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Regulation in a changing healthcare landscape: the role of the General Medical Council

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ABSTRACT

The healthcare sector is on the cusp of a major change in the availability of data on how institutions, teams and individuals are performing, driven by technology and by changes in how the healthcare professions are viewed by wider society. With the introduction of revalidation, the relationship of the General Medical Council (GMC) with doctors is already changing. The challenge for the GMC in the coming years will be to help ensure patient safety and improve standards, working closely with the profession, employers, educators and patient groups.

KEYWORDS: General Medical Council, regulation, revalidation, patient safety, data

Introduction

Most of us have an ambivalent relationship with regulation. On the one hand we decry the red tape that binds us, the needless box ticking and the futile bureaucracy that invades our lives and stifles innovation; however, we are appalled when it is proved to be inadequate, and our phones are hacked, our banks lose billions or our hospitals fail to care for the most vulnerable of patients.

The Mid Staffordshire experience[1] and other scandals in both health and social care suggest that we have some way to go before we get healthcare regulation right. This is not to suggest that regulation is the answer to all the problems that have recently emerged – far from it – but it is to acknowledge that the models of both system and professional regulation were found wanting. Indeed, perhaps the first lesson should be to acknowledge the necessary limitations of formal, national and external regulation in all its guises; while they are important, they can never be a guarantor of safety and quality. Those responsible for national regulation need to imbibe a strong dose of humility and recognise our limitations as much as our potential.

The role of regulation in a changing healthcare landscape

As a safety-critical industry, healthcare has been slow to embrace system regulation; indeed, the science of measuring how well care is delivered, as opposed to how much, is relatively new. Until the late 20th century there was comparatively little discussion about variation in the quality of care or treatment either at individual practitioner level or in terms of services or institutions. Professionals often knew or thought they knew where good or bad practice lay among their peers, and which hospitals or surgeries they would avoid for themselves or their families, but it was regarded as 'insider information', seldom objective and rarely shared beyond their immediate circle.

Even as objective evidence emerged and the quantity of data grew, the system was often not quite sure what to do with it. Sir Ian Kennedy's observation during the Bristol enquiry[2] that the health service was 'awash with data' resonated with many, and at Mid Staffordshire the debate about the meaning of above-average death rates rumbles on.[3]

We are nevertheless on the cusp of a major change, entering a world in which data will not only be more accessible, but will provide us with a much better picture of how well institutions, departments, teams and individuals are performing. It should enable us to identify trends, previously hidden, which if managed correctly will in turn allow earlier intervention. While this is not a world of perfect knowledge, it will mean that at every level of healthcare there are much greater opportunities to understand not only the impact of different treatments, but also the influence of how a system is organised. It should also allow publically available comparison of performance on a much greater scale exposing difference and variation.

This technologically driven change is already transforming professional practice and regulation. In cardiac surgery we have seen how powerful data can be in raising standards and creating a race to the top.[4] Thus, surgery more widely is now embracing principles that include publication of measures of individual performance.[5] While surgical outcomes are easier to measure and evaluate than those of other non-procedure based specialties, this holistic approach to review and reflection is emerging in other areas. Across the specialties the advent of patient and colleague feedback, patient-reported outcome measures, referral and prescribing patterns, and a host of other measures will help to shine a more objective and brighter light on professional practice.

However, the data revolution is only one of the factors driving change. Patient and societal expectations have been transformed within a generation and the acceptance of mediocrity and the assumptions that the doctor knows

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best and all are the same and equally good have either been undermined or have disappeared from public consciousness. Patients still trust their doctors – especially in the UK[6] – but this faith is no longer unconditional. In the 21st century trust will need to be earned and bolstered by external assurance.

In part this is the logical consequence of changes within medicine itself. In the 20th century medicine was transformed: the levels of understanding, the body of knowledge, the range of treatments have changed out of all recognition, moving from '…simple, ineffective and relatively safe' to become '…complex, effective and potentially dangerous'.[7]

In other words, doctors now have greater capacity to do good but can also do more harm. Fifty years ago a GP who failed to refer a patient with a breast lump which turned out to be malign may not have affected her prognosis significantly; today such an act of omission could shorten the patient's life by years.

