Original Article

Impact of the COVID pandemic on functioning of the institutional ethics committee: A comparison study

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Abstract

Purpose and Aim: In COVID 19 pandemic, it was essential to document the functioning of the institutional ethics committee (IEC), how the organization adapted and faced challenges posed, thus forming the rationale behind this particular audit. The objectives were to assess the impact of the pandemic on the structure, review process, outcomes, and administration of IEC and to compare the same during its functioning in the prepandemic stage.

Subject and Methods: The study was conducted as a retrospective audit. After exemption from ethics review, the data were collected from the IEC office situated in KEM Hospital and were segregated into four domains: structure, review process, outcomes, and administration. The data were analyzed using descriptive statistics. Mann–Whitney *U*-test was used to compare the turnover time for approval of projects between the two study periods at 5% level of significance. SPSS software version 22 was used to analyze the data.

Results: Constitution changed , more protocols pertaining to COVID 19 studies were reviewed, meetings frequency doubled, and Standard Operating Procedures was amended to incorporate the changes faced during pandemic. Significant decrease in turnover time was noticed with respect to submission to query letter and study completion. There were more protocol deviations. Financial burden and expenditure decreased due to less paperwork and meetings being held online.

Conclusion: The ethics committee infrastructure and functioning had to undergo a paradigm shift to adapt to the various changes and overcome the various hurdles occurring during the COVID-19 pandemic.

Keywords: Contrast, ethics committee, infrastructure, COVID-19, pandemic, prepandemic

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INTRODUCTION

The right to privacy of health-related information is a foundational bioethical principle. In India, the significance of right to privacy and its protection is included in law and ethical guidelines. The institutional ethics committee (IEC) is an organization which is entrusted with the responsibility of regulating clinical research in the institution and to protect fundamental ethical principles, including privacy and confidentiality.[1]

The proper functioning of the IEC is bound by strict standard operating procedures (SOP) which are followed

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diligently. However, the COVID-19 pandemic and the exponential increase in the number of cases induced unforeseen lockdowns which challenged the IEC functioning to a great extent. The onset of the pandemic hampered and challenged the conduct of research and various clinical trials across the country.[2]

With the established framework at hand, while facing an enormous public health challenge, it becomes necessary for the scientific community to conduct clinical research for etiology finding, pathological basis, prevention and control of COVID-19 transmission, and prognostic features, reduction in the number of severe cases, prevention of various types of physiological disorders, and development of effective drugs, targeted treatments, and vaccines.[3]

Adaptation in publicly declared emergencies should ideally be guided by preparedness plans for emergency research ethics review which has to be developed by IECs and the institutions before the emergence of the crisis. Failure to do so can lead the ethics committee to face a lot of hindrances in handling research. The investigators can be exposed to similar situations in the acute times of crisis. Manpower is affected by a substantial amount, offline meetings are converted into online ones with its own challenges, but it surely has facilitated the accelerated review process which was necessary during the pandemic.[4]

Key elements required primarily in conducting effective review of studies include rigorousness, responsiveness, and timeliness.

Rigorousness is the upholding of ethical principles in a consistent manner that are contextualized in the public health emergency through some essential values of giving equal respect, helping in decreasing suffering and being fair at times. Responsiveness includes timeliness which is a characteristic feature of ethics committees that reflects their flexibility in adoption of innovative research designs, and to have productive discussions with researchers and the affected communities. Timeliness is something that can be achieved by revision of SOP in the review process that may include increased frequency of meetings to be held, using of technologies like teleconferencing, electronic submission of study documents and prior review by members in order to combat the challenges posed by the pandemic.[5]

There was lot of difficulty in the conduct of other studies (non COVID) which were not possible to initiate or to continue because many of the general hospitals were converted into COVID hospitals, many of the out patient departments were closed down, patients could not travel to the research sites due to lock down/no travelling facility supplemented with anxiety in visiting hospital sites as well.[6]

Initial submissions, review processes, meetings, communication letters after review, and approval found places in various online platforms during the pandemic crisis. SOPs were amended, and new addendums were added. Many sites were not functioning due to lack of transport facility and were extremely short-staffed, thus affecting the follow-ups for patient care and safety to a great extent.[7,8]

In these acute times of the pandemic, the Indian Council for Medical Research (ICMR) in 2021 came out with a guidance document for reviewing biomedical and health research during COVID pandemic. This document highlighted key points for the functioning of ethics committee.[9]

Hence, it was essential to document the functioning of IEC in COVID 19 Pandemic, how the organization adapted and faced the challenges posed, thus forming the rationale behind this particular audit. The primary objectives of the study were to assess the impact of the COVID pandemic on the structure, review process, outcomes, and administration of IEC from March 23, 2020, to March 23, 2021 and to compare the structure, review process, outcomes, and administration of IEC with the functioning during prepandemic stage from March 23, 2019, to March 22, 2020.

