



REGULATORY FRAMEWORKS FOR ARTIFICIAL INTELLIGENCE IN HEALTHCARE: LESSONS FROM KENYA'S DIGITAL HEALTH ACT AND COMPARATIVE INSIGHTS FROM AFRICA

Background:

Artificial Intelligence (AI) is reshaping healthcare through predictive diagnostics, patient monitoring, and efficient resource allocation. However, the absence of robust regulatory frameworks in many African countries raises ethical, legal, and governance concerns. Kenya's Digital Health Act (2023) provides a pioneering attempt to regulate digital health through provisions on data protection, patient rights, and governance structures. Although the Act does not explicitly regulate AI, it offers a policy foundation for contextualizing AI oversight in healthcare. This study examines Kenya's approach in comparison with South Africa, Nigeria, and Rwanda, identifying gaps, ethical considerations, and lessons for developing inclusive AI regulatory frameworks across Africa.

Conclusion:

Kenya's Digital Health Act (2023) provides a strong foundation for AI regulation in healthcare but requires expansion to address algorithmic fairness, transparency, and accountability. Comparative insights highlight the need for a harmonized continental framework that embeds ethics, equity, and inclusivity in AI governance. Strengthening national policies while aligning with the African Union's Digital Transformation Strategy (2020–2030) can enable African countries to regulate AI in healthcare in a way that balances innovation with patient rights and ethical safeguards.

Methods:

A comparative policy analysis was undertaken, focusing on Kenya's Digital Health Act (2023), South Africa's Protection of Personal Information Act (POPIA), Nigeria's digital health strategies, and Rwanda's e-health policies. Key governance dimensions assessed included data protection, patient consent, liability in AI-driven decisions, transparency, and inclusivity. The analysis also drew on international benchmarks such as the European Union's AI Act and the U.S. FDA guidance on AI/ML-based medical devices.

Results:

Kenya's Digital Health Act (2023) strengthens digital governance through a dedicated Digital Health Agency, provisions on patient data ownership, and interoperability standards. However, it lacks AI-specific oversight mechanisms, especially around algorithmic accountability and ethical safeguards. South Africa offers stronger personal data protection under POPIA, but sectoral AI regulation in health is limited. Nigeria's frameworks remain fragmented with weak enforcement, while Rwanda demonstrates strong political will and e-health adoption but little regulatory focus on AI. Across the cases, common gaps include inadequate clarity on liability, limited patient engagement, and exclusion of vulnerable populations such as Persons with Disabilities.

Author – Comfort Achieng