Editorial

The Experience of Trial Participation

The demand for evidence about the effectiveness of treatments has led to the increasing dominance in funded health services research of the randomized controlled trial (RCT). The RCT is widely recognized as the gold standard within clinical research. It is the most effective method available to minimize bias and provide valid answers to important clinical questions[1]. However, there is a growing awareness of issues associated with the quality of trials and their results, including questions about precision, bias and validity[2]. Textbooks and reports in journals such as this focus on the design, methods, and results of trials[3-5], suggesting that each decision in the planning and design of a trial, from selecting the intervention, the population, and the aims of the trial, occurs in isolation and according to standard rules.

However, trialists are becoming increasingly aware that decisions such as these may influence the behavioral dynamics of participation (of both recruiting clinicians and the eligible patient population) and may in turn affect the internal and external validity of a trial[6]. Thus both recruiting clinicians and participants are a potential source of bias.

Surprisingly, so far little research has examined the patient's perspective of participation, and studies that have been conducted have tended to use hypothetical scenarios to determine willingness to participate among the public, potential trial populations, specific treatment groups, or racial and ethnic groups often underrepresented in trials, and the types of trials examined have predominantly been those for rare conditions (such as oncology)[7] or trials that present specific ethical issues, for example pediatric trials[8]. Few studies have examined trials for common or chronic conditions. One exception is Pope, *et al*[9], who point out in this issue that there is "a paucity of research on understanding (and patients' perceptions) of the consent process in clinical trials involving patients suffering from chronic diseases." While the authors must be commended for being one of the few to examine recall and understanding of informed consent for common chronic conditions, more studies are needed that explore the participant's perspective.

There is a need for studies that do more than point out the flaws in current practice. The provision of information occurs within a social context, with trust and the quality of the doctor/patient relationship important. Attitudinal and psychological barriers, such as trust and the impulse to disregard potential risk, mean that even strict informed consent procedures do not guarantee understanding.

Thus there are both conceptual and methodological problems with many of the studies, such as Pope, *et al*, that examine informed consent. One of the central problems is the difficulty of determining when informed consent has actually been achieved. The majority of studies such as this one are not from the patients' perspective and are based on recall rather than understanding. Often these studies fail to examine or define how these participants, clinicians, and researchers understand trial concepts.

There is a small but increasing number of studies focusing on the perspectives of actual participants in trials, asking them to describe their experiences of participation and reflections on their motives for taking part, using in-depth, semi-structured interviews. There may be resistance to the use of such qualitative methodologies; however, Snowdon, *et al*[8], Appelbaum, *et al*[10], and Featherstone and Donovan[11,12] have shown that approaches such as this can provide trialists with important insights into the practical barriers/problems of providing informed consent.

In addition, there are a host of issues around the conduct and "natural history" of trials that may impact on the quality of the trial and that have yet to be adequately understood. These include practical, social, ethical, and study design issues[13-15] such as the nature of the organizational context and everyday working practices that may influence the precision and validity of a trial.

An examination of both the patients' and recruiting clin-

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icians' perspectives of trial participation is crucial for both the ethics of running a trial and the validity and reliability of their findings. While the impetus to improve the process of providing informed consent, the experience of trial participation, and the reliability of trials must come from those running common pragmatic trials for common chronic and non-life threatening conditions such as arthritis and rheumatism.

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