Ethics committee accreditation: Journey from voluntariness to essentiality for quality sustenance

Accreditation is defined as a process of external evaluation performed by an independent body (evaluator) assessing how well an organization meets its established standards.[1] The activities or the deliverables that organization offers are evaluated with an aim to improve the quality, efficiency, and effectiveness of activities or services provided by the given organization. Accreditation involves a thorough review of various aspects of the organization, including its policies, procedures, safety protocols, and practices. Thus, successful accreditation guarantees quality assurance of activities undertaken.[2] When the organization in question, is ethics committee (EC) and it gets accreditated it does ensure that ECs are competent to perform activities which are credible and accountable for safeguarding the rights and welfare of research participants.

In India the National Accreditation Board for Hospitals and Healthcare Providers (NABH) announced accreditation of ECs, which was voluntary in nature to begin with in 2015 and later was mandatory for a brief time period from 2016 to 2019. With the release of new drug clinical trials rules in November 2019 it was stated that accreditation was again voluntary and mandatory was registration of ECs with the Central Drugs Standard Control Organization (CDSCO) office for regulatory trials.[3] Thus, the onus now lies on the felt need of the stakeholders (predominantly the institutional head and EC members) for accreditation of EC. Accreditation does improve quality and capacity of ECs, resulting in benefits for participants, investigators, institutions, and regulatory authorities. This fact has been revealed in the study conducted by Desai *et al*.[4] The study highlighted the impact of process of accreditation in improvement of functioning of the Institutional Review Boards/ECs especially in the terms of: (a) submission of good clinical practice training certificate by investigators and clinical trial team members; (b) completeness of EC application form; (c) completion of quorum requirements; (d) documentation of declaration of conflict of interest; and (e) submission of project progress reports when compared to their preaccreditation status.

The mandatory registration of EC does involve a comprehensive evaluation of their composition, functions performed as per the established standard operating procedures (SOPs), and competency of the EC members based on their bio-data and training records (training in good clinical practice, national ethical guidelines for biomedical research issued by ICMR and NDCT rules). This evaluation performed by CDSCO office is fulfillment of checklist items and quantitative based. At present in India, nearly 1500 ECs are registered with CDSCO office while accreditation by NABH is conferred to approximately 180 ECs who volunteered thus accounting to a meager 12% ECs being accredited and registered as evident from Dhakale study published in this issue.[5] Very few ECs <5% in India have sought international accreditation from agencies such as Association for the Accreditation of Human Research Protection Program and Strategic Initiative for Developing Capacity in Ethical Review.

EC accreditation process is mainly qualitative (in contrast to registration) and does offer several benefits such as:[6,7]

- Quality assurance: Accreditation ensures that ECs meet established standards of competence, independence, and integrity in reviewing research protocols. Thus enhancing the credibility and reliability of the clinical research review process
- Protection of trial participants: Accredited ECs are better equipped to evaluate the ethical implications of research studies and to safeguard the rights, safety, and well-being of trial participants. This prevents inadvertent unethical practices and minimizes potential risks to the participants
- Facilitation of International/National Collaboration: Accreditation offers recognition of credentials of ECs across national and international borders. This streamlines the review process for multicenter research studies and promotes collaboration in global research endeavors
- Continuous improvement: Sustaining the accreditation status serves as a driving force for continuous quality improvement within the ECs. By identifying areas for enhancement and implementing corrective actions, accredited committees strive to maintain and enhance their ethical review capabilities over time. Accreditating agencies also do hand holding so that ECs improve and sustain their quality work.

These benefits were evaluated by Dhakale *et al.*, in 2024, in their study, where in they compared the functioning of accreditated versus nonaccreditated EC in terms of quality and governance for NABH standards before and after accreditation. The study brought to light facts regarding the lapses/deficiencies seen in non accreditated ECs ($n = 16$ vs. $n = 12$ accreditated ECs which were surveyed in the study) namely: nonupdated EC - SOPs, lack of process to prepare SOPs, failure to categorize the review process, lack of process to handle vulnerability, noncompliance, and protocol violation. In addition, lapses were also in documentation of conflict of interest, confidentiality, and handling participant complaints. In contrast, the ECs which were accreditated did document timely updating of SOPs, optimum procedures to handle vulnerability, maintenance of confidentiality, declaration of conflict of interest and handling trial participant complaints (before accreditation documentation of procedures was 8.3% increased to 100% after accreditation as evident from results of the study). The study did reinforce that accreditation had resulted in significant improvement of ECs in completeness of review (both initial and continuing review of projects), archival procedures and ongoing self-assessment process. Thus, sustaining the highest ethical standards will conduct of clinical research, ensuring participant protection and complete adherence to national regulations and SOPs.[5]

