REPORTING ETHICAL PROCESSES IN INDIAN JOURNALS

Reporting on ethical processes in two Indian pediatric journals in this issue of Indian Journal of Medical Sciences, Bavdekar et al.\(^1\) have concluded that a significant proportion of articles published in these two journals have not provided information regarding obtaining of ethical approval, written informed consent, and assent; and imagine, I am asked to write a commentary on this article (or defend myself), being the editor-in-chief of one of the journals in question!

Bavdekar et al.\(^1\) have raised a valid issue, and their findings are in conformity with studies from the rest of the globe indicating that the problem is not limited to Indian journals alone. On a positive note, I am rather happy that ethical clearance is reported for more than one third of the prospective studies, despite the fact that the authors were not being guided by the journals on reporting of ethical processes. I am sure that once journals take up these issues and incorporate them in their instructions to authors, reviewers’ pro forma sheet, and checklist for authors, matters will improve. But till then, who is to be blamed for the current dismal reporting of ethical processes: editors, who publish these studies without verifying whether ethical approval and written informed consent/assent was taken or not; reviewers, who do not give appropriate importance to this important information while sending their recommendations; or the authors, who fail to obtain/report the desired ethical permissions? Everyone will have one or the other excuse [Figure 1]

I agree with the authors that the results can be extrapolated to other biomedical journals in India. However, one of the major limitations of the study was that the individual authors were not contacted to determine the reason(s) for nonreporting of ethical processes. This mattered a lot. It would have not only documented the discrepancy between what was done and what was reported but also the reasons thereof. Absence of a statement does not automatically imply that consent was not taken. Many a times due to shortage of space (for example, letter to editor) or ignorance of writing style, this may not be mentioned. On the other side (for manuscripts which reported adherence to ethical processes), it was also important to determine whether the process of such reporting in itself was ethical or not.

FIGURE 1: Excuses offered for lack of reporting of ethical research

MISSED OPPORTUNITIES

There is a lack of exposure to culture of reporting medical research (ethics, in particular), starting right from the undergraduate days in the medical school. Even later, such opportunities are far and few in between. As a result, most of the researchers in India are ill informed about, and poorly equipped with, the process for obtaining ethical clearance, access to tools for taking consent, and requirements for assent, etc.

During undergraduate days, though a medical student learns about medical ethics, consent, and assent while studying forensic medicine, there is hardly any emphasis, during clinical training, on its application. Also, students are not supposed to do research. In fact, it is discouraged; an undergraduate medical student I closely knew drew up a research project, only to be told by the concerned authorities, “This is not your job, you only study, write the exam, get the degree, and then do whatever. No wonder, the flowers don’t bloom. A laudable initiative is the Indian Council of Medical Research (ICMR) Student Fellowship that promotes research by medical students and also exposes them to the tools of research methodology, including ethical considerations. However, the proportion of students applying for and ultimately executing such research is very low, compared to the total number of medical undergraduate students in India.

Every postgraduate student is supposed to write a dissertation/thesis before the degree is awarded. Most of the time, the protocols are presented, discussed, and approved in departmental/institutional meeting and ethical clearance is presumed. There is no formal approval of the institutional review board (IRB), because the IRB either does not exist or remains nonfunctional. Of the more than 250 medical colleges in India, not more than 20 (a rough estimate) have a properly constituted institutional advisory board/ethical committee
The registration of clinical trials will help improve reliability of data generated, help clinicians interpret research, minimize duplication of trials and prevent exposure of volunteers to potential risks.[1] The Clinical Trial Registry India (CTRI; www.ctri.in) hosted at the National Institute of Medical Statistics (NIMS), Indian Council of Medical Research (ICMR), New Delhi, was formally launched on July 20, 2007. This is a free online registry of clinical trials established with the aim to encourage all clinical trials conducted in India to be prospectively registered before the enrollment of the first participant and to disclose details of the 20 mandatory items of the WHO International Clinical Trials Registry Platform (ICTRP) database and a few additional items.[2] Thus, the CTRI becomes a WHO’s ICTRP and ICMJE compliant Primary Register for India. Clinical trial has been defined by the ICMJE.[3]

Within about 3 months of its launch, the response received has been overwhelming with over 90 clinical trials already registered. But registration of trials is just a beginning. Active steps are on to sensitize researchers who actually conduct trials, funding agencies, ethics committee members, pharmaceutical companies, health professionals and medical journal editors on the need to register all trials that need registration. The WHO’s ICTRP and ICMJE have drawn up clear guidelines on these issues.[4-6] However, only prospectively registered clinical trials will be considered for publication.

While participants of clinical trials volunteer with an altruistic motive, it is too obvious that all is not well in experiments involving human subjects.[7] There have been reports that trials have failed in their objective to carry out experiments fairly, report honestly and follow the ethical principles in India and abroad.[8] There have been several instances of selective reporting or not reporting at all, depending upon the outcome of the trial and when financial interests are at stake. Despite best efforts to ensure transparency and honesty, most initiatives to discourage the conduct of unethical trials have largely been unsuccessful.

Attempts to regulate clinical trials through system of record keeping at a public registry that would provide access to data on trials being carried out have not been very successful, as trial registration is voluntary and there is reluctance of pharmaceutical companies to disclose data. As a step to ensure complete awareness of trial details, the ICMJE proposed comprehensive registration for clinical trials submitted for publication for the 12 member journals [Annals of Internal Medicine, British Medical Journal, Canadian Medical Association Journal, Croatian Medical Journal, Journal of the American Medical Association, The Dutch Medical Journal (Nederlands Tijdschrift voor Geneeskunde, INDIAN JOURNAL OF MEDICAL SCIENCES 131 132]

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