Original Article

Impact of accreditation on registered ethics committees in terms of quality and governance in India: A cross-sectional study

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Abstract

Background: Ethics Committee accreditation is a process to assess the performance against a set of standards. Very few studies have shown that process of accreditation results in the improvement of the overall functioning of ECs. in terms of quality and governance. Hence, the present study was planned to evaluate the impact of accreditation on registered EC in terms of quality and governance and to compare functioning of accredited versus non accredited EC in terms of quality and governance.

Materials and Methods Study Design: This was a cross sectional, observational, questionnaire-based survey conducted on 28 registered Ethics Committee in India after approval from the Institutional Ethics Committee.

Results: Accredited EC's (n = 12) were compared for NABH standard for accreditation before and after accreditation in terms of percentage. It was found that majority of the standards related to structure and composition, adherence to specific policies , completeness of review and after approval process were met by majority of EC's after accreditation. Only a few EC 's fulfilled some of the criteria before accreditation. There was a statistically significant difference with reference to adherence to specific policies by accredited and non-accredited EC's like updating SOP according to changing requirements ($P < 0.0237$), process for preparing SOP ($P < 0.0237$), categorization of review process mentioned in SOP ($P < 0.0237$) procedure to be followed for vulnerable population ($P < 0.0103$) , process of handling issues related to complaints by participants and other stakeholders violation ($P < 0.0103$) etc.

Conclusion: Accreditation results in improving of EC functioning in terms of quality and governance.

Keywords: Accreditation, ethics committee, National Accreditation Board for Hospitals and Healthcare Providers

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INTRODUCTION

Accreditation of ethics committee (EC) is a systematic and independent examination of the activities and documents to determine whether it functions as per the local regulations, guidelines, and standard operating procedures (SOPs). It is an intensive, in-depth evaluation of the policies, procedures, and practices of EC.[1] Therefore, it is formally recognized that an organization

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that has received accreditation can carry out certain tasks of a specified scope, meeting the highest possible ethical and professional standards.[2] Although accreditation is voluntary, it is now accepted worldwide as an important aspect of an organization's internal activities pertaining to the improvement of quality.[3] Till 2013, functioning of most of EC's was as per the SOPs of their own based on Schedule Y (Drugs and Cosmetics Act 1940 of the Parliament of India, amended on January 20, 2005),[4] International Conference on Harmonization-Good Clinical Practices (GCPs) (1996),[5] Indian Council of Medical Research guidelines (2006).[6]

Considering many irregularities that were reported in the conduct of clinical trials in India during the past decade, the Drug Controller General of India (DCGI), under the Central Drugs Standard Control Organization (CDSCO), made registration mandatory for ECs that approve clinical trials.[7] This definitely ensures quality control during the conduct of clinical trials. Approximately 1505 EC's in India have registered themselves with the DCGI (www.sugamonline portal as accessed on Jul 10, 2023).[8] However, to improve the quality of review and to ensure that the highest ethical standards were met to protect research participants, ECs should go through the process of accreditation.

In India, the CDSCO has tasked the National Accreditation Board for Hospitals and Healthcare Providers (NABH) to accreditate ECs in India.[9] However, this would be applicable only to clinical trials and it is voluntary.

Few institutions have sought accreditation from international agencies, such as the Association for the Accreditation of Human Research Protection Programme (AAHRPP) and the Strategic Initiative for Developing Capacity in Ethical Review. AAHRPP is an independent, non-profit body, established in 2001.[10] The primary purpose of AAHRPP accreditation is to strengthen protections for research participants.[11] Forum for Ethical Review Committees in the Asian and Western Pacific Region has taken a lead role in conducting the recognition process in the Asia Pacific region. An EC is recognized if it meets five standards, i.e., standards related to its structure and composition, adherence to specific policies, completeness of the review process, after-review process, and documentation and archiving. An EC that meets the five criteria is issued a certificate of recognition and granted recognition for a maximum period of 3 years.[10]

NABH Standards for EC accreditation contains the complete set of standards for evaluation of EC for grant of accreditation. NABH for accreditation of EC has 10 standards and 49 objective elements. 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 clinical trials, ensuring scientific integrity and protection of subject rights, safety, and well-being. At present, 179 ECs have been accredited by NABH in India and 187 ECs have applied for accreditation.[12] (www.nabh.co.in accessed on May 20, 2023).