Thus, EC accreditation is beyond doubt a pivotal process to sustain the quality, credibility and patient safety has been reflected in Dhakale *et al.*'s study but there are certain limitations. The study was conducted pan India and only 28 ECs were enrolled. Given the small sample size generalizability of the findings is questionable. The study did utilize questionnaire incorporating all NABH standards and tested the compliance of ECs on these standards in terms of "Yes" or "No." Thus, it was quantitative checklist and authors did not probe into the quality of the evidence which would have further added comprehensiveness to their findings. Another point was that questionnaire was responded by member secretary or EC coordinator who are the most learned and experienced candidates regarding awareness and practice of all EC function procedures, regulations, and guidelines. If the questionnaire was filled by other EC members may be the findings could have got diluted as all EC members may not be updated/well versed with all procedures irrespective of the accreditation process.

EC accreditation though perceived vital, there has been reluctance from the stakeholders to seek accreditation. Dhakale *et al.* in the study did discuss the hindering factors such as extensive documentation, time consuming accreditation procedure, training of EC members and financial burden. Apart from the hindering factors, bioethicist Fernandez Lynch and Taylor[8] have questioned the process of accreditation itself. Are accreditating agencies able to successfully measure the quality, effectiveness, and efficiency of the performance of the ECs in ensuring and validating the safety of the research participants? Accreditation requires ECs to provide evidence in terms of their policies, procedures, and practices which reflects the commitment and function of the EC to offer scientific and ethical research review on a continuous basis. The standards/criteria listed in the assessment strategies put forth by accreditating agencies check the compliance in terms of "Yes or No" or as Likert scale. Fernandez Lynch and Taylor did put forth that measurable definitions of quality, effectiveness and efficiency of "EC performance" are not stated in the assessment tools used by accreditating agencies. If accreditation utilizes indicators that are not able to measure "how well" a function/activity is performed by the EC then is the accreditation needed?

Stakeholders involved in clinical research and drug/device development have to introspect and review the enabling factors/situations too. Majority of the ECs in India have mandatorily even re-registered which did require them to submit additional data on the type of regulatory trials reviewed and SAE data with relatedness and causality. Thus, there is documentation; need to add some additional effort on risk stratification of protocols and handling of protocol noncompliance. Similarly, ECs located in private hospitals/medical colleges also undertake NABH for hospitals and do have quality assurance departments for the same. This department can be called for assistance for EC accreditation too. It is perceived that internal EC members (affiliated to the institute) are responsible to prepare the EC for accreditation. This mind set needs to be changed. With NDCT rules nearly 50% members are from outside the institute, these members could also be requested to support the EC secretariat in the accreditation process. Thus the accreditation must be intrinsic felt need and all ECs in the country must strive for it. Some efforts may be made by the central licensing authority, i.e., CDSCO Office. Post registration CDSCO office may appoint an ethics review expert/s preferably within 3 or 6 months of registration, to form a quality check which could focus on training records of EC members, SOPs, documentation of conflict of interest, protocol and trial related documents review, safety review, monitoring, minutes of the meeting, record keeping, etc., This audit can be repeated again after re-registration. Such serials audits done by CDSCO office would definitely help all ECs to function with uniformity across India and sustain the ethical standards. In addition,

this audit will be less expensive (in contrast to NABH) and less burdensome for the ECs.

Accreditation of ECs is a vital component of the research ethics infrastructure, promoting ethical conduct of clinical research. By ensuring the competency, independence, and accountability of ECs, accreditation contributes to the protection of research participants and the integrity of the scientific enterprise. Research institutions, hospitals, medical colleges, investigators, and funding agencies should prioritize accreditation as a means to uphold ethical standards and promote public trust in research. Equally, important is that accreditating agencies do develop indicators/standards to measure quality, effectiveness and efficiency of ethical review to offer trial participant protection.

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