

ARTICLES

Establishing institutional ethics committees: challenges and solutions—a review of the literature

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Abstract

This review of the literature was conducted to identify the challenges faced while establishing institutional ethics committees (IECs) as well as to suggest some solutions. The search of the literature was carried out with the help of the PubMed search engine, using "research ethics committees" (MeSH) and "India" (MeSH) as the key words for articles published between 2004 and 2012. We found 31 articles related to the topic, and the most common challenge mentioned was inappropriate functioning of IECs (n=17), followed by inappropriate structure (n=14). The authors identified many challenges related to the lack of oversight by regulatory bodies (n=14) as well as issues pertaining to the ethical training of IEC members and investigators (n=13). It is evident from the multitude of papers on the issue that the challenges related to the constitution and functioning of IECs must be given the attention they deserve to ensure that research participants in India are better protected.

Introduction

Biomedical research involving human participants requires mandatory approval from an appropriately constituted institutional ethics committee (IEC), also referred to as the institutional review board (IRB), ethics review board (ERB) and research ethics board (REB) in other countries. As mentioned in the Belmont report, the ethics committee (EC) must ensure beneficence, as well as justice and respect for research participants, thereby protecting their rights, safety and well-being (1).

The guidelines of the Indian Council of Medical Research (ICMR)(1) state that it is mandatory for any biomedical research on human participants to be approved by the IEC/IRB before its initiation. This is also supported by the revised Schedule Y in Amendment 2005 of the Drugs and Cosmetics Act, 1940 (2), which is the local law. Schedule Y also elaborately sets forth the structure and function of the IEC, and gives a detailed explanation of the approval letter. Further, it prescribes that the ICMR guidelines be followed, thus indirectly giving these guidelines the status of a law.

The number of clinical trials in India has increased a great deal in recent years. The country is becoming a hub of research for pharmaceutical companies due to the availability

of a vast number of participants, a technically competent workforce, lower costs and a system of regulatory oversight that is relatively relaxed. Apart from this, due to the enormous progress in the field of research, multicentric studies, genetic studies, stem cell studies, etc, are increasingly being conducted in the country.

A survey conducted by the ICMR in 2003 showed that only 200 of the more than 1200 institutions in India had functional IECs (3). According to a report in the Bulletin of the World Health Organisation (WHO), India has less than 40 IECs that are properly constituted and functioning (4). This fact has been reiterated in many articles published in scientific journals (5).

Although guidelines pertaining to the structure and functioning of IECs were laid down on paper in 1980, they have not been implemented satisfactorily because they are not backed by the strength of legal protection. Thus, there are a number of problems connected with the functioning of IRBs. Although in February 2013, the Government of India passed a rule making it compulsory for IECs to register themselves with the Central Drugs Standard Control Organisation (CDSCO) (6), several challenges remain.

This review of the literature was conducted to identify the challenges faced while establishing IECs with a special emphasis on their structure and functioning as well as to suggest some solutions.

Methods

We conducted a review of the literature, especially Indian studies, investigating the challenges faced by IECs, the relevant issues pertaining to them, as well as their deficiencies, and examined any solutions offered by these studies. The initial search, for articles published between 2004 and 2012, was carried out with the help of the PubMed search engine using the medical subject headings [MeSH] "research ethics committees" and "India" as the key words. The study was restricted to articles in the English language. The review covered articles that focused on challenges and relevant solutions related to the structure, functioning and role of IECs, the training of their members, regulatory issues, societal concerns and conflicts of interest.

Results

We found and reviewed 108 studies related to the topic. Thirty-one articles related to the structure and functioning of IECs in India were shortlisted. The following types of articles were included: observational studies, review articles, “viewpoint by expert” articles (7 each), editorials (n=5), correspondence (n=3) and news bulletins (n=2). The maximum number of reviewed articles was published in the *Indian Journal of Medical Ethics* (n=17) and *Perspectives in Clinical Research* (n=5) while seven were from other Indian journals. One article each was from the *New England Journal of Medicine* (NEJM) and *Biomed Central (BMC) Medical Ethics*. Some authors have been quoted more than once because they have published different articles addressing various issues related to IECs and the challenges faced by them. This matter has been noted while tabulating the data. Table 1 provides a summary of the challenges mentioned. The most common challenge mentioned is the inappropriate functioning of IECs (n=17) followed by their inappropriate structure (n=14). The authors have identified many challenges related to the lack of oversight by regulatory bodies (n=14) as well as issues related to the ethical training of IEC members and investigators (n=13).

