Mapping AI Governance in Health

From Global Regulatory Alignments to LMICs' Policy Developments

HEALTH AI
The Global Agency for Responsible AI in Health

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Tools acknowledgements:

When documents were not available in English, all authors relied on Google Translate to assist with translation. While every effort was made to ensure accuracy, some nuances or technical details may have been affected by the limitations of automated translation tools.

LAO followed responsible advice for the usage of ChatGPT [https://chat.openai.com/ version 4.0 prompt: "check the grammar of this [text]"] as a complementary tool for grammar and spelling revisions [1,2]. The feedback generated by ChatGPT was reviewed critically and re-revised using own words and expressions. ChatGPT was not used for ideation purposes, content generation, data collection or data analysis.

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Abbreviations & Acronyms

AI: Artificial Intelligence
AIaMD: AI as a Medical Device
AMDF: African Medical Devices Forum
ASEAN: Association of Southeast Asian Nations
ASTP/ONC: Assistant Secretary for Technology Policy and Office of the National Coordinator for Health Information Technology
AU: African Union
C4IR: Centre for the 4th Industrial Revolution
CMDE: Center for Medical Device Evaluation
CONPES: Consejo Nacional de Política Económica y Social
EMA: European Medicine Agency
EU: European Union
FDA: Food and Drug Administration
FDCA: Federal Food, Drug, and Cosmetic Act
FG-AI4H: Focus Group AI For Health from the ITU/WHO
G7: Group of Seven
G20: Group of 20
GDPR: General Data Protection Regulations
GHWP: Global Harmonization Working Party
GHTF: Global Harmonization Task Force
GPAI: Global Partnership on AI
GIZ: German Agency for International Cooperation
HHS: Department of Health and Human Services
IAWG: Inter-Agency Working Group on Artificial Intelligence (UN)
ICT: Information and communications technology
IDRC: International Development Research Center of Canada
IEC: International Electrotechnical Commission
IEEE: Institute of Electrical and Electronics Engineers
IMDRF: International Medical Device Regulators Forum
ISO: International Organization for Standardization
ITU: International Telecommunication Union
LMIC: Low to Middle Income Countries
MDR: Medical Device Regulation
MHRA: Medicines and Healthcare Products Regulatory Agency
MinCiencias: Ministry of Science, Technology and Innovation
ML: Machine Learning
MLLMs: Multimodal Large Language Models
MoH: Ministry of Health
NB: Notified Body
NDH: National Digital Health
NHS: National Health Services
NICE: National Institution for Health and Care Excellence
NIST: National Institute of Standards and Technology
NMPA: National Medical Products Administration
OECD: Organization for Economic Cooperation and Development
PAHO: Pan-American Health Organization
PNAI: Policy Network on Artificial Intelligence
PRC: People's Republic of China
RISA: Rwanda Information Society Authority
RURA: Rwanda Utilities Regulatory Authority
SaMD: Software as a Medical Device
TFS: The Future Society
UN: United Nations
UNESCO: United Nations Educational, Scientific and Cultural Organization
UK: United Kingdom
USA: United States of America
WEF: World Economic Forum
WHO: World Health Organization

Foreword

Artificial intelligence has the potential to accelerate the transformation of health systems, ultimately leading to the equitable improvement of citizens' health outcomes at a global scale. Such AI-driven leapfrogging will only be possible if the proper governance models and guard-rails are in place to build trust in the use of the technology. Without trust, leaders and citizens alike will hold back from adopting AI solutions, consequently not allowing patients to benefit from this so-called intelligence revolution.

HealthAI, as the global agency for responsible AI in health, envisions a world where AI catalyzes equitable and inclusive improvements in health and well-being for all individuals and communities. Propelled by our mission to advance the development and adoption of Responsible AI solutions in health through the collaborative implementation of regulatory mechanisms and global standards, we at HealthAI partner closely with governments, international organizations and other stakeholders to translate international standards to fit local regulatory contexts as well as strengthen their capacity and infrastructure to validate AI innovations in health. We strongly believe that an ecosystem that ensures compliance with internationally defined Responsible AI standards, protects national data sovereignty, and supports local validation processes will foster trust, as well as increase investment and innovation in Responsible AI solutions in health.

This report on "*Mapping AI Governance in Health: From Global Regulatory Alignments to LMICs' Policy Developments*" represents a first step in our implementation of national and regional regulatory mechanisms to form a Global Regulatory Network. It also demonstrates our commitment to not leave the low resourced countries behind, as well as push for decentralization of regulatory processes to cultivate local innovation and trust. Through this report, we examined global AI governance policies developed by key international institutions through an interoperability lens, explored influential jurisdictions setting global regulatory trends and expectations, as well as presented country-specific analyses of four countries representing different regions, namely Africa, Latin America, Middle East and Asia, to offer diverse perspectives on the challenges and progress in the governance of AI in health.

Moving forward, this report will provide the basis for a living knowledge base for HealthAI's Community of Practice and the wider public. We will also use the landscape knowledge to develop training materials to increase awareness of, adherence to, and application of AI regulations in health amongst regulators, policymakers, researchers and innovators. Given the speed at which this field is moving, we are mindful that maintaining such a knowledge base in a timely manner will be critical but yet a herculean task. We are grateful to our global and regional collaborators who have already reached out to join hands in this endeavour and would like to encourage new partners to connect and be part of this effort.

Finally, we would like to thank our funder, the International Development Research Centre (IDRC) Canada, and the Foreign, Commonwealth and Development Office (FCDO), United Kingdom, for supporting the mission of HealthAI and making this landscape possible. Our deepest gratitude to HealthAI's colleagues and collaborators who have worked tirelessly and made essential contributions to the development of this report. We hope it will serve as a compass to help our community navigate the complex landscape of AI governance in health and inspire the responsible and equitable development of, and access to, AI innovations that can lead to better health and well-being for all.

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Executive Summary

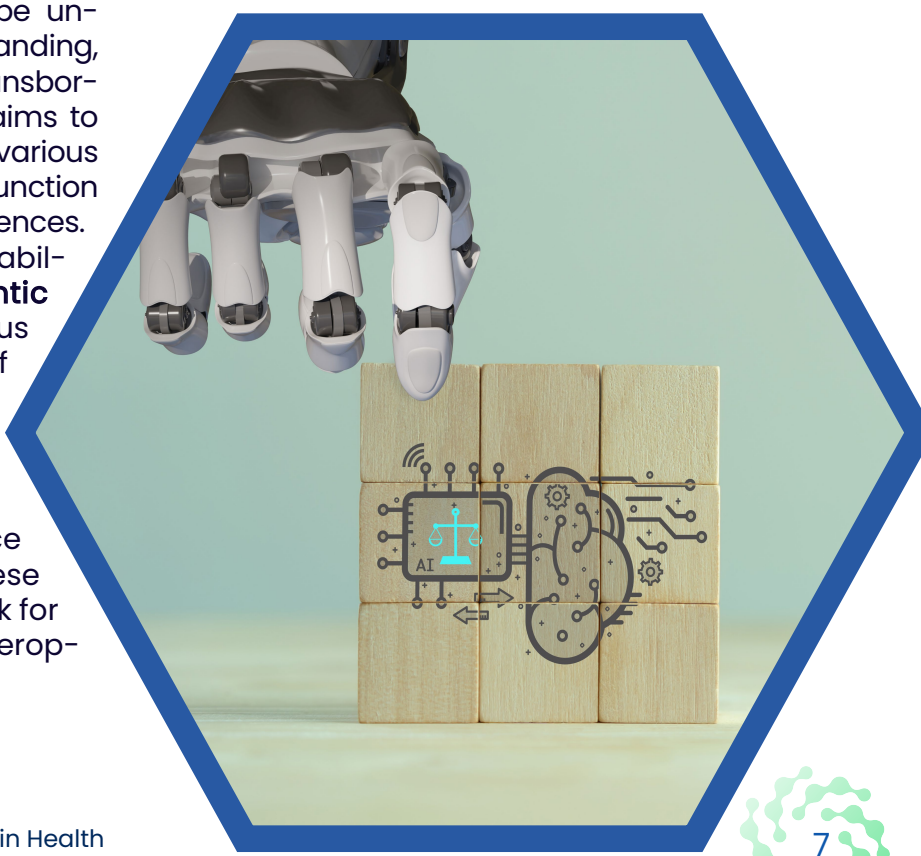
Given AI technologies' rapid and transformative integration into healthcare, effective and agile governance frameworks must be established to ensure these advancements are safe, effective, ethically sound, as well as developed and deployed responsibly. Globally, different regulatory bodies and institutions have adopted varied strategies. This landscape report examines AI in health and cross-sectoral AI governance policies created by key global institutions through an interoperability lens, explores widely influential jurisdictions setting global regulatory trends and expectations, as well as presents country-specific analyses for four countries. This approach allows us to capture both global trends and local nuances, providing a comprehensive landscape of AI regulations in health.

Global AI Governance Interoperability in Health

Interoperability of AI governance can be understood as having a common understanding, interpretation, and implementation of transborder governance mechanisms for AI. It aims to foster a cooperative environment where various governance models can coexist and function effectively despite their inherent differences. Inspired by the key aspects of interoperability, we focus our analysis on (i) **Semantic interoperability** examining the various vocabularies used in the regulation of AI; (ii) **Mechanism interoperability** of the type of measures utilized by international organizations for AI governance; (iii) **Participatory engagement** during the development of governance frameworks. The combination of these three aspects forms a robust framework for evaluating the global AI governance interoperability in health.

Semantic interoperability - In this report, we focused on the foundational aspect of how AI is defined in the establishment of AI policies and governance mechanisms. AI is defined differently based on the varying focuses, regulatory scopes, and priorities of key international organizations. AI systems are commonly recognized as machine-based, involving algorithms and models to perform tasks that typically require human intelligence. Despite most definitions agreeing on the various outputs of AI systems, there is a lack of alignment on the scope of inclusion of the type of technologies. In addition, organizations such as the WHO, and ISO/IEC emphasize the human-centric approach by highlighting the role of human-defined objectives in their definition, while others such as IEEE and ITU have more technical-based definitions.

Mechanism interoperability – Ethical principles and strategic visions are often the foundation to ensure that governance pathways have a cohesive and harmonized direction, while technical (procedural) documentations - such as assessment toolkits, regulatory



recommendations or standards - offer opportunities to operationalize the principles and strategies. Laws, international treaties and commitments play a focal role, as they create binding obligations that ensure the principles, strategic visions, technical procedures and standards are upheld and enforced.

- ## Principles for AI:

  In 2020 alone, there were over 160 organizational, national, and international sets of AI governance principles. Although there is a lack of a common platform to harmonize these initiatives, there is already a significant degree of alignment when principles are analyzed through the lens of their desired outcomes. The most frequently referenced desired outcomes in AI principles include: (i) ensuring processes that are transparent and understandable to stakeholders (transparency/explainability/intelligibility); (ii) promoting human and societal well-being (safety, do no harm, respect for human rights, human-centered values); (iii) establishing clear mechanisms for accountability and responsibility; (iv) ensuring equitable access and outcomes, avoiding bias and discrimination (justice, equity, fairness, non-discrimination); and (v) respecting privacy and data security. Important considerations—such as economic, social and environmental costs (of use, misuse, and under use), information integrity, dignity, and the need for participatory approaches—are less prominently reflected.

- ## Standards for AI:

  Standards are the most common mechanism for AI governance, with ISO/IEC 42001:2023 being the world's first international standard dedicated to AI management systems. Standards can complement other governance mechanisms by providing the technical foundations that support regulatory frameworks, guiding industry best practices, and offering structured frameworks for self-regulation. ITU alone has published over 100 international AI-related technical standards across multiple sectors, with an agenda to set the fundamental standardization of multimedia systems and services to support digitalization. However, the sheer number of standards can overwhelm organizations, complicating implementation and increasing costs associated with compliance, training, and development. There are also multiple gaps regarding their enforceability, and overcoming this hurdle requires concerted effort from country-level regulators and innovators alike to incentivize or mandate compliance. Many general technology standards would be applicable to AI in health, depending on how the applications or solutions are implemented. Once fundamental infrastructure standards are established, the focus of standards-setting bodies may shift toward AI, including the development of AI-specific standards in areas like health. This could lead to an increase in the overall number of standards for AI in health.

- ## Approaches for AI Regulatory Frameworks:

  Most institutions, such as WHO/ITU, UN, UNESCO, UNICEF, OECD, and WEF, have published at least one document dedicated solely to recommending specific steps for effective regulatory frameworks for AI. There is a growing alignment around two key regulatory requirements. First, as discussed, transparency, especially in documentation, has become a fundamental principle guiding AI development and is widely recommended as an essential requirement for enabling human oversight within regulatory frameworks. Transparency is often viewed as a tool that allows for evaluations and to determine thresholds for safe usage of AI technologies. Second, in a risk-based approach, impact assessments are essential for accurately defining risks and determining the appropriate level of mitigation strategies and regulatory requirements.

Participatory engagement – Given AI's complexity and its broad impact on global health, it is widely acknowledged by global institutions that participatory engagement serves as a key tool in the policy-making process, enabling different stakeholders, including governments, regulatory bodies, healthcare providers, developers, manufacturers, patients, and civil society, to contribute their expertise and perspectives to shape AI regulatory policies. While diverse stakeholder engagement is often promoted in global institutions, a closer examination reveals significant disparities in representativeness and challenges to meaningful participation in the formulation of AI governance policies. The majority of stakeholders engaged tend to come from predominantly high-income countries, often with double the representation compared to other income groups. There is also a global trend where men experts are more prevalent than women. These disparities may stem from the uneven global distribution of AI experts, who are predominantly male and based in high-income countries. Finally, the presence of patient voices, advocacy groups, youth perspectives, and the public in general remains limited, suggesting a need for further exploration.

Jurisdictions Influencing AI Regulations in Health

There are multiple global players influencing the approach to AI regulatory frameworks in distinct ways, given the current lack of a unified global approach. It is important to note that although no sui generis AI legislation exists yet for the health sector in many jurisdictions/countries, AI applications in healthcare are not unregulated and currently fall in the broader category of existing medical device regulations concerning software as a medical device or software related to medical devices. Considering the increased support for binding laws, this report will focus on legislation and soft guidance aimed at regulating AI in health in the United States of America, European Union, United Kingdom, and the People's Republic of China. These global stakeholders have strong geopolitical influence in their regions and worldwide, and have demonstrated advancements towards having government oversight in the mitigation of risks posed by AI across various sectors. In particular, they have also been identified as pioneers in regulating AI in the sector of health. Through them, examples of how varied approaches towards regulation of AI in health can work for different jurisdictional visions and needs are highlighted.

Country Profiles: AI Governance Readiness in Health

When designing regulatory mechanisms, it is essential to consider not only ethical and technical principles but also the cultural, social, and historical context as well as the legal system of each country. In particular, low- and middle-income countries face unique challenges in establishing regulatory mechanisms for AI in health that can adequately address local needs while attempting to align with global standards. An in-depth analysis of AI governance readiness in health across four countries with unique contexts, namely Rwanda, Colombia, Lebanon, and Pakistan, is presented in this report. These countries represent different regions—Africa, Latin America, Middle East, and Asia respectively— offering diverse perspectives on the challenges and progress in AI health governance. Each country profile examines four key aspects—AI governance readiness in health, semantic interoperability, mechanism interoperability, and participatory engagement—and provides a summary of the key takeaways, allowing for a nuanced understanding of each country's unique regulatory landscape, while comparing their alignment with global practices.

1. Overview

Artificial intelligence (AI) in healthcare is ushering in a new era by revolutionizing care pathways, promoting early prevention and well-being, streamlining processes, and pushing the boundaries of medical knowledge and research. Given AI technologies' rapid and transformative integration into healthcare, comprehensive regulatory frameworks must be established to ensure these advancements are safe, effective, ethically sound, as well as developed and deployed responsibly. However, creating policies to regulate AI in health is an intricate process, given AI's multifaceted nature and its complex ripple effects.

There are many approaches to govern AI, such as in the form of international treaties, national strategies, national legislation, regulatory sandboxes, ethical guidelines, standards, or mandates for technical specifications. Globally, different regulatory bodies and institutions have adopted varied strategies. However, regulatory frameworks are intricate and layered, with multiple regulations often overlapping and building upon one another. For example, AI can be dissected into various components, such as algorithms and data, each of which could require distinct regulatory considerations and approaches. Alternatively, policies may have a sectoral focus on regulating AI's specific applications and potential risks within different fields. Some regulators, especially in Europe, have taken a legislative and horizontal approach, encompassing a cross-sectoral perspective and addressing the entire AI lifecycle from development to deployment. While some institutions might focus on regulating individual components of AI, such as data protection, others might focus on the context of its application, such as medical device regulations, leading to a patchwork of regulatory frameworks. Each approach has its own set of advantages and disadvantages. Hence, it is crucial to map the current regulatory landscape, identify existing gaps, and propose potential ways forward to ensure the effective governance of AI in health.

Regulating technology in the health sector is not a new challenge; it builds on a long-standing tradition of overseeing medical research and devices to ensure new developments are safe, effective, and ethical. Over the years, a solid framework has been established to meticulously evaluate and monitor medical innovations, ensuring they meet high clinical and technical standards, benefit patients and communities, and present acceptable risk ratios. As AI becomes an integral part of health delivery, it is essential to recognize that AI is evolving within an already well-defined regulatory landscape. In that sense, medical device regulations provide a valuable foundation for monitoring and evaluating AI applications in health. More specifically, these regulations fall within the category of Software as a Medical Device (SaMD) or machine learning-enabled medical devices. However, current AI regulatory frameworks also include cross-sectoral regulations, which guide AI applications across various domains, and regulations targeting inter-related areas of AI, such as data protection, intellectual property, and cybersecurity.

