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Regulation of Artificial Intelligence in Healthcare – A Global View

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ABSTRACT

As artificial intelligence (AI) becomes a cornerstone of healthcare and medicine, the global focus has shifted from innovation to regulation. Across the world, efforts to regulate AI are rapidly evolving as governments and legal systems struggle to keep pace with the advances and novel applications of AI in healthcare. To support regulators and stakeholders in this task, we have examined and evaluated global AI regulatory frameworks focusing on the efforts of international organizations (WHO, EU) and individual nations (USA, UK, Australia, and Canada) to analyze the progress made in this area. While stakeholders are advancing legislation to guide AI development and deployment, gaps persist in implementation, oversight, and long-term monitoring, especially within the healthcare sector. Despite competing economic and political realities, the dilemma between centralized and decentralized policies continues to define international efforts. However, ethical standards must guide regulation, ensuring flexible yet principled frameworks that strike a balance between autonomy and human oversight. As patient data increasingly fuels AI systems, ensuring data security and patient privacy is paramount. Regulatory fragmentation, medico-legal uncertainty, and a lack of uniform best practices challenge the safe and equitable use of AI technologies. Key concerns include preserving patient autonomy, ensuring transparency, managing bias, securing data, and maintaining human oversight in medical decision-making. We suggest that future regulatory efforts be built on collaboration between stakeholders around the globe and concentrate on providing good governance, enhancing patient safety and ensuring the responsible use of AI in healthcare and medicine.

Keywords: Artificial intelligence, Regulation, Patient safety, Patient-centered care, Medico-legal risk

INTRODUCTION

Artificial Intelligence (AI) is revolutionizing the delivery of healthcare and the practice of medicine worldwide. The advent of generative AI has unlocked unforeseen potential to address long-standing patient and provider concerns through advances such as early disease detection, patient safety initiatives, and system-wide monitoring (Chustecki, 2024; Kalra and Seitzinger, 2023). The integration of AI into mainstream clinical care is advancing at a rapid pace, however, concerted efforts at both international and national levels of

government continue to struggle with providing appropriate governance and oversight without stifling innovation (Aboy et al., 2024; World Economic Forum & Boston Consulting Group, 2025; World Health Organization, 2023).

At the leading edge of these advancements, there is a critical need to balance human factors, such as clinical expertise, shared decision-making, and usability, with the integration of AI into healthcare (American Medical Association, 2024; World Health Organization, 2021). Human-factors challenges are equally pivotal, such as talent shortages, limited training, and clinician reluctance to rely on AI recommendations (World Economic Forum, 2025). Contemporary oversight increasingly requires post-market performance monitoring, transparency, and bias mitigation to address these gaps (International Medical Device Regulators Forum, 2023; Medicines and Healthcare products Regulatory Agency, 2024; U.S. Food and Drug Administration, 2025a). Across jurisdictions, global strategies for governing AI in medicine emphasize the importance of preserving patient autonomy, ensuring transparency, mitigating bias, securing data, and maintaining human oversight in medical decision-making (Health Canada, 2025a; World Health Organization, 2023). These principles are central to building trust among clinicians, patients, and regulators.

Despite these efforts, global regulation of AI remains fragmented. While individual countries and regions are advancing frameworks, there are no harmonized international standards to bridge existing gaps (Aboy et al., 2024; Palaniappan et al., 2024). This paper examines and evaluates AI regulatory frameworks currently in place across leading jurisdictions including the World Health Organization (WHO), European Union (EU), United States (US), United Kingdom (UK), Australia, and Canada and highlights progress, ongoing challenges, and future directions. Our focus is on how regulation can serve not only as a safeguard against risk but also as an enabler of responsible adoption, patient safety, and global collaboration.

