Review Article



Future of AI-Enabled Medical Devices in India

Jayasree.P*1, Raji. M.K²

 ORCID ID: 0009-0006-9132-3703. Post Graduate Scholar, Department of Pharmaceutical Regulatory Affairs, Chemists College of Pharmaceutical Sciences & Research(Affiliated with Kerala University of Health Sciences, Thrissur), Varikoli P.O., Puthencruz, Ernakulam 682308, Kerala, India.
 ORCID ID: 0009-0001-0901-3911. Associate Professor, Department of Pharmaceutics, Chemists College of Pharmaceutical Sciences & Research (Affiliated with Kerala University of Health Sciences, Thrissur), Varikoli P.O., Puthencruz, Ernakulam 682308, Kerala, India.
 *Corresponding author's E-mail: jayasreesandeep05@gmail.com

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ABSTRACT

Artificial intelligence (AI) is transforming the healthcare industry, particularly through the development of AI-enabled medical devices. These innovations promise improved healthcare efficiency. In India, the market for these devices is expected to grow significantly, reaching \$35 billion by 20301. However, it brings several challenges also. This article examines the current state of AI in healthcare in India, both the opportunities and the obstacles. This discusses the existing regulations and highlights the need for new guidelines specifically designed for AI technologies. Traditional regulations may not adequately address issues and concerns about data privacy, which are crucial for maintaining patient trust. Additionally, the article addresses the issue of digital inequality, where access to advanced healthcare technologies can vary greatly between urban and rural areas. It emphasizes the importance of ensuring that all segments of society can benefit from these innovations. The article also explores potential growth opportunities through partnerships between government and private companies, as well as the vibrant start-up ecosystem in India that is driving local innovation. By showcasing successful examples of collaboration and innovation, it illustrates how India can leverage its strengths to become a leader in health technology. In conclusion, this article offers practical recommendations for policymakers and stakeholders to create a supportive environment for AI-enabled medical devices. By working together, India can navigate the complexities of AI in healthcare and harness its full potential to improve health outcomes for all citizens.

Keywords: Artificial intelligence, AI-enabled medical devices, advanced healthcare technologies.

INTRODUCTION

rtificial intelligence (AI) is changing the way healthcare is delivered around the world, and India is no exception. With its vast population and diverse healthcare needs, India stands to benefit greatly from AIenabled medical devices. These devices use advanced technology to assist doctors in diagnosing diseases, monitoring patients, and improving overall healthcare services. As India faces significant challenges, such as limited access to quality healthcare in rural areas and overcrowded hospitals in cities, AI has the potential to provide innovative solutions that can make a real difference. The Indian healthcare market is expected to grow rapidly, reaching an estimated \$35 billion by 2030¹. This growth is driven by a rising demand for better healthcare services and advancements in technology. The government is also taking steps to support this growth through initiatives like the National Digital Health Mission and Ayushman Bharat, which aim to improve access to healthcare and incorporate digital solutions into everyday medical practices⁷. However, as exciting as these developments are, they also come with challenges that need careful consideration. For instance, issues related to data privacy-how patient information is collected and used—are critical⁷. There is also the risk of algorithm bias, where AI systems might make decisions that favour certain groups over others, leading to unfair treatment. Additionally, the current regulatory frameworks may not be fully equipped to handle the unique aspects of AI technologies, which raises questions about how to ensure these devices are safe and effective. This article, aims to explore the current state of AI in Indian healthcare. It will look at the various opportunities that AI-enabled medical devices present, such as improving diagnostics and enhancing patient care. At the same time, it will address the regulatory challenges that must be overcome to ensure these technologies are used responsibly. By finding a balance between encouraging innovation and establishing clear regulations, India can harness the power of AI to improve healthcare for everyone. This article will discuss how collaboration between government agencies, private companies, and healthcare providers can create a supportive environment for AI technologies. Ultimately, the goal is to ensure that all citizens have access to high-quality healthcare services that meet their needs.

