Advancing the Cause of Informed Consent: Moving from Disclosure to Understanding

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In this issue of the *Journal*, Chan and Sulmasy (1) present the results of a novel attempt to define consensus about informed consent for a common laboratory test in primary care practice, the prostate-specific antigen (PSA). As the authors point out, while virtually all physicians understand informed consent in the abstract, few if any guidelines exist for its actual practice. Variation in state laws and regional practices further this gap between concept and application. Many physicians equate the concept of informed consent with the practice of obtaining signed authorization for surgery or invasive procedures. As a result, any general guidance in law or ethics for what constitutes adequate informed consent in clinical practice is seldom seen as relevant to other kinds of clinical decisions, such as those involving medications or laboratory tests.

Because of these barriers, any attempt to develop guidelines to foster better physician performance in the realm of informed consent is welcome. The authors used group decision-making techniques to lead groups of physicians and patients (and their spouses) to a consensus about the necessary and sufficient data that should be presented to a patient to meet the ethical obligations inherent in informed consent. The result is a clear and concise list of key pieces of information deemed necessary to any discussion of PSA testing. This contribution to the practice of informed consent signals recognition of the need for more explicit guidelines for practice.

However, there are some problems with this study that warrant attention. The conceptualization of informed consent used by the authors is based on a narrow view of the ethical basis of informed consent that focuses on duty-driven disclosure, rather than moving to a model of informed consent that focuses on fostering understanding to promote patient participation in shared decision-making.

The main methodologic issue pertains to the issue of rigor in qualitative research (2). Concepts of internal and external validity, so central to quantitative research, have their corollaries in qualitative inquiry. The construct most closely related to internal validity is trustworthiness, made up of the components of truth, value, applicability, consistency, and neutrality (3). For instance, in this study the most obvious approach to understanding the factual knowledge that patients in a primary care setting desire would be to interview them in that setting. This study drew patients from both primary care and specialty care (urology) settings. Are these patients and their spouses representative of the population of interest? Interestingly, of the 12 patients who had received PSA testing, half had screened positive and had prostate cancer. By this measure alone, this group is not representative of the typical patient undergoing PSA testing.

Similarly, the consensus from physicians on informational needs may have been too heavily influenced by the views of urologists, which may not be representative of the view of physicians most often ordering PSA test, nor of the context in which prostate cancer screening occurs.

Another measure of the trustworthiness of qualitative inquiry is the exhaustiveness of the themes identified. Does the researcher have evidence that all relevant themes have been elicited? There is no specific sample size to ensure that this criterion is met. Rather, the criterion is evaluated by, among other things, the extent to which the researcher finds that themes are repeating themselves, and that further data gathering is yielding redundant, rather than new, information. This study did not meet this criterion. First, both group processes were designed to reduce themes rather than expand them: The methods were consensus seeking, not hypothesis generating. Some important themes may have been dropped or missed in the drive to consensus. Secondly, the group process was influenced by having the patients view an informational video, which may have limited the range of responses that patients provided.

The most controversial aspect of this paper is the assumptions the authors make about the conceptual basis of informed consent. They distinguish two legal models of the amount of information disclosure deemed adequate in informed consent, the "reasonable person" standard and the "professional practice" standard. They did not discuss the "subjective standard," in which the correct amount of information disclosure is determined by what information is relevant to a particular patient (4).

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The authors claim that the professional practice standard is morally preferable, yet offer no argument in support of this. The informed consent literature and law suggest a different opinion. The President's Commission (5) suggested that the aim of informed consent was to foster patient participation in shared decision-making, and that the individual subjective standard for disclosure was morally preferred. Most states use the reasonable person standard as the legal standard for disclosure. The question of the morally preferred disclosure standard is still unanswered.

What should be the ultimate motivation of informed consent? Informed consent in clinical practice has been influenced by a narrow interpretation as motivated by a legal obligation towards full disclosure, rather than an ethical obligation towards mutual decision-making through fostering understanding. Promotion of understanding is the most critical element in the mutual decision-making model of informed consent. The goal is to foster informed participation by the patient, motivated by respect for person, not merely to disclose information to meet a duty. Any discussion of disclosure requirements needs to focus on the informational needs of the particular patient, not an hypothetical "reasonable person." Each patient will have a unique situation, history, educational background, life experience, and set of values; and the ethical basis of informed consent favors guiding disclosure to meeting individual, subjective information needs.

Despite its obvious conceptual centrality to the informed consent process, understanding is not routinely achieved in clinical practice. In a recent study of the adequacy of informed decision making in routine office practice, assessment of understanding was one of the least frequently observed elements (6). Clearly, the idea of informed consent as mutual decision making fostered by promoting understanding has not yet permeated clinical practice.

Chan and Sulmasy have made a valuable contribution to recognizing the need for informed consent around common clinical decisions like PSA testing. However, their focus on a disclosure model does not advance a broader understanding of the ethical foundation of informed consent. Disclosure is not the ultimate goal of informed consent, but merely a means to the end of promoting understanding so patients can be informed participants in shared decision-making.

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