Health Tech Asmnt Act. 7(4). doi: 10.18502/htaa.v7i4.14653

Review Article

Legal and Ethical Challenges of Artificial Intelligence Applications in Healthcare

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Received 2022 August 18; Accepted 2022 September 03.

Abstract

Artificial intelligence (AI) has become an integral part of modern healthcare, with its algorithms and other AI-enabled applications supporting medical professionals in clinical and research settings. The digital revolution is transforming the way we approach medical care. Currently, numerous AI products have been developed to cover various aspects of healthcare, such as predicting the risk of acute and chronic diseases (e.g., cardiovascular risk, gastrointestinal bleeding, and eye conditions) and forecasting cancer risk, among other cases. Artificial intelligence has the capacity to revolutionize the utilization of health information collected in datasets. However, the specific characteristics of AI, including vagueness, complexity, data dependency, and automated behavior, can pose potential risks to users' fundamental rights and safety. Therefore, it is crucial to recognize and mitigate these risks and provide legal solutions for any harm resulting from these risks. In the realm of healthcare, AI plays a pivotal role in advancing reliable prediction capabilities. Consequently, the storage and processing of data are imperative for emerging diagnostic and decision-making technologies. Nevertheless, these advances also introduce privacy risks, raising significant legal challenges for medical institutions. Understanding the various levels of these risks assists healthcare professionals and institutions in managing these challenges and complying with regulations. This descriptive research article comprehensively examines and implements the regulatory frameworks governing the United States and the European Union. Additionally, it draws upon documented research in this field to discuss the utilization of AI in healthcare, along with the associated legal issues, including informed consent and malpractice.

Keywords: Intellectual Property; Artificial Intelligence; Health Rights

1. Context

Currently, a substantial amount of data is collected naturally, encompassing not only descriptive information but also comprehensive data from imaging sensors (e.g., those obtained from endoscopy) and molecular and genetic sources. Both medical and non-medical devices routinely gather data that prove invaluable for predictions aimed at preserving and enhancing individual and societal health. Health and genetic data represent the most critical forms of personal information, and their misuse can have severe and discriminatory consequences.

In advanced and numerous developing countries, various regulatory and legal approaches have been adopted to safeguard this information, with the European Union (EU) regulatory framework being one of the most prominent examples. However, it is essential to recognize that, from a legal perspective, privacy is never an absolute right; rather, its boundaries are defined by specific circumstances. The integration of intelligent systems into healthcare holds enormous potential. Nevertheless, successful implementation in the healthcare sector necessitates attention to fundamental principles, including organizational, managerial, economic, and technical training factors, in addition to addressing the issues outlined in this article. These considerations are vital for healthcare professionals seeking to implement these systems effectively.

Extensive research indicates that information technology (IT) has become a common facet of healthcare systems worldwide. Electronic medical records, as one of the most crucial sources of medical and health information, exemplify the practical application of IT in the healthcare sector. Consequently, studies have demonstrated that experts in medical records play a pivotal role in the successful integration of technological capabilities within

healthcare systems (1-3).

Artificial intelligence (AI) technology has been in use both on a personal and industrial scale for many years. Artificial intelligence and other digital technologies have the potential to revolutionize society and enhance our economic well-being. Artificial intelligence-powered tools are already assisting medical professionals in identifying skin tumors, aiding recruiters in finding qualified candidates, and assisting banks in making lending decisions. Algorithms are driving advancements in product recommendations, targeted advertising, content search, job placement, employee retention, risk assessment, image categorization, fraud detection, cybersecurity defense, and a myriad of other applications (4).

The lack of novel doctrinal approaches in the field of civil law poses practical challenges for legislators when addressing the complexities of civil law regulating societal relationships. Smart technologies represent a pivotal stage in the digitalization of society and the creation of a digital space within the post-industrial landscape. The absence of regulations governing the unique aspects of the legal framework for AI entities and the intellectual output generated by them creates ambiguity in the regulatory environment (1).

The applications of AI, particularly in the realm of robotics, present fundamental issues encompassing ethics, law, economics, philosophy, technology, psychology, and more (5). The current study delves into the legal and ethical concepts surrounding the primary applications of AI in healthcare. By adapting and applying the regulatory frameworks of the EU and the United States, the study focuses on legal and ethical challenges related to informed consent, medical malpractice, diagnostic algorithms, telemedicine, and other relevant topics. The aim is to propose solutions for managing and preventing violations in these areas and introduce a model for consideration.

According to the constitution of the World Health Organization, access to the highest level of healthcare services is regarded as a fundamental and universal human right, irrespective of factors such as race, religion, political beliefs, economic status, or social standing. In recent decades, in order to supervise the production and supply of health-oriented products and healthcare services globally, the field of health law has been seriously pursued by national and international institutions, relying on its theoretical and practical areas; as a result, the control frameworks, supervision, adjustment and adjustment, is defined under the title of regulatory and regulation, which is considered an important tool in managing and monitoring the quality and efficiency of health products and services.