Very few studies have shown that the process of accreditation results in the improvement of the overall functioning of ECs.[1] and despite an extensive literature search, we could not find any study comparing the functioning of accredited and nonaccredited EC in terms of quality and governance.

Hence, the present study is planned with the following objectives.

Primary objective

1. To evaluate the impact of accreditation on registered EC in terms of quality and governance.

Secondary objectives

1. To compare the functioning of accredited versus nonaccredited EC in terms of quality and governance
2. Challenges faced by registered ECs during accreditation
3. Various reasons for other registered ECs not going for accreditation.

Exploratory Objective

1. Reasons for accredited registered ECs not going for re-accreditation/accreditation renewal post expiry of initial accreditation.

MATERIALS AND METHODS

Study design

This was a cross-sectional, observational, questionnaire-based survey conducted on ECs in India after approval from the Institutional EC. The duration of the study was approximately 5 months.

Inclusion criteria

1. Accredited and nonaccredited ECs reviewing clinical trials and registered with CDSCO were included in the study
2. ECs ready to participate in the survey as consented to by the member secretary.

Exclusion criteria

Ethics committees not willing to participate in the survey

Respondents were member secretaries/EC coordinators of the respective EC. ECs registered with CDSCO were selected from the official CDSCO site and those accredited were selected from the official site of NABH. Respondents were administered the study instrument by the study team by mail in the form of excel sheet. They were explained about the nature and purpose of the study, and necessary consent from the Member Secretary was obtained.

The study instrument was a self-developed, pre-validated, semi-structured, self-administered questionnaire consisting of both open and close-ended items. The questionnaire was first pre-tested in five participants, and suitable modifications were made. The final version of the questionnaire was administered to 28 respondents. Appropriate instructions about filling out the questionnaire were given. Personally identifiable information was not recorded in the questionnaire. The anonymity of participants and confidentiality of data were maintained.

For testing the validity of the questionnaire, the face validity of the questionnaire was evaluated in terms of readability, feasibility, layout, style, and clarity of wording. Face validity was done by five subject experts who were not part of the study. Changes related to readability and clarity of wordings, as suggested by them, were incorporated into the questionnaire. For content validity, the questionnaire was sent to experts in EC. Content validity was assessed by calculating the content validity index (CVI). CVI for scale (S-CVI/Ave) was calculated by taking the average of the I-CVIs for all items on the scale. Reliability was tested by sharing questionnaires at different time periods with the same subset of responders. The score was calculated and compared using Pearson's correlation coefficient formula.

The questions included the following components, broadly based on NABH and AAHRPP standards.[10-13]

1. Structure and composition – Membership requirement, administrative requirements, EC office, conflict of interest management
2. Adherence to specific policies – Availability of SOP, areas covered under SOP, submission process, meeting requirements
3. Completeness of the review process – Review of protocols, elements of review, decision making
4. After-review process – Minutes of meeting, communication of decision, amendment review
5. Documentation and archiving
6. Challenges encountered during and after accreditation.

Statistical analysis and data management

Sample size calculation

Assuming improvement in conflict of interest management from 35% to 100% after accreditation from the previous study,[1] 5% alpha error, and 90% power, sample size estimation comes to 12 in each group. Considering non-compliance of about 15%, the total sample size was rounded to 14 in each group. Hence, the total sample size of the study was 28.

Statistical analysis

Data obtained from accredited and nonaccredited EC with respect to the above standards is expressed in percentages and compared to see whether the accreditation process has any impact on the quality and governance of EC.

RESULTS

Of the 28 ECs, 12 were accredited and 16 were nonaccredited. To see the impact of accreditation, the accredited ECs were compared to the NABH standards before and after accreditation [Table 1]. Results were expressed in percentages.

