Informed consent

SIR,—The article on informed consent in randomised clinical trials, with special reference to breast conservation (2 April, p 1117) summarises well the dilemma of whether a surgeon should enter a trial to establish the effectiveness of a new treatment which has not yet been accepted or whether he should use the new treatment believing it to be better but not having absolute evidence from a prospective randomised trial.

In stage I carcinoma of the breast I believe that lumpectomy with or without radiotherapy is the most acceptable treatment, and in most cases, but with some exceptions, I would not be willing to subject my patients to a simple mastectomy. The words "believe" and "acceptable" are deliberately chosen because surgeons are fully aware of the controversy, the lack of evidence, and the need for trials. Informed consent in my present state of thinking would lead to the patient refusing to enter the trial. I therefore cannot enter a randomised trial.

Similarly, in cases of squamous cell carcinoma of the oesophagus I do not know what the best treatment is. This has prevented my joining the necessary randomised trial comparing the "new" treatment of radiotherapy with surgery in tumours less than 5 cm long organised by Mr L R Celestin because the long term survival figures with radiotherapy appear similar to those with surgery and the operative mortality whether it be 1%, 10%, or 30% is avoided. In this disease the decision is influenced greatly by the mortality of major surgery, and after seeking informed consent in my practice the patient would probably refuse the randomised chance of having surgery and opt for radiotherapy.

In both cancers there is doubt about the normally acceptable operation and a randomised clinical trial must be done to test the "new" treatment, but how can those surgeons who think it is not justified to continue the old form of treatment contribute. Would it be possible for their patients to be carefully assessed in a manner similar to a trial to act as a data base for the new treatment?

In 1978 there were 3863 deaths from oesophageal cancer and 1000 oesophagectomies were done. About 25% of these operations were probably done for early tumours suitable for entry into a clinical trial—that is, 250 a year. In 1978 21 768 patients died from breast cancer and 13 800 mastectomies were performed, of which the minority would have been for stage I disease. The total number of patients suitable for entry into randomised clinical trials is small.

We already register every case of cancer. Should we record every operation performed for cancer and should every patient with cancer enter a trial of treatment so that there is one prospective randomised trial comparing old and new as well as properly collected data available for both the old and the new treatments, which might possibly be of use for comparison? In breast cancer this would then imply that there are always three groups on trial simultaneously: (*a*) a randomised trial comparing old versus new; (*b*) all patients treated by simple mastectomy and radiotherapy; and (*c*) all patients with a lumpectomy and radiotherapy. Similarly, in oesophageal cancer there would be three groups: (*a*) a randomised trial of surgery versus radiotherapy; (*b*) operations done by the group of surgeons who do not have available or do not trust radiotherapy; and (*c*) results from those who preferentially use radiotherapy. This method would educate and satisfy most surgeons, but not necessarily all statisticians, and it could be achieved only by persuasion not compulsion.

RICHARD EARLAM

The London Hospital,
London E1 1BB