Personal View

"All operations are elective—the patient always has a choice."
The Master of the Rolls, 1984.

A short time ago I was in Dublin for the bicentenary celebrations of the Royal College of Surgeons in Ireland and ruptured my right Achilles tendon. I was due to fly back the following morning and so did not see an orthopaedic surgeon until I arrived home. I was waiting—with two surgical friends—for him to arrive when one of them pointed out that there are two ways of treating a ruptured Achilles tendon, suture and plaster or plaster alone. Which did I favour? My immediate reaction was "I will leave it to him." My friend then suggested that this would be the reaction of most patients and added "Patients come to us because they believe we know how to treat them. Now, you have coordinated quite a lot of random control clinical trials and I want you to tell me what your attitude would be if, when the orthopaedic surgeon has examined you, he tells you that he does not know which way is best but is taking part in a multicentre trial and wishes to randomise you to one or other treatment."

My immediate reply was, "He is the specialist, he is supposed to know how to treat a rupture of the Achilles tendon." On the other hand, I have been organising controlled clinical trials for over 10 years and I know that there are few circumstances in which one treatment, and one treatment alone, is correct. On consideration, therefore, I had to say that I could never look myself in the face again if I said that I would not agree to randomisation. In the event, that decision was not called for as the orthopaedic surgeon advised operation.

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While recovering I thought more about it. We are not talking about giving consent to treatment, we are talking about consent to randomisation. The first is obligatory, the second controversial. A lot has been written and said about "informed consent" in which the two meanings have been used as if they were synonymous. Perhaps this is because there are still people who are not ready or willing to accept that they are two totally different things.

Two eminent professors of surgery have recently expressed views on informed consent to randomisation in these pages. One I think could be regarded as the leading protagonist of the multicentre controlled trial; the other, on occasion, the devil's advocate. The former is concerned in a trial of lumpectomy with radiotherapy versus mastectomy for carcinoma of the breast, and has recently suggested a trial of partial versus total gastrectomy for carcinoma of stomach. The latter pointed out that informed consent must inevitably be incomplete and that the request for consent to randomisation can upset the doctor and patient relationship. In addition, there are aspects of clinical surgery that are simply not amenable to the techniques of the random control trial. As Marcia Angell wrote in the *New England Journal of Medicine* "Not all problems have solutions."

Technical matters, such as the direction of an abdominal incision

and the method of closure, the suture material, and the prophylactic antibiotic to be used lend themselves to testing by random control clinical trials provided that the surgeon has told the patient the necessity for and the nature of the operation, and provided that there is no reason to presuppose that one treatment regimen is better than another. In these circumstances the patient is not affected by the randomly allocated instructions and it is not necessary to ask for consent to randomisation.

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It is a different matter, however, when the random instructions are to carry out total or segmental mastectomy for carcinoma of the breast, excision of a limb sarcoma or amputation, radical prostatectomy for carcinoma or transurethral resection, or total or partial gastrectomy for antral carcinoma. In these cases (and indeed if one arm of the trial demands the prescription of toxic drugs or the giving or withholding of radiotherapy) the question surely is—is it proper to obtain consent only to the treatment to which the patient has been allocated, or should the patient be informed that his or her treatment is being decided at random? Should the patient also be told that there are alternative treatments available, even though these are not part of this particular trial?

It is not difficult to understand why some doctors would shy away from this type of confrontation with patients who are of necessity under a lot of stress. I suspect also that the rates of accrual to such trials might be even lower than they are now, detracting from their value to such an extent that any results that they produce will be worth little or nothing because the number of eligible patients excluded will outweigh the number who complete the study protocol.

In my case if the condition under consideration had been breast cancer I would not have agreed to be randomised to one of only two of the numerous possible regimens, none of which has been convincingly shown to be any better than the others; I would have requested the least noxious and the least mutilating.

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I realise now that there are two totally different things: academic discussions about informed consent to randomisation and personal informed consent. On balance, I think that I would rather not know that my treatment—be it medical or surgical—was decided by the toss of a coin. I am sure that my orthopaedic surgeon—had he been concerned in a clinical trial—would have applied the highest ethical standards to the protocol, that he would only be taking part in a trial if he was truly uncertain which treatment was better and that he would not knowingly recommend a treatment that was not in my interests. All in all, however, for my own peace of mind, I would rather say "I leave it to you, doctor."

MARY EVANS
Research coordinator

Scarborough