



REPUBLIC OF KENYA



MINISTRY OF HEALTH

Kenya Health Information Systems Interoperability Framework



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Abbreviations and Acronyms

API	application programming interface
eHealth	use of information and communication technologies for health
EMR/EHR	electronic medical records/electronic health records
HIE	health information exchange
HIS	health information system
HIS ICC	Health Information System Interagency Coordination Committees
ICT	information and communications technology
IFMIS	Integrated Financial Management Information System
IL	interoperability layer
KHISIF	Kenya Health Information Systems Interoperability Framework
MOH	Ministry of Health
OHIE	open health information exchange
SDGs	Sustainable Development Goals
UHC	universal health coverage

Foreword

The Government of Kenya is determined to improve access to and equity of quality essential health care services and to ensure that the health sector plays its role in the realization of Vision 2030¹ and attainment of the Sustainable Development Goals (SDGs) through implementation of universal health coverage (UHC). To fulfill this mandate, the Ministry of Health developed the Kenya Health Policy (2014–2030). One of the revised policy objectives is to plan, design, and install information and communications technology (ICT) infrastructure, and health information systems (HIS) for the management and delivery of essential health care.

The Ministry of Health (MOH) and county health departments have made considerable investments to strengthen health information systems across the spectrum of data collection, information generation, analysis, and utilization. This commitment is intended to support effective decision-making among producers and consumers of health information. Nonetheless, vast amounts of available medical information are often stored in many different formats across various systems and locations, making access, sharing, and analytics difficult or impossible to achieve. Ongoing efforts by the MOH are geared towards digitizing health records and making different HIS interoperable to improve data sharing and access.

This document defines a collection of specifications aimed at facilitating the interoperability of health information systems across its ecosystem. By using interoperability specifications in this framework, health systems owners can ensure interoperability between health information systems while leveraging existing or new digital health infrastructure.

I am happy to note that this framework has been developed and realized through an elaborate, inclusive, participatory, and consultative process. This effort has involved a wide range of stakeholders drawn from the Ministry of Health, county governments, development partners, civil society, research institutions, academics from universities, and the international community. It is my sincere hope that this well-informed document will foster sanity in the application of eHealth to support health information management while underscoring the importance of adhering to the core principles, values, the right to information, and the bill of rights as enshrined in the constitution.

Lastly, I'm positive that all the stakeholders will embrace this framework in order to realize the shared benefits that the guidance in this document will bring to the health sector as we embrace the automation agenda. It is envisaged that this framework will spur the uptake and adoption of information technology in the sector and thus improve service delivery and quality of care with resultant improvement in health outcomes.

Hon. Mutahi Kagwe, EGH
Cabinet Secretary, Health
Government of Kenya

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Susan Mochache, CBS
Principal Secretary

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Executive Summary

The launch of the Sustainable Development Goals (SDGs) in September 2015 by the United Nations put the spotlight on the need for better data to monitor progress and inform decision-making. However, timely and relevant data that can help decision-makers and other leaders better understand the current state of play for the 2030 Agenda for Sustainable Development are in short supply. Too many governments, companies, investors, multilateral institutions, and civil society organizations have limited access to the data they need to make the right decisions to drive progress on the SDGs.

As part of its five-year Big 4 Agenda (2018–2022), the Government of Kenya has prioritized the attainment of universal health coverage (UHC). The use of Information and Communication Technologies (ICT) for health³ will improve quality, and safe patient-centric health services. A key part of eHealth will be the timely, seamless, and frictionless sharing of health data and information.

The MOH is committed to fulfilling the right to the highest attainable standard of health through universal health coverage as envisaged in the Constitution of Kenya, 2010. Several investments have been made to improve the quality of health care. One such investment is the strengthening of health information systems across the spectrum of data collection, information generation, analysis, and utilization to support effective decision-making among producers and consumers of health information.⁴

The MOH has also developed several policies and guidelines that relate to the use of national health information systems. These systems have generated a massive pool of data at different levels, often stored in different formats across various systems and locations, making access, sharing, and analysis difficult or impossible to achieve. Ongoing efforts by the Ministry of Health are geared towards digitizing health records and making different health information systems interoperable.

The KHISIF supports the Ministry of Health's strategy of providing patient-centric, joined-up health services by facilitating the interoperability of health information systems.

The term “interoperability” describes the ability of different information systems, devices and applications (‘systems’) to access, exchange, integrate and cooperatively use data in a coordinated manner, within and across organizational, regional and national boundaries, to provide timely and seamless portability of information and optimize the health of individuals and populations across all levels.⁵

The KHISIF defines a collection of specifications aimed at facilitating the interoperability of health information systems. By implementing these interoperability specifications, health systems owners can ensure interoperability between HIS while at the same time leveraging

existing or new digital health infrastructure. The KHISIF applies to both public and private health service providers offering health services, and with an obligation to return health information reports to the Ministry of Health, as stipulated in the Health Act, 2017 (Part XVII, chapter 112 (e)). All new Ministry of Health, HIS, hardware, and software infrastructure will be developed in compliance with the KHISIF, and it is highly recommended that all other new HIS conform to the KHISIF appropriately.

For existing HIS, given the diversity of current platforms and systems, conformance and compliance to certain specifications may not be readily achieved. Henceforth, HIS owners will be subjected to MOH HIS compliance testing on health information exchange (HIE) capabilities aligned to KHISIF requirements. The KHISIF implementation at national and county levels is a long-term MOH strategy that must be continually reviewed and updated. Given the emergence of new HIS requirements and the pace of eHealth advancements, there are likely to be frequent changes to the specifications. The technical specifications under the KHISIF will be reviewed periodically or as-needed based on the evolving technology environment.

Scope and structure of KHISIF document

Chapter 1: Overview of the KHISIF, including objectives, scope, and interoperability principles.

Chapter 2: The management of the KHISIF, including terms of reference for the governance bodies, membership criteria, change management issues, and compliance, including compliance policy and governance with other institutions.

Chapter 3: Interoperability architectural technical specifications selected for the identified interoperability components.

Chapter 4: HIS certification and procedure.

Dr. Patrick Amoth
Ag. Director General for Health

Introduction

While recognizing eHealth as a mode of health service, the Kenya Health Act, 2017 emphasizes the need for the standardization of health information exchange through an interoperability framework, and establishment and maintenance of a comprehensive integrated health information system. Accurate, readily available, timely, and complete data for health planning, workforce management, policy development, monitoring, and evaluation are critical for optimal health system functioning and can only be achieved from well matured and integrated HIS.

The Government of Kenya's (GoK) attention to e-government, with a focus on health information systems in particular, has resulted in a reasonably mature HIS ecosystem. The Ministry of Health has been at the forefront of strengthening the health information ecosystem in Kenya by optimizing availability and use of information for decision-making in the health sector through the implementation of targeted health information systems. These HIS implementations have, however, been tailored around specific functions resulting in the mushrooming of domain-specific and parallel HIS, some of which do not adhere to the requisite HIS standards.

Government and private health care providers have invested considerably in the acquisition of various systems, but these systems cannot generate expected outcomes unless they are integrated to achieve common national goals such as measuring health service delivery and morbidity control. A fundamental concern in health management is the integration of health information across distributed, heterogeneous, and disparate information systems. Lack of interoperable health systems is one of the major barriers to the use of health data and information in policy and decision-making. Moreover, it is not in the interest of the government to discard existing systems, as a lot of data and investment will be wasted. Rather, it should integrate these systems as far as possible to generate a holistic approach to collection and use of health data.

This document sets out the overarching framework towards achieving large-scale and feasible interoperability in the health sector through the adoption of good practices in HIS governance and standardization. It also sets out recommendations for health information exchange architecture and certification requirements and provides a roadmap to impactful interoperability.