Current State of AI in Healthcare

The current state of AI in healthcare reflects a rapidly growing market with transformative applications that promise to enhance patient care. As India positions itself as a key player in this space, it faces both opportunities and challenges that will shape its future in the global healthcare landscape. The global market for artificial intelligence (AI) in healthcare is experiencing remarkable growth. As of 2023, the market was valued at approximately \$19.27 billion and is projected to grow at an impressive compound annual growth rate (CAGR) of 36.83%, reaching around \$613.81 billion by 2034⁸. This surge is driven by the increasing



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demand for enhanced efficiency, accuracy, and better patient outcomes in healthcare².

In 2024, the market share for Artificial Intelligence (AI) in precision medicine is prominently distributed across various therapeutic applications, with oncology leading the way at 33%. This significant share underscores the advancements in cancer diagnostics and personalized treatment approaches facilitated by AI technologies. Following oncology, the neurology segment holds a substantial 26% of the market, driven by the increasing prevalence of neurological disorders and the growing demand for early detection and tailored therapeutic interventions. Meanwhile, cardiology accounts for 21% of the market share, reflecting the rising integration of AI in managing cardiovascular diseases. The respiratory segment captures 12%, indicating a notable interest in leveraging AI for respiratory health solutions. Lastly, other therapeutic applications collectively represent 8% of the market, showcasing the expanding scope of AI in precision medicine across diverse medical fields.

A recent study indicated that 79% of healthcare organizations are currently utilizing AI technology, with a return on investment (ROI) of \$3.20 for every \$1 invested within just 14 months. AI technologies are being applied across various areas in healthcare, significantly transforming traditional practices. AI algorithms analyze medical images (like X-rays and MRIs) to assist radiologists in detecting diseases more accurately and quickly⁹. By analyzing large datasets, AI can predict patient outcomes and identify individuals at high risk for certain conditions, enabling early intervention⁹. In Personalized Medicine, AI helps tailor treatment plans based on individual patient data, improving the effectiveness of therapies⁹. AI accelerates the drug development process by predicting how different compounds will behave in the body, potentially reducing the time and cost involved in bringing new drugs to market⁹.



India is poised to become a significant player in the global AI healthcare market, with projections indicating it could reach \$35 billion by 2030¹. The country's large population

and increasing demand for efficient healthcare solutions create a fertile ground for Al innovations². The growing incidence of chronic diseases and an aging population further emphasize the need for advanced healthcare technologies that can provide timely and accurate care².

Several Indian companies and start-ups are at the forefront of AI advancements in healthcare. "Niramai" is an Indian start-up which specializes in using AI for early detection of breast cancer through thermal imaging technology. Another Indian company, "SigTuple", leverages AI for automated analysis of medical data, particularly in pathology and radiology, enhancing diagnostic accuracy⁹. Other notable players include "Qure.ai", which focuses on using AI for radiology diagnostics, and "Practo", which integrates AI into its health management platform to improve patient engagement and care delivery⁹. These companies exemplify India's innovative spirit and its potential to lead in the development of AI-enabled medical devices that can transform healthcare delivery both locally and globally.

Regulatory Landscape

While India has made significant strides in regulating medical devices through the MDR 2017 and CDSCO's oversight, there is a pressing need for tailored guidelines that specifically address the complexities of AI-enabled technologies¹⁰. Learning from international best practices can help India create a robust regulatory environment that fosters innovation while ensuring patient safety and trust in these advanced healthcare solutions¹⁰. In India, the regulation of medical devices is governed primarily by the Drugs and Cosmetics Act, 1940, along with the Medical Devices Rules (MDR) 2017¹¹.

The MDR 2017 was a significant step in establishing a comprehensive regulatory framework for medical devices, categorizing them into four classes (Class A, B, C, and D) based on their risk levels¹¹. This classification determines the licensing requirements and regulatory scrutiny for manufacturing, importing, and selling these devices¹¹.

