Health Data Governance

Legislative and Regulatory Landscape Review

ZAMBIA

COUNTRY REPORT

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Transform Health

1. Introduction

This report analyses the legislative and regulatory landscape of Zambia to understand how and to what extent the governance of health data is addressed. The Health Data Governance Principles (HDG Principles)[1] served as a framework for this analysis to explore and document how the principles manifest in the existing legal and regulatory environment. This review entailed a content analysis of relevant legal texts against the eight HDG Principles.

This report identifies best practices for Zambia's health data governance, including recommendations on how to strengthen the health data governance landscape. The country summary emphasises the need for reform in digital health governance, sustainable investment, workforce development, enhanced policy frameworks, and infrastructure improvements. The recommendations aim to address these gaps, suggesting the establishment of a national steering committee, a financing plan for digital health technologies, and the development of an interoperability framework. These measures are intended to enhance the governance, efficiency, and effectiveness of digital health initiatives in Zambia, aligning with broader e-Government objectives.

Health Data Governance Principles

Protect People

Protect individuals & communities

Build trust in data systems

Ensure data security

Promote health value

Enhance health systems & services

Promote data sharing & interoperability

Enhance health systems & services

Prioritise equity

Establish data rights & ownership

Promote equitable benefit from health data

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1 View the Health Data Governance Principles: https://healthdataprinciples.org

2. National Legislative and Regulatory Overview

The following sources were used for purposes of analysing the legislative and regulatory system of Zambia:

- The Constitution of Zambia (Amendment), Act No. 2 of 2016 (Zam.)

- Data Protection Act No. 3 of 2021 (Zam.)

- Zambia National Public Health Institute Act No. 19 of 2020 (Zam.)

- Electronic Communications and Transactions Act No. 4 of 2021 (Zam.)

- The Cyber Security and Cyber Crimes Act No. 2 of 2021 (Zam.)

- Information and Communications Technologies Act No. 15 of 2009 (Zam.)

- Republic of Zambia Ministry of Health, *Digital Health Strategy 2022–2026* (2022).

- Republic of Zambia Ministry of Communications & Transport, *Smart Zambia Electronic Government Master Plan 2018–2030* (2018)

- Health Professions Council of Zambia, *Guidelines for Good Practice in the Health Care Profession: Maintaining Patient Confidentiality* (2021)

- Republic of Zambia Ministry of Health, *National Health Policy: A Nation of Healthy and Productive People* (2012)

- Selina Kadakwiza Halubanza, *Douglas Kunda & Brian Halubanza, A Framework for an E-Health System for Zambian Health Centres that Incorporates Data Mining Reporting*, Int'l J. Comput. Appl. (2018)
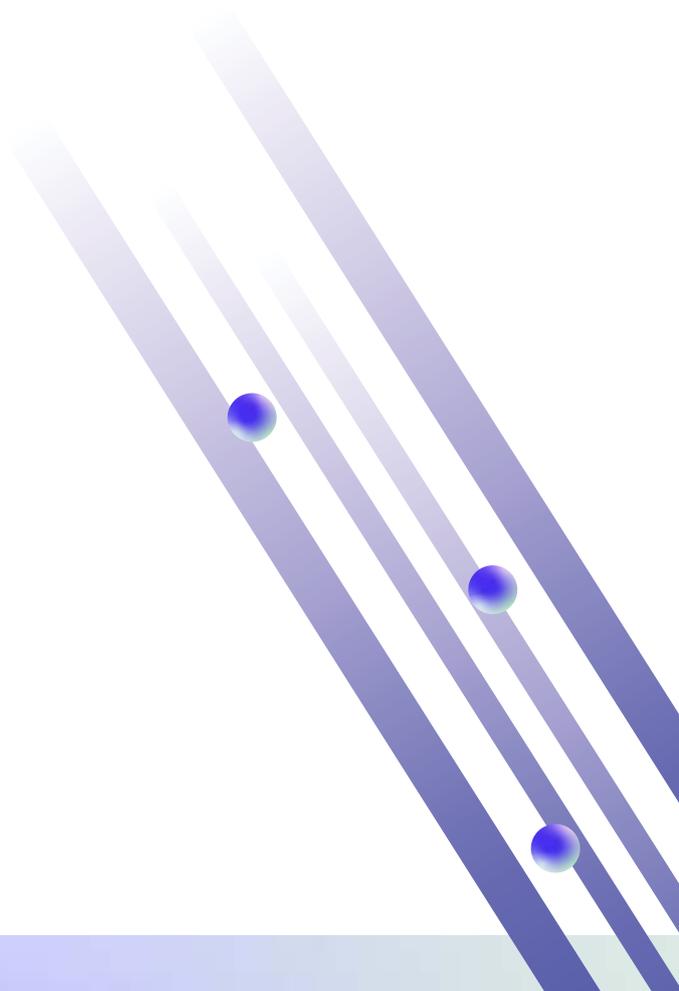
3. Analysis of the National Legislative and Regulatory Environment

