002):

(1) declining trust in governing elites (including the professions) to safeguard public interests, and a corresponding turn towards formal institutions for securing transparency and accountability;

(2) the rise of risk-based ideologies and so-called "risk-based approaches" to the management and governance of potential hazards; and

(3) the proliferation of new forms of knowledge combined with enhanced consumerism.

By the time the public sector reforms associated with NPM had become firmly embedded within the UK and elsewhere, notions of risk and institutions of risk-management had grown more prominent in both policy and academic discourse, exemplified in Beck's (1992) *Risk Society*. According to Beck, if modernity can be characterised by the

production of "goods" with corresponding social divisions in terms of class, then advanced industrial societies involve the production of "bads", that bring with them new social inequalities. A major theme within the work on the so-called "risk society" is the idea that society has become sceptical about the expertise of designated groups appropriately to identify and control risks, thereby requiring individuals reflexively to navigate these uncertainties themselves. As such, growing awareness of risk reflects and exacerbates doubt and distrust in established expert groups, including healthcare professions, and reinforces reliance upon individual choice and reflection. The position of doctors as both mediators of and sources of risk has not evaded this more general questioning of the authority and expertise of professionals.

The apparent loss of faith in the capacity of the medical profession to self-regulate effectively is perhaps most vividly illustrated in the state's explicit and purposeful management of clinical judgment, arguably the domain lying at the heart of the medical profession's claim to professional autonomy. Since the publication of *An Organisation with a Memory* (DoH, 2000), standardised, routinised and bureaucratic systems of knowledge management have been introduced (Waring, 2005) as a way of effecting improvements, and guidelines and protocols have penetrated British medical practice to an extent never previously seen. Such direct interventions in clinical work are seen by some as evidence of a turn towards "Scientific-Bureaucratic Medicine" (Harrison, 2002) as medical work becomes increasingly rationalised.

The declining trust and deference accorded to experts and other professional groups can also be understood as fuelling the turn towards formal systems for enhancing transparency and accountability in public (and private) governance. In this respect, NPM mechanisms that were intended to inject greater market-like, competitive pressures into the delivery of public services, including healthcare, can be seen as both reflecting and reinforcing public and political demands for greater visibility and accountability. A key characteristic of NPM is that, in its pursuit of greater "economy, efficiency and effectiveness" (Hood, 1991) in public service provision, it involves more explicit and transparent modes of accountability, as the state retreats from direct provision and the mixed economy has a greater role in the delivery of public services. So-called "post-bureaucratic" modes of accountability require more unambiguous, and ideally measurable, standards or expectations of performance that can be routinely assessed to assure service delivery and to satisfy public accountability. Power (1997) famously described the emergence of the (seemingly boundless) appetite for accountability as the rise of the *Audit Society*. He noted the proliferation of systems and procedures to monitor and audit activities and performance, that, modelled on the finance and accounting sectors, have been imposed on virtually all public service domains. In particular, Power highlights how public sector organisations have become seemingly trapped within a cycle of performance review or "rituals of verification" where they are required to demonstrate their conformity with and performance against policy expectations.

Power's more recent work points to the pervasiveness of risk management thinking in the design and practice of regulatory systems across both public and private domains, aligned the rise of a new technical-moral project in which organizational virtue and virtuosity are mutually constitutive (Power, 2007). It is against the backdrop of calls for improved mechanisms for ensuring accountability that the significance of major innovations in information communications technology can be appreciated. The

proliferation and diversification digital information and communication technologies (including the internet) over the last quarter century has rendered information more accessible than ever, at least to populations on the technologically-rich side of the digital divide. Individuals can now either directly or virtually avail themselves of experiences, ideas and bodies of knowledge that were once beyond their reach.

Some have argued, that, as a result of such changes, traditional or customary ways of making sense of the world have become fragile as the meta-narratives of modernity have lost their hold (Lyotard, 1984). More broadly, control of information has been progressively democratised with the development of new media and new forms of access. Enhanced diversity of and access to specialist knowledge has long been recognised as undermining professional status (Haug, 1973), as the underlying asymmetries of knowledge that undermine claims to occupational monopoly, autonomous working and indeed self-regulation are called into question. Users of services are now able, on an unprecedented scale, to access information about their illness and about healthcare intervention, including information about the quality and effectiveness of interventions and services.

