

# Health Data Governance

Legislative and Regulatory  
Landscape Review



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**MALAWI**  
COUNTRY REPORT

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This health data governance country landscape report was developed by Transform Health, with contributions from Research ICT Solutions and Baker Botts. This work was funded by the Patrick J. McGovern Foundation and Fondation Botnar.

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# 1. Introduction

This report analyses the legislative and regulatory landscape of Malawi to understand how and to what extent the governance of health data is addressed. The Health Data Governance Principles (HDG Principles)<sup>1</sup> 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 Malawi’s health data governance, including recommendations on how to strengthen the health data governance landscape. The summary delves into the regulatory frameworks that underpin health data governance, emphasising the protection of individuals and communities, the establishment of trust in data systems, and the promotion of equitable benefits from health data. It discusses the critical role of leadership, governance, legislation, policy, compliance, human resources, and digital health services in effectively managing health data.

The report also highlights gaps, such as the reliance on paper-based systems and challenges in interoperability, that impede efficient health service delivery and data utilisation. It concludes with a set of recommendations aimed at enhancing health data governance, including the establishment of leadership structures, the development of legislation and policies, and the improvement of interoperability and data security. These recommendations are designed to strengthen health information management, support evidence-based decision-making, and ultimately improve health service delivery in Malawi.

## 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

<sup>1</sup> 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 Malawi:

- Constitution of the Republic of Malawi, 1994 (Malawi)
- Access to Information Act, Act No. 13 of 2017 (Malawi)
- Public Health Act, Cap. 34:01 (Malawi)
- Data Protection Act, Act No. 3 of 2024 (Malawi)
- Ministry of Health, Gov't of the Republic of Malawi, *National Digital Health Strategy 2020–2025* (2020)
- Ministry of Health, Gov't of the Republic of Malawi, *Data and Digital Priorities: Digital Health for Universal Health Coverage*
- John Åge Haugen & Dag Roll-Hansen, *The Health Management Information System in Malawi: Assessment of Data Quality and Methods for Improvement* (Statistics Norway, Discussion Paper No. 434, 2006)

## 3. Analysis of the National Legislative and Regulatory Environment

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

### 3.1. Protect individuals and communities

Malawi's regulatory framework offers a robust legal foundation for safeguarding individuals and communities by addressing personal freedoms, privacy, and public health. The Constitution of Malawi establishes core protections, including the right to personal liberty (Section 18), human dignity and personal freedoms (Section 19), and privacy (Section 22), forming the bedrock of individual rights. The Access to Information Act complements these constitutional protections by regulating personal data through provisions like Section 29, which safeguards personal information, and Section 31, which protects data related to life, health, and safety. Additionally, the Public Health Act focuses on public health protection, mandating the notification of infectious diseases and outlining measures to prevent and suppress outbreaks. The Data Protection Act further expands protections by codifying principles for data processing (Sections 8–18), recognising data subject rights (Sections 19–26), and requiring strict data security measures (Sections 35–37).

Malawi's National Digital Health Strategy reinforces these safeguards through Objective 5 in Chapter 4, which prioritises securing information systems, while the Health Information System Policy ensures confidentiality (Section 7) and proper data storage (Section 12). Together, these legal and strategic frameworks protect the rights of individuals and communities by balancing privacy with public health needs.

### 3.2. Building Trust in Data Systems

Building trust in Malawi's data systems relies on transparency, accountability, and effective governance across various legislative and policy instruments. The Constitution of Malawi underscores the importance of open and accountable governance in Chapter III, which fosters trust by promoting transparency and ethical administration. The Access to Information Act supports these principles by mandating proper record-keeping, capacity building, and the appointment of information officers (Sections 12-14), ensuring institutions are equipped to handle and share data responsibly. Similarly, the Public Health Act enhances trust through structured notification and management of infectious diseases (Part III, Sections 11-15), ensuring timely and transparent communication of health risks.

The Data Protection Act introduces rigorous standards for data processing, rights enforcement, and security protocols, while Malawi's Digital Health Strategy highlights the need to improve data quality and utilisation, particularly in Priority 6, which focuses on securing ICT systems and promoting ethical data use.

