Assessing the Interoperability of mLab and Ushauri mHealth Systems to Enhance Care for HIV/AIDS Patients in Kenya

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ABSTRACT

The core thesis of this study is to explore the legal and technological feasibility to interoperate two mobile health-based solutions in Kenya: Ushauri-Text for Adherence (T4A), and Mobile Laboratory (mLab), to enhance HIV/AIDS care and treatment. This paper focuses on two aspects namely data interoperability by analysing secondary data abstracted from the mLab and the Ushauri databases from June 2017 to June 2018 and doctrinal analysis of the legal and policy environment to support the interoperability. This paper is a case study of the mLab and the Ushauri systems in terms of the technological stack for interoperability which has some legal implications. It includes a pilot study that employed a multistage sampling method in which thirty-nine health facilities in Siaya, Homa bay, Nyeri, and Muranga were selected. Findings show a satisfactory legal environment to augment the interoperability of the two mHealth systems. It is also evident that the two systems were considerably interoperable in terms of technology, semantics, data, and processes. However, interoperating them could largely be compromised by language semantics leading to a discrepancy of characters and numbering in unique identifiers in data entry. Though data in the systems were for

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the same individuals, it is critical to note that there was a low level of concordance in patient identification numbers in the same facilities where the same patients were receiving clinical services. Additionally, healthcare workers across the various facilities did not follow the NASCOP (2010) eleven-digit unique identifier system. Standardizing human activities while using systems such as the allocation of patient identifiers and following laid down standards while developing systems are critical ways of ensuring interoperability. This paper highlights the need to achieve full-scale implementation of laid down policies and legal requirements such as the systems' interoperability certification process to standardise the systems and make them interoperable.

Keywords: Heath Systems, Interoperability, mHealth, mLab, Ushauri-T4A

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I. INTRODUCTION

The use of information communication technology (ICT) in healthcare delivery has gained global momentum (CDBPS, SURE, & EVIP Net, 2012; Blaya *et al.*, 2010). By the end of 2016, there were over 420 million unique mobile phone subscribers in Sub-Saharan Africa (GSM Association, 2017). The increasing affordability of new devices; improved technology, and a growing market for second-hand devices have seen smartphone connections in Sub-Saharan Africa double between 2015 and 2017 to nearly 200 million, accounting for a quarter of mobile connections globally in 2016 (GSM Association, 2017).

As a result of mobile phone technology penetration, the role of, and need for mobile health (mHealth) solutions in healthcare continues to grow rapidly. However, some evidence shows that in developing countries, most health systems do not meet the World Health Organization (WHO) minimum standards (Mendoza *et al.*, 2013). In the year 2000, WHO defined a health system to include all the activities whose primary purpose is to promote, restore or maintain health (Packard, 2007; Musgrove et al., 2000). The WHO Global Observatory for eHealth (GOe) describes mHealth or mobile health as medical and public health practices supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices (Martinez-Perez *et al.*, 2013). Evidence shows that ICT including mobile-based solutions has the potential to improve access, quality, effectiveness, and efficiencies in healthcare service delivery (Free *et al.*, 2013; Hall AK, Cole-Lewis H, 2015; Mishra *et al.*, 2011; Blaya *et al.*, 2010) (Dekoekkoek *et al.*, 2015) (Brath et al., 2013) (Mendoza et al., 2013). mHealth has great potential to contribute to universal health coverage by improving access and availing healthcare to remote under-served populations (World Health Organization, 2017) through health systems.

The concept of interoperability was introduced to health system management to encompass what Li *et al.* (2021), described as

'having an electronic health system with the capability of health information systems to work together within and across systems for effective delivery of healthcare for individuals and communities. Interoperability of digital systems is increasingly becoming widespread as its adoption has improved patient medical records within the primary care systems and provided an opportunity to allocate and share patient records across organizations, which was previously impossible with paper-based records (Tao *et al.*, 2015). For example, in Kenya, the e-citizen portal provides a single gateway to accessing several services such as business registration, transport documentation, and immigration permits.

Data interoperability is a common concept yet quite complex to understand and implement. As the systems grow in coverage, it is critical to look at the data captured from the dimension of big data which has five key characteristics and they include i) volume - its dimension in terms of bytes is huge; ii) velocity - its speed requirements for collecting, processing and using data; iii) variety - its heterogeneity in terms of data types to be managed and data sources to be merged; iv) variability - its variability from time to time or place to place in the collection, processing, and use; and, v) value - its accuracy and reliability are key in leading to measuring improvements and decision-making at the end of the day (Hadi *et al.*, 2014; Trifu *et al.,* 2014).

A. Interoperability and its challenges

Due to the ubiquity of technological gadgets, vast data are being collected and stored (Bernstein et al., 2015). Interoperability enables stakeholders, targeted users, and beneficiaries to optimize the use of systems. Knowledge management and connectivity of national health information systems play a pivotal role in improving the quantity and quality of information available for decision-making (Menachemi, & Collum, 2011; Yaqoob *et al.*, 2017). According to Li *et al.* (2021), patient safety and health system costs can be detrimental if interoperability is meagre. In-

teroperating healthcare systems has several advantages including easy access to patient records at various points of care, easy and harmonized understanding of medical terms and concepts, reduction of errors in medical data and information, cost-effectiveness in the delivery of healthcare, and enhanced management of chronic diseases (Iroju *et al.*, 2013).

