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**PART II
FULL RESEARCH
PAPERS**

**Harnessing the poten-
tial of Digital Health
Technology to build
hardened, sustainable
and learning health
systems**



Editors: Nicky Mostert, Ghislain Kouematchoua,
Ulrich Kemloh

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Editorial to JHIA Vol. 5 (2018) Issue 2

Nicky Mostert

Nelson Mandela University, Port Elizabeth, South Africa

The HELINA 2018 Conference

The 11th HELINA (HEaLth INformatics in Africa) conference was organized from 3 to 5 December 2018 in Nairobi, Kenya. The conference was hosted and organized by the Kenya Health Informatics Association (KeHIA). HELINA 2018 was co-located and held back to back with the popular OpenMRS implementers meeting. The conference focused on how technology is used to strengthen health systems in the African region. Issues of specific interest included the development and implementation of integrated e-Health plans and policies that enable capacity building for eHealth professionals, improving quality of health information and promotion of the meaningful use of health data to support and ground decision-making, improving access to essential medical supplies through improved supply chain and logistics, development of sustainable health information systems for service delivery and innovative health financing models that improve access to health. The role of digital health in health surveillance systems particularly due to emerging health threats including Non-Communicable Diseases, and therefore, the core participatory role of the client in detection, response, treatment and care. Special attention will be paid to the role of e-Health in achieving the Sustainable Development Goals (SDG) voted by the UN in September 2015 and more specifically to goal 9, target 9c which aims to “*Significantly increase access to information and communications technology and strive to provide universal and affordable access to the Internet in the least developed countries by 2020*”.

The Conference Themes

The call for submissions for HELINA 2018 covered a broad range of health informatics topics with relevance for Africa under the title “*Harnessing the potential of Digital Health Technology to build hardened, sustainable and learning health systems*”. Academic research papers, work in progress papers, and case study/experience papers were solicited within the following themes:

- National and Regional e-Health Strategies and Policies
- Health Information Systems Interoperability
- Continuous Quality Improvement and use of health data and systems
- Human capacity building for e-Health
- Application of technology in supply chain management
- Sustainable ICT-solutions for health service delivery
- Technology enabled health financing

Submissions of papers that fell outside any of these themes were also acceptable as long as they demonstrated any relevance for the health informatics domain in Africa.

Review process

After a call for papers was sent out a total of 76 submissions were received. A double blind peer review process was used for evaluating each paper. All submissions were anonymized before being submitted to at least 2 reviewers according to their expertise. The SPC chairs based their final decision on the acceptance of each submission on the recommendations and comments from reviewers. Accepted submissions were then sent back to the authors for revision according to the reviewers’ comments. This review

process resulted in the following acceptance rates:

Full research papers: 16% (n=12)

Work in progress papers: 8% (n=6)

Case studies and experience papers: 43% (n=33)

Rejected or retracted papers: 33% (n=25)

In order to be included in the conference proceedings, an accepted paper had to be presented at the conference. Presentations at the conference indicated that a lot of work is being done towards harnessing the potential of technology systems to build sustainable health systems.

Nicky Mostert
HELINA 2018 SPC Chair

mHealth4Afrika - Co-designing an Integrated Solution for Resource Constrained Environments

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Background: mHealth4Afrika is a collaborative research and innovation project, co-funded under Horizon 2020. It is focused on supporting Sustainable Development Goal 3 and Horizon 2020 Societal challenges by researching and evaluating the potential impact of co-designing and developing an open source, multilingual enabled mHealth platform to support quality community-based primary maternal healthcare delivery at semi-urban, rural and deep rural clinics, based on end-user requirements in Southern Africa (Malawi, South Africa), East Africa (Kenya) & Horn of Africa (Ethiopia).

Methods: A mixed methods strategy is applied. For technical development of the platform, design science research techniques are applied. The various platform iterations are implemented using an agile development process. Qualitative data collection and ethnographic observation was used during the needs requirements and base line study and validation of system iterations. These methods support regular interaction with policy makers, district and clinic managers and healthcare workers as part of the co-design process.

Results: This paper aims to share insights into the co-design process to develop a platform that integrates Electronic Medical Records, Electronic Health Records, medical sensors and visualisation tools, and automatically generates monthly program indicators.

Conclusions: mHealth4Afrika has developed a custom application to strengthen primary healthcare delivery in resource-constrained environments. It supports a range of interdependent programs defined in consultation with key stakeholders. This is achieved by interacting with a data model set up in DHIS2 via a WebAPI to facilitate holistic monitoring of a patient's wellbeing.

Keywords: Africa, Ethiopia, Kenya, Malawi, South Africa, Electronic Healthcare Records, Sensors, mHealth

1 Introduction

1.1 Background

In the context of Sustainable Development Goal 3 (SDG3) - "Ensure healthy lives and promote well-being for all at all ages", governments are working towards achieving Universal Health Coverage [1]. This requires a number of pillars to be put in place to support people-centred health services (eHealth strategies including a regulatory and data privacy environment, skills development programs and electronic health records). WHO highlights that eHealth is an *"integral part of delivering improvements in health"* care delivery and electronic health records enhance patient diagnosis and treatment through access to accurate and timely patient data [2]. An electronic health record (EHR) is defined as: *"real-time, patient-centred records that provide immediate and secure information to authorized users. EHRs typically contain a patient's medical history, diagnoses and treatment, medications, allergies, immunizations, as well as radiology images and laboratory results"* [2]. [3] notes that *"mHealth in the high-income countries is driven by the imperative to cut healthcare costs, while in developing countries it is mainly boosted by the need for access to primary healthcare"*.

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Despite the progress being made in introducing electronic patient records in larger hospitals in urban areas, paper-based registries are the default data capture method in resource constrained urban, rural and deep rural health centres in Ethiopia, Kenya, Malawi and South Africa (current mHealth4Afrika beneficiary countries). None of the participating health centres have access to a complete electronic patient record system [4, 6, 7]. Prior to engaging with mHealth4Afrika, intervention clinics in Ethiopia, Kenya and Malawi were not using electronic medical devices or an electronic system to record patient data at the point of care [5].

One of the driving forces in increasing the use of EHRs in Africa has been around addressing requirements for specific donors and programs including Human Immunodeficiency Virus (HIV) and Tuberculosis (TB) [9 - 10]. In South Africa clinic staff input specific data sets related to HIV and TB into separate health information systems. They do not currently use a single integrated electronic health information system to collect all patient medical data [8]. However, there is a growing awareness that using silo applications is not sustainable, for a variety of reasons including data fragmentation and duplication of effort.

As highlighted in [4], the importance of interventions taking account of information needs at different stages in the continuum of care is well documented in literature [11 - 12].

1.2 mHealth4Afrika Research Focus & Objectives

mHealth4Afrika is primarily focused on supporting SDG3 by co-designing a modular, multilingual, state-of-the-art health information system, aimed at strengthening primary healthcare delivery in resource constrained environments [4 - 7]. Since November 2015, the mHealth4Afrika platform has been co-designed with and validated by Ministries of Health, district health officers, clinic managers and health workers in primary healthcare facilities in resource constrained urban, rural and deep rural environments in Southern Africa (Malawi, South Africa), East Africa (Kenya) and Horn of Africa (Ethiopia). This input has informed an iterative development approach [4 - 8]. mHealth4Afrika integrates Electronic Medical Records and Electronic Health Record functionality with medical sensors and data visualisation tools to facilitate the interpretation and monitoring of the patient results [5].

The overall objectives [4 - 7] include to:

- research end-user requirements for rural and deep rural communities in developing country contexts;
- research and evaluate the challenges and potential benefits associated with co-designing a common multilingual patient record framework that integrates readings and clinical data from tablets and medical sensors used at the point of care;
- train healthcare workers in urban, rural and deep rural clinics on the coordinated, integrated use of medical sensors and electronic patient records to support more efficient, high quality healthcare delivery in resource constrained environments and
- pilot the integrated solution in semi-urban, rural and deep rural health clinics in Southern Africa (Malawi and South Africa), East Africa (Kenya) and Horn of Africa (Ethiopia) to assess usability and user acceptance and modifications required to facilitate wider adoption at national, regional and continental level.

mHealth4Afrika aims to provide both direct and indirect contributions to primary healthcare delivery at health centre level by supporting improvements in: (a) the quality and impact of primary healthcare delivery through timely capture of information, systematic storage of important data points in the patient electronic record, and improved follow up; (b) data quality (by reducing human error); (c) frequency of contact with a focus on prevention through adoption of state-of-the-art technologies at the point of care; (d) accuracy and quality of monthly aggregate program indicators; and (e) access to educational materials for clinic staff and patients to strengthen digital literacy and health skills [5, 7].

mHealth4Afrika has introduced the use of medical sensors at the point of care [5- 7]. The intervention clinics currently have access to an oximeter (SpO₂, pulse), glucometer (sugar levels), blood pressure, contactless thermometer, weighing scales and the HemoCue Hb 201 (haemoglobin). Sensors can be used to identify non-communicable diseases (including hypertension, diabetes) at the point of care and facilitate triage through the use of a range of medical sensors (not currently practiced at health centre level) [8].

Through integrated use of state-of-the-art technologies in a platform co-designed with key stakeholders, mHealth4Afrika aims to strengthen building the status and skills of healthcare workers in the participating health centres. mHealth4Afrika has compiled a series of tools and multimedia training materials to improve the digital literacy capacity and health skills of healthcare workers. This is complemented by face-to-face training provided to all staff nominated by clinic managers in intervention health centres [5].

This paper is focused on sharing insights into the co-design process followed to develop and validate the mHealth4Afrika platform. Section 2 outlines the methodology applied. Section 3 provides insights into the mHealth4Afrika platform, limitations of the study and ongoing research. Section 4 presents the conclusion.

2 Methodology

mHealth4Afrika is applying a mixed methods strategy [13]. For technical development of the platform, design science research techniques are applied whereby the problem is identified, artefact requirements defined, and the artefact is designed, developed, demonstrated and evaluated [14]. The various platform iterations are implemented using an agile development process. This supports regular interaction with policy makers, district and clinic managers and healthcare workers as part of the co-design process to validate the current iteration and prioritise functionality and data sets for subsequent iteration(s) [5, 7].

Qualitative data collection and ethnographic observation was used during the needs requirements and base line study (November 2015 - January 2016, 40 informants from 19 health centres in the four intervention countries), alpha validation (November - December 2016, 49 participants from 14 health clinics in the intervention countries) and validation of the first iteration of the beta platform (November - December 2017, 36 participants from 11 health clinics in the intervention countries). Based on the use of purposive sampling techniques, intensity sampling was the most appropriate approach [15, 16].

The needs assessment and baseline studies provided critical insights into national protocols, clinical workflow and reporting requirements, as well as the nature of the environments within which the platform would be used, to inform the alpha design. The baseline study provided valuable insights into relevant human resource capacity, practical and technical challenges, equipment and infrastructure related deficits [8].

The alpha and initial beta validations focused on validating user interfaces, functionality, workflow and initial data sets to be collected for Maternal Health and Child Under 5 Programs [4, 5]. These programs were selected based on their priority for each country. Each validation informed the specification of the next iteration of the platform.

mHealth4Afrika secured the necessary ethical approval required in each country [4 - 7]. There were no risks to participants based on their contribution to this study, which was voluntary. Participants were all adults and nursing school or university graduates. They were generally fluent in English, and no vulnerable people were targeted. The intervention clinics/health centres are identified by the Ministries of Health and district health offices. This study is taking place at a mix of semi-urban, rural and deep rural health centres in the Amhara Region, Northwest Ethiopia, Bungoma County, Western Kenya, Zomba and Machinga Districts, Southern Malawi and Eastern Cape, South Africa. None of these facilities have doctors. Clinic management signed an Informed Consent form during Quarter 4 2015 agreeing that data collected throughout the project duration could be used for the purposes of research, informing policy and associated publications. To ensure anonymity, each transcript per health facility was allocated a unique numerical code. With the consent of participants, interviews were audio recorded to facilitate creating transcripts to complement field notes taken during interviews. Following validation sessions, transcripts based on the audio recordings were created to provide raw data for analysis. Each participant or group of participants was allocated a code to ensure that data was sufficiently anonymised prior to data analysis, which leveraged Creswell's Data Analysis Spiral [15].

3 mHealth4Afrika Iterations

3.1 Technologies

One of the research objectives for mHealth4Afrika was to design a patient record framework leveraging some of the functionality of District Health Information System 2.0 (DHIS2). The rationale for this was based on a significant number of Ministries of Health in Africa including Kenya, Malawi and South Africa using DHIS2 as the back-end Health Management Information System (HMIS) for routine reporting of monthly aggregated program data. As a result of participation in mHealth4Afrika the Ministry of Health in Ethiopia is now transitioning to DHIS2 as the HMIS for aggregated data.

The DHIS2 has two main modules: a statistical processing module for routine reporting of numeric health data from health facilities and a single events module "Tracker" for individual patient information. The majority of DHIS2 installations are focused on statistical health data (aggregated data) from health facilities.

It was a conscious decision for mHealth4Afrika to research whether a patient focused application could be built on top of DHIS2 to support a consistent data model to store and retrieve patient data as well as support automatic generation of aggregate monthly indicators based on patient data.

The Tracker module is used in some countries for specific applications, e.g., tracking malaria patients in Zambia and maternal deaths in Uganda. The eRegistry module (adaptation of Tracker) has been used since 2017 in Palestine to capture reproductive and maternal health data based on WHO Essential Interventions. While Tracker supports a data model to be configured for programs, its user interface is not intuitive.

Having analysed both the user interface (UI) for Tracker and eRegistry during the preparation for the mHealth4Afrika alpha platform, two main challenges were identified. The current user interface of the DHIS2 Mobile Tracker Capture is not intuitive and is difficult for healthcare workers to navigate. The current architecture does not support easy adaptation of the user interface or necessary reconfiguration to support end user workflow. It is primarily used as a simple data entry form for a single program.

mHealth4Afrika reviewed the configuration of eRegistry and determined that the data set based on WHO Essential Interventions is not sufficiently comprehensive for mHealth4Afrika intervention clinics. The researchers also determined that the eRegistry use of Tracker was not appropriate for the clinical environments addressed by mHealth4Afrika. The findings and limitations identified from the extensive research undertaken by mHealth4Afrika continues to be fed back to University of Oslo to inform their roadmap for future iterations of Tracker.

As a result, it was necessary for mHealth4Afrika to develop a custom application and user interface using the Angular JS v1.6.9 programming tool that interacts with the mHealth4Afrika data model set up in DHIS2 via a WebAPI (Application programming interface). It was necessary to address a number of technical challenges interacting with the WebAPI based on the complexity and volume of data sets in each program.