The wider challenge to the professions and the general decline in deference, especially in the latter half of the 20th century, has changed the notion of trust. The original 19th-century compact between the state, the medical profession and the public[8] was based on the idea that doctors could by their education and erudition be trusted, and that there was merit in differentiating them from 'quacks' and charlatans. It was accepted that as only they knew what good looked like, they should be left to regulate themselves. This model was above all reactive – it was assumed that all doctors were equally good and effective unless for some reason they demonstrated they were not. The General Medical Council (GMC) almost never intervened because of a failure in clinical standards, being more concerned with poor or amoral behaviour. Indeed, it was not until the 1990s that it defined what good practice should look like,[9] as opposed to what type of behaviour was not acceptable. As late as the 1940s Sir Robert Eason, president of the GMC, informed a group of recently qualified doctors:

> *The simple rule which should govern your professional career… begins at the public school… and is that same unwritten rule which guides the true Englishman: namely, certain things are not done. Keep these words in mind and you will never come before the tribunal over which I have the honour to preside.*

This model of professionally dominated reactive regulation was increasingly challenged, especially in the last decade of the 20th century when a series of medical scandals highlighted the apparent inability of the system to identify and deal with rogue practitioners before they had caused death and injury to patients. The 'compact' was being challenged at every turn.

The subsequent failures exposed by the 'big three' health enquiries of Bristol,[2] Shipman[10] and Mid Staffs[1] all pointed to the fact that a model of professional regulation that is essentially reactive is neither accepted nor effective. The Bristol Inquiry, reporting in 2001, found that there was no agreed means of assessing the quality of care, no standards for evaluating performance and confusion as to who was responsible for monitoring the quality of care. Shipman exposed weaknesses in the healthcare system, including at the GMC. Here the state flirted with a takeover of professional regulation but instead, in the case of medicine at least, sought to move from self-regulation to what might be termed independent regulation, relying on accountability to Parliament rather than government. But it also challenged reactive regulation and sought a rigorous system for monitoring and assuring the quality of medical practice.

In fact, the consequences of such scandals were predicted as far back as 1998, when the front cover of the *British Medical Journal* quoted WB Yeats: 'All changed, changed utterly'.[11] In an explanatory editorial, key areas identified by the GMC investigation into Bristol were highlighted, which included the need for clearly understood clinical standards, identifying who carries responsibility in team-based care, the need for effective medical and clinical audit and the enablement of systems for those concerned about patient safety to make these concerns known. The need for doctors to take prompt action at an early stage when a colleague is in difficulty was also highlighted.

While the implications of the failings at Mid Staffordshire are still being played out, these conclusions have resonance there, suggesting that while some progress may have been made, there was still much that was wanting. It also suggests that the inquiry was right in assuming that the underlying issues at Mid Staffordshire were more deep-rooted and general within the NHS and were not peculiar to that place and that time.

In its 2005 report *Doctors in Society*,[12] an RCP working group redefined the concept of professionalism in medicine, moving away from the ideas of mastery and autonomy and instead linking it to trust, arguing that 'medical professionalism comprises a set of values, behaviours and relationships that underpin the trust the public has in doctors'. However, unlike in the past such trust is not unquestioning. The days of medical supremacy – when patients simply took the doctor at his or her word – have passed. Patients and their relatives want to be active partners rather than passive recipients. Increasingly they will, for example, expect to decide themselves what level of risk is acceptable against the prospect of cure.

Within medicine, the most significant change to underpin if not re-establish trust in the UK has been the introduction of revalidation at the end of 2012. The fact that doctors, in the same way as pilots, have to demonstrate on an ongoing basis that they are competent and fit to practise fundamentally changes the compact and indeed the relationship between the profession and its regulator. Part of the new compact is that it is reasonable for patients and society to have ongoing assurance; in Sir Bruce Keogh's words, 'A doctor who does not know how well they are doing, should not be doing it'.

It is too early to assess the impact of this new intervention but early signs are encouraging. Many members of the public appear to think such a system has always existed, so improved levels of trust may be hard to achieve, but its most obvious effect is as a major catalyst for the development of clinical governance. The proper oversight of clinical practice has been an ambition for at least twenty years, but remains patchy. Revalidation, or to be more precise the regulations creating designated bodies and responsible officers, are driving behavioural changes and greater awareness of the need to monitor and improve the quality of medical practice. The fact that appraisal rates have increased – not least among doctors who are not in any form of formal training – is an encouraging first step.

Crucially, evidence about doctors' knowledge, skills, performance, safety, quality, communication, team-working and maintenance of trust is coming from local performance data, annual appraisal and other elements of clinical

governance including multi-source feedback. Further, those responsible for making recommendations concerning these standards are part of the clinical governance structure within the NHS and other healthcare providers.

