Medical informed consent in the digital age: Usability of a computerized informed consent application among Cardiology and Ophthalmology patients and clinician users at the Amarillo VA Health Care System (AVAHCS)

By Julito Uy, MD

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Paul Gorman, MD – Capstone Project Adviser

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ABSTRACT

A. Study purposes:

- To evaluate the overall usability of a computerized software application, iMedConsent, among patients in the AVAHCS Cardiology and Ophthalmology clinics and AVAHCS clinician users.
- To compare the relationship between a patient's perceived level of computer knowledge and the satisfaction rating in using the various features of the software.

B. Design:

The two arms of the study yielded 161 completed questionnaires for analysis. The patient arm of the study involved 152 patients in the Cardiology and Ophthalmology clinics at the Amarillo VA Health Care System (AVAHCS) about to undergo procedures that required informed consent using iMedConsent software. The clinician arm involved 8 clinician users (nurse, mid-level practitioners and physicians) who used iMedConsent to obtain consent. All participants were asked to rate their level of satisfaction with the various features of the software on a Likert scale. Participants were then asked to state their perceived level of computer knowledge. Data analysis was performed to recognize overall trends and identify statistically significant differences on the levels of satisfaction among groups of patients with different levels of computer knowledge.

C. Measurements:

Standard descriptive statistics employing frequency distribution was used to identify trends on patients' and clinicians' data. Using a level of significance of 0.01, SPSS's non parametric Kruskall-Wallis test was used to detect differences in satisfaction ratings among patient groups. Analysis of recommendations identified common themes.

D. Results

There were no statistically significant differences among patient groups in overall satisfaction with the computerized consent process ($p = 0.185$). However, statistically significant differences were observed in the level of satisfaction with using the computer as a medium for learning about the procedure ($p = 0.001$) and using computer-based instead of paper forms ($p = 0.006$). Similar trends were also observed when patient users were classified as unskilled computer users (UCUs, $p = 0.0$) and skilled computer users (SCUs, $p = 0.002$). Among clinician users surveyed, a majority (5/8) reported that they were satisfied with the computerized consent process.

E. Conclusion

A computerized consent software product such as iMedConsent is a useful digital tool for obtaining informed consent and is highly acceptable to patients and clinicians alike. However, patients with less computer knowledge and experience may be less satisfied with using a computer to learn about a procedure. These differences merit further consideration in the future widespread implementation of computerized consent software.

I. Background: Review of the Literature

A. Informed Consent, Ethics, and the Law

The Western healthcare delivery system is founded on patient consent. Whether it is expressed directly or implied, consent constitutes a binding contract that allows a physician to legally perform a medical intervention on a patient[1]. Elements of informed consent acceptable both from legal and ethical standpoints include disclosure of the nature of the disease and the proposed treatment, chances of success based on medical knowledge, risks, and possible adverse effects, reasonable alternatives and their chances of success, and risks and potential consequences of not proceeding with the recommended therapy.[2] To ensure that informed consent is valid, the patient must demonstrate competency by expressing an understanding of the nature of the medical intervention and a willingness to accept the risks, benefits, and alternatives involved in the intervention. Except in circumstances allowed by law [2], medical interventions performed in the absence of a valid informed consent constitute a violation of patient rights. Even a routine needle stick for blood-drawing is considered a violation if done without a patient's consent.

In today's highly litigious healthcare environment, physicians cannot afford to neglect proper documentation of informed consent, which can profoundly influence the outcome of litigation. Appropriate disclosure, as documented by the provider in the consent form, is the usual defense for litigation involving informed consent[3]. Failure to provide valid documentation of consent could transform informed consent violations from battery to

medical negligence. The latter carries a more ominous connotation and typically is associated with heavier jury awards once guilt has been established.

Failure to obtain proper consent ranks among the top ten reasons for malpractice claims[4]. Allegations of informed consent violation can be interpreted as negligence in a court of law[1]. A lack of proper informed consent is listed as a factor in 40%-60% of all malpractice cases[5]. A report from Jury Verdict Research's Medical Malpractice Verdict and Settlement Study in 2002 on medical malpractice awards from 1994-2000 found a median award of $500,000 in medical liability lawsuits involving lack of informed consent[6]. An updated 2005 study showed stable trend in informed consent litigations that only one-fourth of cases result in a judgment against the physician[7]. However the considerable time and cost involved in legal proceedings can still adversely affect a physician's practice. Likewise, state medical boards investigate patients' allegations of violations involving informed consent. Physicians found to be in violation can face fines, suspensions, or revocations of their professional licenses. Indeed, even a non-guilty verdict can still damage a physician's professional reputation and career.

Although fear of litigation is considered to be the major factor motivating healthcare entities to obtain informed consent, the process has strong roots in the ethical principles of patient autonomy and respect for persons. Protection of patient rights is embodied in the policies, regulations, and ethical codes of state medical boards, healthcare institutions, medical societies, accrediting organizations, and healthcare facilities. *Autonomy* refers to the patient's right to make free decisions about his or her own health care. *Respect for*

persons requires that health care professionals refrain from carrying out unwanted interventions and that they foster patients' control over their own lives[8]. Believed to be an outgrowth of the consumerism movement, these principles bestow the decision-making capacity upon the patient[9].

