Scenarios in Medical Ethics-5: Informed Consent Process

Informed consent process is becoming more challenging these days with researchers involved in collecting data during complex situations like an emergency or an epidemic. Other concerns are about translating into local language of informed consent documents prepared in English and consent for reuse of stored samples to obtain additional information, to name a few. To address some of these issues, a 1-h panel discussion session on "Informed consent process" was held during the 2-day workshop organized for Institutional Ethics Committee (IEC) members on September16–17, 2019, at Jawaharlal Institute of Postgraduate Medical Education and Research, Puducherry, in association with Indian Council of Medical Research Bioethics unit, Bangalore.[1,2]

We planned each session to have a lecture followed by case discussions. Each session included 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.

Four similar panel discussion sessions on other topics have already been published in earlier issues of this journal. In this article, we discuss the session on "Informed consent process." The answers provided by the participants are listed first followed by the expert opinion by the panelists.

Scenario 1

A study is planned to be conducted on patients admitted to emergency services with traumatic injuries due to road traffic accidents who are planned for fracture repair under general anesthesia. This randomized controlled study aims to compare the efficacy of two different surgical approaches to fix the fractures and facilitate healing of fracture. The decision to operate needs to be taken immediately after admission.

Questions

1. When should the consent be taken and from whom?
2. What are the other ethical issues in this situation?

Participants' answers

- Consent may be taken in the emergency ward once the patient is stabilized. If the patient is conscious, consent may be taken from him/her; if not, it can be taken from the legally acceptable representative (LAR).

Additional questions

- If there is no one accompanying the patient, can the surgeon take the decision to include the patient as a participant?
- What is the role of re-consent from the participant in this situation?
- During re-consent, what if the participant is not happy with including him/her in the study?

Comments of the panelists

- While designing the protocol for studies involving medical emergencies, all possible situations that may arise with respect to obtaining informed consent need to be anticipated and put forth
- Whenever possible, consent needs to be taken from the participant. When the participant is unconscious or not in a position to give the consent, it can be obtained from a LAR and re-consent taken once the patient recovers
- If there is no one accompanying the patient, then the principal investigator who is the surgeon in this case can decide and take the opinion of another surgeon in the same hospital not involved in the study to agree to this decision and sign on behalf of the patient who is unconscious (this should have been included in the protocol and prior approval obtained from the EC)
- In case, the participant does not want to be a part of the study and is informed only after the surgery is completed as he/she was unconscious when the recruitment was done, he can withdraw from the study at any time without his routine treatment being affected and decide not to include his/her data in the study.

Scenario 2

Due to unprecedented heavy rains, the huge water reservoir in a city broke down flooding the entire city. Many houses were submerged in floodwater. People in low lying areas were shifted to a camp. To prevent waterborne illness chlorination of water was planned. Dr. XYZ, a community health researcher, wants to conduct a clinical trial with two different chlorine preparations for water sanitation. Considering the emergency situation, the researcher applies for exemption from ethical review and waiver of consent with the justification that both are chlorine preparations and hence individuals are not exposed to additional risk due to participation in the study.

Questions

1. Should the IEC grant review exemption?
2. Should the IEC grant waiver of consent?

Participants' answers

- As it is an emergency situation and there will not be enough time to submit protocol to IEC and get the approval, an administrative approval from the concerned authorities may be sufficient and an IEC approval need not be required

- Such studies can be done in nonemergency situations
- They are vulnerable population and there must be a review mechanism in place.

Comments of the panelists

- Since it involves research, an IEC approval is definitely required. As it is an emergency, an expedited review can be obtained from the IEC within a short period of time.[3] The IEC can be asked to grant waiver of consent as it involves a large population and it may be difficult to obtain consent in an emergency situation.

