Ethics Committees: Challenge of evidence-based accreditation

Accreditation of Ethics Committee (EC) is a public recognition by the National Healthcare Accreditation body, of the achievement of accreditation standards confirmed by an independent external peer assessment of EC's level of performance in relation to the established standards.[1] In 2015, the National Accreditation Board for Hospitals and Healthcare Providers (NABH) announced accreditation of ECs, which was voluntary in nature. This accreditation requirement will become mandatory for ECs from next year. Accreditation is expected to improve quality and capacity of ECs, resulting in benefits for subjects, investigators, site staff, institutions, and regulatory authorities. However, these benefits of NABH Accreditation of ECs are yet to be assessed and confirmed.

The Strategic Initiative for Developing Capacity in Ethical Review (SIDCER), a World Health Organization initiative for addressing human participant protection in global health research, has been reviewing quality of EC function and providing SIDCER Recognition since 2005.[2] In this issue, Desai *et al.* reported their evaluation of the impact of process of accreditation in improvement of the Institutional Review Board (IRB) functioning.[3] The study showed that five standard operating process (SOP) parameters – (a) submission of good clinical practice training certificate for investigators and staff; (b) completeness of IRB application form; (c) fulfillment of quorum requirements; (d) nonfinancial conflict of interest; and (e) submission of continuing review application/status report – showed improvement compared to preaccreditation status. These improvements are admirable. Nevertheless, whether such process improvements can meet the NABH standards and can translate into benefits for subjects – high quality of care, subject safety, respect and protection of rights and welfare of the subjects – is doubtful.

NABH standards finalized in 2015 define the objective, outcome, 10 standards, and 49 elements for accreditation.[4] The objective of accreditation is to confirm that the EC is adequately qualified, experienced, and knowledgeable in ethical issues and applicable rules and regulations for conducting of clinical trials ensuring scientific integrity and protection of subject rights, safety, and well-being. The accreditation process includes (1) EC application with self-assessment of compliance to NABH standards, and submission of relevant documents – protocols, SOPs, etc., (2) NABH review and feedback of self-assessment toolkit and other documents, (3) onsite visit by NABH assessors for facility inspection, SOPs, document and records review, and interview of EC members and subjects, (4) submission of corrective actions, if any by the EC, and (5) grant of accreditation if compliance to NABH standards confirmed.

Among the NABH standards, most difficult would be compliance to some of the objective elements of Standard 1.4 Protection of subject rights, safety, and well-being.[4] These are:

- 1.4.1. Rights and responsibilities of subject shall be documented and are specified
- 1.4.3. Subjects shall be informed and comprehend (initial and ongoing) of the associated risks and benefits of the trial
- 1.4.5. Monitoring of trials shall be done to ensure equitable selection of subjects, with special attention to vulnerable and high-risk subjects
- 1.4.9. Complaints and concerns of subjects shall be addressed and managed appropriately, if the need arises.

These elements demand that the EC follows documented procedures for subject protection to meet the requirements of these objective elements. A review of SOPs of some leading ECs showed that the rights of subject are neither defined nor documented in the SOPs. It would be advisable for ECs to develop a bill of rights for the subjects such as the US National Institutes of Health the Clinical Center Patients' Bill of Rights.[5,6] It would be essential for the EC to create awareness among research subjects about their rights by displaying the bill of rights in a multilingual poster, to review Informed Consent Process documentation and audio-visual recording, and active monitoring of the subject recruitment procedures.

Another major challenge would be to develop or modify SOPs to meet NABH standards. The SOPs would require supporting documentation, e.g. checklists, forms, and logs

to document how SOP was put in practice. For example, SOP for review of informed consent document (ICD) and informed consent form (ICF) would require (1) a checklist to confirm whether all essential regulatory elements for ICD and ICF are included, (2) a document of validity of ICF translations and backtranslations, (3) a review form to document opinion of each EC member on the ICD and ICF, and (4) documentation of decision on ICF in minutes/EC letter.

The NABH assessor's onsite visit will pose a major challenge to EC members as very few ECs in India have experience of such external assessment. The assessment visit will be like an audit of EC's function. During the assessment visit, the EC members would be interviewed about (1) training and awareness of regulations and guidelines, (2) understanding of critical processes – protection of subject rights, safety and well-being, risk: benefit assessment, ICD/ICF review, decision-making, handling conflict of interest, and monitoring, and (3) their roles and responsibilities. The assessor will then focus on how the SOPs and supporting evidence – forms, logs, checklist, minutes, correspondence – by looking for interconnecting audit trails between different SOPs, and documentation of conduct of clinical trial project approved by the EC.

The NABH accreditation process would be long, arduous, and demanding. The EC would require definite plan of action for obtaining accreditation, which is supported by the hospital/institution management. The action plan should include development of competence, creation of policies/processes, and preparing documentary evidence of compliance to NABH accreditation requirements. However, such readiness for accreditation requires a change in EC's attitude to accreditation. Despite SIDCER's encouragement and educational support, only nine Indian ECs have achieved SIDCER recognition.[2] In contrast, other Asian countries have more accredited ECs – China 71, South Korea 29, Philippines 28, Taiwan 24, and Thailand 21. In addition, there are no direct benefits to EC except improvement in quality and capacity. There is no penalty for an EC not obtaining accreditation except that it cannot review and approve regulatory clinical trials. Unless an EC values accreditation as an initiative to strive for excellence in functioning, and believes in an altruistic goal of supporting clinical research and development, it will not make efforts to obtain accreditation.

Indian ECs will need knowledge, resources – manpower, funds, time – planning and commitment from management, guidance from experienced ECs, and understanding from regulators to develop capabilities to meet the challenge of evidence-based accreditation.

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