Health Data Governance

Legislative and Regulatory Landscape Review

SOUTH AFRICA

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.

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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1. Introduction

This report analyses the legislative and regulatory landscape of South Africa 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 South Africa's health data governance, including recommendations on how to strengthen the health data governance landscape. The summary report emphasises the importance of human rights recognition, data quality, safety, and transparency in healthcare data governance. It further highlights significant gaps in policy environment, health workforce, awareness, and data infrastructure. Recommendations include enhancing human rights recognition, improving data quality, ensuring safety and accountability, and developing a holistic data governance framework to address these gaps and improve health data governance, protection, and utilisation in South Africa.

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

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 South Africa:

- S. Afr. Const., 1996
- National Health Act 61 of 2003 (S. Afr.)
- Electronic Communications and Transactions Act 25 of 2002 (S. Afr.)
- Health Professions Act 56 of 1974 (S. Afr.)
- Medicines and Related Substances Act 101 of 1965 (S. Afr.)
- Technology Innovation Agency Act 26 of 2008 (S. Afr.)
- Protection of Personal Information Act 4 of 2013 (S. Afr.)
- South African Medical Research Council Act 58 of 1991 (S. Afr.)
- Cybercrimes Act 19 of 2020 (S. Afr.)
- Health Professions Council of South Africa, *General Ethical Guidelines for the Healthcare Professions – Booklet 1* (2021)
- Jan D. Pretorius et al., *Data Governance in Healthcare Information Systems: A Systematic Literature Review,* 34 INT'L J. HEALTH POL'Y & MGMT. 287 (2022)
- Data Integrity: Challenges in Health Information Systems in South Africa: Faith Khumalo, *Data Integrity: Challenges in Health Information Systems in South Africa*, CSIR RS 2020
- Nosipho N. Duma et al., *Data Protection, Data Management, and Data Sharing: Stakeholder Perspectives on the Protection of Personal Health Information in South Africa*, PLOS ONE (2021)
- Dep't of Health, Republic of S. Afr., District Health Management Information System (DHMIS) Policy (2011)
- Info. Regulator (S. Afr.), Guidance Note on Exemptions from the Conditions for Lawful Processing of Personal Information (2021)
- Info. Regulator (S. Afr.), Guidance Note on Information Officers and Deputy Information Officers (2021)
- Info. Regulator (S. Afr.), Guidance Note on Processing of Personal Information of Children (2021)
- Info. Regulator (S. Afr.), Guidance Note on the Processing of Personal Information in the Management and Containment of COVID-19 Pandemic (2020)
- Helen Schneider et al., *Hospital Management and Health Policy—A South African Perspective,* COHSASA J. (2019)

- Faith Khumalo, Data Integrity: *Challenges in Health Information Systems in South Africa*, CSIR RS 2020
- T. Rampedi et al., *Laws and Regulations on Big Data Management: The Case of South Africa*, EAI INT'L CONF. ON E-HEALTH NETWORKING, APPLICATIONS & SERVICES (2019)
- Dep't of Health, Republic of S. Afr., National Health Research Strategy: Research Priorities for South Africa 2021–2024
- Dep't of Health, Republic of S. Afr., National Digital Health Strategy for South Africa 2019–2024
- Health Professions Council of S. Afr., PAIA and POPIA Manual (2021)
- S. Afr. Med. Ass'n, Manual on the Promotion of Access to Information Act 2 of 2000 (2021)

3. Analysis of the National Legislative and Regulatory Environment

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

3.1. Protect individuals and communities

South Africa's regulatory framework for protecting individuals and communities is deeply rooted in its Constitution and legal instruments. The Constitution ensures the protection of personal privacy under Section 14 and guarantees access to healthcare services through Section 27. Complementing this, the National Health Act includes provisions for the confidentiality of health records (Sections 14–17) and patients' rights in accessing and controlling their health information.

The Protection of Personal Information Act (POPIA) sets a robust foundation for personal data protection, establishing principles such as consent, data minimisation, and security safeguards. This framework is critical for securing sensitive health information while enabling its lawful processing for healthcare delivery and research. Additional protection is offered by the Health Professions Act, which promotes ethical standards for healthcare professionals.

