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# Profile and role of the members of ethics committees in hospitals and research organisations in Pune, India

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## *Abstract*

***Objectives**: Appropriate constitution of ethics committees (EC) is crucial to ensure a high quality review of research proposals. We studied the profile and role of EC members of Pune-based health and research organisations. Method: 52 ethics committee members representing 12 health and bio-medical research institutions in Pune city completed the structured questionnaires. Results: The respondents represented ECs of hospitals (67%), research organisations (23%) and NGOs (10%). The attendance of members at EC meetings was significantly associated with higher qualification (p=0.004), more than 20 years of research experience (p=0.023) and more experience of working with ECs (p=0.032). Most of the chairpersons or secretaries had a medical background (p=0.027), and were more likely to be formally trained in ethics compared to other members (p=0.049) and had more research experience (0.043). Overall, 62% had doctorate degrees and 38% were post-graduates or graduates. Forty four percent had the correct knowledge of ethical principles. A majority (79%) of EC members felt that formal training was necessary and 84% said that there should be networking of the various ECs to share thoughts and experiences. Conclusions: EC members were generally senior in age, highly educated and well-experienced in research. Representation of lawyers, ethicists and non-scientific members needs to be increased. Even with an appropriate EC constitution, the members had sub-optimal understanding of ethical issues and ethical principles. Formal training of EC members in ethics, and networking of ECs, is crucial. The scope of the role of EC members needs to be clearly recognised and understood by the constituting institutes.*

Ethics plays a central role in health research. Research involving human subjects is based on a moral commitment to achieve human welfare and gain knowledge. Clinical research runs the potential risk of causing harm, and therefore sound standards of ethics must be established to protect research participants (1). This has become more important in India where large numbers of clinical trials are being conducted and where such trials are likely to substantially increase in the coming years (2).

In India, the constitution of ethics committees (ECs) started with extramurally sponsored research. The Indian Council of Medical Research (ICMR) formulated ethical guidelines for biomedical research, primarily a guidance document for medical, epidemiological and public health research (1). One of the major recommendations was a review by an appropriately constituted EC. The purpose of an EC in reviewing biomedical research is to safeguard the dignity, rights, safety, and well-being of all actual or potential research participants (3).

Since a large amount of research is carried out in India by autonomous bodies as well as various research organisations and hospitals, it is necessary to understand and explore the quality and performance of ECs. The performance of an ethics committee is expected to depend on its appropriate constitution. The ICMR and the World Health Organisation (WHO) carried out a survey on the functioning of ethics committees in 2001 and 2003, involving about 250 institutes all over India. The survey used 20 questions and identified some deficiencies, but the data on the functioning of the ECs were collected from various institutes (4).

In the current study, the data were collected from EC members who were direct contributors to the ethical review process and not from the organisations constituting the committees. We explored the profile and role of the members of ethics committees of health and research organisations in Pune, India. The findings of our study are expected to complement the efforts of the ICMR in strengthening the ECs of various health research institutions in India.

## Methods

A list was compiled of the major hospitals and research organisations involved in health research in Pune. The organisations were approached for their permission to interact with their EC members. A final list was prepared of the institutions that had functional ECs in place and that agreed to provide details of their EC members. There are five medical colleges, four major biomedical research organisations and 10 big hospitals where biomedical research or clinical trials are ongoing in Pune. In all, we approached 13 organisations that had ethics committees, including two NGOs. Of these, one hospital refused to provide the list of EC members and did not participate in the study.

Based on the themes derived from the qualitative data and responses from the six interviews conducted prior to this study, a self-administered questionnaire for this study was developed which consisted of 67 multiple-choice and open-ended questions covered under six sections: personal information, working procedures of the EC, approval procedure, decision

making, knowledge of ethics and opinions on various issues related to ethics. The questionnaire was computer-enabled. Check boxes were provided for each option and participants had an option to click to select one or more options for each question. The expected time required to complete the questionnaire was 30 to 60 minutes. In this paper we present the data pertaining to the role and profile of the EC members.

