hospitals. We estimate that, in a district general hospital receiving 750 to 1000 referrals of patients who have attempted suicide a year, an emergency team could be adequately staffed by two or three trained nurses and a social worker. A team of this size could probably carry out all initial psychiatric and social assessments and offer subsequent treatment in many cases. A visiting senior psychiatrist could provide regular supervision.

In some district general hospitals with existing psychiatric units setting up such a team would not present great difficulties. In other hospitals lack of nurses might be an obstacle, but the potential saving in medical beds and specialists' time would probably justify special measures to establish new nursing posts and recruit suitable applicants.

An essential requirement would be that nurses and social workers selected for this work should receive special training. While the assessment of most patients who have attempted suicide does not call for the clinical skills of a trained psychiatrist, none the less thorough training is needed to provide a sound knowledge and understanding of suicidal behaviour and its determinants, and to develop interviewing techniques for eliciting information from patients and relatives. Such training could be provided by secondment to specialist units, and could include evaluation to ensure that trainees attained a satisfactory level of competence.

Our overall conclusion is that in areas where the present services for patients who have attempted suicide are being reappraised, serious consideration should be given to the possibility of establishing a small multidisciplinary team including suitably trained non-medical staff in the district general hospital. Such a team would probably enhance the quality and efficiency of service at a relatively low cost.

We thank Dr John Bancroft, who in the first three years was largely responsible for developing the service described in this paper, and Dr J Catalan, who played an important part in establishing and evaluating the training procedure. We also thank Professor Michael Gelder and Professor David Weatherall for their helpful comments.

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Clinical Topics

Work of a district ethical committee

M J DENHAM, ANN FOSTER, D A J TYRRELL

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Many ethical research committees were created in Britain after the publication in 1967 of the Royal College of Physicians report *Supervision of the Ethics of Clinical Investigation in Institutions*. The report, however, did not give specific guidance on the structure or functioning of such committees since it considered that what might be appropriate in one institution might be inappropriate elsewhere. A similar choice faced regional research committees, which resulted in a wide variation in their structures.[1] Since 1967 publications or reports have discussed either special ethical problems[2-6] or the work of a large area ethical committee.[7] Little has been written of the work of district-based committees. We therefore thought it appropriate to describe how the Harrow District Ethical Committee has evolved its own structure, function, and expertise during the eight years of its existence.

Northwick Park Hospital and Clinical Research Centre, Harrow, Middlesex HA1 3UJ
M J DENHAM, MD, FRCP, chairman of ethical committee, consultant physician in geriatric medicine
ANN FOSTER, BA, secretary to the committee
D A J TYRRELL, MD, FRS, chairman of the scientific advisory group, consultant physician

Background, constitution, and aims of the committee

When first constituted, the Northwick Park Hospital Ethical Committee considered projects from both the hospital, a National Health Service establishment, and the Clinical Research Centre, which, although integrated with the hospital, is administered by the Medical Research Council. After the NHS reorganisation in 1974 area health authorities became responsible for clinical research conducted in all premises under their control, so the ethical committee began to consider research projects in the community and changed its name to the Harrow District Ethical Committee. The responsibility of the committee to the AHA emphasises its independence from any medical establishment within the hospital.[8]

AIMS

The ethical committee decided it had three main aims: firstly, to ensure that the highest ethical standards are maintained during research investigation on man while ensuring that, at the same time, research is not stifled; secondly, to ensure the protection, safety, and well being of the patient or volunteer, whether or not the procedure is to be of benefit to him; and, thirdly, to ensure that subjects are fully informed about any research that affects them and also that consent is properly obtained. A secondary effect of these aims is that consultants who have their proposals accepted by the committee may have some protection if their work is subsequently criticised on ethical grounds. More recently, the committee has also acted for another MRC establishment, the National Institute for Medical Research at Mill Hill, by reviewing projects in which human fetal tissue is used.

SCIENTIFIC ADVISORY GROUP

The committee, like others,[9 10] considered that badly planned, poorly designed research, perhaps causing the patient inconvenience without producing useful or valid results, is unethical. As a first and possibly unique action it created a scientific advisory group consisting of a chairman and three members of the scientific staff of the Clinical Research Centre nominated by the director. One of the three members is always a statistician. The group appears to have some similarities to regional research committees,[1] although its membership is much smaller and possibly more scientifically orientated. It was agreed that the group should see all projects before they were submitted to the committee to ensure that the proposals were clearly set out, had a clearly defined, reasonably attainable objective, and that the design and methods were appropriate to achieve that objective.

