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Professional regulation

Developing standards, criteria, and thresholds to assess fitness to practise

Richard Baker

Do we need explicit, clear guidance on the professional behaviour of doctors or should guidance be largely implicit to account for the context and circumstances of clinical practice? In the aftermath of the Shipman case, doctors need to answer this question

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The medical profession in the United Kingdom was shaken by the discovery that Harold Shipman murdered around 250 of his patients when working as a junior hospital doctor and general practitioner between 1971 and 1998.¹ A public inquiry recommended fundamental changes to the accountability of doctors. Issues addressed by the inquiry include death certification, monitoring of prescribing, complaints systems, disciplinary procedures, and regulation. Medical regulation in the UK shares many features with other countries, so that although this case is unique to the UK, the implications are of international importance. The case and subsequent inquiry have revealed the weaknesses of current systems of medical regulation and shown that radical reform is necessary.

This article discusses how detailed the standards to judge a doctor's fitness to practise should be, and the way in which explicit standards can be developed. The recently published fifth report of the Shipman Inquiry highlights the lack of explicit standards, a shortfall that makes it unclear when questions should be raised about a doctor's fitness to practise and may lead to inconsistent decisions.² The development of detailed standards would be a major step in improving regulation, as would defining the relationship between doctors and patients.³ It could be argued that specifying standards of fitness to practise would reduce the complex art of clinical practice to a naive checklist. However, patients expect the profession's regulatory body (the General Medical Council (GMC) in the UK) to define minimum standards for doctors. If the

regulators are not clear about what is unacceptable, how can patients decide when a doctor should be reported for investigation, and what confidence can they have in medical regulation?

Some examples

The tables show how systematically developed standards, criteria, and thresholds could lead to precise statements to inform people making decisions on whether a doctor should be referred to the GMC, and to help the GMC reach a decision. Although the examples are hypothetical, they have been informed by cases considered by the GMC during 2003 and others discussed in detail in the inquiry's fifth report.² The general principles governing medical practice set out in *Good Medical Practice* (currently under review by the GMC) provide a basis for the standards and criteria.⁴ Two of the examples that follow are based on these principles and one is based on the inquiry's review of the GMC's procedures for dealing with cases of drug misuse.

The inquiry put forward three categories of practice—acceptable, unacceptable, and seriously unacceptable—building on the concept of the “unacceptable general practitioner” used in *Good Medical Practice for General Practitioners*.⁵ Unacceptable practice should trigger action by an NHS hospital trust under its disciplinary code or by a primary care trust under its management procedures, and may involve oral and written warnings and referral to the National Clinical Assessment Authority for retraining. The thresholds define the medical practice or conduct that determines whether a case is acceptable, unacceptable, or seriously unacceptable, and they are framed in terms of precise criteria.

The first example (table 1) shows the distinction between an occasional problem of competence or attitude, which has not resulted in harm to a patient, and a problem that has caused or is highly likely to cause harm. In the latter case, fitness to practise should be considered and the case referred to the GMC. The case of a general practitioner who failed to visit or to consider the possibility of a heart attack in a patient with typical chest pain and failed to arrange the immediate assessment of a child who had been losing weight and had glycosuria would meet the criterion for seriously unacceptable practice (the GMC found the doctor guilty of serious professional misconduct and issued a reprimand).⁶ If no patient had been harmed but the doctor had occasionally failed to assess the need for prompt action, a review of competence would be indicated.

The second example (table 2) shows the distinction between error due to lack of attention and dishonesty.



The Shipman Inquiry revealed the weaknesses of current systems of medical regulation and showed that radical reform is necessary

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A surgeon preparing a report for a personal injury claim failed to state that he had not carried out the examination of the patient concerned but had relied on the report of a less experienced clinician, and the GMC's professional conduct committee found him not guilty of serious professional misconduct.⁷ In this case, the criterion for unacceptable practice would apply, but if he had also given false information in reports the criterion for seriously unacceptable performance would have applied.

