Original Research Article

Perception of ethics committee members and investigators on implementation of e-EC software for ethics committees

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ABSTRACT

Background: An e-EC software (Create 4) was introduced since past 4 years at few institutional ethics committees (EC) in India. The software provided facilities for submission, online review and communication between investigator and EC. The study was to assess the perception of different stakeholders: investigators, chairperson, member secretary (MS), EC members, administrative staff regarding their experiences of using software, challenges faced and recommendations for improvisation.
Methods: Following approval of the institutional EC, the participants were enrolled after obtaining their written informed consent. The questionnaires specifically designed and validated for each category of investigators, EC members and administrative staff were administered. Strict confidentiality was maintained. The data was analysed using descriptive statistics.
Results: A total of 64 stakeholders who participated, there were 34 investigators, 18 EC members, 2 Chairpersons, 4 member secretaries, 6 administrative staff. The e-software was accepted well by majority of the stakeholders. Overall, the software was found to be user-friendly. A few challenges faced were: lack of adequate training for investigators and new EC members, inconvenience faced while downloading study documents one by one and the need to ensure uninterrupted internet access at workplace. The user ECs should ensure that the investigators and EC members are tech-savvy and they receive prior training. It was suggested that there needs to be an autofill option built-in while uploading document/s.
Conclusions: E-software was found to be useful by the stakeholders and provided suggestions to optimize its us.

Keywords: Software, EC, Investigators, E-submission, Perception, MS

INTRODUCTION

Digital India is a campaign launched by the government of India, to ensure that government services are made available to citizens electronically by improved online infrastructure and internet connectivity (Digital India, 2014).[1] In the healthcare sector, medical education, hospital management and clinical research have taken steps in this direction. An EC is an important social control mechanism for protection of research participants and to the progress of medical science. Efficiency of functioning of EC depends on following strict timelines as per standard operation procedures (SOPs) for holding meetings, establishing rigorous review process, timely decisions regarding approval /disapproval. A lot of paper work and documentation are needed for communicating

with all stakeholders-investigators. EC members and regulators. Hence having paperless working strategy is environment friendly and it is need of the time. Moreover, there is a requirement by the regulatory authority to maintain EC SOPs and all records in the form of soft copies (Registration of ethics committees. GSR72E; 08 February, 2013). Hence it was felt necessary to initiate software-based EC functioning (New drugs and clinical trials rules, 2019-CDSCO). A software-based e-submission and review process was adapted for King Edward memorial (KEM) hospital ECs in 2017. It is called as " e-EC" and it has been developed by forum of ethical review committees of India (FERCI) along with program for appropriate technology in health (PATH)- an international nonprofit organization working in global health innovation (Create4 2018).[2-3] It was designed in accordance with the national ethical guidelines for biomedical and health research involving human participants 2017 (National ethical guidelines for biomedical and health research involving human participants, 2017), the FERCI standard operating procedures for ethics committees (Forum for ethics review committees in India [FERCI]) and also subsequently revised to comply with the requirements of new drugs and clinical trial rules 2019 (New drugs and clinical trials rules, 2019-CDSCO).[4-6] The main purpose of e-EC is to achieve paperless submission of projects to EC for review. The team of members from PATH and FERCI had conducted a series of workshops across India to create awareness about the software and also to train the ECs issuing the same. It was of interest to see how this change was accepted by research stakeholders and whether it benefitted them.

With this background, we had planned the present study. The objectives were to assess the perception of different stakeholders (investigators, EC members, MS, administrative staff, chairperson) regarding the e-software, to find out the challenges faced by them and their suggestions to optimize its use.

METHODS

This was a cross-sectional observational questionnaire-based study. Approval for the study was obtained from the institutional ethics committee. (IECII/OUT/637/18). The study was initiated and conducted during June 2018-June 2019 after obtaining informed consent from all participants.

The e-EC software was installed in the EC office since 2017. The following flowchart depicts working of the software (Figure 1).

As this was a pilot study, no formal sample size calculation has been done. Convenience sampling method was used. The stakeholders- EC members, investigators and administrative staff of EC of Seth Gordhandas Sunderdas medical college (GSMC) and KEM hospital of Mumbai were approached for this project. The