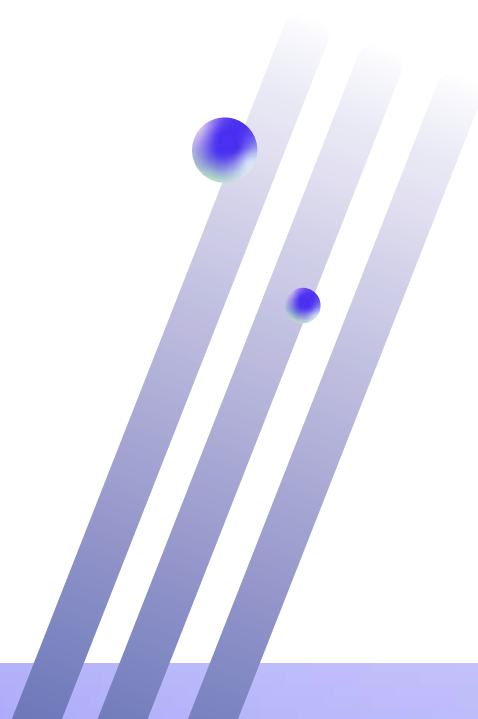
Frameworks like the Health Information System (HIS) and Health Management Information System (HMIS) further strengthen trust by emphasising confidentiality, accountability, and data quality assessment. By embedding these principles into governance, Malawi creates a reliable environment for data use, fostering public confidence in health and other data systems.

### 3.3. Ensuring Data Security

Malawi's approach to data security is anchored in a combination of constitutional rights, legislative instruments, and digital health strategies. While the Constitution of Malawi does not explicitly address data security, it lays the groundwork for privacy and governance protections.

The Access to Information Act includes key safeguards, such as Section 29, which protects personal information from unreasonable disclosure, and Section 31, which regulates exemptions to balance transparency with security. The Data Protection Act provides more specific protections, requiring data security measures (Section 35), breach notification (Section 36), and direct communication to affected data subjects (Section 37).

Malawi's Digital Health Strategy strengthens these measures by focusing on disaster recovery, threat protection, and ethical security management processes, particularly in Priority 6. Policies within the Health Information System Framework also address data confidentiality (Section 7) and breach accountability, while the HMIS contributes indirectly to data security by improving data reliability and integrity. Together, these measures establish a robust legal and operational framework for ensuring the secure handling and protection of personal and health data in Malawi.



### 3.4. Enhancing Health Services and Systems

The enhancement of Malawi's health services and systems is underpinned by constitutional commitments, legislative provisions, and digital health strategies. Chapter III, Section 13(c) of the Constitution of Malawi affirms the state's responsibility to provide adequate healthcare that aligns with societal needs and international standards. The Access to Information Act supports this goal by safeguarding data related to life and health (Section 31), enabling effective decision-making.

The Public Health Act introduces hospital governance mechanisms (Sections 10A and 10B) to improve operational efficiency and service delivery. Meanwhile, the Data Protection Act permits the processing of sensitive health data for public health, medical diagnosis, and health system management (Section 16).

The Digital Health Strategy prioritises ICT infrastructure development, interoperability, and data accessibility, while the Health Information System Policy addresses the technical resources, skilled personnel, and robust structures needed for effective health data governance. Collectively, these frameworks promote the integration of digital health technologies and the improvement of health systems, ensuring better service delivery and patient care across Malawi.

