



SHORT COMMUNICATION

Why ethics is indispensable for good-quality operational research

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This article outlines challenges encountered when ethics is taught and promoted in the Operational Research courses of the International Union Against Tuberculosis and Lung Disease, with a focus on ethical issues related to studies that involve health records reviews. Problems observed by the Ethics Advisory Group include engagement of all stakeholders, maintenance of confidentiality and authorship. The omission of ethics in the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) statement and its explanatory commentary published in 2007 is highlighted and questioned.

The Centre for Operational Research of the International Union Against Tuberculosis and Lung Disease (The Union) has offered modular courses since 2009 in collaboration with Médecins Sans Frontières, Brussels Department of Operational Research. The philosophy, objectives, course programme, modules and achievements are described elsewhere.¹ The importance of ethics in project proposals is emphasised in the course by devoting a full day to the subject in the 5-day module on proposal development. The principles of ethics are outlined and discussed, and participants are assisted in the completion of ethics application forms related to their study proposals for submission to The Union's Ethics Advisory Group (EAG). The first milestone required for each participant is submission of a proposal together with the completed ethics application form within 2 weeks of completion of the first module.

Course participants are encouraged to use record reviews for their studies, as these are relatively simple to access and evaluate, yet can potentially produce important results that can influence policy and practice. Even where studies use existing records, ethical issues should be considered despite the absence of direct contact with human participants. These include ensuring the relevance of each study and potential benefits to both the health service and the community being researched, obtaining permission from relevant bodies, maintaining confidentiality of all study data so that individuals cannot be identified, ensuring access to relevant results by participants and their communities, and collaborative co-authorship with local partners.

The Union EAG reviews all proposals of studies for which Union staff are principal investigators or collaborators, co-authors of resulting publications or if stud-

ies are Union-sponsored or funded. EAG policies, forms and documents are available on the Union website.² The majority of the proposals submitted by course participants of operational research involve studies of existing records. These are managed through a rapid review process, with approval granted within a few days of application if there are no problem issues. A shorter application form designed specifically for record review studies has recently been developed.³ These changes have been instituted to help operational researchers, as it is our belief that ethics reviews should not present barriers for busy researchers, particularly those conducting operational research, who usually also have programme responsibilities. Multiple reviews for authors from different institutions and lengthy review processes need to be avoided without undermining the importance of the review process.

The EAG does observe some problems. 1) Applicants sometimes fail to recognise that confidentiality can be breached even if individual names of participants or their records are not collected, as there may be other identifying characteristics. 2) The right of participants and their communities to receive the study results, appropriately presented, is often neglected. 3) It is ethical practice to obtain ethics approval for studies in the host country as well as from the sponsoring country or institution.^{4,5} This is often initially overlooked, particularly when the host is a developing country; obtaining this approval is sometimes a problem for researchers. Where national ethics committees do not exist and until these are constituted, a local solution could be to obtain general approval (not ethics approval) from the local Ministry of Health or other authority having jurisdiction over the site of the research. We would be interested to hear readers' experiences and suggestions on this issue.

The Union's journals (*International Journal of Tuberculosis and Lung Disease* and *Public Health Action*) include in their instructions for authors the statement 'Details of ethics approval (or a statement that it was not required/was judged not to be required) should be provided in the Methods section of all research studies submitted to the Journal' (<http://www.theunion.org/index.php/en/journals/>). These recommendations follow guidelines provided in the Code of Conduct and Best Practice Guidelines for Journal Editors of the Committee on Publication Ethics, which state that editors should endeavour to ensure that the research they publish is carried out as per the relevant internationally

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accepted guidelines, and should seek assurance (and evidence) that all research has been approved by an appropriate body.⁶

The STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) statement and its explanatory commentary published in 2007 in multiple international journals are landmark documents that provide a checklist of items that should be addressed in reports of observational studies (cohort, case control and cross-sectional study designs).^{7,8} The statement sets out to improve the quality of reporting of studies and will, without doubt, help to achieve that aim. However, ethics is not listed as a recommended item, and in fact is not mentioned at all. A subsequent paper, the updated CONSORT (Consolidated Standards of Reporting Trials) 2010 Statement, presents a list for reporting of randomised controlled trials.⁹ Ethics is not included in that document either, and the omission is justified by the authors because, they say, funding bodies insist on ethics review and medical journals usually require a statement that these have been done.

We are of the opinion that failure to consider ethics in guidelines for reporting research is an omission. The consideration of ethical issues by researchers and the review by objective ethics committees reflect comprehensive modern ethical thinking. The rights of research participants and the safeguarding of the records of individuals being researched are ethical requirements that are well documented.^{10–12} No research should proceed without consideration of ethical issues anticipated by researchers and without review by an independent and competent ethics review body. These two actions should be considered as integral parts of the research process, and are thus logical and indispensable elements of the study report checklist. The STROBE list serves as a model for reporting findings for many journals, including *Public Health Action*, and thus must include ethics in its list. We also note that all authors and people acknowledged in the STROBE statement are from industrialised countries, and we would suggest that participation from members of communities in developing countries, common sites for research activities, would add valuable local advice and opinions to further discussion about the statement.

Finally, we recommend the addition of ethical considerations and the statement of review and approval by an ethics committee to the STROBE list.

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Cet article souligne les défis rencontrés lorsque, dans les cours de Recherche Opérationnelle de L'Union, on enseigne et on promeut l'éthique en se focalisant sur les problèmes éthiques liés aux études qui comportent des revues de dossiers de santé. Les problèmes observés par l'Ethics Advisory Group comportent l'engagement de tous les responsables et le respect de la confidentialité et de la propriété

des auteurs. L'omission de l'éthique dans la prise de position STROBE (Strengthening the Reporting of Observational Studies in Epidemiology, *Renforcement des rapportages d'études observationnelles en épidémiologie*) et son commentaire explicatif publié en 2007 est mise en évidence et remise en question.

En el presente artículo se describen las dificultades que plantea la enseñanza y el estímulo de la ética en los cursos de investigación operativa impartidos por la Unión Internacional Contra la Tuberculosis y Enfermedades Respiratorias (La Unión), con un interés particular en los aspectos éticos de los estudios donde se examinan los expedientes clínicos. Entre los problemas observados por el grupo consultivo de La Unión en materia de ética se encuentran el compromiso de todas

las partes interesadas, el respeto de la confidencialidad y la autoría. Se destaca y se objeta la omisión de la ética en la declaración de STROBE (Strengthening the Reporting of Observational Studies in Epidemiology, sobre las recomendaciones para mejorar la calidad de la comunicación de los estudios de observación en epidemiología) y en su nota explicativa, publicadas en el 2007.