

# Regulatory system to promote the culture of quality at Indian medical schools: Are we doing enough?

HIMANSHU PANDYA, THOMAS CHACKO, CIRAJ ALI MOHAMMED

## ABSTRACT

The replacement of the Medical Council of India (MCI) with the National Medical Commission (NMC) was an important change in regulatory oversight to bring about transparency in regulatory procedures for improving quality of medical education and meeting the needs of healthcare in India. Similarly, due to globalization of medicine including migration of health workforce and desire to raise standards of medical education and healthcare, efforts have progressed well towards transnational regulation and establishment of an overarching body, which recognizes regulatory agencies for their adherence to good practices. We describe the global collaborative efforts to improve the quality of medical education by the promotion of accreditation through the recognition programme of the World Federation of Medical Education (WFME), the publication of the expert consensus standards across the continuum of medical education and the Guidelines for Accreditation of Basic Medical Education. We also highlight that many medical schools across the world have adopted the WFME standards and many regulatory and accrediting agencies have achieved recognition status. Based on appraisal of the NMC Act and notification on minimum standard requirements (MSRs) for medical colleges, we point out the gaps between the intent stated in the preamble of the NMC Act and the notification on MSRs. We recommend a way forward to develop a regulatory model and approaches that match NMC's stated intent and meet the requirement for medical schools in India to gain international recognition.

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## BACKGROUND

Quality assurance and accreditation of medical education, and models of regulation and regulatory practices, are important issues of discourse among medical educators.<sup>1–3</sup> The reasons are growth of medical education with many new medical schools; increasing opportunities for students to pursue education abroad and surge in migration of physicians, which requires that relevant stakeholders are well informed about the quality of education.<sup>4</sup> Most countries have a system of regulation, but regulatory authorities have different priorities. Recent

approaches emphasize patient safety and minimization of risks. Regulation ensures accreditation of educational programmes and enables setting and ensuring standards so that the graduates are competent for professional practice.<sup>3,5</sup>

There are different frameworks for regulation: professional self-regulation, physician-led regulation with wide consultation, professional–public partnership and external regulation; each with inherent benefits and drawbacks.<sup>1,3,5</sup> There are several models of regulation, but the common ones are process-based, principles-based, outcomes-based and risk-based, each having strengths and weaknesses; occasionally, a mix of more than one model might come into play.<sup>6–11</sup> Regulation faces challenges across the world according to the local context and model. Some factors influencing regulators are information revolution, changing roles of professionals, mass media, political and professional expectations, advances in medical sciences, changing disease pattern and societal expectations.<sup>1,12–14</sup>

## GLOBAL COLLABORATION TO IMPROVE MEDICAL EDUCATION

The International Association of Medical Regulatory Authorities (IAMRA), a membership-based organization of regulatory agencies, expects that regulatory authorities apply the following principles in regulation: accountability and acceptability, fairness, feasibility and affordability, materiality, transparency and openness.<sup>15</sup> There have been shifts towards transnational regulation and an over-arching regulatory body due to globalization of medicine.<sup>16</sup> The driving forces for international accreditation are: a desire to raise standards of education and quality of healthcare, provision of assurance that a doctor had satisfactory preparation in major domains of medicine irrespective of wherever training occurred and policy of Educational Commission for Foreign Medical Graduates (ECFMG) to admit graduates from appropriately accredited schools for postgraduate training in the USA after 2024. To satisfy this requirement, the physician's school must be accredited by an accrediting agency recognized by the World Federation of Medical Education (WFME).<sup>4,17</sup>

Formal worldwide collaboration to augment quality of medical education began with creation of the WFME in 1972. The current priorities of WFME are: the promotion of accreditation through the WFME Recognition Programme, raising the standards for basic and postgraduate medical education and continuing professional development through the publication of expert consensus of minimum and quality standards and maintaining the World Directory of Medical Schools.<sup>18</sup> A list of known accrediting agencies is maintained in the Directory of Organizations that Recognize/Accredit Medical Schools. Recognition status is awarded by the WFME to an accrediting agency working to internationally accepted standards and confers understanding that quality of accreditation of undergraduate medical schools is to an appropriate and rigorous standard.<sup>19</sup> The Guidelines for Accreditation of Basic Medical Education were published by the WHO and WFME in 2005. These guidelines shaped the ground for the 2013 WHO policy

