AI Governance in Global Health: An analysis of AI governance architecture and its influence on health systems

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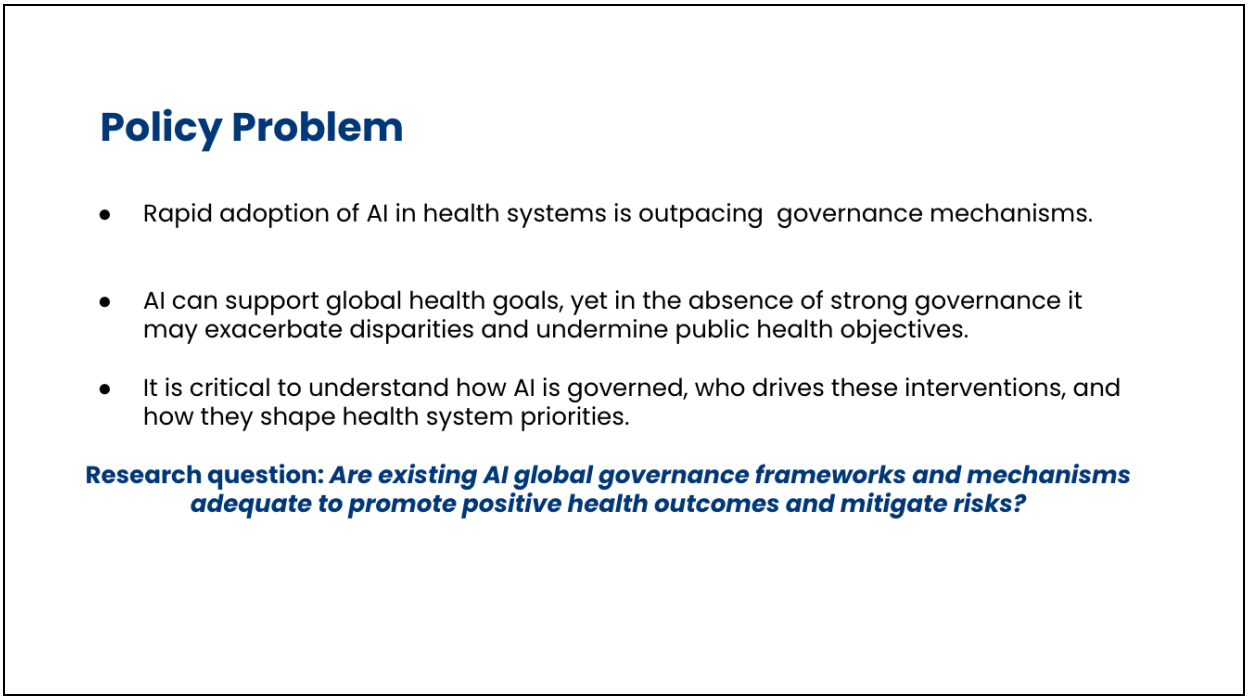
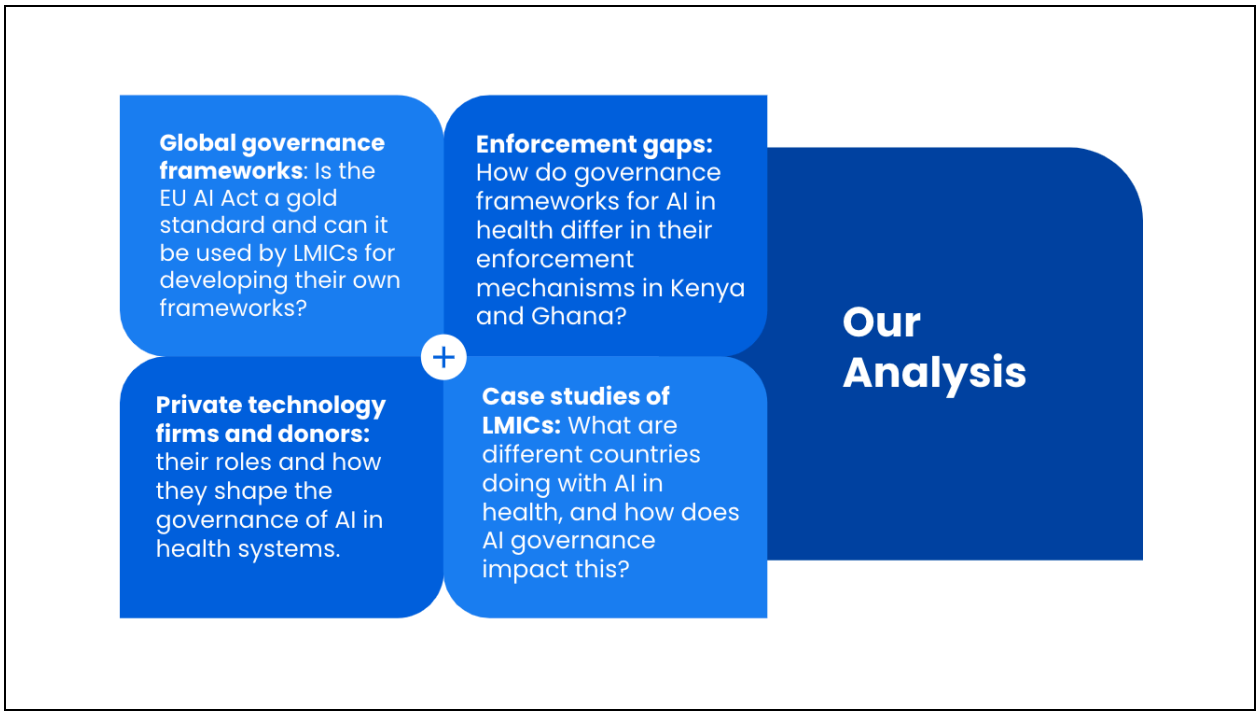


