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Informed consent for inguinal herniorrhaphy and cholecystomy: Describing how patients make decisions to have surgery¹

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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 VA's computer-based tool iMedConsent. Participants completed semi-structured telephone interviews exploring their attitudes about informed consent, iMed and the decision-making process. We used the qualitative methods of Crabtree and Miller to code and analyze the data.

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Results: 69% 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 healthcare providers (81%) or family members (58%).* Most (68%) 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 non-surgeon clinicians connect patients to educational resources like iMed closer to the time of initial diagnosis and before meeting the surgeon.*

Keywords

Informed Consent; Informed Decision Making; Decision Making; iMed Consent; Decision Aid; Herniorrhaphy; Cholecystectomy

INTRODUCTION:

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.² 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 that the patient's choice can be informed.³ Unfortunately there are many and complex barriers to achieving this laudable goal,⁴⁻⁶ and there is substantial evidence that the actual practice of informed consent rarely fulfills its theoretical *objective*.⁷⁻¹⁶ Many have focused efforts on supportive tools for patients and clinicians that might enhance the informed consent process.¹⁷⁻²³ Others look at the preponderance of data and recommend developing a new paradigm for ethical decision making.²⁴⁻²⁶ 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.

In order to support the processes informed consent in the Veterans Affairs Administration implemented in 2004 a system-wide computer-based tool (iMedConsent, Dialog Medical, Atlanta, Georgia) to facilitate the processes of informed consent throughout the VA.²⁷ iMed is integrated into the electronic medical record and includes over 1000 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, two recent studies showed that iMed improves patient comprehension of procedure-specific risks, benefits and alternatives.^{28,29} 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 two 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 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 non-elective 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, imprisoned, or had severe visual impediments that limited their capacity to read written material.

We followed the enrolled patients through their clinical workup, and if they documented their informed consent to have the indicated surgery, we contacted them within 7 days to conduct *an open-ended*, semi-structured 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 where further diagnostic workup was required, we continued to follow patients over more than one clinic visit until a decision for (or against) surgery was made.

The semi-structured 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: “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 multi-dimensional, 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 digitally recorded for analysis. *The research assistant was trained to listen carefully to each interviewee’s responses in order 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.*

Using the “editing style” for qualitative analysis, developed by Crabtree and Miller³⁰ for use within medical settings, we used an iterative approach to qualitative coding. First, *we engaged two trained analysts (PM & CN) 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. In order to identify themes relevant to the research topic, the two analysts reviewed a portion of the audio files in consultation with the principal investigator (DEH) who is a general surgeon familiar with the subject matter. After reviewing a quarter of the files, the analysts then met with the DEH and the qualitative expert (SLZ) 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 Kappa statistics after roughly half of the interviews were double coded, and found that the Kappa had achieved the necessary minimal intercoder reliability (> 0.7) enabling the analyst to complete the remaining coding independently.* The analysts also noted portions of the interviews that were particularly revealing and these responses were subsequently transcribed *verbatim*.

All final codes were entered into a database (Microsoft Access 2007, Microsoft Co.) for statistical analysis using SPSS (Version 20.0.0, IBM Co.). The presence or absence of each code was recorded for each interview, allowing us to calculate code frequencies. We then summarized the frequencies of codes as a proportion of the respondents and linked the codes to representative quotations.

RESULTS:

We enrolled 75 of the 165 Veterans presenting consecutively to the general surgery clinic for possible inguinal herniorrhaphy or cholecystectomy. Of these, 44 were offered surgery and documented their consent using the iMed system. 41 patients then completed the telephone interview and 38 of the interview tapes were suitable for coding and analysis (See Figure 1). Demographic data regarding this sample was typical for the VA population (results published elsewhere).²⁹

