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## Focus: current issues in medical ethics

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### The drawbacks of research ethics committees

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#### Editor's note

*Research ethics committees, while in many ways an excellent innovation, do have some drawbacks. This paper examines three of these. The first problem of such committees is that their approval of specific projects in their own institutions acquires intrinsic value.*

*The second problem relates to the possible devolution of responsibility from the investigator to the committee. The committee approves, the investigator feels relieved of some responsibility and things can be done to patients which neither the committee nor the investigator might countenance if they had sole responsibility.*

*The third problem arises directly from the bureaucratic nature of the committee itself. And one consequence of the resulting rigid guidelines is the insistence, by most committees, on the written consent of patients. Demanding this can, in some circumstances, mean giving the patient very disturbing information. The paper suggests that in patients with a fatal disease where trials compare two accepted therapies committees dispense with written consent.*

*There is a commentary on this paper by Dr D J Weatherall of the Nuffield Department of Clinical Medicine, University of Oxford.*

Research ethics committees have been established in most institutions where clinical medical research is carried out. In the UK there is no central statutory authority which regulates their activities so that each operates autonomously, sanctioning or rejecting clinical research proposals according to guidelines laid down by the governing body of the institution concerned. In outline what usually occurs is that all investigations involving human subjects, either patients or healthy volunteers, have to be considered and approved by the committee before such studies can be begun. Membership of the typical research ethics

committee is broad-based and usually at least one lay person is included.

In many ways the establishment of these committees is an excellent thing. Their existence restrains the over-enthusiastic researcher and provides protection to those who take part in research both as subjects and investigators. However, having served as a medical member of a research ethics committee in two different institutions, I have become aware of a number of negative aspects of the present system, which I think are worthy of discussion.

The first problem is that the approval of a research project by a research ethics committee is a process which has acquired an intrinsic value. Such approval is a valuable commodity because it is required by outside bodies who are not directly concerned with the investigator-subject relationship. Grant-giving bodies regularly require approval for any project involving human subjects before they will even consider an investigator's grant application. Editors of medical journals often require documentary evidence from authors that the studies they report have been approved by the relevant ethical committee. Finally, such statutory bodies as the American Food and Drug Administration actually require documentary evidence that each of the studies submitted to them has been approved by a local research ethics committee.

The problem with this is that whatever the committee considers to be a reasonable investigation when carried out in its institution by a particular investigator with particular facilities then gains currency as being ethical in absolute terms. It has been known for an outside sponsoring body, such as a pharmaceutical company, to use the ethical approval of one institution as a bargaining counter with another. This whole process of outside bodies using such certification breaches confidentiality and adds a dimension to the deliberation of the research ethics committee of which the members are often not aware.

A second problem relates to the 'institutionalisation of ethics' in medical research and here my objection is a more subtle one. In effect what approval by the committee gives to the investigator is a measure of security; in approving an investigation the committee agrees to shoulder a portion of the investigator's responsibility. The investigator or his (or her) assistant has a measure

of responsibility lifted from him and begins to act as if his actions were directed by a higher authority. Such division of responsibility is a common enough situation but precedents show it is hazardous. In the state of devolved responsibility between the committee and the investigator, each can push its ethical responsibilities off onto the other. In consequence an investigator can press on in what he realises to be a dangerous procedure reassured that he has institutional approval for it. Likewise the committee feels no qualms in that it has merely given a responsible investigator permission to do what is reasonable. In such a situation things can be done to a patient or normal subject which neither the committee nor the individual investigator would ever do if they were solely responsible.

Historically this devolution and sharing of responsibility has been the mechanism whereby most atrocities inflicted on Man by Man take place. Those actually committing the acts do so under orders and those ordering do not take part. The ethical committee system establishes the danger of a similar situation.

A third problem relates to procedure. Committees are by nature bureaucratic and process applications using guidelines which tend to become stereotyped. Every research proposal has to be submitted to the committee in a standard format, every investigator has to inform the subject's family doctor of his (or her) participation, every subject has to be medically examined after any experimental procedure and so on. In this way the routine ensures that every essential action is carried out but at the cost of much being done which is unnecessary. One does not object very strongly to this situation and indeed bureaucracy imposes such costs throughout our whole society today.