Other laws, such as the Cybercrimes Act, address unlawful data access and ensure the security of personal information against cyber threats. Collectively, these laws and frameworks create a strong protective environment for individuals and communities, balancing rights to privacy with the needs of the healthcare system.

3.2. Building Trust in Data Systems

South Africa's regulatory environment fosters trust in health data systems through transparency, security, and ethical governance. The National Health Act requires the establishment and coordination of health information systems (Section 74) to ensure reliable and accessible health data. POPIA enforces stringent data handling protocols, particularly in Chapters 3 and 4, mandating safeguards to prevent unauthorised access and breaches.

The Technology Innovation Agency Act promotes the ethical use of technologies, indirectly contributing to trust by ensuring innovations align with societal and legal standards. Trust is further supported by the Cybercrimes Act, which criminalises unauthorised data manipulation, thereby enhancing confidence in the safety and reliability of digital health systems. Together, these provisions work towards fostering public and stakeholder trust in the integrity and security of South Africa's health data systems.

3.3. Ensuring Data Security

Data security in South Africa is governed by comprehensive legislation designed to protect sensitive health information. POPIA obliges data controllers and processors to implement technical and organisational measures to secure data (Sections 19–22). The Cybercrimes Act complements this by penalising unauthorised data access, ensuring the security of critical information systems.

The National Health Act includes provisions for safeguarding health records (Sections 14–17), while the Electronic Communications and Transactions Act 25 of 2002 addresses broader information security principles. These measures are supported by ethical guidelines from professional bodies, such as those under the Health Professions Act, which emphasise confidentiality in handling patient information. Together, these instruments establish a resilient framework for securing personal and health data across various sectors.

3.4. Enhancing Health Services and Systems

South Africa's legislative and policy frameworks aim to enhance health services and systems through robust data governance. The Constitution guarantees the right to healthcare (Section 27), while the National Health Act provides a detailed framework for health system management, including standards for service delivery and the use of health data (Sections 25 and 74).

Innovation and collaboration are central to enhancing healthcare, with the Technology Innovation Agency Act and Medical Research Council Act promoting research and technological advancements. POPIA ensures that such advancements are underpinned by stringent data protection measures, enabling secure and effective use of health data. These instruments collectively aim to improve healthcare quality, accessibility, and efficiency through enhanced data governance.

3.5. Promoting Data Sharing and Interoperability

Data sharing and interoperability are critical components of South Africa's health data governance framework. The National Health Act (Section 74) mandates the development of interoperable health information systems, while the Electronic Communications and Transactions Act supports electronic data exchange standards.

POPIA outlines conditions for lawful data sharing, ensuring that interoperability efforts align with privacy and security standards. Additionally, the Cybercrimes Act safeguards the integrity of data systems, enabling trusted data sharing across platforms. By fostering collaboration and standardisation, these frameworks facilitate efficient data exchange and integration within South Africa's healthcare ecosystem.

3.6. Facilitating Innovation Using Health Data

South Africa's regulatory framework supports innovation through structured health data governance. The National Health Act and Medical Research Council Act promote research and the ethical use of health data for medical advancements. The Technology Innovation Agency Act fosters technological innovations, indirectly supporting healthcare innovation through data applications.

POPIA ensures that innovation is aligned with data protection principles, enabling lawful and secure use of health data. These provisions, combined with the Cybercrimes Act's focus on data integrity, create an environment conducive to innovation while prioritising privacy and ethical considerations.