The data model for each program (data elements, option sets, program sections and stages, program rules) is configured using the tools in DHIS2. The data model determines the program structure, with its stages, sections and rules. This allows a significant amount of data model related work to be implemented without programming. The mHealth4Afrika application has been programmed to dynamically render the data model for each program. This is very important in terms of maintenance and ease of modifying and adding programs going forward. It significantly reduces the requirement for access to scarce technical resources.

3.2 Functionality

The functionality and user interface of the mHealth4Afrika platform has evolved over time based on feedback received to the alpha prototype [4] and initial iterations of the beta platform [5 - 7] and user requirements.

The initial use case selected for the alpha and initial iteration of the beta was based on antenatal care. This was selected for two primary reasons. First, it is quite complex, thus providing demanding terms of reference for data collection requirements. Second, it is a free service in most African countries, and will impact many people due to the high level of demand. Detailed analysis was undertaken in terms of national protocols, clinical workflow and reporting requirements to prepare a common framework addressing the needs of the four intervention countries.

Based on the pre-beta validation in June 2017 and the Beta platform v1 validation during November - December 2017, it was very clear that health centres require a health information system that allows any patient to be registered once and then over a period of time enrolled in multiple programs depending on their health conditions [5]. This resulted in a re-architecture of the mHealth4Afrika Beta application and data model structure.

Functionality included in the mHealth4Afrika Beta v3 platform includes:

Clinic related functionality

- Set up, view and edit Healthcare workers as system users; Assign access rights based on specific program responsibilities
- Patients - Add, view and edit a new patient record, search the patient list
- Clinic Appointments - Add, view, edit patient appointments, search appointment list

Patient related Functionality

- Patient Profile - provides access to demographic information, programs, appointments, risk factors, and visualisation of program specific readings
- Programs - Add, view, edit data collected during visits related to:
 - Medical History
 - Maternal Health (Pregnancy Test, Antenatal, Delivery, PostNatal)
 - Family Planning

- Cervical Cancer Screening
- Child Under 5 (Growth & Nutrition, Childhood Illnesses, Immunisation, Vitamin A, Deworming)
- Communicable Diseases: Tuberculosis, Antiretroviral therapy (ART)
- General Out Patient Department (OPD)
- Patient Reports by Program

3.3 Use Cases & User Interface

Use cases were developed around different roles and actions taken to support program specific workflow. The data elements, workflow and associated logic were set up to provide a common back end data storage and reporting framework.

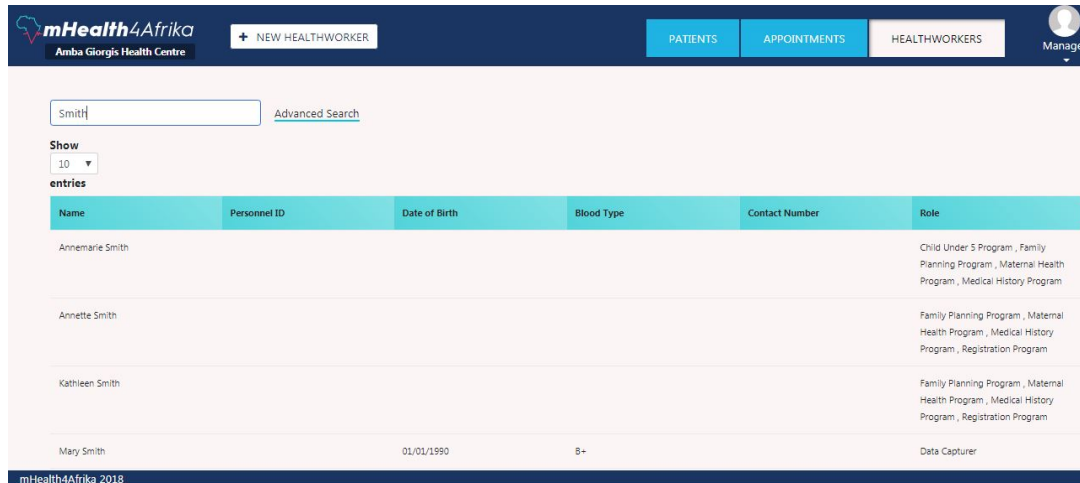


Figure 1. Clinic Manager searching Health Worker List to update access rights

The clinic manager assigns access rights to each nurse / healthcare professional based on the programs for which they have operational responsibility. For example, the registration clerk can be assigned responsibility to the Registration program while a nurse can be assigned responsibility to Maternal Health, Child Under 5, TB and ART programs.

When a patient comes to the clinic, they first visit the reception desk or records office. The registration / records clerk logs into the system, searches for the patient and checks pending appointments. If the patient has not already been registered, the clerk will set up an electronic patient record and assign a medical record number based on the normal health facility protocols. The patient will then queue for a consultation for the relevant program.

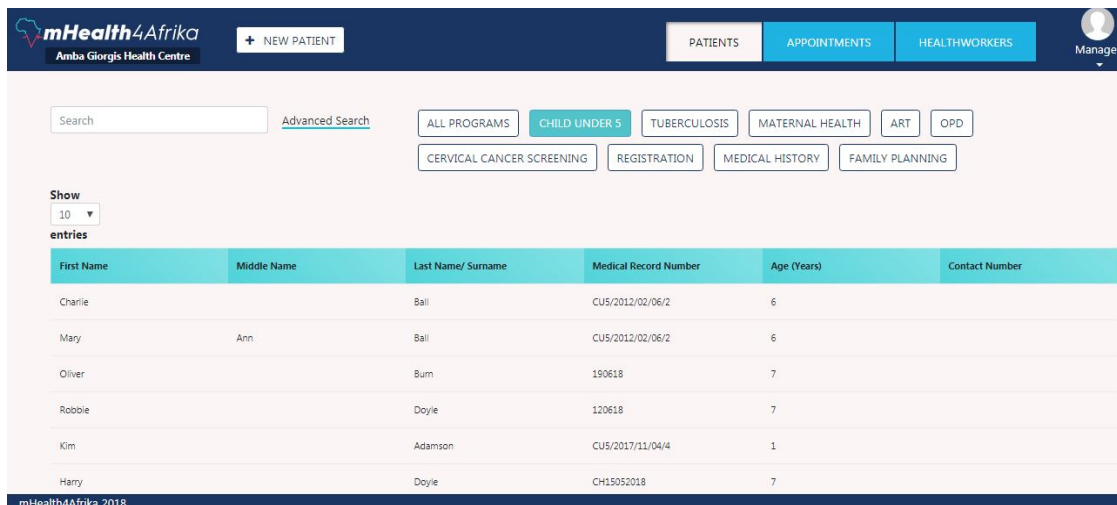


Figure 2. Clinic Manager searching Patient List by Program

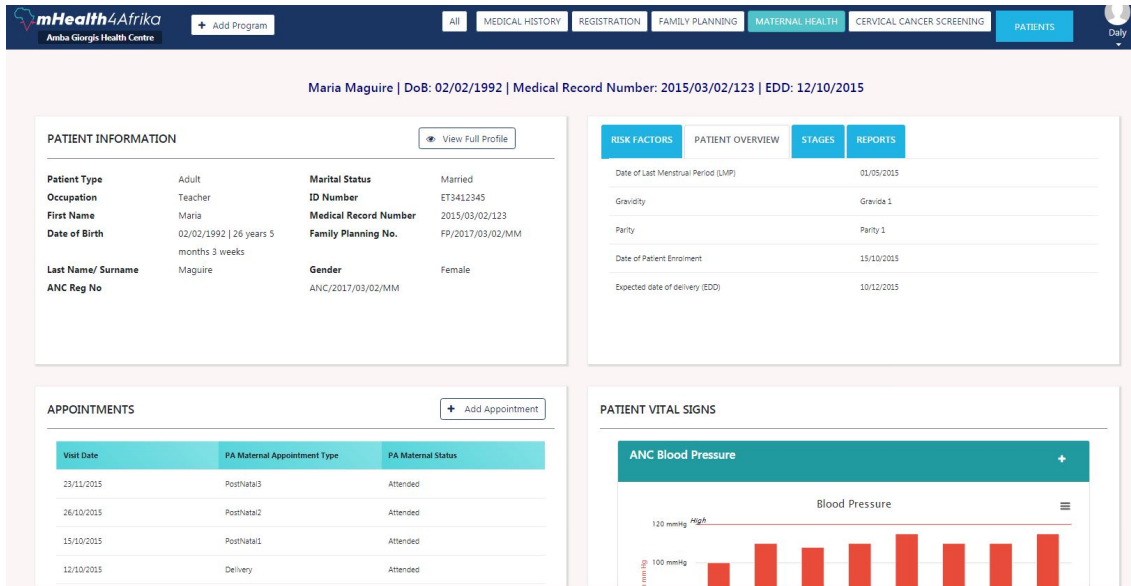


Figure 3. Nurse viewing Patient Overview for Maternal Client

A nurse / healthcare professional undertakes a consultation for each program. They log into the mHealth4Afrika platform, search the patient list and retrieve the patient profile page. Depending on the access rights that the nurse has, they can see the patient profile page related to a number of programs as tabs at the top of the page.

The Patient Overview page has a common structure across all programs providing access to patient demographics, risk factors, program specific information including program stages and reports, appointments and visualisation of relevant data sets.

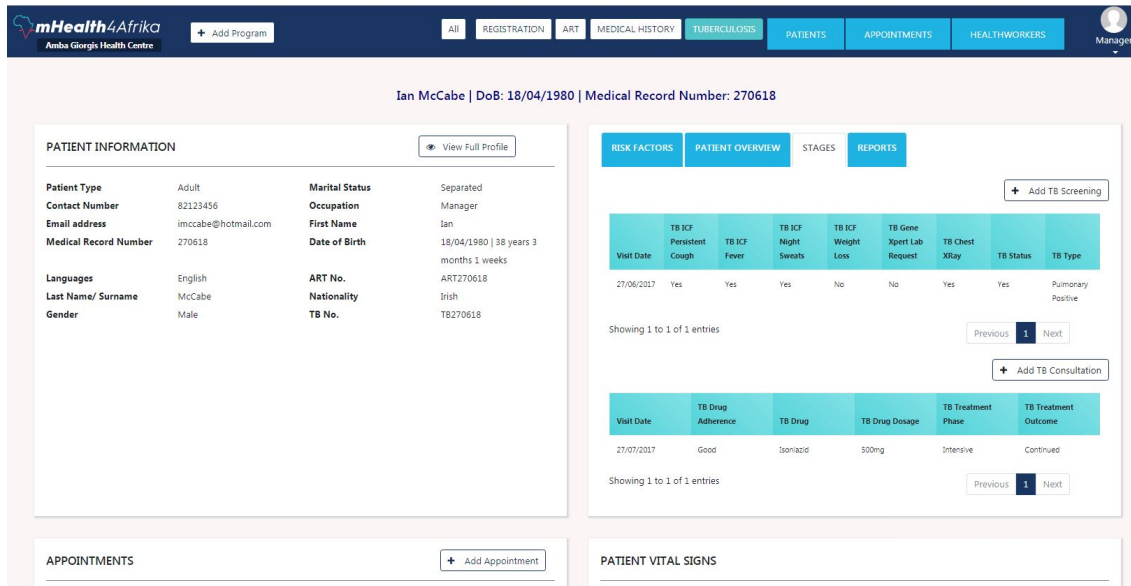


Figure 4. Clinic Manager viewing Patient Overview for a Tuberculosis Client

The screenshot displays the 'Patient Overview' page for a child named Siobhan Maguire. The interface includes a navigation bar with options like 'MEDICAL HISTORY', 'CHILD UNDER 5', 'REGISTRATION', 'PATIENTS', 'APPOINTMENTS', and 'HEALTHWORKERS'. The patient's details are shown at the top: Siobhan Maguire | DoB: 06/02/2012 | Medical Record Number: 2012/02/06/34.

PATIENT INFORMATION

Patient Type	Child	CUS No.	2012/02/06/34
First Name	Siobhan	Medical Record Number	2012/02/06/34
Date of Birth	06/02/2012 6 years 5 months 1 weeks	Last Name/ Surname	Maguire
Gender	Female		

Child Under 5 Summary Growth & Nutrition

Weight (kgs)	4.5
Length/Height (cms)	51
Mid-Upper Arm Circumference (cm)	15
Enrolment Date	06/02/2012

Child Under 5 Summary Immunisation

APPOINTMENTS

Visit Date	PA CUS Appointment Type	PA CUS Status
06/02/2012	Growth & Nutrition	Attended
06/02/2012	Immunisation	Attended
06/02/2012	All Birth Consultation	Attended

PATIENT VITAL SIGNS

- Weight for Age
- Weight for Height
- Length for Age Chart

Figure 5. Clinic Manager viewing Patient Overview for a Child Under 5 Patient

The healthcare professional can then review data collected during previous visits and add data for the current consultation. The visualisation tools on the patient overview page are dynamically updated to reflect the latest data collected. Tool Tips are included within the data collection forms as an online learning /support tool. Program specific data can be viewed and downloaded as a series of patient reports.

The screenshot displays the 'Immunisations' page for the same patient, Siobhan Maguire. It shows the date of visit (06/02/2012) and date of report (06/02/2012). A list of vaccines is shown with checkboxes, including Bacillus Calmet-Guérin (BCG) Vaccine, Oral Polio Vaccine (OPV), Diphtheria, Pertussis, Tetanus, Hepatitis B, Haemophilus influenzae Type B, Rotavirus Vaccine, Pneumococcal Vaccine (PCV), Measles Vaccination, and Hexavalent (DTaP-IPV-Hib-HBV) - South Africa.

Child Immunisation Oral Polio Vaccine

Was Oral Polio Vaccine (OPV) given at this visit? Yes

OPV Vaccine given **OPV0 (birth to 2 weeks)**

Oral Polio Vaccine (OPV) - Date Given

Batch Number for Oral Polio Vaccine Given

Clinical Notes (OPV)

Figure 6. Clinic Manager viewing Immunisation Details input for a Child Under 5 Patient

3.4 Limitations

There are a number of limitations of this research. A deliberate limitation has been to engage with policy makers and professional healthcare participants in rural, deep rural and semi-urban clinics in Northern Ethiopia, Western Kenya, Southern Malawi and Eastern Cape in South Africa, to gather intelligence from clinical staff responsible for local healthcare delivery. While this provides geographic representation from Southern and East Africa and ensures that the programs available through the platform are based on national requirements in these four countries, the study findings may not be representative of other Southern and East African Member States, let alone all African Member States. The sample size is also relatively small due to costs associated with equipping clinics in some countries.

