BRITISH JOURNAL OF HOSPITAL MEDICINE

REVIEW

Artificial Intelligence in Healthcare: Current Regulatory Landscape and Future Directions

Nurittin Ardic[1,*], Rasit Dinc[2]

[1]Med-International UK Health Agency Ltd., Leicestershire, UK
[2]Research and Development Department, INVAMED Medical Innovation Institute, New York, NY, USA
*Correspondence: nurittinardic@yahoo.com (Nurittin Ardic)

Abstract

The integration of artificial intelligence (AI) in healthcare offers the potential to play a critical role in reshaping clinical practice. However, it also brings regulatory, ethical, implementation, social, and technical challenges that healthcare systems must overcome. It is necessary for the responsible parties in AI applications to be well defined by the regulations. To create standards that encourage innovation and address ethical and security concerns, collaboration between policymakers, AI developers and healthcare providers has a vital role. In this review, it was presented an overview of the current regulatory landscape for AI in healthcare, focusing primarily on frameworks in the European Union (EU), the United States (USA), and the United Kingdom (UK), which are leading countries in this regard. The review also emphasized the challenges that need to be addressed.

Key words: artificial intelligence; healthcare; machine learning; deep learning; ethics

Submitted: 2 December 2024 Revised: 8 February 2025 Accepted: 14 February 2025

Introduction

Clinical care directly affects patient health and encompasses a process that includes diagnosis, treatment, and follow-up of patients. This process requires health professionals to have a wide range of knowledge and skills (Dinc, 2025). Healthcare services hold unique features in protecting and improving human life. However, healthcare systems face challenges worldwide due to reasons such as changes in demographics and epidemiology of chronic diseases, increases in their prevalence, and increasing costs of medical services (Bajwa et al, 2021; Palaniappan et al, 2024). Increasingly widespread digital health interventions, including artificial intelligence (AI), appear to have the potential to solve some of the challenges facing health systems (Bajwa et al, 2021). AI is used in healthcare across a spectrum from prevention, diagnosis, and pharmacology to treatment (Palaniappan et al, 2024). In radiology, for example, AI-powered diagnostic tools can accurately analyze medical images and identify details that the human eye might miss. Similarly, AI algorithms can sift through large datasets, helping to predict which treatments will be most effective and even offer personalized treatment options (Udegbe et al, 2024). While it seems unlikely that human doctors will be replaced in the foreseeable future, AI can certainly help doctors make better clinical decisions and even replace human judgment in certain functional areas of healthcare (Jiang et al, 2017).

How to cite this article:
Ardic N, Dinc R. Artificial Intelligence in Healthcare: Current Regulatory Landscape and Future Directions. Br J Hosp Med. 2025. https://doi.org/10.12968/hmed.2024.0972

AI represents a force that is reshaping the landscape of the healthcare sector, including reducing cost and time of the operational and clinical workflows of hospitals, laboratories, and research institutions (Lekadir et al, 2022; Mehta et al, 2019; Mesko, 2017). There is a fierce global race in AI research and development spanning Europe, North America and Asia, and medicine and healthcare are not exempt from this race (Čartolovni et al, 2022; Gerke et al, 2020). A study conducted considering the current trends and needs of the world's population predicts that by 2030 there will be 5 million fewer doctors working worldwide than society needs (Bajwa et al, 2021).

While the increase in available health data and the rapid development of big data analytics methods are making these successful applications of AI possible, this rapid adoption also brings a number of regulatory challenges (Dilsizian and Siegel, 2014; Mesko, 2017). These challenges range from data acquisition, technology development, clinical implementation, to ethical and social issues (Aung et al, 2021). Significant efforts are being made to ensure that AI applications are safe, effective, and compliant with data privacy laws (Mesko, 2017). However, studies regulating AI in the healthcare sector are still in their infancy and are struggling to keep up with technological advances. Moreover, AI systems are often dynamic and adapt over time by constantly learning from new data (Gerke et al, 2020; Ulnicane, 2022).

AI has the ability to increase clinical efficiency, improve patient outcomes and reduce the number of healthcare workers required. AI also holds significant potential to bridge critical gaps in healthcare delivery, especially in under-resourced areas and specialties facing workforce shortages (Attaran, 2022; Palaniappan et al, 2024; Udegbe et al, 2024; Ugajin, 2023). Taken together, the urgency of adopting and implementing AI in the medical field is evident.

However, despite its promise, the regulatory landscape for AI in healthcare is fragmented and nascent. While many countries are working to establish regulatory frameworks, countries, and regions such as the United States, the European Union, and the United Kingdom are taking the lead. However, these efforts are still evolving to accommodate technological advances (Busch et al, 2024; van Kolfschooten and van Oirschot, 2024).

This review aims to provide a comprehensive overview of the regulatory landscape for AI in healthcare, focusing on the current regulatory framework of global leading countries or associations. Specifically, it reviews and analyzes existing frameworks, identifies challenges, and highlights opportunities to align regulatory efforts. By seeking solutions to these issues, this study highlights the need for collaboration among stakeholders and aims to contribute to the ongoing discourse on the integration of AI in healthcare systems.

Understanding AI

The primary goal of AI is to tackle complex problems by mimicking human thinking through intelligent machines. To achieve this, it involves transferring data and information to machines that can provide this intelligence, combining various disciplines to produce an output. This process includes tasks such as understanding

natural language, recognizing patterns, learning from experiences and ultimately choosing the right path (Udegbe et al, 2024).

AI can be broadly defined as a computerized system capable of performing tasks or reasoning processes typically associated with human intelligence (Steerling et al, 2023; Topol, 2019). AI uses a variety of computational techniques and methodologies such as machine learning (ML), natural language processing (NLP), computer vision, and deep learning (DL) (Steerling et al, 2023). To gain a better understanding of the fundamental terminology associated with AI, the following key terms are described below (Alowais et al, 2023; Chahal and Gulia, 2019; Jordan and Mitchell, 2015; Tejedor et al, 2020) (Fig. 1):

Artificial intelligence (AI): Overarching term encompassing the use and development of computer systems to perform tasks requiring human intelligence. It represents several subfields (such as ML and DL), either individually or in combination.

Machine learning (ML): This refers to the study of algorithms that enables computer programs to decide wisely or predictions based on experience. In healthcare, ML is commonly used for predictive modeling, risk assessment, and disease diagnosis (Fig. 2). ML meanwhile automatically improves over time. ML can be further categorized into supervised, unsupervised, and reinforcement learning.

Supervised learning (SL): Involves training algorithms with labeled data under guidance of a teacher who has access to both inputs and outputs and creates outputs based on inputs. The learning dataset contains the target or outcome of each instance in the dataset; for example, detecting tumors in new images using labeled X-ray images of known tumors.

Unsupervised learning (uSL): Involves identifying patterns in unlabeled data independently, without a teacher' guidance. When encountering new data, the clustering model selects the cluster to which the new data belongs; for example, it can determine a common cause of disease by categorizing groups of patients with similar symptoms.

Reinforcement learning (RL): Is an algorithmic approach is used to understand and automate goal-oriented learning and decision making; for example, designing a fully closed-loop controller that provides a personalized insulin dosing regimen based solely on the patient's own data.

Neural networks (NNs): Computational models comprising interconnected nodes or neurons simulate the complex functions of the human brain, enabling tasks like pattern recognition and decision making in ML.

Deep learning (DL): Is a class of algorithms that utilizes multilayered neural networks to learn. Advancements in information technology have enabled DL to create networks with multiple layers, a feat not achievable by traditional NNs. In this way, DL analyzes and solves large data sets (Fig. 2).

Natural language processing (NLP): Is a ML technology that enables computers to understand written or spoken human language, interpretating and generating human language. NLP eventually converts synthesized free language into automatic and structured text.

Big data: Refers data sets that are too large to be effectively analyzed using traditional AI techniques, prompting the use of new methods like DL for analysis.