3.7. Promoting Equitable Benefits from Health Data

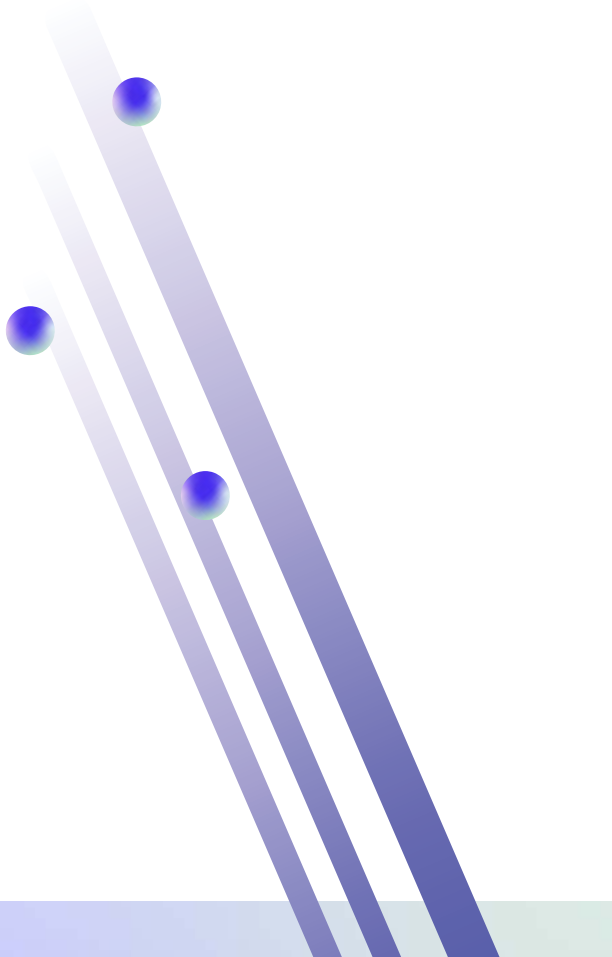
Equitable benefits from health data are addressed through South Africa's constitutional and legislative provisions. The Constitution (Section 27) emphasises equitable access to healthcare, complemented by the National Health Act's focus on fairness in service delivery. POPIA ensures transparency and accountability in data use, indirectly promoting equity in health data applications.

Additionally, the Medicines and Related Substances Act and Medical Research Council Act contribute to equitable health outcomes by regulating the safety and efficacy of medicines and promoting research for public benefit. Together, these instruments aim to maximise the societal benefits of health data while ensuring fairness and accessibility.

3.8. Establishing Data Rights and Ownership

Data rights and ownership in South Africa are established through a combination of constitutional and legislative measures. The Constitution provides a foundation for privacy and access to information (Sections 14 and 32). The National Health Act further specifies rights related to health records, including access and protection measures (Sections 14–17).

POPIA elaborates on data subject rights, including consent, access, and rectification, ensuring individuals retain control over their personal information. These rights are reinforced by the Medical Research Council Act, which addresses data usage in research. Collectively, these laws provide a comprehensive framework for data rights and ownership, balancing individual control with the needs of the healthcare system.



4. Best practices

South Africa's health data legislative and regulatory framework demonstrates several best practices that contribute to effective governance and protection of health data:

- **Comprehensive Legal Protections:** POPIA sets a benchmark for data protection, mandating lawful processing, consent mechanisms, security safeguards, and accountability. This robust legal foundation ensures health data is handled ethically and securely.
- **Strong Ethical Guidelines:** The Health Professions Act and ethical codes developed by HPCSA establish high standards for patient confidentiality, informed consent, and professional conduct, fostering trust in the healthcare system.
- **Integration of Health Systems:** The National Health Act promotes standardisation and interoperability across healthcare information systems, facilitating efficient data exchange while safeguarding patient privacy.
- **Focus on Innovation:** The Technology Innovation Agency Act and the South African Medical Research Council Act encourage research and development, leveraging health data to advance medical technologies and improve healthcare delivery.
- **Pandemic-Specific Measures:** Guidance on managing health data during the COVID-19 pandemic demonstrates adaptability in balancing public health needs with individual privacy, ensuring data collection aligns with legal and ethical standards.
- **Emphasis on Data Integrity:** Policies within the District Health Management Information System (DHMIS) ensure accurate, reliable, and timely data reporting, supporting effective decision-making at all levels of the health system.

These best practices highlight South Africa's efforts to maintain high standards in health data governance, balancing innovation, privacy, and patient-centred care.