From a global view, a landscape must begin with an overview of international institutions while acknowledging developments in influential regions such as the United States of America (USA), Europe, China, Singapore, and the United Kingdom (UK), which often set the pace for regulatory development in the health sector. At the same time, it is essential to include the perspective of a larger pool of countries, including low- and middle-income countries (LMICs), as they have unique needs and contexts that make regulations for AI in health particularly important and challenging. Brazil, Kenya, Rwanda, and Indonesia, for instance, are standout innovators in their regions. They are often at the forefront of developing and deploying AI regulatory policies tailored to local health challenges, which can provide valuable models for other LMICs. Other countries, such as Lebanon, Tanzania, and Pakistan, face unique challenges in their political

setups that have encouraged policymakers to rely on alternative non-legislative regulatory approaches. Understanding the global and regional regulatory landscapes will allow one to better grasp how innovation spaces within countries and regions can be developed safely and responsibly, ultimately ensuring more effective and equitable healthcare outcomes.

The biggest takeaways from examining regulations for AI in healthcare worldwide reveal a landscape that is still evolving but facing significant gaps. Many countries are relying (consciously or not) on their existing medical device regulatory structures to oversee AI in health. However, this approach may not be sufficient to address the unique aspects of AI, as evidenced by instances where approved technologies have had unintended and significant socio-ethical consequences. Reports highlight the need for better-tailored regulatory measures to capture the complexities of AI applications in health [3,4].

Harmonizing regulations remains an important goal, as global institutions often operate in isolation without a unified and interoperable approach. Many United Nations (UN) agencies, such as the United Nations Educational, Scientific and Cultural Organization (UNESCO) and the World Health Organization (WHO), are developing AI policies, including those for AI in health, using diverse methodologies. LMICs face unique challenges as they often draw inspiration from global institutions or influential regions but may be adversely affected by potential inconsistencies. This would result in regulations that are poorly suited to their specific contexts or fail to responsibly guide AI integration into healthcare. While there is global pressure for regulators to unify their approaches, it is equally important to maintain local jurisdictional control to address the distinct needs of each region effectively.

In LMICs, innovators are facing an unclear regulatory landscape, risking falling through gaps and at times, wrongly assuming that AI in health is unregulated. This issue is compounded by the misconception that general AI regulations may not apply to the health sector. To ensure the safety, effectiveness, and responsible development of AI in healthcare, substantial work is needed to create, update, and reconsider the scope, applicability and specificity of global governance frameworks. This effort requires a collaborative approach that balances global harmonization with local adaptability, ensuring that AI technologies can thrive and deliver their promised benefits to all populations.

While attempting to map the regulatory landscape for AI in health is an important task, we must also acknowledge the inherent limitations of this analysis. The rapidly evolving nature of AI technologies means that regulatory frameworks are a work in progress. New documents could still be released, national and multilateral deliberations are ongoing, or existing frameworks require constant updates and adaptations, making them challenging to track. Additionally, the diversity of regulatory environments across different countries and regions poses a significant challenge, as each has unique legal, cultural, socio-economic, and healthcare contexts that influence their approach to regulation and their unique interpretations of AI. Moreover, the intersection of various regulatory domains, such as data protection, cybersecurity, and medical device standards, adds complexity that can be difficult to navigate comprehensively. This report is not meant to provide insights on every policy about AI and AI in health. Instead, it serves as a starting point for discussion, fresh insights, and recommendations, laying the groundwork for HealthAI's future work within AI regulations for health.

1.1. Scope

To achieve the purpose of creating a landscape of global and local AI regulations for health, we build from the concept of interoperability of AI governance and evaluate the governance efforts at both international and national levels, with a focus on health-related applications. We continued our analysis by examining global regulatory alignments, identifying overarching trends and frameworks that guide AI regulations in health. This global perspective sets the foundation for understanding widely influential world regions that have significant regulatory impacts globally, as we turn our attention to China, Europe, and the USA, which are not only establishing distinct governance frameworks but also setting global expectations. Finally, we conducted a country-specific analysis for countries selected based on the following criteria: number of projects funded by International Development Research Center (IDRC) of Canada, pioneer country at a regional level and population size. We selected a total of four countries representative of each world region as a starting point for this report: Americas (Colombia), Africa (Rwanda), Asia (Pakistan), and Middle East and North Africa (Lebanon). This approach allows us to capture both global trends and local nuances, providing a comprehensive landscape of AI regulations in health. By focusing on health-specific and AI-specific policies, we ensure a targeted understanding of the regulatory environment, while also acknowledging the broader context in which these regulations exist.

The primary sources of information for this review included online databases, scientific publications, and official websites of country-level authorities such as ministries of health and international organizations (Annex 1). A keyword search strategy was employed where possible, and manual searches were conducted when necessary. It is important to recognize that reviewing this type of documentation is an iterative process, requiring flexible methods and often involving a snowballing approach, where one document leads to the discovery of others. Inclusion criteria encompassed documents published between 2010-2024 that are health-specific or AI-specific, such as guidelines, principles, regulatory considerations, and best practices. Documents were excluded when not available online and those focusing on specific technologies not broadly including AI such as telemedicine. High priority was given to policies directly applicable to AI in health, those including AI (explicitly or implicitly) in medical device regulations and policies focusing on AI in general. Policies focusing on inter-related areas to AI, such as data protection and privacy, were considered out of scope for this review. This approach ensured that the primary focus remained on AI governance specific for health, providing a clear and targeted understanding of the regulatory landscape. However, references to such inter-related policies were still included to provide context and acknowledge their influence on AI governance, ensuring an overview of the regulatory environment impacting AI in health.

Given the variations in data, this report utilized a narrative analysis focusing on the extent and impact of harmonization efforts between global and local regulations for AI in health. This analysis aimed to identify gaps and potential recommendations for future regulatory alignment, but it is not meant to be exhaustive.

2. Global Interoperability of AI Governance in Health

Global harmonization of regulatory efforts will reduce hurdles for innovators and improve efficiency for regulators. Therefore, analyzing the alignment between AI in health policies and generic AI policies created by key global institutions is a critical step to building a cohesive and effective regulatory framework worldwide. In that way, the similarities and differences between the various policies can be uncovered, providing recommendations towards improving the consistency, transparency, and effectiveness of regulatory efforts. This integrated perspective is essential for encouraging innovation, maintaining ethical standards, and ensuring that AI technologies are used responsibly and effectively in healthcare systems worldwide.

Interoperability is generally understood as the ability of different systems to communicate and function seamlessly together. Building from the definition of Policy Network on Artificial Intelligence (PNAI)[5], interoperability of AI governance can be understood as having a common understanding, interpretation, and implementation of transborder governance mechanisms for AI[a]. However, promoting interoperability does not imply imposing identical frameworks or standardized norms across different contexts. Instead, interoperability aims to foster a cooperative environment where different governance models can coexist, communicate, and function effectively despite their inherent differences. The World Economic Forum (WEF) acknowledges that coordinating multi-stakeholder dialogue and knowledge sharing is crucial for informing governance interoperability discussions [6].

International cooperation to achieve jurisdictional interoperability is essential for ensuring global cohesion and building trust in AI [7].

Inspired by the key aspects of interoperability, we focus our analysis on (i) **Semantic interoperability** examining various vocabularies used in the regulation of AI, for example, how AI is defined in policies and medical device regulations; (ii) **Mechanism interoperability** of the type of measures utilized by international organizations for AI governance (principles, norms, technical specifications, standards, and processes); (iii) **Participatory engagement** during the development of governance frameworks. The combination of these three aspects - semantic interoperability, mechanism interoperability, and participatory engagement - forms a robust framework for evaluating the interoperability of AI governance for health. A consistent understanding of the meaning of AI across different policies and regulations would allow comprehension of the variety of complementary mechanisms for effective governance, and by involving a wide range of stakeholders in the the decision-making process, we can expect more harmonized global AI governance efforts.

a PNAI brings together three key aspects that must be harmonized: (1) the substantive tools, measures and mechanisms involved in guiding and developing AI, (2) ways of multistakeholder interactions and interconnections, and (3) agreed ways to communicate and cooperate. In their definition all three are necessary to achieve interoperability of governance of AI.

2.1. Global Institutions, Reach, and Roles

At least 12 global institutions (including many of the UN specialized agencies) are actively working on governance mechanisms for AI or AI in health (Table 1). These institutions are shaping collaborations and the global AI governance landscape, which has resulted in an ever-increasing amount of documentation and varied recommendations.

It is important to note that current global regulatory frameworks for using AI (and AI in health) predominantly fall into the soft law category, making them non-legally binding. It is at the discretion of governments and industry stakeholders to integrate these guidelines, recommendations, or standards into their local regulatory environment. Beyond the inherent jurisdictional limitations of international institutions, soft-law approaches offer advantages such as flexibility and adaptability on a global scale. However, the voluntary nature of soft-law instruments may lead to inconsistent application and enforcement due to an absence of accountability mechanisms for non-compliance. Furthermore, the lack of legally binding requirements can create uncertainty, risks, and varying safety and efficacy standards across different regions and organizations.

Despite these challenges, soft regulations established by international institutions can significantly impact country-level formal legislation. They provide direct and indirect guidance for global governments on interpreting and regulating AI and AI in health. By setting benchmarks and offering a framework for best practices, these international soft-law instruments influence the development of binding laws and regulations across different jurisdictions. In particular, instruments negotiated and approved by Member States carry significant weight and standing in expressing their commitments or directing implementation efforts[8] . However, different organizations may have slightly divergent perspectives, leading to inconsistencies in the guidelines, recommendations, and standards they establish.

Several global institutions host AI governance initiatives aimed at identifying, analyzing, and making recommendations to harmonize efforts in regulating AI. For instance, the UN created a multi-stakeholder high-level advisory body comprised of international experts to foster a globally inclusive approach to AI governance[9]. UNESCO launched the first-ever global standard on AI ethics—the "Recommendation on the Ethics of Artificial Intelligence"—in 2021, adopted by 194 countries[10]. The Organization for Economic Cooperation and Development (OECD) launched the OECD AI Principles in 2019, which were updated in May 2024 and have been influential across jurisdictions[11]. The OECD has recently partnered with the Global Partnership on AI (GPAI), a multilateral initiative comprising 28 member countries and the European Union "to harness the potential of human-centric, safe, secure, and trustworthy AI for the good of all"[12]. The WEF Centres on Cybersecurity, Financial and Monetary Systems, Health and Healthcare, Nature and Climate and Advanced Manufacturing and Supply

"Soft regulations established by international institutions can significantly impact country-level formal legislation. They provide direct and indirect guidance for global governments on interpreting and regulating AI and AI in health".

Chains further support and lead the "AI Governance Alliance"[13]. The Global Initiative on AI and Data Commons was established by the International Telecommunication Union (ITU) in 2020 as an open framework for collaboration to support sustainable development, AI knowledge-sharing and common humanitarian action with AI[14].

Regional initiatives have also marked the AI governance landscape. In Africa, the African Union (AU) Development Agency and the AU High-Level Panel on Emerging Technologies drafted the "African Union Artificial Intelligence (AUAI) Continental Strategy for Africa[15]. The AI Hub for Sustainable Development is a collaboration between the Group of Seven's (G7) Italian Presidency and the United Nations Development Programme (UNDP) to steer private sector collective action across AI ecosystems within African countries. Smart Africa, an AI initiative in collaboration with the German Agency for International Cooperation (GIZ), published a blueprint for the development of AI strategies, including governance recommendations, in Africa in 2021[16]. In Asia, the "Association of Southeast Asian Nations" (ASEAN) launched the "Guide on AI Governance and Ethics"[17]. In Latin America, the Inter-American Development Bank and its innovation laboratory presented in November 2023 the "fAIr LAC+," a multi-stakeholder partnership that aims to offer a one-stop-shop for support on designing and applying regulatory frameworks; developing, adopting, and using technologies; and strengthening skills and capacities[18].

Institution	Scope	Documents	Role	Reach	Relationships
World Health Organization (WHO)	Sectoral (health)	Guidelines, reports, standards, policy briefs, regulatory frameworks	Develops global guidelines and standards for health, including AI ethics and governance	Global (194 countries)	UN Agency that collaborates with various national and international health organizations such as IMDRF and IAMRA to establish health standards.
International Medical Device Regulators Forum (IMDRF)	Sectoral (health)	Guidelines, frameworks, technical documents	Harmonizes international regulatory practices for medical devices, including AI-based software	International (regulators in 20+ countries between the official committee and affiliated members. Official observers include WHO, SwissMedic, and Argentina)	Facilitates cooperation among national regulators (e.g., FDA, Health Canada) to harmonize standards. WHO is an official observer.
Global Harmonization Working Party (GHWP)	Sectoral (health)	Guidelines, technical documents, regulatory frameworks	Harmonizes international regulatory practices for medical devices, enhances the regulatory capability of member economies	International (regulators and industry from 34 member countries, with a focus on emerging economies)	Facilitate knowledge exchange among regulators and industry. Works with global entities (e.g. WHO, IMDRF, OECD)
International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC)	Sectoral (health) and Cross-sectoral	International standards, technical specifications, guidelines	Develops international standards across various industries, including AI	Global (165 member countries)	Works with global entities (e.g., WHO, EU) to develop universally applicable standards.
United Nations Specialized Agencies (UNESCO, UNICEF, UN-DESA, UNDP, UNICRI, UNIDO, WIPO)	Cross-sectoral	Declarations, guidelines, reports, toolkits, regulatory frameworks	Promotes international cooperation in AI	Global (193 member countries)	United Nations Agencies that engage with international bodies (e.g., WHO, EU, ITU) to advocate for ethical and safe AI practices
Organization for Economic Co-operation and Development (OECD)	Cross-sectoral	Reports, regulatory frameworks, guidelines	Promotes policies and international cooperation for economic growth, including AI development	International (38 member countries)	Works with governments, policymakers, and other international organizations to promote AI principles

Institution	Scope	Documents	Role	Reach	Relationships
Institute of Electrical and Electronics Engineers (IEEE)	Cross-sectoral	Standards, guidelines, technical reports	Develops ethical standards and technical guidelines for AI and autonomous systems	Global (160+ countries)	Professional association. Engages with international bodies and technical communities to establish ethical AI standards
G7	Cross-sectoral	Declarations, communiqués, reports, commitments	Develops and promotes international AI governance frameworks and principles among member states	International (7 member countries)	Works with international bodies like OECD, UNESCO, and GPAI to establish and promote AI principles
G20	Cross-sectoral	Declarations, action plans, reports, commitments	Promotes international cooperation and alignment on AI principles and policies among member countries	International (20 member countries)	Collaborates with international organizations like OECD to promote alignment and adoption of AI principles
International Telecommunication Union (ITU) (FG-AI4H)	Cross-sectoral	Standards, recommendations, reports	Fosters international cooperation in AI standards, organizes global AI events	Global (193 member countries)	Collaborates with UN agencies, industry, academia, and civil society to promote global AI standards
Global Partnership on Artificial Intelligence (GPAI)	Cross-sectoral	Reports, recommendations, policy briefs	An international initiative that aims to promote the responsible and human-centered development and use of AI	International (29 member countries along with the European Union)	Hosted by OECD. Works with other international bodies such as UNESCO, the European Union, and various national governments to harmonize AI governance efforts and promote a unified approach to AI development
World Economic Forum (WEF)	Cross-sectoral	White papers, guidelines, regulatory frameworks	Facilitates multi-stakeholder dialogue, develops best practices, and provides policy recommendations	Global (190+ countries)	Partners with governments, private sector, academia, and NGOs

Table 1: Global Institutions that have released documentation on cross-sectoral AI or AI in health: principles, recommendations, standards, or regulatory advice. This is indicative and not exhaustive.

2.2. Semantic Interoperability

Semantic interoperability in the context of AI governance in health encompasses the analysis of the convergence or divergence of terminologies and their meanings across different AI policies and regulations. Several aspects can be examined, such as the definition of AI, medical devices, SaMD, and AI medical devices. It is also important to understand how AI ethics and guiding principles such as transparency, inclusivity, autonomy and accountability are defined and interpreted at the global and national levels to identify gaps and challenges in fostering a harmonized approach. In this report, we focused on the foundational aspect of how AI is defined across international organizations and national levels in the establishment of AI policies and governance mechanisms.

The diverse perspectives and evolving understanding of AI across various international organizations are reflected in their varying definitions of AI. The main challenges in achieving a universally accepted definition of AI include: **(i) Diverse context and applications:** Perspective of what constitutes AI is influenced by cultural, technological, and regulatory contexts, across diverse stakeholders in different sectors; **(ii) Rapidly evolving technology:** Fast-paced development of AI makes it challenging to create a definition that remains relevant over time; **(iii) Technical vs human-based definitions:** Technical, capability-based definitions offer precision but may become obsolete quickly, while human-based definitions, considering the broader socio technical context, are more flexible but less specific; **(iv) Scope of inclusion and varying levels of AI capabilities:** Determining whether to include only complex modern AI systems or also classical algorithms and statistical methods can be a point of debate but lobal definitions must consider the needs of nations with different levels of AI development and adoption; **(v) Interoperability with existing laws and policies:** AI technologies are often also regulated by ancillary regulatory frameworks such as data protection laws, ICT policies. Compatibility with these existing laws, regulations, and policies is essential to support the AI ecosystem without requiring extensive legal overhauls.

1. OECD

- OECD's definition was revised in 2023 to align with the latest technological advancements. It defines an AI system as a machine-based system that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments. Different AI systems vary in their levels of autonomy and adaptiveness after deployment.

2. WHO

- In its guidance on the ethics and governance of AI for health, WHO quoted the definition of AI from OECD's recommendation of the Council on AI: An AI system is a machine-based system that can, for a given set of human-defined objectives, make predictions, recommendations, or decisions influencing real or virtual environments. AI systems are designed to operate with varying levels of autonomy.

