
The views of members of Local Research Ethics Committees, researchers and members of the public towards the roles and functions of LRECs

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Abstract

Background—*It can be argued that the ethical conduct of research involves achieving a balance between the rights and needs of three parties – potential research participants, society, and researchers. Local Research Ethics Committees (LRECs) have a number of roles and functions in the research enterprise, but there have been some indications that LREC members, researchers and the public can have different views about these responsibilities. Any such differences are potential sources of disagreement and misunderstanding.*

Objectives—*To compare the views of LREC members, researchers and the public towards the roles and functions of LRECs.*

Design—*A questionnaire that contained items concerned with a variety of such roles was distributed to general practice patients (as proxies for potential research participants), researchers and LREC members.*

Findings—*While general practice patients believed that the main function of LRECs is to ensure that research participants come to no harm, LREC members were more concerned with the protection of participants' rights. There was also some disagreement between members and researchers with regard to the consideration of proposals on the grounds of scientific merit.*

Conclusions—*Local Research Ethics Committee members need to be aware of potential differences in views, that they ought to make their priorities clear, and that membership of LRECs ought to reflect the views of both researchers and potential research participants.*

In recent years there has been an increasing emphasis on the roles, functions and responsibilities of Local Research Ethics Committees (LRECs). First, and perhaps foremost, there are the rights of research participants to consider. Local Research Ethics Committee members are expected to review the appropriateness of information sheets (so that potential participants are able to

acquire and understand the information needed to make a valid decision to enter into the study) and to ensure that facilities and insurance arrangements are adequate to cope with any untoward consequences for participants. Second, LRECs have obligations towards society at large, since it both provides resources for the conduct of research and can be affected by its findings. The damage done as a result of the Bristol Cancer Centre study provides a reminder of the emotional distress which can be caused by poor design/misinterpretation of findings.¹ Third, LRECs have obligations to researchers. They, too, have legitimate rights in the enterprise. Researchers have responsibilities towards potential research participants and society but they also have the right to have their proposals treated with respect and due consideration.

While there is broad consensus on these responsibilities in theory, in practice the picture is less clear. It has been argued that the achievement of valid consent in research, at least as defined by bioethicists,² is a myth³ because many research concepts (such as randomisation) are complicated and because there are many barriers to understanding messages such as potential risk.⁴ Also, it is difficult for LRECs to guard against all the ways in which society's interests could be compromised. Data can be interpreted and applied in a wide variety of ways and LRECs do not have the resources to audit the extent to which researchers follow their advice. Nor can they guard against misconduct.

As to the interests of researchers, Gilbert *et al*⁵ and Harries *et al*⁶ have pointed out that there is considerable variation between decisions made by different committees, resulting in much disquiet within the research community.^{7–9} Foster¹⁰ argues that this may be due to different committees holding different values, with one committee perhaps valuing the consequences of research, another the rights of potential participants. Partly as a result of such difficulties, LREC members are encouraged to attend training sessions and recently the Department of Health has issued training guidelines.¹¹

There are, however, several fundamental issues

Key words

Ethical review; attitudes.

which no amount of training in ethical analysis will resolve. For one, there is no universally accepted definition of what constitutes "good science". Although some argue that randomised controlled trials (RCTs) provide the only sound method, many disagree: not all legitimate and significant research questions can be answered in this fashion and RCTs only rarely address the meaning of interventions for participants.¹²

Another difficult issue involves conflicts of interest between the parties involved in the research enterprise. A study which could have benefits for society may expose the individual participant to risk without potential benefit to him or her. There can also be conflicts of interest in clinical research between the researcher as health professional and the researcher as clinician.¹³ Researchers working in universities, for example, have a variety of obligations – to their institutions and to themselves as well as to participants and to science. Insofar as conflicts occur, there are temptations to "massage" or concoct data in order to achieve publication¹⁴ and to recruit patients into studies when this might not be in their best interests.¹⁵ Observational studies of researcher/clinicians talking to their patients, for example, demonstrate that doctors can be caught between the "voice of research" and the "voice of caring".¹⁶

It has been argued that a crucial role of LRECs is to mediate between these sometimes conflicting interests, ensuring that the rights of participants are not overridden by those of researchers, the scientific enterprise or the needs of the community at large.¹³ However, there is little systematic research on this topic. There is some literature in other areas of medical care where the views and beliefs of health care professionals have been compared with those of patients. One area concerns proxy decision-making. Research on this topic has indicated that professionals can make assumptions about patients' welfare which do not correspond to patients' actual feelings and beliefs.^{17 18} Another area concerns patients' rights to confidentiality, where patients expect much higher levels of confidentiality and privacy than that afforded by clinicians.^{19 20} It is likely that such differences in viewpoint are the results of training, experience and vested interests.

