EDITORIALS

Can ethics committees address society's concerns about standards in research?

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Two years ago in an editorial (1) we discussed the importance of bringing the spotlight onto the functioning of ethics committees (ECs) in India. Since the first ethical guidelines for biomedical research were formulated by the Indian Council of Medical Research (ICMR) in 1980 (and their subsequent versions in 2000 and 2006), India has officially adopted a decentralised system of ethics review and monitoring of biomedical research by institution-based ECs. We expressed serious concern on the lack of any oversight over these institutional ECs by the Drugs Controller General of India (DCGI), the legal regulator of drug research, and the ICMR (which is also the department of health research of the Government of India), the original proponent of this system. We had opined that "the present decentralisation of clinical trial governance is a highly irresponsible decentralisation of governance, exposing the legal regulator to the criticism of effectively abandoning its obligations to regulate" (1). We had also pointed out that ECs have become enigmas, with very little known about their functioning and their competence to discharge their duties. We had given a call to all those involved in the ethics review of biomedical research to make ECs more transparent, to conduct research on them and to critically assess the system. Since not enough research on them was coming out, we had exhorted members of ECs to break their silence by sharing their experiences.

We are happy to learn that in last two years there has been increasing discussion and sharing of experiences and views on the pages of *IJME*. We were able publish a special section titled "Ethics in Ethics Committees" twice, each time with three contributions. Besides, our sections on commentaries and discussion have covered some major controversies in ethics in biomedical and public health research; the Gadchiroli trial and the HPV vaccine demonstration project are two major examples of this.

Special issue on ethics committees

We are happy to take the discussion forward in this issue by publishing a collection of five papers on the subject, making it a special issue on ethics committees. All credit for bringing together this collection goes to Prof Silke Schicktanz and Prof Michael Dusche who have guest edited this collection and also written a thought provoking introduction to it. Our readers will be immensely benefitted by this collection in two ways. First, it provides a history, situation analysis and reflections on ECs in Israel, Bulgaria and India and also on the international situation in the report on the 8th Global Summit of National Ethics Committees in Singapore in July 2010. Clearly, the EC as a system for rigorous and appropriate ethics review is facing serious challenges (and perhaps a crisis) not only in India but globally as well. The historical and empirical information provided by these papers should make all of us reflect on whether the weaknesses of the EC system lie only in "not doing it right" and in the paucity of trained ethics experts. Are the weaknesses more in the fundamental assumptions, both theoretical and systemic, on which the system is established?

The second strength of the collection is that it also provides some deep philosophical and political reflections on the fundamental assumptions on which the EC system for ethics review of research is established. Are ECs meant to simply regulate research? Surely, legal experts and human rights activists would like to look at it that way. But then, on whose behalf is this regulation of research being done? The first objective of most ethics guidelines would say that it is for the protection of research participants. To put it in plain, political terms, participants are citizens, diseased or not diseased. And thus, ECs are actually there to work for these citizens, for their protection and welfare. In that case, by getting citizens and their representatives to work on their behalf, ECs ought to effect or create a process of democratisation of science or research; and empower citizens. Interestingly, at the ground level, ECs are anything but representatives of citizens. While the guidelines talk about the independence of ECs from their appointing bodies, the institutions, they hardly ever mention their "dependence" on citizens and give them fair, if not dominant representation. Our experience of work in ECs suggests that the ECs are, in fact, most dependent on the institutions from which they are supposed to be independent; we still have to see an EC that regularly goes to research participants to get their views, let alone being open to inviting some of them into their midst. This situation exposes ECs to the criticism of being bodies of experts, reviewing scientific protocols of experts for the furtherance of the work of experts. Indeed, the ECs are more complex entities than has hitherto been understood in our country. For us the challenge is to understand whether they have the potential to be vehicles of democratisation, or at least to make science and research transparent and accountable to the people.

Another point for reflection is provided in a paper that proposes a four-stage deliberative democratic process for formulation of ethical standards and, thus, ethics guidelines. The paper emphasises the process of deliberation, not just with scientists and the health professionals (the "experts"), but also with the people, particularly the marginalised and vulnerable communities, who are used the most in research. This does beg a few questions for India. Indian society has multiple languages, religions, ethnic groups and so on. What would be the best process and method to elicit the views of these different groups on various ethics standards? Would people be more interested in having elaborate rules on informed consent and privacy, or would they like more practical and achievable rules for, say, post-trial access of the drugs that are tested on them? Interestingly, our guidelines pay lip service to ethical standards using more rhetoric when it comes to post trial access. We are sure that ethics committee members would agree that there is very little available in these guidelines to operationalise post-trial access at the micro-level of the institution where research is conducted. In essence, would such a deliberative process, if made workable and adopted with all sincerity, turn the priority we accord to the ethics standards upside down?

Changing scenario

The period since 2000 when the ICMR released ethics guidelines is marked by two, relatively separate developments. One, occurring among scientists and ECs, is moving slowly, while another, involving people and civil society, is gaining momentum. Scientists as a community (there are many individuals who are honorable exceptions, but are in a minority) are taking their own sweet time to acknowledge, let alone be strict about implementing, ethics standards in their work. They often find it difficult to incorporate ethics into their research process as they have got used to the old way of functioning. Yet there is a perceptible change, and that is in terms of moving away from the denial that ethics is important in research, though this on its own may not translate into a change in behaviour. On the other hand, some ECs have started taking their work seriously, and there is an increase in their knowledge about procedures and guidelines, as shown in the study on ethics committees in India in this issue.

But all of them are still very slow processes. What is overtaking them very fast is another process reflected in the increasing activism on biomedical research in civil society, media and sections of people. Unlike the ECs that are entrusted with the job of contributing through a positive approach in the improvement of observance of ethics, this process is driven more by "negative happenings" or ethical violations. This is very natural. Like human rights, ethics becomes publicly more visible because of ethical violations. Interestingly, as ethical violations are publicly more debated, the demand for more and stricter regulations grows, and ECs which were so far spared in public campaigns may increasingly find themselves in the eye of public controversies.

We hope that the arguments and empirical material presented in this special issue, combined with the consciousness that there is increasing public pressure for accountability and participation, will motivate many among us to reflect on the system and governance of research ethics.

Reference

1. Jesani A. Ethics in ethics committees: time to share experiences, discuss challenges and do a better job. *Indian J Med Ethics*. 2009, Apr-Jun; 6 (2): 62-3.

Inclusion of ethics matters in the undergraduate medical curriculum

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Ethics is now at the centre stage of medical education and calls to intensify its formal teaching in the curriculum are getting louder (1, 2).

In the past, ethics was often given short shrift in the Indian MBBS curriculum, and consigned to a few forgotten pages in textbooks of forensic medicine. These mostly dealt with legal ethics; clinical and research ethics hardly ever found their way into classroom teaching. Students were expected to imbibe lessons in ethics from their seniors and learn to solve medical ethical dilemmas on their own. Unfortunately, all too often, their role models fell short of their expectations and there was a chasm between what was preached and what was practised (3).

Nevertheless, there have been glimmers of hope with formal ethics teaching being introduced in institutions like the St John's Medical College in Bengaluru (4) and universities like the Rajiv Gandhi University of Health Sciences (RGUHS) and the Maharashtra University of Health Sciences (MUHS). As I write, a mammoth churning exercise is being carried out on the directive of the Board