King's Fund Consultation response

King's Fund response to the public consultation on proposals for change to health care professional regulation

November 2006
A Department of Health consultation

Introduction

We are grateful for the opportunity to respond to the report prepared by the Chief Medical Officer (CMO) for England, Sir Liam Donaldson, on medical regulation *Good Doctors, Safer Patients* and the review by the Department of Health on the regulation of non-medical health care professions (referred to herein as the CMO's report and the Foster review respectively). We agree with many of the recommendations made in the reports, for example:

- professionals who fail to meet standards of revalidation should spend a period in supervised practice, and a plan for remediation and rehabilitation should be put in place for them
- regulators should be accountable to parliament
- professional members of councils should be appointed rather than elected
- unique and permanent identifiers should be used to track professionals
- investigations should be made into whether financial incentives associated with lower insurance premiums could be used to promote safe practice.

Overall, the reports have identified the central issues that must be resolved and have presented a mass of evidence and argument bearing on them. However, we believe that more needs to be done to ensure there is a consistent overall framework for professional regulation that fits with the reality of regulatory and employment practice in the health systems operating in the UK.

1. Do stakeholders support the principles upon which *Good Doctors, Safer Patients* is based?

We agree with the principles set out in Conclusion 1 of the Foster review –namely, that regulation of the professions should be coordinated with the regulation of health services; that it should form one integrated and consistent framework and that any new regulatory activities should be as simple and light touch as possible consistent with their patient safety goals. However, in our view these principles have not been systematically implemented in either report.

Furthermore, there is a mismatch between the proposals in the CMO's Report and those in the Foster review. For example, the Foster review does not consider the CMO's proposal for GMC affiliates for other professions. More generally, neither report identifies what an integrated and consistent framework would look like and how it might be achieved.

The need for integration stems from four main factors.

First, there are changes in the way that health care is delivered:

- the boundaries between professions are being eroded
- new roles are emerging that combine existing areas of professional expertise
- health care delivery is increasingly a team, network or system effort in which the contributions of individual professionals do or should form an effective whole.

Taken together these changes suggest that we should be moving towards a system of regulation with common standards across professional regulators in which some functions are carried out by single bodies. At a minimum, a single process of adjudication should be established but ensuring that each tribunal has the appropriate professional background represented on it.

Second, the existence of three distinct regulatory strands

- for individual professionals (GMC, NMC etc)
- for whole organisations (Healthcare Commission, Audit Commission, service contracts), and
- for individuals working within organisations (employment contracts, clinical governance arrangements).

It will be important for each strand to mesh effectively together and for appropriate links to be made to ensure that information about registrants is transmitted between bodies. In particular, details of registrants whose licence has been suspended or who are struck off the register should be notified to other regulators.

Although both reports refer to the need to integrate professional regulation with other systems for ensuring good quality of care, they do not succeed in practice in bringing the various elements together into a seamless whole.

Third, in England, new forms of organisation, including the commercial and not for profit sector, are being actively encouraged to provide NHS services. Any new regulatory system must be able to regulate practitioners working within these organisations, as well as those in traditional NHS organisations. Current proposals appear to rely to some extent on governance and management arrangements that are peculiar to NHS employees, particularly those relating to appraisal and revalidation.

Fourth, neither report deals systematically with the range of employment situations in which practitioners work, which range from very large teaching hospitals through small organisations such as general practice to individual practitioners and locums working for more than one employer. The relative advantages of employer- and regulator-based systems differ widely from one end of this spectrum to the other.

We also accept that the principles of good regulation set out by the Better Regulation Executive are applicable to health professionals. These require, among other things, that regulation in general and specific regulations should be based on an understanding of their impact and their expected costs and benefits, should be evidence based, and should be proportionate to risk. However, neither report has systematically met these requirements.

Expected costs and benefits: The information presented in the Regulatory Impact Assessment is very limited. For example estimates of the cost of introducing local affiliates simply refer to

'substantial savings likely elsewhere in the system' without presenting further details of their size or nature.

