



In the Literature

RECONCEPTUALIZING THE INFORMED CONSENT PROCESS AT EIGHT INNOVATIVE HOSPITALS

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The principle of informed consent—that patients have the right to participate in decisions about their own health care—is a widely accepted tenet of ethics and law. Yet hospitals are challenged to make informed consent understandable not only for their general patient base, but also for the more than 100 million patients with limited literacy, health literacy, or English proficiency, including recent immigrants and the elderly.

A new Commonwealth Fund-supported article, “[Reconceptualizing the Informed Consent Process at Eight Innovative Hospitals](#)” (*The Joint Commission Journal on Quality and Patient Safety*, Mar. 2008), describes the move toward a more patient-centered model of informed consent, and the obstacles encountered, at selected hospitals. “Our case study approach allows us to explore informed consent dilemmas at institutions that have given these issues a great deal of thought and attention,” say authors Jennifer Matiasek, M.S., and Matthew K. Wynia, M.D., M.P.H., of the American Medical Association.

Redesigning Patient Consent Forms

The researchers, working in conjunction with the American Medical Association’s Ethical Force Program, selected eight hospitals from 38 that submitted applications to a call for nominations in February 2005. Selections sought to balance hospital size, type, and populations and focus on hospitals with strong commitments to patient-centered communication (see box on next page).

Among the hospitals visited, there was considerable debate surrounding the role of

patient consent forms. These forms serve two main purposes: to document informed consent discussions between clinicians and patients, and to protect hospitals from liability. The forms, which often contain complex medical and legal language, are typically presented to patients after speaking with their doctor, and rarely invite reflection and further discussion.

All of the hospitals in this study had considered redesigning their consent forms. Some were concerned, however, that simplified forms would take the place of a meaningful discussion with a health care professional. Others suggested that simplified forms could expose hospitals to litigation from patients who claimed they were not informed about procedures and potential risks.

As a result, only a few of the hospitals had succeeded in simplifying their patient consent forms. When simplification did occur, it entailed close collaboration among the hospital’s clinicians, managers, lawyers, and risk managers. Notably, leaders in those hospitals communicated a new goal for the forms: to guide a semistructured discussion about informed consent and provide opportunities for patients to ask questions.

Even with simplified forms, discussions about informed consent may be meaningless, or harmful, if the clinician and patient do not speak the same language. Some hospitals provide trained medical interpreters during informed consent discussions as needed. The authors point out, however, that “examples abound of clinicians using a patient’s family member or a few words

and sign language to get a point across to a patient, only to find out later that the patient has no idea—or the wrong idea—about what has taken place.”

Although translating patient consent forms seems like an obvious solution, few hospitals have done so. Some feared that translating the forms would allow clinicians to abandon the use of medical interpreters. Others were concerned about the accuracy of translated forms. Hospitals that had translated their patient consent forms, or planned to do so, cited an interest in improving patient safety and health care quality, as well as protecting the hospital from liability.

Promising Practices

Some additional innovative practices for improving the informed consent process emerged during the authors’ visits to the hospitals. One strategy involves building systematic redundancies into the process, such as asking patients to explain their understanding of a procedure’s benefits and risks at more than one point prior to undergoing the procedure. This recognizes that full informed consent is a process that often takes more than a single conversation. It also takes advantage of the “repeat-back” strategy—one of the few interventions that has been shown to improve patient comprehension and recollection of health care information. It has been recommended by the Agency for Healthcare Research and Quality, the National Quality Forum, and the Leapfrog Group.

Another strategy involves using interactive tools to enhance the delivery of health information. For example, some hospitals now use computer-based programs that teach patients about conditions and treatment options, document informed consent, and test patient understanding. Staff members at one hospital were concerned about overreliance on computer programs, lest health care professionals neglect the interpersonal aspects of the process as a result.

Finally, a number of the clinicians interviewed urged greater sensitivity to cultural differences regarding informed consent. In the United States, the informed consent process aims to provide patients with enough information—including an extensive list of a treatment’s potential benefits and risks—to make their own health care decisions. However, this practice may be foreign to patients who have had few opportunities to make choices about their health care, or where lawsuits are less prevalent. For patients who are unfamiliar with the concept of informed consent, clinicians should first explain what informed consent means and why the discussion is taking place.

Despite variation in the informed consent process in hospitals across the United States, a more patient-centered model is beginning to emerge. The authors emphasize the need for additional studies to evaluate which practices enhance informed consent and improve health outcomes.

Eight Hospitals Selected for Study

- Caritas Good Samaritan Medical Center, Brockton, Mass.
- Harborview Medical Center, Seattle
- Iowa Health System, Des Moines
- San Francisco General Hospital, San Francisco
- Sherman Hospital, Elgin, Ill.
- University of Virginia Health System, Charlottesville, Va.
- WakeMed Health and Hospitals, Raleigh, N.C.
- Woodhull Medical and Mental Health Center, Brooklyn, N.Y.