These new sources of information about healthcare have, in many ways, been fostered by policy-makers seeking to enhance patient choice and consumerism in healthcare. This can be seen, for example, with the proliferation of statistics and league tables related to public service performance. The rise of "radical consumerism" (Harrison, 2002) places new demands on public services to respond to service users in much the same ways as other private or commercial services. It has required service providers to develop more user-focused services with explicit standards of delivery and forms of consumer guarantee, for instance following hospital discharge.

3.3 High-profile public failure

Perhaps the most significant and direct challenge to the profession's regulatory bargain with the state was the evidence that began to appear from the mid-1990s onwards of the profession's inability to prevent or respond effectively to instances of appalling medical performance and conduct. A series of medical scandals involved doctors who sexually assaulted and abused their patients, doctors whose standards of clinical competence were unacceptably poor, and, in the case of Harold Shipman, a doctor who murdered hundreds of his patients. High-profile inquiries into these scandals have had a key role in motivating and legitimising regulatory change.

One prominent feature of these inquiries was their casting of the professional ethics of medicine as part of the problem. Rather than protecting patients, professional ethics were argued to be a problem in two quite distinct ways. First, the claims of trustworthiness made by the profession were seen to provide a cloak under which nefarious activities could be conducted. The betrayals committed by rotten apples appeared especially egregious since it was the very trust that doctors demanded that allowed the perpetrators to go unchecked. Esmail (2005) comments that:

> [. . .] many doctors in the United Kingdom argued that there is no need for systemic reform because there will never be another Shipman. A common refrain was that Shipman was a killer who just happened to be a doctor. I take the view that it was the very fact that Shipman was a doctor that enabled him to kill and remain undiscovered. His profession provided him with the opportunity to kill, and the lack of safeguards and controls allowed him to avoid suspicion.

A second way in which the professional ethics were seen to be at fault was in their promotion of the wrong values, particularly in cultivating an ethos in which doctors were very reluctant to complain about their colleagues. Many of the inquiries were highly critical of the apparent failure of professional colleagues who had concerns about colleagues but failed to act on them appropriately. Moreover, those who did raise concerns were often ignored or sanctioned.

The Bristol Inquiry made 198 recommendations for change, including reforms to the GMC and the creation of an inspectorate for the NHS (Kennedy, 2001). The Shipman Inquiry, reporting some years later, not only raised significant doubts about the efficacy of existing regulatory procedures, but also called for a review of regulatory approaches to safeguard patients and support doctors (Smith, 2005). The culmination of these scandals plays into the wider concerns with risk and the questioning of authority, as outlined above, but also provided a major source of political legitimacy to initiate radical reforms in the regulation of medicine and other healthcare professions. Reforms that, until this time were either unthinkable, or contested. Following Shipman, the Chief Medical Officer's review, *Good Doctors, Safer Patients* (DoH, 2008) contrasted the UK approach to medical regulation with those found in other countries and industries. It argued that, despite progress in raising standards, monitoring performance and organisational learning, medical regulation remained an under-developed area for reform. Its 44 recommendations largely centred on changes to the structure and function of the GMC, including a shift in membership, the devolution of many GMC responsibilities to the local level and a greater emphasis on supporting and working with problem doctors at an early stage. These were subsequently developed within the White Paper *Trust, Assurance and Safety* (DoH, 2008), which provides the backdrop to the major changes now occurring.

4. The "new" UK medical regulation

The medical profession is hardly the only profession to have faced a crisis of legitimation in recent years; acute turmoil has affected a range of different professional groups. The failure of the professional project of accountancy, for example, was highlighted by collapse of Enron and Arthur Andersen (Suddaby *et al.*, 2007) and has continued through the economic crisis of the late 2000s. The response to such crises of the professions tends to follow a pattern of restoring some level of control to the state and establishing more formal, explicit and transparent modes of regulation. The principles informing such reforms can be delineated along a number of lines. First, regulation should be independent from both the profession and the state, so it is not seen as promoting or protecting sectional interests. Second, regulation should be "transparent" and open to greater scrutiny to assure probity. Third, the regulated community must be accountable, with clear lines of responsibility and authority for decision-making. And finally, regulation should be a continuous and developmental process, rather than *ad hoc*, unresponsive and unreflective. However, these principles engage an inherent tension between the respective roles, customs and jurisdictional boundaries between the state and the professions for which straightforward resolution is likely to prove elusive.