Eighty seven EC members of 12 institutes were contacted initially by telephone. The purpose of the study was explained to them along with their role and expected contribution. EC members who consented to participate in the study or who showed interest were provided the structured self-administered questionnaires. EC members who raised any queries about the questionnaire were provided with clarifications over the telephone or in person.

Most ethics committee members worked at a senior level in their respective organisations and were computer literate. Self-administered questionnaires were sent to the EC members by e-mail with instructions about how to fill these offline. They were requested to return the completed form by email within eight days. The questionnaire was designed to be very user-friendly. However, those members who preferred a hard copy of the form were provided them.

Systematic records were maintained of dates when the forms were sent to EC members and when they were returned. The members who did not complete the forms in the stipulated time of eight to 10 days were reminded by an email and also over telephone subsequently. Efforts were made to get the completed forms by sending reminders to each EC member who failed to submit the form on time. Those who did not return the completed forms even after sending two emails and telephone reminders were assumed to be either not interested in participating or not able to complete the forms due to lack of time and other important commitments and were not contacted again.

Contact with EC members was initiated in July 2005 and the survey was completed in December 2005. Fifty two EC members finally participated in the study. Out of 52 members, 26 (50%) completed the form electronically and 26 (50%) completed the paper copies.

The questions either had direct responses or check boxes for choosing multiple options. A code list was prepared to convert the data into numeric codes for those questions that permitted open-ended answers. A database was developed and analysed using SPSS package (version 14.0). The data entry was completed for all closed and open-ended questions. Quality control of the data was ensured by cross checking the electronic data against manual listing with the forms. Univariate and bivariate analyses for all key variables were carried out. For assessing the statistical significance, the chi-square test was used.

## Results

Out of the 87 members representing 12 ECs in Pune city, 52 (60%) participated in the survey. This included 35 (67%) EC members from seven medical colleges and hospitals, 12 (23%) from three research organisations and five (10%) from two NGOs.

Members who participated in the study were mainly from the medical profession or had a research background. Thirty-five members who did not participate included those who were employed outside Pune, those who were lawyers by profession or representatives of the community or private practitioners. Some of the members mentioned that the questionnaire was very lengthy and they did not have time to fill it up. Three participants were part of the pre-test interviews carried out for formative research and hence not considered in the final analysis.

## Profile of EC members

Table I summarises data on the profile of EC members who participated in the study and some characteristics related to their participation in EC meetings. A majority of the 52 study participants were men (71%) and 27 (52%) were aged up to 60 years. Many (62%) had a doctorate degree (MD or PhD), while 38% were educated up to post-graduate or graduate level. Nearly half of the participants had medical backgrounds. Among the remaining, 15% were social scientists and 33% were others (from social/behavioural science, community representative, social worker, lawyer, etc). Most of them were members of the ECs of hospitals (67%), and 33% were members of ECs of research organisations or NGOs. Among the study participants, 41 (79%) were EC members and 11 (21%) were chairpersons or member secretaries. In all, 38% of EC members were working on ECs for more than three years. Nearly 55% had more than 20 years of research experience (Table I).

Most of the EC members (81%) said that they had opted to become EC members because they had an interest in ethics. Nearly 54% of respondents mentioned that they were professionally connected with the organisation and hence became members of the EC. Other reasons for joining ECs included an invitation to join the EC, a wish to work for a social cause, and a wish to have experience of working in clinical trials or being a part of a stakeholder community like the HIV-positive community (8%). (Data not shown in the table)

We tried to compare the profile of the EC members with their attendance at EC meetings.

We observed that those with higher qualifications (p=0.004), those with more than 20 years research experience (0.023) and those with more experience of working with ECs (p=0.032) were more likely to attend EC meetings (Table I).