In the third example (table 3), all cases that involve dishonestly obtaining drugs for misuse must be referred. All such cases are classified as seriously unacceptable practice. Full investigation and review by a fitness to practise panel is mandatory, and sanctions will follow if dishonesty is established. In reviewing the GMC's handling of doctors who misuse drugs, the Shipman Inquiry noted that similar cases were dealt with under either the disciplinary or voluntary procedures for doctors with health problems. This can lead to unfairness and a lack of clarity. The criteria improve fairness and clarity because all cases of obtaining drugs for misuse are classified as seriously unacceptable practice.

Developing standards, criteria, and thresholds for fitness to practise

I use the term standards to describe general statements of what is expected of doctors and the term criteria to describe statements derived from the standards that detail the exact requirements. The threshold is the level of non-compliance with a criterion that leads to specific action—for example, suspending a doctor from the register. Defining these terms would provide a basis for modern medical professionalism, and this task is too important to be left to the regulators alone. Involving patients, managers, and policymakers would result in a new compact between the profession and the public.³ Leadership by the GMC and its continued responsibility for setting the standards for medical practice are necessary to sustain a culture of professionalism among doctors. Therefore, the GMC should retain the authority to set the new standards, criteria, and thresholds, and to decide the methods by which they should be developed. Nevertheless, wide consultation and more systematic methods, such as those used for the development of guidelines, are needed to retain the confidence of patients and doctors. Two important issues are who to involve and what techniques to choose to synthesise evidence and opinion.

Wide involvement

Patients and health service managers should be involved in developing the standards, criteria, and thresholds because they will have different perspectives and experiences to doctors. Patients and managers need to know that the GMC is aware of their expectations of doctors, and a systematic, open, and widely involving process would promote public confidence.

The process of development should be led by a group constituted under the auspices of the GMC, which must include patients, health service managers, and doctors. This standard development group must also direct a systematic process for involving a wide range of stakeholders.

Table 1 Taking prompt action. The doctor should assess the need for prompt action, initiate action quickly when indicated, and ensure that the action is appropriate¹²

Acceptability of practice	Criteria	Action
Acceptable practice	The doctor consistently assesses the need for prompt action and responds accordingly	None
Unacceptable practice	The doctor occasionally fails to assess the need for prompt action, or fails to take prompt action when this is indicated	Full assessment of competence followed by retraining as required
Seriously unacceptable practice	The doctor consistently fails to assess the need for prompt action or to take prompt action when necessary; or the doctor has caused serious harm to a patient by failing to assess the need for prompt action or to act promptly	Fitness to practise should be considered

Involvement could take many forms, from relatively informal consultation through to the commissioning of systematic surveys of professionals, managers, and the public. Consultation with relevant professional and patient organisations is a convenient and low cost option, but is not adequate. Although the publication of responses to consultation can improve transparency,⁸ consultation generally restricts involvement to a narrow range of people. The GMC already has a patient reference group, and options for systematically consulting patients more widely include the formation of a citizens' council, such as that established by NICE (National Institute for Health and Clinical Excellence),⁹ or commissioning interviews or representative surveys. Involving health service managers, doctors, and other health professionals through focus groups or surveys would widen participation and enable issues to be explored in depth. The standards development group would receive the information from these sources and have responsibility for formulating standards, criteria, and thresholds that take account of the views of professionals, managers, and patients.

