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Innovation and challenges of artificial intelligence technology in personalized healthcare

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As the burgeoning field of Artificial Intelligence (AI) continues to permeate the fabric of healthcare, particularly in the realms of patient surveillance and telemedicine, a transformative era beckons. This manuscript endeavors to unravel the intricacies of recent AI advancements and their profound implications for reconceptualizing the delivery of medical care. Through the introduction of innovative instruments such as virtual assistant chatbots, wearable monitoring devices, predictive analytic models, personalized treatment regimens, and automated appointment systems, AI is not only amplifying the quality of care but also empowering patients and fostering a more interactive dynamic between the patient and the healthcare provider. Yet, this progressive infiltration of AI into the healthcare sphere grapples with a plethora of challenges hitherto unseen. The exigent issues of data security and privacy, the specter of algorithmic bias, the requisite adaptability of regulatory frameworks, and the matter of patient acceptance and trust in AI solutions demand immediate and thoughtful resolution. The importance of establishing stringent and far-reaching policies, ensuring technological impartiality, and cultivating patient confidence is paramount to ensure that AI-driven enhancements in healthcare service provision remain both ethically sound and efficient. In conclusion, we advocate for an expansion of research efforts aimed at navigating the ethical complexities inherent to a technology-evolving landscape, catalyzing policy innovation, and devising AI applications that are not only clinically effective but also earn the trust of the patient populace. By melding expertise across disciplines, we stand at the threshold of an era wherein AI's role in healthcare is both ethically unimpeachable and conducive to elevating the global health quotient.

Keywords Artificial intelligence, Healthcare, Virtual assistant chatbots, Remote patient care, Data security

Artificial Intelligence (AI), a burgeoning domain within computer science, is increasingly being harnessed to execute tasks that demand human-like intelligence, such as solving complex problems, logical reasoning, and conducting learning analysis based on voluminous data sets. In the realm of healthcare, AI's significance cannot be overstated, particularly in areas like patient monitoring and telemedicine where it is driving transformative breakthroughs¹. One of the most dynamic frontiers within AI in healthcare is the swift evolution of Natural Language Processing (NLP) algorithms. These sophisticated tools are capable of deciphering and comprehending human language, a skill that has profound implications for patient care. When applied to analyze symptoms narrated by patients, NLP can facilitate more natural and effective communication, thereby enhancing patient engagement and elevating the overall telemedicine experience². Another significant milestone is the application of computer vision algorithms for interpreting medical imaging, such as CT scans and MRIs. By leveraging AI to diagnose and categorize diseases from these images, healthcare providers can make more precise and expedited diagnoses³. The strides made in machine learning are also noteworthy, with AI algorithms being trained on vast repositories of data to identify patterns and make predictions. This capability can be harnessed to analyze a wealth of patient data, including vital signs and test results, to anticipate health complications and tailor personalized care plans⁴. Furthermore, the rise of AI-driven virtual assistants in telemedicine is redefining patient-provider interactions, offering patients convenient access to healthcare information and resources, along with the ability to communicate with healthcare professionals in a manner that is both efficient and personalized.

As AI revolutionizes healthcare interactions, ushering in an era of more individualized, streamlined, and accessible care, it becomes imperative to ensure that the development and deployment of AI systems prioritize patient safety and privacy. This review article endeavors to present a comprehensive overview of the current state

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of AI technology within patient monitoring and telemedicine sectors, scrutinizing the potential benefits as well as the challenges these innovations face. Additionally, we aim to proffer guidance for researchers, clinicians, and policymakers to foster the judicious and effective use of AI technology in healthcare.

Applications of artificial intelligence in healthcare

Virtual assistant chatbots for patient support and education

Virtual assistant chatbots can provide personalized medical support and education to patients based on their individual needs and preferences. By utilizing Natural Language Processing (NLP) and machine learning algorithms, chatbots can learn from patient interactions and adjust their responses to match the patient's language and style, making the user experience more natural and engaging^{5,6}. Moreover, virtual assistant chatbots can offer round-the-clock service, which is particularly valuable for patients who are unable to access healthcare providers during regular working hours. With 24/7 availability, chatbots can help patients obtain the information and support they need when they need it. Additionally, virtual assistant chatbots can provide personalized health information and advice based on a patient's personal medical history and risk factors⁷. They can analyze a patient's medical records and generate tailored prevention and treatment recommendations, ensuring that patients receive the most appropriate care. Virtual assistant chatbots can provide personalized reminders and medical education, helping patients understand and comply with treatment plans. However, further research is needed to evaluate its effectiveness in improving patient compliance and motivation. For instance, a chatbot might recommend healthy meal plans or exercise routines to diabetic patients based on their dietary preferences and physical activity habits. There are already several online chatbots, such as *Your.MD*, *Your Symptoms*, *Babylon Health*, *AI Health*, *Iodine*, *Molly*, and others, that use artificial intelligence and machine learning to provide personalized health information and support for minor illnesses, chronic diseases, and mental health issues.