Most developed countries own functional and interoperable health information systems (Gambo *et al.,* 2011; Tao *et al.*, 2015). The National Health Interview Survey (NHIS) of any country should provide technological infrastructure to allow information storage and sharing in the most appropriate manner (Yaqoob *et al.*, 2017). In line with the Kenya Big Four Agenda to improve health care, the Ministry of Health established the eHealth unit to oversee the adoption of digital health and support the national-level systems such as the master facilities list (MFL) and the District Health Information Software (DHIS2) to collect health statistics (Muinga *et al.,* 2020; Nyangena *et al.*, 2021). The Kenya Health Information Systems Interoperability Framework (KHISIF) fosters the health information systems' interoperability initiatives, that facilitate services that work together within and across the county and national levels to contribute to a coherent interoperable environment (MOH, 2021).

However, there are some overriding challenges to interoperating mHealth solutions. One of the attributable factors is the country's adoption of Health Information Systems (HIS) in health facilities from different information technology vendors (Muinga *et al.,* 2020). The lack of standardization of the products, incompatible language, the legality of the systems, and resistance to change among players have led to a lack of integration of the systems (Iroju *et al.,* 2013; Tao *et al.,* 2015; Muinga *et al.,* 2020; and, Nyangena *et al.* 2021) as much as Kenya has a robust technological environment that has supported HIS activities. However, some studies found little to no interoperability among e-health systems at the national level (Muinga *et al.,* 2020; Nyangena *et al.,* 2021). Lack of interoperability not only

denies patients the ability to access services efficiently, but also denies caregivers access to important information required to provide services to their patients (Menachemi, & Collum, 2011). This paper examines the readiness of two mobile-based digital health solutions (mLab and Ushauri) to be interoperable. The paper is a case study analysis of the mLab and the Ushauri systems in terms of the technological stack for interoperability and legal implications. The study is based on data abstracted from the two systems and desktop review and further analysis of the legal environment regarding the interoperability of data systems in Kenya.

B. mHealth solutions

mHealth Kenya, funded by the Centres for Disease Control and Prevention (CDC), under a Cooperative Agreement titled 'Enhancing Kenyan mHealth innovations to impact care and treatment of HIV/AIDS programs, 2015 – 2020' was mandated to develop, utilize, and enhance mobile solutions within the public health sector. This was in line with Vision 2030 which requires the relevant actors to improve access and enhance efficiencies in healthcare services with a definite impact on the overall health system in the country (Vision 2030, 2018; Muinga *et al.,* 2020). This objective is also in line with Sustainable Development Goals (SDG) 3, to ensure healthy lives and promote well-being for all by improving access and enhancing efficiencies in HIV/AIDS healthcare services. Towards the realization of this mandate, mHealth Kenya has come up with two solutions discussed in this paper. Therefore, this paper aims to explore the feasibility of interoperating the two mHealth solutions: Mobile Laboratory (mLab) and Ushauri system developed by mHealth Kenya to enhance care and treatment for persons living with HIV/AIDS (PLWHA).

mHealth systems involve the use of the mobile phone's core utility of voice and short messaging service (SMS) as well as more complex functionalities and applications including general

packet radio service (GPRS); third and fourth generation mobile telecommunications (3G and 4G systems); global positioning system (GPS), and Bluetooth technology (WHO, 2011; Davis *et al.,* 2016). Similarly, the mLab and the Ushauri systems capitalize on such features and functionalities to facilitate access, effectiveness, and efficiencies in healthcare service delivery in the country. Both the mLab and the Ushauri systems have web portals and mobile apps that provide administrative functions such as user management, data analytics, and visibility of data. The mobile applications allow for data entry and viewing of summary results, including providing links to web portals. The strength of the systems is the ability to work in low-resource settings because of the simple technology used and the minimal infrastructural requirements. The systems also provide users with the option of either using short messaging services, applications on smartphones, or web-based access.

The Ushauri system provides the service provider with an electronic appointment diary at the facility level, making it possible to schedule and re-schedule appointments including tracing defaulters; thereby facilitating better management of clients on antiretroviral therapy (ART). The pilot for the Ushauri-T4A system started in March 2017 and was later rolled out in June 2017. The mLab system uses short messaging services (SMS) to send the Viral Load (VL)[1] and Early Infant Diagnosis (EID)[2] laboratory results, through a secure and confidential platform, to the designated caregiver at the health facility. The solution aims to cut down on the turnaround time (TAT)[3] and improve timely interventions for the care and treatment of PLWHA in Kenya. Reducing the turnaround time from when results are dis-

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[1]   The amount of HIV in a sample of blood. An important goal of antiretroviral therapy (ART) is to suppress a person's VL to an undetectable level—a level too low for the virus to be detected by a VL test. Viral load is recommended as the preferred monitoring approach to diagnose and confirm treatment failure.

[2]   Infants born to women living with HIV are tested within the first two months of life to determine their HIV status and eligibility for antiretroviral therapy is determined by a test result.

[3]   The time, whether in hours or days, between when a sample or specimen is received at the laboratory and the time when testing is complete, and results are established and released.

patched by the reference laboratory, to the delivery of results to the health facility improves the efficiency of health referral and linkage of patients to care and treatment services.

This paper is divided into five parts; part I is the introduction which gives background to the study and the importance of interoperability. Part II presents the concept of interoperability, its types, and its data protection requirements and examines this concept in light of the mLab and the Ushauri Systems. Part III pragmatically studies the interoperability of the mHealth Systems in Kenya which segues into part IV to discuss findings. Lastly, part V gives recommendations and concludes the study.

II. INTEROPERABILITY

A. *Types of Interoperability*

Healthcare as a system is highly transaction-intensive and therefore requires coordinated interaction between the parties involved (service delivery, health workforce, health information systems, financing, and leadership and governance) (Alleyne *et al.,* 2006; WHO, 2010; Manyazewal, 2017).). Trends of technological innovations are now very dynamic, and the world is rapidly moving towards a more substantial and national-level implementation of health-related information systems (Yaqoob *et al.,* 2017).