The impact of accreditation was seen in criteria like the existence of a document/procedure authorizing the EC of its independence in functioning and decision-making by the institution. All 12 ECs reported to have it after accreditation as compared to only two before accreditation. Similarly, a major change was seen with respect to specific policies, like the inclusion of process by ECs for preparing and updating SOP, the procedure to be followed for vulnerable population in trials, the process for declaration of conflict of interest of members and maintaining confidentiality, process for handling complaints by participants and stakeholders increased from 8.33% before accreditation to 100% after accreditation. Certain policies like provision for ensuring the appropriateness of compensation, provision for initial review of protocol for risk assessment and scientific validity by primary and secondary reviewers, provision for assessment of informed consent document, provision for review of amendments to the protocols, consent forms, Investigator's brochure in formal meetings and provision for evaluation of recruitment strategies were included by all the 12 EC only after accreditation (only 4 ECs included these provisions before accreditation). The process required for self-assessment and archival of records, like training staff in record keeping and the process of doing and documenting self-assessment, was

Table 1: Difference in structure and functioning of accredited ethics committees before and after accreditation (*n*=12)

Criteria	Number of ECs fulfilling the criteria before accreditation (%)	Number of ECs fulfilling the criteria after accreditation (%)
Comparison of structure and composition before and after accreditation		
Appointment of authority establishing and governing EC	10 (83.33)	12 (100)
Existence of document/procedure authorizing the EC of its independence in functioning and decision-making by the institution	2 (16.66)	10 (83.33)
Adherence to the composition of EC as per regulating authority	11 (91.66)	12 (100)
Existence of process for induction of new member, including policy and duration of appointment, disqualification, resignation, and replacement procedure of members in SOP	11 (91.66)	12 (100)
Comparison of adherence to specific policies before and after accreditation		
Policy regarding frequency of meeting	12 (100)	12 (100)
Provision of adequate financial and human resources	1 (8.33)	11 (91.66)
Terms and conditions for appointment of administrative staff	4 (33.33)	8 (66.66)
Policy regarding training of members	3 (25)	9 (75)
Existence of SOP	12 (100)	12 (100)
Provision for updating SOP	1 (8.33)	11 (91.66)
Process for preparation of SOP	1 (8.33)	11 (91.66)
Process for circulating proposals	5 (41.66)	7 (58.33)
Implementation of categorization of review process	1 (8.33)	11 (91.66)
Process for periodic review	3 (25)	9 (75)
Process for receipt, review and decision making of proposals	10 (83.33)	12 (100)
Process for vulnerable population	1 (8.33)	11 (91.66)
ICD review	5 (41.66)	7 (58.33)
Adherence to the timelines for SAE reporting	11 (91.66)	12 (100)
Process of training members for SAE analysis	2 (16.66)	10 (83.33)
Process of handling issues related to noncompliances, protocol deviation and violation	5 (41.66)	7 (58.33)
Process of handling issues related to complaints by the participants and other stakeholders	1 (8.33)	11 (91.66)
Process for declaration of conflict of interest of members and maintaining confidentiality	2 (16.66)	10 (83.33)
The process to know whether the participants are aware of their rights and responsibilities	2 (16.66)	10 (83.33)
Process for financial declaration of payments received and disbursed	5 (41.66)	7 (58.33)
Comparison of completeness of review process and after approval process before and after accreditation		
The process to communicate the decision of EC in timely manner to stakeholders	11 (91.66)	12 (100)
Provision for monitoring of the approved research by the EC to ensure compliance with the GCP guidelines and protocol	2 (16.66)	10 (83.33)
Inclusion of process of recording minutes of meeting in SOP	10 (83.33)	12 (100)
The process of ensuring that the reimbursement paid to the subject is appropriate as per the contract	4 (33.33)	8 (66.66)
Ensuring the appropriateness compensation paid to the subject	4 (33.33)	8 (66.66)
Provision for the initial review of the protocol for risk assessment and scientific validity by primary and secondary reviewers	4 (33.33)	8 (66.66)
Provision for assessment of informed consent document, translations	2 (16.66)	10 (83.33)
Process for checking trial agreement and budget, for indemnity, compensation, roles and responsibility	6 (50)	6 (50)
Provision for review of all the amendments to the originally approved protocol, consent forms investigators brochure in formal meetings	4 (33.33)	8 (66.66)
Provision for evaluation of recruitment strategies for patients	4 (33.33)	8 (66.66)
Existence of decision-making process (approval/disapproval/pending) as per applicable rules and regulations ensuring quorum and consensus	10 (83.33)	12 (100)
Implementation of practice of declaring conflict of interest	2 (16.66)	10 (83.33)
The provision in monitoring procedures to ensure the adequacy and continuity of consent process	5 (41.66)	7 (58.33)
Conducting for-cause assessments following serious noncompliance and complaints for the trials approved by EC before accreditation	4 (33.33)	8 (66.66)
Comparison of adherence to self-assessment and archival procedures before and after accreditation		
The process of training staff in record keeping and updating of the records as per required regulations	4 (33.33)	8 (66.66)
The process of record keeping and archiving of all the proposals of EC as per regulatory requirement	3 (25)	9 (75)
The process of doing and documenting self-assessment	4 (33.33)	8 (66.66)