The currently enacted or most recently published legislative and regulatory instruments in Zambia relating to the eight HDG Principles are discussed under the sub-heading of each respective principle below

3.1. Protect individuals and communities

The regulatory framework in Zambia protecting individuals and communities concerning their health and personal data is underpinned by multiple legislative acts and guidelines.

The Constitution of Zambia guarantees fundamental rights, including the right to life, liberty, and security of the person under Article 11. It further protects personal liberty under Article 13 and guarantees the right to privacy in Article 17, safeguarding individuals' personal information. Complementing these constitutional guarantees, the Data Protection Act sets out principles for processing personal data (Part IV) and imposes strict requirements for protecting sensitive data (Sections 13-17). The Zambia National Public Health Institute Act mandates the protection of public health data while managing health emergencies (Section 19).

Supporting these provisions are the Information and Communication Technologies Act (ICT Act), which ensures electronic transactions respect privacy and data protection standards, and the Guidelines for Good Practice in Healthcare Profession that reinforce patient confidentiality. Furthermore, Zambia's National Health Policy emphasises building robust health information systems to protect personal health data. Collectively, these frameworks ensure the safeguarding of individual and community health and personal data rights in Zambia.

3.2. Building Trust in Data Systems

Zambia's framework for building trust in data systems is multifaceted, focusing on legislation, digital health initiatives, and robust ICT policies.

The Data Protection Act and Cyber Security and Cyber Crimes Act promote secure data processing and the prevention of cybercrimes, which are critical for fostering trust in data systems. For instance, the Cyber Security and Cyber Crimes Act establishes mechanisms to ensure the reliability of electronic evidence in legal proceedings. The Electronic Communications and Transactions Act (ECTA) also plays a vital role, mandating security measures for electronic communications to protect against breaches and unauthorised access.

The Zambia National Health Policy and the Digital Health Strategy (2022–2026) emphasise transparency, accountability, and secure health information systems. Notably, the proposed e-health system integrating data mining capabilities aims to enhance data accuracy and reliability, thereby increasing public trust in health systems. These measures collectively contribute to establishing a secure and trustworthy data governance environment.
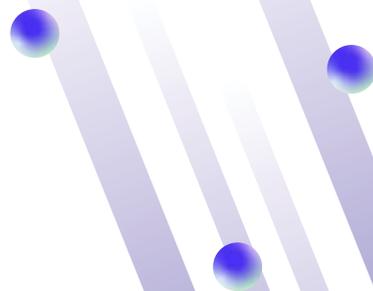
3.3. Ensuring Data Security

Ensuring data security is central to Zambia's legislative framework, as reflected in the Data Protection Act. Part VIII details security obligations for data controllers and processors, including mandatory breach notifications (Sections 47-49). The Zambia National Public Health Institute Act further supports secure public health data management during emergencies.

The ECTA and the Cyber Security and Cyber Crimes Act provide overarching measures to safeguard electronic transactions and critical information infrastructure. For example, Part V of the Cyber Security and Cyber Crimes Act outlines stringent standards for securing information systems and protecting infrastructure from cyber threats. These are complemented by the ICT Act, which imposes responsibilities on service providers to ensure the security of their networks.

These regulations, alongside specific guidelines for healthcare practitioners on confidentiality and electronic data processing, establish a robust framework for safeguarding sensitive health and personal data in Zambia.

3.4. Enhancing Health Services and Systems

Enhancing health services and systems is a priority in Zambia, which is guided by several legislative and policy measures.

The Data Protection Act permits the processing of sensitive health data for medical and public health purposes (Section 14(1)(b)). Similarly, the Zambia National Public Health Institute Act focuses on improving public health infrastructure and emergency response systems. The National Health Policy emphasises enhancing health service delivery, infrastructure, workforce development, and financing.

The proposed e-health system framework incorporates data mining tools to optimise healthcare delivery and patient care. The Digital Health Strategy (2022–2026) complements these measures by outlining strategic objectives to improve service efficiency and accessibility through digital technologies. Together, these initiatives contribute to strengthening Zambia's healthcare system and services.

3.5. Promoting Data Sharing and Interoperability

Zambia's regulatory framework promotes data sharing and interoperability through legislation and strategic initiatives.