For a system to be termed 'interoperable', two or more systems should be able to exchange and use the same data. The mHealth solutions' interoperability is guided by the Health Level Seven Standards (HL7's)[4]; which define the frameworks and layers upon which interoperability should be based and the Fast Health Interoperability Resources (FHIR)[5] architecture. The

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[4]   International framework that governs how electronic health information is shared and transferred and integrated. These guidelines bridge the gap between health IT applications and make sharing data easier.

[5]   Standard that defines how healthcare information can be exchanged between different computer systems regardless of how it is stored in those systems.

HL7 standards are aimed at tackling issues and concerns about traditional bottom-up integrations[6] which is an approach to data integration; where the process starts from the native data in the sources and targets, up to the integration flows (Hasselbring, 2000). The advantage of this approach is the ability to continually build on system components. Interoperating mHealth solutions can be done from various viewpoints, including the ones listed below.

1. Technical interoperability

Technical interoperability means the ability of two or more information systems or technology applications to perform a task between themselves appropriately and satisfactorily without any human intervention (DeNardis, 2012). Both the mLab and the Ushauri have been developed with the technical ability to exchange data. The Application Programming Interfaces (APIs) Interoperability of the mLab and the Ushauri use is the FHIR to support a consistent set of interactions across all resource types, including search, read, create, update, and delete data.

2. Semantic interoperability

Semantic interoperability means that systems exchanging content are able to understand, interpret and make use of the content exchanged, that is, shared meaning of data exchanges between the said systems (Bourgeois & Bourgeois, 2014; HIMSS, 2022). It is possible for Ushauri and mLab to semantically communicate given that the two systems are focused on the HIV program in Kenya. For instance, the clinical terminologies used on T4A and mLab conform to the universal standards of International Classification of Diseases Revision 10 (ICD 10)[7] for dis-

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[6] A specific type of software integration testing that tests the lowest components of a code base first. It involves taking integrated code units and testing them together, before testing an entire system or code base, that is evaluated for overall functioning.

[7] Globally used diagnostic tool for health management, epidemiology, and clinical purposes.

eases, Systematized Nomenclature of Medicine (SNOMED)[8] for clinical data coding and Logical Observation Identifiers Names and Codes (LOINC)[9] for laboratories for semantic, process and data interoperability between mLab and Ushauri.

3. Process interoperability

Process interoperability entails the businesses or programmatic processes and that the people involved share a common understanding of the content exchanged, that is, the integration of systems within work processes (Tao *et al.,* 2015). Both the mLab and the Ushauri are integrated within the HIV program or processes in the comprehensive care centres in health facilities in Kenya. The processes are clear - making it easy for the system to be incorporated and share information seamlessly.

4. Data interoperability

Data interoperability means the ability of systems and services to create, exchange and consume data. The systems should have clear, shared expectations of the content and meaning of the data (Hasselbring, 2000; Health Information and Quality Authority, 2013; Guedria *et al.,* 2015). This informs the core thesis of this paper.

According to Benson and Grieve (2016), the FHIR architecture, consists of three layers: i) the device translation layer which consists of software for interfacing between various medical devices and mobile platforms; ii) the Integration of the Healthcare Enterprise (IHE)[10] domain workflow layer contains software

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[8] A systematic, computer-processable collection of medical terms, in human and veterinary medicine, to provide codes, terms, synonyms and definitions which cover anatomy, diseases, findings, procedures, microorganisms, substances, etc.

[9] A database and vocabulary coding system created specifically to facilitate a standardized and universal method of identifying and reporting medical laboratory observations.

[10] An initiative by healthcare professionals and industry to improve the way computer systems in healthcare share information, including the use of standardized procedures to support optimal patient care.

that ensures ease of communication between computer systems by use of standardized processes; iii) the enterprise translation layer consists of software that interfaces with the Electronic Health Records (EHRs); and the security layer provides software that ensures the transmission of data is done in a secure and encrypted manner. The FHIR architecture provides guaranteed interoperability of Ushauri and mLab systems by adopting all three layers of interoperability and its APIs to meet the IHE and HL7 standards.

B. Illustration of interoperability between the mLab and the Ushauri systems

This paper inspects the data in the two systems and the possibility of sharing data between them. The technical interoperability of the two systems is possible when the same unique identifier is used to identify the same patient on both systems. The diagram below shows the ideal situation of how interoperability should occur between the mLab and the Ushauri systems. *Figure 1* illustrates technological interoperability and data flow as indicated by the arrows between mLab and Ushauri.

Figure 1: Illustration of the interoperability between the mLab and the Ushauri - T4A systems
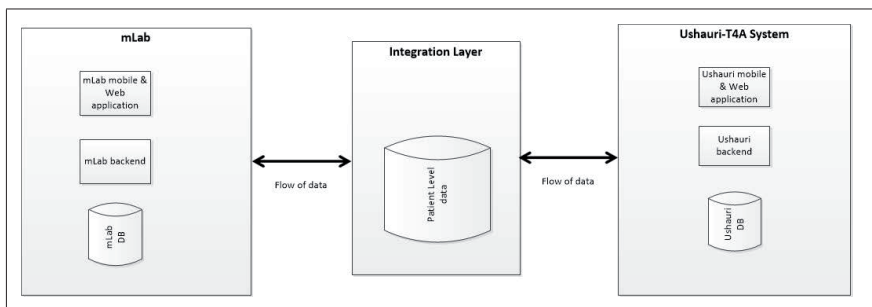
This framework consists of various components: i) the front end (the mobile and web application interfaces), ii) the back end and iii) a database each for the mLab and the Ushauri systems.

The two systems are then joined together by a database that links them and contains patient-level data. Patient data flows from Ushauri to mLab through an integrated database layer called the IL layer thus allowing health facilities to manage patient treatment.