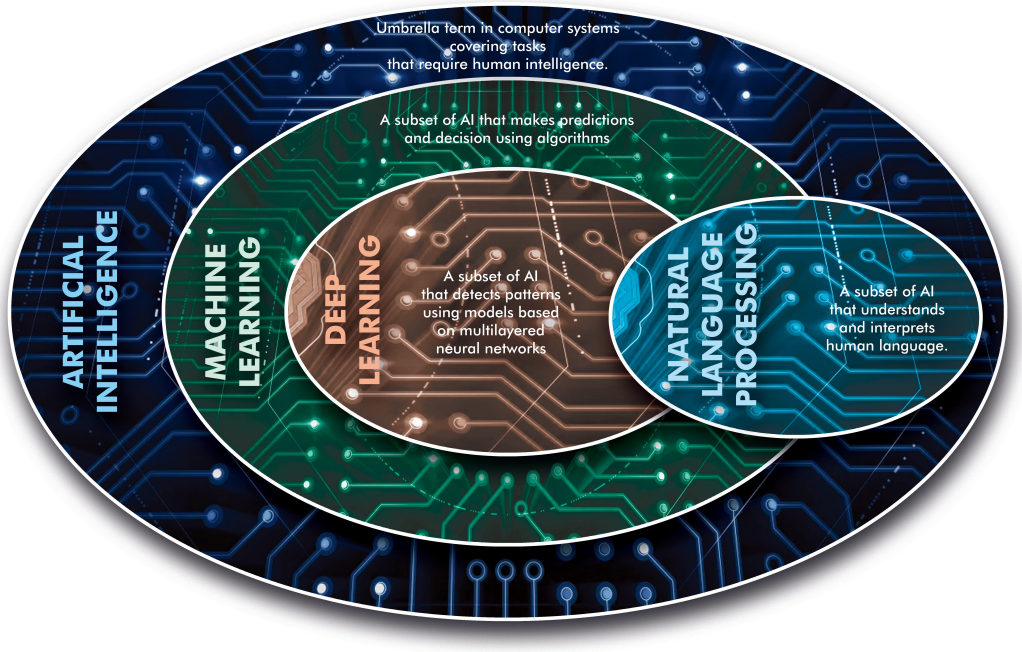

Fig. 1. Simplified illustration of artificial intelligence and its subfields, natural language processing, machine learning and deep learning. Drawing with Adobe Creative Suite Package [(Illustrator, version 28.7.1 and Photoshop, version 25.12) (Adobe Systems Incorporated, San Jose, CA, USA)]. Adapted from Alowais et al (2023), BMC Medical Education, and Chen and Baxter (2022), Frontiers in Medicine, which are available under the CC BY 4.0 (https://creativecommons.org/licenses/by/4.0/). AI, artificial intelligence.

It is important to note that the algorithms mentioned above are not entirely independent from each other (Sun et al, 2023).

AI Applications in Clinical Practice

In recent years, the use of AI in the field of medicine has become significantly widespread, and the high-speed integration of AI into the healthcare sector has opened new horizons in this field (Topol, 2019; Xie et al, 2023). The analytical capability of AI also allows the possibility of reducing the likelihood of error and predicting health outcomes, ultimately leading to more effective and timely treatments or preventive measures (Vallée, 2023). By analyzing a variety of patient data, including genetic information, environmental factors, and patient history, ML algorithms can determine optimal treatment strategies, even at a personalized level. This level of analysis not only improves treatment outcomes, but also minimizes adverse effects and reduces the trial-and-error process often associated with finding the right drug or treatment (Udegbe et al, 2024).

AI technologies have been successfully applied in many clinical areas, including clinical applications, biomedical research, public health, and healthcare administration (Lekadir et al, 2022).

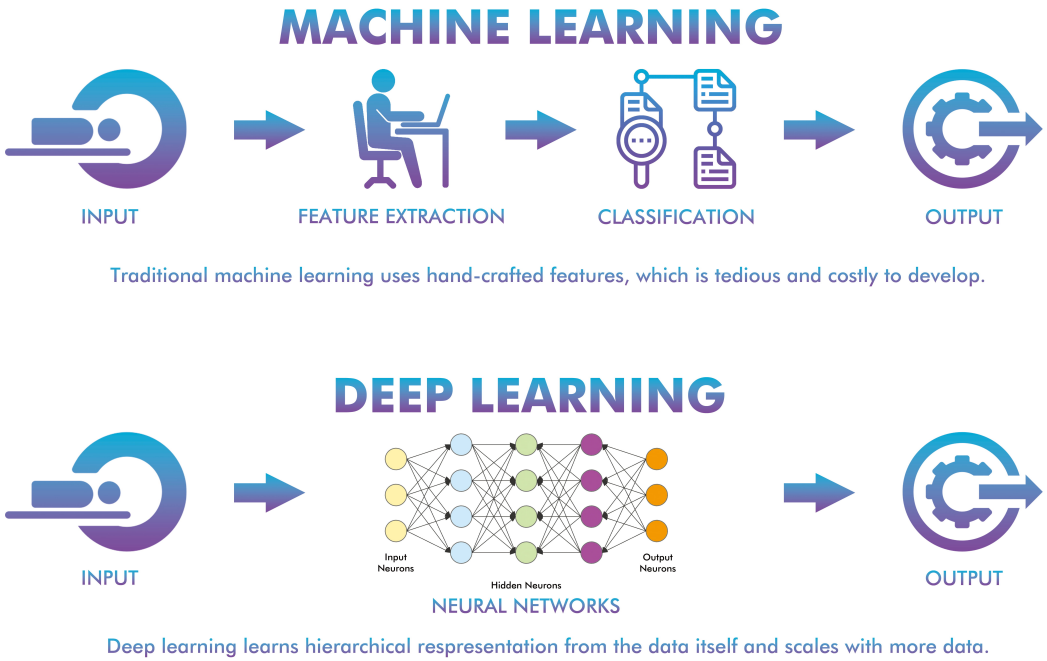

Fig. 2. Diagrammatic comparison of the processing framework of machine learning and deep learning. Drawing with Adobe Creative Suite Package [(Illustrator, version 28.7.1 and Photoshop, version 25.12) (Adobe Systems Incorporated, San Jose, CA, USA)]. Adapted from Alowais et al (2023), BMC Medical Education, and Yuan (2023), Applied and Computational Engineering, which are available under the CC BY 4.0 (https://creativecommons.org/licenses/by/4.0/).

One of the most transformative applications of AI in the clinic is in the field of radiology, which adapts quickly to technological innovations (Yordanova, 2024). AI technologies provide significant assistance to radiologists in medical imaging studies. They can prioritize and monitor findings that require early attention, and further enable radiologists to concentrate on images (Lekadir et al, 2022). Applications of AI play a role in all forms of radiology, including radiography, computed tomography (CT) scans, magnetic resonance imaging (MRI), and ultrasound (Yordanova, 2024). In both the USA and Europe, more than 100 AI/ML-based medical devices have been approved or Confromité Européenne (CE) marked for radiological use, significantly more than in any other medical specialty (Muehlematter et al, 2021). AI is applied in almost all areas of radiology, including breast radiology, neuroradiology, musculoskeletal radiology, and cardiovascular radiology (Mello-Thoms and Mello, 2023; Richardson et al, 2021). An impressive example of AI's capabilities in medical imaging is evident in Google's DeepMind, specifically designed to detect diabetic retinopathy from retina scans (Gouripur, 2024). In the field of radiology, AI-supported platforms offer the opportunity to reduce the workload of radiologists and increase the speed of interpretation by automating the segmentation of tissues. While AI can certainly assist doctors in making better clinical decisions, concerns have been raised that it may replace radiologists. A study conducted in Canada found that 48% of medical students surveyed were anxious about choosing radiology specialization due to this concern (Gong et al, 2019).

In a meta-analysis study, Liu et al (2019) found that the diagnostic performance of DL models was equivalent to that of radiologists. Remote consultations with AI-enabled tools for image analysis may reduce this disparity not only in radiology but also in underserved pathology areas (Ling Kuo et al, 2024; Ugarte-Gil et al, 2020). Collaborative efforts between healthcare providers and policymakers are critical to overcoming these challenges.