CHAPTER 1

Overview of the Kenya Health Information
Systems Interoperability Framework and
Interoperability Principles

1.1 Interoperability

The term interoperability describes the ability of two or more information systems or components to exchange information based on standards, and to use the information that is exchanged. Interoperability enables different HIS to work together in and across organizational boundaries to advance the health status of individuals and communities and the effective delivery of health care to them.⁶

There are three levels of health information technology interoperability:

- I. Foundational interoperability allows data from one information technology system to be received by another. It does not require the ability for the receiving information technology system to interpret the data.
- II. Structural interoperability is an intermediate level that defines the structure or format of data exchange (i.e., the message format standards). There is uniform movement of health care data from one system to another such that the clinical or operational purpose and meaning of the data is preserved and unaltered. Structural interoperability defines the syntax of the data exchange. It ensures that data exchanges between information technology systems can be interpreted at the data field level.
- III. Semantic interoperability provides interoperability at the highest level. This is the ability of two or more systems or elements to exchange information and to use the information that has been exchanged. Semantic interoperability takes advantage of both the structuring of the data exchange and the codification of the data, including vocabulary, so that the receiving information technology systems can interpret the data. This level of interoperability supports the electronic exchange of patient summary information among caregivers and other authorized parties via potentially disparate electronic health record (EHR) systems and other systems. It allows improvement of quality, safety, confidentiality, and efficiency of health care delivery.

The KHISIF aims to define the set of specifications to facilitate MOH HIS to communicate and interoperate, both within public and with private health care HIS owners. It also seeks to collaboratively support delivery of health care services, with an obligation to return health information reports to the Ministry of Health. The KHISIF will promote and foster health information exchange, providing patient-centric and linked-up health information for efficient and effective delivery of health services across the continuum of health care.

1.2 Scope of the KHISIF

According to the World Health Organization Health Metrics Network Framework and Standards for Country Health Information Systems,⁷ a health information system consists of six components. The standards for each are clearly described below, including what constitutes a HIS and how its components interact with each other to produce more accurate information for better decisions and better delivery of health care services.

To support the establishment of the interoperable HIS, it is necessary to clearly understand the HIS components in the following key areas: inputs, processes, and outputs.

Inputs refer to (i) health resources, while processes touch on how (ii) indicators and (iii) data sources are selected and (iv) data is collected and managed. Outputs deal with the (v) production, (vi) dissemination and use of information.

The KHISIF's overarching focus is on the attainment of the above-mentioned six components of a HIS. Henceforth, the KHISIF will foster collaboration among HIS owners to jointly work out interoperability specifications more effectively.

It covers:

- I. A set of standards and data standards that help define the interface across different systems.
- II. Guidelines for project teams to work out some of the HIS business-oriented specifications, where it is feasible to provide guidelines in that area.
- III. Other standard documents that define infrastructure architecture, conventions, and procedures aligned to international standards, guidelines, and best practices.
- IV. The technical standards are listed in Chapter 2 of this document. The data standards are being progressively developed in the form of common services as per Kenya MOH health-sector priorities. The common services define the information model of data elements that are often used in HIS, and they serve as reusable components for HIS data specifications. See Chapter 3 for more details.

1.3 KHISIF Objectives

The KHISIF is intended to guide national- and county-level approaches towards implementation of the HIS, with information-sharing capabilities. It helps to create a shared understanding of interoperability in the Kenya eHealth ecosystem.

The specific objectives of this framework are:

- I. To promote the use of interoperability concepts and standards in harmonizing health information exchange technical and architectural activities within the Kenya eHealth ecosystem;
- II. To enhance the application of interoperability guidelines to facilitate interoperability design, analysis, and assessment;
- III. To introduce appropriate governance mechanisms and organizational practices in support of interoperability;
- IV. To provide an interoperability conceptual framework; and
- V. To provide guidance on interoperability maturity.

The lack of interoperability is a major obstacle to universal health coverage and effective management of patients across the continuum of care. Using the KHISIF will foster health information systems' interoperability initiatives, contribute to a coherent interoperable environment, and facilitate the delivery of services that work together within and across national and county levels.

1.4 Underlying Principles

The interoperability principles are fundamental behavioral aspects to drive interoperability actions. This section sets out general interoperability principles, aligned to the principles for digital development,⁸ with guiding practical implementation use cases, which are relevant to inform the process of establishing interoperable HIS ecosystems. They describe the context in which HIS are designed and implemented.

The underlying principles of the KHISIF are grouped into three categories:

1. Core interoperability principles;
2. Principles related to generic user needs and expectations; and
3. Foundational principles for cooperation among public administrations.

1.4.1 Core interoperability principles

Transparency

Transparency, in the KHISIF context, refers to:

1. Enabling visibility and endorsement inside the health administrative environment at the national and county level. This is about allowing all health stakeholders, public and private, to view and understand the role of health information systems' administrative rules, processes, data, services and decision-making.
2. Ensuring availability of Application Programming Interfaces (API)⁹ with internal information systems. HIS environments often consist of multiple systems that are heterogeneous and disparate. This is necessary, as they have to respond to the data needs of domain-specific internal processes. If policymakers are to obtain cross-domain insights from multiple HIS, these systems must interoperate. This requires ensuring that APIs are available to these systems and the data they handle.
3. Securing protection of personal data, by respecting applicable legal frameworks on health information sharing and confidentiality (Heath Act, 2017, Data Protection Act, 2019). This will also require the application of appropriate standards-based technical safeguards, including encryption of databases and files, as well as pseudonymization and anonymization of potentially (re)identifiable data fields within datasets housing sensitive medical and other personal data.

Reusability

Health systems developers and implementers confronted with a specific problem can benefit from the work done by other health systems developers. This benefit is realized by looking at what is available, assessing its usefulness or relevance to the problem at hand, and, where appropriate, adopting solutions that have proven their value elsewhere. Doing so requires health systems developers and implementers to openly share their interoperability solutions, concepts, frameworks, specifications, tools, and components with others.

Reusability of IT solutions (e.g., software components, APIs, standards), information, and data enables interoperability and improves quality because it extends operational use and

saves money and time. The use of open-source software technologies and products can help save development costs, avoid a lock-in effect,¹⁰ and allow fast adaptation to specific business needs because the developer communities that support them are constantly adapting them. (For more information, refer to section 3.2). Health systems developers and implementers should not only use open source software but, whenever possible, contribute to the pertinent developer communities. Open source is an enabler of the underlying KHISIF principle on reusability.

1.4.2 Principles related to generic user needs and expectations

Technological neutrality

The KHISIF will focus on key functional needs to minimize technological dependencies and avoid dependence on specific technical implementations or products for HIS ecosystems. This will enable the framework to adapt to the rapidly evolving technological environment.

User-centricity

Stakeholder engagement and ownership is critical for achievement of long-term success on KHISIF compliance and implementation. Thus, a mechanism for engaging all care providers including public and private health care stakeholders, at national and county levels during the design process of digital development interventions, solutions, technologies, and programs for evolution of HIS ecosystems, is key.

1.4.3 Foundation principles

Inclusion and accessibility

Inclusion is about enabling everyone to take full advantage of the opportunities offered by new technologies to access and make use of KHISIF. Accessibility ensures that companies, individuals, government, partners, and private developers and implementers can utilize the KHISIF.

Inclusion and accessibility are also improved by the KHISIF's ability to allow third-party applications and stakeholders to utilize its resources and benefits.

Security and privacy

Clients must be confident that when they interact with the framework they are doing so in a secure and trustworthy environment and in full compliance with relevant regulations, e.g., the Kenya Data Protection Act, 2019. The framework must guarantee citizens' privacy, confidentiality, authenticity, and integrity of information provided by client.

Security and privacy are primary concerns of interoperability, and the implementation of interoperability should ensure that:

- » Privacy-by-design and security-by-design approaches are used to secure their complete infrastructure and building blocks;
- » services are not vulnerable to attacks that might interrupt their operation and cause data theft or data damage;
- » legal requirements and obligations regarding data protection and privacy acknowledge the risks to privacy from advanced data processing and analytics.