However, the application of virtual assistant chatbots still faces certain limitations. In the United States, patients' medical histories are often scattered across different systems, making it very complex to access and integrate these records⁸. Currently, AI faces major challenges in handling these tasks, including issues with data interoperability, standardization, and integration. Firstly, data interoperability is a major issue. Patients' medical records may be stored in different electronic health record (EHR) systems, which lack unified standards and protocols, making it difficult to share and integrate data⁹. To address this problem, health information exchanges (HIEs) and data standardization protocols (such as HL7 FHIR) are continuously evolving, aiming to improve the seamless exchange of medical information between different systems¹⁰. Secondly, data standardization is also a challenge. Different healthcare institutions and EHR systems may use different data formats and coding systems, making data integration more complex. For example, the same medical condition might be described using different terms and codes in different systems, posing difficulties for AI in processing and analyzing this data. Overcoming these obstacles requires the promotion of unified data standards and coding systems across the industry¹¹. Additionally, data integration itself faces technical and policy barriers. Many healthcare institutions lack sufficient technical support for data management and sharing, or they may be unwilling to share patient data due to privacy and security concerns. These factors further limit the application of AI technology in integrating and analyzing dispersed patient data¹².

Despite these challenges, virtual assistant chatbots hold great potential in personalized healthcare. By continuously improving data interoperability, standardization, and integration technologies, and addressing policy and technical barriers, AI tools can better serve patients, providing more accurate and personalized health recommendations.

Real-time patient monitoring and telepatient monitoring using wearable devices and sensors

Real-time patient monitoring and remote patient care can be achieved through the use of wearable devices and sensors, which enable healthcare providers to continuously track vital signs and other biometric data¹³. For instance, smartwatches can monitor a patient's heart rate and blood pressure, wirelessly transmitting this data to a central monitoring station for analysis and interpretation by healthcare professionals. Wearable sensors, another compact and portable option, can be worn on the body or integrated into clothing, jewelry, or other accessories to monitor vital signs and health metrics such as heart rate, blood pressure, respiratory rate, blood oxygen saturation, body temperature, and physical activity, transmitting the data wirelessly to a central monitoring station for in-depth analysis. Moreover, smartphone applications can utilize built-in sensors and wearable devices to monitor patients' health in real-time, tracking information such as physical activity, sleep patterns, and dietary habits, while providing feedback and suggestions to help manage their health. Additionally, smart home devices like smart speakers and thermostats can also be used to monitor patients' health status in real-time. The use of wearable devices and sensors for real-time patient monitoring offers many potential benefits for both patients and healthcare providers. Patients may experience increased security and peace of mind, knowing that their health status is being monitored and that any changes in their condition can be quickly detected. For healthcare providers, it can help better understand patients' health needs and monitor the progression of their conditions, leading to more personalized and targeted care¹⁴. Furthermore, real-time patient monitoring with wearable devices and sensors can automate some monitoring tasks, thereby reducing the burden on healthcare providers and decreasing the risk of human error.

However, there are also potential challenges associated with using wearable devices and sensors for real-time patient monitoring. Firstly, the process of real-time monitoring can generate a vast amount of data, some of which may be difficult to analyze and interpret, especially when dealing with data from multiple sources in different formats. Moreover, these wearable devices have made significant advancements in data collection and self-monitoring, but their accuracy still has limitations. In particular, wrist-worn devices can be affected by wrist position and user activity when measuring blood pressure, leading to inaccurate data¹⁵. In contrast, upper-arm

cuffs are generally considered more reliable for blood pressure measurement. Therefore, when using AI tools that rely on such data, it is crucial to fully understand the limitations of these devices and take necessary precautions in practical applications to ensure the effectiveness and reliability of AI tools, avoiding potential risks caused by inaccurate data.

Some data may even be unreliable or inaccurate, posing a risk of misjudgment. In healthcare, unreliable or inaccurate data can have a significant impact on diagnostic and treatment decisions. For example, research has shown that the accuracy of wearable devices in measuring physiological parameters such as heart rate and blood pressure may be affected by the wearing method, user activity, and technical limitations of the device itself^{16,17}. In addition, integration issues between different data sources may also lead to inconsistent or incomplete data, thereby affecting the performance and reliability of AI models. To address these issues, strict data validation and quality control measures must be implemented to ensure that the data used for AI model training and application has high quality and reliability¹⁸. Therefore, healthcare providers and policy makers must consider the limitations of these devices, take necessary preventive measures in clinical applications, avoid potential risks caused by inaccurate data, help researchers, clinicians, and policy makers better understand and apply AI technology, and ensure that patients can benefit from it.

Additionally, there are potential risks to patient privacy and data security. Sensitive information about patients' health and well-being could be misused by unauthorized third parties if not adequately protected. To address these challenges, researchers are developing AI-driven systems to analyze large amounts of data from various sources, providing actionable insights for clinicians. Moreover, anonymization and encryption technologies are being employed to further protect patient privacy and data security.