In contrast, paternalism, an often-criticized ethical concept juxtaposed with autonomy and respect for persons, bestows the decision-making capacity upon the physician alone[10]. The patient is relegated to a passive dependency relationship with the physician. The popularity of this ethical practice is higher among non-Western cultures that subscribe to the mantra, "Doctor knows best." In an essay on paternalism, Lim[11] expounds on the compromised principle called guided paternalism that grants the physician the charge of making medical decisions by virtue of being "better informed." Often maligned in Western cultures, paternalism is not consistent with acceptable standards of care in which the physician is expected to share medical decision making with the patient and his or her surrogates. Autonomy and respect for persons are sacrosanct ideals that govern interactions with the patient. The physician is required by legal and ethical principles to educate the patient so that he or she can make voluntary informed medical decisions.

During the informed consent process, patient education may occur through formal and informal communication. Teaching aides such as brochures containing the various aspects of planned procedures are common fixture in physician offices. The process usually culminates in a formal face-to-face encounter with the provider or his or her

representative, when detailed discussions are held, questions are answered, and patient apprehension is allayed. Communication is primarily verbal, but usually aided by pre-printed consent forms, which describe the procedure and spell out the risks, benefits, and alternatives of the procedure. Failure to communicate is an important reason for malpractice claims and can be prevented by improving the process of obtaining informed consent and the documentation of the communication that took place[5].

Effective dialogue during the process of obtaining informed consent requires the undivided time and attention of the provider. Despite the best of intentions, physicians in busy practices may be predisposed to taking shortcuts and omitting important details. The communication process can easily become one-way and shift from shared decision-making toward an interaction centered solely on the acquisition and documentation of the patient's signature. In the process, potential risks and alternatives are understated, compromising the patient's ability to make a truly informed decision. Indeed, failure to warn or disclose risks is the most common basis for informed consent litigation[12]. In a health care environment where productivity is a major impetus for workflow design, such propensity to downplay the negative aspects of a procedure flourishes.

B. The state of paper-based informed consent

The current standard of obtaining informed consent is a paper-based form. Health care entities provide standard forms in order to comply with ethical and legal requirements of the informed consent process. Generic standardized consent templates are seen in outpatient clinics that are filled out depending on the procedural requirements.

Customized consent forms, which contain the pre-printed procedure name description, risks, benefits and alternatives designed for specific interventions are common in surgical units. Patients sign the form to indicate an understanding of the procedure and awareness and acceptance of the risks, benefits, and alternatives as described. The signed form is the informed consent document and becomes an official component of a patient medical record.

In the Department of Veterans Affairs (DVA) system, the Computerized Patient Records System (CPRS) contains procedure-specific template under the "Notes" tab, which the providers fill out separately to complete documentation of the informed consent process. Signatures are captured with the traditional paper based consent document, which is subsequently scanned for integration with the CPRS. In a recorded lecture available at the Veteran Affairs training website, Ray Frazier of the VHA's National Center for Ethics in Health Care[13] lists factors that raise the need for improving the paper-based informed consent process. These include lack of compliance with VA policy, incomplete or incomprehensible paper forms, the inefficiency and high cost of scanning, the tendency for paper forms to be lost, the inconsistent information provided to patients, and risk of liability for inadequate consent[13].

In 1994, Bottrell et al[14] conducted a content analysis of 540 paper-based informed consent forms for procedures from randomly selected hospital members of the American Hospital Association. Each form was studied for the presence of the required elements of an informed consent based on Joint Commission on Accreditation of Healthcare

Organizations (JCAHO) requirements, informed consent guidelines in 28 states, and commonly accepted professional standards. The study found that the consent forms were flawed in many aspects. Although an overall 96% compliance rate was observed in stating the nature of the procedure, the numbers were inconsistent; there was greater variation with regard to discussion of risks, benefits and alternatives involved. Indeed, only 26% of the forms studied had complete documentation of all four essential elements of a valid informed consent, 35% had only three, 23% had only two and 14% had only one. The authors concluded that most consent forms studied did not meet accepted standards for informed consent. The study also evaluated the forms for their value as educational tools. Only 14% of the forms were useful in helping patients in their decision-making. In a health literacy study among public hospital patients, a significant majority (59.5%) of the patient surveyed had difficulty understanding the standard informed consent documents[15].

In 1996, Braddock et al[16] investigated the process of communication for informed decision-making in outpatient settings. The researchers reviewed audiotapes of patient-physician encounters and analyzed them for the presence of standard informed consent elements. These include discussion of the patient's role in decision making, describing the procedure along with its benefits, risks, alternatives and uncertainties, assessment of the patient's understanding, and exploration of patient preferences. Of 1,057 encounters and 3,552 clinical decisions categorized by level of complexity, inclusion of all necessary elements was observed among only 10.2% of encounters with surgeons and 7.7% of encounters with primary care physicians. Discussion of laboratory orders was complete in

only 21.85% of encounters with surgeons and 18.9% of encounters with primary care physicians.

