



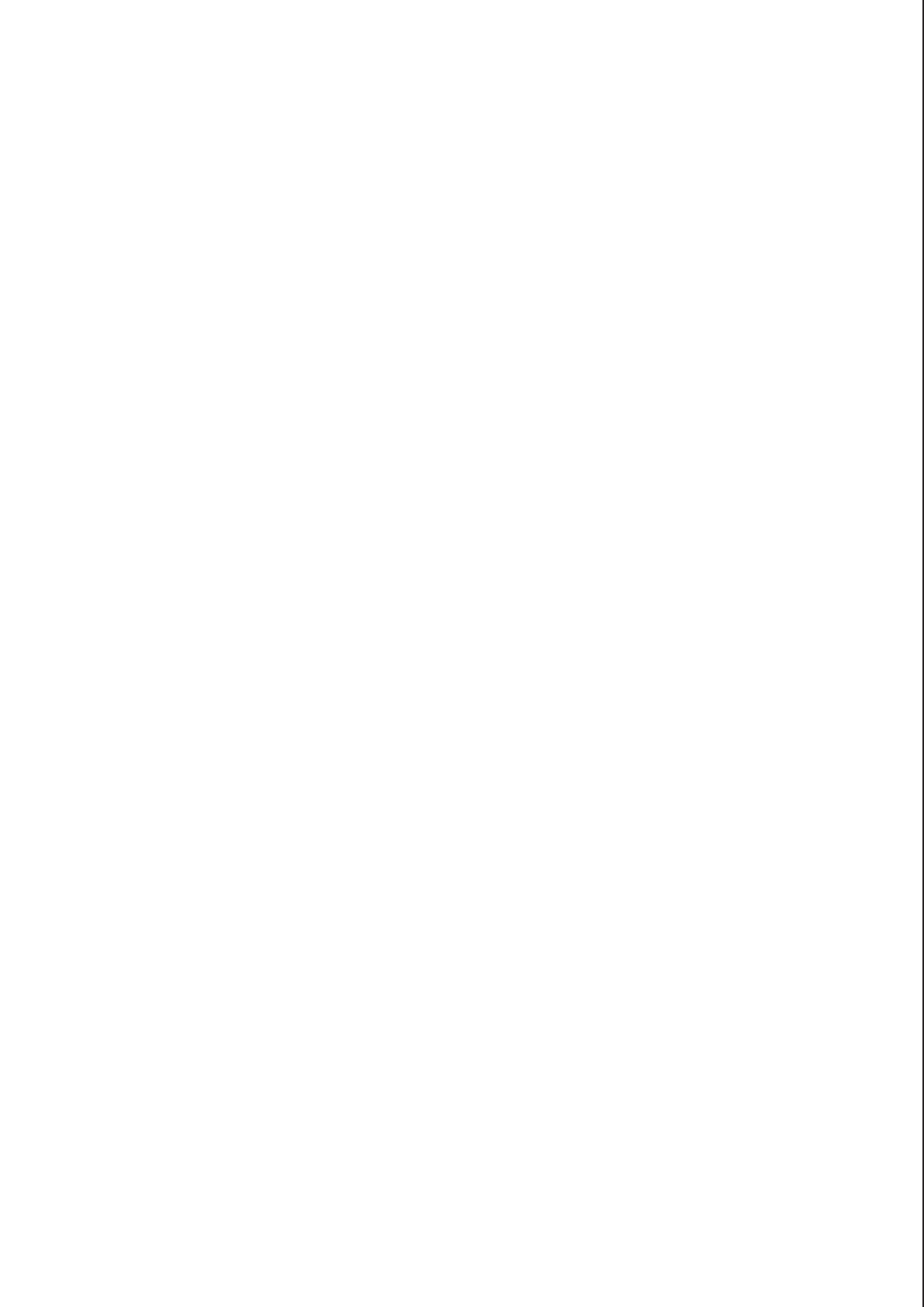
Analysing and Enhancing Digital Health Standards for Effective Digital Health Transformation in Kenya

May 2024



**Transform
Health**
KENYA

H Kenya Health
Informatics
Association



Acknowledgements

The Kenya Health Informatics Association (KeHIA) expresses its deepest gratitude to all who contributed to this report. Transform Health has a goal to build a global movement that brings together organisations and institutions across sectors who are committed to achieving UHC within the next ten years by expanding the use of digital technology and increasing access to data. We are particularly grateful to [Transform Health Kenya](#) for their invaluable guidance and financial support, which were instrumental in making this research possible. This research was conducted under the first strategic objective of developing laws and policies on digital health technologies to ensure UHC commitments are developed and adopted at both national and county levels by 2030. This research aimed to advocate for people-centred digital health standards and for standardisation of digital health applications to achieve the goals of UHC. This piece of work aims to contribute to an enabling environment within the country feeding into Transform Health's global objective of Political will and enabling environments, it further aligns with global standards of system development and standardisation such as FHIR, WHO SMART guidelines.

The Kenyan Legal and Ethical Issues Network (KELIN) deserves immense appreciation for their unwavering commitment to ensuring the project's success.

Our sincere appreciation extends to the Council of Governors, the County Governments of Kitui, Kisumu, Tharaka Nithi, and Kiambu for their contributions in validating the research document and providing invaluable local perspectives. We are also grateful to the Kenya Healthcare Federation for their support in convening the private sector meeting, which helped us gain crucial insights from diverse stakeholders within the health sector.

The KeHIA Board of Directors served as a constant source of support and guidance throughout the report's development, offering invaluable insights and feedback that helped shape its direction. We sincerely thank the Ministry of Health (MOH)-Kenya Team for their willingness to share their expertise and knowledge, which significantly enriched the report's content and depth.

Finally, a special word of thanks goes to the entire team at KeHIA for their unwavering dedication and commitment throughout the project. Their tireless efforts and collaborative spirit were essential in bringing this report to a successful conclusion. We are deeply appreciative of the support and contributions of all those involved. Their invaluable assistance has significantly enriched the development and depth of this report.

Table of Contents

ACKNOWLEDGEMENTS.....	3
ABBREVIATIONS AND ACRONYMS.....	5
LIST OF TABLES.....	6
EXECUTIVE SUMMARY.....	7
INTRODUCTION.....	10
OBJECTIVES.....	11
METHODOLOGY.....	12
LIMITATIONS.....	13
DIGITAL HEALTH STANDARDS IN KENYA.....	14
STANDARDS AND GUIDELINES IN KENYA'S DIGITAL HEALTH SERVICES.....	14
FINDINGS.....	23
OVERVIEW OF TECHNOLOGIES, STANDARDS AND IMPLEMENTATION	
CHALLENGES IN KENYA'S DIGITAL HEALTH ECOSYSTEM.....	25
ANALYSIS.....	30
RECOMMENDATIONS.....	32
NEXT STEPS FOR THE TRANSFORM HEALTH COALITION.....	34
REFERENCES.....	36
Appendix 1: Standards and Guidelines that are used on a Global Level.....	38
Appendix 2: Digital Technologies Reviewed.....	44

Abbreviations and Acronyms

AI	Artificial Intelligence
COG	Council of Governance
DHIS	District Health Information Service
eCHIS	Electronic Community Health Information Service
HER	Electronic Health Records
EMRs	Electronic Medical Records
GDPR	General Data Protection Regulation
HIE	Health Information Exchange
HL7	Health Level 7 Standards
HRIO	Health Records Information Officer
ICT	Information and Communication Technology
ID	Identification Documentation
ISO	International Organization of Standardization
KEBS	Kenya Bureau of Standards
KeHIA	Kenya Health Informatics Association
KMHFL	Kenya Master Health Facility List
KNHTS	Kenya National Health Terminology Service
mHealth	Mobile Health
MoH	Ministry of Health
NHDD	National Health Data Dictionary
NHIF	National Health Insurance Fund
NHIS	National Health Information Service
UHC	Universal Health Coverage
UPI	Unique Person Identifier
WHO	World Health Organization

List Of Tables

Table 1. Research questions and Methods.....	11
Table 2. Research questions and Results.....	23
Table 3. the technologies used in Kenya's digital health sector	25
Table 4. The Health Level 7 (HL7) standards	38
Table 5. Digital Teachnologies Reviewed	44

Executive Summary

Background

In recent years, the global healthcare landscape has witnessed a notable shift towards digital technologies to enhance healthcare access and delivery. This transformation, driven by the potential of digital health technologies to improve healthcare outcomes and promote equity, has been actively embraced by Kenya, aligning with its goal to achieve Universal Health Coverage (UHC) by 2030. Recognising the paramount role of digital health standards, policies, and implementation strategies, the Kenya Health Informatics Association (KeHIA), with support from [Transform Health](#), has played a pivotal advocacy role in providing independently researched, quality evidence to inform expert opinions and guide investments in the implementation and meaningful use of data and digital health interventions. The increased use of digital health technologies in Kenya has revolutionised healthcare, with innovations like Electronic Health Records (EHRs), telemedicine and telehealth platforms, and health information exchange platforms significantly enhancing healthcare delivery, data management, and patient engagement. This research aims to comprehensively explore and address the multifaceted challenges and opportunities surrounding the integration of digital health technologies within Kenya's healthcare framework, contributing to the country's pursuit of accessible, equitable, and quality healthcare through digital health integration.

Methodology

The study employs qualitative methods to address the key research questions about digital health in Kenya, examining a sample of technologies from both the government and private sectors. The primary sources of information collected for the purpose of this research were through literature reviews and roundtable discussions that were held with the four select counties; Kiambu, Kisumu, Tharaka Nithi and Kitui. The private sector was also engaged as part of this process. A total of 80 stakeholders were engaged.

Limitations

One significant challenge encountered during the research was our dependence on pre-existing data sources. Many technologies and systems have been developed and deployed for use in Kenya but a key challenge we encountered was gathering documentation that linked specific technology deployment with a set standard. This limitation was curbed by holding the stakeholder engagement sessions where we received information from the teams responsible for the implementation of technologies.

Research Questions

The research questions were designed to provide a comprehensive overview of the technologies used in the country, as well as the standards that guided their implementation. With this understanding, we evaluated the global benchmark and identified gaps in our adherence to standards. The validation sessions with county government stakeholders assisted us in understanding the barriers to their adoption of standards as they implement technologies throughout the county.

1. What are the current digital health standards and guidelines in Kenya?
2. What standards were used to operationalize digital health technologies in Kenya?
3. What challenges are experienced in the implementation of standards and guidelines?

Key Findings

The analysis unveiled a multitude of digital health standards and guidelines in Kenya, reflecting the country's commitment to aligning with international best practices and advancing its healthcare transformation efforts towards achieving Universal Health Coverage (UHC) through digital health technologies.

- There was a visible gap in the understanding of standards by the representatives from the public sector versus those from the private sector. This gap can be attributed to differing priorities: the private sector must stay competitive by ensuring that their technologies comply with globally recognized best practices. For private companies, aligning with international standards is not only crucial for competitiveness but also for scaling innovations, ensuring interoperability, and entering new markets. In contrast, the public sector may prioritise compliance with national regulations and may not fully leverage global standards, which can lead to mismatches in expectations during collaborations. Addressing this gap is essential for fostering partnerships that drive sustainable growth and innovation, especially in a globally interconnected economy.
- Beyond the knowledge of some policy documents such as the Health Act, 2017, the Data Protection Act, 2019, and the UHC policy 2014-2030, and their role in enhancing health service delivery, there was a significant gap from the counties in their understanding of the digital health legislations that have been newly ascended and guidelines that will impact the operations within the health sector. The knowledge gap is due to the limited access to information from the digital health space or the lack of need to remain competitive that gives the private sector an edge.
- Policy implementation is also a major challenge for the county stakeholders who were engaged as part of the project validation sessions. The lack of engagement of county personnel in the development of policies, standards and guidelines makes it challenging to adopt and implement standards and this is owed to a lack of understanding of the provisions within the documents.

Key Recommendations

Policy transition has often been a challenge in Sub-Saharan Africa with this process being riddled with challenges such as improper planning, government bureaucracy, and lack of adequate management structure.¹, and particularly in Kenya, and this in turn slows down sustainable development.