SUBJECT AND METHODS

The study was conducted as a retrospective audit. After the exemption from ethics review, the following documents were used as source data from the IEC office situated in a tertiary care hospital in India: SOP, project registers, project files, and minutes of meetings.

The data were collected from March 23, 2019, to March 23, 2021.The confidentiality of all documents and stakeholders was maintained strictly.

The variables recorded were:

Structure (1st domain)

- Change in the constitution of the ethics committee
- Number of expert reviews conducted
- Trainings conducted.

Review process (2nd domain)

- Meeting frequency, member attendance, queries raised
- SOP changes

- Change in the review process.

Outcomes (3rd domain)

- Number of studies, decisions taken, serious adverse events (SAE) meetings conducted, compensations paid
- Protocol deviations, study terminations, study completions
- Study timelines
- Recruitment number.

Administration (4th domain)

- Infrastructure and staff
- Budget
- Number of documents.

The data were analyzed using descriptive statistics. The Mann–Whitney *U*-test was used to compare the turnover time for approval of projects between the two study periods at 5% level of significance. SPSS software version 26 (IBM, Armonk, USA) was used to analyze the data.

RESULTS

In the first domain (structure) of the variables observed, it was found that the constitution of the ethics committee was altered, in which 3 members resigned in the pandemic due to other hospital-based commitments and 6 new members were appointed. Furthermore, more training sessions were conducted, and more protocols were sent to expert review during the pandemic stage as compared to in the prepandemic stage.

In the second domain (review process), it was observed that the frequency of meetings was doubled during the pandemic stage, and they were held online even after frequent meetings attendance being met during pandemic. Twelve members on an average in the pandemic attended the meetings in comparison to 11.5 members on an average who attended the meeting in the prepandemic stage.

Because of COVID guidelines for emergency research coming into force, SOP changed (2 SOPs were added of managing COVID protocols during pandemic), online meetings were conducted through online platforms,1st recruitment had to be informed, a 6 monthly report of non-COVID studies had to be submitted and quarterly review for COVID studies which was yearly before pandemic. Even without appropriate documentation, studies were reviewed and fast tracked. The government was partnered with all the sponsored researches conducted during the pandemic crisis. The table 1 below gives a detailed report of the changes made in the SOP during the pandemic stage as compared to the prepandemic situation.

Table 1: Changes made in the standard operating procedures during the pandemic as compared to the prepandemic situation

Prepandemic	Pandemic
Offline review/meeting	Online review and online meeting
Processing fees and complete documentation was a must for review	10/38 studies were reviewed without processing fees and proper documentation
Offline NABH corrections for 1 SOP	Online NABH corrections for 2 SOPs
Add recruitment strategy	1st recruitment to be informed
Participant compliant form in vernacular versions to be made available	Logbook in IP room, training of all nonscientific members
All studies to be monitored	Emergency research review
Yearly report to be submitted	6 monthly-non-COVID studies
	45 days-COVID studies

SOPs: Standard operating procedures, NABH: National Accreditation Board for Hospitals & Healthcare Providers, IP: Investigational Product

In the queries section, it was observed that mean administrative queries were 3.7 in the pandemic in comparison to 0.8 in the prepandemic phase, which was found to be statistically significant with Mann–Whitney *U*-test [Figure 1]. Among the administrative queries few to mention were missing appropriate documentation, missing signatures in important documents like protocol. In collaborative research, signatures were not found of collaborating departments, review fees were not paid during submission. Furthermore, the mean scientific queries were 12 in the pandemic in comparison to 6 in the prepandemic phase, which was also found to be statistically significant with Mann–Whitney *U*-test [Figure 2].

