



REPUBLIC OF UGANDA

MINISTRY OF HEALTH

STRENGTHENING UGANDA'S HEALTH SYSTEM THROUGH STANDARDIZING DIGITAL HEALTH

**Requirements for Digital Health Standards
and Enterprise Architecture Framework**

December 2021



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Enterprise Architecture Framework*

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LIST OF ACRONYMS

DH-ASK	Digital Health Architectures, Standards, and Knowledge products/eRegistries
DHIS	District Health Information System
eHealth	Electronic Health
EMR	Electronic Medical Records
HIS	Health Information System
ICT	Information and Communication Technologies
IP	Implementation Partners
MoH	Ministry of Health
PEPFAR	Presidents' Emergency Plan for AIDS Relief
OpenMRS	Open Medical Records System
UgandaEMR	Uganda Electronic Medical Records
WHO	World health Organization

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Hon Dr. Jane Ruth Aceng
Minister of Health



FOREWORD

The Government of the Republic of Uganda recognized the use of information and communication technology (ICT) in the National Development Plan III 2020/21 - 2024/25 as an enabler to improve the delivery of services to its citizens across its sectors. The Ministry of Health Strategic Plan 2020/21 – 2024/25 has also recognized eHealth as a key enabler for supporting the health system in order to deliver good health to the population. In addition, the National eHealth Policy 2016 provides guidance on how to use ICT to facilitate improvement in the flow of information, through electronic means, to support

the delivery of health services and the management of the health system in a bid to facilitate universal access to care, health sector efficiency, and social transformation.

Although the government, partners, and private institutions are continuing to invest in various ICT initiatives, without a national plan and coordination, development of a digital health enterprise architecture (EA) and adoption of digital health data standards, there is a risk of continued duplication, ineffective expenditure, and creation of new solutions that cannot be integrated or scaled across the continuum of care.

The Digital Health EA will guide the process of translating the health sector business vision and strategy into an effective health system (enterprise) change by creating, communicating, and improving the key principles and models that describe the health system's future state and enable its evolution. Whereas the digital/eHealth standards will facilitate the development of electronic Health Information Systems (eHIS); gathering, aggregating, analyzing and synthesizing of data from multiple sources to report on health situations and trends (disease burden, patterns of risk behavior, health service coverage and health system metrics). At the National level, the eHIS strategies will enhance improved decision-making, policy development, health services management, response to emerging threats and better allocation of health resources.

With the completion of this study by Makerere University in collaboration with the Ministry of Health on the requirements for standardizing digital health in Uganda's health sector; these requirements will guide the development of the digital health Enterprise Architecture and Data Standards that should standardize digital health in Uganda as such reinforcing health information management in Uganda's health system.

Dr. Diana Atwine
Permanent Secretary
Ministry of Health



PREFACE

The Ministry of Health recognizes the potential of information and communication technology (ICT) in transforming healthcare delivery by enabling information access and supporting healthcare operations, management, and decision making. However, Uganda's health sector is characterized by a fragmented landscape of ICT pilot projects and numerous data and electronic health information systems (eHIS) silos with significant barriers to the effective sharing of information between healthcare participants.

Although much of the data needed for clinical care, patient safety, and quality improvement resides on computers, there is no means to transfer these data easily and economically from one computer to another, despite the communications technologies to support such data exchange. The chief obstacle to achieving this capability is the availability of data standards for organizing, representing, and encoding clinical information so that the data can be understood and accepted by the receiving systems. At the level of the health facilities, the lack of common data standards has prevented information sharing for decision making purposes and continuum of care. The lack of standards has also prevented the reuse of clinical data to meet the broad range of patient safety and quality reporting requirements.

Accordingly, this handbook provides a set of requirements that should guide the development of the digital health standards and Enterprise Architecture (EA) in order to enhance health information management and decision-making processes across the health sector. Production of these requirements was achieved through a participatory process spearheaded by Makerere University Health Informatics Research Group in collaboration with the Ministry of Health led by Dr. Sarah Byakika (Commissioner, Health Services, Planning, Financing and Policy), Division of Health Information (DHI) and the HIRE (eHealth) Technical Working Group. We extend our profound appreciation to each of the contributors to these requirements for playing a key role in standardizing digital health to optimize Uganda's health system.

A handwritten signature in black ink, appearing to read 'H. Mwebesa', written over a horizontal line.

Dr. Henry Mwebesa

Director General, Health Services
Ministry of Health

THE RESEARCH TEAM

The research study was conducted by a team of seven researchers to understand the digital health landscape of Uganda's health system from which they developed digital health requirements that should inform the Government of the Republic of Uganda through the Ministry of Health on how best to strengthen its health system through standardizing its digital health.

PRINCIPAL INVESTIGATOR



Prof. Josephine Nabukenya is a Professor of Information Systems & Health Informatics in the School of Computing and Informatics Technology, Makerere University. She is the Founder and Chair of the Health Informatics Research Group. She is a member of the Uganda Health Information & Research (HIRE/eHealth) Technical Working Group, and Digital Health and Interoperability Working Group of Health Data Collaborative. She was part of the 10-member Core Team that developed the Uganda eHealth Policy and Strategy, and collaborating with the Ministry of Health (MoH) for its implementation. Josephine has over 19 years of research experience and published widely in Information Systems with a focus on health informatics and data science. She is currently leading research on: 1) Potential for Transforming Health in Uganda through an Electronic Health Data Sharing Platform and Data Science; 2) Development of an Evaluation Framework to Measure Performance Outcomes and Impact of Digital Health Interventions on Healthcare in Uganda; 3) Designing and Piloting of a Mobile-based Technology linking Mothers to Health Providers and Health Facilities to Reduce Maternal and New-born Deaths in Uganda during- and post- COVID-19 Pandemic; and 4) Implementing and Evaluation of a low-resource digital infrastructure in Uganda: Visualization and Interpretation of Radiographic Images to improve access to imaging services in regional referral hospitals.

CO-INVESTIGATORS



Dr. Andrew Kambugu is the Sande - McKinnell Executive Director, Infectious Diseases Institute, College of Health Sciences (CHS), Makerere University and is an honorary Senior Lecturer in the Department of Medicine at MakCHS. Andrew directed the HIV Clinic at the IDI for seven years. He is a Fellow of the Royal College of Physicians (FRCP), London, UK. His research interests include HIV treatment outcomes in resource-limited settings, as well as the diagnosis and management of opportunistic infections in these settings with a focus on cryptococcal meningitis and tuberculosis. He is a principal investigator on a number of clinical trials spanning the fields of HIV therapeutics, HIV treatment strategies and implementation science in Uganda.



Dr. Mercy Rebekah Amiyo is a Lecturer at the School of Computing and Informatics Technology, and Researcher in the Health Informatics Research Group, Makerere University. Her research interests focus on Information Systems, Business Process Management, Health Informatics and Data Management. She has led joint research in; 1) A Mobile Health Tool Combining Text and Voice to Support Tuberculosis Medication Adherence: A Case Study of Joint Clinical Research Center; 2) A HIE Model for Timely Reporting of Health Management Information System Data at Public Health Facilities in Kampala District, Uganda; 3) A Data Mart System for Patient Disease Diagnosis and Clinic Performance; Case study of TASO Entebbe HIV Clinic.

RESEARCHERS



Andrew Alunyu Egwar is a PhD student in the Health Informatics Research Group, School of Computing & Informatics Technology, Makerere University. His research focuses on computer and data communications, standardization of the digital health environment particularly the communication infrastructure that supports patient data sharing and health information exchange, securing patient data / health information in the eHealth system; as well as Collaboration Engineering for collaborative problem solving.



Moses Baygendera is a PhD student in the Health Informatics Research Group, School of Computing & Informatics Technology, Makerere University. His research focuses on the Interoperability for data use and utilization in health care institutions in Uganda. His research background is in both industry and academics with a strong international research reputation for his work on eHealth policy formulation, implementation and use in Africa and more specifically at WHO.



Achilles Kiwanuka is a PhD student in the Health Informatics Research Group, School of Computing & Informatics Technology, Makerere University. He has carried out research on the adoption and standardization of digital health technologies and systems. Currently, he is researching about how international eHealth medical coding standards can be contextualized to improve semantic interoperability in Uganda focusing on the three standards: Systemized Nomenclature of Medicine – Clinical Terms (SNOMED), Logical Observation Identifiers Names and Codes (LOINC) and International Classification of Diseases (ICD).



Joseph Wamema is a PhD student in the Health Informatics Research Group, School of Computing & Informatics Technology, Makerere University. His research is aimed at developing a digital health Enterprise Architecture Framework to streamline the digitalization of Uganda's healthcare system. He is particularly interested in research studies that focus on the interoperability of digital health Systems, barriers to successful adoption of digital health and the technology-fit of digital health in the African context. He has hands-on practical experience with Enterprise Architecture Frameworks such as The Open Group Architecture Framework (TOGAF) and Zachman framework.

1 EXECUTIVE SUMMARY

The contents of this handbook report on the requirements for the digital health standards and enterprise architecture. To derive these requirements, an exploratory study on the landscape for digital health in Uganda's Health System was conducted to understand the challenges that impeded digital health standardization and data use for action when managing HIV/AIDS and Tuberculosis (TB) diseases electronic health information systems.

The HIV/AIDS and TB diseases were chosen on grounds that several global and local interventions, though duplicated and disintegrated, electronic health information systems (eHIS) have been developed to manage the HIV/AIDS and TB. As such, the data about one patient have continued to be fragmented, sitting on several isolated digital health systems, lacking integration and support for such data to be used to inform patient care or make a clinical decision. In light of these, standardizing is required in order to facilitate proper implementations of eHISs that support health information exchange (HIE) across Uganda's health system.

