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Characteristics of Electronic Informed Consent Platforms for Consenting Patients to Research Studies: A Scoping Review

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Abstract

Informed consent process assures that research study participants are properly informed about the study prior to their consent. Due to the increasing significance of electronic informed consent (eIC) platforms, particularly during the COVID-19 pandemic, we conducted a scoping review of eIC systems to address the following characteristics: 1) technological features of current eIC platforms, 2) eIC platforms usability and efficacy, and 3) areas for future eIC research. We performed a literature search using publically available PubMed repository, where we included studies discussing an eIC platform or multimedia educational module given to patients prior to signing a consent form. In addition, we tracked first author, year of publication, sample size, study location, eIC procedure, methodology, and eIC's comparison to paper consent. Our results showed that with a few noted exceptions, electronic consent improves patient usability, satisfaction, knowledge, and trust scores when compared to traditional paper consent.

Keywords: *electronic informed consent, scoping review*

Introduction

Informed consent ensures that research study participants are competent and adequately informed. The research project team is responsible to relay essential information to potential study participants in a cohesive and clear manner, while assuring participants' understanding of the informed consent [1-3].

Even prior to COVID-19 pandemic, there was an increasing interest in electronic informed consent (eIC) for research studies and surgical procedures. In the current health situation, the possibilities of remote healthcare and telemedicine are further exploited. Unfortunately, with the exception of knowledge, other eIC metrics have not been examined in details. In this study, we were interested to inspect additional consent metrics such as usability, satisfaction, enjoyment, accessibility, enrollment, trust, time, and capacity of participants.

We conducted a scoping review with three main objectives: (1) to describe the technological features of current electronic consent platforms, (2) to summarize the usability and efficacy of these platforms in consenting patients in research studies, and (3) to identify areas for future research regarding electronic consent.

Methods

Search Strategy

In December 2020, conducted an online literature search, using PubMed database, to identify articles for our review. We used the following search terms: ((("electronic consent") OR ("e-consent") OR ("econsent") OR ("eIC")) AND ("Informed Consent") AND (English[lang]). We needed to assemble common terminology for eIC due to the current lack of terminology standardization across papers. We only included English language articles.

Study Strategy

In our review, we included 1) studies discussing an eConsent platform or multimedia educational module given to patients in advance of signing either an electronic consent or a paper form; 2) studies including a description of the features or interface of the eConsent platform, and 3) studies including either a usability or efficacy evaluation of the platform. We excluded reviews, surveys, and studies that had electronic signatures, but no educational portion of the consent.

Data Extraction

We documented first author, year of publication for each of the included studies, sample size for each study, study location, the research procedure discussed in the eIC module, methodology, and whether the eIC was compared to traditional paper consent. In addition, we recorded the name of each eIC, the technological platform that ran each eIC, whether the eIC was developed by the researchers, and the theoretical framework used to develop the eIC. We also explored whether each eIC was interactive, contained visual or auditory content, assessed patient comprehension, included electronic signatures, and had a mechanism or ensuring patient identity.

Results

Study characteristics

Using our search strategy, study strategy, and data extraction, we identified 85 articles through PubMed search and 14 articles through citation search for a total of 99 articles to be used for this study. Out of the 99 articles, 58 articles were excluded during title/ abstract review. For the remaining 41 articles, 10 articles were excluded during a full-text review. 31 articles were used for the purposes of this scoping review.

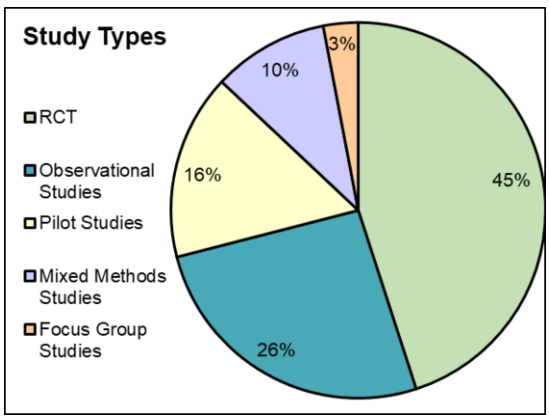

Figure 1– Distribution of study types

Out of the 31 articles included in our review, 71% (n=22) were published between 2016 and 2020. The earliest included study was published in 2009. All other studies were published after 2012 [4-34].

