How Does AI Handle Informed Consent in Clinical Settings?

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Abstract

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Introduction

The integration of artificial intelligence (AI) into healthcare is rapidly transforming the landscape of clinical practice, from diagnostics to treatment recommendations. As these powerful tools become more prevalent, they bring to the forefront a critical ethical and legal consideration: informed consent. The traditional model of informed consent, which relies on a clear and comprehensive discussion between a healthcare provider and a patient, faces new challenges in the age of AI. This article explores the complexities of AI and informed consent, patient perspectives on the use of AI in healthcare, and strategies for navigating this evolving terrain.

The Challenge of Informed Consent in the Age of AI

The very nature of AI, particularly the “black box” phenomenon where the inner workings of an algorithm are not easily interpretable, presents a significant hurdle to obtaining meaningful informed consent [3]. How can a patient provide truly informed consent when the clinician themselves may not fully understand why an AI system has generated a particular recommendation? This lack of transparency can lead to a breakdown in trust and communication, which are the cornerstones of the doctor-patient relationship. Furthermore, the current informed consent process often fails to adequately address the nuances of AI, such as the data used to train the algorithms, the potential for bias, and the limitations of the technology.

Patient Perspectives on AI in Healthcare

Recent research sheds light on what patients want to know when AI is involved in their care. A 2024 study published in *Digital Health* found that while patients desire transparency regarding the use of AI, the specific information they want varies based on factors such as age, gender, and income [1]. This suggests that a one-size-fits-all approach to informed consent for AI is unlikely to be effective. The study also highlights the need for ethical guidelines that go beyond mere legal requirements to ensure that patients are truly empowered to make informed decisions about their health.

Strategies for Effective AI-Informed Consent

To address the challenges posed by AI, a re-evaluation of current informed consent practices is necessary. A 2025 article in *Artificial Intelligence in Medicine* proposes several strategies for redesigning informed consent forms to be more effective in the age of AI. These include using plain language, visual aids, and personalized information to improve patient understanding and trust [3]. Additionally, the article emphasizes the importance of educating healthcare professionals about AI technologies to enable them to have more effective conversations with their patients. Continuous monitoring and feedback mechanisms are also crucial to ensure that informed consent processes are continuously improving and adapting to the rapid advancements in AI.

The Role of Large Language Models (LLMs)

Large Language Models (LLMs), such as GPT-4, have shown promise in enhancing patient education and, by extension, the informed consent process. A 2025 study in *JNCI Cancer Spectrum* explored the use of LLMs to simplify complex medical information from clinical trial registries, making it more accessible to patients [2]. The study found that AI-generated summaries and multiple-choice questions significantly improved patient comprehension. While the use of LLMs in patient-facing roles is not without its concerns, including the potential for AI “hallucinations” and the need for regulatory oversight, they represent a promising avenue for bridging the communication gap in clinical trial communication and beyond.

Conclusion

The integration of AI into clinical settings offers immense potential to improve patient care, but it also necessitates a thoughtful and proactive approach to informed consent. By understanding patient perspectives, redesigning consent processes, and leveraging new technologies like LLMs, we can ensure that the use of AI in healthcare is not only innovative but also ethical and patient-centered. The path forward requires a collaborative effort between healthcare providers, researchers, ethicists, and patients to develop a new paradigm for informed consent that is fit for the age of AI.

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