The Data Protection Act governs cross-border data transfers (Sections 70-71) to ensure consistency in data protection standards during international exchanges. Similarly, the Zambia National Public Health Institute Act establishes repositories for disease surveillance, enabling data sharing among stakeholders. The ICT Act regulates telecommunication services to ensure interoperability across networks, while the Cyber Security and Cyber Crimes Act supports collaboration in addressing cybersecurity challenges.

Strategic initiatives like the Digital Health Strategy and e-health system framework promote the seamless exchange of health data through interoperable systems, enhancing data accessibility and utility for stakeholders.
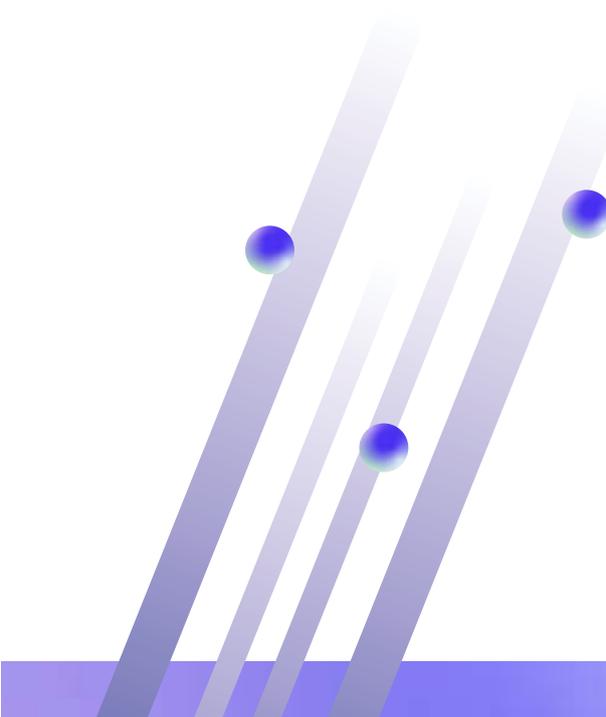
3.6. Facilitating Innovation Using Health Data

The framework for facilitating innovation using health data in Zambia integrates legislative and technological advancements.

The Data Protection Act and the ECTA provide a legal foundation for secure and innovative data use, while the Zambia National Public Health Institute Act enables research and innovation through public health data systems. The Digital Health Strategy identifies areas for leveraging ICT to enhance healthcare delivery and outcomes.

Further, the e-health system framework incorporates advanced data analysis techniques to optimise healthcare services. These combined efforts create an environment conducive to innovation while ensuring compliance with data protection and ethical standards.

3.7. Promoting Equitable Benefits from Health Data

Zambia's framework emphasises equitable access to health data benefits.

The Zambia National Public Health Institute Act establishes a public health security system to ensure data accessibility for public health improvements. The National Health Policy outlines measures to reduce health disparities through improved data collection and utilisation.

Initiatives like the Digital Health Strategy and the proposed e-health system framework aim to ensure equitable access to quality healthcare by leveraging data for decision-making and service provision. These efforts collectively promote fairness and inclusivity in the use of health data.

3.8. Establishing Data Rights and Ownership

The regulatory framework for data rights and ownership in Zambia is anchored in the Data Protection Act, which defines principles for data processing and establishes data subject rights (Parts IV and IX). The Zambia National Public Health Institute Act further regulates data collection and dissemination for public health purposes, subject to existing laws.

Other relevant acts, such as the Electronic Communications and Transactions Act and the Cyber Security and Cyber Crimes Act, establish data protection standards for electronic systems and infrastructure. These provisions collectively ensure clear data rights and ownership frameworks in Zambia, supporting transparency, accountability, and compliance with data governance principles.
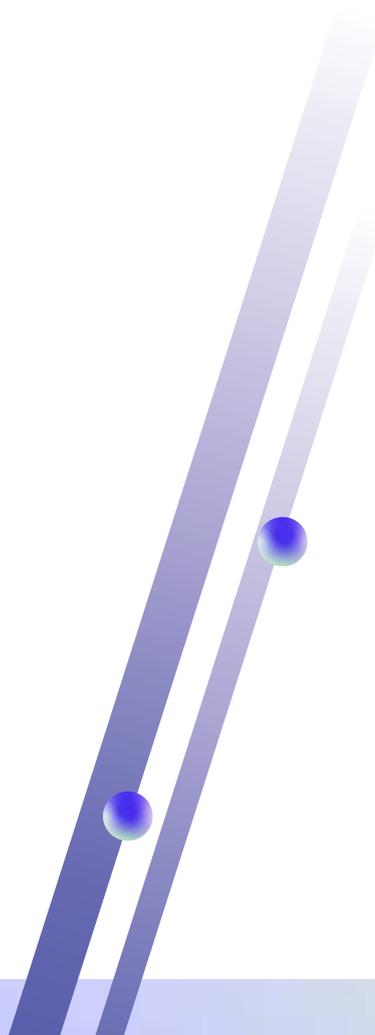
4. Best practices