Digital pathology has made significant contributions to traditional clinical pathology with its tasks from preanalytical to analytical and postanalytical workflow stages (Hosseini et al, 2024). ML algorithms can recognize pathological patterns, speeding up the diagnostic process and improving the accuracy of detecting subtle abnormalities that indicate various diseases, including cancer (Klauschen et al, 2024). International Business Machines (IBM)'s Watson for Oncology is a prime example of an AI-powered system in this field (Lee and Yoon, 2021). As AI technology advances, it has become possible to predict not only histological features but also genetic alterations in pathology samples (Shafi and Parwani, 2023). Coudray et al (2018) were able to predict mutations in genes such as Kirsten rat sarcoma viral oncogene homolog (KRAS), epidermal growth factor receptor (EGFR), and tumor protein p 53 (TP53) with high accuracy using Convolutional Neural Networks (CNNs) models.

In the field of cardiology, AI applications have shown the potential to significantly accelerate the diagnosis and treatment of cardiovascular diseases (CVD), including heart failure, atrial fibrillation, valvular heart disease, coronary artery disease, cardiomyopathy, etc. (Sun et al, 2023). AI has made significant progress in diagnostic imaging modalities such as echocardiography, cardiac MRI, and CT angiography by improving image acquisition, segmentation, and interpretation. It increases the accuracy of detecting structural and functional abnormalities by providing real-time, automated analysis with ML algorithms (Ghassemi et al, 2020; Hannun et al, 2019). New AI algorithms developed in depth to capture subtle connections from large amounts of health data are expected to tackle even more complex tasks than traditional methods (Sun et al, 2023). By integrating clinical, imaging, and genomic data, predictive models powered by AI may be able to create personalized risk profiles and support proactive interventions, improving outcomes for millions of patients worldwide (Quaglio et al, 2019; Quer et al, 2021).

AI is also used in many other medical fields, one of the important ones is surgery. In conditions of time constraints and uncertainty regarding a patient's diagnosis and treatment (such as insufficient patient data, lack of evidence-based guidelines), AI allow timely intervention, improve operative precision, and personalize postoperative recovery plans (Loftus et al, 2019). AI also improves preoperative planning by analyzing imaging data, patient history, and clinical variables. It even supports postoperative monitoring by identifying individuals at high risk of complications such as infection or delayed healing to determine the best surgical approach (Mithany et al, 2023). AI-powered robotic systems provide enhanced dexterity, precision, and visualization, allowing surgeons to perform complex operations with less invasiveness (Iftikhar et al, 2024). Table 1 provides a summary of AI applications in some fields of clinical practice.

Table 1. AI applications in some fields of clinical practice.

Clinical field	AI technology	Major task	Outcome
Radiology	Deep learning algorithms	Analyzing MRI, CT, X-ray	Early detection of abnormalities
Pathology	Classical neural networks	Analyzing histological image	Improved detection of cancer
Surgery	Robotic	Facilitating minimal invasive intervention	Improved precision and reduced recovery time
Cardiology	Predictive analysis	Monitoring cardiac event risk	Timely intervention
Public health	Big data analysis	Pandemic modelling	Optimized resource allocation

AI, artificial intelligence; CT, computed tomography; MRI, magnetic resonance imaging.

AI-supported applications also significantly contribute to the continuous monitoring of patients through telemedicine and wearable technologies, eliminating the need for frequent hospital visits (Bajwa et al, 2021; Haleem et al, 2022). AI offers significant advantages in research projects from *in vitro* and experimental models to clinical trials (Stokes et al, 2020; Zhu, 2020).

It is important to note that AI technologies are not limited to clinical applications, but also extend to optimizing administrative and operational workflows in healthcare systems, involving various actors and institutions, including healthcare professionals, healthcare facilities, organizations (e.g., patient flow and billing management), laboratories (e.g., consumables supply chain), pharmacies, and regulators (e.g., standard coding) (Jimma, 2023; Ugajin, 2023). Despite the risk of hacking and concerns about privacy and security remain in its use in administrative applications, AI can perform these routine tasks more efficiently, accurately, and impartially (OECD, 2020).

Challenges of AI Applications in Healthcare

As AI becomes more integrated into healthcare, ethical and security challenges become more apparent. At the heart of these ethical issues is patient privacy. While striking the balance is a complex ethical dilemma, these concerns need to be addressed to ensure AI-powered healthcare is not only effective, but also ethical and trustworthy (Anyanwu et al, 2024). In this section of the review, an overview of the primary ethical and safety concerns associated with AI in healthcare is addressed under the following headings.

Data Privacy and Security

One of the biggest challenges for AI in healthcare is security. The integration of AI often involves analyzing large datasets that include sensitive personal information. Misuse or unauthorized disclosure of this data can lead to serious consequences, such as discrimination, social stigma, and financial harm (Naik et al, 2022). In addition to issues with data privacy and security, AI tools are vulnerable to cyberattacks such as data breaches and hostile attacks (Margam, 2023). Regulations in this area, such as the Health Insurance Portability and Accountability Act (HIPAA) in the United States and the General Data Protection Regulation (GDPR)

in the European Union, aim to protect patient privacy by setting strict rules for data collection, storage, and sharing (Cohen and Mello, 2018; Yuan and Li, 2019).

Biases and Fairness

Algorithms in AI systems are not immune to biases, and these algorithmic biases are a critical ethical concern in AI for healthcare. Because they can inadvertently prioritize certain variables that favor one group over another, raising concerns about fairness and equity from diagnosis to treatment (Agarwal et al, 2023; Chen et al, 2021; Obermeyer et al, 2019). It is possible to reduce bias by training AI tools on diverse datasets and regularly auditing models by developers to ensure fair performance (Obermeyer et al, 2019).

Billions of people around the world experience inequality due to the lack of access to essential health services, whether due to living in a low-income country or region, rural and remote communities, local ethical norms, or older age (Khan et al, 2024; World Health Organization, 2023). In this context, it is crucial to create AI applications tailored to specific healthcare needs at the local community or individual level.

Explainability and Transparency

Explainability is crucial in healthcare, where patients have the right to understand the rationale behind their care (Topol, 2019). However, the "black box" nature of some AI models, especially those based on ML and DL, limits transparency. Therefore, it is important for healthcare providers to ensure transparency and explainability in AI systems in order to build trust with both patients and healthcare providers. Some researchers advocate for "glass box" models that prioritize transparency and allow for influencing the AI's recommendations (Rai, 2020; Robson and Baek, 2024). Explainable AI can improve transparency and trust, ultimately increasing confidence in AI-driven solutions. Explainability also strengthens the possibility of training and using AI tools effectively and responsibly (Rudin and Radin, 2019).

Accountability and Liability

In traditional healthcare settings, medical professionals are responsible for their clinical judgements. In AI-enabled healthcare, there are legal gaps in accountability internationally. Determining roles and responsibilities for accountability and liability of AI-enabled judgements in healthcare is difficult due to the large number of actors involved from design to implementation (Bottomley and Thaldar, 2023).

Human-AI Interaction and Accessibility

When implementing AI in healthcare, it is not enough to consider only the technical aspects of AI. While AI has the potential to significantly improve healthcare outcomes, there are many obstacles to its implementation and integration in clinical settings. These obstacles include different platforms and technologies, each with their own standards and protocols, heterogeneous clinical centers, and lack of sufficient integration across electronic health records. Moreover, factors such as the awareness of practitioners and patients about AI tools, differences in perspectives

within the community, and low-income levels are significant barriers to implementing AI in healthcare (Aung et al, 2021; Dwivedi et al, 2021; Lee and Yoon, 2021).

Harmonizing AI regulations across countries requires an international collaborative approach that strengthens coordinated efforts among policymakers, regulators, and industry leaders (Ghassemi et al, 2021; US Food and Drug Administration, 2023; World Health Organization, 2023). Toward these goals, a "Global AI Governance Consortium" could be established to facilitate dialogue across nations, promote common standards, and mutual recognition of regulatory certifications. "Collaborative Standards" could then be defined to ensure that AI systems meet universally accepted criteria for safety, transparency, and effectiveness, and establish "Joint Initiatives" focused on addressing global challenges such as reducing bias and equal healthcare access. Crucially, "Ongoing Monitoring and Feedback Mechanisms" would ensure that AI systems remain compliant with evolving ethical and regulatory expectations.

