



WAYS TO IMPROVE THE EFFECTIVENESS OF GLOBAL HEALTHCARE GOVERNANCE BASED ON ARTIFICIAL INTELLIGENCE: INTERNATIONAL REGULATORY AND INSTITUTIONAL PERSPECTIVES

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Abstract: *This article examines ways to improve the effectiveness of global healthcare governance through the application of artificial intelligence (AI), drawing on international regulatory and institutional practices. Effectiveness is understood as the capacity of governance systems to ensure safety and clinical effectiveness, equitable access to healthcare, accountability, and timely cross-border coordination. While AI offers significant opportunities for enhancing clinical decision support, disease surveillance, resource allocation, and biomedical research, it also introduces substantial risks, including algorithmic bias, weak data governance, cybersecurity vulnerabilities, limited transparency, and performance drift of deployed models.*

The article situates these challenges within the emerging global governance framework shaped by the World Health Organization, which has issued guidance on the ethics and governance of AI for health as well as regulatory considerations for its deployment. Building on this baseline, the analysis connects key foreign regulatory practices—such as the European Union's risk-based AI Act, the U.S. Food and Drug Administration's lifecycle approach through Predetermined Change Control Plans and Good Machine Learning Practice, and harmonization

efforts led by the International Medical Device Regulators Forum. The article argues that integrating these approaches can strengthen trust, interoperability, and real-world performance oversight, thereby increasing the overall effectiveness of global healthcare governance in the AI era.

Keywords: *Artificial intelligence, global health governance, regulation, patient safety, Good Machine Learning Practice, international harmonization.*

Artificial intelligence has major potential to improve the effectiveness of global governance in healthcare because it helps make decision-making more data-driven, faster, and more predictive. However, like any digital innovation in medicine, AI delivers results only when it functions not merely as a technology, but as a system of rules, institutions, trust, and accountability. From a global governance perspective, the core challenge is to balance two goals: on the one hand, accelerating the deployment of safe and effective AI systems in practice; on the other hand, ensuring that these systems do not violate human rights, fairness, or clinical safety.

The World Health Organization's guidance has been an institutional response aimed at finding this balance: its 2021 "AI for health" publication set out major risks and overarching ethical and governance principles, while in 2023 WHO issued additional regulatory guidance on AI. In 2025, WHO also released separate guidance on large multimodal models, a type of generative AI, underscoring that governance requirements are becoming critically important for a new generation of medical AI systems.

A central avenue for strengthening global governance effectiveness is stabilizing internationally recognized “minimum common requirements” and translating them into operational processes. This means widely accepted standards for safety and performance evaluation, clinical validation, data quality, cybersecurity, human oversight, and accountability. Internationally, this trend is visible in regulatory cooperation.

For instance, the U.S. FDA, Health Canada, and the UK MHRA developed ten guiding principles for Good Machine Learning Practice for AI/ML-based medical devices, supporting product safety and quality across the entire lifecycle. The International Medical Device Regulators Forum is also advancing principles through its work on AI/ML-enabled medical devices, serving as an important platform for aligning regulatory approaches across countries.

Another avenue is making continuous monitoring of AI performance in real-world settings a global norm. In healthcare, it is risky to assume that once a model is approved it will remain consistently accurate: clinical protocols change, population characteristics shift, data sources differ, and model reliability can decline over time. In this context, the FDA’s guidance on a Predetermined Change Control Plan for AI-enabled devices is significant because it is designed to manage iterative updates while maintaining a “reasonable assurance” of safety and effectiveness. For global governance, this approach is practically valuable because it turns model updating from uncontrolled innovation into a pre-planned, documented, and verifiable cycle.

A further avenue is to make transparency and explainability an institutional precondition for clinical trust. International practice is

tightening in this direction. Health Canada's principles on transparency for machine learning-based devices emphasize providing users with clear and necessary information and improving the effectiveness of human-AI teamwork. This matters for accountability as well, because it directly relates to the question of who made the clinical decision. Even if AI provides recommendations, a human remains responsible for the decision, but to make that responsibility meaningful the system's capabilities and limitations must be communicated clearly.

Strengthening fairness and protection from discrimination is also becoming a key performance criterion of global governance. In medicine, algorithmic bias can lead to misdiagnosis, unequal access to services, and unfair outcomes in insurance-related decisions. The growing prominence of "equity-first" approaches, including calls for bias audits and transparency reporting, shows that this issue is becoming increasingly urgent on the global agenda. At the same time, UNESCO's recommendation on the ethics of AI frames human rights, fairness, transparency, and human oversight as universal principles. The OECD AI Principles likewise support the development of trustworthy AI aligned with human rights and democratic values, providing an additional normative foundation for governance models in health.

Improving effectiveness also requires stronger regulatory coordination and mutual recognition mechanisms. The EU AI Act, adopted in 2024, establishes harmonized rules that regulate AI systems based on risk levels. From a healthcare perspective, an important point is that certain AI systems used for medical purposes may fall into high-risk categories, which increases requirements for risk management, conformity assessment, and documentation. For global governance, the

critical issue is compatibility between such rules and national systems: for clinical evidence and risk controls approved in one jurisdiction to be credibly accepted elsewhere, shared terminology, common test protocols, and minimum transparency standards are needed. Here, platforms such as the International Medical Device Regulators Forum play a special role by helping converge technical requirements across regulators.

Finally, data governance must be strengthened at the level of global cooperation. In medical AI, the most important resource is data: electronic health records, laboratory results, medical imaging, genomic datasets, and real-world evidence.

Overall, increasing the effectiveness of global governance in healthcare through AI is not simply a matter of “more technology”; it is a matter of more trustworthy institutions and better-coordinated rules. International experience suggests that successful models connect regulation, standards, real-world monitoring, transparency, and fairness into a single system. A risk-based legal framework in the EU, lifecycle oversight of iterative updates through mechanisms such as the PCCP in the United States, the GMLP principles developed through regulatory cooperation, and international alignment through IMDRF are complementary directions that reinforce one another.

In conclusion, artificial intelligence can make global governance in healthcare more effective by enabling rapid analysis, supporting clinical decision-making, and optimizing resource allocation. Yet if these capabilities are not balanced with safety, fairness, and accountability, a crisis of trust and heightened clinical risks may follow. Therefore, pathways to greater effectiveness should integrate international standard-setting and guidance, lifecycle governance, controlled

management of model updates, transparency requirements, protections for fairness and human rights, and deeper regulatory coordination and international alignment.

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