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Attitudes to research ethical committees

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Authors' abstract

A questionnaire on the attitudes towards the functions of research ethical committees was sent to members of selected research ethical committees in Wessex and some controls. Almost all respondents felt there was a need for ethical review of research projects; 42 per cent thought there was a need for some training before joining a committee; 67 per cent thought the system could be improved and 47 per cent thought that monitoring or follow-up procedures should be adopted. Ethical committees were thought to be purely advisory, as opposed to mandatory, by 33 per cent, and 63 per cent thought they should restrict their review to ethical problems as opposed to scientific or design problems. Views about the function of non-medical members ranged from 'none at all' to 'very important'. Of the 10 controls who were asked whether they would become a member of an ethical committee if asked, seven said that on balance they would and the reasons stated varied from the view that it was a 'very important committee' to the feeling that it was 'a necessary but irksome job'.

Introduction

The few articles about research ethical committees which have appeared in British journals in recent years have concentrated on the structure of the committees together with their methodology and workload (1,2,3). The views of individual members of such committees, and other members of the medical profession, about the review process have not hitherto been studied. It was decided to incorporate into a recent study of the development of the Southampton ethical committee (4), a survey of the attitudes towards the ethical review process of members of some of the ethical committees in Wessex, and of a number of medical staff who had never been members of an ethical committee.

Method

In 1981 a questionnaire, and stamped addressed envelope, were sent to all present and retired members of the Southampton ethical committee. The questionnaire was also sent to an equal number of doctors who were employed in the Southampton and South West Hampshire Health District, but who had never been members of an ethical committee. These controls were matched for year of qualification, and specialty, with the members of the Southampton committee. The questionnaire was also sent to the members of four ethical committees, chosen at random, from the other nine health districts within the Wessex Regional Health Authority. The questionnaire contained questions about general attitudes towards ethical committees and their functions. Most of the questions required a Yes/No answer and were followed by space for a brief explanation. Another copy of the questionnaire and another stamped addressed envelope were sent, with a reminder, to all non-respondents after a period of four weeks.

Key words

Research ethics committees; attitudes; medical research; medical ethics.

Survey findings

Of the 58 people who were invited to complete the questionnaire only two actively declined to take part: one was a control and the other, previously a member of the Southampton ethical committee, declined to take part in our study as he felt that ethical judgment should be a matter of individual concern rather than a committee problem. The respondents were divided into four groups and the percentage of replies received was: 100 per cent of the non-medical members; 89 per cent of Southampton committee medical members; 67 per cent of other Wessex ethical committee medical members and 56 per cent of Southampton medical controls. Table 1 (overleaf) lists the first seven questions and the percentage of respondents in each group who answered 'yes'.

The comments contained in Question 3 regarding possible improvements fell into three main categories.

1) Nine people felt both members and researchers should have more familiarity with the committee terms of reference, methodology and recurring ethical problems.
2) Five people felt that committee membership was too narrow and that more contact with other committees to discuss particular problems would be desirable, as

Table 1: The percentage of respondents who answered 'yes' to questions 1–7 of a survey of attitudes towards research ethical committees

Questions	Southampton Committee (medical)	Southampton Controls (medical)	Other Wessex Committees (medical)	All Non-Medical members	Mean %
	16 replies = 100%	10 = 100%	10 = 100%	7 = 100%	43 = 100%
1. Do you think that, in general, medical research projects need reviewing by an ethical committee?	100	90	100	100	97.7
2. Do you think there is any need for 'training' before becoming a member of an ethical committee?	50	50	20	43	41.9
3. Do you think that the overall system for considering/reviewing research projects could be improved?	67	60	80	57	67.4
4. Do you think a system of monitoring research in progress should be adopted?	44	40	30	86	46.5
5. How do you see the role of the ethical committee					
Purely advisory?	38	40	30	14	32.6
Mandatory?	63	60	70	86	67.4
6. Do you think that the ethical committee should restrict its review to:					
Ethical consideration?	50	70	80	57	62.8
Scientific or design problems as well as ethical problems?	50	30	20	43	37.2
7. Are there any elements of research design which you think need more ethical attention than any others?	38	60	80	43	53.5

would greater access to expert medical and non-medical opinion.
3) Three people suggested a more effective system of monitoring or follow-up.

