**Role of legal expert in the Research Ethics Committees: A questionnaire based survey.**

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**Abstract (216 words)**

All Indian and intenational guidelines clearly state the inclusion of legal expert (LE) as quorum member in the ECs. However, the exact role and responsibility of legal expert in the EC is still not much clear. The present survey was undertaken to assess the knowledge and attitude of LEs regarding their role in the research ECs. LEs serving the ECs in Mumbai and adjoining areas were approached. After obtaining written informed consent a pre-validated questionnaire (27items) was administered. LEs from 23 out of 66 ECs gave consent to participate. Questionnaire was administered to 15 LEs affiliated to 23 ECs. 9 LEs were associated with more than one EC. More than half LEs had postgraduate degree (8/15) in law with two having additional medical degrees. 8/15 LEs had EC experience more than 5 years and 10/15 had training in GCP and SOPs. The knowledge assessment showed that total average score was 9.33 (out of 17) and only 6/15 LEs scored more than 60%. There was significantly better knowledge of regulations and review process in LE with postgraduate degrees (p<0.01; compared with graduate LE). Majority of the LEs had perceived their role in EC was critical and essential. But lack of training, time constraints were the challenges which deterred them to play their role effectively.

Keywords: CTA, Insurance policy, SOPs.

**Background**

Ethics Committees (EC) play a pivotal role in reviewing biomedical research and in ensuring that the research proposed to be carried out is ethical and within the boundaries of the law. The purpose and role of the EC is to protect the dignity, rights, safety and well being of the potential and actual participants. Each member of the EC contributes to ensure that valid, worthwhile, scientific, legal and ethical research is carried out. This task is successfully accomplished by the medical / scientific/ nonmedical/ nonscientific members of the EC who review the research proposals for their scientific, medical, ethical, legal and social contents and requirements. The Indian Council of Medical Research (ICMR) guidelines on bioethics – National Ethical Guidelines for Biomedical and Health Research involving Human Participants, 2017, the New Drugs and Clinical Trial Regulations, 2019 and other national and various international guidelines require the non-scientific and nonmedical members to include a lay person, social scientist and a legal expert, who are essential to form the quorum of the EC. The performance of an EC largely depends on the contribution of each member, including the non-medical and non-scientific members.

The importance~~,~~ and contribution of the legal expert (LE) depend largely on the skills, knowledge and character traits of the individual member. The lawyer members in ethics committees must be conversant with basic knowledge on the law, (especially research related law and ethics), how the legal concerns may impact the ethical analysis, for example, informed consent and confidentiality, and the importance of contracts during research trials, such as Memorandum of Understanding/ Clinical Trial Agreement, Insurance contracts, and the like.

In India there are Institutional Ethics Committees and Independent Ethics Committees, though the latter are fewer in number. The decision making process of the EC and the bar that they set for ethical research depends largely on how much encouragement, importance and weightage the members give to the contributions of the non-medical and non-scientific members, including the LE. In one study, conducted by Brahme et all in year 2009, it was found LE was not part of most of the ECs earlier (1).

It is important for ECs to not only appoint LE as a part of the committee, but also for the LE to contribute in the discussions and meetings of the EC. Thus, in order to evaluate the competence, contribution, the profile, knowledge and attitudes of the LE in EC, a questionnaire based study was designed, and the results are presented and analysed herewith. The active participation of LE in deliberations of EC will ensure balanced decision making considering legal as well as ethical issues.

**Method**

A prospective observational questionnaire based study was designed to study the role of the LE in ECs. It was submitted to the Institutional Ethics Committee, and after receiving approval from the committee (project no. EC/OA-63/2016), the study commenced.

A list of ECs – both Institutional as well as Independent was made from the database of registered ECs with the Central Drug Standard Control Organization (CDSCO), during the study period August 2016 to August 2017, in the Mumbai, Thane city and Navi Mumbai areas. The investigators contacted the ECs, telephonically or via email, seeking an appointment to administer the questionnaire for the purpose of the study to the LE on the committee.. LEs having at least one year of experience of serving ECs were only approached.