Most consent forms contain a list of risks, benefits and alternatives that guide the discussion and help with patient education. To evaluate the effectiveness of this method of educating patients, a study compared the rate of recall between head and neck surgical patients who were educated using a checklist only (the control group) and those who were also given a pamphlet containing illustrations (the intervention group). Chan et al[17] found a significantly higher rate of recall in the intervention group than in the control group (50.3% vs. 29.5%). These results suggest that use of educational materials separate from a form promotes better recall and probably better understanding of the risks, benefits and alternatives.

Electronic media have assumed an important role in patient education. Materials that inform patients and help them make sound decisions has advanced from printed forms to videotapes and discs and interactive computer software. In a Department of Veterans Affairs report, on shared decision-making programs[18], videotapes tailored to specific patient populations for patient education were well received by patient users. In the same report, physician buy-in was identified as one of the factors necessary for full adoption. In a study on the impact of interactive videodisc on prostate cancer screening, Volt et al[19] described better patient decision making that translated to reduction of unnecessary PSA testing. From shared decision-making perspective, electronic decision aids help to

improve knowledge and understanding of procedures.

C. Informed consent and computer applications

Computer technology has radically transformed healthcare delivery and clinician workflow. With automation comes improved efficiency, enhanced productivity, and better record-keeping. A multitude of successful computer applications have been developed for increasing efficiency and safety in the healthcare arena. Computer applications are slowly gaining popularity for obtaining informed consent among researchers and clinicians alike. Interactive and customizable computer programs are finding their way into the health care arena. In a meta-analysis of computer use for patient education, Wofford et al[20] noted a emerging positive role of computers in office patient education. There is currently a multitude of free interactive Internet websites on health care topics available to patients..

In clinical research, a structured multimedia tool can help the understability of informed consent content among patients with potential cognitive impairment. In a paper in 1998, Jimison[21] presented a needs assessment study using focus groups and interview on the potential role of a prototype multimedia system in patient education for obtaining an informed consent. Patients, researchers, and IRB members all expressed agreement on the deficiency of the paper based document. Patient participants felt "using the (prototype) system would be less stressful, because they would have a greater sense of control and could proceed at their own pace."

Computer technology can easily adapt educational materials to accommodate patients' varying levels of literacy. In a study on the use of multimedia for patient education, Campbell et al[18] presented similar consent information to 233 low-income parents with different reading skills in four different formats: written forms, enhanced print, narrated videotapes, and self-paced Powerpoint presentations with audio and visual aids. The multimedia presentation improved information recall among all groups of patients overall. However, among patient with lower reading comprehension, the print format offered slightly better recall among parents.

In a related study, computer-assisted instruction promoted a better understanding of the various aspects of the procedure and higher satisfaction ratings in colonoscopy patients. In a study of 83 patients comparing anxiety, satisfaction and comprehension levels between standard education and standard education plus computer-assisted instruction, Shaw et al[23] noted a positive correlation between satisfaction and comprehension and the use of computer assisted instruction. In a small study of patients undergoing colposcopy, Martin et al[20] compared pre- and post-procedure knowledge of patients who were either instructed by a computerized educational application or given a structured presentation by a nurse practitioner. There was no significant difference in patient understanding about the procedure, although there was more time needed for the computerized education.

Computer applications can also help patient visualize the different aspects of a procedure. Enzenhofer et al conducted a study of gastroenterology and cardiology patients who were

scheduled to undergo invasive procedures. Compared to standardized conversation, a computer-based visualization of the procedure facilitated education and improved patient satisfaction and comprehension. In addition, patients in the study group reported having less anxiety about the procedure[25].

D. Informed consent and the imedConsent software

In the area of informed consent and shared decision-making, one computer software product that is slowly gaining wide acceptance is Dialog Medical's iMedConsent software[26]. It is designed to help standardize the informed consent process. Adopted by the Department of Veterans Affairs system in 2003, it is being positioned for full implementation after undergoing successful pilot studies involving Urology, Ophthalmology, General Surgery and Gastroenterology patients at the Atlanta VA Medical Center[27]. The paper-based informed consent is being slowly phased out as the VA system adopts iMedConsent software as part of its "Electronic Support for Patient Decision" program that began in 2001[27,28]. With the goal of achieving a shared decision-making conceptual model, the informed consent process was targeted initially because of the known fundamental deficiencies of using paper-based forms.

Studies have shown that the acceptance of iMedConsent software among early users has been encouraging. The product simplifies and standardizes the process of obtaining informed consent by using templates that were constructed based on DVA and JCAHO standards. The structure of each template promotes dialogue with the patient and presents a comprehensive discussion of all essential elements of the procedure and covers risks,

benefits, and alternatives in a time-efficient way. The structured format also helps to prevent the physician from omitting important information.

