Challenges faced by members of Institutional Ethics Committees (IEC): Focus on the non-affiliated,non-medical/non-scientist member

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Introduction

- Ethical Review must be guided by diverse professional view points to ensure an adequate and an all-encompassing expertise to confront ethically problematic questions.

- The IEC must share the researcher's burden in seeking a balance between the pursuits of scientific interests on the one hand and the needs of society and the rights of the individual research subject on the other.

Introduction

- There is limited qualitative research on Institutional ethics committees in the country.
- The discussion today is based on a M.Phil research study for which semi-structured interviews were conducted with IEC members across 5 selected hospitals (2 public, 2 private and 1 Trust hospital) in the city of Delhi.

The Context

- The multinational drug industry's expansion of its clinical trial operations to India has been facilitated by the 2005 amendment to the country's drug development laws.
- The reasons for expansion include lower costs and easier and quicker recruitment of large numbers of willing research subjects.
- There is little information in the public domain on the kind of research subjects being recruited but from media reports we know that they are usually India's poor and vulnerable who participate in a trial in the hope of treatment, a cure and also a source of income.
- The globalized clinical trial has brought with it many concerns that the IEC must confront.

Non-affiliated, non-medical/non-scientist members of ethics committees

A multidisciplinary group with the likelihood of having "no vested interest in the success or failure of the research" and who are more inclined to view the harms and benefits of a clinical trial from a research subjects perspective is critical to the strength of human subject protection systems (Anderson 2006:136).

Study Findings

Challenges faced by non-affiliated, non-medical/non-scientist members

- The medical/scientist members on the IEC—majority of whom have an institutional affiliation—are the most assertive voice in ethics committee deliberations. There is little room for the non-affiliated, non-medical member to express an opinion.
- Barriers to the effective participation of non-affiliated, non-medical/non-scientist members include the inherent hierarchy that exists between the medical expert and the non-medical expert and as well as the highly technical nature of clinical trial protocols.

Study Findings

A non-affiliated/non-medical member from a public hospital's IEC describes her experience in ethics committee meetings:

We can't ask the doctors. Doctors are not conducive, they assert their knowledge of medical technology…it is a closed circle, they [the doctors] don't open up. At times I feel I am not doing justice. Three of us are from outside. We don't usually say anything. You have to be well studied if you say anything.

Study Findings

A non-affiliated, non-medical member from a private hospital's IEC stated*:*

*We have to sit through medical presentations for one hour. The investigators present what the sponsor has given. But we are interested in basic information***.**

Study Findings

A social scientist member from an IEC of a private hospital stated the inability of investigators to adapt protocols for ethics review:

Although there is a separate technical committee, for an ethics committee they [investigators] present the same information.It's a huge amount of literature and none of it makes sense. Nothing in the proposal says what the ethical issues are. There is no effort to make it easier.

Study Findings

- **Responses of clinicians**:

  They [non-medical/non-scientist members] usually keep quite. Training will help and clearly define roles.

  Lay persons are ignorant about medical terminology or diseases. They should be explained in laymen's language.

Study Findings

Some challenges common to both medical and non-medical IEC members

- Lack of ethics training
- Workload and lack of administrative support
- Negotiating with drug companies
- Monitoring clinical trials

Conclusion

While strengthening ethical oversight of the clinical trial process will not transform the structural inequality that underlies the global clinical trial it can however prevent ethical violations from occurring.

Since the research subject's only recourse to protection is the ethics committee, it is imperative that the system is reformed.