The included studies were based on multiple methodologies. The most common design was randomized controlled trials (45%, n=14), followed by observational studies (26%, n=8), pilot studies (16%, n=5), mixed-methods studies (10%, n=3), and focus group studies (3%, n=1) (Figure 1).

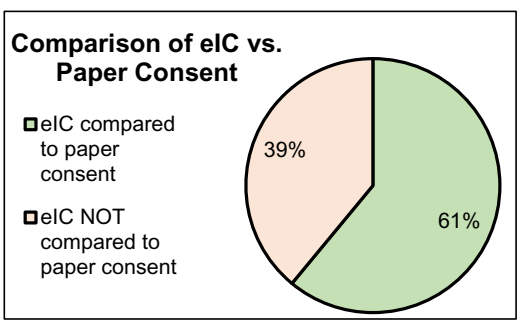

Figure 2– Comparison of eIC and Paper Consent

Technological features of the eIC platforms

In 61% of the studies (n=19), the eIC platforms were compared to traditional paper consent forms. Furthermore, we examined whether the electronic consent platforms was original (developed by the researchers) or widely used eIC platforms (Figure 2). 81% (n=25) of the papers described original platforms, 16% (n=5) described outsourced platforms, and 3% (n=1) did not specify who built their platform. 52% (n=16) of the reviewed studies included information about the framework on which their electronic consent platform was based. The rest of the studies did not specify how their platform was conceptualized (Figure 3).

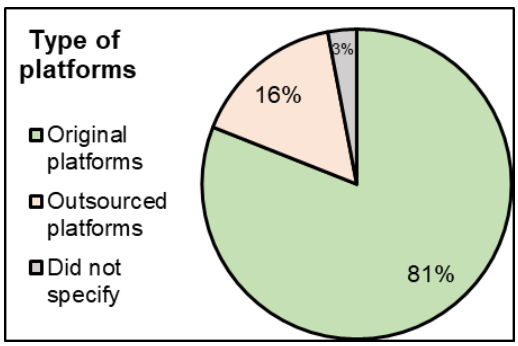

Figure 3– Type of eIC platforms

In addition, 83% (n=26) of the educational modules of the 31 studies were interactive, 71% (n=22) included auditory features, and 100% featured visual platforms. Patient understanding of the consent was assessed through surveys in 45% of studies (n=14) and multiple-choice questions in 35% (n=11) of studies. Six studies did not look into patient comprehension (Figure 4).