The health data regulatory framework in Zambia demonstrates several effective practices for health data governance, focusing on legal, infrastructural, and collaborative strengths:

o **Strong legal and policy foundations:** Zambia's legislative frameworks, including the Data Protection Act and the National Public Health Institute Act, establish a robust foundation for protecting health data and enabling secure public health data management.

o **Digital health leadership and coordination:** The Ministry of Health has provided clear guidance through the Digital Health Strategy, prioritising governance, investment, and stakeholder collaboration to ensure cohesive digital health efforts.

o **Public-private partnerships and stakeholder collaboration:** Encouraging collaborations between government and private entities has bolstered resources and expertise for health data management and digital health innovation. Fostering cooperation among government agencies, healthcare providers, and other stakeholders supports a cohesive approach to health data governance.

o **Capacity building for digital health:** There is a sustained emphasis on training healthcare and IT professionals in health data governance, increasing capacity and ensuring adherence to privacy and security standards.

o **Infrastructure development:** Investment in ICT and health information systems supports the digitalisation of healthcare services and better data interoperability.

o **Interoperability and standards development:** Zambia's focus on developing a unified interoperability framework and clinical data standards facilitates efficient data exchange across platforms.

o **Patient confidentiality and ethical practices:** Guidelines emphasising patient confidentiality and ethical data handling practices reflect Zambia's commitment to privacy and trust in the health system.

o **Monitoring and continuous improvement:** The regulatory framework supports ongoing evaluation and adaptation to emerging challenges, ensuring sustainable digital health development. Continuous monitoring and evaluation of health data governance practices supports identifying areas for improvement and ensures compliance with national and international standards.
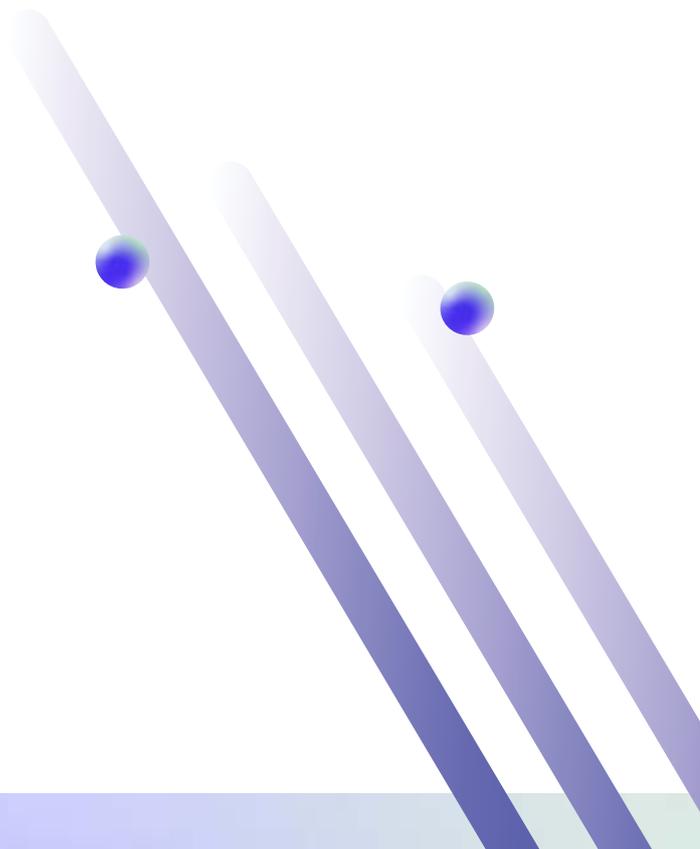
5. Gaps

Despite these strengths, Zambia's health data governance framework exhibits the following gaps:

- o **Governance and oversight:** Weak coordination and oversight mechanisms, including a steering body to guide digital health efforts comprehensively.

- o **Sustainable investment:** Digital health initiatives face challenges in securing long-term financing, with reliance on external funding, thereby posing risks to continuity.

- o **Workforce limitations and capacity:** Insufficient training opportunities and talent development programmes hinder the effective deployment and management of digital health technologies and systems. Absence of specific strategies for building capacity in health data governance among healthcare professionals and IT staff within the health sector.