Predictive models for disease progression and patient risk stratification

Predictive models for disease progression and patient risk stratification utilize machine learning algorithms to analyze patients' medical history, genetic information, and other data to predict their risk of developing certain diseases or the progression of existing conditions. These models can also identify patients at risk of developing certain diseases, enabling healthcare providers to implement preventative measures to reduce risk¹⁹. They are also used to forecast the progression of patients' current diseases, allowing healthcare providers to adjust treatment plans accordingly. Predictive models are trained on large patient datasets using machine learning algorithms, including information about medical history, genetic data, and other relevant information, analyzing the data to identify patterns and relationships that can be used to predict the risk of patients developing certain diseases²⁰. Predictive models for disease progression and patient risk stratification have the capability to identify patients at risk of developing certain diseases and to predict the progression of current diseases, which allows healthcare providers to take preventative actions to reduce the risk of certain diseases and to adjust their treatment plans to better manage patients' current conditions²¹. Numerous models have been applied to the prediction and risk assessment of various diseases. For example, researchers have developed deep learning models that can predict the progression of Alzheimer's disease based on brain MRI scans and other patient information, helping doctors to better understand the progression of the disease and adjust treatment plans accordingly. Cardiovascular disease risk prediction models can use patient data such as blood pressure, cholesterol levels, and genetic information to forecast the risk of heart disease, aiding doctors in identifying high-risk patients and providing early intervention measures²². Cancer risk prediction models can predict cancer risk based on patient data (such as family history, lifestyle factors, and genetic information), helping doctors identify high-risk patients and offer early interventions to reduce their cancer risk²³. Risk prediction models for surgical complications can predict the risk of postoperative complications based on patient data (such as age, medical history, and type of surgery), helping doctors identify high-risk patients and provide additional monitoring or interventions to reduce the risk of complications²⁴. Readmission risk prediction models can forecast the risk of readmission based on patient data (such as age, medical history, and severity of illness), helping doctors identify high-risk patients and provide additional monitoring or interventions to reduce their risk of readmission. These are just a few examples of how deep learning is used to predict disease progression and patient risk stratification²⁵. As deep learning models become increasingly widespread in healthcare, we can expect to see more such predictive models used to improve patient care and outcomes.

Predictive models for disease progression and patient risk stratification serve as indispensable tools within the medical domain, affording healthcare practitioners the capability to proactively identify individuals at elevated risk of specific pathologies and implement preemptive interventions²⁶. Despite their utility, the deployment of such models is fraught with challenges pertaining to the veracity and integrity of the data underpinning model training, as well as potential systemic biases or inaccuracies inherent to the predictive analytics. To uphold the precision and fidelity of these models, it is imperative to meticulously curate high-caliber, pristine datasets for model training purposes and to persistently appraise model efficacy to discern any latent errors or biases that could compromise predictive outcomes. Additionally, the conscientious application of these models is paramount, ensuring that patients are not subjected to inequitable treatment predicated on model-derived predictions. As the adoption of these models expands within clinical practice, ongoing scrutiny of their performance metrics and a rigorous evaluation of their therapeutic impact become vital components to guarantee their judicious and efficacious deployment. Moreover, the datasets harnessed for model training must be faithfully representative of the demographic being studied, encompassing an array of pertinent patient information—demography, genetic lineage, and environmental exposures included—to foster the development of models that accurately forecast disease progression and risk stratification across the entire patient spectrum, irrespective of individual backgrounds or characteristics²⁷. It is equally expedient to ensure that the utilization of such models adheres to the highest ethical standards, secured through informed patient consent, and buttressed by stringent oversight

and regulatory frameworks designed to forestall any potential misapplication or discriminatory practices against targeted patient populations²⁸.

Personalized treatment recommendations based on patient data

Personalized treatment recommendations based on patient data represent a highly meaningful domain within healthcare, as they can improve patient outcomes and reduce medical costs. Deep learning models are capable of analyzing vast amounts of patient data, including genomic, genetic, demographic, and lifestyle factors, to determine how patients respond to different treatments. Genomic data, such as whole-genome sequencing, single-nucleotide polymorphisms (SNPs), and gene expression profiles, provide critical insights into the molecular underpinnings of diseases and individual responses to therapies²⁹. Subsequently, this information can be used to develop personalized treatment recommendations tailored to the unique characteristics and medical history of an individual patient³⁰. For instance, researchers have developed deep learning models capable of analyzing the genomic and genetic features of a patient's tumor and predicting their response to various chemotherapy drugs³¹. By incorporating data on gene mutations, copy number variations, and epigenetic modifications, these models can identify specific biomarkers that correlate with treatment efficacy. This information can then be used to recommend the most effective treatment approach for that patient, thereby increasing their chances of a successful outcome³². Similarly, deep learning models can analyze patient data such as age, medical history, and type of surgery, alongside genomic data, to predict the risk of complications like infections or bleeding. This allows for the recommendation of additional monitoring or preventative measures for high-risk patients, reducing their risk of complications and improving their overall outcomes. Moreover, pharmacogenomic data can be utilized to predict adverse drug reactions and optimize drug dosing, further personalizing patient care³³.

Pharmacogenomics is a rapidly evolving field that integrates genetic information to optimize drug therapy, analyzing how genetic variations affect drug efficacy and potential side effects, significantly enhancing the precision of personalized medicine³⁴. Deep learning models can utilize pharmacogenomic data to predict a patient's metabolism and response to specific drugs. For instance, genetic variations in genes encoding drug-metabolizing enzymes, transport proteins, and drug targets influence drug concentration in the body and subsequent therapeutic outcomes³⁵. By integrating pharmacogenomic data, AI models can recommend the most suitable drugs and dosages for each patient, minimizing side effects and maximizing therapeutic benefits.

