Informed Consent in Clinical Care
Practical Considerations in the Effort to Achieve Ethical Goals

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Informed Consent is a fundamental tenet of the US health care system, rooted in the ethical principles of respect for patient autonomy and enhanced patient well-being. As famously stated in a pivotal court case, “every human being of adult years and sound mind has a right to determine what shall be done with his own body.” Over the past century, that has come to mean that patients should be able to participate in decisions about their medical care, weighing the risks, benefits, and alternatives of a proposed intervention to ensure that the care they receive reflects their goals, preferences, and values.

Although practice varies widely, the current reality of informed consent for medical and surgical interventions often falls far short of stated goals. In many settings clinical informed consent involves a laundry list of potential risks recited to a patient who has already committed to a procedure, followed by the requisite signatures on a form. It is not surprising that patient comprehension is often poor. In a recent study of patients who had just provided informed consent for elective diagnostic cardiac catheterization with possible percutaneous coronary intervention, 88% had mistaken beliefs about the benefits of the procedure.

Without a basic understanding of risks, benefits, and alternatives, patients cannot meaningfully participate in decision making (although providing such information does not guarantee that patients will understand the information, use it, and use it wisely). Although failures of informed consent can have disastrous consequences, more commonly the process simply takes up valuable time and does little to promote patient autonomy or well-being, leading to cynicism of some physicians and patients who view informed consent as a legal nuisance without true meaning, and the conclusion of some scholars that expectations for patient understanding and involvement in medical care are unreasonable.

Accumulating evidence suggests that the informed consent process can be improved. A recent systematic review identified 44 controlled trials of a wide range of interventions designed to improve patient comprehension in informed consent for medical and surgical procedures. While standardized measures of understanding in informed consent are lacking, the majority of these studies showed some benefit. The challenge lies in how to implement these research findings to achieve an agreed-on minimum standard of comprehension, with the overall goal of elevating the process of informed consent in clinical care to fulfill the ethical principles on which the process was founded. In this pursuit, 3 practical issues bear special consideration.

More Is Not Always Better

First, more is not always better. Additional information—whether provided on consent forms or in discussion—does not ensure that this information will be read or understood, and may in fact have the opposite effect (as anyone who has signed a form without reading the fine print can attest). The overriding challenge of informed consent involves synthesizing and simplifying complex medical information in a balanced manner that is meaningful to patients. Thus, efforts to improve informed consent must focus not simply on what information is given, but on how such information is delivered and received. Teach-back, a technique in which patients repeat key elements of a discussion to demonstrate understanding, can help to focus patients (and clinicians) on what is important. In a multicenter randomized controlled trial conducted at 7 Veterans Administration medical centers, teach-back significantly improved patient comprehension after informed consent for elective surgical procedures, while prolonging the informed consent process by only 4 minutes.

Timing Matters

Second, timing is everything. Often in clinical practice, the consent process occurs immediately before the procedure, ie, after the decision to undergo the procedure has been made...
and the time for weighing risks and benefits has passed. Additional information is unlikely to be of value at this point, because patients are psychologically committed to undergoing the procedure. Patients may feel pressure to sign the consent form because the clinician is waiting and feel hesitant to ask questions because a delay may disrupt the flow of a busy clinic or operating suite. If patients are expected to engage in informed consent as a meaningful process of shared decision making, they must be given time for contemplation before having to decide. When the procedure in question is already a fait accompli, informed consent becomes formalistic—little more than a medical Miranda warning. Lengthening mandated expiration times for informed consent while instituting mechanisms to confirm that ongoing consent remains valid may help to facilitate procedure informed consent workflow.

Technology Can Help

Third, strategies that do not involve physicians are needed to improve informed consent. Although the traditional model of informed consent emphasizes a discussion with the physician performing the procedure, and many health care systems limit authority to obtain informed consent to this individual, there is no legal requirement that information be given and consent obtained by a physician. In reality, physician-led informed consent discussions are often ill-timed or ineffective. Given the constraints of clinical practice, this is not surprising. A busy gastroenterologist, for example, may perform 20 endoscopic procedures (accompanied by 20 informed consent discussions) in one day. Is it any wonder that such discussions are less often individualized or patient centered, and more often memo- 
 
ized and rushed recitations focused on collecting the required number of signatures on a form? Although physicians must establish trust and be available to answer questions, interactive, computer-based programs—possibly under the tutelage of a nurse or other educated health care professional—may be more suitable and practical vehicles for improving patient understanding. Such programs, such as the iMedConsent software currently used by the Department of Veterans Affairs hospitals, may free up physicians to address individual patient concerns more effectively. The content of these programs can be updated to include new medical information, as deemed appropriate by expert panels, and personalized to reflect individual patient risks. Mandating the use of interactive technology can help keep costs down and reduce variation in the quality of informed consent across institutions.

If there is real value in obtaining informed consent—if it is more than just a way to avoid legal liability—work must be done to achieve the ethical principles on which informed consent was founded. Reducing the amount of information conveyed while focusing on how and when it is delivered, and using technology to improve traditional consent discussions, can help move informed consent away from a meaningless piece of required paperwork and toward a focus on patient autonomy and well-being.

**REFERENCES**

2. Schloendorff v Society of New York Hospital, 105 NE 92 (NY 1914).