Although, the broad goal of the Digital Health Architectures and Standards is to provide complete and reliable data standards and underpin decision-making processes around data use for action related to HIV/AIDS and TB; this study only focused on strengthening Uganda's health system through standardizing digital health by deriving requirements for the digital health standards and enterprise architecture. The derived requirements were validated through virtual walkthroughs and focus group discussions at national and sub-national levels. The requirements are categorized as; *i).* digital health standards, *ii).* digital health architecture, and *iii).* digital health capacity building. These requirements should guide the development of contextual Digital Health Standards and Enterprise Architecture framework for Uganda.

2 INTRODUCTION

2.1 BACKGROUND

This handbook provides a set of requirements for the digital health standards and enterprise architecture framework for Uganda's Health System. To derive these requirements, an exploratory study on the landscape for digital health in Uganda's Health System was conducted to understand the challenges that impeded digital health standardization and data use for action when managing HIV/AIDS and Tuberculosis (TB) diseases electronic health information systems. The HIV/AIDS and TB diseases were chosen on grounds that several global and local interventions (i.e., Uganda Government and Development Partners) as well as enormous investments have been made to control the epidemic (Ministry of Health-Uganda, 2010). Particularly, various though duplicated and disintegrated, electronic health information systems (eHIS) have been developed to manage the HIV/AIDS and TB. As such, the data about one patient have continued to be fragmented, sitting on several isolated digital health systems, lacking integration and support for such data to be used to inform patient care or make a clinical decision. Besides the pilotitis, Huang, Blaschke, & Lucas, (2017) painted a very grim picture of Uganda as having multiple and fragmented implementations of digital health systems lacking scalability beyond the pilot phase that needs to be reversed. In light of these, standardizing is required in order to facilitate proper implementations of eHISs that support health information exchange (HIE) across Uganda's health system.

An estimate of 6.7% of the Ugandan adult population have been diagnosed as currently living with HIV (Uganda AIDS Commission, 2017). Notably, PEPfAR sponsors 80% of the resources for Uganda's HIV/AIDS response, which places great emphasis on the use of data-driven approaches to facilitate decision-making ensuring appropriate interventions are implemented in relevant populations in the right way (PEPFAR, 2019). The data-driven approach has been facilitated by the development and implementation of various eHIS called electronic medical records (EMRs) (METS, 2019; Ministry of Health-Uganda, 2016), to facilitate tracking of People Living with HIV/AIDS (PLHAs) through HIV treatment cascade and guiding clinical decision-making.

Uganda's MoH have numerous EMR-based eHIS initiatives including OpenMRS/ Uganda Electronic Medical Records (UgandaEMR), Integrated Clinic Enterprise Application (ICEA), DHIS2, OptionB+ that are used for data reporting, documenting and management of HIV and TB patient care, within different health system levels (Ministry of Health-Uganda, 2016). However, translating data into effective use for decision-making and policy development remains a challenge.

Although, the broad goal of the Digital Health Architectures, Standards, and Knowledge products/eRegistries (DH-ASK) is to provide complete and reliable data standards and underpin decision-making processes around data use for action related to HIV/AIDS and TB; this study only

focused on strengthening Uganda's health system through standardizing digital health by deriving requirements for the digital health standards and enterprise architecture framework. The derived requirements will be used to develop contextual Digital Health Standards and Enterprise Architecture Framework for Uganda.

To achieve this objective, we explored Uganda's digital health system to (1) determine impediments to accessing reliable, timely and integrated patient data through investigating the processes for collection, analysis, and presentation of data across various healthcare sites; (2) establish the state of current practice regarding data standards for monitoring and evaluating healthcare interventions in HIV/AIDS and TB in Uganda's EMR-based HIS. The exploratory study helped to investigate how existing international digital health standards could be used to facilitate the development of contextual standardized digital health to improve data use for action within Uganda Health System, as stipulated in its eHealth Policy and Strategy (2016/17-2020/21), other aligned policies/plans including Uganda's National Development Plan (2015/16–2019/20), Uganda Vision-2040; Health Sector Development Plan (2015/16–2019/20) on digital health development and implementation in Uganda; WHO global strategy on digital health (2020-2024) where standardizing eHIS is among the primary health systems strengthening building blocks; UN-SDG 3 to "ensure healthy lives and promote well-being for all at all ages", one of its targets being elimination of epidemics related to infectious diseases.

Accordingly, from the exploratory study, we identified the challenges in the digital health environment in Uganda which are presented in Appendix 2.0. The challenges guided the development of requirements for standardizing digital health in Uganda as presented in this handbook.

2.2 METHODOLOGY

This study followed the cross-sectional research design, with a case study of the HIV/AIDS and TB disease model in Uganda's healthcare system. The HIV/AIDS and TB disease model was adopted because of the heavy reliance in use of eHIS. Four geographical regions of Uganda (Kampala/Wakiso, Northern, West Nile, and Mid-Western) representing the full spectrum of HIV and TB prevalence were included in this study. Additionally, the case study included two HIV/AIDS program implementing partners i.e., Makerere University Infectious Disease Institute (IDI) and the Monitoring Evaluation Technical Support (METS), since both institutions have experienced some challenges transitioning from purely paper-based to hybrid medical records systems (i.e., ICEA and OpenMRS/UgandaEMR, respectively).

The study was conducted at both national and sub-national levels of Uganda's healthcare system. At the sub-national level, 28 health facilities drawn from National Referral Hospitals (NRHs), Regional Referral Hospitals (RRHs), District Hospitals (DHs), and Health Center Fours (HC IVs) participated in the study. A health facility was chosen to participate in the study if it was in the Northern, North-Western, Western or Central regions of Uganda. Additionally, a health facility was chosen if they had adopted and implemented an eHIS of some nature and or were a Makerere University IDI supported site. Table 1 shows the study sites.

Table 1. Distribution of Study Sites, Government MDAs and Healthcare Implementing Organizations

Subnational level – Health Facilities							
Region	Districts	Health Facilities	Classification				
			RRH	NRH	HC IV	PNFP	Total
Central	Kampala, Wakiso	Entebbe RRH, Kasangati HC IV, Kitebi HC IV, Namayumba HC IV, Ndege HC IV, Wagagai HC IV, Wakiso HC IV	1	0	6	0	7
Western	Hoima, Kibuye, Kibaale, Kakumiro	Kakindo HC IV, Kakumiro HC IV, Kikuube HC IV, Kigoroby HC IV, Kibaale HC IV, EMESCO HC IV, Hoima RRH	1	1	5	0	7
West Nile	Arua, Pakwach, Nebbi, Zombo	Adumi HC IV, Warr HC IV, Kuluva Hospital, River Oli HC IV, Nebbi Hospital, Omugo HC IV, Packwach Hospital	1	1	5	0	7
Nothern	Amuru, Gulu, Kole, Lira	Aboke HC IV, Amach HC IV, Atiak HC IV, Awach HC IV, Gulu RRH, Lira RRH, St. Mary's Lacor	2	0	4	1	7
National Level					MDA	HDP	TRI
MoH, NITA-U, MolCT, UNBS, UCC, NIRA, CPHL, WHO, UNICEF, IDI, MedicMobile, MEETS, MRC/UVRI, Mobile Telecom Companies, Makerere college of health sciences, Faculty of Medicine-Gulu University, and Mbarara University faculty of Medicine					7	6	4

We used questionnaires to discover what the digital health stakeholders thought about timely, reliable, and integrated access to patient data. Interviews were used as a follow-up to further authenticate and/or corroborate the responses. Additionally, we did a document analysis to establish the existing data standards from key stakeholders including Health Facilities (from the level of HC IVs and above), MoH, WHO-Uganda, and implementing partners. Permission to conduct

the study was sought from both the MoH and Makerere University School of Public Health Institutional Review Board (MaKSPH-IRB).

Both qualitative and quantitative data were collected using semi-structured interviews and questionnaires that had been programmed into the Open Data Kit (ODK) software. Subsequently, data analysis was performed using NVivo 12 (for qualitative data) and (for quantitative data).

The above process helped to identify challenges that impeded standardizing digital health in Uganda. These challenges were used to derive a set of requirements, and validated using both face-to-face and virtual walk-throughs and focus groups discussions. Relevant stakeholders (critical users of the Uganda eHealth systems) were engaged / walked-through to validate the derived requirements. The target participants were purposively selected and included 146 participants from the national and subnational study sites. National participants included policy makers, eHealth NGOs, M&E personnel, Health Development partners, research institutions, and Academicians whereas sub-national respondents included health facility administrators, clinicians, nurses, pharmacy personnel, laboratory personnel, medical records/ICT personnel and biostatisticians. Participation in the validation exercise involved different stakeholders as shown in Figure 1.