Policy problem: Artificial intelligence has experienced unprecedented growth across many sectors, advancing at a pace that surpasses most previous technological innovations. As of today, AI is already used in health facilities all around the world. As the healthcare sector is faced with continuous challenges and stressors, such as a shrinking healthcare workforce, rising rates of chronic diseases and climate change intensifying environmental catastrophes, AI is increasingly being recognized as the potential solution towards building stronger and more resilient health systems globally. Within this environment, AI creates both enormous opportunities for improving health outcomes and very real risks around equity, accountability, and oversight.

This leads us to our central research question: Are existing AI global governance frameworks and mechanisms adequate to promote positive health outcomes and mitigate risks?



Overview of each of the members' individual research focus.

Overview of governance frameworks

- Evolution: From voluntary principles to binding frameworks
- Most active countries: USA, EU, China, Middle East (emerging)
- Approach differences by region
  - EU and Brazil: risk-based
  - USA: decentralized, guideline-based
  - UK: context-based Japan and India: deregulated
- Across 14 jurisdictions, only one framework is both binding and healthcare-specific (Chakraborty & Karhade, 2024)

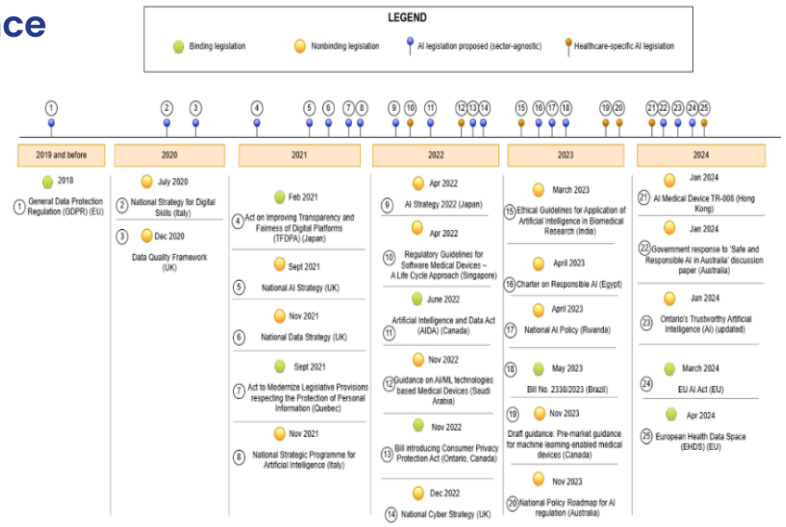
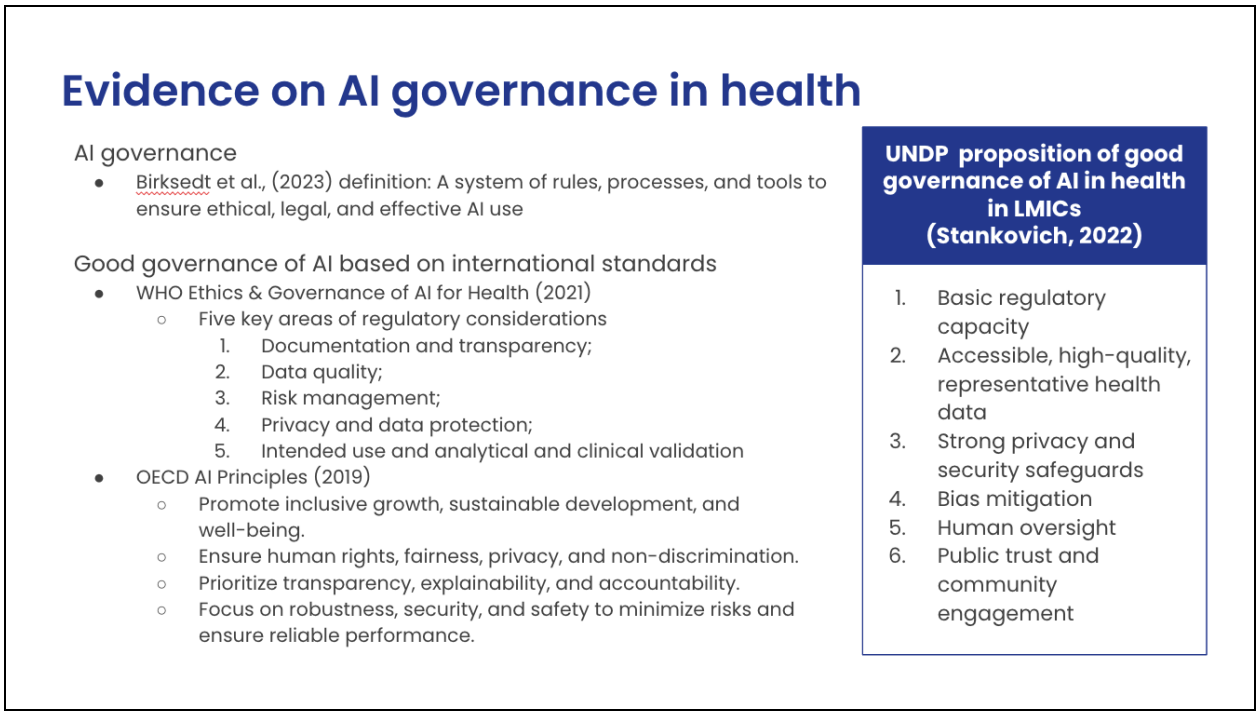


