Journal of Ecohumanism
2024
Volume: 3, No: 8, pp. 10582 – 10589
ISSN: 2752-6798 (Print) | ISSN 2752-6801 (Online)
https://ecohumanism.co.uk/joe/ecohumanism
DOI: https://doi.org/10.62754/joe.v3i8.5673

Artificial Intelligence in Healthcare: Bridging Innovation and Regulation

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Abstract

Regulations must be clear and stringent for both healthcare providers and patients. Regulations have been progressively refined due to identifying weaknesses within the regulatory process. For example, regulatory principles applied to pharmaceuticals have been extended to cover other medical technologies. This paper provides a solid foundation of the meaning of Artificial Intelligence and machine learning as well as the usage of these technologies in healthcare to provide better diagnosis and more personalised medicine. Also, this paper proposes the challenges and regulation in Artificial Intelligence and machine learning in the healthcare domain. This paper emphasises the importance of establishing regulations for artificial intelligence and machine learning to ensure safety in the healthcare domain.

Keywords: *Artificial Intelligence, Machine Learning, Regulating AI.*

Introduction

Regulations must be clear and stringent for both healthcare providers and patients. Regulations have been progressively refined due to identifying weaknesses within the regulatory process. For example, regulatory principles applied to pharmaceuticals have been extended to cover other medical technologies. As mentioned by Van Laere and colleagues, regulators are now addressing how to manage the use of artificial intelligence in healthcare, particularly in clinical decision support systems. Regulating that focus on healthcare technologies presents several challenges, such as managing unforeseen side effects not identified in initial trials, ensuring the safety of biological agents with manufacturing variations, recruiting enough patients for rare disease trials, and addressing inconsistent regulatory oversight of medical devices, which has often resulted in weak control in many settings. The way a medical device performs, especially in complex healthcare environments, is critical. This performance of any medical device is linked to the experience and skills of the operator. Regarding devices that utilise AI, regulatory governance becomes even more critical. Therefore, designing a regulatory framework that strikes the right balance between promoting innovation and fast market access on the one hand and ensuring safety and quality on the other remains highly challenging (McKee & Wouters, 2023). Due to the vast amount of data being generated, healthcare providers nowadays use AI and ML tools in their services because they provide insights in terms of disease diagnosis and treatment. This data can be analysed effectively, and, of course, it can lead to an improvement in overall healthcare efficiency. However, the use of these technologies could lead to errors , in some cases, that impact patient lives. Patients typically visit doctors for various health issues. Doctors can use AI and machine learning to assist in diagnosis, personalized treatment, and drug discovery. However, strict regulations must be followed to prevent errors in the use of AI to ensure patient safety (Alqodsi & Gura, 2023). The healthcare sector is revitalized by using AI and ML as they improve workflow performance, patient diagnoses, personalized treatment, and drug discovery. As these technologies are expected to grow more significantly in the coming years, they must be implemented in ethical way and legally within a robust framework. In this paper, we will explore the meaning of AI and ML and discuss their applications in the healthcare sector and their potential benefits. We will also explore the challenges faced by regulatory AI and ML in the healthcare sector and highlight the current regulation framework for AI healthcare. Finally, we will propose solutions for effective AI regulation.

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We are humans, called Homo sapiens because we can discover and learn from the environment around us. We try to understand everything based on our observations, learning, and experiences. Children, for instance, from the time they are born, gain knowledge from their families and the surrounding environment. As they grow, they begin to analyse and predict based on what they have learned. The field of artificial intelligence, or AI, goes further still: it attempts not just to understand but also to *build* intelligent entities. This field is one of the newest in science and engineering. Currently, AI plays an important role in many industries, such as playing chess, math, driving a car, disease diagnosis, personalized treatment, and others. AI has been defined as the study of mental faculties through the use of computational models. Also, it the study of the computations that make it possible to perceive, reason, and act (Russell & Norvig, 2010). In other words, AI is a branch of computer science that uses computational power to simulate human thinking and problem-solving. Machine Learning (ML) is a branch of AI that uses historical data to train models and make predictions. Machine learning consists of supervised learning, unsupervised learning, and reinforcement learning. Supervised learning works by using historical data where the target variable to be predicted is known. In contrast, unsupervised learning deals with data where the target variable is unknown, and the goal is to cluster the data into groups with similar characteristics. Reinforcement learning, on the other hand, trains models based on a system of rewards and penalties. The following image shows that ML is a sub-field of AI and Deep Learning is a sub-field of ML (Tiwari, Tiwari & Tiwari, 2018).