Further, two fundamental dilemmas attend the realisation of the principles in practice as they apply to medicine. First, the medical profession is ideologically, culturally and politically committed to some notion of self-regulation. Second, it

remains practically difficult for non-experts effectively to assess and regulate professional performance given asymmetries of knowledge and the practical difficulties of routinely reviewing medical performance. As such, the emerging model of regulation is intended to deliver greater independence, transparency and accountability, while still being workable and legitimate in the eyes of medical professionals. Although reform is only in its early and delicate stages, as indicated by the papers in this collection, it is possible to elaborate the broad framework of regulatory change.

The first major change is the incremental development of the Council for Healthcare Regulatory Excellence (CHRE), which was created following the Bristol Inquiry to promote standards of good regulation and regularly to review the performance of the professional regulators. It is also responsible for reviewing cases adjudicated by the regulatory councils and to refer those that are seen as "unduly lenient" to the High Court for subsequent legal hearing. Within the new model of medical regulation, the CHRE retains this role, but also has a responsibility for directing regulatory practices, for example devising the protocol for investigatory procedures, and monitoring the conduct of specific cases and their outcomes. The CHRE's role in directing, enforcing and monitoring the emerging framework of medical regulation through oversight of the policies and processes of other regulatory institutions within the British healthcare system bears a strong resemblance to a form of regulatory governance that several academics have termed "meta-regulation", in which the state regulates the self-monitoring of regulated institutions rather than exerting direct regulatory control (Gunningham and Grabosky, 1998; Parker, 2002).

The second radical change is to be found in the reforms to the GMC. Although the constitution of the GMC was revised steadily throughout the nineteenth and twentieth century, until the latest round of reforms it retained a professional majority. This was appointed – indeed until recently largely elected – by the profession. The GMC was the primary body for investigating and adjudicating on a doctor's "fitness to practice", and it thus retained at least some of the trappings of a self-regulating agency. Following reform (The General Medical Council (Constitution) Order, 2008), the Council is now made up of a mix of lay, professional and educational representatives with no professional majority. Further, appointment to the Council is made through the Public Appointments Commission against explicit criteria. In addition, the Council is has direct and explicit lines of accountability to Parliament, not (as in previous incarnations) to the Privy Council.

In terms of function, the GMC retains some of its responsibilities for informing medical education, determining the standards for "good medical practice" and providing licensure, and thus retains considerable control over what might be termed professional "entry". It also continues to be central in the investigation of doctors whose "fitness to practices" has been called into question, but it will no longer be responsible for the adjudication of complaints. Instead, the final decision over culpability and disciplinary action will be made by a newly created Office of the Health Professions Adjudicator from April 2011.

Another important feature of the reforms is that the wider environment in which both doctors and the GMC work is also now much more explicitly recognised. A continuing transfer of emphasis to the role of organisations in which doctors work in all stages of the regulatory process is directed at closing the "regulatory gap" between

employers and the GMC. The GMC will be required, for example, to co-operate with the National Clinical Assessment Service and employers to agree specific packages of rehabilitation and conditions of practice where an individual's fitness to practice has been called into question. On the NHS side, several recommendations relating to improved recruitment and screening processes arising from the Neale Inquiry have been incorporated into NHS Employers' Guidance. Relationships between the regulator and employing organisations will be facilitated by a proposed regional system of "GMC affiliates", which will involve both lay and medical input, and is intended to provide support, advice, and guidance to employers in managing concerns about doctors. Affiliates will advise on thresholds for referring doctors to the GMC, and arrange case conferences between hospital trusts and other relevant parties where there are potentially complex issues. GMC Affiliates are therefore intended to offer a much closer and continuous level of local regulation than has previously been the case.

