

Current Status, Challenges, and Future Prospects of Artificial Intelligence in Medicine

Bowen Shi

Department of Electrical Engineering and Automation, Nanjing Normal University, Nanjing, China
2030432477@qq.com

Abstract. With its enormous potential and value, artificial intelligence (AI) technology is being incorporated into every facet of the medical industry at a never-before-seen pace, from basic research to clinical practice to public health management. This study thoroughly examines the development of AI applications in several necessary fields, such as emergency medicine, medical research, treatment planning, disease diagnosis and typing, medical device regulation, and patient management. It focuses on how fundamental technologies like computer vision (CV), natural language processing (NLP), deep learning (DL), and machine learning (ML) can propel medical advancements in areas like image analysis, genomics data integration, assisted decision making, and process optimization. The study also highlights AI's central issues in medical applications, such as model interpretability and data privacy and quality, ethical rules, algorithmic bias, and clinical translation obstacles. To achieve the safe, efficient, and responsible deployment and application of AI technologies in medicine—which will ultimately enable precision medicine and improved human health—it concludes by offering an outlook on the future direction of development, highlighting the necessity of interdisciplinary collaboration, bolstering regulatory science, encouraging data standardization, and investigating explainable AI (XAI).

Keywords: artificial intelligence; machine learning; medical AI; precision medicine; clinical decision support.

1. Introduction

Artificial intelligence (AI) has emerged as a significant force behind change in the medical industry and is a strategic technology for the future [1]. Its two main subfields, machine learning (ML) and deep learning (DL), can extract deep rules from extensive, multi-source medical data to offer previously unheard-of assistance with illness prevention, diagnosis, treatment, and rehabilitation [2, 3]. AI-based products (such as AI-assisted diagnostic software) have been progressively making their way into clinical applications in the medical device industry [1]; in clinical diagnosis and treatment, AI is helping doctors with image interpretation, risk assessment, and customized treatment planning [4, 5]; in biomedical research, AI helps with the integration of multihistology data, animal model optimization, and the development of new medications [6]; and in high-risk settings like emergency medicine, the AI is crucial for rapid triage and early risk identification [7].

However, the road to medical applications of AI is not a straight path. The heterogeneity and privacy of data, the "black-box" nature of models, the lack of ethical regulations, and the complexity of clinical validation are significant barriers to its widespread adoption [1, 4, 7]. It is essential to realize that AI is imperfect, and in some aspects, AI still needs to be developed and transformed. Nowadays, AI is still far from meeting human beings' expectations. The purpose of this paper is to systematically sort out the panorama of the application of AI in the core fields of medicine, objectively analyze the challenges it faces, and look forward to its future development based on the recent critical literature, with a view to providing a reference for relevant researchers and practitioners.

2. Progress of AI Application in Medicine

2.1 Medical Device Regulation and Clinical Trials

AI medical devices, especially machine learning-enabled device software functions (ML-DSFs), are characterized by the need for continuous iterative updates. This poses a challenge to the traditional

medical device regulatory model. To address this challenge, the US FDA has proposed a prospective regulatory framework of the Predefined Change Control Program (PCCP) [1]. The PCCP allows manufacturers to plan the scope of future algorithmic modifications, validation protocols, and impact assessments before the product is released to the market, which, while ensuring safety and efficacy, dramatically reduces iterative updates required in the approval time [1]. China's Drug Administration has also successively issued several guidelines to regulate the review and registration of AI medical devices and has refined the clinical evaluation requirements for AI-assisted testing products [1]. In addition, using real-world data (RWD) for clinical evaluation has become a trend. Still, retrospective studies may have problems such as data bias and need to be treated cautiously [1].