C. Application of data protection principles and regulations

Part IV, Section 25 of Kenya's Data Protection Act (DPA) (2019) outlines eight key principles to guide data processors. According to these principles, data should be: i) processed considering the right to privacy of the data subject, ii) processed lawfully, fairly and in a transparent manner, iii) collected for explicit, specified, legitimate purposes, iv) adequate, relevant and limited to what is necessary, v) collected only where an adequate explanation is provided vi) maintained in accuracy and where necessary, kept up to date, vii) kept in a form that identifies the data subjects for no longer than the expected period, and viii) not transferred to other parties without guaranteeing adequate data protection safeguards and consent from the subject.

Both the mLab and the Ushauri systems hold de-identified data from patients who provide consent after being assured of their privacy. Apart from de-identifying patients with auto-generated numbers, the systems have mechanisms that make it mandatory for users to have facility-owned phones with SIM cards that are password protected. Additionally, access to records is limited to designated individuals at the facility - specifically, the laboratory person and the Comprehensive Care Unit clinician.

On the second principle, the systems are lawfully approved by the Ministry of Health and are not discriminatory in any manner. The data sets collected via the systems were arrived at in collaboration with the Ministry of Health. Clients who consent are eligible to be recruited on the systems to benefit from the services. The Health Amendment Act 2021 Article 9(i) requires

the clients to consent to be provided health services and Article 11 stresses the need for confidentiality pertaining to health information.

Thirdly, the data held in the two systems is only to improve clinical decision-making within the HIV/AIDs program. Fourthly, the two systems collect adequate data on appointments and laboratory results for people living with HIV/AIDS. The systems, therefore, focus on appointment management and transmission of laboratory results of PLWHA.

Fifth, the development of the system was participatory. It involved all the key stakeholders from government, private organizations, health facilities and the community to ensure consensus on the models of data to be collected and their use. Related to the sixth principle, the systems have inbuilt data validation processes to ensure that only valid data is collected. Further, patient information can only be updated at the facility level, which ensures that the information is up to date. Part of the key data sets that are capable of updates are treatment outcomes for instance where the patient dies, transfers out of a facility or declines care. The systems are designed to keep data as long as the patients are willing to be in care and as per the policies guiding the destruction of data. Lastly, the data in the two systems are only accessible in Kenya and are stored in servers at the Ministry of Health.

III. DETERMINING THE INTEROPERABILITY OF THE MHEALTH SYSTEMS IN KENYA

A. Methodology

This paper is a case study analysis of the mLab and the Ushauri systems in terms of the technological stack for interoperability which has some legal implications. The research was a pilot study, conducted on data collected from thirty-nine government facilities in Siaya, Homa Bay, Nyeri, and Murang'a counties where Ushauri and mLab systems had been rolled out. The

data spans from June 2017 to June 2018. Sampling was therefore multi-staged. The first stage was selecting the two systems (mLab and Ushauri) because they serve the same people living with HIV.

The second stage involved selecting health facilities. At this stage, all the thirty-nine facilities that had both systems at the time of analysis were considered. The third stage involved purposively sampling records. Selected records in the two systems from the thirty-nine facilities were abstracted for analysis. The analysis was done separately on data in both systems and later the two data sets from the mLab and the Ushauri were merged using the patient identification numbers. To maintain confidentiality, patient identification numbers were abstracted without other identifiers such as names and mobile numbers as subject to DPA (2019, s. 25).

This study also benefits largely from a desktop review of the literature on various aspects of interoperability. Findings are presented and discussed in three main sections: legal framework for interoperability, technological interoperability, and patient identification number formats.

B. Findings

1. Legal framework for interoperability

This study finds that Kenya has adequate laws to ensure that systems achieve interoperability. The problem lies in the ability of the solutions to interoperate and give adequate effect to these laws based on how they are technically designed to receive data. Key legal documents that advocate for interoperability in Kenya include the Standards for eHealth Systems Interoperability (MOH, 2015); the Kenya National eHealth Policy (2016-2030); and the Kenya Standards and Guidelines for mHealth Systems (MOH, 2017).

The Kenya Health Information Systems Interoperability Framework (KHSIF) Legal and Regulatory Interoperability de-

fine the margins for interoperability and provide guidelines for health data exchange in the Kenyan context (MOH, 2021). The two systems conform to Kenyan law on the implementation and interoperability of mobile solutions to efficiently run the projects including open standards for data exchange, messaging, security, and adherence. The mHealth solutions authenticate to the interoperability requirements outlined in the Kenya Interoperability Standards and Guidelines (MOH, 2017). Specifically, the mHealth applications conform to the following.

i). The acceptable data exchange standards for terminology, messaging, and documentation. Ushauri and mLab were developed following the HL7 Clinical Data Architecture (HL7 CDA). In line with Kenya Interoperability Standards and Guidelines, the project generated the production of systems requirement specifics (SRS), software design outlining the software development methodology, flow charts, monitoring and evaluation procedures including deployment, test plans and implementation manual.

ii). Section 1.1 outlines methods of exchange and specifies automated methods, such as the use of 'middleware' or API-based recognized formats, which the mLab and the Ushauri systems application layer consists of the business logic for the application in addition to a web API for interaction between the database and the patient data layer. The patient data layer consists of a web-based user interface. Together, the components of the three logical layers form a system capable of implementing all functionality required by the system.

iii). Section 1.3 on unique identifiers for clients, facilities, health care professionals, and non-medical institutions. This is in line with the Health Information Systems (HIS) Interoperability compliance to personal data relating to health in the DPA No. 24 of 2019, part V, and

section 46(1) which provides that 'personal data relating to the health of a data subject may only be processed by or under the responsibility of a health care provider'.

iv). Client unique identifiers used in the two systems followed the format that consisted of the first five- digits which comprised the MFL of the facilities followed by an individual patient number. At the health facility level, service users who have access to information related to clients have the right to enter personal information and edit or delete information. This ensures that the service providers register clients on the systems and that they are able to use the systems to provide the needed services. However, any user above the health facility for example at the sub-county level, county level or national level only has access to aggregate data. At the facility level, consenting clients' data are entered using a facility-based tablet, laptop, or computer that is password-protected and designated to one individual at the facility (adherence nurse, counsellor or data person).

