Volume 2 Issue 2
www.westlandpublishers.com

ISSN: 3066-3822

WestLand Publishers

Digital Journal of Science (DJS)

Opinion

Artificial Intelligence (AI) in Healthcare: How to Regulate this Brave New World?

Jawahar (Jay) Kalra[1*], Bryan Johnston[2]

[1]Jawahar (Jay) Kalra, Department of Pathology and Laboratory Medicine, College of Medicine, University of Saskatchewan, Saskatoon, Canada

[2]Bryan Johnston, Department of Pathology and Laboratory Medicine, College of Medicine, University of Saskatchewan, Saskatoon, Canada

***Corresponding Author:**

Jawahar (Jay) Kalra, Royal University Hospital, Saskatchewan Health Authority, 103 Hospital Drive, Saskatoon, Saskatchewan, S7N 0W8, Canada, Tel: (306) 655-2152; Fax: (306) 655-2223.

Received Date: **12 February, 2024** ; **Published Date:** **03 March, 2025**

Keywords:

Artificial Intelligence; Patient-Centered Care; Medico-Legal Risk; Regulation; Quality Care

Citation:

Kalra J, Johnston B (2024) Artificial Intelligence (AI) in Healthcare: How to Regulate this Brave New World?. Digital J Sci 2(2): 117.

Abstract

Healthcare is a human endeavour aided by a sophisticated set of diagnostic tools. Healthcare systems are challenged with incorporating new and unfamiliar technology into existing systems of practice. The capabilities of Artificial Intelligence (AI) in healthcare are expanding at an unprecedented pace. Artificial Intelligence has the potential to serve as an invaluable asset in harnessing large amounts of data to generate new diagnostic models, inform clinical decision-making, and expand the capabilities of modern medicine. As diagnostic tools such as AI have entered the realm of clinical practice, new opportunities have arisen to optimize healthcare delivery. The implementation of AI warrants careful deliberation to ensure that implications are considered and consequences are mitigated. Effective regulation of AI in clinical practice is essential for managing medico-legal risks and ensuring patient safety. Artificial Intelligence systems incorporate and often amplify existing patterns of practice, including societal biases and inequitable healthcare practices. The momentum created by such innovations can lead to implausible optimism and unintentional consequences. Navigating the transition to an Artificial Intelligence-assisted era of healthcare delivery will require an appreciation of the opportunities and limits of each technology. We suggest that professional regulatory bodies should establish standards for AI use in healthcare. This would promote safe adoption, build public trust, and encourage innovation.

Introduction

Artificial Intelligence (AI) is revolutionizing healthcare delivery around the globe. As AI-driven solutions become a part of mainstream practice, the global focus has shifted from one of predominantly innovation to one of regulation. Patient care is becoming increasingly complex, and improvements in efficiency are urgently needed, prompting the widespread adoption of AI into healthcare [1]. However, regulatory gaps remain a prevalent issue and effective regulation of AI in clinical practice is essential for managing medico-legal risks and ensuring patient safety [2]. Numerous studies have emphasized the need for clear regulations concerning the ethical and safe use of AI in healthcare, and we now find ourselves at a critical juncture in the history of AI and patient care.

Patient-Centered Regulation of AI in Healthcare

In the absence of policies directing appropriate AI oversight and accountability, there is a significant risk to patient safety if AI-related errors are not monitored and addressed. The "black box" nature of AI, where decision-making processes remain opaque, raises significant legal concerns related to liability in case of errors [3]. Current legal frameworks struggle to effectively address the unique challenges posed by AI, particularly in terms of negligence and accountability [4]. Failure to regulate AI effectively compromises ethical medical practice and patient autonomy, as patients and clinicians are unable to properly consider and consent to treatment decisions impacted by AI. Ethical AI governance is critical in managing the consequences of AI-related biases and ensuring social accountability. Advances in increasingly powerful AI models have sparked international concern, disrupting global markets and calling into question the validity of existing regulations. International summits are being organized to provide a forum for a convergence of international perspectives on the regulation of AI in all aspects of daily life, including the provision of healthcare and medicine. Given that existing attempts at regulation have struggled to keep pace with innovation, an outcomes-based approach is now being tabled to focus on the specific applications of AI, stratified by their inherent risk [5].

Regulatory Frameworks for AI: A Global View

In response to global concerns, the World Health Organization (WHO) has published a set of regulatory considerations emphasizing the importance of trust, safety, rigorous evaluation, and stakeholder engagement in the development and implementation of AI technologies [6]. However, without mandatory reporting mechanisms, the opportunity to enhance AI safety and quality assurance is jeopardized. Effective communication between AI developers, healthcare providers, and regulators throughout the regulatory process is integral in sustaining and developing trust in AI-assisted patient care. We have examined and evaluated various AI regulatory frameworks that are in practice in the European Union (EU), United States, United Kingdom (UK), Australia, and Canada to analyze the progress made in this area.

