Although it would add words and therefore increase the length of the DoH, the guideline should identify such under-represented populations, with explicit mention of women.

In 2008, the US FDA abandoned adherence to the Declaration of Helsinki for foreign studies (7). But the rest of the world still looks to the DoH as the leading ethical guidance for research involving human beings. The WHO's ethics review committee is guided in its work by the DoH, in addition to the CIOMS international ethical guidelines. In my keynote address at the satellite conference, I noted that to continue to be timely and relevant, the Declaration of Helsinki should remain at the forefront of international ethical guidance for research involving human beings. In so doing, it can help to promote global justice in human subjects research.

References

1. World Medical Association. WMA Declaration of Helsinki- Ethical principles for medical research involving human subjects [Internet]. WMA;2008Oct [cited 2012 Sep 05].5p. Available from: http://www.wma.net/en/30publications/10policies/b3/
2. Macklin R. The Declaration of Helsinki: another revision. *Indian J Med Ethics*. 2009 Jan-Mar;6(1):2-4.
3. World Medical Association. WMA satellite meeting during the 11th World Congress of Bioethics: Thinking ahead – the future of the Declaration of Helsinki[Internet]. Rotterdam: WMA;2012 Jun 26[cited 2012 Sep 05]. Available from: http://www.wma.net/en/50events/20otherevents/10doh1/index.html.

3a. Wiesing U. The future of the Declaration of Helsinki: Introduction – remarks about the next revision[Internet]. Rotterdam: WMA;2012 Jun 26[cited 2012 Aug 27]. Available from: http://www.wma.net/en/50events/20otherevents/10doh1/Wiesing.pdf

3b. Macklin R. The future of the Declaration of Helsinki: Maintaining a leadership role in global health research ethics[Internet]. Rotterdam: WMA;2012 Jun 26[cited 2012 Aug 27]. Available from: http://www.wma.net/es/50events/20otherevents/10doh1/Macklin.pdf

4. European Medicines Agency. EMEA/CPMP position statement on the use of placebo in clinical trials with regard to the revised Declaration of Helsinki. [Internet]. London: EMEA; 2001 Jun 28[cited 2012 Sep 05]; EMEA /17424/01:[Available from: http://www.ema.europa.eu/ema/pages/includes/document/open_document.jsp?webContentId=WC500017646
5. Varmus H, Satcher D. Ethical complexities of conducting research in developing countries. *N Engl J Med*. 1997Oct 2;337(14):1003-5.
6. CIOMS in collaboration with the WHO. *International ethical guidelines for biomedical research involving human subjects* [Internet]. Geneva: CIOMS;2002 [cited 2012 Sep 05].113p. Available from: http://www.cioms.ch/publications/layout_guide2002.pdf
7. Kimmelman J, Weijer C, Meslin EM. Helsinki discords: FDA, ethics, and international drug trials. *Lancet*. 2009 Jan 3;373(9657):13-4.

IMA strike: need for public debate

B Ekbal

Consultant Neurosurgeon, Former Professor of Neurosurgery and Former Vice Chancellor, University of Kerala, Thiruvananthapuram 695 034 INDIA e-mail: ekbalb@gmail.com

The Indian Medical Association (IMA) called for a nationwide strike on June 25, 2012 to protest against the formation of the National Council for Human Resources in Health and the promulgation of the Clinical Establishments (Registration and Regulation) Act, 2010 The strike call raises two issues that need to be examined in detail: whether the opposition to the government legislation is justified from a professional and societal point of view, and whether it is ethically justifiable for doctors to go on strike.

The National Commission for Human Resources for Health Bill, 2011, was introduced in the Rajya Sabha on December 22, 2011, by the Minister for Health and Family Welfare, Ghulam Nabi Azad(1). It was referred to the Department Related Standing Committee on Health and Family Welfare under the chairpersonship of Brajesh Pathak, which is scheduled to submit its report.

Regulation of health education

The Bill seeks to establish a mechanism to determine and regulate the standard of health education in the country. It will repeal the Indian Nursing Council Act, 1947, the Pharmacy Act, 1948, the Dentists Act, 1948, and the Indian Medical Council Act, 1956, on such date as decided by the central government. It seeks to set up the National Commission for Human Resources for Health (NCHRH), the National Board for Health Education, and the National Evaluation and Assessment Council. It also establishes various professional councils at the national and state level and an NCHRH Fund to meet expenses.