Development and implementation of interoperability should comply with the MOH's Data, System Governance and Change Management Framework¹¹ for HIS, by addressing the following considerations:

- » "Risk management plans" to identify risks, assess their potential impact, and plan responses with appropriate technical and organizational measures. Based on the latest technological developments, those measures must ensure that the level of security is commensurate with the degree of risk.
- » "Business continuity plans" and "back-up and recovery plans" that put in place the procedures needed for functions to operate after a disastrous event and bring all functions back to normal as soon as possible.
- » A data access and authorization plan, which determines who has access to what data and under what conditions, to ensure privacy. Unauthorized access and security breaches should be monitored, and appropriate actions should be taken to prevent any recurrence of breaches.
- » Use of qualified trust services to ensure the integrity, authenticity, confidentiality, and non-repudiation of data.
- » Transfer mechanisms should facilitate information exchanges between systems that are:
 - » registered and verified, so that both sender and receiver have been identified and authenticated through agreed procedures and mechanisms;
 - » encrypted, so that the confidentiality of the exchanged data is ensured;
 - » time stamped, to track electronic records' transfer and access; and
 - » logged, for electronic records to be archived, thus ensuring a legal audit trail.

Appropriate mechanisms should allow secure exchange of electronically verified messages, records, forms, and other kinds of information between the different systems. It should handle specific security requirements and electronic identification and trust services, such as electronic signatures/seals creation and verification, and should monitor traffic to detect intrusions, changes of data, and other types of attacks. Information must also be appropriately protected during transmission, processing, and storage.



CHAPTER 2

KHISIF Governance, Management, and Compliance

2.1 Interoperability Governance Framework

Interoperability governance refers to decisions on KHISIF, institutional arrangements, organizational structures, roles and responsibilities, policies, and agreements. It also includes other aspects of ensuring and monitoring interoperability at national, county, and facility levels.

Important parts of interoperability governance include the Kenya Health Information Systems Interoperability Framework; the Data Protection Act No. 24 of 2019; the Kenya Health Act No. 21 of 2017; the Kenya Standards and Guidelines for eHealth Systems Interoperability, Version 2, July 2015; the Kenya National eHealth Policy 2016–2030; and the Data, System Governance and Change Management Framework of 2018.

Political support is necessary for interoperability efforts to facilitate cooperation between public and private health institutions. For effective cooperation, all stakeholders must share a vision, agree on objectives and timeframes, and align priorities. Interoperability between public and private health institutions at different administrative levels will only be successful if the Ministry of Health gives sufficient priority and assigns resources to their respective interoperability efforts.

The lack of the necessary in-house skill sets is a barrier to implementing interoperability policies. Stakeholders should include interoperability skills in their interoperability strategies, acknowledging that interoperability is a multidimensional issue that needs awareness and skills in legal, organizational, semantic, and technical fields.

The implementation and delivery of a given health service often rely on components that are common to many health services. Interoperability should be guaranteed in a sustainable way and not as a one-off target or project. Interoperability governance is the key to a holistic approach on interoperability, as it brings together all the instruments needed to apply it.

2.2. Leadership and Governance

The MOH shall set guiding principles for digital health, eHealth, HIS developments, and implementation through coordination of a health-sector partnership mechanism. The MOH will work to foster political goodwill and administrative authority to manage national HIS affairs, and consultatively advise subnational governments on HIS governance matters.

The MOH shall ensure that the existing stakeholders' coordination mechanisms such as the national HIS Interagency Coordination Committees (ICC) or health-sector working groups across all levels progressively include representatives from key HIS subsystems and relevant partners supporting the MOH to strengthen its leadership and governance structure.

2.3 Legal and Regulatory Interoperability

On this level, compatible legislation and regulatory guidelines shall define the boundaries for interoperability across borders, at national and subnational levels. A bilateral or multilateral written agreement, or memorandum of understanding, between health-sector players shall anchor the interoperability areas and means by which they will collaborate on health data exchange. Hence, health institutions shall align to the said guidelines for health data exchange as recommended by the Data Protection Act No. 24 of 2019, part V, and section 46(1).

2.4 HIS Interoperability Compliance

The MOH shall ensure implementing partners and stakeholders adhere to health sector policies, procedures, and best practices related to HIS while implementing health data exchange. This includes open standards for data exchange, messaging, security, and adherence to Data Protection Act No. 24 of 2019, part V, and section 46(1). MOH shall moderate and coordinate HIS stakeholders on the HIS certification process and ensure HIS owners adhere to MOH reporting requirements, open interoperability standards, and standardized health information outputs.

2.5 Data Ethics

Ethics is concerned with justice, rights, respect of human dignity, autonomy of the individual, and respect for the community.¹² Hence, ethics in the interoperability of health care systems refers to practice, attitudes, values, principles, and codes that guide health care professionals and patients during the exchange and use of health information in an unambiguous way. The KHISIF governance committee will define a set of procedures and contiguous plans to be executed.

2.6 Oversight and Accountability

The coordination of KHISIF implementation shall be governed through existing coordination and collaboration mechanisms outlined as follows:

2.6.1 KHISIF management process

Appropriate management mechanisms are required to develop and manage the common schemas used within the Ministry of Health, as well as to ensure prompt review and updating of the set of specifications that comprise the KHISIF.

At the national level, the Interagency Coordination Committees is the multi-stakeholder body that brings together all the players in the health sector. It is the highest decision-making forum for national-level Ministry of Health actions. The functions of the ICC are coordinated through three technical working groups (TWGs):

1. Health Informatics (HI);
2. Health Metrics (HM); and
3. Research and Innovation (R&I).

These working groups are established according to the policy orientations set out in the Kenya National eHealth Policy 2016–2030. Each TWG sets out to address priority issues and areas of focus and to better coordinate the investments of health sector stakeholders.

These management mechanisms share several key requirements:

- » They have to be sufficiently flexible to address the changes within the respective subject areas, such as technology changes;
- » They have to address the fact that certain aspects, such as business-specific conventions or technical specifications, would be more effectively owned and managed by program domain experts or dedicated specialist groups rather than under a common ownership; and
- » The coordination of the change management process of the KHISIF shall be the responsibility of the HIS Interagency Coordination Committees TWGs and informed by relevant established sub-TWGs. This entails:
 - » Appointment of a KHISIF review coordination team, to be conducted by MOH-ICC members. The appointed team will oversee the organization of the review by coordinating health stakeholders and academics to be involved, preparation of background materials, identification of funding partners and potential donors, and consultatively building national interest in the review.

Health Informatics

The purpose of this TWG is to coordinate HIS and electronic medical records/electronic health records (EMR/EHR) stakeholders. Its aim is to strengthen HIS, promote information exchange, and promote real-time data and standard analytical tools to improve health care delivery within the country.

Functions

- » Provide leadership and coordination of HIS and EMR/EHR-related activities with the relevant stakeholders in order to avoid duplication of effort and deliverables.
- » Provide guidance on HIS and EMR/EHR-related requirements aligned to national policies, standards, and guidelines for dissemination and implementation by county governments, development partners, civil society organizations, and other end users in line with relevant strategies.
- » Institute mechanisms for effective liaison between national or county governments, development partners, communities, county proximate university, and implementing partners.
- » Establish and maintain a country inventory of existing eHealth solutions across counties and monitor implementation to identify key milestones towards improved use of eHealth solutions for real-time information exchange.