However, there is one particular aspect of this uniformity which has unfortunate consequences. Most, although not all, research ethics committees insist that every subject taking part in research projects gives informed consent to the research in writing. In practice much of the work of the research ethics committee is concerned with reviewing the consent documents which the subjects have to sign. The committee tries to ensure that the research procedure outlined in the consent form and which the subject is required to read and sign, is honest, accurate and intelligible. All this is reasonable and necessary. It is the cornerstone of an ethical medical experiment that the subject participating should understand what is to be done to him and agree to submit to it, fully informed as to the likely consequences of consent.

In most situations there can be no objection to this. However, in some circumstances written consent can be distressing to the subjects and hence, in my view, the antithesis of 'ethical'. An example may explain the point.

A young patient is diagnosed as having acute leukaemia. He is referred to a specialist unit for chemotherapy. The unit is taking part in a nationally agreed comparative trial of two different chemotherapeutic

regimes. One regime is the established treatment which emerged as best in the last comparative trial. The other regime is a variant which it is hoped might be superior. Patients are being allocated at random to receive either one treatment or the other. As in most of these nationally organised trials, there is a continuous evaluation of results by the co-ordinating group and if one regime proves superior to the other, then the trial will be stopped and the better treatment adopted for all the patients until the next trial is mounted. This is how most progress has been made in leukaemia treatment to date.

However, as a result of the local research ethics committee procedure, before receiving treatment, the patient is asked to sign a consent document outlining the nature and purposes of the trial and his participation in it. Because the committee requires written informed consent the patient will be told, by the document, that he has leukaemia, that there is no entirely satisfactory treatment and that continuing experiment is necessary to determine which drugs are best. The patient will have to be told that his allocation to one or other treatment regime will be at random.

Thus, at a stroke, the patient is asked to sign a consent form with some very disturbing information on it. He does not have 'serious anaemia' or 'an abnormality of the white cells', he has leukaemia. Furthermore, however it is phrased the patient will realise the treatment for his condition is unsatisfactory: experiment is necessary, outcome is being measured. There is a further implication. The ultimate outcome will not be cure but worse. His attendants intend to measure his progress to an end point.

Let us suppose that the patient is sufficiently upset by this consent document to decline to participate. This course is fully open to him. However, all this means in practice is that he cannot be included in the trial. Nevertheless all that can be offered him is one of the two standard treatments. Hence all that has been achieved by presenting the research ethics committee's consent form to the patient is unnecessary distress and the delay of the result of the comparative trial. This is not a situation unique to leukaemia. In any clinical trial involving comparison of two different treatment methods in patients with a serious or fatal condition similar problems arise.

It may be argued that in all these situations the patient will be aware of the diagnosis. With today's more open attitude to cancer, this is generally, although not always, the case. However, why should the research ethics committee, which is there primarily to protect subjects, insist on a procedure which cannot benefit a patient but which can only cause harm? The answer is really administrative convenience, rigidity of procedure.

It would seem important under certain carefully defined circumstances to vary the procedure. In patients with a fatal disease where trials compare two accepted therapies could not the committees dispense with written consent? In an alternative procedure the

investigators could be charged with sensitively and sympathetically explaining to patients that while they were being treated they were also participating in research. Patients would be told that their inclusion in research assessments would never be to their detriment and that they would receive the best treatment for their condition. The investigator could himself sign a declaration to the committee that he had made such explanation and the committee would have to be satisfied that each treatment regime being studied was, on present evidence, likely to be the best available. Exempting certain specified investigations from the necessity of written consent would not undermine the principle of informed consent for the majority of protocols where it is appropriate.

## Commentary

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Dr Lewis has three main worries about ethics committees. The first is that their approval of a research project endows it with an intrinsic value. Surely this is inevitable. The opinion of an ethics committee is complementary to that of a scientific referee. Both wish to know whether the work is worth doing; in addition one decides whether it is being carried out as humanely as possible and the other determines whether the scientific method is appropriate. Granting bodies and reputable journals will require assurance from both sources. An ethics committee is responsible for both patients and scientists. If it allows either to become bait for unscrupulous practices by drug companies or anyone else it is failing in its basic function.