According to the MDR, Manufacturers must obtain a license to manufacture and sell medical devices¹¹. Class A and B devices require state-level licensing, while Class C and D devices necessitate central licensing¹¹. These rules also specify the requirements for conducting clinical trials and evaluations for new medical devices to ensure their safety and efficacy¹¹. In addition, Manufacturers are required to monitor the performance of their devices after they are on the market and report any adverse events¹¹. The Central Drugs Standard Control Organization (CDSCO) is the national regulatory authority responsible for overseeing the implementation of the Drugs and Cosmetics Act and the Medical Devices Rules in India¹¹. CDSCO issues licenses for manufacturing, importing, and selling medical devices based on compliance with established regulations¹¹. It ensures that medical devices meet safety and quality standards through inspections and audits¹¹. The organization is involved in developing guidelines and



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policies that govern the medical device sector in India¹¹. By regulating medical devices, CDSCO aims to protect public health by ensuring that only safe and effective products are available in the market¹¹.

International Comparisons

When comparing India's regulatory approach to those of other countries, notable differences emerge: The U.S. Food and Drug Administration (FDA) has established specific guidelines for AI-enabled medical devices, including a focus on pre-market review processes that emphasize algorithm transparency and performance validation^{10,12}. The FDA also manufacturers to submit real-world encourages performance data post-market to ensure ongoing safetv^{10,12}. The European Medicines Agency (EMA) has developed a framework that includes provisions for adaptive pathways for innovative therapies, allowing faster access to promising treatments while ensuring rigorous oversight¹². Their guidelines emphasize collaboration with developers throughout the regulatory process to address challenges unique to AI technologies¹².

Challenges with AI

While the existing regulatory framework provides a foundation for medical device regulation, it may not be sufficient for addressing the unique challenges posed by Alenabled devices.

Al holds great promise for improving healthcare delivery, but challenges such as lack of transparency in Algorithms, algorithm bias, data privacy concerns, and digital inequality must be addressed proactively. By recognizing these challenges and implementing strategies to mitigate them, stakeholders can work towards a more equitable healthcare system that leverages the full potential of Al technologies^{13,14,15}.



1. Lack of Transparency in Algorithms

A key issue is lack of transparency in Algorithms. Achieving transparency in Al is a pressing concern, as many systems function as 'black boxes,' concealing their decision-making mechanisms¹³. This lack of transparency can hinder trust among healthcare providers and patients. Traditional

clinical trial methods may not adequately assess the performance of AI algorithms, which can learn and evolve over time. This raises questions about how to validate these systems effectively before they reach the market¹³. AI systems often rely on large datasets that include sensitive patient information. Ensuring data privacy while leveraging this data for training algorithms is a critical challenge^{15,16}.

2. Algorithm bias

Algorithm bias refers to systematic errors in AI systems that result in unfair outcomes for certain groups of people. In healthcare, this can lead to significant disparities in treatment and diagnosis based on factors such as race, gender, or socioeconomic status¹³. For example, if an AI algorithm is trained predominantly on data from one demographic group, it may not perform well for individuals outside that group. This can exacerbate existing inequalities in healthcare, where marginalized communities may receive less accurate diagnoses or inadequate treatment options¹³.

Several notable cases illustrate the implications of algorithm bias in healthcare:

Example 1: Radiomics algorithms used for reading chest X-rays were shown to be less effective when applied to female patients due to their training on predominantly male data.

Example 2: Algorithms designed for detecting skin cancer often performed poorly for patients with darker skin tones because they were primarily trained on images of light-skinned individuals, leading to higher rates of undiagnosed skin cancer in these populations.

3. Patient Data Security

As AI applications increasingly rely on vast amounts of patient data, concerns about data privacy and security have become paramount^{14,15,16}. Sensitive health information can be vulnerable to breaches, unauthorized access, or misuse. The integration of AI into healthcare systems raises questions about how patient data is collected, stored, and utilized. Ensuring robust security measures is essential to maintain patient trust and comply with legal requirements. India's Personal Data Protection Bill (PDPB) proposes a wide-ranging framework to regulate and protect personal data, promoting data privacy and security. According to this, Healthcare organizations must obtain explicit consent from patients before collecting and processing their personal data. This bill also states that providers are encouraged to collect only the data necessary for specific purposes, reducing the risk of exposure. It also necessitates organizations to implement security measures that are accountable for any breaches or misuse of data. Compliance with the PDPB will be crucial for healthcare providers utilizing AI technologies, and failure to adhere could result in legal repercussions.