3. UN

- Generally describes AI as a discipline of computer science aimed at developing machines and systems capable of performing tasks that require human intelligence, such as machine learning and deep learning.

4. G7 and Group of 20 (G20)

- Do not have a standalone definition of AI.
- Adopt and build on definitions developed by other international organizations, particularly OECD.

5. International Medical Device Regulators Forum (IMDRF)

- AI is described as a branch of computer science, statistics, and engineering that uses algorithms or models to perform tasks and exhibit behaviors such as learning, making decisions, and making predictions.

6. Global Harmonization Working Party (GHWP)

- According to GHWP, AI in medical devices encompasses technologies that utilize machine learning and other AI methodologies to enhance the functionality and performance of medical devices.

7. International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC) (ISO/IEC 22989:2022)

- AI is defined as a technical and scientific field devoted to the engineered system that generates outputs such as content, forecasts, recommendations, or decisions for a given set of human-defined objectives.

8. ITU

- AI is defined as the capability of a machine to imitate intelligent human behavior, utilizing algorithms and models to perform tasks that typically require human intelligence, such as visual perception, speech recognition, decision making, and language translation.

9. Institute of Electrical and Electronics Engineers (IEEE)

- AI is defined as systems that simulate human intelligence processes, including learning from vast datasets, reasoning, and self-correction.

Although the varied definitions reflect the different focuses, regulatory scopes, and priorities of the international organizations, there are core elements shared across the definitions. AI systems are recognized as machine-based, involving algorithms and models to perform tasks that typically require human intelligence. Despite most definitions agreeing on the various outputs of AI systems, there is a lack of alignment on the scope of inclusion of the type of technologies. While organizations such as the WHO, and ISO/IEC emphasize the human-centric approach by highlighting the role of human-defined objectives in their definition, others such as IEEE and ITU have more technical-based definitions.

This highlights the complexity of creating a universally accepted definition of AI that can serve as a foundation for regulation and governance. Striking a balance between overly broad and restrictive definitions is crucial to enable effective regulation.

2.3. Mechanism Interoperability

While there is a wide variation in available mechanisms for AI governance in health, most mechanisms must have the capacity to seamlessly work together. It is, however, unlikely that one single document or mechanism can encompass all that is necessary to ensure AI is safe, ethical and responsible.

Ethical principles and strategic visions are often the foundation to ensure that governance pathways have a cohesive and harmonized direction, while technical (procedural) documentations - such as assessment toolkits, regulatory recommendations or standards - offer opportunities to operationalize the principles and strategies. Laws, international treaties and commitments play a focal role, as they create binding obligations that ensure the principles, strategic visions, technical procedures and standards are upheld and enforced.

In principle, all regulatory mechanisms should help manufacturers and regulators answer the question: "Does the evidence (included in the regulatory submission) support the conclusion that the AI is safe and performs sufficiently well to justify entry into the market and public access?"[19]. Manufacturers and regulators should adopt principles as a guiding foundation and take complementary actions to assess whether the AI system is safe and to verify that its performance claims can be substantiated and maintained overtime, through the deployment of validation methodologies as well as establishment of robust and timely post market surveillance systems.

Global institutions have published a total of 30 policies and more than 90 standards on AI/ML applications have been - or are planned to be - published (Lists in Annexes 3 and 4) (Figure 1).

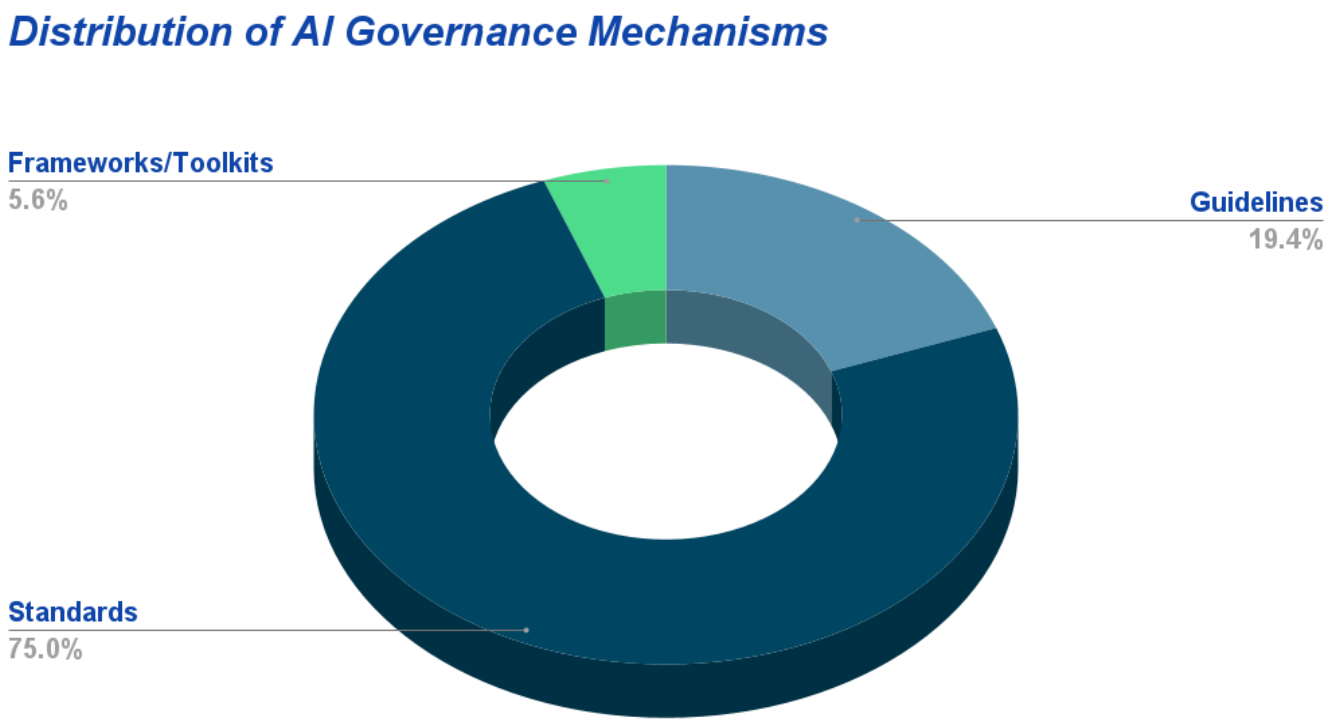


Figure 1: Representation of the distribution of AI governance mechanisms [non-exhaustive]

A report published by the Inter-Agency Working Group on Artificial Intelligence (IAWG) and ITU in 2024 found that over 20 policies have already been published by the UN's Agencies about AI governance or AI in healthcare 10 (List in Annex 2), demonstrating a lack of unified effort in AI governance even within UN agencies. While our review is not exhaustive, the past two years have seen a significant increase in cross-sectoral AI policies, with more than 20 documents published in 2022 alone (Figure 2).

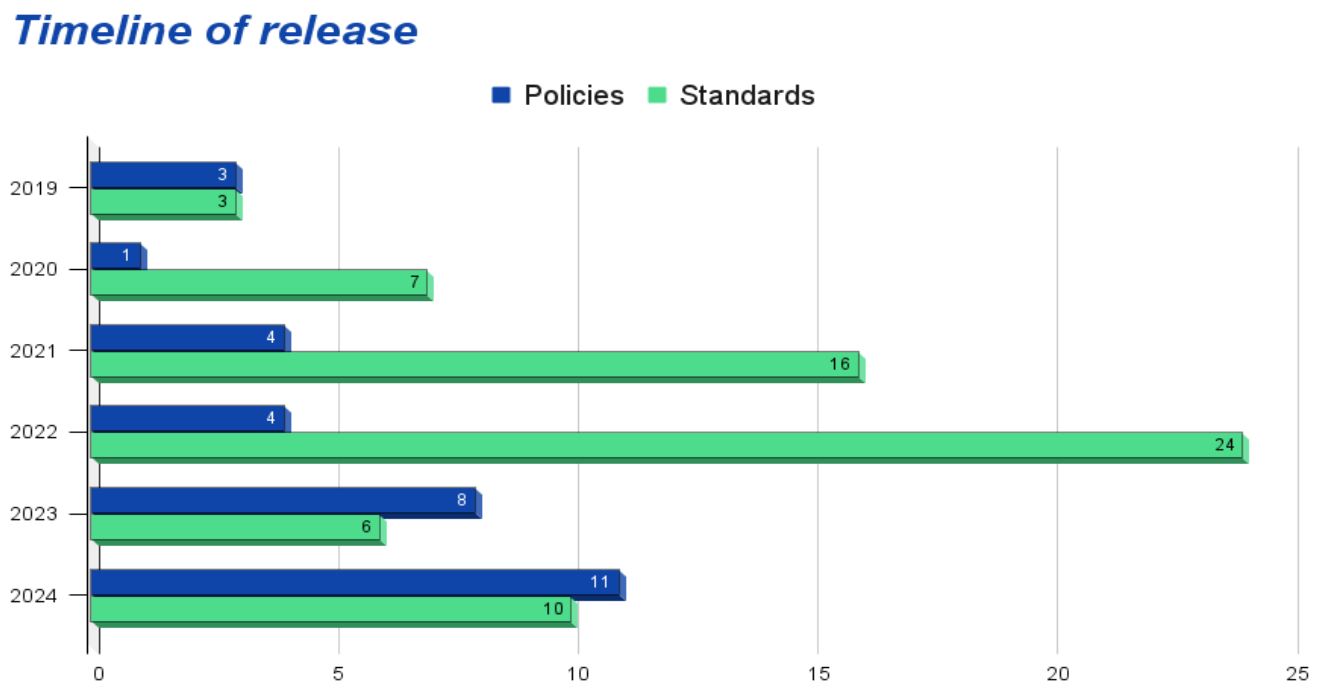


Figure 2: Timeline of AI policies released per year

At the current pace of documentation development, 2024 could be just as, if not more, productive. The surge in global policies may be driven by the widespread public advancements in AI - particularly OpenAI's ChatGPT - and the rapid adoption of AI across various sectors. This has likely intensified pressure on global regulators to devise new strategies and accelerate the release of AI policies.

The WHO has released three documents specifically for AI in health stating ethical principles to be upheld and general governance recommendations for AI and Generative AI. In collaboration with ITU/WHO and stemming from the FG-AI4H work, one publication "*regulatory considerations on artificial intelligence for health*" was released in 2023. The OECD released an analysis for healthcare and provided policy recommendations in their 2024 "*AI in health: huge potential, huge risk*"[20].
The IMDRF published in 2022 "*Machine Learning-enabled Medical Devices: Key Terms and Definitions*" and in 2024 a draft for "good machine learning principles". However, only approximately one-quarter of the governance mechanisms are healthcare-specific. In particular, the ITU/WHO Focus Group on AI for Health (FG-AI4H) has approximately 30 pre-publication documents covering various aspects of clinical evaluations for AI, including but not limited to essential considerations for regulating the full AI lifecycle, best practices for AI development, and processes for technical and clinical validation. These publications and recommendations are expected to be released in the upcoming years[21],[22]. However, their recommendations are currently advisory, and it is yet to be determined if they will be officially endorsed by relevant institutions or nations.

Positively, this documentation surge reflects a growing recognition of the importance of practical and process-oriented mechanisms in ensuring the ethical, responsible, and effective deployment of AI. There is convergence on the need to move from principles to prac-

tice as many of the policies released in 2024 provide either recommendations, standards, frameworks, checklists or toolkits that can directly and indirectly affect the processes and expectations for AI's development. This marks a refreshing shift, to increase the potential applicability of these policies. It is expected that policymakers have progressed from the "understand" stage, where they recognize the potential benefits and risks of AI, to the "shape" stage, where they are actively seeking to influence how AI is developed and used as well as mitigate the risks it can bring[23].

The AI policies encompass various thematic areas, incorporate diverse regulatory mechanisms, and address a range of technologies, as detailed in Table 2. Many AI policies include principles, best practices, development recommendations, or recommendations for regulatory frameworks. More than half of the policies include recommendations for AI development or for regulatory frameworks with a varying degree of details and strengths. Many institutions have either established their own set of AI principles or endorsed those developed by other global organizations. While the majority of policies (23) address AI as a general concept, some have also focused on Machine Learning (ML). Particularly in the past year, there is greater focus on large multi-modal models (LMMs) and Generative AI.

Organi-zation	Name of Instrument	THEMATIC AREAS					
		Technology	Health Specific	General AI's Concep-tual Clarifications or Position Statement	Guiding Principles (ethical or procedural)	Recommendations for AI's development & implementation	Recommendations for regulatory framework
WHO	Ethics and governance of artifi-cial intelligence for health (2021)	AI	Yes				
WHO	Ethics and governance of ar-tificial intelligence for health: Guidance on large multi-modal models (2024)	Large Multi-modal models	Yes				
WHO/ITU (FGAI4H)	Regulatory considerations on artificial intelligence for health (2023)	AI	Yes				
WHO/ITU (FGAI4H)	DEL2.2 Good practices for health applications of machine learn-ing: Considerations for manu-facturers and regulators (2022)	Machine Learning	Yes				
WHO/ITU (FGAI4H)	DEL0.1 Common unified terms in artificial intelligence for health (2022)	AI	Yes				
WHO/ITU (FGAI4H)	DEL7.4 Clinical evaluation of AI for health (2023)	AI	Yes				
IMDRF	IMDRF/AIMD WG/N67 (Edition 1) Machine Learning-enabled Medical Devices: Key Terms and Definitions (2022)	Machine Learning	Yes				
IMDRF	IMDRF/AIWG/N73 DRAFT: 2024 Good machine learning practice for medical device develop-ment: Guiding principles	Machine Learning	Yes				
UN	A/78/L.49: Seizing the opportuni-ties of safe, secure and trust-worthy AI systems for sustain-able development (2024)	AI					
UN	Interim Report: Governing AI for Humanity (2023)	AI					
UNESCO	UNESCO Recommendation on the Ethics of Artificial Intelligence (2021)	AI					
UNESCO	Ethical impact assessment: a tool of the Recommendation on the Ethics of Artificial Intelligence (2023)	AI					

Organi-zation	Name of Instrument	THEMATIC AREAS					
		Technology	Health Specific	General AI's Concep-tual Clarifications or Position Statement	Guiding Principles (ethical or procedural)	Recommendations for AI's development & implementation	Recommendations for regulatory framework
UNESCO	Readiness assessment method-ology: a tool of the Recommen-dation on the Ethics of Artificial Intelligence (2023)	AI					
UNICEF	Policy Guidance on AI for Chil-dren (2021)	AI					
UNICEF	Core Considerations for Explor-ing AI Systems as Digital Public Goods - developed together with (DPGA) (2023)	AI					
OECD	OECD AI Principles (2019)	AI					
OECD	Recommendation of the Council on AI (the Recommendation) (OECD/LEGAL/0449 amended 03/05/2024)	AI					
OECD	OECD FRAMEWORK FOR THE CLASSIFICATION OF AI SYSTEMS (2022)	AI					
OECD	TOOLS FOR TRUSTWORTHY AI: A FRAMEWORK TO COMPARE IMPLE-MENTATION TOOLS FOR TRUST-WORTHY AI SYSTEMS (2021)	AI					
OECD	AI IN HEALTH HUGE POTENTIAL, HUGE RISKS (2024)	AI	Yes				
OECD	AI, data governance and pri-vacy. SYNERGIES AND AREAS OF INTERNATIONAL CO-OPERATION (2024)	AI					
IEEE	IEEE Ethically Aligned Design (2020)	AI					

Organi-zation	Name of Instrument	THEMATIC AREAS					
		Technology	Health Specific	General AI's Concep-tual Clarifications or Position Statement	Guiding Principles (ethical or procedural)	Recommendations for AI's development & implementation	Recommendations for regulatory framework
G7	Hiroshima Process: Industry, Technology and Digital Minis-terial Declaration and Annex3 "Advancing the Outcomes of the Hiroshima Artificial Intelligence Process (HAIP)" (March 15, 2024)	AI					
G20	G20 AI Guidelines (2019)	AI					
WEF	AI for Impact: The PRISM Frame-work for Responsible AI in Social Innovation (2024)	AI					
WEF	Presidio AI Framework: Towards Safe Generative AI Models (2024)	Generative AI					
WEF	Unlocking Value from Genera-tive AI: Guidance for Responsible Transformation (2024)	Generative AI					
WEF	Generative AI Governance: Shaping a Collective Global Future (2024)	Generative AI					
WEF	The Presidio Recommendations on Responsible Generative AI (2023)	Generative AI					
WEF	A Framework for Developing a National Artificial Intelligence Strategy (2019)	AI					

Table 2: Thematic areas covered by global AI policies:

indicates an explicit coverage of the thematic area in the policy.

indicates only high-level mentions of the thematic area, for example, general considerations for AI regulatory frameworks or endorsing principles from another document in the list published by the same institution

2.3.1. Principles for AI

According to the PNAI, already in 2020 there were over 160 organizational, national, and international sets of AI governance principles[5]. However, they acknowledge the lack of a common platform to harmonize these initiatives. This is a common challenge observed in global governance efforts.

From an international perspective, the following principles have been established for AI in health:

WHO (ethical principles): (1) Protecting human autonomy; (2) Promoting human well-being and safety and the public interest; (3) Ensuring transparency, explainability, and intelligibility; (4) Fostering responsibility and accountability; (5) Ensuring inclusiveness and equity; (6) Promoting AI that is responsive and sustainable.

IMDRF (draft: guiding principles for good machine learning practice): (1) The device's intended use/ intended purpose is well understood, and multidisciplinary expertise is leveraged throughout the total product life cycle; (2) Good software engineering, medical device design, and security practices are implemented; (3) Clinical study participants and datasets are representative of the intended patient population; (4) Training datasets are independent of test sets; (5) Selected reference standards are fit-for-purpose; (6) Model choice and design are tailored to the available data and the intended use/ intended purpose of the device; (7) Performance is assessed with a focus on the human-AI team in the intended use environment; (8) Testing demonstrates device performance during clinically relevant conditions; (9) Users are provided with clear, essential information; (10) Deployed models are monitored for performance and re-training risks are managed.

