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Research Article

EVALUATION OF FUNCTIONING OF ETHICS COMMITTEE OF A TERTIARY CARE TEACHING INSTITUTE DURING COVID 19 PANDEMIC

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A B S T R A C T

Introduction: Since December 2019, the world is facing a new humanitarian emergency due to a novel corona virus. Lack of effective treatment or prevention of COVID-19 demands research on a priority basis. Despite the urgent situation, safety and quality of research must be guaranteed. Absence of any SOP to deal with emergency situations and lockdowns hampered the functioning of the ECs.
The present study was planned to evaluate the functioning of ethics committee of a tertiary care teaching institute during COVID 19 pandemic.
Material and method: A retrospective observational study was initiated after obtaining approval from Institutional Ethics Committee (IEC). Evaluation of the activities of the IEC was done in respect to the protocols of regulatory clinical trials and academic research submitted to IEC between March 2020 to October 2020.
Results: The number of meetings conducted by IEC for review of regulatory trials was 11. Four were conducted virtually and the rest were face to face. The protocol synopsis was circulated 2-8 days prior to the meeting to the EC members for review for protocols of COVID regulatory trials. Monitoring by EC was done for 8 out of 14 clinical trials.
Conclusion: IEC was able to carry out its duties even in emergency situation despite number of challenges mainly because of amendment of SOP for emergency research review for conducting virtual meeting, accelerating the review and approval process by shortening timelines whenever required.

INTRODUCTION

Since December 2019, the world is facing a new humanitarian emergency due to a novel corona virus – severe acute respiratory syndrome corona virus 2 (SARS-CoV-2). This virus has caused a global outbreak of corona virus disease COVID-19, which is characterized by severe progressive pneumonia, multi-organ failure, and death.[1] At present, there is no effective therapy for treatment or prevention of COVID-19 and therefore the present situation demands research on a priority basis in finding new strategies for disease prevention, diagnosis, and treatment. Despite the urgent situation, safety and quality of research must be guaranteed. Ethics committees (EC) need not only to improve the review efficiency, but also to make sure the standard of ethical review is not relaxed.[2] Therefore, role of ECs in reviewing research during the COVID-19 pandemic is very important and ethics committees have to deal with operational challenges like conducting virtual meetings, more frequent meetings, online circulation of project related documents, absence of standard operating procedure (SOP's) for emergency research review, ongoing and periodic review as well as monitoring and are still adjusting to and coping with the challenges that have emerged. The need for rapid action to conduct clinical trial of an infectious disease outbreak requires expedited review of the study proposal by the EC, which will have limited information to evaluate risk–benefit ratio of investigational product in participants who are vulnerable but at the same time ensuring competent ethics review, as well as for monitoring conduct of research. Many EC's did not have SOP's for reviewing research in emergency situation. The absence of an SOP to deal with emergency situations and lockdowns hampered the functioning of the ECs.

The present study was therefore planned to evaluate the functioning of ethics committee of a tertiary care teaching institute during COVID 19 pandemic.

MATERIAL AND METHODS

This was a retrospective observational study which was initiated after obtaining approval from Institutional Ethics Committee (IEC). Administrative approval for accessing the

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documents from the concerned authorities was obtained and complete confidentiality of the investigators and the study titles was maintained. Evaluation of the activities of the ethics committee was done in respect to the protocols of regulatory clinical trials and academic research submitted to IEC from the period of March 2020 to October 2020. Academic research included studies sponsored by ICMR or other funding agency as well investigator initiated studies. Protocols for Post graduate thesis was excluded from the study.

Functioning of EC was evaluated for the following

1. Number of protocols of regulatory trials reviewed by Ethics committee.
2. Number of protocols of academic research reviewed by Ethics committee.
3. Number of meetings conducted during the period.
4. Number of days prior to meeting for circulation of proposals.
5. Number of virtual meetings and meetings in person.
6. Days taken by Ethics committee to grant approval
7. Whether ongoing review and monitoring was done
8. Number of Serious adverse reaction (SAE) reviewed by EC during the period.
9. Whether the EC has amended the standard operation procedure for emergency research review.

Data obtained was expressed as percentage.

RESULTS

The present study evaluated the activities undertaken by EC from the period of March 2020 to October 2020. It was seen that the number of meetings conducted by IEC for review of regulatory trials was 11. Out of these, 4 meetings were conducted virtually and the rest were face to face. The number of clinical trials and academic research reviewed by EC during this period is given in Table 1.

