Who defines and controls the protocol for communicating information on the pandemic?

How is the information disseminated? What measures are being taken to inform the population likely to be affected? Are any mechanisms in place for the redressal of complaints or grievances, and how are decisions on such matters taken and communicated?

The plan of the healthcare organisation should clearly specify the line of authority and define a single command which would serve as the channel for the communication of all information. This may entail identifying and appointing designated nodal officers for pandemic control and surveillance.

There should be mechanisms to ensure the proper collection and compilation of the necessary guidelines, as well as the systematic issuance of the guidelines to all the stakeholders concerned. No miscommunication, duplication or delay should be allowed in the percolation of the important information. Efforts should be made to promptly involve and notify the sections of the public likely to be affected by the pandemic. In this context, utilising the services of a dedicated team of the community health officials of the organisation or help from NGOs would be useful, as would be targeted public health education and awareness campaigns. Such campaigns would minimise the spread of panic, while the public's involvement and support would help in addressing many ethical issues in a more fair and transparent manner. A mechanism to ensure accountability must be put in place so that the process of decision-making is ethical throughout the crisis. Further, scope should be given for the elaboration and refinement of the contingency plans on the basis of inputs from the stakeholders, government guidelines, public complaints and suggestions.

Conclusion

Influenza pandemics pose an ever-growing threat and in the near future, the morbidity and mortality associated with them might greatly increase among all age groups. Our healthcare system needs to gear up for this challenge and plan strategic measures well in advance. Several ethical issues of a complex nature may crop up and hamper healthcare efforts or undermine public trust, but if we adopt an ethical framework for decision-making in our plans, our efforts to control the pandemic may well make a considerable impact. The aim of this article has been to highlight the importance of an ethical process while planning for the eventuality of a pandemic, and to outline and find ways of addressing the various ethical problems which may come up during the preparedness or response phase of an influenza pandemic.

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Medical regulation in India: an outsider's perspective

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Abstract

This personal comment briefly describes the working of the General Medical Council, the medical regulator in the United Kingdom (UK), with the aim of informing the discussion on how to regulate medical education and doctors' practice in India. Given that the ministry of health and family welfare is still debating the final constitution of the Medical Council of India, this paper is timely.

Introduction

The issue of the regulation of medical education and doctors' practice continues to attract attention in India due to the ongoing uncertainty about the future of the Medical Council of India (MCI), the media attention sparked by programmes such as "*Satyamev Jayate*" and the subsequent reaction of the Indian Medical Association (1). Since 2010, various boards of governors (BOGs) have been established for short terms, and the ministry of health and family welfare established yet another one with effect from May 2013, with a term of six months (http://mciindia.org/). The lack of a properly constituted BOG and the continuing uncertainty are not helping to take forward the

much-needed programme of reform or to build confidence in the minds of both doctors and the public. The training and professional standards of doctors are increasingly coming under scrutiny. The public wants to know when and how doctors will be regulated, and how patients can be assured that their doctors are trained properly and practising ethically. Patients want to be treated with respect and dignity, and not be overcharged or treated unnecessarily. While there is no denying the fact that the current discourse is doing a disservice to doctors who have high professional standards and practise in accord with the Hippocratic Oath, the absence of an objective, independent and validated mechanism for assessing medical education, training and practice means that it is impossible to defend them and to reassure the public. This lends urgency to the need to address the gap in medical regulation in India.

This paper is based on my recent experience as a member of the board of the UK's medical regulator, the General Medical Council (GMC). It is a personal account and builds on my previous paper, which commented on developments in India (2) as well as on attempts to promote collaboration between the MCI and GMC over the past few years. The paper starts with a description of the work of the GMC, and goes on to assess its successes and the challenges it faces, in the hope that such an analysis may be of use to my colleagues who are involved in medical regulation in India.