Additionally, pharmacogenomic data can help identify patients who might experience adverse drug reactions, allowing for preventive measures or alternative treatment strategies. This data-driven approach ensures that patients receive safe and effective treatments based on their unique genetic makeup. For example, in oncology, pharmacogenomic profiling can guide the selection of targeted therapies that are more effective for patients with specific genetic mutations³⁶. By incorporating pharmacogenomic data into personalized treatment plans, healthcare providers can achieve better clinical outcomes and improve overall patient care.

Automatic appointment scheduling and reminders

Automatic appointment scheduling and reminders are invaluable tools in the healthcare sector, capable of improving patient compliance and lessening the workload of healthcare providers³⁷. As the capability of deep learning models to analyze vast amounts of patient data continues to advance, we can look forward to an increasing number of examples where automatic appointment scheduling and reminders are employed in healthcare.

Automated appointment scheduling and reminders are crucial tools in healthcare as they can enhance patient adherence to treatment plans and reduce the burden on healthcare providers. Artificial intelligence (AI), especially deep learning models, can significantly improve these processes by analyzing large amounts of patient data to make more accurate and personalized recommendations. Deep learning models can analyze patient data, including their medical history, previous appointment schedules, and preferences, to recommend the best appointment times for individual patients. This advanced analysis reduces the likelihood of missed appointments or the need for rescheduling, leading to better outcomes and increased efficiency in the healthcare system. For example, AI can identify patterns in patient behavior and appointment history that may not be evident in traditional scheduling systems, optimizing the scheduling process to better meet patient needs and provider availability.

Additionally, automated appointment reminders are a key aspect of AI-enhanced scheduling. By analyzing patient data such as demographics, medical history, and past responses to appointment reminders, deep learning models can determine the most effective reminder strategy for each patient³⁸. This personalized approach reduces the number of missed appointments and ensures patients receive the care they need when they need it. AI can also adjust reminder strategies in real-time based on patient responses, further enhancing the effectiveness of these reminders.

Real-world examples of AI-enhanced automated appointment scheduling and reminders include platforms like PatientPop, Zocdoc, and Vyasa. These platforms utilize AI to analyze patient data and recommend the best appointment times based on patient history and previous appointment schedules. They also send automated, personalized appointment reminders to patients, increasing the likelihood of appointments and necessary care. These AI-driven platforms provide seamless automated scheduling, allowing patients to easily book online and receive reminders via text or email, thereby improving overall patient compliance and reducing the workload on healthcare providers.

Research has shown that automated appointment scheduling and reminder systems can indeed improve patient compliance in certain situations. For example, research has found that using text message reminders can significantly reduce the occurrence of delayed medical visits, thereby improving patient compliance³⁹. Another study suggests that email reminders have also played a positive role in increasing vaccination rates and follow-up appointments⁴⁰.

However, relying solely on reminder systems cannot fully address compliance and motivation issues. The compliance of patients with treatment plans is also influenced by various factors, including trust in doctors, relationship with the medical system, and the effectiveness of treatment models.

As AI and deep learning models continue to advance, we can expect to see more examples of AI-driven automated scheduling and reminders being used in healthcare, leading to improved patient outcomes and increased efficiency in healthcare delivery.

The transformative impact of AI on healthcare

Artificial intelligence (AI) is revolutionizing various aspects of healthcare, with several key areas being the focus of current research and development. In medical imaging and diagnosis, deep learning models are currently used to assist in the detection and diagnosis of diseases in medical images such as X-rays, MRIs, and CT scans. For example, AI systems are employed to identify early signs of cancer, cardiovascular diseases, and neurological disorders with remarkable accuracy and speed. In personalized medicine, AI aids in analyzing genetic, demographic, and lifestyle data to provide personalized treatment recommendations. This approach is particularly beneficial in oncology, where AI can predict a patient's response to different chemotherapy drugs, thus formulating more effective and individualized treatment plans. Predictive analytics and risk assessment is another crucial area of AI research, where AI models are used to predict patient outcomes, such as the likelihood of disease progression, readmission rates, and potential risks of surgical complications. These predictions enable healthcare providers to take preventive measures, enhance the quality of patient care, and reduce healthcare costs. Natural language processing (NLP) technology is used to extract meaningful information from unstructured medical data, such as clinical records and research articles. This technology helps improve electronic health record (EHR) systems, streamline administrative tasks, and enhance patient care through better data utilization.

Challenges and concerns

Data security and privacy issues

The application of artificial intelligence in healthcare generates and stores vast amounts of sensitive personal and medical information, making data security and privacy a paramount concern⁴¹. Various data security risks exist, such as data breaches where hackers or malicious actors gain unauthorized access to patient data (like medical records or insurance information), potentially causing significant financial and reputational damage to healthcare providers. Inadequate data encryption, whether at rest or in transit, can leave patient data vulnerable to unauthorized access or misuse. Lack of access control, failing to manage user access to patient data properly, can also lead to unauthorized access or misuse. Without proper data retention strategies, the storage period of patient data may extend beyond what is necessary, increasing the risk of unauthorized access or misuse. Furthermore, the absence of data breach prevention and response plans can leave healthcare providers unprepared in the event of a data breach.