To curb the challenges highlighted above, the following list summarises our recommendations for key decision-making actors in Kenya:

1. National Government of Kenya (Ministry of Health, Ministry of ICT, Treasury)

- **Policy Integration:** Accelerate the implementation of the Digital Health Act through model digital health roadmaps for counties which outline the Act requirements, standards, and guidelines.
- **Policy Dissemination:** Educate relevant stakeholders, including the county management teams, county policy divisions/department personnel, ICT department staff and system end users, on the policies to enhance the policy transition processes. Support all counties in domesticating these policies and aligning them with their priorities by building their understanding of the documents.

¹Ajolor, "The challenges of policy implementation in Africa and sustainable development goals."

- **Funding and Resource Allocation:** Secure financial resources to implement the Digital Health Act, ensuring at least 50% of human and financial resources needed are allocated by 2026.
- **Establish National Interoperability Framework:** Continue developing the national health information exchange (NHIE) to improve data sharing across different health systems and providers.
- **Workforce Development and Digital Literacy:** Enhance digital literacy by incorporating digital health competencies into the National Human Resource for Health Strategy and linking digital health certifications with Continuing Professional Development (CPD) requirements.
- **Multi-Sectoral Approach:** Encourage inclusion of multiple sectors, for example the Ministry of Information, Communication and the Digital Economy, in policy development processes by advocating for adequate representation in the relevant Ministry of Health TWG as well as through the Council of Governors.

2. County Governments

- **Domestication of Standards:** Develop county-specific roadmaps to guide the operationalization of policies, standards, and guidelines.
- **Training and Capacity Building:** Implement digital literacy and standards training workshops for healthcare workers in 20 counties by the end of 2025. Conduct quarterly training for county officials, health facility managers, and other key stakeholders.
- **Stakeholder Engagement:** Conduct quarterly engagement sessions to introduce and review new digital health developments and coordinate efforts between county governments, public, and private sector representatives. This will help to improve public sector understanding and engagement with the latest standards.

3. Digital Health Implementers

- **Adopt and Follow National Guidelines:** Ensure compliance with standards under the new 2023 Digital Health Act and guidelines.
- **Change Management Strategies:** Implement comprehensive change management strategies to support digital health programs. This should include annual refresher training sessions for healthcare workers to maintain competency in using digital health tools.
- **Partnerships with Academia:** Collaborate with academic institutions to establish pre-service, and medical/nursing professional bodies to establish in-service training programs, focused on digital health standards.
- **Incentivizing Adoption and Compliance:** Work with county governments and the Ministry of Health to create incentives tied to performance-based grants or county funds disbursement to encourage compliance with standards under the Digital Health Act, Primary Healthcare Act, and Facility Improvement Fund (2023)

Introduction

For several years now, the global healthcare landscape has witnessed a significant shift towards the integration of digital technologies to enhance healthcare delivery and access. The transformative potential of digital health technologies in improving healthcare outcomes, promoting equity, and enhancing patient-centred care has led to their increased adoption on a global scale. Recognizing the need to align with these advancements, Kenya has been at the forefront of leveraging digital health solutions to achieve its healthcare goals, particularly achieving Universal Health Coverage (UHC) by 2030.

The increase in internet usage by 8% between 2022-2023² and the rising adoption and implementation of digital health technologies in Kenya³ marks a turning point in the country's health system. These technologies include Electronic Medical Records (EMRs) systems, such as the KenyaEMR which has been implemented in over 300 facilities in Kenya⁴, which has modernised the way patient data is collected and managed, leading to more efficient and informed clinical decision-making.

Digital technologies have enabled healthcare providers to expand their reach and serve a larger and more diverse population, thereby reducing healthcare disparities. Patients can now have the convenience of accessing medical advice, consultations, and essential health information using smartphones and other devices, hence enhancing their ability to take control of their health.⁵ The collection and analysis of health data collected on KHIS2 (The District Health Information System, DHIS) has not only improved healthcare delivery but also supported evidence-based policy-making and resource allocation⁶. This ensures that healthcare services are more efficient, responsive, and tailored to the specific needs of the population. Additionally, a health information exchange, which allows healthcare providers and patients to access and securely share patient information⁷ is intended to facilitate seamless communication and collaboration among healthcare providers, resulting

in more coordinated and patient-centred care (not yet operational in Kenya; led by the Ministry of Health).

Telemedicine and mobile health applications such as WhatsApp chatbots and USSD codes, have extended the reach of healthcare services, especially in remote and underserved areas, ensuring that healthcare access is more equitable⁸. Expanding digitization in the health sector has also supported the expansion of financial inclusivity which in turn helps the Kenyan population contribute to their care. For example, the National Health Insurance provider, NHIF, partnered with M-Pesa, a mobile money transfer platform to help patients contribute to their monthly NHIF premiums. This initiative helped NHIF expand contributions by low- and irregular-income earners.⁹ Since its launch in 2010, the number of NHIF members using M-Pesa to make monthly premium contributions has grown nearly ten-fold from 10,000 in 2010 to 8.1 million in 2024, however out of the 8.1 million only 1.6million regularly contribute over 80% of members from the informal sector have defaulted on their payments, leading to substantial financial losses for NHIF.

²Digital 2023.”

³Muinga et al., “Digital Health Systems in Kenyan Public Hospitals.”

⁴Health Information Systems in Kenya.”

⁵ [\[Updating\]](#)

⁶Olubulyera, Transforming the Kenya Health Information System (KHIS) to an Early Warning and Real-Time Electronic Disease Notification System.

⁷What Is HIE? | HealthIT.Gov.”

⁸Haleem et al., “Telemedicine for Healthcare.”

⁹Bruno Meessen, “The Role of Digital Strategies in Financing Health Care for Universal Health Coverage in Low- and Middle-Income Countries,” *Global Health, Science and Practice* 6, no. Suppl 1 (October 10, 2018): S29-40, <https://doi.org/10.9745/GHSP-D-18-00271>.

<https://www.businessdailyafrica.com/bd/economy/nhif-takes-sh39bn-hit-from-rising-defaults-4194540>

Objectives

Implementing standards helps reduce the risk of failed implementation of technologies, lowers costs of operationalizing systems, and ensures the safety of the information stored within the systems, uniformity, and compliance with nationally and globally accepted criteria. Standardising technology implementation can help break down silos and solve the challenges we have witnessed with digital health fragmentation.

The objectives of this study were identified in collaboration with Transform Health Kenya are as follows:

I. Identifying Digital Health Standards in Kenya

This research examines the current state of digital health standards, infrastructure, systems, and applications in Kenya.

II. Assessing the extent of awareness and adoption and implementation of standards and guidelines by the public and private sector.

Research Question	Method Used to Answer Question
1. What are the current digital health standards and guidelines in Kenya?	Desktop review
2. What standards were used to operationalize digital health technologies in Kenya?	Desktop review/round table sessions
3. What challenges are experienced in the implementation of standards and guidelines?	Desktop review/round-table sessions

Table 1. Research questions and Methods

III. Providing Recommendations that advocate for Effective Digital Health Standards Implementation at the National and County Level.

A more critical aspect of this research is to lay the groundwork for formulating and effectively implementing digital health standards and guidelines across all sectors in Kenya. This research will be shared with government officials to equip these officials with the knowledge and skills necessary to advocate for and drive standards and guidelines implementation to support the strengthening of the existing regulatory framework, ensuring that it effectively supports the integration and expansion of digital health solutions to achieve the objectives of UHC.

Specifically, this assessment of the digital health standards implemented in Kenya is aimed at:

1. Identified Digital Health Standards in Kenya

- **Purpose:** This part of the study aimed to map and understand the existing digital health standards in Kenya, including the relevant infrastructure, systems, and applications. We:
 - Examined national policies, regulations, and frameworks that guide digital health practices.

- Explored the technological landscape (e.g., electronic health records, telemedicine platforms, mobile health apps) to see how they align with national and global standards.
- Identified gaps or discrepancies between current systems and internationally recognized standards, such as those from WHO, ISO, and other relevant organisations.

2. Assessing the Extent of Awareness, Adoption, and Implementation of Standards and Guidelines by the Public and Private Sectors

- **Purpose:** The second objective was to evaluate the awareness and the level of adoption and implementation of digital health standards across both public and private sectors in Kenya. This involved:
 - Gauging how well health practitioners, public health institutions, and digital health service providers understand and follow the established standards.
 - Investigating the implementation challenges faced by these stakeholders, such as interoperability issues, lack of technical capacity, or insufficient resources.
 - Assessing the extent to which these standards are integrated into daily operations, decision-making, and policy implementation in both government and private healthcare settings.

The study provided a comprehensive overview of the current landscape of digital health standards in Kenya and identified areas where awareness and implementation can be improved to strengthen the country's digital health ecosystem.

This involved a detailed analysis of the existing standards and the awareness of standards and guidelines by the key stakeholders. By identifying gaps and misalignments, this research aims to provide recommendations for achieving better compliance and alignment with digital health standards. This alignment will be crucial for ensuring interoperability, data exchange, and the ability to leverage global innovations and best practices effectively.

Methodology

In-depth roundtable discussions were conducted with key stakeholders within each selected county. A total of 80 stakeholders that were engaged at the county level and included;

- Members of County Health Management Teams
- Staff of digital health departments/divisions i.e. Kisumu County
- Health Record Information Officer (HRIO's)
- System Users e.g. Nurses, Clinical Officers
- ICT Department Staff
- Staff of policy divisions/departments
- Finance and planning department staff members
- County health economists and finance department team members
- County Research staff

The sample of digital technologies that were identified through desktop review have been listed in [Appendix 2](#) The sample encompasses governmental interventions in digital health technologies as well as private sector technological deployments.

Limitations

Data Availability

A key limitation of this study is its reliance on secondary data sources and documents for the desktop review. The accuracy and comprehensiveness of findings depend on data accessibility and reliability. Additionally, some digital technologies e.g EMRs have widespread implementation but lack comprehensive guiding principles and global health standards and guidelines. This limitation has resulted in gaps in fully understanding the digital health landscape in Kenya. This limitation was mitigated by gathering feedback from the stakeholders during the stakeholder validation sessions to better understand the process of technology implementation at the county level.

Digital Health Standards in Kenya

The landscape of digital health standards and guidelines within Kenya's healthcare ecosystem includes policy, strategy and frameworks with transformative technologies. The policy documents that are in existence have made significant efforts to help accommodate the rapid evolution of digitization. Some technologies such as EMR systems and community health systems have specific documentation that provides for their operationalization structures, but other emerging technologies lack specific guiding documents.

This literature review provides an in-depth exploration of these frameworks.

Standards and Guidelines in Kenya's Digital Health Services

In Kenya, the Health Act governs all health-related activities. It serves as a legislative guide for all health operations throughout the country. It also makes recommendations for other supporting frameworks that should be put in place to ensure the optimization of health service delivery. The legislative documents that have developed all govern specific aspects of health service delivery and converge towards the achievement of UHC in Kenya.

Health Act ¹⁰

Enacted in 2017, the Health Act emerged as a pivotal legislative cornerstone integrating digital health technologies, prioritising data privacy, and enhancing security measures. Serving as a benchmark for digital health standards, it upholds patient rights, consent, and confidentiality, while establishing the framework for eHealth initiatives under Part XV. The Act recognizes e-health as a mode of health service provision, it also advocates for the development of a comprehensive integrated health information system, alongside policy guidelines for its establishment. According to the Act, this system shall encompass:

- a. an integrated comprehensive health information system relating to the national government health functions;
- b. an integrated comprehensive health information system relating to every county and in respect of county functions;
- c. the consolidation and harmonisation of health information
- d. the minimum standards applicable for the establishment and maintenance of health information systems;
- e. a guide on the minimum indices to be captured by each county health information system;
- f. the mechanism for ensuring inter-connectivity between each county information system and the national system.
- g. the guiding principles for the management and administration of health information banks;
- h. any other information on health services, including sources of health financing, human resources available in the health sector

Efforts are currently underway to ensure that the provisions of this act are implemented as part of our health operations as represented in the 'Kenya Digital Health Superhighway'.