In 2024, the European Union (EU) mandated the EU AI Act regarding risk-based classification of AI applications in healthcare and other critical sectors. It categorizes AI into four risk levels: prohibited, high-risk, general-purpose AI and foundation models, and low-risk. The Act imposes strict requirements on high-risk AI systems, ensuring transparency and independent assessment. This builds on the success of the existing General Data Protection Regulation (GDPR) which has significantly shaped legislation worldwide [7]. In the United States, the Food and Drug Administration (FDA) AI/Machine Learning-Based Software as a Medical Device (SaMD) Action Plan offers a flexible approach that addresses the unique interests of patients, clinicians, and regulatory authorities [8]. This effort blends well with existing foundational regulations such as the Health Insurance Portability and Accountability Act (HIPAA), which mandates that organizations implement robust cybersecurity programs to protect personal information, including electronically stored protected health information [9].

Collaborative Approach toward Unified Standards

Global efforts also include novel approaches like the UK's Medicines and Healthcare Products Regulatory Agency (MHRA), which has implemented an "AI Airlock" pilot scheme to test and improve regulatory frameworks, streamling their route to market while ensuring safety and efficacy [10]. In Australia, there is no dedicated AI legislation, instead voluntary AI Ethics Principles guide AI development while policymakers consider regulatory reforms [11]. Similarly, in Canada, a Voluntary Code of Conduct on the Responsible Development and Management of Advanced Generative AI Systems acts as a precursor to formal legislation, while the Artificial Intelligence and Data Act (AIDA) is under consideration [12]. Canada is making remarkable progress in responsible AI development, as shown by the majority of its provinces and territories embracing voluntary AI compliance guidelines established by their professional regulatory bodies. These regional initiatives not only demonstrate a commitment to best practices but also foster consistency in the AI landscape, paving the way for future unified national legislation [13, 14].

Conclusion

There has been a global shift towards risk-based AI governance, prioritizing transparency, safety, and ethical considerations in healthcare [15]. We suggest the implementation of a unified AI regulatory policy centred on transparency, accountability, and fairness in a non-punitive yet enforceable manner that prioritizes patient rights and respects clinical judgment as the standard of practice. A prime role exists for regulatory agencies, industry leaders, and policymakers to initiate regulatory reforms and promote international alignment in this area. AI transparency, bias mitigation, and patient-centered clinical decision-making should be the standard of care in the deployment of AI in healthcare to enhance patient

safety, ensure responsible use of AI, and uphold ethical standards in digital health innovations.

Conflict of Interest

The authors declare no conflicts of interest.

Financial Support and Sponsorship

No financial support or sponsorship was received.

References

1. Kalra J, Seitzinger P (2023) Expanding Our Grasp: Artificial Intelligence as the Next Leap Forward in Healthcare Quality. Healthcare and Medical Devices. AHFE International Conference, AHFE Open Access, AHFE International, USA vol 79: 7-11.

2. Chustecki, M (2024) Benefits and Risks of AI in Health Care: Narrative Review. Interact J Med Res 13: e53616.

3. Henderson B, Flood CM, and Scassa T (2022) Artificial Intelligence in Canadian Healthcare: Will the Law Protect Us from Algorithmic Bias Resulting in Discrimination? Canadian Journal of Law and Technology 12(2): 1-30.

4. Jassar S, Adams SJ, Zarzeczny A, Burbridge BE (2022) The future of artificial intelligence in medicine: Medical-legal considerations for health leaders. Healthc Manage Forum 35 (3): 185–189.

5. (2025) World Economic Forum & Boston Consulting Group. The Future of AI-Enabled Health: Leading the Way.

6. Bouderhem, R (2024) Shaping the future of AI in healthcare through ethics and governance. Humanit Soc Sci Commun 11 (1): 416.

7. Aboy M, Minssen T, Vayena E (2024) Navigating the EU AI Act: implications for regulated digital medical products. Npj Digit Med 7 (1): 237.

8. Harvey HB, Gowda V (2020) How the FDA Regulates AI. Acad Radiol 27 (1): 58–61.

9. Kelly BS, Quinn C, Belton N, Lawlor A, Killeen RP, et al. (2023) Cybersecurity considerations for radiology departments involved with artificial intelligence. Eur Radiol 33(12): 8833-8841.

10. Medicines and Healthcare products Regulatory Agency (2024) AI Airlock: the regulatory sandbox for AIaMD.

11. Chau M (2024) Ethical, legal, and regulatory landscape of artificial intelligence in Australian healthcare and ethical integration in radiography: A narrative review. J Med Imaging Radiat Sci 55(4): 101733.

12. (2025) The medico-legal lens on AI use by Canadian physicians. Canadian Medical Protective Association (CMPA).

13. (2024) The College of Physicians and Surgeons of Manitoba, Advice to the Profession: Responsible use of Artificial Intelligence in the Practice of Medicine.

14. Anawati A, Fleming H, Mertz M, Bertrand J, Dumond J, et al. (2024) Artificial intelligence and social accountability in the Canadian health care landscape: A rapid literature review. PLOS Digit Health 3(9): e0000597.

15. Palaniappan K, Lin EYT, Vogel S, Lim JCW (2024) Gaps in the Global Regulatory Frameworks for the Use of Artificial Intelligence (AI) in the Healthcare Services Sector and Key Recommendations. Healthcare 12 (17): 1730-1743.