Scenarios in Medical Ethics-6: Public Health Research

Indian Council of Medical Research (ICMR) ethical guidelines 2017 had for the first time introduced the chapter on public health research, which is a replacement of the chapter on epidemiology in the previous version.[1] In this chapter, guidance has been provided for studies which involve surveillance, community trials, surveys, and implementation research. The Institutional Ethics Committee (IEC) needs to distinguish public health service from research and take appropriate decisions about informed consent and ethical review. To clarify some of the issues related to public health research and ethical review, a panel discussion session was organized as a part of the 2-day workshop at JIPMER, Pondicherry, India, to train IEC members.[2,3]

In this workshop, six panel discussion sessions were conducted and each session consisted of a series of 3–6 scenarios 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. Five panel discussions were discussed in the earlier issues of this journal. In this issue, we discuss the sixth panel discussion on "Public Health Research." The answers provided by the participants are listed first followed by the expert opinion by the panelists.

Scenario 1

An investigator proposes to study the prevalence of suicidal ideation among the elderly in a rural community using a questionnaire. He plans to take written informed consent from the elderly people in the community who are willing to participate. A participant expressing suicidal tendency is a sensitive issue, and as per the ethical principles, confidentiality needs to be maintained about the participant data.

Questions

1. What are the types of consent applicable in this study?
2. Is the special training required for the investigator in such studies to reduce the risk to the participants
3. Discuss the investigators duty to disclose sensitive information versus confidentiality of information collected.

Participants answer

Gatekeeper consent needs to be obtained from the community head in addition to individual consent when a questionnaire-based survey is conducted in the community.

Comments of the panelists

- Here, the consent must be obtained from the head of the family as well as the participant (individual consent). If individual consent is not possible due to any reason, then implied or gatekeeper consent may be sufficient with prior approval of the IEC.
- The investigator must be trained to asking sensitive questions.
- When two rights are involved as in this case (right to safeguard confidentiality of information versus right to safety and well-being of the individual), one may be forgone for the other right to confidentiality may be forgone to safeguard right to safety.[4] Poststudy counseling arrangements need to be a part of the methodology and the IEC needs to make sure it is incorporated in the study protocol and there is a trained person to administer such a questionnaire.[5]

Additional comment

- Studies on the vulnerable population such as adults or children on the streets need to be considered on case-to-case basis to analyze the ethical issues. Investigators could consider involving Nongovernmental Organizations who in turn could take responsibility of these vulnerable participants.

Scenario 2

Case A

A multicentric study has been proposed to determine the effectiveness and impact of rotavirus vaccine in states that have introduced this vaccine into their routine immunization schedule. An active surveillance system will be established to identify acute gastroenteritis cases among children <5 years of age. For all children enrolled at sentinel sites, case-reporting forms will be completed, and a copy of vaccination record and a stool specimen will be obtained.

Case B

Pondicherry government announced the inclusion of rotavirus vaccine in its Universal Immunization Programme. A researcher wants to study the acceptance of the vaccine and adverse event following immunization (AEFI) reported from the records in primary health centers (PHCs) of Pondicherry.

Question

The investigators in both the studies have applied for exemption from review.

How should the ethics committee approach these two scenarios?

Participants answer

The first case is a research and as it involves the collection of stool specimen from children, it requires ethics review

and informed consent needs to be obtained. The second case involves collection of AEFI reports from the records and if it is done in an anonymized manner, then waiver of consent can be applied for.

Comments of the panelists

- Both the cases seem to be research rather than surveillance programs by the government. Hence, they need to be submitted for ethics review. The decision regarding review exemption, waiver of consent or to obtain informed consent needs to be decided by the IEC and not the researcher[6]
- If an investigator collects the data on the impact of a government intervention program to be reported to the government (not the case here), a review exemption may be considered by the IEC
- All research involving human interaction, collection of data or biological samples needs to reviewed and informed consent needs to be obtained. However, collecting data merely from the case records in an anonymized manner without any human interaction could be granted waiver of consent.

Scenario 3

The government has decided to increase workforce in PHCs as a health-promoting initiative. A researcher is interested in delegating Ayurvedic physicians in PHCs to treat diabetes. Hence, he submits a proposal that involves training the Ayurvedic physicians through few modules in the treatment of diabetes using allopathic medicine. The investigator's main objective was to compare the outcome of diabetes treatment through patient satisfaction which will be assessed using a questionnaire before and after training the Ayurvedic physician. Claiming this as an implementation research, the principal investigator applies for a waiver of consent as he is worried that the people may not like the idea of being treated by an Ayurvedic Physician at PHC.

Questions

i. As an ethics committee member how will you assess the above scenario?
ii. Is the above study eligible for waiver of consent?

Participants answers

- Since an Ayurvedic physician cannot practice allopathy, this research will not be permitted.

Comments of the panelists

- A waiver of consent cannot be given in this case since it involves the administration of a questionnaire
- All questionnaires need to be submitted for IEC review.

At the end of the six panel discussions and lectures on topics of recent relevance such as stem cell research and vaccine research, a feedback was obtained from the participants.

Feedback and final remarks

In the online feedback, 68 (85%) of the participants responded and 64 of them rated it as excellent or very good. Many of the participants appreciated the sequence of a lecture followed by panel discussion with practical case scenarios for discussion and they wanted such programs to be conducted regularly.

The workshop was planned to include all contemporary ethical issues involving biomedical research and clinical trials which could be of practical relevance to the ethics committee members. Group tasks were initially planned, but we found that the number of topics that could be covered in 2 days fitting the lectures and panel discussions would be too limited and hence not included. The positive comments were very encouraging and supportive of organizing future workshops with practical scenario-based panel discussions. Regular refresher courses for the members of ethics committees will be beneficial to keep them updated with the latest changes in guidelines and seek clarifications on evolving issues in each of the research domains.

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Conflicts of interest

There are no conflicts of interest.

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