## Constitution of ECs and role of EC members

A majority of the institutions constituted their ECs by selecting members from various fields (92%). Nearly 83% of EC members felt that those invited to join ECs should be experts in their areas of work and also trained in ethics (64%). The EC members opined that there was a need to reconstitute ECs (92%) preferably every two years (98%). Nearly 67% of EC members felt that they had a role to play in approving or rejecting research proposals. Nearly 70% felt that the role of

ECs could be extended to that of mediator between media and researchers or to monitor serious adverse events (69%) or to ensure that the community is benefited by the research (59%). Almost all (94%) of EC members felt that it was within the rights of EC members to approve or reject any study. A majority (79%) felt that formal training was necessary and 84% felt that there should be networking of the various ECs for sharing of thoughts and experiences (Table II).

## EC office-bearers and members: comparison of profiles and knowledge

An attempt was made to find out whether there were differences in the profile, knowledge, and level of participation of EC office bearers and members. It was observed that a significant number of chairpersons or secretaries had a medical background (p=0.027), had more than 20 years of research experience (p=0.043) and had acquired formal training in ethics (p=0.049) when compared with other members. There was no significant difference for any other knowledge based or demographic variables among the EC office-bearers and members (Table III).

Among the 52 study participants, only 29% (15/51) had acquired formal training in ethics. The knowledge assessment of EC members showed that 44% (23/52) had the correct knowledge of ethical principles and awareness about interim approval (40%, 21/52). However, very few had understanding about consent comprehension (21%, 11/52).

## Discussion

India is viewed as an ideal, cost-effective location for undertaking clinical trials, meeting international regulatory requirements (5). However, institutional mechanisms for ethical review of research involving human participants in India are weak and vulnerable and a concerted effort is required to strengthen them to fulfil their stated missions (6).

Realising the need for strengthening the ECs, the ICMR has been trying to promote the establishment of ECs and has also started offering training programmes for EC members and researchers in ethics (7).

The current study aims at understanding the profile of EC members in health research institutes in Pune, exploring their background and understanding their role in the functioning of ECs. This assessment in various biomedical research organisations in Pune has helped to identify deficiencies in the participating ECs. It is possible to take appropriate measures to improve their profile and performance through appropriate interventions.

We observed that the EC members who actually participated in the study were representative of the overall membership of ECs of participating institutes with respect to gender and area of research. However, the findings in our current study are not necessarily generalisable because many of the health research organisations in our study were involved in sponsored clinical research and trials and thus may be following ethical guidelines rigorously. It was satisfying to note that ECs had moved in the direction of appropriate constitution following national guidelines. It is necessary that all ECs quickly conform to the requirements of the national guidelines.

EC members who had a legal background did not participate in the study. In the study that was carried out by ICMR, it was noted that there were no legal experts on most of the committees and there were problems with the appointment of committee members and procedures. The record-keeping was poor and the independence and competence of the EC members was questionable (4). It is important to ensure that EC members of different backgrounds actively participate in the functioning of the ECs (8).

In one qualitative study in the US, a significant observation was that although there have been calls for increased representation of lay community members in institutional review boards (IRBs), little is known regarding their experiences or their perceptions of human subject protections and the IRB process (9). Even in our study, lack of representation and enthusiastic participation of EC members with a legal background and those representing the general community was observed as a significant weakness. It is important to ensure participation of EC members in the field of social science, law, community and politics in a balanced proportion. Similar observations have also been made in one study carried out among IRBs in the USA (10). Participation of non-medical members is very critical with respect to ethical reviews related to protection of human rights and human subjects. Significant weaknesses identified in ethics committees of medical schools in Japan were the dominance of non-campus members, younger professionals, the absence of women members and the committees' essentially closed review process. It was commented that this process has not been adequately opened to the public even in cases where the issue of patient confidentiality does not arise (11).

The EC members who participated in this study were quite senior in their professional careers. Also, a majority of them were highly qualified. They were primarily scientists or persons with a medical background. It was noted that the ECs were generally formulated according to the ICMR guidelines regarding the number and representativeness of EC members (4).

