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Guest Editorial

Should ethics committees review the scientific merit of research proposals?

Many ethics committees explicitly take a view of ethics that excludes scientific issues. Consequently, poor or useless studies pass such review even though they can reasonably be considered to be unethical.

So wrote Douglas Altman recently in the *British Medical Journal* (1994). It is tempting to believe that research ethics committees could review the scientific aspects of research protocols in a way that improves the scientific quality of research. Yet the experience in New Zealand, where ethics committees have been given this role explicitly since 1988 (Draft Standard for Ethics Committees, 1988), suggests that such a belief is misplaced.

The idea of giving scientific assessment explicitly to ethics committees came out of the Cartwright Report (Cartwright, 1988). At the inquiry evidence was presented that the main investigator had drawn faulty inferences from his own data and had abandoned usual scientific conventions, and these deficiencies had put his patients at risk. Cartwright stated "If it is not well designed, a research proposal is unethical".

But the ways in which ethics committees have dealt with scientific review appear to have been unsatisfactory in at least two respects. There have been detailed and sometimes misplaced concerns about scientific aspects of observational studies, and an apparent lack of consideration of scientific aspects of intervention studies. Although both types of study design may raise ethical issues, there is a fundamental difference between them (ibid, 1988). In intervention (or experimental) studies the conditions of the study are determined by the investigator - in terms of giving or withholding treatment, for instance. In an observational study the investigator observes only, for instance by using case notes, questionnaires or interviews.

For example, Dockerty and Elwood (1992) described further scientific review being commissioned by an ethics committee despite their observational study having already been assessed by the Health Research Council (HRC). The commissioned review was very critical of the study design in contrast to the HRC review which had rated the study very highly. Furthermore the review procedure by the ethics committee took 36 weeks and Dockerty and Elwood were critical of the unnecessary time and resources involved.

It is not uncommon to have real differences of opinion about the scientific merit of particular research designs. Another such difference occurred in relation to a national case-control study of asthma deaths and medications. Though the study was subsequently published in the *Lancet* (Crane et al, 1989), and the results have helped to form the basis for important public health action, one geographical area was not included in the study because the local ethics committee declined permission (ie access to case notes) on scientific grounds.

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On the other hand failure of ethics committees to review the scientific design of intervention studies is suggested by the approval of very small clinical trials. Moreover the National Standard (Department of Health, 1991) which ethics committees are supposed to use, has little to say about the sorts of issues that arise in the ethical and scientific assessment of intervention studies.

The rigour of scientific assessment should be matched to the potential risks involved in a study. Such an approach was outlined in the 1991 revision of the National Standard (ibid, 1991). A statement was added to the scientific validity section, "for some studies that carry no risk to participants and do not involve a significant intrusion on their privacy, the provisions of this paragraph may be relaxed". There is logic in this approach. The only reason to send research for ethical review is that it involves some potential risk to human (or animal) participants. Research in chemistry or history does not as a rule, go to an ethics committee, because it entails no such risks. Similarly audit doesn't get ethical review. Ethics committee review can never be a method to ensure all research undertakings are valid.

Ethics committees should be able to make a valuable contribution to scientific review, by using external reviewers for experimental research which hasn't been peer reviewed, and by commenting to researchers on scientific issues. But it is a difficult business. The Royal College of Physicians guidelines (1990) warn:

A committee should reject an application on grounds of low scientific quality only where it has carefully satisfied itself that it has adequate knowledge and expert advice to justify this step.

This could be a particular problem in New Zealand where ethics committees are required to have half lay membership (Department of Health, 1991). Delivering the committee's views in absolute terms, without giving reasons for proposed changes to a protocol (Dockerty and Elwood, 1992) will not do anything to encourage investigators to improve scientific quality. We need more than a note in the National Standard to make this approach work.

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Public Health Commission

At the Centre

The Bioethics Research Centre has seen a busy first semester in 1994. The new third year paper, *Introduction to Bioethics* has attracted a diverse group of students, and the first candidates have enrolled for the Master of Health Science degree. Courses already established continue to attract students to the study of ethics.



Scott Hollingsworth, an American Rotary Ambassadorial scholar, is with the Centre for 1994, and working on a thesis on Health Care Justice. We have also enjoyed a two month visit from **Tina Banerjee**, from Germany, whose area of interest is animal experimentation.

In addition to public seminars on *Community Psychiatric Care* and *Care of the elderly: asset testing*, the Centre has run a series of journal club discussions on qualitative research, and staff and students have made presentations at various conferences.

Associate Professor Grant Gillett was visiting Professor at University of British Columbia, Vancouver in April.

Professor Campbell is presently on sabbatical at John Carroll University, Cleveland, Ohio, USA, and will be back at the Centre in July.

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