Figure 6: Timeline presenting the evolution of AI legislation across 14 jurisdictions, categorizing each legislation as binding or non-bi and sector-agnostic or healthcare-specific

Evolution of AI governance frameworks

- At first, based on ethical guidelines, voluntary principles and self-regulation that had limited impact because there were no real enforcement mechanisms.
- Now there is a shift toward binding regulations
  - Example: EU AI Act (2024) is the world's first comprehensive law on AI
    - Turns ethical principles into concrete obligations.
    - Adds oversight bodies and promotes collaborative governance.
    - Aims to influence global norms through the 'Brussels effect' (like GDPR and EU MDR with Kenya and South Africa's respective frameworks.
- The global AI governance landscape is shaped by international, regional, and national frameworks.
  - Most active: US, EU, China, Middle East (emerging in health-specific AI policies)
- Countries are at different stages of developing AI governance frameworks and approaches also vary a lot across regions.
  - EU and Brazil both use risk-based models
  - US remains decentralized and guidance-driven (Ex: FDA Regulatory Framework for Medical AI/ML)
  - UK focuses on context
  - Japan and India have a more deregulated and flexible view on AI
- The illustration shows the evolution of AI legislation across 14 major jurisdictions. Out of all the 25 legislations, only one framework is both binding and tailored specifically to health. This highlights a major gap, most frameworks risks having a legislation that is too broad and does not address health specific governance needs.

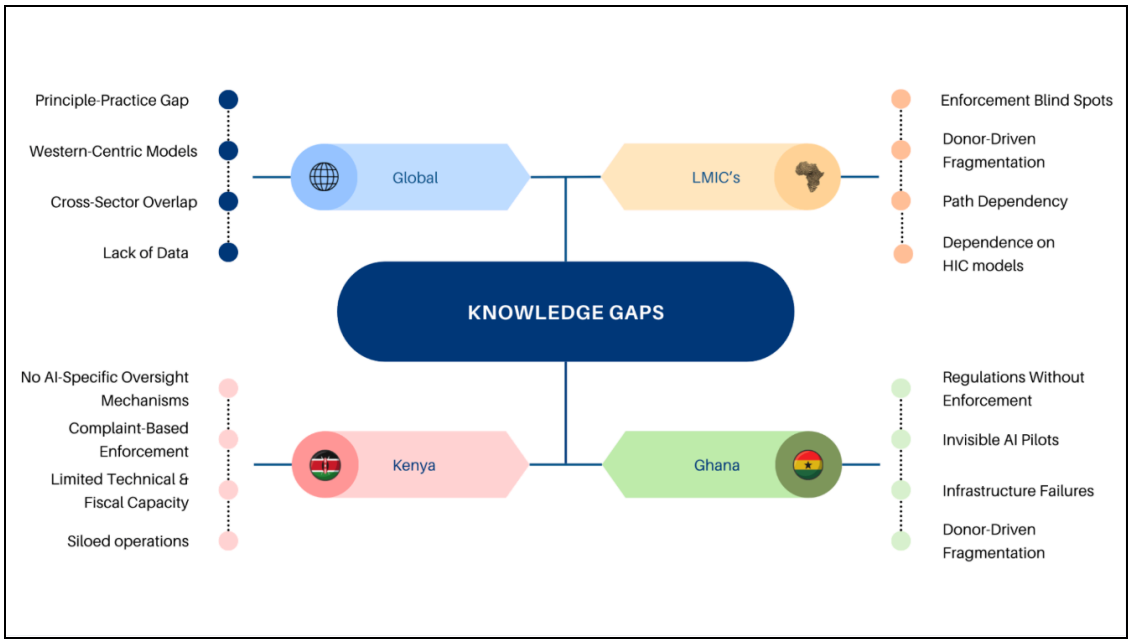


The evidence on what works specifically in health is still limited. Birksedt et al. (2023) examined the main themes, gaps in existing research, and future directions in the academic literature on AI governance. They found only a few explicit definitions of what AI governance is and defined it as "a system of rules, practices, processes, and technological tools that are employed to ensure an organization's strategies, objectives, and values; fulfills legal requirements; and meets principles of ethical AI followed by the organization".

International standards established by the WHO and OECD can help guide the development of effective governance frameworks.

- WHO Ethics and Governance of AI for Health (2021):
    1. Documentation and transparency
    2. Data quality
    3. Risk management
    4. Privacy and data protection
    5. Intended use with clinical validation
- OECD AI Principles (2019) emphasize on inclusive growth, sustainable development, human rights, fairness, transparency, explainability, accountability, and the robustness, security, and safety of AI systems.

To ensure that a governance framework is effective in LMICs context, these standards have to take into account the specific needs and constraints of LMICs. To do so, other international institutions such as the UNDP studied what good governance of AI in health should look like in low-resource settings. They came up with six essential elements to consider when building AI governance frameworks.