Transparent synthesis of evidence and opinion

Guidance on what is expected of doctors can be found in legislation, NHS regulations, and international codes of medical practice, including the Declaration of Helsinki and the international code of medical ethics of the World Medical Association.^{10 11} However, formal

Table 2 Completing reports honestly. The doctor should be honest and trustworthy when writing reports and completing or signing forms¹²

Acceptability of practice	Criteria	Action
Acceptable practice	The doctor invariably completes reports truthfully to the best of his or her knowledge	None
Unacceptable practice	The doctor pays insufficient attention to the importance of completing reports accurately, and repeatedly makes errors in reports	Consider retraining or a warning
Seriously unacceptable practice	The doctor deliberately omits important information from one or more reports, or enters untruthful information; alternatively the doctor pays insufficient attention to the importance of completing reports accurately and refuses to take part in retraining	Fitness to practise should be considered

Table 3 Criteria relating to allegations of drug misuse

Acceptability of practice	Criteria	Action
Acceptable practice	The doctor does not misuse drugs	None
Seriously unacceptable practice	The doctor has obtained drugs for misuse by writing prescriptions in the name of a patient but using the drug personally	Full investigation and hearing by fitness to practise panel, leading to erasure

evidence on the factors to be considered in judging fitness to practise is limited. Some evidence can be found in research commissioned by the GMC,¹² and this could be supplemented by data on cases referred to the GMC or cases referred by health service trusts ("case law"). Although better evidence may be obtained, the development of standards, criteria, and thresholds will depend on blending evidence with opinion and principle. The standards development group should begin by documenting the principles that will guide its deliberations. They should then discuss the evidence and draw on their own opinions to prepare standards, criteria, and thresholds. This could be done in an informal way, but a transparent process would help gain public confidence.¹³ Formal methods such as the nominal group technique for blending evidence and opinion are preferable because they help the user to understand the development group's decisions.¹⁴ Formal methods also enable the range of opinions to be reported and the standards, criteria, and thresholds to be justified.¹⁵

The final version of the standards and criteria should be subjected to pilot tests of clarity before publication. After publication, the standards, criteria, and thresholds should be reviewed occasionally to keep them up to date. New research should be taken into account, and omissions identified through experience or the emergence of new concerns should be addressed. Finally, the consistency of decisions should be monitored, and the standards, criteria, and thresholds subject to most variation in interpretation should be revised.

Discussion

I have considered how standards, criteria, and thresholds to assess fitness to practise might be developed and used. In addition to reviewing case summaries, a systematic approach could be established, drawing on methods of guideline development that involve doctors, patients, and managers. Continued monitoring and research should enable improvements to be introduced if necessary. Although prompted by a serious event in the UK, this approach should be considered by regulatory bodies in other countries.

Systematic approaches and those with greater involvement of patients, managers, and others are preferable because they will generate confidence in the fairness and consistency with which decisions about fitness to practise are made. Systematic approaches require more methodological expertise, take longer to complete, and have higher costs, but this should not prevent urgent steps being taken to develop standards, criteria, and thresholds, as recommended by the Shipman Inquiry. Doctors should support and if necessary fund a method of developing standards, criteria, and thresholds in which the public can have confidence.

The examples presented have the weaknesses of standards and criteria that have not been developed and tested systematically. Some examples are unclear and in others the concepts do not adequately reflect the experience of case examiners or GMC panels. They were not devised in consultation with others, such as patients and managers, and they are not precise because they were not tested or refined in the light of experience. Nevertheless, they do show that a more explicit set of standards, criteria, and thresholds could

Summary points

The Shipman Inquiry recommended that urgent steps should be taken to develop standards, criteria, and thresholds to guide decisions on fitness to practise

Methods used to develop clinical practice guidelines can be adapted to develop these

The standards, criteria, and thresholds should be based on the evidence that is available, up to date, clear, and interpreted consistently

To promote public confidence, the development methods should ensure wide involvement and transparency

be developed, which would assist in decision making at different stages in the assessment of doctors' fitness to practise. The Shipman Inquiry was critical of aspects of the GMC's procedures to assess fitness to practise, and doctors who wish to defend regulation led by the profession must seek effective ways of responding. The development of standards, criteria, and thresholds would be a key step in creating the medical professionalism needed in the 21st century.

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Contributors and sources: RB is a general practitioner and researcher. He undertook a review of Shipman's clinical practice and was a witness in, and attended seminars at, the Shipman inquiry.

Competing interests: RB was a witness in the Shipman Inquiry.

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