The questionnaire designed was to capture the knowledge, attitude, practices regarding role the LEs serving on the ECs. The questionnaire contained three broad domains and a fourth part on recommendations:

1. ***Demographic* profile of LE**: Age, gender, qualification, practicing or non-practicing lawyer, number of ECs affiliated, experience in years for being legal expert in ECs, nature of appointment, name of the documents reviewed, received standard operating procedure (SOP) and Good Clinical Practice (GCP) training, etc.
2. ***Knowledge*** domain had questions on the following themes: *i)* regulatory guidelines related to clinical research (n=3 questions); *ii )* Informed consent (n=5); *iii )*Serious Adverse Events (SAEs) (n=2); and iv) compensation (n=3) *v)* Legal documents reviewed, i.e. insurance policy, MOU and/or CTA (n=4). This section comprised of a total of 17 questions, and each question had 4 responses with one correct response. 1 Mark was assigned to each correct answer and total score was calculated. Total maximum score was 17.
3. ***Attitude and practice evaluation regarding*** participation as LE in the ECs, comprised of the frequency of EC attended meetings; the issues LEs deal with in the review process, and the LE’s views on their position in the ECs as well as on the work of the committee. This section comprised of a total of 10 questions and the respondents (LEs) were required to choose from a 5-point Likert scale ranging from 1 to 5 (1-strongly agree, 2-agree, 3-not sure, 4-disagree and 5-strongly disagree). Percentage of participant responding to each scale for the particular question was calculated.
4. The fourth and final part consisted of the questionnaire consisted of open ended questions wherein LEs could provide comments and recommendations too.

The draft questionnaire was validated by administering it to 10 subject matter experts. Each expert assigned a scale to each question i.e. essential, useful but not essential and not essential. The Content Validity Ratio (CVR) for each question was calculated by the *Lawshe’s* Formula (3) - CVR = (Ne - N/2)/(N-2). According to this formula, a minimum CVR value of 0.51 is required for fourteen (14) panel members. The questions with CVR value of 0.51 or more were retained and the questionnaire for the study was finalised. The average CVR value for the finalised questionnaire was 0.84.

*Administration of questionnaire:* The questionnaire was administered to the participants of the study directly by the investigators after obtaining written informed consent. Questionnaires filled by the participants were collected approximately after 30-40 min. Participants were provided privacy and extra time if needed to fill the questionnaire.

*Statistical evaluation:* Descriptive statistics was used to analyse the collected data. The data was expressed in percentage or mean±SD, as applicable. The number of years of experience as an ECs member was tested and correlated with the knowledge score using Pearson correlation test,whereas, the knowledge scores of LEs with postgraduate degree (PG) and without PG degree was compared using chi-square test.

**Results**

Total 90 ECss were registered with the CDSCO, as on 1.1.2016, from the Mumbai, Navi Mumbai and Thane city area. 58 were institutional ECss and 32 were Independent ECs. The recruitment of LEs in the study is explained in the flowchart given below (Fig.1). The response rate from ECs was approximately 35% with LEs from 23 out of 66 ECs gave consent to enter the study. Therefore, the questionnaire was administered to 15 LEs who were affiliated to 23 ECs, data of which is presented in this paper.

**Part A: Demographic profile:** All the LE participants (n=15) were invited to serve as LEs on the ECs and/or were recommended by other EC members. They were appointed by the director or the head of the institution. Nearly all LEs (14/15) mentioned that they reviewed all study related documents except 1 LE who stated that the CTA and the Insurance policy only were sent for review to him. The demographic profile of the LE participants is depicted in Table 1

**Part B: Knowledge:** The score for the knowledge pertaining to important aspect of conduct of a research project under the domains i) regulatory guidelines related to clinical research ii) Informed consent iii) Serious adverse events and compensation and iv) legal documents review, is shown in Table 2.

When we compared the profile of the EC members with their knowledge score,  
we observed that there was no correlation between number of years of experience of EC work and knowledge score (Pearson correlation test, p< 0.05, r=0.268). In addition, there was no significant difference between the scores of LEs with postgraduate degree (PG) and without PG degree (Chi-square test, p,0.05).

**Part C= Attitude**

The number of LEs responding as agree and strongly agree is presented in the Figure 2. All LEs perceived that they play very important role in ECs and majority of them opined that they have important role in EC meetings (11/15) as well as approval of the clinical studies (13/15). At the same time the LEs also felt that LEs should be trained to review the legal documents (11/15). There were very few LEs who were intimidated by other EC members with clinical background (2/15).

**Discussion**

The current study explored the knowledge and perception of LEs on their roles in the research ethics committee. The study process started with contacting ECs registered on CDSCO site. The site provides the details of registered ECs including address and contact numbers. However among 90 ECs from the Mumbai, Navi Mumbai and Thane city, the contact details of 17 ECs were incorrect and hence those ECs could not be contacted and located at the given addresses. The possible reason for this as opined by authors can be that there was no process to confirm the details of these ECs by the authorities or the ECs have moved out or stopped functioning and the database is not updated. However, this also brings out the importace of uploading the contact details of the ECs on the official website only after actual confirmation and also to formulate process to update the EC addresses at regular intervals by the authorities.

