Editorial
NOT ANOTHER MISSED OPPORTUNITY: REGULATION OF HEALTH CARE PROFESSIONALS

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On the 1st March 2012 The Law Commission published proposals for reform of health care professional (HCPs) within the United Kingdom (Law Commission 2012). These proposals are part of a consultation on changes the way that HCPs are regulated.

Various consultation exercises, government reports and public inquiries have criticised aspects of the regulation of HCPs and made recommendations for change in recent years.[1] Some of these criticisms have been levied at the professional regulatory bodies and their failure to adequately protect the public and patients. There have resulted in calls for radical changes to the existing regulatory bodies, so that those deemed to be failing are reformed into effective agents of public protection

It would seem logical that if a particular part of the regulatory system was not working that it was fixed. Yet, this is not what has happened in previous HCP regulatory reform, instead of undertaking wholesale reform of these bodies and fixing what is broken, new regulatory bodies such as Council for Healthcare Regulatory Excellence are inserted into the regulatory framework as a check upon the professional regulatory bodies.

Instead of constant reorganising and adding to existing regulatory bodies, regulation of HCPs needs to be sorted once and for all. However, any regulatory system that is put in place needs to be effective.

Assessment of efficacy of the principles of regulation

In order to assess whether the regulatory framework that has been put in place is effective and achieves the desired purpose, there needs to be a number of set criteria against which the regulatory framework can be judged. However, the setting of criteria against which to judge regulatory frameworks can be as difficult to put in place, as can the implementation of

[1] For instance, see Secretary of State for the Home Department and the Secretary of State for Health (2004) Shipman Inquiry Fifth Report: Safeguarding Patients: Lessons from the Past - Proposals for the Future (Chair Dame Janet Smith DBE) Cm 6394 The Stationery Office, London; and Kennedy I (Chair) (2001) Learning from Bristol: The report of the public inquiry into children's heart surgery at the Bristol Royal Infirmary 1984 – 1995 CM 5207(1) Stationery Office, London.

the regulation in the first place. As Baggott states, 'it [is] difficult to assess the impact of regulation because there are different value judgments about the criteria that should be used' (Baggott, 2002, 32); a view echoed by Baldwin and Cave who believe that 'to decide whether a system of regulation is good, acceptable, or in need of reform it is necessary to be clear about the benchmarks that are relevant in such an evaluation' (Baldwin & Cave, 1999, 76).

The 'Better Regulation Task Force',[2] although not specifically looking at regulation of health care and HCPs, has identified a number of principles of good regulation, against which regulation can be assessed to identify its effectiveness. These principles are that any system of regulation should have: transparency; accountability; consistency; proportionality; and it should be targeted at the regulatory problem (Better Regulation Task Force, 2000, 29).

Pyne, on the other hand, has identified key principles which he believes should underpin professional regulation. These are:

> identifying the purpose of regulation; clarifying the essential elements of a regulatory system; considering how the interested parties are and how they should be involved [interested parties includes HCPs; patients; employers; educators; Government; professional associations e.g. royal colleges of medicine; and trades unions e.g. British Medical Association]; recognising any hazards which must be avoided; and ensuring that the system is both fair and just for those regulated (Pyne, 2003, 176.

There are a number of areas that can be considered to be influential on regulatory efficiency and it is to these that I now turn.

Regulatory purpose

Braye & Preston-Shoot note that there are two assumptions made about regulation:

> The first assumption is that regulation will lead to improved practice, and will promote accountability by making clear the requirements for the exercise of professional judgement. [Whilst] the second assumption is that inspection against set standards can improve accountability. (Braye & Preston-Shoot 1999, 238 & 240)

[2] The 'Better Regulation Task Force' is an 'independent advisory group' whose terms of reference are 'To advise the Government on action which will improve the effectiveness and credibility of government regulation by making sure that it is necessary, fair and affordable, and simple to understand and administer, taking particular account of the needs of small businesses and ordinary people'. Better Regulation Task Force' (1999) Self-regulation: interim report Cabinet Office, London, at Annexe A.