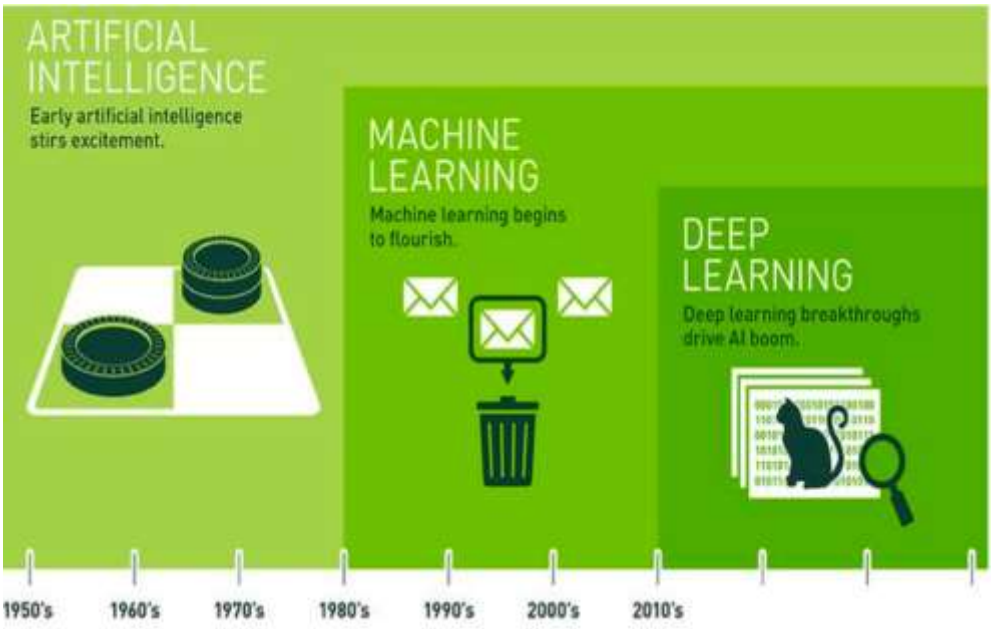

Fig1. The Evolution of AI Through the Years

The first type of machine learning is supervised learning, which uses historical data to train a model. Imagine we need to predict house prices based on previous historical data; the actual prices are known. The data should contain independent variables that contribute to predicting the price. Supervised learning algorithms such as decision tree (DT), support vector machine (SVM), or Neural Networks (NN) use this data to train these models by finding the relationship between the independent variables and the target. This problem could be a classification problem, where the target variable is categorical, or regression problem, where the target values are continues numbers. The second type is unsupervised learning, where there is no target label. This type of learning is based on discovering similar characteristics that could cluster the data into groups. The last type is Reinforcement learning where the decision is made based on receiving feedback in the form of rewards or penalties. Through trial and error, the agent learns which actions yield the highest rewards, gradually improving its behaviour to maximise long-term rewards. Deep learning, which is a subset

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of machine learning, can be supervised or unsupervised depending on the task that needs to be solved. Deep learning has become a promising tool for solving complex problems in a variety of fields. Deep learning uses various methods, including Convolutional Neural Networks (CNNs), Generative Adversarial Networks (GANs), Recurrent Neural Networks (RNNs), and Autoencoders (Imtiaz et al., 2024).