It was also observed that on an average ethical queries were 7 in the pandemic in comparison to 5 in the prepandemic, which was not found to be statistically significant [Figure 3]. The ethical issues raised were on (Issues in consenting, reimbursement, legally acceptable representative [LAR] consenting, not mentioning the use of online platform along with investigations and visits also online, not mentioning the design appropriately as placebo controlled studies or comparator used was not a standard of care). Investigational product (IP) dispensing method and laboratory change, recruitment strategy, e-consenting, virtual visits, pausing dosing and withdrawing patients who were not compliant to protocol or because of the deviations, compassionate drug use and posttrial access.

The other queries raised were on some missing statements in (Memorandum of understanding, Clinical trial agreement and insurance) and on an average the queries were 4 in the pandemic in comparison to 2 in the prepandemic phase which was found to be statistically significant with Mann–Whitney U test [Figure 4].

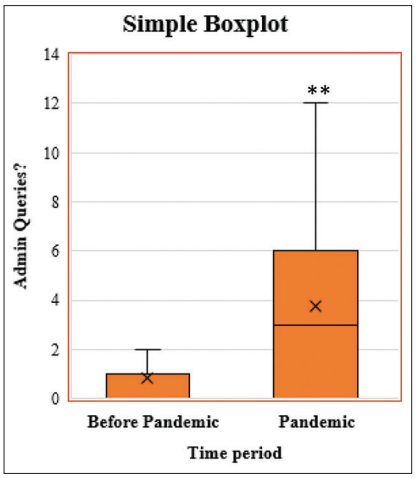

Figure 1: Simple box plot for admin queries during prepandemic and pandemic phase. ($P < 0.05$** Mann–Whitney *U*-test)

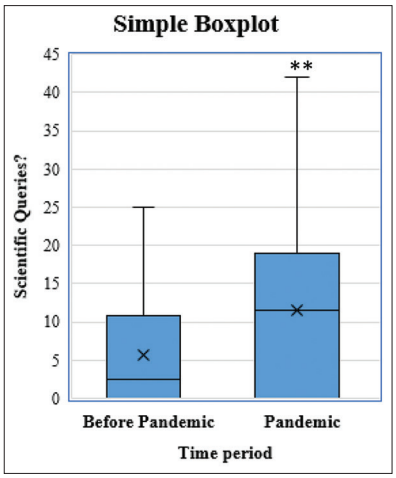

Figure 2: Simple Box plot for scientific queries during prepandemic and pandemic phase. ($P < 0.05$** Mann–Whitney *U*-test)

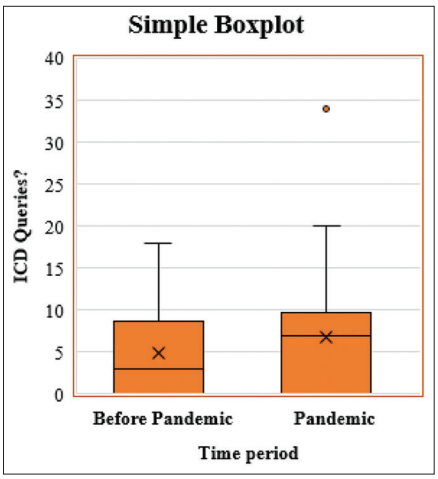

Figure 3: Simple box plot for ICD queries during prepandemic and pandemic phase. ($P > 0.05$** Mann–Whitney *U*-test). ICD: Informed consent document

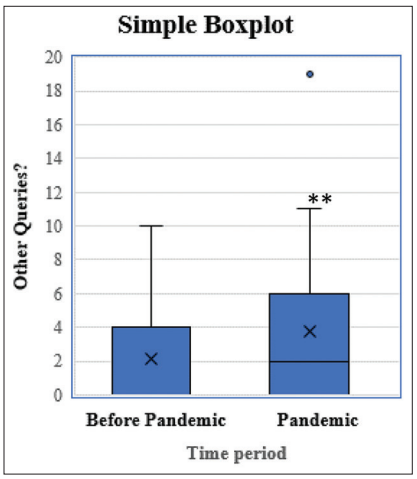

Figure 4: Simple Box plot for other queries during prepandemic and pandemic phase. ($P < 0.05$** Mann–Whitney *U*-test)

Outcomes of ethical committee functioning was the third domain evaluated, it was observed that even the number of studies doubled during the pandemic, the time taken for the 1st query letter to be sent by IEC from submission by the investigator was 26 days in pandemic stage in comparison to 40 days in the prepandemic period, similarly for study approval it took 130 days in pandemic in comparison to 102 days in prepandemic stage. The timeline from submission to completion of the study was 555 days in the pandemic and 914 days in the prepandemic era, which was statistically significant by Mann–Whitney test ($P < 0.05$) [Table 2].