The General Medical Council

In the UK, the fifteenth century saw the beginnings of an interest in medical regulation with the Royal College of Physicians finally starting the licensing of doctors in 1511. Driven by the need to separate qualified from unqualified practitioners to prevent "great harm and slaughter of many men." the discussions continued, until finally, the General Council of Medical Education and Registration of the United Kingdom (since shortened to the GMC) was established in 1858 through a Medical Act (3). Much work has been done since then and The Medical Act, 1983 provides the current statutory basis for the GMC's four main functions, which are to:

- keep the register of qualified doctors up to date,
- foster good medical practice,
- promote high standards of medical education and training, and
- deal firmly and fairly with doctors whose fitness to practise is in doubt.

The overall purpose of the GMC is to protect, promote and maintain the health and safety of the public by ensuring proper standards in the practice of medicine. It reports directly to Parliament and is funded by the annual retention fees paid by all registered doctors and examination fees. It is a registered charity. It should be noted that the GMC is a regulator for the whole of the UK and that given the differences between England, Scotland, Wales and Northern Ireland in terms of how the National Health Service (NHS) and health services are organised and delivered, the GMC has to find the right balance between UK-wide and country-specific areas of work.

The following is neither a historical, nor a detailed account and I strongly recommend that readers visit the GMC website (www.gmc-uk.org) to learn more. Rather, the paper focuses on some key and recent developments to inform readers about the background and help them understand the implications for the Indian situation. Each of the developments discussed merits detailed papers in its own right.

Often, the most visible element of the work done by the GMC relates to the doctor's fitness to practise. Over the last two decades, there have been changes in how this function is discharged, and four main developments are worth highlighting. One, the procedures earlier considered the concerns arising out of doctors' fitness related to health, conduct and performance separately, but now a more holistic approach has been adopted since these three dimensions sometimes overlap. At the same time, there is recognition of the aspects of sensitivities and confidentiality, especially in the sphere of health concerns. Two, given the tensions caused by the GMC's dual role as prosecutor and judge, attempts were made to compartmentalise these functions. This finally led to the establishment of a separate organisation, the Medical Practitioners Tribunal Service (MPTS), in 2011, to adjudicate the cases brought to it by the GMC. It should also be noted that patients can still pursue their complaints in the courts, and that the MPTS's final decisions can, and do, get challenged. Thus, there are safeguards in the system. Three, recognising that the GMC is part of a whole system which looks into issues related to doctors' fitness to practise (the other main bodies being the employers of established doctors and the deaneries for trainees), the GMC established the position of liaison advisors. These people were posted in discrete geographical areas and entrusted with the job of engaging all relevant stakeholders in dealing with problems promptly and speedily. Four, although purists would argue that revalidation (the GMC is the first regulatory body in the world to require all doctors to demonstrate that they are fit to practise and hence can hold the licence, every five years) is not about fitness to practise, which is invoked when things have gone wrong; the very fact of introducing revalidation means that there is now a much more proactive, rather than reactive, way of dealing with concerns regarding a doctor's practice.

The last point links up with another major area of work, ie maintaining an updated register of doctors. Over the years, the register has been repeatedly refined, both in terms of its content as well as online access to it, to make it more meaningful to employers, the public, policy-makers and the doctors themselves. Anyone can look up the register to find out whether his/her doctors are qualified or whether there are any matters of concern regarding them (although details regarding the latter are not available in the public domain). The register is proving to be a valuable resource for the purpose of manpower planning also. Like most other areas of work, it remains under regular review so that its utility and utilisation for various purposes can be improved.

Education is obviously a very important function of the regulator. The GMC has ultimate oversight of all education, from the Professional and Linguistic Assessment Board (PLAB) test for "foreign" doctors, to under- and postgraduate medical education, to continuing professional development for trained doctors. The GMC works closely with the Royal Colleges and Faculties, which provide the specialist input, and the medical schools and deaneries, which deliver or arrange for under- and postgraduate education. There are both proactive reviews and assessments of all stages of medical education, as well as reactive assessments based on reports of concerns identified either through surveys of training, for example, or by other regulators, colleges, employers and doctors. For example, the PLAB test is undergoing a review currently and there are plans to develop "credentialing," which is the "formal accreditation of capabilities at defined points within the medical career pathway that takes into account knowledge, capabilities, behaviour, attitudes and experience."