Information contained in the software is updated regularly to incorporate the latest scientific developments. Physician reviewers, including internationally recognized authorities in their fields, ensure that the information is current and accurate. Educational documents are easily retrieved at the touch of a button. Illustrations depicting anatomical structures are readily retrievable and can aid providers in the discussion. Patient education materials in 4th grade readability levels can be printed for home use. There is also a drug information library containing detailed information about drugs of interest. Users can alter the font size to improve readability. Initial usability studies have shown that the software assists physician users in educating patients and creating awareness of the various aspects of procedures and interventions. As a result, patients are more knowledgeable and prepared to make informed medical decisions[26].

Most importantly, the application creates a legal document that is legible, retrievable, verifiable and complete, a defense against medical liability claims arising from failure to inform. A well-executed informed consent is the best protection against the threat of future litigation. A computerized informed consent process is an essential risk management tool.

An advanced feature of the software is the ability to capture patient signatures electronically by using ePad. Produced by Interlink Electronics[29], ePad transforms a

patient's written signature into a digital signal that is stored in the electronic health record. It eliminates the time-consuming work involved in preparing a paper form and then scanning it. Also, a patient's verifiable electronic signature can help validate the authenticity of a patient's identity and consent in case of litigation. There are currently two kinds of ePad devices in use. The ePad-ink device allows the patient to see the signature on the pad during the act of signing, whereas the regular ePad only shows the signature once it is integrated in the final consent document.

In Atlanta VA where pilot tests were conducted, satisfaction ratings were high among early users. Deficiencies in some areas that were identified in the pilot studies were addressed in an updated version of the software. According to the company website, iMedConsent is gaining acceptance a computerized informed consent tool in both the public and private sector. The reported early adopters include 10,000 physicians nationwide. Its use is limited because it is only available in an English version, and the materials are provided only in textual form. In addition, there is no informed consent template available for emergency department use.

II. Hypothesis.

The two main hypotheses of the study are:

- iMedConsent software, an interactive computerized informed consent program is a usable tool for patient and clinician users.
- The usability of the software is comparable among patients with diverse level of computer knowledge.

III. Methodology

A. Setting

This research study was conducted at the Amarillo VA Health Care System, Amarillo Texas from May 20, 2005 to December 30, 2005. The local Amarillo IRB (#3219) and the Amarillo VA Health Care System thru the research and development office (AVAHSC#2005-03) approved the study.

B. Subject population

Cardiology and Ophthalmology patients seen in the outpatient clinics from May 20, 2005 to December 30, 2005, who were to undergo a procedure that required a complete informed consent document, were asked to participate in the study. Inclusion criteria include age 20 years old and above and ability to understand the English language. Fifteen active clinician users of iMedConsent software at AVAHCS comprised the clinician arm of the study. These included urologists, general surgeons, an oncologist, a cardiologist, midlevel providers in the cardiology, surgery urology and oncology services, and a cardiology nurse. The Chief Information Officer of the hospital provided the list of active clinician iMedConsent users.

C. Intervention

i. A one-page questionnaire form (Appendix A and Appendix B) containing 11 simple survey items, without any form of identification was made

available to patients who consented to a procedure using the iMedConsent in the Cardiology (red forms) and Ophthalmology clinics (yellow forms). The software versions used during the course of the study were v3.81 patch 347 and 3.81 389b. Patient signatures were captured by a regular ePad. The survey asks patients to rate the level of satisfaction regarding:

- Overall understanding of the procedure
- Understanding of risks involved
- Understanding of benefits
- Understanding of alternatives
- Whether concerns about the procedure were addressed
- Ease on signing the ePad
- Use of computer as a medium for learning about the procedure
- Comparison of the computerized method with the paper-based form
- Overall satisfaction with the process.

ii. The clinician questionnaire forms were printed in white paper (Appendix C) and were mailed out to active clinician iMedConsent users at the Amarillo VA. Interdepartmental mail system was used for mail distribution and collection. A self-addressed envelope was included in the mailing. Clinician participants were asked about their level of satisfaction regarding:

- Amount of time or training needed or spent learning iMedConsent.
- Amount of time needed to complete a computerized inform consent document
- The information presented to the patient regarding:
    - Indications for the procedure
    - Risks and benefits of the procedure
    - Alternatives to the procedure
- Patient concerns about the procedure being addressed by using the software
- Use of computer as a medium for discussion and documentation of an informed consent
- Added features such as anatomical images, diagrams, patient education materials and drug information
- Overall satisfaction with the process

iii. Each survey form included a checklist on a participants' perceived level of computer knowledge. The patient survey forms included a checklist of procedures confirms the inclusion in the group (Cardiology or Ophthalmology). The clinician survey included a checklist on the participant's profession. A space was included for additional comments

and recommendations for improvement not covered by the survey questions.

D. Measurements

i. 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.

ii. The levels of computer knowledge were: none, beginner, average, above average and advanced.