Studies got terminated more in the pandemic because non-COVID studies did not happen due to lockdown and travel restrictions. Also, protocol deviations submitted were more in the pandemic phase 73/36 studies in comparison to 69/28 studies in the prepandemic phase, but on an average, 2 protocol deviations were reported per protocol.

IEC was functioning well in terms of SAE review as SAE meetings happened timely in pandemic as it was before pandemic. Equal number of SAE occurrences were reported in both the phases of the study. For all SAEs, the participant received free medical treatment along with financial compensation over and above that needed management of SAE. Three cases were related to the study were paid compensation.

Recruitment was more during pandemic because all the drug/device and vaccine studies increased, people were very eager to participate. Patients enquired and booked themselves for drug/plasma/vaccines. Also, more amendments were made during the pandemic stage than during the prepandemic stage.

Regarding the complaints made in the pandemic phase, it was observed that participants in vaccine studies on turning COVID positive complained that they were not being taken good care by the team. Also, the participants in placebo

Table 2: Turnover time of various parameters during prepandemic period and pandemic period

Turnover time	Prepandemic (days), median (IQR)	Pandemic (days) (IQR)	*P* (*P*<0.05)
Submission to 1st query letter	40 (10–70)	26 (1–45)	0.345
Submission to approval	102 (93–151)	130 (78–205)	0.345
Submission to completion of the study	914 (564–1960)	555 (405–747)	0.017**
Number of studies	21	38	

**$P<0.05$ Mann–Whitney test was considered to be statistically significant. IQR: Interquartile range

arm wanted vaccines after unblinding of the trials. Also, the investigators in the pandemic situation were observed to be registering complaints against the ethics committee regarding not being able to follow the SOPs, due to some communication gap under most probable circumstances. Monitoring of studies was same in both the periods.

In the fourth domain (Administration) it was observed that during pandemic E-mail communications increased significantly as compared to paperwork. IEC correspondence to regulators also increased (23 in the pandemic in comparison to 13 in the prepandemic phase). Also, before the pandemic, money was spent on infrastructure and there were two IECs functioning had meeting offline where expenditure on paperwork, eatables and honorarium to external members. During the pandemic, there were three IECs functioning, (in which 50% members were from other institution) paying honorarium to external members, meetings were held online, communication with investigators was through email, documents were printed later for hard copy archiving and monitoring increased. Even then, IEC made a saving of Rs. 188,576/ in pandemic.

DISCUSSION

The COVID-19 pandemic induced subsequent lockdowns that drained the research infrastructure in India which affected not only the society at large but also the researchers and particularly IEC members as the number of proposals related to COVID-19, submitted for evaluation, increased considerably which altered the dynamics of the meetings and the review process of the different studies requiring urgent attention due to the acute crisis of the situation in the country.[8]

IEC functioning works on constitution which went through few changes because few members left the committee due to extra COVID duties and so new members needed to be appointed for filling the gaps. This usually is encompassed with trainings which was also more during the pandemic, because this is mandatory required as per the New Drugs and Clinical Trials Rules 2019 guidelines.[10] The expert review also increased during the pandemic because the studies were on new technology, vaccines, and drugs repurposed, for which expert review was required which was not available in the ethics committee.

The number of proposals for research on COVID-19 increased exponentially that required urgent submission to the IECs for consideration. However, due to the pandemic, IECs, like other institutions, faced a lot of hurdles and challenges due to the impact the virus had on their members at an individual level as well as restricting the conduct of physical meetings and discussions. This, thus, speaks of the timely preparedness of the ethics committee to plan adequately and to manage accordingly as per the direness of the situation.

The number of meetings increased because meetings were held as and when the COVID related protocols were submitted and the number of members attending the meeting increased as the meetings were held online, and they were also prepared because many were working from home or alternate day of work which left them with lot of time. Because of the travel restrictions, time, energy and money was saved. SOPs changed as per the guidance led by ICMR 2021 COVID guidelines in the pandemic phase. SOP mentioned had meeting guidance, post approval process also was defined for COVID protocols. National Accreditation Board for Hospitals & Healthcare Providers (NABH) accreditation also happened online, and they issued recommendations which was somewhat different than that given before the pandemic.[11]

