EDITORIAL

Ethics in ethics committees: time to share experiences, discuss challenges and do a better job

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In August 2008, a report in the *Bulletin of the World Health Organisation* on ethical concerns about clinical trials in India quoted CM Gulhati, editor of the *Monthly Index of Medical Specialities,* as saying: "Fewer than 40 ethics committees in India are properly constituted and functioning." (1) While there is evidence that in terms of numbers, many more ethics committees exist, Dr Gulhati may not be too far off the mark in his claims on their proper and competent functioning. A search on PubMed (March 22, 2009) for the keywords "India" and "institutional ethics committees" produced 42 hits, of which nine were essays from the *Indian Journal of Medical Ethics.* All the articles were descriptive essays. None of them mentioned the number of ethics committees (ECs) in the country or assessed their functioning. There was not even one comprehensive review.

In 2002, the Indian Council of Medical Research (ICMR) conducted a survey of 149 ICMR-supported ongoing clinical research/trials in 71 institutions but interestingly, despite the ICMR being the funder, only 36 institutions responded. While all 36 claimed to have institutional ethics committees (IECs), only 23 had standard operating procedures in place for their review functions and only 14 claimed that they had trained IEC members in research bioethics. Besides, of 149 research projects analysed in this study, only 107 (72%) researchers had furnished IEC clearance certificates. Of 107 IEC certificates, only 37% were issued on the IEC's letterhead, 43% did not mention the name of the researcher, only 73% provided the date of the IEC meeting but only 18% provided the venue and time (2). Unfortunately, the full report of the survey is neither published nor available in the public domain, though the media has reported its summary findings (3).

While we must give full credit to the ICMR for at least making some efforts to assess the situation at the ground in institutions undertaking ICMR-supported trials, there is no independent assessment of the ethics review and its quality in other institutions. Despite a massive increase in number of clinical trials, the website of the Drugs Controller General of India (DCGI) contains no information about the number of trials it has approved (4). In November 2008, an official of the DCGI was quoted as saying that about 100 clinical trials received approval in 2005, going up to 150 in 2006 and 240 in 2007 and "In the current year around 450 have already been approved." (5) It is safe to assume that the number will go up further in 2009. If there are more than 500 clinical trials running in India today, and each trial has multiple sites, we may need to account for the functioning of thousands of ECs and the competence of several thousands of committee members.

Thirty years of ethics committees

Officially, institutional ethics committees (IECs) are 30 or more years old. The first official ethical guidelines for the establishment of ethics committees in all "medical colleges and research centres involved in clinical research" were released by the Central Ethics Committee of the Indian Council of Medical Research (ICMR), popularly known as the Justice H R Khanna Committee, in February 1980 (6). The 1980 guidelines included recommendations on membership criteria and ethical standards for review. They also asserted that ethics committees "must be independent" and, in order to empower them as regulators, made a commitment that "the Council would not consider support for any proposal for research on human subjects unless the research proposal has been approved by the ethical committee of the institute concerned". Unfortunately these guidelines are not easily available in the public domain, thus creating the mistaken impression that the governance structure for institutional level ethics review was started only with the release of the ICMR's guidelines of 2000 which were revised in 2006 (7,8).

Since the ICMR guidelines are not legislated, ECs do not have the power to punish those who violate ethics in clinical trials. At the same time, they are not merely ethics advisors and facilitators of clinical trials. The EC's power to conduct an ethics review, including the power to reject trials not conforming to ethical standards laid down in the ICMR's ethical guidelines, flows from the legal requirement wherein the DCGI provides clearance to clinical trials only on the condition that they will be reviewed and certified by an EC. Therefore, ECs not only reflect on ethical aspects of research, they also play the role of ethics regulator for the DCGI.

Ironically, though the DCGI fully depends on ECs for implementing ethical standards in clinical trials, there is absolutely no direct linkage of any kind between the DCGI and ECs. The DCGI neither cares for the proper functioning of ECs nor assures their competence–these tasks are left to institutions which have a direct interest in trials. The legal regulator has no idea how well

the ethics regulator is working–or whether it is working at all. Thus, 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.

Further, ECs do not report to an independent public authority that is responsible for supervising these committees and ensuring their proper and competent functioning. Nor is their expenditure financed by public funds. Thus they are, in reality, either self-sufficient private bodies obliged to the institutions or independent private entities charging for their services. There is no transparency of their functioning and no public scrutiny of their review and regulation of clinical trials. So, more than 30 years after the first one was set up in India, ECs remain an enigma.

Breaking the silence

While little is known about the bulk of ECs in India, many of us know a little about some of them as their members or close associates. In the last decade I have been involved in the formulation of ethical guidelines (for social science research in health) and as a member of at least six ECs. Many readers of this journal must have also either served on ECs in the past or may be their current members. All of us have some understanding of how they function and have contributed in making them effective while at the same time being acutely aware of their limitations. We have worked with commitment to protect research participants and improve the quality of research. As individuals we have also helped each other when faced with difficult choices in ethics review and counselled each other when we made mistakes or felt frustrated.

Yet, there is hardly anything substantial available on the functioning of ECs and on the problems and dilemmas faced by their members. Barring the rare exception, even the best intentioned ECs have not put a comprehensive report of their functioning in the public domain. While research bioethics training has increased in the country, no EC has come forward to allow its meetings as practical training ground for trainees.

Why is it that even 30 years after ECs were first established in India, we do not have even experiential accounts (let alone systematic studies) on ECs in the public domain? Why have EC members not narrated the challenges and dilemmas they have faced, and discussed how to make regulations effective? Would doing so compromise the confidentiality of research and the ethics review process?

Unless committed individuals find ways of speaking out on EC functioning, ECs will continue to function as secret societies unaccountable to the public and with poor public credibility. While specific information related to projects and individuals may be confidential, this is not true of the ethics review process itself–the ethical challenges and dilemmas faced, and the methods used to resolve them in ECs. I strongly believe that those involved in ethics work have an ethical obligation to speak out, in public, without breaking confidentiality. Such a process will not only strengthen and improve ECs; it will also result in advocacy that could improve the general governance of clinical trials in the country.

We call upon ethics committee members to start systematic exchanges on this subject in the pages of the *Indian Journal of Medical Ethics*.

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