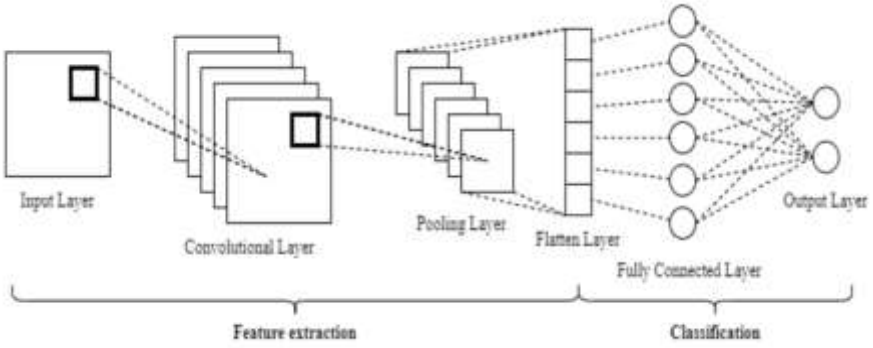

Fig2. Layers of a CNN

All AI and ML algorithms must be evaluated to assess their effectiveness. In healthcare, clinics and software developers need to understand how AI and ML algorithms can improve patient care. Essentially, metrics should be used to demonstrate model performance and to allow for comparison with different models (Hicks et al., 2022). In healthcare, there are many applications that use AI and ML to enhance decision making, to develop personalized treatment plan, drug discovery. AI systems can automate administrative tasks, streamline clinical workflows, and optimise resource allocation. Additionally, AI and ML can analyse healthcare data to provide insights that are difficult for human analysts to capture (Nagarajaiah et al., 2024). AI and ML application in healthcare such as Identifying Diseases and Diagnosis, Drug Discovery and Manufacturing, Medical Imaging Diagnosis, Personalized Medicine, and Smart Health Records.

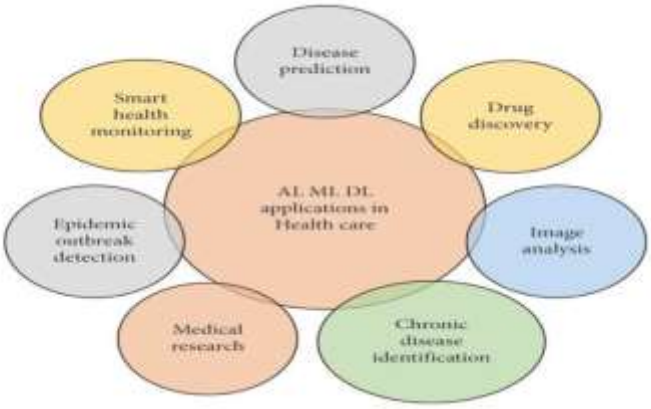

Fig3. AI & ML Applications in Healthcare

The integration of AI in healthcare has transformed and revolutionized the healthcare industry with the use of advanced algorithms and smart technologies that help diagnose patients, perform surgeries, and make data-driven decisions related to critical care. It enhances the quality of treatment by using machine learning and deep learning models which are very efficient in healthcare-related matters such as cancer detection, disease classification, and predicting cardiovascular conditions as compared to the existing traditional methods which are not so efficient. Such advanced systems increase the quality and speed of treatment and complex surgeries by minimizing human error. AI has a major role in personalized medicine which is made as per the patient's requirements and betterment by predicting the patient's response to a specific drug component based on their medical history. Apart from this, AI helps in therapeutic drug monitoring (TDM)

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which can detect adverse side effects of a specific medicine by analysing the patient's data. AI also contributes to clinical decision-support systems by exploring real-time data to make informed decisions and manage the health population to prevent chronic diseases. Despite these advantages of AI in clinical practices, certain precautions must be taken to ensure data privacy as patients' data is sensitive (Alowais et al., 2023). However, there are difficulties faced while taking responsibility regarding advancements in AI. Two Aristotelian factors set the groundwork guided by AI which is 'control' and 'knowledge'. The people who face repercussions due to AI-driven conclusions by discussing the relational approach to responsibility. Explainability is about both meeting the needs of the ones affected by AI and maintaining transparency. Moral responsibility is not only about being updated but also about the capability to answer to the affected ones. Humans are accountable for decision-making factors (agency) as artificial intelligence may not be able to fully exercise agency. However, shared accountability among users raises a complexity. Apart from shared accountability and transparency issues related to 'Black Box' AI, more socially relevant development systems are needed which make it easier for users to communicate, collaborate, and exercise (Coeckelbergh, 2020).