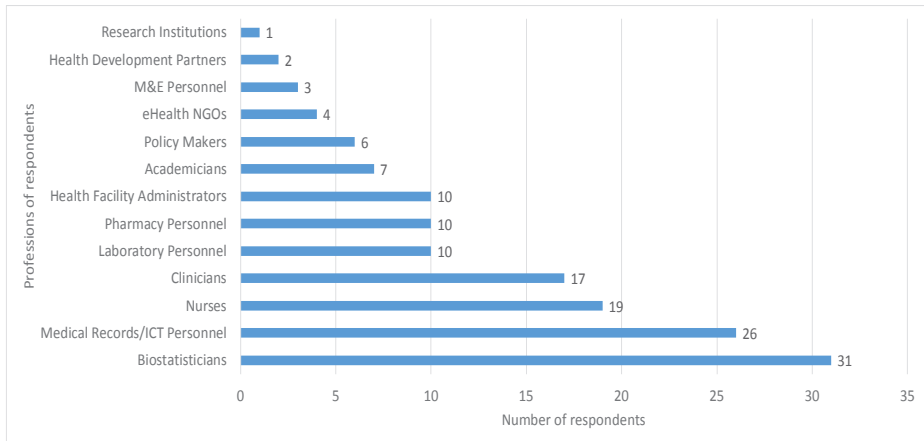


Figure 1. Distribution of Respondents by Category

3 REQUIREMENTS FOR STANDARDIZING UGANDA'S DIGITAL HEALTH

In light of the various challenges to the standardization of digital health in Uganda's health system (Alunyu et al., 2021; Kiwanuka et al., 2021), we derived and validated requirements to guide the development of the digital health standards and Enterprise Architecture (EA) framework. These requirements were also informed by literature and success stories in other countries in addition to the field study findings as shown in Appendix 2. The requirements are presented under three broad categories as follows;

- A. **Digital Health Standards** – are requirements that should be met by MoH when developing standards/guidelines/SOPs for patient and health data, standards for the communication infrastructure (ICT including devices, network and connectivity, and use), security and privacy standards, and when conducting the activities of the digital health standardization process.
- B. **Digital Health Architecture** – are requirements that should be met by MoH, Health Development Partners and other stakeholders to streamline digital health implementations and governance in Uganda.
- C. **Digital Health Capacity Building** – are requirements for building the human resources required to implement and use digital health. These includes requirements for ICT skills development and training, sensitization of healthcare professionals and health informaticians on emerging digital health trends, adopted technologies, and guidelines/SOPs, and training on the digital health standards itself and how to apply such standards.

3.1 DIGITAL HEALTH STANDARDS

Requirements for the digital health standards shall cover the scope of data standards (semantic and syntactic interoperability), the communication infrastructure that support HIE, and the security and privacy of both the patient data that is collected, and the components of the communication infrastructure. Table 2 presents the three main categories of the digital health standards.

Table 2. Categories of Requirements for Digital Health Standards

Code	Requirement Category	What for?
DHS_DS	Data Standards	Ensure that all parties use similar formats, language and approach to code, store, share, and interpret health information to support interoperability
DHS_CI	Communication Infrastructure	Standards / Minimum requirements to guide each party implement an electronic communication infrastructure that support reliable patient data sharing and HIE
DHS_SP	Security and Privacy	Guidelines for security and privacy measures that need to be taken

		into account during the implementation and use of the digital health communication infrastructure
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3.1.1 Data Standards

The following standards shall be applied to ensure that the patient (health) data collected, information processed, shared, and stored are in formats that support both semantic and syntactic interoperability.

Requirement DHS_DS01

DHS_DS01: Develop contextual comprehensive standards (SOPs/ guidelines/ frameworks) for sharing and exchanging electronic patient data; these should be based on the international standards for HIE (e.g., syntactic - HL7, IHE, FHIR, DICOM, and semantics - SNOMED, ICD, LOINC, MeDRA, etc.), and in alignment with the Uganda Data Protection and Privacy Act, 2019.

DHS_DS01 Requirement's Specification

- (i). The standards should be explicit about data sharing and exchange across the four domains including business, data, applications, security and technology.
- (ii). The standards should be implementable using the available resources (technical expertise, technology, infrastructure, finance etc.).
- (iii). The standards should be well documented and with a clear dissemination strategy.

Requirement DHS_DS02

DHS_DS02: Adopt digital health standards for electronic sharing and exchange of patient data.

DHS_DS02 Requirement's Specification

- (i). Develop guidelines on what and how to (harmonize) adopt digital health standards.
- (ii). Create regulatory frameworks that guide the adoption and implementation of digital health data exchange standards in **DHS_DS01**.
- (iii). Allocate resources for the adoption process for digital health standards.

3.1.2 Communication Infrastructure / Technology Standards

Four key requirements need to be met to realize the role of electronic health communication infrastructure to support reliable and timely exchange of patient data for the purposes of patient care and health information sharing for timely and informed decision making. The requirements are;

Requirement DHS_CI01

DHS_CI01: Develop minimum requirements for the acquisition and maintenance of ICT infrastructure for digital health.

DHS_CI01 Requirement's Specification

- (i). Specify minimum requirements for health facilities and agencies for acquiring ICT devices for digital health.
- (ii). The minimum requirements for health facilities and agencies for acquiring communication infrastructure for digital health should be contextual, ubiquitous and secure to enable protection, privacy and confidentiality of shared data.
- (iii). The guidelines should specify topologies, protocols, middleware, security and privacy mechanisms.
- (iv). The guidelines should specify a set of administrative, technical and managerial actions that should be applied during the lifecycle of the digital health infrastructure.

Requirement DHS_CI02

DHS_CI02: Establish Memoranda of Understanding (MoUs) with Internet Service Providers (ISPs) to provide quality service.

DHS_CI02 Requirement's Specification

- (i). Specify the terms for zero rating of healthcare services by telecommunication service providers.
- (ii). Specify the expected quality of service to support healthcare communication in Uganda's healthcare system.

Requirement DHS_CI03

DHS_CI03: Develop a funding model for the digital health communication infrastructure for health facilities.

DHS_CI03 Requirement's Specification

- (i). The model should specify critical areas of infrastructure to be funded, possible sources of funding and the responsible authorities.

Requirement DHS_CI04

DHS_CI04: Develop/operationalize a policy on cost effective energy alternatives like renewable energies/solar for essential systems and equipment for digital health.

DHS_CI04 Requirement's Specification

- (i). The policy should emphasize the use of diverse sources of energy focusing on clean energy (renewable energy) such as solar, wind, water (hydro), biomass, and geothermal.

3.1.3 Security and Privacy Standards

The scope of digital health security includes authentication, data integrity, system security and network/Internet security. Therefore, for Uganda to ensure digital health security and privacy of its data systems, the following requirements should be met.

Requirement DHS_SP01

DHS_SP01: Adopt officially the digital health data security guidelines to support the core data security elements of confidentiality, integrity, and availability.

DHS_SP01 Requirement's Specification

- (i). The guidelines for digital health data security should be tailored towards the digital health strategy for Uganda as well as the Uganda Data Protection and Privacy Act 2019, and international information security standards such as ISO/IEC 2700 series among others; outlining how the cardinal principles of confidentiality, integrity, and availability (CIA) should guide policies/controls designed to protect health data.
- (ii). The guidelines should specify a mechanism for monitoring implementation and enforcing compliance with health data security controls.

Requirement DHS_SP02

DHS_SP02: Develop a digital health information security and privacy standard/guideline to ensure all health facilities deploy security and privacy measures that protect privacy and confidentiality of electronic patient data.

DHS_SP02 Requirement's Specification

- (i). The security and privacy standard/guideline should outline how the cardinal principles of confidentiality, integrity, and availability should guide policies/controls designed to protect health data.
- (ii). The standard should define the full scope of digital health security and data privacy measures that goes beyond physical security to identifying health information and related assets plus potential threats, vulnerabilities and impacts.
- (iii). The security and privacy standard/guideline should have clear indicators for compliance with the Uganda Data Protection and Privacy Act.

- (iv). The security and privacy standard/guideline should outline how personal identifiable data can be protected.
- (v). The security and privacy standard/guideline should have an M&E plan specifying how risks faced by health data residing on digital health systems can be mitigated.
- (vi). Also, the guidelines for digital health data security should be tailored towards the digital health strategy for Uganda as well as the Data Protection and Privacy Act 2019, and international information security standards such as ISO/IEC 2700 series among others; outlining how the cardinal principles of confidentiality, integrity, and availability (CIA) should guide policies/controls designed to protect health data.

3.2 THE DIGITAL HEALTH STANDARDIZATION PROCESS

To keep abreast with developments in technology, standards are reviewed from time to time. Also, it is important to ensure proper implementation and monitoring of compliance with agreed-upon standards. The entire process that entails standards determination, implementation, compliance monitoring and review is what is referred to as the standardization process. The requirements for the process of standardization of digital health in Uganda include the following.

Requirement DHP_SP01

DHP_SP01: Develop a framework to aid the development of digital health standards to address interoperability of eHIS.

DHP_SP01 Requirement's Specification

The framework should;

- (i). Specify components of the digital health interoperability platform.
- (ii). Specify criteria for determining suitable standards for syntactic (rules and format) and semantic (shared meaning) interoperability.
- (iii). Clearly define a systematic process to guide the MoH and stakeholders who are selecting/determining the digital health standards.
- (iv). Properly articulate the implementation plan for digital health standard.
- (v). Specify criteria and tools for testing / validating the standards.
- (vi). Have a clear M&E plan including who conducts it, frequency, and criteria.
- (vii). Have a clear strategy for the selection and composition of stakeholders who participate in the digital health standardization process.

Requirement DHP_SP02

DHP_SP02: Create a collaborative platform where all stakeholders can participate online in the development, review and/or monitoring compliance with digital health standards.

DHP_SP02 Requirement's Specification

- (i). Avail centralized (online) resources and tools to support interaction and/or group decisions when developing/reviewing digital health standards.
- (ii). Develop a mechanism for determining stakeholders to participate in the development, review and compliance monitoring process.
- (iii). Identify and allocate financial resources to support the digital health standards development and review process.
- (iv). The collaborative platform should have guidelines on user involvement specifying how users / stakeholders will be involved in initiation activities (readiness assessment, requirements elicitation, capability assessment), adoption / adaptation / development processes, and implementation of digital health.