2.2 Disease Diagnosis, Staging, and Assisted Decision Making

Artificial intelligence (AI) is used extensively in disease diagnosis because, compared to human intelligence, it can analyze the cause of a disease more quickly and accurately. This reduces the workload for doctors and allows them to better implement medical solutions for patients. For instance, Convolutional Neural Networks (CNNs) have achieved or nearly achieved the expert level in lung nodule detection, stroke typing, and other imaging-related tasks, such as lesion detection, segmentation, and classification of X-ray, CT, MRI, and other images [3, 4, 6]. Beyond imaging, artificial intelligence (AI) is also utilized in pathology analysis, including tumor identification and Whole-Slice Image (WSI)-based grading, which enhances pathology objectivity and diagnostic efficiency [6]. In emergency medicine, AI models can predict critical complications such as sepsis and acute kidney injury (AKI) early, gaining valuable intervention time [7]. More importantly, AI can integrate clinical, imaging, genomic, and multi-omics data for fine-grained disease typing (e.g., different subtypes of sepsis, ARDS), laying the foundation for truly personalized treatment [6, 7].

Generative AI and Large Language Models (LLMs) bring a new paradigm to the medical field. Through retrieval-enhanced generation (RAG) architecture and professional fine-tuning, evidence-based medical grand models (evidence-based grand models) can be constructed, effectively reducing model "illusions" and providing reliable sources of evidence and traceable support for the diagnoses and recommendations they provide, which has great potential for clinical Q&A, medical record structuring, patient education, etc. [2].

2.3 Treatment planning and personalized medicine

AI is driving the transformation of healthcare to the aspect of tailoring. With the support of AI, patients can get more treatment options and doctors can get more treatments, thus increasing the feasibility and efficiency of treatment. Regarding treatment planning, AI can analyze patients' genomic information, clinical data, and treatment plan history to recommend the most effective drugs and treatment strategies, especially useful in managing complex chronic diseases such as oncology and diabetes [4, 5]. Reinforcement learning (RL) can be used to optimize dynamic treatment strategies [4]. In drug discovery, AI accelerates new target discovery, new use of old drugs, and clinical trial design by analyzing massive compounds and biological data, significantly reducing R&D cost and time [4, 6]. AI-driven platforms such as DeepMind's AlphaFold, Atomwise, and BenevolentAI are revolutionizing drug discovery by predicting protein structures, identifying druggable targets, and optimizing lead compounds with unprecedented speed and accuracy [8]. These tools leverage deep learning and generative adversarial networks (GANs) to model molecular interactions and predict drug efficacy, toxicity, and bioavailability. Moreover, AI is used to personalize drug formulations—optimizing excipients, predicting drug-excipient compatibility, and even guiding the 3D printing of personalized dosage forms. Such advancements enhance therapeutic outcomes and streamline the drug development pipeline, reducing time and cost [8]. However, translating these technologies into clinical practice requires robust validation, regulatory approval, and integration into healthcare workflows. In terms of personalized medicine, through the prediction and projection of AI models, multiple treatment options can be integrated and generate many different branches, so that patients

can receive treatment more efficiently, and AI can give more different therapies through the big data model projection, thus reflecting the word "personality".

2.4 Patient Monitoring and Health Management

With the support of wearable devices and Internet of Things (IoT) technology, artificial intelligence (AI) enables continuous remote monitoring of patients' vital signs, allowing for real-time detection of anomalies and facilitating prompt medical intervention [4,5]. In chronic disease management, AI-powered systems deliver personalized lifestyle recommendations, medication adherence reminders, and tailored rehabilitation guidance, significantly enhancing patient compliance and improving long-term health outcomes [4]. Furthermore, large language model-based chatbots can provide 24/7 medical inquiry services and emotional support, alleviating the burden on healthcare professionals and promoting patient engagement and overall satisfaction with care services [2].

2.5 Medical Research and Methodology Innovation

AI has become an essential tool in basic biomedical research. It is used for: multi-omics data integration—deep learning models can combine genomic, transcriptomic, proteomic, and metabolomic data to identify new biomarkers and classify diseases at the molecular level [6]; experimental animal models—AI helps optimize the selection and design of animal models, automates the analysis of animal behaviors, and enhances the reproducibility of experiments and animal welfare [6]; literature mining and knowledge discovery—natural language processing (NLP) technology rapidly extracts valuable information from large volumes of literature, generates hypotheses, and speeds up the research process [2, 6].

