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Sources of patient uncertainty when reviewing medical disclosure and consent documentation

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ABSTRACT

Objectives: Despite evidence that medical disclosure and consent forms are ineffective at communicating the risks and hazards of treatment and diagnostic procedures, little is known about exactly why they are difficult for patients to understand. The objective of this research was to examine what features of the forms increase people's uncertainty.
Methods: Interviews were conducted with 254 individuals. After reading a sample consent form, participants described what they found confusing in the document. With uncertainty management as a theoretical framework, interview responses were analyzed for prominent themes.
Results: Four distinct sources of uncertainty emerged from participants' responses: (a) language, (b) risks and hazards, (c) the nature of the procedure, and (d) document composition and format.
Conclusions: Findings indicate the value of simplifying medico-legal jargon, signposting definitions of terms, removing language that addresses multiple readers simultaneously, reorganizing bulleted lists of risks, and adding section breaks or negative space.
Practice implications: These findings offer suggestions for providing more straightforward details about risks and hazards to patients, not necessarily through greater amounts of information but rather through more clear and sufficient material and better formatting.

1. Introduction

The purpose of medical disclosure and consent documentation is to assist patients in making an educated decision about whether to follow through with a recommended treatment or diagnostic protocol [1]. Unfortunately, there is evidence that disclosure and consent forms do a poor job of communicating the very material that they are designed to convey, and that patients struggle to interpret key pieces of information [2–5]. Research suggests that the majority of patients who sign consent documents do not understand the material that has been presented, and almost half do not even understand the nature of the procedure that they are about to undergo [6]. Based on numerous studies, the American Medical Association concluded that a serious mismatch exists between typical patient abilities and the skills needed to understand medical forms [7].

The comprehension barriers in current medical documentation constitute a serious patient safety and quality of care issue. Patients who cannot understand the terminology included in a form, and thus who cannot make sense of what will happen to them and what might go wrong, are fundamentally unable to provide truly informed consent. This is an ethical issue and a practical matter that warrants scholarly attention, so that evidence-based recommendations can be implemented in order to make the disclosure and consent process more informative, effective, and just. Consequently, patient advocacy groups are becoming more determined and active in their efforts to make these forms as user-friendly as possible [8].

1.1. Informed consent as uncertainty management

A vital means of addressing the flaws of the consent process is to improve the readability and comprehensibility of existing disclosure and consent forms, so that legal directives are met but not at the expense of patients' confidence in their care. In order to accomplish this goal, we need to learn more about precisely what patients do not understand. To study this issue, we propose that the practice of disclosing medical risks and obtaining informed consent is a process of communication and uncertainty manage-

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ment. That is, reading a consent form before a medical procedure has the potential not only to reduce but also to increase a patient's uncertainty—about the procedure itself, the possible risks, the desire to follow through with the course of action, and the individual's own ability to use the information presented in the form.

Theories of uncertainty management in health contexts [9,10] conceptualize uncertainty as a person's perception that he or she is unable to explain, predict, or make sense of health-related circumstances or information. Research framed by these perspectives, in particular Mishel's theory of uncertainty in illness, has demonstrated that people experience uncertainty when confronted with ambiguous or inadequate information. For example, patients may be uncertain about the implications of a diagnosis or the specifics of a treatment regimen, or they may be confused about conflicting recommendations. People also experience uncertainty when attempting to navigate systems of treatment and care that are often highly complex [9]. This includes trying to figure out how to access healthcare services and what resources are available for assisting patients with insurance and paperwork.

It is important to advance research on the disclosure and consent process by identifying which aspects of the forms cause uncertainty so that they can be made more user-friendly. We designed this study to assist with a current initiative to revise standardized disclosure and consent forms that are used throughout the state of Texas, USA. Conceptualizing the barriers to patient comprehension in terms of sources of uncertainty, we posed the following research question: What sources of uncertainty do patients report when reviewing medical disclosure and consent documents?

