

Local research ethics committees

Widely differing responses to a national survey protocol

ABSTRACT—The diversity in responses of local research ethics committees (LRECs) is illustrated with reference to consideration of the protocols for a national survey of physical activity, fitness and health in healthy volunteers. The survey included a questionnaire administered in the home, followed by a physical appraisal carried out in a mobile laboratory. The study was eventually approved by the 30 local committees to which it was submitted, but there was marked variation in the type of enquiries received and the special arrangements requested. At one extreme, some committees approved the study before seeing the detailed ethical submission; at the other extreme, suggested expensive and time-consuming alterations to the standard procedures. Our experience reveals a lack of uniformity in the operation of LRECs, serious enough to delay and even inhibit useful research, and a failure of some committees to adhere to guidelines suggested by the Royal College of Physicians and the Department of Health.

A recent survey of a sample of local research ethics committees (LRECs) highlighted the diversity in their membership and demands [1]. The diversity in responses of local committees is also illustrated in cases where multicentre trials receive approval from some but not all the committees to which they make submissions [2,3]. This variation is likely to be in part the result of lack of guidance on functions and procedures when the committees were first established. Although recently a profusion of guidelines has been issued to committees, there is no way of monitoring how far this guidance has been implemented [4].

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This article reviews the experience of a national survey of physical activity, fitness and health during the process of consultation with 30 LRECs. It should be noted that submission to the committees was made prior to the release of the Department of Health draft guidelines for LRECs [5]. Although the study was eventually approved by all committees, the variety of response is illustrated by the special arrangements requested by some committees and the different issues raised. In some cases, these arrangements led to significant expenses for the survey, which would have prevented the study from going ahead had they been requested in all areas.

Description of the survey and submission

The national survey of physical activity, fitness and health was a two-phase survey carried out in 30 parliamentary constituencies across England. A random sample of 200 addresses was taken from the electoral register in each of the selected constituencies, and a letter introducing the survey was sent to each address prior to a personal visit from an interviewer.

The first phase of the survey consisted of a structured interview carried out in the respondent's home. The questions concerned levels of physical activity, both past and present, as well as general health, lifestyle, attitudes to health and physical activity, and demographic information.

After the interview, respondents were asked if they would be willing to take part in the second phase of the survey, a physical appraisal. The appraisal of those respondents who agreed to take part was carried out in a mobile laboratory located in the grounds of a nearby hospital, with a telephone connected to the hospital switchboard and, if needed, medical cover by the hospital emergency resuscitation team.

A series of tests was carried out, involving anthropometric measures, shoulder flexibility, lung function, hand-grip and quadriceps strength, lower limb power, and blood pressure. There was also a cardio-respiratory exercise test which involved walking on a motorised treadmill, with the workload increased at one-minute intervals by small increases in either the speed or the gradient of the treadmill. The test was submaximal and involved walking only, not running. It was stopped when the subjects reached 85% of their predicted maximal heart rate, or earlier if they expressed any discomfort or significant ECG abnormalities were detected. The survey methods are described in more detail in the project report [6].

The survey was commissioned by the Health Education Authority and the Sports Council, and funding was provided by these agencies in conjunction with the Department of Health and Allied Dunbar Assurance plc.

A comprehensive submission to LRECs was prepared following the guidelines suggested by the Royal College of Physicians [7]. This covered the objectives, background and description of the survey methods. The principal investigators were named, and copies of consent forms and information given to subjects included. There was also a section on the arrangements for public liability insurance. The survey arranged public liability cover up to a maximum of £2 million, but there were no arrangements for 'no-fault' compensation, except at one site. A list of the contents of the submission is given in Table 1.

Because the cardio-respiratory exercise test was likely to receive the closest scrutiny, both the method of performing the test and the criteria for its discontinuation were given in considerable detail. The precautions to ensure the safety and comfort of subjects at all times were made explicit, and are shown in Table 2. These included an age cut-off for the physical appraisal at 74 years (older subjects could take part in a modified battery of tests at home), the involvement of medical personnel in the screening of all respondents who reported contraindications to physical activity from a simple screening questionnaire, and the provision of medical supervision during the tests for all subjects aged 60 years or over. (A full copy of the 30-page submission is available from the authors on request).

Although there is no national ethics committee, the

advice of three national bodies was sought before making our submission to local committees. The chairman of the medical ethics committee of the British Medical Association took action under his delegated powers to support the submission. The Department of Health (as joint funders of the survey) and the Royal College of Physicians were also consulted.