Regulations on AI Applications Around the World

It is an undeniable fact that AI will provide significant advances in healthcare. A clear understanding of the regulatory frameworks that govern the implementation of these technologies is essential to protecting patients from misdiagnosis, misuse of personal data, and biases embedded in algorithms. One of the key areas that regulators must focus on is patient safety, and the frameworks that are created must demonstrate high standards of accuracy and reliability (Jiang et al, 2017; Palaniappan et al, 2024). However, regulating AI in healthcare is a complex challenge that requires a delicate balance between protecting patients' rights and unlocking AI's full capabilities. The current healthcare regulations for AI technology are still in its formative stages and lack the flexibility needed to cope with the rapid technological advances in AI and ML (Nikolinakos, 2023).

Various actors are involved in AI applications, necessitating regulations to balance AI's capabilities and risks (Jiang et al, 2017; Palaniappan et al, 2024). However, a global regulatory framework for AI applications in healthcare is not yet. Additionally, the existing frameworks lack detailed comparative analysis that highlights key differentiators (Nikolinakos, 2023). In the global regulatory landscape, the current application of AI in healthcare is predominantly regulated for medical devices, more specifically Software as a Medical Device (SaMD) (Lal et al, 2022). The regulatory environment for AI in healthcare varies significantly across countries in terms of priorities such as ethics, security, privacy, economic considerations, and cultural values. Even though China is also an important actor, the United States (USA), European Union (EU) countries, and United Kingdom (UK) have taken a pioneer role in establishing regulatory frameworks governing these technologies worldwide (Nikolinakos, 2023; Schmidt et al, 2024; Steerling et al, 2023). Therefore, this review primarily covers the regulatory frameworks of the USA, EU, and UK, with a brief mention of some other countries.

European Union (EU)

AI system regulations are primarily aimed at creating a secure and reliable ecosystem in the EU (van Kolfschooten and van Oirschot, 2024). The EU has developed one of the most comprehensive regulatory frameworks for AI in healthcare, which is supported by the General Data Protection Regulation (GDPR) and proposed an AI Act that came into force in 2018. In this Act, the GDPR requires healthcare providers and AI developers to obtain informed consent before using patients' data and to take adequate measures to ensure data minimization, purpose limitation, and data security (Local Government Association, 2018).

In April 2021, the European Commission proposed an AI Act that addresses security and human rights concerns across EU member states. This Act adopted a risk-based approach by classifying AI applications into four risk categories: unacceptable, high, low, and minimal risk. Within the framework of this act, AI applications in healthcare generally are associated with the high-risk class because of their significant impact on human health and safety. Under the AI Act, key requirements for these high-risk AI systems are data governance and risk management. Manufacturers must meet these requirements, including obligations to demonstrate integrity, honesty, transparency and accountability (European Commission, 2021; van Kolfschooten and van Oirschot, 2024). The AI Act prohibits certain AI applications that pose unacceptable risks. It also focuses on the classification and liability of high-risk AI systems and general-purpose AI (GPAI) models (Busch et al, 2024).

A regulatory framework for health and medical products, including those powered by AI, is provided at the EU level by the Medical Devices Regulation (EU) 2017/745 (MDR) and the *in vitro* Diagnostic Medical Devices Regulation (EU) 2017/746 (IVDR). These regulations address stricter pre-market control, clinical evidence, and continuous post-market surveillance approaches throughout the device lifecycle to ensure that AI-based medical devices meet high safety standards. The EU MDR also classifies medical devices into one of four classes, based on the potential risk of harm to users of the device, from low to high risk: Class I, Class IIa, Class IIb and Class III medical devices. High-risk ones are subject to the most stringent requirements (Medical Device Coordination Group, 2019).

The EU has started to establish regulations on AI with non-binding guidelines. European legislators have been working on a legally binding instrument for the creation, deployment, operation, and utilization of AI systems since 2021. The final AI Act was implemented by August 2024 and will be fully enforced by August 2027, 36 months after its enactment. Actors will need to adhere to the regulations on specific issues by February 2025. This marks as significant step in the regulatory supervision of AI systems in the EU (van Kolfschooten and van Oirschot, 2024).

United States (USA)

There is a decentralized approach to AI regulation the USA, with multiple agencies playing a role. However, primary overseer of the regulatory framework for AI-enabled healthcare is by the Food and Drug Administration (FDA). The FDA, in collaboration with other departments such as the Center for Biologics Evaluation and Research (CBER) and the Center for Drug Evaluation and Research (CDER),

is actively exploring ways to create a regulatory framework for AI-enabled medical devices and SaMD used in healthcare (US Food and Drug Administration, 2024). The FDA's approach to AI regulation is based on a framework that categorizes AI applications based on the level of risk they pose to patients.

In April 2019, the FDA published a "Proposed Regulatory Framework for Changes to AI/ML-based SaMD". This framework emphasizes a "total product lifecycle (TPLC)" approach, recognizing that AI/ML-based software frequently changes over time as it learns from new data. Accordingly, developers are responsible for the real-world performance of AI systems and must restart the approval process if there is a change in its intended use (US Food and Drug Administration, 2019). In 2021, the FDA created the Digital Health Software Pre-Certification (Pre-Certification) Program (US Food and Drug Administration, 2019). This program prioritizes evaluating software developers over individual products, certifying companies that demonstrate a commitment to quality and patient safety, allowing these developers to bring products to market more quickly while undergoing periodic evaluations (US Food and Drug Administration, 2023).

Regulatory challenges remain unresolved in the USA and there is currently no specific finalized regulatory framework for AI-based technologies in healthcare. AI algorithms can be difficult to interpret, even by developers, in applications where they produce "black box" outputs. Questions remain about how to ensure transparency and accountability (Gerke et al, 2020).

United Kingdom (UK)

Post-Brexit, the UK has set out to develop its own regulatory framework for AI in healthcare, while still complying with EU standards in some areas. The UK Medicines and Healthcare Products Regulatory Agency (MHRA) is responsible for regulating medical devices, including AI-based software, under the UK Medical Devices Regulations. These regulations mandate that AI-based medical devices must meet safety, efficacy, and clinical evidence standards to be marketed in the UK (National Institute for Health and Care Excellence, 2022).

In 2021, the UK government released its National AI Strategy, outlining its approach to AI innovation and regulation across healthcare and other sectors. A key component of this strategy is an innovative regulatory framework that promotes AI development while ensuring safety and efficiency (Regulatory Horizons Council, 2022). The NHS AI Lab, established by the National Health Service (NHS), is another significant initiative aimed at supporting the adoption of AI in healthcare. It focuses on developing rigorous standards for evidence and validation, as well as emphasizing transparency in use of AI tools within the NHS (NHS England, 2023). Additionally, it operates on the sandbox model, providing a controlled environment for innovation.

The MHRA has been collaborating closely with the FDA and Health Canada to establish common principles for AI in medical devices. This collaboration suggests that as the UK shapes its regulatory framework, it will likely share common elements with future AI regulations in the USA (US Food and Drug Administration, 2023).

Table 2. Key comparative metrics for regulatory frameworks in the EU countries, USA, and UK.