3.5 Ongoing Research

The current version of the beta platform is being piloted in the intervention clinics while additional functionality is being added to the next iteration. Functionality prioritised for inclusion in Beta v4 includes automatic counting of aggregated monthly program indicators and SMS notifications for patient appointments. Literature indicates that SMS appointment reminders can be effective in increasing engagement with health service delivery [17]. Based on consultation with clinic managers, automated generation of monthly program indicators will save on average three to five person days' effort per month per clinic. These time savings can strengthen primary healthcare delivery by facilitating access to continuous professional medical education and provide more time for difficult consultations.

mHealth4Afrika is continuing research on integration of additional readings from medical sensors. The process for selecting the medical sensors and transferring data using the secure data communication standard Health Level 7 Fast Healthcare Interoperability Resources (FHIR)[®] to the electronic patient record is addressed in a separate paper.

4 Conclusions

This paper provides insight into the objectives and co-design process followed to develop, validate and inform the design of the mHealth4Afrika platform iterations, Beta v3 functionality and ongoing research activities.

mHealth4Afrika has developed a custom application to strengthen primary healthcare delivery in resource constrained environments. It supports a range of interdependent programs (Medical History, Maternal Health, Family Planning, Cervical Cancer Screening, Child Under 5, TB and ART) defined in consultation with key stakeholders. This is achieved by interacting with a data model set up in DHIS2 via a WebAPI to facilitate holistic monitoring of a patient's well being. The Patient Profile Page provides the healthcare professional with insight into the current records and risk factors for a specific patient, based on data collected during previous visits and visualisation of vital signs. This is limited to those programs for which the healthcare worker has access rights.

mHealth4Afrika aims to assist primary healthcare facilities to increase the quality and impact of care through timely and accurate capture of information, systemic storage of important data points in the electronic patient record and improved follow up. It aims to support preventative care by providing a state-of-the-art platform designed to encourage patients to attend relevant free services such as antenatal care as well as other services.

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A Conceptual Model for Adaptation of eHealth Standards by Low and Middle-Income Countries

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Background and Purpose: Electronic health (ehealth) is the use of information and communication technology to support healthcare. It is used to driving efforts to achieve sustainable development goals (SDGs) particularly “good health and well-being for all”. Nonetheless, just like other technologies, ehealth has rapidly gained ground in low and middle-income countries (LMICs) although with scanty government intervention. In fact, governments in LMICs have only lately developed ehealth strategies. Much as ehealth offers the promise for improved and affordable healthcare and service delivery, its success is still dependent on the specifications (standards) to support interoperability and information exchange. Regrettably, standardization efforts in LMICs are greatly curtailed by resource constraints.

Methods: We reviewed literature on ehealth standardisation in LMICs using four African countries as our case studies. The objective of the study was to explore the challenges of ehealth standards development and or adoption by LMICs and posit that adaptation of existing international ehealth standards is a better option for LMICs. Qualitative analysis was used to derive key themes.

Results: Our study findings indicate several challenges to ehealth standardization in LMICs including delayed standardisation efforts and unregulated penetration of ehealth, slight industry involvement, inadequate funding for the standardisation process, insufficient human resources, less to none participation in the international standards development process, and inadequate technical infrastructure for standards participation among others.

Conclusions: This study recommends adaptation of international ehealth standards to local context of individual LMICs to help streamline both patient data and health information sharing. To achieve this, we developed the ehealth standards adaptation model. The model offers better opportunity to fast-track ehealth standardisation efforts in LMICs, as such creating an enabling platform for ehealth systems interoperability and support for health information exchange.

Keywords: Adaptation Model, eHealth Standardization, Standards

1 Background and Purpose

Technological advancement in LMICs has always preceded the regulation. Governments and regulatory bodies are slow to develop or adopt standards and regulations to guide technological adoption, implementation, usage, access, security and privacy. While innovators continue to develop solutions for health problems in LMICs, they need to use and follow standards that should guide them to develop products suitable for use in resource-constrained environments. Standards are specifications necessary for proper co-existence and interoperability of systems; essential for meeting national and international regulations and critical for safe operation of devices without causing harm to people or equipment [1] [2] [3]. In health, standards are needed to foster effective health information exchange, co-existence and interoperability of systems [2] [3] [4]. In addition, standards for ehealth aim at provision of reference criteria that a solution (product or service) must meet; provision of information that enhances safety, reliability,

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and performance of such solutions, product or services; assure stakeholders about their reliability and guarantee choice of technology, solutions and services [2] [5]. Notwithstanding the benefits of ehealth standards, many LMICs are still slow in adopting ehealth standards [6]; as such they have lagged behind in the implementation of interoperable ehealth systems. For this reason, pilot ehealth projects in LMICs including Uganda, have failed to scale-up [7] [8] and remain standalone, that is, non-interoperable health systems. This has hindered attainment of one vital goal for ehealth, that is, access to health information whenever and where required by authorized persons [9] [10]. To address such gaps, various studies on ehealth in LMICs suggest priority areas to include; e-Health standards, ICT and health policies, e-legislation, e-Health infrastructure, ehealth education and ICT competence [6] [11] [12] [13].

Given the background above, this study focuses on adapting ehealth international standards to address the LMICs' ehealth interoperability initiatives. Using Uganda as an example of LMICs, several ehealth interoperability challenges have been observed key ones being the lack of ehealth standards and guidelines [14] [15]. However, developing standards for the complex ehealth environment is more challenging than for general innovations [16]. As such, our study suggests, paying more attention to developing ehealth standards that can be adapted to address LMICs' ehealth interoperability challenges. We note, however, lack of a powerful process to develop ehealth standards [17] or even contextualise existing international standards to meet requirements of resource constrained environments in LMICs. Existing adaptation models only consider technology adaptation, quality adaptation, and content adaptation [18] [19] [20] among others, but none presents ehealth standards adaptation model. While some of the international ehealth standards are applicable in LMICs, others require adaptation to support the unique resource requirements or use cases [12]. The concept of "Adaptation" also called co-shaper refers to adjustment of existing international standards to suit a country's specific needs and deployment of such adjusted standards [5]. The need for adaptation of ehealth standards by LMICs is heightened by the demand to fast-track the standardisation of ehealth to ensure interoperability of already existing ehealth implementations; and the need to promote innovation of standardised ehealth technologies [6] [11] [12]. To this end, we reviewed the challenges of ehealth standardization in LMICs and suggested that adaptation of existing international ehealth standards is a better option. In fact, Kern [21] argues for standards adaptation for new regularly emerging technologies; and [22] recommends adaptation to meet a country's specific needs.

2 Methods

To conduct our study, we surveyed various literatures including specific country ehealth policy and strategy documents on ehealth standards in LMICs. We identified four African countries to represent LMICs. We conducted desk reviews of published and unpublished literature on the standardisation of ehealth systems in Rwanda, Malawi, Kenya and Uganda. The qualitative analysis method was used to synthesise the data we collected; the aim was to derive common themes on the challenges of ehealth standardisation, as well as to deduce sound conclusions regarding the state of e-health initiatives in LMICs, that is the standards that support interoperability and integration of ehealth systems.

3 Results

From our literature reviews, we derived a number of ehealth standards challenges as discussed below;

Little participation in international ehealth standards development: Standardisation can be at national, regional, international or industry context, where stakeholders agree upon a repeatable way of doing something [23]. The standards are grouped as formal, informal, official, voluntary, industry, private or open standards [17] [24]. This study considered formal de jure standards. These types of standards are developed by standards development organisations (SDOs), the bodies mandated within the industry, nation, and region or internationally to develop the standards. Table 1 presents LMICs participation in some of the international ehealth SDOs (using February, 2018 data).

Table 1. eHealth Standardisation Organisations

SDO	LMICs Participation	
ISO–TC215 Health informatics	27/59	(45.8%)
GS1	66/113	(58.4%)
European Committee for Standardization	0	(0.0%)
International Health Terminology SDO - SNOMED	3/31	(9.7%)
Institute of Electrical and Electronics Engineers (IEEE)	Individuals	N/A
National Electrical Manufacturer Association (NEMA)	0	(0.0%)
International Electrotechnical Commission (IEC)	41/85	(48.2%)
Health Level Seven (HL7)	Individuals	N/A
Clinical Data Interchange Standards Consortium (CDISC)	Individuals	N/A
Regenstrief Institute	0	(0.0%)

Lack of a formal standardisation process suitable for LMICs: SDOs have a formal process for standards development and approval [25]. The process can be summarised into five stages of demand for standards, organization and management of the workgroup, development and implementation of standards, education and support services, testing and evaluation of standards, and conformance monitoring and review [21] [22] [26]. The process presents a structured procedure of producing standards /specifications based on outlined principles [23].

High penetration of ehealth systems: Electronic health implementation in LMICs started in the 1980s – 1990s. Evolving of ehealth technologies followed, but their penetration in the health sector has remained largely unregulated. Much of these implementations remain isolated and fragmented [12] [19] [27] [28]. The reviewed LMICs in Africa have small, fragmented and generally donor led health information systems (HIS) and technologies [12] [13].

Delayed ehealth standardisation efforts in LMICs: LMICs including Uganda have multiple health sector challenges, including shortage of health professionals and facilities. Hence, the individual LMICs moved quickly to adopt ehealth solutions to curb various shortages in the health sector. A review of ehealth in Uganda, Kenya, Rwanda, and Malawi revealed similar patterns in adoption of ehealth, for example the computerised health records (CHR), hospital management systems (HMS), health information system (HIS), health management information system (HMIS), among others; ehealth strategies and corresponding standardisation efforts (see Table 2).

Table 2. Examples of ehealth strategy development efforts in LMICs [8] [13] [29] [30] [31] [32]

Country	Start of eHealth implementation	eHealth Strategy	National eHealth Standardisation Body	
			Specialised	General
Uganda	1997 (HIS)	2012	Taskforce, Collaboration	UNBS, MoH
Kenya	2001 (CHR)	2011	Taskforce, Collaboration	KBS
Rwanda	1997 (HMIS)	2009	RITA	RSB, RITA
Malawi	2002 (HMIS)	2003	MoH	MBS, MoH

Common Standardisation Challenges: The following have been identified as the most common challenges to hamper adoption of existing ehealth standards in resource constrained-environments, particularly Uganda; little industry involvement [23] [33], inadequate funding for standardisation process, insufficient human resources [15] [23], inadequate technical infrastructure for standards participation [23] [34], competing and overlapping of standards [33] [34], and complexity of ehealth data / information and its components [23].

4 Discussion

The review of ehealth standardisation in LMICs revealed various challenges that continue to limit eHIS interoperability and deter health data / information sharing. Table 1 shows that LMICs' involvement is an average low of 23.3% only (participatory and observatory) in the seven common ehealth SDOs. Active participation remains greatly in developed countries (76.7%), and not LMICs [12]. Limited input from resource-constrained countries suggests developed standards may not be 'exact fit' for resource-constrained nature of the LMICs. Hence the need to develop and or contextualise these standards to meet individual country ehealth interoperability needs. We note however, that existing SDOs standardisation processes only emphasise development, adoption and implementation, and overlooking the need for adaptation, yet Kern [21] argues for standards improvement and adaptation for new regularly emerging technologies. Besides, [22] recommends adaptation to meet a country's specific needs. Also, the "standardization process takes too long for a fast-moving industry or product development" [25] like the ehealth environment. Regards LMICs, they lack resources to develop standards. Similarly, adopted international ehealth standards may not fully apply to LMICs due to varying resources environments. Thus, we argue that neither the development nor adoption of ehealth standards is a viable alternative for LMICs.

In the presence of unregulated mix of government, donor and private HIS unguided by standards, most HIS remain isolated, fragmented and noninteroperable [12] [13] [19] [27] [28]. Thus, there is need to urgently standardise HIS, communication systems, data structure, terminologies, security and privacy to support health data / information sharing. Unfortunately, delayed standardisation efforts continue to aggravate the interoperability problem. In fact, despite early entry of ehealth implementations in LMICs in 1980s and 1990s [8], they remain unstandardized and lack interoperability. The four case countries reviewed in this work, have only recently developed the ehealth strategies and or policy (see Table 2).

Since standardisation is a difficult undertaking, when done after the country has mature noninteroperable ehealth systems across health facilities [9], an alternative to development should be considered. In addition, the resource-constrained countries experience general standardisation challenges like, inadequate funding for standardisation; insufficient human resources; limited technical infrastructure for standards participation and complexity of ehealth data / information and its components [23] [24] [34]. These limit the possibility of LMICs developing contextualised ehealth standards. Therefore, this study suggests the need for LMICs to explore ehealth standards adaptation as a better alternative to development or adoption.

4.1 Adaptation Model for eHealth Standardisation by LMICs

LMICs should fast-track ehealth standardisation efforts to overcome interoperability challenges. Besides, they need to ensure interoperability of already existing multiple ehealth implementations. This study suggests the adaptation of the ehealth standards as a better option to fast-track ehealth system interoperability and data exchange. Although, there exist many adaptation models, including the technology adaptation model, the quality adaptation model, and the content adaptation model [18] [19] [20] among others the current literature presents no ehealth standards adaptation model. As suggested in [19], the components of existing technology adaptation and quality adaptation models were used to develop the ehealth standards adaptation model in Figure 1. This model was derived from the technology adaptation model and the quality adaptation model [27] [33]. The model's component relationships include; first, the standards-country fit, which represents choice of ehealth standards suitable for resource-constrained nature of LMICs and their long-term needs. Second, the standards-HIS (infrastructure) fit, which represents standards tailored to the resource needs of respective ehealth systems.

The Model's three phases, include; the scanning phase, design phase and implementation and evaluation phases. The scanning phase, is the formative stage when assessment of a country's resources and existent international ehealth standards are done. The design phase handles adaptation and delivery of ehealth standards. This is the point where existent international standards are harmonized / tailored to make them relevant and accessible in a given context. Third, is the implementation and evaluation of adapted standards; these three phases have the following components:

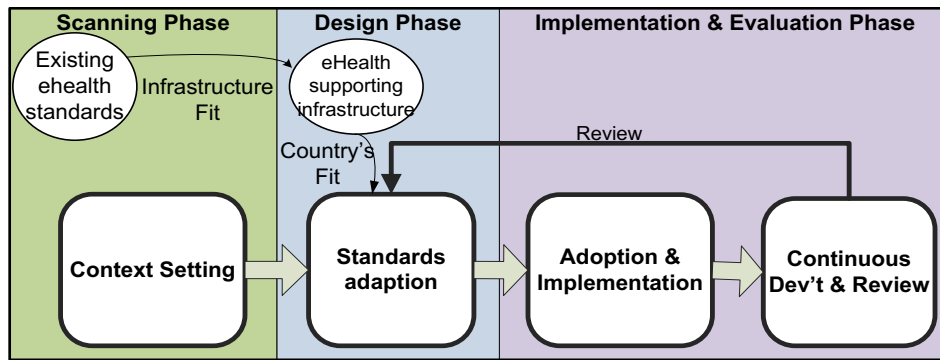


Figure 1. Model for ehealth Standards Adaptation

The context setting stage: This is the ground breaking and laying of the foundation to ehealth standards adaptation. All health stakeholders and consumers are sensitized on the strategic importance of ehealth standards. It includes, a country's ehealth strategies like the one that Uganda has already developed [15].