The act also provides that within three years of its passing, there shall be legislation developed for health service delivery through M-health, E-learning, and telemedicine. A collective decision to refer to all e-health and m-health activities as 'digital health' was made to align with globally accepted terminology. The Digital Health Act is intended to govern all digital health-centred

¹⁰HealthAct21of2017.Pdf.

operations in Kenya. The Ministry of Health has been working to develop the Telemedicine Standards and Guidelines that are anticipated to be launched and enacted soon.

The Data Protection Act 2019¹¹

The act provides for the regulation of the processing of personal data, the rights of data subjects and obligations of data controllers and processors; and for connected purposes. The Office of the Data Protection Commissioner was established as per the act and its mandate is to oversee the operationalization of the act. The act also provides for the following measures as part of the regulation of data within Kenya;

- The registration of data controllers and data processors
- Principles and obligations of personal data protection
- Processing of sensitive personal data
- Transfer of personal data outside Kenya

The Data Protection Act outlines strict conditions for processing personal health data. It allows health data to be processed only by healthcare providers or individuals bound by professional secrecy laws.

Additionally, such data processing is permitted only when it serves the public interest in public health or is carried out by individuals legally obligated to maintain confidentiality. This ensures that personal health data is handled with care, safeguarding privacy while allowing for its use in essential public health scenarios. The enactment of this act provides boundaries for system developers, and they are required to adhere to the outlined provisions of the act to ensure lawful use of data that is collected through their systems.

The Digital Health Act 2023¹²

Kenya passed the Digital Health Act in October 2023. This pioneer legislation is intended to revolutionise digital technology implementation in Kenya. In its efforts to drive the achievement towards achieving UHC by 2030, the government of Kenya is making efforts to ensure that the correct legislative foundations are set to support digital technology implementations and provide a legislative framework that governs the operations of a rapidly evolving health sector in Kenya.

This act is intended to supplement the provisions of the Data Protection Act, 2019. The act provides for the establishment of a digital health agency that will establish a regulatory framework for the e-Health ecosystem data life cycle and establish a comprehensive integrated digital health information system for connected purposes. Other notable elements of the act are;

- The development of a data governance framework
- The classification of health data
- Establishment of health data banks
- Confidentiality, privacy, and security measures to control access to personal data.
- E-waste management
- Health Tourism

The proposed Digital Health Act in Kenya is expected to significantly improve digital health standards by providing a legal and regulatory framework that supports the safe, effective, and equitable use of digital technologies in healthcare.

¹¹Kenya-Gazette-Data-Protection-Act-2019.Pdf.

¹²TheDigitalHealthAct_2023.Pdf.

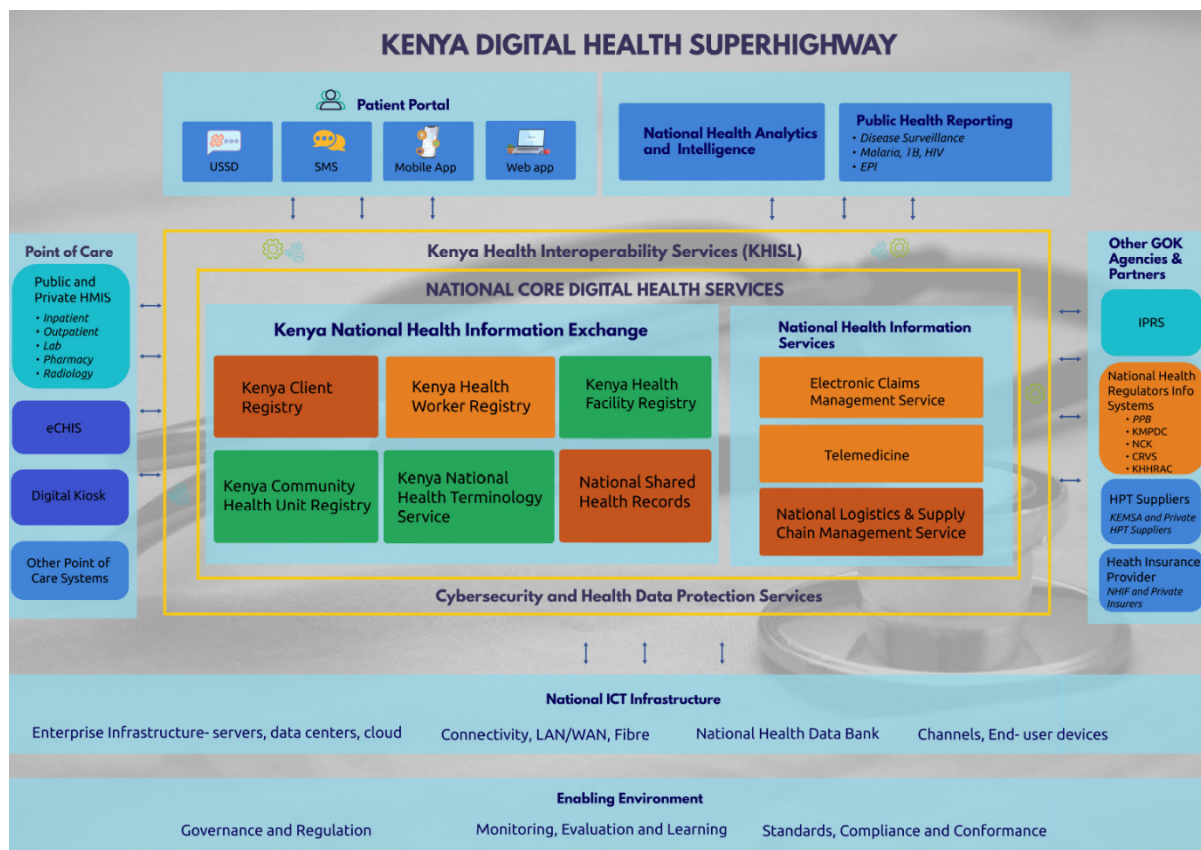


Figure 1. A pictorial representation of the Kenya Health Enterprise Architecture

The Kenyan government enacted the Health Act, 2017, which makes it easier to establish and maintain a comprehensive integrated health information system. To achieve this goal, the Ministry of Health has developed policies and guidelines to help inform the consolidation and harmonisation of the country's health information systems, allowing for a data-driven health system. In addition, it establishes interconnectivity mechanisms and foundational guiding principles for the management and administration of health information banks to support Kenya's healthcare system.

A national health information exchange (NHIE) is a system that enables healthcare providers to securely share electronic health information. It also directly benefits clients by providing a mechanism for implementing self-care through digital tools like a personal health record. A NHIE has the potential to improve the quality of health-care delivery by allowing the creation of longitudinal health records for individuals, providing a more complete picture of a patient's medical history. It can also help to save money by removing duplicate tests and procedures.

To accomplish this, the Ministry of Health collaborated with stakeholders to create a sector-wide health enterprise architecture that will be implemented throughout the country. The enterprise architecture envisions an established and managed data-driven digital health enterprise that optimises the use of its digital resources to deliver quality healthcare in a holistic and coherent manner. This KHEA is intended to serve as a blueprint for establishing various components of Kenya's health enterprise and guiding how they should be organised, governed, and collaborated to transform service delivery and data management in the health sector. The implementation of this enterprise architecture aims to achieve a national health information exchange system.

Kenya Universal Health Coverage Policy 2020 - 2030

Aligned with Kenya's Universal Health Coverage (UHC) commitment, this policy aims to ensure that all Kenyans access and receive essential quality health services without suffering financial hardship. These services include promotive, preventive, curative, rehabilitative, and palliative health services.

The policy has various principles guiding it among them being health as a human right, social solidarity, equity, effectiveness and quality, efficiency, people-centred, appropriateness and responsiveness, transparency, and accountability. The policy goals include strengthening access to health services, ensuring quality of health services, and strengthening the responsiveness of the health system through digital health among others.

To ensure alignment with other recently passed digital health policies and with the current government's manifesto for economic transformation agenda (BETA), the UHC policy is currently undergoing review to address the gaps that were identified.

Kenya National eHealth Policy

The Kenya eHealth Policy (2016-2030) is a strategic framework aimed at promoting the integration and effective use of information and communication technologies (ICT) in the healthcare sector. This policy seeks to create an enabling environment for the sustainable adoption, implementation, and efficient use of eHealth products and services at all levels of healthcare delivery in Kenya.

Its primary objectives are to support informed policy decisions, improve the quality and efficiency of clinical practices, enable a connected healthcare system, and foster linkages between health research and information technologies. The policy's vision is to develop efficient, accessible, equitable, secure, and consumer-friendly healthcare services enabled by ICT. \

Kenya Health Policy 2014 – 2030¹³

The goal of the Kenya Health Policy is to attain the highest possible standard of health in a responsive manner. The health sector aims to achieve this goal by supporting equitable, affordable, and high-quality health and related services at the highest attainable standards for all Kenyans. The policy document outlines principles that recommend the development of adequate and appropriate health infrastructure that provides the necessary logistical support, including transport, communication and IT, e-health, and medical devices to establish an appropriate and efficiently functioning referral system.

Kenya Health Information System Policy¹⁴

This policy document was developed to support the achievement of the following objectives;

- Promote the mobilisation and efficient use of resources needed to improve health information
- Improve data collection, collation, analysis, storage, dissemination, and use
- Create the necessary regulatory framework for information management and reporting in the health sector
- Enhance the application and use of information communication technology (ICT) to enhance access and quality of healthcare
- Improve privacy, confidentiality, and security of information sharing and use
- Provide a framework for implementation, monitoring, and evaluation, and financing of the HIS policy objectives
- Create an environment for continual improvement of a devolved NHIS in line with the new constitutional mandate
- Provide an overarching institutional framework that defines roles and responsibilities

¹³FinalKenyaHealthPolicyBook.Pdf.

¹⁴PA00TB2Q.Pdf.

The document prioritises the mobilisation of resources aimed at maintaining the National Health Information Systems (NHIS), Improving data management initiatives at the national and county levels, and strengthening partners and stakeholder collaboration and participation in the HIS implementation. It addressed the increasing demand for the use of research in policy advocacy initiatives and the creation of a legal and regulatory framework for HIS reporting.

Kenya National eHealth Strategy

The Kenya National eHealth Strategy serves as a comprehensive framework within the healthcare and technology integration landscape. It acknowledges and tackles the urgent requirement for effective, accessible healthcare services leveraging Information and Communication Technology (ICT). Importantly, this strategy acknowledges and underscores several challenges, such as inadequate infrastructure, a dearth of skilled personnel, and limited funding. These challenges are highly relevant within the literature on eHealth, as they mirror common impediments to successful eHealth adoption and implementation in numerous developing countries. The strategy's vision and mission focus on improving healthcare through ICT. It aligns with global eHealth trends and highlights the transformative power of digital technologies in healthcare, reflecting key themes in eHealth literature. Furthermore, the strategy's emphasis on patient-centric care resonates with prominent discussions in eHealth literature, as it accentuates the drive to improve patient outcomes and experiences through technological advancements.

The strategy acknowledges fundamental principles such as strong leadership and governance, collaboration, resource optimization, and the protection of patient confidentiality. These principles reflect established best practices within the sphere of eHealth governance and policy development. This reaffirms the strategy's pertinence to the broader body of literature on eHealth policy and governance. Additionally, the five strategic areas of implementation, including Telemedicine, Health Information Systems, Information for Citizens, M-Health, and E-Learning, are indispensable components within the literature review. These areas resonate with the diverse applications of eHealth technologies, encompassing clinical practice, patient engagement, and healthcare workforce training topics that recurrently feature in discussions within eHealth literature. Thus, the Kenya National eHealth Strategy stands as a valuable resource within the literature review, encapsulating several key themes and challenges pertinent to eHealth implementation in developing nations, thereby enriching the broader discourse on eHealth within the academic literature. This document is out of date and would need to be revised.

Kenya National Cybersecurity Strategy 2022- 2027¹⁵

The National Cybersecurity Strategy provides direction for a unified approach to the implementation of cybersecurity activities in Kenya. The Strategy establishes foundations and pillars for effective cybersecurity for the public and private sectors by combining good governance with a set of initiatives and interventions. Based on 6 strategic pillars, it provides a framework for:

- Cybersecurity governance,
- Cybersecurity policies, laws, regulations and standards;
- Critical Information Infrastructure Protection (CIIP);
- Cybersecurity capability and capacity building;
- Cyber-Risks & Cyber-Crimes Management; and
- Cooperation and collaboration

¹⁵National Cybersecurity Strategy 2022 – 2027 – NC4.