Figures in parentheses indicate percentage. EC=Ethics Committee, SOP=Standard operating procedure, GCP=Good clinical practice, ICD=Informed consent document, SAE=Serious adverse event

followed by 33.33% ECs before accreditation and it increased to 100% after accreditation.

When accredited ECs were compared with nonaccredited ECs for structure and composition, it was found that

Table 2: Comparison of structure and composition of accredited and nonaccredited ethics committees

Question	Accredited (*n*=12)		Nonaccredited (*n*=16)		*P*
	Yes, *n* (%)	No, *n* (%)	Yes, *n* (%)	No, *n* (%)	
Is there any authority establishing and governing EC?	12 (100)	0	15 (93.75)	1 (6.25)	>0.99
Is there any document/procedure authorising the EC of its independence in functioning and decision-making by the institution?	12 (100)	0	10 (62.5)	6 (37.5)	0.0237*
Is the composition of EC as per relevant regulation/registering authority?	12 (100)	0	16 (100)	0	>0.99
Is there any process for induction of new members including policy and duration of appointment, disqualification, resignation, and replacement procedure of members in SOP?	12 (100)	0	15 (93.75)	1 (6.25)	>0.99
Does the SOP mention frequency of meeting	12 (100)	0	16 (100)	0	>0.99
Does the EC have adequate financial and human resource allocation, and secretariat for the administrative work and record keeping?	10 (83.33)	2 (16.67)	15 (93.75)	1 (6.25)	0.5604
Are the adequate financial and human resource allocation, and secretariat for the administrative work and record keeping mentioned in the SOP?	12 (100)	0	14 (87.5)	2 (12.5)	0.4921
Are there any terms and conditions for appointment of administrative staff?	11 (91.67)	1 (8.33)	11 (68.75)	5 (31.25)	0.1965
Does the EC have any policy regarding training of its members?	12 (100)	0	15 (93.75)	1 (6.25)	>0.99
Is the policy regarding training of members mentioned in the SOP?	12 (100)	0	13 (81.25)	3 (18.75)	0.2381

*$P<0.05$ is considered statistically significant. Statistical analysis - Fisher's exact test. Figures in parentheses indicate percentage. EC=Ethics Committee, SOP=Standard operating procedure

Table 3: Comparison of adherence to specific policies by accredited and nonaccredited Ethics Committees