5. Gaps

Despite its strengths, South Africa's health data governance framework faces significant challenges:

- **Policy Implementation Gaps:** There is often a discrepancy between policy intent and practical implementation, particularly in areas like human resource planning and infrastructure development.
- **Fragmented Systems:** Interoperability challenges persist, with fragmented health information systems limiting seamless data sharing and integration across platforms.
- **Workforce and Training Deficiencies:** The healthcare workforce faces inadequate training in digital health technologies, compounded by limited succession planning and capacity-building efforts.
- **Data Infrastructure Shortfalls:** Underinvestment in digital infrastructure, including health management information systems (HMIS), results in inefficiencies and data quality issues.
- **Legal and Ethical Challenges:** Gaps in addressing privacy concerns, particularly with emerging technologies such as AI, create risks related to data re-identification and unconsented use of personal health data.
- **Limited Stakeholder Engagement:** Community involvement and feedback mechanisms are insufficient, reducing trust and accountability in health data governance practices.

Addressing these gaps requires coordinated strategies that prioritise policy enforcement, system integration, and stakeholder collaboration.

6. Recommendations

The following recommendations aim to address the identified gaps and build on best practices within South Africa's health data regulatory framework. These proposals are streamlined to eliminate redundancy and ensure complementarity with existing practices:

- **Strengthen Human Rights Protections:** Prioritise the recognition of human rights in health data governance by ensuring alignment with constitutional values, including dignity, equality, privacy, and access to healthcare.
- **Enhance Data Quality and Address Bias:** Invest in infrastructure and methodologies that improve data quality and mitigate biases, particularly in AI-driven applications, to promote equitable and accurate health outcomes.
- **Improve Safety and Accountability Mechanisms:** Implement robust systems for pre-implementation testing, ongoing monitoring, and accountability in healthcare decision-making to prevent harm and uphold patient safety.
- **Foster Transparency and Trust:** Develop transparent policies and practices for data collection, processing, and AI decision-making. Publish algorithms and datasets in public repositories where appropriate to promote oversight and trust.
- **Advance Patient-Centred Care and Workforce Readiness:** Equip healthcare professionals with the training and tools necessary to engage effectively with digital health systems. Address workforce concerns regarding automation through capacity building and integrating data-driven practices into patient-centred care models.
- **Strengthen Data Governance and Integration:** Develop a cohesive data governance framework that ensures interoperability, reduces fragmentation, and mitigates risks such as re-identification and misuse of personal data.
- **Support Organisational Culture and Ethical Practices:** Foster a culture of accountability and openness to reporting errors or concerns in data management, ensuring adherence to ethical standards and promoting data integrity.
- **Expand Capacity and Infrastructure Development:** Invest in the development of national digital health systems, including sustainable infrastructure, interoperable health information systems, and skilled personnel to ensure effective implementation and maintenance.
- **Address Language and Translation Nuances:** Accommodate linguistic diversity by ensuring health data systems, consent forms, and policies are available in all official languages and designed for inclusivity.
- **Align Policies and Legislation:** Ensure existing policies and legislative frameworks, such as POPIA, are updated and enforced to address emerging technologies and data governance challenges.
- **Engage Stakeholders and Foster Collaboration:** Facilitate meaningful engagement with stakeholders, including communities, policymakers, and private sector actors, to co-design solutions and align efforts in health data governance.
- **Promote Sustainability in Digital Health:** Develop coordinated investment frameworks that balance government support and donor contributions, ensuring long-term sustainability for digital health initiatives.
- **COVID-19 and Future Health Emergencies:** Build on lessons learned during the COVID-19 pandemic to establish clear guidelines for lawful, accountable, and secure health data management during public health crises.

7. Discussion of Research Results

The analysis of South Africa's health data governance framework reveals a combination of strengths and challenges. Best practices such as strong legal protections under POPIA and ethical guidelines from HPCSA have fostered trust and integrity within the system. However, gaps in infrastructure, workforce training, and system integration hinder progress. Recommendations focus on strengthening enforcement, enhancing interoperability, and addressing privacy concerns. By addressing these issues, South Africa can align its health data governance with global standards and better support its healthcare objectives.

8. Conclusion

South Africa's health data governance framework is a vital component of its healthcare system, balancing the imperatives of innovation, privacy, and equitable access. While robust legislation and ethical guidelines provide a solid foundation, challenges in policy implementation, system integration, and stakeholder engagement require attention. Addressing these gaps through targeted recommendations will enable South Africa to enhance its health data governance, aligning with international best practices and driving improvements in healthcare delivery and outcomes.