Kenya Standards and Guidelines for mHealth Systems¹⁶

Kenya has been a pioneer in mobile health (mHealth) which are well captured in the guidelines and standards governing their use and operation of mHealth systems. M-health is defined as health services, interventions and/or programs accessed, delivered or availed through use of mobile technologies and devices.

The overall goal of mHealth standards in Kenya is to ensure the design, development and implementation of interoperable, scalable, sustainable mHealth solutions that benefit clients and healthcare workers in a cohesive and holistic manner for better health outcomes. The purpose of the m-Health standards and guidelines is to provide a regulatory framework that will enable coordination and implementation of robust mHealth solutions.

These guidelines cover the requirements and considerations for the development, implementation, support and maintenance of mHealth systems. It outlines the phases that stakeholders should follow in the development of systems and the validation process for the expected outputs. It provides a comprehensive overview of minimum functional and non-functional requirements when developing an m-health system, the requirements for integrating the system within a health information exchange as well as guidelines to conform to the standards outlined in the Kenya Interoperability standards and guidelines.

In the document, there are standards specified for digital messaging, electronic consultation, and e-prescriptions that provide guidance on risk management in cases where patient information is at risk. The document goes a step further in providing governance structures for m-health systems, legal ethical and compliance requirements that all m-health systems should adhere to.

Standards and Guidelines for Electronic Medical Record Systems in Kenya¹⁷

The Standards and Guidelines for Electronic Medical Record Systems in Kenya reflect the Ministry of Health's recognition of the importance of information and communication technology (ICT) in healthcare. These guidelines stem from a need to standardise Electronic Medical Record (EMR) systems in Kenya, as the development and implementation of these systems lacked coordination, resulting in fragmentation and data sharing challenges. The document acknowledges the diversity of healthcare settings in Kenya, making it infeasible to enforce a single national EMR approach. Instead, the guidelines aim to define development, implementation, interoperability, and governance requirements. The document provides guidance for EMR system developers, health facilities, policy makers, and donors. These evolving guidelines align with global standards including the ISO Health Informatics Standards, emphasising the importance of information sharing, data security, and accuracy in EMR systems for holistic healthcare delivery in Kenya.

Kenya Standards and Guidelines for E-health Systems Interoperability¹⁸

These guidelines emphasise both manual and automated methods of data exchange. They define unique identifiers for patients, facilities, and service providers. The objectives of this are to:

- Support more-informed policy, investment, and research decisions through access to timely, accurate and comprehensive reporting on Kenyan health system activities and outcomes
- Improve the quality, safety and efficiency of clinical practices by giving care providers better access to consumer health information, clinical evidence and clinical decision support tools
- Enable the Kenya health sector to be more effectively operated as an inter-connected system, overcoming the current fragmentation and duplication of service delivery
- Create linkages between health research and information technologies

¹⁶Kenya-Standards-and-Guidelines-for-mHealth-Systems-April-2017.Pdf.

¹⁷Standards_and_Guidelines_for_EMR_Systems.Pdf.

¹⁸PA00TB2K.Pdf," accessed February 12, 2024, https://pdf.usaid.gov/pdf_docs/PA00TB2K.pdf.

It provides guidelines for data exchange (including methods of exchange, data types and levels where data is exchanged), information security and the rules to govern data exchange (both physical and technical safeguards) and data quality, reliability, performance and governance within a national health information system (NHIS).

Health Sector ICT Standards and Guidelines (2013)¹⁹

These standards and guidelines developed to provide guidance to both levels of government, to ensure that ICT resources are optimised to achieve efficiencies in healthcare delivery. The objectives of the guidelines as outlined in the document include;

- Support the development, implementation and maintenance of ICT Systems in MOH;
- Enhance information security of MOH ICT systems.
- Promote efficient and effective operations and usage of ICT systems within the MOH
- Encourage innovations in technology development, use of technology and general work flows within the MOH;
- Facilitate the development of ICT skills to support ICT systems in the MOH;
- Promote efficient communication among the MOH's staff and stakeholders;
- Promote information sharing, transparency, and accountability within MoH and towards the general public and other stakeholders.

The guidelines provide for the equipment and the software that run within them. The guidelines are focused on ensuring the ministry of health is informed on the adequate procedures for equipment procurement and management. They also provide guidelines on software applications including the acquisition process, the software development process, maintenance, and disposal procedures for software that is no longer required. The guidelines reference and ensure conformity to internationally acceptable standards such as the WHO health informatics standards and various ISO standards including those targeted for software product quality and evaluation. It comprehensively addressed IT Security guidelines and measures for backing up data and recovering/ restoring deleted data. To complete the holistic elements of the ICT sector, it addressed capacity building and human resource development for staff members.

Vision 2030

The Kenya Vision 2030 aims to transform Kenya into a newly industrialising, middle-income country providing a high quality of life to all its citizens by 2030 in a clean and secure environment.²⁰

One of the objectives that is aligned with digitization is the goal to establish E-health hubs both in the county and national facilities established and equipped.

Kenya Unique Identifier Framework²¹

To realise the vision of having all patient information in a shared health record that can be accessed across multiple facilities, clients must be identified using a unique identifier. The UPI (Unique Personal Identifier), uniquely identifies patients for the purpose of collecting and retrieving necessary patient information, assisting in the administration of health functions, improving patient identification and tracking, and protecting patient privacy and confidentiality. The UPI system will identify all individuals seeking healthcare services at all levels of service delivery, including public, private, and faith-based health facilities. National identifiers such as National ID, Huduma Numba, passport number, birth certificate number, NEMIS, Alien ID, National Health Insurance Fund (NHIF) ID, National Social Security Fund (NSSF) ID, and birth

¹⁹MEDBOX | Kenya: Health Sector ICT Standards and Guidelines." accessed February 12, 2024, <https://www.medbox.org/document/kenya-health-sector-ict-standards-and-guidelines#GO>.

²⁰Kenya Vision 2030 | Kenya Vision 2030.

²¹Health-Sector-Unique-Identification-Framework-30-August-2022.Pdf."

notification number will be added to the national registry as one of many potential personal attributes associated with individual patients. The UPI will be linked to the various identifiers linked to an individual.

Establishing a UPI system in Kenya will allow the government to:

- Improve quality, safety, and access to care by ensuring that everyone is correctly identified. This will enable healthcare providers to collect and retrieve the necessary information to deliver optimum care at any service delivery point across the country.
- Promote the efficient use of healthcare resources through better tracking of patients across the continuum of care and the healthcare system, and by improving scheduling, billing, and insurance benefit claims.
- Maintain a centralised repository of all patients within the Kenya health sector. This will support the correct and unambiguous identification of patients at service delivery points, thereby promoting the quality, safety, access, and affordability of healthcare by facilitating data exchange with health, financial, and other sector-specific information systems.
- Maintain a database of accurate statistics devoid of multiple counts for effective and efficient planning.

Kenya National Health Terminology Service

Formerly known as the National Health Data Dictionary (NHDD), The Ministry of Health has established and implemented a National Terminology Service that will provide a standardised and consistent set of health terms, definitions, and concepts that all stakeholders can use to enable the realisation of health information exchange and promote efficiency across systems to communicate effectively, accurately, and unambiguously.

This will provide for the collaborative management, publication, versioning, and distribution of standardised data dictionaries and other relevant content, which the health sector stakeholders will access and utilise the digital health systems they deploy at various levels of the health system. The National Terminology Services will be implemented across the health sector and accessed by both state and non-state actors.²²

Kenya Master Facility List (KMFL)

A facility census was conducted and concluded in 2023 to map out the health facilities that exist in Kenya. The activity targeted 14,366 health facilities; 12,384 facilities, across all counties, were fully assessed.²³

The objectives of the census were to:

- Enumerate all the public, faith-based, and private health facilities in Kenya
- Determine specific health service availability and readiness across the country's network of health facilities
- Develop a comprehensive database of all health facilities with the health services they provide and their readiness to provide those services.
- Determine the status and the gaps in health system inputs (human resource for health, infrastructure, amenities, tracer commodities, and equipment) to serve as the basis for improving provision and quality of healthcare services in the country

Each facility can be identified through a unique code on the KHML website.²⁴

²²About KNHTS.

²³Kenya Master Health Facility List: Find All the Health Facilities in Kenya.

²⁴Kenya Master Health Facility List: Find All the Health Facilities in Kenya.

Kenya Bureau of Standards

The Kenya Bureau of Standards is a government agency responsible for maintaining and governing standards in Kenya. KEBS has established technical committees that collaborate to establish robust standards, ensuring that health information systems in Kenya are efficient, secure, and aligned with global best practices. Their work contributes significantly to the advancement of healthcare delivery and management.

A Health Informatics Technical Committee composed of various stakeholders meets under the auspices of KEBS to review and adopt standards relevant to the Kenya health setting.²⁵

The Health Informatics Technical Committee (KEBS/TC 142)

Operating under the Kenya Bureau of Standards (KEBS), this committee plays a crucial role in shaping health information standards within the Kenyan context.²⁶ This committee focuses on standardisation in the field of health information. It encompasses the application of Information and Communications Technology (ICT) for managing health information at various levels—personal, corporate, communal, industry, national, and international. From individual health records to large-scale health systems, KEBS/TC 142 ensures that information exchange, data security, and interoperability are addressed effectively.

KEBS/TC 143/SC 01

This committee deals with ergonomics in health services. Ergonomics aims to optimise the interaction between humans, technology, and the environment to enhance safety, efficiency, and well-being in healthcare settings.

Landscape Analysis of Digital Health & Universal Health Coverage in Kenya (2022)

The “Landscape Analysis of Digital Health & Universal Health Coverage in Kenya” scrutinises Kenya’s journey towards Universal Health Coverage (UHC) through digital interventions. While

highlighting successes and achievements, the report addresses challenges including political goodwill, legal frameworks, and equitable distribution of digital health solutions. It aligns with Kenya’s constitutional commitment to healthcare access and emphasises the need for comprehensive digital health planning.

²⁵Standards and Guidelines for EMR Systems.Pdf.

²⁶Technical Committees – Kenya Bureau of Standards.

Findings

Research Question	Results
1. What are the current digital health standards and guidelines in Kenya?	<p>The analysis revealed the presence of numerous policy and guideline documents, governing various aspects of digital health within Kenya's healthcare ecosystem detailed in the 'Digital Health Standards in Kenya' section.</p>
2. What standards were used to operationalize digital health technologies in Kenya?	<p>Although the study identified the adoption of globally recognized digital health compliant standards and guidelines such as the Medical Terminology Standards, Diagnostics Standards and the Quality Management and Information Security Standards among other standards that are listed under Appendix 1 of this document, the majority of technologies that were implemented in the country were not guided by these standards.</p> <p>The challenge that this pose is that as we work towards transitioning and onboarding all systems onto the NHIE, there is a risk that many systems that are currently in existence will be declared redundant as they do not meet the criteria set in the certification framework.</p>
3. What challenges are experienced in the implementation of standards and guidelines?	<p>Given this, many systems will be declared redundant once the KHEA is fully operationalized. There is a need to have reviews done to align the standards and guidelines documents with the current state of the health ecosystems as well as to capture considerations for the rapidly evolving technologies.</p> <p>This alignment is pivotal for ensuring interoperability, data exchange, and the ability to leverage global innovations and best practices effectively, thus advancing the country's healthcare transformation efforts.</p> <p>The alignment between Kenya's digital health standards and Universal Health Coverage (UHC) goals is aimed at improving access, quality, and efficiency in healthcare through technology.</p> <p>With clear standards in place, digital health systems across public and private sectors can seamlessly share data and communicate. This interoperability supports continuity of care as patient records and medical information can be accessed across different healthcare providers, improving the efficiency and effectiveness of health service delivery. Digital health technologies, such as telemedicine and electronic health records (EHRs), expand access to healthcare, particularly in remote and underserved areas.</p>