Table 1

Challenges faced by institutional ethics committees (IECs) in India as raised by various authors

Issues	Number of articles mentioning these issues (n=31)
Inappropriate structure of IEC	14
Inappropriate functioning of IEC	17
No or inadequate training of IEC members/ investigators	13
Issues regarding regulatory authorities and their guidelines	14
Societal concerns	2
Conflicts of interest	7
Additional issues	
Compensation issues not addressed	2
IEC accountability for exporting tissues	2
Lack of standard operating procedures	4
No “bioethics” in curriculum	1
Post-trial access	1

The most common solutions suggested focused on methods to improve the functioning of IECs (n=19), inputs to improve their structure (n=5), ways to strengthen the procedures for the training of IEC members/investigators (n=17), and strengthening the whole system by modifying or revising the guidelines laid down by the regulatory authorities (n=13). A few authors suggested solutions in the areas of societal concerns

(n=4), conflicts of interest (COI) (n=2), and financial issues (n=5). We analysed these issues further.

Structure of the IECs

Challenges

Although Schedule Y of the Drugs and Cosmetics Act(2) mandates that the chairperson of an IEC should not belong to the institution, it has been repeatedly pointed out that the head of the institution acts as chairperson(7). Some of the other issues that have been frequently raised are: that the required quorum is not met, and that the manner in which IECs are constituted is inappropriate, inefficient or biased (8–10). The absence of an IEC and the lack of financial and administrative support to enable IECs to function smoothly are the other challenges that have been identified (11,12).

Solutions

The authors have strongly urged institutions to lend the IECs administrative and financial support to enable them to make improvements in their structure(7,12,13). The inclusion of a representative of patients as a member of the IEC, a suggestion also made in several guidelines, was a solution recommended by the authors to ensure that proposals are reviewed appropriately (7).

The creation of a central registration system has been strongly recommended to address issues related to the structure of IECs(3). The registration of IECs was made mandatory under the amended Drugs and Cosmetics Rules, 2013, via a gazette notification dated February 8, 2013(6), a step aimed at ensuring that IECs across India are constituted properly.

Functioning of IECs

Challenges

The literature contains only sparse data on the functioning of IECs (14). It has been suggested that IECs do not adhere to national guidelines and “work more as secret societies” which are not accessible in the public domain, and that there is no mechanism to verify the qualifications and experience of the members (15,16).

Among the important problems identified with respect to the functioning of IECs are: the lack of active participation of the non-medical members in the committee’s deliberations, as well as the fact that they lack training and are diffident (5,9,17,18); a lack of interest on the part of invited IEC members(7); the absence of standard operating procedures(SOPs)(3,9) and a separate IEC application form(7); irregular meeting schedules (once or twice a year) (19,20); inappropriate review of protocols (21); irregular or no monitoring of the approved projects(5); poor archiving and record-keeping (5); approval letters not in keeping with the specifications in Schedule Y, with a few documents missing (such as insurance certificates, clinical trial agreements and translated versions of the informed consent document)(9); the failure to conduct internal audits; and the absence of accreditation (19,20). While it has been found that

some IECs have no process of expedited review, there are instances where warning letters were issued for the misuse of this expedited review(9,22).

Many articles mention that as the majority of IEC members are from the medical field, the scientific aspects of studies are discussed at the committees' meetings and not enough attention is paid to ethical issues such as risk-benefit analysis, compensation, undue inducement, protection of vulnerable participants, the issue of distributive justice, provision of a proper standard of care, post-trial benefits, autonomy, the use of placebo, and obtaining and documenting consent (3).

Another of the problems mentioned in the articles is that of sponsors putting pressure on the IEC to approve their project by arguing that the IECs of other institutes have already approved the project. Alternatively, instead of complying with the recommendations of the IEC, the sponsor moves the study to another site, which has a more "compliant" ethics committee (23).