The new procedures for continuously assuring doctors' "fitness to practice" through revalidation represent a further major change in medical regulation. In principle, revalidation aims formally to re-confirm a doctor's license to practice every five years, rather like a UK Motor Vehicle Inspection (MOT). Revalidation is described as being supportive, rather than punitive, with the intent of verifying that a doctor meets the required standards for "good medical practice" as set out by the GMC, and of providing support, retraining and rehabilitation in cases where attainment of standards cannot be demonstrated. These standards include formal criteria in the fields on knowledge and skills, quality and safety, communication and working with others, and maintained trust (DoH, 2008).

Revalidation has two components: relicensing and recertification. Relicensing requires that the GMC shows it has received a positive assurance that a doctor continues to practise in accordance with the core ethical guidance and standards of conduct specified by the GMC in their guidance *Good Medical Practice*. Practically, relicensing will involve an annual appraisal, based on a portfolio or a folder of information (e.g. regarding continuing personal development, audit, and feedback) that doctors must keep about their practice. Doctors must also participate in an independent process for obtaining feedback from patients and colleagues, known as "multi-source feedback" or "360° feedback". Patients' views are intended to play an important role. They will be asked for their views on doctors' communications skills, involvement in treatment decisions, care coordination and support for self-care, and showing respect for patients. The revalidation process may also draw on audit and performance data and review patient complaints. Doctors must also obtain confirmation from a "responsible officer" (a specially designated doctor, usually the medical director of the local healthcare organisation) that any concerns about their practice have been resolved and that the doctor should be relicensed based on the information available.

Recertification will similarly be introduced for specialist disciplines based upon criteria developed by the relevant Royal College or Society. These processes are likely to be undertaken by clinical leaders and directors within healthcare provider organisations with the support and guidance of the GMC Affiliates. Beyond the extreme cases of malpractice or negligence, revalidation thus ends the established custom of doctors being licensed to practice at the beginning of their career without necessarily being required ever again to demonstrate and prove their "fitness to practice". But more than that, it signals the emergence of a model where responsibility

no longer lies with the GMC for the conduct and performance of doctors, but rather is shared and overseen by multiple partners. Implementation of revalidation is a shared responsibility involving the GMC, the four UK Departments of Health, the medical royal colleges, and members of the medical profession. It will be supported by a Department of Health-funded Revalidation Support Team.

5. The turn to state-directed bureaucratic regulation

As Greenwood *et al.* (2002) argue, the jurisdictions of professionals are not absolute but are the outcome of ongoing claims and counterclaims, and the boundaries of such communities are subject to continual redefinition and defence. Our analysis of the transitions in medical regulation suggests that there has been a move from state-sanctioned, collegial, self-regulation to a form of regulation that can be understood as state-directed bureaucratic regulation. We use "bureaucratic" here in its Weberian sense, to describe a formalised system of hierarchy and rules to which each member must submit, but we also use it in the sense described by Hood and Scott (1996) to describe the regulation of state agencies by other state agencies.

The GMC, we propose, is no longer a bastion of "club government", but is now intended to operate as a modern, independent regulatory agency (Levy and Spiller, 1996). Its remit is carefully delimited, and many of the regulatory roles and functions the profession traditionally kept for itself, have been hived off to other agencies. The GMC is subject to multiple forms of oversight and required to work in partnership with a wide range of parties. The formal and substantive locus of responsibility has thus been seized from the profession, which is now charged not with implementing rules it has determined for itself, but rather with conforming to rules imposed largely by the state. In terms of form, we see a shift away from "in house" and collegial forms of peer review, towards more formal, independent procedures. Regular, systematic and transparent appraisals of conduct and the development of more accessible measures of performance, are intended to provide a less obscure window for outsiders to understand medical performance, whilst also encouraging doctors to "raise their game" or be more open about their developmental needs. Significantly, activities, such as appraisal, revalidation and "fitness to practices" investigations are guided by standardised and explicit processes of assessing performance, reporting results and data analysis, in keeping with the drive for risk-based regulation. The form of medical regulation has therefore moved from one based upon collegiality to one that is more bureaucratic in character.