- » Guide the health programs at national and county TWGs in HIS and EMR/EHR prioritization and coordinate informatics capacity-strengthening approaches across all levels.
- » Promote interoperability by developing and disseminating HIS interoperability framework and standards among the eHealth solutions stakeholders across all levels.
- » Consultatively collaborate with counties on efforts to operationalize and track Interoperability Implementation Roadmap of the eHealth components in the county health annual work plans and County ICT department annual work plans. (See Annex I).
- » Identify, establish, and encourage compliance with standards and legal frameworks to guide implementation of eHealth solutions across all levels.
- » Guide the establishment of HI TWGs at county levels to coordinate and promote physical security of health infrastructure and promote confidentiality of health data and information during access.
- » Report to and take on responsibilities as may be assigned by the health stakeholders' forums, e.g., the Interagency Coordination Committees, Council of Governors peer-to-peer learning, Health Metrics, and Research & Innovation TWG, among others.

Health Metrics

The main objective of this TWG is to coordinate the HIS monitoring and evaluation stakeholders. Its aim is to strengthen health information systems and monitor the progress of the Health Sector Strategic Plan, which reflects a series of health indicators that are supposed to be measured monthly, quarterly, and annually through surveys or surveillance.

Functions

- » Keep abreast of the progress of the health sector's planned M&E interventions.
- » Assess the need for corrective measures to achieve health targets set in annual plans.
- » Monitor the collection of information on health services based on routine and non-routine HIS.
- » Make recommendations to the ICC on prioritization of indicators that provide useful measures of health performance.
- » Expand disease and demographic surveillance, encourage more collaboration between health programs, and provide input to the creation of a national health research agenda.
- » Provide guidance and oversight to all M&E-related activities to streamline the number of registers and reporting tools while maximizing the relevance and effectiveness of the indicators and measures they produce.

- » Promote the objectives of the National Integrated Data Analytics Framework (see Annex V), by outlining the structured processes of health data and information analysis, for tracking of SDG 3 indicators aligned to UHC Kenya health targets and generation of strategic information products to inform actionable insights at national and county levels.
- » For cross-cutting issues, the HM TWG needs to collaboratively monitor the progress of M&E subcommittee TWGs at the county level.

Research and Innovation

Research and innovation are essential tools for the Directorate of Health Policy, Research, Monitoring & Evaluation, as they support continuing efforts to address issues and concerns for the health sector. The Directorate will oversee and provide an advisory role to all prioritized research activities. The ICC-R&I TWG will provide support services to health-sector stakeholders on identification and coordination of the health research agenda.

Functions

- » Review proposed research and innovation topics, agendas, and proposals.
- » Provide necessary technical assistance to the stakeholders at national and county levels in line with research and innovation in health.
- » Recommend regular capability-building and skills enhancement activities for both national- and county-level members regarding research and innovation development.

For more details on terms of reference for the TWGs, refer to Annex IV.

2.6.2 KHISIF change management

Responsible: The Health Informatics TWG has its secretariat in the Department of Health Sector Monitoring & Evaluation and Informatics. The Department provides policy and strategic advice, capacity-building and technical assistance at national and county departments of health. In addition, the department is tasked with developing and maintaining enterprise-level eHealth applications and digital health solutions. Some of the electronic systems under its purview include Kenya Health Information System for aggregate reporting, and Kenya Master Health Facility List, among other digital health solutions.

The HI-ICC TWG terms of reference provide the scope of work and guides on the duties, responsibilities, composition, and operations of the: Systems Management Team, selected from its members and from the MOH HIS Unit to act as the secretariat to support the effective functioning of the TWG; and the EHR task force technical team as part of the Health Informatics TWG.

One of the HI TWG's responsibilities shall be to define the KHISIF terms of reference (aligned health sector priorities).

- » It shall consist of health managers and IT management and control the formulation and implementation of the KHISIF Roadmap.
- » The HI TWG shall concentrate on transforming KHISIF implementation as needed to meet the present and future demands for management of HIS.
- » It shall implement support of the KHISIF.

2.7 Complying with the KHISIF

Compliance with the KHISIF is mandatory for all HIS system owners, for ensuring standardization of health information exchange between HIS subsystems, and among interoperating HIS subsystems. Compliance means all HIS system owners are required to use those technical specifications and matured common services, plus guidelines, shared health digital infrastructure, and procedures specifications listed in the KHISIF document library. The Health Informatics TWG will coordinate the certification process for all HIS through the Kenya HIS certification framework.

2.8 HIS Governance

The MOH shall ensure involvement of representatives from relevant government ministries such as the Ministry of Information and Communications Technology and the Communications Authority of Kenya. This should include representation from implementing partners supporting the MOH with ICT for health and health informatics. Experts in HIS, with knowledge of HIS enterprise architecture, data management processes, and data exchange standards are likewise critical.

2.9 Human Resource Health

The MOH shall ensure representatives from all MOH departments, programs, semi-autonomous agencies, civil service, private sector, and health service delivery and implementing partners, and development partners, among others, are informed on KHISIF and involved during implementation of KHISIF at national and county levels. The coordination process will be through the institutionalized Interagency Coordination Committees Health Informatics, Health Metrics, and Research and Innovation TWGs.



CHAPTER 3

Interoperability Architectural Technical Specifications

3.1 Interoperability Architectural Framework

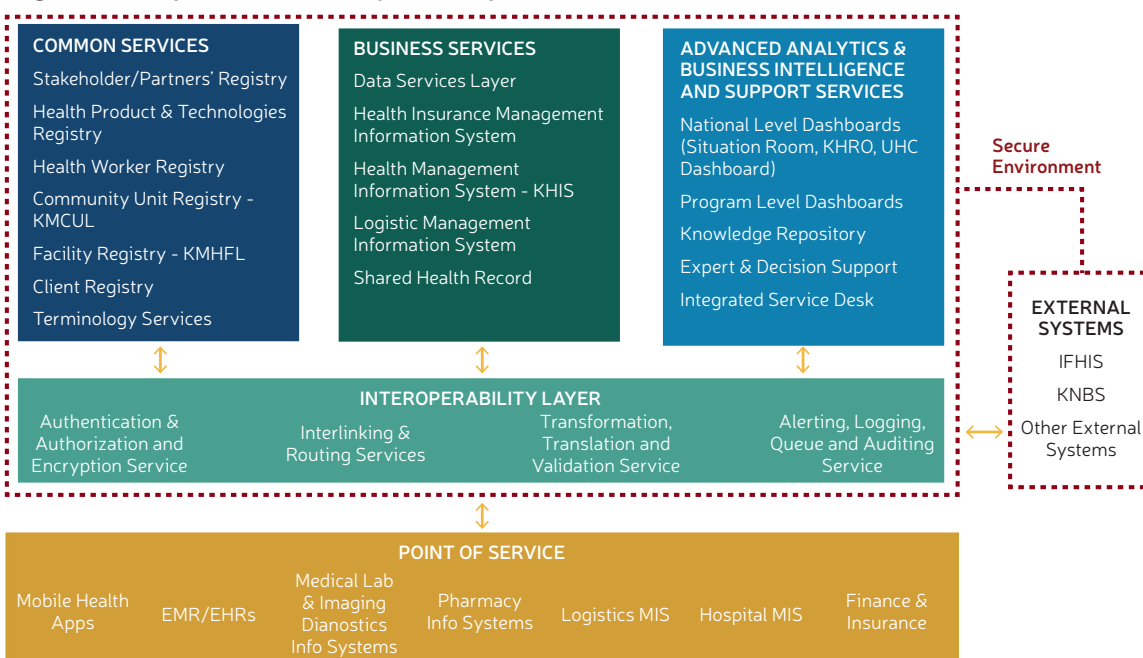
This chapter proposes a conceptual model for integrated architecture to guide the planning, development, and implementation of the KHISIF. It is relevant to all governmental levels. The model is modular and comprises loosely coupled components interconnected through shared infrastructure.

The conceptual model promotes the idea of interoperability by design and is anchored in the open health information exchange (OHIE) framework.¹³ This means that for Kenya health systems to be interoperable, they should be designed in accordance with the proposed model and with certain interoperability and reusability requirements in mind.

