Using Artificial Intelligence to Improve Readability and Comprehension of Informed Consent Forms for Orthopaedic Clinical Trials

Bryce Fletcher[1,2], Haley Huff[1,2], Vicki Jones[1,2], James L. Cook[1,2], Lisa A.Royse[1, 2]

[1]Department of Orthopaedic Surgery, University of Missouri-Columbia, Columbia, Missouri [2]Thompson Laboratory for Regenerative Orthopaedics, University of Missouri, Columbia, Missouri, USA.
brycefletcher@health.missouri.edu

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INTRODUCTION: Informed Consent Forms (ICFs) play a vital role in ensuring the informed participation of individuals in medical studies, upholding ethical standards, and protecting patient rights. However, the traditional approach to writing ICFs has significant limitations. Lengthy written documents may be difficult for individuals to fully comprehend, resulting in incomplete understanding of study procedures and potential risks. Consequently, this compromises the integrity of the informed consent process. Therefore, the need arises to explore alternative methods to generate consents that are accessible, concise, and understandable.
This mixed-methods study aimed to assess the feasibility and acceptability of using artificial intelligence (AI) to generate ICFs for orthopaedic clinical research, with a focus on enhancing participant comprehension and engagement. This study sought to understand the potential benefits and challenges associated with this approach while examining the perspectives of participants. Through an exploration of the experiences and perceptions of key stakeholders, this work aims to inform the development of guidelines and best practices for implementing AI-generated consents in clinical research settings.

METHODS: For the study, two clinical research consents were developed based on a proposed orthopaedic clinical trial: the "Researcher Written Consent" created by a researcher through protocol analysis, and the "AI Written Consent" generated by inputting protocol information into the AI system Chat-GPT. Both consents were adapted to fit an IRB-provided template.
The readability of both consent forms was analyzed using six readability metrics. Statistical significance was determined using a two-sample independent t-test with $p < .05$.
Additionally, a Research Patient Advisory Team (n = 12) received both consents without knowledge of their development method. They were asked to read both consents, complete a brief survey, and participate in a focus group session. Qualitative content analysis was performed on the focus group data to identify and highlight the patients' perspectives on both consent forms and gather insights to improve the consent process.

RESULTS: The AI Written Consent (M = 10.92, SD = .991) had significantly higher readability scores compared to the Researcher Written Consent (M = 12.0, SD = .935), $t(6) = 1.86$, $p = .0466$. Furthermore, 58.3% of the Patient Advisory Team preferred the AI Written Consent over the Researcher Written Consent. Qualitative analysis of the focus group identified five factors that patients use to assess research documents, including document formatting, comprehensiveness of information presented, redundancy, word choice, and document length. Additionally, the analysis identified three techniques to improve consent documents.

DISCUSSION: Using AI to generate ICFs holds promise for addressing the limitations of traditional consent procedures. By developing consents that are more accessible, concise, and easy to understand, AI has the potential to enhance participant comprehension and engagement in the informed consent process. The insights gained from this work can inform the development of improved consent processes that better serve the needs of both researchers and participants, ensuring ethical standards and protecting patient rights in clinical research. However, further research and careful consideration of ethical implications are necessary to establish comprehensive guidelines and best practices for implementing AI-generated consents in clinical research settings.

SIGNIFICANCE/CLINICAL RELEVANCE: This study explores the feasibility of using artificial intelligence to create more accessible and comprehensible orthopaedic Informed Consent Forms (ICFs) for clinical research. The results indicate that AI-generated ICFs offer enhanced readability and are preferred by a significant portion of patients, potentially improving the informed consent process, safeguarding ethical standards, and improving patient engagement in clinical research.