have to obtain ethics approval before they can seek funding for the project. The location and composition of committees linked to commissioning authorities and of those set up by provider units are constantly changing. There may be additional costs in the future if committees levy a charge for considering applications.

These issues, together with the concerns that, despite guidelines,[2] local committees differ widely in their response to applications,[3] have led to a debate on the role of a national ethics committee in multicentre clinical trials and national surveys.[4,5] We suggest that there may be complementary roles for a central committee and local committees. A national committee could be asked to consider the scientific and methodological aspects of the study before the application is submitted to the funding body. A single copy of the application and the national committee's recommendations could then be sent to local committees, whose unique understanding and knowledge of their populations and local factors could inform their decision whether to review the project protocol further using a standard application form available in electronic form. This arrangement would reduce the time and cost for both local committees and researchers, without jeopardising the interests of research subjects.

Funding: AJ and AM were funded by the Department of Health. CM, TP, and LS were funded by Action Research to test the feasibility of the survey.

Conflict of interest: None.

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(Accepted 29 June 1995)

Cross district comparison of applications to research ethics committees

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BMJ 1995;311:660-1

Meade has criticised the current need to obtain approval for multicentred research from many different ethics committees.[1] Variability between committees has led to research having to be modified or even abandoned in some districts but not others.[2] I report the results of applying to 13 ethics committees within a region for approval of a study of young people.

Subjects, methods, and results

A regional study of the mental health needs of young offenders was proposed in which adolescents aged 13 to 17 were to be identified by health, social, and juvenile justice agencies. They were to be studied by means of a social and psychiatric interview, an educational assessment, an interview with staff, a postal questionnaire from parents, and a study of notes. The regional health authority identified 14 ethics committees. Approval for the study was obtained from one committee in advance. Applications were then sent to the remainder, informing them that this was a cross district study and that one committee had already given approval.

One committee did not respond to the initial inquiry. Two neighbouring committees had reciprocal arrangements for approval from each other. Eleven committees provided application forms, which were all different. One committee provided a form specifically for non-clinical studies. None provided a form on disk. Information requested varied between committees (table). Two forms asked if the study was multicentred, seemingly without this making a difference. One committee's guidelines stated that non-therapeutic research was generally unacceptable in children. One indicated that consent to a study using only interviews or questionnaires might not be required in writing, while another advised that consent for postal questionnaires should be obtained in person.

Two committees lost the original application. Two committees invited the researchers to the committee meeting: in one case four days' notice was given. One committee accepted its neighbour's decision. The table shows the responses of the remaining committee. The median time from application to the committee meeting was 4·0 weeks and from the meeting to a reply 3 days.

Eight committees had a median of three queries. Most of the queries concerned how consent was to be obtained and recorded, although three committees

Characteristics of application forms and responses from 12 committees

Committee	No of pages in application form	Information requested on application form						Time (weeks) from:			No of changes requested
		Aims	Scientific background	Method of consent	Consent of children	Data analysis	Adverse effects	Application to meeting	Meeting to reply	Application to approval	
A	2	Yes	No	No	No	Yes	Yes	2·4	0·4	8·6	1
B	4	No	No	No	No	No	Yes	3·4	0·1	13·0	1
C	0*	NA	NA	NA	NA	NA	NA	5·0	3·0	8·0	0
D	10	Yes	Yes	Yes	No	No	Yes	8·6	0·4	9·0	1
E	5	Yes	Yes	Yes	Yes	Yes	Yes	6·3	0·3	9·6	2
F	5	Yes	Yes	Yes	No	No	Yes†	4·9	0·2	9·1	2
G	5	Yes	Yes	No	No	Yes	Yes‡	4·0	0·9	14	4
H	5	Yes	Yes	Yes	Yes	No	Yes	0·3	1·9	2·2	0
I	9	Yes	No	Yes	Yes	Yes	Yes	3·1	0·1	13	3
J	4	Yes	No	Yes	Yes	No	Yes	4·0	1·7	5·7	0
K	3	No	No	Yes	Yes	Yes	Yes	NA§	NA	8·9	1
L	8	Yes	No	Yes	No	Yes	Yes	3·4	0·2	3·6	0