The Kenya National eHealth Policy 2016-2030 recognizes the need for shared health records through the development or use of a client registry (CR) that encompasses the Unique Patient Identifier (UPI), the master facility index, and the terminology service for health information exchange to promote functionality towards interoperability. To facilitate transparency and functionality, mHealth's solutions for information exchange and interoperability were based on the Ministry of Health's (MOH) Kenya Standards and Guidelines for eHealth Systems Interoperability (Version 2, July 2015). The standards recommend the need for efficiently and securely sharing patient digital medical information to improve patient care by using the UPI developed by healthcare workers in the health facility. This is also in line with the DPA No. 24 of 2019, part V, and Section 46 (1a) stated above. The two systems were built based on the standards. Additionally, the systems are able to mine patient data from other

already existing electronic medical records (EMRs) to ease the data entry work. Patient data is linked to the patient's number as provided by the health facility.

Considering the principles of security and privacy, the mLab and the Ushauri systems were designed to have several security measures put in place to ensure the results of the patients are safe, private, and confidential. The Kenya Health Information Systems Interoperability Framework (KHISIF) primarily concerns itself with interoperability based on security and privacy. It ensures the systems' privacy-by-design and security-by-design approaches are used. The framework adopted on mHealth solutions facilitates privacy, confidentiality, and integrity of clients' health information. By securing their complete infrastructure and building blocks; when data is pulled from the two systems, the data is generated with encrypted identifiers which are usually numbers and letters that are randomised to ensure no one is able to identify the clients.

The documents call for the need to move from developing and implementing silo-based pilot phases to scalable fully-fledged interoperable solutions that can assure both the service provider and client of efficient and effective services. However, the development and implementation of many systems with little or no attention to policies and strategies documented by the MOH leads to challenges seen in the lack of compliance with data exchange standards, data ethics, monitoring and evaluation, resource mobilisation, and business continuity (Iroju *et al.,* 2013; Tao *et al.,* 2015; Muinga *et al.,* 2020; Nyangena *et al.,* 2021). For instance, one of the major challenges with the two systems is that they did not undergo the HIS certification process to formally ensure they conform to the required Kenyan interoperability standards.

2. Technological Interoperability

The transfer of data between the Apps and the backend (Web portal) was via SMS technology. The technical interoperability of the two systems was facilitated using a unique identifier to cat-

egorize the same patient on both systems. Data captured on the mobile applications were converted and sent as text messages to the backend for processing. On the backend, data was converted back to hypertext mark-up language (HTML)[11] data, processed and saved, and vice versa.

3. Patient identification number formats

i). Unique patient numbers analysed

A total of 7,040 unique patient numbers were abstracted from the Ushauri system. This figure represented the number of patients living with HIV who had been registered in the system. mLab had a total of 89,373 records with unique patient numbers eligible for analysis in this study. The mLab system pulled data from the reference laboratories. Patient numbers and other vital details were reflected on the mLab data as captured at the reference laboratories.

ii). Patient identification numbers format

There were significant variations in the format in which patient identification numbers appeared both within each system and between the two systems. Ideally, a unique patient number for patients enrolled for HIV care [defined by National AIDS Sexually Transmitted Diseases Control Program (NASCOP)] takes the format of a facility number from the MFL and patient serial number (PSN) where; the first five digits represent the health facility followed by the last six digits generated by the health care worker at the HIV care facility (NASCOP, 2010).

The most common format used in the two systems was when the first five digits comprised the Kenya Master Facility List (KMFL) Code of the facilities and then followed by an individual patient number. In the mLab system, sixty-five point five percent of patient identification numbers had an MFL code as

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[11] A standardized system for tagging text files to achieve font, color, graphic, and hyperlink effects on World Wide Web pages

the first five characters while about thirty percent were identified as missing. This was found to be a result of having either a few numbers missing the first five characters, letters (especially indicating abbreviations for being clients under the transfer in maternal and child health categories), and other symbols that could not be identified as MFL codes by the analysis system.

In the Ushauri system, ninety percent of the entered patient identification numbers had an MFL code as the first five characters while only ten percent did not have an MFL code. Patients' identification numbers categorized as 'without MFL codes' were found to have less than five characters in total, had letters, symbols, and space as the first five digits were not MFL codes.

iii). Characters in the patient identification numbers

The analysis revealed that there were huge variations in the total number of characters that built up the patient identification numbers as captured in the two systems. In the Ushauri system, the characters that built up a patient's identification number ranged from one character (digit, letter, or symbol) to twenty characters (digits, letters, symbols, or a combination), while in mLab, the characters that built up a patient identification number ranged from one character (number) to twenty-seven characters (digits, letters, symbols, or a combination).

A few results in the mLab system (n=179/89373) did not have any patient identifier. *Table 1* shows the distribution of the characters making up patients' identification numbers in the two systems.

