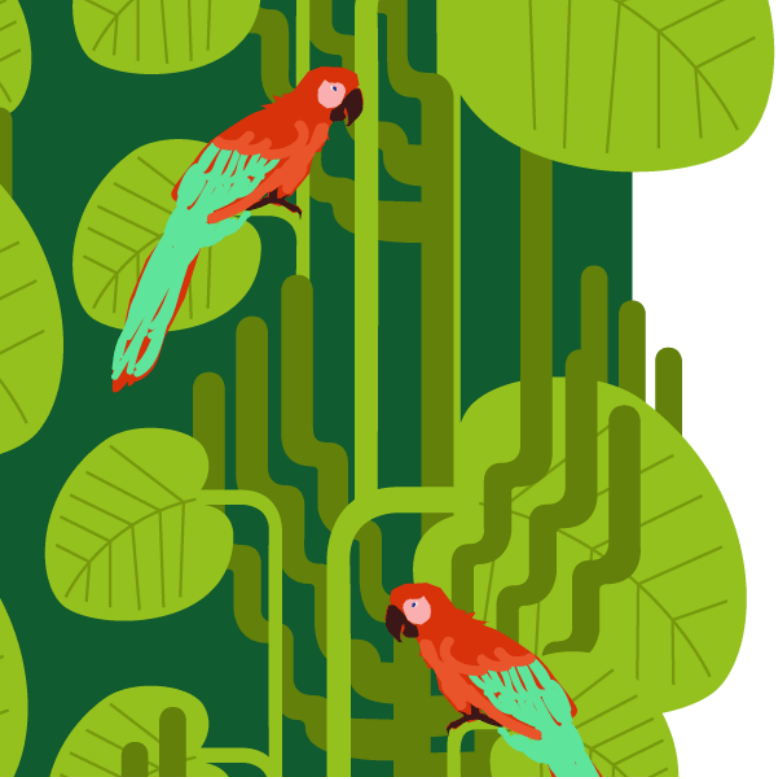




Governance, regulation and guardrails: What countries must put in place



 **AIDS** 2026

Fola Adeleke, Global Center on AI Governance
AI and HIV: Who owns the future of public health?

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MY VANTAGE POINT

Fola Adeleke

Global Center on AI Governance

- Law & human rights
- AI governance research
- African regulatory practice

I work on the rules AI operates under, not the models themselves.

Why I'm speaking to this

WHAT SHAPES THIS ARGUMENT

1 Governance first, not tools first

I come to this as a governance researcher, not a developer or vendor. The questions I work on (who is accountable, under what rules, with what remedy) are usually asked far too late.

2 Grounded in high-burden settings

This argument draws on landscape studies of countries carrying the greatest HIV burden (where AI is arriving faster than the regulation meant to govern it.)

3 HIV as the hardest test

Stigma, criminalisation and surveillance make HIV the domain where weak AI governance does the most damage and where getting it right teaches us the most.

So the question I bring is not whether AI works in HIV programmes but under what rules, and accountable to whom.



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AI is reshaping HIV care but governance hasn't kept pace

- **AI is entering routine care.**

ML targets prevention, flags treatment interruption; chatbots deliver testing and treatment information.

- **The legal infrastructure lags.**

Oversight is fragmented and not attuned to HIV stigma, criminalisation and surveillance.

THE CORE PROBLEM

A race to the bottom

Without binding rules, AI markets reward speed and scale over safety:

- Bias testing, privacy-by-design and validation cost more so responsible developers are penalised.
- The least carefully built tools reach deployment fastest.
- Those who bear the harm have the least power to demand better.



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Landscape of regulatory oversight

1 Overlapping mandates

Health Ministries, data-protection authorities, medical device regulators and new AI councils all play a role but none owns it end-to-end.

2 Underdeveloped pathways

Medical Device authorities treat AI as generic hardware, with no route to register or monitor adaptive software-as-a-medical-device.

3 Donor-mediated governance

Pilots are funded and hosted by external partners, often beyond domestic regulators' reach.

4 Weak community redress

Complaint mechanisms exist on paper but are untailored to AI and inaccessible to marginalised groups.

Responsibility is diffuse.

AI can be deployed with no clear line of liability, transparent evaluation or meaningful recourse for those affected.



Why HIV requires a distinct governance approach

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Where criminalisation and stigma push people out of care, the data that trains AI systematically under-represents key populations.

Errors then compound: mis-scoring hidden groups, feeding surveillance through integrated records, and eroding the trust that public health depends on.

The tools most likely to reach high-burden settings fastest are the least likely to have been rigorously evaluated.

From data gap to rights harm





Challenges for distinct governance of AI in HIV care

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- **Market power** - Multinationals outmatch national regulators; governments court the firms they must regulate.
- **Fast-moving technology** - AI evolves faster than legislative cycles; static rules go stale, vague ones leave gaps.
- **Fragmentation** - Dispersed mandates at home and slow regional alignment across borders.
- **Accountability deficits** - Opaque systems, diffuse liability and thin community redress.
- **Capacity & donor dynamics** - Under-resourced regulators; pilots framed as innovation bypass scrutiny.
- **Criminalisation & inequality** - Punitive laws distort data and can compel access to health analytics.



