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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Objective

- To evaluate the usability of a computerized informed consent software product, iMedConsent, by analyzing trend in satisfaction ratings to survey questions among Cardiology and Ophthalmology patients and clinician users in a Veterans Affairs Hospital in southwestern United States .

- Specifically, this study attempts to demonstrate that positive rating is observed in all levels of computer knowledge.

Background

- In the US, lack of proper informed consent is listed as a factor in 40%-60% of all malpractice cases.
- Failure to obtain proper consent itself ranks among the top ten reasons for malpractice claims with median award of $500,000 from 1994-2003 [1].
- 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.

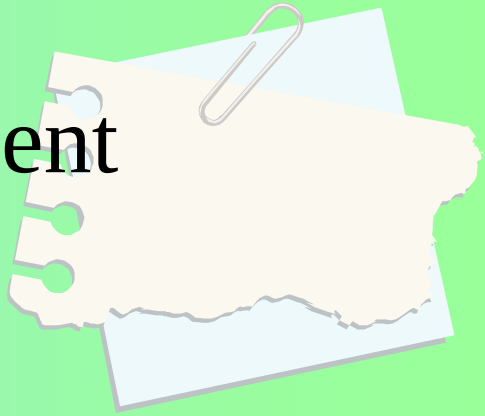
The Paper-based Informed Consent

- The Veteran's Health Administration (VHA) National Center for Ethics in Health Care reported that the paper based consent process does not completely comply with the VA policy on informed consent.[2]

Content analysis of 540 paper-based informed consent forms for procedures from members of the American Hospital Association showed [3]:

- **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.
- Only **14%** of the forms were useful in helping patients in their decision-making.

The Paper-Based Informed Consent



- Only **10.2%** of encounters with surgeons and **7.7%** of encounters with primary care physicians out of 1,057 encounters studied showed inclusion of all elements of informed consent [4].

- Significant majority (**59.5%**) of patients had difficulty understanding the standard informed consent documents in a study on health literacy among public hospital patients [5].

Materials and Methods

- iMedConsent simplifies and standardizes the process of obtaining informed consent by using templates constructed based on US Department of Veteran Affairs and Joint Commission on Accreditation of Healthcare Organizations standards [6].

- Presents a comprehensive discussion of nature of procedure, risks, benefits, and alternatives in a time-efficient way.
- Contains illustrations depicting anatomical structures with patient education materials in 4th grade readability levels.
- Contains a drug information library.
- Comes with a signature capture device ePad.
- Creates a legal document that is legible, retrievable, verifiable and complete, a defense against medical liability claims arising from failure to inform.

- The software versions used were v3.81 patch 347 and 3.81 389b.

Materials and Methods

- Questionnaires provided to Ophthalmology and Cardiology patients and clinician users who use iMedConsent software.

- Level of satisfaction was rated on a Likert scale:

5 – very satisfied,

4 – somewhat satisfied,

3 – neither dissatisfied nor satisfied,

2 – somewhat dissatisfied,

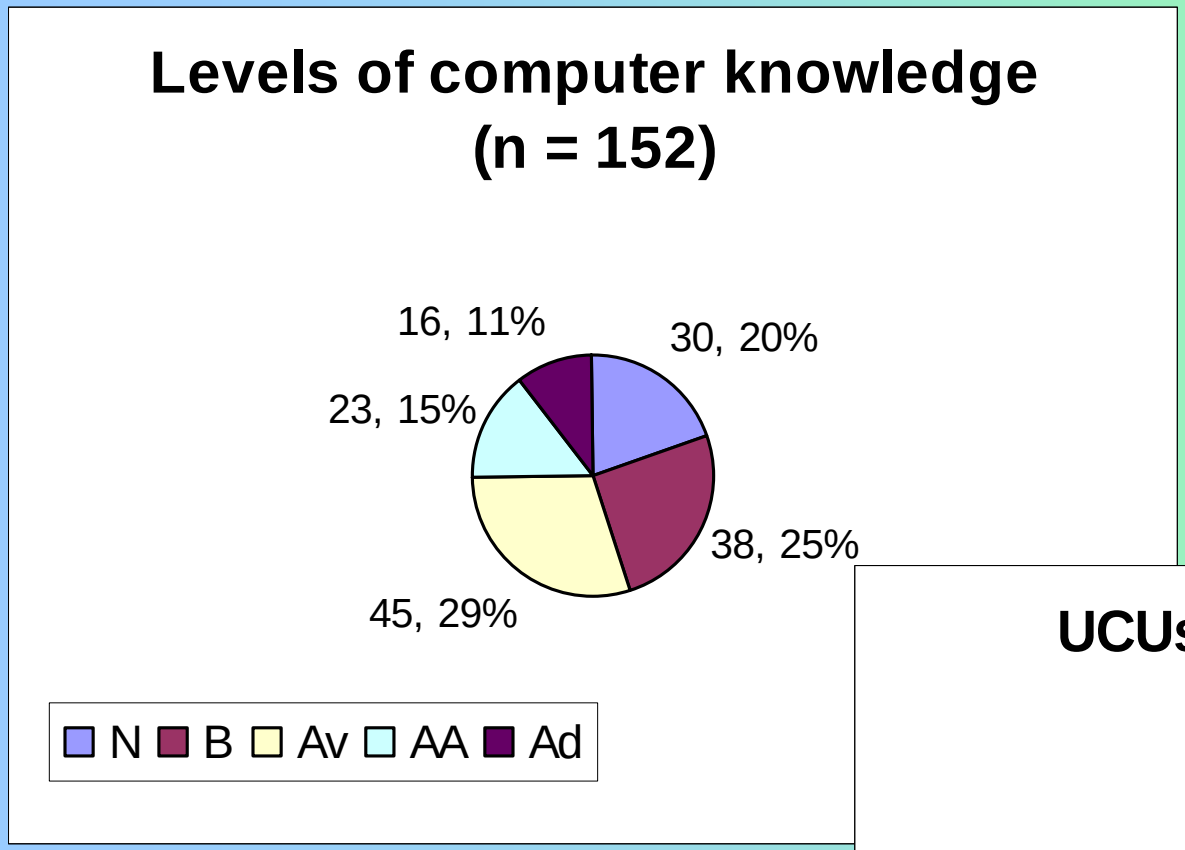
1- very dissatisfied.