Solutions

The need to have and follow SOPs is unanimously identified as a prerequisite for improving the functioning of an IEC (10). Some authors have suggested that scientific review be carried out by a separate committee to allow the IEC to make a thorough review of the ethical issues, which otherwise get ignored (24). IEC members from different backgrounds must be encouraged to participate actively, and even the short-term studentship projects, such as dissertations/theses, must be scrutinised carefully (25). One of the suggestions for upgrading the review process entails the use of a checklist on a scale of 1-5, 1 being not serious and 5 being the most serious. This will ensure that all ethical issues are given a thought by the IEC members (10).

No approval letter should be issued till the study has been registered with the Clinical Trial Registry of India (CTRI), if applicable. Even after approval has been granted, continuous oversight must be ensured through regular monitoring of the study. This will help to uphold the safety, dignity and rights of the participants (17,26). It has been suggested that an IEC consortium or a state-level IEC be set up to address multicentric studies and minimise "ethics committee shopping" (5,23). Many have strongly recommended taking the next step forward, ie accreditation of IECs by the Strategic Initiative for Developing Capacity in Ethical Review (SIDCER) or the Association for the Accreditation of Human Research Protection Programmes (AAHRP) to achieve higher standards, apart from periodic random audits and inspections by the independent auditors of the Drugs Controller General of India (DCGI)(5,9,10,27). Since the gazette notification dated February 8, 2013, regarding the registration of IECs (6), the Professor Ranjit Roy Chaudhury expert committee has also recommended the accreditation of institutes (for the conduct of clinical trials), clinical investigators and IECs in India (28).

Training of IEC members and investigators

Challenges

The members of IECs are selected randomly, with no consideration being given to whether they are trained in the fundamentals of ethical clinical research (24). Some members do not have knowledge of the functioning of IECs and the Schedule Y/ICMR guidelines. Some do not even know the name of the regulatory body that oversees clinical trials in India. The factors that lead to such a situation are the absence of good clinical practice (GCP) and bioethics education, lack of resources, as well as a shortage of faculty to teach medical ethics (29).

Solutions

Many authors have suggested that apart from the training of IEC members, training of investigators in ethics and research methods should be made mandatory (5,10,11,27,30). It has been suggested that this could be done through the ICMR, independently or in collaboration with the Forum for Ethics Review Committees in India (FERCI) and other organisations (3,5,7,10). Interestingly, it has also been suggested that groups of patients must be made aware of their rights (10). The inclusion of bioethics in the medical curriculum (10,17), the creation of a separate department of ethics in medical schools (29), and the introduction of professional examinations certified by the institutional review board (IRB) to encourage expertise in the field of ethics (10) are some of the solutions suggested.

Regulatory issues

Challenges

The lack of appropriate laws or gaps in their implementation has been repeatedly identified as a challenge to the efficient functioning of IECs (30,31). Due to the lack of communication either among IECs or with the DCGI, ethical issues are not conveyed to the regulatory bodies or other IECs (9). The IECs work independently, without any supervision. Provisions for the inspection of IECs are still only on paper.

Solutions

The authors have recommended that the ICMR guidelines be given greater legal authority (24). The ICMR has developed general research guidelines, has established a bioethics cell under the guidance of senior faculty members, hosts a website that has links to bioethics journals, and has identified mid-career professionals to be trained in bioethics through fellowships (17). On June 15, 2009, the DCGI made the registration of trials with the CTRI mandatory, and Indian journals agreed to publish the findings of clinical trials only if they were registered. Some authors have suggested that the DCGI must impose a penalty if a trial is not registered with the CTRI, and should also formulate guidelines for taking corrective action if there are any complaints against IEC members (4). One of the suggestions is that the Medical Council of India (MCI) should grant recognition only to those institutions/hospitals that have established an IEC (7). As for curbing IEC "shopping"

practices, the authors have proposed the adoption of the Pune model, an experimental initiative to bring together all functional IECs (9).

Societal concerns

Challenges

Studies on drugs and devices and the issues related to these need to be brought into the public domain so that the general population is aware of the facts. Some papers have criticised the ICMR guidelines for the statement “the participant can withdraw anytime”, as this is impractical if the study involves a one-time questionnaire or one-time blood collection (20,32).