Table 1 Protocols reviewed by EC during March 2020–October 2020

Protocols	COVID	Non-COVID	Total
1.Clinical trials	14	15	29
2.Academic research	26	15	41
Total	40	30	70

The protocol synopsis was circulated 2-8 days prior to the meeting to the EC members for review for protocols of COVID regulatory trials. Approval for regulatory trials was given within 1-8 days while for academic research it was given within a period of 8-24 days (Table 2). Total meetings conducted by EC were 11, out of which 4 were virtual and 7 were face to face meetings. Attendance for virtual meetings was found to be higher than face to face meetings (Table 3).

Table 2 Timelines followed by ethics committee for various activities

Activities	Timelines for COVID	Timelines for Non-COVID
Circulation of protocol to members prior to meeting	2-8 days	8-10 days
Approval granted	1-8 days	8-24 days

Table 3 Number of meetings conducted and average attendance per meeting

	Full committee Meetings	
	No. of meetings	Average attendance (Range)
Virtual	4	13.5(13-14)
Face to face	7	13.28(12-14)

Monitoring by EC was done for 8 out of 14 clinical trials.

During this period, 17 serious adverse events occurred in regulatory trials and all were reviewed by EC. Out of the total, 9 deaths were reported in COVID trials and one in Non-COVID trials whereas 7 were SAE's other than deaths.

Table 4 Number of SAE reviewed by ethics committee

Number of SAE	Death	Other than death
COVID trials	9	3
Non COVID	1	4
Total	10	7

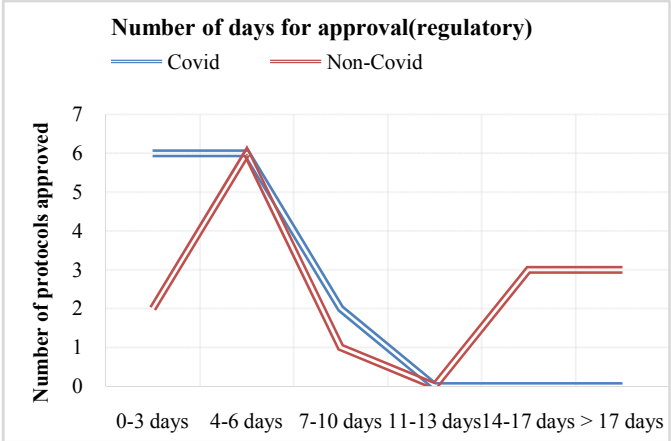

Fig 1 Frequency polygon indicating number of regulatory protocols approved and number of days taken for approval

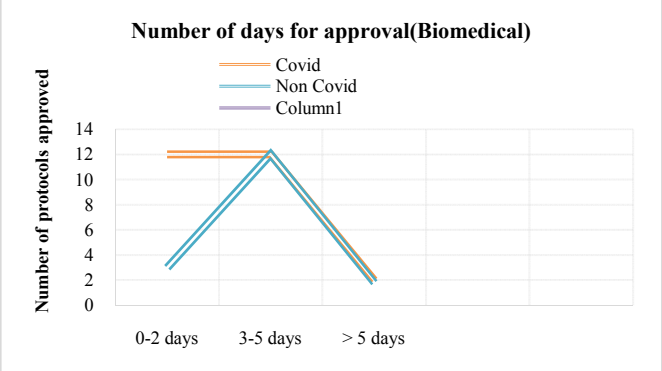

Fig 2 Frequency polygon indicating number of biomedical protocols approved and number of days taken for approval

DISCUSSION

The present study was conducted to evaluate the activities undertaken by IEC of a tertiary care teaching institute in reviewing protocols in emergency situation like COVID 19 pandemic. ECs have added responsibilities in reviewing research during this pandemic and one of the most important challenges they have to face is that of providing ethics review in time sensitive circumstances. The need for immediate action to contain an infectious disease outbreak may make it difficult to stick on to the usual timeframes for research ethics review. The EC must adapt its SOPs in time, without undermining any of the substantive protections that ethics review is designed to provide. [3]

The Ethics Committees (ECs) in India have varying capabilities and are in different stages of evolution.[4] This study, therefore attempts to evaluate the activities undertaken by IEC during this pandemic. However, comparison with other EC's could not be done as very few EC's got adjusted to the situation by amending the SOPs with flexibility in working and presently we could not find any study of this kind.