The second question raised by Dr Lewis is much more difficult. In essence, he argues that there is a danger of an ethics committee becoming the conscience of an over-enthusiastic or unscrupulous investigator. Once the ethics committee has approved a research programme the investigator and the parent institution may consider themselves absolved from any further moral responsibility and also the project assumes instant respectability. A worrying example of this type was shown on a BBC Horizon programme. An American investigator who wished to carry out what was, arguably, an unethical experiment, was unable to get it approved by his local ethics committee but was allowed to carry out the experiment with the approval of an ethics committee in a foreign country. The difference in the approach of the two committees was highlighted by the programme. Although the American committee did not understand the details of the experiment they took infinite pains to obtain help from outside experts; though not fully comprehending the experiment either, the other ethics committee approved it, influenced possibly by the reputation of the investigator.

This type of problem can only be prevented if medical members of ethics committees are extremely thorough in investigating each project; there will always be a minority of clinical investigators who either knowingly or unknowingly attempt to mislead ethics committees and whose programme, if it is approved, thereby gains an acceptability which it would not have, had it been judged by the worker's peers. Members of ethics committees require the same level of understanding of a project as its scientific assessors. When in any doubt they must take expert advice.

Dr Lewis's final point relates to procedure and here I think he has raised a particularly important question, although perhaps he has weakened his argument by an inappropriate example. Few physicians looking after patients with leukaemia would tell them that they had a 'serious anaemia' or 'an abnormality of the white cells'. Rather, the patients would be told that they had leukaemia, that a great deal could be done for this condition, and, if appropriate, that some forms were curable.

During the course of such an explanation it would be quite proper to point out that the treatment for many forms of leukaemia could be carried out in several different ways, all of which seemed to be more or less equally effective, and that a trial was being carried out to determine whether one treatment was marginally better than the others. These facts could be set out simply to patients or parents and consent to enter a trial could be obtained without upsetting them in any way. The important question, however, is whether this has to be written consent.

Much more difficult situations arise in clinical trials. For example, a patient is admitted to a coronary care unit with a myocardial infarction. The patient is in severe pain, drowsy with diamorphine, attached to a variety of monitors, and surrounded by worried relatives in a totally strange environment. In rushes the investigator who says that he is doing research and that he wishes the patient to swallow a pill which will contain either sugar or a beta-blocker; a garbled account of the pharmacology of beta-blockers follows and a piece of paper representing 'informed consent' is produced for signing. It is signed; both ethics committee and investigator are persuaded that the patient has been duly protected.

While this may be an extreme case, there are many situations in which it seems inappropriate to ask patients to give written permission for a particular investigation. Indeed, the whole concept of 'informed consent' applied in this way is intellectually dishonest and ill-conceived. Who is informed? Certainly not the patients. Often they are totally confused by an over-simplified or over-detailed description of the research programme, particularly if this is presented to them or their relatives during the course of an acute illness. To ask a patient to sign what may appear to be a legalistic piece of paper under these circumstances is simply adding another burden to what is often an intolerable situation; surely it is not good clinical practice.

The concept of 'informed consent' of this type is a self-deluding exercise designed only to reassure ethics committees (and investigators) that they are discharging their moral obligations. It is medico-legal and pastoral nonsense. Why restrict this practice to research? Almost every form of treatment is an experiment, largely empirical and based on fairly wobbly scientific evidence.

The role of an ethics committee is to analyse research programmes in great detail and, when fully informed, to balance possible benefits against potential risks to patients. This should be a continuing process. Medical members of the committee should not be averse to visiting research workers and watching them at work. Animal inspectors are regularly seen in research departments; medical members of ethics committees rarely are.

However, as suggested by Dr Lewis, serious consideration should be given to dispensing with the written consent process in many research programmes. I

entirely agree that the investigator should be charged with 'sensitively and sympathetically' explaining to the patients the nature of their illness, the therapeutic options and the objects of the research programme, after which the patients could be invited to participate. If the research procedure is not related directly to the patient's illness, its aims in helping other patients must be described in detail. This is simply an extension of good clinical practice; there is no reason why clinical research should be different simply to perpetuate the self-delusioning process of 'informed consent'. The committee should ask for a detailed account of the content and timing of these explanations; they should not slavishly demand written consent in every case.

Ethics committees exist to protect patients and to ensure that uninformed opinion does not hinder good clinical research. In their endeavour to carry out the first of these functions they must not impose pressures on clinical investigators which, in practice, may cause unnecessary stresses for patients or their families.

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