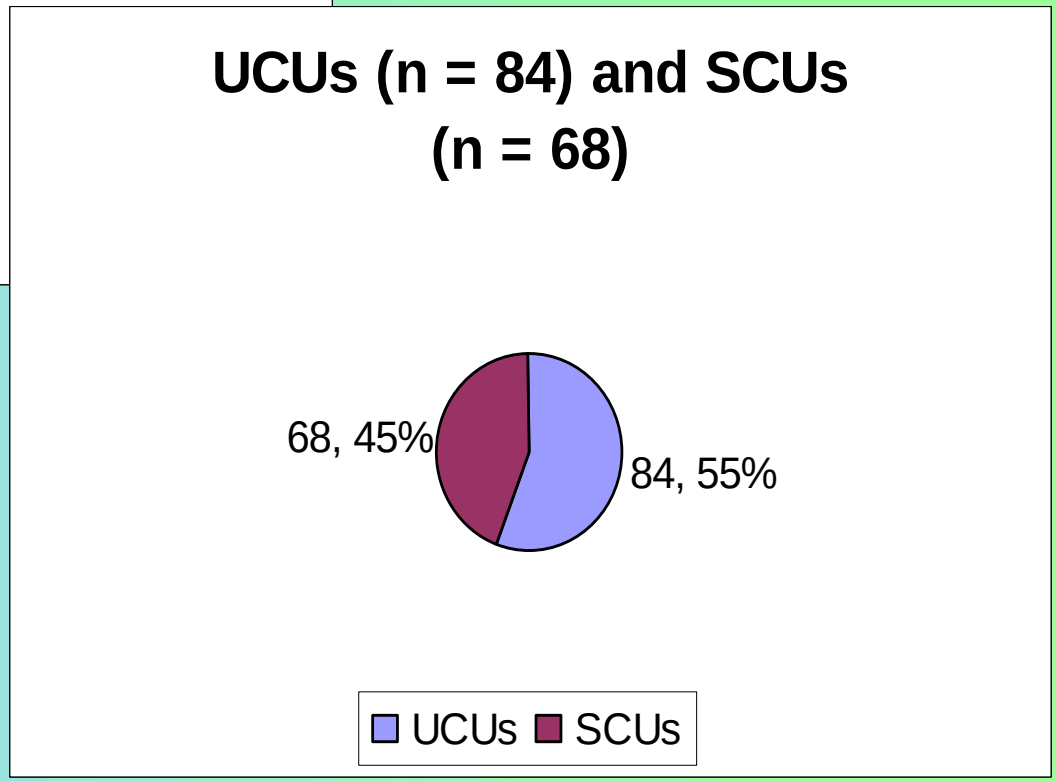
- Levels of computer knowledge were: none (N), beginner (B) , average (Av), above average (AA) and advanced (Ad).

- To improve statistical power, N and B users were grouped as “Unskilled Computer Users” or UCUs and Av, AA and Ad were grouped as “Skilled Computer Users” or SCUs.

- Comments and recommendations

Results


Levels of computer knowledge
(n = 152)
16, 11%
30, 20%
23, 15%
38, 25%
45, 29%
N
B
Av
AA
Ad


UCUs (n = 84) and SCUs
(n = 68)
68, 45%
84, 55%
UCUs
SCUs

Percentage of patients who were somewhat satisfied and very satisfied.