Question	Accredited		Nonaccredited		*P*
	Yes, *n* (%)	No, *n* (%)	Yes, *n* (%)	No, *n* (%)	
Is there any process to communicate the decision of EC in a timely manner to stakeholders?	12 (100)	0	15 (93.75)	1 (6.25)	>0.99
Is the process to communicate the decision of EC in a timely manner to stakeholders mentioned in the SOP?	12 (100)	0	13 (81.25)	3 (18.75)	0.2381
Does EC monitor the approved research to ensure compliance with the GCP guidelines and protocol?	12 (100)	0	11 (68.75)	5 (31.25)	0.0525
Do the minutes of meeting accurately reflect actions taken during the meeting also indicating the members present?	12 (100)	0	16 (100)	0	>0.99
Is there a process of recording minutes of meeting mentioned in SOP?	12 (100)	0	13 (81.25)	3 (18.75)	0.2381
Does the EC ensure reimbursement paid to the subject is appropriate as per the contract?	12 (100)	0	9 (56.25)	7 (43.75)	0.0103*
Does the EC ensure compensation paid to the subject is appropriate as per the regulations?	12 (100)	0	9 (56.25)	7 (43.75)	0.0103*
Is the initial review of the protocol done for risk assessment and scientific validity by primary and secondary reviewers?	10 (83.33)	2 (16.67)	12 (75)	4 (25)	0.6730
Are the informed consent document, translations assessed and evaluated to ensure that appropriate, accurate information being provided?	12 (100)	0	16 (100)	0	>0.99
Is the trial agreement and budget, for indemnity, compensation, roles and responsibility evaluated and checked if it is as per applicable regulations?	10 (83.33)	2 (16.67)	12 (75)	4 (25)	0.6730
Are all the amendments to the originally approved protocol, consent forms investigators brochure reviewed in formal meetings to evaluate the risk to trial subjects?	10 (83.33)	2 (16.67)	14 (87.5)	2 (12.5)	>0.99
Is the provision for review of all the amendments to the originally approved protocol, consent forms investigators brochure reviewed in formal meetings mentioned in SOP	12 (100)	0	9 (56.25)	7 (43.75)	0.0103*
Are the recruitment strategies evaluated? (Ex. Advertisements by the committee)	9 (75)	3 (25)	11 (68.75)	5 (31.25)	>0.99
Is the decision making process (approval/disapproval/pending) as per applicable rules and regulations ensuring quorum and consensus/voting requirements are fulfilled?	11 (91.67)	1 (8.33)	16 (100)	0	>0.99
Is the conflict of interest declared prior to the decision making process?	12 (100)	0	14 (87.5)	2 (12.5)	0.4921
Do the monitoring procedures ensure the adequacy and continuity of consent process, including audio-video consenting?	12 (100)	0	10 (62.5)	6 (37.5)	0.0237*
Is the committee conducting for-cause assessments following serious noncompliance and complaints for the trials approved by the EC?	12 (100)	0	8 (50)	8 (50)	0.0084*
Is the provision of the committee conducting for-cause assessments following serious noncompliance and complaints for the trials mentioned in the SOP	9 (75)	3 (25)	7 (43.75)	9 (56.25)	0.1358

*$P<0.05$ is considered statistically significant. Statistical analysis - Fisher's exact test. Figures in parentheses indicate percentage. EC=Ethics Committee, SOP=Standard operating procedure, GCP=Good clinical practice

there was a statistically significant difference ($P < 0.023$) for the criteria of existence of any document/procedure authorizing the EC of its independence in functioning and decision-making by the institution [Table 2]. Whereas some of the criteria, like SOP mentioning the frequency of meetings, allocation of adequate financial and human resources for EC, policy regarding the training of members, did not show any statistically significant difference between accredited and nonaccredited EC.

Table 3 shows the comparison of adherence to specific policies by accredited and nonaccredited ECs. The statistical significant difference was found between accredited and nonaccredited EC's with respect to the process of updating and preparing

Table 4: Comparison of completeness of review process and after approval process between accredited and nonaccredited Ethics Committees