The telephone interviews lasted between 20 and 90 minutes (mean 29 minutes) and most (64%) were completed within 48 hours of the decision to have surgery. The mean delay from documenting consent and completing the interview was 3.4 days. *Half (50%) of the interviews were double coded, and the mean Kappa across all codes was 0.94, representing what Landis and Koch describe as “almost perfect” agreement (0.81–1.00).³¹ As described above, not all participants were asked or answered all questions because the semi-structured design of our interview guide permitted variation in the interview structure. Therefore the frequencies expressed represent the proportion of patients responding to a particular question; the raw data (numerator and denominator) are shown with each proportion. Most reported proportions are calculated from a sample of N = 36 and should thus be representative of the study sample.* Quotations are shown in *italics* with the participant's age and surgery type indicated in parenthesis (C=cholecystectomy; H=herniorrhaphy).

Timing of decision-making

When asked to describe when they made their decision to have surgery, only 29% [11/38] stated they made the decision after meeting with their surgeon:

I made the final decision after I spoke with the surgeon. I wasn't sure what my options were until they explained it to me. Ever since I discovered that I had this hernia, I knew something had to be done and barring the fact that I wasn't sure what all of the options were, I did know that the major option was surgery (Age 63, H).

By way of contrast, the majority of patients (69% [26/38]) acknowledged making their decision, or at least developing a clear preference for a specific decision, *before* they met the surgeon. For example, some (37% [14/38]) made their decision to have surgery at the moment of diagnosis, seeming to conflate learning the diagnosis and deciding to have surgery: “*The doctor said I had a hernia so I figured I have to go to the hospital and have it fixed*” (Age 55, H). Others (32% [12/38]) made their decision after the diagnosis, but they had developed a preference for surgery before meeting the surgeon, and the surgeon only served to confirm their decision: “*I knew I was definitely gonna have the surgery, I just had a couple questions... talking to the surgeon was sorta like the icing on the cake, it solidified it*” (Age 59, H).

Choice vs. Necessity

Most (78% [29/37]) patients acknowledged that they were free to choose operative or non-operative management of their disease. However, as illustrated above, many patients did not appreciate the opportunity for substantial deliberation after diagnosis and before deciding to have surgery. Confirmation of the diagnosis and the *need* to operate were often perceived *in parallel*, and, as such, nearly one quarter (22% [8/37]) of patients provided answers that seemed to indicate that they did not recognize a choice between operative and non-operative management: “*There is no choice: You either have the surgery or you have this for the rest of your life... I knew right away that I had to, you know, I had to have the surgery*” (Age 55, H).

Assistance in decision-making

Our interview probed patients’ decision making in several related ways, inquiring if anyone helped them make their decision, and if so, who. We also explored the kind of assistance provided by these helpers. The first question asked, “Did anyone help you make your decision [to have surgery]?” Although some (18% [7/38]) clearly articulated a decision-making process independent of external influence, most (82% [31/38]) identified at least one or more people who helped them make their decision for surgery. In response to the question “Can you tell me who helped you?” patients often named more than one helper: The patients’ PCP or other non-surgical providers were most frequently identified as a helper in the decision-making process (64% [22/34]), though the surgeon was also frequently identified as helpful (47% [16/34]). Assistance was also frequently rendered by family and friends (41% [14/34]) or the spouse (29% [10/34]): “Well I had my mother here and she was like, well, I don’t want one [gallstone] to get stuck and you to get jaundice and stuff” (Age 28, C).

A related, but separate question asked, “In what ways did your surgeon influence your decision [to have surgery]?” Many patients (38% [14/37]) described the surgeon primarily as a source of information, but a few (11% [4/37]) claimed that the surgeon actually made the decision for them (as opposed to the patient making the decision). In contrast, nearly half (46% [17/37]) stated that the surgeon had no influence at all: “He didn’t influence anything, he just, it just reassured me that, OK, this is a necessary procedure and I should have it done” (Age 56, C).

