

Dilemma and Countermeasures of Informed Consent of Clinical Patients in Digital Medicine Era

Bo Lv

Qilu Medical University, Zibo 255000, Shandong, China

Abstract: This paper investigates the dilemmas and countermeasures of informed consent for clinical patients in the digital medicine era. It employs the methods of literature review, case study and comparative study. The study identifies key challenges: digital literacy gaps, algorithm opacity, legal ambiguities, and patient distrust in AI. It concludes that resolving these requires a tripartite solution: a tiered informed consent system adapted to patients' digital capabilities, blockchain for secure data preservation, legislative updates to clarify standards, and social mechanisms like digital literacy training and AI ethics review. These measures aim to balance technological innovation with patient autonomy, ensuring ethical and secure informed consent in digital healthcare.

Keywords: digital health, informed consent, solutions

1. Introduction

1.1 Research background

Digital technology is transforming healthcare, enhancing the speed, accuracy of diagnoses, and patient engagement. While electronic informed consent systems have improved efficiency, they also reduce the understanding of consent, making the process more formalized. Privacy issues, especially those related to AI algorithms and health data, exacerbate information asymmetry, placing patients at a disadvantage in decision-making.

1.2 The legitimacy crisis of the traditional informed consent system

In the era of digital healthcare, traditional informed consent systems face formalization issues. Digital technology exacerbates the information asymmetry between doctors and patients, while artificial intelligence and electronic health records have altered medical communication, increasing the difficulty of understanding. In the age of big data and biobank research, long-term data storage and unforeseen secondary use render "one-time consent" ineffective[1]. Although electronic consent systems bring convenience, they can also lead patients to sign agreements without fully understanding the medical information, thereby undermining the substantive significance of informed consent. The content of electronic consent forms is complex, screen displays are limited, and the consent button may mislead patients, harming their rights.

2. Three challenges to informed consent in digital health

2.1 Technical challenges

The digital divide is particularly evident in the field of digital healthcare, affecting patients' ability to use electronic consent systems and limiting their right to informed consent. Elderly patients and those with lower education levels may lack the necessary digital skills to operate these systems independently. This can result in them not fully understanding the content of the consent, thereby impacting their right to make autonomous decisions. Complex medical jargon and lengthy text often lead to a situation where patients are "informed but not understood[2]." Even if patients can operate electronic devices, the complexity of technical terms and numerous clauses can still make it difficult for them to fully comprehend the content of electronic informed consent forms, thus preventing them from making truly informed consent decisions based on sufficient information. The opaque nature of algorithms makes it challenging for patients to understand the diagnostic and treatment recommendations from AI systems, hindering informed consent and further exacerbating patients' concerns and anxiety, which in turn affects the quality of informed consent and the fairness of medical decisions.

2.2 Legal challenges

Digital medical technology is rapidly advancing, and the current legal system falls short in addressing AI decision-making transparency and protecting patients' right to informed consent. Issues of data ownership and security have become focal points, yet traditional healthcare laws fail to adapt to the characteristics of AI technology. There is an urgent need to establish regulatory mechanisms to ensure that AI decisions are explainable and clearly define liability. Currently, laws do

not clearly delineate responsibilities for AI decisions, affecting patients' ability to protect their rights. There are gaps in the legal protection of electronic health records privacy and remote medical services. Globalization has driven the development of cross-border medical services, but differences in electronic consent laws across countries lead to uncertainties regarding patients' right to informed consent. The international community needs to enhance collaboration, develop unified standards or protocols, and coordinate national legal provisions to ensure the protection of patient rights.

2.3 Moral Challenges

Patients express concerns and distrust regarding the application of artificial intelligence in medicine, believing it lacks the emotional understanding and clinical experience of human doctors, thus failing to adequately consider individual differences. This distrust leads to resistance against treatment plans, with patients refusing treatments recommended by AI, which can result in delayed treatment and worsening conditions. The crisis of trust in technological decision-making also stems from concerns about decision transparency[3]. AI systems trained on historical data may be susceptible to racial or gender biases. This crisis of trust hinders informed consent and has a negative impact on the development of digital healthcare