	EU countries	USA	UK
Regulatory body	EMA	FDA	MHRA, NHS AI Lab
Essential characteristics	AI Act for risk-based classification, MDR for clinical evidence, GDPR for data privacy	TPLC approach; Flexible frameworks for AI/ML; Digital Health Pre-Certification	NHS AI Lab for standards, regulatory sandbox for testing
Scope	Emphasises harmonisation among member states and promotes unified standards	Typically focuses on innovation-friendly policies	Post-Brexit, it aims to balance harmonisation with the EU while promoting innovation-focused policies, but in the future, it is expected to have more common elements with the USA
Adaptability	May be slow because of the need for consensus among member states	The decentralized approach provides a testing ground for adaptability	Demonstrates moderate adaptability through initiatives such as "sandbox" programs, enabling innovations to be tested safely
Cost	High, usually due to stringent compliance requirements	Vary, greatly due to decentralized and industry-specific regulations	Moderate, reflects a balance between the USA and EU models and independent initiatives
Innovation impact	Potentially stifles innovation in favour of consumer protection	Encourages innovation and experimentation due to a more permissive regulatory environment	Flexible post-Brexit regulations provide a more innovative environment
Challenges	Potential stifling of innovation, high compliance costs	Balancing flexibility with accountability, and algorithmic bias	Balancing innovation with patient safety, and trust in AI

EMA, the European Medicines Agency; FDA, the Food and Drug Administration; MHRA, Medicines and Healthcare Products Regulatory Agency; NHS, National Health Service; MDR, Medical Devices Regulation; GDPR, General Data Protection Regulation; TPLC, total product lifecycle; AI/ML, artificial intelligence/machine learning; ML, machine learning.

The EU, UK and USA have set their own policies to adapt to the rapid advancement of AI technologies in healthcare (Table 2). The EU offers a structured regulatory approach with comprehensive coverage through the AI Act and MDR/IVDR, focusing on data privacy and ethical issues. However, this approach can be costly and limit innovation. The USA FDA is working on developing a regulatory framework for AI in healthcare that encourages innovation while ensuring patient safety. By adopting a flexible, adaptable approach through a total product lifecycle model, it allows AI systems to evolve post-launch with proper oversight. Despite the benefits for innovation, concerns remain about ensuring accountability and eliminating bias in AI algorithms in the long term. The UK is in the process of defining its own framework drawing combines elements from both the USA and EU models while aiming to align with USA and Canadian regulations to remain flexible and responsive to technological advances in future. It is expected to share common elements with USA AI regulations in the future.

Apart from the aforementioned efforts, many countries are also working on establishing their own regulations for AI. For example, in Turkey, healthcare regulations fall under the jurisdiction of the Ministry of Health, while data protection is overseen by the Personal Data Protection Authority (KVKK). Similar to the EU's GDPR, KVKK in Turley requires patient consent before processing personal data and enforces strict data security and privacy standards (KVKK, 2016). In China, following the release of the "Technical Guide on AI-Assisted Software" in 2019, the Medical Device Evaluation Center associated with the NMPA published the "Guidance Document for the Registration and Review of Artificial Intelligence-Based Medical Devices" in 2022. These guidelines aim to standardize the regulation of AI-based medical devices at a national level and promote international harmonization by focusing on risk factors and TPLC management (Song et al, 2022). In Australia, SaMDs is regulated by the Therapeutic Goods Administration. In 2021, the Therapeutic Goods (Medical Devices) Regulations 2002 were updated, and a guide titled "Regulatory changes for software-based medical devices" was released to explain these updates. This guide incorporates a risk-based classification approach and emphasizes the importance of national regulation for AI-based medical devices, particularly those with high risk factors impacting on patient safety (Australian Therapeutic Good Administration, 2024). Similarly, in Brazil, the approval of the "Brazilian Legal Framework for AI" by the Brazilian Chamber of Deputies led to the Brazilian Senate drafting an AI law in 2022, inspired by regulatory frameworks in OECD countries. This draft law also highlights the strict liability of providers for any harm caused by AI systems (da Conceição and Perrone, 2022; de Meneses et al, 2023).

Innovative Aspects and Limitations of This Review

This review analyses regulatory approaches from the EU, USA, and UK, including the EU's AI Act's risk-based approach and the USA FDA's lifecycle-focused strategy. The aim is to provide a detailed critique of the EU's AI Act, adding depth to the understanding of global regulatory landscapes. Theoretical models that enable dynamic learning, equity, and ethical assurance are proposed by highlighting

the adaptive and inclusive editable features to address the unique challenges of rapidly evolving AI technologies.

The potential of AI to bridge critical gaps by addressing the needs of vulnerable populations, such as the elderly and residents of remote areas, in accessing healthcare is highlighted. Recommendations are made to reduce these inequalities globally, including concrete steps for international harmonization strategies, such as the inclusion of global governance consortia and interoperability standards.

While this review examines innovative contributions to AI regulation in healthcare, it is not without limitations. Broadening the geographical scope could have increased the global applicability of the findings. This review focuses primarily on the EU, USA and UK, leaving out other important regions such as Asia-Pacific, Latin America and Africa.

The lack of more comprehensive case studies of specific AI tools would provide empirical rather than detailed support for its theoretical propositions. The analysis is heavily weighted within existing regulatory frameworks. However, AI development is a dynamic process, and its evolution is unpredictable, which may undermine recommendations regarding future ethical concerns.

Future Perspective

The future of AI in healthcare promises unprecedented opportunities to improve patient outcomes, increase clinical efficiency, and advance personalized medicine. However, its current limitations, ethical aspects, and regulatory gaps remain challenging issues to overcome. Human intervention in the design and implementation of AI tools can lead to bias, even resulting in its amplification by AI if not closely monitored. To overcome these multifaceted challenges and provide constructive solutions, an interdisciplinary approach, innovative data annotation methods, and the development of more rigorous AI techniques and models are required (Alowais et al, 2023; Chen et al, 2021).

Countries around the world have passed laws to protect the privacy of their citizens, such as the Health Insurance Portability and Accountability Act (HIPAA) in the USA and the GDPR in Europe (Cohen and Mello, 2018; Yuan and Li, 2019). However, there is a lack of consensus across countries, and each region has developed different approaches to address the ethical, security, and privacy challenges that AI poses in healthcare, reflecting differences in regulatory priorities, economic considerations, and cultural values. In the future, regulatory frameworks could be harmonized in terms of core aspects, ensuring compatibility across regulators. International collaboration is essential to reduce regulatory disparities that could hinder cross-border research and adoption of AI solutions.

Future research should address how ethical frameworks and bias reduction techniques can be incorporated into AI applications. Stakeholder collaboration is also critical to ensuring robust AI systems, ethics, and patient and provider trust. Because ethical AI development requires a commitment from both developers and institutions to prioritize patient safety, privacy, and fairness, regulations can set ethical guidelines that AI developers and healthcare organizations must follow to

ensure that AI technologies align with societal values and respect patient rights (Ghassemi et al, 2021; World Health Organization, 2021).

As AI increasingly becomes an integral part of healthcare, it is vital that healthcare providers and practitioners have the knowledge and skills. Continuous education and training of healthcare practitioners at all levels enable safer and more effective practices and can significantly reduce costs and risks. For example, AI training workshops and certification programs can be organized to cover basic topics such as interpreting AI outputs, assessing algorithmic bias, and understanding data privacy implications.

While transparency and explainability are crucial to building trust in AI among healthcare providers and patients, many advanced AI models, particularly deep learning algorithms, are opaque in evaluating options (Ghassemi et al, 2021; Rudin and Radin, 2019). Future research should focus on developing explainable and interpretable AI models, and regulators and standards bodies may provide guidelines requiring AI systems in healthcare to meet minimum explainability standards. For AI-driven healthcare, where issues of accountability and liability are complex, future regulatory frameworks should clarify the roles and responsibilities of AI developers, healthcare providers, and institutions.

To achieve the best results, healthcare providers must not only ensure compliance with evolving standards for AI-powered tools, but also guide policymakers. Policymakers should take steps to harmonize regulations, address ethical challenges, and encourage innovation in health technology. AI developers must be aware of regulations and design appropriate algorithms to make the job of practitioners easier.

Conclusion

As conclusion, AI in healthcare has the potential to transform diagnosis, personalized treatment, and operational efficiency. As AI technology advances, it will be able to identify massive electronic health datasets across a broad range of diseases without the need for specific inputs or outputs. This will ultimately lead to recommendations for personalized medical diagnosis and management. However, the integration of AI is accompanied by challenges such as technical complexity, regulatory gaps, and ethical dilemmas. Regulatory frameworks must strike a balance between innovation and safety by ensuring patient trust and equitable access. Close collaboration among policymakers, healthcare professionals, and AI developers can lay the groundwork for creating tools that address bias, promote equitable access, and protect patient data. Providing accessible technical documentation and implementing robust oversight mechanisms can enhance public trust and ensure regulatory compliance. To achieve international harmonization, policymakers should prioritize establishing global governance consortia that align regulatory requirements across regions and countries. Furthermore, holding periodic forums with healthcare practitioners and AI developers can help build consensus on adapting to emerging technologies.