The standards adaptation stage: Although the existing international ehealth standards are extensive and accessible for ehealth implementation in resource-constrained environments (LMICs like Uganda), they may not fully apply to their ehealth sector [12]. This means, the standards need to be harmonised for such environments. This phase in our adaptation model will involve identifying ehealth stakeholders (actors), international standards for ehealth ecosystem, determining of methods/tools/instruments for adaptation of such standards, determining their fit for the country and its infrastructure. The country's and infrastructural fit depend on the individual country's ehealth resources.

The implementation and adoption stage: At this stage adapted / developed standards are introduced into the country's healthcare ecosystem. A standard must be implemented to derive its true benefits. Gaps in the standards implementation and compliance monitoring will stall success of ehealth. The implementation and compliance monitoring process are gradual and a responsibility of all stakeholders. Just like in other sectors of government, there is need for national standards body to monitor the implementation and compliance to agreed standards. Where no national institution has the competence to take binding decisions, a workgroup may coordinate such activities [35]. This requires the collaboration effort of many stakeholders to ensure compliance to both industry and government specifications.

The continuous development and review stage: The standards lifecycle require that there are periodic reviews. Depending on new ICT innovations, standards may need to be improved and adapted to the new technology [21]. Therefore, besides scheduled reviews, ad hoc reviews may be done if that particular standard is believed not to fit its purpose. The process confirms, revise or depreciate and replace a standard. Those ehealth standards that are either confirmed or revised to fit its purpose are then adopted for further use.

5 Conclusion

In conclusion, existence of ehealth standards cannot be disputed; however, there is a concern about LMICs participation in their development, adoption and implementation. In this research, we have identified various challenges facing ehealth standardization in LMICs and hindrances to their participation in international SDOs. We argued that the normal standardization process cannot solve these challenges and thus proposed a model for adaptation of ehealth standards by LMICs. Though, the study was limited to four African countries as the case studies, the proposed model can be used to fast-track ehealth standardization in all LMICs that have lagged behind in their standardisation efforts due to lack of common standardisation efforts and un-regulated ehealth penetration. Moreover, this study will provide an enabling implementation platform for ehealth system interoperability suitable for resource-constrained environments. In future work, we propose to empirically test and evaluate the usefulness of this model in LMICs using Uganda as our case study.

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Maternal and New-born Mortality Surveillance – Case for Kwale, Kisumu, Vihiga and Siaya

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Background and Purpose: An analysis of DHIS2 data was done and a comparison of the number of deaths reported on the Integrated Disease Surveillance and Response (IDSR) and MoH 711, discovered that IDSR is under-utilized and inaccurate. This data analysis revealed that on average only 39% and 11% of maternal and neonatal deaths respectively, are reported as emergency events in the four counties. The aim of the study was to unearth the challenges hindering real-time submission of data and to understand the surveillance cycle in use.

Methods: A purposive sampling was used to select the research participants and regions to collect the data from. The staff directly involved in the reporting of maternal and new-born deaths were targeted. They included maternity ward-in-charges, surveillance focal persons, health records personnel, and the county health management teams. The awareness of the standard operating procedures and notification policies on zero-reporting was evaluated, as well as the preparedness of reporters, the availability of IDSR reporting tools, the reporting process, and the challenges hindering reporting to IDSR.

Results: The maternity staff were not aware that they were required to send death notifications to the IDSR office within 24 hours after the death occurs, only 3 (8%) respondents had seen a maternal and perinatal death standard operating procedure (SOP), the weekly reporting tool was not readily available in 15 (38%) facilities, only 8 (20%) facilities had a clear reporting cycle.

Conclusions: There is need for improving the reporting process of the maternal and new-born deaths in Kenya.

Keywords: Real-time data, Integrated Disease Surveillance and Response (IDSR), District Health Information System (DHIS2), Reporting Process Flow, Standard Operating Procedures (SOP)

1 Introduction

Kenya implemented the World Health Organisation technical guidelines to include maternal and neonatal deaths in the list of notifiable events through the Health Management Information System (HMIS) [13]. Orientation workshops and training were conducted for all healthcare workers at all levels. Studies conducted in the earlier years revealed that there was underreporting of these deaths, poor compliance with the Ministry of Health (MoH) circular on perinatal and maternal death notification, as well as lack of evidence of responding to the Maternal Death Review (MDR) recommendations at the national and facility levels [2]. The main recommendations from the reviews were to do capacity building for healthcare workers on forms completion and having a lead MDR person at each hospital.

In the technical guideline new amendments were also made to existing reporting tools. As part of these changes the reporting form MoH 505 which is one of the surveillance weekly reporting tools added maternal and neonatal deaths in the list of events on the form. There are other tools used in various ways at the health facilities: birth and death notification forms are used to register persons who were born or died, MoH 333 is used to collect data at the maternity and delivery ward, MoH 711 is an integrated summary tool for

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reproductive health, HIV/AIDS, malaria, TB and child nutrition. Maternal audit forms and D1 forms are used to register patients who have died.

A review by WHO in 2014 showed that the system appeared to be working well under partner sponsored programmes in selected counties but reporting and notification of the deaths have not improved [8]. The main focus by the partners is on malaria, HIV, TB, and outbreaks data. Furthermore, a study [3] revealed that despite the Maternal and Perinatal Death Surveillance and Response (MPDSR) notification and evaluation forms being incorporated into the DHIS2, the reporting still had gaps, and not all maternal deaths were adequately captured by the Civil Registration and Vital Statistics (CRVS) and DHIS2 systems.

In support of the MPDSR notification and evaluation forms being incorporated into DHIS2, technical guidelines and standard operating procedures (SOP) were developed to support the implementation of MPDSR in 2016. Some of the principles of the technical guidelines were: sending maternal and neonatal death notifications within 24 hours, conducting death reviews within 7 days, completing the weekly IDSR reports, and adopting zero reporting. Considering any maternal and perinatal death review as incomplete if no response from the audit team is provided was also added as a principle [6].

The German Development Cooperation through its Technical Agency in the Health Sector in Kenya (GIZ HSP), has as its mandate to ‘Improve Access to Quality Healthcare particularly for the poor and persons working in the informal sector’. GIZ HSP works in collaboration with four county governments, namely: Kwale, Kisumu, Vihiga and Siaya. GIZ HSP monitors the maternal and under-5 mortalities through the District Health Information Software (DHIS2) which is used in all facilities as a national reporting tool. During an analysis of this data covering January 2016 to December 2017, a comparison of the number of deaths reported on the Integrated Disease Surveillance and Response (IDSR) (as emergency events) and MoH 711 (a summary of the monthly statistics) was done (Figure 1) [14]. It was discovered that IDSR is under-utilized and inaccurate. On average only 39% of the maternal deaths and 11% of the neonatal deaths are reported as emergency events in the four counties.

January 2016 to December 2017				
	Maternal Deaths 20+ years	IDSR Maternal deaths	Neonatal deaths	IDSR Neonatal deaths
Kwale County	46	15	240	66
Kisumu County	102	17	539	192
Vihiga County	13	2	139	29
Siaya County	34	70	378	4
Kenya	1,861	584	19,347	3,729

Table 1. Comparison between IDSR and monthly data

This study was conducted as a follow up research in the specific hospitals where GIZ gives direct support: Kwale (11), Kisumu (12), Vihiga (11), and Siaya (8). The health facilities are run by private institutions, the Ministry of Health, and faith-based organizations. From the definitions above, the following research questions were deduced: what workflow processes are followed when reporting neonatal and maternal deaths? What challenges are hindering emergency reporting of neonatal and maternal deaths to DHIS2?

1.1 Background

Despite the heightened attention and major global commitments along with significant funding, maternal health still remains a significant issue in low-income economies such as Kenya. Although maternal deaths have been reported as having reduced between 1990 and 2013, [12] found that approximately 830 mothers die on a daily basis due to pregnancy complication and childbirth. Whereas solutions to these problems are available, the implementation is constrained by lack of access to quality maternal care.

Mobile Health (mHealth) has been proved to have the potential to significantly reduce the inequality of maternal health care through various technological applications that aim at facilitating efficient communication between healthcare providers and patients. These applications can also assist in the

collection of data with the overarching objective of enhancing access to quality maternal health care. Other African countries like Tanzania show that having the necessary preconditions in a developing country can enhance surveillance of maternal and perinatal deaths by implementing legal and policy frameworks to support it [4].

The Ending Preventable Maternal Mortality (EPMM) working group composed of representatives from various national and international development partners is working towards ending preventable maternal mortality by ensuring universal health coverage (UHC), hospital accessibility to all without discrimination, addressing all maternal death causes, strengthening systems to collect high quality data, and finally ensuring accountability [11].

The GIZ Health Sector Programme in Kenya has also been working in four counties to strengthen the capacities of the health management teams to plan and manage the provision of health services. GIZ main aim is to enhance access to high-quality basic health services for the poor, workers in the informal sectors and their families. GIZ has supported the MPDSR process since 2015 and has had some gains in Kisumu County, for instance MPDSR meetings are now held on a monthly basis to discuss what went wrong, steps to ensure it doesn't happen again, and insights to learn from mistakes, at the county level; facilities and communities are now able to discuss the maternal death cases regularly, and clinicians give their input at each County MPDSR meeting [1].

In relation to the emergency reporting Kisumu is now able to notify the County Reproductive Health Coordinator immediately a death occurs in a facility, and the community conducts verbal autopsies within 7 days of any maternal death. Save the Children has also implemented emergency and developmental health programmes in some parts of the country since 2011 [7]. Their focus has been to provide support to the health systems and to endow communities to ask for health services. The quality of data has always been considered as an important matter because it has a huge impact on the government budget and is also used in stimulating high standards of patient care. Poor data quality has a negative impact on the quality of healthcare. This data is used at hospital level for assessing their service delivery, hence, make appropriate financial and administrative plans [9]. At the county and national levels, the statistics are used for planning of healthcare services and resource allocation in order of priority. Therefore, accurate, well-timed and accessible healthcare data play a critical role in the development, planning, and maintenance of healthcare services [9].

As the healthcare sector moves to progressive evidence-based healthcare systems, it has become critical for providers to embrace data for reasons such as making informed decisions to advance the quality of care, and by using data of good quality to enhance facility performance [9]. IT tools for data collection have been proved to help clinicians and patients access the latest evidence-based, lifesaving practices at their work stations.

Reporting structures in Kenya .

UNFPA and other partners introduced the maternal death surveillance and response (MDSR) as a new way of conducting maternal death reviews to Kenya in 2013. Since MDSR had well-established review processes, it was beneficial because it put more emphasis on the significance of timely reporting (surveillance) of the deaths and action implementation (response) to avert further deaths [13]. Implementation of MDSR entails the establishment of a system that links surveillance and review of maternal deaths at the facility and community levels so as to notify the national level with confidential investigation of the deaths. In 2016 the national guidelines incorporated perinatal deaths in MDSR to make it MPDSR and thus conduct surveillance and reporting for both maternal and perinatal deaths [8].

Kenya IDSR reporting .

Among the key components in the technical guideline, maternal and perinatal deaths were made notifiable events and thus incorporated in the notifiable disease reporting system IDSR. The technical guidelines directed that wherever the maternal mortalities were included as notifiable events, the IDSR platform must be strengthened during the MDSR implementation process [13]. The guidelines also instructed that zero reporting be done when no death occurs for every reporting period.

In the case for Kenya, the IDSR platform on DHIS2 is where all maternal related deaths should be reported within a week and notifications sent within 24 and 48 hours if it happens in a facility or in the

community respectively, through the fastest means available. The IDSR guidelines advise that after the death of a pregnant woman has been determined, a health facility must contact the district authority and give information (notify) about the case. They should then follow the notification with a written case-based report and a weekly report on the IDSR Weekly Reporting Tool (MoH 505) filled in triplicate.

Surveillance concept .

Surveillance data is information for action which must be transmitted to bodies that can take action to prevent or control further damage to communities and individuals. These bodies may not only include the MoH but also other sectors, industries, non-governmental organizations, community groups and many others. Health surveillance is a cycle of ongoing public health activities and actions that involve public health agencies, health workers, and the public. The first stage of the cycle starts when a health event occurs and is reported by a health worker to the public health office; this does not stop until the information about the case has been collected, integrated, analysed, interpreted, surveillance products produced and disseminated to the users (in this case those who will act on it)[10].

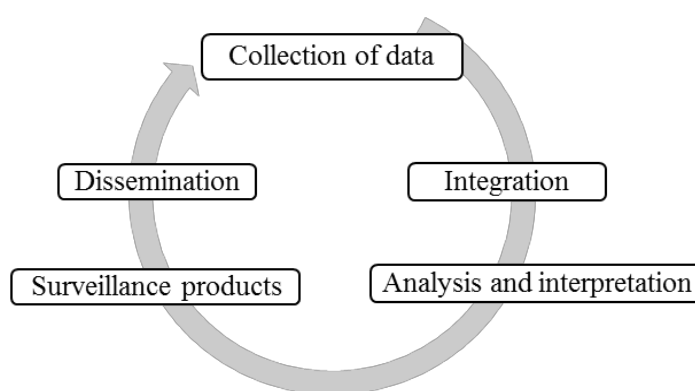


Figure 1. Surveillance cycle model “(adapted from [10])”

2 Materials and methods

In this research a purposive sampling procedure was used to select the research participants and regions to collect the data from. The staff that are involved directly in the maternal and perinatal deaths reporting were targeted. They included maternity ward in-charges, facility surveillance focal persons, health records personnel, and the county health management teams.

2.1 Data collection tools

The semi-structured interview format was used where an interview guide containing a set of questions was prepared prior to the interview sessions and additional questions asked in no particular order for further clarification and as a trigger to an open discussion.

Focus group discussions were done with preformatted questions focusing on the main area of interest were prepared and tabled before the participants for discussion in a group. The discussions triggered further questions within the participants which they were able to answer. They were also able to share their experiences and views on the MPDSR reporting process and challenges faced at the higher levels.