Pramukhswami Medical College, Karamsad 388325, Gujarat, India  
HIMANSHU PANDYA Department of Medical Education

Believers Church Medical College and Hospital, Thiruvalla, Kerala, India  
THOMAS CHACKO Department of Medical Education

Manipal Academy of Higher Education, Manipal, Karnataka, India  
CIRAJ ALI MOHAMMED Centre for Continuing Education and Interprofessional Development

Correspondence to HIMANSHU PANDYA; [dr\\_hvp@yahoo.com](mailto:dr_hvp@yahoo.com)

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briefing on medical accreditation and the 2016 IAMRA statement on accreditation of medical education programmes, recommended as blueprint for the development of accreditation mechanisms and regulatory agencies.<sup>20</sup>

In 1990s, with the help of medical educators across the world, the WFME took the lead to develop standards of medical education at all levels in the continuum of medical education (basic medical education→postgraduate medical education→continuing professional development), based on good practices and systems that foster quality in education. These standards, first published in 2003, had broad representation in their formulation and embraced the concept of core minimum and quality development standards to bring developed and developing nations, generalized and specialized institutions and new and established organizations under the same system of measurement. The standards have been updated thrice (2012, 2015 and 2020).<sup>21</sup> With increasing appreciation of relevance of context in medical education, the WFME has published revised standards in 2020 to ensure that they are applicable globally in all cultures and circumstances. It has decided to move away from prescriptive and process-based requirements to a principle-based approach, which allows institutions to frame implementation of basic standards contextually within all areas of design, delivery, management and quality assurance of education.<sup>22</sup>

Standards relate to models of regulation and standards specified must match the model selected. Some regulatory bodies have policy statements related to good medical practice and ethical standards and behaviours expected of the medical profession. The presence of such a statement facilitates development of a principle-based system of regulation.<sup>23</sup> The WFME global standards provide a framework, but medical schools at any level of development might need to write specific standards to build on the WFME framework because countries and institutions have additional context-related requirements that are locally determined. Adapting global standards necessitates the development of consensus among various stakeholders keeping in mind local health needs identified by hard data generated locally. The use of shared standards is one way of ensuring that core knowledge, skills and attributes are achieved by physicians anywhere in the world.<sup>21,24</sup>

#### AGENCIES ENSURING STANDARDS OF MEDICAL EDUCATION IN INDIA

The National Accreditation and Assessment Council provides a general system of accreditation for higher education in India, and it is a voluntary option for institutions providing medical education, which are interested in improving the standards of medical education.<sup>25</sup> The Medical Council of India (MCI), the erstwhile regulator, provided a system of regulation specific and mandatory for medical schools in India. After a general outcry against its functioning, it was subject to scathing indictment by the Parliament and judiciary.<sup>26,27</sup> In March 2016, the Department-Related Parliamentary Standing Committee on Health and Family Welfare observed that the MCI as a regulator had failed its mandate repeatedly over decades and concluded that major institutional changes in regulatory oversight of the medical profession needed to be instituted urgently.<sup>28</sup> The Government of India constituted a committee to examine all aspects of the IMC Act, 1956 and suggest reforms, leading to an improved medical education system.<sup>26</sup> The Central Government replaced the MCI with the National Medical Commission (NMC) to bring about reforms in regulating medical education and practice.<sup>29</sup>

With the establishment of the NMC, healthcare in India is perhaps witnessing the most important change since Independence. Major structural changes in regulatory oversight are expected to have a potential to revolutionize medical education and healthcare in India. As a country with large number of medical schools catering to the undergraduate medical programme, these changes are likely to have implications beyond its borders. Whether the new regulator delivers on its promises will depend upon how effective and appropriate a regulatory system it puts in place.