Although 67 per cent of the respondents felt that the system of reviewing projects could be improved (Table 1, Question 3), only 47 per cent felt this should include a system of monitoring research in progress (Table 1, Question 4). However, on this point the medical and non-medical respondents differed most markedly. Only 38 per cent of the medical respondents were in favour of monitoring compared to 86 per cent of the non-medical members. It is not clear whether this lack of enthusiasm for monitoring relates to a feeling that the logistical problems of undertaking this would render it of little use or whether the medical members feel that researchers, having once had a project approved, should be allowed to proceed without further interference.

The majority of respondents in all groups thought the decisions of an ethical committee should be viewed as mandatory (Table 1, Question 5). However, 33 per cent of the respondents, who are presumably familiar with the guidelines published by the various medical organisations as well as their own committee's terms of reference, feel that decisions are purely advisory. This finding suggests that an attempt should be made to determine the status of ethical committees' decisions as being either advisory or mandatory and the situation made clear to all concerned. A much smaller proportion of the non-medical respondents felt that the decisions should be advisory.

Although the members of the Southampton committee were equally divided over the question of whether the review should be restricted to ethical con-

siderations, or whether it should also include scientific or design problems (Table 1, Question 6), five members noted that they felt the two problems were not mutually exclusive as an 'unscientific' project must *per se* be unethical.

A total of 23 respondents felt that there were some special elements of research design which needed more attention (Table 1, Question 7). The comments were fairly wide-ranging but fell mostly into two broad categories:

1) Fourteen respondents mentioned basic scientific design problems. Risks to patients in certain types of trials, such as trials of new drugs and placebo trials, were specifically mentioned.
2) Legal problems were mentioned by nine people. These included the problems of explanation to be given to enable 'informed consent' to be obtained, especially with regard to projects involving minors and persons suffering from mental illness.

Participants were asked to construct an 'ideal committee' to contain any number of persons in the categories suggested, providing the total membership did not exceed 10 persons (Table 2, Question 8). This was not always done. Some indicated categories without giving numbers, and some stated that they felt that 10 was too large a committee and consequently did not fill in a total of 10. Some indicated that they felt a set number of members made up from any of certain categories would be acceptable. The totals shown in Table 3 therefore do not always add up to the maximum possible.

Table 2: Questions which required an open answer

8. Who, of the following categories, do you think should serve on a committee? Please state the numbers to give a total of 10 persons.
(See Table 3.)
9. What function do you think non-medical members have on an ethical committee?

10a. What were your reasons for agreeing to serve on an ethical committee? (To be answered only by committee members.)
10b. If asked, would you agree to become a member of an ethical committee? State reasons. (To be answered only by controls.)

Table 3: Question 8: Who, of the following categories, do you think should serve on a committee? Please state the numbers to give a total of 10 persons

	Medically Qualified			All Non-Medical Members
	Southampton Committee	Southampton Controls	Other Wessex Committees	
Number of questionnaires sent	18	18	15	7
Number received	16	10	10	7
Possible total number of members*	160	100	100	70
Medical staff with an interest in research	50 (31%)	24 (24%)	23 (23%)	23 (33%)
Medical staff with *no* specific interest in research	27 (17%)	14 (14%)	24 (24%)	13 (19%)
Basic scientist	8 (5%)	7 (7%)	2 (2%)	3 (4%)
Nursing representative	10 (6%)	5 (5%)	7 (7%)	6 (9%)
Lawyer	7 (4%)	11 (11%)	3 (3%)	4 (6%)
Clergy	9 (6%)	5 (5%)	2 (2%)	1 (1%)
Social worker	5 (3%)	2 (2%)	2 (2%)	1 (1%)
Community health council representative	12 (8%)	5 (5%)	5 (5%)	4 (6%)
Patient representative	8 (5%)	—	7 (7%)	1 (1%)
Other	6 (4%)	5 (5%)	9 (9%)	4 (6%)

**If each respondent had given 10 committee members as requested: this was not always done.*

The general attitude of the non-medical respondents to their function on an ethical committee (Table 2, Question 9), was that of 'representing the general public interest' with 'a broader view' thereby 'checking the natural enthusiasm of doctors' and 'ensuring that "medicalese" did not cloud the ethical issues in question'. The attitude of the medical respondents varied from a view that lay-members 'had no function', or were 'merely a window-dressing exercise', to 'show that the profession is not frightened of letting the public know what is going on' to the view that they could provide 'a balancing, often dispassionate view' and ensure that 'there is proper control of research' as well as 'providing expertise in areas outside medicine such as law, sociology and religion'.