OECD (principles for responsible stewardship of trustworthy AI [a]): (1) Inclusive growth, sustainable development and well-being; (2) Respect for the rule of law, human rights and democratic values, including fairness and privacy; (3) Transparency and explainability; (4) Robustness, security and safety; (5) Accountability.

To analyze AI principles, the OECD developed a framework that aligns each principle with desired outcomes and the mitigated risks[20]. For example, the principle of "transparency and explainability" addresses the risks of AI systems lacking transparency and the potential for biases. When this principle is implemented, the outcome is an AI system that is clear, trusted, and easily understood. The interoperability of AI principles can thus be viewed through the lens of achieving desired outcomes while mitigating shortcomings.

While some principles may support multiple outcomes or institutions may use different terminology, there is already a significant degree of alignment when principles are analyzed through the lens of their desired outcomes (Table 3). The most frequently referenced desired outcomes in AI principles include: (i) ensuring processes that are transparent and understandable to stakeholders (transparency/explainability/intelligibility); (ii) promoting human and societal well-being (safety, do no harm, respect for human rights, human-centered values); (iii) establishing clear mechanisms for accountability and responsibility; (iv) ensuring equitable access and outcomes, avoiding bias and discrimination (justice, equity, fairness, non-discrimination); and (v) respecting privacy and data security.

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a Endorse to be applicable to healthcare in OECD "AI IN HEALTH HUGE POTENTIAL, HUGE RISKS (2024)"

However, some important considerations - such as economic, social and environmental costs (of use, misuse, and under use), information integrity, dignity and the need for participatory approaches - are less prominently reflected in the principles. An interesting contrasting example is the WHO's Pan-American Health Organization (PAHO) principles 'for the use of AI in public health,' which explicitly emphasize human dignity, openness, and scientific integrity - principles that are not commonly observed on a global scale[24]. However, in 2024, transparency and explainability continue to be central themes in the global discussion. Many principles are often grouped into broader categories such as well-being, security, or "do no harm." This is likely because most principles (from 7 out of 9 institutions) are developed within ethical or human rights-based frameworks, which are generally broader to accommodate diverse moral expectations across different populations. Process-oriented principles (such as those from IMDRF or G7) are more explicit about providing specific guidance and explicitly address performance expectations.

Sustainability is treated as a standalone principle by only two institutions, while others incorporate it into broader concepts like sustainable growth or development. These trends are consistent with findings from previous landscape research on AI principles adopted by private companies and global governmental institutions[25,26]. In the UN report on governing AI for humanity, similar conclusions are drawn due to AI governance efforts already sharing a common language around principles like fairness, accountability, and transparency. However, they also highlighted the absence of key debates, such as balancing access with safety, limited global alignment on AI's implementation and addressing present versus future risks[27].

Organization	Framework	DESIRED OUTCOME								
		Preserve and enhance human decision-making	Promote human and societal well-being	Perform adequately and appropriately	Respect fundamental rights (privacy and security	Ensure equitable access & outcomes, avoid bias and discrimination	Foster clear accountability & responsibility mechanisms	Allow transparent & understandable processes to users and stakeholders	Consider long-term environmental & resources impact	Encourage involvement & collaboration of deiverse stakeholders
WHO	Ethics or human rights-based	(1) Protecting human autonomy	(2) Promoting human well-being and safety and the public interest			(3) Ensuring inclusiveness and equity	(4) Fostering responsibility and accountability	(5) Ensuring transparency, explainability and intelligibility	(6) Promoting AI that is responsive and sustainable	
UNESCO	Ethics or human rights-based	(1) Proportionality and Do No Harm		(2) Safety and Security	(3) Right to Privacy and Data Protection	(4) Fairness and Non-discrimination	(5) Responsibility and Accountability	(6) Transparency and Explainability	(8) Sustainability	(7) Awareness & Literacy (9) Multi-stakeholder and Adaptive Governance & Collaboration
OECD	Ethics or human rights-based	(2) Respect for the rule of law, human rights and democratic values, including fairness and privacy	1) Inclusive growth, sustainable development and well-being;	(4) Robustness, security and safety		(2) Respect for the rule of law, human rights and democratic values, including fairness and privacy	(5) Accountability	(3) Transparency and explainability	1) Inclusive growth, sustainable development and well-being;	
UNICEF	Ethics or human rights-based	(1) Support children's development and well-being		(5) Ensure safety for children	(4) Protect children's data and privacy	(2) Ensure inclusion of and for children (3) Prioritize fairness and non-discrimination for children (9) Create an enabling environment	(6) Provide transparency, explainability, and accountability for children		(1) Support children's development and well-being	(7) Empower governments and businesses with knowledge of AI and children's rights (8) Prepare children for present and future developments in AI
G20 (draw from OECD)	Ethics or human rights-based	(1) Inclusive growth, sustainable development and well-being (2) Human-centered values and fairness		(4) Robustness, security and safety	(2) Human-centered values and fairness		(5) Accountability	(3) Transparency and explainability	(1) Inclusive growth, sustainable development and well-being	

Organization	Framework	DESIRED OUTCOME								
		Preserve and enhance human decision-making	Promote human and societal well-being	Perform adequately and appropriately	Respect fundamental rights (privacy and security	Ensure equitable access & outcomes, avoid bias and discrimination	Foster clear accountability & responsibility mechanisms	Allow transparent & understandable processes to users and stakeholders	Consider long-term environmental & resources impact	Encourage involvement & collaboration of deiverse stakeholders
G7	Process-based		(1) Take appropriate measures throughout the development of advanced AI systems, including prior to and throughout their deployment and placement on the market, to identify, evaluate, and mitigate risks across the AI lifecycle. (5) Develop, implement and close AI governance and risk management policies, grounded in a risk-based approach – including privacy policies, and mitigation measures, in particular for organizations developing advanced AI systems (6) Invest in and implement robust security controls, including physical security, cybersecurity and insider threat safeguards across the AI lifecycle (7) Prioritize research to mitigate societal, safety and security risks and prioritize investment in effective mitigation measures				(2) Patterns of misuse, after deployment including placement on the market (3) Publicly report advanced AI systems' capabilities, limitations and domains of appropriate and inappropriate use, to support ensuring sufficient transparency, thereby contributing to increase accountability. (4) Work towards responsible information sharing and reporting of incidents among organizations developing advanced AI systems including with industry, governments, civil society, and academia. (5) Develop, implement and close AI governance and risk management policies, grounded in a risk-based approach – including privacy policies, and mitigation measures, in particular for organizations developing advanced AI systems (6) Develop and deploy reliable content authentication and provenance mechanisms, where technically feasible, such as watermarking or other techniques to enable users to identify AI-generated content		(8) Prioritize the development of advanced AI systems to address the world's greatest challenges, notably but not limited to the climate crisis, global health and education	
UN (also ITU)	Ethics or human rights-based	(1) Do no harm (7) Human autonomy and oversight		(2) Defined purpose, necessity and proportionality (3) Safety and security	(3) Safety and security (6) Right to privacy, data protection and data governance	(4) Fairness and non-discrimination	(9) Responsibility and accountability	(8) Transparency and explainability	(5) Sustainability	(10) Inclusion and participation

Organization	Framework	DESIRED OUTCOME								
		Preserve and enhance human decision-making	Promote human and societal well-being	Perform adequately and appropriately	Respect fundamental rights (privacy and security	Ensure equitable access & outcomes, avoid bias and discrimination	Foster clear accountability & responsibility mechanisms	Allow transparent & understandable processes to users and stakeholders	Consider long-term environmental & resources impact	Encourage involvement & collaboration of deiverse stakeholders
IEEE	Ethics or human rights-based	(1) Human rights: Respecting and protecting internationally recognized human rights	(2) Well-being: Prioritizing the overall well-being of humanity and the environment	(5) Minimizing misuse: Designing systems to achieve their intended purpose while minimizing unintended consequences	(1) Human rights: Respecting and protecting internationally recognized human rights		(3) Accountability: Ensuring that designers and operators are responsible and accountable	(4) Transparency: Ensuring AI systems operate transparently	(2) Well-being: Prioritizing the overall well-being of humanity and the environment	
IMDRF	Process-based	(7) Performance is assessed with a focus on the human-AI team in the intended use environment		(1) The device's intended use/ intended purpose is well understood, and multidisciplinary expertise is leveraged throughout the total product life cycle (3) Clinical study participants and datasets are representative of the intended patient population (4) Training datasets are independent of test sets (5) Selected reference standards arefit-for-purpose (6) Model choice and design are tailored to the available data and the intended use/ intended purpose of the device (7) Performance is assessed with a focus on the human-AI team in the intended use environment (8) Testing demonstrates device performance during clinically relevant conditions (10) Deployed models are monitored for performance and re-training risks are managed	(2) Good software engineering, medical device design, and security practices are implemented			(9) Users are provided with clear, essential information	(7) Performance is assessed with a focus on the human-AI team in the intended use environment	

Table 3: Institutional principles categorized per expected outcome (when these are adopted).

2.3.2. Frameworks and Recommendations for AI

While AI principles provide the general foundation for global regulatory debates, many of the reviewed policies include explicit policy-making recommendations, each with varying levels of detail. Most institutions, such as WHO/ITU, UN, UNESCO, United Nations Children's Fund (UNICEF), OECD, and WEF, have published at least one document dedicated solely to recommending specific steps for effective regulatory frameworks for AI. The WEF developed a framework for national AI policies (2019), UNICEF focused on AI policies for children (2023). Recently in 2024, WEF and WHO addressed governance of generative AI and LMMs, respectively. The WHO's regulatory guidelines specifically address the unique challenges of AI in health, while other institutions propose broader, cross-sectoral approaches to AI regulation. Generally, recommendations can be categorized into three areas: first, those suggesting processes for developing effective regulations; second, those addressing specific regulatory considerations such as accountability mechanisms and documentation transparency; and third, those recommendations focused on creating policies that foster environments conducive to the effective development and use of AI, such as investing in research and development and building human and economic capital. Many of the recommendations aimed at fostering supportive environments are not unique to AI but are standard tools governments use to enhance technological growth and deepen their understanding of emerging technologies. For example, the OECD has provided such suggestions for governments in their 2019's recommendations[28].

All institutions have expressed their support for the development of governance frameworks at a global and national level. The WHO has recommended that governments must introduce and enforce regulatory standards for AI in health[19,29]. The G20 promoted the development of multi-stakeholder, consensus-driven global AI technical standards and agile policies. The OECD suggested establishing methods for certification and regulation of AI solutions in health[20]. The WHO has suggested flexible and scalable regulatory approaches but has also suggested governments consider "adopting models of co-regulation with the private sector to understand an AI technology, without limiting independent regulatory oversight"[30]. Other institutions have been less detailed in their recommendations for frameworks, focusing instead on offering guidance around the requirements and processes needed to effectively evaluate AI systems. International institutions like the OECD[20,30,31] and WEF[32] have also advocated for the use of regulatory sandboxes in policy development. These controlled environments allow for the testing and refinement of new technologies, such as AI, in a safe and supervised setting before broad implementation.

The UN has emphasized that AI governance **"cannot rely on self-regulation alone: binding norms enforced by member states consistently are needed to ensure that public interests, rather than private interests, prevail"**[27]. There is increasing support for adaptive regulatory frameworks, rather than relying on rigid, prescriptive measures. However, no institution has yet published a model law outlining what such binding norms might look like. The European Union's (EU) AI Act (2024), though, serves as a regional example of a potential approach to establishing binding regulations. Other jurisdictions appear to be taking inspiration from the EU's risk-based model. For instance, Brazil and Chile have recently introduced bills or drafts for discussion that adopt a risk-based approach to AI regulation[33]. Particularly, the **risk-based approaches**, which prioritize measuring harms and mitigating risks in proportion to their impact on life, safety, security, and other critical areas, **are also increasingly supported** by international organizations. The WHO, G7, ITU have proposed a risk-based approach to AI regulatory frameworks[19,34,35] while the OECD has recommended an outcome-based approach[29]. The UN recommended that governments implement ethical impact assessments for AI technologies, while UNICEF proposed a child rights' impact assessment, both implicitly are risk-based approaches as they evaluate different levels of impact. In healthcare, risk-based approaches have long been used to address the nuances and complexities associated with the use of technology in patient care, and they are

a well-established foundation in MDRs. Recognizing this, the WHO acknowledges that the IMDRF's risk-based frameworks for SaMD could serve as a valuable model for developing effective regulatory approaches for AI in health[19]. This alignment could ensure that AI technologies are held to the same rigorous safety and performance standards as other medical devices, and potentially utilize already available regulatory infrastructure.

In recently released governance recommendations for LMMs applications in health, the WHO explicitly stated that "governments should, as resources permit, **assign an existing or new regulatory agency** to assess and approve LMMs and applications intended for use in health care or medicine" [36]. Similarly, the UN emphasizes that "effective governance should l**everage existing institutions that will have to review their current function**s in light of the impact of AI. **New horizontal coordination and supervisory functions** are required and they should be entrusted to a new organizational structure"[27]. Both statements suggest that, at the national level, leveraging established medical device regulatory processes offers a viable path for implementing AI regulations but that it may require adaptations - particularly for addressing emerging technologies not traditionally classified as having a medical purpose. To establish an effective governance system for AI in healthcare, a combination of regulatory frameworks will likely be required. National policies could include AI standards, binding norms based on risk-based approaches, and regulatory frameworks which also offer opportunities for both co-regulation and self-regulation. The choice lies within a regulatory spectrum: from permissiveness with softer regulations to restrictions through binding norms. However, how different jurisdictions will implement and strike a balanced, multi-layered governance framework remains to be seen.

There is a growing alignment around two key regulatory requirements. First, as discussed, **transparency** - especially in documentation - has become a fundamental principle guiding AI development and is widely recommended as an essential requirement for enabling human oversight within regulatory frameworks. Transparency is often viewed as a tool that allows for evaluations and to determine thresholds for safe usage of AI technologies. Second, in a risk-based approach, impact assessments are essential for accurately defining risks and determining the appropriate level of mitigation strategies and regulatory requirements. The use of **impact assessments** is strongly endorsed by leading institutions (such as WHO/ITU, UNICEF, UNESCO, UN, OECD, WEF, and IEEE) and typically encompass a combination of ethical, human rights, safety, and data protection/privacy considerations. Various institutions bring their unique perspectives to these assessments. For instance, responding to health-specific needs, the WHO/ITU FG-AI4H provides recommendations for impact assessments that include clinical evaluations, pre-market development and post-market continuous surveillance.

UNICEF highlights the importance of including children's rights perspectives in impact assessments - a consideration often overlooked[36]. The WEF emphasizes factors like business impact, operational readiness, and investment strategy. Meanwhile, the OECD recommends developing measures for the availability, use, and impact of AI in health[20]. Together, transparency and impact assessments form one of the most recommended foundations for responsible AI regulation. Based on the impact assessment and determined risk level, other regulatory requirements to be recommended

"AI governance cannot rely on self regulation alone: binding norms enforced by member states consistently are needed to ensure that public interests, rather than private interests, prevail".

could be risk-proportional. For example, needing more documentation and record-keeping for AI systems that are high-risk. The WHO and IMDRF have suggested such an approach for regulatory frameworks on AI health[19,36]. While an in-depth discussion of cybersecurity, data privacy, and data handling requirements is beyond the scope of this subsection, it is important to highlight that health data is typically classified as sensitive and is generally recommended to be subject to higher levels of security and privacy requirements.

The WEF highlights a significant issue: although there is widespread agreement on the need for risk-mitigation strategies and increasing endorsement of risk-based frameworks, the details remain unclear - especially concerning key factors like accountability, effectiveness, and benchmarking that are essential for evaluating risk [9]. Uncertainty exists over when and at what stages of the AI design, development, and deployment process different guardrails should be applied. In terms of benchmarking, two recommendations stand out. The WHO advises that evaluations should be made against widely accepted standards, such as human performance in similar tasks or other well-established models, like those based on logistic regression or validated through randomized control trials, with robust supporting evidence [19]. The WEF, meanwhile, calls for holding AI models accountable to the highest established benchmarks while also exploring new metrics that go beyond traditional measures, integrating human-centric dimensions 33. However, harmonizations in these areas have yet to be fully established.

Another key consideration from a risk perspective is the need to categorize and address unacceptable risks, especially those deemed too high to allow for the continued development or implementation of AI systems. However, discussions around what constitutes unacceptable risk are relatively rare on a global scale. In the case of the UN, they emphasize the need to "refrain from or cease the use of artificial intelligence systems that cannot be operated in compliance with international human rights law or that pose undue risks to the enjoyment of human rights"[37]. WHO suggests that regulators may need to ensure developers have considered whether there are specific circumstances in which a tool should not be used. For example, this could include cases where there is insufficient training data for certain patient groups or a lack of validation in particular settings, as well as risks associated with using the tool outside its intended context [19]. However, what specific AI technologies will be deemed unacceptable for use in health has yet to be clearly defined. Establishing explicit guidelines will require careful consideration of ethical concerns, safety, compliance with human rights standards, and potential risks to human well-being. These determinations will likely evolve as regulatory bodies, industry experts, and international organizations work to establish clear criteria for evaluating, validating and categorizing (very) high-risk AI technologies in health.