Thus, it is essential for healthcare providers to ensure their systems and processes are secure and that patient data is protected from unauthorized access or misuse. A combination of technical and organizational measures can be employed to tackle these issues, including data encryption, access control, and data breach prevention and response planning⁴². Beyond technical measures, healthcare providers must comply with legal requirements such as the Health Insurance Portability and Accountability Act (HIPAA) in the United States, which regulates the use and disclosure of patient data. Adherence to such regulations is crucial for ensuring the protection of patient data. Data security and privacy concerns are a critical issue within the healthcare sector, and healthcare providers must take steps to ensure that data used for training and deploying deep learning models is secure and patient privacy is safeguarded⁴³.

Bias and discrimination in AI algorithms

The potential for bias and discrimination arises in artificial intelligence algorithms when the data used to train them reflects the biases of the data collectors or inherent biases within the data itself. This can lead to decisions made by the algorithms that result in unfair outcomes for certain individuals or groups⁴⁴. When the proportion of a certain class of patient data is low in the training dataset, AI algorithms may exhibit lower accuracy in diagnosing and treating these patient groups. A study found that a skin cancer diagnostic algorithm performed excellently on patients with light skin but showed significantly lower accuracy for those with dark skin⁴⁵. Additionally, research has shown that gender balance in medical imaging datasets is crucial for training AI systems for computer-aided diagnosis. Failing to achieve this balance leads to a persistent decline in diagnostic performance for underrepresented genders⁴⁶. Therefore, when developing and deploying AI algorithms, it is essential to identify and mitigate these biases. This can be achieved by using diverse and representative datasets for training, regularly monitoring algorithm performance across different groups, and employing fairness correction techniques to adjust the algorithms and reduce biases.

To address issues of bias and discrimination in AI algorithms, healthcare providers must be aware of potential sources of bias in the data they collect and the algorithms they use. This may involve analyzing potential biases within the data, using diverse datasets for algorithm training, and implementing measures to monitor and address any biases or discrimination that may occur within the algorithms. It is equally important to recognize that biases and discrimination in AI algorithms can have serious consequences, as they can lead to unfair outcomes for patients and potentially erode trust in the healthcare system.

The adoption of artificial intelligence (AI) in the healthcare sector faces significant obstacles due to the conservatism of existing medical systems. Resistance to change is a major issue, as healthcare systems tend to favor established practices over new technologies. This resistance can slow down the adoption of AI, with physicians and administrators potentially skeptical of its benefits and concerned about disrupting current workflows.

Integration with existing systems is another challenge; AI solutions must be compatible with current health information systems (HIS) and electronic health records (EHR). Technical incompatibilities and the need for substantial infrastructure changes can be major barriers to seamless integration.

Training and expertise are also critical factors. The successful implementation of AI in healthcare requires that medical professionals receive adequate training and have a thorough understanding of these technologies. A lack of sufficient education and expertise can hinder the effective adoption and use of AI tools. By clearly understanding these systemic barriers, we can develop targeted strategies to address these issues and promote the successful integration of AI into medical practice.

Regulatory frameworks and approval processes

Regulatory frameworks and approval processes ensure that new technologies are reviewed and approved by regulatory agencies before being used in patient care, helping to protect patient safety and promote the use of effective technologies in the healthcare industry⁴⁷. The reliability and effectiveness of wearable devices, in particular, need special attention, as the data from these devices directly impact the decision-making quality of AI tools. For example, wrist-worn devices may significantly differ from traditional upper-arm cuff devices in measuring blood pressure⁴⁸, potentially leading AI tools to make incorrect judgments based on inaccurate data, affecting patient health management. Therefore, evaluating and validating the reliability and effectiveness of wearable devices is crucial. In the United States, the Food and Drug Administration (FDA) regulates medical devices, including AI-driven medical applications and wearable devices, requiring all medical devices to undergo a rigorous approval process before being marketed to ensure their safety and effectiveness⁴⁹.

In other countries, such as the United Kingdom, the regulatory frameworks and approval procedures for medical devices may differ, with the *Medicines and Healthcare products Regulatory Agency* (MHRA) responsible for regulating medical devices in the UK, having its own requirements and approval procedures⁵⁰. The regulatory framework for AI-based diagnostic and decision support tools is rapidly evolving, as these technologies become increasingly integral to healthcare. The FDA, for instance, has developed a regulatory approach specifically tailored to Software as a Medical Device (SaMD), which includes AI-based tools⁵¹. The FDA's Digital Health Innovation Action Plan and the proposed regulatory framework for modifications to AI/ML-based SaMD are key initiatives aimed at ensuring the safety and effectiveness of AI tools. These frameworks outline premarket review pathways, postmarket surveillance, and the importance of transparency in AI algorithm modifications. Similarly, international bodies such as the European Medicines Agency (EMA) and Japan's Pharmaceuticals and Medical Devices Agency (PMDA) have established guidelines for the evaluation and approval of AI-based medical technologies^{52,53}. The European Union's General Data Protection Regulation (GDPR) also plays a significant role in governing the use of AI in healthcare by setting stringent requirements for data protection and privacy⁵⁴.

In addition to regulatory bodies, organizations like the International Medical Device Regulators Forum (IMDRF) have provided global harmonization efforts through documents such as the "Software as a Medical Device (SaMD): Key Definitions" and "SaMD: Clinical Evaluation" guidelines. These initiatives help create a consistent framework for the development, evaluation, and regulation of AI-based medical devices globally⁵⁵.

