Exploring a risk-based approach to medical regulation

On 14 July 2005, the GMC held a seminar on the subject of exploring a risk-based approach to medical regulation. The seminar brought together GMC members and staff together with delegates from a wide range of organisations including the NHS, patient safety and quality assurances bodies and those representing the interests of patients and consumers and doctors.

The seminar was chaired by Sir David Arculus, Chairman of the Better Regulation Task Force.

Discussion at the seminar was informed by an exploratory paper which the GMC had prepared.

The regulatory environment in the UK today

The seminar began by reviewing the current regulatory environment in the UK. Risk-based regulation is a regulatory approach which is being driven from the heart of Government. It is strongly supported by the Prime Minister, the Chancellor of the Exchequer and other senior Ministers.

Regulation in the UK costs our economy 10% of Gross National Product (GNP). Significant proportions of these costs are absorbed through compliance and in demonstrating compliance.

The Better Regulation Task Force, established in 1987, has the role of promoting effective regulation in accordance with five key principles which it has identified:

- Proportionality
- Accountability
- Consistency
- Transparency, and
- Targeting
The Hampton review

The publication of the reports of the Hampton review in December 2004 and March 2005 is widely regarded as representing a significant step forward in developing a risk-based approach to regulation. Hampton’s benefits include highlighting the potential to reduce regulation where it is safe to do so, based on robust risk assessment, so freeing up resources to focus on areas of higher risk and/or poor compliance. The remit of the Hampton review did not include professional regulation, but there is resonance between its findings and the GMC’s emerging thinking on risk-based regulation. Thus, there may be a significant opportunity for the GMC to draw upon the conclusions of the Hampton review work as the GMC continues its programme of modernising medical regulation.

The Hampton review, in addition to underlining how regulators can base decisions on priority and resources according to scale of risk, also helpfully identified ways in which regulators should take forward developing a risk-based approach in order to maintain the confidence both of those whom they regulate and of the public and other stakeholders. It is particularly important that, among other things, risk assessment should be dynamic, balanced in including past performance and potential future risk, based on good quality data, open to scrutiny and impartially implemented. Regulators should consider potential future risk in the round and not assume that past performance is the only indicator of future performance.

The seminar noted that some regulators’ claims to apply a risk-based approach do not necessarily stand up to scrutiny. For example, their processes may involve the exercise of discretion to the extent that regulatory outcomes are not really based on risk and are neither predictable nor consistent. Alternatively, the regulator may undertake a good quality risk assessment, but still operate a uniform inspection and enforcement regime which offers no incentives for compliance and is therefore poorly targeted. There are some examples of very good practice, however, including the Environment Agency whose approach is much more positive, has been devised out of extensive consultation and changes its focus at frequent intervals.

Medical regulation does differ from economic regulation in that there is greater emphasis on overall quality improvement rather than on the identification of those who fail to meet minimum standards.

Proportionality is a key factor to be considered when developing a risk-based approach. Some forms of regulation can be designed purely on the basis of an objective, scientific, assessment of risk. However, in the case of medical regulation, as with other kinds of social regulation, regulators have a duty to factor in the need to maintain public confidence. That may justify the use of measures, or decisions on resources, that go beyond the parameters of the risk assessment. For example, high visibility policing is often a necessary response to the need to assuage the public’s fear of crime even though it may not be any more effective in actually tackling crime than other approaches.
Towards risk-based medical regulation

International evidence suggests that impairment of fitness to practise in doctors, and perceptions of impairment, is as much to do with behaviour, attitude and communication skills as with clinical skills. The fact that only 3% of patients make a claim for negligence does not mean that adverse incidents are not occurring with greater frequency. Research from Australia suggests that a patient is most likely to take action against a doctor if there are both precipitating and predisposing factors, for example, where an adverse clinical incident is combined with bad communication or rudeness.

The relationship between complaints and impairment of fitness to practise is complex. Good interpersonal skills could mask poor clinical performance. Conversely, a doctor with poor interpersonal skills could have high quality clinical skills. The former doctor might attract few complaints, the latter many.

So far as the GMC is concerned, impaired fitness to practise involves serious or persistent failures to meet the principles in *Good Medical Practice*.

Approximately 120,000 doctors are currently in active practice in the UK. The CMO for England has estimated that around 5% of these will be impaired to some extent at any one time. Most of these cases do not need the GMC to be involved and are dealt with in other ways including locally within the NHS, or with advice and support from NCAS.