2.3.3. Standards for AI

As illustrated previously in Figure 2, standards are the most common mechanism for AI governance. ISO/IEC 42001:2023 is the world's first international standard dedicated to AI management systems, which was developed through international collaboration involving diverse stakeholders. Additionally, the ITU has been developing international AI-related technical standards across multiple sectors. To date, it has published over 100 standards, many of which focus on technical architecture or sectors not directly related to healthcare. There are reports of 120 more standards currently in development as of 2024 10. While standards can complement other governance mechanisms - because they provide the technical foundations that support regulatory frameworks, guide industry best practices, and offer structured frameworks for self-regulation - the increasing amount of documentation is a potential challenge for innovators and regulators worldwide[10,38]. At the current high-level summary, we are unable to evaluate the degree of harmonization among the standards, however, fragmentation and inconsistency is a likely challenge that global institutions may face with every new document published. The sheer number of standards can overwhelm organizations, complicating implementation and increasing costs associated with compliance, training, and development. There are also multiple gaps regarding their enforce-

ability and overcoming this hurdle requires concerted effort from country-level regulators and innovators alike to incentivize - or mandate - compliance.

The WEF also recognized that there are concerns that substantial divergences in approaches to setting AI standards threaten a further fragmentation of the international AI governance landscape, lending to downstream social, economic and political implications internationally[6]. According to the WEF, there is no assurance that every country will adhere to these standards, particularly if there are concerns that local interests were not adequately considered during their development. Therefore, it is essential to create the capacity and opportunities for broader participation in the standards-making process.
Many general technology standards would be applicable to AI in health, depending on how the applications or solutions are implemented. As countries develop their national AI in health policies, including Medical Device Regulations (MDRs), it is essential to observe which standards gain the most traction. This will inform future development efforts and ensure that the most effective and widely adopted standards continue to adapt to AI's changing landscape. For the ITU, their agenda 2022-2024 was set on the fundamental standardization of multimedia systems and services to support digital health applications[21] . Once fundamental infrastructure standards are established, the ITU's focus may shift toward AI, including the development of AI-specific standards in areas like health. This could lead to an increase in the overall number of standards for AI in health.

2.4. Participatory Engagement

Collaboration at both national and international levels is essential for the successful development of interoperable AI governance in health. Given AI's complexity and its broad impact on global health, coordinated efforts across a diverse range of stakeholders—including governments, regulatory bodies, healthcare providers, developers, manufacturers, patients, and civil society - are crucial. Effective AI governance in health cannot be accomplished in isolation; it demands a collective effort that tackles both the opportunities and challenges posed by AI, responds to the nuances of healthcare systems and acknowledges the important role of communities. This approach ensures that AI technologies benefit society while safeguarding safety, human rights, and public trust.

It is widely acknowledged by global institutions that participatory engagement serves as a key tool in the policy-making process, enabling different groups to contribute their expertise and perspectives to shape AI policies. This engagement operates both at the individual group level and on a broader international scale, ensuring diverse input and alignment across regions. At a group level, global institutions widely recognize the need and have emphasized the importance of participatory approaches in AI policy development. In particular, the WHO highlights the critical role of engagement and collaboration among diverse stakeholders - such as developers, manufacturers, healthcare practitioners, patients, patient advocates, policymakers, and regulatory bodies - to improve the safety and quality of AI in health[19]. In various ways, institutions consistently promote AI governance that is inclusive, universal, and collaborative. Particularly for experts, AI standards offer a strong example of how this group-level participation can be effective. These standards are built on and with expert opinions and require direct involvement from relevant stakeholders. This collaborative approach forms the foundation of work conducted by organizations such as the IMDRF, WHO/ITU FG-AI4H, ISO, IEEE, and ITU.

Unlike other participatory engagements - such as UN Groups of Experts, which primarily serve in advisory capacities - experts involved in standards-setting organizations have the authority to directly shape what is expected on AI's developmental lifecycle. These standards can carry significant weight, influencing global governance both in practice (de facto) and in legal frameworks (de jure). On an international scale, the UN's 2023 interim report calls for a global framework that ensures equal participation from all member states, promoting broad inclusivity, mitigating the risks of geopolitical competition driving irresponsible AI development or unequal distribution of its benefits[27]. Similarly, the OECD supports fostering knowledge-sharing through international, cross-sectoral, and open multi-stakeholder initiatives to build long-term expertise in AI governance[20,29].

While diverse stakeholder engagement is often promoted in global institutions, a closer examination reveals significant disparities in representativeness and challenges to meaningful participation in their own AI policies. In the case of WHO policies, the majority of external contributors tend to predominantly from high-income countries, often with double the representation compared to other income groups[19,30,36]. The FG AI4H document for "Good practices for health applications of machine learning" had 12 contributors from high-income countries, with a significant portion coming from Germany and the USA[39]. The IMDRF Authoring Group on AI/ML had participants from 11 high-income countries and three upper-middle-income countries, but none from low-income countries[40]. However, the African Medical Devices Forum (AMDF) and the GHWP represent Africa and Asia in IMDRF's group, respectively. Latin America is included through Argentina, Brazil, and PAHO. Organizations like the OECD, G20, and G7 are represented by their member states, which are mostly high-income countries. Industry involvement is prominent in the authorship of AI policies, with direct collaborations with the

WEF, WHO and through industry associations in IMDRF. In terms of gender representation, it is worth noting that there is a global trend where men experts are more prevalent than women[41,42].

The presence of patient voices, advocacy groups, and the public in general remains limited, suggesting a need for further exploration. While some lower- to middle-income countries, such as Brazil, Argentina, Saudi Arabia, South Africa, India, and Uganda, are frequently represented through their experts, many others are notably absent from the reviewed policies. This disparity may stem from the uneven global distribution of AI experts, who are predominantly male and based in high-income countries[41,42]. This highlights the need for greater efforts to improve participatory engagement, including valuing diverse forms of expertise, such as the lived experiences of patients, and actively building human capital to promote broader representation of diverse people and countries perspectives. Bélisle-Pipon et al., has cleverly used the term "black-box problem," in reference to the opacity surrounding authorship and representation on global AI policies - including those developed by industry[43]. UNICEF similarly emphasizes the challenge of integrating young perspectives into AI governance, an important but often neglected aspect that could provide significant benefits if given proper attention. However, unless global institutions take the lead in setting a standard for participatory engagement, it is unlikely that other organizations will rise to the challenge.

3. Jurisdictions Influencing AI Regulations in Health

As outlined in Section 2, countries, when addressing AI governance in health, commonly deploy a combination of soft guardrails, such as principles, guidelines, standards and strategies, to encourage the development and deployment of Responsible AI in health. On a country-level, the creation of binding laws is one additional tool commonly used by governments to ensure AI is compliant with specific practices and requirements.

It is important to note that although no sui generis AI legislation exists yet for the health sector in many jurisdictions/countries, AI applications in healthcare are not unregulated and currently fall in the broader category of existing MDRs concerning SaMD or software related to medical devices. Indeed, IMDRF defined SaMD as "software intended for one or more medical purposes that perform those purposes without being part of a hardware medical device. To encourage harmonization of SaMD regulation in different countries, IMDRF has released several guidelines on key definitions, risk categorization, quality management system, clinical evaluation and software validation[44]. Additionally, some countries are starting to release specific considerations for regulating AI/ML in health such as the UK's ML-enabled medical device guiding principles or FDA's guidelines for AI and medical device products. While there are many open questions regarding the extent to which MDRs can effectively support the responsible implementation of AI in healthcare, at the moment, all AI that has a medical purpose - whether explicitly or implicitly regulated - will most likely require compliance with MDRs.

Regarding the creation of national AI laws, the AI Index Report 2024 put forth by Stanford University, concluded that mentions of legislation examining AI took place in 128 countries in 2023 and 32 of them have passed at least one AI-related law[45]. Currently, a total of 148 AI-related laws have been enacted worldwide. As legislators across the globe demonstrate increased interests to regulate AI, moving from voluntary alignment to mandatory compliance, a multi-layered regulatory framework will eventually emerge for AI applications in healthcare, consisting of AI regulations, MDRs as well as other fundamental laws addressing data, intellectual property and human rights.

There are multiple global players influencing the approach to AI regulatory frameworks in distinct ways - as there is currently no unified global approach. Given the increased support for binding laws, this section will focus on legislation and soft guidance aimed at regulating AI in health in the USA, EU, United Kingdom (UK) and the People's Republic of China (PRC). These global stakeholders have strong geopolitical influence in their regions and worldwide, and have demonstrated advancements towards having government oversight in the mitigation of risks posed by AI across various sectors. In particular, they have also been identified as pioneers in regulating AI in the sector of health[46,47]. Through them, examples of how varied approaches towards regulation of AI in health can work for different jurisdictional visions and needs would be highlighted.

3.1. United States of America

Since its establishment in 1906, the Food and Drug Administration (FDA) has positioned itself as a leader in the regulation of medications and medical devices amongst an array of other products. Many countries with less regulatory capacity rely on strategies where FDA-approved health products would follow an expedited regulatory process to gain access to their local markets. It is therefore not surprising that countries around the world continue to observe FDA's approach in regulating AI applications in health, while calibrating their own measures. The Federal Food, Drug, and Cosmetic Act (FDCA) is the overarching legal framework under which the FDA operates for the regulation of drugs and medical devices. In 2016, FDCA (Section 520) was amended to include specific provisions for SaMD (21st Century Cures Act, 2016) where broad guidelines for SaMD regulation, such as defining what constitutes SaMD, pre-market approval requirements and post-market controls, were established[48].

The US FDA has harmonized its regulatory framework for SaMD with IMDRF guidelines while taking in consideration US legislation and context. The FDA has adopted many IMDRF principles and frameworks, including key definitions and quality management system principles for SaMD. In terms of its risk classification framework for SaMD, the FDA has adapted IMDRF's four-class system to a three-class system (I to III with I being low risk and III being high risk) to ensure alignment with its existing classification for medical devices[49]. Pre-market clearance (510(k)) is needed to demonstrate safety and effectiveness of medical devices from all risk classes, while pre-market approval is required for class III devices which support human life, prevent impairment of human health, or present high risks of illness or injury[50]. De Novo classification is another regulatory process for devices that present low to moderate risk but do not have a legally marketed predicate.

However, it has been acknowledged that the above-mentioned regulatory pathways are insufficient when regulating adaptive AI and other ML technologies[51]. A paradigm shift is warranted and **since 2019, the FDA has published discussion papers, action plans and guiding principles, putting forth regulatory considerations for AI/ML-based SaMD.** Notably, ten guiding principles for **Good Machine Learning Practice for Medical Device Development** were published jointly with Health Canada, and the UK's Medicines and Healthcare Products Regulatory Agency (MHRA) in 2021[52]. Through these principles, emphasis are placed on (i) leveraging multi-disciplinary expertise in the development of AI/ML-based SaMD, (ii) implementing good software engineering and security practices; (iii) ensuring representation of the targeted patient population through inclusive selection of clinical study participants and establishment of data sets based on best available methods; (iv) maintaining training and test datasets to be independent of each other; (v) designing models where the clinical benefits are clear and known risks actively mitigated with a focus on human interpretability of the model outputs; (vi) testing the device in clinically relevant conditions; (vii) providing users with concise and contextually relevant information appropriate for various stakeholders, such as patients and healthcare professionals; and (viii) monitoring models for performance and adverse events once it has been deployed in the real-world. It is interesting to note that the principles focus mainly on performance metrics and do not include ethical and societal considerations, such as sustainability, inclusiveness and equity, which have been promoted by international organizations like the WHO and UNESCO [30,53].

Given that significant changes to a model can occur post deployment in real-world settings, additional regulatory oversight would be necessary to ensure continued safety and effectiveness of the AI/ML-SaMD. To address such risks in a timely and continuous manner, FDA has also published recommendations and guiding principles in 2023 for **predetermined change control plans** where during pre-market clearance, the manufacturer could provide details on predicted planned modifications to a device and protocols for implementing and controlling them, as well as, how they would evaluate the impact resulting from the modifications[54].

In its latest guidance on **ensuring transparency for AI/ML-SaMD** (2024), the FDA highlighted the need to communicate appropriately to various stakeholders contextually relevant information on the intended medical purpose and function, product development and risk management activities across the total product lifecycle, performance (including summaries of clinical studies demonstrating safety and effectiveness and clinically relevant limitations) and where possible, logic, of the device[55]. For such communication to be useful and effective, one should have a comprehensive understanding of the users, environments and workflows and utilize the most appropriate media, timing and strategies to do so. Finally, the importance of "human-centered design" which emphasizes on the whole user experience and the need to engage end users and other relevant stakeholders in the design and development of AI/ML-SaMD was further underscored in the guidance.

Although **there is currently no wider AI legislation in place that would apply to the health sector in addition to MDRs**, the President's Executive Order on Safe, Secure, and Trustworthy AI which emphasizes the creation of new standards for AI safety and security among other directives, have set several initiatives in motion[56]. Notably, the National Institute of Standards and Technology (NIST) has released an AI Risk Management Framework (NIST AI 100-1, RMF 1.0, 2023) which provides recommendations on establishing processes, documents, schemes and accountability structures to anticipate, identify, measure and mitigate AI risks[57]. How these voluntary suggestions would be taken up in the health sector remains to be seen. In addition, the Department of Health and Human Services (HHS) has also recently announced a reorganization that would strengthen their AI strategy and policy function[58]. The new Assistant Secretary for Technology Policy and Office of the National Coordinator for Health Information Technology (ASTP/ONC) would have additional focus on developing AI policy and strategy, and coordinating the department's approach to AI in the sectors of health and human services.

It is interesting to observe how in its efforts to govern AI, the USA adopts a sectoral approach, as opposed to a horizontal one. In particular, for health, current regulatory infrastructure and capacity have been leveraged, with existing health and regulatory agencies having opportunities to restructure and reconsider the scope and applicability of existing regulations for AI in health. This is in contrast to other parts of the world, especially Europe, covered next.

3.2. European Union

The EU has been considered a trailblazer when its Council adopted the EU AI Act in May 2024, which has since gone into force across all the EU member states on the first of August 2024. Enforcement of the totality of the provisions of the AI Act is expected to take place 24 months after. **As the world's first extensive law for AI, the AI Act (2024) is a horizontal legislation which applies across all industries, including health, and adopts a risk-based approach to the regulation of AI**[58].

All AI systems are classified into four categories depending on whether they have minimal, limited, high, and unacceptable risks. AI systems are always considered to be high-risk if it profiles individuals. For example, in the health sector, AI systems which use personal data to assess various conditions of a patient to create an individual profile, such as for diagnosis and triage, are classified as high risk. High-risk AI systems must comply with requirements, including data governance, quality management systems, technical documentation, record-keeping, transparency, human oversight, accuracy, robustness, and cybersecurity, risk management, and post-market surveillance. A conformity assessment is mandated for each high-risk AI system before market entry [58 Art. 43]. This assessment can be conducted by providers themselves through internal processes or by third-party Notified Bodies (NBs) [58 Art. 34]. NBs are accredited organizations authorized to evaluate and certify AI systems' compliance. They conduct pre-market assessment, issue CE certificates for compliant products, and perform ongoing surveillance of certified products. A new assessment is required if the AI system undergoes modifications that significantly impact its compliance to the AI Act. The main objective here is to ensure that the AI systems meet the required safety and performance standards before being marketed in the EU.

Before the AI Act came into effect, **AI applications in health have been primarily regulated under the "European Medical Devices Regulations" at the EU member state level**, with the European Medicines Agency (EMA) providing technical and scientific support during the regulatory process. Medical devices are classified into four risk classes, namely I, IIa, IIb or III, depending on their intended medical purposes[59]. AI/ML-SaMDs are generally classified as Class IIa, IIb or III. For example, AI systems used for interpreting diagnostic images as well as for monitoring patient vitals and providing alerts for critical conditions are classified as Class IIa or IIb. On the other hand, AI systems that provide therapeutic decision support are often classified as Class IIb or III. Similar to the AI Act, under the EU MDRs, Class IIa, IIb, and III AI systems will also have to undergo a NB conformity assessment [59 Article 51, Annex VIII]. In particular, it has to be subjected to comprehensive clinical evaluations to demonstrate its safety and performance. Quality management system that covers the entire life cycle of the AI/ML-SaMD, together with a robust post-market surveillance system should be in place. To enhance traceability and transparency, the use of Unique Device Identifiers is mandatory.

It is not yet clear how the AI Act will interplay with the EU MDRs. Currently, the AI Act could potentially complement the EU MDRs, and any AI/ML-SaMD must comply with both legislation, ensuring they meet safety, efficacy and ethical standards[60]. Table 4 further highlights key areas of interplay between the two legislations.

There is evidence that regulations in Europe can affect how other regulators implement law in different world regions and it is currently still an open question how the AI Act will influence AI legislative initiatives globally. The Brussels effect, a term coined by Anu Bradford in 2012, describes the EU's ability to influence norms and standards beyond its borders through market mechanisms[61]. Indeed, the General Data Protection Regulations (GDPR) has impacted data protection legislative debates in the USA, Latin America, Africa, and Asia[62].

Area of Consideration	Interplay between EU AI Act and EU MDRs
Risk classification	Both adopt a risk-based approach but apply different classification criteria: MDRs use specific medical-related criteria based on intended use and potential risk of harm to users while AI Act employs broader criteria that considers the impact of the AI systems on fundamental rights and safety. AI/ML-SaMD that fall under risk classes IIa, IIb or III under the MDRs are automatically classified as high risk AI systems under the AI Act.
Regulatory target	MDRs regulate medical devices as a whole, including AI/ML-SaMD, while the AI Act specifically targets the AI component within those devices.
Regulatory requirements	There are overlaps between both legislation in areas like risk management, technical documentation and post-market surveillance. However, clinical evaluation is mandated under the MDRs, while the AI act has additional requirements with regards to data governance, human oversight, transparency, accuracy, robustness and cybersecurity.
Conformity assessment	The AI Act aims to integrate its conformity assessment procedures with the MDRs, allowing for a single assessment by NB authorized for both legislations. • In terms of technical documentation, a single set of documentation for both legislation is permitted.