Regulating AI in Healthcare

The considerable increase in the use of AI technologies in healthcare leads to various legal and ethical concerns. Even though AI has a vast contribution to medicinal treatments, diagnostics, and individual care, it also brings up issues with responsibility, accessibility, and biases. There are various challenges in following the guidelines in AI-related healthcare where four primary concerns arise- data privacy, data utilization, system transparency, and fair decision-making. Since these AI technologies are independent of human intervention, it becomes a major concern for whom to blame in any faulty cases or harm as health-related matters can be quite critical and sensitive. AI has a 'black box' nature where it's difficult to understand their decision-making ability which further increases the complications and biases in AI models due to skewed datasets. These irregularities in data may lead to unfair decisions. Therefore, it is important to understand the limitations and develop a more responsible AI platform, especially in the healthcare field which can ensure smart and fair decisions for the efficient functioning of the healthcare industry that can collaborate with humans so that someone can be held accountable. It can be concluded that AI enhances the healthcare system rather than replacing the prevailing system (Coeckelbergh, 2020). Implementing AI can utilize huge amounts of patient's sensitive data, leading to data protection and privacy challenges as these systems are more vulnerable and can be easily hacked by unauthorized users. This calls for more secure and reliable measures to protect data. Implementing AI in treating a patient must require their consent and they should be aware of the implementation of AI while treating them and about any risks, errors, or chances of failure that may occur. Consultation empathy is yet another factor that needs attention as AI cannot replace human empathy while treating any patient which can cause a negative impact on the patient's mindset, especially in the cases of mental health or psychiatrist. AI can also lead to social inequality as it may create bias among advanced and developing countries. Automating healthcare diagnosis may lead to job loss, which further contributes to social inequality. Therefore, a balance between AI technologies and ethical issues is very crucial for humankind (Farhud & Zokaei, 2021). The use of AI technologies should be properly governed and monitored in terms of ethical, legal, and technical aspects so that these systems can be unbiased, transparent, and held accountable in case of any misleading or incorrect information. These governance measures include ethical governing where the AI system is carefully monitored to avoid any data privacy breach while maintaining transparency among users. Also, due to automation, job opportunities have comparatively reduced which needs to be addressed actively by implementing an ethical foundation. Ethical auditing is another measure to revise the input and output provided by AI which is too complex to understand which ensures responsibility. Explainability and Interpretability are some other measures proposed to establish equality and clarity. Having said that monitoring AI systems must balance ethical, legal, and technical aspects while keeping in mind the need for a global framework that goes beyond the existing Al monitoring system which justifies human rights and safety. Such a measure allows users to trust the technology they are using without any legal fear or bias (Cath, 2018). From an ethical point of view, four primary concerns such as informed consent, safety and transparency, algorithmic fairness and biases, and data privacy arise. Informing the patient before implementing the use of AI while treating them is inappropriate as they must be aware of the risks and disadvantages associated with it. This makes these

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systems more safe, fair, and transparent for the patients to rely on. Keeping their data private is another crucial aspect as AI systems are prone to hacking and can lead to the misuse of sensitive data. Apart from these ethical issues, some legal issues must be taken care of such as safety and effectiveness, liability, data protection and privacy, cybersecurity, and intellectual property law. Different countries have their specific legal management structure like the FDA in the US and MDR in Europe. Assigning liability for faults related to AI applications used in healthcare can be challenging apart from protecting the patient's data privacy (Gerke, Minssen & Cohen, 2020).