Gaps appear at three levels: global, LMIC-wide, and national, using Kenya and Ghana as case studies.

Global-level gaps

- While frameworks are well developed, there is limited empirical evidence explaining why enforcement breaks down or what makes it effective in various health systems.
- Most governance models are derived from high-income country contexts, with limited research on what different contexts/countries can sustain.
- Regulation is largely cross-sector, resulting in major gaps in health-specific evidence, including clinical validation, patient safety monitoring, bias in diagnostic tools, and appropriate regulatory oversight of AI-driven care.
- Little empirical evidence exists on how LMIC regulators audit, investigate, or sanction AI systems. In many contexts, the meaning of "enforcement" is unclear.

LMIC-wide gaps

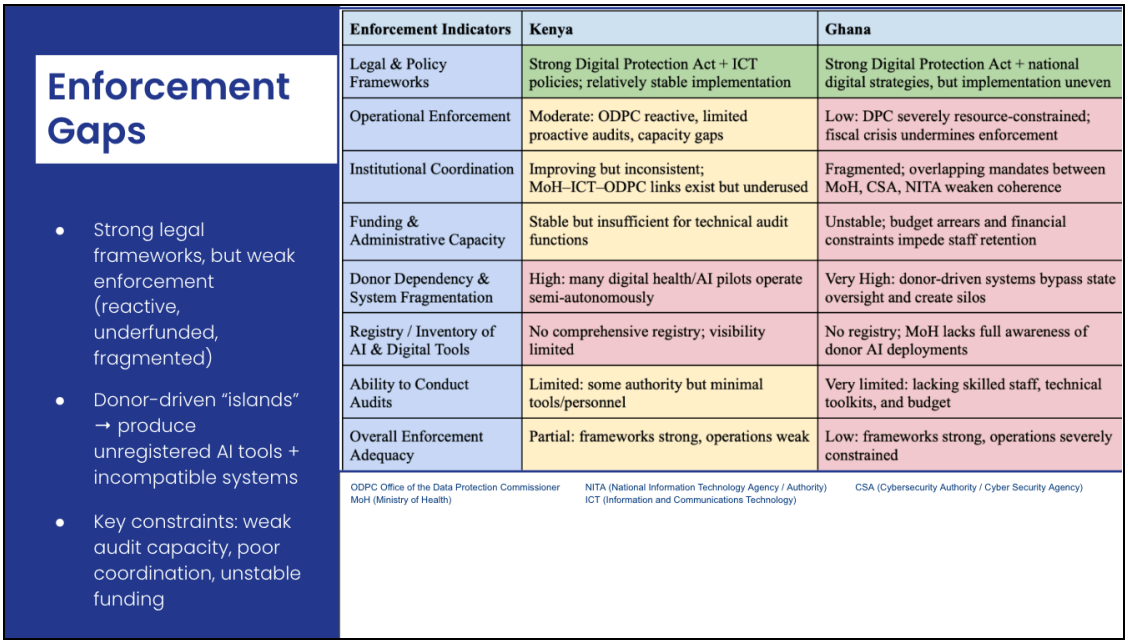
- How fiscal constraints and weak coordination across ministries shape oversight.
- Donor-driven fragmentation is widespread, yet its long-term effects on regulatory capacity and alignment with government systems are poorly understood.
- AI is frequently layered onto existing digital health infrastructures, with limited evidence on impacts on equity or access.
- LMICs continue to rely heavily on governance frameworks developed in high-income countries, often without evidence that these models function effectively under local constraints.

Kenya

- No dedicated AI-in-health oversight mechanism exists, and evidence is limited on which governance models best align with Kenya's institutional context.
- Enforcement remains largely reactive, with little evidence on the feasibility of proactive audits within current capacity.
- Regulatory bodies often lack AI-specific technical expertise, and there is limited guidance on which capacity-building investments yield the greatest impact.

Ghana

- Strong legal frameworks are in place, but evidence on implementation is limited, particularly under fiscal pressure.
- Numerous AI pilots operate with minimal visibility, making it difficult to assess their scale or associated risks.
- Infrastructure and connectivity gaps constrain equitable deployment, and minimum requirements for safe AI use in health is unclear.
- As in many LMICs, donor-driven fragmentation persists, with little guidance on how to build collaboration without slowing innovation.



