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Artificial Intelligence in Healthcare: A Legal and Ethical Point of View

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ABSTRACT

Artificial intelligence (AI) is a computer program that is designed to initiate specific tasks like a human and, sometimes, better than a human; it may even perform tasks without additional review or involvement by a human. Generative AI models are algorithms that could be trained on and understand data, can produce new data, predict outcomes, and generate human-like text. Nowadays AI has many important applications in the healthcare system. These applications have changed the medical field. AI facilitated the clinician's role by helping him in report preparation. It also helps perform administrative tasks, speeding up data storage and access for health systems. It also improved diagnostic modalities and shared in developing preventive medicine, drug therapy and medical education. Some AI models act under human supervision; others act autonomously. The progressive integration of various AI models into healthcare system in the coming years obligates us to ask about many ethical and legal issues that may face everyday use of AI in healthcare. This is because AI in the healthcare system deals directly with humans and can affect decision-making regarding their diagnosis and treatment. Healthcare data is very sensitive information and should be highly secured. Any data used for machine learning should be preceded by informed consent from corresponding patients. This review article highlights the legal and ethical issues of AI uses in healthcare systems.

I. Background

AI can be defined as a computer program designed to initiate specific tasks like, or better than, humans and sometimes without additional review or involvement by a human user (Griffin, 2021).

History:

In 1966, shaky robot was considered a great step towards AI, where it was the first mobile robot that could interpret inputs and information, give proper action, put a plan in place, and obtain goals (Kuipers et al., 2017). The first AI medical consultant, called INTERNIST-1, was implemented in 1971, where it used an algorithm dependent on the symptoms of patients and concluded diagnosis (Miller et al., 1982 & Kulikowski C.A. (2019). Then the ideas progressed where the MYCIN program was developed. MYCIN utilized input data, which is a long chain of questions, and then suggested the probable infective bacteria to help the doctor to describe the proper antibiotic for infectious diseases. It provided an early information bank for physicians to look for up-to-date medical information (Shortliffe and Mycin, 1977). Great progress occurred in 1980 when the DXplain program was

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designed by Massachusetts University. It utilized symptoms as input information and generated a differential diagnosis. It provides a bank of medical information for physicians (Amisha et al., 2019). In 2007, one of the most extensive applications of AI in healthcare had developed. International Business Machines Corporation (IBM) created a question-answering machine called Watson. This technology which utilizing deep question answering (DeepQA) and language processing, analyzed information from variant texts to generate probable answers (Ferrucci et al., 2013). The COVID-19 pandemic has boosted the use of AI in health care, where algorithms could diagnose COVID-19 through analysis of chest scans and predict the severity of infection. Food and Drug Administration (FDA) clearances for clinical use had considered artificial intelligence/machine learning (AI/ML) as medical devices (Benjamens et al., 2020; Griffin, 2021).

With the progressive expansion of AI in the healthcare system, it is necessary to address the associated legal and ethical issues. This review article aimed at highlighting legal and ethical issues of AI uses in healthcare systems.

II. Applications of AI in healthcare systems

Artificial Intelligence (AI) in healthcare acts as a transformative power, which adds novel solutions that enhance the quality, efficiency, and accessibility of healthcare services (Bajwa et al 2021).

Non-autonomous and autonomous AI tools

Non-autonomous or assisting AI has the ability to give clinical, diagnostic, and therapeutic decisions and help physicians make decisions, such as using a non-autonomous AI tool that can help radiologists by recognizing the normal and abnormal images. (Clark, 2018), robot-assisted surgery Chuchulo and Ali (2023), personalized medicine Kline et al. (2022), progression of drug discovery (Qureshi et al. 2023). On the other hand, an autonomous AI system might act independently. Autonomous AI Physician uses algorithmic reasoning, takes medical decisions (diagnoses and describes treatment, etc.), and no human is included in that medical decision-making process. (Saenz et al., 2023)

In 2018, the FDA approved Luminetics Core for the diagnosis of diabetic retinopathy. Nurses or assistants capture images of their patients' retinas with a fundus camera that captures the back of the eye. The system's cloud-based platform securely receives the photos, scans them for lesions or signs of disease, and provides a report in less than a minute (U.S. Food & Drug Administration, 2018).

