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LEGAL ASPECTS OF USE OF ARTIFICIAL INTELLIGENCE TECHNOLOGIES IN HEALTHCARE

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Abstract:

This article examines the theoretical and legal aspects of using artificial intelligence technologies in healthcare system. Focusing on key elements such as the current applications of AI in medical practice, its potential prospects and emerging challenges, the application of international standards and legal accountability, the article analyzes various studies demonstrating the diverse uses of AI in healthcare, highlighting both the benefits and challenges associated with its implementation. The article also emphasizes the legal basis for AI decision-making, algorithmic bias, transparency and the need for human oversight.

Keywords: artificial intelligence (AI), medical law, GDPR, data regulation, confidentiality, AI ethics, transparency, medical treatment, human control.

Artificial Intelligence (AI) has shown tremendous potential in revolutionizing the healthcare sector, as can be seen in several applications. AI-powered predictive analytics have played an important role in improving patient outcomes by providing information about disease progression and enabling early intervention. For example, machine learning algorithms have been used to predict the likelihood of readmission of patients with chronic diseases, helping clinicians develop appropriate post-discharge plans [1].

AI plays an important role in the development of personalized medicine. Deep learning algorithms have demonstrated the ability to analyze complex genomic data to identify disease risk and tailor treatments to individual patients. A prime example of this is the use of AI in oncology to develop personalized treatment plans based on the genetic makeup of a patient's tumor. AI has made significant contributions to medical imaging by significantly improving diagnostic accuracy. Machine learning models have been developed to detect pathologies in various types of images, including radiographs, computed tomography, and magnetic resonance imaging. This may help in early detection and treatment of diseases, including cancer [2].

AI has also found applications in robotic surgery, where robotic systems such as the da Vinci surgical system help surgeons perform complex procedures with greater precision, flexibility and control than is possible with traditional techniques. This has resulted in improved patient outcomes, including less pain, less blood loss, fewer complications, shorter hospital stays, and faster recovery times. AI chatbots and virtual health assistants offer patients 24/7 access to health information, appointment scheduling, medication reminders and emotional support. They can also reduce the burden on healthcare providers, especially when dealing with routine requests and follow-ups [3].

Artificial intelligence (AI) is playing an increasingly important role in advancing biomedical research, transforming traditional paradigms and creating new discoveries. Here are some examples of how AI is impacting medical research:

Drug discovery: AI algorithms can analyze vast amounts of biological and chemical data to identify potential therapeutic targets, generate new drug candidates, and predict their effects and potential side effects. This not only speeds up the drug discovery process, but also reduces the associated costs [4].

Genomics and precision medicine: AI is playing an important role in analyzing vast amounts of genomic data, leading to significant advances in precision medicine. By understanding genetic variations and their association with diseases, AI can help create personalized treatment plans.

Clinical trials: AI can streamline the clinical trial process, from participant selection to data analysis. AI can also predict the results of clinical trials, which can save time and resources.

Medical imaging. Deep learning algorithms have demonstrated exceptional ability to analyze medical images, diagnose diseases, and predict treatment outcomes. This can improve the accuracy and efficiency of disease diagnosis and improve patient care [5].

Data integration: AI can integrate and analyze different types of health data, including electronic health records, imaging data, genetic data, and even wearable device data. This comprehensive analysis can provide insight into disease mechanisms and treatment responses [6].

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Public health surveillance: AI can monitor and analyze online data (such as social media posts and online news) to identify early signs of disease outbreaks, providing valuable time for public health response.

While the integration of AI in medical research promises numerous benefits, it also raises a number of legal and ethical concerns, particularly regarding data privacy, consent, and property rights, which will be discussed in the following sections.

The potential future applications of AI in healthcare are vast and could revolutionize the industry in several ways. Here are some areas that may witness the impact of AI in the future:

1. Advanced diagnostics. Using deep learning algorithms, artificial intelligence can potentially improve the accuracy and speed of diagnosis. Future artificial intelligence could even potentially outperform clinicians in diagnosing complex conditions, such as rare genetic disorders or difficult-to-diagnose neurological conditions.

2. Robotic operations. Although robotic surgeries using AI already exist, advances in AI could lead to fully automated surgeries. Robotic systems can perform standardized procedures, potentially reducing human errors and increasing patient safety.

3. AI in mental health: AI-powered apps and chatbots can provide mental health support, offer cognitive behavioral therapy, and even predict mental health crises based on patient data. This may lead to improved access to mental health resources and reduced stigma associated with seeking help.

4. Remote patient monitoring. Future artificial intelligence systems may enable more effective remote patient monitoring. AI can analyze data from wearable devices to detect abnormalities, potentially predict health crises before they occur, and notify healthcare providers [7].

