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Therapeutic misconception and the appreciation of risks in clinical trials

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Abstract

Studies repeatedly have shown that clinical research subjects have trouble appreciating the implications for their clinical care of participating in a clinical trial. When this failure is based on a lack of appreciation of the impact on individualized clinical care of elements of the research design, it has been called the “therapeutic misconception”. Failure to distinguish the consequences of research participation from receiving ordinary treatment may seriously undermine the informed consent of research subjects. This article reports results concerning appreciation of the risks of trial participation from intensive interviews with 155 subjects from 40 different clinical trials at two different medical centers in the USA.

Working from transcripts of the interviews, every statement of a risk or disadvantage of trial participation was identified and coded into one of 5 different categories. Totally, 23.9% of subjects reported no risks or disadvantages in spite of being explicitly asked about them. Another 2.6% reported only incidental disadvantages such as having to drive a long way to get to the experimental site. In all 14.2% reported only disadvantages associated with the standard treatment (usually side effects). Another 45.8% told the interviewer about disadvantages and risks associated with the experimental intervention (usually side effects). Only 13.5% could report any risks or disadvantages resulting from the research design itself, such as randomization, placebos, double-blind designs and restrictive protocols.

The results of this research suggest that subjects often sign consents to participate in clinical trials with only the most modest appreciation of the risks and disadvantages of participation.

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Introduction

It is now widely accepted that, except in a few specialized situations, a meaningful informed consent is a precondition for the ethical involvement of human subjects in clinical research. From the Nuremberg Code through the Declaration of Helsinki and the adoption of the so-called Common Rule for federally funded research in the United States to the most current debates on research ethics, there has been a growing consensus

that subjects generally should not participate in clinical research without effective informed consent.

What does informed consent require? US federal regulations, encapsulated in the so-called Common Rule (45 C.F.R. 46), require disclosure of at least eight elements:

- The *nature* and *purpose* of the study, including that the study is research.
- The reasonably foreseeable *risks*.
- The foreseeable *benefits*.
- Appropriate *alternatives*.
- The *confidentiality* of the information collected.
- An explanation of any *compensation* available for research with more than minimal risks.

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- Information about how the subject can get pertinent *questions answered*.
- A statement that participation is *voluntary*.

Disclosure of this information merely begins the process of obtaining informed consent. Ideally, subjects then combine the information with their own values and knowledge of their personal situation to make decisions that fit their needs and values. Although it is probably legally not necessary for subjects to understand the information disclosed, if informed consent is to achieve its goals of promoting autonomous and rational decision making (Berg, Appelbaum, Lidz, & Parker, 2001; Faden and Beauchamp, 1986), it is important that subjects not only understand the elements of the disclosure, but also appreciate its applicability to their own situation. Subjects who lack the capacity to undertake any one of these tasks may be incompetent to make a decision about participation. But even subjects with the capacity for these functions may not be able to make decisions in this manner for many reasons (e.g., because the disclosure was inadequate or because of a lapse in attention to the disclosure).

In this paper, we concentrate exclusively on subjects' *appreciation* of the *risks* of participating in clinical trials. Whereas understanding requires an ability to grasp the meaning of the information disclosed, *appreciation* involves the *recognition of the relevance of that information for one's own situation* (Appelbaum & Grisso, 1988). Thus, subjects can understand that half of the participants will receive placebo without appreciating that they too run a 50% risk of not getting active medication (Appelbaum, Roth, & Lidz, 1982). Appreciating how risks may affect one's own situation is obviously only one component of a full appreciation of the consequences of participating in a clinical trial, but it is certainly a critical component. It is difficult to imagine a person making an autonomous, rational decision about participation in a trial without an appreciation of both the risks and the benefits of participation.

The difference between the risks of treatment and of research

There are major differences between the basic ethical requirements of doing research and providing treatment. In the treatment setting, the clinician owes a primary allegiance to the patient's well-being. Fried calls this allegiance the principle of "personal care" (Fried, 1974).

Researchers—even when they are also clinicians and their studies involve the provision of treatment—have a different and competing obligation. They must insure that their studies generate valid data (Shatz, 1990). This obligation derives from the commitment that researchers make to the scientific community, which depends on the validity of their results; to funding agencies, which

support research that will yield generalizable findings; and to research subjects themselves, who are promised that their participation will lead to socially useful knowledge. To be sure, clinical researchers are ethically obligated to guard their subjects from needless harm (Nuremberg Code, 1946). But many of their decisions inevitably are not aimed at maximizing the benefits that specific subjects receive (Churchill, 1980; Hellman & Hellman, 1991). The competition between the need to collect valid data and protecting the best interests of the patient/subject is manifest in many ordinary techniques of clinical research:

- Subjects typically are assigned to treatment conditions randomly, rather than on the basis of an individualized judgment as to which treatment will best meet their personal needs. Although the treatments being randomized may be in collective equipoise (i.e., there may be no evidence that any one treatment is better than another), this may not be true for the individual. For example, Appelbaum et al. (1982) reported that some subjects in their study had previously failed to improve on one of the medications to which they were randomized.
- Subjects may receive placebos for reasons unrelated to improving their condition, something that would not occur in ordinary clinical settings. Although often placebo controls are not used when there is evidence for the effectiveness of one of the treatments being tested, placebo controls are frequently used in studies of depression and other disorders, even when there exist medications that are widely thought to be effective (Carpenter, Appelbaum, & Levine, 2003; Charney, 2000; Miller, 2000).
- Clinicians may be expected to treat subjects without knowing which of the several treatments being provided in the study the subject is receiving and, similarly, subjects may be kept ignorant of which treatment they are getting (a "double-blind" procedure). Although studies in which treating clinicians are blind to the treatment being used typically have protocols available for, e.g., managing side effects, clinicians' and subjects' abilities to recognize physical and mental symptoms as related to the intervention they are experiencing may be impaired by their ignorance about the identity of the treatment involved. In an emergency, the blind can be broken, but researchers are often hesitant to do that because it involves losing a subject from the study and risks biasing the sample.
- A protocol, rather than patients' responses to treatment, will often determine the dosage of medication that an individual subject receives, responses to side effects, and the like. In circumstances in which physicians might increase the amount of medication prescribed in response to a

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