3.3 DIGITAL HEALTH ENTERPRISE ARCHITECTURE

The purpose of the digital health (eHealth) EA is to support the deliberate development of digital health technical architecture, technologies and operational capabilities of the health system in a standardized and aligned manner. To achieve this purpose, two main categories of requirements have been developed as see in Table 3.

Table 3. Categories of Requirements for the Digital Health Enterprise Architecture

Code	Requirement Category	What for??
DHA_IM	Digital health Implementations	To ensure that there is interoperable implementations of the digital health applications that support HIE across the entire health system
DHA_GS	Digital health Governance Structures	To ensure that there are rules and stakeholders play their roles and responsibilities to achieve national digital health policy

Requirement DHA_IM01

DHA_IM01: Develop a digital health Enterprise Architecture (EA) framework to guide standardized implementation of digital health in the country.

DHA_IM01 Requirement's Specification

The EA Framework should;

- (i). Outline digital health EA vision and principles.
- (ii). Outline the Business Reference Model (BRM), Service Reference Model (SRM), Data Reference Model (DRM), Application Reference Model (ARM) and Technology Reference Model.
- (iii). Detail the digital health Information Security Architecture.
- (iv). Outline digital health Interoperability profile.
- (v). Define a suitable HIE model.
- (vi). Determine a suitable criterion for readiness assessment.
- (vii). Outline the digital health implementation plan (Transition Architectures).and processes
- (viii). Outline the digital health skills model for Uganda.
- (ix). Outline digital health impact assessment criteria.
- (x). Be aligned (specify what and how) to the eGovernment EA for Uganda.

Requirement DHA_IM02

DHA_IM02: Develop guidelines on user involvement in the design, development and implementation of digital health.

DHA_IM02 Requirement's Specification

- (i). The guideline on user involvement should specify how users / stakeholders will be involved in initiation activities (readiness assessment, requirements elicitation, capability assessment), adoption / adaptation / development processes, and implementation of digital health.

Requirement DHA_IM03

DHA_IM03: Develop guidelines on digital health applications designing and development to support the integration of the eHIS in order to ease seamless sharing of patient health data.

DHA_IM03 Requirement's Specification

The guidelines should;

- (i). Specify a common structure for data capture
- (ii). Specify modes for linking (sharing) health data from one digital health application with another applications
- (iii). Clearly stipulate mechanisms for testing and evaluating digital health applications before committing to use.

Requirement DHA_IM04

DHA_IM04: Develop a health data reference model to describe data from healthcare processes independent of current indicator definitions.

DHA_IM04 Requirement's Specification

The health data reference models should;

- (i). Map all healthcare business processes to determine relevant data entities.
- (ii). Include a class model of the main data items (the healthcare process data entities) and their relationships.

Requirement DHA_IM05

DHA_IM05: Develop a strategy for migrating paper-based health records to electronic formats that cannot only be easily stored but also accessible in an integrated manner.

DHA_IM05 Requirement's Specification

The strategy should stipulate;

- (i). Acceptable digital formats for capturing patient health data.
- (ii). Procedure to be followed to ensure that the quality of patient data is not compromised during the migration process (i.e., process of transforming manual records to the digital formats).
- (iii). Acceptable forms of electronic health data storage devices (hard drive disk, Compact Disc (CD), DVD and Blu-ray Discs, USB Flash drive, or tapes) and storage sites such as cloud storage and offsite storage.

Requirement DHA_GS 01

DHA_GS01: Develop and operationalize a digital health governance framework to oversee the development and implementation of ICT at all levels of the health sector in Uganda's health system.

DHA_GS 01 Requirement's Specification

The digital health governance framework should specify;

- (i). Roles and responsibilities of the digital health governance structure as well as the governance processes.

- (ii). How the digital health governance teams are to be empowered and or provided with resources to oversee development, and implementation of digital health standards.

Requirement DHA_ GS 02

DHA_GS02: The responsible authority/unit should be empowered to monitor compliance of digital health standards at all levels.

DHA_ GS 02 Requirement's Specification

- (i). In addition to specification of requirements in DHA_GS01 (i) and (ii);
- (ii). The responsible authority/unit should be provided with resources to monitor compliance to digital health guidelines at all levels.
- (iii). The technical capacity of the responsible authority/unit should be strengthened and empowered to monitor compliance to digital health guidelines at all levels.

Requirement DHA_ GS 03

DHA_GS03: Develop a compliance framework for digital health standards.

DHA_ GS 03 Requirement's Specification

The digital health standards compliance framework should;

- (i). Identify / specify stakeholders to the compliance monitoring process.
- (ii). Have enforcement mechanisms for compliance to digital health standards.
- (iii). Have criteria for assessing risk of non- compliance with digital health standards.
- (iv). Provide a mechanism for monitoring and reviewing compliance with digital health standards.
- (v). Provide a procedure for reporting level of compliance with digital health standards.

Requirement DHA_ GS 04

DHA_GS04: Sensitize the health workers on the requirements for monitoring compliance and structures for digital health.

DHA_ GS 04 Requirement's Specification

- (i). Develop a roadmap for sensitizing health workers on requirements for monitoring compliance and structures for digital health.

3.4 DIGITAL HEALTH CAPACITY BUILDING

Being a developing field, healthcare practitioners require training in the use of digital health technologies and the application of digital health standards. Ways in which skills and knowledge regarding digital health and standards can reach the expected persons are categorized into ICT skills and training, training in digital health standards, and sensitization of stakeholders regards digital health applications, technologies and standards (see Table 4).

Table 4. Categories of Requirements for Building Capacity to use Digital Health and Standards

Code	Requirement Category	What for?
DHC_IT	ICT skills & Training	Equip practitioners with the required computer skills to use digital health technologies with level of comfort
DHC_ST	Digital Health Standards Training	Equip practitioners with knowledge of digital health standards adopted/contextualized for use in Uganda's Health system
DHC_SN	Digital Health Sensitisation	Introduce, orient and or familiarize DH implementers and users with new/emerging digital health applications and technologies

Requirement DHC_IT01

DHC_IT01: Develop training guidelines for health workers on basic ICT Skills and digital health Information management.

DHC_IT01 Requirement's Specification

- (i) The specialized digital health training may include short courses on electronic health data coding, digital health applications development, digital health data security and privacy, digital health standards, digital health EA and emerging digital health technologies.

Requirement DHC_IT02

DHC_IT02: Advocate for digital health courses to be incorporated in health workers' training curricula.

DHC_IT02 Requirement's Specification

- (i). The in-service training curricula should incorporate short courses on electronic health data coding, digital health applications, digital health data security and privacy, digital health standards, EA, Emerging digital health technologies, etc.
- (ii). The pre-service training curricular /training programmes may focus on technology literacy and usage skills; literacy in medical and digital health terminologies; digital health standards; information and data literacy; security and privacy Literacy; digital

communication; digital health products and services; regulation and compliance (implementation); healthcare business processes; networking and programming; and data analytics.

- (iii). The MoH should work / collaborate / partner with HEI/Academia to review their health sciences programmes to include / accommodate digital health courses for pre-service health workers.

Requirement DHC_ST01

DHC-ST01: Develop training guidelines for health workers on basic ICT Skills and digital health Information management.

DHC_IT01 Requirement's Specification

- (i) The specialized digital health training may include short courses on electronic health data coding, digital health applications development, digital health data security and privacy, digital health standards, digital health EA and emerging digital health technologies.

Requirement DHC_SN01

DHC_SN01: Sensitize all relevant stakeholders at national and sub-national levels on the data exchange and sharing standards in **DHS_DS01**.

DHC_SN01 Requirement's Specification

- (i). Develop a roadmap for nationwide sensitization and campaigns on data sharing and

4 CONCLUSION AND RECOMMENDATIONS

Despite the numerous implementations of digital health technologies in Uganda, most of them have only stopped at the pilot level. Some have lived beyond the donor sponsorship, though with interoperability and data use problems. It is to this end that the study sought to unravel the challenges to digital health implementations that continues to hamper success in Uganda's health system. The study further derived requirements for developing the Digital Health Enterprise Architecture (EA) and Standards Framework. The requirements were validated by digital health stakeholders in Uganda, and accordingly can be used by the MoH, Health Facilities and Digital Health implementers in the development of the digital health EA and standards for Uganda's health system. To this end, using the validated requirements, the next step is to develop a Digital Health EA and Standards Framework that can be used to standardize and strengthen Uganda's Digital Health System.

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APPENDICES

APPENDIX 1: THE DIGITAL HEALTH LANDSCAPE IN UGANDA

A. Study Sites

The study explored the digital health situation in Uganda to determine (1) challenges to assessing reliable, timely and integrated patient data healthcare sites and (2) the state of practice about digital health standards. The study was conducted at both national and sub-national levels. The study site for subnational data collection included districts in Central, Mid-Western, Northern and West-Nile regions of Uganda (Figure 2).