2.6 Emergency Medicine and Process Optimization

Artificial intelligence is revolutionizing emergency medicine by enhancing the efficiency and accuracy of care delivery in this time-critical field. Its applications span multiple stages of emergency care, beginning with pre-hospital management. Integrating with 5G technology, AI enables a "boarding the ambulance is equivalent to being admitted to the hospital" approach. Inside ambulances, AI algorithms perform real-time preliminary analysis of vital signs and medical data, supporting early diagnosis and allowing emergency departments to prepare in advance for arriving patients. Upon arrival, machine learning-based triage systems quickly and accurately classify patient risk levels, optimizing the allocation of medical resources and significantly reducing overcrowding and treatment delays in busy emergency settings. Furthermore, AI supports prognostic assessment by predicting key clinical outcomes such as required hospitalization duration, mortality risk, and potential complications, providing valuable data-driven support for clinical decision-making [7]. Nevertheless, current AI systems still exhibit limitations in computing complex clinical scores that require nuanced interpretation and cannot replace the comprehensive judgment of experienced physicians.

3. Challenges and Limitations

Despite the promising future, the full deployment of AI in medicine still faces multiple challenges.

3.1 Data Challenges

As the core element of the deep integration of AI and the health industry, medical data faces multiple challenges in the actual application process, which seriously restricts the effective integration and utilization of high-quality data resources. First, the quality of medical data varies, and different medical institutions have different standards for data collection, recording, and storage, resulting in much missing, erroneous, or inconsistent data, seriously affecting the reliability of subsequent analysis and modeling. Second, the formats and standards of medical data vary significantly [1,2]. There is a lack of unified data interfaces and semantic standards among hospital information systems (e.g., HIS, PACS, LIS, etc.), with structured data (e.g., test indicators) as well as a large amount of

unstructured text (e.g., medical record descriptions, image reports), making cross-institutional data fusion exceptionally difficult. Moreover, medical data involves patient privacy, which is strictly regulated by laws and regulations such as the Personal Information Protection Law and the Measures for the Management of Medical Data, with a high risk of privacy leakage and strict ethical requirements, further limiting data sharing and circulation. The above problems have led to the prevalence of "data silos" and the difficulty of data interoperability between organizations, which prevents the formation of a large-scale training sample set, thus restricting the development and application efficiency of high-quality medical AI models [4, 7].

3.2 Model Interpretability

Although many high-performance deep learning models perform excellently in prediction accuracy, image recognition, or natural language processing tasks, their internal decision-making mechanisms are often highly opaque and widely regarded as "black boxes". These models often rely on multiple layers of nonlinear transformations and high-dimensional feature representations for inference, making it difficult for humans to intuitively understand the paths and rationale for their conclusions. This non-interpretability significantly reduces physicians' trust in model outputs in clinical scenarios. Due to the lack of traceability of the logic of diagnostic recommendations or predicted results - for example, why the model judged a lesion to be malignant, or based on which features a specific treatment plan was generated - clinicians are often afraid to easily incorporate AI recommendations into the actual diagnosis and treatment decisions. And when a model makes a wrong judgment, it becomes tough to define its responsibility: a training data bias, an algorithmic flaw, an inconsistent deployment environment, or a human error. This opacity of the decision-making process hinders clinical acceptance and poses a serious challenge for medical malpractice liability determination, model auditing, and ethical regulation. [4, 7].