METHODOLOGY

This study synthesizes regulatory frameworks, policy papers, and legislation published between 2020 and 2025 by major international and national bodies, including the WHO, the Organization for Economic Co-operation and Development (OECD), European Union, United States, United Kingdom, Australia, and Canada. Primary sources comprise statutes, agency guidance, and multilateral documents. Secondary sources include peer-reviewed literature, white papers, and policy analyses that address the ethical, legal, and technical dimensions of AI governance.

INTERNATIONAL SCENE

The World Health Organization has assumed a central leadership role in shaping the global governance of artificial intelligence in health and medicine (World Health Organization, 2025, 2023). Through its Global Initiative on Artificial Intelligence for Health, the WHO provides a collaborative

platform aimed at harmonizing international standards for the safe, ethical, and equitable use of AI in healthcare. The initiative seeks to ensure that AI strengthens rather than disrupts health systems, particularly in low and middle-income countries where regulatory infrastructures and technical capacity remain underdeveloped (World Health Organization, 2025).

Building on its Global Strategy on Digital Health, the WHO articulates a vision for integrating digital health technologies across all 193 member states in alignment with the United Nations Sustainable Development Goals (SDGs). The Global Initiative on AI for Health (GI-AI4H) has three primary objectives: (1) to develop technical standards and policy guidance for the design, validation, and deployment of AI in health; (2) to facilitate knowledge and data sharing across member states; and (3) to support evidence-based decision-making in the adoption and oversight of AI solutions.

Complementing WHO efforts, the World Economic Forum (WEF) released Earning Trust for AI in Health: A Collaborative Path Forward (World Economic Forum, 2025), which introduces dynamic governance tools—such as regulatory sandboxes, life-cycle evaluation, and post-market monitoring—to encourage adaptive regulation and public–private collaboration. Similarly, the FUTURE-AI International Consensus Guideline (Bouderhem, 2024) has provided a benchmark framework for trustworthy AI in healthcare, addressing technical, clinical, socio-ethical, and legal dimensions. Additional contributions from the United Nations Educational, Scientific, and Cultural Organization (UNESCO) and the European Commission highlight inclusivity, data quality, transparency, privacy, and security as cornerstones of equitable AI deployment in medicine (UNESCO, 2024).

EUROPEAN UNION

The European Union has taken a pioneering step in regulating artificial intelligence with the passage of the Artificial Intelligence Act (EU AI Act) in 2024, the first comprehensive, legally binding framework for AI in the world (Aboy et al., 2024; European Union, 2024). The Act introduces a risk-based classification system that categorizes AI systems into four tiers: prohibited, high-risk, limited-risk, and minimal-risk, according to their potential impact on human health, safety, and fundamental rights.

Healthcare applications, including diagnostic tools, decision-support systems, and predictive analytics models, are typically classified as high-risk under this framework; however, final categorization depends on the specific use case and the degree of clinical influence. High-risk systems are subject to rigorous conformity assessments, documentation requirements, post-market monitoring, and lifecycle compliance obligations, ensuring continuous safety and ethical integrity throughout deployment. This includes maintaining risk management systems, continuous logging, bias mitigation measures, and periodic reassessment of model performance; a lifecycle approach that reflects the EU's shift toward proactive rather than reactive governance.

The Act also establishes specific obligations for General Purpose AI (GPAI) systems, such as large language models and multi-modal foundation models, recognizing their broad societal impact and potential downstream

use in health and other high-risk sectors (European Commission, 2024). These systems must meet enhanced transparency, testing, and documentation standards and disclose essential information about data provenance, training methods, and limitations to both regulators and end-users.

Building on the success of the General Data Protection Regulation (GDPR), the EU AI Act reinforces data protection, algorithmic transparency, and human oversight as central pillars of trustworthy AI (European Union, 2016). The Act's risk-based framework, combined with its explicit focus on GPAI oversight, human-centric design, and transparency, has made it a global reference model. It has influenced legislation and policy initiatives in other jurisdictions, including Canada's Artificial Intelligence and Data Act, the UK's pro-innovation AI governance roadmap, and ongoing WHO and UNESCO ethical AI guidelines (Aboy et al., 2024; UNESCO, 2024; World Health Organization, 2023).