Contacting local ethics committees

The initial approach in each area was made to the director of public health of the health district of each of the 30 selected constituencies. A standard letter was sent from the survey director of the field operations director asking for help in contacting the LREC. In some cases the director of public health put us in direct contact with the chairman of the local committee; in others, all enquiries were handled through the director or a nominated representative. Initial enquiries were usually addressed to the field operations director, but were passed on to the research officer with responsibility for medical liaison if they raised issues best dealt with from a medical standpoint. The submission was accompanied by a covering letter acknowledging that the cardio-respiratory exercise test was likely to receive the closest scrutiny, and it highlighted the particular precautions taken to ensure the safety and comfort of the subjects throughout this test.

Outcome of the submission

None of the 30 committees rejected the proposal outright. However, some of them suggested significant

Table 1. Contents of the ethical submission.

•	Purpose of the survey
•	Subjects
•	Objectives
•	Background
•	Personnel
•	Consent, ethical approval, informing district health authority and family health service authority
•	Procedures, including considerations of hazards
•	Schedule
•	Precautions
•	Information for subjects and informed consent
•	Insurance
•	References
<i>Appendices:</i>	1. Management structure and members of the scientific advisory board.
	2. Screening questionnaire.
	3. Introductory letter, information for subjects and consent forms.
	4. Emergency and resuscitation equipment held in the mobile laboratory.

The document totalled 15 A4 pages plus appendices.

Table 2. Precautions and points to note regarding safety for the treadmill test.

1. The treadmill test is based on walking, a familiar form of physical activity.
2. The test is conducted at an intensity less than maximal, and an alternative low level protocol will be used when required.
3. Heart rate and ECG waveform are monitored prior to and throughout all tests.
4. The subject or the administrator may stop the test at any time if adverse symptoms or undue stress are apparent.
5. The treadmill has sturdy easily grasped handrails and front support bar at lower chest height. The subjects are instructed how to dismount in an emergency. Two emergency stop buttons for use by the subject are strategically placed.
6. The administrator is always in close attendance to give immediate support to the subject if necessary. Resuscitation equipment is to hand. All test administrators are trained in exhaled air resuscitation, closed chest cardiac massage, and recognition of serious cardiac arrhythmias. In addition, the testing always takes place on a hospital site, and the mobile laboratory has a telephone connection to the hospital switchboard with access to the emergency resuscitation team.
7. The risk of injury by tripping and/or falling on the treadmill is minimised by rehearsal and close supervision while the degree of such injury is also minimised by having the subject walk rather than run.
8. Subjects are excluded if they are taking medication which affects heart rate response to physical activity, have locomotion problems, respiratory disorders, angina, claudication, excessive anxiety, poor motor co-ordination, or give a history of recent or current cardiovascular disease, hypertension, physical activity-induced asthma, symptomatic arthritis of the knees or hips, or epilepsy.

alterations to the standard protocol. The outcome categories are summarised in Table 3.

Four committees approved the study without seeing the full submission document. They based their decision on background material sent by us to the director of public health. This included a broad description of the survey, but gave no details about the methods of screening subjects for the tests or the information and consent forms, although there was a brief description of the arrangements for ensuring the safety of subjects.

Another 11 committees granted approval after seeing the full submission document without further correspondence with the survey team. It was not always made explicit whether the submission had gone to the full committee or whether chairman's action had been taken, although the latter is known to have been the case in at least one district.

Eight of the remaining committees granted approval for the study after their enquiries had been satisfactorily answered. Five of them made enquiries

regarding the insurance situation and the liability of the health authority. The survey obtained legal advice from the Department of Health to confirm that any hospital employees who answered an emergency call on behalf of the survey would be covered by National Health Service (NHS) indemnity arrangements which came into operation in January 1990 (two months before the start of the fieldwork). Five enquired about the information given to subjects, and 11 wanted further details on arrangements for following up any subjects who showed conditions that might need medical attention. The remaining seven committees recommended alterations to our standard protocol before giving their approval.

Three committees requested the presence of a doctor in the mobile laboratory at all times when exercise testing was taking place, notwithstanding the back-up support of the hospital emergency services. At another site, this requirement applied to evenings and weekends only, when it was felt that it would be more difficult to obtain help from the hospital.

Two committees asked us to alter the wording of the consent form for subjects. In one instance, a paragraph was added to draw the subjects' attention specifically to the fact that no claim for injury or damage to person or property could be brought unless negligence could be proved; in the other, the change was an additional sentence encouraging subjects to allow the survey to report their results to their general practitioners. One LREC would not give approval until 'no-fault' insurance cover was arranged for all subjects who underwent the exertional tests (the treadmill test and the test of lower limb power). This cost £2,500.00 for that single survey site.