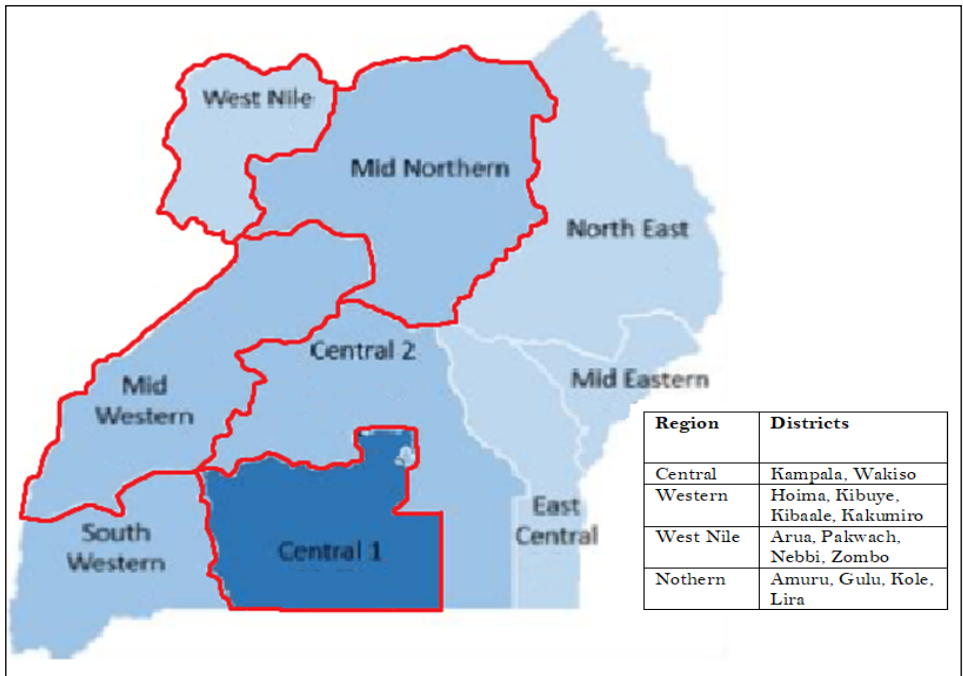


Figure 2. The Study Sites

B. Respondent Distribution

Overall, two hundred and one (201) responses were obtained from healthcare providers and key digital health stakeholders including MoH, HDPs, digital health collaborating MDAs and researchers. Figure 3 shows the distribution of their participation.

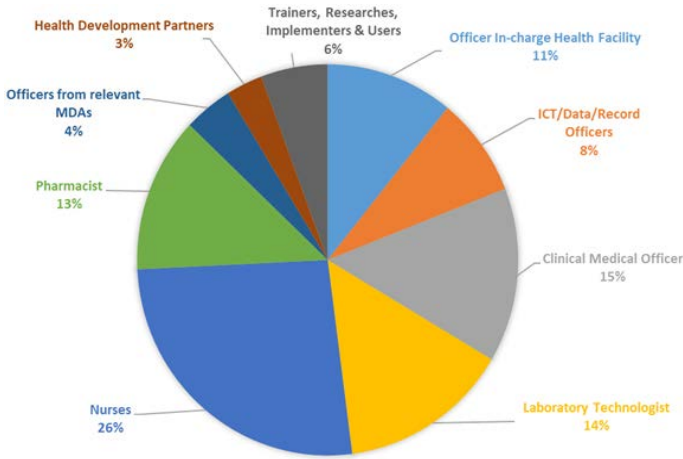


Figure 3. Participation in the exploratory study of Uganda's digital health system

C. Challenges to Reliable, Timely, and Integrated Patient data

The study identified several impediments to digitizing healthcare in Uganda which have been categorized into technology-related impediments; inadequate skills, knowledge and training on digital health; and healthcare organizational environment.

Technology-related Impediments

Major gaps in the technology field relates to the characteristics of existing digital health applications, technology and infrastructure being used in the studied health facilities. Figure 4 shows respondents agreed that 2 out of 7 characteristics existed in the currently used digital health applications/infrastructure to support reliable, timely and integrated patient data.

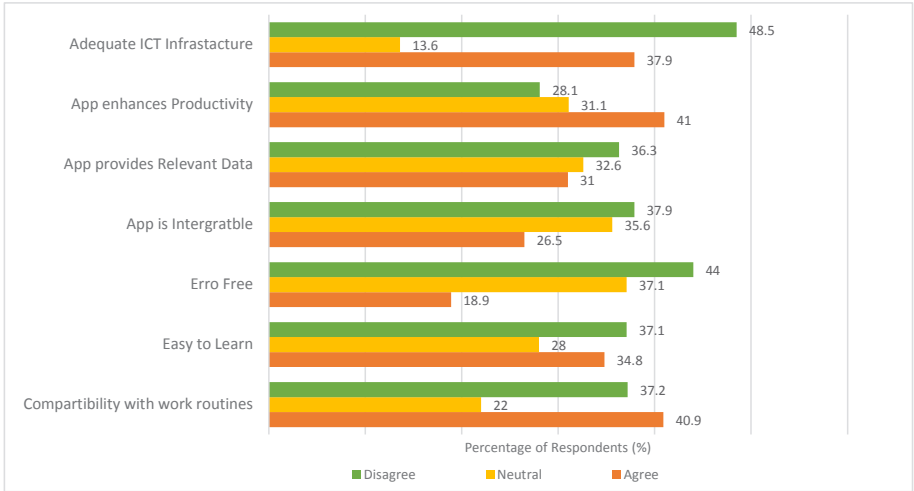


Figure 4. Characteristics that make digital health applications suitable to support healthcare processes in health facilities

Inadequate Skills, Knowledge and Training on Digital health

User skills and knowledge were found to be inadequate in most health facilities as reflected in their lack of confidence and minimal expertise to use digital health applications (see Figure 5). Majority of respondents disagreed on having been trained on use of digital health applications.

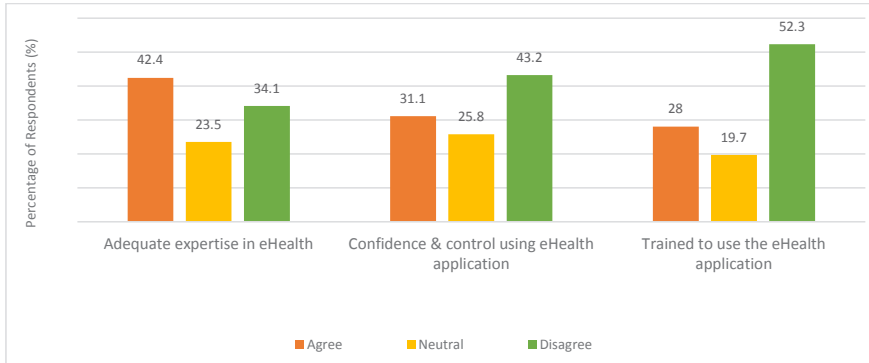


Figure 5. Capacity in Using Digital health Applications/Technologies in Healthcare Processes

Healthcare Organizational Environment

Although Figure 6 shows that management prepares an implementation plan and implementation agencies coordinates it and Figure 7 shows that management totally support digital health; challenges were shown to remain (lack of majority agreement/those who remained neutral) with structures for governance of digital health implementation and compliance monitoring.

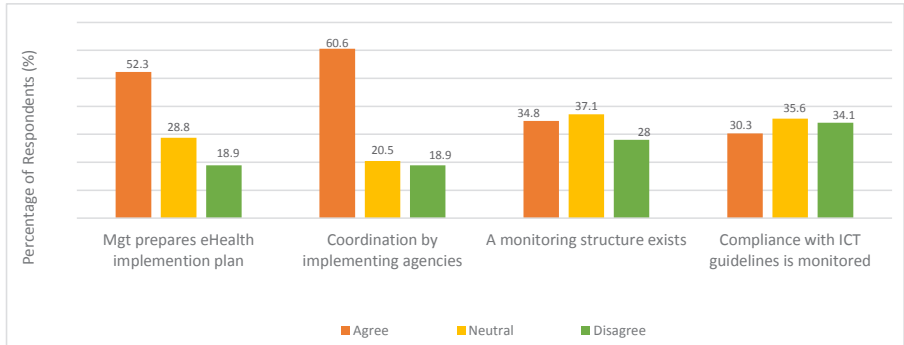


Figure 6. Digital Health governance factors that affect management of electronic patient data

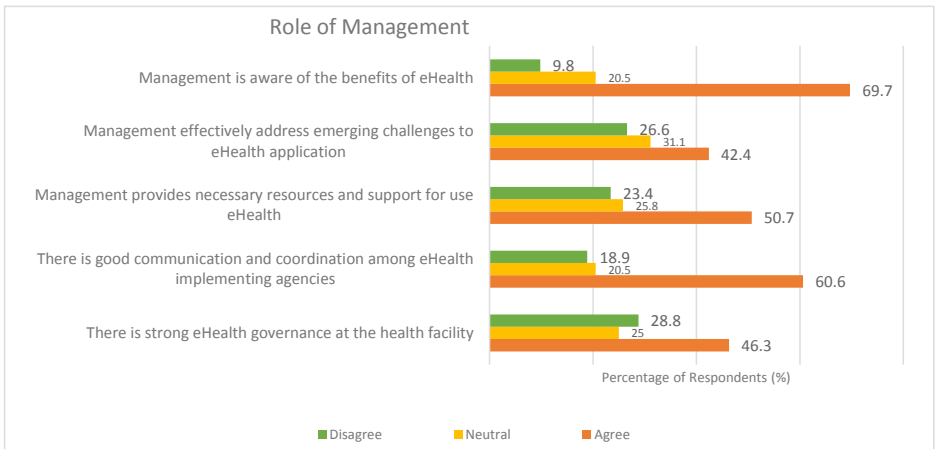


Figure 7. Role of Management to Support of Implementation and Use of Digital Health Applications/Technologies at Health Facility

D. State of Practice about Digital Health Standards

We categorized digital health standards as medical coding, data exchange and sharing, and supporting communication infrastructure, and data security and privacy standards. In addition, we also explored the process that produces the standards, i.e., the standardization process.