UNITED STATES

The United States continues to lead in developing a flexible, adaptive regulatory model for artificial intelligence in healthcare, emphasizing innovation while maintaining patient safety and accountability. The U.S. Food and Drug Administration (FDA) plays a central role through its Artificial Intelligence and Machine Learning–Based Software as a Medical Device (AI/ML SaMD) Action Plan, first introduced in 2021 and subsequently expanded through new guidance documents, including the 2025 Draft Guidance on AI Lifecycle Management and Transparency (Harvey and Gowda, 2020; U.S. Food and Drug Administration, 2025b, 2021).

Recognizing that AI systems differ from traditional medical devices due to their capacity for continuous learning, the FDA introduced the Predetermined Change Control Plan (PCCP) framework, allowing iterative improvements to approved AI algorithms within predefined safety, transparency, and traceability parameters (U.S. Food and Drug Administration, 2025a). The FDA also collaborates with international partners through the publication of Good Machine Learning Practice (GMLP) principles, jointly developed with the UK Medicines and Healthcare Products Regulatory Agency (MHRA) and Health Canada. The FDA's collaborative, risk-based, and lifecycle-oriented approach continues to serve as an influential model in global AI governance (International Medical Device Regulators Forum, 2023).

UNITED KINGDOM

The United Kingdom has positioned itself as a leader in regulatory experimentation through its Medicines and Healthcare Products Regulatory Agency and the AI Airlock pilot program, launched in 2024 (Medicines and Healthcare products Regulatory Agency, 2024). The Airlock acts as a regulatory sandbox, offering a controlled environment in which AI developers can test healthcare AI systems in partnership with regulators, clinicians, and patient representatives prior to market authorization.

This initiative promotes collaboration, transparency, and evidence-based oversight, enabling regulators to refine evaluation criteria while allowing developers to address safety and performance issues early in the innovation process. The Airlock complements the UK's AI Regulation White Paper (2023), which sets out five cross-sector guiding principles for responsible AI: safety, transparency, fairness, accountability, and contestability (U.K. Government, 2023). The UK model prioritizes human-centric oversight, ensuring that AI augments, rather than replaces, clinical judgment.

AUSTRALIA

Australia presents a distinct regulatory model, emphasizing ethical alignment over statutory control. The Australian Government's AI Ethics Principles, first issued in 2019 and reaffirmed in 2023, form the ethical foundation for AI governance nationwide. These eight principles, human, social, and environmental wellbeing; human-centered values; fairness; privacy protection; reliability and safety; transparency; contestability; and accountability, continue to shape policymaking and guide the responsible use of AI across sectors, including healthcare (Australian Government, n.d.). In 2024, Australia adopted the (International Organization for Standardization/International Electrotechnical Commission) ISO/IEC 23894:2023 international standard for AI risk management, marking a significant step toward harmonization with global best practices (ISO Standards Australia, 2023). Australia's approach demonstrates how ethical frameworks can serve as an interim regulatory bridge, fostering responsible innovation while policymakers deliberate on formal legislative reform (Australian Digital Health Agency, 2024; Chau, 2024).

CANADIAN FEDERAL LEGISLATIVE INITIATIVES

At the federal level, Canada has made incremental but meaningful progress toward establishing a national framework for AI in healthcare. The proposed Artificial Intelligence and Data Act (AIDA), introduced in 2022 as part of Bill C-27, aims to regulate "high-impact" AI systems—those influencing health, safety, and fundamental rights—through mandatory standards for risk management, transparency, and accountability (Government of Canada, 2022). AIDA would require developers of such systems to implement governance mechanisms ensuring that AI outputs are safe, explainable, and non-discriminatory.