By incorporating these regulatory frameworks and guidelines into the development and deployment of AI-based diagnostic and decision support tools, developers and healthcare providers can ensure compliance with safety and efficacy standards, ultimately enhancing patient care and trust in AI technologies.

Patient acceptance and adoption of AI-driven technologies

Patient acceptance and willingness to adopt AI technologies are crucial factors for the success and sustainability of these technologies in healthcare. Patients may have varying attitudes towards AI technologies in healthcare. For instance, some patients might be satisfied with AI-driven technologies, while others may have concerns about their accuracy and reliability. Patients' understanding of the technology, trust in it, and their perceptions of the risks and benefits associated with the technology can influence their attitudes towards accepting AI.

Here are some real-world examples where patients have accepted and adopted AI technologies in healthcare: The *Mayo Clinic* is utilizing an AI chatbot named *Mayo Clinic AI* to provide patients with personalized information about their health conditions and answer questions related to their health. The *National Health Service (NHS)* in the UK is using Florence, an AI virtual nursing assistant, to support patients with chronic health conditions. AI-driven robotic surgery is another example of patient acceptance and adoption of AI technology in healthcare. Robotic surgery involves the use of surgical robots to assist surgeons during operations, with some robots using AI to increase precision and accuracy in the surgical process⁵⁶.

Patients' acceptance of AI technology significantly impacts the success and sustainability of these innovations. For those reluctant to adopt AI, several strategies can help increase their acceptance. Educating and training patients about AI technology, including its functions, benefits, and potential risks, can help them understand how these technologies can improve their health management. Maintaining transparency and communication is crucial; explaining how AI technology uses their data and what measures are taken to protect their privacy and data security can alleviate concerns. Offering personalized experiences tailored to patients' specific needs and preferences can make them feel that these technologies are customized for them. Building trust is essential, and this can be achieved by showcasing successful case studies and validation data of AI technologies in clinical applications. Additionally, involving patients in the decision-making process helps them feel a sense of agency and control in their healthcare journey⁵⁷. Lastly, respecting the choices of patients who are unwilling to adopt AI technology is important, and providing alternative options ensures they continue to receive high-quality medical services.

To improve patient acceptance and adoption rates of AI technologies in healthcare, it is essential to provide clear and transparent information to patients about the technology and its uses, as well as to address any concerns

or questions they may have about the technology. Patient willingness to accept and adopt AI technologies is a significant factor affecting the technology's success and sustainability, so patient attitudes, understanding, and trust in the technology should be specially considered when implementing AI technologies in healthcare.

Recommendations for future research

The advent of artificial intelligence in the realm of healthcare portends a transformative era, with the potential to radically enhance patient care and optimize therapeutic outcomes. Nevertheless, the integration of AI into clinical practice necessitates a scrupulous examination of its ethical, legal, and societal ramifications⁵⁸. As such, a seminal direction for subsequent research initiatives is to cultivate robust collaborative frameworks between investigative researchers and clinical practitioners. It is essential that the research fraternity engages in synergistic partnerships with frontline clinicians to ensure that the AI technologies they conceive and develop are not only innovative but also directly applicable and relevant to the exigencies of clinical practice. Furthermore, policymakers must be at the vanguard of establishing comprehensive policies and regulatory scaffolding to oversee the responsible and ethical deployment of AI technologies within the healthcare sector. The formulation of stringent policies is critical to harnessing AI technologies in a manner that engenders transparency, accountability, and, above all, prioritizes the sanctity and protection of patients' data privacy and security⁵⁹. Only through meticulous governance can we ensure that the benefits of artificial intelligence in healthcare are realized without compromising the trust and well-being of those who seek our care.

Data availability

Data generated during the current study are available from the corresponding author upon reasonable request.