Of course, as a regulator, the GMC is involved in influencing health policy and developing guidance on medical practice. The most recent example of the GMC's influence on policy was its initiative to introduce English language testing for doctors from the European Union (EU) (the GMC is also bound by the EU rules). This step was taken in the wake of a tragic case (4), apart from other concerns. Of course, the GMC periodically reviews the Good Medical Practice (the "Bible" for doctors) to take stock of changes in health policy and the delivery of healthcare. It also provides guidance on major issues affecting doctors, such as around the care of patients at the end of life, or for doctors involved in management.

The GMC's work involves a great deal more, but for the purposes of this paper, I will mention just another area, which is the nature of its board (surprisingly called the council). The board has undergone major changes in recent years. The main changes are the reduction in the number of members from 104 to 35 to 24 to 12 starting in 2013; the equal numbers of lay and medical members now; the "appointment" of all members by an external body and not by "election" by medical members; and the appointment of the chairman by the external body rather than by election from among the appointed members. The latter is the most recent change. These appointments are for fixed terms.

A critique of the work of the GMC

The GMC is a much envied and valued regulatory body, both within the UK and abroad, and its perseverance in the matter of introducing revalidation has catapulted the organisation into the spotlight internationally.

As with many other aspects of regulation, the GMC has also been through major changes over recent years. Clinical quality, patient safety and regulation are relatively new concepts in the grand scheme of things, at least as far as explicit and formal approaches to such issues are concerned, and the GMC has had to change radically to fulfil its mission and generally keep up with the needs and demands of the whole host of stakeholders, including the government, the public and healthcare professionals. A few years ago, when the case of Dr Harold Shipman (the general physician who murdered over 200 patients) came up, there were serious concerns about the survival of the GMC. The confidence of the government, media and public had been shaken, and the GMC became a target for the "anger" engendered by the case. The failure of the GMC led to calls for its dissolution. This, in turn, acted as a stimulus for the GMC to become much more proactive and responsive. The introduction of revalidation and the move to introduce parity in the number of lay and medical members in the council are just two examples of the changes thus introduced.

In critiquing the work of the GMC, it would be worthwhile to focus on two dimensions: the work it does on its own and the work it does in its capacity as a part of an overarching healthcare system. The GMC has a specific remit in the sphere of doctors' education, training and practice, but increasingly, doctors are not working in isolation from other professions and, in any case, all professionals are part of the wider healthcare system.

Judging the GMC's effectiveness is, therefore, not an easy task. One has to decide on whose perspective one is viewing the matter from and which function one is judging. At the risk of oversimplification, one could say that there are two types of "independent" regulators in the NHS apart from the policy-makers and funders/commissioners who also look at how well (or poorly) the services perform. These are the professional regulators and the system regulators. There are nine professional regulators, including the GMC; the others being the General Chiropractic Council, the General Dental Council, the General Optical Council, the General Osteopathic Council, the Health Professions Council, the Nursing and Midwifery Council (NMC), the Pharmaceutical Society of Northern Ireland and the General Pharmaceutical Council. These are overseen by the Commission for Healthcare Regulatory Excellence (CHRE, now renamed the Professionals Standards Authority for Health and Social Care). The system regulators, which oversee the performance of healthcare organisations in terms of clinical quality and financial performance, include the Care Quality Commission and the Monitor in England. It is to be noted that systems regulation is very country-specific, and there are different arrangements in Scotland, Wales and Northern Ireland, whereas most professional regulators are UK-wide.

It would be no exaggeration to say that among the professional regulators, the GMC is seen as the leader in terms of the manner in which it works and constantly adapts to the changing landscape of healthcare. Moreover, it has provided leadership in professional regulation, something which the CHRE reports attest to (5). As for my assessment of the GMC's work, some of its very valuable functions, which it has fulfilled in an exemplary manner, are maintaining the register, setting standards for medical practice through the Good Medical Practice and providing policy guidance on important issues.