Sources of Information

When asked “*Where did you learn the information that you used to make your decision [to have surgery]?*” many patients described more than one source of information. Most patients identified the surgeon as an information source (81% [29/36]) and nearly half (57% [16/28]) stated that the surgeon was the *most important source* of information. However, patients frequently described additional information sources antecedent to the visit with the surgeon. For example, 81% [29/36] described the PCP or the diagnosing physician in the emergency department as a source of the information used to make their decision:

The primary care physician said you need to get that fixed and I said, yeah, it seems like I really ought to, and when the physician in [city] said you really need to get that fixed because there is a small danger of it pushing out and getting twisted that just, you know, just pushed me over the top. And it didn’t take much pushin” (Age 71, H).

Indeed, over one third (36% [10/28]) identified the PCP or other provider as the *most important source* of information: “*It was the PCP come to think of it. He’s the one that talked to me about how they typically do it with the patches or net or screen*” (Age 59, H).

Patients also described information sources outside the medical profession. In fact, over half (56% [20/36]) described their family members as a source of the information used to make their decision to have surgery, and about one fifth (18% [5/28]) mentioned family as the *most important source* of information: “*My mother had gallbladder surgery and my sister so, they kinda told me what’s what, you know, and I checked into it*” (Age 74, C) Other sources of information included printed material (17% [6/36]) or the internet (36% [13/36]), though none of the respondents indicated that either of these were the *most important source* of information.

Approaches to decision-making

Despite the fact that our questionnaire did not inquire directly about decision-making styles, three distinct approaches to decision-making emerged through our qualitative analysis. Some patients articulated the kind of dispassionate, deliberative process that the theory of informed consent presumes to be normative:

I’m a Marine so I’m the type of person you can throw everything out, good, bad, or indifferent, it doesn’t matter and then I can make an informed decision from there. You don’t have to sugar coat stuff, you don’t have the beat around the bush. Give it to me straight (Age 41, C).

However, others described their decision-making process in terms of establishing the trust necessary to proceed with the recommended treatment:

When the doctors were sayin”, “hey this is what you should do” I trust their opinions. They know what they’re talking about and they said, “yeah we believe you should do this, it’ll make your life a little easier”...If they needed anything signed I woulda signed it for „em because I was really comfortable after talking to him, he knew exactly what he was doin” (Age 28, C).

Finally, another group of patients expressed some frustration with the way the formalized consent process extended or reopened a decision they felt they had already made: *“I really wanted to just jump through the hoops that I needed to jump through and get on with it”* (Age 71, H).

Perceptions of iMed

The majority of respondents perceived the iMed system as a legal formality (68% [26/38]): *“It’s a legal thing to keep everybody covered”* (Age 71, H). Most (66% [25/38]) understood iMed as functioning to protect the hospital and surgeon: *“He needs a little protection because if he didn’t have that protection, you know, he could...be hung out to dry”* (Age 41, C). Indeed, only a minority thought that the iMed system was aimed at protecting the patient (13% [5/38]) or enhancing decision quality (39% [15/38]). Nearly half (47% [17/36]) found it helpful, but more as reassurance than as a decision aid:

I kinda, like, had my mind made up at that time. You know, it woulda had to been something in there, you know, really devastating to make me change it. But, you know...I find it helpful and it kinda reinforces the decision I was making. (Age 69, H).

The remaining patients were either neutral (39% [14/36]) with regard to iMed (e.g., *“It’s just standard procedure”* [Age 64, H]) or found it unhelpful (14% [5/36]): *“I wasn’t interested in even lookin’ at it”* (Age 78, H).

