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Medical Informed Consent in the Digital Age: Usability of a Computerized Informed Consent Application among Cardiology and Ophthalmology Patients and Clinician Users

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Abstract

The study evaluated the usability of a computerized informed consent software product, iMedConsent by analyzing the trend in satisfaction ratings using Likert scale to survey questions. Cardiology and Ophthalmology patients and clinician users in a Veterans Affairs Hospital in southwestern United States were provided questionnaires to describe levels of satisfaction upon using the software. Data analysis of satisfaction ratings demonstrated that, iMedConsent is highly usable to patients and clinicians alike. However, patients with less computer knowledge and experience may be less satisfied with using the computer to learn about an upcoming procedure. These differences merit further consideration in the future widespread implementation of computerized consent software.

Keywords:

informed consent, ethics, medical malpractice, Veterans Affair

Introduction

In the US, lack of proper informed consent is listed as a factor in 40%-60% of all malpractice cases. Indeed, failure to obtain proper consent itself ranks among the top ten reasons for malpractice claims [1]. State medical boards investigate patients' allegations of violations involving informed consent. Physicians found to be in violation can face fines, suspensions, or revocation of their professional licenses.

The current standard of obtaining informed consent is a paper-based form. Nonetheless, different studies echoed the need to improve the paper based consent process [2]. In 2003, the Department of Veterans Affairs system adopted computerized informed consent software, iMedConsent based on Department of Veterans Affairs and Joint Commission on Accreditation of Healthcare Organizations standards [3]. It is being positioned for full implementation after undergoing successful pilot studies.

Materials and methods

A questionnaire form was made available to patients who consented to a procedure using iMedConsent in the Cardiology and Ophthalmology Outpatient clinics from May 20, 2005 to Dec 30, 2005 and clinicians who actively use iMedConsent. The level of satisfaction was rated on a Likert scale: 5 – very satisfied, 4 – somewhat satisfied, 3 – neither dissatisfied nor satisfied, 2 – somewhat dissatisfied, 1- very dissatisfied. Each participant was asked to state perceived level of computer knowledge: none (N), beginner (B), average (Av), above average (AA) and advanced (Ad). A space was provided for comments not covered by survey questions.

Frequency distribution was used to identify statistical trends on patients' and clinicians' data. SPSS's nonparametric Kruskall-Wallis test was used to establish statistically significant similarity ($p=0.01$) of satisfaction ratings among different patient groups. To improve statistical power, patients were divided into two major groups. Unskilled computer users (UCUs), consisted of N and B groups and skilled computer users (SCUs), consisted of Av, AA and Ad groups.

Results

Clinicians' comments encompassed software implementation concerns (downtime, does not always load up), design issues (inability to edit, the need for physician's availability, procedures selection) and knowledge problems (related to finding the right procedure).

Table 1 - Percentage of patients (N = 152) who were somewhat satisfied and very satisfied

Survey question	N	B	Av	AA	Ad
Understanding of the procedure	90	92	100	100	100
Understanding of a) risks	83	92	100	100	100
b) benefits	86	92	100	100	100
c) alternatives	75	92	95	100	100
Addressing patient concerns	86	97	98	100	94
Ease on signing	83	91	100	96	100
Computer as learning medium	67	81	95	96	100
Computer- based versus paper-based consent	74	81	98	100	100
Overall satisfaction	86	97	100	100	100

Table 2 - Percentage of clinician users (N =8) who were somewhat satisfied and very satisfied

Amount of time/training needed/spent learning iMedConsent	75
Amount of time needed to complete an informed consent document	75
The information presented to the patient	
a. Indications of a procedure	63
b. Risks/Benefits of a procedure	75
c. Alternatives of a procedure	63
Do you feel that the patient concerns about the procedure have been addressed?	50
Computer as medium for discussion and documentation of an informed consent	63
Anatomical images and diagrams, patient educationmaterialsanddruginformation.	37
Overall satisfaction with the process	63

Discussion

Using a p value of 0.01, there were no statistically significant differences in the satisfaction ratings among different patient subgroups (p range: .03-.166) on overall satisfaction with the process, overall understanding of procedure, understanding of risks, benefits and alternatives involved (Table 1). However, use of iMedConsent as a learning medium and comparison of paper-based versus computer based consent process were met with mixed responses. There were statistically significant differences noted on the low ratings among N and B users (p = .001, .006 respectively) which was demonstrated also by comparison of the UCUs and SCUs (p = .000 and .002).

Five out of eight clinician users expressed satisfaction with using the software. However, only 4 out of 8 clinician users surveyed felt that patient concerns were addressed and only 3 out of 8 were satisfied with the educational support features (Table 2).

Conclusion

Overall, iMedConsent software is a highly usable digital tool for obtaining a patient's informed consent in the outpatient Ophthalmology and Cardiology clinics for patients of all levels of computer knowledge and among early clinician users. However, iMedConsent as an educational tool, showed significant differences in the satisfaction ratings of patients with varying levels of computer skills. This was mirrored in the clinician arm of the study. This finding needs consideration in the future widespread implementation of the software.

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