this would be true for participation in clinical trials.

Clinical trials are here to stay. Patients who participate should not be sidelined by overbearing researchers. Trials are not a form of treatment and are not part of the patient-doctor contract. Informed consent is imperative and should not be a contest between researchers and ethicists. It is a basic right; it is about the freedom of choice.

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. . . of the principles of clinical trials

EDITOR,—As a patient I welcome Jeffrey S Tobias and Robert L Souhami's article highlighting the cruelty of obtaining consent and the hurdles that must be overcome if recruitment into trials is to be improved.[1] The difficulty of maintaining equipoise and having to explain randomisation is well described, as also is the unfairness of the ethical double standards that currently operate, resulting in the frustration of clinicians attempting to conduct trials.

Speaking from experience, I believe strongly that if patients understood better the concept of and rationale for trials and had input into the design and monitoring of trials then accrual would be hastened and acceptance of trials improved. Education of the public—when they are well—about the need to root out useless or harmful treatment and assess new ones by means of trials, as advocated by Baum,[2] would be a step in the right direction. It would enable the public to make a more useful contribution and might give the profession a clearer idea of what constituted an acceptable range of trial options on the basis of patients' preferred outcomes.

As stated: "The people's health ... is the concern of the people themselves.... No plan, however well designed and well intentioned, will succeed if it is imposed on the people."[3] The inflexible imposition of a rigid method of obtaining consent inhibits progess, as is illustrated by the "humanly inappropriate" means of obtaining consent in the US for the second international study of infarct survival. The resulting poor accrual delayed findings and resulted in many thousands of unnecessary deaths.

A greater appreciation of the principles of trials by the public would also reduce the clamour for new drugs whose efficacy is unproved by trials: new is not always better.

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Consent may not be possible

EDITOR,—We agree with Jeffrey S Tobias and Robert L Souhami that informed consent is not always in the best interests of the patient.[1] Not only can it be distressing but it can detroy the relationship between the doctor and the patient. Provided that there are no clear data in favour of any one of the treatment arms in a trial, we believe that informed consent is not required.

Another issue concerns a patient's ability to give informed consent; this may arise because of the circumstances under scrutiny (such as medical emergencies) or because of cognitive impairment. The number of elderly people is increasing rapidly, and research projects targeting this group have proliferated.[2] A substantial number of elderly people cannot give consent because of either an acute confusional state or a progressive organic brain disease. The level of cognitive impairment below which informed consent can no longer be given has not yet been addressed, and it may be insulting, distressing, and inappropriate to turn to a patient's close relative to ask permission before randomisation.[3]

These problems have surfaced during recruitment into the international stroke trial. Although there are no clear data in favour of any of the four treatments (aspirin, low dose heparin, high dose heparin, and neither aspirin nor heparin), patients with no close relatives have been excluded from the trial if they have pre-existing cognitive impairment or an extensive infarct complicated by a disturbed level of consciousness.[4] Both of these exclusions will not only distort the results of the trial but deprive clinicians of information on a large group of patients of specific interest. The rehabilitation of this group not only provides the greatest challenge but consumes a large proportion of already overstretched resources.

Provided that a trial has a sound ethical and scientific basis, the issue of informed consent need not always arise; the number of patients recruited to valuable clinical trials will then be increased.[5]

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Strengthen ethical committees' role

EDITOR,—The issue of fully informed consent merits discussion.[1] I have long contended that in my specialty it is frequently unethical to attempt to gain ethical permission.

Neonatal intensive care has developed rapidly over the past 20 years, with many infants born weighing less than 1000 g and more than three months early now surviving. The limits of our physiological, biochemical, and clinical knowledge have been pushed back, but at what expense? Is it appropriate to ask parents in the panic of labour three to four months before term for permission to try a new treatment (for example, artificial surfactant) on their infant as soon as he or she is born—"We don't know whether or not it works, you see, and we need to find out." After such a baby is born is it appropriate to ask: "We are comparing the effects of drug A (for example, morphine) and drug B (for example, fentanyl) as we think your baby is likely to be in pain and we don't know which one is best (or worst); will you allow us to toss a coin and use one of these treatments on your infant?"

I believe that the role of an ethics committee should be much more positive than it generally is now. The scientists on the committee should take independent scientific responsibility (even with the aid of expert referees) for seeing that the question asked is scientifically worth asking and that the study is designed to answer it. The lay members of the committee should take responsibility for the question being of general importance and the study being humane.

With rare exceptions, in the neonatal period it is possible to get permission and signed informed consent from parents to do almost anything to their baby, but is this really ethical? We need discussion about this and not just the traditional knee jerk reaction, "Have you got ethical permission?"

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Clinical judgment determines disclosure

EDITOR,—Last Christmas Eve I was in the accident and emergency department of an NHS hospital in England, discussing whether my comatose son should have HA-IA Centoxin for his presumed meningitis. I knew that this was a monoclonal antibody that acted against Gram negative organisms and was the subject of a placebo controlled trial whose main outcome measure was death. The paediatrician seemed less than happy when I asked if my son should be included in the trial, and the matter was finally resolved when he said to me and my wife, "In my clinical judgment he needs this drug. Anyway, it's a monoclonal antibody. How can it be harmful?" My son got HA-IA. I am glad to say that he recovered completely from what turned out to be atypical, possibly viral, pneumonia. A few weeks later I noted that HA-IA had been voluntarily withdrawn on the grounds that it "may increase mortality among patients who do not have gram-negative bacteraemia."[1]

If the paediatrician had explained that neither he nor anyone else could possibly know whether the treatment was likely to do more harm than good, another patient might have been recruited for the trial and my son would have had a chance of being spared a (possibly) harmful treatment. I suggest that during training we internalise a powerful rule that tells us never to admit ignorance of the best course of action. This rule conflicts with the ethical imperative to conduct formal trials of new treatments. Jeffrey S Tobias and Robert L Souhami's oncological example admirably describes the contortions of a doctor trying to justify a random choice by finding reasons why that choice might in fact be best.[2]

It is therefore humane to doctors, as well as to patients, not to insist on full disclosure. I support Tobias and Souhami's recommendation that the extent of disclosure should be a matter for clinical judgment within suitable guidelines. Additionally, I suggest that medical training should produce doctors who find it easier to admit to the limits of medical knowledge. This is a further reason to encourage educational approaches that teach reasoning, as well as received wisdom, at all stages of medical training.[3]

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