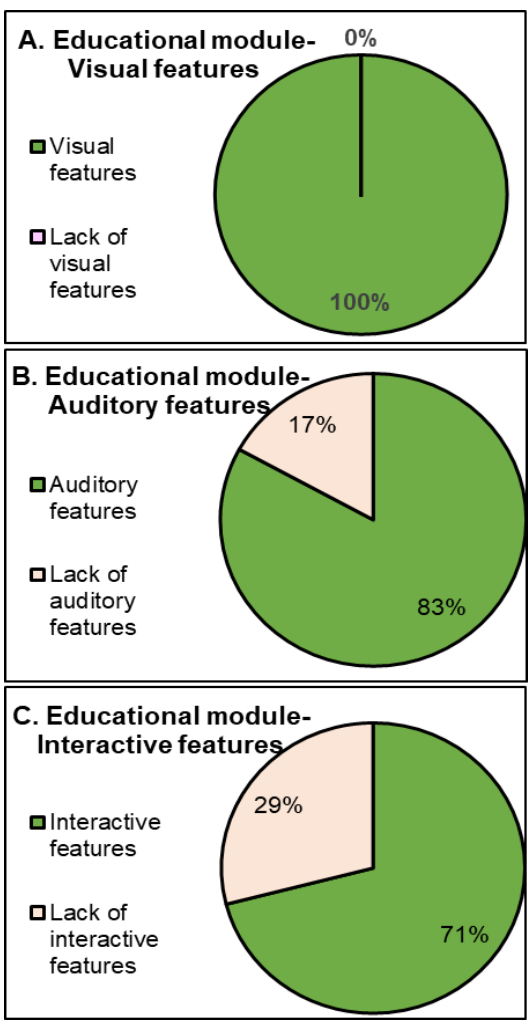

Figure 4– Type of educational modules in econsent platforms

Electronic signatures were used in 45% (n=14) of eIC studies, while paper-based signatures followed digital educational modules in 19% (n=6) of the studies. Furthermore, 26% (n=8) of the studies did not specify the collection of patients' signatures and 10% (n=3) did not collect signatures because they were hypothetical studies. 10% (n=3) studies had digital patient identity authentication methods.

Usability analysis of eIC platforms

48% (n=15) of the studies in our review addressed the eIC platform usability. According the results, eIC platforms exhibited high or improved usability in comparison to paper consent.

Satisfaction

45% (n=14) of the papers examined patients' satisfaction with eIC platform. According to the results, there was high or improved satisfaction of eIC in comparison to paper consent.

Enjoyment/ Preference

42% of the 31 studies looked at patients' enjoyment of the eIC platform. Over 50% of the participants preferred electronic consent to paper consent. However, 22% of participants prefer papered consent.

Enrollment

Only 6% (n=2) of the studies addressed enrollment outcomes for eIC platform vs. paper consent. However, overall the results of the eIC impact on patients' enrollment were inconclusive.

Knowledge

77% (n=24) of the 31 studies were interested in alterations in patient knowledge or understanding. Most of them exhibit improvement in patients using eIC platform compared to paper consent groups. Still, one of these studies showed that their improvement was no longer significant at a 6 week follow-up, a second study revealed increased subjective but not objective comprehension, and a third of the study showed that only 55% of participants could verbalize one key knowledge concept after completing the education module. Interactive and more engaging platforms, involving multiple clicking options, showed increased knowledge scores for participants. Similarly, visual and audio features increased knowledge significantly. There were no studies that showed better knowledge scores with paper consent.

Trust

Patients' trust in participating in research was addressed in 29% (n=9) of the reviewed papers. With the exception of a single study conducted amongst rural, African American, and veteran participants, all of the studies showed significant increase or improvement in trust with electronic consent.

Time to complete the consent

Time to complete the consent was documented in 45% (n=14) of the articles. The results were inconclusive for length of time for eIC vs. paper consent.

Capacity to consent

13% (n=4) of the studies included mentally impaired patients and addressed the impact of electronic consent on patient capacity to consent. In two of the studies concerning schizophrenic patients, there was an increased capacity to consent using with electronic consent within the impaired group. Furthermore, a study featuring psychiatric outpatients also saw a significant increase in capacity to consent. In a study involving elderly patients, there was a significant increase in capacity to consent immediately after the consent, but that increased was not maintained after a week (Table 1) (Figure 5).

Table 1– Metrics of Electronic consents – Number of Studies and Percentages

	# Studies	Percentages (%)
Usability		
Assessed	15	48
Not	16	52
Satisfaction		
Assessed	14	45
Not	17	55
Enjoyment/Preference		
Assessed	13	42
Not	18	58
Accessibility		
Assessed	12	39
Not	19	61
Enrollment		
Assessed	2	6
Not	29	94
Knowledge		
Assessed	24	77
Not	7	23
Trust		
Assessed	9	29
Not	22	71
Time to Consent		
Assessed	14	45
Not	17	55
Capacity to Consent		
Assessed	4	13
Not	27	87

Discussion

The impact of electronic consent platforms for research purposes has increased in the last few years, but became particularly crucial during the continuous COVID-19 pandemic. However, currently, there is a lack of standardization amongst electronic consents.