E. Data Analysis

Standard descriptive statistics employing frequency distribution was used to identify trends on patients' and clinicians' data. In addition SPSS's nonparametric Kruskall-Wallis test was used to analyze the patients' Likert scale scores for statistically significant differences using $p = 0.01$ as the level of significance. The level of computer knowledge was treated as the independent variable. To improve the power, the "none" and "beginner" levels of computer knowledge were grouped into "unskilled computer users" (UCUs) and "average", "above average" and "advanced" computer users were grouped into "skilled computer users" (SCUs). Among the clinician users with eight completed survey forms, standard descriptive statistics employing frequency distribution was used to identify trend. The comments and recommendations were analyzed for common themes.

IV. Results

A. The patient arm

There were 153 completed patient questionnaires, with 152 patient questionnaires acceptable for the study (Appendix D). Of these, 116 were from the Cardiology clinic and 36 were from the Ophthalmology clinic. One questionnaire was not included in the study because of obvious misinterpretation of the keys. As shown in Table 1 and Table 3, the satisfaction ratings are predominantly Likert 4s and 5s. Majority of the patient users (Table 2) considered themselves as average (29.6%), above average (15.1%) and advanced (10.5%) computer users (SCUs=55.2%) while minority considered themselves as none (19.7%) and beginner (25%) computer users (UCUs = 44.7%). Comments and recommendation were scanty among patient users.

Table 1. Distribution of patients' ratings

Survey Question and Rating	1	2	3	4	5
Overall understanding of the procedure	1	1	4	33	112
Understanding of the risks involved	1	2	5	29	112
Understanding of the benefits	1	1	5	32	109
Understanding of the alternatives	1	2	9	37	98
Do you feel that concerns were addressed	1	3	3	27	113
Ease on signing the ePad	2	4	3	27	113
Use of computer as a medium for learning about the procedure	4	4	11	38	83
Computer based consent versus paper based consent	4	0	10	39	83
Overall satisfaction with the process	1	1	4	33	110

Table 2. Distribution of level of knowledge

Level of computer knowledge	Number of patients
None	30 (19.7%)
Beginner	38 (25%)
Average	45 (29.6%)
Above average	23 (15.1%)
Advanced	16 (10.5%)

Comments and recommendations from patients:

- Three patients reported having difficulty with the ePad as their signatures were not visible on the screen at the time of signing.

Table 3. Percentage of patients who responded somewhat satisfied (4) and very satisfied (5)

Survey Question	None	Beginner	Average	Above average	Advanced
Overall understanding of the procedure	90	92	100	100	100
Understanding of the risks involved	83	92	100	100	100
Understanding of the benefits	86	92	100	100	100
Understanding of the alternatives	75	92	95	100	100
Do you feel that concerns were addressed	86	97	98	100	94
Ease on signing the ePad	83	91	100	96	100
Use of computer as a medium for learning about the procedure	67	81	95	96	100
Computer based consent versus paper based consent	74	81	98	100	100
Overall satisfaction with the process	86	97	100	100	100

B. Clinicians arm

There were 8 completed surveys received from the clinician arm of the study. All of them were usable for study. In order not to identify the survey participants, I did not include the demographics of the clinician participants. The majority of satisfaction scores consisted of Likert 3, 4 and 5 (Table 4, Table 5). Four clinicians considered themselves as average users and four considered themselves advanced users. Some clinicians offered comments and recommendations for improvements:

- "Alternative procedures should be those available at the VA. This form is general and lists procedures that may not be available or are available only after other requirements have been meet. Description of some procedures lists more than the test."
- "System always down. Difficult to edit. Not all procedure listed. When it works it

is good."

- "Does not always load up (Software issues). Need ability to edit. Poor selection of procedures, strange method of grouping procedures into specialty areas."
- "Concerned as a midlevel that the consent has to be signed when the doctor is available and not when the patient fully understands the information.

Table 4: Distribution of clinician users ratings

Survey Question	1	2	3	4	5
Amount of time/training needed spent learning iMedConsent	1	0	1	2	4
Amount of time needed to complete an informed consent document	0	1	1	3	3
By using the software, are you satisfied with the information you presented to the patient as to: Indication of a procedure,	0	0	3	4	1
Risks/Benefits of a procedure,	0	0	2	5	1
Alternatives of a procedure.	0	0	3	3	2
Do you feel that the patient concerns about the procedure have been addressed by using the software?	0	1	3	3	1
Use of computer as a medium for discussion and documentation of an informed consent	0	1	2	4	1
Rate your level of satisfaction with the added features such as anatomical images and diagrams, patient education materials and drug information.	0	1	4	1	2
Overall satisfaction with the process	0	0	3	3	2

Table 5. Percentage of clinician users who responded somewhat satisfied (4) and very satisfied (5)

Amount of time/training needed spent learning iMedConsent	75%
Amount of time needed to complete an informed consent document	75%
By using the software, are you satisfied with the information you presented to the patient as to: Indication of a procedure,	63%
Risks/Benefits of a procedure,	75%
Alternatives of a procedure.	63%

