The Algorithmic Dilemma: How AI is Redefining Informed Consent in Digital Health

Rasit Dinc

Rasit Dinc Digital Health & AI Research

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Abstract

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The integration of Artificial Intelligence (AI) into healthcare, from diagnostic tools to personalized treatment plans, promises a revolution in patient care. However, this technological leap introduces profound ethical and legal challenges, particularly to the foundational principle of **informed consent**. Once the gold standard of medical ethics, informed consent—the process of ensuring a patient understands the risks, benefits, and alternatives of a medical procedure before agreeing to it—is struggling to remain meaningful in the age of complex, opaque, and constantly evolving AI systems [1].

The Challenge of the "Black Box"

The primary ethical hurdle AI presents to informed consent is the **opacity** of many advanced machine learning models. These are often "black-box systems," where the input (patient data) and the output (a diagnosis or treatment recommendation) are clear, but the internal workings and decision-making logic are not humanly comprehensible [1].

Traditional informed consent relies on the physician's ability to disclose material information about a procedure or intervention. When an AI system's recommendation cannot be fully explained—even by its developers—it becomes nearly impossible for a clinician to provide the patient with a truly comprehensive understanding of the risks and rationale. This lack of transparency undermines the patient's ability to exercise **autonomy** and make a genuinely informed decision [2].

The Problem of Perpetual Data Re-use

A second critical challenge lies in the nature of data use and re-use in AI systems. Patients may consent to their health data being used for a specific,

immediate purpose, such as training a diagnostic model for a particular disease. However, AI models are designed to learn and evolve. The data used to train them often becomes permanently embedded in the model's structure and contributes to all future predictions, blurring the limits of the use cases to which the patient originally agreed [1].

This perpetual re-use of data raises questions about the temporal validity and scope of consent. Does a one-time consent cover the continuous, evolving application of the AI system? Furthermore, the aggregation of vast datasets for AI training increases the risk of re-identification and potential misuse, demanding a re-evaluation of data governance and patient rights in the digital health ecosystem [3].

Redefining Consent for the Algorithmic Age

To address these challenges, legal and ethical scholars are advocating for a shift from the traditional, static model of informed consent to a more dynamic, layered, or process-based approach.

1. Layered Consent: This model proposes presenting information in stages, starting with a simple overview and allowing the patient to drill down into increasing levels of technical detail about the AI system, its limitations, and its data use [4]. **2. Process Consent:** Recognizing that AI systems change over time, process consent treats the agreement as an ongoing dialogue rather than a one-time signature. It involves continuous communication about how the AI is being used and how the patient's data is contributing to its evolution. **3. Materiality-Based Disclosure:** Some legal frameworks suggest that disclosure should be proportional to the risk. Practitioners would be required to disclose higher-risk AI systems (e.g., those making life-altering diagnostic decisions) without necessarily requiring the same level of detail for low-impact, administrative AI uses [1].

The ethical imperative remains clear: patient autonomy must be protected. The complexity of AI should not be an excuse for obfuscation. Instead, it should drive innovation in how we communicate risk and benefit. For more in-depth analysis on this topic, the resources at www.rasitdinc.com provide expert commentary on the intersection of digital health, ethics, and policy.

Conclusion

AI's impact on informed consent is a defining issue for the future of digital health. It forces us to confront the limitations of our current ethical and legal frameworks when faced with technology that is inherently non-transparent and constantly learning. Moving forward requires a collaborative effort between clinicians, ethicists, policymakers, and AI developers to establish new standards of transparency, accountability, and patient education. Only then can we ensure that the promise of AI is realized without compromising the fundamental rights and trust of the patient.

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References

[1] Petrie-Flom Center. Informed Consent, Redefined: How AI and Big Data Are Changing the Rules*. Harvard Law School. [https://petrieflom.law.harvard.edu/2025/04/11/informed-consent-redefined-how-ai-and-big-data-are-changing-the-rules/] (https://petrieflom.law.harvard.edu/2025/04/11/informed-consent-redefined-how-ai-and-big-data-are-changing-the-rules/) [2] Astromskė, K., Peičius, E., & Astromskis, P. (2021). Ethical and legal challenges of informed consent applying artificial intelligence in medical diagnostic consultations.* AI & Society*. [https://link.springer.com/article/10.1007/s00146-020-01008-9] (https://link.springer.com/article/10.1007/s00146-020-01008-9) [3] Wang, Y. (2025). Ethical and legal challenges of medical AI on informed consent.* Journal of Medical Ethics*. [https://pubmed.ncbi.nlm.nih.gov/38240080/] (https://pubmed.ncbi.nlm.nih.gov/38240080/) [4] Park, H. J. (2024). Patient perspectives on informed consent for medical AI.* Journal of Medical Internet Research*. [https://pmc.ncbi.nlm.nih.gov/articles/PMC11064747/] (https://pmc.ncbi.nlm.nih.gov/articles/PMC11064747/)