	<p>By aligning digital health standards with UHC objectives, Kenya can ensure that these technologies reach a broader segment of the population, helping achieve equity in healthcare access.</p> <p>Adhering to established digital health standards also allows for better health data collection and management, which is essential for monitoring and improving public health. Accurate data enhances decision-making at both local and national levels, ensuring that healthcare resources are allocated effectively and supporting preventative care measures, a key aspect of UHC.</p> <p>Digital health technologies, when implemented according to standard guidelines, can reduce healthcare costs by streamlining administrative processes, improving care coordination, and minimising redundant tests.</p> <p>These efficiencies make healthcare more affordable and sustainable, aligning with UHC's goal of financial protection for all. The use of standardised digital health systems ensures that healthcare providers adhere to best practices and protocols, leading to improved patient outcomes. As healthcare quality improves, it contributes to the overall objective of UHC to provide high-quality care to all citizens.</p> <p>The standards and guidelines are intended to create an enabling environment for the uptake and adoption of digital technologies that will enhance the uptake and access of health services among the Kenyan population.</p> <p>There remains a significant gap in implementing the standards. The standards that have been domesticated (i.e. adapted to the Kenyan context at the national and/or county level do not cover all of the digital health systems in place in Kenya today.</p> <p>Given this, many systems will be declared redundant once the KHEA is fully operationalized. There is a need to have reviews done to align the standards and guidelines documents with the current state of the health ecosystems as well as to capture considerations for the rapidly evolving technologies.</p>
--	---

Table 2. Research questions and Results

The guiding questions that were presented were intended to gauge the stakeholders' understanding of digital technologies, the technologies that are currently being implemented, the guidelines that support the implementation of these technologies, and the challenges witnessed that hinder the widespread adoption of technologies. Feedback from the stakeholder engagement sessions can be summarised as follows:

Overview of Technologies, Standards and Implementation Challenges in Kenya's Digital Health Ecosystem

This table provides a detailed analysis of the technologies used in Kenya's digital health sector, the standards and guidelines governing their implementation, and the primary challenges encountered. With Kenya's ongoing efforts to strengthen its healthcare system through digitalisation, understanding these components is crucial for aligning digital health initiatives with national goals, such as Universal Health Coverage (UHC). The table outlines how specific technologies adhere to national and international health standards, while also highlighting the obstacles, such as interoperability and resource limitations, that must be overcome to fully realise the potential of digital health solutions.

Technologies Used	Standards And Guidelines That Are Used in Implementing Systems	Primary Challenges in Implementing Standards
KITUI COUNTY		
<ul style="list-style-type: none"> • KHIS • National Cancer Register • Kenya EMR • Logistics Information Systems • Patient Information System that also ensures Revenue Collection • Damu KE • NHP • e-CHIS 	<ul style="list-style-type: none"> • Health Act, 2017 • Digital Health Act, 2023 • Data Protection Act, 2019 • UHC Policy, 2014 - 2030 • Health insurance portability and accountability act (HIPAA) 1996 • ICT Policy • ICD 10 	<p>Challenges to the implementation of standards and guidelines:</p> <ul style="list-style-type: none"> • Lack of involvement of all relevant stakeholders leads to challenges in policy transitions. • Current terminology standards in use such as the ICD codes are not up to date. • Poor understanding of these standards and guidelines by the county teams due to lack of technical capacity • Lack of Staff Motivation owing to inadequate understanding of the standards and guidelines • Guidelines do not provide for e-waste disposal measures and procedures. • Budgetary challenges such as the delayed disbursement of funds from the county treasury to the County Department of Health that hinder full adoption of digital technologies once donor funding is exhausted.

Technologies Used	Standards And Guidelines That Are Used in Implementing Systems	Primary Challenges in Implementing Standards
KISUMU COUNTY		
<ul style="list-style-type: none"> • EMRS • Elephant • Funsoft • LIMS • eCHIS • FIS - Financial Information System • DHIS • Maisha Meds • M-Tiba • IRIS • Kenya EMR • TiBU 	<ul style="list-style-type: none"> • Health Act • Digital Health Act • Data Protection Act • ICT Policy • ICD 10 • Standards and guidelines for EMR systems • Kenya Standards and Guidelines for E-health Systems Interoperability • UHC Policy 	<ul style="list-style-type: none"> • Lack of interoperability among systems due to siloed implementations that do not adhere to any set of guidelines • User Readiness and attitude towards implementing standards. • Lack of adequate skilled human resource • Hospital staff lack relevant computer skills.
THARAKA NITHI COUNTY		
<ul style="list-style-type: none"> • Kenya-EMR • HMIS • Biometric registration for patients using NHIF • KHIS • ECHIS • Telemedicine • 1513 TOLL FREE line • Lab IMS • Drone technology • ANC SMS prompt • KEMSA Logistics Management Information System (LMIS) • Chanjo system • AfyaKE • SoftCare • SANITAS • M-Tiba • M-Pesa • HICS 	<ul style="list-style-type: none"> • Kenya Constitution 2010 • Data Protection Act 2019, • National ICT Policy • Health insurance portability and accountability act (HIPAA) 1996 • Kenya Health Policy 2014-2030 • Kenya Universal Health Coverage Policy 2020 - 2030 • Kenya Health Act 2017 • Digital Health Act 2023 • Tharaka Nithi ICT Policy 2021, • Kenya Health Information Policy 2014-2030 	<ul style="list-style-type: none"> • Skills and capacity: Inadequately trained ICT Personnel • Change management for staff: negative attitude among the healthcare workers towards adoption of DHT's due to low digital literacy levels • Inadequate workforce at the county facilities required to support the full adoption of technologies.

Technologies Used	Standards And Guidelines That Are Used in Implementing Systems	Primary Challenges in Implementing Standards
KIAMBU COUNTY		
<ul style="list-style-type: none"> • Kenya-EMR • HMIS • KEMSA Logistics Management Information System (LMIS) • Chanjo system • AfyaKE • Telemedicine services 	<ul style="list-style-type: none"> • The team adheres to established health guidelines, including those from Human Resources for Health and Kenya Quality for Health. However, there are currently no dedicated guidelines in place for digital health practices within the team. • When a new system is introduced, the ICT team sends out an implementation team who adhere to set out guidelines for implementation, whilst offering training, maintenance, and support. • Various departments implement their various operational guidelines. 	<ul style="list-style-type: none"> • Lack of staff capacity in implementing standards

Technologies Used	Standards And Guidelines That Are Used in Implementing Systems	Primary Challenges in Implementing Standards
PRIVATE SECTOR		
	<ul style="list-style-type: none"> • Digital Health Act 2023, • Kenya’s national eHealth strategy, • eHealth policy, • Health Act, • Data Protection Act, • ICT policy 2019, • Community Health Digitization Strategy, • Kenya Health Information Systems Interoperability Framework • International Standards Organization (ISO) • Digital Imaging and Communications in Medicine (DICOM) • Health Level Seven International (HL7) • ICD 11 • SNOMED • LOINC • Standards and Guidelines for Electronic Medical Record Systems in Kenya 	<ul style="list-style-type: none"> • Some standards and guidelines are out of date as of the study review in 2023, some of these include the UHC Act which is currently under review to include the digitisation component and the Kenya National eHealth strategy (which was passed as the Digital Health Act in late 2023). Others are incomplete in setting standards and guidance for current realities and future state of digital technologies. • Regulatory authorities are unaware of some standards or how to apply them, and they are applied unequally across health facilities. • There are significant gaps in standards and guidelines that require closing for effective and useful implementation. • Interoperability Issues- Ensuring interoperability among different health information systems, devices, and software platforms can be challenging, especially when integrating legacy systems or dealing with proprietary standards. Interoperability: One of the biggest challenges is ensuring that different DHT systems and applications can communicate and work together. Different organisations and developers may use proprietary systems or standards, making interoperability difficult. This extends to the integration of new technologies with existing healthcare IT systems, which are often outdated or based on diverse standards. • Data Security and Privacy Concerns: Protecting sensitive health information from security breaches, unauthorised access, and data breaches is paramount. • Change Management and Resistance: Resistance to change among healthcare providers, administrators, and other stakeholders can impede the adoption and implementation of new technologies and processes. • Technological Complexity: Rapid advancements in technology, evolving healthcare delivery models, and diverse user needs pose challenges in designing, developing, and implementing DHTs that are user-friendly, intuitive, and adaptable to different contexts. • Ecosystem: The lack of an innovation ecosystem for DHT presents a significant challenge, hindering collaboration and knowledge exchange between organisations, government, and stakeholders. • Lack of Widespread Digital Systems in Kenyan Health Facilities and

	<ul style="list-style-type: none"> • Kenya Standards and Guidelines for mHealth System • Kenya Standards and Guidelines for E-Health System Health Sector • ICT Standards and Guidelines • National Health Data Dictionary (NHDD) • WHO Global Strategy on Digital Health 	<p>County Health Systems: The limited presence of digital systems within health facilities and at the county level results in inconsistent healthcare delivery and data management, complicating efforts to achieve comprehensive healthcare coverage and efficient patient care coordination.</p> <ul style="list-style-type: none"> • Lack of a unified National Electronic Health Record System: The absence of unified electronic health record (EHR) systems at national and country levels poses a challenge, leading to fragmented patient data and hindering seamless healthcare delivery and data exchange across different healthcare providers and settings. • Rapid Technological Advancement: The pace of technological change these days, can outstrip the development of corresponding standards and guidelines. By the time standards are developed and implemented, the technology may have evolved beyond them. A prime example is the rapid pace of advancement in AI. Regulations, however, should seek to foster and not to tightly control such innovations. • User Adoption and Digital Literacy: For DHTs to be effective, healthcare providers and patients must be willing and able to use them. Challenges include varying levels of digital literacy among these groups, resistance to change from traditional healthcare practices and abundant, affordable access to the Internet and mobile data.
--	--	---

Table 3. The technologies used in Kenya's digital health sector

Analysis

The available evidence indicated in the table above titled “Overview of Technologies, Standards, and Implementation Challenges in Kenya’s Digital Health Ecosystem”, suggests that while there is some level of awareness of digital health policy documents, public sector stakeholders have limited awareness of relevant digital health standards and guidelines and are inconsistent in their application to digital tools.

Public sector stakeholders: County officials expressed an awareness of some digital technologies particularly those that are in use in their counties. These include EMR systems, Logistics management systems, drones, telemedicine platforms, and e-CHIS. However, beyond the policy documents, public sector stakeholders had minimal to no information about standards and guidelines that are used to guide the implementation of digital technologies.

On their awareness of the policy documents, they admitted to knowing of their existence but have not been keen to read the documents and to understand the impact of their implementation. Some counties have domesticated some of the policy documents to develop county-owned guidelines. For example, Tharaka Nithi County uses the Tharaka Nithi ICT policy 2021 to enhance proper digital data management. This is intended to complement other existing national policies.

Private sector stakeholders: The private sector stated that regulatory authorities are frequently unaware of standards or inconsistent in their application, therefore complicating implementation. Many standards that are currently in existence need to be updated to align with the technologies that are in existence. For example, stakeholders from the private sector stated that current standards and guidelines, such as the ICD codes, are obsolete.

Cross-cutting findings: A common theme identified in the research is a lack of comprehensive stakeholder participation during the policy development and transition phases. This presents difficulties in gaining widespread acceptance and smooth transitions from policy to practice.

There is a significant need to update standards to reflect current and future digital health environments. Existing guidelines frequently contain gaps that fail to address all aspects required for effective implementation. Kenya’s policies and guidelines need to contain provisions that accommodate the rapid developments in technology which often move faster than policy development and implementation processes. For example, the current UHC policy requires updating since it does not capture the current government’s priorities of adopting digitization as a driver for achieving UHC.

At the county level, a recurring issue is a lack of understanding of the standards and guidelines and lack of technical capacity among county teams and healthcare staff. Counties such as Tharaka Nithi and Kiambu reported inadequately trained ICT personnel and a shortage of skilled human resources, impeding the adoption and effective implementation of standards and guidelines. This challenge is made worse by negative attitudes and resistance to change among healthcare workers, which can be attributed to low digital literacy levels.

Resistance to change remains a significant barrier to the adoption of new standards and digital technologies. This resistance stems from existing system users, healthcare providers, and administrators who are often hesitant to give up traditional practices. Introduction of change management strategies is required to effectively address this resistance.

