Supporting stronger health data governance legislative frameworks

Malawi Case Study

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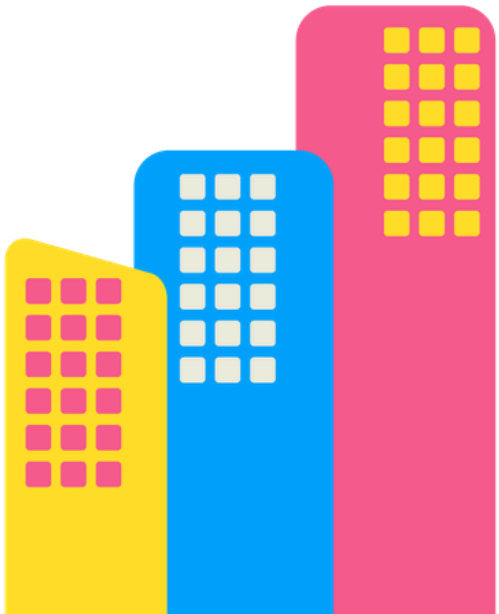


Background

The digitalisation of health systems and the rapid development of digital tools and Artificial Intelligence (AI) for health has increased the amount of health data that is collected and used. As a result, the issue of how health data is governed is a rising concern amongst populations and growing on political agendas. Health data needs to be effectively and equitably governed to safeguard data privacy and rights, mitigate risks of data misuse, and support responsible data use for improved health outcomes and public benefit. Particularly important is the need to ensure robust legislative and regulatory frameworks are in place to establish the legal guardrails for this to happen and hold data stewards accountable.

Transform Health works with governments, national stakeholders and regional partners to strengthen national health data governance legislative and regulatory frameworks. This is supported through Transform Health's technical support approach and tools, including:

- Health Data Governance Principles, which provide equity and rights-based guidance for the governance of health data;
- National health data governance legislative and regulatory landscape assessment tool, which provides a framework to review the legal landscape;
- Health data governance Legislative blueprint (Model Law) and its Implementation Guide, which provide a legislative guide to support in strengthening national laws and frameworks.

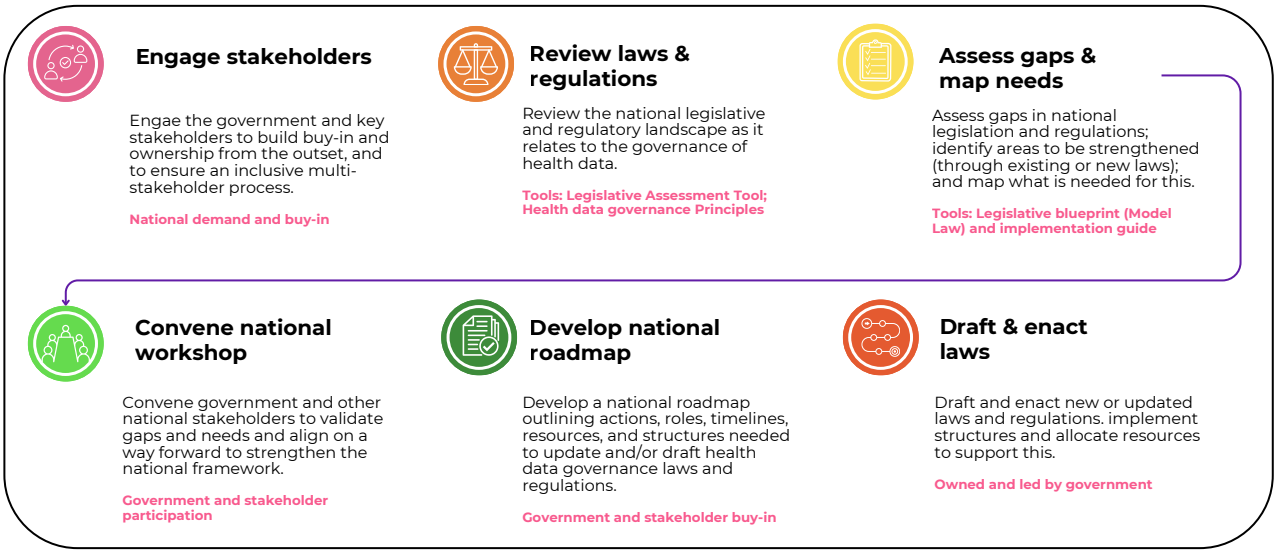
In Malawi, Transform Health worked with Health Informatics in Africa (HELINA) and the Health Informatics Association of Malawi (HIAM), together with government and national stakeholders to review and strengthen the health data governance legislative and regulatory environment.