Future challenges and the role of the GMC

A regulated system focussed on patient safety and improving standards of medical practice is one, and only one, part of what should be a complex web of assurance mechanisms that would be found in any safety-critical industry. It does however have an important impact on the relationship between the regulator and the regulated. The GMC's contact with doctors has traditionally been regarded as intermittent and occasionally, from the doctor's viewpoint, catastrophic. Instead the new relationship is ongoing throughout a doctor's career and should for most be supportive. It also demands that the regulator works much more closely with those charged with monitoring and supporting doctors at local level. In short, the reactive model of the past is no longer fit for purpose, a fact reflected in the GMC's decision to create a team of employer liaison advisors (ELAs) who support responsible officers and medical directors not just over revalidation, but also in their wider responsibilities for managing weak performance, supporting the doctors for whom they assume responsibility and ensuring the quality of medical practice overall.

If revalidation has challenged the reactive, isolated form of medical regulation, so too has the adoption by the GMC of responsibility for regulating postgraduate education. The impact of having responsibility for overseeing the training of 50,000 doctors who provide much of the nation's front line care has been considerable, bringing professional regulation on to the ward, and into the clinic and surgery, more extensively than ever before. It also brings responsibility not just for the individual doctor in training but for the learning environment in which they operate; the concern of the regulator is focussed more often not upon the actions of the doctor, but what the system is doing to support them. As with revalidation, this means close working with those responsible for local oversight as well as the organisations that provide education and rely on these doctors to treat and care for their patients.

The challenge for professional regulation now will be to help ensure patient safety and improve standards, working much more closely with the profession, employers, educators and patient groups, and developing the means to support those ends. This means the GMC and other regulators need to develop a new, more sophisticated relationship with the profession, reaching frontline practitioners and ensuring that they shape its work, embrace what it is trying to do and see its relevance in their practice. To this end, the GMC has established a Regional Liaison Service[13] in England to meet directly with doctors and their representatives and to bring its guidance to life.

We also need to produce guidance that has traction on the ground. Our professional standards work is highly regarded and used as the basis for medical standards around the world.[14] Yet we know from Mid Staffordshire that in many cases that such guidance was ignored.[1] Often this was less about the direct care doctors provided, but related to their limited view of their responsibilities. Doctors have responsibility for all patients in their organisation, not just for the medical treatment they supply but for the overall standard of care. While we work towards a system whereby those who raise concerns are supported, we recognise that doctors can feel they are putting their own careers at risk by speaking out against colleagues. In 2012, we set up a confidential helpline for doctors who are facing local difficulties and are not sure how to tackle them. The helpline has already taken hundreds of calls and we have opened a number of investigations into serious allegations made.

It is good that doctors are prepared to speak out, but we know from Mid Staffordshire that there were instances where medical professionals witnessed failings but failed themselves to intervene. However, the GMC is clear: 'walking by' is poor care by omission. In 2014 we are consulting with the profession and the public on new indicative sanctions guidance, which will specifically seek to address the fitness to practise of those doctors who see poor care but fail to act. Measures such as these and support for those who are prepared to put their head above the parapet are vital, not only to enable the profession to carry out its role, but to provide the assurance the public will increasingly require.

This new more involved form of regulation is not without dangers. Healthcare is littered with well-meaning initiatives that foundered on the law of unintended consequences, creating more problems than they solved. Thus, national regulation in all its forms is necessarily a blunt tool; it can do good but can also stifle innovation, suppress professional ethos and demotivate staff. Overbearing regulation can prevent good professionals from working well, and bureaucracy and paperwork can get in the way of delivering good care.[15]

The story at Mid Staffordshire included failures of regulation, but the answer is not more regulation and certainly not more of the same regulation. The Professional Standards Authority has referred to 'right touch' regulation which must be the way forward, even if the definition of what is right touch may change over time. We need instead to develop smarter regulation, which first recognises that it begins at the clinical front line. Today that means seeing patients and their relatives as vital sources of feedback. It means that individual professionals remain central, acting as the smoke alarms of the system, and reflecting individually and within their teams on their performance. As all the inquiries have noted, senior clinical management and the Boards of these institutions are vital too, both in setting the culture and monitoring the quality of what is delivered. In a sense, national regulation comes after all that, accepting its own limitations and moving upstream to work in the educational sphere, using its standards and guidance to shape future practice and practitioners, identifying areas of risk and holding a mirror to the system.

The next few years are likely to be even more challenging as demands grow and funding does not. Maintaining a focus on quality (as opposed to churning patients through the system) will almost certainly become more difficult and for those concerned about the education of professionals a vigilant eye will be required to ensure short term decisions do not have adverse long term consequences. The new compact for professional regulation has real potential to help drive improvements but it can only do so with others – employers, doctors, educators and providers must work closely together to develop a system that has the capacity to evolve for the benefit of patient care and safety. ■

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