Using $p < 0.01$, No statistically significant differences among patient subgroups (p range: .030-.166) on

- understanding of procedure,
- understanding of risks, benefits and alternatives involved,
- overall satisfaction with process

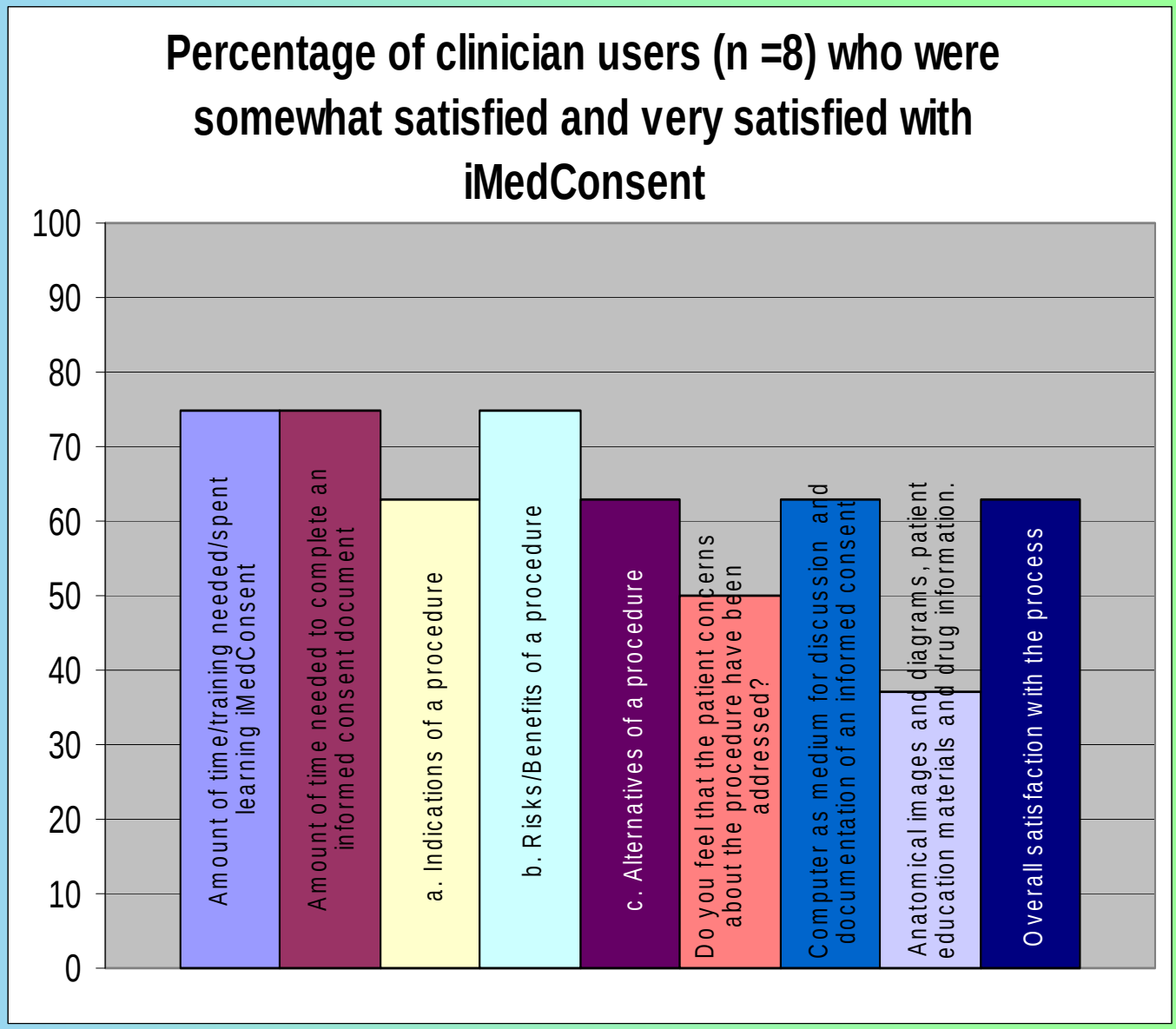
Statistically significant differences observed among patient subgroups on:

- Computer as a medium for learning ($p = .001$)
- Comparison of paper-based versus computer-based consent process ($p = .006$)
- Statistically significant differences were also demonstrated by comparison of UCUs and SCUs ($p = .000$ and $.002$).

Survey questions	N	B	Av	AA	Ad
Understanding of 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 for learning	67	81	95	96	100
Computer based versus paper based consent	74	81	98	100	100
Overall satisfaction	86	97	100	100	100

- Majority expressed overall satisfaction with using iMedConsent.
- 4/8 of clinician users surveyed felt that patient concerns were addressed.
- 3/8 were satisfied with the educational support features.
- Comments:

a. software implementation concerns
b. design issues
c. knowledge problems



The number of returned questionnaires is small from the clinician users arm to attain statistical significance.

Conclusion

- Overall, iMedConsent software is a highly usable digital tool for obtaining a patient's informed consent in outpatient Ophthalmology and Cardiology clinics for patients of all levels of computer knowledge and among clinician users.

- However, as an educational tool, there are significant differences in satisfaction ratings of patients with different computer skills.

- This finding needs consideration in future widespread adoption of iMedConsent software.

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