81% of electronic consent platforms were developed by the research team that published the study. All eIC platforms in our review contained multimedia elements, where all platforms contained visual elements and 71% of the platforms included auditory elements. 84% of the platforms were interactive. Even though most of the platforms contain multimedia tools rather than are interactive, our search showed that interactivity improved patient knowledge scores significantly and independently of multimedia features [17].

Furthermore, user satisfaction and enjoyment increases with electronic consent in comparison to paper consent. In most cases, knowledge increases with electronic consent vs. paper consent.

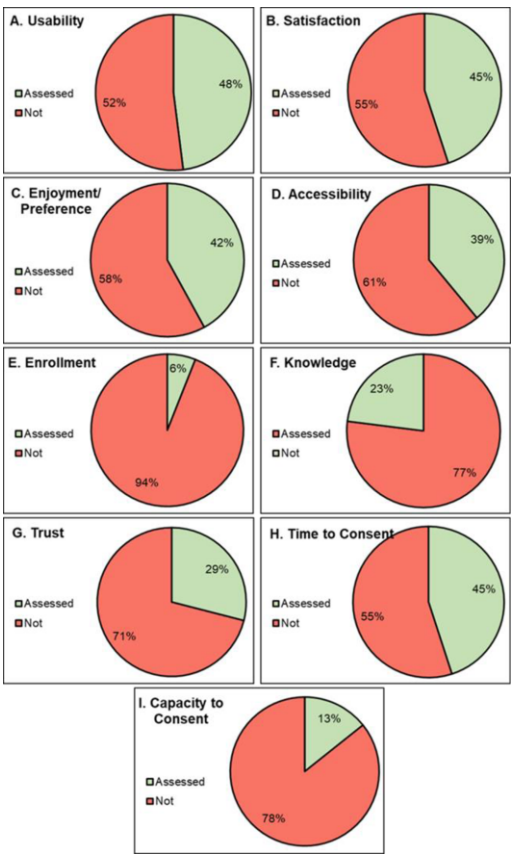

Figure 5– A-I – Metrics of Electronic consents

A notable upside of electronic informed consent is that it has been shown to be better at engaging vulnerable and impaired populations. For instance, two of the featured studies, including schizophrenic patients, revealed increased capacity of the patients to consent when using eIC platforms in comparison to patients who used paper consent [14-15]. In addition, another study presented increased knowledge and capacity to consent among psychiatric outpatients using eIC [22].

However, there are concerns about the implementation of electronic consent platforms for research purposes amongst rural, Black, and veteran populations. In general, Black and low education participants had lower satisfaction, understanding, voluntariness to participate, and trust scores than white and higher educated participants when utilizing electronic consent, due to data privacy concerns [7, 12]. In addition, a portion of the featured patients were not comfortable using computer devices and internet [19]. Unfortunately, many sociodemographic groups were underrepresented in the 31 papers we reviewed for the purposes of exploring eIC, where many of the studies featured mainly white, educated, and English-speaking participants.

There is not a clear conclusion on the length of electronic consent process in comparison to paper consent for research. Reasons for these differences can be the lack of standardized eIC platforms, as well as the ability to scroll and skip for some electronic consent platforms, without completely engaging with all of the content. This is a notable danger of eIC since, where patients may skip through the educational and consent modules without being fully informed. In contrast, research staff could assist the consenting participants throughout the consent document, ensuring that all crucial information has been covered.

The impact that electronic informed consent on study enrollment is not discussed in details in this study. Most of the featured studies were randomized controlled trials with a small sample size. One large scale study, which included 35,000 participants, reported that eIC was more effective for enrollment than email campaigns but less effective than approaching patients face-to-face in clinics [8].