Objectives and scope

The primary objective was to work with and support the government to strengthen their national health data governance legislative and regulatory framework, through the development of a national actionable implementation roadmap that charts the way forward for this to happen. This entailed the following:

- **REVIEW AND ASSESS:** Reviewing the national legislative and regulatory landscape as it relates to the governance of health data to assess gaps and identify areas to be strengthened (through existing or new laws) and mapping how and what is needed.
- **CHART THE WAY FORWARD:** Developing a national roadmap to take forward the drafting and/or updating of national laws and regulations, setting out actions, roles and responsibilities, and timelines, as well as capacity, financial resources and other structures that would need to be established.
- **NATIONAL OWNERSHIP:** Ensuring national ownership and buy-in from both government and other stakeholders that need to be involved (Responsible, Accountable, Consulted, Informed) to update, draft, or enact legislation.
- **INCLUSIVE MULTI-STAKEHOLDER PROCESS:** Facilitating an inclusive multi-stakeholder process, including civil society and communities, to validate gaps and needs and to align on a way forward.

This work included the following key steps:



Approach and process in Malawi

In Malawi, a multistakeholder consultative approach was adopted, involving 29 government and other national stakeholders. This included representatives from the Ministry of ICT, the Ministry of Health, and the WHO and UNICEF country office, among others. The engagement aimed to build government ownership and stakeholder buy-in of the process and the resulting roadmap from the outset. It also ensured a broad range of perspectives were reflected.

A comprehensive landscape review was conducted to assess existing health data governance laws, regulations, and related frameworks, including strengths, gaps and needs. The review also sought to identify recommended actions to strengthen legislation and regulations. National workshops were then convened to bring together key stakeholders - government officials, healthcare practitioners, legal experts, data protection authorities, and civil society representatives - to discuss and validate the findings of the landscape review. These consultations also supported the development of an actionable roadmap outlining how Malawi could implement the recommendations.

Key laws in Malawi relevant to health data governance

2024

Data Protection Act, Act No. 3

2020

National Digital Health Strategy 2020–2025

2017

Access to Information Act, Act No. 13

1994

Constitution of the Republic of Malawi

1948

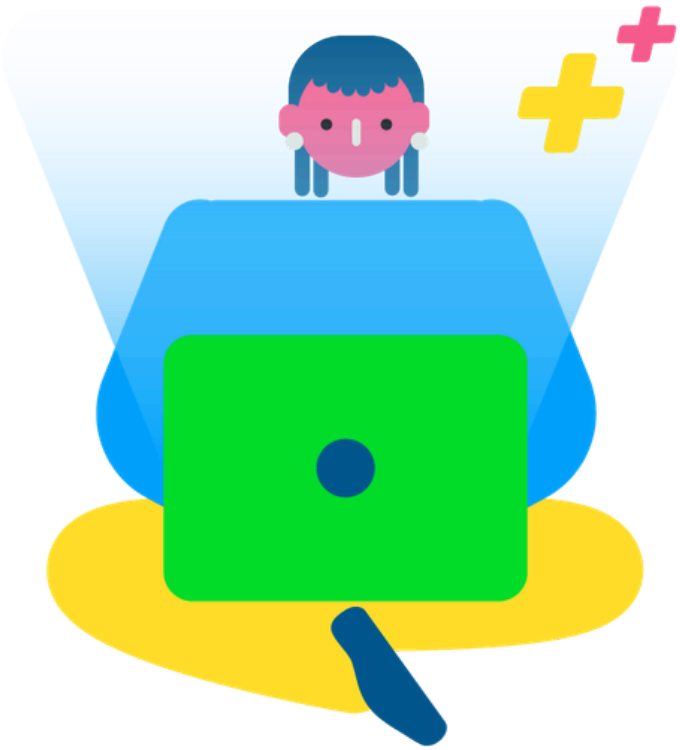
Public Health Act, Cap. 34:01

This section provides a timeline and brief snapshot of the laws and regulations in Malawi relevant to health data governance.

Malawi has 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, human dignity, and personal freedoms and privacy, forming the bedrock of individual rights.

The Access to Information Act complements these constitutional protections by regulating personal data through provisions which safeguard personal information and protect 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, recognising data subject rights, and requiring strict data security measures.

Malawi's National Digital Health Strategy reinforces these safeguards by prioritising the security of information systems and proper data storage. Together, these legal and strategic frameworks protect the rights of individuals and communities by balancing privacy with public health needs.