Medical Coding

Figure 8 shows the perception of digital health stakeholders regarding state of medical coding standards in the digital environment in Uganda.

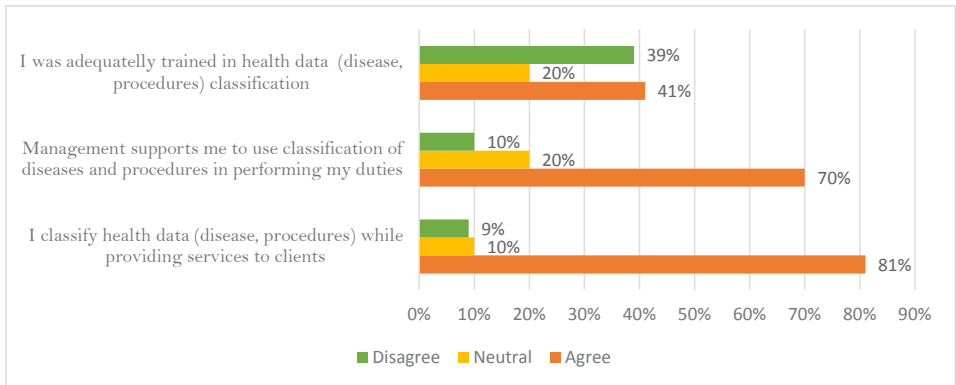


Figure 8. Perception of Coding Practices by Health Worker

Data Exchange and Sharing

Regarding data exchange, we identified a few standards that have been adopted by NITA-U or MoH to support HIE and the electronic communication infrastructure. Table 5 shows reported state of standards for components of the digital health communication infrastructure that is required to support health information exchange. These were found to be restricting and largely not applicable as is to our limited resource environment.

Table 5. Electronic Communication Infrastructure Standards

Category	Standard
Health Informatics	US ISO 17090-1:2013 - Public key infrastructure - Part 1: Overview of digital certificate services
	US ISO 17090-2:2008 Public key infrastructure - Part 2: Certificate Profile
	US ISO 17090- 3:2008 - Public key infrastructure - Part 3: Policy management of certification authority
Data Management and Interchange	US ISO IEC 9075-2: 2011 - Information Technology – Database Languages - SQL - Part 2: Foundation (SQL/Foundation)

	US ISO IEC 9075-11: 2011 - Information Technology – Database Languages - SQL - Part 11: Information and Definition Schemas (SQL/Schemata)
	US ISO IEC 9075-14: 2011 Information Technology – Database Languages - SQL - Part 14: XML –Related Specifications (SQL/XML)
Telecommunications and Information Exchange between Systems	US ISO IEC 9594-8:2008 - Information Technology - Open Systems Interconnection - The Directory: Public-key and Attribute Certificate Frameworks
Information and Documentation	US ISO IEC 15489-1:2016 - Records Management - Part 1: General
	US ISO 13008:2012 - Digital Records Conversion and Migration Process
	US 1717:2017 - Implementation Guidelines for Digitization of Records
Information Technology Service Management	US ISO IEC 20000-1: 2018 - Information Technology – Service Management - Part 1: Service Management System Requirements
	Guidelines and Standards for Acquisition of Information Technology Hardware & Software for Government Ministries, Departments and Agencies

Digital Health Data Security and Privacy

Figure 9 shows stakeholder views regards the state of digital health security and privacy concerns in the country. Whereas majority agree about the commitment of management regards information security, existence of security guidelines/controls, and that health data is valuable and needs to be protected, most were hesitant to agree that the electronic data that they handle are secure and privy.

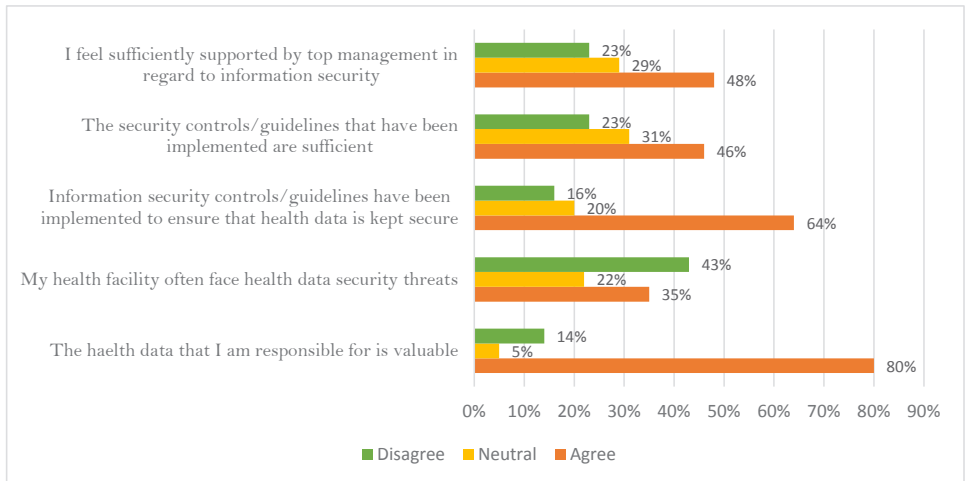


Figure 9. Perception of Digital Health Security at Health Facilities

Digital Health Standardization Process

The evidence in Figure 10 reveal issues from respondents concerning the process that the MoH goes through to develop, adopt or contextualize standards for the digital health environment. The respondents either disagreed or were uncertain about the process, team composition or stakeholder engagement in the process.

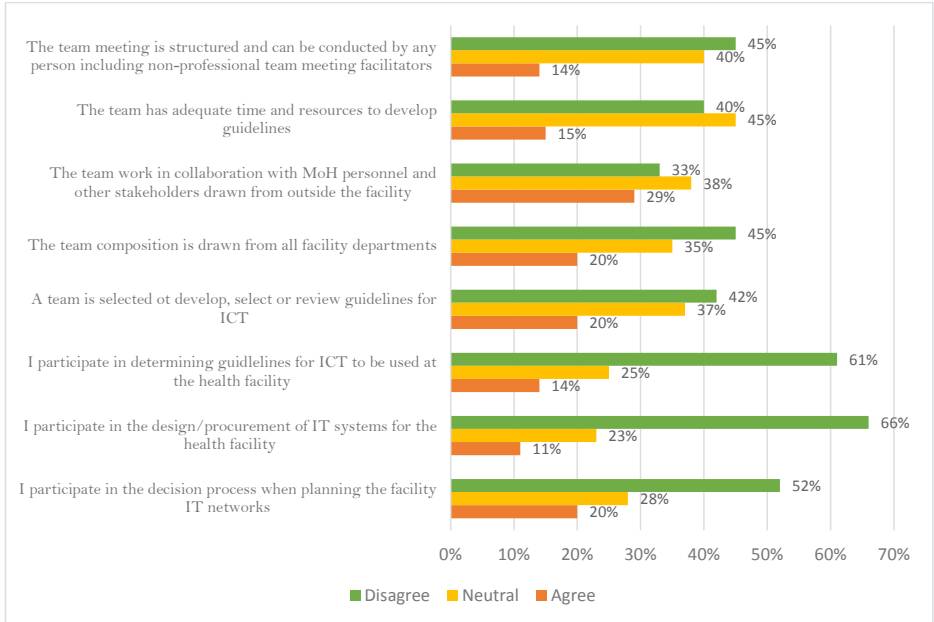


Figure 10. Perception of Digital Health Adoption and Standardization

Governance structures

Figure 11 shows that health facilities are willing to participate in decision-making and governance of the digital health environment, but most of the facility level digital health stakeholders feel their decisions are not sought regarding development and implementation of digital health technologies.

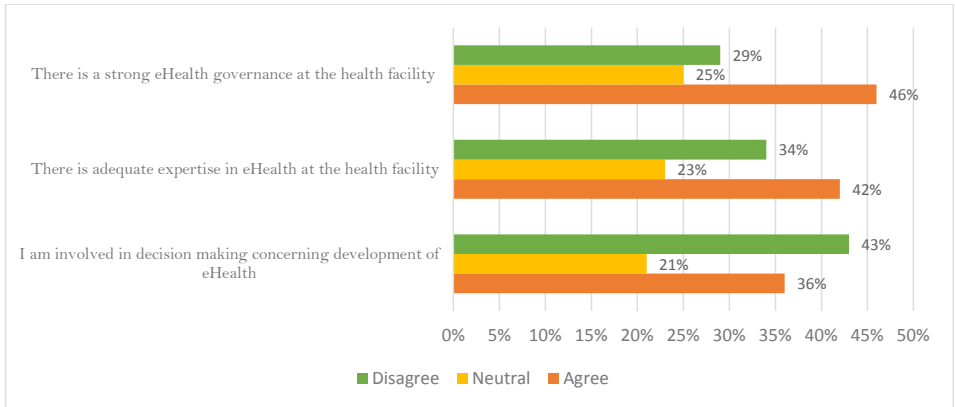


Figure 11. Governance Structure of Digital Health at Health Facilities

Compliance with Digital health Standards and Guidelines at the Health Facility and National Levels

Figure 12 shows there is great uncertainty about guidelines for implementing and monitoring use of ICTs at health facilities or about structures for compliance monitoring. In fact, end users are not familiar with guidelines that govern use of ICT in healthcare processes.