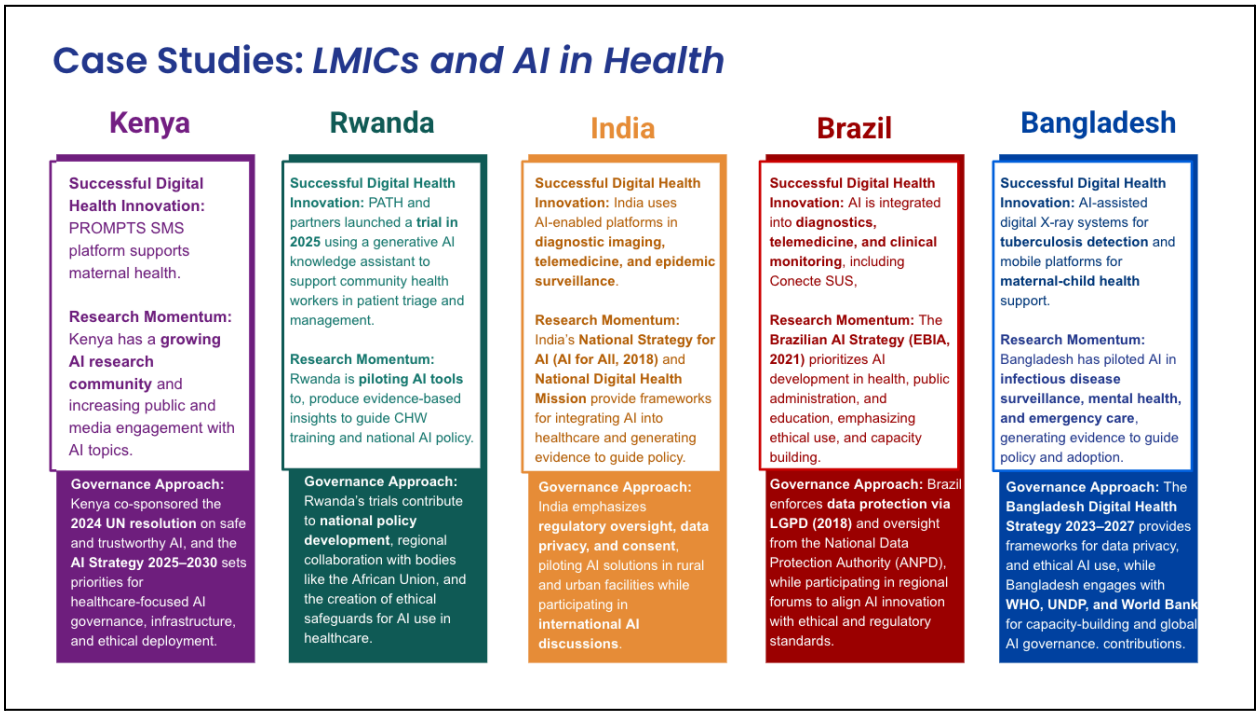
- Green indicates areas where enforcement is functioning relatively well/strongly.
- Yellow reflects partial or uneven enforcement.
- Red highlights areas of weak enforcement or significant gaps.

Key findings from the comparison

- Both Kenya and Ghana have relatively strong legal and policy frameworks, yet operational enforcement remains weak.
- Enforcement tends to be reactive, with limited audits, constrained budgets, and fragmented or overlapping mandates.
- Many donor-funded digital and AI tools operate outside government systems, limiting state visibility, risk monitoring, and integration into national health systems.
- Structural constraints, including limited audit capacity, weak inter-agency coordination, and unstable funding, weaken enforcement efforts.
- Kenya and Ghana both possess data protection laws, digital health strategies, and emerging AI policies. Despite these frameworks, enforcement remains low-intensity, relying more on guidance and complaints than on proactive oversight.
- Enforcement responsibilities are distributed across multiple bodies, including ministries of health, ICT and digital economy agencies, data protection authorities, cybersecurity institutions, procurement offices, and national audit bodies. These actors often operate in silos, contributing to the fragmentation illustrated in the chart.