However, as of late 2025, AIDA remains unenacted, following Parliament's prorogation, and thus serves as draft legislation rather than law. In the absence of federal statute, the Voluntary Code of Conduct on the Responsible Development and Management of Advanced Generative AI Systems, introduced in 2023, continues to guide ethical AI use (International Medical Device Regulators Forum, 2023). Complementing these initiatives, Health Canada has strengthened oversight through its Guidance on Machine Learning–Enabled Medical Devices (MLMDs), which outlines regulatory expectations for clinical validation, bias mitigation, performance monitoring,

and post-market surveillance (Health Canada, 2025b). This guidance bridges a key policy gap by defining the operational parameters for AI-driven medical devices under existing federal legislation.

In 2025, Health Canada and all provincial and territorial governments jointly endorsed the Pan-Canadian Guiding Principles on Artificial Intelligence for Health, establishing a unified reference point for AI governance (Health Canada, 2025b). These principles emphasize safety, transparency, Indigenous data sovereignty, inclusivity, and sustainability, providing a shared ethical framework to guide both public institutions and private innovators. They mark a critical step toward bridging jurisdictional divides and reflect a growing consensus that national coherence can be achieved through cooperative governance rather than centralized control.

CANADIAN PROVINCIAL LEGISLATIVE INITIATIVES

Each province and territory maintains its own legislation governing personal health information, as shown in Table 1, including Ontario's Personal Health Information Protection Act (PHIPA), Alberta's Health Information Act (HIA), and British Columbia's E-Health Act. However, recent developments indicate a growing recognition of AI's regulatory implications. In Quebec, Law 25 introduced landmark reforms, explicitly addressing automated decision-making and AI accountability across public and private sectors, requiring organizations to disclose when personal data are used for algorithmic decisions and to ensure human oversight (Government of Ontario, 2024; Government of Quebec, 2023). Similarly, Ontario's Bill 194 amended PHIPA and related statutes to establish algorithmic transparency obligations and safeguards for AI-assisted clinical decision-making, making Ontario one of the first provinces to legislate AI-specific protections within its healthcare privacy framework.

Across Canada, provincial variability remains a concern. For instance, while Ontario and Quebec have introduced AI-specific provisions, other provinces continue to rely on general privacy acts, such as Saskatchewan's Health Information Protection Act (HIPA) or Newfoundland and Labrador's Personal Health Information Act (PHIA), which lack direct references to AI governance (Government of Saskatchewan, 2020).

Table 1: Canadian provincial and territorial regulation.

Geographic Area	Regulation
Eastern Provinces	
Ontario	PHIPA, AI Scribe Program, Bill 194
Quebec	Law 25, Act Respecting the Protection of Personal Information in the Private Sector
Newfoundland and Labrador	PHIA, Pharmacy Network Regulations
Nova Scotia	PHIA
New Brunswick	PHIPAA
Prince Edward Island	PHIA

Continued

Table 1: Continued

Geographic Area	Regulation
Western Provinces	
Manitoba	PHIA
Saskatchewan	HIPA
Alberta	HIA, PIPA
British Columbia	E-Health Act, PIPA
Territories	
Northwest Territories	HIA
Nunavut	Access to Information and Protection of Privacy Act
Yukon	HIPMA

Personal Health Information Protection Act (PHIPA), Personal Health Information Act (PHIA), Health Information Protection Act (HIPA), Personal Information Protection Act (PIPA), Health Information Privacy and Management Act (HIPMA)

The resulting regulatory heterogeneity poses significant challenges for AI developers and healthcare providers, who must navigate multiple compliance regimes and privacy standards across jurisdictions (Henderson et al., 2022; Jassar et al., 2022). This complexity impedes cross-provincial data sharing, complicates AI model validation and clinical deployment, and risks eroding patient trust in AI-driven healthcare. In recognition of these gaps, several provinces, including Ontario, Quebec, and British Columbia, have initiated AI sandbox programs to test governance models in controlled environments, signalling an emerging shift toward harmonized oversight (The College of Physicians and Surgeons of Manitoba, 2024).