Table 1: Distribution of characters making up the patient identification numbers on the mLab and the Ushauri systems

Number of characters	Patient numbers on mLab	% within mLab	Patient numbers on Ushauri	% within Ushauri
0 (blank /no id)	179	0%	0	0%
1	81	0%	5	0%
2	848	1%	23	0%
3	4558	5%	205	3%
4	10854	12%	393	6%
5	5596	6%	76	1%
6	4841	5%	30	0%
7	4187	5%	25	0%
8	2707	3%	71	1%
9	11480	13%	459	7%
10	24165	27%	2084	30%
11	12522	14%	3397	48%
12	3150	4%	154	2%
13	817	1%	18	0%
14	1552	2%	9	0%
15	1402	2%	84	1%
16	119	0%	4	0%
17	72	0%	1	0%
18	72	0%	2	0%
19	63	0%	5	0%
20	36	0%	23	0%
21	33	0%	0	0%
22	14	0%	0	0%
23	8	0%	0	0%
24	6	0%	0	0%
25	7	0%	0	0%
26	3	0%	0	0%
27	1	0%	0	0%
Total	89373	100%	7040	100%

iv). *Matching patient identification numbers across the two mHealth solutions*

All records were pulled from a pool of thirty-nine facilities that had both systems at the time of analysis. From the analysis, only 1099 records in eighteen facilities matched. This represented only fifteen point six percent of all the unique patient identification numbers on Ushauri (1099/7040) and about one percent of all records in the mLab system (1099/89,373). The majority of the numbers that matched in both systems (sixty-nine percent) were for female patients (n=761/1099). In addition, based on mLab data, which had the gender variable, the number of results belonging to female patients was almost double those belonging to male patients (female n=58995; male n=29334).

From the selected facilities, Gongo dispensary (n=207/1099) and Othaya Sub-District Hospital (n=206/1099) had a majority of the patient numbers matching on both systems. *Table 2* presents matching patient identification numbers in the mLab and the Ushauri by characteristics such as gender and result type by the facility.

Table 2: Distribution of matching patient identification numbers between the mLab and the Ushauri systems[12]

Fa-cility code[12]	Patient numbers on Ushauri				Records on mLab				
	F	M	Missing data on gender	Total	EID Neg-ative	VL In-valid	VL Sup-pressed	VL Unsup-pressed	Total
01	47	36	1	84	0	3	68	13	84
02	4	1	0	5	0	0	5	0	5
03	156	51	0	207	0	0	191	16	207
04	5	4	0	9	0	0	8	1	9
05	31	13	0	44	0	1	35	8	44
06	20	4	0	24	0	0	23	1	24
07	44	20	0	64	0	0	58	6	64
08	0	1	0	1	0	0	1	0	1

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[12]   The facilities have been coded for privacy and data protection purposes.

Facility code[12]	Patient numbers on Ushauri				Records on mLab				
	F	M	Missing data on gender	Total	EID Negative	VL Invalid	VL Suppressed	VL Unsuppressed	Total
09	4	0	0	4	0	0	3	1	4
10	4	1	0	5	5	0	0	0	5
11	73	24	1	98	0	0	90	8	98
12	1	0	0	1	0	0	1	0	1
13	36	15	0	51	0	0	46	5	51
14	12	6	0	18	0	0	16	2	18
15	45	23	0	68	0	0	56	12	68
16	96	42	0	138	0	3	117	18	138
17	134	67	5	206	0	1	187	18	206
18	49	23	0	72	0	0	64	8	72
Total	761	331	7	1099	5	8	969	117	1099

v). *Characteristics of matching patient identification numbers in both systems*

The number of characters forming patient identification numbers that matched across the two mHealth solutions (n=1099) ranged from eight to fifteen characters. More so, sixty-three point three percent of the numbers that matched across the two systems had eleven characters. The ideal unique number resulting from NASCOP standardization would result in eleven characters [e.g., 12345-000001], whose format replaced the generated unique number from province code + district code + PSN (NASCOP, 2010). The eleven-character patient identification numbers comprised of the first five digits - being the MFL code, followed by a dash (-), then the additional six-character-individual-patient number (xxxxx-xxxxxx).

Patient identification numbers with ten characters (thirty-five point four percent) had two main formats: the first five characters, as the MFL code, followed by a dash (-), then an additional four character-individual-patient number (xxxxx-xxxx) or first five characters comprising of the MFL code followed

by a five-character individual patient identification number (xxxxxxxxxx). The first format with ten characters was used in one facility while the second format was used across seventeen facilities.

Formats for the nine-character patient identification numbers varied. Nonetheless, the bulk of these numbers had the first five characters as MFL codes followed by a four-character individual patient number (xxxxxxxxx). One of two patient identification numbers with eight characters had the first four characters/digits presumably as the MFL code, followed by a dash and a three-character individual patient identification number comprising of two digits and one letter (xxxx-12y).

Interestingly, all the fifteen-character-patient identification numbers (zero point four per cent) were from one implementing partner (organization managing the HIV program in some health facilities). The patient identification numbers comprised the first five characters as MFL codes, followed by a dash (-), then the year (2018), and a four-character individual patient identification number (xxxxx-2018-xxxx). *Figure 2* presents a summary of the frequency in the number of characters forming matching patient identification numbers.