Key Points

- While the integration of AI into healthcare offers critical potential, it also presents regulatory, ethical, implementation, social, and technical challenges. AI also undergoes dynamic learning, and all of these requires a regulatory landscape.
- The EU, USA and UK are leading the world in creating AI regulatory frameworks. EU regulatory frameworks take a risk-based approach, while those in the USA take a TPLC-based approach.
- The "black box" nature of AI models presents critical challenges. The "black box" nature of AI models presents critical challenges. Policymakers, AI developers, and healthcare providers need to address issues such as making AI algorithms transparent and explainable, adapting to AI's dynamic learning capabilities, and addressing the needs of vulnerable populations.
- For global harmonization, it is suggested practical strategies, such as establishing governance consortia and universal security standards, to align regional regulatory approaches.

Availability of Data and Materials

All supporting data are included in the article.

Author Contributions

RD and NA designed the study. RD and NA drafted the manuscript. RD and NA contributed to critical editorial changes. Both authors read and approved the final version of the manuscript. Both authors have participated sufficiently in the work and agreed to be accountable for all aspects of the work.

Ethics Approval and Consent to Participate

Not applicable.

Acknowledgement

Not applicable.

Funding

This research received no external funding.

Conflict of Interest

RD is president of the INVAMED Medical Innovation Institute. NA is a volunteer consultant for Med-International UK Health Agency Ltd.

References

Agarwal R, Bjarnadottir M, Rhue L, Dugas M, Crowley K, Clark J, et al. Addressing algorithmic bias and the perpetuation of health inequities: An AI bias aware framework. Health Policy and Technology. 2023; 12: 100702. https://doi.org/10.1016/j.hlpt.2022.100702

Alowais SA, Alghamdi SS, Alsuhebany N, Alqahtani T, Alshaya AI, Almohareb SN, et al. Revolutionizing healthcare: the role of artificial intelligence in clinical practice. BMC Medical Education. 2023; 23: 689. https://doi.org/10.1186/s12909-023-04698-z

Anyanwu EC, Okongwu CC, Olorunsogo TO, Ayo-Farai O, Osasona F, Daraojimba OD. Artificial intelligence in healthcare: a review of ethical dilemmas and practical applications. International Medical Science Research Journal. 2024; 4: 126–140. https://doi.org/10.51594/imsrj.v4i2.755

Attaran M. Blockchain technology in healthcare: Challenges and opportunities. International Journal of Healthcare Management. 2022; 15: 70–83. https://doi.org/10.1080/20479700.2020.1843887

Aung YYM, Wong DCS, Ting DSW. The promise of artificial intelligence: a review of the opportunities and challenges of artificial intelligence in healthcare. British Medical Bulletin. 2021; 139: 4–15. https://doi.org/10.1093/bmb/ldab016

Australian Therapeutic Good Administration. Understanding if changes to software-based medical device regulation affect you: Guidance about regulatory changes for software based medical devices, including software as a medical device (SaMD). 2024. Available at: https://www.tga.gov.au/resources/guidance/understanding-if-changes-software-based-medical-device-regulation-affect-you (Accessd: 26 November 2024).

Bajwa J, Munir U, Nori A, Williams B. Artificial intelligence in healthcare: transforming the practice of medicine. Future Healthcare Journal. 2021; 8: e188–e194. https://doi.org/10.7861/fhj.2021-0095

Bottomley D, Thaldar D. Liability for harm caused by AI in healthcare: an overview of the core legal concepts [published correction appears in Frontiers in Pharmacology. 2024; 15: 1366004. https://doi.org/10.3389/fphar.2024.1366004]. Frontiers in Pharmacology. 2023; 14: 1297353. https://doi.org/10.3389/fphar.2023.1297353

Busch F, Kather JN, Johner C, Moser M, Truhn D, Adams LC, et al. Navigating the European Union Artificial Intelligence Act for Healthcare. NPJ Digital Medicine. 2024; 7: 210. https://doi.org/10.1038/s41746-024-01213-6

Čartolovni A, Tomičić A, Lazić Mosler E. Ethical, legal, and social considerations of AI-based medical decision-support tools: A scoping review. International Journal of Medical Informatics. 2022; 161: 104738. https://doi.org/10.1016/j.ijmedinf.2022.104738

Chahal A, Gulia P. Machine learning and deep learning. International Journal of Innovative Technology and Exploring Engineering. 2019; 8: 4910–4914. https://doi.org/10.35940/ijitee.L3550.1081219

Chen IY, Pierson E, Rose S, Joshi S, Ferryman K, Ghassemi M. Ethical Machine Learning in Healthcare. Annual Review of Biomedical Data Science. 2021; 4: 123–144. https://doi.org/10.1146/annurev-biodatasci-092820-114757

Chen JS, Baxter SL. Applications of natural language processing in ophthalmology: present and future. Frontiers in Medicine. 2022; 9: 906554. https://doi.org/10.3389/fmed.2022.906554

Cohen IG, Mello MM. HIPAA and Protecting Health Information in the 21st Century. JAMA. 2018; 320: 231–232. https://doi.org/10.1001/jama.2018.5630

Coudray N, Ocampo PS, Sakellaropoulos T, Narula N, Snuderl M, Fenyö D, et al. Classification and mutation prediction from non-small cell lung cancer histopathology images using deep learning. Nature Medicine. 2018; 24: 1559–1567. https://doi.org/10.1038/s41591-018-0177-5

da Conceição LHM, Perrone C. The Brazilian Proposed Regulation of AI: Contextualization and Perspectives. MediaLaws. 2022. Available at: https://www.medialaws.eu/the-brazilian-proposed-regulation-of-ai-contextualization-and-perspectives/ (Accessed: 26 November 2024).

de Meneses AO, Shepherd N, Van Quathem K. Brazil's Senate Committee Publishes AI Report and Draft AI Law. 2023. Available at: https://www.insideprivacy.com/emerging-technologies/brazils-senate-committee-publishes-ai-report-and-draft-ai-law/ (Accessed: 26 November 2024).

Dilsizian SE, Siegel EL. Artificial intelligence in medicine and cardiac imaging: harnessing big data and advanced computing to provide personalized medical diagnosis and treatment. Current Cardiology Reports. 2014; 16: 441. https://doi.org/10.1007/s11886-013-0441-8

Dinc R. Machine Learning for Healthcare. Troubador Publishing Ltd.: Leicester, UK. 2025.

Dwivedi YK, Hughes L, Ismagilova E, Aarts G, Coombs C, Crick T, et al. Artificial Intelligence (AI): Multidisciplinary perspectives on emerging challenges, opportunities, and agenda for research, practice and policy. International journal of information management. 2021; 57: 101994. https://doi.org/10.1016/j.ijinfomgt.2019.08.002

European Commission. Artificial Intelligence Act. Proposal for a regulation of the European parliament and the council laying down harmonised rules on artificial intelligence (artificial intelligence act) and amending certain union legislative acts. 2021. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A520210206 (Accessed: 24 November 2024).

Gerke S, Minssen T, Cohen G. Ethical and legal challenges of artificial intelligence-driven healthcare. In Adam B, Kaveh M (eds.) Artificial intelligence in healthcare (pp. 295–336). 2020. Academic Press: London and New York. https://doi.org/10.1016/B978-0-12-818438-7.00012-5

Ghassemi M, Naumann T, Schulam P, Beam AL, Chen IY, Ranganath R. A Review of Challenges and Opportunities in Machine Learning for Health. AMIA Joint Summits on Translational Science Proceedings. 2020; 2020: 191–200.