5. Personalized medicine. By analyzing genetic data and environmental factors, AI can potentially develop personalized treatment plans. This can lead to improved treatment outcomes, reduced side effects, and increased cost-effectiveness of healthcare.

6. Predictive analytics in healthcare management: AI can optimize resource allocation, streamline healthcare delivery, predict patient flow, and even predict disease outbreaks or public health emergencies.

These future prospects for AI in healthcare hold great promise. Addressing these issues will be important as we move toward a more AI-integrated healthcare future. Successful integration of artificial intelligence (AI) can be obviously seen in some cases. Specifically, in example of Google DeepMind. Google DeepMind has been successfully used to diagnose eye diseases such as age-related macular degeneration and diabetic retinopathy. The AI system can interpret eye scans with a high degree of accuracy, in some cases potentially outperforming human experts [8]. The predictive capabilities of an artificial intelligence system can help prevent vision loss by facilitating early diagnosis and treatment.

Another striking example of the use of artificial intelligence technologies in current medical practice is IBM Watson. IBM Watson for Oncology helps doctors diagnose and treat various types of cancer. The AI system uses machine learning to analyze vast amounts of medical literature, clinical studies, and patient data to recommend personalized treatment plans [9]. Although the technology is still in its early stages, early results show promising treatment results.

Zebra Medical Vision, an Israeli startup, uses artificial intelligence to read and diagnose data from medical images such as X-rays, CT scans and magnetic resonance imaging. The AI system can detect various diseases, including lung cancer, cardiovascular disease, and liver disease [10]. By improving diagnostic accuracy and speed, this technology has the potential to revolutionize medical imaging.

The legal framework for decisions made by AI systems in healthcare is in its infancy and raises complex issues related to liability and accountability. AI's decision-making abilities challenge traditional legal paradigms as it becomes increasingly difficult to determine who should be held accountable when AI decisions lead to negative outcomes.

Under traditional liability rules, a party can be held liable for negligent actions or decisions. However, in the context of AI, it is difficult to determine who is responsible for the decision made by the AI system: the AI developer, the healthcare provider using the AI system, or the AI itself. This is especially true when AI systems use machine learning algorithms that constantly evolve and learn from new data, making their decisions less predictable and harder to trace back to specific human actions.

Current legal systems are largely unprepared to address these issues. For example, under US law, a software application used in healthcare may be considered a medical device subject to regulation by the Food and Drug Administration (FDA). However, traditional FDA methods for ensuring safety and effectiveness may not be sufficient for AI systems, especially those that continually learn and evolve after they have been approved for use.

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A similar conundrum exists in EU law, where AI systems can be classified as medical devices and regulated under the Medical Device Regulation (MDR). However, MDR requires that the device have a manufacturer who is responsible for its safety and performance, a concept that becomes more complex with AI systems where the lines of responsibility between developers and users can become blurred [11].

Some legal scholars advocate the creation of a new legal entity—electronic persons—to hold AI systems accountable, similar to how corporations are treated as legal entities. Others propose adapting existing legal principles, such as product liability, to fit the AI context. In any case, developing a legal framework for AI solutions is a complex task that requires careful consideration of the unique characteristics of AI systems, the interests of all stakeholders, and the ultimate goal of promoting safety and innovation in healthcare.

The issue of algorithmic bias in AI systems is one of the most pressing legal and ethical issues in the healthcare context. Simply put, algorithmic bias occurs when an AI system makes decisions or predictions that systematically favor certain groups over others. As Alexandra Chouldechova mentions in her article this bias can arise from various sources, such as biased training data, inherent biases in the algorithmic model, or misuse of the AI system [12].

Algorithmic bias can have serious consequences in healthcare. For example, if an AI diagnostic system is trained primarily on data from certain demographic groups, it may be less effective at diagnosing conditions in underrepresented groups. Such biases can exacerbate existing health disparities and not only interfere with ethics, but can also lead to legal liability under anti-discrimination laws.

For example, in the United States, the Civil Rights Act and the Americans with Disabilities Act prohibit discrimination in health care. If an AI system produces discriminatory results, healthcare providers could potentially be held accountable under these laws [13]. Similarly, in the EU, the Charter of Fundamental Rights prohibits discrimination, including on the basis of genetic characteristics and health status, which may be relevant in cases of AI bias [14].