Solutions

Most authors believe that researchers should be accountable to the public, and that there should be a sustained and inclusive dialogue between researchers, research participants and others to reduce the harm that can result from research (10,21,33). They highlight the need for the consent/engagement of the community for studies involving research on tissues and are of the opinion that post-trial access must be made mandatory(20).

Conflicts of interest

Challenges

It has been reported that neither the regulatory authorities, nor the IECs seek a declaration of conflict of interest (COI) from either investigators or IEC members (4,10,17,30). With the increasing number of privately owned hospitals and physicians employed by these institutions, and the benefits accruing to investigators from companies, COI is a major concern(9).

Solution

Many authors feel that there is a need for impartial IEC members to solve the issue of COI (34).

Miscellaneous

Exporting of tissue samples is another grey area that has been identified. Accountability and training of IEC members is a must to prevent unethical utilisation of the samples taken from research participants, with or without their knowledge (21).

The IEC should ask the sponsors or investigators to mention how the tissue samples will be disposed of after the research has been completed. The informed consent document should also contain an assurance that the tissues will be disposed of. Other issues, such as lack of guidance or regulations regarding post-trial access to beneficial treatment, have also been mentioned (32). The authors have recommended that the results of a trial must be published only in scientific journals and not in the media for the purpose of publicity (13).

Discussion

This paper summarises the challenges identified and solutions proposed with regard to the constitution and functioning of

IECs in India. Over a period of nine years, we found 31 papers addressing these aspects. There are several common refrains (summarised in Table 1), pertaining mainly to the constitution of IECs, the quorum, lack of institutional support, absence of or inadequate training, non-participation of the non-technical members in deliberations, conflicts of interest, and the lack of regulatory oversight. The authors have put forward some interesting solutions, such as the mandatory certification of IEC members and registration of the IEC for a medical school to be recognised by the MCI.

The notification making the registration of IECs mandatory (6) may result in a significant improvement in their structure and functioning. It is likely to help solve the problems in areas such as the composition of IECs, SOPs, schedule of meetings, quorum of meetings, the presence of legal experts and laypersons at meetings, documentation of IEC activities (including keeping the minutes of meetings), the regular use of GCP, and ethical training of IEC members. To date 586 IECs are registered with the CDSCO (35). However, the details of the constitution and functioning of these IECs are not available in the public domain. Certain measures such as compulsory monitoring of sites still need to be implemented by the DCGI and organisations such as the ICMR or FERCI.

It is evident from the multitude of papers on the issue that the challenges related to the constitution and functioning of IECs must be given the attention they deserve to ensure that research participants in India are adequately protected.

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Teaching of public health ethics in India: a mapping exercise

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Abstract

Public health ethics has been receiving increasing attention in recent years. Frequently, public health practitioners have to confront complex decisions, with numerous and often conflicting ethical implications. The objective of this study was to obtain information on the teaching of public health ethics in India by making a detailed examination of the public health and community medicine curricula. The specific areas of interest included the content and structure of the courses and electives available to students. The results of this study indicate that ethics courses are yet to find their rightful place in the teaching of public health in India. The curricula vary across institutes in terms of the time and content devoted to the teaching of public health ethics. It is suggested that public health programmes in India develop and incorporate ethics courses so as to keep pace with the emerging challenges in the field. An interdisciplinary consortium should preferably be formed at the national level to take up this academic endeavour.

Introduction

The link between ethics and health has been a major concern for human society since antiquity. This preoccupation dates

back at least to the time of Hippocrates, who was the first to delineate the importance of ethical practice in healthcare (1). With the gradual advancement of health technology and increasing complexity of healthcare, bioethics and clinical ethics have become integral and important elements of contemporary medicine and research, respectively. The principal focus of medical ethics is on the physician's role vis-à-vis patients, while bioethics deals with decision-making and public policy in the domains of biology, medicine, and healthcare (2). In recent years, there have been efforts to broaden the scope of ethical analysis in healthcare so that it also embraces public health issues. This has given rise to the relatively young discipline of "public health ethics." In contrast to traditional ethics, public health ethics essentially pertains to the population level, focusing primarily on the designing and implementation of measures to monitor and promote the health of populations. Further, it transcends the conventional boundaries of healthcare to consider the structural conditions underlying the development of healthy societies (3).

The evolution of public health ethics over the past several decades has been triggered by a confluence of events. The first