DISCUSSION:

The findings of this study suggest that a substantial number of patients electing to have inguinal herniorrhaphy or cholecystectomy make their decision to have surgery before meeting the surgeon and engaging in the formal process of informed consent. *In addition, although they still found the surgeon to be an important source of information, most patients gathered information from a variety of other sources before they ever talked to their surgeon or encountered the iMed system.* We also found that patients describe several different approaches to the informed consent process, including an approach that focuses on the trust between physician and patient. *Attitudes about iMed were mixed with most patients finding it to be a legal formality that at best reinforced the decision they had already made.*

Patients often stress the importance of consent for building trust rather than a weighting of risks and benefits. These findings are similar to those reported by McKneally among patients consenting to esophagectomy³² and cholecystectomy³³ suggesting that patients view the decision to have surgery primarily as a leap of trust rather than a favorable risk benefit calculus. Our data provide further corroborative empirical evidence supporting the observation that the process of informed consent has a broader purpose than merely conveying information about risks and benefits. If informed consent is to be truly patient centered, it may be necessary to develop a diversity of approaches that are sensitive to patient values, goals and preferences *such as building trust*. The current standardized approach to informed consent may not serve all patients equally well, even if it does meet existing legal requirements.

The informed consent process with iMed improves patient comprehension of procedure specific risks, benefits and alternatives. For example, Fink, et al²⁸ found that an enhanced version of iMed improved patient comprehension *from 68% to 71%* over standard iMed by asking patients to “repeat back” the risks, benefits and alternatives before signing the consent document. Indeed, in previously published data from the sample described here, we found that patient comprehension improved from 50% before meeting the surgeon to 60% after documenting consent with iMed.²⁹ However, in both these samples, the *measures of comprehension were designed so that well-informed patients would score close to 100%, and thus the absolute level of comprehension demonstrated by patients in these studies* at the time of informed consent (71%²⁸ and 60%²⁹) was still low.

Findings from this qualitative analysis may begin to explain why our patients’ comprehension was so low: Just to the extent that patients make their decision before meeting the surgeon or reading the standardized iMed document, the window for educating patients has closed, perhaps prematurely. Given the fact that the iMed system is available to any clinician in the VA from any computer, and given the rich resource of information contained in the standardized iMed documents, *future research might examine if patient comprehension and decision-making could be enhanced by prompting clinicians to give patients an unsigned, printed copy of the iMed document at the time of initial referral for surgical evaluation.*

Finally, the VA’s policy for informed consent specifies that it is a process (not an event) that involves multiple clinicians over time from diagnosis through treatment.³⁴ Our data are among the first to suggest that this inter-disciplinary approach to informed consent actually occurs in clinical practice. However, the fact that many patients make their decision based on their interactions with non-surgeons suggests that future research might explore ways of adapting the iMed system to permit more than one clinician to sign the document, thus better reflecting the team nature of the consent process.

Our findings are limited *in several ways. First, the inductive nature of our qualitative methods requires subsequent quantitative research to confirm our primary findings regarding the use of iMed by non-surgeons earlier in the course of diagnosis and treatment.* However, the purpose of qualitative methods such as ours is to *provide rich data from which to generate precisely these kinds of innovative hypotheses for future research. Second, we recruited participants from only a single site and a single group of surgeons. However, the sample size was, in fact, adequate to reach thematic saturation,³⁵ and we plan future work aimed at confirming these findings in a broader sample of sites and surgical specialties. Third, our recruitment strategy focused exclusively on patients consenting to have surgery, and therefore we do not have interview data from patients who decided against surgery. A complete picture of the informed consent process requires examination of decisions against surgery, and we hope to address this limitation in future work. Finally, our findings may be biased by our choice of surgical procedures which, though common, do not present a particularly complex choice between multiple treatment methods as might be found in the treatment of prostate cancer.*

In conclusion, these *findings* provide new data about how patients make decisions about cholecystectomy and herniorrhaphy, suggesting that the optimal window for educating patients may be earlier in the course of care than the initial surgical consult. Our findings also suggest that the process of informing patient is, in fact, shared between surgeons and other non-surgical providers. However, we are careful to note that the dance between physician and patient we call “informed consent” is extremely complex, and further work is needed to clarify and corroborate these initial findings.

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Figure 1:

Recruitment of study sample.

Legend: H=inguinal herniorrhaphy; C=cholecystectomy; U=unknown