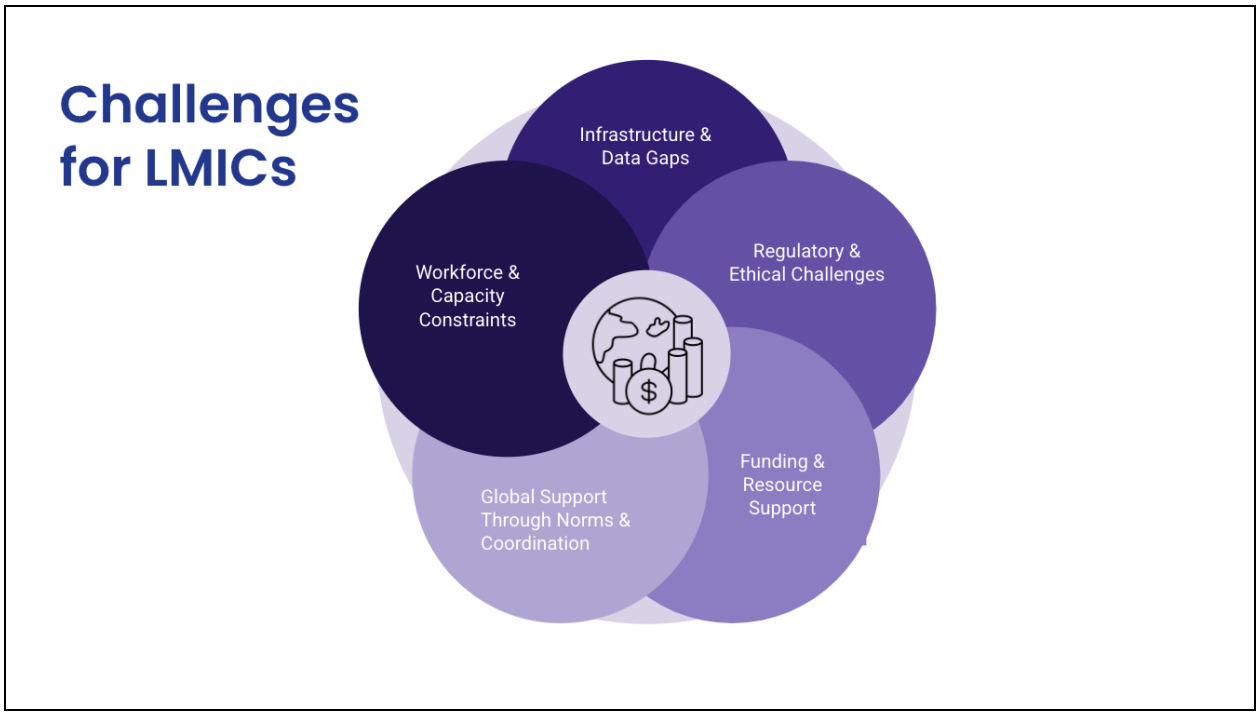
Key takeaway

- Strengthening operational enforcement is essential to ensure AI improves health outcomes without introducing new clinical, ethical, or privacy risks.
- Ghana's enforcement capacity has been further constrained by fiscal pressures, a significant consideration for innovation capabilities.
- Kenya's system is comparatively more stable, but still under-resourced.
- AI governance must take into account the ability of states to sustain its use, risks, and impacts.



Across several LMICs, AI is transforming healthcare through digital innovation, research, and governance. In Kenya, the PROMPTS SMS platform, with AI-enabled triage, has enrolled over 750,000 women and improved maternal knowledge and newborn care outcomes in a national trial. Rwanda piloted a generative AI knowledge assistant to support community health workers, assessing AI accuracy and safety to complement clinical decision-making. India deploys AI tools in diagnostic imaging, telemedicine, and epidemic surveillance, including radiology AI for tuberculosis detection, helping frontline workers prioritize high-risk cases. Brazil integrates AI through platforms like Conecte SUS, improving diagnostic accuracy, reducing analysis time, and expanding remote consultations, particularly in rural areas. In Bangladesh, AI-assisted digital X-rays and mobile platforms support maternal-child health and TB detection, reducing delays, aiding outbreak prediction, and assisting clinical triage.

These innovations are underpinned by strong governance frameworks. Kenya's AI Strategy 2025–2030 and co-sponsorship of the 2024 UN AI resolution guide ethical healthcare AI deployment. Rwanda's pilots feed national policy development and regional collaboration with the African Union. India emphasizes regulatory oversight, data privacy, and informed consent while engaging in international AI discussions. Brazil enforces data protection through LGPD (2018) and aligns AI innovation with regional ethical standards. Bangladesh's Digital Health Strategy 2023–2027 provides guidance on data privacy and ethical AI use, complemented by partnerships with WHO, UNDP, and the World Bank for capacity-building and global governance. Together, these countries demonstrate how LMICs are leveraging AI to improve health outcomes while prioritizing safe, ethical, and evidence-based deployment.



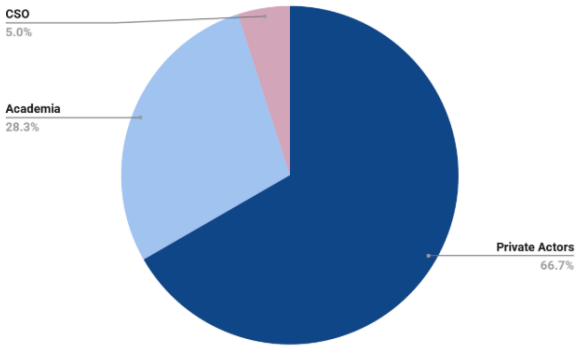
1. **Infrastructure & Data Gaps:** LMICs face limited digital infrastructure and insufficient high-quality health data, constraining effective AI development and deployment.
2. **Workforce & Capacity Constraints:** Shortages of trained AI, data science, and digital-health professionals reduce countries' ability to implement, regulate, and monitor AI tools.
3. **Regulatory & Ethical Challenges:** Many LMICs lack strong or consistently enforced governance frameworks, creating risks around privacy, accountability, and bias.
4. **Global Support Through Norms & Coordination:** The global health system—led by WHO, UN agencies, and regional bodies—provides ethical guidelines, technical standards, training, and platforms for knowledge sharing to help strengthen LMIC governance and capacity.
5. **Funding & Resource Support (Uneven):** Development banks, global health funds, and multilateral initiatives provide financial and technical resources for digital health and AI projects, though access remains uneven and long-term support is needed.

The Role of Private Actors

Private firms and donors are now central to how AI enters health systems, often more influential than states.

This reflects a structural dependence on external funding, infrastructure, and expertise.

- Soft law AI frameworks leave private actors significant leeway.
- Ethics-washing
- States face persistent challenges: underfunding, fragmented mandates, limited technical capacity, and weak data governance infrastructure.