As per ICMR guideline, the LEs should have a basic degree in Law from a recognized university, with experience and training in medical law is desirable (4). The LEs who participated in this study were qualified (Graduates: 9 and Postgraduates: 6) and experienced (5.43±3.56 years) to serves as LEs in the ECs. One LE had degree in medicine and law. Four of the LEs stated that they did not receive any SOP and GCP training. On further enquiry with these LEs verbally, the reason stated by all 4 LEs was that they could not attend the training due to unavoidable reasons. However, it is responsibility of the institutional head, member secretaries and chairpersons to arrange for the training of all the EC members who were unable to attend the training.

The ICMR guidelines, 2017 state that EC members should undergo initial and continuing training in human research protection, on the applicable EC SOPs and related regulatory requirements. All trainings should be documented. The New clinical trial rules,2019 states that, SOP and regulatory training from time to time and those members who have not received such training will be disqualified (5). The institution and the Secretary need to ensure that all members are conversant with New Drug and Clinical Trial Rules,2019 and Good Clinical Practice to safeguard the rights, safety and well being of the participants. Although, it needs to be noted, that this research study was conducted prior to the formulation of the new clinical trial rules, 2019 and the ICMR guidelines, 2017, the principles governing training and updating the members with the new laws and guidelines have been there even prior to the latest amendments.

As a part of the study procedure we contacted head of the institutions/ hospitals of the ECs and if required chairpersons as well for the approval of their LEs participation in the study. But administrative permission was denied by institutional heads of the 21 ECs, whereas 22 LEs denied/ refused consent to participate in the study. The response rate for the study was approximately 35% only. The reason for denial of LEs for the participation in the study could be busy schedule of the practicing lawyers, disinterest and/or hesitancy to take the knowledge test. The reason for denial of administrative permission from the institutional heads to contact LEs is difficult to ascertain. However, it definitely shows the probable defensive behavior and lack of confidence of institutional heads to allow their LEs to participate in an exercise that would probably scrutinise the knowledge of the LEs by the researchers (though anonymization and confidentiality was assured).

The presence of LEs in the EC meetings is important for decision making, as discussed hereinabove. In this study we found that at least 9 lawyers were associated with more than one ECs. 5 LEs were affiliated to 2 ECs, 1 LE was affiliated to 3 ECs and 1 LE was affiliated to 7 ECs. This indicated that only few lawyers who are interested in joining and doing the EC work, have to get affiliated to more than one EC. Besides lawyers maybe busy and may also not have the time or motivation to join ECs. This could also affect the attendance, quality of review conducted by the LEs at the EC meetings, etc. A matter of concern is when LEs serve on more than 2 to 3 ECs, whether they are able to justify their role and functions in ECs they are affiliated to.A study conducted by Kaur, et al. (6) in 2017 found that only 53% of ECs had LEs representation and study by Taur, et al. (7) who studied EC approval letters noted that legal experts or social scientists were not present during the approval granting meetings of the ECs. Our study brings to notice fact that there is dearth of expert and motivated legal experts to join the ECs. In addition, those who are members of the ECs may sECometimes be unable to be present for the EC meetings. This may also affect the decisions making process of ECs during meetings. This highlights the need to put forth/recommend a regulation regarding maximum number of ECs a legal expert can join as a member. On the other hand this point can be argued that an LE serving more than 3 ECs may be more well versed with the regulations and justify his role appropriately. For example in two tier cities where LEs may be less in number and hence may be attached to multiple ECs in that city.

Although the average total score for knowledge component was more that 50% of the total score, the average score of LEs for knowledge regarding core concepts of informed consent process, serious adverse event reporting, compensation to the participants and review of legal documents like CTA, insurance policy was less than 50% of the total score for that respective domain of the knowledge. This displayed not only the low level of knowledge, but also the quality of expertise and contribution that the LE brings to the EC, that could lower the bar of the legal and ethical review of research projects. An online survey conducted by Kannan, *et al.* (8) found poor knowledge of EC members regarding inclusion of important clauses in the CTA or Insurance policy reflecting poor review process of LEs of these documents.

In our study most of the LEs have stated that they received SOP and GCP training (11/15), yet, the knowledge component was low. ICMR guidelines 2017 states that legal experts should review proposal, ICDs along with translations, MoU, Clinical Trial agreement , other site approvals, investigators undertaking and other protocol specific administrative permission like HMSC, stem cell committee, etc. However, SOP and GCP training does not include training to review legal documents. Further, whetting all documents is a time consuming process, for which the LE may not have enough time – either due to their own work, or due to being so various ECs. It may be required that the LEs are provided summary information about the research projects proposed, so that they are able to scrutinize the legal documents carefully and meticulously. But, some LEs did express that training of LEs may be of essence, not only for SOP and GCP, but specific training should also cater to whetting legal documents relating to research trials and studies.