Legislative landscape review - key strengths, challenges and gaps

	Strengths	Challenges and gaps
Laws and policies	Malawi has a strong legal foundation for safeguarding personal health data through the Access to Information Act and Data Protection Act. These outline data security measures, patient rights, and cross-border data transfer regulations, helping build trust in digital health systems. The Digital Health Strategy and HIS Policy add vision and structure for digital health governance, together providing a necessary legal and strategic baseline.	Malawi lacks standardised protocols for encryption, access control and breach response. There are no legal provisions addressing emerging technologies such as artificial intelligence (AI), big data analytics, and cross-border data flows are largely unregulated in practice. Although the Data Protection Act designates health data as "sensitive", there are no tailored rules for clinical care, public health surveillance, genomics or research, nor any framework for open access to anonymised and non-identifiable health data. Together, these gaps limit transparency and the ethical use of health information.
Implementation & oversight	The regulatory and institutional mandate in Malawi spans the Ministry of Health, the Malawi Communications Regulatory Authority (MACRA), the National Statistics Office, and the Ministry of Information and Digitisation (also known as e-Government). The Ministry of Health has demonstrated 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).	At the national level, there is limited institutional ownership, as no single body provides sustained leadership and coordination for health data governance across the health sector. At the implementation level, consent processes remain weak in many health facilities, with insufficient safeguards to protect sensitive health data. There is a lack of enforcement mechanisms (e.g. audits and penalties) for non-compliance with data protection standards, and many health professionals and institutions lack the capacity to effectively manage, secure, and ethically use health data. These gaps contribute to ongoing concerns about legal and ethical compliance in the health sector. More broadly, Malawi's data governance structures remain inadequate. While frameworks exist, enforcement mechanisms - such as regular audits and penalties for non-compliance - remain weak, and there are no frameworks for whistleblower protection or the adjudication of data disputes.
Technical and infrastructure	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. 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. While challenges remain, Malawi has begun promoting interoperability across health information systems, with a focus on integrating platforms such as the Electronic Medical Record System and the Health Management Information System.	Despite the adoption of digital platforms like DHIS2, many health facilities continue to use manual reporting systems, slowing the digitisation process. Although digital platforms such as EMRs and HMIS exist, health information systems remain siloed, with no binding national interoperability framework - preventing seamless data exchange and limiting system efficiency. In addition, challenges with incomplete, untimely, or inaccurate reporting undermine the reliability of health data for decision-making. Malawi also has a shortage of skilled personnel to manage, maintain, and utilise digital health systems, which reduces the effectiveness of these technologies.

Recommendations to strengthen the health data governance legislative and regulatory environment in Malawi

To strengthen Malawi's health data governance legislative and regulatory framework, coordinated action is required from the Government of Malawi, including the Ministry of Health, the Ministry of Information and Digitisation, the Malawi Communications Regulatory Authority (MACRA), the National Statistics Office and relevant regulatory bodies, in collaboration with civil society and the private sector.

Laws and Policies

- Update existing legislation to close gaps in privacy, security, and consent, and to regulate the use of emerging technologies such as AI in healthcare.
- Introduce Whistleblower protections and clear mechanisms for resolving data-related disputes.
- Establish provisions enabling open access to anonymised health data for research and policy purposes.

Implementation and Oversight

- Establish dedicated oversight mechanisms - either through a new body or by expanding the mandate of existing institutions - to ensure compliance and manage grievances.
- Ensure regular stakeholder engagement and reviews of the legal and regulatory framework to keep governance systems responsive to evolving technologies and health sector needs.

Technical and Infrastructure

- Fully implement the national interoperability framework to enable seamless and secure data exchange across health systems.
- Invest in expanding the digital infrastructure and connectivity to ensure all health facilities, including in rural areas, have access to digital tools and reliable connectivity.
- Scale up proven digital solutions, such as EMRs and DHIS2, to under-resourced facilities and regions, ensuring equitable access to health data benefits.
- Secure sustainable financing by transitioning from donor reliance to government-led funding models, incorporating health data governance into national budgets to ensure long-term sustainability.

Capacity Building and Awareness

- Prioritise training programmes for healthcare professionals, policymakers, and IT specialists to enhance understanding of health data governance, risks, and responsibilities.
- Carry out public awareness campaigns to empower citizens with knowledge of their health data rights and the importance of data protection.

Actionable implementation roadmap

The following section sets out priority steps to update key national legislative instruments, which and conduct inclusive public consultations to ensure the revised legislation reflects stakeholder priorities and safeguards public trust. Subsequent steps entail the updated legal framework undergoing a formal legislative approval process. Parallel efforts will focus on establishing and strengthening institutional structures to support effective enforcement, alongside targeted capacity-building initiatives and ongoing monitoring to ensure the consistent adoption and implementation of the updated regulations.