PATIENT-CENTERED PRINCIPLES AND HUMAN OVERSIGHT

At the core of healthcare regulation lies a simple but essential truth that all innovation must ultimately serve the patient. The integration of artificial intelligence into clinical care must therefore prioritize patient-centered values, autonomy, trust, transparency, and human oversight. These values are reflected across leading frameworks, including the World Health Organization's six guiding principles for AI in health, the Pan-Canadian AI for Health (AI4H) Guiding Principles, and the American Medical Association's (AMA) Principles for Augmented Intelligence (American Medical Association, 2024; World Health Organization, 2023). Together, they affirm that AI should enhance care rather than automate clinical judgment.

While AI can improve diagnostic accuracy, accelerate workflows, and reduce errors, it also introduces new vulnerabilities. The "black box" phenomenon, where decision logic is not transparent, undermines trust and complicates informed consent. Patients may be unaware that AI contributed to their diagnosis or treatment, limiting their ability to make informed decisions. To preserve clinical integrity, human-in-the-loop oversight must remain a regulatory requirement. The AMA and WHO explicitly state that physicians bear ultimate responsibility for patient outcomes and must be empowered to interpret, override, or contextualize AI recommendations.

AI must therefore act as an assistive instrument, supporting, not substituting, human expertise.

OVERSIGHT CENTRALIZED VERSUS DECENTRALIZED MODELS OF REGULATION

The debate between centralized and decentralized regulatory systems defines much of the global conversation on AI oversight. Centralized models, such as the EU AI Act, provide consistency, reduce redundancy, and facilitate enforcement, but they risk inflexibility in fast-moving technological environments (European Union, 2024). In contrast, decentralized systems, as seen in Canada and the United States, enable regional autonomy and innovation but can result in fragmented oversight and inconsistent ethical standards (Health Canada, 2025a; U.S. Food and Drug Administration, 2025b).

Emerging analyses advocate for hybrid or federated models, which combine centralized coordination with regional implementation. This approach allows standards to remain adaptable to local clinical realities while upholding national or international benchmarks for safety, transparency, and equity (Health Canada, 2025a; Henderson et al., 2022). Canada's dual federal-provincial framework exemplifies this balance, blending national leadership with provincial flexibility through cooperative mechanisms, such as the Pan-Canadian AI for Health Guiding Principles. A national AI oversight agency could serve as a coordinating hub within such a federated structure, establishing uniform evaluation criteria for risk classification, clinical validation, and bias mitigation. By centralizing guidance yet permitting regional customization, these models promote efficient, scalable, and ethically consistent AI governance suited to complex healthcare systems (Palaniappan et al., 2024).

FUTURE DIRECTIONS AND CONCLUSION

The future of AI regulation in healthcare must embrace collaborative governance, ethical responsibility, and patient-centered innovation. The ultimate goal is not merely to control technology but to ensure that it evolves in the service of humanity. This requires a dynamic, adaptive framework capable of evolving alongside AI (International Medical Device Regulators Forum, 2023; Organisation for Economic Cooperation and Development, 2025; World Economic Forum, 2025; World Health Organization, 2025, 2021).

Future global efforts should focus on: 1) developing harmonized international standards for AI validation and safety certification. 2) establishing ethical AI registries and real-time monitoring mechanisms for adverse outcomes. 3) investing in capacity building across developing nations to ensure equitable access to AI technologies. 4) fostering interdisciplinary education for clinicians, policymakers, and AI developers. 5) embedding ethics-by-design principles into every stage of AI development and deployment.