The integration of modern technologies, including AI, into medical and healthcare applications has ushered in a transformative era in healthcare. Economists predict explosive growth in the AI health market in the coming years. As this sector expands, it becomes increasingly vital to uphold ethical and legal principles in the implementation of AI within the healthcare system.

2. Artificial Intelligence Applications for Health Research

Individuals achieve significant accomplishments by relying on their intelligence rather than speed and strength. Therefore, the proliferation of AI, considered an inherently "highly intelligent" system due to its practical abilities often surpassing those of the human brain, has the potential for profound impacts on humanity. Therefore, this path should be approached with caution (6).

Our perspective is rooted in the notion that it is human intelligence that fosters the creation and development of tools and technologies that enable us to exert control over our environment. Consequently, it stands to reason that a super-intelligent system is equally capable of developing its own tools and technology for exercising control (7). The associated risks stem from the fact that AI lacks our evolutionary history, giving rise to uncertainty regarding whether these systems possess human traits, such as a desire for power. Consequently, we must acknowledge that the system lacks human emotions, whether related to fairness, compassion, or conservatism (8).

Therefore, the responsibility falls upon AI developers to design and train these systems to cultivate super-intelligent "ethical" behavioral patterns that align positively with societal interests, avoiding negative outcomes, or what is commonly referred to as "aligned with human interests". To achieve this objective, designers must create and implement agent architectures that mitigate incentives for systems to manipulate and deceive human operators, thereby keeping programmer errors to a minimum (9).

The utilization of data generated for the electronic health record (EHR) represents a critical domain in AI-driven health research. If the IT system and underlying database fail to prevent the release of heterogeneous or low-quality data, its utility might be compromised. However, when properly constructed and trained with sufficient data, AI within EHRs can serve various purposes, including scientific studies, quality enhancement, and clinical care optimization. Before following conventional paths, such as scientific publication, guideline formation, and clinical support tools, AI, when adequately equipped and trained, can assist in uncovering best clinical practices from EHRs. Furthermore, by analyzing trends in clinical practices derived from electronic health data, AI can contribute to the development of novel clinical practice models in healthcare delivery (10).

3. Legal Responsibility (Liability)

One of the legal challenges involves compensating for damages and accepting responsibility, making the legislative implementation of this mechanism in the country's internal system a crucial challenge. In Iran's legal system, there is currently no mechanism for the ex-

change of private information between subsidiaries and other transnational companies or entities based in other countries. The adoption of AI technology within various sectors of Iran's healthcare system will necessitate such exchanges, especially in cases where data processors exclusively operate in a limited number of countries (11).

3.1. Data Protection and Privacy

One of the most fundamental and cherished rights in any society is the right to privacy, allowing individuals to lead their private lives with complete security, free from concerns about personal information disclosure and violations of their privacy (8).

In the realm of big data, it is of paramount importance that data protection laws be enacted in a timely manner to safeguard the privacy of individuals, particularly patients, effectively. The processing of personal data is intricately linked to the protection of personal privacy. Organizations utilizing personal data for AI applications might encounter challenges in complying with global data protection laws. These laws are in effect worldwide and generally pertain to the collection, use, processing, disclosure, and security of personal information. They might also impose restrictions on the cross-border transfer of personal data (12).

Some countries have comprehensive data protection laws that regulate AI and automated decision-making concerning personal information. In contrast, other countries, such as the United States, lack a single, comprehensive federal law governing privacy and automated decision-making and instead rely on provisions from other legislations.

3.2. Cybersecurity

Numerous issues arise concerning cybersecurity, including fully automated decision-making leading to errors and substantial losses. The utilization of AI weapons without human intervention and concerns related to AI vulnerabilities within cybersecurity are among other significant topics that are not covered in this introduction.

3.3. Intellectual Property Law

The development and utilization of AI and associated technologies, such as computer hardware, bring intellectual property issues to the forefront, encompassing matters of ownership and infringement (IP), particularly in the context of health AI (13).

4. Ethical Challenges

The applications of AI in the healthcare sector, particularly its use in treatment, have brought about substantial changes and optimization; however, they also present numerous challenges in this regard.

4.1. Inequality and Discrimination (Fairness Bias)

One of the significant challenges associated with using AI systems is the potential for these systems to make discriminatory and biased decisions, leading to what is known as algorithmic discrimination (4). The ability of AI to gather information from its environment depends on the quality of the designed protocol and the algorithms provided to it. If variables such as age, race, and gender are not defined in a system, the system might fail to process information related to these variables, potentially impacting its decision-making. Additionally, the algorithms designed for the system might inadvertently exacerbate discrimination, creating conflicts between different societal classes or races. This challenge becomes particularly evident when AI is applied within the judicial system (14).

4.2. Informed Consent

Artificial intelligence applications in healthcare, such as medical imaging, disease diagnosis, and surgery, have significantly transformed the relationship between patients and healthcare institutions. However, the question arises: How does the use of AI contribute to patient care and the principles of informed consent? Despite its critical importance, this issue has not received extensive attention in ethical debates. Informed consent is considered one of the foremost challenges in the intersection of AI and healthcare, addressing the extent of medical centers' commitment and responsibility to educate patients about the intricacies of AI in their field of practice, informing them about AI applications, and ensuring their satisfaction with AI utilization. Only with consent can the collection and processing of personal data have meaningful legitimacy. The general regulations of the EU outline four conditions for valid and meaningful consent: free, informed, specific, and unambiguous. More or less similar conditions are foreseen in the laws of other countries (4).

