

A qualitative study of Institutional Ethics Committees: Members' understanding of research guidelines, privacy, and challenges to privacy protection

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Abstract

Right to privacy of health-related information is a foundational bioethical principle. In India, the importance of protecting privacy is included in law and ethical guidelines. Institutional Ethics Committees (IECs) are entrusted with the responsibility of protecting fundamental ethical principles, including privacy and confidentiality. The present qualitative study was designed to understand IECs' privacy-related obligations and the members' experience in implementing ethical guidelines and privacy protections in their institutions. An interview guide was prepared regarding knowledge of ethical guidelines. Interviews of nineteen IEC members were recorded, transcribed, and translated. Interviews were analysed using thematic analysis. Themes related to these issues were extracted after analysis: awareness, understanding, and implementation of ethical guidelines; understanding of privacy-related obligations and their implementation; and juridical risks to privacy of patients and research participants. The results suggest that training programmes and awareness workshops should be organised for IEC members to protect the rights of research participants, especially in confidentiality issues.

Introduction

Recognition of the right to privacy regarding health-related information is a corollary to the foundational bioethical principle that people have the right to give informed consent / refusal to control access to their bodies. The right to privacy

refers to the right to limit "access of others to one's body or mind... through physical contact or disclosure of thought or feelings" (1: p.496). The related right to confidentiality—and the concomitant obligation to maintain it—arises in a fiduciary relationship, often a professional relationship, like that between patients and clinicians or between research participants and investigators. It requires that the professionals maintain the privacy of information revealed by or about the patient or research participant. Patients' and research subjects' trust that their privacy will be protected and that information disclosed will be held in confidence facilitates their truthful and frank disclosures to those who seek to help them or who rely on such information in research (2). Privacy is also valued for its own sake as a prerequisite for individuals' autonomy and is a constitutive element of their flourishing as unique individuals (3). The right to privacy enables people to keep "disruptive material out of the public arena" and protects "private life from the crippling effects of the external gaze" (4: p. 104-5), particularly where those "crippling effects" include discrimination, stigmatisation, and censure.

In India, the importance of protecting privacy is enshrined in law and ethical guidelines. Interpretation of Article 21 of the Constitution of India—Right to Life and Personal Liberty—has established a penumbral right of privacy or the right to be free from encroachment on private life (5). The Medical Council of India's proposed amendments to the Professional Code of Ethics Regulations state that confidence entrusted to physicians by their patients should not be revealed unless compelled by law (Article 2.2) (6), though the article also suggests, in apparent contradiction, that physicians need to share the patient's prognosis with family members when doing so will serve the best interests of the patient *and the family* (6). The principle of ensuring privacy and confidentiality in the Indian Council for Medical Research (ICMR) National Ethical Guidelines For Biomedical And Health Research Involving Human Participants (2017) articulated privacy protections that are to be implemented by Institutional Ethics Committees (IECs) to protect the interests of research participants (7).

Chatterjee has reported that there were challenges faced by IECs, including (among other issues) lack of formally trained manpower and the absence of standard operating procedures (SOPs) (8). Some IEC members may be knowledgeable, but all members might not be aware of the guidelines, especially with confidentiality related issues. SOPs of IECs did not include confidentiality as an essential requirement for research studies. Different IEC members may have different attitudes towards confidentiality depending on their background. The present

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study was designed to explore IEC members' viewpoints regarding privacy and confidentiality related issues.

We report the first empirical study in the Indian context examining IEC members' awareness of the ICMR's ethical guidelines, how they understand their privacy-related obligations, and their experience in implementing ethics guidelines and privacy protections in their institutions. Then, we report IEC members' views regarding the Right to Information Act, 2005 (RTI Act) and the Persons with Disabilities (Equal Opportunities, Protection of Rights and Full Participation) Act, 1995 (PWD Act), which have been shown to present risks to patients' and research participants' privacy (9-11).

Methodology

Recruitment and informed consent

Lists of hospitals and medical teaching institutions were downloaded from the Medical Council of India website. These institutes were approached to find out whether they had IECs, and if so, who the members were. The IEC members were approached individually and their consent was obtained for interview as this was regarding their personal views. Interviewees were given the option of conducting the interview in either Hindi or English. IEC members were approached individually but through addresses provided by their institutions.

Following approval dated July 3, 2009 (Number 18-62/06-RMLH(HA-1)/Vol II/145) for this interview-based study by the IEC of Dr. Ram Manohar Lohia Hospital and Post Graduate Institute of Medical Education and Research, New Delhi, a letter explaining the study was sent to members of the 22 IECs in the National Capital Region, Delhi (ie, Delhi and surrounding area) whose addresses were publicly available (n = 55).