When asked for reasons for agreeing to serve on an ethical committee (Table 2, Question 10a), it was pointed out that membership in some cases was automatic as part of another commitment such as chairmanship of another hospital committee or being a chosen representative of an outside body, such as a health authority or community health council. Other members had been invited to join ethical committees and indicated that they became members, 'because I was asked to!' One respondent said that the committee was 'necessary to protect the public' whereas one said that it was 'necessary to protect good research'.

The controls were asked if they would agree to join an ethical committee (Table 2, Question 10b). Seven of the 10 controls who completed the questionnaire said that on balance they would probably agree to join. Reasons varied from the feeling that it was a 'necessary but irksome' job 'that had to be done by someone' to the view that it was 'a very important committee'. Only one person stated that he would 'definitely refuse'.

Discussion

The basic question of whether or not there is a need for ethical committees still provokes widely differing responses from the medical profession. The fact that 42 per cent of the respondents felt there was a need for some 'training' before becoming a member of an ethical committee indicates some lack of confidence in the subject of medical ethics, which is often felt to be a matter of individual conscience rather than a subject for open discussion. Such a situation can produce views which are very far apart. On the one hand, ethical committees can be viewed cynically as purely window-dressing exercises serving little or no useful function while providing a great deal of extra work and irritation for all concerned. Research workers sometimes feel their work is so specialised that a broad-based committee cannot appreciate the finer details of their projects and only serves to hinder the progress of medical research. On the other hand, ethical committees can be viewed as very important committees serving to aid research workers, particularly the less experienced, in designing a worthwhile and ethical project for the benefit of both research workers and general population.

The replies to Question 3 regarding improvements to the review system indicate that most respondents felt the system could be improved although less than half advocated a system of monitoring research in progress. It is interesting to note that a greater proportion of the non-medical respondents were in favour of monitoring than the medical respondents, who perhaps more readily foresaw the problems connected with monitoring.

Although the terms of reference of the Southampton committee state that the role of the committee is advisory, over half of the Southampton respondents felt their decisions should be treated as mandatory. If some of the research community regard the decisions of the committees as purely advisory that would probably answer the question: 'Why are some projects not submitted?'. After all, why go to all the bother of submitting a protocol when you don't have to take any notice of the decision?

There was little difference in the various categories of people suggested to form an ethical committee. Lawyers and clergymen had slightly more support from the Southampton committee and controls, whereas medical staff with no specific interest in research had more support from the other Wessex committees. Both of these slight differences could be explained by the relative availability of each category in either catchment area, as well as by respondents drawing on their knowledge of past membership. Most respondents seem to feel that membership of an ethical committee would be interesting although few are very enthusiastic. The ethical committees are still a relatively unknown quantity and it appears that in the 15 years or so since ethical review of research projects has been widely undertaken in Britain, little has been done to allow any problems to be brought into the open for discussion either by the medical profession as a whole, or by the general public, with the result that sometimes even research workers are unaware of the requirements of the ethical committee within their own health districts. Committees have been allowed to develop *in vacuo* so that it is perhaps only the actual members of an ethical committee who know how to submit a project for consideration with the minimum amount of delay and irritation. Such a lack of information about the system is evidenced by the fact that although the Royal College of Physicians has had occasional meetings of some ethical committee chairmen, these seem to have involved relatively few committees at infrequent intervals. Certainly there is no record of the Southampton committee, which is one of the most active in England, ever having been invited. The reaction to this study has shown that the members of this committee would appreciate more contact with other ethical committees to discuss frequently encountered problems. It is likely that the members of smaller, more remote, committees would also benefit from such contact.

If it is accepted that ethical committees are here to stay, then it would be in everyone's interest to publicise their procedures and requirements to the profession to

a much greater extent than is done at the moment. Whilst it is obviously not desirable to have a rigid set of rules for designing 'the standard ethical research project', wider publicity of persistent problems could provide a much greater appreciation of the problems of designing research projects which would not only further medical knowledge but be considered ethical. It is all too easy to sit on the fence and not see the problems on either side. A more detailed set of guidelines, available to anyone intending to undertake a research project, indicating problem areas consistently encountered by ethical committees, relating both to ethical problems and method of submission, could help the researcher to design an 'ethically acceptable' project. This would save time and irritation for both committee members and researchers.

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