Do you feel that the patient concerns about the procedure have been addressed by using the software?	50%
Use of computer as a medium for discussion and documentation of an informed consent	63%
Rate your level of satisfaction with the added features such as anatomical images and diagrams, patient education materials and drug information.	37%
Overall satisfaction with the process	63%

V. Data analysis

A. Patient arm

Using Kruskall-Wallis testing ($p = 0.01$), there was no statistically significant differences in the satisfaction ratings among the five levels of computer knowledge with regard to overall satisfaction with the process, overall understanding of the procedure, understanding of the risks, benefits and the alternatives involved. Within each level of computer knowledge, 75% to 100% of patients were satisfied or highly satisfied. The majority of patients were satisfied that their concerns about the procedures were addressed, and there were no statistically significant differences among the different levels of computer knowledge. Although three participants reported dissatisfaction with use of ePad under in their comments and recommendations, use of ePad was generally rated positively (p range: 0.030-0.414). Inability to visualize the signature on the regular ePad was cited as the reason for the dissatisfaction. The shift to ePad-ink should address this concern.

Use of the iMedConsent as a medium for learning about the procedure was met with mixed responses. Although considered to be still a predominantly positive response, the

levels of satisfaction was lower in users with "none" (67%) and "beginner" (81%) users compared to "average", "above average" and "advanced users" (95%, 96% and 100% respectively). Similar trend among the five different user groups was observed on the question about computer-based consent versus paper-based consent. Participants who considered themselves "none" (74%) and "beginner" (81%) users scored lower than the "average", "above average" and "advanced" users (98%, 100% and 100% respectively). Kruskall-Wallis testing showed statistically significant difference (p = .001, .006) on these two survey questions (Table 6). Statistical analysis of patient groups as UCUs and SCUs produced similar statistically significant differences (p =0.0 and .002) (Table 7).

Table 6: p values of the five levels of computer knowledge

	p values
Overall understanding of the procedure	0.056
Understanding of the risks involved	0.030
Understanding of the benefits	0.055
Understanding of the alternatives	0.166
Do you feel that concerns were addressed	0.143
Ease on signing the ePad	0.166
Use of computer as a medium for learning about the procedure	0.001
Computer based consent versus paper based consent	0.006
Overall satisfaction with the process	0.155

Table 7: p values of UCUs and SCUs

	p values
Overall understanding of the procedure	0.102
Understanding of the risks involved	0.049
Understanding of the benefits	0.098
Understanding of the alternatives	0.107
Do you feel that concerns were addressed	0.414
Ease on signing the ePad	0.166
Use of computer as a medium for learning about the procedure	0.000
Computer based consent versus paper based consent	0.002
Overall satisfaction with the process	0.120

B. Clinician arm

Statistically significant analysis is difficult to perform in a survey with only eight samples. However, except in its use as an adjunct for patient education, the majority of the early clinician users (5/8) expressed satisfaction with using the software. The added features to help educate patients and address concerns did not elicit significant positive impact among clinician users (3/8). Otherwise, the clinician ratings are generally positive. Issues raised in the narrative could be categorized as software implementation (downtime), design (inability to edit, the need for physician's availability, procedures selection) and knowledge problems (related to finding the right procedure).

VI. Limitations of the study

There was no formal validation study conducted on the questionnaires for both the patients and the early clinician users. The number of returned questionnaires from the early clinician users arm is small to attain statistical significance.

VII. Conclusion

Overall, iMedConsent software is a highly usable digital tool for obtaining a patient's informed consent in the AVAHSC's outpatient Ophthalmology and Cardiology clinics for patients of all levels of computer knowledge. Among clinician users, majority reported high satisfaction ratings in using the software. However, as an educational tool, there are significant differences in the experiences of patients with different computer skills, which was mirrored in the clinician arm of the study. This finding needs consideration in the future widespread implementation of the software. Further study is

needed to evaluate the effectiveness of computerized informed consent applications in other clinical settings.

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Appendix A: Patient Questionnaire for the Eye Department

Filling out this form means that you agree to participate in this survey. DO NOT write your name on this form

Procedure (please check):

☐ Cataract Surgery
☐ Posterior Capsulotomy
☐ Diabetic Retinopathy
☐ Flourescein angiography
☐ Peripheral iridotomy
☐ Other:

Key:

5. Very satisfied
4. Somewhat satisfied.
3. Neither dissatisfied nor satisfied.
2. Somewhat dissatisfied
1. Very dissatisfied

a.	Overall understanding of the procedure.	1	2	3	4	5
b.	Understanding of the risks involved.	1	2	3	4	5
c.	Understanding of the benefits.	1	2	3	4	5
d.	Understanding of the alternatives	1	2	3	4	5
e.	Do you feel that your concerns about the procedure have been addressed?	1	2	3	4	5
f.	Ease on signing the *epad*	1	2	3	4	5
g.	Use of computer as a medium for learning about the procedure	1	2	3	4	5
h.	If you have signed the paper consent in the past, how would you compare this computerized method with the paper based form?	1	2	3	4	5
i.	Overall satisfaction with the process	1	2	3	4	5

