Are ethical committees reliable?

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SUMMARY

This paper aims to assess the reliability of Local Research Ethical Committees (LREC), using a genuine research proposal which was sent to six LRECs. The main outcome criteria were modifications demanded by committees and the degree of agreement between them. All but one of the committees demanded some change in the proposal. None of the committees asked for the same changes. Our conclusion is that LRECs are highly variable.

INTRODUCTION

Whilst it is the responsibility of Local Research Ethical Committees (LREC) to ensure patients are not subjected to dangerous new procedures or drugs, and to protect them from exploitation, they would not wish to impede safe clinical research.

There has been much discussion[1-3], examining alternative ways in which LRECs could be standardized including the setting up of a National Ethical Committee or a National Association of Ethical Committees[4]. Guidelines for LRECs were produced by the Royal College of Physicians in 1990[5] and the Department of Health (DoH) in August 1991[6]. These were criticized for not being sufficiently comprehensive. The aim of the DoH guidelines was to introduce a degree of reliability into the operation of LRECs. We report a small study suggesting this has yet to be achieved.

METHOD

The research took place in the context of a longitudinal study examining the effects of various viral infections on psychological well-being. Subjects had all been admitted to hospital with either viral meningitis (cases) or other viral infections (controls). The purpose of the study was to compare the risk of psychiatric morbidity and fatigue between the two groups. As viral meningitis is fairly uncommon and the numbers of subjects required was large, subjects were identified from several reference virology laboratories and clinics, covering hospitals in six health authorities. In accordance with the DoH guidelines[6,7] it was necessary to gain ethical committee approval from each health authority.

Each of the LRECs had its own form to complete regarding the research. The questions asked were broadly similar, but the format was different. There was no difference in the information we gave to each LREC. All were informed that subjects would be sent a questionnaire consisting of standardized measures of psychiatric morbidity which had been used in other epidemiological research. The main assessment was the General Health Questionnaire (GHQ-12). In addition, part of the questionnaire asked for sociodemographic details. Each LREC was sent a copy of the questionnaire and the accompanying patient information leaflet. They were told that the consultants responsible for the patient would be asked for their permission and that the general practitioner (GP) would be informed. The design called for a proportion of the subjects (around 20%) to be interviewed in order to validate the results of the questionnaire. Finally, all were informed that the proposed study had sufficient power to detect a clinically meaningful difference.

RESULTS

Replies were received from committees after a mean duration of 47 days (range 15–125). Only one of the LRECs (Committee 1) passed the project without comment. Each of the remaining five committees made comments regarding the research and demanded changes in methodology, but in no two cases were the same changes demanded. Committee 2 demanded that the GPs give permission before the subjects were contacted. Committee 3 commented on the patient information sheet and asked for minor alterations in the wording. Committee 4 demanded assurance that the questionnaire would not cause distress to the subjects. Committee 5 felt that the questionnaire was likely to engender such fear in the cases that they would suffer an increase in psychological morbidity and suggested that the questionnaire be completed in the presence of the GP. The sixth committee felt that patient confidentiality would

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be broken if any information about the patient was given, and demanded that the patients should give their consent prior to being contacted by the researcher. It is noteworthy that the committees which were most accepting of the research (numbers 1–3) were based at teaching hospitals.

Since the receipt of these comments the research has progressed according to protocol wherever possible. Cases who came from the catchment areas of committees 5 and 6 had to be excluded from the research.

DISCUSSION

This study raises several issues. The research which the committees were asked to comment on was being done on limited time and resources. The process of completing six different forms was time consuming. This would have been avoided if all committees used the same standardized form. Only one committee provided the form on a computer diskette compatible for a word processing package which expedited its completion.

Our results suggest that the judgements made by the six LRECs were inconsistent. Moreover the changes demanded were not trivial. There are at present over 100 LRECs in England and Wales. There is a clear need for all committees to use the same checklist to assess proposals.