3. Ways to solve the dilemma of informed consent in digital health care

3.1 Technical adaptation plan

According to the patient's level of cognition, providing different information levels, developing a tiered informed consent system is key to overcoming the challenges of informed consent in digital healthcare[4]. By carefully designing interfaces that fully consider patients' digital capabilities, it enhances their participation in the informed consent process. The system can flexibly customize services based on multiple factors such as the patient's educational background and health literacy, providing tiered informed consent services that precisely meet the actual needs of different patients, thereby effectively safeguarding their right to informed consent. Blockchain data preservation uses distributed ledger technology to convert data preservation operations into transaction records on the blockchain, thus achieving credible data preservation and traceability. Blockchain technology closely aligns with the requirements for evidence storage, and its distributed ledger structure enhances data security and reliability[5]. Any modification to the content of the consent form will cause a change in the hash value, and the system rejects modification requests to ensure the integrity and authenticity of the data. Blockchain-based evidence storage technology enables data sharing and collaboration, allowing different medical institutions to share patients' informed consent forms through blockchain technology, improving the efficiency and quality of medical services.

3.2 Legislative update

To adapt to the development of digital healthcare, it is necessary to clearly define standards and exceptions. The way digital healthcare information is communicated differs from traditional methods, necessitating a redefinition of notification formats, content, and approaches. In terms of form, ensure that electronic notifications are legally valid and user-friendly, with an intuitive interface and clear procedures. Regarding content, explain medical plans, risks, and alternative options in simple language, clarifying complex terms. In terms of method, adopt diverse notification methods to meet the needs of different patients. In special circumstances, such as emergency resuscitation or specialized medical research, healthcare institutions may not be able to fully comply with notification standards. Clearly defining these standards and exceptions provides legal guidance for healthcare institutions and patients, ensuring informed consent rights and promoting the healthy development of digital healthcare. Legislative bodies should monitor technological advancements, such as digital therapeutics, and promptly revise and improve relevant laws and regulations to ensure the safe and effective application of technology.

3.3 Social coordination mechanism

3.3.1 Patient education

Digital literacy training helps enhance patients' digital skills and participation in the informed consent process. The training covers basic skills and understanding of medical information, enabling patients to better use electronic devices and healthcare applications, as well as interpret medical information. For example, a hospital improved cancer patients' understanding of treatment through videos and case studies, promoting their involvement in decision-making. Training should integrate online and offline resources, providing professional explanations and interactive exchanges to meet personalized learning needs.

3.3.2 Ethics review

In artificial intelligence medical systems, explainability evaluation criteria are crucial for protecting patient information rights and building trust. The assessment should include algorithm transparency and decision explanation. Transparency

requires developers to disclose the principles of algorithms, data sources, and training processes to identify biases and risks, ensuring that data is legal, accurate, and representative. Decision explanation demands that systems provide diagnostic or treatment recommendations in an understandable manner and explain the decision-making process, typically through advanced visualization and natural language processing technologies. Implementing these standards can enhance patients' trust in AI decisions, reduce resistance, and promote cooperation with treatments. At the same time, they ensure patients' right to know, facilitate informed medical decisions, regulate the development of AI medical technology, and improve the quality and safety of healthcare services.

4. Conclusions

Technology, legal, and ethical frameworks are crucial for informed consent in digital healthcare. Blockchain provides tamper-proof consent tracking, while quantum encryption enhances data security. Laws mandate transparent disclosure of risks and alternatives, allow for relative or representative consent in emergencies, and exempt liability through technical rationality. Society should prioritize enhancing digital literacy and AI interpretability. These measures ensure ethical innovation and safety in the digitalization of healthcare.

References

- [1] Minerva C Rivas Velarde, Christian Lovis et al. "Consent as a compositional act – a framework that provides clarity for the retention and use of data." *Philosophy, Ethics, and Humanities in Medicine : PEHM*(2024).
- [2] Jose Manuel Garcia-Alvarez, Alfonso Garcia-Sanchez. "Readability and Understanding of Informed Consent for Anesthesia in Spanish County Hospitals: An Observational Study." *Nursing Report* (2024).
- [3] E. Frost, S. Carter. "Reporting of screening and diagnostic AI rarely acknowledges ethical, legal, and social implications: a mass media frame analysis." *BMC Medical Informatics and Decision Making*(2020).
- [4] Brian James McInnis, Ramona Pindus et al. "Exploring the Future of Informed Consent: Applying a Service Design Approach." *Proceedings of the ACM on Human-Computer Interaction*(2024).
- [5] M. Sigwart, M. Borkowski et al. "A secure and extensible blockchain-based data provenance framework for the Internet of Things." *Personal and Ubiquitous Computing*(2020).