The group may discuss projects with the investigators to eliminate problems or offer advice on how the study may be improved. It may suggest additional tests or alternative designs to increase the amount of scientific information obtained or it may suggest ways of obtaining the results with less material—for example, by taking smaller or fewer blood samples. The group is free to seek advice from outside experts when this is appropriate. The ethical committee emphasised that this group was only to make scientific, not ethical, judgments and that it had no power to reject a project. May[9] has suggested that the separation between scientific and ethical committees may lead to duplication but this has not been our experience.

MEMBERSHIP OF THE COMMITTEE

The membership of the ethical committee itself is broadly based, with medical, nursing, scientific, administrative, and lay representatives (table I). The consultant members, who represent the major disciplines in the hospital, are nominated by the medical executive committee, but to avoid possible allegations of bias it was decided that those with paid MRC contracts should not be eligible for election. It may be argued that the committee has too strong a medical bias, but its membership is similar to that of regional research committees[1] or institutional review boards.[10] In addition, the presence of several consultants means that skill is available in many research topics; undue pressure from strong personalities, which might develop in small committees, can be resisted; and investigators are prevented from becoming their own reviewers.[9]

The inclusion of lay representatives may be criticised because they may not fully understand complex research, but we have found that they do wish to be informed about research so that they can form a valid opinion of the risks and the benefits of the proposals. Lay representatives can give useful opinions when problems of consent are considered and help to interpret the nature of the research to the public[9] or, in our case, to the AHA, who receives the minutes of the meetings. Lawyers are often chosen as lay representatives, but we have not done this since a legal opinion can be obtained from the hospital solicitors if necessary. Table I shows that some of the committee members have voting rights. The reason for this stems from the history of the hospital because the ethical committee's constitution was modelled on those of the district management team and the medical executive committee. No vote has ever been taken, and agreement is by consensus. This is unlike some American committees where voting appears common.[10]

TABLE I—*Ethical committee membership*

Medical	
*NHS consultants	6
*Director, Clinical Research Centre	1
*District community physician	1
*Junior hospital doctor	1
*GP representatives	2
Nursing	
District nursing officer nominee	1
Scientific	
Scientific advisory group representative	1
Lay	
*Area health authority nominee	1
Administrative	
District administrator	1
Member of hospital administrative staff to act as secretary to the committee	1

*Indicates voting member.

FORMAT OF PROJECTS

The Committee meets monthly to consider projects, which have been submitted on a two-part form and examined by the scientific advisory group. The front section of the form consists of "Notes to investigators" and explains, for example, the method by which the patient's consent should be obtained, the responsibility of investigators, and the procedure governing the selection of volunteers, and indicates those procedures that may be considered as "minor," for which patient's consent is not required.

The second section lists headings under which the project has to be described. These headings include the names of the research workers (one of whom must be a consultant if the project is hospital based); the objectives of the research, its design and scientific background; the number of subjects and controls required; the substance to be given to the subjects; samples to be taken; other tests to be administered; and degree of discomfort likely to be experienced. Investigators are asked to exclude pregnant women from any study whenever this is appropriate. The headings have proved particularly helpful in identifying the value of the research, inducing clarity of thought, and reducing the number of submissions that lack essential information.

Details of approved projects are sent to appropriate heads of departments, such as ward sisters and pharmacists. The details used in our forms are similar to the suggested "standard" form,[7] but we would not necessarily agree with such a concept, although it is being explored by the DHSS. Investigators are not forced to submit projects to the ethical committee, but if they do not do so they cannot obtain retrospective approval of the committee.

MONITORING RESEARCH

Once the Committee has approved projects it wishes to ensure that they are completed as agreed and that no harm comes to the subject. It has been argued that doctors should be able to trust their colleagues to obviate the necessity to review research, but the institutional review boards in the United

States,[10] set up under the National Research Act of 1974, and regional research committees[1] in Britain take a different view, and we would agree that monitoring research is necessary so that an account can be given of the problems and difficulties experienced, particularly ethical ones.[11] Again, it may be argued that monitoring research after the work is completed limits any sanctions that may be taken by an ethical committee.[9 12] To some extent this is true, but editors of journals can help by rejecting work that they consider unethical.[9]

With these factors in mind the committee debated the best mechanism for monitoring research. Initially committee members visited wards to assess progress, but this did not prove satisfactory and consequently a yearly review was established. A specially designed "project review form" is sent to the principal investigator of each project asking for information on the progress of the study; the number of subjects studied and whether any alterations in the study have been made; what difficulties, especially ethical ones, have been encountered; and what future developments are planned. Each year the secretary prepares an analysis of the completed forms which details the number of projects completed, continuing, abandoned, or in abeyance, and this is presented to the committee. The completed review forms are also circulated to committee members. We have found that investigators often inform us of proposed changes in design study independently of being asked in the formal review.