Misunderstandings

Similarly, it could be expected that the different parties involved in the ethical review of research will have different views of the roles and functions of LRECs. If so, then the process of ethical review could be disrupted, antagonism and misunderstandings between parties could arise and a central responsibility of LRECs – to safeguard as far as possible the interests of participants – might be compromised.²¹

There is a small body of research comparing the

views of different parties in the ethical review process. Schrier and Stadler²² asked potential research participants, researchers and members of Institutional Reviews Boards (IRBs – the American equivalent of LRECs) to comment on a hypothetical research proposal in psychology. The researchers gave similar views to the potential participants when risks were considered, but their views were more similar to the IRB-member view when the design of the study was considered. Smith²³ surveyed the perceptions of lay members of LRECs in the West Midlands, but the sample was small ($n=17$) and the study did not compare views of the various groups. The Medical Research Council of Canada²⁴ contends that participants have little concern for the methodological soundness of studies but are vitally concerned with issues of psychological or physical harm, economic loss or inconvenience, but presents no data to support this claim.

The aims of this study were to examine: (a) the relative emphases placed by LREC members, members of the public and researchers on areas of responsibility vested in LRECs and, (b) the differences between the groups in their views of these areas of responsibility.

Methods

PARTICIPANTS

Three groups were asked to complete a questionnaire (see appendix 1). Doctors employed in a general practice representative of socio-economic backgrounds in the Sheffield area agreed to have the questionnaire distributed in their practice. Fifty patients were recruited by the receptionists as they checked in for their appointments. One hundred lead investigators who had submitted consecutive proposals to two LRECs in 1995 were identified from the records of the respective offices. The chairs of six LRECs in the region were requested to distribute questionnaires to the 70 members of their committees.

MATERIALS AND PROCEDURES

The items on the questionnaire are shown in appendix 1. The items were designed to reflect the balance between the three kinds of issues outlined above; that is, the furtherance of science for the benefit of society, the protection of research participants, and the furtherance of researchers' interests. Participants were asked to indicate their levels of agreement with each item on 6-point Likert scales, ranging from 1 ("strongly agree") to 6 ("strongly disagree"). (The 6-point scale is shown only after the first item in the appendix, although it was included after all items in the actual questionnaire.) The covering letter indicated the purpose of the study, how the participants were selected and an assurance that anonymity would be maintained.

The questionnaires were returned in two ways. For the general practice patients, the questionnaire

Table 1 Mean scores for the three groups for the three factors. Low scores indicate strong agreement

Group	Factor 1 Beneficence	Factor 2 Scientific methods	Factor 3 Avoid harm	Factor 4 Autonomy
Researchers	3.14	3.19	2.86	1.59
LREC members	3.28	2.40	1.93	1.34
Participants	1.87	1.90	1.23	1.62

was returned to the receptionist. For the researchers and LREC members an envelope was provided for the return of the questionnaire, either through the university's internal post or via a freepost address. Approval for the study was given by the two LRECs involved.

Results

SAMPLE CHARACTERISTICS

Of the 50 questionnaires distributed to the general practice patients, 46 were returned to the receptionists fully completed. Of the 100 questionnaires distributed to researchers, 77 were returned (77% response rate) while 58 of the LREC members (80%) responded to the survey. The researchers tended to be younger than the other groups (mean ages=38.4, 48.5 and 43.5 years for researchers, members and patients respectively) and the researchers and members of LRECs were predominately male while most general practice patients were female (76%, 69% and 29% males respectively).

Factor analysis

In order to make statistical comparisons more manageable, a factor analysis of the data was performed. This technique allows for the grouping of items together, depending on the pattern of responses. Items which correlate together are combined and then considered as a single score. The factor analysis indicated that the participants' responses fell into four categories. Factor 1 consisted of items 5 and 9 as shown in the appendix, and could be described as those relating to the ethical principle of beneficence. Factor 2 (items 1, 3) were those associated with the scientific enterprise, factor 3 (items 4, 6) with the avoidance of harm (non-maleficence) while factor 4 (items 2, 7, 8) comprised items related to the protection of the individual participants (autonomy).