Data collection and analysis

With a goal of enrolling and interviewing a maximum of two members from each IEC, by a combination of random and snowball sampling, IEC members were approached for their individual consent to be interviewed. Although IEC approval was obtained to interview as many as 45 IEC members, the actual number interviewed (n=19) was determined by the goals of maximising the diversity and range of responses and reaching "saturation" in the data collected. The qualitative research method of thematic analysis was employed in this study where data saturation (or redundancy in information gathered) is the goal for collecting data (12). Transcription and translation were conducted simultaneously and after five interviews we started coding and theme extraction. Themes started recurring after 12 participants and we continued till 19 when saturation was reached.

Between March 2010 and May 2011, 19 participants were interviewed using semi-structured interview guides. The majority of the interviewees were males, clinicians (n=12),

middle aged and were highly educated. Six participants were members of government ethics committees, four from private hospital IECs and one from independent ethics committee which was not related to any institution. All but one chose to be interviewed in English. Interviews were audiotaped, professionally transcribed, translated into English as necessary, and coded by the principal investigator (NNM) and one co-investigator (TB), who conferred to ensure intercoder reliability.

As is typical when employing thematic analysis, data collection and analysis were integrated. The interview guide had pointers regarding interviewees' knowledge and attitudes towards confidentiality and participant privacy. The interview guide was continually revised to explore emerging concepts and themes. Interview responses were systematically analysed to identify responses clustering around common themes. Analysis proceeded through a series of sequential steps (12): repeated close reading of transcribed interviews followed by coding of interview data by NNM. The coding was verified by TB and inter-investigator reliability in coding was checked. If there was inconsistency, the coding was discussed again with SND and LS and the final code was decided. The final step involved normative analysis of the themes or concerns identified. The themes were discussed among all authors and finalised. Reporting of the results of this thematic analysis is thus integrated with the normative analysis or discussion of the themes identified. All authors participated in discussion regarding theme analysis. NNM, TB, and SND discussed the transcriptions and codes and then themes were extracted. These themes with discussion points were sent to LS and VLN and their perspectives were included. Finally, themes were finalised by many to-and-fro discussions, and as needed, by conference calling. Themes were not predetermined and were based on qualitative analysis of the interview replies and discussions.

Results and Discussion

Demographic information about those interviewed is presented in Table 1. It is noteworthy that while all IECs are required to have at least one community representative (6),

	Approached via mail	Agreed to be contacted	Finally enrolled
IEC/IRBs contacted	22	15	11 ^{1,2,3}
IEC/IRB members	55	32	19
Gender M/F	-	-	13/6
Median age in years	-	-	55
School years	-	-	16 ⁴
Experience	-	-	6 to >10 years

¹ 6 government hospital IECs; 4 private hospital IECs; 1 Independent EC (not affiliated to any institution)
² 12 clinicians; 4 specialists; 2 law graduates
³ 6 interviewees served more than one IEC; 2 IECs had only one member interviewed in the study
⁴ one had a Ph.D. in psychology and worked as a psychiatric social worker but was considered a community representative

the one community representative interviewed had a PhD and experience as a psychiatric social worker. Thus, all IEC members interviewed have graduate degrees and experience working in healthcare institutions.

Awareness, understanding, and implementation of ethical guidelines

Of the 19 interviewees, only three expressed less than full awareness of the ICMR guidelines, which guide their review and monitoring of research protocol. One of these three expressed familiarity with guidelines from the United Kingdom and had a preference for following them and stated that "there is not a set protocol or a set guideline that is followed" on the IEC. The second among the three referred to a lack of occasion to become familiar with the ICMR's guidelines, and the third expressed having no knowledge of them: "We have been going by general perception. We have not been given any guidelines for this." A fourth interviewee reported that the committee mainly relies on the ICMR *guidelines* but noted that guidelines from the Department of Science and Technology are sometimes used and that there is "not much difference between them." Still another commented that the ICMR guidelines are "the law of the land, and they are accepted by NIH of USA; they are as good as any international guidelines as of now."

Interviewees were also asked about their familiarity with international research guidelines, such as the Declaration of Helsinki or Council for International Organizations of Medical Sciences (CIOMS) guidelines (13, 14). While a third of those interviewed were not familiar with any international research guidelines, just over half were conversant with international guidelines and said that they referred to these to evaluate research protocols. One interviewee discussed that the International Organization for Standardization has guidelines focused on medical laboratories (ISO 15189) to be used for development of quality management systems and laboratory assessment. He observed that the laboratory assessment process requires assessors to sign a pledge that they will maintain confidentiality and suggested that such a confidentiality agreement should be in place for every research project. IEC members with less than a year's experience had less familiarity with the ICMR guidelines and did not know of the international documents.

