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Informed consent

In this issue (*Can J Surg* 2005;48:271-2), Bernstein provides a provocative view of the consent process involved in randomized clinical trials. He argues, with some success, that patient consent in randomized clinical trials is not truly informed and that investigators must approach their subjects with great care. I would like to add to his view.

We all recognize that some surgical or adjunctive procedures are not suitable for randomized clinical trials. For example, in open fractures of the tibia, wound irrigation and debridement plus systemically administered antibiotics are accepted treatment; therefore, a randomized clinical trial to compare surgery to no surgery or antibiotics to no antibiotics would be inappropriate. However, the decision on the type of antibiotic, the dose and duration of administration might be suitable. The challenge in multimodal therapy is to pick the therapy that is appropriate for randomization and ensure the remainder of the treatment remains the same. From a therapeutic perspective, this is simple; however, patient (subject) comprehension of the difference between the 2 treatment regimens may be incomplete because of the complexity of the information, the effects of injury and analgesia, and the relative urgency of the decision: "we have to go to the operating room soon." In this type of situation the patient may not have time to absorb all the information available, leading to a lack of truly informed consent. Of course, in the urgent surgical situation, even patients not participating in clinical trials have an incomplete understanding of the risks of the surgical procedures being recommended, which will affect the 3 critical areas of

disclosure, capacity and voluntariness.

All investigators in clinical trials want potential subjects to participate. Randomized clinical trial designs are carefully constructed to ensure adequate numbers of subjects to meet power analyses, account for dropout rates, etc. Therefore, there is a very human tendency for the treating physician to promote participation in the trial as a possible benefit to the patient. This tendency is clearly inappropriate and should be resisted. Recognizing this tendency, what steps should be taken to ensure that no harm comes to patients if they participate in the trial? What are your obligations to your patient?

First and foremost you must be satisfied that the trial is well designed and, to the best of your knowledge, poses no risk to your patient. As Bernstein points out, it is impossible to predict all of the potential complications of a new therapy, but it should be possible based on your expert knowledge to assure the patient with some certainty that the treatment he or she might receive will not be harmful. Second, and equally important, you must ensure that the details of the trial are clearly defined in a written document that you explain to the patient and then leave with the patient and family to ensure maximum disclosure. Finally, there must be no question in your mind or that of the patient that participation in this trial is truly voluntary and that patient care will in no way be compromised by unwillingness to participate in the trial.

As Bernstein notes, there are significant issues around the consent process in randomized clinical trials for elective surgical procedures; these issues are magnified in trials designed for acute surgical situations.

As always, reader comment and reports of experiences are welcomed.

James P. Waddell, MD
Coeditor