Question	Accredited		Nonaccredited		*P*
	Yes, *n* (%)	No, *n* (%)	Yes, *n* (%)	No, *n* (%)	
Does the EC have SOPs with which they comply?	12 (100)	0	16 (100)	0	>0.99
Is the SOP updated according to changing requirements?	12 (100)	0	10 (62.5)	6 (37.5)	0.0237*
Is there any process for preparing SOP's?	12 (100)	0	10 (62.5)	6 (37.5)	0.0237*
Is there any process and timelines for circulation of proposals to members before meeting?	12 (100)	0	14 (87.5)	2 (12.5)	0.4921
Is the process and timelines for circulating proposals mentioned in the SOP?	10 (83.33)	2 (16.67)	9 (56.25)	7 (43.75)	0.2232
Do you categorize the initial review process into full review and expedited review/ exempted?	11 (91.67)	1 (8.33)	12 (75)	4 (25)	0.3553
Is the categorization of review process mentioned in the SOP	12 (100)	0	10 (62.5)	6 (37.5)	0.0237*
Is there any process for periodic review and oversight mentioned in SOP?	11 (91.67)	1 (8.33)	11 (68.75)	5 (31.25)	0.1965
Is there any process for receipt, review and decision making of proposals?	12 (100)	0	14 (87.5)	2 (12.5)	0.4921
Is the process for submission, review and decision-making mentioned in the SOP?	12 (100)	0	12 (75)	4 (25)	0.1131
Is there procedure to be followed for vulnerable population?	12 (100)	0	9 (56.25)	7 (43.75)	0.0103*
Is the procedure to be followed for vulnerable population mentioned in the SOP?	12 (100)	0	8 (50)	8 (50)	0.0084*
Does the EC review ICD?	11 (91.67)	1 (8.33)	15 (93.75)	1 (6.25)	>0.99
Is the reporting of SAE as per timelines as specified by our regulatory authorities?	12 (100)	0	15 (93.75)	1 (6.25)	>0.99
Are the members trained for doing analysis of SAEs and making opinion on compensation?	12 (100)	0	12 (75)	4 (25)	0.1131
Do you have a process of handling issues related to noncompliances, protocol deviation and violation	12 (100)	0	9 (56.25)	7 (43.75)	0.0103*
Is the process of handling issues related to noncompliances, protocol deviation and violation mentioned in the SOP	12 (100)	0	9 (56.25)	7 (43.75)	0.0103*
Do you have a process of handling issues related to complaints by the participants and other stakeholders?	12 (100)	0	9 (56.25)	7 (43.75)	0.0103*
Is the process of handling issues related to complaints by the participants and other stakeholders mentioned in the SOP?	12 (100)	0	9 (56.25)	7 (43.75)	0.0103*
Do you have any process for declaration of conflict of interest of members and maintaining confidentiality?	12 (100)	0	8 (50)	8 (50)	0.0084*
Is the process for declaration of conflict of interest of members and maintaining confidentiality mentioned in the SOP?	12 (100)	0	8 (50)	8 (50)	0.0084*
Does the EC have any process to know if the participants are aware of their rights and responsibilities?	12 (100)	0	8 (50)	8 (50)	0.0084*
Is the process to know if the participants are aware of their rights and responsibilities mentioned in the SOP?	12 (100)	0	7 (43.75)	9 (56.25)	0.0028*
Is there any process for financial declaration of payments received and disbursed?	10 (83.33)	2 (16.67)	10 (62.5)	6 (37.5)	0.4010
Is the process for financial declaration of payments received and disbursed mentioned in the SOP?	7 (58.33)	5 (41.67)	8 (50)	8 (50)	0.7177

*$P<0.05$ is considered statistically significant. Statistical analysis - Fisher's exact test. Figures in parentheses indicate percentage. EC=Ethics Committee, SOP=Standard operating procedure, ICD=Informed consent document, SAE=Serious adverse event

SOP's ($P < 0.023$), SOP mentioning categorization of the review process ($P < 0.023$), the procedure to be followed for vulnerable population and mention of the same in SOP ($P < 0.008$), process for declaration of conflict of interest of members and maintaining confidentiality and mention of the same in SOP ($P < 0.008$), the process of handling issues related to non-compliances, protocol deviation, and violation as well as the complaints by participants and stakeholders ($P < 0.01$), the process to know if the participants are aware of their rights and responsibilities and mention of the same in SOP ($P < 0.002$).

A comparison of completeness of review process and after approval process between accredited and nonaccredited ECs is shown in Table 4. Statistical significant difference was found between accredited and nonaccredited EC with respect to certain policies like EC ensuring reimbursement and compensation paid to the subject if appropriate as per the contract ($P < 0.010$), provision for review of all the amendments to the originally approved protocol, review of consent forms, investigators brochure in formal meetings and its mention in SOP ($P < 0.010$), monitoring procedures ensuring the adequacy and continuity of consent process, including audio-video consenting ($P < 0.023$), conducting for-cause assessments following serious non-compliance and complaints for the trials approved by the EC ($P < 0.008$).