administrative staff of all the outside ECs (13) shortlisted from the home page of e-EC software (https://iecmanager.org/) who are using this software were approached.[2] The outside ECs were contacted through email communication. Verbal consent was obtained from the EC chairperson/ MS of the 13 participating ECs to allow them to participate in this study.
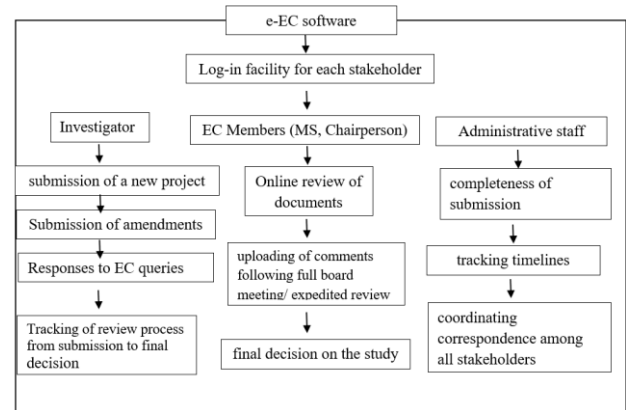

Figure 1: Working of the e-EC software.

There were 5 questionnaires (having questions 12-21 in no) used for different stakeholders The questions were of 'yes/no type', 'multiple choice' as well as open ended descriptive type questions. The questions were regarding feasibility in the usage, challenges if any and suggestions for future use. The content validity of all 5 questionnaires were done by group of subject experts (who were not part of this study team and had not participated in this study) and content validity indices for the five questionnaires were as follows: 0.942-investigators, 1-members, 0.841-MS, 1-chairperson and 0.941-EC administrative staff.

Confidentiality was maintained by coding all the filled questionnaires with unique identifiers. The data was entered in Microsoft excel of the computer version Microsoft office 2016. The responses were analysed using descriptive statistics. Mean and SD or median and range were used for numerical data. The categorical data were presented as proportions and percentage.

RESULTS

Out of 100 stakeholders approached from our institution, 64 consented to participate in the study which included 34 investigators, 18 EC members, 2 MS, 4 EC administrative staff and 2 chairpersons. A total of 13 ECs outside KEM were contacted, out of which 4 ECs responded (2 administrative staff members and 2 member secretaries). The perceptions of the investigators (n=34) have been summarized in Table 1.

Three fourth of the investigators (26/34) reported that there was adequate internet access in their respective departments. They used their personal internet when department facility was not available. The majority of the

investigators (23/34) felt that the online submission is preferable. They felt online submission was paperless and convenient due to easy accessibility. Also, a follow up of the submitted project can be seen on the website and there is no need to visit the EC office. More than half of the investigators (20/34) got the queries within the stipulated period and after they answered the queries, approval letter was received. Nine PIs got their query letters on the dashboard. Four investigators felt access to the query letter was quicker as compared to hard copy correspondence.

On the contrary, other investigators (11/34) stated that there was problem with logging into the software and they preferred the handling of hard copies to e-submission. Seven of them said that there was enough space for uploading but no option of deleting the incorrectly uploaded documents. Seven of them reported that they did not receive email from EC or had missed it and they registered as PI later at the time of submitting their research study. Six of them had difficulty logging in as principal investigator (PI). Six of the investigators had difficulty in uploading documents and they consulted the EC office regarding this issue. They felt that it was time consuming. As per 20/34 investigators, the difficulty in understanding the e-software occurred due to lack of formal training.

The challenges faced by 30/35 investigators while accessing the e-software were mainly about unavailability of auto-save option and mandatory requirement of the PDF version of the study document for uploading in the portal. Although the section for uploading additional documents as "any other document" is available in the software, one can upload only 10 documents (such as curriculum vitae, good clinical practice, Maharashtra medical council registration etc.) and if documents were more than 10, the investigator has to approach EC office. Further, when an essential document (marked with as

mandatory for submission) is not applicable for a particular; (e.g. informed consent document or clinical trial agreement though mandatory is not applicable for retrospective document-based study); an investigator has to upload a blank document to fulfill this requirement. In view of these observations, suitable changes in the e-submission software process were suggested by the investigators. They also recommended that there should be training of investigators for using the software. A mobile version of the software application was recommended by the investigators. The perceptions of EC members (n=18) regarding the e-software usage in EC submission are summarized in Table 2.

The EC members had adequate internet access and received mail for registering as members. Twelve out of 18 members preferred e-software to review protocols. Five members had difficulty in logging in as an EC member. Two members did not get the list of protocol allotted to them. Half of the members (9/18) said they had difficulty in downloading the documents. All the members were able to save and upload the comments. They felt that e-EC review process was more convenient than previous manual submission with respect to time and place. It saved paper. Five of them said that too many different documents/pages need to be accessed and opened while reviewing a project and the prolonged use of computer caused strain to their eyes. Two members had an opinion that one needs to be software savvy to use the e-software. Four felt that it was difficult to edit the documents. EC members suggested that training in e-software is necessary for all EC members and it must be conducted along with GCP-SOP training. Three EC members felt that the software need to be made more user-friendly.