Ghassemi M, Oakden-Rayner L, Beam AL. The false hope of current approaches to explainable artificial intelligence in health care. The Lancet. Digital Health. 2021; 3: e745–e750. https://doi.org/10.1016/S2589-7500(21)00208-9

Gong B, Nugent JP, Guest W, Parker W, Chang PJ, Khosa F, et al. Influence of Artificial Intelligence on Canadian Medical Students' Preference for Radiology Specialty: ANational Survey Study. Academic Radiology. 2019; 26: 566–577. https://doi.org/10.1016/j.acra.2018.10.007

Gouripur K. The Impact of Artificial Intelligence on Healthcare: A Revolution in Progress. The North and West London Journal of General Practice. 2024; 10: 1–9.

Haleem A, Javaid M, Singh RP, Suman R. Medical 4.0 technologies for healthcare: Features, capabilities, and applications. Internet of Things and Cyber-Physical Systems. 2022; 2: 12–30. https://doi.org/10.1016/j.iotcps.2022.04.001

Hannun AY, Rajpurkar P, Haghpanahi M, Tison GH, Bourn C, Turakhia MP, et al. Cardiologist-level arrhythmia detection and classification in ambulatory electrocardiograms using a deep neural network. Nature Medicine. 2019; 25: 65–69. https://doi.org/10.1038/s41591-018-0268-3

Hosseini MS, Bejnordi BE, Trinh VQH, Chan L, Hasan D, Li X, et al. Computational pathology: A survey review and the way forward. Journal of Pathology Informatics. 2024; 15: 100357. https://doi.org/10.1016/j.jpi.2023.100357

Iftikhar M, Saqib M, Zareen M, Mumtaz H. Artificial intelligence: revolutionizing robotic surgery: review. Annals of Medicine and Surgery (2012). 2024; 86: 5401–5409. https://doi.org/10.1097/MS9.0000000000002426

Jiang F, Jiang Y, Zhi H, Dong Y, Li H, Ma S, et al. Artificial intelligence in healthcare: past, present and future. Stroke and Vascular Neurology. 2017; 2: 230–243. https://doi.org/10.1136/svn-2017-000101

Jimma BL. Artificial intelligence in healthcare: A bibliometric analysis. Telematics and Informatics Reports. 2023; 9: 100041. https://doi.org/10.1016/j.teler.2023.100041

Jordan MI, Mitchell TM. Machine learning: Trends, perspectives, and prospects. Science. 2015; 349: 255–260. https://doi.org/10.1126/science.aaa8415

Khan MS, Umer H, Faruqe F. Artificial intelligence for low income countries. Humanities and Social Sciences Communications. 2024; 11: 1–3. https://doi.org/10.1057/s41599-024-03947-w

Klauschen F, Dippel J, Keyl P, Jurmeister P, Bockmayr M, Mock A, et al. Toward Explainable Artificial Intelligence for Precision Pathology. Annual Review of Pathology. 2024; 19: 541–570. https://doi.org/10.1146/annurev-pathmechdis-051222-113147

KVKK. Personal Data Protection Law. 2016. Available at: https://www.kvkk.gov.tr/Icerik/6649/Personal-Data-Protection-Law (Accessd: 28 November 2024).

Lal A, Dang J, Nabzdyk C, Gajic O, Herasevich V. Regulatory oversight and ethical concerns surrounding software as medical device (SaMD) and digital twin technology in healthcare. Annals of Translational Medicine. 2022; 10: 950. https://doi.org/10.21037/atm-22-4203

Lee D, Yoon SN. Application of Artificial Intelligence-Based Technologies in the Healthcare Industry: Opportunities and Challenges. International Journal of Environmental Research and Public Health. 2021; 18: 271. https://doi.org/10.3390/ijerph18010271

Lekadir K, Quaglio G, Garmendia AT, Gallin C. Artificial intelligence in healthcare: Applications, risks, and ethical and societal impacts. European Parliament. 2022. https://doi.org/10.2861/568473

Ling Kuo RY, Freethy A, Smith J, Hill R, C J, Jerome D, et al. Stakeholder perspectives towards diagnostic artificial intelligence: a co-produced qualitative evidence synthesis. eClinicalMedicine. 2024; 71: 102555. https://doi.org/10.1016/j.eclinm.2024.102555

Liu X, Faes L, Kale AU, Wagner SK, Fu DJ, Bruynseels A, et al. A comparison of deep learning performance against health-care professionals in detecting diseases from medical imaging: a systematic review and meta-analysis [published correction appears in The Lancet. Digital Health. 2019; 1: e334. https://doi.org/10.1016/S2589-7500(19)30160-8]. The Lancet. Digital Health. 2019; 1: e271–e297. https://doi.org/10.1016/S2589-7500(19)30123-2

Local Government Association. The general data protection regulation (GDPR): Guidance for members. 2018. Available at: https://www.local.gov.uk/sites/default/files/documents/The+General+Protection+Data+Regulation+(GDPR)+-+Guidance+for+Members.pdf (Accessed: 20 November 2024).

Loftus TJ, Upchurch GR, Jr, Bihorac A. Use of Artificial Intelligence to Represent Emergent Systems and Augment Surgical Decision-making. JAMA Surgery. 2019; 154: 791–792. https://doi.org/10.1001/jamasurg.2019.1510

Margam R. Ethics and data privacy: the backbone of trustworthy healthcare practices. Socio-Economic and Humanistic Aspects for Township and Industry. 2023; 1: 232–236. https://doi.org/10.59535/sehati.v1i2.115

Medical Device Coordination Group. Guidance on qualification and classification of software in regulation (EU) 2017/745–MDR and regulation (EU) 2017/746–IVDR. European Commission. 2019. Available at: https://health.ec.europa.eu/system/files/2020-09/md_mdcg_2019_11_guidance_qualification_classification_software_en_0.pdf (Accesed: 24 November 2024).

Mehta N, Pandit A, Shukla S. Transforming healthcare with big data analytics and artificial intelligence: A systematic mapping study. Journal of Biomedical Informatics. 2019; 100: 103311. https://doi.org/10.1016/j.jbi.2019.103311

Mello-Thoms C, Mello CAB. Clinical applications of artificial intelligence in radiology. The British Journal of Radiology. 2023; 96: 20221031. https://doi.org/10.1259/bjr.20221031

Mesko B. The role of artificial intelligence in precision medicine. Expert Review of Precision Medicine and Drug Development. 2017; 2: 239–241. https://doi.org/10.1080/23808993.2017.1380516

Mithany RH, Aslam S, Abdallah S, Abdelmaseeh M, Gerges F, Mohamed MS, et al. Advancements and Challenges in the Application of Artificial Intelligence in Surgical Arena: A Literature Review. Cureus. 2023; 15: e47924. https://doi.org/10.7759/cureus.47924

Muehlematter UJ, Daniore P, Vokinger KN. Approval of artificial intelligence and machine learning-based medical devices in the USA and Europe (2015-20): a comparative analysis. The Lancet. Digital Health. 2021; 3: e195–e203. https://doi.org/10.1016/S2589-7500(20)30292-2

Naik N, Hameed BMZ, Shetty DK, Swain D, Shah M, Paul R, et al. Legal and Ethical Consideration in Artificial Intelligence in Healthcare: Who Takes Responsibility? Frontiers in Surgery. 2022; 9: 862322. https://doi.org/10.3389/fsurg.2022.862322

National Institute for Health and Care Excellence. Evidence standards framework for digital health technologies. 2022. Available at: https://www.nice.org.uk/corporate/ecd7/resources/evidence-standards-framework-for-digital-health-technologies-pdf-1124017457605 (Accessed: 26 November 2024).

NHS England. Artificial intelligence (AI) and machine learning. 2023. Available at: https://www.england.nhs.uk/long-read/artificial-intelligence-ai-and-machine-learning/ (Accessed: 26 November 2024).

Nikolinakos NT. A European Approach to Excellence and Trust: The 2020 White Paper on Artificial Intelligence. In EU Policy and Legal Framework for Artificial Intelligence, Robotics and Related Technologies-The AI Act (pp. 211–280). Springer International Publishing: Cham. 2023. https://doi.org/10.1007/978-3-031-27953-9_5

Obermeyer Z, Powers B, Vogeli C, Mullainathan S. Dissecting racial bias in an algorithm used to manage the health of populations. Science. 2019; 366: 447–453. https://doi.org/10.1126/science.aax2342

OECD. European Union. Health at a Glance: Europe 2020: State of Health in the EU Cycle. OECD Publishing: Paris. 2020.