Analysis of submitted projects

Between August 1970 and December 1978, 623 projects were prepared for submission to the ethical committee, and of these 580 received approval. A total of 43 projects were withdrawn before reaching the committee, usually because discussion between the investigator and the scientific advisory group had shown up some weakness in the project or proposal, but sometimes because the research had been incorporated into another project or the investigator had left before proceeding with the research.

The 580 projects approved include three initially rejected by the committee until substantial modifications had been made. In the first case this amounted to procedures being reviewed, in the second the design of the study was improved, and in the third an outside opinion was sought and the recommendations incorporated. Of the approved projects, 70% were approved without reservation, while the rest were subject to one or more restrictions (table II). This rate of approval is higher than that found in the Newcastle study,[7] although in our study more projects were subject to restriction. Gray and colleagues[10] found that 40% of American studies were modified for reasons similar to our own, and in a further 10% more information was sought. The lower proportions in our study may be due to the filtering mechanism of the scientific advisory group.

An analysis of the departments concerned with the research projects showed that most were medical, which is not surprising in view of the high proportion of clinical workers in the Clinical Research Centre (table III). It was not possible to separate projects conducted by the CRC staff from those of the NHS staff because much research was undertaken jointly or entailed a high degree of co-operation. The annual review of approved projects carried out in May 1978 showed that about two-fifths of the projects had been completed, one-fifth were continuing, and about the same number had been abandoned, either because the research method had failed to yield useful results or because the investigator had left or time for the study was lacking (table IV).

TABLE II—*Reservations or restrictions imposed by the committee, August 1970-December 1978. A submission may have been subject to more than one condition*

	Number	% of 580 (to nearest 1%)
Approved unreservedly	410	70
Approved subject to:		
Restriction on subjects (ages, numbers, etc)	70	12
Further information on procedures	28	5
Special conditions relating to consent	26	4
Procedures being restricted or amended	17	3
Interim reports being prepared	13	2
Approval of radioisotopes panel	17	3
Special care in informing other workers—for instance, GPs, nurses, etc	18	3
Other	14	2

TABLE III—*Departments concerned in research, August 1970-December 1978*

Department	No of times mentioned	% of 580 projects (to nearest 1%)
Medicine	328	57
Pathology (incl radiology)	106	19
Surgery	66	12
Obstetrics	34	6
Paediatrics	47	9
Psychiatry	40	7
Anaesthesia	30	5
Geriatrics	21	4
Epidemiology	22	4

TABLE IV—*State of 519 research projects reviewed up to May 1978*

Project review forms returned	92% of total projects	
Projects completed	43	% of returned project review forms
Projects abandoned*	20	
(abandoned because investigator left)	(6)	
Projects in abeyance	3	
Projects continuing	26	

*Projects were usually abandoned for lack of time or staff.

Some problems discussed by the committee

The discussions and deliberations of the committee on ethical principles have been influenced and enriched by the varying personal philosophies and religious beliefs of members, some of whom have read widely of the substantial literature on ethics.[13] Despite these differences the committee has evolved an ethical "attitude" based on a high regard for the importance of the individual and a recognition of the need for strict honesty in all dealings.[14] It is therefore considered ethical that normal subjects or patients should be able to volunteer to take part in research, which, although it may produce inconvenience and minor risk, may make possible significant advances in medical knowledge.

The committee debated the best way of obtaining informed consent without distressing or confusing the patient. It was considered that written consent might make the patient think that he had signed away his right to withdraw from the project, which is not the case, and it did not necessarily ensure that an adequate explanation was given. Consequently, the committee decided that it would be best to make the consultant in charge of the project responsible for ensuring that verbal or written consent is obtained from the patient in the presence of a witness, who in the hospital should be a nursing officer, ward sister, or charge nurse. The witness has the vital function of protecting the patient by ensuring that the implications of the procedure are fully understood and preventing undue pressure being applied by medical staff.[15] Initially, the patient's general practitioner was asked to be the witness, but this proved to be impracticable. A specially designed "consent form" recording that the explanation has been given, and the patient's agreement obtained, is then completed by the investigator, signed by the investigator and the witness, and placed in the patient's case notes. This helps to identify the person as having taken part in research, is part of good research record keeping,[3] and should prevent excessive use of volunteers. Gray and his colleagues[10]

considered that the ideal consent form should contain six items of information—the purpose of the research, the procedures, the risks, the benefits, a statement that subjects are free to withdraw from the research, and an invitation to ask questions. They criticised existing forms as incomplete, inadequate, and difficult to understand. We think, however, that it is more important to be sure the patient really understands the procedures proposed than to obtain a signature on a document, whose content—although detailed and explicit—may not be fully understood.