Perception of MS (n=4) and chairperson (n=2) regarding the e-software usage in EC submission is summarized in Table 3.

Table 1: Perception of investigators, (n=34).

Questions	Yes	No	No response
Availability of internet access in the respective department	26	8	-
Received a mail from the EC office for registering as PI	26	7	1
Difficulty in logging in as PI on e-software	6	26	2
Sufficient provision for uploading documents	28	6	-
Option for deleting or replacing wrong documents	26	7	1
Uploaded documents accepted by the administrative staff	29	5	-
Received acknowledgment of uploading documents successfully on dashboard	31	3	-
Received changes in review status from time to time-administrative screening to review by MS/ review by members	23	9	2
Ease of uploading replies to EC queries	31	1	2
Received the approval letter	26	6	2
Preference for online submission of projects for EC review	23	11	-

PI: Principal investigator, EC: Ethics committee.

Table 2: Perception of EC members, (n=18).

Questions	Yes	No	No response
Availability of adequate internet access in the respective department or at home	17	1	-
Received mail from the EC office for registering as EC member	18	0	-
Difficulty in logging in as EC member on e-create software	5	13	-
Confusion for log in email id as PI and as EC member	4	10	4
Received the list of protocol allotted	16	2	-
Able to save and upload the comments	18	0	-

PI: Principal investigator, EC: Ethics committee.

Table 3: Perception of MS, (n=4) and chairperson, (n=2).

Questions	Yes	No
Availability of adequate internet access in the respective department or at home (for both)	6	-
Received mail from the EC office for registering as PI/MS/Chairperson on e-EC software (for both)	6	-
Difficulty in logging in as PI/ MS on e-create software (for MS)	1	3
Faced problem at the time of registration-(question for chairperson.)	1	1
Approached EC office for help-(question for chairperson.)	2	-
Received notification on email from MS regarding the list of assigned projects-(question for chairperson.)	2	-
Confusion for login email id as PI and as MS (for MS)	1	3
Received list of all protocols (for MS)	4	-
Reviewed all the protocol-related documents (for both)	5	1
Had a problem in assigning projects to the reviewer (for MS)	-	4
Members sent comments on e-EC dashboard (for MS)	1	3
Could save and upload the comments (for MS)	5	1
Could compile the comments sent by members (for MS)	1	2
Uploaded items disappeared from the dashboard (for MS)	1	3
Could categorize the protocols into exempt/expedited/Full board review (for MS)	4	-
Executed the procedure within time as per SOPs (for MS)	3	1
Could generate the agenda on time and circulate (for MS)	3	1
Able to divide the agenda into different periods using e- EC software (for MS)	1	3
Could upload the query letter to respective PIs (for MS)	3	1
Could upload the minutes on time (for MS)	3	1
Could review another EC agenda or minutes on the dashboard (for MS)	1	3

The secretaries and chairpersons felt that the software saves a lot of paper and is convenient for reviewing protocol with respect to time and place. All the MS were able to categorize the protocols into exempt/expedited /full board review. It was convenient for MS to upload query letter to PI and minutes in the portal. One out of four MS faced difficulty in logging in the software. Few members (scientific members, social scientist) continued to send comments via email to MS/ by filling the review assessment forms citing the problem of internet access/convenience of using hard copies. Hence the MS from two institutional ECs could not compile the comments sent by members through e-software for a number of meetings. One MS from KEM experienced that uploaded documents disappeared from the dashboard occasionally. All the MS commented that it is inconvenient to download the study documents one by one. They felt that there should be a mechanism to view the documents without downloading.

One MS recommended that there is a need for incorporation of a simple, user-friendly review assessment form in e-EC software. Also, if there is a facility to compile the reviewers' comments on the dashboard of MS, that will help the MS for presenting the comments at the full board meeting. The difficulties stated by Chairpersons were initial problems in registration and need to download the documents one by one. Chairpersons also suggested that the software should be made more user-friendly.

Two EC administrative staff from institutional EC had difficulty in tracking the projects as there is a need to open each project for knowing the status. Three staff members stated that the uploaded documents disappeared from the dashboard a few times. They faced issues initially with the uploading of documents in the portal and had to contact the software manager. It was suggested that there should be an option available to

delete the uploaded article in the portal. They further suggested that in event of an EC member resigning from the committee, they should be able to delete her/his profile from the portal. They felt that the most efficient use of e-EC is for the EC-resubmission process. Post-review, a query letter is uploaded by MS on the portal and investigator can upload his/her reply in response to the letter making the review process faster. It saves the time and efforts needed for physical correspondence. EC administrative staff faced some difficulties initially in using the software and they commented that they needed more training.