More work is needed in the areas of doctors' fitness to practise and of education. There has been a yearly increase in the

number of cases of "poorly performing doctors" being referred to the GMC and this is neither sustainable nor desirable. There is a need to examine how this whole issue is managed from the local level up to the national level. It could be argued that due to the easy access to the GMC, cases of "relatively minor" severity also end up before this body. Of course, all cases should be dealt with proportionately and speedily to maintain the public's confidence, but this would be better achieved if there were a seamless system of medical regulation from the local to the national levels. The introduction of the liaison advisors may prove to be useful over time, but there is a long way to go yet. In addition, there are continuing concerns about the inconsistencies in the sanctions awarded in cases of poor performance. These are most notable when it comes to the treatment of cases involving international medical graduates (IMG) who tend to receive harsher sanctions. The GMC could also be criticised for not being tough enough on figures in the establishment. This includes failing to take proactive action against medical directors or other senior doctors whose management performance has been found wanting. It is too early to comment on the possible (hopefully positive) effect of revalidation on the issue of poor performance of doctors. Finally, this may sound strange but there is also the issue of whether the bar is too high, ie whether the standards expected of doctors are unrealistic. The "zero-tolerance" mentality that has pervaded the NHS does not help anyone. Maybe there is a need for a discussion of what constitutes poor practice, but this is a thorny issue and it is hard to see how to promote the necessary debate, which is, after all, a societal issue.

Challenges will also be faced in the sphere of education – both under- and postgraduate – for various reasons. These include the changing health systems in general and the recent reorganisation of the NHS in England; the difficulties being faced in planning of the workforce; and the rapid changes in medical practice. Education/training is not keeping pace with the breathtaking speed at which medical and technological advances are being made. New challenges await the UK, with the possibility of the establishment of private medical schools, the established UK schools opening campuses overseas, and the royal colleges starting to offer their diploma examinations internationally. The GMC has not always been seen as being tough on medical schools. For example, until recently, there was hardly any example of a medical school being handed down serious sanctions, or of the GMC being able to comprehensively and systematically ascertain the fairness and quality of postgraduate qualifying examinations. Concerns have also been voiced over the possibility that colleges view postgraduate examinations as a source of income, with doctors in training having to pay high fees. There is no mechanism yet to try to determine the appropriate fees, an amount which would not place too much of a financial burden on doctors.

In my view, the problems facing the GMC are not necessarily related to how it goes about its own work, although there is scope for further improvement. The problems also arise from a lack of coordination between the professional and systems regulators. The recent publication of the enquiry into the care of patients at Mid Staffordshire Hospital shows how this lack of coordination is compromising the safety of patients (6). All the parties concerned – the GMC, NMC and systems regulators – were partially aware of the problem, but failed to come together in a timely fashion to tackle the situation. It will be interesting to see what happens in the next few years. My assessment is that a fundamental rethink on regulation is required in the NHS, which has swung from a "light" touch favouring self-regulation to a "heavy" touch leaning towards external regulation over the last two decades. A new model is necessary to keep patients safe; to ensure that doctors continue to be committed and do not retreat into defensive medicine or shy away from "challenging specialities"; and to see to it that healthcare remains affordable.

Generally speaking, the GMC must be credited with having played its part well so far, but it needs to find a balance between protecting patients and supporting doctors. It has yet to get the "right" touch – neither light, nor heavy – as far as regulation is concerned. Further, it needs to be seen as one part of the entire regulatory system, and not as the provider of solutions to all the problems facing the healthcare system.

Lessons for medical regulation in India

So what does the above mean for India? I do not know enough about what is happening with the MCI and in the sphere of medical regulation to be able to make detailed comments. However, I would like to offer the following in the spirit of sharing and helping. The reader may also wish to go through a report commissioned by the GMC that examined medical regulation in the 10 countries from which doctors come to the UK to work (7).