Evidence: While we recognise the paucity of evidence in the field of regulation we believe a more systematic analysis of how the goals could be met effectively through different arrangements is still needed. Although the CMO's report presents a great deal of evidence, including from overseas and from other high-risk industries, it is not always clear how this evidence supports the conclusions. For example, the proposal to relieve the GMC of its responsibilities for undergraduate education is not supported by any analysis in the main report. However, we accept that there may well be a case for bringing responsibility for undergraduate and postgraduate education together.

The CMO's Report presents examples of medical regulation in other jurisdictions (Chapter 6). He notes the common framework for professional regulation in both Ontario, Canada and in New Zealand. Yet the idea of creating a single framework is not discussed in detail in either the CMO's report or the Foster review. The fact that the two reports were commissioned separately meant that neither had a remit to look at the overarching approach to professional regulation in different systems.

Risk: *Despite the emphasis on patient safety, the Foster review presents very little data on the risks currently posed to patients by non-medical health care professionals. The CMO's report presents considerable evidence on risks posed by medical practitioners. His proposals are designed to identify practitioners whose practice is sub-standard and who pose a risk to patients. Local mechanisms are intended to enable early detection. If regulation is to be proportionate to risk, the size and nature of the risks need first to be well-established.*

2. Do stakeholders support the approach advocated in the two reports?

We have a number of observations in relation to the approach to professional regulation advocated in the two reports.

First, both reports appear to put forward dual aims for regulation: patient safety and raising professional standards. The Foster review states: 'the goal of professional regulation is patient safety' and then goes on to modify that statement by introducing the further goal of raising standards. The CMO's Report also makes patient safety the prime concern but goes on to propose measures designed to raise standards across the board. Although the desire to protect patients and the public from harm and the aim of raising professional standards are not mutually exclusive, they may require different approaches. Lessons from the regulation of other sectors may be useful in order to identify the appropriate balance between punitive and facilitative regulation.

The proposals to establish (re)certification for doctors are to be commended. Although re-licensing is important to ensure basic minimum standards of practice are met, certification ensures that practitioners have the competence and knowledge to practise as a specialist. Such proposals could be extended to specialist roles undertaken by other health care professionals. There is a basic need for any system of regulation to identify and deal with those practitioners whose practice falls below basic standards. Through rehabilitation and retraining it would be hoped that the standards of the worst are raised. However, regulators have a particular and somewhat circumscribed role in driving improvements in professional practice overall. These will be primarily

influenced by effective clinical governance arrangements, clinical audit and other peer-led assessments and feedback processes.

Second, both reports refer at various points to the wide range of functions which regulators may carry out. However, neither report considers explicitly whether there are benefits in bundling them together – ie, making them the responsibility of a single body – or splitting them between different organisations. The question of what is the right *combination* of regulatory functions is not asked.

Third, work on patient safety has shown the importance of the systems in which practitioners work. As noted above, the way that health care is delivered is changing in ways which reduce the freedom of individuals to act on their own initiative. Mistakes are often likely to be due to a combination of factors, many outside the control of any one professional. There is a need therefore to ensure that any proposed system for local reporting, investigation and resolution of complaints and adverse events should be able to handle both those concerning an individual's performance or competence and those concerning a team or organisation's performance. The local system would need to refer individual cases to professional regulators where appropriate.

Fourth, although The CMO's Report reviews the findings of public inquiries into cases of serious professional misconduct (such as Kerr/ Haslam, Neill and Shipman) it does not systematically address their recommendations; in particular it would have been helpful if Dame Janet Smith's Report had received a point-by-point response.

Fifth, there is a difficult balance to be struck between public disclosure and the right to privacy as recognised in the CMO's Report. The CMO proposes that recorded concerns will not be made public but held securely on the Medical Register. We acknowledge that some concerns might not be recorded if there were any possibility of them being disclosed publicly. However, we believe there need to be clear and explicit criteria for determining which matters are recorded concerns and which are matters of patient safety and therefore need to be escalated. We welcome the suggestion that there will be national oversight of locally recorded concerns.

Sixth, the policy context in Scotland and Wales is different from that in England. Both reports currently fail to reflect fully the fact that regulators are having to regulate professionals in very different clinical settings, with different employers and different employment contracts and in different jurisdictions. More needs to be done to ensure that a single professional regulatory system can deal adequately with these national differences.