Managing the risk of impairment within a four layer regulatory model

The variety of means, or layers, via which a doctor can be regulated can be highlighted through a four-layer model of regulation. This comprises the following layers of regulation:

- Personal regulation
- Team regulation
- Workplace regulation
- National regulation

The concept of the ‘GMC approved environment’, where effective workplace and team regulation are in place within an organisation according to defined standards, opens up the possibility of a lighter GMC touch (for example, in evaluating fitness to practise for the purposes of revalidation).

Where doctors are not in an approved environment, that in itself potentially gives rise to a higher risk meaning that the GMC should directly evaluate doctors’ fitness to practise at the point of revalidation, in the first instance, through patient and colleague questionnaires.

Over and above the use of the four layer model as a risk indicator, the question arises as to which groups of doctors are most at risk of developing some form of impairment?
Some other regulators have begun to develop risk indicators to help answer this question. In Quebec, the regulator has identified a number of risk categories including doctors who graduated over 35 years previously, specialists who spend over 30% of their time working outside their own specialty, and locums. The regulator applies a higher level of scrutiny to doctors in these categories.

To apply an effective risk-based approach the GMC recognises the need to take a similar approach. This requires developing an evidence base about where the risks of impairment lie. The four-layer model, and the Quebec indicators provide a starting point but more development work needs to be undertaken.

The seminar discussed a number of questions arising from the GMC’s discussion paper.

**Questions**

**Q1. Does applying a risk-based approach to professional regulation raise different issues of principle from applying it to other types of regulation?**

There is a definite distinction between the regulation of individuals and the regulation of organisations. However both approaches are founded on common principles and both require public assurance, although the management of outcomes may be handled differently.

The drivers of risk-based regulation in the medical field include reducing the regulatory burden and the overall costs of regulation, targeting resources where they can be deployed to maximum effect, and, above all, maximising the protection of the public through preventing or mitigating the risk of impairment, and contributing to the promotion of good practice. In the economic sphere, some of the drivers are the same as in healthcare but the overall aim is in preventing market failure, which is quite different.

**Q2. What needs to be done to ensure a risk-based approach is fair?**

The approach needs to flow through all four levels of regulation and be transparent and inclusive. But the GMC does not necessarily need to await the outcome of academic research before identifying and applying a set of indicators (see below Qs 5 and 6). Greater clarity is needed on the extent to which a risk-based approach is about systems – individuals cannot be considered separately from the systems within which they work.

**Q3. Is the four-layer model of regulation a good starting point for the GMC?**

The four-layer approach is extremely helpful. The team level is currently the least developed – regulators need to work together to demonstrate that team regulation can be effective. The GMC also needs to make clear what the respective roles of the GMC and employers are. There should be a presumption that routine monitoring of risk indicators is a matter for employers though clinical governance.
Q4. What implications does this have for how we approach the targeted sampling of doctors' revalidation folders?

Once our understanding of risk becomes more sophisticated, there may be scope for differential revalidation intervals to be developed. But we need to constantly bear in mind that revalidation is an affirmation of fitness to practise rather than an exercise in finding dysfunction.

Separately, the GMC may wish to consider, as a condition of initial licensing, the value of obtaining a description of every doctor’s practice. This data would more readily enable risk indicators to be applied to the doctor population.

Q5. What evidence about risk factors is needed that we do not yet have which would help? What research is needed now?

In discussion, a distinction was drawn between professional activity which involves the doctor and patient alone (such as GP consultations) and professional activity which is open to the scrutiny of others (such as surgery). Even within ‘private’ activities it might be possible to base evidence in part on GP prescribing behaviour - identified by pharmacists, or possibly through psychometric testing (although it is not clear whether such tests have value in this context).

There was general agreement that hard, factual data about clinical outcomes is needed. Research would help into adverse incident reporting and the causes of such incidents. This pointed to looking at individual specialties and defining what an adverse incident looks like.

There was recognition that what is defined as an adverse incident or as a good outcome might look very different depending on whether it was seen from the doctor's perspective or the patient's. There would be value in seeking patient feedback following discharge from hospital on their experience (telephone surveys/questionnaires), rather than relying simply on the hard data of outcomes. One note of caution was that it may be easy to score well on patient satisfaction questionnaires – by doing what patients want even if this may not necessarily be in their best interests.

Overall, there is a need to use a combination of different indicators that would enable the triangulation of evidence to establish an overall profile of impairment and risk. It is unlikely that one indicator alone would be sufficiently discriminating to identify a target population that needed monitoring and more likely that a combination of the presence of risk factors would be required.

