

AI in Medicine¹: A Human-Centric Approach

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Artificial intelligence (AI) in medicine presents a significant opportunity, but it demands responsibility, a focus on ethics, and the active involvement of healthcare professionals. Doctors should not be passive recipients of AI but should instead guide its use. The ultimate goal is an enhanced form of medicine that is not dehumanized. It is crucial to ensure fairness and transparency, avoiding discrimination in the use of healthcare AI.



Responsibility and the Evolving Role of the Physician

Although AI's diagnostic performance may exceed that of a specialist in certain fields, the final clinical decision-making responsibility remains with the physician. In the event of an error, liability can involve various parties, including the developer, the data provider, or the user who misinterpreted the AI's suggestions. This highlights the need for constant human review and transparency in the AI's clinical reasoning. The widespread use of AI also carries risks, such as the potential for "deskilling" of medical professionals and the alteration of the doctor-patient relationship. The professional role of doctors is evolving, requiring new competencies such as knowledge of AI, critical thinking, and strengthened relational skills. The goal is an active collaboration between humans and machines.

The European Regulatory Framework and the "Legislative Adoption Gap"

In Europe, three primary legislative frameworks govern the use of AI in medicine:

- **The Medical Devices Regulation (MDR):** Classifies AI software with a clinical purpose as a medical device, requiring it to undergo a conformity assessment and obtain a CE mark to demonstrate its safety and effectiveness.
- **The AI Act:** Classifies AI software for medical use as high-risk, especially when used for diagnosis or treatment. This requires strict adherence to risk management, data quality, and human supervision.
- **The GDPR:** Mandates that the use of AI in medicine must be based on a valid legal basis, such as explicit consent, and prohibits

The "Black Box" Problem and Trustworthy AI

One of the main challenges with AI in medicine is the difficulty in understanding the decision-making processes of systems based on deep learning. These systems often function as a "black box," which undermines trust among medical professionals and complicates the process of obtaining informed consent from patients. To build "trustworthy" AI, these systems must adhere to several key principles: continuous human supervision, transparency in decision-making, technological robustness, respect for privacy, the absence of discrimination, and a patient-centered approach. Promoting a culture of critical thinking among healthcare professionals is essential.

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decisions from being made solely by automated systems without significant human oversight.

A significant challenge, known as the "Legislative Adoption Gap," arises from the disparity between the rapid pace of technological development and the slow process of regulatory adaptation. This asymmetry creates legal uncertainties and hinders innovation. Bridging this gap is crucial to balance patient protection with regulatory flexibility. Collaboration between different healthcare centers is also essential to create representative and secure knowledge bases, reducing reliance on non-European data.