The intersection of AI, medicine, and ethics represents one of the most transformative frontiers in modern healthcare. As we move forward, trust, transparency, and collaboration must guide every aspect of regulation. Aligning global standards with local realities will not only enhance patient safety and quality of care but also strengthen the shared moral foundation upon which healthcare is built. In this sense, regulating AI in healthcare is not only a technical or legal task; it is a moral and societal imperative that is necessary to establish a strong foundation based on trust and patient-centered care.

REFERENCES

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

American Medical Association, 2024. AMA Principles for Augmented Intelligence in Medicine.

Australian Digital Health Agency, 2024. AI in Digital Health Strategy: Implementation Framework.

Australian Government. AI in government policy. URL https://www.digital.gov.au/policy/ai/policy (accessed 1.19.25).

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

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, 101733.

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

European Commission, 2024. AI in Healthcare: AI Office Publications 2024.

European Union, 2016. General Data Protection Regulation (Regulation (EU) 2016/679).

European Union, 2024. Artificial Intelligence Act (Regulation (EU) 2024/1685).

Government of Canada, 2022. Artificial Intelligence and Data Act (AIDA), Bill C-27.

Government of Ontario, 2024. Strengthening Privacy Protections Act (Bill 194).

Government of Quebec, 2023. Act to Modernize Legislative Provisions as Regards the Protection of Personal Information.

Government of Saskatchewan, 2020. Health Information Protection Act (HIPA).

Harvey, H. B., Gowda, V., 2020. How the FDA Regulates AI. Acad. Radiol. 27, 58–61.

Health Canada, 2025a. Pan-Canadian Guiding Principles on AI for Health.

Health Canada, 2025b. Guidance on Machine Learning–Enabled Medical Devices.

Henderson, B., Flood, C. M., Scassa, T., 2022. Artificial Intelligence in Canadian Healthcare: Will the Law Protect Us from Algorithmic Bias Resulting in Discrimination? Can. J. Law Technol. 19, 475–504.

International Medical Device Regulators Forum, 2023. Good Machine Learning Practice for Medical Device Development: Guiding Principles.

ISO Standards Australia, 2023. ISO/IEC 23894:2023 Artificial Intelligence Risk Management Standard.

Jassar, S., Adams, S. J., Zarzeczny, A., Burbridge, B. E., 2022. The future of artificial intelligence in medicine: Medical-legal considerations for health leaders. Healthc. Manage. Forum 35, 185–189.

Kalra, J., Seitzinger, P., 2023. Expanding Our Grasp: Artificial Intelligence as the Next Leap Forward in Healthcare Quality. Presented at the 14th International Conference on Applied Human Factors and Ergonomics (AHFE 2023).

Medicines and Healthcare products Regulatory Agency, 2024. AI Airlock: The regulatory sandbox for AIaMD.

Organisation for Economic Cooperation and Development, 2025. OECD. AI Policy Observatory: Reports (2023–2025).

Palaniappan, K., Lin, E. Y. T., Vogel, S., Lim, J. C. W., 2024. Gaps in the Global Regulatory Frameworks for the Use of Artificial Intelligence (AI) in the Healthcare Services Sector and Key Recommendations. Healthcare 12, 1730.

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

U.K. Government, 2023. AI Regulation White Paper.

U.S. Food and Drug Administration, 2021. Artificial Intelligence/Machine Learning–Based Software as a Medical Device (AI/ML SaMD) Action Plan.

U.S. Food and Drug Administration, 2025a. Predetermined Change Control Plans (PCCP) Draft Guidance.

U.S. Food and Drug Administration, 2025b. Total Product Lifecycle (TPLC) Model for AI/ML Devices.

UNESCO, 2024. Recommendation on the Ethics of Artificial Intelligence.

World Economic Forum, 2025. Earning Trust for AI in Health: A Collaborative Path Forward.

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

World Health Organization, 2021. Global Strategy on Digital Health 2020–2025.

World Health Organization, 2023. Ethics and governance of artificial intelligence for health guidance.

World Health Organization, 2025. Global Initiative on Artificial Intelligence for Health (GI-AI4H).