Research in children, handicapped adults, and the elderly has caused much discussion in the committee, particularly about the advisability of investigating these groups of patients and the obtaining of informed consent. The committee agrees with the view that research on the young and the old should be performed, otherwise medical and therapeutic care of these groups will not advance. A child's "capacity to consent depends on his or her intellectual capability and the complexity of the procedure in question. Where a child is incapable of consenting on his own behalf, a parent may give a legally effective consent to non-therapeutic procedures which are in the public benefit and are not in any important way detrimental to the child's interests."[16] The concept of the "risk-benefit" ratio[16] may be particularly helpful here. Risk may be defined as non-risk, minimal risk, or significant risk[16–18] and must be weighed against the benefit which may be of direct value to the individual or increase generalised knowledge of the disease being studied or provide information about the health and welfare of the individual.

One of us (MJD) has found the Tooting Bec Questionnaire[19] useful when assessing an elderly person's ability to give informed consent. Those who score more than 7 out of 16 are usually well able to give consent, while those who score less may not, and the consent of a relative is often necessary. It also helps to keep the nursing staff fully informed of proposed research in the elderly. Reitch[20] considers that in some cases a legal guardian could act for the aged who are "morally incompetent." The committee decided that where informed consent could not be obtained from patients with mental handicap and where no relatives were available, then the research could be carried out provided the agreement of another consultant in the hospital was obtained after full explanation of the circumstances and the project. Under normal conditions, patients subject to statutory orders are not subjects of clinical research.

The committee agreed that some minor procedures entail so little discomfort to the patient that it would be more likely to cause him distress to be asked for consent than if the investigator were to proceed without permission.[8] The committee therefore defined a minor procedure as one when nothing is done that introduces appreciably more inconvenience or discomfort than would be experienced by the patient undergoing diagnostic procedures that are performed as part of normal patient care. Examples of such minor procedures were considered to be unlimited collection of urine or faeces, nasal and throat swabs, the withdrawal of a volume of blood not exceeding half of a sample being taken at the same time for diagnostic purposes, and the taking of one extra film of a patient undergoing a diagnostic *x*-ray procedure provided this is limited to non-pregnant adults. Repeated blood tests or radiographs, however, could not be considered minor procedures. Research entailing minor procedures on patients must be submitted to the committee.

The question of payment to volunteers was considered. The committee noted that the MRC had ruled that their workers should not be paid for volunteering for research and agreed that this rule should apply to non-MRC employees who volunteered, although it was appreciated that there might be a need to meet their out-of-pocket expenses. We understand that the non-payment of volunteers is now being questioned elsewhere, particularly by medical students.

Research may often entail the use of the patient's case notes, which are confidential and are legally the property of the hospital. The committee agreed that if district medical staff wished to use notes for research without contacting patients, they need not submit their proposals to the ethical committee, although such investigators would be expected to discuss the project with the consultants in charge of the patients concerned. If medical staff from other hospitals or health service institutions wanted access to case notes, however, they would be expected to submit their request and proposals to the ethical committee. Non-medical personnel would be allowed access to case notes only if their project was sponsored by a doctor who would be expected to make the investigators fully aware of the confidential issues, a point emphasised by the working group.[7]

The use of fetal material for research has been considered, and the committee agreed with the report[2] that all research using fetal material should be approved by the ethical committee using the code of practice as guidelines. The committee considered that parental consent would not be required for the use of this material in approved research since it was not the current clinical practice to ask parents about the disposal of fetal tissue, although opportunity is given to allow stipulations to be made.

Conclusion

The ethical committee has a well-established and respected role in the Harrow Health District. Cynics may yet say that its presence can be ignored and research started without its knowledge. Communications between the committee and department heads is good, however, and, should any of them become aware of research about which they have not been notified, they can easily bring this to the attention of the committee. This has indeed happened on a few occasions because the investigator was unfamiliar with district procedures. Explanations resulted in the error not being repeated. The committee itself has not become aware of any significant research that was being conducted without its approval.

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Is a lumbar puncture during the acute phase of measles likely to cause a measles meningoencephalitis by introducing live virus into the cerebrospinal fluid? If so how would one manage a child aged 5 years with convulsions during the acute stage of measles?

A lumbar puncture in measles does not cause meningoencephalitis. There is no risk of causing it by lumbar puncture.