The IMA feels that the decision to dissolve the Medical Council of India (MCI) and other paramedical bodies like the Nursing Council of India and the Dental Council of India and replace them with the NCHRH will be deleterious to the best interests of the medical profession. It argues that the NCHRH will be governed by bureaucrats instead of members of the medical profession; and that this will lead to vested interests controlling such bodies, and is also likely increase red tapism and lead to harassment of doctors (2, 3).

The IMA also argues that the formation of the NCHRH will lead to the centralisation of decision making in matters concerning medical education and the medical profession. Though there is a provision for the formation of medical, nursing and other

councils that were already in existence, the final arbiter of all decisions will be the NCHRH, taking away the autonomy of such bodies, making them practically irrelevant. Moreover, it argues, as health is a state subject in a federal set-up, it is not even constitutionally valid to appropriate the rights already given to the state government. The Bill is aimed at usurping the powers of states as it makes it compulsory for all medical professionals to register with the national council.

It should be conceded that the points raised by the IMA deserve closer examination. As regards the centralisation of decision making by the formation of the NCHRH, the higher education policy of the second UPA government is increasingly tilted towards the establishment of such centralised bodies. The Human Resource Ministry has already tabled a Bill to establish the National Commission for Higher Education and Research which will make bodies like the University Grants Commission irrelevant, and will nullify the academic autonomy of universities and other higher education institutions, for which reason it is being vociferously opposed by the academic community.

But the main objection of the IMA is with regards to the composition of the council. The IMA points out that there is no provision for the inclusion of professional bodies like the IMA in the council and hence the larger interests of the medical profession will not be protected. The IMA demands the nomination of its office bearers to these bodies.

It is not morally or ethically justifiable on the part of the IMA to make such a demand. In fact both the process of dissolution of the MCI and the move for legislation to establish the NCHRH were initiated because of the serious corruption charges against Ketan Desai, former President of the MCI. It is to be noted that Dr Desai was also a former president of the IMA and was nominated to be the next president of the World Medical Association (4).The unholy relationship between the mushrooming self- financing medical colleges and the MCI has been widely discussed in the media and also criticised by the Supreme Court. The IMA did not take a position against the corrupt practices of the MCI; instead it was a willing accomplice to the MCI's nefarious activities under Dr Desai. In fact, in several other instances of social importance, the IMA has taken public positions to protect the narrow "professional interests" of the elitist sections of its members, rather than the larger interests of society.

From a societal point of view, the government by bringing in the NCHRH may be attempting a bureaucratisation of academic bodies like the MCI which can be manipulated by a section of the corrupt political leadership. The strike call can be seen as a tussle between the elitist group within the IMA and the "interested" sections of the political leadership.

Regulating private medical services

The IMA's other concern was with regards to the Clinical Establishments (Registration and Regulation) Act, 2010, introduced by the government to regulate private clinics and hospitals(5). The Act envisages that no hospital or clinic can function unless registered in accordance with the prescribed procedure. In fact, the Act was introduced because of the relentless struggle by the Peoples' Health Movement in India for several decades, demanding regulation of corporate hospitals in our country. The Act includes provisions such as classification of various levels of hospitals as well as fixing minimum standards and responsibilities for them.

The health movement while welcoming the government move to finally come up with a law to regulate the private sector has also pointed out several lacunae and limitations of the Bill. Its key limitation is that the implementing, and especially the monitoring, agencies comprise only bureaucrats and governmental agencies. Independent observers from civil society organisations and health movements have been kept out of such bodies. Moreover, while even solo practitioners' clinics come under the purview of the Bill, the demand for effective regulation and social control of big corporate hospitals is not given adequate importance.

The IMA also points out the problems likely to be faced by solo practitioners once the law comes into effect. However, it mentions these problems only in passing. Its major concern is the government's move to control private hospitals. The IMA rejects the very need for regulation of private hospitals on the ground that existing laws such as the Consumer Protection Act, the Indian Medical Council Act and the Indian Penal Code are sufficient. The IMA suggests, in the place of the Bill, accreditation which will "retain the independence of this vital sector and ensure quality", and demands that healthcare institutions run by doctors be exempted from the purview of the Bill. It is to be noted that in India recently there has been a spurt in the number of corporate hospitals being established by doctor families or groups of doctors. It is obvious that the IMA is not comfortable with the very idea of regulating corporate private hospitals in our country. Obviously it feels that though the Bill does not have stringent rules to control corporate hospitals, even provisions to control solo practitioners, if left unopposed, may later lead to social control of corporate hospitals; hence the "nip the problem in the bud" attitude.