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References

1. Esteva, A., Kuprel, B. & Novoa, R. A. Dermatologist-level classification of skin cancer with deep neural networks. *Oncology* **19**(11–12), 407–408 (2017).
2. Wiriyathamabhum, P. et al. Computer vision and natural language processing: Recent approaches in multimedia and robotics. *ACM Comput. Surveys* **49**(4), 1–44 (2017).
3. Gulshan, V. et al. Development and validation of a deep learning algorithm for detection of diabetic retinopathy in retinal fundus photographs. *Jama-J. Am. Med. Assoc.* **316**(22), 2402–2410 (2016).
4. Susymary, J. & Deepalakshmi, P. Machine learning for precision medicine forecasts and challenges when incorporating non omics and omics data. *Intell. Decis. Technol.-Netherlands* **15**(1), 69–85 (2021).
5. Aggarwal, A. et al. Artificial intelligence-based chatbots for promoting health behavioral changes: Systematic review. *J. Med. Internet Res.* **25**, e40789 (2023).
6. Kurniawan, M. H. et al. A systematic review of artificial intelligence-powered (AI-powered) chatbot intervention for managing chronic illness. *Ann. Med.* <https://doi.org/10.1080/07853890.2024.2302980> (2024).
7. Abd Rahman, R. et al. Application of machine learning methods in mental health detection: A systematic review. *IEEE Access* **8**, 183952–183964 (2020).
8. Calvaresi, D. et al. Exploring agent-based chatbots: A systematic literature review. *J. Ambient Intell. Hum. Comput.* **14**(8), 11207–11226 (2023).
9. Bertagnolli, M. M. et al. The electronic health record as a clinical trials tool: Opportunities and challenges. *Clin. Trials* **17**(3), 237–242 (2020).
10. Kiourtis, A., et al. *Improving Health Information Exchange through Wireless Communication Protocols*. In: *16th International Conference on Wireless and Mobile Computing, Networking and Communications (IEEE WiMob)*. Electr Network. (2020).
11. Nickel, B. et al. Words do matter: A systematic review on how different terminology for the same condition influences management preferences. *BMJ Open* **7**(7), e014129 (2017).
12. van Panhuis, W. G. et al. A systematic review of barriers to data sharing in public health. *BMC Public Health* <https://doi.org/10.1186/1471-2458-14-1144> (2014).
13. He, T. & Lee, C. Evolving flexible sensors, wearable and implantable technologies towards BodyNET for advanced healthcare and reinforced life quality. *IEEE Open J. Circuits Syst.* **2**, 702–720 (2021).
14. Nguyen, T. N. et al. Guest editorial innovations in wearable, implantable, mobile, & remote healthcare with IoT & sensor informatics and patient monitoring. *IEEE J. Biomed. Health Inform.* **27**(5), 2152–2154 (2023).
15. Hrabovska, N., Kajati, E. & Zolotova, I. A validation study to confirm the accuracy of wearable devices based on health data analysis. *Electronics* **12**(11), 2536 (2023).
16. Wang, T.-L. et al. Assessment of heart rate monitoring during exercise with smart wristbands and a heart rhythm patch: Validation and comparison study. *Jmir Form. Res.* **7**, e52519 (2023).
17. Mukkamala, R. et al. Evaluation of the accuracy of cuffless blood pressure measurement devices: Challenges and proposals. *Hypertension* **78**(5), 1161–1167 (2021).
18. Zamani, E. D. et al. Artificial intelligence and big data analytics for supply chain resilience: A systematic literature review. *Ann. Oper. Res.* **327**(2), 605–632 (2023).
19. Cai, Y. et al. Artificial intelligence in the risk prediction models of cardiovascular disease and development of an independent validation screening tool: A systematic review. *BMC Med.* <https://doi.org/10.1186/s12916-024-03273-7> (2024).
20. Lopez-Cortes, X. A. et al. Machine-learning applications in oral cancer: A systematic review. *Appl. Sci.-Basel* **12**(11), 5715 (2022).
21. Mohsin, S. N. et al. The role of artificial intelligence in prediction, risk stratification, and personalized treatment planning for congenital heart diseases. *Cureus J. Med. Sci.* <https://doi.org/10.7759/cureus.44374> (2023).
22. D'Agostino, R. B. et al. General cardiovascular risk profile for use in primary care: The Framingham heart study. *Circulation* **118**(4), E86–E86 (2008).
23. Zheng, Y. et al. Risk prediction models for breast cancer: a systematic review. *BMJ Open* **12**(7), e055398 (2022).
24. Zeng, S. et al. Machine learning approaches for the prediction of postoperative complication risk in liver resection patients. *BMC Med. Inform. Decis. Mak.* <https://doi.org/10.1186/s12911-021-01731-3> (2021).
25. Monteiro Costa, M. L. et al. Development and validation of predictive model for long-term hospitalization, readmission, and in-hospital death of patients over 60 years old. *Einstein-Sao Paulo* https://doi.org/10.31744/einstein_journal/2022AO8012 (2022).
26. Yarborough, B. J. H. et al. Clinical implementation of suicide risk prediction models in healthcare: A qualitative study. *BMC Psychiatry* <https://doi.org/10.1186/s12888-022-04400-5> (2022).