Figure 2: Number of characters in matched records between Ushauri and mLab
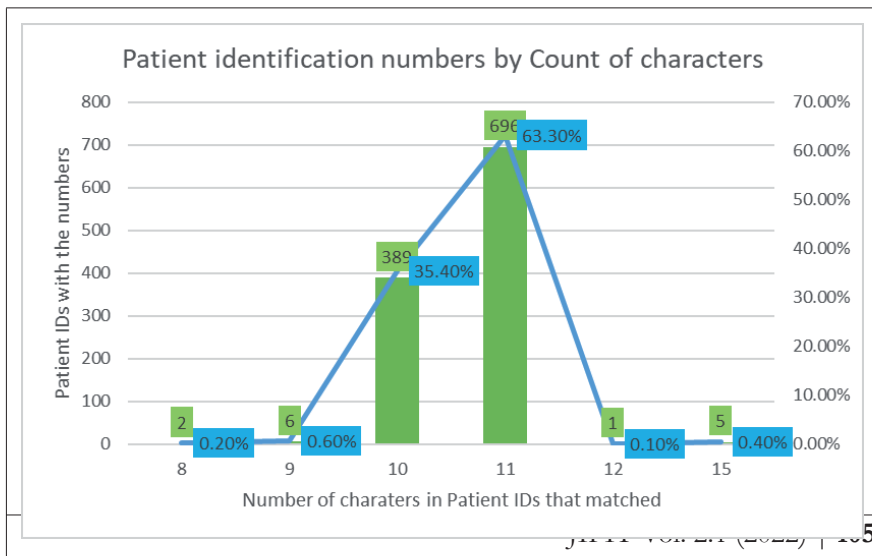
IV. DISCUSSION

The ability of the two mHealth systems to share data is very critical for the effectiveness and efficiency of care and treatment for people living with HIV (Adebesin *et al.,* 2013). Interoperating the two systems provides a well-connected continuum of care and the ability to monitor key performance outcomes and progress toward reducing the AIDS epidemic, which goes beyond the deployment of e-health and EHRs systems efforts. Accelerating uptake and interoperating the mLab and the Ushauri systems as tools for HIV/AIDS treatment would significantly contribute to the new ambitious 95-95-95 UNAIDS targets of ensuring that the number of AIDS-related deaths is eighty-one percent lower by the year 2030 (UNAIDS (Joint United Nations Programme on HIV/AIDS), 2014).

Evidence from developed countries such as the United States and Israel shows that it is possible to interoperate health systems within departments in a health facility and among several healthcare sites (Catan *et al.*, 2015). Success stories from these jurisdictions show that healthcare systems can derive several benefits from interoperating health information systems (Electronic Health Record Association (EHRA), 2017). Comparing findings from this study and success stories from the developed world calls for concerted efforts to work towards ensuring that interoperating health information system in low-resource settings is successful. This could greatly enhance already overburdened and slim healthcare systems in terms of human resources.

Technically, the mLab and the Ushauri systems are interoperable. The technologies employed in developing the two systems are able to communicate with each other seamlessly. The systems are built on international standards specifically HL7 standards which allow the exchange, storage, and use of electronic health information (DeNardis, 2012; Adebesin *et al.,* 2013). This implies that the systems are not just open to interoperation with other locally developed systems but can also interoperate and

communicate with other electronic and medical records systems, including international systems while and only if they satisfy the data protection principles and requirements.

This study highlights the different standards available categorized as either semantic or syntactic standards. In terms of semantic interoperability, the two systems have the ability to exchange and understand clinical information independently of each other. Conferring the records that match, demonstrates that the two systems can communicate and link patient data from one system to the other. 'Semantic interoperability ensures that the precise meaning of exchanged information is understood and preserved throughout exchanges between parties' (Guedria *et al.,* 2015). This is very important given that data in both systems are for common people in the same health facilities where they receive care and treatment. Two ways that have been suggested for ensuring semantic interoperability are: firstly, archetype transformation, and, secondly, data transformation (Martínez Costa *et al.,* 2011). Semantic analysis of the data in the two systems shows that data fields are semantically valid, based on the meaning of medical concepts and the formulation of unique patient identifiers shared across the systems termed as a 'digital lingua franca' ideally understood by users across the two (Lehne et al., 2019).

The two systems comply with HL7 standards both in architecture and implementation. Ushauri and mLab systems are interoperable and compatible with the HL7 version 3 standards in terms of clinical messaging, clinical terminologies,[13] concepts,[14] and architecture.[15] Additionally, the two systems share a common reasoning mechanism, which makes them effective with the capability for seamless end-to-end communication as a result of

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[13] Terminologies, and classifications for clinical concepts (diseases and medications).
[14] For transmission of information between systems without any loss of the meaning or context of that information.
[15] Define a generic model of the system, thereby providing data elements and the business logic of the system.

compliance with HL7 in development and implementation (Khan *et al.,* 2013). Both mHealth systems have been designed to be compliant with the HL7 push model standard, which allows one system to send information to one destination system and the destination system receives the data, meaning the semantics, process and technical interoperability on the source system provides appropriate access control according to the contributions of Dobson (2019). Correspondingly, the HL7 specifications on FHIR make it possible for Ushauri and mLab systems to interoperate healthcare through specified data formats, elements, and web-based application programming inter-phases that allow sending, receiving, and access to EHRs through UPIs (Dobson, 2019).

With support and collaboration from all partners, the two mHealth solutions followed the interoperability maturity model through technology conceptualization and development, establishing the broad area of leadership and governance of the HIS, and ensuring the requisite human resources were in place. However, one key legal limitation of the two systems is that they did not undergo the HIS certification process to formally ensure they conform to the required Kenyan interoperability standards in accordance with the Kenya Standards and Guidelines for mHealth Systems (2017).

Findings from this study reveal that the interoperability of the two systems is purely compromised by semantics in language causing a discrepancy in data entry. Logical semantics (in language) are based on the difference of understanding in the formulation of UPIs. Logical semantics, presupposition, and reference of how unique identifiers are perceived across healthcare workers within the different regions may vary, hence the inconsistency in characters. Some previous studies have found that standards are subject to different interpretations, which means that system development will vary from one organization to the next, making it difficult to have them achieve interoperability (Iroju *et al.,* 2013; Yaqoob *et al.,* 2017; Ogutu, 2017). These findings are consistent with Muinga et al. (2020), and Nyangena et

al.'s (2021) findings that established interoperability issues in Kenya were compromised during data entry as HIS were mostly managed by health records and information officers who had little or no training in the current digital health policies.