The most important lesson is that things do take time – the GMC did not achieve success overnight. It is over 150 years old and has had rough times during its journey. Also, the GMC sits within a national health system which is part of British society, and reflects the values and aspirations of that society including the medical profession. At the risk of being controversial and judgmental, the medical profession in India is neither ready, nor organised enough, to either provide leadership or be seen as sufficiently trustworthy to provide leadership yet. The debacle following the "*Satyamev Jayate*" programme, with the Indian Medical Association asking the actor, Aamir Khan, for an apology, shows how far behind the times the organised profession is. The reason I emphasise the organised profession is that I am well aware of the existence of many good doctors who are equally concerned about the issue as Aamir Khan and others. The article by the Medico Friends Circle is just one example (8). This lack of leadership by the organised profession is not helped by the apathy and inability of the policy-makers to take control and mandate a properly constituted and resourced medical regulator.

So, the most urgent task facing the country is the establishment of such a body. It is not necessary, or possible, to get everything right from the beginning, but it is absolutely essential to get some principles and values right. The new body should be independent, with properly appointed (not elected) members, including lay members. It should start with a modest yet

achievable programme of work. No one with a criminal record or who is not in good standing should be appointed. Independent evaluation and external scrutiny should be carried out by an internationally selected group, the members of which can act as critical friends.

With regard to the programme of work, I have four suggestions, as follows.

1. An up-to-date and ongoing system of registration of doctors should be established so that people can check the status of their doctors. Unqualified doctors should be separated from qualified ones, so as to create the right conditions for cleaning up the system. It would be useful to follow the GMC's model of charging an annual retention fee from all doctors (although I do believe that the GMC should moderate its costs).
2. A federal system should be established to deal with the issue of doctors' fitness to practise, with the states having operational responsibilities within a national framework. Given the rampant corruption in India, all efforts should be made to involve "clean" and well-trained people in such a system.
3. An equivalent of the Good Medical Practice should be developed to provide the national framework. A programme of ongoing national policy guidance on issues of importance to the medical profession can be based on this.
4. There is a need for a review of the current arrangements for monitoring medical colleges, given the scandals related to high fees, the absence of or limited faculty, and almost bogus degrees. The much-needed and planned expansion of medical colleges is a recipe for disaster, unless we sort out the current problems.

I am aware that these suggestions are not new, that there is no shortage of policies, and that the usual problem of implementation – a problem which has perennially plagued India – is what is holding things back. I could also be accused of ignoring other issues such as review of the medical curriculum or post-graduate education and training. However, there is a trade-off between trying to get a few things right, which might help one gain experience and confidence, and trying to do everything. I personally do not believe that India is ready for a comprehensive system of medical regulation yet and the suggestions made above should be seen as the first steps in a long journey.

In conclusion, being an Indian doctor in the twenty-first century is both a responsibility and a privilege. With almost one in six persons in the world being an Indian and the vast scale of health inequalities in India, Indian doctors have a huge responsibility. Equally, with almost 1.2 million doctors of Indian origin working worldwide and given the interconnectedness in the global village, it is a privilege to be able to share and work with like-minded colleagues (of whom there are many), and to try to make a difference in India and globally. The current situation in India is a lose–lose proposition; both doctors and the public are losing out. The bad doctors and vested interests are getting in the way of the good doctors who wish to reform the system to ensure affordable and quality care to the public. Putting our house in order, therefore, is a pressing issue and we urgently need to establish an effective system of medical regulation.

Note

This paper was commissioned following the publication of my reflections on working as a GMC council member (9). Among other things, I was a member of the UK Revalidation Board. The British Association of Physicians of Indian Origin had invited Dr Ketan Desai to visit the GMC in 2009 and subsequently, I took part in hosting the (then) MCI's visit to the GMC in 2010. I am often asked how I can be so positive about the GMC, given its track record in dealing with international medical graduates (10) and my answer is that just because it has failed in that regard (although attempts are being made to address racial discrimination), we should not dismiss its successes in many other areas. In any case, I also cannot see how the stark inequalities arising from the factors of caste, religion and financial status in India are any different, not that I condone either. It is important to try to change the system, but not destroy it. The views expressed here are personal. Any shortcomings are my own. Further details of my work are available at www.leadershipforhealth.com.

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