The current audit of IEC functioning thus highlights and enlists some of the significant issues and problems regarding proper functioning of the ethics committees to ensure the conduct of principled research during such dire emergency situations such as the COVID 19 pandemic. There was an urgent need for finding out newer drugs, develop latest vaccines and the need for identifying easy diagnostic techniques which resulted in increased submission of scientific protocols that affected the functioning of the ethics committees to a great extent.[12]

The submission of research proposals by e mail and through other online platforms initially triggered fear and doubt among the ethics committee members because they felt that there can be breach of confidentiality of the study documents being online.[13]

However, later on, licensed copies of online platforms provided some relief in this regard and provided

reassurance to the committee members regarding protection of data safety. Many of the ethics committee members in the present study had adopted a virtual online mode of functioning and were pretty much comfortable joining meetings through this newly developed mode of communication. Similar such experiences were recorded and evaluated upon by the investigators of a study conducted among the ethics committee members of a research institute in Chennai.[14]

Non-COVID projects, on the other hand, suffered a lot. Those studies requiring fieldwork and projects requiring blood for sample collection or other intervening techniques were halted or prematurely terminated and there was a sharp drop in the number of non COVID projects submission also as a result of prioritizing COVID 19 research. Similar problems were reported from other countries, such as China, which were affected by COVID-19 pandemic to a great extent.[15,16]

Administrative queries and scientific queries increased during pandemic because there was crunch of manpower at the sponsor and investigator site , lot of turmoil happened because many of the study team members were tested positive while working for the study and were quarantined, so documentation was not complete, and protocol were not written as per the requirement.

Certain concerns still existed like no site monitoring visits conducted and lack of proper causality assessments in SAE reporting by the investigator was a finding which can jeopardize the safety of the participant in the conduct of the research studies. However, the ethics committees allowed the continuation of the studies in the interest of participants after evaluating the benefit risk considerations. In contrast, London and Kimmelman, in their study[17] mentioned and highlighted the significant of rigorousness in the methodology. They further emphasized and mentioned that pandemics should increase the responsibility of ethics committees to coordinate their activities and to uphold the standards necessary for proper functioning and to review the studies through proper protocols as far as possible. In the present study, the studies doubled in the pandemic, the first query letter sent by IEC ,study approval by IEC, patient recruitment to completion of the study by the investigator site everything was on time and better than the prepandemic, so IEC and the study sites worked efficiently online with few supporting staff working on the investigator or IEC site.

Efficiency of EC depends on ethical review and following the timelines in post approval process as was found in the study. Research Ethics Committees (RECs) in China have reported meeting four times a month and have a mean time taken of 2 days from submission to approval, while other countries have reported that COVID 19 ad hoc committees have slowed approval and research.[18]

Common ethical queries raised in the study were issues in consenting, writing reimbursement paragraphs in the patient information sheet, comment on inclusion of LAR for consenting , mentioning of online platform for study visits , investigations and comment on placebo controlled studies and on comparator used is not a standard of care in the consenting document.[19]

Our study found an overload of projects, but the process of ethical review was rigorous and diversion from SOPs happened many times. The survey was conducted in Italian IECs also found lot of studies in COVID pandemic but may have exposed IECs to the risk of decreasing the adoption of ethical principles and standard protocols of evaluation of research applications.

Post approval process such as quarterly updates, submission and reviewing protocol deviations, SAE reporting, monitoring all happened timely. There were many terminations of non-COVID studies because of the lock down or travel restrictions.[20] The IEC administration played a major role during pandemic and IECs saved a lot of money due to online meeting, no spending on food, print outs and communication to investigators and regulators was through E mail.

The limitation of our study was that it was a retrospective study and personal bias could not be eliminated. It was a single centric study so the data generated could only be extrapolated to tertiary care hospital ethics committees. The investigators did not check the impact of functioning of ethics committee on participant well-being and safety along with data credibility. The strength of our study is that of being first of its kind to compare data (ethics committee related work) from prepandemic to pandemic era.

CONCLUSION

The study, thus, entails and enlists the paradigm shift the ethics committee had to undergo and the plethora of challenges it had to face owing to the acute crisis situation of the pandemic. The entire infrastructure had to be altered in order to adapt to the various changes occurring during the COVID 19 pandemic which surely transformed the working SOPs and functioning of the ethics committee to a great extent.

Recommendations

The study did not check the actual impact of pandemic on participant protection and quality of research that needs be explored in the near and distant future.

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Conflicts of interest

There are no conflicts of interest.

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