3.3 Algorithmic Bias and Fairness

if the data used to train a healthcare AI model is inherently biased in terms of representativeness- such as over-including a particular demographic group (e.g., people of a specific race, gender, age, or geographic region) while ignoring data characteristics of other groups- the -the model will not only learn and replicate these inherent biases, but is more likely to amplify their effects during the inference process further. This phenomenon of bias amplification can lead to a significant decline in model performance when dealing with under-documented or under-represented minorities, as evidenced by reduced diagnostic accuracy, incorrect risk assessment, or mismatched treatment recommendations. The result is not only an imbalance in technical performance but also a profound reflection in the actual distribution and quality of healthcare services: marginalized groups may not be able to enjoy the same advantages of AI-assisted diagnosis and treatment. They may even be denied access to timely and effective interventions due to systematic miscalculations. In this way, instead of failing to become a driving force for healthcare equity, AI may solidify or even exacerbate the structural inequalities in the distribution of existing health resources, posing a serious challenge to the ethics of healthcare fairness and the overall health and well-being of society [2, 4].

3.4 Ethical and Regulatory Issues

Currently, the use of AI in healthcare faces a range of serious ethical and governance challenges. These include, but are not limited to, how to effectively protect patient privacy when using big data to train models; how to prevent leaks during storage, encryption, and transmission of healthcare data throughout its lifecycle; how to assign responsibility and create accountability mechanisms when algorithms make errors or cause harm; and how to establish a framework for accountability. People need clarity on how responsibility and accountability should be constructed when algorithmic decisions go wrong or cause harm, as well as how to define reliance and ethical boundaries when AI generates diagnostic recommendations, medical record summaries, or synthetic data. Despite the significance of these issues, the development of supporting laws, regulations, industry standards, and

ethical review frameworks is still behind technological progress. Existing rules are often strong in principle but weak in practice. They lack effective mechanisms for cross-sector collaborative governance, resulting in regulatory uncertainty and unclear compliance requirements during implementation. This hampers efforts to ensure the safety, fairness, and controllability of healthcare AI advancements.

3.5 Clinical Integration and Validation Challenges

A key barrier to translation is how to seamlessly embed AI tools into existing clinical workflows and conduct rigorous prospective clinical trials to prove their clinical utility (rather than just algorithmic accuracy) [1, 7]. In addition, the ability to generalize AI models may not perform well across hospitals and devices [2].

4. Future perspectives and recommendations

To overcome the above challenges and unleash the full potential of AI in medicine, the following directions should be emphasized in the future.

4.1 Promote data standardization and secure sharing

To crack the problem of medical data silos, efforts can be made to build cross-institutional and cross-regional secure data collaboration platforms. Such platforms adopt privacy computing technologies such as federated learning, which can realize multi-party joint modeling without sharing original data and only through the encrypted exchange of model parameter updates. This not only strictly protects patient privacy and institutional data sovereignty, but also integrates dispersed data resources and improves AI models' performance and generalization ability. Ultimately, under the premise of complying with laws and regulations, it effectively promotes the safe circulation and collaborative utilization of high-quality medical data, and provides a reliable data foundation for disease research, auxiliary diagnosis, and public health management. [1, 7].

4.2 Strengthen the research on explainable AI (XAI):

The key to improving clinical utility and credibility is to develop medical AI models with intrinsic explainability, so they can clearly and intuitively show the decision-making basis and logical reasoning path. Such models can not only output diagnostic predictions but also provide key features, confidence estimates, and case comparison bases to support the conclusion (e.g., highlighting lesion areas in image recognition or citing similar clinical guidelines or cases in diagnostic recommendations), thus effectively enhancing physicians' understanding of and trust in AI-assisted decision-making. At the same time, explainable AI mechanisms also help to meet increasingly stringent regulatory compliance requirements (e.g., FDA, NMPA's transparency and auditability regulations for AI medical devices), provide a reliable basis for model responsibility determination and ethical review, and promote the scaling of healthcare AI under the premise of safety and responsibility. [4, 7].

