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Strengthening ethics of ethics committees in India

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It is often said that the ethics committees (ECs) in India are mushrooming in numbers, but not all are functioning properly. Chatterjee[1] referred to the existence of less than 40 ethics committees that function properly in India. There are only two institutional ethics committees in the country (Ethics Committees of Seth G. S. Medical College and Tata Memorial Hospital in Mumbai) accredited by the Forum for Ethical Review Committees in the Asian and Western Pacific Region (FERCAP) under its Strategic Initiative for Developing Capacity in Ethical Review (SIDCER) recognition programme[2]. Recently, the Indian Council of Medical Research (ICMR), New Delhi, in collaboration with FERCAP organized a symposium on human subject protection course followed by a training programme on developing standard operating procedures for ethics committee members at the Sanjay Gandhi Post Graduate Institute of Medical Sciences (SGPGIMS), Lucknow, where 13 ECs participated, indicating a rise in their number. This exercise was undertaken as a part of the programme to accord recognition to the ethics committee at SGPGIMS and questions raised were related to how its functioning can be monitored, whether the selection of members was done in conformity with the ICMR guidelines[3], and whether it was monitoring clinical research projects efficiently. It is being gradually realized that unless proper monitoring is done an EC will not ensure compliance of an approved protocol. While questions are being raised about the functioning of ECs in developed countries[4] and reforms are being proposed[5], it is time for introspection in developing countries as well. This has been further necessitated by a recent report on the criticism of ethics surrounding the human papillomavirus (HPV) vaccine project[6].

ICMR guidelines consider competence and independence as the hallmarks of institutional ethics committees (IECs). The competence relates to expertise in the committee and independence is concerned with freedom accorded to take decision without any coercion. In India, there is no structured information available on these aspects of ECs. The European Forum for Good Clinical Practice (EFGCP) has brought out a report on research ECs in Australia, Brazil, Canada, China, India, Japan and USA, now available on its website[7]. This report was uploaded in July 2010 and addresses information regarding 12 carefully planned questions on the functioning of ECs in the countries mentioned above. There are two major aspects of ECs, namely constitution and mode of functioning. In India, there is no collective information about ECs in the public domain. A recent report from Clinical Trial Registry India (CTRI) revealed that there is lack of awareness on regulatory processes, especially related to ethical review and many institutes have no ECs[8]. ICMR, in collaboration with the World Health Organization, conducted a survey of ongoing clinical research/trials in 71 institutes in 2002. Thirty-six institutes responded and each reported having IECs and 24 also had separate scientific review committees. Standard operating procedures were in place for review procedures in 23 IECs and 14 claimed that they had trained members in research bioethics[9]. The expertise requires having members with training in identifying and resolving the ethical issues that are becoming complex with newer scientific advances. Therefore, there is a need to define training level for such labelling of ethics expertise. The following questions remain unanswered and need immediate attention in the light of the controversy surrounding ethical issues of the HPV vaccine study: what should be the minimal expertise level? Is certification by attending an ethics workshop sufficient for complexities encountered in ethics review or continued updating is essential? How does one decide on updating modalities? Are such facilities available to EC members easily and do they have enough interest to devote their time?

The Drugs Controller General of India (DCGI) has stake in adequate EC functioning and depends primarily on ECs for implementing ethical standards in clinical trials. Schedule Y implemented by the DCGI is proposed to be further amended – with the introduction of Schedule Y3, wherein research ECs overseeing clinical trials in the country will have to be registered with the office of the DCGI, as also reported in the EFGCP report (www.efgcp.eu).

Streamlining the ethics review

Each country should have its own mechanism to improve the functioning of ECs, and the institutes involved in health research must send a strong message to

society and individuals that they are committed to conducting research of the highest quality and that protecting participants is a top priority. The role of individual ECs may vary and may reflect specific requirements. This is further compounded by the fact that in India the same ECs have to review clinical research and clinical trials. However, clinical trials are regulated by DCGI at the central level also and has legal empowerment through schedule Y, but the regulation of all clinical research in India is governed at the local level by ECs observing ICMR guidelines. The responsibility of ECs at the local level extends beyond the initial review, i.e. to oversee the compliance of safety procedures throughout the conduct of the study. This requires functioning of ECs at a higher level without encroaching into the freedom of clinical researchers. The major issue in streamlining the EC functioning is the variability in stringency of ethics review in evaluating projects, and this calls for uniformity in assessing the research projects involving human subjects[10,11]. It would be appropriate if proportionate ethics review, despite its inherent difficulties, is undertaken, which should preferably be based on identifying the level of risk involved in research and improving the communication/comprehension of consent to be obtained[12,13]. Although ICMR guidelines require each EC to have a standard operating procedure for proper functioning, the guidelines do not suggest any mechanism for compliance. Therefore, there is a need for quality assurance through accreditation. Christina Torres, the programme coordinator for FERCAP emphasizes that accreditation programmes should be undertaken by the country itself and till then WHO and FERCAP are supporting it[14]. In India, the FERCAP–CIDCER programme for ethics committee recognition is still an optional activity and only two ECs accredited, including those from Seth G. S. Medical College, Mumbai and Tata Memorial Hospital, Mumbai. Meanwhile, the ethics committee of SGPGIMS was accredited in November 2011, making it the third such committee now.

Conclusion

The movement towards IECs in India is still in its formative stages, but represents the development of a dynamic process to address complex issues before a vibrant ethics system is established. There is a need to strive not only for registration, but also for accreditation through improvement in ethical review processes by institutes in view of the outsourcing of clinical trials to developing countries. The two pertinent issues that need emphasis if functional ECs are to become a reality in India are: focus on proper constitution of ECs for smooth functioning and to streamline the ethics review procedures resulting in uniformity of review processes. If institutes involved in clinical research perceive that it is complementary to be ethical for carrying out good science, the efforts would be successful in improving the functioning of ECs. This is essential to assure the society in general that enough is being done for protection of human participants.

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