### 3.5. Promoting Data Sharing and Interoperability

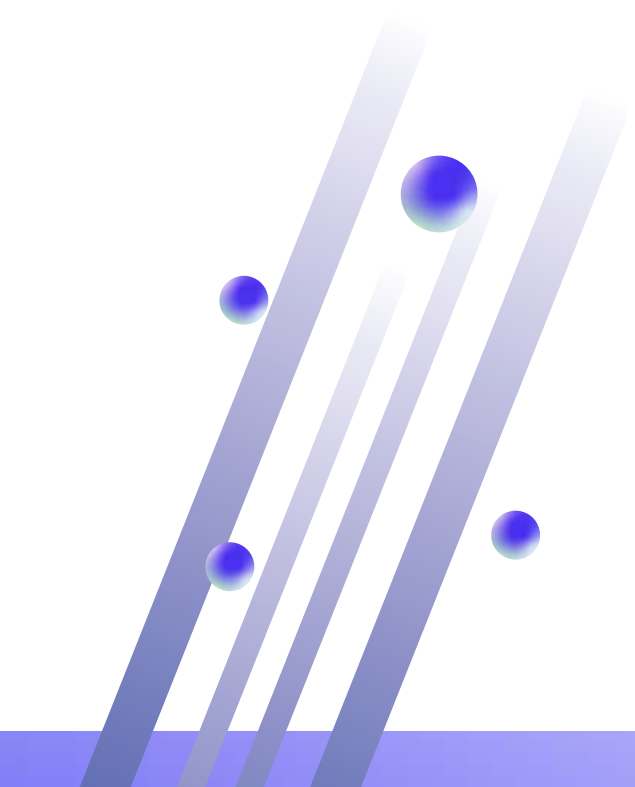
Malawi's regulatory framework for promoting data sharing and interoperability ensures secure and efficient exchange of information across health systems. The Access to Information Act facilitates these objectives by requiring proper record-keeping and capacity-building practices (Sections 13–14), creating the foundation for seamless data sharing.

The Data Protection Act addresses cross-border data transfers (Sections 38–39), ensuring adequate protections during international exchanges, while the Digital Health Strategy explicitly outlines interoperability frameworks in Chapters 4 and 5 to enhance data sharing and healthcare delivery.

Malawi's HMIS Framework builds on these measures by adopting standardised systems, such as DHIS2, to streamline data collection and analysis. These instruments collectively advance interoperability and enable data sharing while safeguarding privacy and security, contributing to improved coordination and decision-making in the healthcare sector.

### 3.6. Facilitating Innovation Using Health Data

The facilitation of innovation in Malawi's health sector is supported by laws and policies that balance data protection with the potential for transformative applications. The Data Protection Act provides a foundation for using health data for research and public health purposes under strict ethical conditions, while the Digital Health Strategy highlights the use of ICT systems, shared health records, and advanced analytics to drive innovation. Additionally, the HMIS Framework contributes by improving data quality and enabling evidence-based decision-making and predictive analytics. These measures collectively create an environment where health data can be used responsibly to support innovation, research, and enhanced healthcare outcomes in Malawi.



### 3.7. Promoting Equitable Benefits from Health Data

Promoting equitable benefits from health data in Malawi involves policies that emphasise inclusivity, transparency, and accessibility. Section 13(c) of the Constitution of Malawi commits to providing equitable healthcare, which implicitly includes fair use of health data to address disparities. The Access to Information Act safeguards personal privacy while enabling access to relevant information, ensuring that health data benefits are distributed fairly. Similarly, the Digital Health Strategy focuses on stakeholder capacity building, ensuring inclusive participation in and equitable benefits from digital health initiatives. The HMIS Framework further contributes by improving data quality and reliability, enabling informed and equitable decision-making. Together, these instruments ensure that health data serves as a tool for promoting fairness and reducing disparities in healthcare access and outcomes.

### 3.8. Establishing Data Rights and Ownership

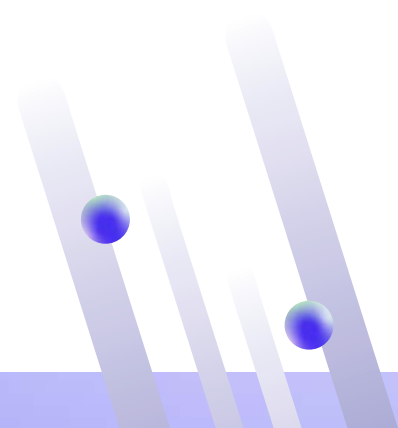
Malawi's regulatory framework establishes data rights and ownership through comprehensive legal and policy measures. While the Constitution of Malawi does not explicitly address data ownership, the Access to Information Act includes provisions like Section 29, which protects personal information, and Section 13, which mandates record-keeping to ensure accountability.