Overall results indicate huge variations in how particularly the patient identification number, which is the most critical single identifier in the two systems differs within and between the systems. Implementation of such systems and other customized systems makes interoperability difficult especially when the systems are developed without any determined standards as discussed above (Iroju *et al.*, 2013).

It is clear that different health facilities across the country may have not yet adopted the current NASCOP patient identifiers and are using paper-based clinical forms to collect patient data (Omoro *et al.,* 2018), or adopted the same patient identifier number used prior to the year 2010 which comprised province code + district code + PSN as designed by NASCOP (NASCOP, 2010).

The lack of a common format for how PLWHA in Kenya can be identified poses a major gap both at the policy and programmatic levels (Kariuki *et al.*, 2016; Omoro *et al.*, 2018). Ideally, the UPIs provided by NASCOP should result in eleven characters formed by facility number from the MFL number and PSN (NASCOP, 2010). Although the two systems (mLab and Ushauri) were designed following the NASCOP 2010 (eleven digits) UPI numbers, different facilities have different ways of allocating unique identifiers to the patients. It is a quagmire that the same person at a facility whose sample was collected, and VL/EID results availed through mLab cannot be identified on the Ushauri platform from where they received a text encouraging them to take drugs and ensure they keep the appointment due to differing formats of the patient identification numbers.

According to Yaqoob *et al.* (2017), the complexity of the healthcare domain arises from the various actors. The ability to

exchange this information across platforms and systems while maintaining data confidentiality, integrity, and availability ensures its safety and enhances effectiveness in healthcare (Ogutu, 2017). In this regard, there is a need to assess how these critical aspects of data would influence the successful interoperability of mLab and Ushauri. mLab relays laboratory results that are high in volume, and go at a high speed, which could vary in terms of the type of results being transmitted and the correctness of data capture depends on how well it is done at several points: facility (either at the critical care clinic (CCC) or the laboratory during filing of the sample request form). The Ministry of Health, through the division of health systems, and in collaboration with the Ministry of Information Communications and The Digital Economy, need to come up with simple, clear, and structured procedures to help system developers ensure that their systems are certified as per the law.

The findings of this study should be interpreted with caution given that the data analysed especially on the Ushauri system does not comprise all the people living with HIV in the facilities under study. Therefore, it is possible that some of the people who had been registered on Ushauri by the time of data abstraction and analysis did not have their samples taken for testing and hence did not have results on mLab.

V. RECOMMENDATIONS AND CONCLUSION

A. Recommendations

This paper strongly recommends standardizing the patient unique identifiers for PLWHA. This enables the exchange of data not only between the two systems studied in this paper but other systems for example Electronic Medical Records (EMR) and the web antiretroviral drug-dispensing tool. These systems are used within the HIV/AIDS program in Kenya to enhance service delivery. The systems enable patients to access services across

all health facilities and ensure that there are no cases of double counting of clients. The systems also reduce duplication of efforts thus leading to cost-effective service delivery.

The authors conclude that interoperability of systems, especially those enhancing service delivery within the same program area is a concept that should be implemented in Kenya. This could be achieved by strict implementation of the standards as provided by the Kenya National eHealth Policy (2016-2030), and Kenya Standards and Guidelines for mHealth Systems (2017) It is critical to note that there was a low level of concordance in patient identification numbers in the same facilities where the same patients were receiving clinical services. This finding requires all stakeholders to think through the current efforts toward the development of an interoperability layer in the country.

Whereas the legal environment and process of access to services within the health services sphere support interoperability, systems are not yet fully fledged interoperable because of the lack of follow-up on certification for Interoperability compliance. There is a strong need to ensure policies documented by the MOH are followed up. The process of providing systems' interoperability certification needs to be implemented effectively to ensure systems are certified and conform to the Kenya eHealth interoperability standards. All systems should undergo the interoperability maturity model assessment by both internal and external evaluators to objectively determine the level of systems in acquiring interoperability. Standardizing human activities while using systems, such as the allocation of patient identifiers, and following laid down standards while developing systems are critical ways of ensuring interoperability.

With full interoperability, there is potential for the two systems analysed in this paper to be rolled out and scaled up as one application so that the patient is just registered in one system and their details can be imported to the other system. The two systems serve the same clients (PLWHA). In this manner,

the technology will reduce the workload of the service providers who use the systems and are required to register clients on them independently of each other. With the quick availability of patient data in both systems, HIV/AIDS programs will attain timely clinical decisions, ultimately improving the well-being of the patients accessing care and treatment.

B. Conclusion

The Interoperability of health systems in Kenya has been met with challenges despite following international standards to ensure two or more systems interoperate. This paper is based on an analysis of the ability of two mHealth solutions (mLab and Ushauri) to interoperate both technically, semantically, and legally. Data from the two systems were analysed as well as a desktop review of the legal environment on interoperability of health information systems. Conferring to the records that match, it demonstrates that the mHealth systems could communicate and link patient data from one system to the other, however, interoperability of the two systems was purely compromised by semantics in language, that is, the understanding of UPIs across healthcare personnel across facilities in Kenya, causing a discrepancy in PSN. Additionally, in terms of legal limitation, the systems did not undergo the HIS certification process to formally ensure they conform to the required Kenyan interoperability standards.

It is clear that different health facilities across the country may have not yet adopted the current NASCOP 2010 (eleven-digit) patient identifiers as provided by the Kenya National eHealth Policy (2016-2030); to ensure optimal interoperability across the systems the Ministry of Health, through the division of health systems, should ensure health information technology undergo the interoperability maturity model assessment, in compliance to legal requirements and come up with clear, simple, and structured procedures to ensure healthcare workers are updated and comply to the current NASCOP standards for patient identifiers.

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