3. What are the priorities for stakeholders in terms of implementation?

There is a need to bring the recommendations of the two reports into a single proposal for the regulation of health care professionals in the United Kingdom. Proposals for regulation need to recognise the diversity of practice and organisational settings in which health professionals work, the increasingly team-based nature of health care practice, and the differences between the health care systems in each country. It is expected that separate professional regulators will be retained but there should be a clear process of establishing a single framework for professional regulation, with common standards and, where appropriate, carried out by a single body.

There are many proposals such as the re-licensing arrangements and a single adjudication system that should be implemented without delay but our view is that there are aspects of reform that should be pursued cautiously and as part of a broader and sustained process of improving the regulatory regime as a whole. This process should comprise the whole field of health care regulation and all professions. It should not preclude progress being made on specific issues where this can be done.

It should at minimum involve:

- further analysis of the evidence on (categories of) risk with the aim of ensuring that resources are devoted to areas of greater risk;
- systematic exploration of the options for creating a single regulatory framework for professional regulation beginning with detailed proposals for a single adjudication body;
- further examination of the relationship between regulation of individual professionals and other systems of quality monitoring and improvement;
- Further consideration of how these regulations would apply in new forms of provider organisations (e.g. professional chambers, social enterprises and private interest companies) , where practitioners are employed by providers outside the NHS and to the many practitioners working in independent practice who are self employed.

Themes

1. Changes to the governance and accountability of regulators.

We consider that the appropriate rules and procedures bearing on governance and accountability depend on the way the overall framework for regulation is structured.

Where educational responsibilities remain with the regulator it is important that the full range of relevant professional expertise is involved including higher education institutions. Similarly, where the regulator fulfils functions, such as continuing professional development, professional input will of course remain necessary. However, professional members are not representatives of the profession and therefore appointment rather election should be considered.

Where the regulator defines professional standards or has any investigative or disciplinary functions, there should be a lay majority.

There should be more effective means of holding the regulators to account. We believe the best route is to make them all directly accountable to Parliament as recommended in the CMO's Report for the medical profession. This would mean changing the current role of the Privy Council in relation to the regulators. In practice it would mean a much more active role for the Health Select Committee and regulators would be subject to investigation by the National Audit Office. The latter might be asked to consider what form of reporting should be required of regulators on a regular basis i.e. what information they should regularly publish about their activities.

2. The importance of defined operationalised standards against which to regulate.

We believe that the main priority, across professional regulation as a whole, is to have common standards of professional behaviour, which indicate clearly to patients what they can expect from those who advise and care for them and which, if breached, give grounds for complaint.

3. The appropriate standard of proof.

We agree that the civil standard should be adopted.

4. Proposals for a 'spectrum of revalidation' across all health care professions.

Revalidation is essential to ensure that practitioners are up to date with knowledge and practice in their area and they have performed to agreed standards since their registration or the last revalidation. Although it may be justified to have a spectrum of revalidation across health care professions, proportionate to risk, it should be demonstrated that any revalidation process is able to deliver on these basic aspects. A process of revalidation that is based on the NHS appraisal system or on the Knowledge Skills Framework that forms part of Agenda for Change will not be appropriate to all health care professionals, especially given the changing working conditions and patterns of employment as noted above.

Many health care practitioners develop an area of specialist practice or may take on new and extended roles. The knowledge and skill they are required to demonstrate may change over time and the revalidation process needs to be flexible enough to pick this up. In particular it needs to be made clearer, for all professionals, how the relicensing process relates to the need to prove specialisation ie, through (re) certification.

The description of the methods for testing skill, knowledge and competence needs to be further developed. The balance between testing knowledge and reviewing practice remains unclear. While it is difficult to produce valid, robust assessment methods the goal should be clear - moving towards assessment that covers knowledge, attitudes and performance in practice. Clearly some specialties are further advanced than others so the pace of implementation may need to take account of this.

Further work is needed to understand the respective roles of the Royal Colleges, PMETB, regulators and employers (in particular the NHS) in providing information for the revalidation process. The methods of assessment will also have to be designed in order to strike a balance between tests of specific knowledge and checks on ongoing practise.

