law. Despite their good intentions Tobias and Souhami have missed this particular boat.

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1 Tobias JS, Souhami RL. Fully informed consent can be needlessly cruel. *BMJ* 1993;307:1199-201. (6 November.)
2 European Commission. *The rules governing medicinal products in the European Community.* Vol 1. Brussels: European Commission, 1989.

Open discussion promotes trust

EDITOR,—I am concerned by Jeffrey S Tobias and Robert L Souhami's view that obtaining fully informed consent can be cruel to patients.[1] In a research setting the doctor's role as a scientific investigator conflicts with his or her role as a healer whose commitment is to act in the patient's best interests. By participating in a randomised controlled trial patients forego their right to treatment tailored entirely to their needs; hence the treatment policy decided on is not always in the patients' best interests, contrary to what Tobias and Souhami would like their patients to believe. It is for this reason that the requirement for informed consent is more stringent than that in normal practice.

Patients need to be aware that the trial is being conducted because there is genuinely no consensus within the clinical community as to the relative merits of the treatments to be tested. Knowing that their treatment is to be randomised may put some patients off, either rationally or irrationally. In my view, however, to deprive patients of information regarding the manner in which their treatment is selected is unethical, especially when participation in a placebo controlled trial is being considered. The patient to be recruited is one who is willing to accept either treatment, with adequate awareness of the advantages and disadvantages of various treatment options. This avoids the problem of the doctor trying to "sell" one form of treatment and then having to back pedal, as described by Tobias and Souhami, when the patient is randomised to the other treatment. An open, frank discussion of the relevant issues not only would promote trust in the doctor and enhance the doctor-patient relationship but would respect the patient's right to self determination.

Gaining informed consent from patients takes time and effort. Complex issues need to be discussed in an empathic manner. Doctors often find it difficult to admit to uncertainties within themselves or within the clinical community. I believe strongly, however, that ethical standards should not be compromised just because they are hard to attain.

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1 Tobias JS, Souhami RL. Fully informed consent can be needlessly cruel. *BMJ* 1993;307:1199-201. (6 November.)

Doctors should admit uncertainty

EDITOR,—Jeffrey S Tobias and Robert L Souhami's distress in obtaining fully informed consent from patients undergoing trials is almost palpable.[1] Although the authors describe themselves as "committed trialists," their discomfort in recognising the need for randomised controlled trials is obvious. In the example they give it is clear that they see the doctor's role as selling a product ("talking down" and "talking up" chemotherapy) rather than sharing the current state of knowledge. There is a bias in favour of a new treatment rather than the old ("potentially valuable... new remedy"). I suspect that there is also a bias, in this example, in favour of chemotherapy rather than radiotherapy. The authors then seem to transfer their anxieties about challenging the efficacy of a new product to the patient. Naturally, the patient will reflect the doctor's unhappiness at having to question the potential of a new treatment (which will always seem to be better than the old).

What the authors describe seems to be a good example of the difficulty of achieving clinical equipoise—that is, acknowledging uncertainty about the best possible treatment. There is no acknowledgment that it is unethical not to evaluate new treatments as rigorously as possible. Using this as a reason for not obtaining fully informed consent is not paternalism. It carries a high risk of patients feeling like research guinea pigs because doctors find it so hard to admit their uncertainty.

The issue of the *BMJ* containing Tobias and Souhami's article also contains two articles on the training needs of junior doctors, which include training in breaking bad news and pain control.[2,3] It took the profession some time to recognise that doctors need help and specific training in dealing with these difficult tasks. Maybe now doctors need to be supported and counselled in acknowledging the reality of uncertainty and that this is not a source of disgrace but an opportunity to gain wisdom and experience alongside patients. They should then feel able to use the guidelines on fully informed consent published by the Royal College of Physicians.[4]

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1 Tobias JS, Souhami RL. Fully informed consent can be needlessly cruel. *BMJ* 1993;307:1199-201. (6 November.)
2 Gillard JH, Dent THS, Aarons EJ, Crimlisk HL, Smyth-Pigott PJ, Nicholls MWN. Preregistration house officers in the Thames regions: changes in quality of training after four years. *BMJ* 1993;307:1176-9. (6 November.)
3 Gillard JH, Dent THS, Aarons EJ, Smyth-Pigott PJ, Nicholls MWN. Preregistration house officers in eight English regions: survey of quality of training. *BMJ* 1993;307:1180-4. (6 November.)
4 Royal College of Physicians. *Guidelines on the practice of ethics committees in medical research involving human subjects.* 2nd ed. London: RCP, 1990.