In order for these assumptions to become reality, any system of regulation needs to have a purpose, an aim that is both achievable and capable of being understood by both those who are being regulated and those the regulation is seeking to protect. The purpose of regulation should be communicated to the interested parties so that they can understand it. There should be an overarching cohesiveness to regulation, a framework that links it all together, so that the regulation put in place has both procedural and substantive accountability. It is important to identify the issues that need regulating and to ensure that the regulation addresses them and them alone.

With regard to procedural accountability, for Ogus, this means that 'procedures must be fair and impartial' (Ogus, 1999, 111) to both those regulated and to those for whom the regulation is to benefit. Further, Ogus states that substantive accountability means that 'the rules and decisions are themselves justifiable in terms of the public interest goals of the regulatory system' (Ogus, 1999, 111).

For Allsop and Mulcahy, any form of regulation has

> to balance the interests of doctors, who claim to work according to the altruistic ethic of care, with those of the consumer of health care, who has a right to expect competence and information about treatment (Allsop & Mulcahy, 1996, 24).

These two interests, that of those being regulated and those being protected by the regulation, are often competing interests that need to be balanced against each other. For regulation to be effective, it has to have the confidence of those that it aims to provide protection for as well as those being regulated.

Regulation of HCPs has the general purpose of protection of the public and patient safety. Montgomery summarises the

> principal functions of professional [that is regulatory] bodies [as being] to maintain a register of qualified practitioners and to remove those unfit to practise because of ill health or by reason of improper conduct, to oversee professional education, and to give guidance on matters of professional ethics (Montgomery, 2003, 134).

Whilst for Grubb, the principal function of regulatory bodies is the

> maintenance of a professional register controlling admission to (and continued presence on) that register - based upon the satisfaction of

> educational and training requirements … and of good character (Grubb, 2004, 84) .

Any new regulatory activity 'must be consistent with existing regulations' (Better Regulation Task Force, 2000, 29); introducing new regulations that are out-of-kilter with those already in existence will only lead to confusion and uncertainty for those being regulated who will not know which regulatory process takes precedence. However, this does not mean that, once introduced, regulation is fixed; there is a need to be able to adapt regulation that is in place according to future changes in health care, the health care professions, and in society itself.

There should also be proportionality in the impact of the regulation. Constraining the clinical autonomy of a HCP should only be undertaken where the perceived benefit to patients and the public outweighs the negative impact that this will have upon individual HCPs, as well as clinical practice as a whole. There should not be 'unnecessary demands on those being regulated' (Better Regulation Task Force, 2000, 29).

Regulatory authority

Once the purpose of regulation has been settled, any regulation that is put in place needs to be supported by authority. Without the appropriate authority, there is no reason for those being regulated to feel that they are constrained by the regulatory processes and those supposed to be protected by the regulation may not feel that the regulation is adequate to meet this need.

For Baldwin and Cave, the important question is, 'is the action or regime supported by legislative authority' (Baldwin R & Cave M, 1999, 77)? In the case of regulation of HCPs, much of the regulation has been implemented through legislation, giving the regulation the authority of Parliament.

External review and accountability

One of the criticisms of regulation is that of a lack of external accountability. This was particularly so in relation to self-regulation where there is no apparent review of the regulatory process by an agency external to the regulatory body. Therefore in achieving effective regulation, there should be an appropriate level of accountability. Having the regulatory process subject to external review may be a positive factor from the viewpoint of both those subject to the regulation and those being protected by it.

The external review should be able to address the question of whether the regulator is 'acting with sufficient expertise' (Baldwin R & Cave M, 1999, 77).

The question arises as to what level this external review should be. The review could be from another regulatory body undertaking similar processes, for example, doctors review nurses who review physiotherapist who review doctors; or could be from an agency specifically created or the purpose; or, it could be from an agency of Parliament, either Ministers of State or a Select Committee of either House; or it could be through the judiciary element of the state apparatus.

Regulation is a form of administrative law, Ogus sees administrative law as having 'the power of the ordinary courts to review the activities of public authorities' (Ogus, 1994, 115). He goes further to suggest that

> judges are well-equipped to assume the tasks imposed by procedural accountability and undoubtedly have performed a valuable function in this regard. On the face of it, judges might also seem to be appropriate instruments for monitoring substantive accountability. Their independence and autonomy, as well as the rules of the judicial process, suggest that they are insulated from political pressures to a greater degree than regulatory agencies; and there is a long tradition of addressing public interest issues on relation to judicial decisions (Ogus, 1994, 115).