Some interviewees expressed the common concern documented in the bioethics literature internationally, that there is a preoccupation with written documentation and the "letter" of consent forms and guidelines rather than their substance and "spirit" (15). One interviewee with a legal background commented: "The consent form is just being used to get the sign of the patient; they are not reading out the contents clause by clause. Most of these forms are not in vernacular language. It has to be read out to the patient that after the completion of the project, this information has to be shared with other doctors or scientists or even with the media so that the patient is prepared for that. This is not being told to the patient at the time of enrolment by the clinical trial researcher."

Reflecting another common concern that time constraints are a barrier to obtaining truly informed consent, the same interviewee explained that "most of the doctors are full-time employees of the hospital, and research is additional work, so there is lack of time." This participant saw a hands-on role for the committee in training investigators: "Before a particular project is approved by the ethics committee, all [researchers on the project] have to be trained. I have even suggested that... each member of the ethics committee take a separate subject to explain to the researcher, for example, compensation, insurance, privacy, and so on. It has been decided that the ethics committee will organise a seminar or workshops on these topics and impart training."

However, contrary to the provisions of the ICMR guidelines, the same interviewee does not see a role for the committee in monitoring the conduct of research or the management of information: "See, we have no role to play; we only approve the project.... We only see if that agreement [agreement of investigator with sponsor], the consent form, adheres to the various clauses, but thereafter, we have no role to play. Once the trial is approved by the ethics committee, the role of the ethics committee is over. We do not pay any attention to whether the records are being properly maintained or not in the respective hospital. That is the job of the administration; it is not our job. We can suggest to the hospital authorities that the records are to be properly maintained even after the completion of the project.... Our work is only restricted and confined to approving the proposal. The implementation is based on the faith that the researchers shall follow all the guidelines issued by the ICMR or any other national or international body.... After completion of the project, a report is submitted to the ethics committee as a matter of record. What happens to the data thereafter is an administrative matter and does not fall within the purview of the ethics committee."

In contrast, another interviewee from the same IEC referred to a monitoring role, as well as to having faith in the conduct of investigators, who "have to present a paper to our ethics committee for our approval, and we see that all these aspects have been properly described in that declaration.... Usually, the researcher is from our own institution so we also have faith that they shall be following what they commit on paper. Once the study is approved, we also intermittently investigate and inspect if they are following the steps properly during the study." Thatte, in her recent article, has concluded that "Although ECs in India have evolved from being mere rubber stamps for approval of protocols to efficiently functioning accredited ECs, yet there is much to be done for and by Ethics Committees (16)".

Understanding of privacy-related obligations and their implementation

All 19 interviewees expressed a fundamental commitment to protecting the privacy of patients and research participants.

All stated that information regarding a patient's or research participant's disease and other personal information shared during treatment or research should be kept confidential and considered it their responsibility to help maintain confidentiality. Some interviewees demonstrated a rather sophisticated understanding, specifically distinguishing between privacy and confidentiality, and explaining confidentiality as arising with regard to information shared within a professional relationship. Others used the two concepts interchangeably. One of those with less than a year's experience on an IEC referred to the non-instrumental value of privacy: "No patient wants [that] his ailment shall become a topic for broadcast and gossip; it does not matter if that brings him some benefit or not. Patients always want to keep personal health information within a limited space."

Interviewees discussed methods for protecting the security of health information of both patients and research participants. The interviewee who articulated most clearly a monitoring role for the IEC also referred to ensuring that information is stored in a locked fashion as the key means to protecting private information from being publicised.

Others expressed the need for more advanced technological ways of protecting privacy of stored information: "Information that is keyed in is not available to any unauthorised person; that is one thing. Secondly, they should see that there is [an] adequate security setup built in the database so that access becomes limited. It [adequate security] has yet to happen in India, but surely there is a need to do that primarily because more and more information is getting into computer systems. Especially in computers that are networked, it should be made sure that it [data] cannot be accessed by anybody else outside the system. There are so many ways of ensuring this, like password protection at each level, and read or write authorisation to make sure that privacy is maintained. It is possible but we have to put it in a larger way in our country."

Interviewees also referred to security measures taken by investigators: "Some of them keep it as simple as... lock and key kind of security. Some of them have it in their computers with proper passwords, well coded, or some of them may go even into higher levels of security... We have not had one case up to now where there has been a breach in [security of] the information that has been collected." While assignment and use of codes may be considered ideal, another interviewee described and approved of both investigators and IEC members referring to patients and participants by initials or medical record numbers, rather than full names.