4.3. Safety and Transparency

Safety represents one of the most significant challenges of AI in healthcare. Medical institutions employ AI algorithms to assess patient information extracted from medical records, aiding healthcare professionals in evaluating treatment options for diseases. Artificial intelligence technologies must be transparent and comprehensible to developers, medical practitioners, patients, users, and regulators (3). Two primary approaches to achieving understanding are enhancing AI technology's transparency and explainability. Transparency necessitates the publication or documentation of sufficient information before designing or deploying AI technology, enabling public consultation and debate about the technology's design and usage. Artificial intelligence technologies should also be explainable according to the comprehension levels of those to whom they are being explained (15).

5. Application of Laws on Artificial Intelligence

Artificial intelligence has brought about significant changes in the field of medicine and healthcare. It assists doctors and healthcare professionals in providing the best care to patients, enabling accurate disease diagnosis and predicting treatment outcomes.

When it comes to AI, a crucial question arises: Should the government establish specific regulations governing the possession, use, and distribution of this type of AI? In part, the answer is straightforward. When AI technology is combined with prohibited or dangerous items or substances within a device, existing laws might be applicable in the first instance (16).

Devices that integrate AI technology and prohibited items or substances must adhere to both sets of rules. For instance, if an individual equips their AI-controlled drone with a machine gun, their actions with the autonomous vehicle would fall under the purview of both the Firearms Control Act and the Drone Flight Control Act (17).

In cases where an AI device is entirely new, the use of the technology might not be covered by existing laws. In such instances, the only available course of action might be to apply laws governing "dangerous items". For example, if a novel AI system is equipped with a firearm, it would need to comply with laws governing the use and trafficking of firearms (2).

An analogous approach is employed when testing a new military weapon in accordance with international law. As one researcher suggests, "If we have an autonomous robot that has been previously used and a weapon that has been previously used, it might be possible to use them without further authorization". This implies that legal norms applied to new AI technology are merely a collection of legal norms applicable to components of a new independent device or software. Although this approach is sometimes possible and reasonable, there is a significant risk that the characteristics of new technology might not align with the characteristics of its individual parts (18).

Inefficiencies, shortcomings, and negligence in addressing the damages and losses caused by digital technologies can result in incomplete or insufficient compensation for the injured parties. The societal implications of this inefficiency within existing legal systems, coupled with the potential risks posed by cutting-edge digital technologies, raise questions about the anticipated benefits (1).

6. Conclusions

Solving legal and ethical challenges in the emerging field of AI is undoubtedly a complex undertaking. Ensuring the ethics of AI entails the involvement of not only the technology itself but also decision-makers, developers, and the laws and regulations governing AI implementation.

The question of responsibility hinges on which of Halevy's Three Models is applied (commitment by another, possible natural consequence, or direct liability): (A) In cases of perpetration by another, the individual who commands the AI system, whether the user or the programmer, is likely to bear responsibility; (B) In instances of responsibility stemming from natural or possible consequences, accountability might lie with the person who foresees the product's use in a particular manner, whether it be the developer, seller (of a product), or service provider. This is unless the product or service's instructions provide extensive details on the system's limitations and potential consequences of misuse; (C) Artificial intelligence programs might also be subject to strict liability for torts, in which the programmer is likely to be held liable.

However, in all scenarios where the programmer is held accountable, there might be ongoing debates about whether the fault lies with the programmer, the program designer, the expert who provided knowledge, or a manager who appointed an expert or non-expert programmer.

In summary, AI holds significant potential for enhancing medical decision-making. However, its successful implementation in the field of medicine necessitates attention to various principles, including organizational, behavioral, cultural, managerial, economic, educational, and technical factors. This article delves into the key challenges and unanswered questions in the realm of AI application in medicine, which should be explored by thinkers, experts, and researchers to provide suitable solutions and answers. Such efforts will contribute to the increased utilization of AI systems in the medical profession.

Ultimately, as European countries grapple with the legal challenges posed by the expansion of AI technology, it is imperative for us, as consumers of this technology in healthcare, especially in medicine, to develop plans for addressing its legal challenges. Given the existing challenges related to cyberspace laws in Iran, the need to consider legal measures to confront AI challenges becomes even more pressing.

Authors' Contribution

Ehsan Lame, first author: Responsible for data collection and original draft; Shahriar Eslamitabar, corresponding author: Responsible for monitoring the results; Ahmad and Zohre Roozbahani: co-authors: Specialized in AI; Nasrin Rouzbahani, co-author: Responsible for text translation and data collection

Conflict of Interests:

There is no competing interest to declare.

Data Reproducibility:

Data requests can be made to the corresponding author.

Founding/Supporting:

This study received no funding support.

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