A priori Protocol

Scoping Review Protocol:

"Informed Consent and Ethical Considerations in AI for Dentistry and Medicine: A Scoping Review"

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Authorship Statement

The authorship of the final publication may differ from those listed in this protocol, as it will adhere to the authorship criteria set by the International Committee of Medical Journal Editors (ICMJE). Authorship will be granted based on substantial contributions in accordance with ICMJE guidelines, ensuring that all listed authors meet the required criteria:

1. Made significant contributions to the conception or design of the study, or to the acquisition, analysis, or interpretation of data.

2.Were involved in drafting or critically revising the protocol for important intellectual content.

3.Approved the final version of the protocol.

4.Agree to be accountable for all aspects of the work, ensuring its integrity and accuracy.

The individuals listed as authors of this protocol have contributed meaningfully to the study. However, contributors who have provided limited input—such as answering a single research question or briefly assisting with inclusion criteria—will not be included as full authors unless they meet all four ICMJE criteria. Their contributions will be acknowledged appropriately in the final publication.

The final authorship of the completed scoping review will be confirmed based on continued substantial contributions throughout the study. Any modifications will adhere to ethical authorship practices as defined by the ICMJE.

Introduction

The implementation of artificial intelligence (AI) in dental diagnostics, disease prediction, and treatment planning presents significant challenges for patient safety and ethical clinical practice (Iserson, 2024). The variability of AI systems' accuracy, reliability, and interpretability has raised concerns about misdiagnosis, inconsistent care, and treatment errors (Shah and al, 2024). Furthermore, the lack of standardized guidelines for obtaining informed consent when using AI technologies exacerbates issues such as patient autonomy, data privacy, and transparency (Rose and al, 2024). Despite the growing use of AI in dental and medical practices, there is no unified legal or ethical framework to guide the disclosure of AI's role, data use, associated risks, and benefits, leaving unanswered questions about accountability and trust in AI-driven healthcare (Iserson, 2024 ; Cohen, 2020).

Objectives

This scoping review aimed to examine the breadth and scope of evidence on informed consent for AI technologies in dentistry and medicine, focusing on training AI models and clinical practice. The review aims to identify key themes, ethical considerations, and gaps in the current literature to develop a standardized framework for AI informed consent.

Review Question

What is the role and necessity of informed consent in the use of AI for clinical diagnosis and treatment in dentistry and medicine, as well as for training AI models, particularly in deep learning.

Methods

To assess the extent of available evidence on informed consent for AI technologies in both dentistry and medicine, we will follow the PRISMA Extension for Scoping Reviews (PRISMA-ScR): Checklist and Explanation (Tricco et al 2018) and the JBI methodology for scoping reviews (Peters et al. 2015).

Eligibility Criteria:

This scoping review includes quantitative and qualitative studies, Randomized Controlled Clinical Trials (RCT), Comparative Clinical Trials (CCT), narrative review, scoping reviews, systematic reviews, case reports, opinion papers, gray literature, legal and policy documents, educational materials, and patient/public data, all addressing AI ethics and informed consent in dentistry and medicine. Eligible studies must assess clinicians' and patients' perceptions of informed consent in clinical AI applications, examine its implementation in AI model training, and identify challenges or gaps in applying informed consent in clinical practice or training with human participants. Studies must be published in English between 2015 and 2025, with no geographic restrictions, and address ethical, legal, or operational aspects of informed consent in AI-driven model training or clinical practice. Excluded studies will be those

involving non-human participants, lacking a focus on AI-informed consent in dentistry or medicine, not published in English or predating 2015, discussing AI without clinical applications, examining informed consent in research unrelated to AI, or addressing AI ethics without a direct focus on informed consent in healthcare.

Search Strategy:

The search strategy will follow a two-step approach to identify both published and unpublished studies (gray literature, preprints, conferences, and dissertations). An initial search limited to English, in MEDLINE (PubMed) and Google Scholar, refined search terms, followed by a systematic search across MEDLINE, SCOPUS, IEEE Xplore, ArXiv, and Google Scholar to ensure comprehensive coverage of peer-reviewed and emerging research. Controlled vocabulary (e.g., MeSH terms) and free-text keywords related to informed consent, AI, dentistry, medicine, and data privacy were used, with Boolean operators for precision. Search terms were adapted for each database, and Google Scholar was included to capture additional studies. References were managed in Zotero for deduplication, while Rayyan, an AI-powered platform, facilitated blinded screening and selection.

Screening and Data Extraction Process

The screening process will ensure consistency and reliability through a structured approach. Two independent reviewers (P.E. and E.K.), will assess 2,391 titles and abstracts based on predefined inclusion criteria, resolving discrepancies through discussion or consultation with a third reviewer (D.M.). Full-text screening will be conducted by at least two reviewers, with studies managed in Zotero. If the volume of eligible studies is too large, a team-based approach will be implemented, with reasons for exclusion systematically documented.

The screening process will follow a structured approach to ensure consistency and reliability

Risk of Bias Assessment/ Critical Appraisal:

Critical appraisal of the included studies will be performed using the JBI Risk of Bias tool for various study types (https://jbi.global/critical-appraisal-tools)

Ethical Considerations: Mention whether ethics approval is required.

No human subjects or personal data are involved. This review follows best practices for transparent, ethical research.

Dissemination Plan: Indicate where findings will be published (e.g., peer-reviewed journal, conference).

This protocol will be registered on OSF.io for transparency.

Findings will be submitted to a peer-reviewed journal specializing in AI ethics or healthcare quality.

Funding and Conflict of Interest:

The authors received no funding for this study and declared no conflicts of interest.

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