

From the Summer 2003 Newsletter

BEST PRACTICES

Click Here for Informed Consent

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VHA is committed to providing a health care environment that respects patients and protects their right to participate in health care decisions.¹ The informed consent process is an essential feature of the delivery of health care and ensures that patients play a decisive role in determining their course of treatment. Meaningful consent requires that every patient be given the information he or she needs to understand the nature of his or her disorder, and the options for care, including risks and expected benefits.

Implementing informed consent is a challenging process, however. Clinicians must convey often complex medical information in laymen's terms, in ways that take into account how illness can affect patients' ability to process information and are sensitive to patients' religious and cultural traditions. And the process must take place in an environment that encourages patients to voice their questions and concerns.

Quality communication is time consuming, and time constraints can threaten to undermine the consent process. Busy clinicians must balance devoting enough time to individual patients to assure that they can play an active, informed role in treatment decisions, on the one hand, and meeting the needs of all patients who seek care, on the other.

To improve the quality of their consent processes, some VAMCs are exploring computer-assisted methods. The National Center for Ethics in Health Care has been charged by VHA leadership to examine commercially available informed consent software, evaluate how facilities are using technology to assist in educating and obtaining informed consent from patients for clinical procedures, and offer recommendations to VHA's National Leadership Board about whether and how VHA should implement computer-assisted informed consent system wide.

Computers can enhance the quality of patient-clinician interaction in many ways. For example, online resources can give clinicians and patients joint access to a vast amount of quality educational material during the consent conversation, information that patients can later review online or in printed form. Descriptions of treatment risks can be standardized and made available during the consent conversation, directly imported into patients' consent forms, and automatically incorporated into their medical records. There's evidence to suggest that computerized presentation can enhance patients' comprehension of information.²

In addition to providing accurate, up-to-date information to patients, programs can be designed to drive the consent process to assure quality, e.g., in such a way that steps are not forgotten or skipped. Thus consent software could prompt clinicians to assess and document the patient's decision-making capacity—and when patients are deemed unable to make decisions on their own behalf, not allow the clinician to record consent or exit the program until he or she has documented signature by the patient's surrogate, and produced a copy of the signed consent form for the patient.

One practical advantage of using information technology to support the informed consent process is that doing so can document consent for medical procedures directly into CPRS. Currently, consents are one of the few routinely produced clinical records that are not generated electronically and stored automatically in electronic form. In most VAMCs, generic, handwritten consent forms are scanned into the document storage system. "Computerizing" consent can eliminate this time-consuming process, and reduce the likelihood that the consent form will be misplaced, separated from the record, and/or not accompany the patient to the procedure. Computerization can also significantly decrease the problem of illegible, incomplete consent forms.

Yet despite their promise, computer-enhanced systems present concerns when deployed in a health care setting. For example, are there enough computer monitors easily available? We know that approximately 60% of veterans have access to the Internet,³ but how does a patient's level of familiarity with computers affect his or her ability to confidently participate in a computerized informed consent process? Are patients less willing to ask questions when conversation is being directed electronically?

There are also concerns with respect to clinicians' responsibilities when using computer technology in the context of informed consent. First and foremost, clinicians must understand that a computer application is a tool to enhance the consent process—it is not a substitute for one-on-one communication with patients.

Just as in other settings, clinicians must adapt information to the individual patient. Identical procedures may present different sets of risks for individual patients depending on their particular medical circumstances, and thus call for somewhat different consent conversations. A computer program cannot replace sound clinical judgment.

Finally, there are "systems" challenges to consider with regard to implementing computer-assisted informed consent in a responsible way in an organization as complex as VHA. Substantive educational, procedural, and risk information contained in the computer database must be reviewed and updated on a regular basis to reflect changes in standards of care and VHA policy, of course. Questions about technical standards across the system must also be addressed.

And important decisions must be made about whether all facilities should be required to use the same, standardized tool, or whether individual facilities may be permitted to tailor portions of informed consent software for use with their patient populations.

The initial phase of the Ethics Center's evaluation of informed consent tools will coordinate the work of groups focused on technical issues regarding available applications, relevant law and policy, and the clinical quality of patient education materials and consent across a range of clinical specialty areas. The Center will synthesize analyses developed by the working groups in a report and recommendations to the NLB Health Systems Committee later this year. Subsequent phases of the project could address planning, pilot testing, and development of national guidance regarding implementation of computerized informed consent.

References:

1. VHA Handbook 1004.1. Informed Consent for Clinical Treatments and Procedures. Available at: <http://vaww.va.gov/vhaethics/download/ICpolicy.doc>
2. Dunn LB, Lindamer LA, Palmer BW, Schneiderman LJ, Jeste DV. Enhancing comprehension of consent for research in older patients with psychosis: A randomized study of novel consent procedure. *Am. J. Psychiatry* 2001; 158:1911–3.
3. Krumhaus S. 2001 National Survey of Veterans, Table 1.5. Available at: <http://www.va.gov/vetdata/SurveyResults/>