

Opinion

A proposal for digital informed consent to standardize the physician's duty to inform, a mission-impossible job

Running title: Digital informed consent

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Legal ruling on the physician's duty to inform

On January 27, 2022, the Supreme Court of Korea ruled against a hospital for its failure to fulfill its duty to inform. The case involved a patient who underwent spinal surgery in 2018 and subsequently suffered a stroke, leading to paralysis and cognitive impairment. Although lower courts had previously ruled in favor of the hospital, the Supreme Court found that the patient was not given adequate time to consider the risks involved. Only 40 minutes had passed between the explanation of potential complications and the initiation of anesthesia.

This ruling has sparked a debate within the medical community concerning the specifics of informed consent, especially regarding the timing of explanations. The Korean Medical Association has expressed strong disagreement with the decision, pointing out that it introduces an undefined concept of "timing of explanation" that is not explicitly outlined in existing medical law.

No physician would oppose the fundamental purpose of the duty to inform, which ensures patients' right to knowledge and self-determination. Additionally, this duty acts as a protective measure for medical professionals, provided they comply with the specified requirements and procedures.

Lawyers often advise that it is safest for doctors to communicate directly with patients, tailoring explanations to their level of understanding and informing family members. Additionally, they recommend that physicians establish a strong rapport with their patients. Moreover, consent forms for operations and other medical procedures differ in format across hospitals, and the style of explanation varies among doctors.

Content of digital informed consent

To address these challenges and improve the informed consent process, I propose the following digital solution:

1. The Korean Medical Association could develop standardized, interactive digital educational materials for a range of surgical procedures. These materials would include 3D imagery and provide detailed information about the procedures, potential complications, and postoperative care.
2. These materials could be officially certified by expert committees, patient advocacy groups, and legal authorities to ensure compliance with the standards required for patient understanding and legal adherence.
3. The digital format would incorporate intermittent comprehension checks to ensure that patients can only provide consent if they demonstrate understanding.
4. Upon successful completion, patients could provide their electronic signatures, with options for further explanations from physicians if required.
5. The system would enable remote consent from family members or legal guardians when appropriate.
6. This process must be completed at least 24 hours before the scheduled surgery to be considered valid for non-emergency procedures.

Deposition of digital informed consent forms as non-fungible tokens using blockchain technology

The deposition of digital informed consent forms as non-fungible tokens (NFTs) using blockchain technology offers multiple advantages, such as increased security, transparency, and the immutability of consent forms. It has already been implemented in areas such as medical education and credential certification [1]. The procedure can be established as follows:

1. Digitizing the consent form: The informed consent form is first digitized, either by creating it directly in a digital format or by scanning a physical document into a digital file, such as a PDF or image file.
2. Smart contract creation: A smart contract is developed on a blockchain platform, such as Ethereum, to oversee the minting, storage, and access controls of NFTs. This contract contains provisions to verify the authenticity of the consent form and link it to a unique identifier.
3. Minting the NFT: The smart contract associates the digital consent form with an NFT. Metadata linked to the NFT may contain important information such as the patient's identity (anonymized or encoded to protect privacy), the date of consent, and other relevant details.
4. Storing the NFT: The NFT, which represents the consent form, is stored on the blockchain to ensure immutability and traceability. The actual content of the consent form may be stored directly on the blockchain if it is a small file. More commonly, it is stored off-chain, with a reference link (e.g., IPFS, a decentralized storage solution) included in the NFT metadata.

Conclusion

While the system described herein may not address all scenarios, particularly emergencies, it could significantly improve the quality of information provided to patients and reduce legal issues associated with routine operations and treatments. This method would ensure that patients receive standardized, high-quality explanations, while also protecting healthcare providers by clearly documenting the informed consent process. However, a legal framework for establishing NFTs on the blockchain for digital informed consent must be developed. If this innovative technology can be utilized for digital informed consent, it could reduce legal conflicts between physicians and patients or their families, potentially strengthening their rapport.

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