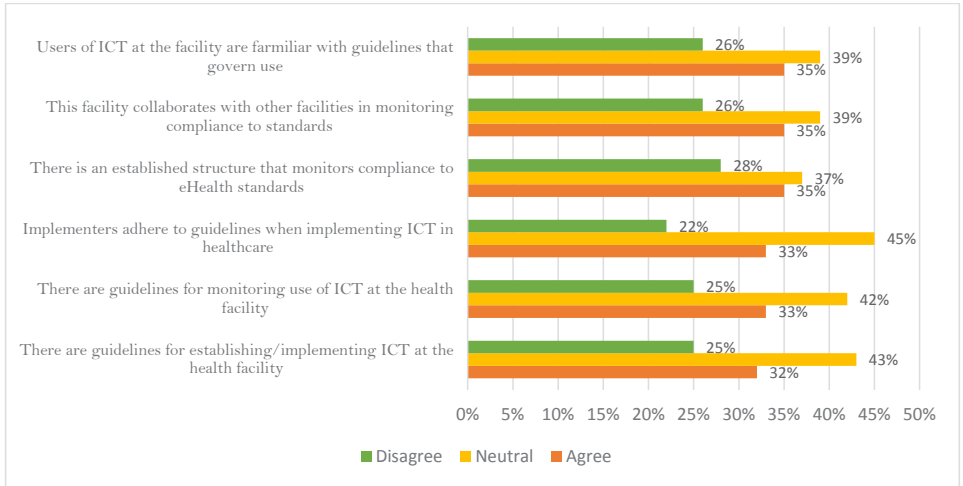


Figure 12. Compliance to Digital Health Standards at Health Facilities

APPENDIX 2: SUMMARY OF THE CHALLENGES AND REQUIREMENTS FOR STANDARDIZING UGANDA'S DIGITAL HEALTH SYSTEM

In Table 6, we present the Digital Health Standards and Enterprise Architecture requirements for standardizing Uganda's health system, which were derived from the challenges identified through an exploratory study of Uganda's digital health landscape. These requirements were validated and approved by digital health stakeholders in Uganda at the Ministry of Health through an e-Meeting.

Table 6. Requirements for Standardizing Uganda's Digital Health System

Challenges/Findings	Requirements	Requirements Specifications
A. Digital Health Enterprise Architecture		
A1. Digital Health Implementations		
<p>Implementations of digital health systems/applications at health facilities have not followed a standardised nor well-documented framework (in terms of digital health principles, reference models, interoperability requirements, capability assessment criteria and information security guidelines). This makes the implementations uncoordinated, fragmented, siloed, non-interoperable with duplicate functionalities and lacking security and privacy</p>	<p>A1.1: Develop and document an digital health Enterprise Architecture (EA) framework to guide standardized implementation of digital health in the country.</p>	<p>A1.1_RS1: The EA framework should outline digital health EA vision and principles.</p> <p>A1.1_RS2: The EA framework should outline the Business Reference Model (BRM), Service Reference Model (SRM), Data Reference Model (DRM), Application Reference Model (ARM) and Technology Reference Model.</p> <p>A1.1_RS3: The EA framework should detail the digital health Information Security Architecture.</p> <p>A1.1_RS4: The EA framework should outline digital health Interoperability profile.</p> <p>A1.1_RS5: The EA framework should define a suitable HIE model.</p> <p>A1.1_RS6: The EA framework should determine a suitable criterion for readiness assessment.</p> <p>A1.1_RS7: The EA framework should outline the digital health implementation plan (Transition Architectures).</p> <p>A1.1_RS8: The EA framework should outline the digital health skills model for Uganda.</p> <p>A1.1_RS9: The EA framework should outline digital health impact assessment criteria.</p> <p>A1.1_RS10: The digital health EA</p>

		framework should be aligned (specify what and how) to the eGovernment EA for Uganda.
Limited involvement in the design, development and implementation of digital health applications / technologies. This affects usage and acceptability of the digital health applications resulting from design-reality gaps, hence limited use (and or abandonment) of the applications to support healthcare processes	A1.2: Develop guidelines on user involvement in the design, development and implementation of digital health.	A1.2_RS1: The guideline on user involvement should specify how users / stakeholders will be involved in initiation activities (readiness assessment, requirements elicitation, capability assessment), adoption / adaptation / development processes, and implementation of digital health
The development of existing digital health applications is not guided by standards set out by MoH; therefore, they lack common format for data capture and modes of data integration resulting into multiple implementations that do not have the ability to integrate health data from all sources	A1.3: Develop guidelines on digital health applications designing and development to support/aid integration of the eHIS in order to ease seamless sharing of patient health data.	A1.3_RS1: The guidelines should specify a common structure for data capture A1.3_RS2: The guidelines should specify modes for linking (sharing) health data from one digital health application with another applications A1.3_RS3: The guideline should clearly stipulate mechanisms for testing and evaluating digital health applications before committing to use.
The changing (dynamic) indicator definitions provided by the MoH affect data collection and reporting in terms of inconsistencies, untimeliness, incomplete, not current and clean, causing poor data quality.	A1.4: Develop a health data reference model to describe data from healthcare processes independent of current indicator definitions.	A1.4_RS1: The health data reference model should map all healthcare business processes to determine relevant data entities. A1.4_RS2: The health data reference model should include a class model of the main data items (the healthcare process data entities) and their relationships.
The health facilities lack guidelines for transforming paper-based patient records into digital formats suitable for EMR; despite most of these health facilities first capturing health data on paper-based patient cards and registries and later entered into the HISs.	A1.5: Develop a strategy for migrating paper-based health records to electronic formats that cannot only be easily stored but also accessible in an integrated manner.	A1.5_RS1: The strategy should stipulate acceptable digital formats for capturing patient health data. A1.5_RS2: The strategy should stipulate procedure to be followed to ensure that the quality of patient data is not compromised during the migration process (i.e., process of transforming manual records to the digital formats). A1.5_RS3: The strategy should stipulate acceptable forms of

		electronic health data storage devices (hard drive disk, Compact Disc (CD), DVD and Blu-ray Discs, USB Flash drive, or tapes) and storage sites such as cloud storage and offsite storage.
A2: Digital Health Governance structures		
Digital health governance structures are not well streamlined and there is no committee or structures or personnel to oversee the development and implementation of ICT at all levels of the health sector.	A2.1: Develop and operationalize the digital health governance framework to oversee the development and implementation of ICT at all levels of the health sector in Uganda's health system.	A2.1_RS1: The digital health governance framework should specify roles and responsibilities of the digital health governance teams as well as the governance processes A2.1_RS2: The framework should specify how the HIIRE TWG of the MoH is to be empowered and or provided with resources to oversee development, implementation, and monitor compliance with digital health standards
There is lack of governance structures/framework to monitor compliance with standards and or guidelines for digital health	A2.2: The responsible authority/unit should be empowered to monitor implementation and compliance of digital health standards at all levels	In addition to A2.1_RS1 and A2.1_RS2; A2.2_RS1: The responsible authority/unit should be provided with resources to monitor compliance to digital health guidelines at all levels. A2.2_RS2: The technical capacity of the responsible authority/unit should be strengthened and empowered to monitor compliance to digital health guidelines at all levels
	A2.3: Develop a compliance framework for digital health standards.	A2.3_RS1: The digital health standards compliance framework should identify/ specify stakeholders to the compliance monitoring process. A2.3_RS2: The framework should have enforcement mechanisms for compliance to digital health standards. A2.3_RS3: The framework should have criteria for assessing risk of non- compliance with digital health standards

		<p>A2.3_RS4: The framework should provide a mechanism for monitoring and reviewing compliance with digital health standards</p> <p>A2.3_RS5: The framework should provide a procedure for reporting level of compliance with digital health standards</p>
	<p>A2.4: Sensitise the health workers on the requirements for monitoring compliance and structures for digital health</p>	<p>A2.4_RS1: Develop a roadmap for sensitizing health workers on requirements for monitoring compliance and structures for digital health.</p>
<p>B. Digital Health Standards</p>		
<p>B1: Data Standards</p>		
<p>Lack of comprehensive guidelines for sharing and exchanging electronic patient data (data and interoperability standards).</p>	<p>B1.1: Develop contextual comprehensive standards (SOPs/ guidelines/ frameworks) for sharing and exchanging electronic patient data; these should be based on the international standards for Health Information Exchange (e.g., syntactic - HL7, IHE, FHIR, DICOM, and semantics - SNOMED, ICD, LOINC, MeDRA, etc.), and in alignment with the Data Protection and Privacy Act, 2019.</p>	<p>B1.1_RS1: The standards should be explicit about data sharing and exchange across the four domains including business, data, applications, security and technology.</p> <p>B1.1_RS2: The standards should be implementable using the available resources (technical expertise, technology, infrastructure, finance etc).</p> <p>B1.1_RS3: The standards should be well documented and with a clear dissemination strategy.</p>
<p>The government of the Republic of Uganda developed e-government interoperability standards (SOPs and guidelines) for data sharing. However, these are yet to be customised for the various sectors including the health sector to support reliable, timely and integrated electronic health data sharing.</p>	<p>Refer to requirement B1.1</p>	<p>Same as specification of requirements B1.1_RS1; B1.1_RS2; and B1.1_RS3</p>
<p>The Ministry of Health has not officially adopted any digital health</p>	<p>B1.2: Adopt officially digital health standards for electronic sharing and</p>	<p>B1.2_RS1: Develop guidelines on what and how to (harmonise) adopt</p>