2.2 Data collection

There were 41 facilities selected to participate in the study. The data necessary for this research was obtained from 39 healthcare facilities which were accessible. Two facilities were inaccessible due to the bad road conditions. The participants were interviewed through a one on one interview. Where the facility

in-charge was not available the records person together with the surveillance focal person were interviewed. A few members of the County Health Management Team (CHMT) were also engaged in group discussions. Completeness of data recorded on registers was also checked by reviewing the maternity registers.

2.3 Data preparation and processing

The data obtained was prepared and processed by the following steps:

- The recorded interview sessions were transcribed for each participant and written on a notebook then later input to the SPSS data editor. Since the data collected was mainly qualitative it had to be coded in order for it to be in a format that could be tabulated into the SPSS analysis tool.
- The open-ended questions were coded to create multiple responses and to develop meaningful relationships. This was dependent on the question asked and the number of responses given. The original data is still available for further reference.
- The data was then filtered to analyse the awareness of zero reporting since this represents the direct cause of non-reporting. This was also helpful in checking the reporting frequency.

2.4 Ethical issues

The research process was conducted within the stipulated clinical rules and ethics. According to the guidelines for ethical conduct of biomedical research involving human subjects in Kenya, a high level of privacy was observed while looking at the maternity registers which had patient's data recorded [3]. The data was handled confidentially exclusively by the researcher. Before this activity begun a written consent was sought from the interviewees and signed for the protected information and all procedures abided by.

3 Results

From the targeted 42 facilities, 39 were visited and interviewed in the various counties as follows: Kwale (9), Kisumu (12), Vihiga (11) and Siaya (7). Ownership of the health facilities was as follows: faith-based 10%, private hospitals 18% and governmental hospitals 72%.

3.1 Awareness of zero reporting

The awareness for the timelines to send maternal and perinatal death notifications was assessed with the following findings:

- No maternity staff was aware that they were required to notify the surveillance focal person
- No maternity staff was aware that they were required to send zero reports to the surveillance person if no death occurred.

A section on the manual maternity register for the registration of the total number of deaths per day was incomplete and the registers had cases of lacking data in the following fields: diagnosis, blood loss, feeding options, delivery conducted by, and birth notification number.

3.2 Preparedness of the reporter

Only 3 (8%) respondents were aware or had seen standard operating procedures (SOP) on maternal and perinatal deaths guideline. The only available SOP was the maternal deaths audit form and none on the general reporting guideline from the MPDSR. A further 8% (3 respondents) were not aware of any SOP and 84% (33 respondents) had no form of policy or guideline. 19 (49%) respondents had not received any form of training on how to report maternal and perinatal deaths while 20 (51%) respondents had been trained more than three years ago.

3.3 Availability of reporting tools

The standard reporting booklet called MoH 505 IDSR Weekly Reporting Tool was not readily available in 38% of the health facilities visited. A good number of the facilities had photocopied pages of the booklet which was only used for outbreak cases and not for maternal or neonatal deaths. The tools in use at the maternity and records department in all the facilities visited were distributed as shown in the graph below:

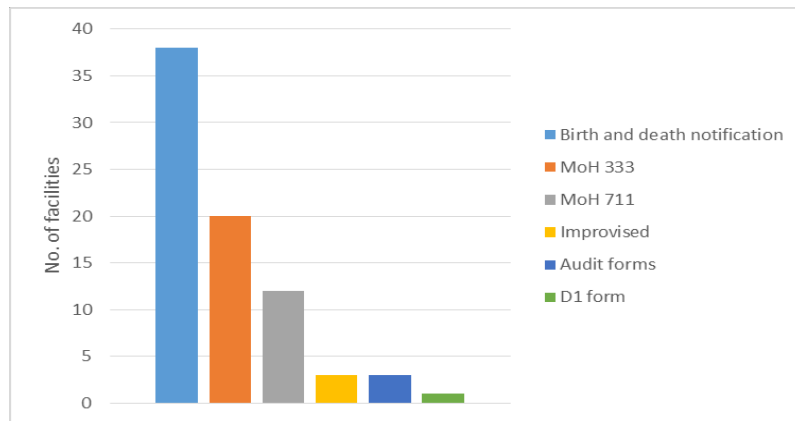


Figure 2. Reporting tools in use at facility level

3.4 Reporting process

Only one facility out of the 39 had a well-defined MPDSR flowchart pinned on the wall at the maternity ward; it was developed with the help of a development partner. 97% of the facilities were issued with MoH tools and in case of a maternal or perinatal death, the hospitals were able to send the written reports to the sub-county offices. There are only 8 (20%) facilities that have a clear reporting cycle in place and are able to complete the process by submitting their data in DHIS2 at the end of the month.

There was no single register in all the 38 facilities which was properly and completely filled as is required. Completeness of the registers was not checked in one facility because it had an improvised general register used in all the departments of the hospital. The registers had numerous misfiling with the wrong content or words instead of codes in some fields.

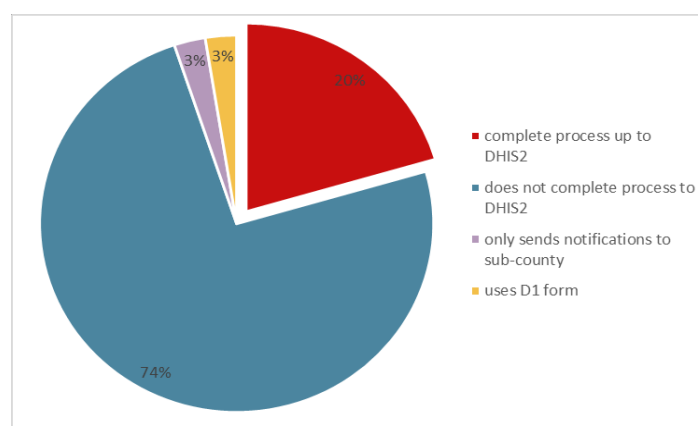


Figure 3. Complete reporting to DHIS2

3.5 Feedback mechanisms in place

Proper feedback mechanisms are lacking and only 26% of the facilities reported to have received feedback from the county management team. None of the respondents has received feedback from the surveillance teams placed at the sub-county or county level.

3.6 Challenges hindering reporting

There were 27 challenges cited to be hindering timely and complete reports within the recommended timelines. The challenge that topped the list was the lack of awareness for immediate notification and zero reporting scoring 69% among others as displayed in the graph.

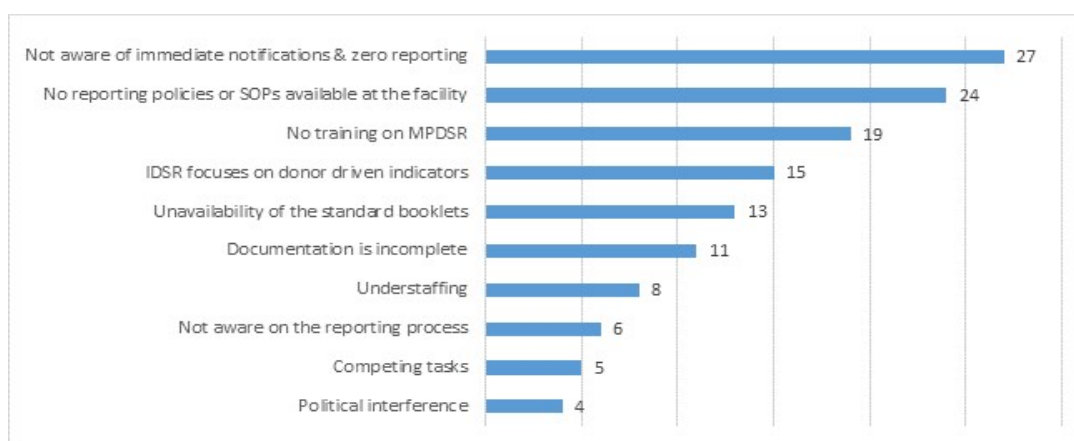


Figure 4. Challenges hindering reporting

The respondents also stated that due to understaffing and other competing tasks the registers had many gaps, were incorrectly filled and incomplete. They also suggested what they needed to support the reporting process and enhance the quality of the IDSR data as listed in table 2:

Needs	Frequency
Capacity building on filling the tools	15
Resources to be availed by the facility	15
Mobile-based system	11
Access to DHIS2 at the maternity	9
EMR	8
Availability of tools	6
More staff	6
Records person	3

Table 2. Participants needs for better reporting

4 Discussion

The study established that the present MPDSR reporting cycle is very inefficient because the flow charts have not been circulated to the facilities and are not in use. This lack of use has led to the delays or lack of death reports. For the reporting cycle to be complete it is expected that feedback is given to the facilities by the surveillance focal persons at higher levels to enhance the data quality.

At the health facilities, the quality of IDSR data was found to be poorer than the analysis done on the monthly DHIS2 data, because there was an alarming lack of awareness of the national reporting procedures

and policies. These national reporting policies and procedures were also missing from more than two-thirds of the facilities. Collection of the IDSR data was also found not be a priority to the facilities based on the DHIS2 data analysis as well as the awareness of the same on the ground. 15 (38%) respondents stated that the focus is mainly on partner-driven data needs which is a hindrance to effective reporting of maternal and neonatal deaths. Facility staff who have been delegated to send the IDSR data in facilities are untrained. In private hospitals surveillance is treated as an external body, therefore, no staff is assigned for this.

It was also established that the health workers were inadequately trained on the job of reporting maternal and perinatal deaths to the surveillance team. 19 (49%) respondents had not received formal training on events and disease surveillance within the last three years. There have been IDSR focal persons deployed to the sub-county and county levels and the facility in-charges act as the focal persons in small facilities. In spite of this effort, no impact has been felt since the IDSR numbers have remained low.

The study also established shortcomings with regard to the IDSR reporting tools: they were either not available at the facility or underutilized due to a lack of perceived ownership as the tools were seen as being donor driven. This underutilization of tools was also seen in the maternity registers which were highly incomplete.

In conclusion, the underreporting of maternal and new-born deaths as reported in previous studies still exists. Poor compliance with the Ministry of Health circular on perinatal and maternal death notification within 24 hours has also not improved as seen in the research results. In addition, the notification and reporting of the maternal and neonatal deaths have also not improved over the years as shown by the DHIS2 data. Despite the Maternal and Perinatal Death Surveillance and Response (MPDSR) notification and evaluation forms being incorporated into the DHIS2, the system still has gaps, and not all maternal deaths are adequately captured by the DHIS2 system. The reporting process for neonatal and maternal deaths has not been circulated to health facilities. There exist numerous challenges that are hindering emergency reporting of the neonatal and maternal deaths to DHIS2; whereas some can be resolved by building the capacity of facility staff, others need a technological solution.

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Statement on conflicts of interest

The author declares that there is no conflict of interest.

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Hospital Information Systems in the Ghanaian Psychiatric Hospitals: Post Act 846 of 2012 Review Analysis

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Introduction: Information systems are expected to exist in every hospital in almost every country to offer a systematic process of collecting appropriate records for health service delivery at all levels. This holds at least for non-computer-based information systems. Quality healthcare by hospitals depends mostly on well-organised data for accuracy, timeliness and completeness and representativeness.

Objective: This study assessed existing the existing information system scenarios in psychiatric hospitals in Ghana since the passage of the Act 846 of 2012 which aims to transform the psychiatric health system in Ghana.

Methods: The authority responsible for psychiatric health in Ghana was contacted for access to the three psychiatric hospitals to arrange interviews and document reviews. The study used structured interviews to gather information from the psychiatric hospitals' directors, hospital administrators, records officers, additional staff each from hospitals for analysis.

Results and Conclusions: The analysis suggests the presence of independent information systems in these hospitals which are manual-based systems. The various systems in the hospitals have been in existence for years with no knowledge of migrating to computer-based hospital information systems. The analysis further suggests the need for a trans-institutional computer-based information system to improve psychiatric service delivery and to ease information exchange for management decisions and policies.

Keywords: Hospital Information System (HIS), Information System (IS), Information Management (IM), Information Technology (IT), Trans-institutional health information systems (tHIS), Psychiatric, Ghana.

1 Introduction

Health service and health delivery are known to be a developmental issue around the globe both in developed and developing countries. Managing the health information system (HIS) ought to be an essential part of all health systems. This will make the provision of information more reliable and timelier for treatment needs, efficient resource allocation and policy formulation. There the need for attention to be given to the importance of healthcare systems to offer the needed medical support. To provide medical assistance if not solutions in countries, hospitals and other international aid agencies and Non-Governmental Organizations (NGOs) will rely on a well-functioning system the information required.

Globally, psychiatric health needs significant attention because of particular issues and problems of placing a significant burden on other aspects of health and well-being. This is true because mental health problems are becoming a growing public health concern (1) as a result of population growth.

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However, healthcare organisations including psychiatry have realised the need to increase efficiency, reduce operational costs and improve patient care and safety to deliver the quality of services to patients as well as staff. To provide high-quality patient care and effective economic management of psychiatric hospitals, it is essential that the hospital information system (HIS) can become an integral part of the service delivery so as to make correct information fully available on when, where and the format needed. This will allow for the fast and efficient processing of important information that cuts across professional boundaries within these institutions and to improve the productivity of health professionals.

Problems in psychiatric health are not only found in rich countries but also in low-income and middle-income countries. Similarly, in Africa, psychiatric problems like low funding coupled with conflicts, natural disasters and brain drain of mental health professionals from government services (1) are also compounded by fragmented and independent information systems (ISs) leading to inconsistent and contradictory information (2) in psychiatric health producing poor quality information and unfavourably affect the smooth delivery of healthcare services and management.

This situation is not different in Ghana with psychiatric health constituting a burden on public health as few resources are allocated for service delivery. Quality healthcare services by hospitals depend mostly on systems to produce important health information (3) which is well-organised data for accuracy, timeliness and completeness and representativeness. An information system is, therefore, expected to exist in every hospital to offer a systematic process of collecting appropriate records for health service delivery at all levels.

However, HIS seems the only promising factor aimed at meeting most operational challenges facing hospitals and the healthcare-related organisations having the task to support patient care, hospital administration and economic business management within hospitals. As “socio-technical subsystem of an institution, HIS comprises all information processing as well as the associated human or technical actors in their respective information processing roles.” (4). Appropriate information and HIS are crucial to strengthening the health system in developing countries (5).

The Ministry of Health (MoH) in Ghana is responsible for all health-related issues and advises the government as well. Before 2012, when the Mental Health Act (Act 846 of 2012) (6) was passed, all public health care delivery services including psychiatry were performed by the Ghana Health Services (GHS) and the Teaching Hospitals.