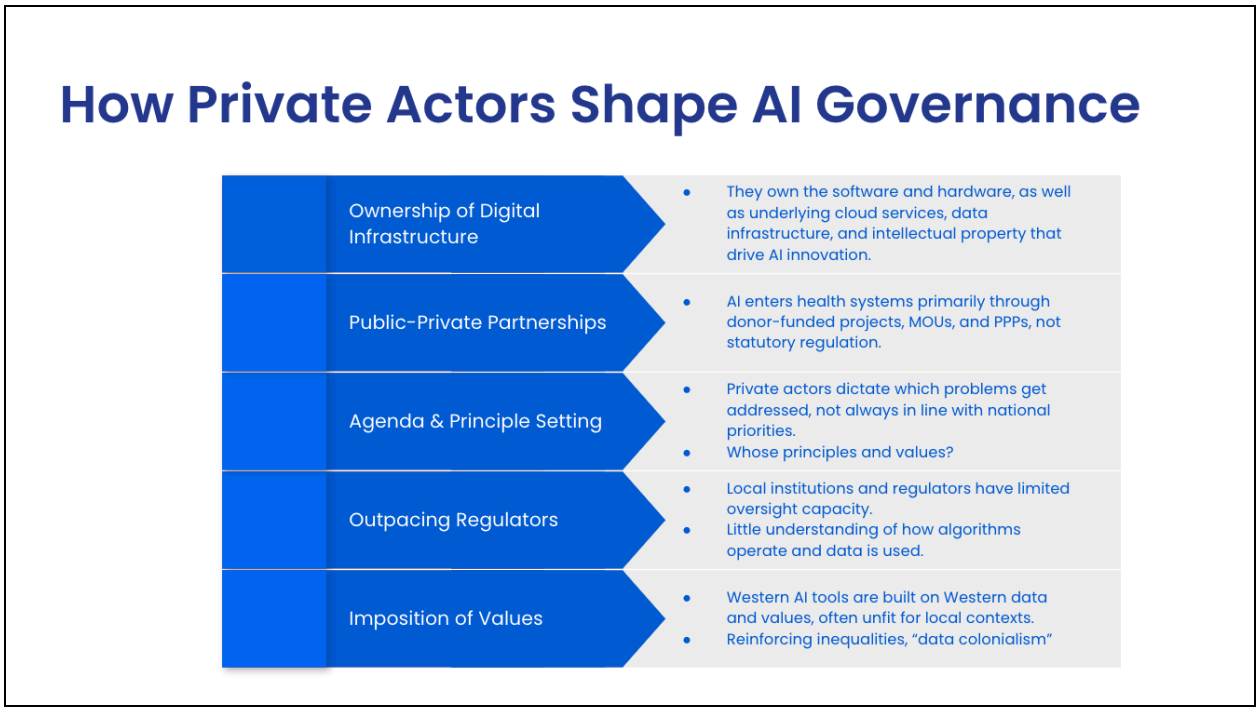
66% of AI health initiatives in Sub-Saharan Africa are led by private actors, compared to 28% by academia and only 5% by civil society (CEIMIA, 2024).

Private firms and donors are now central to how AI enters health systems, often more influential than states. To contextualize their level of involvement:

- 66% of AI health initiatives in Sub-Saharan Africa are led by private actors, compared to 28% by academia and only 5% by civil society (CEIMIA, 2024).
- The main beneficiaries of funding for AI in healthcare are private companies (such as startups and SMEs), followed by universities.

The notorious absence of government and the scarcity of civil society organizations in the funding chain create a governance regulatory problem. Governments already struggle to keep pace and being isolated from the projects, state actors have little oversight as to how AI interventions are developed and deployed, nor can they advocate so that they fit within national health priorities.

Moreover, private actors have a lot of room to play in because most global AI frameworks (WHO 2021; OECD 2019) are soft law—principle-based, voluntary, and non-binding—leaving private actors significant wiggle room (ethics washing). In parallel, states face persistent challenges: underfunding, fragmented mandates, limited technical capacity, and weak data governance infrastructure. Therefore, private actors deeply shape AI governance because governments rely on them for financial resources, technical infrastructure, and expertise, making them de facto governance authorities.



How does their involvement shape governance?

- **Ownership of digital infrastructure:** Scholars point out that firms like Amazon, Apple, Facebook, and Google in "the West," and Baidu, Alibaba, and Tencent in China, not only own hardware and software, but also own the underlying cloud services, data infrastructure, and intellectual property that drive AI innovation. This concentration of control gives these firms outsized leverage over both high- and low-income countries. In effect, a handful of U.S. and Chinese corporations hold near-monopolies across key digital domains. (Couldry & Mejias, 2019).

- **Public-private partnerships:** AI enters health systems primarily through donor-funded projects, MOUs, and PPPs, not statutory regulation. International donor organizations play a complementary role in this landscape, often partnering with private tech firms in AI-for-health initiatives.

- **Agenda and principle setting:** external agenda-setting power. While this critique is broader and applies to the entire international development architecture, it is still an important one. Private donors and firms often pursue their own strategic interests or ideologies, which may not align perfectly with local needs

- **Outpacing regulators:** Across high, middle, and low-income contexts, regulators consistently acknowledge that they are not yet equipped to fully audit, certify, or monitor AI systems used in health care. Even well-resourced oversight bodies such as the U.S. Food and Drug Administration (FDA), the UK Medical Device Regulation (MDR) have struggled to keep pace with emerging AI diagnostics and adaptive algorithms. If high-capacity state regulators cannot (or will not) enforce strict AI rules, expecting low-resource health systems that heavily depend on this technology to do so is unrealistic.

- **Imposition of values**: AI systems reproduce the hierarchies of empire, treating people and cultures as "raw material". They observe that Western-developed AI tools, built on Western data and values, tend to be unfit for local contexts and can displace indigenous innovation, leaving entire regions dependent on foreign algorithms and software.

Private Actors: Governance Implications

- Accountability is Unclear
- Deregulation Trends in High Income Governance
- Soft law governance is insufficient, but perhaps the only option

Private actors are indispensable to AI innovation in health, but their influence reflects a structural governance vacuum.

