much it costs an institution to run an effective and streamlined EC. This information would also be useful for institutions planning to set up ECs.

Limitations

It was challenging to use the limited time we had for conducting this workshop, given the incessant enthusiasm of the participants. We acknowledge that the themes identified and discussion might have been constrained due to paucity of time.

Conclusion

Effectively functioning ECs are crucial for ethical research. This article provides a synthesis of discussions from a workshop at the Second National Bioethics Conference and provides insights about ethics committees in India. We hope that the discussion in the workshop will encourage researchers, heads of institutions and policy makers to identify strategies to further improve the functioning of ECs.

Acknowledgements: *We would like to acknowledge the contributions and involvement of Mala Ramanathan, our co-facilitator for the workshop and Ashish Goel's inputs in planning the workshop. We would also thank all participants for their active participation and inputs.*

Conflict of interest: none

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Use of blanket consent for retrospective research in academic institutions: need for scrutiny and integrating safeguards

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The quantum of research is increasing in most Indian institutions. Linked with academic activities such as postgraduate thesis studies, or with externally and internally funded research projects, this research is often useful in devising better treatment modalities as well as in making policy suggestions. As knowledge about ethical requirements in research becomes commonplace, the need for informed consent (IC) from patients and/or research participants has become the norm. Some institutions have started encouraging researchers to take consent from patients for the use of their samples or case reports for unspecified future research purposes; such consent is often referred to as "blanket consent". Ethicists and researchers in a previous issue have debated whether the use of blanket consent can be justified (1-3). This commentary looks at the concept of blanket consent in the context of research in India. It highlights issues from the perspectives of the researcher and the patient and provides examples of ways to address these concerns.

Informed consent in our context

Obtaining IC is a key component of ethical research and requires that the patient or research participant be adequately informed about the research so that s/he can make a decision about whether or not to participate in the research. This is not just a one-time requirement but a process which is reinforced at the time of subsequent research visits (if these are required by the research protocol). Conventionally, IC requires that all relevant information be understood by the participant, and that the decision to participate be made voluntarily. However there are challenges in obtaining effective consent in our settings due to factors such as low literacy levels and high levels of trust in healthcare providers (4). The quality of IC thus remains an ongoing concern in Indian institutions, whether in the public or the private sector.

Why blanket consent

Often researchers and clinicians do not know in advance what they might want to study in the future, or what might be clinically relevant research in their disciplines. They might be treating a patient or a series of patients with an interesting clinical condition but without the technical knowledge to be able to conduct research on patient samples at that point in time. They may therefore want to preserve tissue samples for possible use in future research. Allowing researchers to store interesting samples will enable them to conduct research and come up with relevant findings once they have new tools or novel research methodologies to apply to the samples. This research could help in the enhancement of knowledge as well as in the discovery of new treatments or research information which might be relevant in treating patients with that clinical condition (including, possibly, the patients to whom the samples belong).

However, researchers will be unable to use the samples at a later time unless the patients to whom the samples belong have permitted to their use in future research. Since consent is usually taken at the time the sample is collected, when the patient reports to hospital, consent for future use of patient samples for unspecified research purposes would have to be "blanket consent" for future use. Blanket consent means that no restrictions are put regarding the purpose of future research. American regulations "allow for existing biological materials to be used for research without consent if they are de-identified". (5)

Why is blanket consent problematic?

Consent is usually specific to a particular clinical procedure or set of procedures or research project; the basic premise of consent in research is based on the participant knowing what kind of research is to be carried out with the samples. Can you give valid consent if you do not know what you are consenting to: the purpose of the research that uses your specimens and samples?

This argument is usually countered by researchers who say that there is no problem with taking blanket consent as long as it is made clear to participants that their samples might be used for research purposes in the future. Usually this assurance is supplemented with an assurance that the samples will be anonymised, thus maintaining the patient's confidentiality. This method might work when conducting research with large data sets. However, it will not work if the research concerns just one very interesting patient with unique clinical characteristics who remained a diagnostic quagmire, and hence will be easily identifiable even in the future to the hospital's staff members. Such a patient could face stigmatisation or loss of confidentiality.