NA=Not applicable.
*No application form.
†Requested side effects of physical treatments only.
‡Requested side effects of drug treatment only.
§Chairman's action taken: initial reply after 3 weeks.

were concerned about confidentiality. The median number of changes requested by the eight committees was 1·5. One committee gave full approval but later decided the original meeting had been inquorate and requested changes. One committee approved the study subject to the advice that "proper legal consent was obtained" without explanation. The median time from application to final approval was 9·0 weeks.

Comment

Only two out of 13 committees had reciprocal arrangements for the approval of multicentre research, despite the recommendations of the Department of Health.[3] The information requested by each committee on their forms varied widely, and the time needed to complete the different applications was considerable. Ethics committees should be encouraged to accept a national standard application form, available on disk.

Most ethics committees replied quickly after the first committee meeting, but delay was considerable when clarification was required. The ethical issues regarding consent were particularly difficult in this study because of the young people's circumstances; many would have severe family difficulties and be living away from home. Given the diversity of inconsistent and sometimes vague recommendations about consent from professional bodies and the Department of Health, however, the ethics committees are bound to spend considerable time in raising queries, which are also likely to be time consuming for researchers. The training of ethics committee members is important and might produce greater consistency across districts, but it requires adequate funding.

Ethics committees have heavy workloads,[4] and they should be encouraged to accept the approval of an application that has been carefully considered by one committee. Such an initiative has been introduced in the Northern region (B Sutherland, personal communication) and might be considered elsewhere. More widely, my experience adds weight to the case for a national ethics committee for multicentred studies.[5]

Funding: Wellcome Trust.
Conflict of interest: None.

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(Accepted 7 August 1995)

Ethics committees: impediments to research or guardians of ethical standards?

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BMJ 1995;311:661

In 1991 the Department of Health issued a memorandum that required every district health authority to establish a research ethics committee.[1] Before this memorandum considerable diversity in the practice of ethics committees had been noted.[2,3]

Method and results

A research study focusing on the needs of and provision of care to children who might be expected to die during childhood was commissioned by the Department of Health. Parents of such children who were resident in four selected regional health authorities recruited themselves to the study through advertisements in voluntary group newsletters, and providers of statutory and voluntary care in the selected health authorities were interviewed. In this study I identified the correspondent of each of the 43 district ethics committees by telephone and sent him or her a letter. The letter was written with the guidance of an ethicist and sought advice about whether the research study required formal ethical approval, given that no children were to be interviewed and all the usual ethical safeguards would be adhered to. Letters were posted in two batches during May 1993.

The replies varied considerably. Twenty one committees required no approval to be sought and 18 required formal applications to be made; four of the committees did not reply. When these four committees were excluded, the number of days until I received a reply ranged from six to 161 days, with a mean of 60·1 days (table). The cost of the approval process in terms of paper and photocopying ranged from the cost of one letter to that of 2151 sheets of paper. The requirements of the ethics committees also differed about who was eligible to sign the application—that is, whether a doctor of consultant status working within the health authority was required to sign the application.

Comment

Although some diversity of practice between different ethics committees is inevitable, my study showed a worrying degree of variation. Substantial inconsistencies in the practice of ethics committees in the United States (institutional review boards) have also been found,[4] and Oakley noted how the social support and pregnancy outcome study "benefited from the irregular means deployed to pass our proposal through the ethics committee barrier."[5]

Unless the practice of ethics committees is improved and made more uniform, large multicentred studies will not be possible and research budgets will be dissipated in photocopying costs and unpredictable waiting times. My results suggest that the establishment of a national ethics committee for multicentred studies needs urgent consideration.

Responsibility for the views expressed, issues of interpretation, and questions of inclusion and omission are mine and do not necessarily reflect the views of the Department of Health.

Funding: Department of Health.
Conflict of interest: None.

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(Accepted 2 June 1995)