Table 5: Comparison of frequency of processes requiring regular implementation between accredited and nonaccredited Ethics Committees

Process	Frequency	Accredited EC (*n*=12)	Nonaccredited EC (*n*=16)
Updating SOP	Once in a year	4	1
	Once in 2 years	0	2
	Once in 3 years	3	2
	As and when required	5	4
	Not updated	0	6
Periodic review and oversight	Once in 6 months	4	5
	Once a year	7	5
	Not done	1	6
Monitoring the approved research to ensure compliance with the GCP guidelines and protocol	Once in 6 months	4	6
	Once a year	8	3
	Not done	0	7
Assessment of informed consent document and translations	Only during the initial review	11	11
	During the initial review and monitoring	1	3
	No response	0	2
Periodic conduct of self-assessment	Once in 6 months	3	0
	Once a year	8	3
	Not done	1	13

EC=Ethics Committee, SOP=Standard operating procedure, GCP=Good clinical practice

Table 6: Comparison of adherence to self-assessment and archival procedures between accredited and nonaccredited Ethics Committees

Question	Accredited		Nonaccredited		*P*
	Yes, *n* (%)	No, *n* (%)	Yes, *n* (%)	No, *n* (%)	
Is the staff trained in record keeping and updating of the records as per required regulations?	12 (100)	0	14 (87.5)	2 (12.5)	0.4921
Is the record keeping and archiving of all the proposals of EC as per regulatory requirement?	12 (100)	0	16 (100)	0	>0.99
Does the EC have and follows documented procedures for self-assessment. Including documented procedure and periodic conduct of self-assessment?	11 (91.67)	1 (8.33)	6 (37.5)	10 (62.5)	0.0060*

*$P<0.05$ is considered statistically significant. Statistical analysis - Fisher's exact test. Figures in parentheses indicate percentage. EC=Ethics Committee

Table 5 shows the comparison of frequency of processes requiring regular implementation between accredited and non-accredited ECs.

DISCUSSION

Accreditation ensures adherence to national and international standards and helps an EC to protect the rights, safety, and well-being of research participants. ECs can strive toward improving their quality through the process of accreditation and thus meet the international as well as national standards.[10] The present study was planned to see the impact of accreditation on ECs and compare the functioning of accredited and nonaccredited ECs in terms of quality and governance.

To see the impact of accreditation, when accredited 12 ECs were compared for various NABH standards before and after accreditation, it was found that with reference to structure and composition majority of the ECs[10] had authority establishing and governing EC before going for accreditation. Furthermore, the process for induction of new members, including policy and duration of appointment, disqualification, resignation, and replacement procedure of members, was mentioned in SOP and the adherence to the composition of EC as per regulatory authority was maintained by 11 (91%) ECs before accreditation itself. The probable explanation for this finding could be as these criteria are mandatory for registration of EC with CDSCO, ECs were compliant with it. However, only 2 ECs had a document/procedure authorizing the EC of its independence in functioning and decision-making by the institution. The same finding was observed when accredited EC's were compared with nonaccredited with respect to structure and composition.

When compared for various criteria for adherence to specific policies, it was seen that the majority of ECs satisfied the criteria only after accreditation like provision of adequate financial and human resources, terms and conditions for appointment of administrative staff, policy regarding training of members, implementation of categorization of review process, process for periodic review etc., procedure to be followed for vulnerable population, process for declaration of conflict of interest of members and maintaining confidentiality and mention

of the same in SOP, process of handling issues related to noncompliances, protocol deviation and violation as well as the complaints by participants and stakeholders, process of updating and preparation of SOP and process to know if participants are aware of their rights and responsibilities. Criteria like adequate review of protocol and handling issues related to noncompliance are very important to ensure the protection of trial participants which were followed by EC only after accreditation. Hence, there was a remarkable improvement in various criteria postaccreditation, which definitely improves the ECs functioning.

Few criteria, like the existence of SOP, policy regarding the frequency of meeting, and process for receipt, review, and decision-making of the proposal, was in existence before accreditation, and again, these criteria are mandatory for registration of EC with CDSCO.

Similarly, criteria for completeness of the review process and after approval processes showed that before accreditation majority of the ECs had process to communicate the decision of EC to various stakeholders, provision for monitoring of the approved research and process of recording of minutes. However amongst the important criteria which were followed by the EC's only after accreditation included process of ensuring reimbursement and compensation paid to the subject and review of all the amendments to the originally approved protocol, consent forms, investigators brochure. Provision for monitoring procedures ensuring the adequacy and continuity of consent process, including audio video consenting, conducting for cause assessments following serious noncompliance and complaints from participants for the trials approved by the EC and its mention in SOP were other important criteria were seen only after accreditation.