The model promotes reusability as a driver for interoperability, recognizing that the health systems should reuse information and services that already exist and may be available from various sources inside or beyond the organizational boundaries. Information and services should be retrievable and made available in interoperable formats as proposed by the Kenya Standards and Guidelines for eHealth Systems Interoperability.

The basic components of the conceptual model are presented in Figure 1, aligned to OHIE component layer, interoperability services layer, and point of service through mapping of existing in-country plans and implementation on common services and relevant digital health solutions.

Figure 1: Kenya Health Interoperability Architecture



Source: MOH technical team (HealthIT) adapting the OHIE model¹⁴

The model's structure includes the following:

Common services such as:

- » Stakeholders registry;
- » Health product and technologies registry;
- » Facility registry and community unit registry;
- » Client registry;
- » Health worker registry;
- » Terminology services; and
- » Interoperability layer.

Business services:

- » Data services layer;
- » Health insurance management information system;
- » Logistics management information system; and
- » Shared health record.

Advanced analytics and business intelligence, and support services:

- » Dashboards;
- » Knowledge repository;
- » Expert and decision support system; and
- » Integrated service desk.

Point of Service Applications.

External Systems.

3.2 Common Services

These are resources that are shared to support functionality and enhance standardization within the interoperability environment. Common/shared services enable resources to be leveraged across an entire enterprise, resulting in lower costs with agreed-upon customer-service levels and standardized data formats and semantics. The following present the existing and currently prioritized common services for Kenya HIS ecosystems.

3.2.1 Facility registry

A health facility registry serves as a central authority to uniquely identify all places where health services are administered within the country. A health facility registry serves as the central authority to collect, store, and distribute an up-to-date and standardized set of facility data.

3.2.2 Client registry

A health care client is a person who is eligible to receive, has received, or is receiving health care services. The client registry is the definitive source for a health care client's identity, facilitating the unique, accurate, and reliable identification of individual clients and others who receive care. The registry provides a unique patient identifier for each client. It includes the functionality of the Enterprise Master Patient Index, a service that matches records from different sources referring to a single health care client. It contains demographic and identification cross-reference data for health care clients registered in one or more point-of-service applications. The client registry is designed to uniquely identify citizens receiving health services within the country.

Some of the services provided by the registry include:

- » Validation of health care client identity information;
- » Searching and resolving information from multiple sources that refer to the same health care client identity;
- » Obtaining summary and detailed demographic information about a health care client;
- » Adding and updating a health care client record;
- » Merging and unmerging health care client records (because they either do, or do not, refer to the same individual);
- » Reconciling duplicates; and
- » Managing publish/subscribe notifications of adds, updates, merges, and splits to downstream systems.

3.2.3 Terminology service

Health care systems may use different local names, codes, or wording for the same clinical concepts – for example, labs may have different names or numerical codes assigned to a lab test. When health care data from different sources is being shared, it is essential to be able to translate or resolve these differences, to ensure correct interpretation by both people and systems. A terminology service serves as a central authority to uniquely identify the clinical activities that occur within the care delivery process by maintaining a terminology set mapped to international standards such as International Classification of Diseases (ICD10/11)¹⁵, Logical Observation Identifiers Names and Codes (LOINC)¹⁶, Systematized Nomenclature of Medicine (SNOMED CT)¹⁷, and others.

In addition, the terminology service provides a centralized source for the health information exchange standards and definitions, including terminologies, ontologies, dictionaries, code systems, and value sets. Other HIE components can use these standards and definitions to normalize clinical data and achieve consistent aggregation and reporting. Using terminology services actualizes semantic interoperability, which enables accurate, consistent reporting and aggregation of clinical data. It also facilitates accurate exchange of information among members of the provider community, including labs, clinics, pharmacies, hospitals, and imaging centers, which leads to improved patient care decisions.

Terminology services also support other architecture components such as the health facility registry and shared health record.

Functions of the terminology services include:

- » Code system query;
- » Concept/code validation;
- » Code translation;
- » Value set (subset) query; and
- » Value set resolution.

(See Annex III for more details.)

3.2.4 Health worker registry

A health worker registry is the digital, central authority designed to interoperate with other systems using international standards.¹⁸ It contains a minimum set of details pertaining to all health workers. The registry assigns a unique identifier to each provider and maintains information about them, including professional accreditations (e.g., licenses, professions,

specialties). It is fed by regulatory colleges, Ministry of Health and long-term care databases, hospitals, and other organizations. The health worker registry performs the following tasks:

- » Creates a minimum data set from different data systems;
- » Harmonizes data from several data sources, which helps in the support analysis for quality measurement, reporting and research, validation, and interoperability;
- » Allows queries of health worker information by various users; and
- » Entails rules and standards for sharing data between systems whereby a beneficial outcome is improved data quality and integrity.

The health worker registry should:

- » Support the updates of health worker data through querying of source data systems;
- » Support the ability to retain source data systems updates;
- » Support the capacity to retain the old versions of health worker data after updates; and
- » Respond to stored queries on health worker data.

Other Common Services

- » Stakeholder/partners' registry; and
- » Health product and technologies registry.

Note: The last two are yet to be fully defined.

3.3 Interoperability Layer

A health interoperability layer receives all communications from point-of-service applications within a health geography and orchestrates message processing among the point-of-service application and the hosted infrastructure elements.

In a complex health care system with multiple stakeholders using siloed health care solutions, it is difficult to share information across disparate systems, making accurate, timely, and complete information hard to obtain and increasing costs and security risks.

To enable sharing that will allow data from multiple sources to be used, it is important to create an architecture that enables systems to better communicate with one another using flexible processes and technologies that can respond to rapidly changing health information needs. The open health information exchange architecture is designed to provide flexibility in meeting country-specific needs through a component-based architecture. The architecture is designed to enable components to work together while providing a secure mechanism for sharing health care information and maintaining a decoupled architecture designed for flexibility.

When software applications can be combined rapidly without complicated and expensive interfaces, solutions can be deployed much more quickly. This is because doing so extends the use of existing systems rather than replacing them with a new solution or redeveloping them to meet new requirements.

Interoperability also encourages technology innovation by providing a means by which smaller companies can compete with larger, more established ones through a standards-based mechanism for connecting systems. This means that the benefits of new, emerging technologies can be harnessed more rapidly and may also assist with preventing vendor lock-in¹⁹. As health information needs evolve in a complex and rapidly changing health care environment, HIS need to be highly adaptable. Standards-based interoperability supports this adaptability.

At the core of the HIE architecture is the interoperability layer, a middleware component that is designed to receive and coordinate transactions in the exchange. Its role is to provide a façade to point-of-service systems and abstract the interfaces between them and the other components within the exchange. This de-coupled approach reduces dependencies and allows for a single point of control and contact into the exchange, enforcing a common security mechanism and allowing for centralized logging and monitoring. An interoperability layer provides the capability to electronically move clinical information between different health care information systems within the exchange while maintaining the accuracy and meaning of the exchanged information.

As a single point of entry, the interoperability layer receives transactions from point-of-service health care systems and coordinates interaction among the different components of the HIE. It also provides common core functionality to ensure that transactions are secured, authenticated, and authorized. Essentially, the interoperability software allows different systems to talk to each other and exchange information in a secure and controlled fashion.

While the roles of other OHIE components that provide services may be more easily understood, it is the interoperability layer that secures and orchestrates the exchange of information. Similar to an orchestra conductor, the interoperability layer provides the central force that enables all of the OHIE components to work together and interact with point-of-service systems outside the OHIE.