The committees also varied in whether or not they wanted a member of the research team to attend the meeting at which the submission was considered. Three committees requested this—which could

Table 3. Summary of outcome of submission to 30 local research ethics committees.

Outcome	No. of LRECs
Approval before full submission	4
Unreserved approval after full submission	11
Approval after full submission and satisfactory response to enquiries	8
Approval only after amendments to protocol	7
<i>Total</i>	<i>30</i>

LREC = local research ethics committee

involve a full day's travel just to be present for 10–15 minutes at the meeting.

One committee also asked us to change the advance letter sent to each household before the interview to make it explicit that the subjects need not take part in the survey. However, this request reached us only after the introductory letter had already been distributed. As far as we know, this was the only condition we failed to meet.

Five of the committees consulted fell within 'teaching districts'. Two of them approved the survey without seeing the full submission, one made enquiries of the survey personnel, and two requested amendments to the protocol.

Discussion

The diversity of responses of LRECs is illustrated by the differing outcomes of a submission for a nationwide survey to 30 committees. The responses ranged from giving approval before the committee had seen the full submission to withholding approval until significant and costly alterations had been made to the submitted protocol. The committees which gave approval without seeing the submission could not have adhered to the guidelines produced by the Department of Health and the Royal College of Physicians, since they had not received sufficient detail to make judgements either on precautions taken or on procedures for obtaining informed consent [4,6]. With wider circulation of these guidelines, it is less likely that committees will be prepared to take decisions in the absence of such information.

Although we do not believe that the alterations requested by some LRECs in any way affected the data collected at different sites, they were time-consuming and costly. The requests made by the committees could not have been predicted at the stage of planning and costing the survey—but the survey might not have been able to continue if some of the extra expense incurred as a result of meeting the requests to provide additional medical supervision of exercise tests had not been met by the Department of Health part of the way through the survey.

Several external factors may have affected the consideration of our submission. The introduction of NHS indemnity introduced some confusion regarding the personal cover held by several NHS employees when asked to provide emergency cover for the survey. The confusion was compounded because the survey was not specifically under the aegis of the NHS, despite sponsorship by the Department of Health and the Health Education Authority. Discussions concerning indemnity cover may have slowed the progress of the submission at some sites. LRECs may also have felt under increased scrutiny following the draft guidelines on the operation of local ethics committees circulated by the Department of Health in October 1989 and also the meeting convened by the Royal College of Physi-

cians in February 1990 to discuss the operation of local ethics committees. There were also instances where local events which may have influenced committees were identified. For example, in one district the hospital was expecting litigation over the sudden death of a local MP.

The impression from the enquiries received was that most committees were oriented towards reviewing clinical research on patients, and were not familiar with the concept of 'minimal risk', as explained in the Royal College of Physicians' guidelines on research on healthy volunteers [8]. When standard application forms were issued by LRECs, their format and wording were geared to applications for clinical trials rather than for epidemiological research. Although all committees had medical representation, some of them had little or no experience of social survey research. It seemed sometimes that the expertise to evaluate the risk attached to specified levels of relative exertion was not available to committees. Many of the points raised were common to several committees, and the process of answering individual committees—and often individual members—was very time-consuming.

In summary, we recommend that where approval for a multicentre study is sought from several LRECs, direct contact with the chairmen of the committees should be established as soon as possible. A readily accessible list of chairmen of local committees would be useful in this respect. (Such a list is available from the Publications Department at the Royal College of Physicians.) We also feel that although a degree of diversity in responses to ethical issues is inevitable, and indeed may even be desirable, the range of responses experienced during this survey was so wide that there is the possibility that useful, and ethical, research could be inhibited. We would support the establishment of a national body to monitor the work of LRECs and improve networking between them.

Acknowledgements

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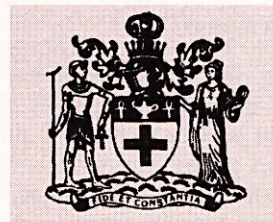
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A list of addresses of LRECs in England, Wales and Northern Ireland, with names of chairmen and contacts, and other useful information, which is updated twice a year, can be obtained on payment of £6.00 per copy from: The Publications Department, Royal College of Physicians, 11 St Andrews Place, Regent's Park, London NW1 4LE.

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