The results of the perceptions (attitude part) of the questionnaire indicated that LEs were aware of the their responsibility towards participants (14/15), importance of their role in the ECs as a legal expert (13/15), their presence in the EC meetings (11/15) and their role in the approval of the study(13/15). Majority of LEs were comfortable with other EC members (13/15)and felt confident for review of study related documents (10/15). However, they felt that LEs should receive separate training for review of documents like ICD, CTA and IP (10/15). Most (11/15)of the LEs recommended that the LEs should receive training in basic research. This suggestion is of much importance as LEs have little or no scientific background, and training in research may help them understand the project proposals and review the legal documents in the proposals better.

Some other recommendations which were expressed by LEs in the comment section were with regard to the review, where the LEs wanted clear directions for review of study related documents (3/15) , more time for review (4/15), and wanted the documents sent to them in advance(1/15). With regard to the EC meetings, the LEs suggested that LEs should be allowed to speak (1/15) and there should be free and frank discussions in the meetings (1/15). Some of the LEs felt that the administrative staff of the ECs required better co-ordination and more staff, so that no bias or partiality seeps in the administrative handling of the projects (1/15).One LE recommended that ‘every member who is legal expert needs to be trained on legal aspects of clinical trials’.

*Limitations*

Unfortunately, the sample size of this study was small, as the ECs were reluctant to provide details of the LEs, or the LEs did not want to participate in the study. Therefore, the results of the study are limited by its small sample size. Study was conducted in 2016-17, just before ICMR guidelines were released in 2017. It would be worthwhile to study if there is improvement in LEs attitude towards their role in EC after these guidelines have been implemented

*Recommendations*

It is important that only motivated and interested LEs should be part of the ECs. However this should not allow the few LEs to be affiliated to more than 2-3 ECs as this may affect the attendance for the EC meeting as well as quality of review process. A training specifically catering to the role of LEs in the Ecs should be provided to the LEs for their efficient working as EC members. Regular training and time to time assessment for understanding related to important aspects of GCP and SOPs can be arranged in form of case based discussions.

The guidelines and the rules relating to ECs provide training on ethics, GCP, SOPs, etc. The role of the legal expert in ECs, the skills and knowledge required by the LEs are not defined, and are not provided in any training manual. Whether such training can be provided, and can such skills be taught is something that needs to be tried, developed and tested. Lawyers are trained in a wide range of laws, and not all lawyers are well versed with the law relating to clinical trials or research studies. LEs also need to understand the research projects, especially the scientific projects in a simplified manner, so that they are able to contribute better to the legal aspects of the project.

It is of much importance that all members of the EC work towards higher legal and ethical standards of research projects. The non-medical and non-scientific members should be encouraged, allowed to speak and participate in the discussions of the committee. Lawyers can contribute substantially to research ethics by keeping themselves updated with the laws, regulations, rules and guidelines with regard to research or clinical trials. Such efforts need to be undertaken by them, and some guidance can be provided through regular training. The lawyers need to be accepted as an integral part of the EC, and should be involved in not just the overall decisions on research projects, but LEs role in ECs can be extended by involving them in the evaluation of the compensation payable for serious adverse events, and any disputes or discussions with regard to the research projects amongst the various stakeholders and the EC members. The role of the LE needs to evolve and be defined with much more clarity and their capacity needs to be developed.

**Conclusion**

Majority of the LEs had perceived their role in EC was critical and essential, but lack of training with respect to core concepts of conduct of trials, review of documents like CTA , recent regulatory updates and time constraints were the challenges which deterred them to play their role effectively.

*List of abbreviations*: LE: Legal expert, EC: Ethics Committee, ICMR: Indian Council of Medical Research, GCP: Good Clinical Practice,SOP: Standard Operating Procedure, CTA: Cliical trial agreement, IP: Insurance Policy, HMSC: Health Ministry Screening Committee.

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*Declaration*

*Ethical approval and consent to participate:*

This study was approved by Ethics committee of Seth GS Medical College and KEM Hospital, Parel, Mumbai. Quetionnaire was administered to all participants after obtaining consent.

*Consent for publication:*Not applicable

*Availability of data and material*The study data is for the internal use and will be made available upon reasonable request.

*Competing interest:*

The authors declare that they do not have any completive interest.