However, compliance with these laws in the context of AI systems is challenging, largely due to the difficulty of establishing intent to discriminate. Unlike human decision makers, AI systems do not have intentions or beliefs. Therefore, the generally accepted concept of discriminatory intent does not apply to them. It is therefore critical for legislators and legal scholars to consider new approaches to regulating AI systems, such as focusing on the impact of AI decisions rather than the intentions behind them or holding developers and users accountable for failing to adequately address the risk of bias. in their artificial intelligence systems. Combating algorithmic bias also requires technological solutions, such as methods to debias the development and deployment of AI, as well as regulatory oversight to ensure the effective implementation of these methods. This is a complex task requiring a multifaceted approach combining legal, ethical and technical aspects.

Transparency and explainability in AI systems are key aspects when discussing the legal implications of AI in healthcare. The opacity of AI, especially deep learning systems, often referred to as "black box" algorithms, poses significant legal and ethical challenges.

In healthcare, where decisions can have a profound impact on patients' lives, it is critical to understand why and how the AI system made a particular decision. For example, clinicians, patients, and regulators may need to understand how an AI system arrived at a particular diagnosis or treatment recommendation, both to ensure trust in the system and for legal liability in the event of adverse results [15].

Different jurisdictions are grappling with this problem by adopting different legal strategies. The European Union's General Data Protection Regulation (GDPR), which came into force in 2018, includes a "right to explanation," where individuals can request an explanation of decisions made about them by automated systems. However, the applicability of this mandate to complex AI systems, in which decision-making may not be easily explained, is controversial [16].

In the United States, the Federal Trade Commission (FTC) has suggested that AI developers should be responsible for ensuring that their algorithms are transparent and fair.

Beyond legal requirements, transparency in AI systems is an ethical imperative in healthcare. For AI systems to be trusted and effectively integrated into healthcare practice, they must be transparent and their decision-making processes understandable to the clinicians using them. Consequently, research into explainable AI (XAI)—AI techniques that create more understandable and interpretable models—is gaining momentum and has great promise [17].

Human oversight of AI decision making in healthcare is the subject of intense legal, ethical, and practical debate. The complexities of AI, especially with autonomous systems, challenge traditional legal norms and increase the need for a special role for humans.

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The concept of "meaningful human control" (MHC) has been common in several legal systems, especially those that regulate important decision-making areas such as autonomous weapons [18]. MHC requires humans to actively participate in the decision-making process and be able to modify or override AI decisions. Transferring this concept to healthcare, where decisions can change lives, seems reasonable and ethically sound.

The European Parliament, in its resolution on civil law on robotics, proposed a "kill switch" requirement whereby people could deactivate the AI if it went wrong. The EU High Level Expert Group on Artificial Intelligence (AI HLEG) has further emphasized the human-centred approach by promoting MHC over AI systems in its Ethical Guidelines for Trustworthy AI [19].

In the United States, the Food and Drug Administration (FDA) is pursuing similar issues regarding the role of humans in AI-enabled medical devices. FDA guidance documents suggest that such devices include "controls" to prevent harmful effects [20]. However, the specifics of what constitutes "control" and how much human supervision is necessary remain controversial.

Regardless of the legal mandate, human oversight of AI decision-making in healthcare is an ethical necessity. AI, despite its potential, is not infallible. Biased training data or deficiencies in algorithms can lead to erroneous results, which can compromise patient safety. Therefore, the safety net of human supervision seems indispensable.

One notable case involves IBM Watson, an artificial intelligence system touted for its potential in cancer diagnosis and personalized treatment recommendations. Watson participated in a joint project with MD Anderson Cancer Center; however, the project has been criticized due to the lack of significant benefits and high costs. The key issue that arose was Watson's "training". Doctors spent thousands of hours entering real patient data, but the results were not as encouraging as expected [21]. This raises legal and ethical questions about the transparency and accountability of AI systems. Expectations for Watson's capabilities have largely fallen short, despite significant financial and data investments. If AI system recommendations are followed and patient outcomes are not optimal, who is responsible? In such cases, legal issues regarding the use of AI in healthcare come to the fore.

Another real case example is represented in Babylon Health AI chatbot. Babylon Health's artificial intelligence chatbot used for pre-diagnosis and triage has faced criticism from doctors and regulators. It was alleged that the health app provided incorrect and potentially harmful medical advice. The UK Medicines and Healthcare Products Regulatory Agency (MHRA) examined these claims and concluded that the app may be unsafe for all patients. The case raises important questions about the regulation and oversight of AI in healthcare. If a patient suffers harm due to the wrong advice of an artificial intelligence system, who will be held responsible? The developer, the healthcare provider, or the AI itself? It reveals the need for clear AI liability legislation in healthcare and demonstrates the role of human oversight in validating AI results.

These case studies highlight the need to develop comprehensive laws and guidelines governing the role of AI in healthcare. They reflect the issues discussed in the previous subsections and serve as practical examples of the theoretical and legal challenges of integrating AI into healthcare.

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