The European Union has approved ChestLink, an autonomous AI system that can separately recognize normal chest X-rays and produce patient reports without any provision from the radiologist. It had been learned through data to make more sophisticated decisions (Bellemo et al., 2019; Oxipit, 2022).

Generative AI models

Generative AI models are algorithms capable of producing new data, predicting outcomes, and even coming up with solutions for complex medical problems based on patterns learnt from existing data (Li et al., 2021).

Applications of Generative AI in Healthcare

Medical imaging analysis

Generative AI technology can assist radiologists in recognizing and diagnosing various clinical conditions from various radiologic techniques (Vert, 2023; Topol, 2023).

Improve the efficacy of drug discovery.

Generative AI also aids in the progression of drug discovery, where vast amounts of data allow generative AI to anticipate the degree of safety and accuracy of new drugs. Additionally, generative AI can reveal biological pathways of a disease from genomic data and can help find novel targets for drug development (Vert, 2023; Topol, 2023).

Personalized medicine

Generative AI can predict a personalized, more effective medication plan by analyzing a patient's genetic information, lifestyle, and disease history, and this will further improve patient outcomes (Kline et al., 2022).

Clinical documentation and healthcare administration

Generative AI may be prepared to read and summarize electronic healthcare reports that contain quiet information, such as therapeutic history, drugs, sensitivities, and lab investigations. This will spare time and guarantee that nothing vital is neglected. It also encourages communication between distinctive healthcare suppliers and between suppliers and patients (Petal and Lam, 2023).

Medical education, learning and training

Chatbot AI programs can comprehend, analyse and answer human questions. They gained great attention because the can generate human like text and share with the others in an interactive conversation (Ghorashi et al., 2023).

Generative AI can be used to generate a wide variety of virtual patient cases with different clinical sets. Medical students can interact with, diagnose and treat these virtual patients without any harm to real patients. If they make mistakes, they will learn from them (Eysenbach, 2023).

Medical Research

In research settings, generative AI can formulate novel hypotheses by making unexpected combinations of concepts, mimicking human creativity and intuition. Claude models are a family of large language models developed by Anthropic and are considered generative pre-trained transformers that can read research papers and propose unexplored directions worth investigating. This unique generative capacity could accelerate scientific advancement. However, corroboration by human researchers is crucial to prevent the blind acceptance of AI-generated findings (Gesk, 2022).

III. Ethical and legal issues

Patient privacy and data protection

Generative AI, as well as other AI modalities, may be a source of security and privacy threats because of their vast data requirements during model training, building, and implementation (Dwivedi et al., 2023). Although data analyzed by AI is de-identified before participating with the data aggregator, it was found in a previous study that an algorithm could be used to re-identify 85.6% of adults and 69.8% of children in a physical activity cohort study (Na et al., 2018). In a study to explore and investigate healthcare data breaches. The results showed different ways used to breach protected health data, like hacking/information technology (IT) incidents, non-authorized access/internal disclosure, thievery/loss, or inappropriate getting rid of data (Seh et al., 2020).

Artificial intelligence biases

Bias may be produced across different AI model creation steps, during collection of data, developing and evaluating the model, or during its clinical application. Bias in generative AI models might lead to inaccurate diagnoses and/or treatments**.** Poor data quality and missed information in an AI system can lead to biases and may result in wrong AI decisions. If an AI model "to identify patients at high risk of cardiac attacks" is biased towards certain demographics or lacks data about a patient's medical history, this could lead to diagnosis mistakes where warning signs may be missed in some cases while healthy ones may be wrongly treated as high-risk cases (Thirunavukarasu et al., 2023).

Effect of algorithmic bias on discrimination and equity in health care

- How could we realize the algorithm is accurate or not, diverse or not?
- AI can widen existing inequity in health care where these new technologies are more available to wealthy, educated, and urban patients. Some opportunities, like personalized medicine, which is tailored to treat specific person but is expensive and out of reach to poor patients and vulnerable groups, with subsequent increasing inequalities in the quality of health care (Hyden, 2019; Veiont et al., 2018)**.**
- If AI algorithms designed patients' profiles and health records to distribute healthcare resources over the population, then poor, elderly and other vulnerable groups that couldn't be registered to

these records wouldn't have access to these records and subsequently to these resources. So, it should be asked what's behind the data, and could we register and reach everyone in the community, keeping in mind that some people do not have this technology (Harvey and Gowda, 2021 & Vokinger et al., 2021).