*Funding:*

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*Author’s Contribution*

Dr. SVJ and Dr. RKT contributed to the thematic conception, protocol writing, ethical approval process. Dr. SVJ, D. PAM, Dr. YCS, JK and VJ were involved in contacting ECs , obtaining permission, and questionnaire administration process. Dr. SVJ and Dr. RKT carried out data compilation and analysis. Dr SVJ, Dr. RKT, Dr. PAM, Dr. YCS and VJ were involved in development of draft manuscript, revision and finalization of manuscript.

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**Table1: Demographic profile of legal experts**

|  |  |  |
| --- | --- | --- |
| **Sr. No.** | **Demographic Characteristic** | **Findings (N=15)** |
|  | Age in years | Range: 30-84 |
|  |  | Mean : 56.33±15.74 |
| 2. | Gender | Male : 9 |
|  |  | Females: 6 |
| 3. | Qualification | Graduates: 9 |
|  |  | Postgraduates: 6 |
| 4. | Practicing as lawyers | Yes : 8 |
|  |  | No: 7 |
| 5. | Number of ECs affiliated to | Range: 1-7 |
|  |  | Mean : 2.07±1.53 |
| 6. | Experience in EC | Range : 1.5- 13 years |
|  |  | Mean : 5.43±3.56 |
| 7. | Received training in SOP and GCP | Yes: 11 |
|  |  | No: 4 |

**Table 2: knowledge of LEs pertaining to** important aspect of a research project

|  |  |  |
| --- | --- | --- |
| **Average total score (Maximum score:17)** | | **9.33±3.50** |
|  | **Question domain/construct** | **No. of LEs giving correct response (N=15)** |
| *i)* Regulatory guidelines *related to clinical research* (Maximum score:3): Average score 2.07±0.68 | | |
| 1 | Regulatory body responsible for clinical trials in India | 14 |
| 2 | Act covers the conduct of clinical trials in India | 13 |
| 3 | Amendment to Schedule Y making it mandatory for all EC to be registered | 4 |
| *ii) Informed consent* : Average score (Maximum score:5): 2.53 ±1.36 | | |
| 4. | Process | 8 |
| 5. | Legally acceptable Representative | 10 |
| 6. | Vulnerable population | 6 |
| 7. | Confidentiality | 8 |
| 8. | AV recording | 6 |
| *iii) Serious Adverse Events (SAEs)and compensation* (Maximum score:5): 2.53±1.46 | | |
| 9. | Entitlement to compensation | 5 |
| 10. | Causality assessment | 6 |
| 11. | Timeline for reporting SAEs to DCGI | 7 |
| 12. | Authority deciding amount of compensation | 12 |
| 13. | Base amount for calculating compensation | 8 |
| *iv) Legal documents review* (Maximum score:4): 2.20 ±1.11 | | |
| 14. | CTA publication policy clause | 6 |
| 15. | Clause on causes for termination of trial | 10 |
| 16. | Clause of Indemnity in Clinical trials in IP | 11 |
| 17. | Importance of IP | 6 |

**Table 3: Perception of the LEs regarding their role in ECs**

|  |  |  |
| --- | --- | --- |
| **Question No.** | **Question** | **Number of LEs Agreeing +strongly agreeing (N=15)** |
| **1.** | Ethics Committee (EC) plays very important role in protection of rights and wellbeing of the participants. | 14 |
| **2.** | As a legal expert I am an essential part of the quorum of the EC meeting | 11 |
| **3.** | Legal expert plays very important role regarding decision of approval of the clinical study. | 13 |
| **4.** | Being the part of the EC, I feel responsible towards the participants of clinical studies. | 13 |
| **5.** | As a non medical person it difficult for me to review the clinical study related documents. | 5 |
| **6.** | Being from non medical background I feel intimidated by doctors during EC meeting. | 2 |
| **7.** | Legal experts should have separate training pertaining to review of clinical study documents | 10 |
| **8.** | There should be clear guidelines regarding role of LEs for reiew of documents by the EC | 11 |
| **9.** | Legal expert in the EC should also play the role to advise other EC members regarding legal aspects of the study. | 8 |
| **10.** | Legal expert should have training on basic clinical research | 11 |

**Figure 1: Flowchart for recruitment of LEs in the study.**

Total ECs in Mumbai, Navi Mumbai, Thane area registered with CDSCO = 90

ECs contact details traceable = 73

ECs non-traceable= 17

ECs contacted: 66

ECs shut = 7 (6 independent 1 institutional)

ECs Giving administrative permission= 45

ECs not giving administratie permission = 21

Data of 15 LEs from 23 ECs analysed

22 LEs from 22 ECs denied consent to participate