Juridical risks to privacy of patients and research participants

Interviewees demonstrated varied levels of appreciation for the risks to patient and participant privacy presented by India's RTI Act and PWD Act (10, 11, 16). In the case of the former, it is misunderstanding of the Act's provisions that could risk breaches of patient privacy. In contrast, the PWD Act does require those seeking its benefits to compromise their privacy.

The RTI Act provides citizens the right to access information under the control of public authorities in order to promote transparency in government, counter corruption, and make the government more accountable (9,16). All but three of the interviewees incorrectly believed that India's RTI Act requires and allows disclosure of an individual's health information to a third party who invokes the Act to request it. Three correctly realised that the RTI Act does not require or permit disclosure of health information, though such information can be subpoenaed by a court or disclosure can be required in the interests of protecting public health. One commented that the Act was the subject of many educational workshops which clarified that, under the RTI Act, otherwise private information may be disclosed but only in cases where the larger public interest warrants it as verified by an appropriate legal authority. Another commented that sometimes employers will seek mental health information about employees and that this can only be disclosed with the explicit consent of the employee.

Interestingly, because transparency has been such an important goal in Indian public life—partly to combat corruption—our questions about the confidentiality of a patient's health information sometimes prompted responses asserting a patient's right to know his/her own health information and stating that such information should not be kept confidential *from the patient*. This suggests confusion on the part of some IEC members regarding patients' rights to privacy and confidentiality and their right to know their personal health information, including prognosis and test results. In contrast, one interviewee (the chairperson of an IEC and a physician) expressed "confidence" in "two points," clearly distinguishing the two rights: first, that "the patient should have access to the files and that nothing could be kept confidential," and second, that "we [must] make sure that the files do not fall into other people's hands.... Otherwise, anybody will come and have that file.... In this Indian setup, first of all, the habit of Indians giving bribe has not gone. Someone has bribed the ward boy and bribed the midwife to show the file of this bed number. And the doctor will not always be there to see... It is not common. I am saying that this is a possibility, and who will get blamed? Doctors." Here the interviewee elaborated on the perceived climate of potential corruption that necessitates both privacy protections and the demand for transparency afforded by the RTI Act.

India's PWD Act (16) enables those of India's roughly 70 million disabled persons who meet particular criteria to obtain some benefits in employment and some governmental services, transportation concessions, and tax rebates. Its implementation, however, requires that individuals seeking benefits obtain a disability certificate from a government healthcare provider and that the certificates themselves display a photograph, name, and address of the disabled individual as well as the diagnosis, duration of illness, and degree of disability. To receive benefits, the individual must show the certificate to relevant officials in government offices as well as at ticket counters and to ticket checkers at railway stations. Elsewhere, we have analysed problems with the

disability certificate and argued for particular improvements that would better protect patient privacy (10).

Although 7 of the 19 interviewees were aware of India's PWD Act, only two immediately recognised that using a disability certificate can violate or limit a person's privacy. One of them commented that, for instance, a patient with a mental disability would have to appear before a panel of doctors; the person's name would be known and they would have to carry a certificate listing the nature of disability. In contrast, another who worked with neurologically disabled individuals initially failed to see a risk to privacy: "I have not thought about it, but certainly yes now [that] we are raising this question.... I have been involved with neurology disability certificates where we write the diagnosis and extent of disability. So [back then] at least I had not thought about it."

Focusing more often on physical disabilities (eg, mobility or blindness), as is common (16), most interviewees expressed a lack of concern about the impact of the certificate on individuals' privacy; for example, one member said: "Most of the time, this disability certificate is given to persons who already have a 60% to 80% disability so it is very apparent.... To a medical person, most of the disabilities are very obvious; it may not be just at the first sight, but even without the certificate, we know about it." Upon being questioned about non-obvious disabilities such as mental illness, however, the member admitted that "there confidentiality is much more needed."

Further, although this interviewee recognised that nonmedical personnel do not have the same training regarding privacy protection as medical professionals, she downplayed the risk to privacy: "We expect that in our profession, people are more thorough about their professionalism." In contrast, in transportation and other sectors, those who see the certificates do not have a fiduciary relationship with the certificate holder; instead, the relationship is one of gatekeeping power. "[Patients] show the disability certificate to persons who give them some benefit, and those persons at those posts know about the role of confidentiality—most of them. But sometimes... there may be some manipulations, some power politics, to cause a leakage [of information] as some opposite party may want to know the weakness [the disability], so there may be issues, but it is very rare and not so common." Some interviewees expressed the opinion that disabled individuals willingly accept this trade-off between invasion of privacy and the material benefit of using the certificate. One member opined that "they are getting some advantages because of this certificate, so that is why they are disclosing" the health information it contains when they use it. Another said, "I think [the patient] is not really bothered about the privacy aspect because the certificate leads to some benefit.... If they are going to use that somewhere, obviously it is not going to be confidential. If it says it is 60% or more of disability, which gets them much more benefits than a person who has 20% to 30% disability, but he is voluntarily coming out of the no-confidentiality clause, I guess, because he is putting it in black and white that he is disabled."