There is a significant challenge in achieving interoperability among various health information systems. Siloed implementations and the use of proprietary systems prevents seamless integration. The stakeholders highlighted the challenges of ensuring that different DHTs and applications can communicate and work together, particularly when integrating legacy systems. If the systems cannot be integrated, many existing technologies will be declared redundant.

Insufficient financial resources impede the acquisition of critical technologies and infrastructure. Budget constraints were raised by all stakeholders as an issue impacting implementation of standards. Finally, political goodwill and support was identified as a key pillar to help in fostering an enabling and conducive environment for digital transformation in healthcare.

Implication of the new 2023 Digital Health Act on these findings: The Digital Health Act of 2023 calls for the creation of a certification framework to help mitigate this issue by establishing minimum standards and criteria that must be met by all systems in use in the country. If a system does not meet these requirements, it cannot be onboarded onto the NHIE and thus cannot communicate with other systems, which is the ultimate goal according to the KHEA.

Recommendations

There is visible interest in implementing standards and guidelines in the health sector. There is a collective understanding that this will be the defining factor in implementing a nationwide health information exchange. The key recommendations that will ensure successful adoption of digital technologies can be summarised into three categories:

1. Awareness, Uptake, and Implementation of Standards & Guidelines

- **Objective:** Increase the adoption and implementation of digital health standards at the national and county levels.
- **Specific Actions:**
 - **Expand Standards Development and Adoption:** By Q4 2025, ensure that 90% of all counties have adopted digital health standards by running a series of training workshops and awareness campaigns for county-level stakeholders.
 - **Stakeholder Engagement:** Conduct quarterly engagement sessions with public and private sector representatives to introduce and review new digital health developments.
 - **Domestication of Standards:** Tailor and implement digital health standards in 4 pilot counties by the end of 2025, ensuring each county's standards reflect its specific healthcare needs.
 - **Technical Working Groups:** By mid-2025, include representatives from the private sector, faith-based organisations, and county officials in digital health standards technical working groups.
 - **Resource Allocation:** Secure funding by Q4 2026 to operationalise the Digital Health Act, ensuring that at least 50% of necessary human and financial resources are allocated to the initiative.
- **Measurable Outcomes:**
 - 80% stakeholder awareness of standards by the end of 2025.
 - 70% adoption rate in pilot counties by Q4 2025.
 - Minimum of four technical working group sessions held annually with diverse stakeholder representation.

2. Partnerships

- **Objective:** Strengthen partnerships to enhance digital health infrastructure and standards uptake.
- **Specific Actions:**
 - **ICT Partnerships:** By Q2 2025, develop at least three partnerships with leading ICT companies to expand telecommunication and digital infrastructure in rural areas.
 - **Resource Mobilisation:** Secure \$30m for implementation over 3 years for the 4 counties assuming 2m\$ per year per county in additional funding from international donors and private sector partnerships by Q1 2026 to support ICT infrastructure upgrades.
 - **Policy Engagement:** Organise bi-annual meetings with county-level policymakers to advocate for digital health standards adoption and build political support.
 - **Industry Collaboration:** Develop a consortium of industry leaders by Q3 2025 to establish updated standards that reflect the latest technological advancements.

- **Measurable Outcomes:**

- Increase ICT infrastructure coverage by 30% in rural counties by 2026.
- Achieve \$30 million in committed funding by the end of 2026. for the 4 counties
- Secure public commitment from at least 4 counties to digital health standards implementation by 2026.

3. Change Management & Training

- **Objective:** Enhance the digital health workforce's readiness to adopt and implement digital health standards.

- **Specific Actions:**

- **Develop Change Management Strategies:** By Q4 2025, design and roll out comprehensive change management strategies for national and county-level digital health transformation programs.
- **Training Programs:** Implement a series of digital literacy and standards training workshops for healthcare workers in 20 counties by Q2 2025.
- **Education for Stakeholders:** Conduct quarterly training for the Ministry of Health (MoH), county officials, and health facility managers on digital health standards and guidelines.
- **Partnerships with Academia:** By mid-2025, establish partnerships with at least two academic institutions to provide pre-service and in-service training on digital health standards.
- **User Ownership and Refresher Trainings:** Hold annual refresher training sessions for healthcare workers in all counties to ensure ongoing awareness and competency in using digital health tools.

- **Measurable Outcomes:**

- Train 1,000 healthcare workers by 2025, with a minimum of 80% demonstrating competence in digital tools.
- 70% of counties to have implemented change management strategies by Q4 2025.
- Partnership agreements with two academic institutions by mid-2025.

Next Steps for the Transform Health Coalition

1. Awareness, Uptake, and Implementation of Standards & Guidelines

Objective: Increase the adoption and implementation of digital health standards at the national and county levels.

- **Link to National Health Strategies:** Position digital health standards as a priority in national health policies. Align the initiative with ongoing reforms in health financing and digital transformation, such as the Digital Health Act 2023.
- **County Engagement:** Develop a model digital health roadmap for counties and eventually development of county specific e-health laws. This ensures that counties have legal frameworks to support the adoption of these standards.
- **Incentivising Uptake:** Work with county governments and the Ministry of Health to create incentive programs (e.g., financial or technical support) for counties that adopt digital health standards. Incentives can be tied to performance-based grants or part of the county funds disbursement.
- **Use advocacy** with county governors and local policymakers to link the adoption of standards to improved healthcare outcomes and economic benefits for counties.

2. Partnerships

Objective: Strengthen partnerships to enhance digital health infrastructure and standards uptake.

- **Public-Private Partnerships (PPP) Policy Frameworks:** Utilise Kenya's existing PPP frameworks to formalise collaborations between the government and private sector to expand digital health infrastructure. Push for county-level adoption of PPP models, focusing on ICT infrastructure development in healthcare.
- **Alignment with the BETA Government agenda:** Link partnerships to Kenya's commitments to achieving the UHC through digitization. Advocate for policy incentives for ICT companies contributing to the achievement of the national government objectives through digital investments.
- **Donor Engagement Policy:** Align resource mobilisation efforts with the country's development cooperation strategy to secure international donor funding. Highlight the importance of digital health standards in advancing national and global health goals.
- **Advocate for policy shifts** that prioritise partnerships with private-sector entities and international organisations in health and ICT. Highlight the economic benefits of digital infrastructure investments in health and rural development.

3. Change Management & Training

Objective: Enhance the digital health workforce's readiness to adopt and implement digital health standards.

- **Workforce Development Policies:** Advocate for the inclusion of digital health competencies in the National Human Resource for Health Strategy. This ensures that digital health training becomes a formal part of capacity-building efforts for healthcare workers.
- **Education and Training Standards:** Work with policymakers to integrate digital

health education into national pre-service and in-service training standards, ensuring a sustainable pipeline of trained professionals. Push for certification in digital health standards as part of continuing professional development (CPD) requirements for healthcare workers.

- **Change Management Integration into Health Reforms:** Embed change management practices into larger health sector reforms, such as those driven by UHC and the Health Sector Strategic Plan. Advocate for the establishment of a national task force to guide digital transformation in healthcare.
- **Position digital health workforce readiness** as a critical component of healthcare reform, especially in the shift towards UHC. Advocate for policy changes that require healthcare workers to demonstrate digital competencies as part of their professional responsibilities.
- **Build political support** around the need for change management strategies in public health sector reform efforts.

Following the findings, Transform Health Kenya will focus on strengthening the awareness, adoption, and implementation of digital health standards across the country. The first step will be to continue regular engagement sessions with stakeholders from both the public and private sectors. These sessions will introduce new developments in digital health and facilitate discussions on the barriers identified, such as the lack of comprehensive stakeholder participation and inadequate understanding of standards. Emphasising the importance of these standards, particularly in light of the 2023 Digital Health Act, will be crucial in fostering a nationwide health information exchange.

In addition to stakeholder engagement, Transform Health Kenya will continue developing strategic partnerships to address cross-cutting challenges such as limited ICT infrastructure and financial constraints. Collaborating with the ICT sector and mobilising resources from multiple partners will be key to expanding and upgrading the necessary infrastructure. Partnerships with policymakers, particularly at the county level, will also be vital in garnering political support and ensuring that the digital health transformation aligns with the needs and priorities of various regions.

Finally, Transform Health Kenya will prioritise change management and capacity-building initiatives to facilitate the smooth adoption of digital health standards.

References

- 14:00-17:00. "ISO 27799:2016." ISO. Accessed February 16, 2024. <https://www.iso.org/standard/62777.html>.
- "About KNHTS." Accessed February 16, 2024. <https://knhts.health.go.ke/about>.
- Adler-Milstein, Julia, and Brian E. Dixon. "Chapter 16 - Future Directions in Health Information Exchange." In *Health Information Exchange*, edited by Brian E. Dixon, 251–64. Academic Press, 2016. <https://doi.org/10.1016/B978-0-12-803135-3.00016-5>.
- "Anatomical Therapeutic Chemical (ATC) Classification." Accessed February 16, 2024. <https://www.who.int/tools/atc-ddd-toolkit/atc-classification>.
- Arora, Dheeraj, and Yatin Mehta. "Use of Picture Archiving and Communication System for Imaging of Radiological Films in Cardiac Surgical Intensive Care Unit." *Journal of Anaesthesiology, Clinical Pharmacology* 30, no. 3 (2014): 447–48. <https://doi.org/10.4103/0970-9185.137306>.
- Bhirud, Nivedita, Subhash Tatala, Sayali Randive, and Shubham Nahar. "A Literature Review On Chatbots In Healthcare Domain," 2019.
- CIS. "CIS Controls." Accessed February 12, 2024. <https://www.cisecurity.org/controls/>.
- DICOM. "About DICOM- Overview." Accessed February 16, 2024. <https://www.dicomstandard.org/about>.
- "Evidence Standards Framework for Digital Health Technologies," n.d.
- "FinalKenyaHealthPolicyBook.Pdf." Accessed February 16, 2024. <https://www.nutritionhealth.or.ke/wp-content/uploads/Downloads/FinalKenyaHealthPolicyBook.pdf>.
- GDPR.eu. "General Data Protection Regulation (GDPR) Compliance Guidelines." Accessed February 12, 2024. <https://gdpr.eu/>.
- "HealthAct21of2017.Pdf." Accessed February 16, 2024. <http://kenyalaw.org:8181/exist/rest/db/kenyalex/Kenya/Legislation/English/Acts%20and%20Regulations/H/Health%20Act%20-%20No.%2021%20of%202017/docs/HealthAct21of2017.pdf>.
- "Health-Sector-Unique-Identification-Framework-30-August-2022.Pdf." Accessed February 16, 2024. <http://guidelines.health.go.ke:8000/media/Health-Sector-Unique-Identification-Framework-30-August-2022.pdf>.
- "HITRUST Alliance | HITRUST CSF | Information Risk Management." Accessed February 12, 2024. <https://hitrustalliance.net/product-tool/hitrust-csf/>.
- "International Classification of Functioning, Disability and Health (ICF)." Accessed February 16, 2024. <https://www.who.int/standards/classifications/international-classification-of-health-interventions>.
- "Kenya Master Health Facility List: Find All the Health Facilities in Kenya." Accessed February 16, 2024. <https://kmhfl.health.go.ke/#/home>.
- "Kenya Vision 2030 | Kenya Vision 2030." Accessed February 16, 2024. <https://vision2030.go.ke/>.
- "KenyaEMR - Kenya - OpenMRS Wiki." Accessed February 15, 2024. <https://wiki.openmrs.org/display/ke/KenyaEMR>.
- "Kenya-Gazette-Data-Protection-Act-2019.Pdf." Accessed February 16, 2024. <https://www.odpc.go.ke/download/kenya-gazette-data-protection-act-2019/?wpdmdl=3235&refresh=65b789b046ec81706527152>.
- "Kenya-Standards-and-Guidelines-for-mHealth-Systems-April-2017.Pdf." Accessed February 16,