- o **Fragmented infrastructure:** Uneven ICT infrastructure development, including network connectivity and electricity, limits access to and use of digital health services, particularly in rural and underserved areas.

- o **Data privacy and security gaps:** Although legislative provisions exist, their implementation lacks specific operational measures for ensuring consistent data privacy and security.

- o **Limited interoperability and integration:** Fragmentation among digital health systems restricts seamless data sharing and integration across health facilities, government bodies, and platforms. Multiple, fragmented digital health solutions with limited integration indicate the need for a more coordinated and standardised approach to digital health applications and services.

- o **Public engagement and transparency:** Mechanisms for involving the public and maintaining transparency in health data use and policymaking are underdeveloped.

- o **Innovation in health data use:** Lack of focus on leveraging health data for innovation in healthcare, such as through the development of health information exchanges, telemedicine, and other digital health initiatives.
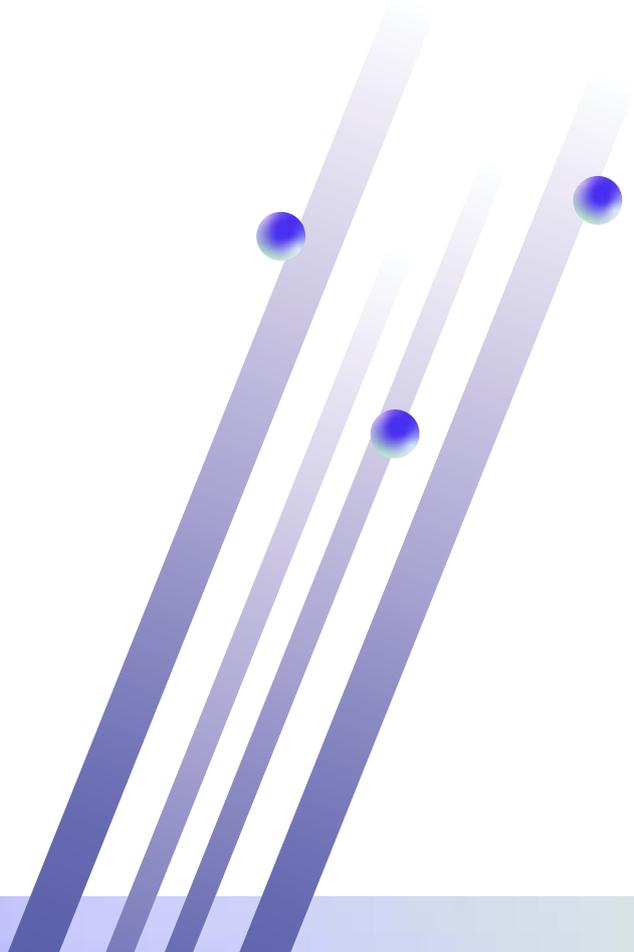
6. Recommendations

To address these gaps, the following recommendations are proposed:

o **Governance and leadership:** Establish a national steering committee charged with coordinating digital health initiatives, as well as developing and overseeing a digital health maturity model for regular assessment and improvement.

o **Sustainable financing:** Implement a long-term financing plan for digital health technologies, reducing reliance on external donors.

o **Workforce development:** Invest in human capital and training programmes to enhance digital health expertise and capacity, leveraging global best practices and e-learning platforms.

o **Policy and compliance:** Strengthen and harmonise policies addressing privacy, cybersecurity, interoperability, and liability in digital health systems.

o **Interoperability and data standards:** Finalise and implement the national interoperability framework and establish accreditation for digital health technologies.

o **Infrastructure development:** Prioritise and coordinate investment to expand digital health infrastructure and ensure equitable access to digital health solutions, prioritising underserved regions.

o **Public engagement:** Develop transparent mechanisms for public participation in health data governance and policymaking processes.

o **Innovation and technology use:** Foster the use of emerging technologies, such as AI and data mining, for healthcare improvements, ensuring ethical considerations.

7. Conclusion

The report evaluates Zambia's current health data governance landscape, identifying best practices, gaps, and recommendations. It highlights significant progress and legal and strategic achievements, while identifying areas needing attention. Key recommendations, including governance reform, sustainable investment, workforce development, and infrastructure enhancements to strengthen health data systems, are essential to addressing these gaps. The discussion emphasises aligning Zambia's digital health goals with global best practices to ensure effective healthcare delivery and public trust. By taking forward these measures, Zambia can establish a resilient digital health ecosystem that promotes data privacy, interoperability, and innovation, ultimately enhancing healthcare delivery and outcomes.