Whether the presence of cotton wool spots can be used to predict the development of either cytomegalovirus retinitis or other cytomegalovirus disease later in the patient's illness has yet to be determined.

We thank Mr R Marsh for his evaluation of these patients.

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1 Humphrey RC, Weber JN, Marsh RJ. The ophthalmic findings of a group of ambulatory patients infected by human T cell lymphotropic virus type III (HTLV III)—a prospective study. *Br J Ophthalmol* (in press).

Informed consent

SIR,—I hope Jonathan Glover's leading article (19 July, p 157) stimulates the debate he rightly proposes about exceptions to the rule that no patient should participate in research without informed consent. The rule raises particular problems with the newborn.¹ Some babies admitted to neonatal nurseries are at risk of lethal illness and damaging complications. If death and handicap are to be reduced further it is essential that research continues rapidly, and with the support and approval of the community.

In neonatal medicine, as elsewhere, randomised trials of adequate size and design are the most reliable way of comparing the safety and value of treatments.² Ethics committees usually approve proposals for neonatal trials if they are relevant, scientifically valid, and involve the parents' permission. When standard or alternative treatment of a sick baby must begin very soon after birth, however, it may be impossible first to obtain the meaningful permission of the parents. They may be in a state of shock or in another hospital, or the mother may herself be ill or recovering from an anaesthetic. Perhaps information should be given about the small risk of a particular illness in newborn infants and parents' attitudes to a trial sought earlier in pregnancy. Evidence that this could be done without unjustifiable anxiety and prohibitive cost would be extremely useful. Meanwhile we must sometimes choose either to exclude infants like this from trials or enter them without prior specific permission.

If such infants are excluded from trials advances in certain critical neonatal illnesses will inevitably be slowed. If such infants are to be included doctors should have the support of the community. This is partly expressed through local ethics committees, which increasingly include lay members. Most ethics committees will give doctors this support if an important trial is likely to fail without it. Doctors in their turn should always examine their motives for pleading an exception to the obligation of prior informed consent. Withholding information from parents is sometimes a form of overprotection and can look very much like deceit.

I hope the debate is conducted sensitively. Those who fuel headlines accusing paediatricians of "experimenting on babies without their parents' permission" could very well polarise it beyond recall. If this destroys the trust on which neonatal research depends the consequences could be severe.

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1 Dawson J. Randomised trials and informed consent in neonatal medicine. *Br Med J* 1986;292:1373-4.

2 Herxheimer A, Zentler-Munro, Winn D. *Therapeutic trials and society*. London: Consumers' Association, 1986.

SIR,—Jonathan Glover's leading article (19 July, p 157) raises important issues on the subject of informed consent in MRC trials. I accept the principle that all patients have a right to be informed and should participate in trials voluntarily.

The example quoted in the leading article seems fairly straightforward. Cancer of the prostate is generally not an immediately life threatening disease, and there is no rush to institute treatment. The two forms of treatment being compared are radically different so patients should be made aware of the alternatives and should be asked to provide informed consent.

However, consideration of the MRC trial for treatment of acute leukaemia is much more difficult. Patients with acute leukaemia have an illness which may prove fatal in the short term and the treatments being compared are extremely similar, precisely the same drugs for remission-induction being given to the patients but simply in a different dose schedule. Most patients have their own preconceived ideas of leukaemia and the initial impact of the diagnosis can be devastating. The hazards of toxic chemotherapy programmes then have to be faced. Do we have to inflict further trauma by raising genuine doubts about the effectiveness of treatment? Whose best interests are being served then?

Jonathan Glover implies that the difficulty in spelling out a grim prognosis is used as an excuse for violating the informed consent requirement. A grim prognosis can still be spelt out, particularly with acute leukaemia, and informed consent obtained, but I cannot agree that this is the most appropriate time to raise doubts in a patient's mind by references to "research." Undoubtedly, better patient education is required, but few of us can deny that there are patients for whom the mention of "research" immediately raises fears of being used as a "guinea pig." This is a difficult issue to tackle at the best of times with a chronic and relatively benign illness but becomes particularly difficult in the context of malignant disease.