#### *Situation analysis: The current status of regulation of medical education in India*

The World Directory of Medical Schools lists 3342 medical schools which are operational. The NMC lists 542 medical schools in India, nearly half of them managed by the private sector.<sup>30,31</sup> Challenges faced by the regulator in India are: the need to expand the system of medical education while maintaining quality, increasing private sector participation in providing medical education, effect of globalization and a country with diverse cultures and resources. Such challenges require the regulator to establish intelligence and risk-based systems that permit them to be proactive to prevent harm.<sup>12</sup> The MCI, a predominantly elected body under a professional–public framework, was replaced by the NMC, a predominantly external regulatory framework, in September 2020.<sup>28</sup> This shift is in line with the trends in international medical regulation wherein most regulators are moving away from self-regulation, which is seen as the profession protecting its own interests, to one that is partnership between profession, regulator and the public (co-regulation).<sup>1,3</sup>

The predominantly prescriptive model of regulation of the MCI focused on structures and functions of educational programme with detailed specifications such as number of teachers and hours allotted to subjects. It specified assessment and control processes to be undertaken, documented and audited, e.g. requirement of daily biometric attendance dashboard on medical school website and close-circuit television system with live streaming of classroom teaching and patient care.<sup>32</sup> Evaluation of an educational programme was relatively simple under this model, whether an institution met the listed requirements or not. The intervention at the end of an evaluation used to be an instruction to meet the requirements without discussion on alternative approaches.<sup>33,34</sup> The MCI emphasized uniform standards with exhaustive input and process standards for medical schools, resulting in minimal academic freedom and flexibility. These standards set out physical facilities, equipment and staffing structures among other things.<sup>35</sup> The MCI might have perceived that such detailed specifications of inputs were relevant throughout the country to ensure that stakeholders comply with specified standards of education. The assessment of educational programmes ended up as tick-box exercise. It is not prudent though to assume that only if the inputs were in order at a medical school, the doctors coming out from it would be competent.

Large tertiary care hospitals are no longer regarded as the best places for undergraduate learning, though essential for postgraduate training. Hospitals now provide technology and team-based care of complex conditions carried out as same-day procedures. According to the World Bank classification of countries into categories of income per head population, India is a lower-middle-income country.<sup>36</sup> There are educational resource issues in low-resource contexts requiring administrators

to explore ways of working effectively with available resources and improve the availability of resources. However, minimum standard requirements (MSRs) of the MCI would not allow sharing of resources by medical schools even in a city with more than one medical school. The cost of medical education in India thus became prohibitive due to infrastructure and human resource requirements. Countries such as China, Russia, Ukraine, Philippines and Nepal became popular destinations for aspiring doctors from India as the cost can be less than half of private medical schools in India.<sup>37</sup>

The match of curriculum to resources is integral to effective education with unlimited possibilities of adapting the curriculum and several ways of delivering an engaging and effective curriculum. There is no strong evidence that one curriculum design is better than any other. The WFME standard 2.1 for basic medical education requires a medical school to define the overall curriculum and not recommend any specific approach to the curriculum. The WFME standards encourage diversity of educational programmes to account for different educational, socioeconomic and cultural conditions.<sup>38</sup>

The preamble of the NMC Act states that the intent of the Act is to provide for a medical education system that ensures adequate number and high-quality medical professionals along with objective periodic assessment of medical institutions. While the NMC is expected to formulate policies for maintaining 'high quality and high standards' in medical education and make necessary regulations (section 10 subsection 1 clause a), the sections 24 and 25 of the Act emphasize MSRs for MBBS programme, postgraduate and superspecialty programmes.<sup>28</sup> Similarly, the preamble of the regulations on MSRs for undergraduate medical training emphasizes the need to define standards based on functional requirements, quality as the benchmark for new standards, optimization and flexibility in utilizing the available resources and new standards in terms of the new educational paradigm.<sup>39</sup> However, MSRs set by the MCI and now by the NMC have remained largely unchanged in spite of the changing healthcare scenario, or are at best 'cosmetic'.<sup>35,39</sup>

In the aforementioned context, it is obvious that the medical regulator in India has a long way to go and adopt approaches and models that match what is espoused in the preamble of the NMC document. The WFME standards offer a possible model framework to adopt especially due to its successful adoption worldwide for ensuring the quality of medical programmes and graduates they produce. Based on the WFME data, about half of the medical schools globally have adopted these global standards.<sup>21,24</sup>

Apart from the WFME standards for individual medical schools, the WFME has now strategically shifted to recognizing the regulatory and accrediting agencies in different countries to ensure a force-multiplier effect in the number of medical schools adopting good practices in medical education that are enshrined in the WFME standards. The WFME now also displays a list of regulatory agencies with recognition status and agencies currently applying for recognition under the WFME recognition programme. As of now, a number of accrediting agencies across the world have achieved recognition status.<sup>19</sup>