Level of computer knowledge:

☐ None ☐ Beginner ☐ Average ☐ Above Average
☐ Advanced

Comments/Recommendations for improvement:

_____

_____

_____

Appendix B: Patient Questionnaire for the Cardiology

Filling out this form means that you agree to participate in this survey. DO NOT write your name on this form

Procedure (please check):

☐ Exercise Stress Testing
☐ Stress Thallium Testing
☐ Adenosine Myocardial Perfusion Scan
☐ Tilt Test
☐ Trans-esophageal Echocardiogram
☐ Elective cardioversion

Key:

5. very satisfied
4. Somewhat satisfied.
3. Neither dissatisfied nor satisfied
2. Somewhat dissatisfied
1. Very dissatisfied

a.	Overall understanding of the procedure.	1	2	3	4	5
b.	Understanding of the risks involved.	1	2	3	4	5
c.	Understanding of the benefits.	1	2	3	4	5
d.	Understanding of the alternatives	1	2	3	4	5
e.	Do you feel that your concerns about the procedure have been addressed?	1	2	3	4	5
f.	Ease on signing the *epad*	1	2	3	4	5
g.	Use of computer as a medium for learning about the procedure	1	2	3	4	5
h.	If you have signed the paper consent in the past, how would you compare this computerized method with the paper based form?	1	2	3	4	5
i.	Overall satisfaction with the process	1	2	3	4	5

Level of computer knowledge:

☐ None ☐ Beginner ☐ Average ☐ Above Average
☐ Advanced

Comments/Recommendations for improvement:

_____

_____

_____

Appendix C: Clinician Questionnaire

Filling out this form means that you agree to participate in this survey. DO NOT write your name on this form

Please check one. ☐Physician☐Resident☐Mid-level Provider☐Nurse

Please describe your experience using the imedConsent software using a rating scale:

5. Very satisfied
4. Somewhat satisfied.
3. Neither dissatisfied nor satisfied.
2. Somewhat dissatisfied
1. Very dissatisfied

a. Amount of time/training needed spent learning *imedConsent*
1 2 3 4 5

b. Amount of time needed to complete an informed consent document
1 2 3 4 5

By using the software, are you satisfied with the information you presented to the patient as to:

c. Indication of a procedure? 1 2 3 4 5
d. Risks/Benefits of a procedure? 1 2 3 4 5
e. Alternatives of a procedure? 1 2 3 4 5
f. Do you feel that the patient concerns about the procedure have been addressed by using the software? 1 2 3 4 5

g. Use of computer as a medium for discussion and documentation of an informed consent
1 2 3 4 5

h. Rate your level of satisfaction with the added features such as anatomical images and diagrams, patient education materials and drug information
1 2 3 4 5

i. Overall satisfaction with the process 1 2 3 4 5

Level of computer knowledge:
☐ None ☐ Beginner ☐Average☐ Above Average
☐ Advanced

Comments/Recommendations for improvement:

_____

_____

_____

Appendix D: Tabulation of patient survey data

Question 1: Overall understanding of the procedure

Level of computer knowledge			Question 1					
			very dissatisfied	somewhat dissatisfied	neither dissatisfied nor satisfied	somewhat satisfied	very satisfied	Total
none		Ophtha	0	1	1	3	4	9
		Cardio	1	0	0	3	16	20
	Total		1	1	1	6	20	29
beginner		Ophtha			0	1	7	8
		Cardio			3	8	19	30
	Total				3	9	26	38
average		Ophtha				4	9	13
		Cardio				11	21	32
	Total					15	30	45
above average		Ophtha				0	1	1
		Cardio				2	20	22
	Total					2	21	23
advanced		Ophtha				0	4	4
		Cardio				1	11	12
	Total					1	15	16

Question 2: Understanding of the risks involved

Level of computer knowledge			Question 2					
			very dissatisfied	somewhat dissatisfied	Neither dissatisfied nor satisfied	somewhat satisfied	very satisfied	Total
none		Ophtha	0	2	2	2	3	9
		Cardio	1	0	0	2	17	20
	Total		1	2	2	4	20	29
beginner		Ophtha			0	2	6	8
		Cardio			3	7	20	30
	Total				3	9	26	38
average		Ophtha				5	7	12
		Cardio				9	23	32
	Total					14	30	44
above average		Ophtha				0	1	1
		Cardio				1	21	22
	Total					1	22	23
advanced		Ophtha				0	3	3
		Cardio				1	11	12
	Total					1	14	15