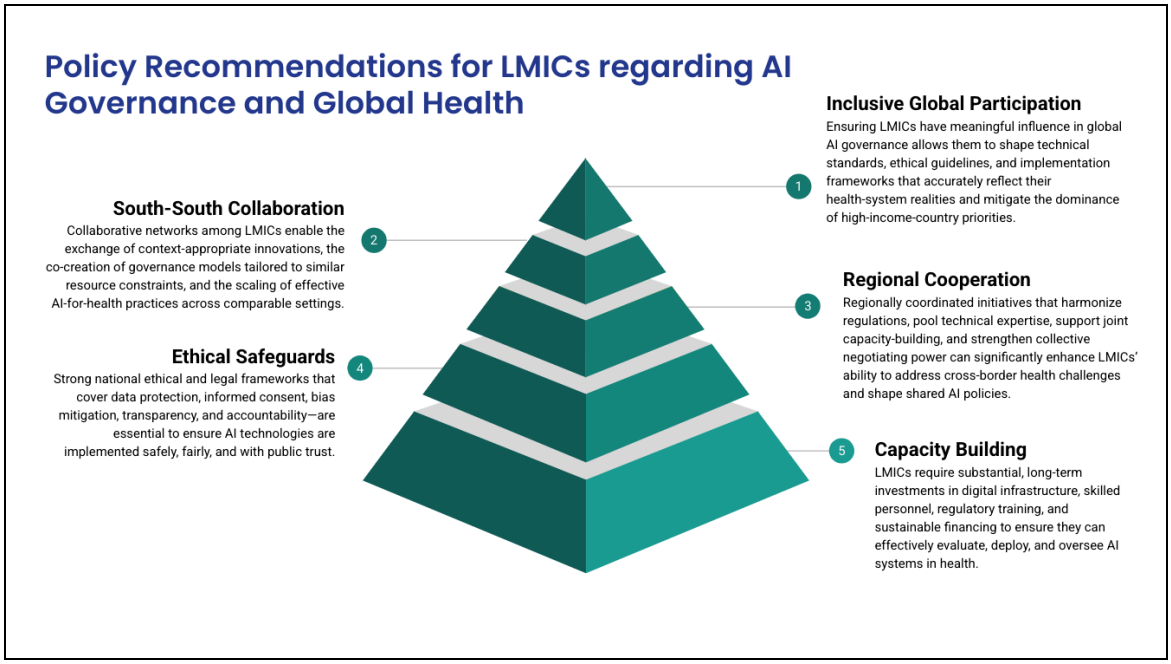
Strengthening national governance, transparency, and public accountability (not limiting private involvement) is essential for **aligning AI tools with public health priorities.**

- Recent shift toward loosening AI regulations in advanced economies The EU, (historically the global leader in digital protections) has begun weakening and delaying key elements of the Global Data Protection Rules (GDPR) and the EU AI Act in an effort to stimulate growth and avoid falling behind the United States and China (Bracy, 2025). The United States is moving even faster. New provisions added to the National Defense Authorization Act aim to pre-empt state-level AI regulation, effectively preventing California, Colorado, and others from imposing stricter requirements on tech companies

- Proposed changes include making it easier for companies to use personal data to train AI models, reducing consent requirements, and postponing the enforcement of stricter rules on high-risk AI systems. Prominent privacy lawyer and digital rights advocate Max Schrems, who has led influential legal cases that have contested and shaped privacy legislation worldwide, has called this the “biggest attack on European’s digital rights in years.
- This shift reflects a broader industrial strategy: prioritize speed, competitiveness, and private-sector growth over precautionary governance

- Rather than viewing this asymmetry as a mere governance failure, it may be more productive to recognize it as a structural feature of contemporary AI. The challenge, therefore, is not to curtail private sector participation in AI health interventions (since their role is often indispensable), but to advocate for appropriate safeguards, accountability mechanisms, and public-oriented regulatory capacities are in place so that partnerships operate under transparent, accountable governance arrangements that align with national health priorities.

- Proposals include greater transparency on the end-to-end process of AI ideation, model training, and development, as well as monitoring and evaluation efforts that identify all entities associated with the technology. Scholars also call for the development of assessment tools and repositories for collecting evidence to support adoption barriers such as bias and transparency



Policy Recommendations: Building the Pyramid

5. Capacity Building: LMICs often lack technical infrastructure, skilled workforce, and funding for AI. Key actions: invest in digital infrastructure and local research facilities, train health professionals, regulators, and data specialists, and develop sustainable funding for long-term evaluation, procurement, and monitoring of AI tools.

4. Ethical Safeguards: Strong ethical frameworks protect patients and build trust. Strengthen data protection laws and informed consent processes, implement bias detection and mitigation strategies, and ensure AI systems in health are transparent, auditable, and accountable.

3. Regional Cooperation: Regional bodies (e.g., African Union) coordinate policies across countries. Promote harmonized regulations, shared technical expertise, joint capacity-building, and pooled resources to address cross-border health challenges, strengthening LMICs' collective influence in global AI governance.

2. South-South Collaboration: LMICs can share knowledge and co-create context-relevant solutions. Exchange successful digital health and AI models, use joint research projects and regional innovation hubs to scale innovations, and amplify LMIC voices in international AI governance discussions.

1. Inclusive Global Participation: Ensure LMICs have meaningful representation in AI standard-setting and governance. Allow them to shape technical norms, ethical guidelines, and implementation frameworks, moving beyond token participation so global standards reflect their realities.