The MCI and now the NMC have invested efforts in national faculty development programme and curricular reforms under Vision 2015, with the establishment of a network of regional centres at medical schools for faculty development since 2009.<sup>40,41</sup> Perhaps the largest programme of faculty development for medical teachers ever undertaken worldwide, it has created a large pool

of faculty who are now oriented to implement competency-based medical education for the undergraduate medical programme. However, by continuing to follow the prescriptive model, the new regulator might fail to promote a climate for internally driven continuous quality improvement. There are indications that there is a lack of congruence between espoused values and values in actions of the new regulator. The situation calls for radical changes in the medical regulatory system to incorporate principles of continuous quality improvement.<sup>42</sup>

#### RECOMMENDATIONS: THE WAY FORWARD

There are medical schools in India whose performance is recognized as world-class. They are high-performing institutions in spite of being judged against uniform standards because they are guided by their own aspirations and values. The guiding principle of WFME standards is that institutions should not only set the minimum target level of achievement through basic standards to be met but also inspire quality improvement through the developmental standards to be met.<sup>21</sup> The theories of motivation suggest that targets ought to be challenging and requiring effort to meet them but should not be so far advanced of the organization that they appear to be elusive.<sup>43</sup> Targets need to be reviewed frequently to ensure that they are offering appropriate challenge and not distant dreams difficult to reach.

The WHO/WFME Guidelines for Accreditation of Basic Medical Education recommend that national standards be set at an acceptable international level.<sup>20</sup> The standards require that the medical school describe and justify the curriculum approach chosen by it and articulate processes in curriculum design, implementation and evaluation.<sup>38</sup> Standards intended for use across a large number of institutions should avoid specifying course content because detailed content could vary from place to place depending upon local health problems. Over-specification of content may curb innovations in teaching methods. Specification would be redundant if good process standards are specified that ensure relevant curriculum design.

The new regulatory model proposed by the NMC must therefore be informed by the prevailing viewpoints instead of persistence with the predominantly prescriptive model which has not served the country well.<sup>3,7-11</sup> The NMC should move away from the prescriptive and process-based model to a mix of principle-based, process-based and performance-based models.<sup>7-10</sup> Principles-based regulation identifies concept of good teaching practices leaving details of teaching practices to the individual medical school. Standards to be attained are written in general terms and assessment of quality of medical education is left to the judgement of external experts. Such an approach is more likely to foster innovation, uniqueness and quality improvement. The interventions at the end of external review focus on quality improvement. Availability of statement on good medical practice favours the development of a principles-based system of regulation. As a corollary to good teaching practices enunciated in 'competency-based medical education' for the MBBS programme, the NMC should publish guidance on good medical practice. In the UK, the document on outcomes for graduates uses a hybrid of a principles-based and outcomes-based model.<sup>44</sup>

In outcomes-based regulation, the regulator is concerned about what the graduate is able to do rather than details of the educational programme. Evaluation of educational programmes and institutions is related to assessment of performance of institutions. Intervention after an external review usually consists of identification of failure to achieve outcomes. One good argument

to specify an outcome without a process is to offer the institution the flexibility in how they proceed to achieve it. Ultimately, detailed outcome standards feed back to the process of education.<sup>9</sup> The Accreditation Council for Graduate Medical Education in the USA uses the outcomes-based approach in its evaluation.<sup>45</sup>

To conclude, the NMC should develop standards of medical education that are locally relevant but aligned to global standards, with an effective regulatory model that is collaborative and not punitive, transparent and not opaque. In line with the IAMRA consensus, and in view of globalization of medicine and medical education, the NMC should consider approaching the WFME for international recognition status rather than remaining isolated from international collaborative efforts in regulation. International recognition status of the NMC would be an indicator to all stakeholders that the quality of medical education in schools and programmes in India accredited by the NMC meet appropriate and rigorous standards.

*Conflicts of interest.* Dr Himanshu Pandya and Dr Thomas Chacko are members of the Executive Committee of the South-East Asia Regional Association for Medical Education (SEARAME), which is a regional association of WFME. The core purpose of SEARAME is to improve quality of medical education in the South-East Asia Region in strategic partnership with the WHO.

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