Informed Consent for Clinical Trials: Is Simpler Better?

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Randomized clinical trials are considered to be the gold standard for testing cancer treatments (1). A major difference between randomized clinical trials and the traditional practice of medicine is that, in clinical trials, the treatments offered are assumed to be of similar benefit for patients. The selection of which treatment they will get is made randomly, rather than individually (2). After a predetermined period of time, each patient group is compared, and the advantages (if any) of one treatment over another are examined. The ultimate benefit of the randomized clinical trial process is to advance knowledge and science. The trial itself may or may not benefit the individual patient. In this regard, randomized clinical trials are often antithetical to how everyday medicine is practiced, and the complexity of the trials has to be carefully explained to each participant. Every patient who takes part in a randomized clinical trial must be well-informed and must participate of his or her own volition (3). Making sure that patients are fully informed before they agree to be included in any randomized clinical trial has been, and continues to be, an immense challenge for all who are concerned with the ethical advancement of science (4).

True informed consent goes well beyond that which is on the patient’s signed legal document. The document merely confirms that the patient understands and agrees to all the risks and all the benefits of the proposed treatment(s). To date, there has been limited inquiry into exactly what, and how, patients understand the document they sign (5).

Even limiting our concern to what patients understand of the document is, itself, a major dilemma. The difficulty of informing patients is exacerbated, in part, by the way in which we inform patients who have variable competence in English (often defined as “low literacy”) and patients with limited education or of diverse cultural backgrounds (6). Previous research (1) has shown that physicians are often reluctant to approach potentially eligible patients if they perceive they may have difficulty inform- ing the patients fully. The hope is that, by improving mechanisms for informing all types of people, clinical trials will more accurately reflect the heterogeneity of the U.S. population.

In this issue of the Journal, Davis et al. (7) report on a study they conducted in 1996 at Louisiana State University Medical Center—Shreveport (LSU). They address the issue of how well patients comprehend a standard informed consent form, versus a simplified form. To test the hypothesis that a consent form catering to those with a 7th grade or less reading ability would increase patient comprehension, particularly among marginally literate patients, Davis et al. initially gave 183 persons of varying backgrounds and levels of education either the standard Southwest Oncology Group (SWOG) consent form (written at a 16th grade reading level) or a simplified LSU form (written at a 7th grade reading level) followed by the alternate form. This was given as a hypothetical exercise; none of the participants were actually expected to enter a randomized clinical trial for which the informed consent form was being discussed.

Davis et al. (7) then attempted to measure the general comprehension of the study subjects and their attitudes toward the consent forms. Not unexpectedly, the simpler LSU version was generally reported to be more popular, and the authors conclude that low levels of literacy are associated with preference for the simpler form. While comprehension was directly related to the level of literacy, comprehension was low regardless of which

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form was used. Thus, Davis et al. postulate that lowering the degree of reading difficulty may not necessarily increase overall comprehension. This could have implications for any attempt to increase comprehension based on reading level, particularly given those studies that hypothesize that poor literacy is one of the chief obstacles preventing informed consent (8–9).

There have been a few attempts to improve the patient’s comprehension of consent forms. For example, a survey of endoscopy patients who received an instructional video and an explanation by a physician revealed that patients prefer this method of obtaining consent information rather than a complex, written informed consent form alone. However, comprehension or knowledge relating to the procedure was not directly tested (10). On the other hand, a recent study (11) did, in fact, report a measurable increase in the understanding by prostate cancer patients after they viewed an instructional video that presented different treatment options for managing localized prostate cancer. However, these results were not compared to any control group (e.g., verbal and/or pamphlet instruction). Thus, it is not clear if multi-media can usefully enhance, or even replace, the traditional written consent form for those with low literacy levels.

Some researchers have expressed concern about the lower level of education and reading comprehension of many African-Americans (12). To remedy this situation, it has been suggested that potential study participants could be effectively screened for reading capability by offering them a variety of reading materials at differing comprehension levels (13). Davis et al. (7) report that the comprehension of participants may indeed be associated with their reading ability. However, simplifying the consent form to a 7th grade level did not appear to increase the comprehension of the study subjects. This finding may be important when considering the development of innovative approaches to obtaining informed consent from persons of low literacy, especially in randomized clinical trials that involve complex treatment modalities.

Systematic research could shed light on whether there is uniform preference of consent forms according to ethnicity, cultural background, primary language, socioeconomic group, or among the elderly (14) or the very young (who may be informed by proxy only) (15). However, if not done with great sensitivity, thought, and methodological rigor, any research on this subject has the potential for serious limitations. For example, in the study by Davis et al. (7), if only a percentage of respondents (25%) actually have or have had cancer and no one is eligible for the trial, what confidence can be placed in their hypothetical responses? Should respondents know in advance that they are being tested on their understanding and preference of an informed consent form? Could that knowledge alone affect their responses? Could a preference for a simpler form make it difficult to include all the required information?

The study by Davis et al. (7) illustrates some major methodologic hurdles to be overcome if one is to create solutions to the dilemma of providing comprehensive, but understandable, information to patients with low literacy. For example, while the use of the Rapid Estimate of Adult Literacy in Medicine (REALM) test to determine general reading ability is generally straightforward, the way in which comprehension, attitude, and preference are actually assessed can prove to be much more challenging. Some of the questions listed in Table 2 of the article by Davis et al. (7) suggest that the assessment may have been of memory recall rather than actual comprehension. Reliable and valid measurements are required for studies of this nature. Did respondents understand both the likelihood of gaining personal benefit from the clinical trial as well as the potential severity of any side effects? Might efficient and powerful statistical techniques be more useful to analyze this issue in the future? Answers to these questions may be key elements to obtaining informed consent in novel ways.

Davis et al. (7) do not propose specific solutions to the problem of ensuring greater comprehension of consent forms. They have, however, provided a first step that could and will encourage others to take a systematic approach to solving this intricate, critical issue of relevance to the advancement of science.

References