At a high level, the interoperability layer performs the following functions:

- » Acts as a single entry point for the OHIE.
- » Manages the security of the OHIE through authentication (identity verification), authorization (permission to interact with specified HIE components), and encryption and decryption of messages.
- » Routes messages to the appropriate architecture component or external point-of-service system.
- » Provides a central logging mechanism for the messages sent through the exchange by logging copies of the messages that travel through the interoperability layer for audit and reporting purposes.
- » Allows for the rerunning of failed transactions at a central level, alleviating the need for point-of-service systems to resend data, for example, in the event of a problem with an infrastructure component.
- » Provides, as necessary, implementation-specific adapters to translate incoming messages into a form that the other HIE components can interpret.
- » Provides additional mediation functions for transactions within the HIE to simplify the business logic required by service consumer systems to interact with the HIE, providing a buffer between point-of-service systems and the HIE components.
- » Provides a mechanism for error management and tracking, e.g., a console for viewing failed transactions.
- » Captures monitoring statistics, such as transaction loads and performance metrics, and provides a view of these for monitoring the flow of messages through the HIE.

Summary of the functions of the interoperability layer:

- » Authentication, authorization, and encryption;
- » Interlinking and routing;
- » Transformation, translation, and validation; and
- » Alerting, logging, queueing, and auditing.

See Annex II for more details.

3.4 Business Services

The health management information system is a repository containing the normalized version of aggregate-level content created within the community, after being validated against each of the previous registries. It is a collection of indicator-centric records for cohorts with health and health related information for exchange. The following list presents the identified business services for prioritization;

- » Data services layer;
- » Health insurance management information system;
- » Health management information system;
- » Logistics management information system; and
- » Shared health record.

Note: Items not covered below are yet to be fully defined.

3.4.1 Data services layer

The data services layer is designed to leverage the progress made through strengthening Kenya's HIS ecosystems and providing an environment for further convergence of multiple factors that affect health for effective decision- and policymaking. The data services layer presents the capability to analyze, predict, and anticipate diverging and converging factors of health for evidence-based decision-making. Hence, it is a platform to facilitate collaboration and sharing of health data and information, to aide M&E, to contribute to the discovery of complex interlinkages in health determinants, and to create health information products to shape health policy, among other outcomes.

3.4.2 Kenya Health Information System for aggregate reporting

KHIS2 is an open-source software program for routine reporting, analysis, and dissemination of health data for all health programs, across all health facilities in-country for aggregate health data reporting.²⁰

3.4.3 Logistics management information systems

Logistics management information systems are digital health solutions used in health care delivery that enable resupply workflows for clinical locations and the vertical programs targeting families of commodities. They also serve as an interface with suppliers' IT systems to ensure that supplies are re-upped as needed. An effective logistics management

information system should ensure that adequate quantity and quality of all medical supplies including vaccines, essential medicines, and non-pharmaceuticals are always available to meet facility demands.

The functions include:

- » Capturing accurate routine administration, dispensing, and consumption data.
- » Real-time, end-to-end logistics management from point of origin to service delivery point (including minimum and maximum levels).
- » Demand forecasting, capacity planning, and modeling based on consumption.
- » Applying user interface practices in a consistent manner throughout the system.
- » Utilization of the national list of essential medicines, or, in its absence, the World Health Organization global list, serves as the basis for monitoring availability and affordability.
- » Linking logistics data to health service delivery data to match demand for essential medicines with availability.
- » Maintaining transaction log history.
- » Automation and Monitoring of the pull systems on requirements.
- » Requisition, receiving, procurement, storage, dispatch, transport, and dispense business processes.
- » Linkages to post-marketing surveillance of medicines and monitoring adverse drug reactions.
- » Utilization of the normalized names for clinical drugs and link its names to many of the drug vocabularies commonly used in pharmacy management and drug interaction software from Drug Information Unit of the Pharmacy and Poisons Board²¹ on the naming system for generic and branded drugs, and supports semantic interoperability between drug terminologies and pharmacy knowledge base systems.
- » Supporting open-data standards to enable seamless interoperability with constituent applications and other health information system applications (e.g., DHIS2, master facility registry, EMR).
- » Accessibility both on the web and offline for routine workflows, e.g. compatible and mobile optimized for General Packet Radio Service (GPRS) and the Global System for Mobile Communications (GSM) data exchange, local server, or cloud-based hosting options.

3.5 Advanced Analytics and Business Intelligence, and Support Services

The National Integrated Data Analytics Framework, as referenced in Annex V, outlines the structured processes of health data and information analysis for tracking of SDG 3 indicators aligned to UHC Kenya health targets and generation of strategic information products to inform actionable insights across all levels. The Kenya HIS ecosystem, applications, and platforms that enhance strategic and operational decision-making by consolidating and analyzing health data and information are categorized as follows.

- » National-level dashboards
 - » Kenya Health and Research Observatory
 - » Universal Health Coverage
 - » HIV/AIDS Situation Room
- » Program-level dashboards
 - » Early infant diagnosis (EID), Viral load (VL), anti-retroviral therapy (ART), reproductive, maternal, newborn and child health (RMNCH) among others
- » Knowledge Repository
 - » HIS Online Learning²²
- » Expert and decision support system
 - » Data services layer
- » Integrated service desk
 - » MOH Service Desk²³

3.6 Point-of-Service Applications

These are digital health solutions used by health workers to facilitate service delivery.

- » Mobile health applications
- » Electronic medical records and electronic health records
- » Medical lab and imaging diagnostic information systems
- » Pharmacy information system
- » Logistics management information system
- » Hospital management information system
- » Billing and revenue collection
- » Other systems that support facility functions

3.7 External Systems

These are organizations or systems that provide data or support data exchange but fall outside the Ministry of Health.

- » Integrated Financial Management Information System²⁴
 - » The National Treasury has rolled out the Integrated Financial Management Information System (IFMIS) electronic procurement (e-procurement) throughout the country to serve Kenyans effectively on issues relating to public procurement. The IFMIS e-procurement module enhances transparency and accountability in the procurement process, encompassing planning, requisition, sourcing, and payment.
- » Kenya National Bureau of Statistics²⁵
 - » The Kenya National Bureau of Statistics was established by the Statistics Act of 2006 to replace the Central Bureau of Statistics. The Act establishes Kenya National Bureau of Statistics as a semi-autonomous government agency incorporated under the National Treasury and Planning State Department for Planning and Vision 2030.²⁶ Its core mandate is to collect, compile, analyze, publish, and disseminate statistical information for public use, with the additional role of coordinating, monitoring, and supervising the National Statistical System.

- » Ministry of Interior and Coordination of National Government: Civil Registration Services
- » Kenya Medical Supplies Authority (KEMSA)
- » National Hospital Insurance Fund (NHIF) and other insurance providers
- » Non-state health care providers (faith-based, NGOs, and private sector)



CHAPTER 4

HIS Certification and Procedure

4.1 Interoperability Certification

A certification framework is driven by the standards or criteria to be achieved, industry expectations, and audience needs. KHISIF leverages the Kenya Health Information Systems certification framework to ensure systems are certified and conform to the Kenya eHealth interoperability standards. The Kenya Health Information Systems certification framework defines the policies that govern the operation of the HIS certification program.

The highlights of the certification focuses on four main criteria:

- » Functionality for health information systems to collate health data, compile, and analyze health data to help manage population health and reduce health care costs. The MOH will define the minimum functions an EHR should perform to help physicians practice better medicine and improve the bottom line.
- » Reporting and alerts aligned to MOH routine health data and information reporting to generate complete and quality data and promote data use for decision-making. Now the health care data analysis can improve patient care and collaborative care.
- » Security, privacy, and confidentiality: MOH will put in place safety measures that limit access on health data and information according to policy.
- » Information exchange and interoperability: MOH advocacy on implementation; deployment of Electronic Health Information Exchanges (HIE) to health care providers to improve patient care by efficiently and securely sharing patient's digital medical information through standards that enable data to be shared across disparate health care subsystems.