- In the same context, AI might augment inequities with regard to different vulnerable and minority groups that already have difficult access to healthcare. For example, the algorithm might be fed on data mostly from white patients, while health records from Black patients were less available (Seyyed-Kalantari et al., 2021; Vokinger et al., 2021).
- The usability of Luminetics Core for diagnosis of diabetic retinopathy in well-resourced healthcare settings will help rich people and those covered by insurance, while other patients that have the same prevalence of disease but are poor or not covered by insurance cannot access such diagnostic tools.
- Also, there are wide variations in using medical AI among different age groups; this may augment the digital gap between generations and magnify health inequity. For example, older patients are less capable of dealing with and using an online system for data entry than younger patients (Mikołajczyk, 2022).

Does AI in healthcare have artificial empathy?

In spite of recent healthcare chatbots seeming more empathetic, not all kinds of empathy could be reached and artificially applied. Empathy is a complex human feeling that a chatbot could not believe to have such interaction; it can't substitute for an empathetic bedside clinician. (Seitz, 2024)

Transparency and Accountability of AI Algorithms

Transparency helps individuals to know how AI systems make decisions about their health, while accountability tells who is responsible if a wrong decision leads to harm (Novelli et al., 2023). An important issue is transparency, where AI algorithms function through deep learning neural networks and act as "black boxes" whose inner workings are ambiguous to us, making it difficult to explain the bases of decision-making processes and how an algorithm attains a certain conclusion. Lack of explanation is a critical issue in health care, where understanding the bases for diagnosis or treatment is mandatory for integrity and accountability. (Rudin, 2019; Parisineni and Pal, 2023). So, it may be difficult to judge that novel medical devices are safe and effective for different age groups. The use of AI may leave us without anyone to hold accountable for any sort of damage done. The extent of danger is unknown, and the use of machines will severely limit our ability to assign blame and take ownership of the decision-making (Fox-Rawlings et al., 2018).

Informed consent

When treatment options are decided for patients, it is mandatory that they get a comprehensive understanding of any procedures and the side effects as well as risk probabilities. However, when AI technology is added to healthcare service, the informed consent process is expected to be more complicated. The physician should inform the patients about AI input and output data and explain to him how the AI acts by training and then generating output data by learning from examples. The patient should be informed of the risks and benefits of the AI. The patient should know about the risk of a cyber-attack and/or algorithmic error, the possibility of hallucination (false-positive or false-negative results), and the right to choose a qualified physician instead of AI. Also, the patient should know that his data will be used outside the treatment process (Hurley et al., 2024; Wałdoch, 2024).

Liability issue

Autonomous AI do not need specialists and act by the primary care physician, who does not have specialized knowledge; this should not be liable for incorrect results, and AI creators or the selling company should assume medical liability for harms produced by the device if it was used properly and on label. Legal scholars have classified eight scenarios involving a physician's use of an autonomous AI system that are relevant to malpractice liability, and they hypothesized that there are only two scenarios in which the physician

might face liability: (A) informed consent: the system correctly recommends management that corresponds with the current standard of care, and the physician disregards this recommendation, resulting in patient harm; (B) the system incorrectly recommends management that is nonstandard care, and the physician follows this recommendation, which results in patient harm (Price et al., 2019; Channa et al., 2021; Bazoukis et al., 2022).

Accountability

Artificial intelligence developer should confirm and assure that the data set that AI programs are supplied with are valid and trustable. Accountability is mandatory for emphasizing that AI producers and developers adhere to the principles of beneficence and non-maleficence by taking responsibility for the impacts of their systems and mitigating potential harms (Novelli et al., 2023).

IV. Conclusion and Recommendations

Like global warming, 30 years ago, the world spoke about its probable hazards; now we are suffering, and the expectations become horrible facts. AI legal and ethical issues will be more apparent in the coming years. Developers tend to overestimate the effect of technology in the short run, but the effects in the long run are underestimated. As AI models advance, liability implications become more complicated. At the same time. Legal systems that govern AI move at slower steps and are not well developed in most countries, so accountability measures and laws should be set. Regular validation of AI models to measure the efficacy of AI in practice. Ethics should be a basic course in the curriculum of an AI data scientist. In spite of accuracy, the importance of joining human-AI decision-making should be emphasized so that patients can get benefit from both the strengths of AI and the expertise of humans.

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