DISCUSSION

The perception of all the stakeholders regarding use of an EC software was important to understand whether the new technology is user-friendly and acceptable. The e-software was found useful by majority of them and investigators and EC members provided useful suggestions. A few of the stakeholders stated they had difficulty in logging in/ uploading the documents. EC members and Chair reported that they could not review all the studies-related documents and they suggested that the documents should be downloadable as one zip file. The other recommendations were to make it more user-friendly for uploading and downloading of any type of file, the facility for editing documents online. It is necessary to have an auto-save option facility after uploading which will ensure documents are saved even if file is closed in hurry, portal is exited or there is connectivity issue. Availability of a user-friendly mobile application was emphasized by the investigators. The administrative staffs' recommendation that EC members profile should be locked immediately on resignation is important to maintain confidentiality of the EC activities.

The need for training in software usage was the opinion of all the stakeholders. A well-designed video training module can be prepared and made available to ECs and investigators for training them. The EC members suggested that the training in e-software can be imparted to EC members along with GCP and SOP training. Currently, the software is designed for the correspondence related to initial submission of new project and resubmission by PI before its approval. Agenda, minutes circulation and subsequent correspondence with investigator for continuing review process (SAEs, protocol deviations, amendments) need to be built in the software in future. Being an EC MS is an additional institutional responsibility for the faculty members over and above their routine teaching, patient care and research work, hence working from the desk is easier for them rather than spending time in the EC office. Hence, the software will be a boon for busy EC member secretaries.

A literature search revealed that limited number of ECs of premium institutes and multispeciality hospitals in India are using electronic portals for EC activities.[7] The same scenario is found in African countries where in one survey reported that 22 of 29 research ethics committees (RECs) had dedicated offices for review activities, however, none of the RECs had an electronic data management and archiving system (Silaigwana and Wassenaar).[8] A paper from India traces the evolution of ECs in India where it mentions the software being used in future (Thatte and Marathe).[9] Since its introduction, the software has been used in more than 40 medical research institutes in India. A survey of users in 2018 showed satisfaction with the software-it saved time, made review processes more convenient, and reduced the overall cost of review (PATH-In India, ethics review goes digital for good). We could find that Tata memorial hospital in Mumbai has created their own IEC software and portal.[10] There are no studies published regarding ECs using and sharing the experience with the online software.

Limitations

The study findings should be viewed keeping in mind the small number of stakeholders interviewed. Those who did not participate may have other viewpoints. It is generalizable only to ECs using e software.

CONCLUSION

The new e-EC software was found to be beneficial by the EC members and the investigators. They emphasized the need for formal training and provided suggestions to strengthen its utility. E-EC software introduction in the institute changed the functioning of EC and all the stakeholders were at ease and at their comfort. With lot of paper saving, there was smooth transition during the pandemic also.

ACKNOWLEDGEMENTS

REFERENCES

1. Digital India. 2014. Available at: https://mygov.in/group/digital-india/. Accessed on 4 March 2024.
2. Create4. 2018. Available at: https://iecmanager.org/. Accessed on 10 March 2024.
3. PATH-In India, ethics review goes digital for good. Available at: https://www.path.org/articles/india-

ethics-review-goes-digital-good/. Accessed on 21 March 2024.

4. Forum for ethics review committees in India [FERCI]. Available at: http://ferci.org/. Accessed on 20 March 2024.

5. National Ethical Guidelines for Biomedical And Health Research Involving Human participants. 2017. Available at: https://main.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf. Accessed on 20 March 2024.

6. New Drugs and Clinical Trials Rules, 2019-CDSCO. Available at: https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/NewDrugs_CT Rules_2019.pdf. Accessed on 19 January 2024.

7. Registration of Ethics Committees. GSR72E. 2013. Available at: http://www.cdsco.nic.in/writereaddata/G.S.R%2072(E)%20dated%2008.02.2013.pdf. Accessed on 24 March 2024.

8. Silaigwana B, Wassenaar D. Biomedical Research Ethics Committees in sub-Saharan Africa: a collective review of their structure, functioning, and outcomes. J Empir Res Hum Res Ethics. 2015;10(2):169-84.

9. Thatte U, Marathe P. Ethics Committees in India: Past, present and future. Perspect Clin Res. 2018;8(1):22-30.

10. Tata Memorial centre Institutional Ethics Committee Standard Operating Procedures Version 6.0. 2021. Available at: https://tmc.gov.in/tmh/PDF/sop/SOP%20V6%2028.04.2021%20Uncontrolled%20Copy.pdf. Accessed on 16 January 2024.