27. Wiberg, H. M., *Data-Driven Healthcare via Constraint Learning and Analytics*. (2022).
28. Obermeyer, Z. & Emanuel, E. J. Predicting the future—Big data, machine learning, and clinical medicine. *N. Engl. J. Med.* **375**(13), 1216–1219 (2016).
29. Liu, Z. *et al.* Effect of SNPs in protein kinase *Cz* gene on gene expression in the reporter gene detection system. *World J. Gastroenterol.* **10**(16), 2357–2360 (2004).
30. Beam, A. L. & Kohane, I. S. Big data and machine learning in health care. *Jama-J. Am. Med. Assoc.* **319**(13), 1317–1318 (2018).
31. Wang, C.-W., Khalil, M.-A. & Firdi, N. P. A survey on deep learning for precision oncology. *Diagnostics* **12**(6), 1489 (2022).
32. Cuocolo, R. *et al.* Machine learning in oncology: A clinical appraisal. *Cancer Lett.* **481**, 55–62 (2020).
33. McKillip, R. P. *et al.* Patient perceptions of care as influenced by a large institutional pharmacogenomic implementation program. *Clin. Pharmacol. Ther.* **102**(1), 106–114 (2017).
34. Ryan, D. K. *et al.* Artificial intelligence and machine learning for clinical pharmacology. *Br. J. Clin. Pharmacol.* **90**(3), 629–639 (2024).
35. Wang, Y. *et al.* DeepDRK: A deep learning framework for drug repurposing through kernel-based multi-omics integration. *Brief. Bioinform.* <https://doi.org/10.1093/bib/bbab048> (2021).
36. Varnai, R. *et al.* Pharmacogenomic biomarkers in docetaxel treatment of prostate cancer: From discovery to implementation. *Genes* **10**(8), 599 (2019).
37. Werner, K. *et al.* Behavioural economic interventions to reduce health care appointment non-attendance: a systematic review and meta-analysis. *BMC Health Serv. Res.* <https://doi.org/10.1186/s12913-023-10059-9> (2023).
38. Posadzki, P. *et al.* Automated telephone communication systems for preventive healthcare and management of long-term conditions. *Cochrane Database Syst. Rev.* <https://doi.org/10.1002/14651858.CD009921.pub2> (2016).
39. Bjornholt, K. *et al.* The effect of daily small text message reminders for medicine compliance amongst young people connected with the outpatient department for child and adolescent psychiatry. A controlled and randomized investigation. *Nordic J. Psychiatry* **70**(4), 285–289 (2016).
40. Dombkowski, K. J. *et al.* The impacts of email reminder/recall on adolescent influenza vaccination. *Vaccine* **35**(23), 3089–3095 (2017).
41. Price, W. N. & Cohen, I. G. Privacy in the age of medical big data. *Nat. Med.* **25**(1), 37–43 (2019).
42. Figueroa-Lorenzo, S., Anorga, J. & Arrizabalaga, S. A Role-based access control model in modbus SCADA systems. A centralized model approach. *Sensors* **19**(20), 4455 (2019).
43. Boyce, B. HIPAA compliance from a private practice purview. *J. Acad. Nutr. Dietetics* **114**(9), 1341 (2014).
44. Selbst, A. D., *et al.* *Fairness and Abstraction in Sociotechnical Systems*. In: *ACM Conference on Fairness, Accountability, and Transparency (FAT)*. Atlanta, GA. (2019).
45. Daneshjou, R. *et al.* Disparities in dermatology AI performance on a diverse, curated clinical image set. *Sci. Adv.* <https://doi.org/10.1126/sciadv.abq6147> (2022).
46. Larrazabal, A. J. *et al.* Gender imbalance in medical imaging datasets produces biased classifiers for computer-aided diagnosis. *Proc. Natl. Acad. Sci. U. S. A.* **117**(23), 12592–12594 (2020).
47. Weenink, J.-W. *et al.* Publication of inspection frameworks: A qualitative study exploring the impact on quality improvement and regulation in three healthcare settings. *BMJ Qual. Saf.* **30**(10), 804–811 (2021).
48. Melville, S. *et al.* A comparison and calibration of a wrist-worn blood pressure monitor for patient management: Assessing the reliability of innovative blood pressure devices. *J. Med. Internet Res.* **20**(4), e111 (2018).
49. Miller, D. D. Machine intelligence in cardiovascular medicine. *Cardiol. Rev.* **28**(2), 53–64 (2020).
50. Lievevrouw, E., Marelli, L. & Van Hoyweghen, I. The FDA's standard-making process for medical digital health technologies: Co-producing technological and organizational innovation. *Biosocieties* **17**(3), 549–576 (2022).
51. Brindza, L. J. FDA regulation of computerized cytology devices. *Anal. Quant. Cytol. Histol.* **13**(1), 3–6 (1991).
52. Wu, Y. *et al.* BERT-based natural language processing of drug labeling documents: A case study for classifying drug-induced liver injury risk. *Front. Artif. Intell.* <https://doi.org/10.3389/frai.2021.729834> (2021).
53. Okamoto, R., Kojima, R. & Nakatsui, M. Toward AI-supported evaluation for safety control measures against near-miss events in pharmaceutical products. *Saf. Sci.* **168**, 106314 (2023).
54. Meszaros, J., Minari, J. & Huys, I. The future regulation of artificial intelligence systems in healthcare services and medical research in the European Union. *Front. Genet.* <https://doi.org/10.3389/fgene.2022.927721> (2022).
55. Moshi, M. R. *et al.* Evaluation of mobile health applications: Is regulatory policy up to the challenge?. *Int. J. Technol. Assess. Health Care* **35**(4), 351–360 (2019).
56. Bruining, N. & de Jaegere, P. The Mayo Clinic: Digital health centre of excellence. *Eur. Heart J. Digit. Health* **3**(1), 5–7 (2022).
57. Haidet, P. *et al.* Shared decision making reimaged. *Patient Educ. Counsel.* **123**, 108249 (2024).
58. Char, D. S., Shah, N. H. & Magnus, D. Implementing machine learning in health care—Addressing ethical challenges. *N. Engl. J. Med.* **378**(11), 981–983 (2018).
59. Topol, E. J. High-performance medicine: The convergence of human and artificial intelligence. *Nat. Med.* **25**(1), 44–56 (2019).

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Y-H L: Conceptualization, Methodology, Writing. Y-L L, M-Y W: Writing—review & editing. G-Y L: Conceptualization, Writing—original draft, Writing—review & editing, Funding acquisition, Resources, Supervision.

Competing interests

The authors declare no competing interests.

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