Scenario 3

The title of a study in English read "Comparison of combined mechanical and oral antibiotic bowel preparation (MOBP) versus mechanical bowel preparation (MBP) alone in reducing surgical site infection (SSI) in patients undergoing elective colorectal surgeries: A randomised controlled trial." This was translated into Tamil as "தேர்ந்தெடுக்கப்பட்ட பெருங்குடல் அறுவை சிகிச்சைக்கு உட்படுத்தப்பட்ட நோயாளிகளுக்கு அறுவை சிகிச்சை தள நோய்த்தொற்றை (எஸ்.எஸ்.ஐ) குறைப்பதில் இயந்திர குடல் தயாரிப்பு (எம்.பி.பி) மட்டும் ஒருங்கிணைந்த இயந்திர மற்றும் வாய்வழி ஆண்டிபயாடிக் குடல் தயாரிப்பின் ஒப்பீடு: ஒரு சீரற்ற கட்டுப்பாட்டு சோதனை."

Questions

1. Is it acceptable to have the exact translation of English words into the regional language?
2. What is the solution when it is not possible to find an appropriate word or phrase for translation?

Participants' answers

- Back translation could be a solution
- An original title, transliterated and another title in simple words may be included.

Comments of the panelists

- According to the CONSORT guidelines, two titles, one the original and another one in a simple language could be provided
- Forum for Ethics Review Committees in India provides explanation to about 1000 commonly used words in the ICD in two formats – one in simplified English (simplifier) and another in the local languages of India (now only three are available – Hindi, Tamil, and Gujarati, will soon be made available in all local languages of India)
- If a community does not have a written language and there is only a dialect as in tribal population, an interpreter who can talk to the community can be involved in the consent process and this needs to be documented.

Scenario 4

A researcher was studying the influence of five different single-nucleotide polymorphisms (SNPs) in two genes on progression-free survival in patients with ovarian cancer. In the protocol, it was mentioned that the biological samples would be discarded at the end of the study. When the researcher submitted a manuscript with results of this study to a journal, the peer-reviewer commented that the study should have included two more SNPs from the selected genes.

The researcher has not taken consent from the patient for storing his/her blood samples after the study or for future use of the samples for research. Now, the researcher applies for waiver of consent to IEC and asks for permission to study two more SNPs.

Question

1. Should the IEC grant waiver in such a scenario?

Participants' answers and comments

- A re-consent needs to be taken
- Since it was informed that the sample will be discarded and not used for any future use, additional testing is not permissible
- The IEC can decide if waiver may be given in this situation
- A tiered consent should have been taken a priory to avoid such a situation.

Comments of the panelists

- If the participant refuses to allow storage of sample and its future use, it cannot be used for any further study
- If the sample was not discarded in this study, then it is violation of protocol
- If in this study, there was no mention of discarding the sample and the study period was completed, the researcher can apply to IEC for extension of the study period and obtain re-consent from the participants for carrying out further analysis.

Scenario 5

Vasopressin has been tried for cardiopulmonary resuscitation in adults with mixed results. A pediatrician wanted to try vasopressin for children with cardiac arrest. He submitted a protocol to IEC and sought waiver of consent for this study involving trial of vasopressin in children who develop cardiac arrest in the intensive care.

Question

1. How should the IEC approach this case?

Participants' answers

- Waiver of consent may be given.

Additional questions

- Can consent be obtained from the husband for the wife to participate in research?
- Can the consent of tribal head be sufficient for research on tribal population?

Comments of the panelists

- Delayed consent can be taken after the child's emergency has been tackled
- Sometimes consent needs to be obtained from the spouse as well just to ensure that the research does not result in a rift within the family considering our cultural habits

- Individual consent always needs to be obtained whether it is from the wife or when it involves the tribal population, giving adequate time for them to consult their spouse or the tribal head as the case may be.

Some Additional Points

The panelists clarified some additional facts regarding informed consent process.

- All telephonic consents must be documented in a logbook and recorded if possible
- For online questionnaire-based surveys, consent is usually "implied." In these studies, there will be an introduction section incorporating the consent requirements. Only when the participant agrees to consent, the questionnaire is visible
- Deception is required in studies involving sensitive issues such as child abuse and illegal abortions where it may not be ideal to disclose the title or purpose of the study as it may alert the participants and they may not come out with the correct information.

In these situations, after collecting data, a debriefing needs to be done in prior consultation with the ethics committee (EC).

The remaining panel discussion will be discussed in the forthcoming issue.

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