The first step that this IEC has taken to deal with the present situation was amending SOP for emergency research review that included allowing digitized submission of protocols and all documents, conducting virtual meetings and allowing flexibilities in various timelines.

The number of regulatory trials reviewed by IEC during this period was 29 which included 14 COVID trials and 15 non COVID trials (Table 1). During the first two months of the study period, IEC did not receive any protocol and activities of the ongoing trials were temporarily suspended due to various reason like inability of the participants and research staff to reach the trial site because of lock down, inability to receive the IP etc.

However, after this the frequency of meetings increased as it received COVID 19 related protocols that needs a rapid review by EC and at the same time ensuring participants safety and well being.

According to ICMR guidelines, priority for ethics review in a defined timeframe is given to COVID-19 related research but at the same time, Non-COVID research must not suffer due to 'covidisation'.[5] Therefore, the review of non-covid trials was undertaken by IEC taking into consideration benefit risk ratio in initiating the trial. Similarly, IEC reviewed a total of 26 academic COVID research protocols and 15 academic Non-COVID protocols during this Period.

Number of meetings conducted by IEC was 11, out of which 4 were virtual and 7 were face to face. Virtual meetings were conducted on ZOOM app and the overall experience was good. Interestingly, out of total 14 members, the average attendance was 13.5 for virtual and 13.28 for face to face meetings. Most of the members were net savvy except a few and did not find it difficult to handle new technology. For review of some academic research studies, 12 subcommittee meetings were held. During the COVID-19 pandemic, and the lockdown, a number of committees have resorted to the use of videoconferencing. Online meetings have significant advantages over physical or face-to-face meetings, though the guidelines and regulations imply that online meetings should not be the norm.[6]

As far as the timelines for approval and circulation of proposals is concerned, IEC has adopted flexibility in timelines. To expedite the review process, the usual timelines can be shortened for emergency-related research. For example, the EC should dispatch research project documents within 24 hours of receipt, ensure that members submit their comments within the next 48–72 h and that meetings are held within the next 24 h.[7] The timelines for circulation of proposal ranged from 2-8 days for COVID trials as against 8-10 days for Non-COVID trials. As depicted in frequency polygon, the 6 regulatory COVID trials were approved within 3days, another 6 within 3-6 days and remaining 2 in within 10 days. Whereas, only 2 regulatory Non-COVID trials were approved within 3 days, 6 were approved in 4-6 days and remaining 7 took 7 to 24 days indicating that priority was given to COVID protocols. Similarly the polygon for biomedical trials indicate that 12 COVID trials were approved within 2 days as compared to only 2 Non-COVID trials approved in same time frame. Hence, the timelines followed as per the EC SOP were shortened to accelerate the drug development process.

The number of SAE's reviewed by IEC that occurred in COVID trials were 12, out of which 3 were death. Similarly, a total of 5 SAE's were reviewed by IEC for Non-COVID trials, out of which 1 was SAE of death.

Another important responsibility of EC is monitoring of the ongoing program for compliance with GCP and protocol. The EC should continually evaluate progress of ongoing proposals, monitor approved study site for compliance, review SAE reports, protocol deviations/violations/ non-compliance/ DSMB reports/ any new information/assess final reports. For protocol deviations/violations, the EC should examine the corrective actions. If the violations are serious, the EC may halt the study.[5]

Monitoring was done for 8 COVID clinical trial protocol by verifying the scanned documents as EC members cannot physically meet the patient or the site in a potentially infectious environment. Most of the ECs were hardly ready for working in these demanding circumstances. However, they gradually got adjusted to the situation. Appropriate amendments in SOPs will support the ECs with flexibility in working, which is extremely important. It will ensure that they are able to play their role in emergency-related research without compromising on the safety of the participants.[8]

CONCLUSION

The present study concludes that IEC was able to carry out almost all the activities even in the emergency situation despite number of challenges in initial review of protocols, monitoring and conducting virtual meetings. This was possible mainly because of amendment of SOP for emergency research review for conducting virtual meeting, accelerating the review and approval process by shortening timelines whenever required. Since studies of similar kind are not available, we could not compare majority of the findings of this study with others and findings of this study are not generalizable.

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