Scenarios in Medical Ethics 2: Challenges for Ethics Committees

A series of panel discussions were conducted as part of the 2-day workshop on medical research ethics, organized for Ethics committee (EC) members at the Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER), Puducherry, India, in association with Indian Council of Medical Research (ICMR) Bioethics Unit, Bangalore, India, in September, 2019.[1,2] During the panel discussions, 3–6 scenarios were discussed followed by 1–3 questions. After presenting each scenario, the participants were invited to give their comments. After a thorough discussion, a set of panelists, who were experts in biomedical ethics, were invited to discuss the scenario and provide more informed and authoritative opinions. The discussions were quite lively and we believe that the case scenarios should be of wider interest.

A summary of the first panel discussion on Scenarios in Medical Ethics 1: Composition and functioning of ethics committees were published previously in this journal. In this article, we discuss the second panel discussion on "Challenges for Ethics Committees." The answers provided by the participants are listed first followed by the expert opinion by the panelists.

Scenario 1

A hospital in Puducherry which did not have an Institutional Ethics committee (IEC) was chosen as one of the sites for a Phase III clinical trial of an investigational new drug developed for the treatment of rheumatoid arthritis. The investigator applied to an Independent Ethics Committee in the city for review and approval. The latter did not approve the protocol citing safety issues with the proposed dose. A week later, the investigator submitted the same protocol to an Independent EC in Chennai (150 km from Puducherry) which approved the study.

Question

1. Can a protocol rejected by an EC be submitted to another EC?

Participant answer

- It was felt that this is an acceptable practice.

Comments of the panelists

- A principal investigator (PI) can approach another EC when a proposal is rejected by one EC, provided the reason for rejection at the first EC is communicated by the PI to the second EC where protocol is resubmitted
- As this is a regulatory trial, the rejection needs to be communicated to the central licensing authority
- According to the new guidelines, an independent EC cannot review clinical trials and review is restricted to BA/BE studies.[3]

Scenario 2

A paediatrician submitted a proposal for a randomized controlled trial on the effectiveness of N-acetyl cysteine, an antioxidant, in children with snake bite to prevent the development of acute kidney injury. He cited a previous case series among adults published in a nonindexed journal as a reference.

Questions

1. Is it acceptable to use the findings of a case-series to justify research on an off-label use of a drug? How will EC approach this case?
2. Further, the PI stated that he had already tried this drug in many children and wanted permission from the IEC for a retrospective record-based study. What are the ethical implications?

Participants answer

- A case series may be quoted as an evidence to do this study in children and N-acetyl cysteine is supposedly a safe drug. Retrospective data need to be published since these are already available.

Comments of the panelists

- Treating physicians have a therapeutic privilege to use a drug off-label in case of a dire need. However, this should be done sparingly as it is unethical and against guidelines to use drugs which are not approved by the licensing authority as a routine practice for a large number of cases
- The researcher can then submit a proposal to IEC to do a larger study based on the results observed in the few patients. The IEC can give approval based on the safety and efficacy data submitted by the researcher. These results can then be published.

Scenario 3

Dr XY conducted an ICMR-sponsored study with IEC approval and has discovered that a novel "Pc" receptor is responsible for cancer pain. He approached the institute to arrange for patent and licensing. While the institute was in the process of establishing an "Innovation and patent cell," Dr XY started a new company outside the institute which developed a Pc receptor antagonist for cancer pain. The product was tested in patients at the hospital where Dr XY worked. He delayed the publication of his work for 4 months to be able to file a patent and complete the licensing documents.

Questions

i. What are the ethical issues involved here?

Participants answers

- An employee working in a government institution cannot start a company. It is unethical to delay publication for the sake of patent application
- Drug companies often delay publication for filing a patent. Hence, an individual researcher cannot be denied this right
- A person cannot be the PI of a study to test the drug developed by his company.

Comments of the panelists

- A researcher in any work place is allowed to start a company and continue development of a new molecule, with the agreement of the original employer
- In order to patent a molecule, the PI needs to apply for novelty certificate which takes at least 30 days for issue. In general, once published patent cannot be filed as this leads to lack of novelty.[4] However, intentional delay in publication, especially in the absence of any other treatment is unethical
- If the researcher wants to test the drug in the place where he works, he cannot be the PI of the study but could be a co-investigator, with declaration of conflict of interest.

Scenario 4

A research project has been cleared by the scientific committee of an institution. During IEC presentation, some comments are made on the scientific aspects, and some modifications have been suggested. The principle investigator is reluctant to make the changes since the project has already been approved by the scientific committee.

Question

i. Should the IEC accept this argument or insist that the changes must be done?

Participants answers

- Scientific committee reviews the scientific aspects of the research and hence the ethics committees need not review the same
- Ethics committee has the final say since it has the legal authority to do so
- Both scientific and ethics committee may review the proposal simultaneously.

Comments of the panelists

- Scientific committees give their opinion on the scientific aspect of a study. However, the IEC first looks at the scientific aspects and only then proceeds to the ethical aspects, since good science is good ethics
- If there is a difference of opinion between the two committees, there can be a communication between the members of the two committees to arrive at a consensus. If, in very rare situations, a difference of opinion persists, then the head of the institution can intervene and call subject experts to resolve the issue
- Whether the two committees should review a project simultaneously or separately needs to be decided by the institution, depending upon the feasibility and the number of proposals submitted for review. For institutions with a large number of proposals, ideally a scientific committee should review the protocols before the ethics committee.

Scenario 5

Head of the Department of Pharmacology at an institution wanted to conduct a study to compare two teaching methods for undergraduate (3rd and 4th semester) students. Students will be randomly assigned to two groups with one teaching method for each group. Performance of students in each group, in the formative assessments will be compared and their feedback on the teaching methods will be obtained. Written informed consent will be taken from all volunteers.

Question

i. What are the ethical issues involved in this situation?

Participants answers and comment

- Students are a vulnerable population and will have some degree of diminished autonomy in such studies
- These studies must be allowed and a junior faculty could be involved in the informed consent process who is less likely to be the examiner in the summative examination.

Comments of the panelists

- Students have diminished autonomy and may participate in research fearing failure in examinations if they do not do so or give a negative feedback. In addition to a junior faculty involved in consent process, anonymous feed backs are the solution to such research.

The remaining panel discussions will be discussed in the forthcoming article/issue.

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Conflicts of interest

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