An ethical committee for general practice in the west of Scotland: proposals received in the first year

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SUMMARY. The particular ethical problems of research in general practice and pressure from local general practitioners and hospital ethical committees led to the development of an ethical committee for general practice in the west of Scotland. The workload of this ethical committee in its first year of existence is described.

Despite the fact that many of the studies considered by the committee were sponsored by pharmaceutical companies and were often sophisticated, the ethical issues of a general practice setting had not always been fully appreciated. Of the 21 study proposals submitted over the year 13 showed areas of ethical uncertainty. However, all the studies were eventually approved. Most of the problems encountered were easily overcome and might have been avoided if the general practitioners undertaking the research had been able to seek advice from those with experience of research in general practice and in particular of the ethical issues involved. Local ethical committees for general practice, made up largely of general practitioners but with at least one lay member, might provide one such source of advice.

Introduction

ETHICS are 'the rules of conduct recognized by society or one's peers'.[1] By its nature research must often come close to, or even go beyond currently 'recognized' rules of conduct. Doctors have long acknowledged this and most health districts and/or individual hospitals now have an ethical committee to consider proposals from research workers. Approval is withheld if study methods are thought to be harmful to the study subjects or are unlikely to provide useful information. The Royal College of Physicians' guidelines[2] state that all ethical committees should include at least one general practitioner, but a recent study by the Institute of Medical Ethics in England and Wales showed that 34 out of 87 ethical committees had no general practitioner member.[3] An earlier study in Scotland[4] showed similar findings.

It is not always possible for a general practitioner to have his/her ideas reviewed by his/her peers before submitting a research proposal to an ethical committee and certain aspects of general practice research require direct experience of that setting. The subjects of a general practice study are also patients with whom the general practitioner has a long-term relationship, which might be affected by certain studies, for example double-blind comparisons. General practitioners are often both observers and participants in studies and this must also be taken into account. It may be difficult for individual practitioners to obtain sample sizes large enough to allow valid conclusions, but multi-practice studies can lead to problems of inter-observer variation.

We were aware that some general practitioners in the west of Scotland had experienced difficulty in obtaining ethical approval for studies and some were involved in studies which had not been submitted to ethical committees for approval. This was an unsatisfactory situation particularly as there is dawning public unease about research in general practice[5] with questions being raised about its ethical propriety.

The ethical committee for general practice

Pressure from local general practitioners and requests for assistance from hospital ethical committees, which were increasingly reluctant to review general practice study protocols, combined with public concern about general practice research led to the formation of an ethical committee for general practice in the west of Scotland in November 1985. The local faculty of the Royal College of General Practitioners, Glasgow University and the Greater Glasgow Health Board nominated members to the committee. Initially the committee comprised eight general practitioners with experience and interest in research but it has recently expanded to include a lay member.

The review of proposals began by circulating committee members with protocols and inviting postal replies. This evolved and now a meeting is held every four to six weeks at which protocols are considered using the *Guidelines in the practice of ethical committees and medical research*.[2] Where individual members of the committee experience difficulty they refer to the *Handbook of medical ethics*.[5] This paper reviews the proposals received by the ethical committee during its first year of existence.

Proposals received

Over the year the ethical committee received 21 study proposals (between one and four per month) from 12 separate sources. Eighteen were from pharmaceutical companies, two were from individual general practitioners and one was from the Medical Research Council Sociology Unit in Glasgow. Fifteen of the studies involved more than one practice, five were based on a single practice and one was a pilot study in a single practice for later application in a number of practices. A wide variety of diagnostic areas was covered with hypertension and respiratory disorders (five studies each) being the most commonly investigated areas. Only one study did not involve drug administration. Ten studies involved the use of drugs before their general release and clinical trials exemption certificates were required for these studies. Five studies investigated a new indication of an existing preparation and a further five investigated new formulations for existing drugs. The study method employed was usually a randomized double-blind group comparison but three studies were single-blind comparisons and one was a cohort study.

The most common ethical problems encountered among these 21 study proposals were as follows:

- Insufficient monitoring of patients was proposed (three studies). For example, elderly patients with hypertension not being reviewed for one month after starting anti-hypertensive medication.

- The study was insufficiently blind (three studies). For example, one group of patients were given tablets, the other group capsules.
- The study numbers were too small. Although this is essentially a question of appropriate study design, in three studies it was felt that no useful information would be obtained and that to avoid wasting the time of both the study subjects and the doctor larger numbers would be required.
- Insufficient information about the drugs used in the study were provided (three studies). Toxicity data from other patient groups and/or animal studies were omitted and for one preparation no data on its previous use in any species, plant or animal, were available.
- The methods of assessing response were dubious and more valid measurements were requested (two studies).

Other problems which arose only once were:

- Uncertainty over the need for an invasive procedure.
- No proposals to measure compliance.
- A threat to confidentiality (notes to be disclosed to unauthorized persons).
- Inadequate exclusion criteria (pregnant women may have been included).
- Inadequate information to be given to patients.
- Deciding if the study was being carried out for scientific or sales promotion purposes.

Studies which were poorly designed often had more than one ethical problem. Four of the studies had four ethical problems but most were well designed and ethically appropriate — eight had no problems, six had only one problem identified and three had two problems.

Overall suggestions were made for protocol changes, most of which were easily achieved, in 13 (62%) of the 21 studies. Only one study, which involved vaccine administration and venepuncture, required several resubmissions before the ethical committee were satisfied that undue distress would not be caused to the children involved — additional quarter yearly checks on immunization rates were requested in participating practices to ensure that there was no reduction in overall compliance with immunization.

Discussion

In order to appreciate the particular ethical problems of research in general practice ethical committees considering study proposals should largely be made up of general practitioners from various types of practice who are experienced in the problems of general practice research. As recommended by the Royal College of Physicians[2] and the British Medical Association[5] there should also be at least one lay member on each ethical committee. The committee members can identify ethical problems before studies begin when they are still only potential problems.

The workload of the ethical committee in its first year was not too onerous as the number of proposals submitted averaged less than two per month.

Although the proportion of studies approved without alteration was only 38%, which is at the lower end of the range from previous studies,[4,6-9] the suggested changes were often minor and the problems easily avoidable. Discussion at an earlier stage with experienced researchers would have avoided many of these difficulties.

General practitioners are likely to face increased problems in obtaining ethical approval as public awareness of the problems of general practice research increases and as general practitioners play a greater part in research. Perhaps more general practitioners who have research/ethical experience should consider sitting on an ethical committee for general practice.

References

1. *Shorter Oxford English dictionary.* Oxford University Press, 1973.
2. Royal College of Physicians. *Guidelines on the practice of ethics committees in medical research.* London: RCP, 1984.
3. Institute of Medical Ethics. Research ethics committees in England and Wales: the institute's survey. *IME Bulletin* 1986; supplement 2: 2-10.
4. Thomson IE, French K, Melieux KM, *et al.* Research ethical committees in Scotland. *Br Med J* 1981; **282:** 718-720.
5. British Medical Association. *The handbook of medical ethics.* Cambridge University Press, 1984.
6. Working group in current medical/ethical problems, Northern Regional Health Authority. Applications for ethical approval. *Lancet* 1978; **1:** 87-89.
7. Denham MJ, Foster A, Tyrrell DAJ. Work of a district ethical committee. *Br Med J* 1979; **2:** 1042-1045.
8. Allen PA, Waters WE. Development of an ethical committee and its effect on research design. *Lancet* 1982; **1:** 1233-1236.
9. Gray BH, Cooke RA, Tannenbaum AS. Research involving human subjects. *Science* 1978; **201:** 1094-1101.

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