Subsequently, the Act established the Mental Health Authority (MHA) in 2012 to oversee the Psychiatric Health activities in Ghana. Since independence in 1957, Ghana with a population of 28 million has only three state-owned psychiatric hospitals; namely, Accra Psychiatric Hospital, Pantang Psychiatric Hospital and Ankaful Psychiatric Hospital.

This study aims at assessing the existing information system scenarios in the psychiatric hospitals in Ghana since the passage of the Act 846 of 2012 which aims to transform the psychiatric health system in Ghana.

2 Methods

The MHA which is responsible for psychiatric health issues in Ghana was contacted for access to the three psychiatric hospitals to arrange interviews and document reviews.

2.1 Data Collection

Interviews using structured questions for qualitative evaluation were conducted in the three psychiatric hospitals to find the information system situation since the Act 846 of 2012 was passed. The first phase period spanned between May and July 2016 during which 13 respondents comprising of the three psychiatric hospitals’ directors, two hospital administrators, two information technology (IT) personnel, three records officers and three additional staff each from hospitals were interviewed to assess the complete information system condition.

During the second phase interviews in a year later between June and July 2017, only the hospital directors and the IT personnel were involved again using structured questions to ascertain if any changes had been made to the information system and management situation.

2.2 Document Analysis

A methodological review of available documents in the facilities was undertaken to obtain an additional comprehensive view of the information system. Available documents in the hospitals containing information for this study were evaluated to supplement the interviews results. These documents were mainly used for data collection, processing, management and exchanges such as different patients' forms folders, and report formats. Such documents offered the source of information, how information is processed, managed and exchanged. The analysis of the documents was successful as it was done along during interviews with the respondents who are all staff of the hospitals.

3 Results

The results of this study are mainly presented based on the three-layer graph-based meta-model (3LGM²) tool after the general information systems and processing in the psychiatric hospitals. The 3LGM² tool provides an effective means for describing and even modelling hospital information system based on hospital functions at the domain layer, logical tool layer concentrating on application components supporting enterprise functions systems and the physical tool layer describing the physical data processing components.

3.1 Information Systems

Information technology in this modern world is seen as an important breakthrough in most if not all aspects of life. The full benefits of IT in health including psychiatry can be realised with a well-organised infrastructure necessary to support service delivery and security during an exchange of health information beyond an individual provider or health care delivery system.

To provide quality and improved services, hospitals need to put in place an information system that is most efficient and effective for the management of information that is vital in healthcare related decision-making. Despite the benefits of a computer-based information system in hospitals, the analysis from the interviews portrayed the complete existence of manual-based information systems in all the three hospitals. The systems are also fragmented within hospitals and independent among them. The respondents are, however, aware of these systems and their effects but have no idea when such systems would be changed for a computer-based to reap the benefits.

Additionally, the current information system in the psychiatric hospitals in Ghana demonstrates a shortfall in meeting these requirements towards the adoption and use of information systems in care delivery. Despite the current information system's ability to support the functions, weaknesses such as low security, duplication of records and missing files with regards to paper-based records still exist.

It came to light through the study that the hospital with IT department does not recognise such department as a core functional unit in the hospital. For instance, the personnel responsible for IT issues are not considered part of management members of the hospitals. Reviewing the available documents, the IT departments were either missing from the organisational structure or not given any prominence. Apart from the Pantang hospital director who shown a keen interest in adopting a computer-based system, the others could not provide any convincing reasons of the readiness to move towards the use of computer-based information systems to support the hospitals' functions.

The interviews at the records department and with other respondents confirmed the existence of non-computer-based information system in these hospitals. Information collection and processing in the psychiatric hospitals are done manually like the use of pens, calculators, paper forms and folders to provide the needed services. All the personnel in charge of records indicated that the storage and management of most information such as patients' and hospital-related records are also in the paper-based filing system and stored on shelves.

3.1.1 Functions and Entity Types (Domain Layer).

Aiming to describe the current situation and to obtain a holistic view of the information system, this study obtained candid information on the existing hospital (enterprise) functions (like Patient admission and Patient Discharge and Transfer) and the entity types (like Patient details and Reports) which were identified

as being similar in the hospitals. These functions and entity types provided a better understanding of the systems for data collection, processing, storage and dissemination within the hospitals or with other external institutions.

The complete psychiatric health care in Ghana as may exist elsewhere comprises information about patients and their relations, specialised medical professionals (psychiatrists and psychiatrists nurses) and other institutions are involved in care delivery. Additionally, the hospitals deal with other external institutions needing their services. The presence of such collaborations means that information is exchanged.

3.1.2 Application systems and their Integration (Logical Tool Layer).

The application components are responsible for the processing, storage and transportation of data representing entity types. The analysis of the interviews results revealed that there is the presence of both computer-based and non-computer-based application components used in the hospitals to support the functions and entity types.

The hospitals’ functions are mainly supported by non-computer-based application components containing the patient records in paper-based forms kept as folders in each hospital. These non-computer-based applications components have no computer-based interface to communicate with any other unit hence are moved and used by human actors. These are used to communicate with the other units of the hospital such as the laboratory and to communicate with any other external institution like the judicial service.

In addition to a special laboratories application software, the analysis further depicted that, only the Pantang psychiatric hospital that uses a Mental health information system (MHIS) software application in addition to the manual system. The MHIS contains a spreadsheet software (Microsoft Excel) and Patient database (EPI info) for easy storage, processing, updating and retrieval of patient health and other related records. Although useful, participants from the other two psychiatric hospitals indicated that there are no such databases in their facilities.

With specific importance to security and storage patients’ information and other information are is kept confidentially in paper format in files and folders. They are only released upon written request.

The responses from the interviews indicate that the hospitals deal with other external institutions to which information is exchanged and as seen in Table 1 below.

Institution Name	Information exchanged
Ministry of Health	Annual review reports
Mental Health Authority	Annual review, quarterly review and financial status reports
Practitioners and other psychiatric hospitals	Medical and status reports
Insurance companies	Claims data
Police, Prisons and Judicial Services	Discharged letters, patient’s status or assessment reports

Table 1. Institutions and the kind of information exchanged

The interview responses further confirmed that the information is exchanged predominantly in printed-paper format. For security and confidentiality purposes, they are kept in a sealed envelope, and either hand-delivered or sent by traditional post. Occasionally, the required information may be sent by via Short-Message-Service (SMS) or WhatsApp messenger especially when they brief.

3.1.3 Computers and their communication (Physical Tool Layer).

The physical tool layer is responsible for the physical data processing components such as computers, servers, network components can be touched and used to receive, forward, store, or purposefully process data but also include non-computer supported devices.

The interview analysis pointed out of the existence of predominantly non-computer supported devices in all units the hospitals. The data generation is basically done with the use of a non-computer-based physical data processing components (like a patient folder, pens, pencils, calculators, telephones and paper-based patient for care services and “Monthly Outpatients Morbidity Returns Tally Sheet” and printed reports for communication with the MHA etc.

In addition to a computer at the Pantang hospital used for the MHIS, each hospital has a computer and printer in its laboratory. There is also the presence of standalone computers, printers and photocopiers in the administrative office not for supporting clinical duties but for secretarial and other administrative works.

3.2 IT Governance and Information Management (IM) Policies

The role of good IT governance and information management serve as the basis for sustaining high-quality health information systems (HIS) in hospitals to produce and manage hospitals' information. A significant component of the interviews was, therefore, devoted to identifying the presence of IT governance and IM policies if any in the hospitals. Despite the existence of information which is non-computer-based, the interviews responses exposed that there are no such policies to provide a strategic means for processing and managing information in the hospitals. Given the findings, IT governance and information management policy issues for effective and efficient use of IT are absent in the Ghanaian psychiatric hospitals. This, thus, suggests that there is the absence of a standard for governance and management of information in the hospitals.

The responses asserted that two of the three hospitals (Accra Psychiatric Hospital and Pantang Psychiatric Hospital) has a dedicated IT department and headed by professional IT staff. Nevertheless, in both situations, the IT staff are not members of management body hence all IT issues and policies are based on the decisions of the non-IT staff who are mainly health workers.

4 Discussions

Information technology in this modern world is seen as an important breakthrough in most if not all aspects of life. The full benefits of IT in health including psychiatry can only be realised using a well-organised infrastructure necessary to support service delivery and security during an exchange of health information beyond an individual provider or health care delivery system.

There are several pieces of evidence to show the growing use of computer-based information systems in healthcare in most developed countries in Europe and the United States leading to improved quality of health care. However, unlike the other industries, healthcare has suffered in benefiting from the capabilities of computers and related to improving services, knowledge, communication, outcomes, quality, and efficiency (7), especially in Ghana.

Between May 2016 and July 2017, a general assessment of the existing information system was performed it came out that the overall health information system management was weak, data collection in the health facilities was poorly organized, and the flow of information was fragmented.

The described results from the study conducted on the information system in the psychiatric hospitals in Ghana revealed the following consequences:

- The use of a non-computer-based tool to capture data is likely to cause errors, inaccuracies and delays information processing and retrieval.
- The fragmented and independent information systems in psychiatric hospitals may produce poor quality information and unfavourably, affecting the smooth delivery of healthcare services and management.
- The improper alignment of the information technology departments functions with that of the hospital's functions may limit the quality of service and delays in the reporting and information exchanges.
- The current manual working system, using a paper-based file system for keeping record, processing and management of patients' records. Such system causes inefficiencies, reduced productivity and delays in assessing the needed information.
- The reported existing information system and communication exchanges have negative effects on patient health because it may become difficult at times to track patient records leading to inaccuracies in reporting on patients' status. This is because accurate information provides a correct representation of the factual value required for effective usage and of the planned characteristics of a concept.
- The presence of manual systems in the hospitals makes the exposes both health and non-health date to lots of vulnerabilities and insecurity.

5 Conclusion

The current information system in the three psychiatric hospitals in Ghana have been assessed using structured interviews, and the results have been presented. The responses confirmed the presence of an information system and information processing in the hospitals which are manual-based coupled with been fragmented and independent. The current system for service delivery has been in existence for years with no knowledge of migrating to computer-based hospital information systems.

Information is considered as a strategic asset in hospitals including psychiatric hospitals hence its integrity, accuracy, security and availability must be observed. It is important to consider supporting the psychiatric hospitals in Ghana with high-quality computer-based information systems through systematic planning, monitoring and direction.

The above consequences further suggest the need for a trans-institutional hospital information system (tPHIS) which will be computer-based information system to improve improved psychiatric service delivery and to ease information exchange for management decisions and policies. The tPHIS will be the best solution to address the issue of fragmented and independent information systems to ease challenges and improve communication among these institutions since it will become the network of the various HISs of the three psychiatric hospitals.

The Mental Health Authority should consider using the Act 846 of 2012 to embrace the use of information and communication technology for information processing and management in psychiatric health service delivery in Ghana. The existing information system situation may have been because of low budgetary allocation and other impediments in the sub-sector.

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Framework for Development and Implementation of Digital Health Policies to Accelerate the Attainment of Sustainable Development Goals: Case of Kenya eHealth Policy (2016-2030)

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Background and Purpose: Most countries in Africa and the world are adopting electronic health (eHealth) interventions seeking to overcome health challenges such as shortage of skilled health workers, and burden of disease. However, due to lack of a clear policy on adoption, implementation and utilization of these systems, we are experiencing disjointed deployment initiatives all-over Africa. To address this gap, this paper proposes a framework for the development and implementation of digital health policies.

Methods: To identify documents relating to digital health policies and strategies, we conducted a desk review using Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA). The sample frame was the entire population comprising of 54 African countries most of whom are members of the World Health Organization (WHO).

Results: The study identified 27 documents that qualified to be considered as policy, strategy or action plan. The meta-analysis of the documents revealed that 18 countries (33%) have digital health strategies but only 8 (15%) have policies. The results further revealed that out of the 27 documents analyzed, 82% of them are strategies or action plans while 36% are policies.

Conclusions: Despite the fact that Africa serves as the test-bed for most digital health intervention, over 67% of the countries do not have policies. This is unfortunate because, lack of a digital health policy exposes a country to violations of privacy and unethical practices.

Keywords: *Digital health*, eHealth; Framework, Innovation, Meta-analyses, mHealth, Observatory, Policy, PRISMA, Strategy.

1 Introduction

Countries in Africa are adopting digital technologies to overcome challenges in the health sector such as shortage of clinicians, burden of disease, and injuries [1]. In Kenya, a study conducted by Njoroge et al. [2] showed that over 69 eHealth systems ranging from mHealth to telemedicine have been deployed across the country. However, the study indicates that there is duplication of efforts in the deployment of the implementation of most of the systems leading to wastage of resources [3]. We argue that disjointed digital health initiatives in Africa may be attributed to lack of clear policies on the adoption, implementation and utilization of digital health systems and products [4][5].

According to the World Health Organization (WHO), about 27% of countries worldwide have digital health policies in place [6]. However, some of these policies have failed to address realistic health challenges due to poor design and implementation. In this study, we argue that lack of comprehensive digital health policy exposes a country to violations of patient's privacy, and unethical practices such as cross-border exchange of sensitive health records. To address these gaps, there is need for holistic approach to development and implementation of digital health policies. The development process should take into

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consideration socioeconomic and technical challenges such as cultural barriers, inadequate funding, changing priorities, political uncertainties, inadequate technical skills, limited sharing of health information, undue influence by development partners, and resistance to change [7].

In this paper, we propose a structured framework that defines a set of components appropriate for systematic and structured development and implementation of digital health policies. Through case-based validation, we believe that the proposed framework has the potential to address most of the challenges experienced by developers and implementers of digital health policies in Africa, and across the world.

2 Research Methodology

To identify documents relating to digital health policies and strategies, we employed a methodology known as Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) [8]. PRISMA is a systematic review process that involves identification, screening, extraction, and analysis of documents. Figure 1 shows the methodology used to identify documents relating to policy, strategy and action plans from online and physical sources.