These interviewees did not focus on how truly willing the patient was to sacrifice privacy, saying for example, "No, I think if the patient voluntarily says that he is say 60% disabled to get the benefits, why does he need a confidentiality clause? He is trying to prove that he is disabled. So, I do not think when you are getting a certificate for a benefit...where does the confidentiality stand? I do not think the question comes in at all at that time." Another interviewee explained that it was precisely because seeking the certificate is initiated by the patient that its privacy implications were of less importance: "I think here the benefit to the people is overriding. Here the patient is walking to the hospital and asking for a disability certificate.... Where people are poor, if the government provides some facilities to them, personally, I feel that is the overriding factor here." It is perhaps disturbing that IEC members, who are charged with ensuring that informed, *voluntary* consent is obtained from research participants, are not more deeply reflective about the conditions required for truly voluntary decisions.

Further, most of those interviewed were not particularly insightful about ways to address the violations of privacy required by the use of the disability certificate. However, when asked whether there was some modification of the certificate that would protect privacy while still affording benefit, one committee member suggested the use of a smart card: "Have[ing] a smart card that means you have all the data there in the chart, but [only] some data is accessible to some people. All the data is not accessible to everybody. So, we have firewalls. You work in silos; the same smart card works in all compartments. So, everybody knows information on a need-to-know basis. If I am the railway clerk who is to give a railway ticket for the individual who has the disability, I really should not be concerned about what disability he has and to what extent the disability is. I should be concerned [with] this individual [who] today is in front of me. This is his photograph. This is [his] biometric mark, and he has come for a claim which I need to know [the information clerk needs to know]. What his disability is, is not my concern." Even if such technological fixes as a smartcard are currently only at the planning stages, the underlying rationale expressed by this interviewee could be implemented in a lower tech manner. Disclosure of diagnosis could be required by the Act on a need-to-know basis. Only those certifying a person as disabled and thus entitled to a range of benefits would need to know the nature of the individual's disability. Just as the handicapped signs that people in the United States are provided with to place on their motor vehicles to entitle them to preferential parking access¹ do not specify the nature of their disability, in India the disability certificate itself need not display that information. It is perhaps unfortunate that the sole suggestion to revise the disability certificate was articulated in terms of relying on technology not widely available in India.

Why should it be hoped that IEC members, charged with protection of the interests of research participants, would have knowledge of privacy-related problems associated with the disability certificate and an insight into ways to address those

problems? Admittedly, such ethical concerns are beyond the purview of an IEC. Nevertheless, IEC members are typically viewed as their institutions' ethics experts, are sometimes called upon to develop or interpret ethical policies not related to research, and most importantly, must have a nuanced understanding of concepts such as voluntariness and privacy in order to interpret and apply ethical guidelines governing research, as per their mandate. Indeed, one interviewee commented, "Generally, all across the board in India, privacy is not given sufficient thought," and suggested that legislators "should consult ethics experts and redraft the law [regarding the disability certificate]... to protect the privacy and confidentiality of an individual." As perceived ethics experts, IEC members may indeed be called upon to suggest revisions or protections in this and other contexts.

Conclusions

Healthcare institutions are increasingly required/called upon to establish institutional ethics committees. The empirical study reported here suggests where strengths and weaknesses in IEC members' awareness of guidelines and of the demands of ethics may lie. These results suggest that training programmes and awareness workshops should be organised for ethics committee members for protection of rights of research participants, especially when it comes to confidentiality issues.

Moreover, the study was conducted in 2011 but detailed analyses took time as authors were based internationally; the scenario may have changed after the Supreme Court verdict 2013 (17) on clinical trials and after mandatory registration of ethics committees. "These results may be used to inform educational workshops for IEC appointees, committees' own self-education activities, and education that they may provide to colleagues within their institutions. The main limitation of the study is that data is dated; however, it is still relevant as there is a need for educational programs in larger institutions. The country is vast, and IECs do not always meet the ICMR criteria.

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Note

¹ Drivers with disabilities are allotted preferential parking closer to buildings in the US because conditions ranging from asthma to neurological or cardiac conditions to a leg injury can impair their ability to walk from parked car to destination.

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