The process should start simply, with some basic risk indicators at each of the four layers of regulation and avoid trying to be over-sophisticated at this stage. Provided that the approach followed is transparent and includes consultation, there should be no grounds for valid objections.
Q6. Can analysis of patterns and trends in complaints help?

Complainants are inevitably a particular sub-group of patients as a whole. Complaints data may not show the bigger picture. Not only do people who have good cause to complain not always do so, but others who do complain may not have good grounds for doing so. Complaints data may be one way of helping to build up an overall picture/profile in conjunction with other data, but in isolation it should be viewed with caution.

If using complaints data, it would be valuable to be able to bring together data from a number of different agencies: NCAS, Healthcare Commission, Health Service Ombudsman, GMC and others. It can be difficult to aggregate data in this way because of different approaches to classification and outcome.

If possible, data about complaints which have been upheld should be used, rather than data about complaints that have been made.

Complaints may have particular value in acting as a prompt for further work. For example, where trend analysis reveals that an issue, or practice group, is giving rise to more complaints, the GMC should undertake more detailed consideration of the reasons behind the trend. That could feed into work on guidance which, if targeted correctly, could avoid the need for enforcement or remedial action at a later stage.

Q7. How can patients and the public contribute to developing a risk based approach?

We need proactively to continue to seek the views of patients about the things that are important to them.

Q8. What screening processes for future impairment, if any, might be legitimate before doctors are first registered and when they should take place (e.g. at the undergraduate or postgraduate stage)?

It was noted that there is already much work going on into student fitness to practise, including a major consultation by the GMC.

Psychometric testing was viewed as something of a mixed bag. As medicine is a diverse profession, requiring lots of different skills and behaviours, a wide range of skills and expertise are required. The use of some screening processes at medical school may raise difficult equality and diversity issues. It could also risk creating a bland homogenised profession lacking the necessary range of aptitudes. The use of such testing could give rise to false reassurance unless its limitations were properly understood.

Within medical schools there are some individuals who are obviously problematic. There is a need to strike a balance in deciding to what extent past or current behaviour could be a predictor of future behaviour, especially in the case of young people whose personalities have not been fully formed. It could be that past dysfunctional behaviour would not always be determinative (in the sense that the individual concerned should be refused graduation) but it might well provide an
indicator – of which the GMC would need to be made aware - that the individual presented a potentially higher risk and should therefore be subjected to subsequent closer scrutiny, especially in the early stages of their career.

The ideal would be to initiate research with a view to tracking a cohort of students throughout their careers, though it was acknowledged this would take decades to yield any meaningful results.

Q 9. What issues of fairness or practicality would the process of screening for future impairment involve?

There can be issues around fairness if certain groups become labelled as ‘problematic’. In addition, the tools for implementing a screening process are largely undefined at present. There are also a number of issues around the practicalities of screening. For example establishing what to screen for and how to screen for it.

If risk factors change over time it may complicate the on-going screening process. Also, data protection has a high transaction cost – there may be difficulty in developing tools that incorporate the correct sensitivity that can identify higher risk.

Fairness may also be impacted by the outcome. For example, if the outcome is a refusal to license an individual that would be unfair, but if the outcome is a heightened state of alert then that may be more appropriate.

Q10. Can our approach to risk based regulation be made to bring tangible benefits for the profession so as to encourage support for and compliance with our strategies?

Focusing on the approved environment by giving a longer interval/period for revalidation could lead to improvements and incentives for all to move towards meeting the standards of an approved environment that benefits both patients and doctors.

There is a need to balance efforts to find and restrict poor practice with the desire to allow innovation – we should not equate non-conformity with risk. There also needs to be sensitivity about where risk indicators or ‘markers’ may lead.

Q11. Are there sources of information that already exist that we can draw on to help us with the identification of emerging and actual impairment?

While there are many potential sources of information these are not currently being integrated. The use of patient or colleague questionnaires could also be a useful tool.

Q12. Are there risks in a risk-based approach and how could they be avoided?

The risks include those from the profession’s perspective (if they do not accept a risk-based approach) and those from the regulator’s perspective (if the wrong risks are identified and a regulatory model is based on a false premise).
These could be resolved through dialogue and also strong evidence based approach tailored to specific practice and identifying best practice.

**General conclusions**

- There is a need to develop an approach that is fit for purpose.
- There needs to be ownership of the problem of impairment within organisations. This raises some important governance questions, including questions about data capture and sharing.
- There are currently many mechanisms for encouraging good practice by doctors, but they need to pull in the same direction.
- The GMC will modify the discussion paper and engage in wider dialogue and consultation on these issues.
- This event is likely to be the first of a series of events on various regulatory issues.

**July 2005**