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Do surgeons and patients discuss what they document on consent forms?

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ABSTRACT

Background: Previous studies of surgeon behavior report that surgeons rarely meet basic standards of informed consent, raising concerns that current practice requires urgent remediation. We wondered if the Veterans Affairs Healthcare System's recent implementation of standardized, procedure-specific consent forms might produce a better practice of informed consent than has been reported previously. Our goal was to determine how the discussions shared between surgeons and patients correspond to the VA's standardized consent forms.

Methods: We enrolled a prospective cohort of patients presenting for possible cholecystectomy or inguinal herniorrhaphy and the surgical providers for those patients. Audio recordings captured the clinical encounter(s) culminating in a decision to have surgery. Each patient's informed consent was documented using a standardized, computer-generated form. We abstracted and compared the information documented with the information discussed.

Results: Of 75 consecutively enrolled patients, 37 eventually decided to have surgery and signed the standardized consent form. Patients and providers discussed 37% (95% confidence interval, 0.07–0.67) and 33% (95% confidence interval, 0.21–0.43) of the information found on the cholecystectomy and herniorrhaphy consent forms, respectively. However, the patient–provider discussions frequently included relevant details nowhere documented on the standardized forms, culminating in discussions that included a median 27.5 information items for cholecystectomy and 20 items for herniorrhaphy. Fully, 80% of cholecystectomy discussions and 76% of herniorrhaphy discussions mentioned at least one risk, benefit or alternative, indication for, and description of the procedure.

Conclusions: The patients and providers observed here collaborated in a detailed process of informed consent that challenges the initial reports suggesting the need to remediate surgeon's practice of informed consent. However, because the discrepancy between the information documented and discussed exposes legal and ethical liability, there is an

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opportunity to improve the iMed system so that it better reflects what surgeons discuss and more frequently includes all the information patients need.

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1. Introduction

Informed consent is a legal and ethical imperative for surgery. What began as a legal protection for a patient's right to make decisions has emerged as a general framework for medical decision making [1–4]. However, initial reports of surgeon behavior found that only 15.2% of discussions about proposed surgery described the nature of the procedure along with at least one risk and one alternative [5]. This report and others similar to it suggested that surgeons rarely meet even the most rudimentary standards of informed consent [4–7].

Failure to meet the standards of informed consent undermines the quality of care, violates ethical norms, and can result in legal liability. One way to support high-quality processes of informed consent is to develop procedure-specific consent forms that detail particular risks, benefits, and alternatives [8–10]. For example, in 2004, the Veterans Health Administration implemented a computer-based tool (iMedConsent; Dialog Medical, Atlanta, GA) that provides over 1000 procedure-specific forms, vetted by national experts and written in nontechnical language. VA Central Office considers these forms a minimum standard for informed consent, instructing surgeons to "go through the entire form with the patient and ensure that all information is accurate and edit as needed." With their signature, the surgeons attest that "*all* relevant aspects of the treatment and its alternatives have been discussed (emphasis added)." As implemented, the iMed system is intended to support the legal and ethical imperative for surgeons and patients to discuss material risks, benefits, and alternatives [11].

Although 99% of the procedures performed in the VA are now documented with iMed [12], it is not known how the documents correspond to the discussions actually shared by providers and patients. We also wondered if the implementation of standardized consent forms would produce more detailed discussions than described by previous studies. Therefore, we designed this study to compare the information discussed in the clinical encounter with the information documented on the iMed forms.

2. Methods

We recruited patients and surgical providers from the general surgery clinic at a large VA Medical Center. We included all patients presenting for inguinal hernia or benign biliary disease. We excluded patients who had previous inguinal herniorrhaphy, required surrogate consent, could not communicate in English, or had visual impediments limiting their reading ability. For surgical providers, we included all attending surgeons, physician assistants, and surgical residents who interacted with enrolled patients. All procedures were approved by the institutional review board.

We used portable audio recorders to capture the patient–provider discussions during the clinic visit. For each patient agreeing to recommended surgery, we printed a copy of the corresponding iMed consent document. Most decisions were reached in a single clinic visit, but in cases where further diagnostic workup was required, we continued to follow and record patients over subsequent clinic visits until a decision for (or against) surgery was made. These methods culminated in a copy of each participant's iMed document and a recording of all patient–provider discussions leading up to and including the completion of the iMed document.

A trained analyst then conducted a chart review to abstract each discrete piece of information from each iMed document. The abstracted information included descriptions of the procedure along with relevant risks, benefits, indications, and alternatives. Each item of information was clearly defined, categorized according to content, and added to a database. The database remained open throughout the chart review to accommodate new information items as they appeared. After abstracting information from all the iMed documents, the same analyst abstracted each discrete piece of information uttered during the recorded patient–provider discussions. The analyst also noted if the providers (a) gave patients an opportunity to ask questions and (b) checked their comprehension by asking them to "repeat back" their understanding of the discussion. The final database included a complete enumeration of each discrete piece of information written on the iMed documents or uttered in the patient–provider recordings.

At the level of the individual patient–provider dyad, we used Stata statistical software (StataCorp, LP, College Station, TX) to compare the information on the iMed documents to the information actually discussed during the clinic visit, summarizing the results with descriptive statistics and calculating the 95% confidence interval around the proportion of information documented that was actually discussed. Based on the coding framework developed by Braddock [4,5], we then calculated the proportion of patient–provider discussions in which patients and providers discussed at least one risk, benefit, alternative, indication for, and description of the procedure. Comparisons between provider types (e.g., resident, physician assistant, staff surgeon) were not possible because the analyst could not reliably identify the providers on each recording.

3. Results

From October 2009–August 2010, we enrolled 75 of 165 patients presenting consecutively for possible inguinal herniorrhaphy or cholecystectomy (Figure). Two patients withdrew from the study, 23 patients never signed an iMed document because surgery was not indicated or desired, 1 recording was discarded for poor quality, and 12 recordings were incomplete