5. Devolution of some regulatory activity to a local level.

We support this. However if such a structure is right for doctors, then *prima facie,* it is right for other professions too, particularly the larger ones.

As they stand, many key elements of the CMO's affiliate scheme remain unclear and the time and other resources required appear to have been underestimated. In addition, the experience of the

Royal Pharmaceutical Society of Great Britain inspectorate, which is in some respects a similar arrangement, does not appear to have been assessed for its possible relevance for those professions where individual professionals often work in isolation. Reliance on local structures to support professional regulation fails to acknowledge the extent of independent and sole practice among professionals such as chiropractors, osteopaths and physiotherapists.

While local action might be advantageous in respect of speed of response, it needs to be complemented by work at national level to draw out what general lessons may be learned from complaints. Systems of complaint need to be reviewed to ensure they are able to deal with a range of complaints and provide easy access for patients wishing to make a complaint wherever they are treated (including by private practitioners)

Other health care staff and colleagues are also an important source of concerns about performance. One option that might be considered instead of creating an additional bureaucracy of local regulation would be to give this responsibility to the person currently responsible for clinical performance (such as the Clinical Director, Medical Director or Nursing Director) who would also have a responsibility to the regulator. If there were concerns that such a local 'affiliate' did not have the confidence of 'whistle blowers' or the necessary independence staff should be able to contact a national body direct (and if necessary in confidence).

6. The number of regulators for the non-medical professions.

No strong arguments for reducing the number of regulators were presented on economic, safety or other grounds. However as we have noted above, there is a *prima facie* case for bringing the regulation of all health care professionals, including medical and non-medical practitioners under a single framework if not a single organisation. How this might be achieved requires systematic exploration of the options.

Any proposals should be fully costed and realistic assumptions made about the economies of scale that could be achieved through developing shared systems for carrying out some of the regulatory functions, transferring some of the responsibilities from the current regulators to other bodies involved in regulation, or through current regulators sharing administration and facilities. We also recognise that the confidence of the professions themselves is important if any regulatory system is to operate effectively.

7. The requirement to record post-registration qualifications.

We agree there is a need to record post-registration qualifications. These should be accessible to the public as well as to the regulator. Recommendations in the Kerr-Haslam report suggest employers should record practice of non-conventional treatments such as hypnotherapy. by employees Consideration should be given to extending the scope of post-registration qualifications to include training in complementary therapies by statutory registered health professionals.

8. The role of regulation for student health care professionals.

We agree that it is appropriate that the standards deemed appropriate for professional practice should be applied to potential entrants to a profession.

9. The need for standardised pre-employment English language testing.

We agree there is a need for this and understand that it should be a matter for employers, given the current interpretation of European Union law. However, this means that practitioners who are self employed may not have levels of English language proficiency that would be desirable to ensure adequate communication with patients.

10. Extending the scope of regulation to include health care support workers and new roles in health care.

This can only be answered on the basis of specific assumptions about the way in which support workers are 'regulated' through their place of employment i.e. what responsibilities for supervision, operational guidelines and mentoring are in place. Any proposals should draw on the experience of the General Social Care Council and should consider the costs and benefits of such regulations.

New roles must come within the scope of regulation, subject to the above comment.

Extended roles in which some functions such as prescribing are carried out by a number of professionals raise different issues. The main requirement is that similar standards should apply to such functions, irrespective of who carries them out.

Concluding comment

Both reports identify many of the important challenges that professional regulators face in the current health care environment. However, as they stand they do not adequately address how regulation will operate in this environment of devolution, team-based approaches to care, and new providers. There is still a need to define a comprehensive system of professional regulation which is fit for purpose in the changing environment in which health care professionals operate. Two key questions remain to be answered:

- How can professional regulation be structured in order to best carry out its primary functions?
- How does professional regulation mesh with other systems of regulation?

Many of the recommendations made in the two reports can and should be implemented without delay but we believe there is still a need for the government to commit itself to a more comprehensive framework for professional regulation which regulators can begin to work towards.