It was observed that institutions generally select institutional EC members. In a study by Campbell in the US, faculty members who served on IRBs were reported to have adequate and desirable research experience and knowledge. However, almost half of them served as consultants to industries and had potential conflicts of interest (12). Inclusion of members with a conflicting interest is likely to limit the ability of an impartial review by the EC. Hence, it is important to induct unconnected and impartial EC members. It is important to have complete clarity in documenting conflict of interest of EC members. Additionally, there should be documentation to show that the actual process of decision-making was not influenced by members having such conflicts of interests.

The actual process of decision-making in the review of our EC members in relation to their conflict of interest and

involvement in research projects remains unclear.

Although periodic re-constitution of ECs would not allow a relationship to develop between the members and the institute, and would provide opportunities for different people to work on ECs, there is an overarching demand for expertise in the field. EC members should be preferably rotated every few years, but not too frequently (4).

The EC members expressed the need for networking of EC committees to share thoughts and experiences. It has been suggested by Nowak that there should be regional ethics organisations and also IRBNet, a proposed web-based programme for cooperative IRB review (13). These appear to be a feasible solution to many problems faced by the review of multi-site clinical studies (13). The feasibility of such a system in our country needs to be explored.

The need to formally train EC members in Good Clinical Practice as well as human subject research was clearly felt in our study. The training of EC members should be focused on ethical principles and other technical requirements of EC reviews. This is important because EC members come from varied academic and research backgrounds and may not be fully aware about ethical principles and how ECs function. Training should also cover philosophical, legal and practical dimensions of research ethics. The institutions should provide formal training and orientation to EC members as deemed necessary. This would improve the ability of the members to do the reviews completely and also might help them to effectively participate in the discussions. There are other studies that have stressed training for EC members, especially the non-affiliated and non-scientist members of ECs (9, 14, 15, 16). The working party of the Nuffield Council has recommended that there should be an international initiative to establish research ECs, train their members and monitor their development in countries that are deficient in such facilities (17).

ICMR and the Nuffield Council have stressed the significant role of ECs in informed consent, standard of care, post-research issues and appropriate review of ethics in research proposals implemented in developing countries and sponsored by the developed countries for consideration of ECs (17, 18). Garrard et al provided a sketch of an alternative model of the role of the EC as an expert body, making judgments about the acceptability of research proposals through a consensual weighing of different moral considerations (19). EC members in our study suggested an expanded role for ECs, to ensure community benefits, examine adverse events occurring during the study, review study material to be given to the media and review findings before publishing in peer reviewed scientific journals. It has also been proposed that ECs can play extended roles in helping physicians to be aware of moral problems by actually training medical doctors and colleagues (20). Whether EC members should also look at study design, prioritisation of research and contribute in the scientific review is debatable. However, a technically unsound proposal is not ethical. Hence, although the scientific review should precede the ethical review, both review committees together should ensure that the research is scientifically sound (21).

According to Karunaratne it is necessary to improve communication between ethics committees, researchers and research participants; ethics committees must also monitor research practices more effectively (22). Another study also stressed the need for EC audits. It was proposed that new ways of thinking are needed about the role of research ethics in promoting moral progress in the research endeavour and improving global health (23).

Our study recommends that more professionals must be trained in bioethics and such training should be strongly recommended in medical, legal and social science curriculums. Institutions should terminate the membership of EC members who repeatedly remain absent from review. The contributions of the members should be assessed periodically and members should be rotated periodically. Professionals such as lawyers should be specifically encouraged and motivated to participate in ECs. EC members should do a self-assessment of their contribution as members. There should be networking of ECs at the state level, the national level and internationally to exchange thoughts and consult on critical issues and problems. The process of awareness, knowledge and orientation about human rights should not be limited to EC members; it could be expanded to researchers, the community and, finally, trial participants.