Table 4: Significant areas of interplay between the EU AI Act and the EU MDRs

Within two years of its launch, major tech companies were seen announcing their implementation of GDPR for all their customers globally[62]. It will therefore not be surprising if the EU AI Act will have a similar global influence. The AI Act has already raised the profile of and increased dialogues on the risks associated with AI applications in everyday life, including health.

During its finalization, the AI Act has received iterative changes to accommodate concerns about the AI Act stifling innovation within the region. The EU has also been in active exchanges with international partners outside the EU regarding this legislation, with the EU-US Trade and Technology Council as an example of such a cooperation. These actions demonstrate commitments by the EU to strike a regulatory balance between keeping citizens safe and promoting innovation, as well as adopting a participatory engagement approach in their development of regulatory frameworks.

3.3. People's Republic of China

The Center for Medical Device Evaluation (CMDE) of the National Medical Products Administration (NMPA) has the responsibility of regulating and registering all medical devices entering the Chinese market. Emphasis is placed on standards management, processes for quality assurance, and post-market risk management[63]. In the area of AI/ML-SaMD, CMDE has released several important regulatory guidelines. **In 2019, it published a report on the "Elements for the Review of Deep Learning-Assisted Decision-Making Software for Medical Devices"**[64]. The scope of the regulation includes deep-learning-based decision support software which uses medical data to assist in clinical decision-making. Within the report, there is a focus on: (i) software requirements analysis; (ii) data quality control, with emphasis on diverse and representative data; (iii) good design and generalization of the algorithm, with attention to interpretability, robustness and reproducibility; (iv) risk management, in particular clinical risk throughout the software lifecycle; (v) and validation, including clinical trials and evaluation, to ensure the safety and effectiveness of the software. Additional considerations on addressing cybersecurity threats were also highlighted.

In 2021, CMDE further released "Guiding Principles for Defining the Classification of AI Medical Software Products", aiming to guide the classification and quality control strategies of AI medical devices based on their intended clinical use, the type of data the system processes, its core functions, and potential risks to patients[65]. AI medical devices with low risk are classified as Class I and assessed according to existing medical device regulations, while AI medical software with high risk is classified and regulated as Class II and III medical devices if they are used for non-decision support and clinical decision support respectively. More recently **in 2022, the organization launched the "Guidelines for the Review of AI Medical Device Registrations"**, which provide an extensive regulatory framework for ensuring proper technical evaluation and quality assurance of Class II and III AI medical devices[66]. These guidelines not only outline standards for the establishment of quality management systems covering the total product lifecycle, including the conduct of an algorithm traceability analysis, but also highlight considerations on cyber- and data security and human factors design to improve usability.

In terms of horizontal AI legislation which would also be applicable to the health sector, the Cyberspace Administration of China, along with six other Chinese regulators, jointly issued the **"Interim Measures for the Management of Generative Artificial Intelligence Services" in 2023**[67]. Based on previous regulations concerning deep synthesis[68] and algorithm management[69], the Interim Measures have been in effect since 15 August 2023 and apply to the development and use of generative AI technologies, including in medical applications, to provide services to the public within China's territory. The Interim Measures introduced a "classified and graded" regulatory oversight which suggests a risk-based approach, but the specific classifications have yet to be released by the relevant authorities. It is interesting to note that such an approach is applied at the sectoral level where providers from varied industries will be regulated by different authorities and departments. This is in contrast to the generalized approach provided by the EU AI Act. Notably, providers must conduct security assessments and file algorithm information for services with "public opinion attributes" or "social mobilization capacity", label generated content conspicuously as AI-generated, as well as establish service agreements between them and the users, specifying rights and obligations of both parties. Given the strong emphasis on balancing innovation and security, the Interim Measures demonstrate both the PRC's global ambitions towards AI innovations, and its commitment in developing a comprehensive AI law in the future[70].

Finally also in 2023, the Chinese government launched the **Global AI Governance Initiative** where it calls on countries worldwide to collaborate on AI governance through knowledge exchange and technical cooperation amongst diverse stakeholders, namely, governments, international organizations, private sector, research academia, civil society organizations and even individuals[71]. Notably, emphasis is placed on (i) promoting people-centric approaches to the sustainable development of AI; (ii) developing AI for good by taking into account relevant global legislation and "humanity's common values of peace, development, equity, justice, democracy, and freedom"; (iii) using a risk-based and agile approach in the assessment and evaluation of AI systems; (iv) putting ethics first and adhering to principles of fairness and non-discrimination; (v) promoting participatory engagement from diverse stakeholder to achieve broad consensus; and (vi) expanding representation of developing countries in global AI governance. The initiative demonstrates an alignment with existing international perspectives and bores well for further harmonization of global AI regulatory efforts.

3.4. United Kingdom

Under the Medicines and Healthcare Products Regulatory Agency (MHRA), the "**Software and AI as a Medical Device Change Programme**", was established in 2021[72]. It represents MHRA's effort to adapt its regulatory framework to the unique challenges presented by SaMD and AI as a medical device (AIaMD). The programme consists of eleven work packages, focusing on key reforms across SaMD lifecycle, including cybersecurity and data privacy risks, and post-market evaluation, while also addressing challenges specific to AIaMD including AI algorithm bias, and interpretability of AI. One of the work packages aims to reform classification rules for SaMD (four risk categories) such that it is more aligned to the IMDRF "**SaMD: Possible Framework for Risk Categorization and Corresponding Considerations**"[73].

MHRA is also working with the National Institution for Health and Care Excellence (NICE) and the National Health Service (NHS) England on the Evidence Standards Framework for Digital Health Technologies to ensure this aligns with SaMD classification rules wherever possible[74]. The framework was first published by NICE in 2019, providing the regulatory framework for a range of products such as apps, software, and online platforms that can be standalone or combined with other health products. In addition, it introduced the idea of a pilot regulatory sandbox, AI-Airlock, for AIaMD, which was launched in May 2024[75]. This proactive, collaborative and agile approach aims to identify and address challenges faced by AIaMD. A key difference between the AI Airlock and other regulatory sandboxes is the need for collaboration across many regulatory, governance, and assurance organizations in healthcare. It will bring together expertise from within MHRA and key partners including the UK Approved Bodies, the NHS, and other regulators to test a range of regulatory issues for AIaMD using real-world products.

In addition, the Regulatory Horizons Council of the UK, which provides expert advice to the UK government on technological innovation, published "**The Regulation of AI as a Medical Device" in November 2022**[76], which complements MHRA's "Software and AI as a Medical Device Change Programme". Key recommendations were provided to develop a regulatory framework that balances patient safety, effectiveness, and equity with the need to bring high-quality AIaMD innovations to patients: (i) Increase regulatory capacity and capability within MHRA; (ii) Create a whole product lifecycle regulatory framework that adopts a "legislatively-light" approach. It also recommends manufacturers provide evidence of safe performance across diverse populations and show efforts to improve equity; (iii) Ensure an open and transparent regulatory process with increased public engagement; (iv) Pursue international collaboration and harmonization.

"The government will seek to establish the appropriate legislation to place requirements on those working to develop the most powerful artificial intelligence models".

– UK Prime Minister Keir Starmer

With regards to broader AI legislation, the UK government issued a white paper titled "**A pro-innovation approach to AI regulation" (March 2023, and subsequently updated in August 2023)**[77], and a written response to the feedback it received as part of its consultation on the white paper (February 2024)[78].

Both documents indicate the UK's context- and sector-specific regulatory approach to AI, instead of a cross-sectoral one. UK supports a principles-based framework for existing sector-specific regulators to interpret and apply to the development and use of AI within their domains, stating that this non-statutory approach currently offers "critical adaptability" to keep pace with the rapid advances in AI technology. Regulators will need to develop sector-specific guidance on how the cross-sectoral principles apply within their domain, having due regard that the principles may eventually become a "statutory duty on regulators". The five key principles include: safety and security; transparency and explainability; fairness; accountability; and suitable redress.

However, in July 2024, the new UK government under Prime Minister Keir Starmer outlined plans for AI regulation, stating in the King's speech that the government "will seek to establish the appropriate legislation to place requirements on those working to develop the most powerful artificial intelligence models" 79. This indicates a potentially new direction of state-led binding measures on AI, which deviates from the previous agile and non-binding approach. The Digital Information and Smart Data Bill was also announced, which will be accompanied by reforms to data-related laws, to support the safe development and deployment of new technologies, including AI[79].

4. Country Profiles: AI Governance Readiness in Health

LMICs face unique challenges in establishing regulatory mechanisms for AI in health that can adequately address local needs while attempting to align with global standards. When designing regulatory mechanisms, it is essential to consider not only ethical and technical principles but also the cultural, social, and historical context as well as the legal system of each country. Recognizing the particularities of each jurisdiction allows for more effective integration of globally adapted regulatory frameworks into local legal environments, thereby strengthening the application and enforcement of regulations in each national context.

In this section, we present an in-depth analysis of AI governance readiness in health across four countries with unique contexts: Rwanda, Colombia, Lebanon, and Pakistan. These countries represent different regions—Africa, Latin America, Middle East, and Asia respectively— offering diverse perspectives on the challenges and progress in AI health governance. Each country profile examines four key aspects—AI governance readiness in health, semantic interoperability, mechanism interoperability, and participatory engagement—and provides a summary of the key takeaways. This approach allows for a nuanced understanding of each country's unique regulatory landscape, while comparing their alignment with global practices.

4.1. Rwanda

4.1.1. AI Governance Readiness in Health

Rwanda currently doesn't have any regulatory instruments specific to AI in health. However, it has a comprehensive national AI policy, including ethical AI principles for developing and implementing AI. Rwanda emphasizes regional and international collaboration to strengthen its AI governance readiness.

The regulatory landscape for AI in health in Rwanda, as in many African countries, is still in its nascent stages. There are currently no regulatory instruments specific for AI in health. There are however other laws that are implicitly applicable to AI in health, such as laws for data protection and privacy, cybersecurity, as well as information and communication technologies, which all play an important role in the development and implementation of responsible AI innovations in health (Table 5)[80].

Rwanda's national AI policy (2023) outlines a clear roadmap for AI adoption across various sectors, including health, with a focus on ethical and responsible AI[81]. One of the objectives is to position Rwanda as a champion and global innovator for responsible and inclusive AI. With Rwanda being the first low-income country to publish its own national AI policy, it is clear that Rwanda wants to play a leading role, particularly in the region, in navigating the complex space of AI governance in health in resource-limited settings. The government's strategic vision, and its efforts to build a robust AI ecosystem, including investments in capacity strengthening, infrastructure, international collaboration, and establishment of ethical principles, highlight a step in the right direction to foster an environment that is conducive to the effective and safe development and use of AI, including in health.

Policy Area	Policies Released and Enacted	Applicability to AI in Health
National AI Strategy	National AI Policy (2023)	Implicit
Strategy for AI in Healthcare	The Fourth Health Sector Strategic Plan for 2018-2024 (2018)	Implicit, not specific for AI in health
AI Laws	-	-
AI Laws in Health	-	-
Medical Device Regulation	Law No. 003 of 2018, Rwanda FDA Regulation Governing the Registration of Medical Devices (2020) Regulations Governing Control of Importation and Exportation of Pharmaceutical Products and Medical Devices (2021)	Implicit, not specific for AI as/in medical device
Inter-related AI Policies (non-exhaustive)	Law No. 058 of 2021, Data protection and Privacy Law National Cybersecurity Policy (2015) Cybersecurity laws (Law No. 60/2018, Regulation No. 010/R/CR-CSI/RURA/020) Law No. 24 of 2016, Information and Communication Technologies	Implicit

Table 5: Summary of policies for AI in the country of Rwanda

4.1.2. Semantic Interoperability

Rwanda does not explicitly provide a specific definition of AI within the policy documents available. Instead, the documents tend to dive directly into focus areas such as frameworks for the development and implementation of AI technologies, guidelines for ethical AI adoption, and assessment and monitoring tools. Given that Rwanda's AI regulatory efforts are largely informed by international standards and principles[82], it will not be surprising that a definition of AI in their future policies will take reference from international organizations such as the OECD or WHO to ensure harmonized efforts.

4.1.3. Mechanism Interoperability

Rwanda's national AI policy addresses three key areas: (i) Building AI literacy and capacity; (ii) Creating a secure data ecosystem; (iii) Driving responsible AI adoption in public and private sectors. To achieve these priorities, local institutions such as the Rwanda Utilities Regulatory Authority (RURA), Rwanda Information Society Authority (RISA), Rwanda ICT Chamber, and the Responsible AI Office, are working together to develop essential frameworks and guidelines to ensure that AI technologies are implemented responsibly and effectively.

Firstly, building 21st century skills and high AI literacy ensures that the workforce as well as students are trained in data and AI-related skills. This highlights the longer-term vision of the government to promote AI that is sustainable. Capacity strengthening of the regulatory authorities through knowledge training on AI and its regulations is also crucial as Rwanda develops its regulatory framework for AI in health. Secondly, a multi-sectoral taskforce will be set up to develop data governance frameworks and protocols with standards for sharing data ethically, responsibly, and securely. This will build on the existing data protection and privacy law which mandates the need to obtain consent, ensure data security, and maintain transparency in data processing activities. Thirdly, the RURA developed AI principles as foundational guidelines for ethical AI development and implementation. These guidelines address risks throughout the AI system lifecycle and promote responsible and trustworthy AI adoption, reflecting the government's commitment to building trust with the public. Rwanda's AI principles are informed by international standards and principles, such as those from WHO and UNESCO, which emphasize beneficence and non-maleficence, autonomy, justice and fairness, and explicability and transparency.

4.1.3.1 AI and Medical Devices Regulations

Medical devices are regulated under the Rwanda Food and Drugs Authority (FDA)[83]. There are regulations governing the registration of all medical devices before being marketed in Rwanda, as well as regulations governing the importation and exportation of medical devices to ensure compliance with regulatory standards. Rwanda FDA has issued guidelines to provide manufacturers and importers with detailed instructions on the submission of documentation for registration of medical devices[84]. Documentation needs to provide detailed information on the device's design, intended use, and compliance with safety and performance standards.

Rwanda's definition of medical devices is largely aligned with that of IMDRF's[85]. Although there is no specific mention of AI in the documents, it is stated that standalone software is considered to be an active medical device. Rwanda also follows the "GHTF/SG1/N15/2006 Principles of Medical Devices Classification" to classify medical devices into four classes (A, B, C, D) depending on their risk levels[86]. It is evident that Rwanda aligns itself with international bodies such as IMDRF and formerly Global Harmonization Task Force (GHTF), by referencing their guidelines in areas such as classification, principles of conformity assessment, and standards in the assessment of medical devices, to ensure compliance with global safety and performance criteria. It is also explicitly stated that Rwanda FDA may rely on regulatory decisions from regional, international, and other stringent regulatory authorities' decisions regarding their own product market authorization when it deems necessary.

4.1.4. Participatory Engagement

The development of Rwanda's AI policy involved collaboration with multiple stakeholders, including international organizations and local entities, to ensure a comprehensive and inclusive approach to AI governance. It is developed by the Ministry of ICT and Innovation, in collaboration with RURA, GIZ FAIR Forward, the Centre for the 4th Industrial Revolution Rwanda (C4IR), and The Future Society (TFS). A robust collective intelligence process was undertaken, engaging over 120 participants

(public sector institutions, private sector, academia, civil society etc.) in 8 workshops, 8 stakeholder surveys, and multi-stakeholder interviews[87].

As part of the policy's implementation plan, an annual industry and society participatory consultation forum is planned to better understand how stakeholders use AI ethics guidelines and any operational challenges they face. Through active stakeholder engagement and feedback, the guidelines can be updated to reflect input from the consultation forum, government priorities, and latest trends in AI development and deployment.

In general, Rwanda emphasizes international collaboration to strengthen its AI readiness. It actively participates in several regional and global platforms such as the AU, WEF, UNESCO, and most recently Rwanda and Singapore announced that they are jointly developing an AI governance playbook to empower small states.

4.1.5. Takeaways

In summary, there are currently no regulatory instruments specific for AI in health in Rwanda. Rwanda's AI governance readiness in health is characterized by a strategic approach outlined in Figure 3 below.

1. AI Strategy:

Rwanda's national AI policy aims to position the country as one of the pioneers in the region, a champion and global innovator for responsible AI and inclusive AI. Despite having a strategic vision, Rwanda needs to overcome the challenge of translating broad ethical principles into actionable regulations that address the unique risks of AI in the healthcare sector.

2. Regulatory Approach:

Although there are no regulations specific for AI in health, existing regulatory frameworks such as MDRs as well as laws such as data protection and cybersecurity laws implicitly apply to AI in health. Rwanda's approach is informed by international standards and principles, ensuring future AI regulations in health align closely with global best practices.

3. Regulatory Focus:

Rwanda's regulatory efforts focus on ethical AI development and implementation, with AI principles addressing risks throughout the AI lifecycle. Its emphasis on a secure data ecosystem aligns with Rwanda's broader digital transformation goals and recognizes data as the foundation for effective AI systems.

4. Engagement and Collaboration:

Rwanda's approach is characterized by a strong emphasis on multi-stakeholder engagement and international collaboration, demonstrating the government's commitment to build trust with the public. Ongoing stakeholder engagement while navigating the rapidly evolving AI landscape will require sustained efforts from the government.

Figure 3: Key takeaways for Rwanda AI governance in health.

4.2. Colombia

4.2.1. AI Governance Readiness in Health

Colombia has a comprehensive national AI strategy with a strong emphasis on ethical AI principles. Currently, there is no hard laws that govern AI in health, but the 2024 roadmap for ethical and sustainable adoption of AI across sectors, including in healthcare, is an indication of Colombia's commitment to strengthen its AI governance readiness in health.