Palaniappan K, Lin EYT, Vogel S. Global Regulatory Frameworks for the Use of Artificial Intelligence (AI) in the Healthcare Services Sector. Healthcare. 2024; 12: 562. https://doi.org/10.3390/healthcare12050562

Quaglio G, Pirona A, Esposito G, Karapiperis T, Brand H, Dom G, et al. Knowledge and utilization of technology-based interventions for substance use disorders: an exploratory study among health professionals in the European Union. Drugs: Education, Prevention and Policy. 2019; 26: 437–446. https://doi.org/10.1080/09687637.2018.1475549

Quer G, Arnaout R, Henne M, Arnaout R. Machine Learning and the Future of Cardiovascular Care: JACC State-of-the-Art Review. Journal of the American College of Cardiology. 2021; 77: 300–313. https://doi.org/10.1016/j.jacc.2020.11.030

Rai A. Explainable AI: From black box to glass box. Journal of the Academy of Marketing Science. 2020; 48: 137–141. https://doi.org/10.1007/s11747-019-00710-5

Regulatory Horizons Council. The Regulation of Artificial Intelligence as a Medical Device. 2022. Available at: https://assets.publishing.service.gov.uk/media/6384bf98e90e0778a46ce99f/RHC_regulation_of_AI_as_a_Medical_Device_report.pdf (Accessed: 26 November 2024).

Richardson ML, Garwood ER, Lee Y, Li MD, Lo HS, Nagaraju A, et al. Noninterpretive Uses of Artificial Intelligence in Radiology. Academic Radiology. 2021; 28: 1225–1235. https://doi.org/10.1016/j.acra.2020.01.012

Robson B, Baek OK. Application of glass box AI to large numbers of medical records for rapid response to future respiratory virus pandemics. Examples considering potential future high-fatality COVID strains and a potential avian influenza pandemic in humans. Informatics in Medicine Unlocked. 2024; 101454. https://doi.org/10.1016/j.imu.2024.101454

Rudin C, Radin J. Why are we using black box models in AI when we don't need to? A lesson from an explainable AI competition. Harvard Data Science Review. 2019; 1: 1–9. https://doi.org/10.1162/99608f92.5a8a3a3d

Schmidt J, Schutte NM, Buttigieg S, Novillo-Ortiz D, Sutherland E, Anderson M, et al. Mapping the regulatory landscape for artificial intelligence in health within the European Union. NPJ Digital Medicine. 2024; 7: 229. https://doi.org/10.1038/s41746-024-01221-6

Shafi S, Parwani AV. Artificial intelligence in diagnostic pathology. Diagnostic Pathology. 2023; 18: 109. https://doi.org/10.1186/s13000-023-01375-z

Song X, Hu M, Li B, Zhang K, Zhang X, Wang L. Advancing medical device regulatory reforms for innovation, translation and industry development in China. Journal of Orthopaedic Translation. 2022; 37: 89–93. https://doi.org/10.1016/j.jot.2022.09.015

Steerling E, Siira E, Nilsen P, Svedberg P, Nygren J. Implementing AI in healthcare-the relevance of trust: a scoping review. Frontiers in Health Services. 2023; 3: 1211150. https://doi.org/10.3389/frhs.2023.1211150

Stokes JM, Yang K, Swanson K, Jin W, Cubillos-Ruiz A, Donghia NM, et al. A Deep Learning Approach to Antibiotic Discovery. Cell. 2020; 181: 475–483. https://doi.org/10.1016/j.cell.2020.04.001

Sun X, Yin Y, Yang Q, Huo T. Artificial intelligence in cardiovascular diseases: diagnostic and therapeutic perspectives. European Journal of Medical Research. 2023; 28: 242. https://doi.org/10.1186/s40001-023-01065-y

Tejedor M, Woldaregay AZ, Godtliebsen F. Reinforcement learning application in diabetes blood glucose control: A systematic review. Artificial Intelligence in Medicine. 2020; 104: 101836. https://doi.org/10.1016/j.artmed.2020.101836

Topol EJ. High-performance medicine: the convergence of human and artificial intelligence. Nature Medicine. 2019; 25: 44–56. https://doi.org/10.1038/s41591-018-0300-7

Udegbe FC, Ebulue OR, Ebulue CC, Ekesiobi CS. The role of artificial intelligence in healthcare: A systematic review of applications and challenges. International Medical Science Research Journal. 2024; 4: 500–508. https://doi.org/10.51594/imsrj.v4i4.1052

Ugajin A. Automation in hospitals and health care. In Nof SY (ed.) Springer Handbook of Automation (pp. 1209–1233). Springer International Publishing: Cham. 2023.

Ugarte-Gil C, Icochea M, Llontop Otero JC, Villaizan K, Young N, Cao Y, et al. Implementing a socio-technical system for computer-aided tuberculosis diagnosis in Peru: A field trial among health professionals in resource-constraint settings. Health Informatics Journal. 2020; 26: 2762–2775. https://doi.org/10.1177/1460458220938535

Ulnicane I. Artificial Intelligence in the European Union: Policy, ethics and regulation. In Thomas H (ed.) The Routledge handbook of European integrations. Taylor & Francis: London. 2022. https://doi.org/10.4324/9780429262081-19

US Food and Drug Administration. Artificial Intelligence & Medical Products: How CBER, CDER, CDRH, and OCP are Working Together. 2024. Available at: https://www.fda.gov/media/177030/download?attachment (Accessed: 24 November 2024).

US Food and Drug Administration. Predetermined Change Control Plans for Machine Learning-Enabled Medical Devices: Guiding Principles. 2023. Available at: https://www.fda.gov/media/173206/download?attachment (Accessed: 24 November 2024).

US Food and Drug Administration. Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) - Discussion Paper and Request for Feedback. 2019. Available at: https://www.fda.gov/media/122535/download?attachment (Accessed: 24 November 2024).

Vallée A. Digital twin for healthcare systems. Frontiers in Digital Health. 2023; 5: 1253050. https://doi.org/10.3389/fdgth.2023.1253050

van Kolfschooten H, van Oirschot J. The EU Artificial Intelligence Act (2024): Implications for healthcare. Health Policy. 2024; 149: 105152. https://doi.org/10.1016/j.healthpol.2024.105152

World Health Organization. Ethics and governance of artificial intelligence for health: WHO guidance. World Health Organization: Geneva. 2021. Available at: https://iris.who.int/bitstream/handle/10665/341996/9789240029200-eng.pdf?sequence=1 (Accessed: 20 November 2024).

World Health Organization. WHO outlines considerations for regulation of artificial intelligence for health. 2023. Available at: https://www.who.int/news/item/19-10-2023-who-outlines-considerations-for-regulation-of-artificial-intelligence-for-health?utm_source=chatgpt.com (Accessed: 28 December 2024).

Xie J, Luo X, Deng X, Tang Y, Tian W, Cheng H, et al. Advances in artificial intelligence to predict cancer immunotherapy efficacy. Frontiers in Immunology. 2023; 13: 1076883. https://doi.org/10.3389/fimmu.2022.1076883

Yordanova MZ. The Applications of Artificial Intelligence in Radiology: Opportunities and Challenges. European Journal of Medical and Health Sciences. 2024; 6: 11–14. https://doi.org/10.24018/ej.2024.6.2.2085

Yuan B, Li J. The Policy Effect of the General Data Protection Regulation (GDPR) on the Digital Public Health Sector in the European Union: An Empirical Investigation. International Journal of Environmental Research and Public Health. 2019; 16: 1070. https://doi.org/10.3390/ijerph16061070

Yuan H. Current perspective on artificial intelligence, machine learning and deep learning. Applied and Computational Engineering. 2023; 19: 116–122.

Zhu H. Big Data and Artificial Intelligence Modeling for Drug Discovery. Annual Review of Pharmacology and Toxicology. 2020; 60: 573–589. https://doi.org/10.1146/annurev-pharmtox-010919-023324