The Data Protection Act explicitly outlines data subject rights (Sections 19–26) and principles for processing personal data (Sections 8–18). Additionally, the Health Information System Policy addresses data ownership in Section 14, ensuring clear guidelines for data sharing and stewardship. These measures collectively ensure individuals' rights over their personal data while promoting responsible governance and ethical use of health information.

## 4. Best practices

Malawi's health data regulatory framework demonstrates several best practices to enhance governance, privacy, security, and interoperability in managing health data systems:

- o **Strong Leadership and Policy Alignment:** The Ministry of Health demonstrates effective leadership by aligning health data initiatives with national policies, such as the Malawi National Health Information System Policy and the National Digital Health Strategy (2020–2025). These documents set a clear vision for digital health and underscore the importance of governance, security, and capacity building.
- o **Legal and Regulatory Frameworks for Data Protection:** The Access to Information Act and the recently passed Data Protection Act provide a strong legal foundation for safeguarding personal health data. They outline data security measures, patient rights, and cross-border data transfer regulations, helping to build trust in digital health systems.
- o **Focus on Data Privacy and Confidentiality:** The Health Information System Policy prioritises confidentiality and security, with mechanisms for protecting patient privacy already embedded in existing health systems. For example, confidentiality protocols and secure storage practices are being implemented in many health facilities.
- o **Adoption of Digital Tools and Platforms:** Malawi has made significant strides in adopting digital health tools, such as the DHIS2 platform, which supports national-level data aggregation, reporting, and analysis. This system helps generate actionable insights for healthcare planning and decision-making.



- **Collaborative Approach to Digital Health Projects:** Many digital health initiatives in Malawi, such as those led by the Ministry of Health in collaboration with donors and non-governmental organisations, promote partnerships and coordination, enhancing the scalability and sustainability of projects.
- **Focus on Capacity Building:** Ongoing training programmes for healthcare workers, such as those addressing the use of health information systems and data reporting tools, are improving data literacy and technical skills at the facility level.
- **Data Quality Assessments (DQAs):** Routine DQAs ensure the accuracy and reliability of health data at various levels of the healthcare system. These assessments help identify gaps and provide opportunities for continuous improvement.
- **Efforts Toward Interoperability:** While challenges remain, Malawi has begun promoting interoperability across health information systems, with a focus on integrating platforms like EMRs and the HMIS.
- **Support for Equity in Healthcare Delivery:** Through initiatives such as the Digital Health Strategy, the government has demonstrated a commitment to improving access to health data systems, especially for underserved regions, contributing to more equitable healthcare outcomes.

These best practices demonstrate that Malawi has laid a solid foundation for health data governance and digital health transformation, despite challenges in scaling and integration.

## 5. Gaps

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Despite these advancements, several gaps remain in Malawi's health data governance framework:

- **Reliance on Paper-based Systems:** Despite the adoption of digital platforms like DHIS2, many health facilities continue to use manual reporting systems, slowing the digitisation process.
- **Sustainability of Digital Health Projects:** Most digital health projects rely on donor funding, with limited government support for sustaining initiatives once donor resources are exhausted.
- **Limited Interoperability Between Systems:** Existing digital health platforms, such as EMRs and HMIS, often operate in silos, preventing seamless data exchange and limiting system efficiency.
- **Data Quality and Completeness:** Challenges with incomplete, untimely, or inaccurate reporting undermine the reliability of health data for decision-making.
- **Technical and Workforce Capacity Constraints:** A shortage of skilled personnel to manage, maintain, and utilise digital health systems reduces the effectiveness of these technologies.
- **Lack of Coordination:** Digital health efforts often lack coordination between government agencies, donors, and implementing partners, leading to inefficiencies and duplication of efforts.
- **Inconsistent Stakeholder Engagement:** Limited communication and feedback between national, district, and facility levels hinder data verification and the consistent application of reporting standards.
- **Inadequate Data Governance Structures:** While frameworks exist, enforcement mechanisms, such as regular audits and penalties for non-compliance, remain weak.
- **Limited Access to Digital Tools in Rural Areas:** Rural and remote healthcare facilities lack the infrastructure and tools needed to fully benefit from digital health innovations.