Step 1: Mobilise key stakeholder and establish technical working groups

Actions	Lead actors
• Mobilise key institutional partners for the health data governance legislative strengthening process. • Identify lead agencies and technical working groups for each of the priority legislative instruments in the roadmap. • Determine roles and responsibilities of key stakeholders.	Health Informatics Association of Malawi (HIAM)

Step 2: Drafting and technical review

Actions	Lead actors

• Update the Public Health Act
  ◦ Provisions on the right to privacy and confidentiality
  ◦ Clauses on individual and population rights, whilst focusing on the control of diseases especially during public health emergencies.
  ◦ Make recommendations in accordance to the constitutions on ethical issues which include consent to medical treatment, privacy and confidentiality, among others.
  ◦ Provisions on the use of digital and information technology for the provision of digital health
	Ministry of Health

• Update the Data Protection Act of 2024 ◦ Ensure explicit clarification on some terms to ensure clear and unambiguous legal meaning. These include terms like Health Status, Anonymized Data and Pseudonymized Data, etc.	Malawi Communications Regulatory Authority
• Update the Digital Health Governance policy ◦ Develop the digital health data governance Framework	Ministry of Health Digital Health Division

Step 3: Public and stakeholder consultation

Actions	Lead actors and partners
• Carry out public consultation on updated draft legislation, including consulting key stakeholders.	Lead: Ministry of Health _____ Partners: Ministry of Justice, Ministry of Health, Malawi Communications Regulatory Authority, National Statistics Office, Ministry of Information and Technology E-Government, World Health Organisation and civil society.

Step 4: Legislative approval

Actions	Lead actors and partners
• Seek legislative approval of the updated legislation through the national legislative process, including: Ministry of Justice review | Cabinet approval | Submission to parliament for bill debate and passing	Lead: Ministry of Health _____ Partners: Ministry of Justice

Step 5: Institutional preparation

Actions	Lead actors and partners
• Launch capacity-building efforts with the Ministry of Health and Ministry of Information and Technology • Establish the Central Monitoring and Evaluation Division (CMED) of the Ministry of Health as a dedicated health data governance (HDG) unit. • Disseminate the available health data governance laws, policies and regulations in Malawi to the general public and relevant users and stakeholders • Promote use and monitor utilisation and adherence of the Malawi health data governance instruments by those that interact with the amended laws eg, hospitals, researchers, academics, policy makers, etc.	Lead: Ministry of Health and HIAM _____ Partners: Ministry of Information and Technology, National Statistics Office, Academic Institution, Researchers and Research Institutions

Step 6: Early implementation and monitoring

Actions	Lead actors
Develop health data governance key performance indicators (KPIs) to use for monitoring and evaluation of application of the health data governance instruments	Ministry of Health, Ministry of Information & Digitial
Conduct institutional health data governance supportive supervision to mentor institutions on the application and use of the health data governance instruments	Ministry of Health, Ministry of Information and Technology, Development partners in digital health
Develop monthly health data governance implementation reporting templates and dashboards to measure number of institutions having copies of the health data governance instruments, health data governance complaints, etc	Ministry of Health, Ministry of Information , development partners in digital health
Track health data governance laws adherence on a quarterly basis	Ministry of Health, Ministry of Information

Overview and acknowledgements

This case study highlights Malawi's efforts to strengthen the health data governance legislative and regulatory framework through a collaborative, country-led process. It outlines the approach taken to review the national legislative landscape, identify strengths and gaps, engage stakeholders from across government, regulation, civil society, academia, health service delivery and the media, and develop a practical roadmap for strengthening health data governance. It also shares lessons and recommendations that can inform similar reform efforts in other countries.

The case study was developed by Transform Health with the Pan African Health Informatics Association (HELINA) and the Health Informatics Association of Malawi (HIAM), who led the process in Malawi. We are grateful to the organisations that have been engaged in the process, including the national stakeholder workshops, where the findings of the landscape review were validated and the priorities and actions set out in the Roadmap were shaped.

Stakeholders engaged in the process include: Malawi Ministry of Health · Malawi Ministry of Information and Communication Technology · Malawi National Registration Bureau · Malawi National Statistical Office · Malawi Communications Regulatory Authority · World Health Organization · Partners in Health · Daeyang Luke Hospital · Malawi Centre for Medical Diagnostics · Malawi Network of People Living with HIV/AIDS (MANET+) · Media Institute of Southern Africa (Malawi Chapter) · HELINA · Health bio-Information Association of Malawi · Global Health Informatics Institute · The HISP University of Malawi Project · Pharmacy Society of Malawi · Physicians Associates Union Malawi.

Transform Health is a global coalition of organisations that work to harness the potential of digital technology and the use of data to achieve universal health coverage (UHC) by 2030. To learn more about Transform Health visit: www.transformhealthcoalition.org.

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All of Transform Health's health data governance tools and resources - including the Health Data Governance Principles, the Legislative Blueprint, national landscape reports, and the assessment tool - are publicly available on our dedicated health data governance website. This website was established as an indepedent platform, to foster collaboration and ownership of this agenda across the sector.

Transform Health