For instance, Adaptive AI refers to an advanced algorithm technology that learns from new data and has scope for improvement even after deployment. These systems consist of multiple components such as cloud facilities, complex algorithms, and datasets. Such technology is integrated into the healthcare domain for better treatment and diagnosis. However certain regulatory complexities arise while using these complex technologies in healthcare which cannot be ignored. It is a challenge to decide which component of adaptive AI should be subject to regulations, the software, or the algorithm. Another challenge is to regulate adaptive changes such as advanced updates which are available even after deployment. These updates are unpredictable and can affect the system's performance which can cause risky situations for the patients as well as doctors. Introducing such updates must be carefully triggered for which, experts have proposed three approaches, which are reviewing every change, and establishing clear performance and use-case scenarios and risk criteria evaluation. The existing regulatory policies are not capable of dealing with such challenges which call for strict regulatory frameworks which are thoroughly monitored by experts and professionals to minimize risk possibilities. Therefore, a balance between advancing algorithms in AI and ensuring safety and transparency is very crucial (Aquino et al., 2024). Also, these technologies raise serious concerns regarding various regulatory aspects such as data safety, responsibility, and security. Therefore, there is a need to ensure these concerns are addressed properly through regulated and reliable measures. Regulation departments like the US Food and Drug Administration (FDA) are responsible for examining the workflow of AI models in healthcare. The FDA follows a framework policy that categorizes these technologies based on the threats and potential risks along with introducing platforms like Software as a Medical Device (SaMD) to monitor these inventions. Some laws such as the Health Insurance Portability and Accountability Act (HIPAA) in the US and the General Data Protection Regulation (GDPR) in Europe govern patient data privacy. Therefore, international cooperation is very crucial in regulating the workflow of AI in healthcare. Some major obstacles in the AI management system are taking responsibility for any damage caused to the patient and keeping up with the advanced technology for diagnosis while ensuring all the safety protocols are followed.The autonomous and independent nature of these technologies raises legal and civil concerns as these technologies are prone to errors and since they are autonomous, no one is responsible for the liability caused. Strict liability arises when doctors, healthcare professionals, and medical staff are blamed for the harm and errors caused by AI systems. If this scenario occurs, people might hesitate to use AI-driven technologies for healthcare-related matters. Another concern is negligence-based liability where the healthcare workers need to explain their precautionary actions in case of a faulty system. Apart from these, medical malpractice can happen with AI technologies as they may or may not comprehend the duties a healthcare professional follow. Product liability focuses on whether AI technologies should be replaced by humans and treated as products or services that can cause complications. Therefore, there is a crucial need for legal reforms that can examine liability in the healthcare domain by introducing a no-fault insurance policy that suggests compensating for the harm without blaming anyone (Eldakak et al., 2024).

The use of Artificial Intelligence in Healthcare sectors brings certain challenges and gaps related to regulatory frameworks. Some of the gaps identified in the existing regulations are data privacy, data integrity, evaluation of algorithms, responsibility, and ethics. In the healthcare sector, patient data is very sensitive and can be easily misused. So, to ensure data safety, strict global regulations must be imposed along with control on data export. Maintaining data integrity is very crucial as the AI system needs to be trained on accurate data for efficient performance and datasets must be diverse, well-balanced, and unbiased as biases in data can cause incorrect decisions or mislead diagnosis which is a serious concern in the medical field. Another gap is evaluating and validating algorithms as AI models have a "black box nature" which makes it difficult to interpret the decision-making of the system. This makes it even more difficult to blame someone when any error occurs as there is a lack of accountability as to who is responsible for making the

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decisions, whether the developers, healthcare professionals, or AI itself. At last, it must be ensured that the ethics are maintained, and the benefits of AI are evenly and fairly distributed.

Challenges and Recommendations

One of the key challenges associated with AI in healthcare is the lack of transparency, especially in complex machine learning models. These "black box" systems make it difficult to explain how certain decisions, such as diagnoses or treatment recommendations, were made. For example, AI tools that predict the risk of sepsis in emergency rooms must be transparent to ensure trust between doctors and patients. Regulators such as the Food and Drug Administration are seeking to address this problem by requiring explainable AI models. These systems should be interpretable by professionals, making it easier to understand and justify decisions (PeW, 2024).