2. Methods

2.1. Recruitment

Participants were 18 years of age or older and fluent in English. Approximately one-third of our sample was recruited from nonprofit clinics in a southwestern United States city that provide care for people who have financial need. We recruited the rest of the sample through traditional advertising methods such as flyers and online classified ads, as well as through network and snowball sampling by research assistants. All procedures were approved by the university IRB and clinic supervisors.

2.2. Participants

The sample was comprised of adults living in the state of Texas ($N = 254$), ranging in age from 18 to 88 ($M = 35.07$, $SD = 14.46$), with 65% of participants being female. They described their ethnicity as African–American (9%), American Indian (<1%), Asian (9%), Caucasian (53%), Hispanic/Latino(a) (29%), Middle Eastern (<1%), and Multi-racial (<1%). The final sample was similar to the makeup of Texas in terms of overall ethnic breakdown [11]. The Newest Vital Sign (NVS) [12] was used to gauge participants' levels of health literacy, i.e., their ability to process and act appropriately on health information. The NVS is an accepted measure of health literacy that demonstrates convergent validity with other standard measures of health literacy such as the Test of Functional Health Literacy in Adults [13]. The NVS is an orally-administered instrument that consists of six questions about a standard nutrition label (e.g., "If you eat this entire container, how many calories will you eat?"). Participants receive a score of 0–6 based on how many questions they answer correctly, with scores of 4–6 typically reflecting adequate health literacy. Scores on the NVS indicated that 29% of our final sample demonstrated low to limited health literacy (scores ranging from 0 to 3).

2.3. Interview procedures

Data were gathered through face-to-face, structured one-on-one interviews. Research team members were trained extensively so that interviews would be as standardized as possible across interviewers. Interviewers asked participants to imagine that they were patients receiving treatment for a health condition, and then gave participants a sample consent form and asked them to read it over as if they were about to undergo the procedure described therein. Interviews typically lasted about 25 min. Each participant received a $10 gift card.

To enhance the generalizability of results, we randomly assigned participants to receive one of two types of forms that had the exact same basic structure and language but different details filled in about the particular nature and risks of the procedure—half received a form for cardiac catheterization (insertion of a catheter into the heart), and the other half received a form for laparoscopic cholecystectomy (surgical removal of the gallbladder). The interview packets were randomly sorted ahead of time so that participants had an equal chance of receiving either version of the consent form. Until interviewers pulled out the packet and began the protocol, they were blind to which consent form the participant would see. (The primary difference between the two forms was that certain risks were only applicable to one or the other procedure) A copy of one of the disclosure and consent form protocols is in the Appendix.

Participants were given time to read the entire medical disclosure form. Then, the interviewers asked them to focus on each section in turn and asked them the same question: "Is there anything about this section that you think might confuse people?" Asking participants to respond in a more abstract rather than personal way (e.g., "what is confusing to you?") was a deliberate linguistic strategy designed to make the interview process less face-threatening to participants [14]. Admitting a lack of understanding or feeling incompetent (especially in health encounters) is face-threatening, and the way that questions are formulated has implications for the extent to which people feel at

Table 1
Primary sources of participant uncertainty broken down by sub-sources.

Primary sources of uncertainty (n = thought units; % overall data)	Sources of Uncertainty: subthemes (n = thoughts units)			
Language ($n = 542$; 36.21%)	Medico-legal jargon ($n = 368$)	Lack of everyday language ($n = 152$)	Undefined language issues ($n = 22$)	
Risks & hazards ($n = 523$; 34.94%)	Identified risks ($n = 441$)	Unidentified risks ($n = 73$)	Undefined risks ($n = 9$)	
Nature of procedure ($n = 168$; 11.22%)	Desire for further explanation ($n = 65$)	Confusion about persons involved ($n = 51$)	Additional procedures ($n = 21$)	Blood and anesthesia ($n = 31$)
Document composition & format ($n = 264$; 17.63%)	Syntax & layout ($n = 172$)	Amount of information ($n = 66$)	Assumptions of the form ($n = 26$)	

Note: "undefined language issues" and "undefined risks" refer to instances in which participants mentioned "language" or "risks" but chose to not elaborate on what they meant.