standards for electronic sharing and exchange of patient data despite some health centres already implementing them.	exchange of patient data.	digital health standards. B1.2_RS2: Create legislation and regulatory frameworks that guide adoption and implementation of digital health data exchange standards in B1.1 . B1.2_RS3: Identify and allocate resources for the adoption process for digital health standards.
B2: CI / Technology Standards		
The MoH has not specified minimum requirements for the acquisition and maintenance of ICT infrastructure for digital health.	B2.1: Develop minimum requirements for the acquisition and maintenance of ICT infrastructure for digital health.	B2.1_RS1: Specify minimum requirements for health facilities and agencies for acquiring ICT devices for digital health. B2.1_RS2: The minimum requirements for health facilities and agencies for acquiring communication infrastructure for digital health should be contextual, ubiquitous and secure to enable protection, privacy and confidentiality of shared data B2.1_RS3: The guideline should specify topologies, protocols, middleware, security and privacy mechanisms B2.1_RS4: The guidelines should specify a set of administrative, technical and managerial actions that should be applied during the lifecycle of the digital health infrastructure
	B2.2: Establish Memoranda of Understanding (MoUs) with Internet Service Providers (ISPs) to provide quality service	B2.2_RS1: The MoUs should specify terms for zero rating of healthcare services by telecommunication service providers. B2.2_RS2: The MoUs should specify expected quality of service to support healthcare communication in Uganda's healthcare system
Implementation of existing ICT infrastructure in health facilities is not adequate to support digital health processes; worse still, majority of the facilities cannot	B2.3: Develop a funding model for the digital health communication infrastructure for health facilities.	B2.3_RS1: The model should specify critical areas of infrastructure to be funded, possible sources of funding and the responsible authorities

afford to establish and maintain required ICT infrastructure.		
Health facilities experience unreliable energy sources (electric power) supply from the main grid and even where alternative sources/backups (generators, solar, UPS, etc) exist, these cannot sustain the digital health systems for a prolonged period of time	B2.4: Develop/operationalize a policy on cost effective energy alternatives like renewable energies/solar for essential systems and equipment for digital health	B2.4_RS1: The policy should emphasise the use of diverse sources of energy focussing on clean energy (renewable energy) such as solar, wind, water (hydro), biomass, and geothermal
B3: Security and Privacy Standards		
The MoH has not officially adopted any guidelines for digital health data security.	B3.1: Officially adopt digital health data security guidelines to support the core data security elements of confidentiality, integrity, and availability.	B3.1_RS1: The guidelines for digital health data security should be tailored towards the digital health policy and /strategy for Uganda as well as the Data Protection and Privacy Act 2019, and international information security standards such as ISO/IEC 2700 series among others; outlining how the cardinal principles of confidentiality, integrity, and availability (CIA) should guide policies/controls designed to protect health data. B3.1_RS2: The guidelines should specify a mechanism for monitoring implementation and enforcing compliance with health data security controls.
Health facilities do implement and/or use insufficient security and privacy measures for electronic health data; which may compromise/put at risk the privacy and confidentiality of patients' data.	B3.2: Develop an digital health information security and privacy standard/guideline to ensure all health facilities deploy security and privacy measures that protect privacy and confidentiality of electronic patient data.	B3.2_RS1: The security and privacy standard/guideline should outline how the cardinal principles of confidentiality, integrity, and availability should guide policies/controls designed to protect health data. B3.2_RS2: The standard should define the full scope of digital health security and data privacy measures that goes beyond physical security to identifying health information and related assets plus potential threats, vulnerabilities and impacts. B3.2_RS3: The security and privacy standard/guideline should have

		<p>clear indicators for compliance with the Data Protection and Privacy Act.</p> <p>B3.2_RS4: The security and privacy standard/guideline should outline how personal identifiable data can be protected</p> <p>B3.2_RS5: The security and privacy standard/guideline should have an M&E plan specifying how risks faced by health data residing on digital health systems can be mitigated.</p> <p>Specification of requirement in B3.1_RS1 should also be included</p>
B4: Standardization process		
<p>The MoH lacks a defined framework to aid the development of digital health standards; which resulted in implementations of several un-interoperable HIS.</p>	<p>B4.1: Develop a framework to aid the development of digital health standards to address interoperability of eHIS.</p>	<p>B4.1_RS1: The framework should specify components of the digital health interoperability platform.</p> <p>B4.1_RS2: The framework should specify criteria for determining suitable standards for syntactic (rules and format) and semantic (shared meaning) interoperability.</p> <p>B4.1_RS3: The framework should clearly define a systematic process to guide the MoH and stakeholders who are selecting/determining the digital health standards.</p> <p>B4.1_RS4: The framework should properly articulate the implementation plan for digital health standard.</p> <p>B4.1_RS5: The framework should specify criteria and tools for testing / validating the standards.</p> <p>B4.1_RS6: The framework should have a clear M&E plan including who conducts it, frequency, and criteria.</p> <p>B4.1_RS7: The framework should have a clear strategy for the selection and composition of stakeholders who participate in the digital health standardisation process.</p>
<p>Insufficient / limited and non-</p>	<p>B4.2: Create a collaborative platform</p>	<p>B4.2_RS1: Avail centralised (online)</p>

<p>inclusive participation of key stakeholders in the development, review and or monitoring compliance of digital health standards.</p>	<p>where all stakeholders can participate online in the development, review and/or monitoring compliance with digital health standards</p>	<p>resources and tools to support interaction and/or group decisions when developing/reviewing digital health standards. B4.2_RS2: Establish a mechanism for determining stakeholders to participate in the development, review and compliance monitoring. B4.2_RS3: Allocate finances to support the digital health standards development and review process. B4.2_RS4: The collaborative platform should have guidelines on user involvement specifying how users / stakeholders will be involved in initiation activities (readiness assessment, requirements elicitation, capability assessment), adoption / adaptation / development processes, and implementation of digital health.</p>
<p>C. Digital Health Capacity Building</p>		
<p>C1: ICT skills & Training</p>		
<p>The ICT skills related to digital health is inadequate among healthcare professionals at health facilities (In-charges, clinicians, nurses, laboratory technologists and pharmacists), both in terms of the numbers and skills mix/set.</p>	<p>C1.1: Develop training guidelines for health workers on basic ICT Skills and digital health information management.</p>	<p>C1.1_RS1: The specialised digital health training may include short courses on electronic health data coding, digital health applications development, digital health data security and privacy, digital health standards, digital health Enterprise Architecture and emerging digital health technologies.</p>
	<p>C1.2: Advocate for digital health courses to be incorporated in health workers' training curricula.</p>	<p>C1.2_RS1: The In-service training curricula should incorporate short courses on electronic health data coding, digital health applications, digital health data security and privacy, digital health standards, Enterprise Architecture, Emerging digital health technologies, etc. C1.2_RS2: The pre-service training curricular /training programmes may focus on technology literacy and usage skills; literacy in medical and digital health terminologies; digital</p>

		<p>health standards; information and data literacy; security and privacy Literacy; digital communication; digital health products and services; regulation and compliance (implementation); healthcare business processes; networking and programming; and data analytics.</p> <p>C1.2_RS3: The MoH should work / collaborate / partner with HEI/Academia to review their health sciences programmes to include / accommodate digital / digital health courses for pre-service health workers.</p>
C2: Digital Health Standards Training		
<p>Healthcare workers have inadequate training, experience and expertise in development, and/or use of digital health standards (i.e., medical coding, interoperability standards, CI standards, etc)</p>	<p>Same as requirement C1.2</p>	<p>Same as the specification of requirements 1.2_RS1 and C1.2_RS2</p>
C3: Digital Health Sensitisation		
<p>Limited awareness of the presence of data exchange and sharing standards at national and sub-national levels.</p>	<p>C3.1: Sensitise all relevant stakeholders at national and sub-national levels on the data exchange and sharing standards in B1.1.</p>	<p>C3.1_RS1: Develop a roadmap for nationwide sensitisation and campaigns on data sharing and exchange standards at all levels.</p>

APPENDIX 3: PUBLICATIONS & ACKNOWLEDGEMENTS

A. PUBLICATIONS

This research study has so far produced three (3) publications as detailed below:

1. Alunyu, A.; Wamema, J.; Kiwanuka, A.; Bagyendera, M.; Amiyo, M.; Kambugu, A. and Nabukenya, J. (2021). Investigating the Impediments to Accessing Reliable, Timely and Integrated Electronic Patient Data in Healthcare Sites in Uganda. In *Proceedings of the 14th International Joint Conference on Biomedical Engineering Systems and Technologies - Volume 5 HEALTHINF: HEALTHINF*, ISBN 978-989-758-490-9, pages 522-532. DOI: [10.5220/0010266705220532](https://doi.org/10.5220/0010266705220532)
2. Kiwanuka, A.; Bagyendera, M.; Wamema, J.; Alunyu, A.; Amiyo, M.; Kambugu, A. and Nabukenya, J. (2021). Establishing the State of Practice about Data Standards in Monitoring Healthcare Interventions for HIV in Uganda's EMR-based Health Information Systems. In *Proceedings of the 14th International Joint Conference on Biomedical Engineering Systems and Technologies - Volume 5 HEALTHINF: HEALTHINF*, ISBN 978-989-758-490-9, pages 200-211. DOI: [10.5220/0010264302000211](https://doi.org/10.5220/0010264302000211)
3. Amiyo, M.; Alunyu, A.; Kiwanuka, A.; Wamema, J.; Bagyendera, M.; Kambugu, A.; Nabukenya, J. (2021). Standards and Enterprise Architecture Requirements needed to Standardize Digital Health for Uganda's Health System. *Health Policy and Technology (submitted for review)*

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