2024. <https://www.telemedecine-360.com/wp-content/uploads/2019/03/Kenya-Standards-and-Guidelines-for-mHealth-Systems-April-2017.pdf>.
- Muinga, Naomi, Steve Magare, Jonathan Monda, Onesmus Kamau, Stuart Houston, Hamish Fraser, John Powell, Mike English, and Chris Paton. "Implementing an Open Source Electronic Health Record System in Kenyan Health Care Facilities: Case Study." *JMIR Medical Informatics* 6, no. 2 (April 18, 2018): e22. <https://doi.org/10.2196/medinform.8403>.
- Mullick, Ashekur, Nabil Rayhan, Kamrun Koly, Dr Nahar, and Irin Hossain. "TELEMEDICINE AND TELEHEALTH: A VIRTUAL CARE PLATFORM WITH PROSPECTS & IMPORTANCE DURING COVID-19 OUTBREAK." *EUROPEAN JOURNAL OF PHARMACEUTICAL AND MEDICAL RESEARCH* 7 (September 20, 2020): 39–45.
- "National Cybersecurity Strategy 2022 – 2027 – NC4." Accessed February 16, 2024. https://nc4.go.ke/national-cybersecurity-strategy-2022-2027/#flipbook-df_2314/7/.
- "NIST Special Publication 1800-Series General Information." NIST, May 21, 2018. <https://www.nist.gov/itl/publications-0/nist-special-publication-1800-series-general-information>.
- "PA00TB2Q.Pdf." Accessed February 16, 2024. https://pdf.usaid.gov/pdf_docs/PA00TB2Q.pdf.
- "SMART Guidelines." Accessed February 16, 2024. <https://www.who.int/teams/digital-health-and-innovation/smart-guidelines>.
- Smith, Aaron Asael, Rui Li, and Zion Tsz Ho Tse. "Reshaping Healthcare with Wearable Biosensors." *Scientific Reports* 13, no. 1 (March 27, 2023): 4998. <https://doi.org/10.1038/s41598-022-26951-z>.
- "Standards_and_Guidelines_for_EMR_Systems.Pdf." Accessed February 15, 2024. http://guidelines.health.go.ke:8000/media/Standards_and_Guidelines_for_EMR_Systems.pdf.
- "Standards_and_Guidelines_for_EMR_Systems.Pdf." Accessed February 16, 2024. http://guidelines.health.go.ke:8000/media/Standards_and_Guidelines_for_EMR_Systems.pdf.
- "Technical Committees – Kenya Bureau of Standards." Accessed February 16, 2024. <https://www.kebs.org/technical-committees/>.
- "TheDigitalHealthAct_2023.Pdf." Accessed February 16, 2024. http://kenyalaw.org/kl/fileadmin/pdfdownloads/Acts/2023/TheDigitalHealthAct_2023.pdf.
- Unknown. "Medicine and Technology." Accessed February 16, 2024. <https://www.medicinandtechnology.com/search/label/CCHIT>.
- "What Is an Electronic Health Record (EHR)? | HealthIT.Gov." Accessed February 16, 2024. <https://www.healthit.gov/faq/what-electronic-health-record-ehr>.
- "What Standards Apply to the Information Technology Industry?" Accessed February 12, 2024. <https://www.nqa.com/en-gb/certification/sectors/information-technology>.
- <https://www.countdown2030.org/wp-content/uploads/2022/10/Kenya-National-and-Subnational-Coverage-and-Other-Services-Report-final-submitted.pdf>

Appendixes

Appendix 1: Standards and Guidelines that are used on a Global Level

HL7 Standards

The Health Level 7 (HL7) standards provide a framework (and related standards) for the exchange, integration, sharing, and retrieval of electronic health information. These standards define how information is packaged and communicated from one party to another, setting the language, structure and data types required for seamless integration between systems. Grouped into different reference categories, they are a set of clinical standards and messaging formats that provide a framework for the management, integration, exchange, and retrieval of electronic information across different healthcare systems. The categories are²⁷ ;

Section 1: Primary Standards	Primary standards are considered the most popular standards integral for system integrations, interoperability and compliance.
Section 1a: Clinical Document Architecture	Clinical Document Architecture (CDA®) Products
Section 1b: Electronic health records(EHRs)	These standards provide functional models and profiles that enable the constructs for management of electronic health records.
Section 1c: FHIR	FHIR® - Fast Healthcare Interoperability Resources
Section 1d: Version 2	
Section 1e: Version 3	HL7 Version 3 (V3) - a suite of specifications based on HL7's Reference Information Model (RIM)
Section 1f: Arden syntax	The Arden Syntax is a formalism for representing procedural clinical knowledge in order to facilitate the sharing of computerised health knowledge bases among personnel, information systems and institutions
Section 1g: CCOW	HL7 Clinical Context Management Specification (CCOW) is aimed at facilitating the integration of applications at the point of use, as a standard for both internal applications programming and runtime environment infrastructure that complements HL7's traditional emphasis on data interchange and enterprise workflow.

²⁷"Introduction to HL7 Standards | HL7 International," accessed February 12, 2024, <https://www.hl7.org/implement/standards/>.

Section 1h: Cross Paradigm/ Domain Analysis models	Cross-paradigm/ Logical Level Standards e.g. Domain Analysis Models
Section 2: Clinical and Administrative Domains	Messaging and document standards for clinical specialties and groups are found in this section. These standards are usually implemented once primary standards for the organisation are in place.
Section 3: Implementation guides	This section is for implementation guides and/or support documents created to be used in conjunction with an existing standard. All documents in this section serve as supplemental material for a parent standard.
Section 4: Rules and references	Technical specifications, programming structures and guidelines for software and standards development.

Table 4. The Health Level 7 (HL7) standards

The goal of HL7 is to enhance interoperability between healthcare information systems that have implemented it. It focuses on the interfaces between dissimilar HISs by creating a common data exchange language.²⁸

Implementing the HL7 standards helps ease the communication between different types of systems used in different organisations within the health ecosystem. The HL7 Standards provide the common language that enables interoperability to be achieved. Due to its customizable nature, implementing HL7 standards supports creation of interfaces that support data exchange. This is a significant cost reduction measure since changes do not need to be made to the existing software. While implementing HL7 standards can pose certain challenges such as adaptation is needed for varying data models based, frequent testing is required when new end points are added which may be time consuming and costly.

Medical Terminology Standards

Standardisation of medical terminology has been identified as a critical component that ensures data sharing and data consumption. Standardisation refers to creation of accepted specifications (e.g. definitions, norms, units, rules) that establishes a common language as a basis for understanding and exchange of information between different parties.²⁹ Examples of commonly used medical terminology standards include:

- Logical Observation Identifiers Names and Codes (LOINC), an open source, universal standard for identifying medical laboratory observations and has expanded to include nursing diagnosis, outcomes classification, nursing interventions and patient care datasets.
- Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT) is a collection of medical terminology that includes terms, codes, synonyms and definitions used in clinical documentation and reporting. This standard encodes clinical information in the patient record.
- The ICD (International Classification of Diseases, Tenth Revision, Clinical Modification), a system used by clinicians and other healthcare providers to classify and code all diagnoses, symptoms and procedures recorded in conjunction with hospital care across the world. It provides a level of detail that is necessary for diagnostic specificity and morbidity classification.

²⁸ "What Is HL7? Definition and Details," accessed February 12, 2024, <https://www.paessler.com/it-explained/hl7>.

²⁹ "B118_8-En.Pdf," accessed February 12, 2024, https://apps.who.int/gb/ebwha/pdf_files/EB118/B118_8-en.pdf.

- International Classification of Health Interventions (ICHI) is a tool for reporting and analysing health interventions for clinical and statistical purposes.³⁰ It is used in the classification of medical procedures.
- Anatomical Therapeutic Chemical (ATC) classification is used in the classification of active therapeutics substances according to the organs or systems on which they act, their therapeutic, pharmacological, and chemical properties. Drugs are classified in groups at five different levels. (ACT Level 1-5)³¹
- RxNorm, an open-source standard that provides normalised names for clinical drugs and links its names to many of the drug vocabularies commonly used in pharmacy management and drug interaction software. By providing links between these vocabularies, RxNorm can mediate messages between systems not using the same software and vocabulary.
- British National Formulary (BNF) is a comprehensive source of medicines guidance, containing information on the selection, prescribing, dispensing and administration of medicines.

Diagnostics Standards

- Digital Imaging and Communications in Medicine (DICOM): Digital Imaging and Communications in Medicine – is the international standard for medical images and related information. It defines the formats for medical images that can be exchanged with the data and quality necessary for clinical use.³² It is recognized by the ISO as the ISO12052 Standard.
- Picture Archiving and Communication System (PACS) for imaging; electronic picture archiving and communication systems (PACS) have been developed to provide economical storage, rapid retrieval of images, access to images acquired with multiple modalities, and simultaneous access at multiple sites.³³ It combines both the hardware and software to obtain, store and retrieve medical images using the DICOM standard.

Quality Management and Information Security Standards

Quality standards are the documentation that provide the requirements, specifications, guidelines, and procedures to ensure that goods, products, processes and services are fit for purpose. In technology development and deployment, quality management standards help ensure security is assured and maintained across the entire data life cycle. With digital transformation being a hot topic in most industries, data privacy measures are a huge source of concern for most systems users. Data breaches are on the rise and adequate measures need to be in place to ensure that sensitive personal health data is protected from unrestricted access.

International Organization for Standardization (ISO) Standards for Information Systems³⁴.

- ISO 27001 Information Security Management Systems: ISO 27001 establishes concrete information security standards for use by data centres and other organisations. Most recently updated in 2013, the latest revisions reflect the increased importance of cloud computing and software-as-a-service. One of the key components of ISO 27001 is the established controls and control objectives – an essential part of any risk management plan. These controls include everything from human resources policy to encryption standards. Cumulatively, they reflect a set of best practices for information security management at the organisational level.

³⁰International Classification of Functioning, Disability and Health (ICF)

³¹Anatomical Therapeutic Chemical (ATC) Classification

³²About DICOM- Overview

³³Arora and Mehta, "Use of Picture Archiving and Communication System for Imaging of Radiological Films in Cardiac Surgical Intensive Care Unit

³⁴What Standards Apply to the Information Technology Industry

- ISO 27701 GDPR Compliance: ISO/IEC 27701:2019 is a data privacy extension to ISO 27001. This newly published information security standard provides guidance for organisations looking to put in place systems to support compliance with GDPR and other data privacy requirements. ISO 27701, also abbreviated as PIMS (Privacy Information Management System) outlines a framework for Personally Identifiable Information (PII) Controllers and PII Processors to manage data privacy.
- ISO IEC 20000-1 Information Technology Service Management: ISO IEC 20000-1 is a set of standards for IT service providers that outlines best practices for maintaining security, delivering consistent service, and adopting new technologies as they become available. The standard sets out system requirements, codes of practice, relationship, resolution and control processes, and more. The most recent revision was published in 2011.
- CMMC (Cybersecurity Maturity Model Certification): The Cybersecurity Maturity Model Certification is the latest verification method put in place by the Department of Defence. This certification is the Department's first attempt to set clear requirements for contractors when it comes to cybersecurity. The ultimate goal of the CMMC is to implement an appropriate level of cybersecurity across the supply chain of the defence industrial base.
- ISO 277799 On information security management in health: It gives guidelines for organisational information security standards and information security management practices including the selection, implementation and management of controls taking into consideration the organisation's information security risk environment.³⁵
- ISO 27017 Security Controls for Cloud Services: ISO/IEC 27017:2015 is a security control for cloud services and is an extension to ISO/IEC 27001 and ISO/IEC 27002. The standard advises on both the cloud service customers and cloud service providers. ISO 27017 is designed to help you and your organisations when selecting security controls for cloud services when implementing a cloud computing information security management system.

The National Institute of Standards and Technology (NIST)

A U.S. government agency that develops standards and guidelines for various industries, including information security.³⁶

- NIST SP 1800 Series
- The SP 1800 series covers various aspects of information security, including risk management, incident response, and supply chain security. Some specific standards within the series include:
- NIST SP 800-53, which provides guidelines for the selection and implementation of security controls for federal information systems.
- NIST SP 800-171 provides guidelines for protecting controlled unclassified information (CUI) in non-federal systems and organisations.
- NIST Cybersecurity Framework (CSF) provides a common language and guidelines for managing cybersecurity risks. It is designed to be flexible and adaptable to the needs of different organisations.