Limitations

39% of the 31 studies included in our review did not compare electronic consent to paper consent. The conclusions of these studies often showed high scores for patient knowledge, satisfaction, and usability. However, there is no way to know if these scores are an improvement from paper consent without comparison between both forms of consent.

Majority of the studies had small sample sizes and included mostly educated English speaking participants. While our review showed promising improvements in outcomes when using eIC, these restrictions prevent general conclusions about the usability of electronic consent.

We limited out search to only electronic consent platforms that have been published.

Conclusions

There is a lack of standardized electronic consent platforms, where many research teams developed their own interface. Future development of guidelines in this field could lead to more streamlined framework for developing electronic consent platforms.

Generally, electronic consent improves patient usability, satisfaction, knowledge, and trust scores when compared to traditional paper consent. No studies included in our review saw a decrease in outcomes from eIC, suggesting that it is not worse but may offer additional advantages over paper consent. These positive outcomes are particularly noticed in cognitively impaired patient populations. However, such advantages are not observed in Black, low educated, and rural populations. Future eIC research should aim to focus on minority, non-English speaking, and other under-represented communities. In addition, future large-scale research studies are needed to understand the impact of eIC on research enrollment rates.

References

[1] C.S. Cocanour, Informed consent-It's more than a signature on a piece of paper, *Am J Surg* **214** (2017), 993-997.
[2] E. Cohn, E. Larson, Improving participant comprehension in the informed consent process, *J Nurs Scholarsh* **39** (2007), 273-80.
[3] L.M. Fields, J.D. Calvert, Informed consent procedures with cognitively impaired patients: A review of ethics and best practices, *Psychiatry Clin Neurosci* **69** (2015), 462-71.
[4] D.C. Haussen et al., Utilization of a Smartphone Platform for Electronic Informed Consent in Acute Stroke Trials, *Stroke* **48** (2017), 3156-3160.
[5] D.C. Haussen et al., Legal authorized representative experience with smartphone-based electronic informed consent in an acute stroke trial, *J Neurointerv Surg* **12** (2020), 483-485.