4.2 Interoperability Maturity Model

A maturity model is a set of structured levels that depict the organizational behaviors, practices, and processes that reliably and sustainably produce required outcomes.²⁷

The maturity model concept is used to measure the ability of an organization or government entity, such as a ministry of health, to continuously improve in a specific discipline until it reaches the desired level of development or maturity.²⁸ The greater the maturity, the stronger the system, and the more likely it is to withstand interruptions, such as changes in staff, fluctuations in funding, changing data needs, or the effects of rapidly evolving technology. The HIS interoperability maturity model addresses the components that are critical to interoperability: technology, the broad area of leadership and governance of the HIS, and human resources.

The HIS Interoperability Maturity Toolkit Assessment Tool supports the MOHs, their implementing partners, and other stakeholders in identifying the key domains for interoperability and the required levels of maturity to achieve HIS interoperability goals.

The interoperability maturity toolkit should:

- » Identify interoperability domains and subdomains.
- » Define maturity levels.
- » Provide an assessment process.
- » Provide an assessment tool.
- » Provide a maturity model worksheet.

The KHISIF proposes the adaption of global best practices such as the MEASURE Evaluation health information systems interoperability maturity toolkit,²⁹ for progressive monitoring and evaluation of the Kenya Ministry of Health interoperability implementation journey over time, as well as *Data Interoperability: A Practitioner's Guide to Joining Up Data in the Development Sector*,³⁰ to explore opportunities and identify good practices for enhancing data interoperability in the SDGs. The KHISIF also incorporates other global best practices for cross referencing to enrich the KHISIF evaluation process. For more information see Annex VI.



ANNEXES

Annex I: Interoperability Implementation Roadmap

The interoperability roadmap defines the implementation process for institutionalizing the defined collection of specifications within the KHISIF 2020, aimed at facilitating the interoperability of HIS ecosystems in Kenya. To actualize the interoperability roadmap, the MOH will foster the process through multi-sectorial collaboration toward eHealth development in Kenya. The MOH will coordinate the interoperability work through the existing stakeholders' coordination mechanisms, the ICC, to ensure that all implementation plans are the agreed-upon consolidated action items elicited from stakeholders' engagements. Henceforth, MOH stewardship is to ensure national-level policies are implemented and guide towards attaining eHealth impact across all levels.

The primary purpose of the implementation roadmap is to achieve the following fundamentals:

- » Supporting counties towards the implementation of national eHealth and HIS One Vision policies (alignment of HIS Vision across all levels of digital health solutions), strategies, and plans in collaboration with development partners for mobilized cost-effective technical assistance.
- » Institutionalization of eHealth interoperability technical standards.
- » Certification and testing of eHealth solutions to support optimization of eHealth products for improvement of continuum of care.
- » Privacy and security protection for health data and information.
- » Advocating for eHealth, HIS, and Kenya health-sector investments and identifying common areas of priority that can be collaboratively and strategically implemented across all levels.
- » Aligning capacity-strengthening strategies with eHealth implementations and optimization of peer-to-peer and cross-county knowledge sharing.
- » Facilitating a knowledge-sharing and learning platform for in-country eHealth implementation for potential showcasing at regional and global forums as a digital global good.
- » Systematically coordinating the monitoring and evaluation of the impact of eHealth, HIS, and ICT for health enhancements and solutions, and documenting operational research on health outcomes and partner support towards an interoperability framework.

Annex II: Development of Interoperability Layer Software Requirements Specification

While recognizing eHealth as a mode of health service, the Kenya Health Act 2017 emphasizes the need for the standardization of health information exchange through the KHISIF, and establishment and maintenance of a comprehensive health information system. Accurate, readily available, timely, and complete data for health planning, workforce management, policy development, and monitoring and evaluation are critical for optimal HIS functioning and can only be obtained from well-matured HIS.

The Kenya HIS includes multiple stakeholders using disparate health-care solutions, making it difficult to share information across these various HIS. Consequently, accurate, timely, and complete information is difficult to obtain, leading to increased costs and security risks as well as impacting negatively on patient management.

There is a need to ensure communication and HIE between disparate HIS, such as client registry, provider registry, facility registry, and shared health records through an interoperability layer. Such communication will enable exchange of information based on standards and the ability to use the information that is exchanged.

Purpose

- » To facilitate the development of minimum requirements of an efficient HIE environment.
- » To promote the use of the interoperability concepts and standards in harmonizing HIE, both technical and architectural activities within the Kenya eHealth ecosystem.
- » To facilitate interoperability design, implementation, analysis, and assessment.
- » To provide guidance on monitoring and evaluating interoperability maturity.

Scope

The interoperability layer software requirements specifications to be adapted for eHealth digital solutions, as per the health policy, are aligned to the technical specification for KHISIF implementation and deployment covered in Chapter 3. Since interoperability layer software requirements specifications and standards are globally evolving, the interoperability layer document will be periodically reviewed and updated, guided by new health areas/domains, standards, versions, and the like.

This document should be read in conjunction with the Kenya Health Policy and interoperability standards and guidelines document that outlines when and how to use the standards in eHealth digital solutions and the KHISIF.

Annex III: Development of Terminology Service Software Requirements Specification

The Kenyan government is in the process of making sure that all HIS in the country are interoperable. The majority of HIS are currently not interoperating on HIE. Hence, a terminology service is a key component to ensure accurate knowledge sharing, consistent data collection, standardized representation of data elements, and comparable analysis of health-care utilization data. Thus, terminology service will be critical for achieving semantic interoperability. The terminology service document defines the minimum functional and system requirements, in Kenya's HIS context, and aligned to the technical specifications for KHISIF implementation and deployment covered in Chapter 3.

Purpose

To provide the functional and nonfunctional requirements for terminology services in Kenya and ensure achievement of:

- » Accurate and consistent data aggregation to improve patient care analysis and reporting of comparable patient data within and between patient populations, leading to more consistent care.
- » Consistent analysis of health-care resource utilization for more informed decisions about resource allocation.
- » Standardized evaluation of treatment plans that affect health outcomes.
- » Reproducible quality, safety, and efficiency measurements of patient care.
- » Identification, evaluation, and re-engineering of patient care processes.
- » Compliance with national standards for health-care delivery.
- » Progress towards evidence-based medicine and the use of clinical decision support.
- » Standardization and reuse of digital health solutions and reports.

Scope

The terminology service will provide a consistent specification for accessing and managing terminology content. Terminology services will represent functions necessary to manage, search, access, and expand terminology content independent of the underlying technology stack. Terminology content represents various resources including lists, value sets, taxonomies, among others. The proposed solution will provide a mechanism for user

management, user authentication, access control, management of requests and feedback for user requests.

Definitions and acronyms

A terminology, also known as a code system, ontology, vocabulary, or dictionary, is a set of names, codes, and descriptions related to a body of knowledge. A terminology can be as simple as the set of Health Level Seven International (HL7) gender codes³¹ or as complex as Systematized Nomenclature of Medicine (SNOMED CT).³²

Annex IV: Terms of Reference and Ministry of Health Templates

At the national level, the Interagency Coordination Committees is the forum that brings together all the players in the health sector to shape policy. The functions of the ICC are coordinated through three technical working groups:

1. Health Informatics;
2. Health Metrics; and
3. Research and Innovation (R&I).

These working groups are established according to the policy orientations set out in the Kenya National eHealth Policy 2016–2030. Each technical working group sets out to address priority issues and areas of focus and to better coordinate the investments of health-sector stakeholders.

These management mechanisms share several key requirements:

- » They have to be sufficiently flexible to address the changes within their respective subject areas, such as technology changes.
- » They have to address the fact that certain aspects, such as business-specific conventions or technical specifications, would be more effectively owned and managed by program domain experts or dedicated specialist groups rather than under a common ownership.
- » The coordination of the change management process of the KHISIF shall be the responsibility of the HIS ICC TWGs, informed by the sub-TWGs and taskforce, respectively.