Monitoring is very important to see compliance with GCP and approved protocol. Although most of the ECs had the provision of monitoring before accreditation, there was no procedure to ensure the adequacy and continuity of the consent process, including audio-video consenting. The difference in the above criteria was statistically significant when accredited ECs were compared with nonaccredited EC's.

Thus, the impact of accreditation is seen with EC's fulfilling the criteria relevant to adherence to specific policies, completeness of the review process and after the approval process and adherence to self-assessment and archival process only after accreditation. Most significantly, as accreditation process focuses primarily on questions about EC's structure and process, such as how committees are constituted, whether their SOPs are complete, and whether the process of protocol review is adequately documented, ECs have fulfilled most of the criteria after accreditation and which ensures about protection of safety, rights and well-being of trial participants.

When compared for record-keeping and documentation, it was seen that most of the ECs did not have the process of record keeping, archiving of all proposals, and process of doing and documenting self-assessment before accreditation but which was implemented after accreditation. There was a statistically significant difference between accredited and nonaccredited ECs when compared for self-assessment ($P < 0.0060$) [Table 6].

On a more practical level, the effectiveness of EC review is often hampered by insufficient financial and human resources.[14] These limitations make it difficult to create committees with sufficient expertise and diversity, to provide funding for staff support, and to provide training for committee members.

Self assessment of EC's makes ECs aware of their weaker aspects and encourages it to work on it, thereby raising its standard. Accreditation usually involves a combination of self-assessment and external reviews, focusing on issues such as committee membership, operating procedures, and the documentation of meetings.[15]

When accredited EC were compared with nonaccredited EC for frequency of processes requiring regular implementation, it was found that accredited ECs updated the SOP once/twice/thrice in a year or as and when required. While 6 non-accredited ECs did not have this provision. The same was the finding observed for monitoring and periodic review and oversight.

When nonaccredited ECs were asked about the various reasons for not going for accreditation, majority of the ECs quoted that it is not mandatory by CDSCO and it adds to the financial burden on the EC, and the accreditation procedure is lengthy and difficult, needs training of all EC members, proper documentation of all records is needed. At the same time, accredited ECs have to face more inspections by accreditation committees and there is no advantage of accredited EC over nonaccredited ECs. ECs in government institutes are not provided with adequate resources, and therefore, it is difficult for EC to prepare for accreditation.

Different challenges encountered by accredited ECs during the process of accreditation included that only few members of EC are involved in the process, and difficulty to meet all standards laid down by the accreditation committee without any guidance document for EC. According to some ECs, accreditation requires extensive documentation and record keeping, and there was a disparity in perception of various standards by the assessor. Some of the ECs quoted that it was challenging to provide Jio-tagged photos of the document during its online assessment.

The challenges that were encountered by ECs after the process of accreditation in implementing various policies included the increased workload of EC's office due to the extensive documentation required and record keeping. Some of the ECs quoted that annual fees and fees for renewal are very high, and in the absence of institutional support, it is the biggest challenge.

Thus, it is clear from the above study that accreditation promotes to development of standardized policies and procedures, which helps to promote the consistent application of ethical principles and GCP. ECs who have sought accreditation tend to implement and adhere to the policies as accreditation is a continuous process which is very clear from the results of the above study. They also provide a means of checking whether ECs are actually adhering to the policies and procedures that they claim to be following. Accreditation also helps to build trust in research and bridges the gap between researchers and the public.[10]

The limitation of the study was that the sample size was small, and getting responses from EC members on various questions related to NABH standards was challenging.

Training of ECs for understanding the importance of accreditation and how to proceed with it may encourage ECs for accreditation. At the same institutional support in terms of infrastructure and various resources may help ECs for accreditation.

CONCLUSION

The present study concludes that accreditation has resulted in significant improvement of EC's performance in terms of fulfilling the criteria relevant to adherence to specific policies, completeness of review process, after approval process, adherence to self-assessment and archival process, thus ensuring protection of research participants. At the same time, accreditation acts as a catalyzer to develop standardized policies and procedures to raise the standards of EC to review protocol and conduct research adhering to the highest ethical standards. Therefore, accreditation programs play a pivotal role and are necessary for better compliance with regulations and SOPs.

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