The lack of globally coordinated regulations and legal frameworks has created challenges for AI in healthcare. For example, under the EU's AI laws, AI in healthcare is classified as a high-risk technology, requiring rigorous risk assessments, data transparency, and human oversight. Unfortunately, such regulations are not universally applied, and there are many different systems governing AI, making it difficult to find a single, effective system globally (Dettling et al, 2024).

For example, the EU's AI regulatory framework focuses on ethics and transparency, requiring independent audits and strict compliance measures under its AI Act. By contrast, the US Food and Drug Administration (FDA) focuses on incremental improvements through frameworks such as the Software as a Medical Device Action Plan. These differences and disparities in regulatory goals and approaches create obstacles to the development and deployment of AI technologies across borders.

Moreover, the use of AI in healthcare requires strong assurance of patient safety, such that the use of AI systems in healthcare must lead to tangible and effective clinical benefits, such as improved health outcomes or reduced mortality, through rigorous trials similar to those required when examining the effectiveness of drugs. However, the challenge facing AI regulators is the issue of defining appropriate standards to apply, given the diverse scope of applications. Also, the issue of AI model updates increases the regulatory burden (Ayers & Desai, 2024).

To ensure the operation of AI systems, these systems require large amounts of sensitive health data, which requires a high level of protection during storage and processing, yet many countries lack effective frameworks to secure the storage of this data. The COVID-19 pandemic has highlighted this challenge, as most AI applications have not been able to effectively protect patient privacy and data, raising concerns about confidentiality breaches (Dettling et al, 2022).One of the challenges facing regulating the use of AI in healthcare is the issue of assigning responsibility for errors made by AI systems. For example, who is responsible if AI devices make a mistake in diagnosing a condition, is it the developer, the healthcare providers, or both? (Dettling et al, 2024).Moreover, AI has emerged as a significant challenge, both nationally and internationally (Albakjaji & Almarzouqi, 2023). Current laws are unable to keep pace with rapid technological advancements (Albakjaji & Adams, 2016; Meskic et al., 2021). In particular, intellectual property (IP) laws are ill-equipped to address the complexities of evolving technologies, highlighting the need for legislative amendments to ensure they remain effective and relevant (Albakjaji et al., 2020; Almarzouqi & Albakjaji, 2022).

Global harmonization of regulations and systems: International bodies and institutions should cooperate and work to create unified frameworks, and work to adopt a comprehensive and rigorous framework such as the European Union's AI regulatory systems. Provide interpretable outputs: Regulatory institutions should require AI systems to provide interpretable outputs, which in turn will help doctors understand and trust their decisions. Privacy, and data protection: Secure means of protecting data privacy should be adopted, and such measures should be applied globally.

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Conclusion

AI technologies have transformed healthcare by providing solutions for many issues, such as disease diagnosis and personalised medicine. AI and machine learning technologies are used as important tools in the healthcare domain to diagnose diseases and provide personalised medicine. However, these technologies need to be regulated to ensure patient safety. The importance of regulations that manage these technologies is essential. This paper has provided the meaning of AI and ML as well as their usage in healthcare. Regulations and frameworks should be designed to regulate these technologies and manage the updates of these technologies in order to ensure safety and address failures when happened. This paper provides a solid foundation of the meaning of Artificial Intelligence and machine learning, as well as the usage of these technologies in healthcare, to provide better diagnosis and more personalised medicine. Also, this paper proposes the challenges and regulations in Artificial Intelligence and machine learning in the healthcare domain. This paper emphasises the importance of establishing regulations for Artificial Intelligence and machine learning to ensure safety in the healthcare domain.

Acknowledgments

The authors gratefully acknowledge the support provided by Prince Sultan University, which covered the Article Processing Charges (APC) for this publication. The university's commitment to advancing research and knowledge dissemination has been invaluable in successfully completing this research.

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