Colombia's regulatory landscape for AI in health is still in its formative stages, with no specific hard laws in place. Currently, the country relies more on cross-sectoral AI policies, existing healthcare regulations, and inter-related AI policies such as data protection law to guide the use of AI in health (Table 6). As the first steps towards establishing a comprehensive regulatory framework for AI in health, the government has been shaping the country's AI ecosystem through strategic directions and numerous policy initiatives. Since 2018, the country has been governed by a pro-technology government and has been investing in new AI policy initiatives. The implementation of AI policies in Colombia is supported by a high-level task force within the Office of the Presidency, ensuring political will, coordination, and policy continuity among various ministries and agencies[88].

The AI Task Force, together with local entities such as the National Council for Economic and Social Policy (Consejo Nacional de Política Económica y Social, or CONPES), and the Ministry of Science, Technology and Innovation (MinCiencias), guide the government on AI-related issues, including the development of Colombia's AI strategy[89]. Colombia is amongst the first three countries in the Latin American region to publish its AI strategy. What distinguishes Colombia's strategy from those of other countries in the region is its inclusion of objectives specifically related to responsible AI, including the establishment of the region's first AI ethics framework. Colombia's approach of utilizing regulatory sandboxes and innovation hubs such as the "sandbox on privacy by design and by default in AI projects" reflects its proactive approach in addressing privacy and data concerns, which are implicitly applicable to AI in health[90]. This approach aims to balance innovation with user protection and is seen as a way to overcome the challenges of traditional regulatory models.

Policy Area	Policies Released and Enacted	Applicability to AI in Health
National AI Strategy	CONPES 3975, National Policy for Digital Transformation and Artificial Intelligence (2019) Presidential Guidelines on the Use of AI (2021) Roadmap for Ethical and Sustainable Adoption of AI in Colombia (2024)	Implicit
Strategy for AI in Healthcare	National Telehealth Plan 2021-2030 Resolution 866 of 2021: Regulates the creation of electronic health records	Implicit, not specific for AI in health
AI Laws	Bill 200 of 2023: Adapt the criteria of respect and protection of human rights for AI (proposed but not approved yet) Bill 059 of 2023: Public policy guidelines for the development, use, and implementation of AI (proposed but not approved yet)	Implicit, not specific for AI in health
AI Laws in Health	-	-
Medical Device Regulation	Decree 4725 of 2005, Regulatory framework for medical devices Decree 581 of 2017, Regulations for IVD devices (high-risk) Resolution 4002 of 2007, Guidelines for registration of medical devices	Implicit, not specific for AI as/in medical device
Inter-related AI Policies (non-exhaustive)	Law 1581 of 2012, General Data Protection Law (implemented by Decree 1377 of 2013) Cybersecurity: Decree 338 of 2022, CONPES 3995 (2020), CONPES 3701 (2011) Law 1978 of 2019, ICT Sector Modernization Law	Implicit

Table 6: Summary of policies for AI in the country of Colombia

4.2.2. Semantic Interoperability

Colombia defines AI as a field of computer science dedicated to solving cognitive problems commonly associated with human intelligence or intelligent beings[91]. When compared to global definitions of AI, this definition is most aligned with that of the UN where AI is described as a discipline of computer science aimed at developing machines and systems capable of performing tasks that require human intelligence, such as machine learning and deep learning. AI is also viewed as a field of study or a branch of computer science in the definitions of IMDRF and ISO/IEC. Human intelligence is also brought up in the definitions of IEEE and ITU. Overall, Colombia's definition of AI leaves out technical details such as the outputs of AI systems and the type of technologies included.

4.2.3. Mechanism Interoperability

The National Policy for Digital Transformation and Artificial Intelligence (CONPES 3975), approved in 2019, guides the integration of AI across various sectors, including healthcare. Colombia's strategy takes a comprehensive approach, emphasizing the importance of digital transformation for economic and social development [91]. Key objectives include reducing barriers to AI adoption in both public and private sectors; creating favorable conditions for AI uptake; strengthening human capital related to AI; and putting in place the right frameworks to mitigate potential risks.

In 2021, the Colombian government issued the Ethics Framework for Artificial Intelligence in Colombia, marking a significant milestone as the first document of its kind in the Latin American region[92]. It provides a set of ethical principles to guide the design, development, and implementation of AI systems. As a member of the OECD, Colombia aligns closely with the OECD's AI principles, as well as adopts UNESCO's Recommendation on the Ethics of AI. Colombia's AI policies emphasize human autonomy, the protection of human well-being and rights, safety and security, transparency, accountability, inclusiveness as well as equity. There is also particular mention that AI systems must also adopt a gender-neutral approach and ensure that gender is not used as a factor of discrimination.

Additionally, the recent roadmap for ethical and sustainable adoption of AI in Colombia, released by MinCiencias, underscores the country's commitment to not only build a strong foundation with ethical frameworks and strategic visions, but also its recognition of the importance to move from principles to practice for the development and implementation of responsible AI innovations[93].

4.2.3.1 AI and Medical Devices Regulations

In Colombia, medical device regulation is overseen by the National Food and Drug Surveillance Institute (INVIMA). INVIMA defines medical devices as any instrument, apparatus, machine, software, or other biomedical equipment, whether used alone or in combination, including their components, parts, accessories, and software necessary for its proper application[94]. These devices are intended by the manufacturer for use in diagnosing, preventing, monitoring, treating, or alleviating disease or injury. This definition is closely aligned with that of IMDRF's. The inclusion of standalone software suggests that AI in health is implicitly regulated under medical devices in Colombia. Colombia is also closely aligned with the EU in terms of their risk-based approach for classification of medical devices (class I, IIa, IIb, and III).

As part of the registration process, INVIMA requires manufacturers to submit technical documentation, including details on the device's design, intended use, manufacturing process, labeling, and commercial history[95]. For higher-risk devices, clinical data and test reports are also required. Applicants are also expected to provide a quality management system certificate, such as ISO 13485, to demonstrate compliance with international standards. In addition, INVIMA prioritizes post-market surveillance to ensure safety and quality of medical devices. Manufacturers and authorized representatives must report adverse events and technical complaints to INVIMA, enabling them to monitor device performance and take necessary actions for safety concerns.

Similar to many countries with limited resources and capacity, Colombia leverages the rigorous evaluation of medical devices in established markets to facilitate the registration process in Colombia. An INVIMA-recognized market refers to countries whose regulatory standards for medical devices are acknowledged by INVIMA as being reliable and stringent. These markets are generally founding members of the GHTF, including US, Canada, EU, Japan, and Australia.

4.2.4. Participatory Engagement

Colombia actively participates in several global platforms and international organizations related to AI in health, such as the PAHO, the OECD, and EU-LAC Digital Alliance, which help enhance its capabilities and align its practices with international standards. In terms of regional collaboration, the Colombian government led a high number of AI initiatives, ranging from AI adoption in the public sector to the development of a dashboard for ethical AI principles. Colombia has been a pioneer in the region, particularly with its emphasis on the ethical components. However, much more can be done locally in terms of active engagement of the public.

Taking the development process for the Ethical Framework for AI in Colombia as an example, it was evident that major gaps, summarized below, exist for participatory engagement when drafting the AI strategy[96].

- Lack of mechanisms to promote engagement of diverse actors such as those without internet access; living outside large urban centers; people with disabilities; historically marginalized groups; and gender diversity. Public consultations, including comments on the documents and technical discussion tables, were solely conducted over digital media.

- Public participation was limited to commentary on documents that have already been produced. Participation in drafting the document, including the technical discussion tables, was only by invite. Consequently, the Colombian context was inadequately represented as international entities were consulted instead of local actors in the drafting process. The people who developed the strategies did not participate in the discussions held by civil society and academia.

- Unstructured process resulted in confusion, as no information was provided on the roadmap and rules of engagement, and commitment required from participants.

- Short time allocated for the provision of comments proved insufficient for people to effectively prepare for and participate in the consultations.

- Regarding decision-making accountability and traceability, it was positive that the received comments and corresponding responses were published on the Office of the President's website and were also sent to the participants to close the loop. However, the report only provided summaries but did not fully document the discussion in the consultation process, and whether the participants' comments were incorporated in subsequent versions of the documents.

4.2.5. Takeaways

In summary, there are currently no hard laws regulating AI in health in Colombia. Colombia's AI governance readiness in health is characterized by several strategic initiatives and policies reflected in Figure 4 below.

1. AI Strategy:

Colombia has developed a comprehensive national policy emphasizing ethical AI development and implementation to drive social and economic development. Strong political will and high-level coordination amongst the pro-technology government is what sets Colombia apart from others in the region.

2. Regulatory Approach:

Colombia's current approach is more focused on strategic guidance through policy documents and bills of law instead of hard laws. Regulatory frameworks such as MDRs implicitly apply to AI in health. Together with learnings from Colombia's approach of utilizing regulatory sandboxes and innovation hubs in related domains, Colombia can leverage existing mechanisms to establish more comprehensive regulatory mechanisms for AI in health.

3. Regulatory Focus:

Colombia emphasizes ethical AI principles such as transparency, accountability, and privacy, that are aligned with global standards. It also adopts a GEI lens with principles on gender-neutral approach and human rights, including that of children and adolescents.

4. Engagement and Collaboration:

Colombia has been a pioneer in the region, leading several AI initiatives. However, there are substantial gaps in local participatory engagement during the development of AI strategies, potentially resulting in inadequate representation of local needs.

Figure 4: Key takeaways for Colombia AI governance in health.

4.3. Lebanon

4.3.1. AI Governance Readiness in Health

Lebanon currently lacks specific strategy, laws, statutes, or regulations that govern AI or its use in health. Instead, regulationg AI applications in health falls under exisitng medical device regulations, which are generally technology-neutral. Lebanon lacks a comprehensive AI strategy, Related regulations, such as those concerning data protection, have been released but remain unenforced due to the lack of implentation decrees.

Lebanon presents a unique and complex landscape, shaped by the country's vision for technological advancement and political challenges. Currently, there is no specific legislation directly regulating AI in health or AI in general (Table 7).

Lebanon has been experiencing significant governmental challenges, including the absence of a president for the past two years, which has hindered the creation and enactment of new regulations. Lebanon's role on the international stage is starting to grow, as evidenced by its election to the Executive Board of the WHO in 2024 for a three-year term[97]. However, Lebanon still faces challenges in implementing existing digital laws. For example, the 2018 e-transactions and personal data privacy law (Law 81) remains unenforced due to the lack of necessary implementation decrees and is not aligned with international standards like Europe's GDPR[98].

Similarly, although the Right of Access to Information (Law 28) was passed in 2017, its application has been delayed, further complicating data generation efforts[99]. Enacting these laws would be a vital step in enabling secure and stable data generation, which is essential for advancing AI initiatives.

While Lebanon is still working to establish the foundational prerequisites for AI implementation, the country remains committed to integrating AI into its healthcare system, guided by its broader strategic vision for digital transformation.

Policy Area	Policies Released and Enacted	Applicability to AI in Health
National AI Strategy	Lebanon Digital Transformation Strategy 2020-2030 (Updated 2022) for public sector digitalization National Artificial Intelligence Strategy in Lebanese Industry (2020-2050) to support the 4th industrial revolution	Implicit
Strategy for AI in Healthcare	National Health Strategy: Vision 2030 Vision for a Digital Health Transformation (2023)	Implicit, not specific for AI in health
AI Laws	-	-
AI Laws in Health	-	-
Medical Device Regulation	Minister Decision No. 181-1 date 30/1/2018 Minister Decision No. 1704-1 date 12/9/2017 Minister Decision No. 1506 date 1/9/2014 Minister Decision No. 455 date 16/4/2013	Implicit, not specific for AI as/in medical device
Inter-related AI Policies (non-exhaustive)	Law No. 81 of 2018, Electronic Transaction and Personal Data (not enacted yet) Law No. 28 of 2017, Right of Access to Information (not enacted yet) Intellectual property legal framework (1946, 1996, and 2000)	Implicit

Table 7: Summary of policies for AI in the country of Lebanon

The United Nations' 2020 Advisory Report on Development of an Artificial Intelligence Strategy for Lebanon stressed the need for greater investment in AI research, workforce development, and the evaluation of AI's socio-ethical impacts[100]. It proposed the formation of a multi-stakeholder "**Technology Council**" under a new or expanded **Ministry of Technology and Communications** to oversee AI adoption and digital governance. On a positive note, the UN acknowledged Lebanon's strong tertiary education and research quality, as well as an already established entrepreneurial ecosystem for technology start-ups, both of which suggest promising potential for building digital capacity. However, the report also emphasized the major challenges Lebanon faces, including a persistent brain drain, low broadband access, high business costs, bureaucratic red tape, poitical instability, and restricted access to global markets.

4.2.2. Semantic Interoperability

The AI strategy in Lebanese Industry (2020) provides definitions for AI, machine learning, deep learning, and various AI fields, though definitions of AI are absent from other national documents[101]. The Lebanese Ministry of Industry's AI strategy describes AI as computer systems designed to replicate intellectual processes characteristic of human intelligence, but with greater speed and accuracy. AI is seen as a tool for decision-making in specific fields, enabling machines to perform tasks that typically require human intelligence. However, this definition is less operational than those used by international institutions such as OECD, suggesting that more nuanced and precise definitions may need to be established or adopted at the national level.

4.2.3. Mechanism Interoperability

Lebanon lacks comprehensive policies, principles, standards and frameworks for AI governance, both in general and specifically for health. However, the AI strategy for Lebanese Industry outlines a vision focused on advancing the industrial sector through Research & Development, innovation, and the adoption of AI technologies. This vision includes operational objectives focused on raising awareness and skills in AI, fostering R&D, strengthening public-private partnerships, encouraging investment, creating a supportive legal framework, expanding exports of AI-driven products, contributing to economic development, and enhancing international cooperation in AI research and technology. These goals align with recommendations from international institutions.

Lebanon's National Health Strategy-Vision 2030, (published in 2023), acknowledges the numerous challenges faced by the healthcare system, such as accessibility issues, financial instability, war, the refugee crisis, and disease outbreaks[102]. However, the strategy also emphasizes the potential of digital health technologies to create a more equitable and sustainable healthcare system. Lebanon's Vision for a Digital Health Transformation (2023) further outlines a commitment to establishing robust governance and fostering a dynamic technical ecosystem that prioritizes sustainability, inclusivity, and interoperability in healthcare. It provides a blueprint for developing a resilient digital health infrastructure, transcending existing policy-making constraints. Additionally, it suggests the creation of a **Digital Health Strategy Steering Committee and Digital Health Strategy Technical Committee** consisting of key stakeholders in the health sector, including representatives from ministries and other relevant organizations.

4.3.3.1 AI and Medical Devices Regulations

The Lebanese Ministry of Public Health (MoPH) is responsible for ensuring the quality, safety, and efficacy of medical products throughout the country. Currently, AI in health is regulated under the broader scope of medical device regulations, primarily in the form of software. Lebanon's definitions for medical devices and IVD are aligned with international standards established by the IMDRF and its GHTF. In Lebanon, a medical device encompasses any instrument, apparatus, equipment, material, or product - along with any associated software and accessories - intended for medical use in humans. Ministerial Decrees 455/1-2013 and 1506-2014 require suppliers to register all imported products with the MoPH to ensure they meet international standards[103,104]. Due to limited local production, Lebanon is highly dependent on imported medical products, all of which must obtain international certification, such as FDA approval or CE marking, before entering the local market. This reliance on international regulatory approvals reflects a common trend in countries with limited regulatory capacity, where decisions are often guided by external authorities.

4.3.4. Participatory Engagement

At the international level, the UN and WHO are actively working with Lebanon, offering guidance and recommendations to support the

development of AI policies. However, many of the official documents published by the Lebanese Ministries lack transparency in terms of participatory engagement and do not clearly acknowledge the contributions of collaborators involved in shaping these policies. This highlights a need for greater inclusivity and recognition of collaborative efforts in the policy development process. An important exception to this is the Lebanon Digital Transformation Strategy 2020-2030[105]. This strategy reflects significant contributions from a wide range of individuals and groups, including former Ministers, advisors, public officials, private sector stakeholders, civil society, and international partners. The strategy was shaped through extensive cooperation, internal and external consultations, and collaboration with international organizations such as the World Bank, OECD, and UNDP as well as support from the governments of the UK, Estonia, Czechia, and the United Arab Emirates.

4.3.5. Takeaways

In summary, Lebanon currently has no policies specifically governing AI in healthcare. The key points outlined below (Figure 5) highlight the current state and the primary challenges Lebanon faces in establishing effective AI governance within the healthcare sector.

1. AI Strategy:

Lebanon aims to harness AI and innovation to drive the transformation of its industrial sector. In its Health Vision, digital health is identified as a key solution to address pressing challenges in the healthcare system, including accessibility, financial instability, war, the refugee crisis, and disease outbreaks. While Lebanon aspires to strengthen its global competitiveness and achieve technological sovereignty, significant obstacles must be overcome to establish policies for its AI-driven vision.

2. Regulatory Approach:

Lebanon has yet to implement a specific regulatory framework for AI, particularly in health. Lebanon is currently in a developmental phase, focusing on identifying the optimal uses of AI to enhance its global standing. In healthcare, progress in regulating AI remains limited, with existing medical device regulations being broad and heavily reliant on international standards rather than local expertise.

3. Regulatory Focus:

Lebanon's regulatory efforts are centered on industrial development and building the necessary infrastructure for AI.

4. Engagement and Collaboration:

International institutions are actively supporting Lebanon in developing an AI governance national framework. However, there is considerable opportunity for increased regional collaboration and local involvement with participatory mechanisms.

Figure 5: Key takeaways for Lebanon AI governance in health.

4.4. Pakistan

4.4.1. AI Governance Readiness in Health

Pakistan hasn't released any laws yet for AI or AI in health. In the last two years, the country has shared a draft for a national AI strategy and data regulations. After a period of public consultation, these policies are still awaiting approval or implementation. As a federated republic with healthcare managed at the provincial level, regulating AI in health may face additional challenges due to decentralization.

