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Use of E-Consent in Healthcare Settings: A Scoping Review

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Abstract. Electronic consent is a technology-driven approach that remains challenging in various healthcare settings. Transitioning from paper-based to electronic consent (e-consent) has streamlined the consent process. This scoping review explores patients' electronic consent in different healthcare settings. We searched four databases and selected 14 studies that met our inclusion criteria. Our results show that E-consent is associated with key measures such as sufficient information, accuracy, enhanced shared decision-making, and efficiency. The majority of studies used a comparative design model to contrast paper-based consent with E-consent. Our findings provide an overview of the current state of E-consent use in healthcare settings.

Keywords. Electronic consent, healthcare, informed consent, e-consent

1. Introduction

E-consent streamlines the consent process by enabling patients to provide informed consent electronically, replacing traditional paper-based methods. This transition offers substantial benefits, enhancing efficiency by eliminating physical paperwork and reducing administrative workload [1,2]. Investigating the adoption and consequences of e-consent across various healthcare settings becomes crucial as healthcare systems increasingly embrace technology-driven approaches. This scoping review aims to explore studies that delve into the use of **E-consent** in different healthcare settings.

2. Methodology

This scoping review followed the Joanna Briggs Institute (JBI) guidelines and the PRISMA-ScR framework [3,4]. We searched PubMed, Wiley Online Library, ScienceDirect, and IEEE Xplore for English-language articles on e-consent in healthcare settings. The selection process involved screening titles and abstracts to exclude studies not specifically focusing on e-consent in healthcare or not written in English. Studies were also excluded if they involved non-healthcare populations, meaning those not directly involved in healthcare services, such as studies focusing on general internet users or administrative data uses. Full texts were then reviewed for eligibility. Authors YE and

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HO independently conducted the selection and extraction, achieving a Cohen's Kappa of 0.66 [5], indicating substantial agreement. Further details on the data extraction and the search terms are provided in Appendices A[2] and B[2] respectively.

3. Results

3.1. Selected Studies

Our search resulted in 184 articles; 16 duplicates were eliminated. In the screening phase, 125 articles were excluded after reviewing the titles and abstracts. These were due to incorrect language, irrelevant study or topic, irrelevant population, and type of publication. A further 29 articles were excluded due to irrelevance in the eligibility assessment after scanning the full texts of the remaining 43 articles. A total of 14 studies were included for data extraction and synthesis. Refer to Appendix C[2] for the PRISMA flow diagram.

3.2. Characteristics of Included Studies

All included studies were journal articles. Nearly all of them [1,2,6-16] were published after 2013, with half of them (50%) [2,11-16] between 2020 and 2023, and one [17] (7.14%) in 2006. All studies but one [1,2,6,7,9-17] were conducted in North America and Europe, with the United Kingdom having the highest number of studies (n=6, 42.86%) [2, 10, 12, 13, 15, 16], and one (7.14%) [8] outside the region, in Korea. Refer to Appendix D[2].

3.3. Study Methods

In this scoping review, more than half of the included studies (n=8, 57.14%) [2, 6, 8, 10, 12, 13, 16, 17] used comparative approaches, comparing conventional consent to e-consent. Three of them [2, 10, 12] were cohort observational studies, while the rest [6, 8, 13, 16, 17] were experimental, with four [8, 13, 16, 17] non-randomized designs and one [6] randomized trial. The rest of the studies (n=6, 42.86%) [1, 7, 9, 11, 14, 15] described the use of e-consent in specific contexts. These included observational (n=2) [9, 15], usability (n=1) [7], and feasibility (n=1) [11] studies.

3.4. Participants, Patients Characteristics and Healthcare Area

While the number of participants varied significantly, they were patients in most of the studies (n=11, 78.57%) [2, 6-13, 15-17]. Some studies recruited other participants in addition to patients like guardians (n=2, 14.29%) [9, 13] and medical staff (n=1, 7.14%) [8]. Consenters in one study [16] were parents or guardians, while another study [14] looked at health institutions in general. Participants that were patients were adults consenting for themselves, and most guardians (n=2) [13, 16] were pediatric patients.

[2] https://github.com/HarisObaidi/E-consent_Scoping_Review.git

Most studies included in this scoping review (n=11, 78.57%) [1, 2, 6, 8-12, 14, 15, 17] were conducted in clinical settings, and the remaining (n=3, 21.43%) [7, 13, 16] were in public health settings. These studies covered diverse health domains, with the majority (n=7, 50%) [1, 2, 6, 10, 12, 15, 17] showing e-consent in surgery. Additional areas of investigation included school vaccination programs (n=2) [13, 16], anesthesiology (n=1) [11], infectious diseases (n=1) [7], behavioral health (n=1) [9], and cancer (n=1) [14]. One study [8] included various domains. The specific type of procedures or use case of each study differed, however, several studies (n=3, 21.43%) [1, 8, 10] reported various or multiple use cases.

3.5. Intervention Characteristics and Measures and Key Findings

In many studies (n=6, 42.86%) [1,7,10,11,13,16], the tool used by consenters to interact with the consent was websites or web-based platforms. In some studies (n=4, 28.57%) [2,12,15,17], it was computer applications, while in some others (n=2, 14.29%) [6,8] it was mobile applications, including an e-book (n=1) [6]. A single study [9] reported the use of an e-consent system embedded within the EHR system.

Three studies [6,7,11] reported ability of e-consent to provide comprehensive information on subject matter, yielding positive outcomes. Accuracy was explored in three studies [1,2,10] and reported positive findings. Two studies [1,2] reported reduced errors, while others [2,12,15] showed pathways for enhancing shared decision-making quality. Notably, completion rates were positively reported in one study [8]. Efficiency gains were documented in two studies [1,8], yet a contrasting negative perspective was reported in one study [13]. Compliance with e-consent was reported by positive findings from two studies [1,17]. Design aspects were showcased by one study [7], reporting positive outcomes. Another study [14] noted the positive implications of e-consent capabilities in implementation. Regarding logistical challenges, one study [16] reported positive outcomes in transitioning to e-consent systems, while a differing perspective in another second study [13] presented negative outcomes. Additionally, mixed results documented by a study [9], reporting positive outcomes in addressing workflow but negative outcomes related to e-consent readability.

4. Discussion

This review underscores the need for further research to compare conventional paper-based consent to e-consent across various healthcare contexts, particularly emphasizing public health programs and different geographical and cultural settings. Future literature reviews could explore the effectiveness of e-consent, aiding healthcare institutions in deciding on adoption and improvement of electronic consent processes. One significant area for future exploration is the interoperability of e-consent systems. As healthcare increasingly relies on integrated digital solutions, understanding how e-consent systems share and manage data across diverse healthcare IT ecosystems is crucial. Security is another critical concern; the studies reviewed reveal a need to ensure that e-consent solutions meet rigorous data protection standards to safeguard patient information. Moreover, researchers may investigate the impact of different interfaces and e-consent form designs on the experiences of consenters and providers. The limitations of this

scoping review include the potential for overlooking relevant publications due to literature retrieval challenges and the dependence on the availability of published studies.

5. Conclusions

This scoping review shows that the use of electronic consent in different healthcare settings has a positive impact on the consent process. The results of the included studies demonstrated the transformation from paper-based to electronic consent to improve the consenting process. However, more research is needed to validate the use of electronic consent in public health programs. The findings from this scoping review lay a foundation for upcoming research in this domain.

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