[6] J.L. Madeira et al., Using the EngagedMD multimedia platform to improve informed consent for ovulation induction, intrauterine insemination, and in vitro fertilization, *Fertil Steril* **110** (2018), 1346.
[7] C.A. Harle et al., Does an interactive trust-enhanced electronic consent improve patient experiences when asked to share their health records for research? A randomized trial, *J Am Med Inform Assoc* **26** (2019), 620-629.
[8] N.T. Boutin et al., Implementation of Electronic Consent at a Biobank: An Opportunity for Precision Medicine Research, *J Pers Med* **6** (2016), 17.
[9] D.E. Hall et al., The impact of iMedConsent on patient decision-making regarding cholecystectomy and inguinal herniorrhaphy, *J Surg Res* **175** (2012), 233.
[10] S.A. Kraft, A randomized study of multimedia informational aids for research on medical practices: Implications for informed consent, *Clin Trials* **14** (2017), 94-102.
[11] A.H. Warriner et al., A pragmatic randomized trial comparing tablet computer informed consent to traditional paper-based methods for an osteoporosis study, *Contemp Clin Trials Commun* **3** (2016), 32-38.
[12] C.M. Simon et al., Perspectives on Electronic Informed Consent From Patients Underrepresented in Research in the United States: A Focus Group Study, *J Empir Res Hum Res Ethics* **13** (2018), 338-348.
[13] D.Y. Ham et al., Prospective Randomized Controlled Study on the Efficacy of Multimedia Informed Consent for Patients Scheduled to Undergo Green-Light High-Performance System Photoselective Vaporization of the Prostate, *World J Mens Health* **34** (2016), 47-55.
[14] A.L. Harmell, B.W. Palmer, D.V. Jeste, Preliminary study of a web-based tool for enhancing the informed consent process in schizophrenia research, *Schizophr Res* **141** (2012), 247-50.
[15] D.V. Jeste et al., Multimedia consent for research in people with schizophrenia and normal subjects: a randomized controlled trial, *Schizophr Bull* **35** (2009), 719-729.
[16] E. Rothwell et al., A randomized controlled trial of an electronic informed consent process, *J Empir Res Hum Res Ethics* **9** (2014), 1-7.
[17] C.M. Simon, D.W. Klein, H.A. Schartz, Interactive multimedia consent for biobanking: a randomized trial, *Genet Med* **18** (2016), 57-64.
[18] F. Abujarad et al., Building an Informed Consent Tool Starting with the Patient: The Patient-Centered Virtual Multimedia Interactive Informed Consent (VIC), *AMIA Annu Symp Proc* **16** (2018), 374.
[19] N. Jayasinghe et al., Establishing the Feasibility of a Tablet-Based Consent Process with Older Adults: A Mixed-Methods Study, *Gerontologist* **59** (2019), 124-134.
[20] A.R. Tait et al., Evaluation of a prototype interactive consent program for pediatric clinical trials: a pilot study, *J Am Med Inform Assoc* **19** (2012), e45.
[21] K. Chalil Madathil et al., An investigation of the efficacy of electronic consenting interfaces of research permissions management system in a hospital setting, *Int J Med Inform* **82** (2013), 854-63.
[22] I. Morán-Sánchez, A. Luna, M.D. Pérez-Cárceles, Enhancing the informed consent process in psychiatric outpatients with a brief computer-based method, *Psychiatry Res* **245** (2016), 354-360.
[23] H. Kim et al., iCONCUR: informed consent for clinical data and bio-sample use for research, *J Am Med Inform Assoc* **24** (2017), 380-387.
[24] M.C. Rowbotham et al., Interactive informed consent: randomized comparison with paper consents. *PLoS One* **8** (2013), e58603.
[25] D. Robins et al., Towards a Highly Usable, Mobile Electronic Platform for Patient Recruitment and Consent Management, *Stud Health Technol Inform* **270** (2020),1066-1070.
[26] A. Bethune et al., e-Consent: approaching surgical consent with mobile technology, *Can J Surg* **61** (2018), 339-344.
[27] J. Finkelstein, D. Robins, J. Liu, Usability Inspection of Multipurpose Scalable Informed Consent Platform, *Stud Health Technol Inform* **262** (2019), 198-201.
[28] S.R. Ramos et al., User-Centered Design, Experience, and Usability of an Electronic Consent User Interface to Facilitate Informed Decision-Making in an HIV Clinic, *Comput Inform Nurs* **35** (2017), 564.
[29] C.S. Sonne et al., Development and pilot testing of a video-assisted informed consent process, *Contemp Clin Trials* **36** (2013), 25-31.
[30] Y.S. Lee et al., The Effect of an Educational and Interactive Informed Consent Process on Patients With Cervical Spondylotic Myelopathy Caused by Ossification of the Posterior Longitudinal Ligament, *Spine* **45** (2020), 193-200.
[31] H. Schneiderheinze et al., Development and Usability Analysis of a Multimedia eConsent Solution, *Stud Health Technol Inform* **267** (2019), 297-303.
[32] R.J. Cadigan et al., Online Education and e-Consent for GeneScreen, a Preventive Genomic Screening Study, *Public Health Genomics* **20** (2017), 235-246.
[33] M. Doerr et al., Evaluation of Participant Experience With Mobile eConsent in the App-Mediated Parkinson mPower Study: A Mixed Methods Study, *JMIR Mhealth Uhealth* **5** (2017), e14.
[34] L. Ellett et al., Use of a multimedia module to aid the informed consent process in patients undergoing gynecologic laparoscopy for pelvic pain: randomized controlled trial, *J Minim Invasive Gynecol* **21** (2014), 602-611.

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