There are major challenges regarding future capacity development and critical ethical reviews. There must be more emphasis on training in human subject research, on sound and well defined operational procedures and motivation of researchers, and on community and regulatory authorities who could contribute maximally in making the research of the highest scientific quality and ethical standards. There are many questions and dilemmas in the minds of EC members about handling complex ethical issues. An appropriate mechanism should be developed–through an ongoing process–in the country to discuss such critical issues and appropriate guidelines should be developed for EC members. Continuous training of EC members is very important in this regard.

Institutions and researchers should strengthen the existing ethical review procedures and systems that would help in laying a good foundation for productive as well as ethical research.

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**Table I: Profile of EC members with attendance in EC meetings**

| Profile | *Total N=52 n (%)* | *Attendance in EC meeting (n=47)* | | | *P value* |
|---|---|---|---|---|---|
| | | *< 5 n (%)* | *6-10 n (%)* | *> 10 n (%)* | |
| ***Age groups*** | | | | | |
| Up to 60 years | 27 (52) | 6 (67) | 11 (65) | 9 (43) | 0.302 |
| Above 60 years | 25 (48) | 3 (33) | 6 (35) | 12 (57) | |
| ***Gender*** | | | | | |
| Male | 37 (71) | 4 (44) | 14 (82) | 14 (67) | 0.140 |
| Female | 15 (29) | 5 (56) | 3 (18) | 7 (33) | |
| ***Qualification*** | | | | | |
| Doctorate/ Post doctorate | 32 (61.5) | 8 (89) | 5 (29) | 15 (71) | 0.004* |
| Post graduate or graduate level | 20 (38.5) | 1 (11) | 12 (71) | 6 (29) | |
| ***Profession*** | | | | | |
| Medical | 27 (52) | 4 (45) | 7 (41) | 12 (57) | |
| Scientists in biology | 8 (15) | 3 (33) | 2 (12) | 3 (14) | 0.447 |
| Law, social science or other | 17 (33) | 2 (22) | 8 (47) | 6 (29) | |
| ***Type of organisation*** | | | | | |
| Hospitals/ medical colleges | 35 (67) | 8 (89) | 12 (71) | 16 (76) | 0.576 |
| Bio medical research institutes or NGOs | 17 (33) | 1 (11) | 5 (29) | 5 (24) | |
| ***Role in EC*** | | | | | |
| Member | 41 (79) | 4 (44) | 12 (71) | 17 (81) | 0.134 |
| Chairman or secretary | 11 (21) | 5 (56) | 5 (29) | 4 (19) | |
| ***Experience of working with EC*** | **N=50** | | | | |
| Up to 3 years | 31 (62) | 5 (62.5) | 14 (82) | 8 (40) | 0.032* |
| More than 3 years | 19 (38) | 3 (37.5) | 3 (18) | 12 (60) | |
| ***Research experience*** | **N=51** | | | | |
| Up to 20 years | 23 (45) | 3 (33) | 13(76.5) | 7 (35) | 0.023* |
| > 20 years | 28 (55) | 6 (67) | 4 (23.5) | 13 (65) | |
| ***Note: * indicates statistically significant p value at p=0.05*** | | | | | |