## 6. Recommendations

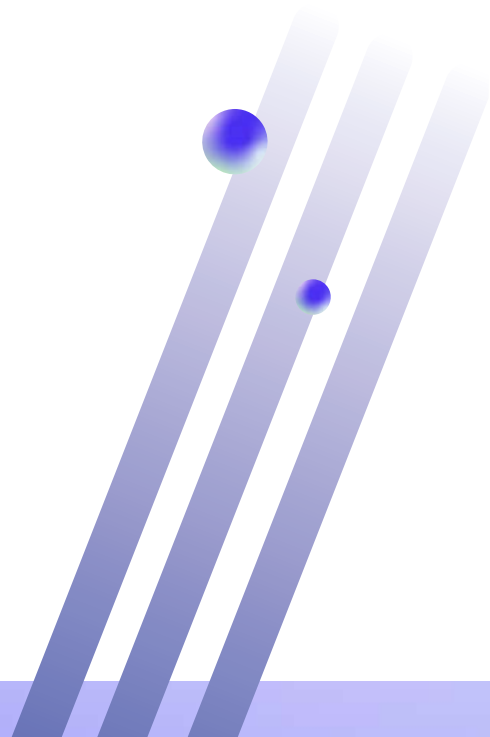
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To address these gaps, the following recommendations are proposed:

- **Expand Digital Infrastructure and Connectivity:** Invest in ICT infrastructure to ensure all health facilities, including rural areas, have access to digital tools and reliable connectivity.
- **Strengthen Data Governance Structures:** Establish robust enforcement mechanisms, including audits and penalties, to ensure compliance with data protection laws and reporting standards.
- **Foster Interoperability Across Systems:** Adopt national standards for data exchange and integrate platforms like EMRs and HMIS to create a unified health information ecosystem.
- **Enhance Workforce Capacity:** Implement targeted training programmes to build the technical skills of healthcare workers and IT personnel, ensuring sustainable system management.
- **Secure Sustainable Financing:** Transition from donor reliance to government-led funding models, incorporating health data governance into national budgets to ensure long-term sustainability.
- **Improve Data Quality:** Conduct regular data quality audits and implement automated tools for error detection, ensuring accurate, complete, and timely reporting.
- **Strengthen Stakeholder Coordination:** Create a central coordination body to align digital health initiatives, avoid duplication, and optimise resource allocation.

- **Expand Use of Digital Health Tools:** Scale up proven digital solutions, such as EMRs and DHIS2, to under-resourced facilities and regions, ensuring equitable access to health data benefits.
- **Promote Patient-Centred Data Practices:** Ensure patients are involved in decisions about their health data, fostering trust and improving participation in digital health initiatives.
- **Establish Interdisciplinary Collaboration:** Encourage partnerships between government agencies, NGOs, the private sector, and academic institutions to drive innovation and strengthen the digital health ecosystem.

These recommendations provide actionable steps to improve Malawi's health data governance framework, ensuring scalability, sustainability, and equitable access to healthcare benefits.



## 7. Discussion of Research Results

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The analysis highlights both successes and persistent challenges in Malawi's health data governance framework. Best practices, such as the adoption of DHIS2 and the enactment of the Data Protection Act, underscore Malawi's progress toward digital transformation and privacy protection. However, gaps in interoperability, workforce capacity, and data quality remain significant barriers to realising the full potential of digital health.

The recommendations, focusing on infrastructure development, capacity building, and sustainable financing, provide a roadmap for addressing these challenges. By implementing these strategies, Malawi can create a resilient and inclusive health data governance system that supports universal health coverage.

## 8. Conclusion

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Malawi's journey toward effective health data governance reflects its commitment to enhancing healthcare outcomes through digital transformation. Despite notable advancements, reliance on manual processes, inadequate interoperability, and limited technical capacity hinder progress.

By addressing these challenges and adopting the proposed recommendations, Malawi can strengthen its health data ecosystem, ensure sustainable and equitable access to healthcare, and support evidence-based decision-making. Aligning national efforts with international best practices will position Malawi as a leader in health data governance within the region, ultimately benefiting its citizens through improved healthcare delivery.