COBIT

The Control Objectives for Information and Related Technology (COBIT) is a framework developed by the Information Systems Audit and Control Association (ISACA) that provides a set of best practices for the governance and management of information and technology (IT). It covers many IT-related topics, including risk management, security, and compliance.³⁷

³⁵14:00-17:00, "ISO 27799

³⁶NIST Special Publication 1800-Series General Information.

³⁷COBIT | Control Objectives for Information Technologies," ISACA, accessed February 12, 2024, <https://www.isaca.org/resources/cobit>

CIS Controls

The Centre for Internet Security (CIS) is a nonprofit organisation that develops best practices for securing IT systems and networks. The CIS Controls are 20 cybersecurity best practices designed to be prioritised and implemented based on an organisation's risk profile.³⁸

HITRUST Common Security Framework (CSF)

The Health Information Trust Alliance (HITRUST) is a nonprofit organisation that develops a set of best practices for protecting sensitive health information. The HITRUST CSF is a framework that provides a set of guidelines and requirements for securing electronically protected health information (ePHI).³⁹

General Data Protection Regulation (GDPR)

The GDPR is a data protection law that applies to organisations operating in the European Union (EU) and European Economic Area (EEA). It sets out specific requirements for collecting, using, and protecting personal data and gives individuals the right to control their data.⁴⁰

CCHIT Certified 2009 EMR Certification Criteria

The Certification Commission for Healthcare Information Technology (CCHIT) is a certification authority that focuses on EHR adoption related to technology and products.) has approved 2009-2010 criteria for certification of ambulatory, inpatient and emergency department electronic health records.⁴¹

Global Strategy on Digital Health 2020-2025 (WHO)

The "Global Strategy on Digital Health 2020-2025," crafted by the World Health Organization (WHO), presents a comprehensive framework for standardised eHealth practices and interoperability. It emphasises seamless coordination in digital health initiatives, patient centric access to health information, and the establishment of national interoperable digital health ecosystems. The strategy responds to the imperative of cross-border health data sharing and informed patient consent.

SMART Guidelines

Standards-based, Machine-readable, Adaptive, Requirements-based, and Testable (SMART) guidelines are a comprehensive set of reusable digital health components (e.g., interoperability standards, code libraries, algorithms, technical and operational specifications) that transform the guideline adaptation and implementation process to preserve fidelity and accelerate uptake. SMART Guidelines provide a five-step pathway to advance the adoption of best clinical and data practices, even if a country is not yet fully digital. SMART Guidelines are a new approach to systematise and accelerate the consistent application of recommended, life-saving interventions in the digital age.⁴² The five SMART guidelines layers comprise documentation, procedures, and digital health components to steer guideline localization and implementation through digital systems.

They inform:

- Guideline developers on how to translate recommendations into specifications and standards;

³⁸CIS Controls

³⁹HITRUST Alliance | HITRUST CSF | Information Risk Management

⁴⁰General Data Protection Regulation (GDPR) Compliance Guidelines

⁴¹Unknown, "Medicine and Technology

⁴²SMART Guidelines

- Technologists on how to integrate recommendations into editable digital systems; and
- Countries on how to localise, make interoperable, institutionalise, and update digital systems consistent with evidence-based recommendations.

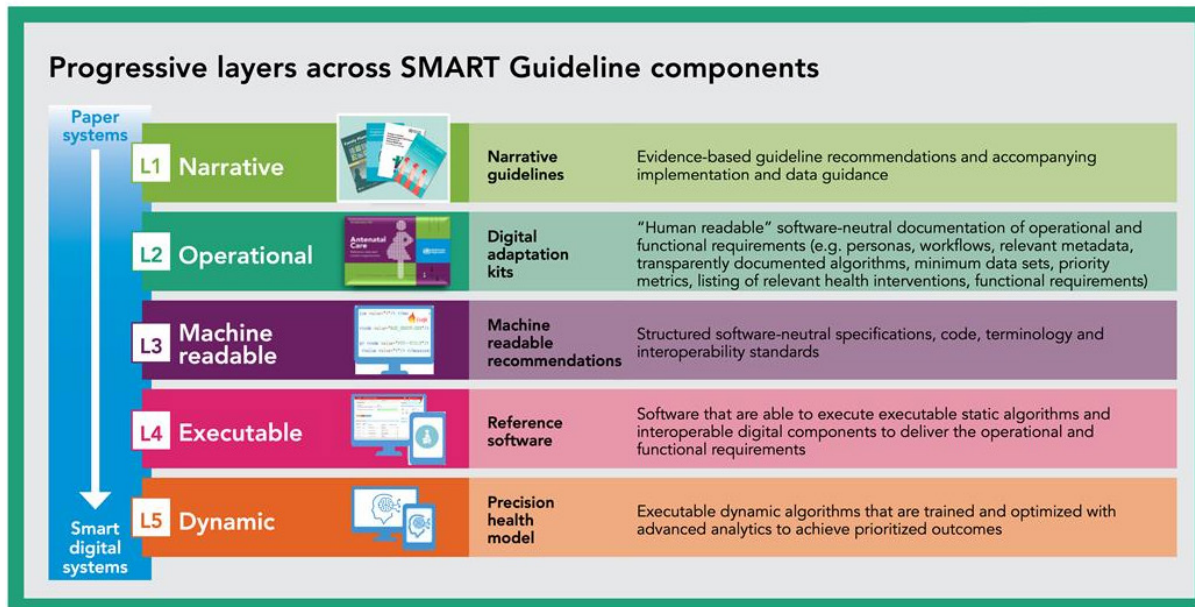


Figure 2. Standards-based, Machine-readable, Adaptive, Requirements-based, and Testable (SMART) guidelines

Evidence Standards Framework for Digital Health Technologies

The National Institute of healthcare excellence (NICE) evidence standards framework (ESF) for digital health technologies (DHTs) describes standards for the evidence that should be available or developed for DHTs to demonstrate their value in the UK health and social care system. The framework encompasses the evidence of performance relevant to the purpose of the technology and evidence of economic impact relative to the financial risk. The guidelines can be used to assess the suitability of a system before purchasing. The framework is intended to assess digital products such as smartphone apps, standalone software, online tools for treating or diagnosing conditions, preventing ill health, or for improving system efficiencies, and programmes that can be used to analyse data from medical devices such as scanners, sensors or monitors.⁴³

WHO Guideline Recommendations on Digital Interventions for Health System Strengthening

The key aim of this guideline is to present recommendations based on a critical evaluation of the evidence on emerging digital health interventions that are contributing to health system improvements, based on an assessment of the benefits, harms, acceptability, feasibility, resource use and equity considerations.⁴⁴

Resolution by the General Assembly (2015)

This resolution acknowledges the transformative power of information and communication technologies, particularly in healthcare, while recognizing the challenges faced by African nations like Kenya in accessing these technologies. The resolution advocates for capacity building, knowledge sharing, and multi-stakeholder cooperation to enhance digital access, particularly for marginalised populations. It highlights the need to bridge disparities in digital access for vulnerable communities.

⁴³Evidence Standards Framework for Digital Health Technologies

⁴⁴Recommendations on Digital Interventions for Health System Strengthening.

Appendix 2: Digital Technologies Reviewed

Technology	Description	Examples of Implementation in Kenya	Standards and Guidelines that guided the implementation in Kenya	Implemented in:	
				Public?	Private?
Electronic Medical Record (EMR)	Electronic medical records (EMRs) are “computerised medical information systems that collect, store and display patient information” ⁴⁵	KenyaEMR is a tailored distribution of OpenMRS ⁴⁶ which has been deployed to over 300 facilities in Kenya ⁴⁷ . KenyaEMR was developed to fulfil the clinical and administrative requirements of healthcare facilities operated by devolved counties in Kenya and to automate the process of collating healthcare indicators and entering them into DHIS2. ⁴⁸	Standards and Guidelines for EMR Systems	✓	✓
Electronic Health Record (EHR) Systems	An electronic version of a patient health record ⁴⁹	Many facilities in Kenya use diverse systems to collect patient information. The systems are diverse and are both public and public sector owned. They have implemented disease-specific functions e.g. HIV, TB, Malaria and others have facility-wide implementations.	Not Available	✓	✓
District Health Information System Version 2 (DHIS2)	DHIS2 is used in the management of aggregate health data.	DHIS2 is one of the most expansive implementations in Kenya which is integrated into KHIS (Kenya’s Health Information System) is in use in 95% of the health facilities across the nation at both the national and sub-national levels for tracking service delivery, disease surveillance and health system performance. ⁵⁰	<ul style="list-style-type: none"> The Fast Healthcare Interoperability Resource (FHIR) 	✓	
eCHIS	Electronic Community Health Information System	Countrywide implementation	<ul style="list-style-type: none"> Community Health Digitization Strategy FHIR 	✓	

KMHFL	Kenya Master Health Facility. A registry of healthcare facilities in the country	A facility census was led by the Ministry of Health and concluded in 2023 to map out the health facilities that exist in Kenya. The activity targeted 14,366 health facilities; 12,384 public, private and faith-based facilities were fully assessed across all counties.	Not available	✓	✓
Digitally mediated clinical diagnostics	Digitally assisted diagnostics	Use of digital systems in improving malaria diagnosis ⁵¹	Not Available	✓	✓
Telemedicine and Telehealth platforms	<p>Telemedicine is defined as the provision of healthcare services and sharing of medical knowledge over distance using telecommunications and it includes consultative, diagnostic, and treatment services as per the Health Act 2017.</p> <p>Telehealth is an assembly of resources or methods for augmenting health care, public health, and health education delivery and support using telecommunications.⁵²</p>	Many telemedicine and telehealth platforms have been developed in Kenya. The majority of them are private sector led.	<ul style="list-style-type: none"> • Digital Health Act 2023 • Kenya National eHealth strategy • Kenya eHealth policy • Health Act • Standards and Guidelines for mHealth Systems • Data Protection Act • ICT policy • Community Health Digitization Strategy • Kenya Health Information Systems Interoperability Framework • Company-specific SOPs • GDPR • ISO 	✓	✓

Remote sensing and wearables	Technologies that are used in supporting remote patient monitoring, prevention, and treatment. ⁵³	Wearables are used in supporting telemedicine and telehealth activities. Patient monitoring is improved, and prompt actions can be taken in case of emergencies. For example, pacemakers, smart watches	Not Available	✓	✓
Chatbots	Chatbots are automated systems that replicate users' behaviour on one side of the chat communication. They mimic systems that imitate the conversations between two individuals. They provide a stimulating platform for effective and smart communications with the user on the other end. ⁵⁴	Chatbots have been adopted by many telemedicine and telehealth platforms to help provide on-demand support to patients.	Not Available	✓	✓
Health Information Exchange (HIE)	A HIE is used to facilitate the exchange of electronic information across systems ⁵⁵	Kenya hopes to fully implement a nationwide HIE by 2025	• FHIR		

Table 5. Digital Technologies Reviewed

⁴⁵Standards_and_Guidelines_for_EMR_Systems.Pdf

⁴⁶KenyaEMR - Kenya - OpenMRS Wiki

⁴⁷Health Information Systems in Kenya

⁴⁸Muinga et al., "Implementing an Open Source Electronic Health Record System in Kenyan Health Care Facilities

⁴⁹What Is an Electronic Health Record (EHR)? | HealthIT.Gov.

⁵⁰In Action

⁵¹Shannen M. C. van Duijn et al., "Connected Diagnostics to Improve Accurate Diagnosis, Treatment, and Conditional Payment of Malaria Services in Kenya," BMC Medical Informatics and Decision Making 21, no. 1 (August 4, 2021): 233, <https://doi.org/10.1186/s12911-021-01600-z>.

⁵²Mullick et al., "TELEMEDICINE AND TELEHEALTH

⁵³Smith, Li, and Tse, "Reshaping Healthcare with Wearable Biosensors

⁵⁴Bhirud et al., "A Literature Review On Chatbots In Healthcare Domain

⁵⁵Adler-Milstein and Dixon, "Chapter 16 - Future Directions in Health Information Exchange



**Transform
Health**
KENYA

H Kenya Health
Informatics
Association