**AI in Healthcare: Legal Challenges Ahead**

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**Abstract**

Artificial Intelligence is one of the fastest-growing technologies, finding its applications across many industries. The healthcare sector, however, is one of the most promising yet challenging areas for this technology. While this has the propensity to increase efficiency and diagnostic precision widely, the impact on the legal system is similarly great. The legal and regulatory implications of the application of AI in medical practice will be of essence, especially to demarcate responsibility, ensure privacy, enhance access to data, and protect the basic rights of a patient. This paper seeks to critically evaluate the legal fields that may emerge due to the use of AI in the delivery of healthcare. Examples of present regulations, legal and policy challenges, and related solutions for the future will be analyzed.

Keywords: healthcare, liability, consent

1. **Introduction**

AI in healthcare is transforming diagnostics, treatment, and patient management, but it also raises important legal concerns. Key issues include data privacy and security, as patient information used by AI must comply with regulations like HIPAA[[1]](#footnote-0) in the U.S. Regulatory bodies like the FDA[[2]](#footnote-1) are working to establish guidelines for approving AI tools, but the legal landscape remains complex as AI technology evolves. Ensuring transparency, fairness, and patient consent are also critical legal considerations in integrating AI into healthcare.

In the context of the medical industry, AI refers to algorithms and machine learning models that analyze data in medicine with diagnostic decision support, patient monitoring, and treatment design. Examples of AI applications range from AI assisted diagnosis of cancer, decision support systems to help doctors find the best course of treatment to remote patient monitoring. With the integration of AI into healthcare however, many questions about liability, data protection and patients rights arise. In light of this, there is a serious need for clear legal frameworks to address these new emerging challenges.

How can legal frameworks keep up with the rapid integration of AI in healthcare to protect patient rights and ensure accountability?

1. **Relevant Legal Regulations**

Due to the nature of AI, protection of personal data–especially health data–is one of the main legal issues for AI use in healthcare. The General Data Protection Regulation (EU) 2016/679, also known as the GDPR, is the basic regulation regarding the processing of personal data within the European Union.

Article 9 of the GDPR[[3]](#footnote-2) stipulates that "health data are a special category of data," requiring special caution. More precisely, processing health data through AI should meet the following conditions:

Explicit patient consent: The processing of health data by means of AI has to be based on the patient's explicit and informed consent. This presupposes that the patient is perfectly aware of the fact that their data will be used by the AI–for instance, in diagnostics analysis or health profile creation.

Data minimization: this principle–enshrined inArticle 5 of the GDPR–dictates that AI will process data for the purposes it was collected and shall be limited to only what is necessary for those purposes. This is highly critical with regards to the diagnosis or monitoring of diseases, facilitated by AI technologies,. It must be ensured that the collection of excessive or irrelevant data is avoided

Data security: AI has to ensure that personal data is protected against unauthorized access, alteration, or loss. All processing of health data has to be done in a secure manner by way of encryption or anonymization in order to avoid abuses or any violations of privacy.

**Liability and Medical Malpractice**

The other pressing issue being discussed along with the introduction of AI into healthcare is legal liability. In the event of a medical accident–one that was caused either by the faulty AI system or the wrong diagnosis given by an algorithm–who would be responsible: the physician who used it, the company which manufactured the software, or the technology provider?

According to Law 24/2017, the so-called "Gelli-Bianco Law,"[[4]](#footnote-3) governing liability in the healthcare sector in Italy, damage to a patient because of a medical error is the responsibility of both the health professional and the structure where the treatment has taken place. The introduction of AI brings new complications. Should the diagnosis or choice of treatment be performed by an AI system, the doctor may be held liable for relying on technologies that were not sufficiently verified , with partial liability due to the technology manufacturer for any defect in the software or algorithm.

For now, no specific rules are provided by the actual legal framework with respect to liability in respect of the use of AI in medicine, and the problem will thus have to be resolved on a case by case basis. One possible approach would be to draw up ad hoc legislation which sets out clearly the limits of liability between the doctor, the health-care facility, and the manufacturer of the AI system.

**Artificial Intelligence and Ethical Oversight**

Another essential legal question relates to the ethical oversight of AI in medicine. There are potential ethical issues with the use of AI: discrimination, data biases, and automated decisions are some factors that could negatively affect a particular group of patients. The European Commission identified, in its White Paper on Artificial Intelligence (2020)[[5]](#footnote-4), non-discrimination and respect of fundamental rights as key requirements for AI. Besides, the European Society of Artificial Intelligence in Medicine–AIME–while pointing to considerations about code of ethics, stressed that human supervision must be given to final decisions regarding areas which are delicate, such as diagnosis and prescription for treatment.

In Italy, the Code of Medical Ethics, revised in 2021[[6]](#footnote-5), details how to use healthcare technologies. It state, "The use of technology by physicians should always be geared towards patient interest, and it is up to the physician to remain responsible for the therapeutic decisions even when these are supported by AI."

