Oops, what about ethics?

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Oops, what about ethics?

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Ethics approval of research studies is essential for the protection and rights of study subjects, whether this is for prospective research or record reviews. This article shares a painful lesson learned from a field experience where the appropriate steps for obtaining ethics approval were not followed by a young researcher. This researcher had embarked on an operational research project, but had omitted to seek ethics approval from a local ethics committee. Young researchers, particularly from low- and middle-income countries, need to learn about the importance and value of ethics.

Submission to an ethics committee for approval of a proposed study is often perceived as a time-consuming and difficult process that constitutes a barrier to research. Occasionally, in the enthusiasm to rush into a research project, the requirement for ethics review may be overlooked or young researchers may be unaware of the need to seek ethics approval before starting a study.

ASPECT OF INTEREST

A colleague recently had a unpleasant experience with a research project, but emerged a better researcher, with an understanding of the 'why' and 'how' of ethics review. As a participant attending a course on operational research run by Médecins Sans Frontières (MSF), Luxembourg, and the International Union Against Tuberculosis and Lung Disease (The Union), Paris, France, he had discussed his proposal with course mentors. The proposed study involved the use of data he had already collected from interviews conducted among patients hospitalised for multidrug-resistant tuberculosis. The participant had actually completed the interviews before involving his course mentors. He had informed the study participants about the objectives of the study (to describe patient experiences during treatment) and had obtained their written consent to ask related questions. He thought this was sufficient, and was unaware that formal ethics review and approval was required before embarking on any research on humans.

Among the first questions posed by the mentors at the start of the research training course was, 'Did you obtain ethics approval for this interview study?' The answer was, 'No, I did not'. In his enthusiasm to proceed with interviews, he had obtained permission from the Tuberculosis Programme Coordinator, but had omitted to apply for ethics approval. There had been no ethics review of the questions to be asked or the study processes—both of which may involve issues of patient protection and social harms. In his defence, this new researcher had never received advice about ethics requirements prior to conducting the research. He was told by the course mentors that the data could not be used as a project for his course, as this important step for the protection of human subjects had been omitted. He was also told that peer-reviewed journals were unlikely to accept a paper without a statement of ethical approval and that post-hoc ethical approval is generally not feasible. The difficult task of developing and conducting interviews with a large number of patients and collecting data for this researcher thus ended up as a restricted learning exercise that could not be further developed.

DISCUSSION

Research ethics was developed after the exposure of several shocking experiments conducted among people without their knowledge or consent, and often with harmful consequences. Following these incidents, a number of codes and declarations were established, emphasising the principles of respect for participants (their right to information, to refuse to participate, to privacy), to beneficence (good outcomes) or at least to non-maleficence (no harm) and to justice (fair selection and fair distribution to participants and their communities of any positive result of the research). Important documents include the Declaration of Helsinki of the World Medical Association, the Belmont report, the report of the Council for International Organizations of Medical Sciences (CIOMS) and others, including national codes of ethics in different countries.[1–3] The recommended process, now well accepted by researchers around the world, requires a review of each study by an independent group mandated to protect the rights of study participants and ensure that ethical principles are upheld.

Studies involving interviews are not without ethical issues and can cause harm, albeit only social harm. Individuals who are being asked to answer questions need to be clearly informed about the purpose and content of the study, and they also need to know that they have the right to refuse to answer some or all of the questions. Furthermore, the content and style of the questions need to be reviewed by an independent ethics committee to ensure that insensitive and/or inappropriate questions are avoided.

Ethics committees/boards/groups have been established by many health authorities, academic institutions and non-government organisations. They consist of members with expertise in international ethics

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and/or knowledge and experience of local situations and cultures, including an understanding of complex humanitarian contexts. MSF, an institution actively involved with operational research, has established its own ethics review committee, which reviews study protocols.[4] The Ethics Advisory Group of The Union, established some years ago, similarly reviews all research proposals developed in the organisation.[5]

Local programme authorities as well as research institutions, both local and international, should therefore provide training and support on the ethics of research and related requirements. This would ensure that studies are conducted in a manner that is respectful, safe and scientifically valid, and that once approved they are acceptable for publication, provided that good scientific and writing standards are met.

CONCLUSION

In our story, the researcher had to abandon plans for his study on patients with drug-resistant tuberculosis, but developed instead a new awareness about ethics issues and processes. With support from his course mentors, he completed a new protocol which was submitted to, and approved by, an appropriate ethics committee. We share this experience to emphasise the need for operational and other researchers and for programme leaders in low- and middle-income countries to be aware of their responsibilities concerning ethics. This will help to ensure that the rights of study participants are protected and will avoid disappointment among investigators who would otherwise find that they have wasted precious time and resources due to their failure to address this essential step in the research process.

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L'approbation éthique des études de recherche est essentielle pour la protection et les droits des sujets de l'étude, que celle-ci soit destinée à une recherche prospective ou qu'elle consiste en une révision de dossiers. Cet article partage une pénible leçon provenant d'une expérience sur le terrain dans laquelle les étapes appropriées d'obtention des accords éthiques n'ont pas été suivies par un jeune chercheur. Ce chercheur s'est embarqué dans un projet de recherche opérationnelle, mais a omis de solliciter l'approbation éthique du comité local d'éthique. Il y a lieu de veiller à ce que les jeunes chercheurs, principalement ceux provenant de pays à revenus faibles ou moyens, s'informent au sujet de l'importance et de la valeur des données éthiques.

La aprobación de los estudios científicos por parte del comité de ética es primordial para la protección de las personas que participan y el respeto de sus derechos, ya sea en las investigaciones prospectivas o en los análisis de las historias clínicas. Por conducto del presente artículo se comparte una dolorosa enseñanza extraída de una experiencia en el terreno, en la cual un joven investigador no cumplió con las etapas necesarias en materia de aprobación por el comité de ética. El investigador se lanzó en un proyecto de investigación operativa, pero omitió buscar la aprobación del comité local de ética. Los jóvenes investigadores, sobre todo en los países de ingresos bajos e intermedios, deben aprender la importancia y la utilidad de los aspectos éticos de su trabajo.

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