Question 3: Understanding of the benefits

Level of computer knowledge			Question 3					
			very dissatisfied	somewhat dissatisfied	neither dissatisfied nor satisfied	somewhat satisfied	very satisfied	Total
none		Ophtha	0	1	2	1	4	8
		Cardio	1	0	0	3	16	20
	Total		1	1	2	4	20	28
beginner		Ophtha			0	3	5	8
		Cardio			3	7	20	30
	Total				3	10	25	38
average		Ophtha				4	8	12
		Cardio				11	21	32
	Total					15	29	44
above average		Ophtha				0	1	1
		Cardio				2	20	22
	Total					2	21	23
advanced		Ophtha				0	3	3
		Cardio				1	11	12
	Total					1	14	15

Question 4: Understanding of the Alternatives

Level of computer knowledge								
			very dissatisfied	somewhat dissatisfied	neither dissatisfied nor satisfied	somewhat satisfied	very satisfied	Total
none		Ophtha	0	1	3	0	4	8
		Cardio	1	1	1	2	15	20
	Total		1	2	4	2	19	28
beginner		Ophtha			1	2	5	8
		Cardio			2	11	16	30
	Total				3	13	21	38
average		Ophtha			0	5	7	12
		Cardio			2	10	20	32
	Total				2	15	27	44
above average		Ophtha				0	1	1
		Cardio				5	17	22
	Total					5	18	23
advanced		Ophtha				0	3	3
		Cardio				2	10	12
	Total					2	13	15

Question 5: Do you feel that your concerns about the procedure have been addressed

Level of computer knowledge			very dissatisfied	somewhat dissatisfied	neither dissatisfied nor satisfied	somewhat satisfied	very satisfied	Total
None		Ophtha	0	1	1	2	5	9
		Cardio	1	0	1	3	15	20
	Total		1	1	2	5	20	29
Beginner		Ophtha		0		2	6	8
		Cardio		1		5	23	29
	Total			1		7	29	37
Average		Ophtha			0	3	9	12
		Cardio			1	9	21	31
	Total				1	12	30	43
above average		Ophtha				0	1	1
		Cardio				1	20	21
	Total					1	21	22
Advanced		Ophtha		0		0	4	4
		Cardio		1		2	9	12
	Total			1		2	13	16

Question 6: Ease of signing the epad

Level of computer knowledge			very dissatisfied	somewhat dissatisfied	neither dissatisfied nor satisfied	somewhat satisfied	very satisfied	Total
None		Ophtha	1	0		4	5	10
		Cardio	1	3		3	13	20
	Total		2	3		7	18	30
Beginner		Ophtha		0	0	3	5	8
		Cardio		1	2	7	17	27
	Total			1	2	10	22	35
Average		Ophtha				4	8	12
		Cardio				8	24	32
	Total					12	32	44
above average		Ophtha			0	0	1	1
		Cardio			1	2	19	22
	Total				1	2	20	23
advanced		Ophtha				1	3	4
		Cardio				4	8	12
	Total					5	11	16

Question 7: Use of computer as a medium for learning about the procedure

Level of computer knowledge			very dissatisfied	somewhat dissatisfied	neither dissatisfied nor satisfied	somewhat satisfied	very satisfied	Total
none		Ophtha	1	1	1	1	3	7
		Cardio	2	2	2	3	11	20
	Total		3	3	3	4	14	27
beginner		Ophtha	0	0	0	3	5	8
		Cardio	1	1	5	12	9	28
	Total		1	1	5	15	14	36
average		Ophtha			0	4	8	12
		Cardio			2	10	16	28
	Total				2	14	24	40
above average		Ophtha			0	0	1	1
		Cardio			1	2	19	22
	Total				1	2	20	23
advanced		Ophtha				0	3	3
		Cardio				3	8	11
	Total					3	11	14

Question 8: If you have signed the paper consent in the past, how would you compare this computerized method with the paper based form?

Level of computer knowledge			very dissatisfied	neither dissatisfied nor satisfied	somewhat satisfied	very satisfied	Total
None		Ophtha	2	2	1	5	10
		Cardio	2	1	3	11	17
	Total		4	3	4	16	27
beginner		Ophtha		2	3	2	7
		Cardio		4	10	11	25
	Total			6	13	13	32
Average		Ophtha		0	5	7	12
		Cardio		1	11	18	30
	Total			1	16	25	42
above average		Ophtha			0	1	1
		Cardio			4	16	20
	Total				4	17	21
advanced		Ophtha			0	3	3
		Cardio			2	9	11
	Total				2	12	14

Question 9: Overall satisfaction with the process

Level of computer knowledge			very dissatisfied	somewhat dissatisfied	neither dissatisfied nor satisfied	somewhat satisfied	very satisfied	Total
None		Ophtha	0	1	2	2	4	9
		Cardio	1	0	0	2	17	20
	Total		1	1	2	4	21	29
Beginner		Ophtha			0	3	5	8
		Cardio			2	8	20	30
	Total				2	11	25	38
Average		Ophtha				4	9	13
		Cardio				10	22	32
	Total					14	31	45
above average		Ophtha				0	1	1
		Cardio				3	18	21
	Total					3	19	22
Advanced		Ophtha				0	3	3
		Cardio				1	11	12
	Total					1	14	15