| Table II: Constitution of ECs and role of EC members | | | |
|---|---|---|---|
| **S.No.** | **Characteristics** | **Frequency** | % |
| 1 | ***Mode of constitution of EC ** ** | **N=52** | |
| | Institute selected the members from various fields/ areas | 48 | 92.3 |
| | Advertisement was given and selected the members | 4 | 7.7 |
| | EC chairman constituted the committee | 2 | 3.8 |
| | Members directly approached the institute for EC membership | 2 | 3.8 |
| 2. | ***Guidelines for membership of EC ** ** | **N=52** | |
| | Expert in the area/field | 43 | 82.7 |
| | Acquired training of human subjects/ ethics | 34 | 63.4 |
| | Recognition in the society in the respective field | 19 | 36.5 |
| | Previous experience in the field of ethics | 19 | 36.5 |
| | Other | 4 | 7.7 |
| 3. | ***Whether reconstitution of EC is necessary*** | **N=51** | |
| | Yes | 47 | 92.2 |
| | No | 4 | 7.8 |
| 4. | ***How frequently the EC should be reconstituted*** | **N=48** | |
| | >= 2 years | 47 | 98 |
| | Once a year | 1 | 2 |
| 5. | ***Role of members in EC ** ** | **N=52** | |
| | Decision making for approval/rejection | 35 | 67.3 |
| | Approval for specific areas only | 13 | 25 |
| | Restricted to giving comments/ suggestion | 9 | 17.3 |
| | Formulating the plans and procedures for the studies | 9 | 17.3 |
| | Administrative work | 6 | 11.5 |
| | Other | 1 | 1.9 |
| 6. | ***EC's roles extended to ** ** | **N=52** | |
| | Mediator between media and researcher | 36 | 69.9 |
| | Ensure whether community is benefited | 31 | 59.3 |
| | Monitor serious adverse events in drug / vaccine trials | 34 | 69.4 |
| | Check whether research is published with due credits | 17 | 32.7 |
| | Any other | 2 | 4.1 |
| 7. | ***Training / orientation to EC members*** | **N=48** | |
| | Necessary | 38 | 79.2 |
| | Not necessary | 10 | 20.8 |
| 8. | ***Networking of all EC for sharing thoughts*** | **N=49** | |
| | Yes | 41 | 83.7 |
| | No | 8 | 16.3 |
| 9. | ***Rights of ECs** ** | **N=52** | |
| | Approving/ rejecting any study on ethical grounds | 47 | 94 |
| | Call for review of existing study | 36 | 72 |
| | Stop any study if any adverse effects observed | 31 | 62 |
| | Approving/rejecting any study on scientific grounds | 23 | 46 |
| | To physically verify the study procedure | 19 | 38 |
| | Other | 4 | 8 |
| **** indicates that multiple options were provided by the participants*** | | | |

| Table III: EC office bearers and other members: comparison of profiles, knowledge and level of participation | | | | |
|---|---|---|---|---|
| **Sr.No.** | **Characteristics** | **Chairperson/ secretaries (11)** | **Members (41)** | **P value** |
| 1. | ***Age in years*** | | | |
| | <=60 | 3 | 16 | |
| | >60 | 8 | 25 | 0.364 |
| 2. | ***Professional qualification*** | | | |
| | Medical | 9 | 18 | |
| | Non-medical (any other) | 2 | 23 | 0.027* |
| 3. | ***Years of research experience*** | **N=51** | | |
| | <=20 | 2 | 21 | |
| | >20 | 9 | 19 | 0.043* |
| 4. | ***Length of affiliation with EC*** | **N=50** | 34 | |
| | <= 8 years | 9 | 5 | 0.487 |
| | > 8 years | 2 | | |
| 5. | ***Whether acquired any training on ethics/human research*** | **N=51** | | |
| | Yes | 6 | 9 | |
| | No | 5 | 31 | 0.049* |
| 6. | ***Number of EC meetings attended*** | | | |
| | <=10 | 6 | 25 | |
| | >10 | 5 | 16 | 0.479 |
| 7. | ***Knowledge of interim approval*** | | | |
| | Correct | 4 | 17 | |
| | Wrong/ Not responded | 7 | 24 | 0.521 |
| 8. | ***Correct knowledge of ethical principles*** | | | |
| | Present | 6 | 17 | |
| | Absent/ Not responded | 5 | 24 | 0.331 |
| 9. | ***Knowledge of consent comprehension procedure*** | | | |
| | Yes | 3 | 8 | |
| | Wrong answers / No | 8 | 33 | 0.425 |
| ***Note: * indicates statistically significant p value at p=0.05.*** | | | | |