Pakistan has yet to implement formal laws for AI and AI in health. Over the past two years, Pakistan has released two key drafts: (i) National AI policy (2023), (ii) Personal Data Protection Bill (2023), that lay the groundwork for effective AI deployment[106,107]. However, despite undergoing a period of public consultation, these policies are yet to be approved.

Many other AI-related policies have been recently published, especially in AI-related areas of cybersecurity, and digitalization (Table 8). There is also the National Digital Health Framework of Pakistan 2022–2030 ("NDH Framework")[108].

According to Fizza Ali's analysis in Modern Diplomacy[109], Pakistan faces significant challenges related to weak personal data protections and data vulnerabilities, with sensitive citizen data being compromised between 2019 - 2023.

As a federated republic, provincial governments have the authority to create their own regulatory frameworks. For example, the province of Sindh enacted the Telemedicine and Telehealth Act in 2021[110]. This decentralization makes a unified national effort to regulate AI in healthcare both necessary and challenging.

Policy Area	Policies Released and Enacted	Applicability to AI in Health
National AI Strategy	National AI Policy (2023, draft)	Implicit
Strategy for AI in Healthcare	National Digital Health Framework of Pakistan 2022–2030	Implicit, not specific for AI in health
AI Laws	-	-
AI Laws in Health	-	-
Medical Device Regulation	S.R.O.32(I)/2018 (Medical Devices Rules, 2017) Drug Regulatory Authority of Pakistan Act, 2012 ("DRAP Act") (Updated as MEDICAL DEVICES RULES, 2015)	Implicit, not specific for AI as/in medical device
Inter-related AI Policies (non-exhaustive)	Personal Data Protection Bill (2023) (not approved yet) National Cyber Security Policy (2021) Pakistan Cloud First Policy (2022) The Computer Emergency Respond Team Rules (2023) Digital Pakistan Policy (2018) Prevention of Electronic Crimes Act (2016) SECP Regulatory Sandbox Guidelines (2019)	Implicit

Table 8: Summary of policies for AI in the country of Pakistan

4.4.2. Semantic Interoperability

The Ministry of National Health Services, Regulations and Coordination of Pakistan released its NDH Framework and defined digital health, AI and ML specifically for healthcare. which specifically addresses digital health, AI, and ML in healthcare. In this framework, digital health is seen as encompassing AI, with AI defined as **"an overarching term used to describe the utilization of machine-learning algorithms and software to emulate human cognition in the analysis, interpretation, and comprehension of complex medical and healthcare data"**[108].

This is an essential turn as it introduces sector-specific nuances and clarifies the purpose of AI in health. There is evidence of a potential alignment with the definition of medical devices, as this AI definition also builds from intended medical use. Going forward, Pakistan could further refine this definition by more clearly specifying what constitutes medical or healthcare data and outlining specific intended medical applications of AI.

4.4.3. Mechanism Interoperability

Pakistan has introduced its NDH Framework to guide the digital transformation of the healthcare sector, alongside a general AI strategy, which is currently still in draft form. The NDH Framework aligns with WHO's recommendations for developing digital health strategies, as adopted by the World Health Assembly, with the aim of strengthening health systems. Instead of focusing on specific technologies, the framework envisions digital health as an integral part of the healthcare system. It aims to promote the safe, equitable, ethical, scalable, and sustainable adoption of digital health technologies to improve health outcomes, manage epidemics and pandemics, and develop the necessary infrastructure and applications. By 2030, Pakistan is committed to digitally strengthening its healthcare system in a technology-agnostic way. This includes laying the foundational groundwork through high-level policy initiatives such as fostering collaborations, allocating budgets, and developing knowledge. It also involves addressing technical requirements, such as building interoperable digital health ecosystems and advocating for people-centered solutions. However, the strategy also acknowledges existing gaps, including inadequate infrastructure, limited ethical considerations, insufficient education, and a shortage of resources. In the coming years, it will be possible to evaluate the success of this strategy and whether these ambitious goals have been achieved.

The (draft) Pakistan National AI Policy (2023) presents an ambitious vision of technological progress, positioning Pakistan as a potential leader in technical innovation[107]. The policy proposes the establishment of a **National AI Coordination Council and a dedicated National AI Centre.**

In many respects, the strategy mirrors international recommendations, focusing on building a robust AI ecosystem and ensuring responsible usage. The policy draws inspiration from the "AI for Good" initiative by the ITU and aligns with the UN's Sustainable Development Goals. According to analysis by Islamabad Policy Research Institute[111], the viability of these goals depends on the availability of adequate resources and infrastructure, which remains uncertain. The policy lacks clear specific objectives and measurable goals, raising questions about its effectiveness and whether enough attention has been put on ethical considerations, human-centered AI, diversity, and inclusion. In addition, concerns remain about whether sufficient resources and infrastructure are in place to ensure the success of these initiatives. This concern is echoed by the Ministry of Information Technology and Telecommunications, which acknowledges that current resources may be insufficient to implement the policy on the envisioned scale. Pakistan has yet to release standards, principles or other mechanisms for AI governance in general and in healthcare.

4.4.3.1 AI and Medical Devices Regulations

Pakistan, like many other nations, is in the process of developing its AI governance for healthcare and may inevitably need to build upon existing medical device regulations as a foundation. The Drug Regulatory Authority's S.R.O.32(I)/2018 Medical Devices Rules, while not explicitly tailored for software, do address software under Rule 11[112]. This rule acknowledges that while most software is integrated within medical devices, standalone software can also be classified as a medical device if it meets the criteria. In Pakistan, the risk classification of medical devices follows four classes (A, B, C, and D), and AI systems with medical applications are implicitly governed under these rules. However, the enforcement of these regulations remains uncertain, as the compliance of AI systems in health to these rules may require further support and stronger enforcement mechanisms in the future.

4.4.4. Participatory Engagement

Both the national AI policy and the NDH Framework involved extensive participatory engagement. For the NDH, key participants included Regional Health Departments, supported by the UNDP, WHO, and USAID. The Ministry of National Health Services, with WHO's support, organized a workshop bringing together provincial health departments, national ministries,

tech companies, and digital health innovators to create a framework aligned with Pakistan's health priorities.

The AI strategy also saw wide participation, involving representatives from various ministries, sectoral authorities, national bodies, professional associations, private companies, startups, industry leaders, international tech firms, academia, NGOs, R&D units, and regulators. Both documents underwent open consultation, with the AI strategy still actively receiving feedback.
While Pakistan's medical device regulations lack formal participatory mechanisms, the country adheres to international guidelines through its involvement in the Asian Harmonization Working Party. Pakistan's transparency in these participatory processes is notable compared to global trends, but whether this leads to better policies remains uncertain, as some gaps have already been identified in the strategies, for example, regarding the limited mentioning of topics related to fairness, inclusion and diversity.

4.4.5. Takeaways

Pakistan is actively developing its AI governance framework with several strategic documents and AI-related policies released in recent years. Below is a summary of Pakistan's current regulatory state and the main challenges facing AI governance in health (Figure 6).

1. AI Strategy:

Pakistan is actively shaping its strategic vision to embrace and integrate AI technology. Their current focus is on establishing a robust technical and governance framework that is stable, interoperable, and tailored to the local context. However, despite the ambitious and comprehensive nature of these goals, concerns persist about the availability of the necessary resources and infrastructure to achieve them.

2. Regulatory Approach:

Pakistan has yet to finalize its approach to AI regulation as there are no laws, standards or regulatory frameworks. The country is currently setting its strategic direction through the release of national AI policies and digital health policies. However, there is still limited clarity on the specific mechanisms that will be employed to regulate AI. In the interim, MDRs will apply to most AI applications with a medical purpose, though primarily under the category of software.

3. Regulatory Focus:

Pakistan's current regulatory focus is on the interconnected areas of data and cybersecurity. This focus is essential for establishing a solid foundation for the responsible development and application of AI, particularly in the health sector. Ethical considerations are also a significant part of Pakistan's approach, including prioritizing people-centered digital health solutions and rethinking AI adoption to align with the local context.

4. Engagement and Collaboration:

Pakistan has a strong commitment to collaboration in developing its national AI and digital health policies by involving a wide range of stakeholders. Their approach is particularly transparent, standing out in comparison to global trends. However, there are still gaps in the extent of inclusion and diversity within this process.

Figure 6: Key takeaways for Pakistan AI governance in health.

5. Conclusion

The governance of AI in health is a rapidly evolving landscape, with numerous new policies and standards emerging in the last two years. Institutions worldwide are increasingly pushing for regulations that address AI, including its applications in healthcare, either directly or indirectly. As regulatory approaches take shape, the choice often lies between adopting more permissive, flexible frameworks or implementing stricter governance through binding legislation. However, the common thread across all efforts is the recognition of the need for policies to ensure responsible AI development and use. Standards, serve as technical guardrails, include automated systems, tools, and controls to ensure safe and effective operations, while policies act as procedural guardrails, relying on human adherence to established processes and protocols[33]. A comprehensive and interoperable approach to AI governance will likely require a balance of both technical and procedural safeguards.

Analyzing the alignment between AI policies uncovers the similarities and differences between them on three key aspects of governance interoperability: (i) semantic; (ii) mechanism and (iii) participatory engagement. In terms of semantic interoperability, many organizations have used AI definition as an initial step to clarify which types of technologies their policies apply to. Notably, the OECD's definition of AI, which focuses on the mechanisms and objectives of the technology rather than its similarity to human intelligence, is adopted by other institutions. This trend indicates progress toward harmonization, though significant work remains to establish a definition that is not only globally accepted but also harmonizes all aspects of AI, including its data, functionality, and particularly its application in healthcare. AI's semantics may require further refinement specific to the complexities of healthcare, likely building or expanding the IMDRF's definition of SaMD.

Mechanism interoperability is challenged by an increasing volume of policies, standards, and frameworks aimed at ensuring the ethical and effective deployment of AI. While the surge in AI governance efforts is necessary, it risks causing fragmentation, complicating implementation, and raising compliance costs for developers. In recent years, many policies have evolved from simply recognizing AI's potential and issuing general statements or risk assessments to actively shaping AI development through tools, standards, and frameworks. Governance principles such as transparency, accountability, human well-being, and equity promoted by international institutions form the foundation of these efforts. However, significant challenges remain in harmonizing the practical implementation of these principles. Critical issues like economic costs, human dignity, environment sustainability, and participatory engagement often receive less attention. At the national level, gaps exist between established governance principles and guidelines and their actual implementation. As most countries are currently adopting the non-binding forms of regulation, it raises the question of compliance, effectiveness, and overall adequacy of such principles and guidelines. However, with the EU AI Act being enforced and its influence on global discussions on AI legislations, the world might go through a transition period that will reshape the balance between soft and hard law approaches to AI regulation.

Besides institutionalizing the appropriate governance mechanisms, participatory engagement is also crucial for effective AI governance, particularly in healthcare. Global collaboration among governments, developers, healthcare providers, and civil society is essential for navigating AI's complexities. Despite the emphasis on stakeholder involvement, disparities in representation persist, particularly for low-income countries and groups like women and communities. Enhancing diversity and representation in global AI policymaking is critical for fostering inclusive governance. Institutions like WHO, UNICEF, and the UN are increasingly stressing the importance of broader participation in shaping AI policies, though much work remains to ensure meaningful engagement

across all demographics and regions. At the national level, participatory engagement of local stakeholders, including the general public, is equally important in the development of AI policies and governance frameworks to ensure that they reflect societal needs, culture, and values. Transparency in how feedback from open consultations is incorporated into policy development is crucial for building trust. Many governments look to international organizations and influential regions for guidance on establishing local regulatory mechanisms. It is therefore critical to balance international alignment with local policy development. Given that the performance of AI systems is highly context-dependent, governance mechanisms must ensure that approved AI innovations in health are appropriately adapted to the local context, considering factors such as cultural nuances, linguistic diversity, local healthcare infrastructure, demographic characteristics, and specific health challenges.

Risk-based approaches to AI regulation are becoming more common, with recommendations increasingly emphasizing adaptive, agile, and flexible regulatory models. Institutions such as WHO, ITU, UNESCO, and UNICEF advocate for impact assessments to measure risks, ensure accountability, and promote safety. Transparency remains central to regulatory recommendations to ensure that AI development is understandable, and its risks are effectively managed. Nonetheless, difficulties persist, especially in defining unacceptable risks and establishing consistent approaches to binding regulations.

In terms of AI regulatory policies in health, it is challenging to define the threshold for the policies that are considered applicable, given that AI governance in health is at the intersection of multiple regulatory domains such as AI, healthcare, digital health, cybersecurity, technology and data. Broadly speaking, there are two key choices: one centers on cross-sectoral regulations that focus on regulating the technology itself, while the other emphasizes sectoral regulations that govern the specific application of the technology for healthcare. A sectoral approach seems to be endorsed by frameworks like the IMDRF's SaMD and WHO's work. However, SaMD and AI do not fully align, as they address essentially different technology. This divergence creates two significant regulatory gaps that are not covered by MDRs: (i) Ethical concerns and dynamic nature regarding AI applications in health and (ii) AI that are general-purpose models, which have no explicit medical intended use or do not fit into the definition of medical devices.

First, MDRs typically focus on performance evaluations and risk management, including clinical validation, pre-market assessments and post-market surveillance to ensure devices meet the high standards required for patient safety and healthcare effectiveness. By regulating AI as medical devices, policymakers rely on already effective infrastructure that is capable of providing robust oversight. However, AI presents ethical and social challenges that extend beyond traditional performance evaluation and may not be fully addressed by MDRs. First, AI technologies often differ fundamentally from traditional medical devices software in terms of their adaptability, learning capabilities, and reliance on large datasets—meaning MDRs may not adequately address the dynamic nature of AI systems[113]. AI is often just one component of a larger clinical system, and its integration may be largely invisible or non-understandable to both doctors and patients, raising concerns about informed consent, data privacy/security, transparency, human oversight and autonomy. Additionally, the training process for AI models can embed existing biases and values without making them explicit, further complicating ethical considerations. The risk categorizations of SaMD typically do not account for ethical and societal risks in the evaluation of medical devices, which poses a significant challenge. To address this gap, new risk categories may need to be developed within MDRs to better assess these types of risks[4].

Second, not all AI used in healthcare fits neatly within the definition of a medical device. AI models designed for general purposes, such as general decision support or language processing, may be applied in medical contexts without being formally classified as medical devices. Similarly, AI innovations used for health monitoring and preventive measures, as well as the promotion of well-being among the public often fall outside the scope of medical device regulation. If regulations focus solely on AI explicitly intended for medical use, these broader applications may remain unregulated,

posing potential risks to the safety of patients and communities at large[114]. This is particularly concerning because many people may inevitably rely on these general-purpose AI models for medical and lifestyle advice, which may potentially influence their health-seeking behavior. Without comprehensive cross-sectoral approaches or specific sectoral regulations, such applications remain largely unregulated, raising concerns about the overall effectiveness of AI governance in healthcare. Recognizing these challenges, organizations such as WHO, WEF, OECD, and PNAI have highlighted the emerging risks posed by general-purpose AI models. The WHO specifically recommends that governments identify and regulate the growing provision of health-related services through online platforms that are not part of the formal healthcare system, particularly in areas where human safety and care cannot be guaranteed [19,36].

It is important to recognize that although existing regulatory frameworks such as MDRs have their gaps and challenges, they constitute an important foundation for countries to build on when establishing local regulatory mechanisms for AI in health. This is evident in our analysis of the four LMICs, revealing that these countries are not operating in a regulatory vacuum. Instead, they have existing structures that can be expanded to cover AI in health more comprehensively. Even in small states or resource-limited settings, AI in health is not completely unregulated; rather, it is not explicitly regulated yet. Implicit laws and regulations, particularly those governing medical devices, often apply to AI systems used in healthcare. For instance, all four countries include software in their medical device definition and regulations, which implicitly extends to AI applications in health. Although there are gaps for general-purpose AI models through this regulatory approach, these existing structures serve as important foundational pieces for countries to create comprehensive regulatory frameworks for AI in health in the future.

Finally, AI governance must integrate several critical dimensions: (i) the AI total lifecycle, encompassing both the technical, clinical and ethical aspects of AI development and deployment; (ii) the broader societal risks and challenges posed by AI; and (iii) the need for sector-specific approaches that reflect the nuances of particular contexts, such as healthcare. At the global level, WHO's vision emphasizes the success of sectoral approaches, which have proven effective in addressing specific, actionable issues by leveraging scientific and political consensus, as demonstrated by the Montreal Protocol and the WHO's Convention on Tobacco Control 8. Such targeted approaches may facilitate quicker consensus on key topics, driving more meaningful progress[19].

The UN's 2024 report on "Governing AI for Humanity" acknowledges the persistent gaps in global AI governance and emphasizes the urgent need for a cohesive framework to manage this rapidly evolving technology[27]. Effective governance is essential, and a robust global framework must create incentives that promote broader, more inclusive objectives and help balance trade-offs, especially given that the science of AI is still in its early stages. The UN's recommendations aim to advance a holistic vision for a globally networked, agile and flexible approach to governing AI. As AI evolves rapidly, it is essential to establish periodic review processes by multidisciplinary expert committees to ensure that regulatory frameworks remain relevant and capable of addressing both current and future challenges posed by AI technologies in health. The current diversity in governance models, lack of standardized approaches, and varying definitions of AI across different frameworks further complicate the landscape, highlighting the need for interoperable regulatory efforts while ensuring global harmonization. Moving forward, global and multi-stakeholder collaborations will be essential in navigating this landscape and ensuring AI's responsible and equitable development.

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We work with governments, the World Health Organization, and many others in the health innovation sector to strengthen the governance and regulation of AI to build trust, advance equity, and deliver on the potential of emerging technologies.

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