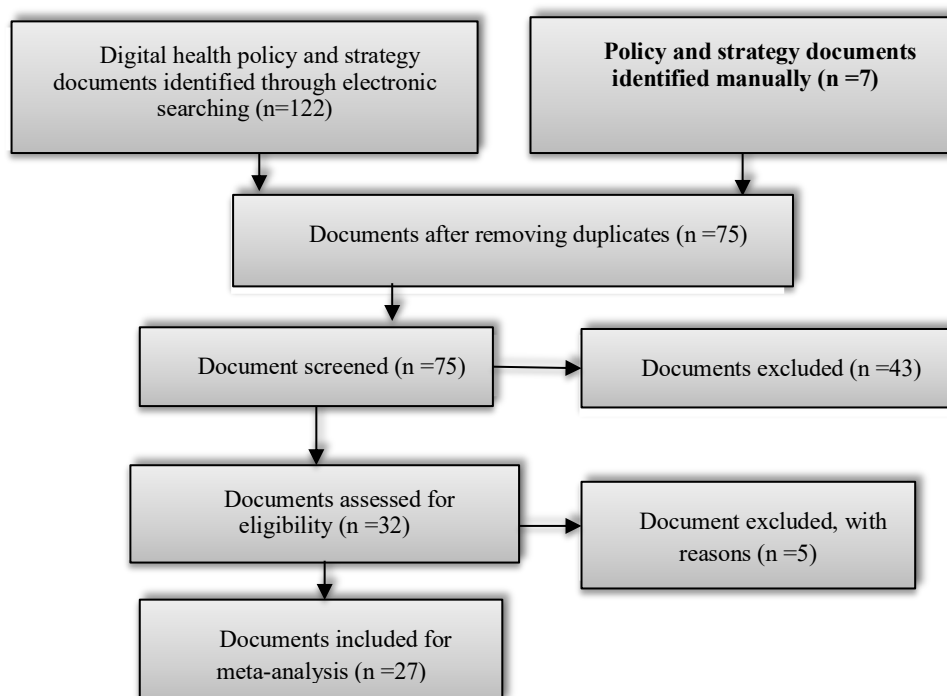


Figure 1. Methodology for identifying digital health policies, and strategy documents

The figure shows that 122 documents were accessed electronically while 7 were manually obtained. The electronic documents were obtained using search tools like Google Scholar, Google search engine, PubMed, Cochrane Library, Directory of Open Access Journals (DOAJ), and Global Observatory for eHealth (GOe) [9]. The search process also involved creating a list of keywords, and then testing them on various search engines to ensure retrieved documents were relevant to this study. Keywords such as “eHealth”, “Health Information Systems”, “Health IT” and “Telehealth” were used in combination with other terms like Policy, Strategy or Action Plan [10]. To further narrow the search space, the consultant used wildcards (*, ?), arithmetic operators and logical operators such as AND, NOT and OR in each search phrase. After removing duplicates from manual and electronic documents, the remaining 75 that were screened for eligibility. After detailed eligibility assessment, only 27 documents were included for comprehensive review and meta-analysis.

3 Results and Discussion

The search methodology used indicates that information on digital health policies was not readily available in digital repositories. This is because some countries may be having such documents existing in printed form, or named differently as principle, strategic plan, national plan of action, or a roadmap. Another reason our search never netted large number of policies may be due to diversity of languages, or simply because such a document may be “hidden” as part of the national health policy [11]. After screening and excluding duplicates, our search strategy identified 27 policy-related documents that qualified for meta-analysis. This includes documents with titles like: eHealth policy; telemedicine policy; telehealth policy; eHealth strategy; or digital health roadmap. Table 1 shows a summary of countries that may be having digital health policies, strategies or action plans.

COUNTRY	TITLE	TYPE	LANGUAGE	DATE
Angola	Estrategico do Sistema de Informação Sanitária 2010	Strategy	Portuguese	2010
Botswana	Botswana's National ICT Policy 2004	Policy and strategy	English	2004
Burundi	Plan National de Développement de l'Informatique de Santé du Burundi	Plan	French	2015
Côte d'Ivoire	Cybersanté en Côte d'Ivoire 2011		French	2011
DRC	Plan de Développement de l'Informatique de la Santé 2014		French	2014
Egypt	National ICT Strategy 2012-2017	Strategy	Arabic	2012
Ethiopia	Ethiopian National eHealth strategy	Strategy		2014
Ghana	Health sector ICT Policy and Strategy	Policy and Strategy	English	2005
Kenya	Kenya National eHealth Strategy 2011-2017	Policies & Strategy	English	2011
Liberia	National Health Management Information System Strategy and Implementation Plan	Strategy		2009
Madagascar	Indicates there is an eHealth Strategy/Policy	No evidence		
Malawi	Malawi National Health Information System Policy	Policy and Strategy		2015
Mauritania	Indicates there is an eHealth Strategy/Policy	No evidence		
Mauritius	Indicates there is an eHealth Strategy/Policy	No evidence		
Mali	Politique Nationale Cybersanté au Mali	Policy	French	2016
Nigeria	Nigeria Health Information System Policy	Policy and Strategy	English	2016
Rwanda	The National e-Health Strategic Plan 2009-2013	Strategy	English	2006
South Africa	eHealth Strategy South Africa 2012-2017	Policy and Strategy	English	2012
Uganda	Uganda National eHealth Policy 2013	Policy	English	2013
Tanzania	Tanzania National eHealth Strategy 2013-2018	Strategy	English	(Draft)
Zambia	E-Health Strategy 2013-2016	Strategy	English	2013
Zimbabwe	Zimbabwe's E-Health Strategy 2012-2017	Strategy	English	(Draft)

Table 1. Countries having digital health Policies in Africa by 2018

The results suggest that most of the countries have digital health strategies but only a few of them have policies. The countries with “no evidence” means that we obtained information from published literature that indicate such a digital policy exists but we could not access the documents. The findings suggest that 18 out of 54 (33%) countries have digital health strategies but only 8 (15%) have policies. Table 2 shows a summary of countries that have digital health policies, strategies or action plans in place. The results further revealed that; out of 22 countries with digital health related documents, 82% of them are strategies while only 36% are policies as shown in Figure 2. This is an indication that majority of the African countries may not be having digital health policies yet Africa is home to the largest number of digital health initiatives.

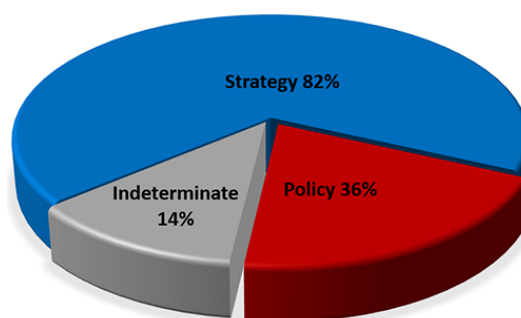


Figure 2. Status of digital health policy in Africa

3.1 Digital Health Policy Development Framework

In a study conducted by Scott and Maurice, it is evident that the process of developing policy process is not anchored on any structure or empirical evidence [12]. Most of the approaches are based on public opinion, electoral considerations, personal preference, and crisis management. Furthermore, the findings from this study uncovered little evidence on guidelines for structured development and implementation of digital health policies. This is the gap we wish to address by providing a structured framework for the development and implementation of digital health policies suitable for African context.

3.2 Structure of Proposed Framework

The framework comprises of three components that are critical to the of design, development and implementation of digital health policies [12][13]. The three components of the proposed framework are governance, guiding principles, and predictable policy development process.

- **Governance:** This component on governance emphasizes on leadership, oversight and administrative support that make it possible to develop and implement a digital health policy. Digital health governance may be in form of advisory boards, and intergovernmental committees responsible for establishing, fostering, and maintaining efficient and effective process for the development, approval, implementation and review of digital health policies.
- **Guiding Principles:** Guiding principles are philosophical ideologies and values that are consistent with global best practices. They are written to support vision, mission, values, priorities, legislations and governing the country's health system(s).
- **Predictable policy development process:** Policy development should follow structured approach shown in Figure 3. To be predictable, it is important that legal mechanism be embedded throughout the development and implementation process.

a) Needs Assessment

Justification for a new digital health policy should start with needs assessments. Needs may be influenced by vision, mission, and strategic direction, new legislations, health policy, or government directive. The need for digital health policy may also come from research findings, public expectations, political decrees, government initiatives, or emerging trends.

b) Planning and Design

When need for a new policy is confirmed, the planning and design phase commences. This involves planning, identifying key principles, and formulating clear policy objectives. Design of a new digital health policy requires collaborative and iterative approach to identify priorities, vision, goals, principles, standards and issues in a country's health system.

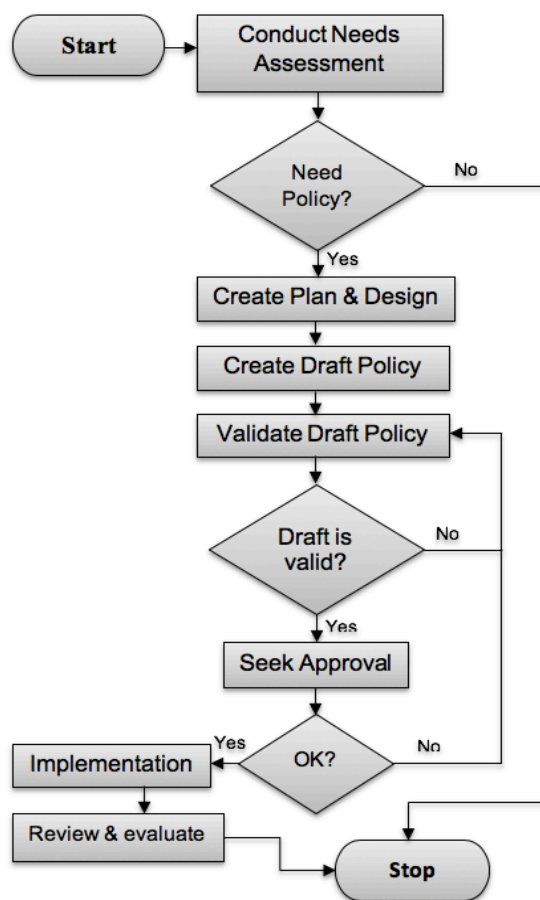


Figure 3. Predictable policy development process

c) Policy Drafting

Drafting entails formulating the layout and creating content provided by subject matter experts. The team of experts may be drawn from ministry of health employees, medical professionals, volunteers, students, contracted providers, and individuals who act on behalf of, or in conjunction with the ministry of health. The content of digital health policy should be consistent with the provisions of the country’s legal and regulatory frameworks.

d) Draft Validation

Stakeholders’ engagement is crucial to the development and validation of digital health policies. Once the draft policy is in a reasonably advanced state, the drafters should provide the stakeholders with an opportunity to make their suggestions in order to minimize implementation risks. If there are issues identified, the policy should be revised and another validation requested once the changes are affected.

e) Policy Approval

The new policy approval demonstrates the government’s commitment. The policy owner should ensure that delegation of approval is permitted with written communication from a senior government official in the health ministry.

f) Policy Implementation

Following the approval, the new policy should be launched and disseminated for implementation. It is important to note that, a well-intentioned policy will fail and put the country at risk if not properly implemented [14]. To avoid this pitfall, stakeholders should be made aware of the launch of a new or revised policy through articles in the media, health forums, websites, policy briefs and academic publications. Furthermore, a well-written policy should have implementation plan comprising of communications, education, training, and change of practice.

g) Review and Evaluation

The review process depends on emerging needs and demands while evaluation is conducted to identify what has worked, what has not, or where there may be gaps or issues to be addressed [15]. Review and evaluation of a policy should be a regular or periodic process or as directed by the sponsor or approving authority. Due to unique circumstances, modifications to the approved policy should adhere to regulations, and procedures governing policy review.

3.3 Application of the Framework

To demonstrate practical utilization of the proposed framework, we developed the Kenya eHealth Policy (2016-2030) [16]. The policy dubbed DigiAfya was officially launched in March 2018 during the Kenya Health Forum. Table 2 shows how KeHP was mapped onto the three components of the proposed framework. The table also shows resources that informed on the structure and content of DigiAfya Policy:

Process Step	Mapping KeHP to Framework Components	Resources
Needs Assessment	Situational analysis, stakeholders’ engagement, alignment to goal, objectives, values, priorities, and aspirations of the Constitution, Health Act 2017, and the Kenya Health Policy 2014-2030.	Field survey and case study reports, Kenya Health Forums, Constitution of 2010, Health Act, Health Policy, Vision 2030, ICT Master Plan,
Policy Design	Principles of best practices involved collaborative design by 10 lead digital health experts and hundreds of stakeholders in ICT and health. The design was also informed by policy development frameworks.	WHO and ITU eHealth Strategy Toolkit, policy development frameworks, Health Act 2017, and journal papers [17][18][7][19].
Policy Drafting	Principles of collaborative and participatory design were employed to draft the KeHP. The content was informed by Kenya Health Policy (2014-2030), WHO&ITU’s eHealth Toolkit, themes provided by Khoja[11], and contributions from hundreds of stakeholders in ICT and health sectors.	Experts from eHealth Unit (MoH), MoICT, Partners, Universities, KeHIA, Oracle, GSMA, mHealth Kenya and KEMRI.
Policy Validation	Extensive validation was conducted by circulating the draft to experts in digital health experts, policy experts and government officials at the national and county levels	Stakeholders from MoH, digital health experts from UoN, KeHIA, Regenstrief Institute, Indiana University, JKUAT, SEKU, and International Leadership University.
Draft Approval	The policy was approved by the Cabinet Secretary (MoH) to demonstrate government’s commitment to uphold the requirements set out in <i>DigiAfya</i> policy.	Former CS, MoH - Dr. Cleopa Mailu
Policy implementation	Governance structure for implementation of the KeHP has been provided. This started with the official launched by CS, Ministry of Health.	CS, MoH, Health providers, Academia, KeHIA, WHO, and development partners,
Review and evaluation	The KeHP has clear provisions on evaluation and review as directed by MoH departments responsible for policy and regulations.	MoH’s eHealth Unit, local universities, County Governments, digital health developers, development partners, university academia, and Ministry of ICT.

Table 1. Mapping Kenya eHealth Policy 2016-2030 to the Policy Framework

4 Conclusions Limitations and Recommendations

In this study, we used the PRISMA model to investigate whether African countries have comprehensive digital health regulatory policies and strategies. Despite the significant role digital health plays in promoting health outcomes, lack of regulatory policies that govern their adoption and implementation is serious

concern. The study revealed that only eight countries in Africa have digital health policies while 18 have strategic plans.

The results from this should be interpreted in light of some limitations. First, there is likelihood that policy related documents were excluded from the meta-analysis due to the search strategies used. Secondly, the language used to conduct the searches was English yet several countries in African have their official languages as French, Portuguese, Kiswahili, Amharic, Afrikaans, Arabic, or Spanish. Consequently, the variables used to identify digital health policies and strategies may have overlooked or excluded such documents published by these countries.

Despite limitations of this study, the findings lay a strong foundation for systematic development and implementation of digital health policies. We believe that the adoption and utilization of the proposed framework will catalyze and improve the process of developing, implementing, monitoring, and evaluating the impact of digital health policies.