1. **Legal Challenges in Integrating IBM Watson for Oncology into Medicine: A Case Study**

Watson for Oncology and the Case of Malformed Treatment Recommendations[[7]](#footnote-6)

Watson for Oncology intended to analyze vast volumes of data and give recommendations on cancer treatments, using big data assistance for the best medical practices and patient data. However, several doctors and hospitals reported that the algorithm suggested wrong treatments– some even not just inadequate but harmful ones.

In 2018, the New York Times reported that in certain cases, Watson for Oncology recommended treatments that did not align with clinical guidelines, including medications not suitable for the patient's type of cancer. Probably the most infamous incident involved the system suggesting a wrong chemotherapy regimen for a colon cancer patient, bringing doubt to those doctors and patients who had trusted the system.

Legal Actions - Ethical Concerns

Although no public lawsuits are known where a patient has directly sued IBM for damages caused by erroneous treatment recommendations from Watson, there have been investigations, disputes, and concerns raised by hospitals and medical professionals. This had led to the revision of contracts between hospitals and IBM. Several healthcare facilities reduced or stopped the usage of Watson for Oncology due to the same reasons.

There are several legal issues presented, which make Watson for Oncology relevant.

Firstly the medical liability, in the case of a therapeutic error due to an inappropriate recommendation given by Watson, who would be legally responsible? The doctor who followed the advice given by AI, the hospital that implemented the system, or IBM itself? Secondly data reliability, it is been argued that Watson for Oncology was never fully "trained" on real-world cases; the treatments suggested were wrong, and hence, problems are created with AI systems in medicine. Thirdly diagnostic and therapeutic mistakes, AI could suggest treatments, which would be based on large datasets but not completely tailored or accurate for the individual patient, with the potential for causing clinical harm.

**Informed Consent Issues**

The integration of AI into clinical practice raises several issues regarding informed consent. Traditionally, informed consent includes the physician explaining to the patient in understandable terms the diagnosis, treatment options, and risks involved.

With AI, it becomes murkier. For example, if an algorithmic diagnosis has been completed, how would a physician explain how a complex, algorithmic system works to the patient? How can the patient be said to make an informed decision if they do not have the expertise in understanding how AI works?

Including an explanation of the AI technologies applied in a particular case, understandable by everyone, in the process of informed consent may enable a patient to agree to or decline treatment on a fully informed basis. Secondly, entirely new legislation will be needed to govern how informed consent is adapted to the new realities brought into being by AI.

The Challenge of Keeping Regulations Up to Speed with a Rapidly Changing Technology

The second legal issue refers to the fast pace at which innovations are being carried out within the artificial intelligence arena, which often leads to growing inability to further revise regulations on a continuous basis. AI-related technologies, especially those applied to medicine, are developing very fast, and laws and regulations often fail to keep pace. Such regulatory challenges are also well reflected in the Personalized Medicine approach, whereby AI is used to tailor treatments to individual patients based on their genetic background. Regulations concerning medicines and medical devices are not always prepared to tackle the peculiarities of these new technologies.

1. **Shaping the Future of Legal Standards in AI-Driven Healthcare**

Upon reviewing all these legal frameworks, various actions could be implemented to enhance and modify them in response to the challenges that AI presents in the healthcare sector. To begin with, it would be prudent to create tailored legislation that explicitly delineates legal responsibility in instances of medical mistakes attributable to AI, clarifying the division of accountability among healthcare providers, medical institutions, and technology creators. This strategy could assist in bridging the existing regulatory void, where liability remains ambiguous.

Moreover, it is imperative to bolster regulations concerning the safeguarding of personal data, especially in relation to sensitive health details. While the GDPR offers overarching principles, the advent of AI introduces heightened privacy threats, such as unauthorized access or data manipulation. As a result, more defined regulations may be necessary regarding the usage and safeguarding of information by algorithms, coupled with stricter surveillance of security implementations.

Another avenue for enhancement involves informed consent. Present regulations are inadequately prepared to deal with the intricacies of algorithmic systems. New legislation should be established to mandate that medical professionals clearly clarify the functioning of AI technologies to patients, allowing them to make genuinely informed choices. This could involve the formulation of consent documents customized to the particular applications of AI in healthcare.

Lastly, there exists a crucial need for the regular updating of regulations to align with the swift evolution of AI technology. Healthcare legislation and regulations ought to be designed with adaptability in mind, ensuring they can be swiftly revised to mirror technological progress. The formation of an interdisciplinary expert panel, comprising legal experts, medical professionals, technology specialists, and patient advocates, could serve as an effective approach to guarantee that regulations remain pertinent and impactful.

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1. *Health Insurance Portability and Accountability Act (HIPAA) sets privacy standards for healthcare information.*

   *https://www.hhs.gov/hipaa/index.html* [↑](#footnote-ref-0)
2. The FDA regulates medical devices, including those powered by AI.

   *https://www.fda.gov/medical-devices* [↑](#footnote-ref-1)
3. GDPR, Article 9: Special conditions for processing health data.

   https://gdpr-info.eu/art-9-gdpr/ [↑](#footnote-ref-2)
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