Key MoH functions

- » Guide the health programs in national and county TWGs in HIS and EMR/EHR prioritization and coordinate informatics capacity-strengthening approaches across all levels.
- » Promote interoperability by developing and disseminating HIS interoperability framework and standards among the eHealth solutions stakeholders across all levels.
- » Consultatively collaborate with counties on efforts to operationalize and track implementation of the eHealth components in the county health annual work plan and county ICT department annual work plan.
- » Identify, establish, and encourage compliance with standards and legal frameworks to guide implementation of eHealth solutions across all levels.

Annex V: National Integrated Data Analytics Framework

The overall objective of this data and analytics framework is to outline a structured process of data analysis, towards tracking of SDG 3 indicators aligned to Kenya UHC targets and generation of strategic information products to inform actionable insights at national and county levels. The ICC and its corresponding TWG's members will advocate and define the guiding procedures for ensuring the following specific objectives of the framework:

1. To outline the key aspects of a data and analytics framework that can guide the process of formulating critical health questions.
2. To outline the key types of health and geospatial data analytics, tools, and techniques used to help build the analysis.
3. To provide logical steps in discovering insights, associations, relationships, and patterns from data to support evidence-based decision-making.
4. To outline potential sources of health data, including, but not limited to, patient-level data, spatial data, and relevant auxiliary attribute data necessary in generating health insights.
5. To generate the best value from data and analytics, it is always better to start from the health outcomes and the hypotheses, as opposed to the available data.

Aspects of data and analytics framework

There are four aspects to the data and analytics framework:

- » Discovery;
- » Insights;
- » Actions; and
- » Outcomes.

Discovery: This phase involves defining the problem, developing hypotheses, and collecting and exploring data with the view of finding value in data. When defining the problem, it is important to review existing documents or publications that have addressed the problems you are trying to solve. It is also important to make reference to national and county-level priority indicators as defined in the SDGs, M&E framework, and other MOH policies. This will help you to better define or refine the problem and avoid duplication in analysis. Common

operations include data cleaning, data formatting, and exploratory spatial data analysis through electrostatic deposition analysis.

Insights: This phase involves application of appropriate analytical techniques to existing and new data to generate new knowledge. It is also important to create a test-and-learn environment for continuously harnessing insights.

Outcomes: This phase involves unlocking the value of data and analytics by transforming institutional functions. To deliver improved health outcomes, it is necessary to develop a training strategy that will improve the skills of personnel.

Actions: This phase involves linking insights with decisions and actions to deliver quick wins.

Annex VI: Interoperability Suite of Tools

Components	Readiness assessment (operational - checklist)	Maturity model module (strategic - organizational)
<p>Governance:</p> <p>Oversight and data control (institutional and human layers)</p>	<p>A literal checklist across all these areas.</p>	<p>Develop an “interoperability module” that can fit into other maturity models. This will require assessment of other models and processes – desk review of:</p>
<p>Interoperability pillars (technical and data layers):</p> <ul style="list-style-type: none"> - Data and metadata - Classifications and vocabularies - Interfaces and access - Linked open data 	<p>Start with easy wins and clear propositions as suggested by focus group at UNSC.</p>	<ol style="list-style-type: none"> 1. GSBPM interop links 2. IBM Information Governance Model 3. Gartner maturity model for data and analytics 4. UNICEF administrative data maturity model
<p>Additional management functions (not covered in our model but to be aware of with links to resources in Guide):</p> <ul style="list-style-type: none"> - Data security (Ch. 1) - Storage and operations (Ch. 2 & 4) - Data warehousing (Ch. 2) - Quality assurance (Ch. 2) - Reference and master data (Ch. 3) - Document and content management (Ch. 5) 	<p>See for instance the Measure Evaluation HIS Interop toolkit.</p> <p>Also see, World Bank Open Data Readiness Assessment tools.</p> <p>US Digital Services Playbook.</p>	<ol style="list-style-type: none"> 5. UK + Australia maturity model for FPOS 6. Carruthers and Jackson 7. Data Orchard <p>We should consider the example of UNICEF in terms of identifying clear outcome statements for each component</p>

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Annex VIII: Stakeholders' Engagement Reference List

Organization	Participant's Name
Office of the Deputy President	Philip Thigo
MOH – Directorate Head	Dr. Charles Nzioka
MOH – Department Head	Dr. Joseph Sitienei
MOH – Health Informatics	Mr. Onesmus Kamau
MOH – Health Informatics	Abdullahi Kimogol
MOH – Health Informatics	Dr. Ayub Many
MOH – Health Informatics	Dr. Wesley Oghera
MOH – Health Informatics	Dr. Martha Muthami
MOH – Research and Innovation	Dr. Joyce Wamicwe
MOH – ICT	Rachael Wanjiru
MOH – ICT	Eric Nderitu
MOH – Health Informatics	Julius Mutiso
MOH – Health Informatics	Dr. Mutile Wanyee
MOH – Health Informatics	Nancy Amayo
MOH – Health Informatics	Sophia Karanja
MOH – UHC	Pepela Wanjala
MOH – Health Informatics	Dr. Liz Wangia
MOH – Health Informatics	Dr. Helen Kiarie
MOH – Health Informatics	Jeremiah Mumo
MOH – Health Informatics	Samuel Cheburet
MOH – Health Informatics	Dianne Kamara
MOH – Health Informatics	Patrick Warutere
MOH – Health Informatics	Dorcas Gichigi
MOH – Community Health	Diana Kamar
MOH – Clinical Services	Judy Kabathi
MOH – Health Informatics	Paul Malusi
MOH – Health Informatics	Peris Wanjiru
MOH – Health Informatics	Otieno Elizabeth
MOH – Health Informatics	Gilbert N. Mboro

NASCOP – M/E, SI	Dr. Violet Oramisi
NASCOP – M/E, SI	Rose Agweny
NASCOP – M/E, SI	Faith Shelmith
NACC – Head	Dr. Nduku Kilonzo
NACC – M/E, SI	Mr. Joshua Gitonga
NACC – M/E, SI	Mr. George Onyango
NACC – M/E, SI	Mercy Khasiani
Council of Governors	Benter Owino
Council of Governors	Stephen Osingo
County ICT Director (Kakamega)	Mr. Sam Wetungu
Kakamega County	Dr. Mike Ekisa
AMREF	Dr. Elizabeth Wala
AMREF	Janekellen Mbai
KEMSA	Mr. Eliud Muriithi
Communications Authority of Kenya	Nixon Mageka
PEPFAR	Larry Sperling
PEPFAR	Christalyn Steers
PEPFAR	Dr. Heather Smith
PEPFAR Kenya	Anne Ojijo
USAID	Mr. Washington Omwomo
USAID	Peter Yegon
USAID	Brian Onyango
CDC	Dr. Davies Kimanga
WHO	Victor Achieng
WHO	Cosmas Leonard
UNICEF	Eunice Ndungu
UNICEF	Dr. Khaing Soe
UON/HealthIT	Prof. Peter Waiganjo
UON/HealthIT	Mr. Raphael Pundo
UON/HealthIT	Mr. Dennis Banga
UON/HealthIT	Mr. Felix Ongati
UON/HealthIT	Duncan Ndiithi
UON/HealthIT	Benzer Bett

UON/HealthIT	Teresia Wangui
FHI360	Dorothy Muruki
I-TECH Kenya	George Owiso
Palladium	Dr. Jacob Odhiambo
HIGDA	Rose Nzyoka
HIGDA	James Kwach
HIGDA	Fredrick Onyango
HIGDA	John Gichangi
HIGDA	Martin Kinyua
PATH	Priscah Teka
Tupime Kaunti	Lilian Mageto
Tupime Kaunti	Hesbon Ooko
Clinton Health Access Initiative	Betty Wariari
RTI	Dr. Martin Osumba
JKUAT	Dr. Ruben Thuo
JKUAT	Prof. Fred Wamunyokoli
JKUAT	Prof. Simon Karanja
JKUAT	Dr. Agnes Mindila
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EMR implementer	Dennis Henry
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