I also fail to understand the preoccupation with consent forms. A signature on a consent form does not make a patient any better informed and is positively disadvantageous. The standard surgical consent form is seen as an absolving of responsibility on the part of the doctor should complications ensue and surely this is not the impression we want to convey before treating someone with malignant disease.

Patients should be informed that there are alternative forms of treatment being compared for the disease, but the problem arises with the use of words such as "trial" or "research". It should be made clear to all patients with malignancy that the treatment they are to receive is still the best currently available. Clear rules are required for the protection of patients but they also have to be flexible rules. I could not agree more that "the exceptions need fuller debate."

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SIR,—Jonathan Glover clearly highlights several important issues on informed consent arising from the debate over the MRC's policies on clinical trials. In the tendency to focus on legal and ethical aspects Dr Glover and many others concerned in the debate about informed consent typically overlook some fundamental empirical questions.

For example, do patients want to know about potential treatment risks? How does such risk disclosure affect their ability to make an "informed" decision? How do pain, fear, and hospitalisation affect patients' recall and comprehension of

information? What are the effects of doctors' own emotions on the way they communicate information to their patients? What are the differential effects of risk disclosure on medical outcome?

Until we can properly address these questions blanket policies on informed consent seem less and less valid or realistic. A rigid policy in favour of "full disclosure" (if indeed there is such a thing) clearly violates the needs of patients who do not want such information. Yet to adopt a flexible approach means that doctors must learn to live with their own uncertainties and be prepared to spend more time exploring the needs of individual patients.

As patients we must also recognise that there are costs (as well as benefits) of "fully informed consent"—namely, fear and uncertainty. The costs to both patient and doctor could be minimised by improving the quality of the communication between them. This aspect is expressed admirably by Brewin.¹ There is a substantial body of empirical evidence (King JB, unpublished paper for the Central Oxford Research Ethics Committee, Oxfordshire Health Authority) which could help to move the informed consent debate towards a greater real consideration of what is best for the patient.

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1 Brewin T. Truth, trust and paternalism. *Lancet* 1985;iii:490-2.

Randomised trial of preterm breech delivery

SIR,—Mr P B Terry and Dr D J Lloyd (12 July, p 138) draw attention to the need for multicentre collaboration if a randomised controlled trial of elective versus selective use of caesarean section for delivery of preterm infants presenting by the breech is to be of sufficient size. They might also have pointed out that the obstacles to such studies have been successfully negotiated in other specialties. For example, on the day that their letter was published a trial (ISIS-1) was reported that involved over 1600 patients with suspected myocardial infarction recruited from 245 collaborating coronary care units.¹

As long ago as 1981 the need for a trial of elective caesarean section for preterm breech delivery was recognised²; this call was reiterated last year by a study group of the Royal College of Obstetricians and Gynaecologists.³ A protocol for a European trial, prepared by Professor Piet Treffers from Amsterdam, was later endorsed by the Royal College of Obstetricians and Gynaecologists. Furthermore, the issue of preterm breech delivery was a feature of the inaugural meeting of the European Association of Gynaecologists and Obstetricians, which took place in London this summer.

The intentions are good, but actions speak louder than words. When will obstetricians begin to take concerted action, similar to that of the many cardiologists who collaborated in the ISIS-1 trial, to address this and other important and longstanding questions that demand collaboration in multicentre trials?

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1 First International Study of Infarct Survival Collaborative Group. Randomised trial of intravenous atenolol among 16 027 cases of suspected acute myocardial infarction: ISIS-1. *Lancet* 1986;ii:57-66.

2 Crowley P. Mode of delivery and survival in babies weighing less than 2000 g at birth. *Br Med J* 1981;282:71-2.

3 Smith ML, Spencer SA, Hull D. Mode of delivery and survival in