Informed consent difficult in paediatric intensive care

EDITOR,—The issues that Jeffrey S Tobias and Robert L Souhami raise with regard to obtaining patients' fully informed consent are important and in urgent need of public and professional debate. I would like to extend the concerns that they voice on behalf of adult patients to newborn babies who require intensive care. In neonatal research, consent is obtained from the parents. They have a critically ill baby and are likely to be scared and confused. The realities of neonatal intensive care are harsh and frightening, but humane clinicians understand that what is necessary is reassurance and a clear and simple description of the treatment necessary. To seek truly informed consent for participation in a research study is to oblige parents to listen to complex medical arguments that spell out the uncertainties of current practice. Although it might be argued that parents have a right to know about all aspects of their baby's care, this would mean that, in many instances, distressed parents were forced to make decisions that they would not normally be asked to make. If the trial is a comparison of two treatments that are both used in routine clinical practice, such as a comparison of antibiotic policies, it seems unnecessarily cruel to ask parents to assimilate the need for randomisation. In addition, in academic units, given the relatively small numbers of babies receiving intensive care, each infant may be suitable for entry into more than one trial, for each of which consent must be sought. In these circumstances many parents opt out of making a positive decision and refuse consent. If it is accepted that participation in a randomised trial confers benefit both on the individual, regardless of the arm of the trial to which he or she is assigned,[2] and on populations then to deny a baby the opportunity of entry to a trial is unethical.

A kind and gentle approach to patients' care should encompass clinical research. There are alternatives to the so called ethically correct approach that is being forced on the medical profession by ethicists and lawyers. Firstly, the public needs to be better educated about the intentions of research.[3] Secondly, to suggest that it is more appropriate to ask parents to opt out of participation in a trial than to ask them to opt in is to recognise that to refuse consent is, in many instances, no more than an understandable reaction to a stressful situation.[4] Finally, there are circumstances when it should not be considered obligatory to confront distressed parents with medical complexities in order to obtain consent for entry to a trial. An example is a comparison of treatments that are both in standard clinical use. In these circumstances it should be the responsibility of those who are truly able to give informed consent—namely, the clinician and the institution's ethics committee—to acknowledge that allocation of treatment by randomisation is clinically legitimate.

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1 Tobias JS, Souhami RL. Fully informed consent can be needlessly cruel. *BMJ* 1993;307:1199-201. (6 November.)
2 Stiller C. Survival of patients in clinical trials and at specialist centres. In: Williams CJ, ed. *Introducing new treatments for cancer: practical, ethical and legal problems.* Chichester: Wiley, 1992:119-36.
3 Baum M. New approach for recruitment into randomised controlled trials. *Lancet* 1993;341:812-3.
4 Mutch L, King R. Obtaining parental consent—opting in or opting out? *Arch Dis Child* 1985;60:679-80.

Raise public awareness...

EDITOR,—Jeffrey S Tobias and Robert L Souhami confuse informed consent for clinical trials with prevarication about treatment.[1] In the basic patient-doctor relationship the doctor leads with the patient's cooperation and participation. With his or her professional knowledge the doctor steers towards the best treatment. It is unjustifiable to leave the burden of decision to the patient even if he or she is medically trained. In this basic relationship consent is implied. A new contract must be negotiated if there is a deviation (as in clinical trials) from this fundamental relationship.

One patient refused to take part in a clinical trial after researching the subject; she found the information given to her to be "partly informed" at best and "ill informed" at worst.[2] Another patient was angry at her inclusion in two clinical trials without her informed consent even though she was randomised to receive the best option.[3,4] The authors cannot ignore these and many similar patients.

It is surprising that the authors suggest that the decision on whether to obtain informed consent should be left to the clinical judgment of individual doctors, although they note that clinicians find it "overwhelmingly difficult" for various reasons.[1] If this was to happen patients would be told less and less. Reticent patients would have to cope with the emotional turmoil of disease and wrestle with a patient-doctor contract that did not guarantee full disclosure in case of experimentation. The role of patients who wished to help advance medical knowledge would become a passive and subservient one; patients would be serving the advancement of medical knowledge instead of the reverse.

The right way to proceed is to teach the facts about clinical trials to schoolchildren and the public before the onset of illness; to identify and dispel myths, including popular images of clinical trials as a desperate measure; and to bring down barriers. Knowledge is an important variable in the decision to become an organ donor,[5] and