The other problem with blanket consent arises when there is a possibility of future commercial use of research derivatives from tissue samples. This may not at present be a concern in public hospitals, but could become one as the government is encouraging the commercialisation of research through agencies like the Department of Biotechnology (http://dbtindia.nic.in). An example would be stem cell lines developed from the tissues of patients with specific clinical conditions which could have commercial applications. This then raises the question: who owns the tissue? Is it the patient, the hospital or the researcher, or a mix of all of these stakeholders? This would be linked with the question of whether the patient should receive a part of the profits or royalty fee if commercialised products are derived from the stored tissue products. Conceptually it would also operate beyond the tissue samples of individual patients to the larger question of tissue ownership. This had happened some years ago, when the Indonesian government refused to share tissue samples from patients with avian (H5N1) influenza with the WHO without an advance commitment that developing countries would get any products, especially vaccines developed from these samples at an affordable price (6).

The third problem concerns the quality of IC. As discussed earlier, when the quality of IC in most institutions (both public and private) is itself doubtful, what difference does the detail (for example, the mention of blanket consent) of the form make? Only when IC is given the importance that it deserves as part of research and clinical activities in public and private institutions, will we be able to also ask whether consent for blanket use was indeed truly informed (otherwise it will just be another clause in the IC form to which no one really pays any attention while administering consent, though it would be used by researchers to be able to justify future research).

It has also been pointed out that patients might not approve of "downstream research uses" of their tissue sample because of personal beliefs or disagreements with the subject of research, such as, for example, stem cell research (5). In this case, general blanket consent would be troubling.

How to approach the issue of blanket consent

The use of blanket consent clauses will probably become common in IC forms. The usual way to build in protection mechanisms in such cases is to ask for anonymisation of samples to respect the confidentiality of the patients to whom the samples belong. In addition, ethics committee should evaluate all future research proposals which aim to use stored tissue samples. Ethics committees in institutions should get involved in developing clear institutional policies on the issue of blanket consent, and ensure that they remain committed to their key duty of protecting patient interests.

Training of researchers is an important part of this approach. Ethics committee members and/or ethics experts can work with the researchers in developing consent forms with clauses which give the participant the right to provide or refuse blanket consent, after giving information about the implications of a particular choice.

In a research project that I have been involved with, the laboratory scientists and clinicians were trained on ethics/regulatory issues; ethics and science policy experts worked with researchers in devising the consent form (so that they would see the importance of the wording and the various clauses through this process and feel ownership of the consent form and consent process). The Regulatory and Ethics Board also deliberated to arrive at a consensus about the permissible content of a blanket consent clause in the IC form. There was a section in the consent form with three choices:

a) The patient does not want to be contacted in the future, and allows for any sort of future use of his/her samples.

b) The patient wishes to be contacted for "re-consent" in the future if the research purposes are different from those of the current research project.

c) The patient does not want to be contacted in the future, and also does not consent to the use of his/her samples for any future research project.

This serves as an example of giving the patient the right to decide on whether or not to go in for blanket consent, and also

what approach to take to anonymisation. Of course this also requires a good, secure system of linking samples with patient information/identifiers to enable the patient choices to be implemented.

Conclusion

Taking blanket consent from patients in institutions for use of their samples for research purposes in the future raises questions about whether this approach is ethical as the patient might not be truly informed about research objectives. Respecting patients' rights and yet accommodating possible future research would require devising consent forms which provide flexibility to obtain blanket consent while respecting the key elements of IC to a large extent. The axis of control of decisions about consent, blanket or not, should remain with the patient. It is for researchers, ethics committees, institutional leadership, and regulatory and policy makers to ensure that this happens.

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