Mean scores were computed for each factor, as shown in table 1, with lower scores indicating higher levels of agreement. Inspection of table 1 suggests several patterns in response. In the description of results which follows, conclusions have been supported by statistical comparisons using non-parametric tests, available on request from the author. First, as shown by comparing the rows of the table, there were differences between groups in their levels of agreement with the statements. Patients tended to show greater agreement with the items than the other groups, indicating that they believed LRECs ought to fulfil the functions to a greater extent than the others.

Second, as shown by making comparisons along columns, there were differences between groups. When the results for the beneficence factor were analysed, patients reported greater agreement than both researchers and members, who were similar in response to each other. For avoiding harm, the same pattern was observed. However, when asked about the role of LRECs in maintaining scientific standards, a slightly different pattern was found: patients showed the greatest agreement, followed by members, followed by researchers. Members of LRECs were more likely than researchers to agree that LRECs ought to advise researchers on how to improve their scientific methods and ensure that a study was scientifically sound.

The results for the fourth factor on protecting participant rights (autonomy) were also different. Local Research Ethics Committee members placed the greatest emphasis on this role, followed by patients and researchers. While this aspect of ethical approval was important for all groups, it was the most significant for members.

Discussion

These findings throw some light on the issues which have been raised in previous discussions on the roles and functions of LRECs. There are both similarities and differences in how LREC members, researchers and potential research participants, the latter being represented here by general practice patients, view the functions of LRECs. The factor analysis of the questionnaire responses indicated that the items fell into four categories, which included the three ethical principles of beneficence (in this case the conduct of research for the good of society), autonomy (the maintenance of participants' rights) and non-maleficence (the avoidance of harm to participants and to the members of society more generally). It should be noted, however, that if additional items were included in the questionnaire other dimensions and principles would have been identified (for example, there was no mention of issues connected with confidentiality or the fraudulent concoction of data).

The groups tended to agree that all of the roles and functions cited were significant functions of LRECs. The mean scores shown in table 1 indicate that on average there was "agreement" or "strong agreement" with most of these responsibilities, particularly by patients and particularly with the protection of participants' rights. However, the perceived significance of these responsibilities varied according

to grouping. For two of the factors (beneficence and non-maleficence), researchers and members tended to agree with one another, with similar views about the importance of facilitating research for the good of society and avoiding the unethical use of results. On the other hand, researchers and LREC members disagreed when the other two factors were considered. Local Research Ethics Committee members were more likely to agree that LRECs ought to monitor and comment upon the quality of research than researchers. This result is consistent with the evidence that some proposals are not approved on scientific grounds, resulting in researchers' vexation.⁷⁻⁹ This is an important issue since, as mentioned above, there is legitimate disagreement as to what constitutes good scientific method, particularly in the social sciences.

This is not to say that one set of views is necessarily more correct than others, only that these differences can be a source of misunderstanding or conflict. The existence of such differing views reinforces the need for representation on LRECs of both researchers and lay personnel.

The results also reinforce the notion that LRECs ought to make their priorities clear to potential research participants. While patients placed most emphasis on the avoidance of harm, LREC members were most concerned with preserving participants' autonomy. Although the difference between members' and patients' was small in absolute terms, it may signal a significant issue. Currently there are no guidelines concerning the insertion of notice of LREC approval on information sheets. On the one hand, potential research participants have the right to know that a study has been granted LREC approval. On the other hand, such information is helpful and appropriate only if patients understand the process and its implications. It is possible, based on these findings, that patients sometimes expect that notice of approval implies that no harm will come to them as a result of volunteering for a study. This is not necessarily how members of LRECs view the meaning of approval. Insofar as notice of approval could be misleading, it ought to be accompanied by a description of what it does and does not imply. There is clear scope for further empirical work on this issue in order to ascertain how this might be best accomplished.

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Appendix 1 Questionnaire

Local Research Ethics Committees have several responsibilities when they examine research proposals. Listed below are some of these. Please read each one, and then circle a number between 1 and 6, depending on how much you agree or disagree with each statement. **There are no right or wrong answers – only what you believe.**

- 1 Strongly agree
2 Agree
3 Not certain, but probably agree

- 4 Not certain, but probably disagree
5 Disagree
6 Strongly disagree

Research Ethics Committees ought to:

- 1 Ensure that a proposed research study is scientifically sound
1 2 3 4 5 6
2 Ensure that people understand the implications of taking part in the study
3 Advise researchers on how to improve their scientific methods
4 Ensure that no harm will come to people who agree to take part in a research project
5 Protect and promote the interests of researchers
6 Ensure that the results of the study are not used in unethical ways
7 Protect patients from any kind of coercion or manipulation
8 Give guidance about ethics for researchers
9 Facilitate research for the good of society
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