The Editor has asked me to write this editorial about recent College reports on ethical matters. These include a new set of Guidelines on the practice of ethics committees in medical research involving human subjects produced by our Committee on Ethical Issues in Medicine (CEIM); a report on Research involving patients, complementary to our 1986 report on Research on healthy volunteers; and a section on ethical considerations in our recently published report on Prenatal diagnosis and genetic screening.

The College has a long history of concern about ethical matters. In 1967, following the statement issued by the World Medical Association (1948), its Declaration of Helsinki (1964) and the MRC’s guidelines for research on humans (1962–3), the College recommended that all clinical research investigations should be subject to ethical review and that committees should be formed in each health district of the country specifically to carry out this function. This recommendation was endorsed by the Department of Health.

In 1984, the College issued a set of guidelines on the practice of these Local Ethics Committees (LECs). In the ensuing five years, medical advances have introduced new and complex ethical issues and public concern about research involving human subjects has intensified. We have also become aware that established LECs do not always function well; indeed some seem not to function at all! The time seemed right for a revised set of guidelines designed to bring the previous recommendations up-to-date and to tighten the ‘rules’ under which LECs operate.

Guidelines for ethics committees and research in patients

The CEIM and the Working Party on Research in Patients, after intensive thought and discussion, reaffirmed the 1967 opinion that all medical research involving human subjects should undergo ethical review before it commences, on the principle that an investigator should not be the sole judge of the ethical issues raised by his research. This view has been questioned by epidemiologists, in particular those who might simply wish to ask patients a few innocuous questions or consult their medical records. Even in such apparently harmless circumstances it was felt that approval should be sought although Chairman’s action might suffice without formal review by the whole committee; ‘class’ approval could be given for much of this type of research and undue delay could thus be avoided.

‘Informed consent’ is another controversial and difficult topic. The adjective itself is not particularly helpful and has been dropped by our committees. Provision of adequate and appropriate information to the subjects of research is more important (except perhaps in a court of law) than the recording of consent. Signed consent is a device frequently thought to protect the investigator rather than the patient, yet in some circumstances it may be advisable. The nature of consent and the need for it in different situations is well discussed in the report on Research involving patients, which contains a proposed model consent form that emphasises the importance of the information given to the subject and testifies to the patient’s satisfaction about what was said to him or her, and the opportunities provided for questioning and discussion.

Our committees endorsed the recent conclusion of the British Paediatric Association that non-therapeutic research on children might be justified if there was a potential benefit to other children, although research which could equally well be done on adults should never be done on children.

Ethical problems associated with randomised controlled clinical trials also caused a few headaches. The inexorable and distressing decline of patients with AIDS has led to their demands for new treatments in advance of evidence to prove efficacy without undue toxicity, ie without the benefits of proper clinical trial. This demand would be easier to condone if clear and unequivocal advantages were known to exist; in such a case the ethics of a trial would seem dubious. In the absence of such clear evidence, proper controlled trials are imperative to evaluate new therapies. The College reports highlight some of the problems associated with such trials: the use of placebos and the need to inform subjects that they will receive placebo or an active form of therapy by random selection; whether consent should precede or follow randomisation; provisions for withdrawal of patients or termination of the trial; the continued availability after completion of the trial of treatment shown to be beneficial.

Perhaps the most difficult of all problems associated with clinical trials is the need for separate and independent approval by the LEC of each district involved in the trial (this troubles epidemiologists as well). Is it possible to ‘impose’ the approval of a central authority on all LECs, or should they retain the right independently to reject a proposal? Should there be a national committee capable of reviewing and approving multicentre trials or studies and to what extent might such a step erode the autonomy of LECs? National ethics committees exist in several European countries, but they tend on the whole to ‘pronounce’ on ethical matters of public interest rather than approving individual
research projects. It is usually accepted that LECs should retain the right to reject a project on ethical grounds even if it had been approved centrally or by another LEC.

These are a few of the many topics discussed in the two reports. Dr Desmond Laurence initiated and produced the first guidelines for LECs in 1984; it is a pleasure to acknowledge his leading role in this revision. Dr Alastair Brewis acted as Secretary to, ie wrote the report for, the Working Party on Research in Patients: the College thanks him for taking so much trouble about it.

Prenatal diagnosis and genetic screening

This was released in early September 1989 and was intended to bring together in a single report an account of the new possibilities for prenatal diagnosis of genetically determined and congenital disorders. The report dealt with the special problems of ethnic minorities, the urgent need for development of sound counselling services, improved public education and a better organised service at all levels of care, in hospitals and in the community. Inevitably, prenatal diagnosis raises ethical problems. If a major fetal defect is shown, termination of pregnancy must be discussed and offered as an option to the parents. It follows that prenatal diagnostic tests should be carried out after discussion of this option, so that testing may be refused by those who prefer not to face the decision to terminate. These and other ethical aspects are discussed in a separate chapter of the report.

Dr Bernadette Modell was responsible for the production of this report which has received many fulsome tributes. The College thanks her for handling such a difficult and complex issue and producing such a lucid report.

Comment

There is no central body in the UK that reflects and advises on major ethical issues. Devolution of decision-making has been the standard practice so far as medical research involving humans and medical practice have been concerned. Guidelines for specific topics have come from a variety of sources — the MRC, medical colleges, faculties and other associations, the Department of Health, the Institute of Medical Ethics and similar bodies. Over the years the Royal College of Physicians has taken the lead in several important ethical areas and their new publications should enhance the reputation they already enjoy of ensuring that the interests of the subject — patient or volunteer — are safeguarded. It is hoped that this has been done without impeding the advance of medical knowledge on which their welfare ultimately depends.

SIR RAYMOND HOFFENBERG
President of Wolfson College and Past President of the Royal College of Physicians

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