For Allsop & Mulcahy:

> administrative law performs a number of different functions in the modern state. First it has a control function, in the sense that it acts as a brake, or check, on the unlawful exercise of executive or administrative power. Second, it can have a command function, by making public bodies perform their statutory duties. Third, it encourages good administrative practice, by providing positive principles according to which an organization should operate. Fourth, it provides a remedy for grievances suffered by citizens at the hands of public authorities. Finally, the law facilitates accountability and participation. In addition, legislation acts to legitimise the activity of professional groups by granting special status to them and it empowers individuals and organisations to act in ways which would not otherwise be legal (Allsop & Mulcahy, 1996, 19 – 20).

Rules, functions and duties

Regulation has to say something to those it regulates; the rules of the regulating body have to be accessible to those being regulated. They need to know whether the regulation is enabling or restrictive, that is, is it telling the HCP to do something or not to do something and, if it is permitting the HCP to do something, is it telling them how to do undertake this action or permitting them to decide for themselves? There needs to be clear statement of any standard that is expected of the HCP.

The functions, powers and duties of regulatory bodies need to be clearly defined. Without this, it would be impossible to decide whether it is an appropriate source of regulation. How will the regulatory body, the bodies to whom it is accountable, those being regulated and those for whom the regulation exists to protect know if the regulation is working or, more importantly, if it is not working, that is, is not meeting its goal of public protection and patient safety?

In addition, there is a need for regulation to be predictable. This means that regulation has to be fair to those it regulates, they need to know that there is consistency in the way that the regulators will approach a given situation and the outcome that they should expect. Otherwise, the HCP would be unable to know how to act in a given situation for fear of being judged to have acted inappropriately by the regulatory body.

Another reason for fairness in the rules of the regulating body is that by making their rules open, all are able to access them and to judge their appropriateness. In addition, having onerous rules may mean that future generations of HCP are discouraged from applying to that particular profession.

One way of ensuring that the rules of regulatory bodies are accessible and fair is to have them originate from statute, so that they are subject to open debate and drafted with precision.

Enforcement

The major issue is whether the regulatory aim can be managed and enforced effectively, or whether it is too wide or cumbersome to be enforceable. Regulatory aims need to be such that they produce rules and regulations that can be enforced.

It is important to know how infractions of the regulatory body's rules and regulations can be raised. Is it possible, for instance, for the patient or members of the public to raise

complaints with the regulatory body? It is equally important to know how far the particular regulatory body can assist in protecting the public and patients from rogue HCPs.

Each infraction or complaint about a HCP needs to be dealt with consistently, according to agreed and accessible procedures. The rules and procedures need to be clearly available, so that they can be understood not only by the HCP against whom they are being used but also by the regulatory body officials who are applying them. As the Better Regulation Task Force states:

> there should be no uncertainty regarding enforcement of rules and regulations. Those being regulated must be made aware of their obligations and be helped to comply by enforcing authorities (Better Regulation Task Force, 2000, 29).

It should be known how the regulatory body will deal with a HCP who is not demonstrating the required level of competence or who is performing below par.

Those who are looking to the regulatory body for protection need to feel that enforcement of rules and regulations is more than a gesture, that the regulatory body is taking this aspect of its role seriously and is implementing it effectively. If there is no enforcement of the regulatory body's rules and regulations, the HCPs who are subject to its jurisdiction may take the view that they are free to ignore them without fear of sanction.

Conclusion

The Law Commission consultation and its subsequent recommendation provide a vital opportunity to reform the regulation of health care professionals within the United Kingdom for once and all. To put in place a regulatory system that is efficient. A system that has a clearly defined purpose, with the requisite authority to undertake its role; a role that is clearly outlined in terms of functions and duties; thereby allowing enforcement to be effective but proportional, and also open.

As a former health care professional and academic lawyer with an interest in this area, I hope that this does not become another missed opportunity.

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