4. Digital Inequality

Digital inequality refers to the uneven distribution of technology access across different regions and



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demographics within India^{13,14}. While urban areas may have better access to advanced healthcare technologies, rural regions often face significant barriers. Many rural areas lack reliable internet connectivity and technological infrastructure necessary for implementing AI solutions¹³. High costs associated with advanced medical technologies can make them inaccessible to lower-income populations¹³. The disparities in access to technology have profound implications for rural healthcare delivery. Patients in rural areas may miss out on the benefits of AI-enabled diagnostics and treatment options available in urban centers. This can lead to delays in diagnosis and treatment, worsening health outcomes. Healthcare providers in rural regions may not have access to the same level of training or resources as their urban counterparts, limiting their ability to utilize AI tools effectively¹³. Addressing digital inequality is essential for ensuring that all populations can benefit from advancements in AI technology. Initiatives aimed at improving infrastructure and providing training can help bridge this gap and promote equitable access to quality healthcare services across India.

Opportunities for Growth

There are significant opportunities for growth in India's healthcare sector through public-private partnerships, a thriving start-up ecosystem, and local innovations. By harnessing these opportunities effectively, India can transform its healthcare landscape, making quality care accessible and affordable for all citizens.

"Public-private partnerships (PPPs)" have emerged as a powerful mechanism to enhance healthcare delivery in India. These collaborations leverage the strengths of both sectors to improve access, affordability, and efficiency in healthcare services. A notable example of a successful PPP is the CoWin portal, which was developed during the COVID-19 pandemic to facilitate the world's largest vaccination drive. This technology-backed initiative demonstrated how public and private sectors could work together effectively to manage health crises. The pandemic catalysed unprecedented collaborations, showcasing the potential of PPPs to address various healthcare challenges. The model has been further supported by government initiatives that streamline project approvals and promote transparency in bidding processes.

In 2021 alone, India saw a significant increase in private investment commitments across various healthcare projects, indicating strong interest in collaborative efforts.

The Indian government has launched several initiatives to through encourage innovation PPPs, such as the Atmanirbhar Bharat scheme, which aims to boost selfreliance in various sectors, including healthcare¹³. This initiative encourages private sector participation in developing medical technologies and infrastructure, thereby fostering an environment conducive to innovation. By combining public resources with private expertise, these initiatives aim to enhance service delivery and improve health outcomes across the country.

India's start-up ecosystem is thriving, particularly in the health tech sector, where numerous companies are developing AI-driven solutions to improve healthcare delivery. Promising start-ups Niramai, SigTuple, Qure.ai etc. are leveraging advanced technologies to create innovative solutions that address specific healthcare needs, making quality care more accessible. Investment in the Indian health tech sector has seen a significant uptick, with venture capital firms increasingly interested in funding health start-ups. In recent years, the sector has attracted billions of dollars in investments as investors recognize the potential for growth and innovation. The COVID-19 pandemic further accelerated this trend, highlighting the importance of digital health solutions and telemedicine¹³. This influx of capital is enabling start-ups to scale their operations and expand their reach, ultimately contributing to improved healthcare access and outcomes.

Reverse Engineering and Local Innovation

Indian companies have a unique opportunity to reverseengineer existing medical technologies to create affordable alternatives tailored to local needs. By adapting proven solutions from developed markets, these companies can design products that are not only cost-effective but also suitable for the Indian healthcare landscape. This approach can significantly reduce costs while ensuring that essential medical devices are accessible to underserved populations. Several successful local innovations illustrate the impact of reverse engineering on healthcare access.

Companies like "Dialvsis at Home" have developed portable dialysis machines that can be used at home, making treatment more accessible for patients who would otherwise need to travel long distances for care. Start-ups such as "Practo" have created platforms that connect patients with doctors remotely, allowing individuals in rural areas to access quality healthcare without needing to travel. Hence local innovation can bridge gaps in healthcare delivery and improve access for populations that traditionally face barriers to care.

