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Informed consent for inguinal herniorrhaphy and cholecystectomy: describing how patients make decisions to have surgery

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Abstract

BACKGROUND: We describe how patients perceive the process of informed consent and its influence on decision making for elective surgery.

METHODS: A cohort of 38 patients documented consent for cholecystectomy or inguinal herniorrhaphy using the Veterans Affair's computer-based tool for documenting informed consent for clinical treatment. Participants completed semistructured telephone interviews exploring their attitudes about informed consent, iMed, and the decision-making process. We used qualitative methods to code and analyze the data.

RESULTS: Sixty-nine percent of patients decided to have surgery before meeting their surgeon, and 47% stated that the surgeon did not influence their decision. Although the surgeon was an important source of information for most patients (81%), patients frequently described using information gathered before meeting the surgeon, such as other health care providers (81%) or family members (58%). Most (68%) patients perceived iMed as a legal formality with little influence on decision making.

CONCLUSIONS: Future research should examine whether patient decision making regarding elective surgery becomes better informed if nonsurgeon clinicians connect patients to educational resources such as iMed closer to the time of initial diagnosis and before meeting the surgeon.
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Informed consent has become a central part of the practice of surgery, emerging out of a legal requirement, but expanding to frame the ethical debate about medical decision making.[1] The law of informed consent protects patients' rights to authorize all interventions on their bodies, and physicians are required to disclose relevant risks, benefits, and alternatives so the patient's choice can be informed.[2] Unfortunately, there are many complex barriers to

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achieving this laudable goal,[3–5] and there is substantial evidence that the actual practice of informed consent rarely fulfills its theoretical objective.[6–15] Many investigators have focused efforts on supportive tools for patients and clinicians that might enhance the informed consent process.[16–22] Other scholars look at the preponderance of data and recommend developing a new paradigm for ethical decision making.[23–25] However, despite the extensive debate about the theory of informed consent, there is relatively little research describing how patients make decisions regarding routine surgical procedures.

To support the processes of informed consent, the Veterans Affairs (VA) Administration implemented a system-wide computer-based tool (iMedConsent, Dialog Medical, Atlanta, GA) in 2004 to facilitate the processes of informed consent throughout the VA.[26] iMed is integrated into the electronic medical record and includes more than 1,000 procedure-specific consent forms vetted by national experts and written in language suitable for patients. iMed is a powerful tool for electronic documentation of consent, and it also has great potential as a decision aid and tool for patient education. For example, 2 recent studies showed that iMed improves patient comprehension of procedure-specific risks, benefits, and alternatives.[27,28] However, relatively little is known about the way this tool is perceived by patients or how, if at all, it influences their decision making. We therefore designed this qualitative case study to explore how patients make decisions about 2 common general surgery procedures (cholecystectomy and inguinal herniorrhaphy) and how they perceived the iMed system. Our objective was to broadly explore informed consent and to generate themes and hypotheses about how patients make decisions through the process of informed consent.

Methods

We recruited participants from the General Surgery Clinic at the VA Medical Center in Pittsburgh from October 2009 to August 2010. We included all patients presenting for possible surgical management of inguinal herniorrhaphy or benign biliary disease. To avoid potential bias from previous hernia repairs, we excluded patients presenting with recurrent hernias or new hernias contralateral to a previously repaired hernia. We excluded patients who required surrogate consent, underwent nonelective surgery, could not communicate in English, had uncontrolled psychiatric illness limiting their capacity to participate in the study, were younger than 18 years of age, were imprisoned, or had severe visual impediments that limited their capacity to read written material. We followed up the enrolled patients through their clinical work-up, and if they documented their informed consent to have the indicated surgery we contacted them within 7 days to conduct an open-ended, semistructured telephone interview exploring how they made their decision to have surgery and their experience with the iMed system. Most decisions about surgery were reached in a single visit to the surgery clinic, but in those cases in which further diagnostic work-up was required, we continued to follow up patients over more than one clinic visit until a decision for (or against) surgery was made. The semistructured interview guide consisted of 27 open-ended questions that explored how and when patients made their decision about surgery, what sources of information they used, who influenced or assisted with the decision, and their attitudes about the iMed system. Sample interview questions included the following: "Can you please describe how you made the decision to have surgery?" "Would you please tell me when you made the decision to have your procedure?" "What purpose do you think those [iMed consent] forms serve?"

The guide was multidimensional, allowing the interviewer to explore different topical pathways, depending on how respondents answered previous questions. We pilot tested the interview among 5 patients, later excluding them from the larger study, and revised the script for clarity and the flow of questions.

All interviews were conducted via telephone by a trained research assistant and were digitally recorded for analysis. The research assistant was trained to listen carefully to each interviewee's responses to guide the interview spontaneously to avoid repetition and probe interesting comments. As such, not all questions were asked of all participants and not all questions were asked in precisely the same way or order. By using the "editing style" for qualitative analysis, developed by Miller and Crabtree[29] for use within medical settings, we used an iterative approach to qualitative coding. First, we engaged 2 trained analysts (P.M. and C.N.) with extensive experience in qualitative coding. To ensure the objectivity of the coding, the analysts were deliberately not surgeons and were not involved in the study's design. To identify themes relevant to the research topic, the 2 analysts reviewed a portion of the audio files in consultation with the principal investigator (D.E.H.), who is a general surgeon familiar with the subject matter. After reviewing a quarter of the files, the analysts then met with D.E.H. and the qualitative expert (S.L.Z.) to review and discuss themes, developing a master codebook. Each code was given inclusion and exclusion criteria along with representative quotations. Each analyst then coded the interviews with the codebook and then met regularly to discuss and adjudicate all differences. We checked intercoder reliability with κ statistics after roughly half of the interviews were double-coded, and found that the κ value had achieved the necessary minimal intercoder reliability ($>.7$), enabling the analyst to complete the remaining coding independently. The analysts also noted portions of the interviews that were particularly revealing and these responses subsequently were transcribed verbatim. All final codes were entered into a database (Microsoft Access 2007, Microsoft, Co, Redmond, WA) for statistical analysis using SPSS (version 20.0.0, IBM, Co, New York, NY). The presence or absence of each code was