Auditing a research ethics committee

ABSTRACT—Research ethics committees approve research on human subjects performed locally. They have been criticised for failing to perform this function adequately. I have, therefore, examined the structure and process of the committee for Leicestershire and compared it with the guidelines for these committees produced by the Royal College of Physicians and the Department of Health. The structure and function of the committee are described and conform well with the recommendations of the Royal College of Physicians and the Department of Health. An annual report to the health authority has not previously been produced but the need for this is now accepted. The suggestion for a lay chairman or vice-chairman has, however, been rejected. The workload has steadily increased over the past 10 years, from 66 protocols a year to 302. During a recent 12-month period, 277 research submissions were received; 143 of them were agreed without amendment, 93 with minor amendments, and 41 were rejected or required further information before they could be reconsidered. Assessment of outcome is more difficult. In future, the committee may ask for annual reports from investigators on their research and on any ethical problems encountered. Ethics committees need to foster good ethical research and inform researchers of ethical issues. Most of the latter are highlighted on the Leicestershire application form but are supplemented by short guidelines on particular topics. The committee consumes time and money; it is not clear if it will be adequately funded under the new NHS structure.

It is open season for research ethics committees. A survey [1] of these committees and a leading article [2] have heralded the publication of the second edition of the Royal College of Physicians’ guidelines [3] and called for an audit of these committees’ activities. The Department of Health has recently formulated its own guidelines [4]. There is unease that these committees can be idiosyncratic, fail to follow existing guidelines, and are subject to no control or review.

In all this, little has been heard from the committees themselves: what they do, why they do it, and why they do not always do what is suggested. The Northwick Park committee reported its activities as long ago as 1979 [5]. As a contribution to debate it seemed worthwhile to describe both the workings and proposals for change of the Leicestershire committee: one with a significant workload and experience and responsible for both health authority and university research. The College guidelines can be used as a standard against which at least structure and process can be assessed.

Structure

The committee was set up by the Leicestershire Area Health Authority (as it then was) in 1975, and is a standing sub-committee of the District Medical Advisory Committee, to which it reports. All research on humans including studies on healthy volunteers carried out in institutions under the supervision of the health authority must be submitted to it. Failure to do so is regarded as a serious matter by the authority. The University of Leicester has agreed that all research involving experiments on human subjects must be approved by the committee. General practitioners are encouraged to submit their research projects to the committee.

The committee’s 12 members are appointed as follows:

3 lay members by the health authority;
2 by the university to represent its clinical departments;
3 by the Medical Advisory Committee to represent the NHS;
1 by the Medical Advisory Committee in the field of clinical pharmacology;
1 by the Nursing and Midwifery Advisory Committee;
2 by the Local Medical Committee to represent general practice.

The lay members may be, but need not be, members of the health authority. At present they are a clergyman, an academic lawyer, and a non-medical academic scientist. The committee tries to keep a balance of the major specialties and finds it helpful to have expertise in those fields well represented in submissions. There is no constitutional requirement for a female member, but so far the nursing representative has always been a woman.

Members are appointed for four years with the possibility of extensions, each of four years, with the support of the health authority and the sponsoring body. A chairman and vice-chairman are elected by the committee from amongst its members each for a period of two years. At the end of that time the vice-chairman becomes chairman. So far the chairman has always been medically qualified. No quorum has been set except that at least one lay member must be present.

J. B. COOKSON, FRCP, Consultant Physician, Glenfield General Hospital, Leicester
The health authority has agreed to indemnify the non-medical members against any legal liability that might arise out of their membership of the committee.

Process

Researchers are asked to submit a standard application form and a copy of the original protocol. The purpose of the form is twofold: to summarise the research and to draw the attention of the researcher to important ethical points. The form asks for the nature, purpose, originality and scientific justification of the research, for any financial contribution from a commercial body, for details of subjects and controls and their number, selection, and how their consent is to be obtained. Drugs and isotopes, their doses, risks, and benefits, are listed with the investigational status of new drugs. Further questions concern additional investigations such as blood tests, monitoring, radiographs, or questionnaires. Finally the form is signed by the investigator and countersigned by the head of the department involved or, in the case of a junior doctor, by his consultant.

The committee meets monthly, applications being circulated to each member about five days beforehand. Most applications are allotted before the meeting to the individual most qualified to review them, but all applications are seen by all members. At the meeting the chairman introduces each application and the member involved then summarises the research and expresses any reservations. General discussion then takes place. Four outcomes are possible: acceptance, acceptance with minor amendments, rejection, or request for further information before reconsideration. Further information can be sought in writing, by inviting the applicant to appear before the committee, or by discussion outside the committee by a member who reports back at the next meeting. Occasionally the opinion of an outside assessor is sought.