It is important to recognise, however, that many regulatory activities continue to rely upon members of the profession in exercising their professional skill and judgement. Lay and other expert groups will progressively acquire a role, but in day-to-day practice, undertaking revalidation or dealing with "fitness to practice" cases will continue to involve doctors having a central role in determining levels of performance, assessing evidence and referring cases onwards or upwards. Thus, a degree of self-regulation continues, but these activities will now be undertaken within a more bureaucratic framework, with greater external oversight and in line with changed political and public expectations.

A key question concerns whether the optimal regulatory approach is now in place for the medical profession. Many of the reforms are likely to help in restoring the legitimacy of the profession and shielding it from criticisms that it favours itself over

its patients. The transfer of adjudicatory functions from the GMC to the Office of the Heath Professions Adjudicator, in addition to a number of procedural reforms including the lowering of the burden of proof from the criminal to civil standard in establishing the facts forming the basis of alleged FTP problems, and greater emphasis on rehabilitative measures for doctors whose FTP appears questionable, all contribute to strengthening regulatory enforcement and sanctioning. Removal of the GMC's adjudicatory role can be expected to enhance the impartiality and independence (both real and perceived) of FTP decisions, and new rehabilitation systems may help to improve the competence and conduct of individual doctors who may be temporarily unfit to practice. The system of revalidation is also intended to help secure ongoing public confidence in doctors. Whether it succeeds in achieving its intended aims, however, remains an open question.

6. Papers in this collection

It might be tempting to think that the framework for regulating doctors is now settled, and that its optimal execution will secure "good doctors, safer patients". The four papers in this collection help in complicating the idea that regulating doctors will ever be straightforward either in terms of regulatory design or execution. Sue Kilminster, Miriam Zukas, Naomi Quinton and Trudie Roberts demonstrate the ongoing importance of forms of professional socialisation throughout doctors' training and careers. Using empirical data, they illustrate how doctors' transitions (e.g. from one level of seniority to another, to different clinical teams, or to different care settings) make intense demands on their ability to learn and prepare for new practice roles and responsibilities. Moreover, their paper identifies persistence of the phenomenon where different senior doctors are able to insist upon different standards and practices that their juniors have to learn and follow, and thus suggests that protocols and guidelines have by no means universal penetration and that definitions of "good practice" and performance may remain chronically contested. Despite the move towards more formal standards of medical performance and the desire to support doctors training and developmental needs in relation to these standards, social norms may thus retain considerable power in determining both how doctors behave and how they are evaluated.

Mark Exworthy, Glenn Smith, Jonathan Gabe and Ian Rees Jones offer an insightful critique of public disclosure of surgical performance, and though they do not identify it explicitly, such disclosure equates broadly to a market mechanism in its intention to promote choice on the basis of quality. Specifically, it illustrates the desire for more transparent, systematic and robust forms of evidence related to medical performance. The idea is that this can be shared with wider stakeholders to inform decisions, for example about commissioning or referral, but also to provide a "window" for both professional and lay groups to compare and appraise performance. This paper suggests that there may be an enduring reluctance to sanction apparently poorly performing doctors, suggesting that attempts at creating reputational incentives may have unanticipated effects. The authors outline some of these, which include the possibility that disclosure may strengthen professional autonomy rather than eroding it, and in a paradoxical way conceal rather than reveal some aspects of poorer quality performance.

Sally Lloyd-Bostock's paper demonstrates ways in which technology or "code" (Lessig, 1999) may operate as a modality in the regulation of doctors. Her analysis of the GMC's Fitness to Practice (FTP) database shows that the structuring of the code of the database serves particular social functions, including organisational concerns relating to accountability and defensibility. However, in its transformation of patients' stories into codes and potentially provable allegations of departures from FTP standards, the database may also suppress or make invisible important information.

Finally, Gerry McGivern and Michael Fischer's analysis of "spectacular transparency" is a perhaps rather bleak reminder of the human impact of law and regulation. Doctors unsurprisingly found investigations into their conduct and performance painful and distressing, and report deep-rooted fear of regulatory processes that they worry will be activated even when they have done little wrong. These four papers therefore offer new insights into the changing landscape of regulation, as well as the constraints and limits of desired reforms.

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