It is to be conceded that both legislations on the anvil need wider discussion, not only by professional bodies but also by civil society organisations, such as the People's Health Movement and other stakeholders. In fact, the IMA has also pointed out the need for a wider discussion on the possible implications of the Bills. However, without putting enough pressure on the government to initiate such a discussion, the IMA unilaterally resorted to a nationwide strike by doctors, resulting in the avoidable suffering of hapless patients.

Ethics of doctors going on strike

The ethical and moral implications of doctors and other health workers going on strike to get their demands approved by governmental agencies have been discussed many times in various countries, including India (6,7). Historically, strikes have been resorted to primarily by industrial workers when they have no reasonable way of getting their share of the wealth generated. Workers must resort to strike as a form of coercion directed against their oppressors, the factory owners. The employer is then faced with the threat of financial damage, since strikes disrupt the production process, and may concede -- partly or wholly -- workers' demands for salary revision and improvement of their working conditions.

In the case of doctors going on strike to press for their demands, the situation is qualitatively different. The strike is not, in any way, going to affect the interests of the political leadership or the functioning of governmental agencies except a few government hospitals. However, it will adversely affect the best interests of a third party. These are patients, whom doctors have vowed to protect, and who represent the weakest and most vulnerable sections of society.

When doctors go on strike, the harm that patients may face includes delays in treatment, prolongation of suffering, irreversible damage to health, dangerous drug interruptions and even death. Other financial implications such as work loss, or wasted money for transport, may also affect patients and their relatives. The patient-doctor relationship is unique in that doctors are duty bound to follow a fiduciary role in protecting the interests of patients under their care. Hence a strike action by doctors will breach the implicit social contract between doctors and patients; it will also negate the doctors' publicly declared commitments to service codes and the principles of medical ethics.

Recent sporadic strikes by medical professionals have been largely confined to minor sections of the medical profession such as junior doctors, internees or post graduates. The IMA is a larger body, including in its fold all doctors without any distinction. Any strike by the IMA, if followed by its members, will result in the paralysis of healthcare in our country. Though the IMA stated that "emergency services" would not be affected, the details were not spelt out clearly. "Emergency services" usually means casualty services, but even inpatients may require emergency help and any medical procedure postponed or delayed because of the strike can have very serious implications for patients.

Responding to civil society

Unfortunately, the IMA has always been hostile towards conscientious members of the profession who have taken the initiative to point out the ethical implications of doctors going on strike. In 1987, in Kerala, the IMA declared a total strike, by doctors, including casualty services. This author and 12 other doctors issued a signed statement expressing our disapproval of such a move, pointing out the human suffering that results from such a strike. The IMA's state office bearers immediately expelled this author, who was the first signatory, from the organisation.

On several issues like the relationship of medical professionals with the pharmaceutical and equipment industries, unethical drug trials, and unethical medical practices, the IMA has never taken the initiative to respond to the debates initiated by civil society organisations, nor taken an ethical stand on such issues. The IMA should realise that the impact of such legislations and issues related to medical practice are not confined to the medical profession alone; they have implications for society at large. The IMA should engage with civil society organisations and movements to debate such issues and arrive at a consensus, taking the larger interests of society into consideration. The government, on its part, should now initiate a debate, ensuring participation by all concerned, regarding the implications and provisions of the proposed legislations.

References

1. The National Commission for Human Resources in Health Bill: 2011: Bill No: LIX of 2011[Internet]. Ministry of Health and Family Welfare: Government of India: New Delhi: 2011[cited 2012 Sep 2]. Available from: http://164.100.47.5/newcommittee/press_release/bill/Committee%20on%20Health%20and%20Family%20Welfare/nationl%20com%20humn.pdf
2. Agenda B: Issues for Discussion and Deliberation: 207th IMA Central Committee Meeting, Mumbai: 2012 Apr 22(cited 2012 Aug 31) Available from: http://www.ima-india.org/downloads/Agenda-B-Topics%20for%20discussions%20and%20deliberations.pdf
3. Reasons for medical strike: Indian Medical Association [Internet]. 2012 Jun 22(cited 2012 August 31). Available from: http://www.amcmumbai.com/manage/files/160Microsoft%20Word%20-%20strike.pdf
4. Nagral S. Doctors in entrepreneurial gowns. *Econ Pol Wkly*. 2012 Sep 8; 47(35):10-2.
5. The Clinical Establishments (Registration and Regulation) Act 2010, No 23 of 2010: Ministry of Law and Justice. New Delhi ;2010 Aug 19.
6. Glick SM. Physicians' strikes- a rejoinder. *J Med Ethics*.1985 Dec;11(4):196-7.
7. Ogunbanjo GA. Doctors and strike action: Can this be morally justifiable? *SA Fam Pract*. 2009;51(4):306-8.