4.3 Improve the Ethical and Regulatory Framework

To promote the safe, effective, and responsible application of AI in medical devices, there is an urgent need to systematically build a system of standards, norms, guidelines, laws, and regulations covering the international and domestic levels. This system should be dedicated to clarifying the technical requirements, ethical guidelines, and responsibilities of AI medical devices and their algorithms during research and development, validation, approval, deployment, and decommissioning. Specifically, it is necessary to accelerate the development of international standards (e.g., ISO, IEC) oriented to data quality, algorithm transparency, robustness, and clinical evaluation, and to form a clinical review guideline that connects with the requirements of the National Drug Administration (NMPA), the U.S. FDA, the European Union's EMA, and other regulatory

agencies. At the same time, the legislation clearly defines the respective legal responsibilities of model developers, clinical users, and medical institutions in the event of medical errors or safety incidents. It establishes a complete life cycle regulatory framework that includes continuous monitoring, algorithm update management, and adverse reaction traceability to safeguard the safety and controllability of AI medical applications and promote the healthy and orderly development of the industry. [1]. In parallel, there is a growing recognition of the need for “AI-literate” expert witnesses in medico-legal cases involving AI-assisted healthcare. These experts must possess clinical and technical knowledge to evaluate AI systems' validity, biases, and adherence to standards of care [9]. Such expertise will be crucial in fair liability assessments and building judicial and public trust in AI-driven medicine.

5. Conclusion

Artificial intelligence is profoundly reshaping every corner of medicine, from microscopic genetic research to macroscopic hospital management, and it provides a powerful technological tool to improve disease diagnosis and treatment, achieve personalized medicine, and optimize medical resource allocation. However, from the maturity of the technology to widespread clinical implementation, it still needs to cross the barriers of data, algorithms, ethics, and regulation. In the future, it is necessary to make concerted efforts through the industry, academia, research, medicine, and management to promote the deep integration of AI and medicine prudently and positively, oriented to solving practical clinical problems, and with safety, effectiveness, fairness, and interpretability as the core principles, to make this technology benefit every patient.

References

- [1] Liang Hao, Wang Shun, Cui Cheng, et al. Progress of regulatory policies and future research outlook of artificial intelligence medical device clinical trials[J]. *Chinese Clinical Pharmacology and Therapeutics*, 2025, 30(3): 427-431.
- [2] YANG Shuqi, ZHU Zheng, WANG Jiaqing, et al. Progress in the construction and application of evidence-based generative artificial intelligence big language model for healthcare[J]. *Journal of Nurse Advancement*, 2025, 40(12): 1317-1324.
- [3] Zhao Xiaoxiang. Processing methods and application scenarios of medical data in AI medical field[J]. *Science and Informatization*, 2024, (August 2011): 148-150.
- [4] Gu Jianying, Song Zhenju, Bai Chunxue. AI-enabled future medicine, opening a new chapter of medical model[J]. *Metaverse Medicine*, 2025, 2(1): 4-5.
- [5] Lv Jianyi, Wang Chunxi, Liu Sicheng. Application of artificial intelligence in biomedical research[J/OL]. *Chinese Journal of Comparative Medicine*.
- [6] Lv Jianyi, Wang Chunxi, Liu Sicheng. Application of artificial intelligence in biomedical research[J/OL]. *Chinese Journal of Comparative Medicine*.
- [7] Yang Fengtao, Ma Liantao, Yu Jianbo, et al. Progress in the application of artificial intelligence in emergency medicine[J]. *Chinese Journal of Modern Medicine*, 2025, 35(14): 38-43.
- [8] Serrano, D. R., Luciano, F. C., Anaya, B. J., Ongoren, B., Kara, A., Molina, G., Ramirez, B. I., Sánchez-Guirales, S. A., Simon, J. A., Tomicito, G., Rapti, C., Ruiz, H. K., Rawat, S., Kumar, D., & Lalatsa, A. (2024). Artificial Intelligence (AI) Applications in Drug Discovery and Drug Delivery: Revolutionizing Personalized Medicine. *Pharmaceutics*, *16*(10), 1328.
- [9] Terranova, C., Cestonaro, C., Fava, L., & Cinquetti, A. (2024). AI and professional liability assessment in healthcare: A revolution in legal medicine? *Frontiers in Medicine*, *10*, 1337335.