Future Directions

India has a unique opportunity to shape the future of AI in healthcare through thoughtful regulation, stakeholder engagement, education, and public awareness initiatives. By addressing these areas proactively, India can harness the full potential of AI technologies to improve healthcare access, guality, and outcomes for all its citizens. To foster innovation while ensuring safety and efficacy in AI-enabled medical devices, India needs a regulatory framework that strikes a balance between these two priorities.

Similar to the Reserve Bank of India's fintech sandbox, establishing a "Regulatory Sandbox" would allow healthcare AI solutions to be tested in controlled environments before wider deployment¹⁷. This approach can help identify potential risks while encouraging innovation.



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Creating Tiered Regulations can be another promising strategy. Different levels of regulation based on the risk associated with specific AI applications can streamline the approval process. For instance, lower-risk applications could undergo expedited reviews, while higher-risk technologies would require more rigorous scrutiny.

Policymakers should create comprehensive guidelines that address issues unique to AI, such as algorithm transparency, data privacy, and accountability^{13,18}. This will help build trust among healthcare providers and patients. Engaging various stakeholders—healthcare providers, technology companies, patients, and regulatory bodies-in policy discussions is crucial for creating effective regulations. Establishing forums where stakeholders can share insights and concerns about AI in healthcare will ensure that regulations are informed by real-world experiences^{17,19}. Encouraging partnerships between academic institutions and industry players can facilitate the development of evidence-based policies that reflect the needs of all parties involved. Involving patient representatives in discussions can also provide valuable perspectives on how AI technologies impact care delivery and patient outcomes.

Workforce Development

As AI technologies become more integrated into healthcare, there is a pressing need for training programs that equip healthcare professionals with the necessary skills to work alongside these technologies²⁵. Medical and nursing schools should incorporate courses on AI applications in healthcare, emphasizing both theoretical knowledge and practical skills^{20,21}. Offering workshops and certification courses for practicing healthcare professionals can help them stay updated on the latest AI developments and their applications in clinical settings^{21,25}. Collaborating with technology firms to provide hands-on training with AI tools can enhance learning experiences for healthcare workers.

Public Awareness

To build trust in Al-enabled devices among patients and the general public, comprehensive awareness campaigns are essential. Launching campaigns that explain the benefits and limitations of Al technologies in simple terms will be beneficial. Utilizing various media channels—such as social media, television, and community events—can help reach diverse audiences. Highlighting successful case studies where Al has improved patient outcomes can demonstrate its value to both patients and healthcare providers⁸. Organizing workshops or seminars in local communities can provide opportunities for direct interaction between patients, healthcare professionals, and technology experts.

CONCLUSION

The article concludes by emphasizing the critical need for a collaborative approach among all stakeholders involved in the integration of artificial intelligence (AI) into medical devices²². As the healthcare landscape evolves, it is essential that policymakers, technology companies,

healthcare providers, and patients work together to navigate the complexities of this integration effectively²². While AI holds immense promise for enhancing healthcare outcomes—such as improving diagnostic accuracy, increasing operational efficiency, and expanding access to care^{13,22}—this potential must be pursued with a strong commitment to ethical standards, regulatory compliance, and equitable access for all segments of society¹³. The accelerated development of AI technologies yields both exciting opportunities and complex issues^{22,23}. Stakeholders must address issues such as algorithm bias, data privacy concerns²³, and digital inequality¹³ to ensure that the benefits of AI are distributed fairly. By fostering an environment where innovation can thrive alongside rigorous safety standards²³, India can position itself as a leader in the global healthcare technology arena^{10,24}. This article encourages readers—including policymakers, industry leaders, healthcare professionals, and researchers—to actively engage in shaping a future where medical devices can truly Al-enhanced benefit everyone^{13,22}. Collaboration is key; by sharing insights and expertise, stakeholders can develop effective policies that promote innovation while safeguarding public health²². In summary, this comprehensive exploration of the current landscape and future potential of AI-enabled medical devices in India highlights the importance of addressing key challenges while seizing opportunities for growth^{10,24}. By working together, stakeholders can ensure that AI technologies not only advance healthcare delivery but also contribute to a more equitable and efficient healthcare system for all citizens13,22.

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