The committee accepts the view of the Royal College of Physicians that ‘badly planned, poorly designed research that causes inconvenience to subjects and may carry risk, without producing useful or valid results, is unethical’ [3]. Nevertheless, the weight to be placed on the scientific aspects of a study, although repeatedly discussed, has not been completely resolved. The other criteria for approval are that the intervention is worthwhile; the information cannot be obtained by simpler means; the risks have been identified as far as practicable and are minimised; the investigator is experienced and in possession of the necessary facilities; and that the subject is fully informed about and consents to the research or that there is sufficient justification to depart from this standard. In practice, the committee member asks himself: ‘Would I let them do this to me (or my wife or child)’?

The letter of approval draws attention to the need to discuss any resource implications with the appropriate managers. The chairman can take ‘chairman’s action’ on non-contentious topics between meetings, but this is subject to scrutiny by the full committee.

Once approved, research projects have not been routinely reviewed but occasionally investigators have been asked to report on their initial results. The minutes (which include the titles of the protocols discussed) are sent to the Medical Advisory Committee and to the health authority, but are not made public. Annual reports have not been made. These policies have recently been reviewed (see below).

Outcome

The number of protocols considered each year has risen from 66 in 1979 to 302 in 1989.

The following is a summary of one year’s work from October, 1988 to September, 1989. A total of 277 new protocols were submitted. Of these 143 were accepted without alteration, 93 were accepted after minor amendments, and 41 were rejected or required further information before a decision could be made. After clarification or amendment, 35 of these were eventually accepted, and six were rejected and not pursued further by the authors.

A number of other issues were also considered during the year; they are summarised in Table 1.

It takes a member about five hours to study the papers each month and a further two to attend the committee. For 12 members the total is 1,008 hours a year, equivalent in cost to more than £20,000. Secretarial assistance has been costed at £6,000.

Comment and proposals for change

The composition and constitution of the committee is in accord with the guidelines of the Royal College of Physicians and the Department of Health. The suggestion that there must be a lay member present for the meeting to be quorate places a particular responsibility on these members. The committee has not produced annual reports but now feels obliged to do so. The suggestion that either the chairman or vice-chairman should be lay has been rejected. A lay chairman would find difficulty in taking ‘chairman’s action’ between meetings and giving informal advice.

Assessment of outcome is as difficult in this field as in any other. How is the correctness of decision-taking to be assessed? Follow-up reports from investigators would highlight clinical problems but for the year surveyed would generate another 277 documents, with a considerable increase in the secretarial workload. It has seemed preferable in the past to concentrate on a few projects of particular concern. Data handling by computer may resolve this problem and the committee may then seek annual reports from investigators. This will provide more information on outcome, and by influencing structure and process will complete the audit cycle.
Two outcomes of the work of ethics committees should be promotion of good ethical research and investigators who are informed of ethical issues. The literature is extensive and is unlikely to be read by many. The application form draws attention to most issues but the committee has issued short statements on investigations on normal subjects and on consent. It still needs to keep informed, without a deluge of paper, the constantly shifting population of researchers, and has now produced a short information sheet (with references) to accompany the form.

What of the criticisms of these committees? [1,2]. Inadequate structure and working practices probably stem from a small workload, one reportedly having only eight applications to consider in a year. Such a committee cannot be criticised for not meeting often! As in medical practice, experience is needed to maintain efficiency. Districts with few researchers might combine their committee with that of a neighbour. National and regional meetings for members would help to reduce discrepancies between decisions.

A national research ethics committee has been proposed [2], and its remit debated [6]. One role would be to encourage uniformity in multi-centre trials, although local approval would still be necessary to ensure that researchers and facilities were adequate. The workload would be considerable, delay probably inevitable, with no guarantee of a better decision. Sometimes only one member of the committee spots a fundamental flaw in a project.

The suggestion that a national committee should monitor local committees is more contentious [2]. The proposal seems to run counter to the principle of audit: that of peer review rather than supervision. A more positive suggestion is that it could act as a resource centre and draw the attention of district committees to important current issues, as does the Bulletin of Medical Ethics. It could have a role as a 'court of appeal' in difficult problems or when there is a conflict of opinion between researcher and committee.

Finally, the work of ethics committees does not just happen; a large amount of time and effort, and some money, are involved. The dedication of lay members is particularly impressive. The directive Working for Patients, with its purchasers and providers, requires activity to be costed and cost-effective. The guidelines of the Department of Health [4] specifically require district health authorities to set up and support these committees appropriately. Provider units may require reimbursement for loss of income before the time spent on these committees appears on the job plans of their consultants. Will anyone purchase my ethics committee?

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Address for correspondence: Dr J. B. Cookson, Glenfield General Hospital, Groby Road, Leicester LE3 9QP.