Confirming Comprehension of Informed Consent as a Protection of Human Subjects

In this issue, Sudore et al.[1] report their efforts to improve comprehension of informed consent information by using a method sometimes referred to as "teaching to goal." In brief, the investigators standardized the informed consent process for an actual study that was evaluating patients' preferences for different types of advance directive documents. The standardized process involved reading a simplified informed consent document that was written at the sixth-grade level to the participants while they read it to themselves. The investigators then quizzed the participants to ensure comprehension of 7 selected aspects of the study. If participants were unable to answer these items correctly, the informed consent process was repeated until participants were able to answer correctly. Initially, only 28% of participants could answer all the items correctly, but this improved to 80% after a second pass at reviewing the informed consent document. Lower comprehension was associated with lower literacy and African American race. The investigators conclude that such modifications in consent might be used with minimal increase in effort. While this may be the case, a series of additional research and practical questions regarding such an approach are readily apparent.

First, the 7 items selected by the investigators were limited to factual items inherent to the study protocol. While understanding these research-related procedures is important, it is unclear both in this particular case and for other types of research whether these are the right types of questions to ask. To meet the ethical goals of informed consent, it is critical that several steps of the informed consent process are satisfied. These steps include ensuring that the potential research participants have adequate decision-making capacity, that they are positioned to make a voluntary choice, that they are given relevant information about the research in a manner that is understandable to them so that they can make a decision about participation and if affirmative, give consent, either orally or by signing a consent document.[2] In this study, the researchers took some efforts to screen out many of those who might lack capacity to consent, and then in common with much of the published literature on informed consent,[3,4] focused their efforts on providing information about the research and ensuring that this was understood before permitting the participants to give consent. Fair enough, but it is also arguably critical for all potential participants to understand that participation is voluntary and that they can leave the research at any time. In addition, for research conducted in health care settings, potential participants need to understand that their decision will not affect their regular medical care. While there is arguably little need to evaluate comprehension of everything mentioned in a consent document, it is unclear why the investigators steered clear of the central ethical requirements that are supposed to be included in these documents (e.g., voluntariness).

While the methods of standardizing informed consent and ensuring comprehension described by Sudore and colleagues are important, it is unclear whether such "big guns" should be used for minimal risk research. Although the details of the time required or nature of the questions being asked of participants in the parent study are surprisingly not found in the simplified informed consent document presented, it is hard to imagine that the study is terribly burdensome. That is, the parent study involving advance directives seems to raise few if any risks, burdens, or inconvenience to participants, save the unlikely possibility that participants may think that these issues are being raised with them because they have a specific medical indication. Nevertheless, the entire consent document is read to the participants, typically twice, and quizzing is used to ensure comprehension. Indeed, in this case, the standardized consent process seems to be more onerous than the parent study itself. That said, for research that poses clear psychosocial, economic, or physical risk to participants, such an approach might be appropriate.

In research that poses such risks to participants, measures that enhance the likelihood of obtaining meaningful informed consent should be used, and a teach-to-goal strategy may be a promising approach. In order to assess whether to implement such an approach, several questions about the process itself should be examined. For example, it would be interesting to assess patients' attitudes toward having a written consent document read aloud to them. Note that U.S. federal regulations for research do not require reading consent documents to all potential participants. In fact, they stipulate that the "form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed."[5] Regardless, reading the consent form verbatim is extraneous to the teach-to-goal process. Would it not be preferable to train research assistants to teach the information, evaluate comprehension, and continue the consent process with additional focused education until the potential subject exhibits comprehension? Reading the text verbatim might be an easy thing to standardize among research assistants, but it only yielded 11% comprehension among subjects without adequate literacy in this study. Similarly, it would be important to elicit patients' attitudes toward quizzing. Not all patients may be comfortable being challenged by questions from those seeking their consent. Indeed, patients with low literacy might be particularly ill at ease when confronted with a test. In addition, it is unclear from the current study whether participants are simply learning to answer the specific items posed to them or are truly comprehending and appreciating the implications of their responses. Further, it will be important to assess the effects of such approaches to consent on the enrollment and retention of subjects. It is conceivable that enrollment rates may go down, but that this may be balanced by better retention that could ultimately be helpful to the quality of the study. Finally, it is necessary to examine whether the person who solicits informed consent can also validly assess comprehension. After all, the person who conducts the consent process has a stake in the outcome. Possibly, these roles should be split.

Address correspondence and requests for reprints to Dr. Paasche-Orlow: Section of General Internal Medicine, Department of Medicine, Boston University School of Medicine, 91 East Concord Street, Suite-200, Boston, MA 02118 (e-mail: mpo@bu.edu).

If this particular approach is found to be acceptable in research that poses more than minimal risk, it will obviously be critical to measure the quality of consent. Nevertheless, developing study-specific methods assessing the quality of consent can require substantial financial and intellectual resources that may not be readily available for all researchers and institutions. Developing measures of the quality of consent alone that are reliable and valid can take years of effort. With this in mind, it may be prudent to use or modify approaches that have already have been developed and are designed to work across different types of research. For instance, the Brief Informed Consent Evaluation Protocol (BICEP) is a means of assessing the quality of informed consent, using a telephone interview immediately following consent, that has good reliability.[6]

Despite this array of unanswered issues, the report from Sudore and colleagues provides evidence that innovations in informed consent can be implemented in the research setting and have scope to work. That is, there is clear evidence that there was a lack of comprehensive understanding of the proposed research even when using a simplified consent form that was read aloud to potential participants. Moreover, they identified potential participants who were deemed ineligible by the fact that they were not able to pass the comprehension test, suggesting that many subjects may be enrolled in research over their own signatures without having given informed consent. In addition, their work supports the assumption found in other studies that those with low literacy are at heightened risk of having difficulty in responding to items aimed at measuring the comprehension of informed consent information. In short, these baseline findings regarding "comprehension" that the researchers found seem unacceptable and indicate that people with low literacy warrant close attention during the informed consent process. Informed consent remains one of the pillars of protection of the rights of research participants. Accordingly, researchers, research sponsors, and those charged with the oversight of research need to develop and fund initiatives aimed at enhancing the quality of consent.—**Jeremy Sugarman,[1] Michael Paasche-Orlow,[2]** *[1]Phoebe R. Berman Bioethics Institute, Department of Medicine at the Johns Hopkins University, Baltimore, MD, USA; [2]Section of General Internal Medicine, Department of Medicine, Boston University School of Medicine, Boston, MA, USA.*

References

1. **Sudore RL, Landefeld CS, Williams BA, Barnes DE, Lindquist K, Schillinger D.** Use of a modified informed consent process among vulnerable patients: a descriptive study. J Gen Intern Med. 2006;21:867–73.
2. **Beauchamp TL, Childress JF.** Principles of Biomedical Ethics. 5th edn. New York: Oxford University Press; 2001.
3. **Sugarman J, McCrory DC, Hubal RC.** Getting meaningful informed consent from older persons: a structured literature review of empirical research. J Am Geriatr Soc. 1998;46:517–24.
4. **Sugarman J, McCrory DC, Powell D, et al.** Empirical research on informed consent. Hastings Center Report. 1999;29:S1–S42.
5. Protection of Human Subjects. 1993 (codified at 45 CFR 46.117.b.1).
6. **Sugarman J, Lavori PW, Boeger M, et al.** Evaluating the quality of informed consent. Clin Trials. 2005;2:1–8.