We note the current confusion about consent and questionnaires: the act of completing a questionnaire usually implies consent when accompanied by an appropriate explanatory leaflet[5], yet one committee insisted on a separate informed consent signature. If this procedure were followed, research based on postal samples would be impossible.

A further area of confusion highlighted here is the issue of confidentiality regarding researchers gaining access to medical case-notes without the consent of the individuals involved. Here the DoH guidelines are particularly vague: LRECs must be satisfied that the project is of sufficient value to outweigh the need to obtain consent. No guidance is provided as to how such a judgement can be made.

Finally, does one research proposal need to be submitted to several different committees? For epidemiological research in which no treatment or interventions are to be carried out could not a single regional or even national committee give appropriate ethical approval? Quite apart from the inconvenience the current system causes to researchers a more important consideration is that different committees introducing different restriction criteria may also substantially affect the results of multi-centre research. In our research the differing procedures demanded by the committees could lead to differing response rates and thus to bias. This problem is hinted at by Gilbert Foster[4]:

> A protocol which went to fifty committees, each of which had a different method and set of ethical criteria, would be so modified, after fifty examinations that it would be unrecognisable from its original.

Can we learn from other countries? New Zealand appears to suffer from similar difficulties as highlighted here[8] with many local committees acting independently. In Europe, France, Germany, Switzerland and Denmark all have central committees involved in medical ethics. However it is only in Denmark that a specific committee for medical research ethics exists and is integrated into the workings of regional committees. In the other countries the central committees take an advisory role and have a wider involvement with clinical ethics in general[4].

In England and Wales the issue of multi-centre research is currently being examined by the DoH following the submission of a report in May 1992[9]. This document starts from the viewpoint that the present system of LRECs is both ineffective and inefficient, a finding which is supported by our research. The working party addressed several possible solutions. A National Ethical Committee was ruled out as unwieldy. The notion that one LREC could pass a protocol on the behalf of others was also ruled out because the individual committees, when canvassed, were fiercely independent. Hence a three tiered system is proposed comprising a Central Committee, Regional Committees and LRECs. The role of the Central Committee was seen as advisory and would be composed specifically of experts. The regional committees would consist of representatives of up to 12 LRECs and would aim to coordinate the workings of the 12 LRECs within their catchment area. If a protocol were accepted unanimously by a regional committee each LREC in the region would go on to accept it or reject it as in the present system. The emphasis of the report is largely on multi-centre drug trials and it is regarding these that the views of the LRECs were canvassed. This is unfortunate because whilst it is understandable that LRECs would want the power of veto over invasive research involving the administration of drugs to live patients, there seem to be less need for individual LRECs to consider non-invasive projects such as the subject of this paper, provided it is approved by the Central and Regional committees. We would therefore propose that the third tier of the process (the LREC) is by-passed for non-invasive research. Despite the apparently cumbersome nature of the proposed system the author of the report claims that a protocol could be passed within 2 months. It has yet to be decided whether these proposals will be passed and whether they will be properly funded.

When referring to the general public's attitude to research Dame Mary Warnock[2] commented 'The voice of an almost Mediaeval obscurantism is increasingly to be

heard'. Ethical Committees are expected to reflect the views of the general public. Under the present system they would appear to be at their most effective in fulfilling this role.

CONCLUSIONS AND RECOMMENDATIONS

(1) All LRECs should have the same protocol and this should be available on a computer diskette compatible with several word-processing packages.

(2) Clear guidelines should be available concerning the use of medical case-notes without a patient's consent for epidemiological research and ethical committees should abide by such guidelines.

(3) In order to establish some degree of standardisation between committees individual committee members should be trained and made aware of the guidelines already in existence.

(4) If a three layered system of ethical committees is to be introduced as suggested in the recent DoH consultation document[9], a distinction should be drawn between invasive and non-invasive multi-centre research as mentioned in the discussion section.

(5) The changes proposed to the DoH will need appropriate funding. If this is not forthcoming the system will be intolerably slow and more unwieldy than the present one.

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