Editorials

Ethical approval for operational research

Laragh Gollogly[a]

This issue of the *Bulletin* contains two examples of a poorly defined area of public health intervention — operational research. Better known for its use in improving assembly lines or military tactics, operational (or operations) research has its own societies, journals, conferences, terminology and conventions.[1] While much health services research could potentially be classified as operational research,[2,3] this is the first time that we have seen authors use this classification as a reason for not seeking ethical approval for a study. Manica Balasegaram et al. report the outcome of two retrospective cohort studies on patients with trypanosomiasis in the Republic of the Congo.[4,5] When the *Bulletin*'s editors asked them why they had not sought informed consent or ethical committee approval for these studies, they explained that they were not reporting primary research.

They also explained that all data were collected as part of routine diagnosis and treatment. Patients had been diagnosed and treated according to national guidelines and agreements, and testing blood and cerebrospinal fluid was an essential step in confirming diagnosis and classifying patients. These tests were done for each patient as part of routine care, not for research purposes. The authors explained that they evaluated the existing national treatment protocol, not an experimental one. They had originally established a treatment programme, not a research project, in the Republic of the Congo. Therefore, they had only sought (and obtained) project approval from the Ministry of Health. They had planned an analysis to look retrospectively at outcomes for a large cohort of patients, and had done this initially as part of an audit/evaluation, so as to improve quality of care provided. The authors explained that the government's decision to change the threshold for the treatment of early stage patients was based on rather weak evidence. Once their analysis had confirmed clinical suspicions that the cut-off for treating early-stage patients was probably too high — exposing patients to a high risk of treatment failure and death — they felt that this information should be shared with the wider medical community, and so submitted it for publication. The authors had also asked their Medical Director for feedback regarding the need for ethical clearance for such a retrospective analysis, and had been advised that this was not warranted.

When these papers were reviewed, and the case was discussed by the WHO Research Council, and the Committee on Publication Ethics, the *Bulletin's* editorial team was asked to weigh up the harm that might result from publication, against the benefits of disseminating these results. The main harm resulting from publication would be to the autonomy of the study's subjects — who had not been informed of, or given the possibility of consenting to the use of their clinical data in this way. The benefit is that the study will inform other physicians of these outcomes, with the expectation of improved treatment for all individuals affected by this neglected disease. The general view of both ethics committees was that it is in the public interest to have the study published, and that it will probably bring benefits to the very people whose autonomy may be harmed by its publication. The Committee on Publication Ethics asked specifically for an accompanying editorial, drawing readers' attention to the matter.

We shared the outcome of these discussions with the authors, who then requested and received retrospective permission from the Ministry of Health to use the data in this way. We are sharing this information with readers, and would like your opinions on the overlap between operational research, audit and evaluations, and the need to think clearly about how to reflect the spirit, rather than the letter, of ethical guidelines for research that does not fit neatly into any one of these categories. ■

1. Ek-Peng Chew, Huei-Chuen Huang, Johnson Ellis J, Nemhauser George L, Sokol Joel S, Chun-How Leong. Short-term booking of air cargo space. *Euro J Operation Res* 2006; 174:1979-90.
2. Emerson PM, Burton M, Solomon AW, Bailey R, Mabey D. The SAFE strategy for trachoma control: using operational research for policy, planning and implementation. *Bull World Health Organ* 2006;84:613-9.
3. Pierskalla WP, Brailer DJ. Applications of Operations Research in Health Care Delivery in: Pollock SM, Rothkopf MH, Barnett A, editors. Handbooks In Operations Research And Management Science: Operations Research And The Public Sector. North Holland. 1994.
4. Balasegaram M, Harris S, Checchi F, Hamel C, Karunaka U. Treatment outcomes and risk factors for relapse in patients with early-stage human African trypanosomiasis in the Republic of the Congo. *Bull World Health Organ* 2006;84:777-82.
5. Balasegaram M, Harris S, Checchi F, Ghorashian S, Hamel C, Karunaka U. Melarsoprol versus eflornithine for treating late-stage Gambian trypanosomiasis in the Republic of the Congo. *Bull World Health Organ* 2006;84:783-91.

[a] Department of Knowledge Management and Sharing, World Health Organization, Avenue Appia, 1211 Geneva 27, Switzerland (email: golloglyl@who.int).
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