Governance requirements for AI in public health

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WITHOUT A REGULATORY FLOOR

- Speed and scale beat safety
- Responsible developers are undercut on cost and time
- The least-validated tools deploy fastest
- Those least able to demand safety bear the greatest risk

WITH A SHARED FLOOR

- Minimum safety & transparency standards for all
- Harm-prevention costs internalised across the market
- Responsible development is no longer a penalty
- Innovation becomes something that can be trusted



Five principles to anchor AI governance in health

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PRINCIPLE 1

Human rights by design

Non-discrimination, explainability, community participation, privacy and accessible remedy.

PRINCIPLE 2

Equity & fair distribution

Reduce rather than deepen disparities; evaluate across subgroups; don't favour tools validated only in rich settings.

PRINCIPLE 3

Non-punitiveness & voluntariness

A hard separation of health data from criminal enforcement; genuine consent; no service gated behind AI.

PRINCIPLE 4

Lifecycle governance

Oversight across the whole life of a system: not a single, one-off approval that ignores how AI evolves.

PRINCIPLE 5

Community stewardship & accountability

AI systems deployed in HIV programmes should be subject to meaningful community stewardship throughout their lifecycle.



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National Governance Architecture

Build on what already exists

1

Activate existing laws



2

Amend & adapt frameworks



3

Introduce de novo AI law

AI enters a highly regulated environment, not a vacuum. Integrate first; reserve new law for genuine gaps.

- **Activate** existing constitutional, data-protection, health and consumer laws now.
- **Amend** frameworks for profiling, certification, monitoring and liability.
- **Legislate** de novo where gaps remain — moving soft law to binding obligation.



The necessity of cross-border governance

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WHY THE CEILING

- AI is built, trained and deployed across borders.
- Developers cluster in a few high-income countries; effects land globally.
- Rigorous national law can penalise responsible domestic actors while the wider market stays ungoverned.

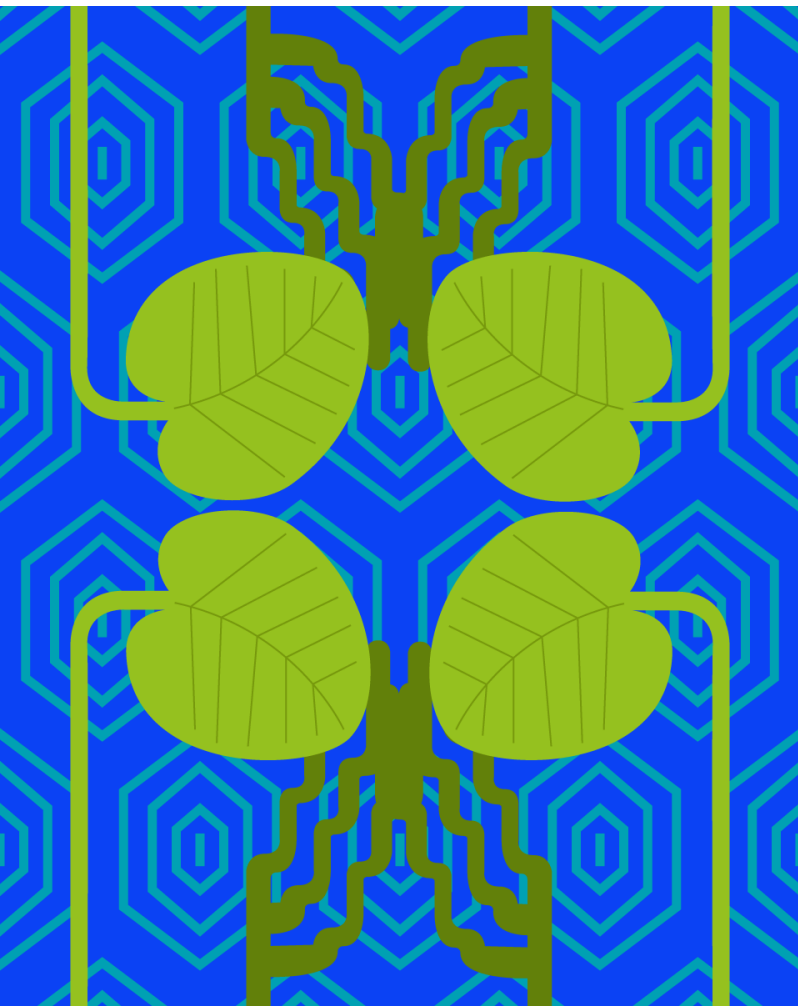
The correction requires a binding global floor.

WHAT GLOBAL GOVERNANCE OFFERS

- **A floor that travels** with the technology (IETF · ICANN)
- **Shared evaluation** infrastructure (WHO PQP · Codex)
- **Cross-border accountability** (Basel · pharmacovigilance)
- **Leverage over developers** (Doha/TRIPS · Global Fund · PEPFAR)



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The real comparison is not regulated versus unregulated. It is a regulated market versus one shaped by its least careful participants.