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Adoption of Health Information Systems in integrated Primary Healthcare in Developing Countries

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Background and Purpose: Several healthcare organizations in developing countries have implemented health information systems (HIS) due to their remarkable information processing power that has lately transformed the way Healthcare practitioners manage health information. However, even with several health information systems in use, Healthcare practitioners still lack processed patient information to enhance primary healthcare (PHC). To advance understanding of the current role played by health information systems in integrated primary healthcare in developing countries, this paper analyses the current HIS in developing countries and their ability to support integrated primary healthcare.

Methods: The paper relies upon related literature of HIS implementations and primary healthcare.

Results: Derived insight is that prominently used health information systems are health management systems that support healthcare secondary roles more than primary healthcare roles.

Conclusions: The paper concludes by suggesting proactive implementation of comprehensive and interoperable health information systems that support both primary and secondary healthcare roles.

Keywords: Health information systems, Primary healthcare

1 Introduction

Healthcare organizations are increasingly adopting healthcare information technologies due to their potential in promoting quality healthcare [1-5]. In order to promote quality healthcare and make informed health care decisions access to accurate and timely health information is important. Incidentally health information systems have shown great information processing power by transforming the way healthcare organizations manage health information [6, 7]. Consequently, health information system implementation has become the subject of continuing interest among the medical community, health leaders and developing countries.

In addition, a number of authors including [8-10] have highlighted Information Communication Technologies role in improving the healthcare system particularly in developing countries. In recent years, developing countries have implemented various HIS at various administrative levels for monitoring public health through known health indicators [11]. A number of them are health management information systems with limited evidence of patient care information systems [12]. Though there is limited evidence of patient care HIS in developing countries [13] they still offer great possibilities of patient care continuity through implementation of electronic health records systems. The case of HIV/AIDS patient records systems in most developing countries, clearly illustrates this [12, 14, 15].

Existing health information systems' research suggests that healthcare systems ought to promote continuous flow of data to aid better decisions [16] and be interconnected in order to achieve quality integrated primary healthcare (PHC) [2, 16]. Given the importance of primary healthcare (PHC) World Health Organization (WHO) calls upon its member-states to strengthen their healthcare systems through primary healthcare principles [17], in order to meet the primary role of healthcare organizations. According

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to [18] the primary role of a healthcare unit is to offer PHC with the support of other secondary roles. Primary care roles are the ones concerned with patient care activities while secondary care roles are the management and support activities to PHC [18]. There are several interpretations of PHC but this study will follow Kringos and Starfield [17, 19] interpretation of PHC about the primary care process as consisting of access, continuity, integration and comprehensiveness of care. To achieve such comprehensive integrated primary healthcare available HIS ought to be integrated and interoperable in order to coordinate both primary and secondary care roles [18] across the continuum of care.

With great PHC expectations from HIS and its increased adoption in developing countries it is very important to analyse current HIS initiatives [20, 21] and their role in PHC. Analysing HIS implementations particularly in developing countries is vital because, as noted by [22] improved public health improves people's living conditions. It's against this background, that this paper addresses the following research question: To what extent do the current health information system enhance primary healthcare? By analysing the current state of health information systems (HIS) in developing countries and their ability to support integrated primary healthcare for improved public health. Such analysis is important as the present HIS are categorised as standalone and non-interoperable systems since they do not easily exchange information [23, 24]. In the healthcare setting patients are able to visit any healthcare unit of choice, and therefore their patient medical history is dispersed across different healthcare units [16] which makes it difficult to trace and share patient medical records within and between healthcare units [9, 23].

This lack of coordination among healthcare partners delays decision making at the point of care due to missing information [15], and further impedes patient care continuity. Expediently, Information Communication and technologies are renowned for their potential in scaling up healthcare initiatives [25, 26]. They have for example restructured the way healthcare organizations manage patients and hospital information [6, 7]. Nevertheless even with health information system implementations, tracing and sharing a patient medical record is still hard. So in light of this, this paper analyses the predominantly used health information systems for primary healthcare delivery in developing countries.

The remainder of the paper is structured as follows: section two presents a brief description of the study approach, followed by a discussion of the literature review in section three. The presentation, analysis and discussion of the results are discussed in sections four and five. The final section outlines the paper's main conclusion and recommendations for future research.

2 Study Approach

The study relies mainly on a literature review to analyse the role of information systems in integrated primary healthcare in developing countries. The steps of the review were: definition of key search terms, search for studies, establish inclusion and exclusion criteria to guide selection of papers, screening of papers and analysis. The following key words guided the search for primary studies: "Health Information Systems", "Health Information Systems in Developing Countries", and "Primary Healthcare".

The major digital databases and journals that were used were: Springer, IEEE Xplore, and ACM Digital Library, and MIS Quarterly and IJMI. Searches on Google scholar were also used to identify references matching the selected search terms. The primary search was based on keyword searches then the secondary search was based on relevant citations and references from the primary search and other identified keywords like "District Health Information Systems" and "information systems interoperability".

Three broad sets of inclusion criteria were applied: 1) studies on health information systems use within developing countries, 2) studies with a focus on primary health care, and research on interoperability issues in information systems. Articles included in the study ranged from 1990-2016.

The paper analysis excluded articles that did not meet the selection criteria, overall 128 articles were identified, 49 were excluded and 62 were considered for the analysis. The process of analysis involved collecting and summarizing the results of the papers that had been selected as relevant studies in relation to the scope of the study.

3 Results

This section presents findings from the literature reviewed and has been categorised under the key main search items.

3.1 Understanding Integrated Primary Healthcare

The fundamental role of a hospital is to deliver quality primary healthcare to patients, all the other secondary roles are in support of this core primary role [18]. World Health Organization (WHO) has recently [17] called on its member states to strengthen their healthcare systems through primary healthcare principles. Primary healthcare plays a central role in healthcare organizations by contributing to the overall health systems' performance [17, 27-29]. Kringos and Starfield [17, 19] refer to primary healthcare as a complex and multidimensional system divided into structure, process and outcome. The primary care structure consists of: governance, economic conditions, and workforce development, while the primary care process consists of: access, continuity, integration and comprehensiveness of care. Following this, the stated outcome of a primary care system consists of: quality of care, efficiency care, and equity in health. Haggerty [30] grouped care continuity- a core principle of primary care under: informational, management and relationship, whereby each of these links elements in a care pathway to achieve overall patient care continuity. Schang [31] agree with [30] that care coordination entails both information and managerial coordination. Whereas information coordination ensures that information is recorded and used by subsequent care providers, managerial coordination ensures longitudinal follow-ups across providers. This kind of coordination leads to what [17] calls integrated primary healthcare.

According to [17] "integrated primary healthcare" can be achieved through a collaboration between secondary care and primary care. In such a plan the patient receives one coordinated and coherent medical record which can be facilitated by pre-arranged protocols or a team that works very closely [32]. Following this, [18] proposes the creation of synergy between the primary and secondary hospital roles through the use of information systems as shown in Figure 1. Several authors agree to this proposition and recommend implementation of comprehensive or integrated HIS that can meet both primary and secondary care needs for improved quality healthcare [33-35] and integrated primary healthcare.

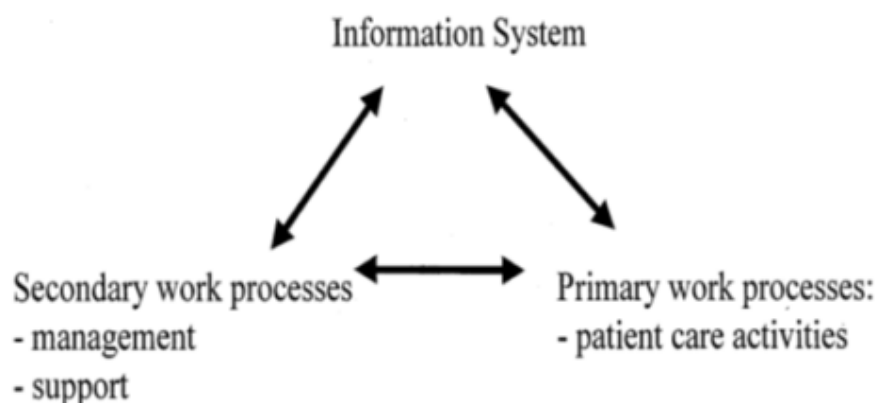


Figure 1. Striving for Synergy through the use of information systems (Source: [18], p. 152)

Figure 1 shows that synergy and harmonization of secondary and primary work processes can be aided by information systems. Secondary roles include managerial, administrative, and support work tasks that typically collaborate with primary work processes. Primary work processes involve all patient care related activities that are essential for the delivery of quality healthcare to patients.

3.2 HIS Implementations in Developing Countries

Several studies including [8-10] have highlighted the role of information communication technologies in developing countries. A study by Namakula [36] that particularly looked at HIS capabilities towards improving healthcare services delivery in developing countries revealed the following capabilities among others; records keeping and faster retrieval, enhanced communication, informed decision making and improved chronic disease management among others. According to World Health Organization (WHO) African countries in 2008 declared to strengthen their health information systems for improved quality healthcare delivery [37]. Developing countries have indeed implemented health information systems mostly to support administrative roles [12, 38]. Most implemented health information systems are normally used to collect and provide information on routine health indicators to higher level health administrators [37, 38] reported in aggregate statistics [11]. They are management health information systems and are therefore, capable of administrative secondary care roles [12, 20, 38]. According [21] to DHIS is an example of such systems that meet secondary care roles.

Over 46 developing countries have implemented the District Health Management System (DHIS) [39-41]. Which is a web-based management information system for handling aggregated data used for national health monitoring and planning [42] meeting secondary roles. However among the implemented HIS there is limited evidence of patient care systems [12]. In most countries either there are no patient care information systems or the existing ones are not interoperable with other health information systems [12, 23]. At times the health information systems in place do not hold complete patient records [40], for example the prominent DHIS in developing countries has capabilities of tracking a patient by use of the DHIS tracker [43, 44] but cannot provide a single coherent patient record.

A study by [12] that covered 10 development countries namely: Angola, Botswana, Ethiopia, Ghana, Kenya, Nigeria, Tanzania, Uganda, Zambia and Zimbabwe, shows that there is evidence of Health Management Information Systems (HMIS) implementations. However, there is lower evidence of implementation of patient care information systems that promote patient care continuity. Other studies by [12, 14] have found that most HIS implementations in developing countries are program specific initiatives by donor agents thus not offering comprehensive care to a patient and are therefore unsustainable.

A comprehensive study [20] on HIS implementations in developing countries investigated three particular successful examples at different managerial levels. The first one, SIGA Saude in Sao Paulo, Brazil was an enterprise resource planning system with electronic medical records to manage patient information flow. The second is, Health Information Management System (HMIS) in India a web-based system that collects health indicators for monitoring, planning and evaluation of national health status. The third one was SmartCare Electronic Health Record System in Zambia that provides a portable patient health record. The SmartCare program provides a complete electronic patient health record and assures the patient of continued, confidential, and high-quality care by providing timely information to caregivers at the point of service.

By and large there is great potential of health information systems in transforming healthcare delivery in developing countries [12, 14]. Most countries have implemented HMIS [12] which are used to collect routine data on health indicators [20] thus meeting secondary roles, though with limited evidence of patient care systems [12]. For example in Uganda HMIS tools have been programmed into the DHIS to enable harmonization of data collected through HMIS registers to be entered directly into the DHIS [45].

Though HIS implementations have been highly adopted in developing countries there are however faced with diverse challenges. According to [46] information system implementation in most developmental sectors is not as difficult as in the healthcare sector. Particularly, information system implementation in healthcare is a complex socio-technical network [18, 24, 47, 48]. With challenges including: duality of the socio-technological networks [49], existence of cultural barriers (especially reluctance to change from paper based practices) [5, 50, 51], lack of HIS standardization and interoperability [5, 20, 23, 34, 52, 53] and regulation, HIS-organizational mis-alignment [1, 48, 54], digital divide challenges particular to developing countries [52, 55, 56], and HIS implementation failures [18, 27, 47, 54, 57].

3.3 District Health Information Systems' Overview

Several countries in developing countries have greatly employed the use of DHIS, which now covers over 46 countries [21, 41]. DHIS was introduced in 1994 by a global network known as the Health Information

Systems Program (HISP) and was first implemented in South Africa [20]. DHIS is a web-based and open-source tool for collection, validation, analysis, and presentation of aggregated statistical data, tailored to integrate state health information management activities [42].

Most countries have employed the use of DHIS as a management system to monitor their operations and improve integration [14, 37]. It allows data entry at district level, data analysis at state level [39] and it empowers users to manage their health services locally [14]. Countries that have been affected by the HIV/AIDS pandemic have greatly employed the use of DHIS to improve surveillance for better prevention and treatment of HIV/AIDS [58]. DHIS has been successfully used to manage ART for HIV/AIDS patients for example in Addis Ababa [14]. DHIS can facilitate state data integration and creation of reports that support decision making [37, 40]. DHIS can also be interfaced with other electronic HIS [35] for example in Addis Ababa: the relevant patient-related data elements from the electronic record systems for HIV/AIDS patients are aggregated monthly and imported into DHIS [14]. There are on-going efforts to integrate DHIS with Open Medical Record System (OpenMRS) to facilitate reporting of aggregated data from the local OpenMRS directly into DHIS [35] for administrative purposes though not for patient information flow.

DHIS has many great capabilities features which when fully explored can greatly improve healthcare delivery. These features include; openness, interoperability, scalability, tracker, customizability, and visualization clearly indicated at the DHIS website [43]. For example the DHIS tracker can be used to record and track a patient medical history [43, 44] which can fully benefit the healthcare organization in promoting patient care continuity and improving primary care. Though DHIS is considered a good system with many capabilities, it still faces challenges particular to developing countries which include: poor infrastructure and internet connections, electricity blackout [59] and lack of frequent training for system users [21, 37, 39, 40] which ought to be addressed.

4 Discussion

This section discusses HIS used in developing countries, their capabilities, and challenges in achieving integrated primary healthcare. According to [17] integrated primary healthcare can be achieved through a synergy of both secondary and primary care roles which can be aided by HIS [18]. In developing countries achieving integrated primary healthcare is still challenging because most of them have strong secondary HIS support but weak primary care support [12]. Most implemented HIS in developing countries are management systems with District Health Information System (DHIS) as the prominently used system since it is implemented in over 46 countries [21, 41], thus it is capable of meeting secondary care roles. However among the implemented HIS there is limited evidence of patient care systems [12] and thus limited systems to meet primary care roles. According to [12, 20, 38] developing countries prioritize: (i) health information systems that support higher administration roles whilst neglecting implementation of patient care information systems. The prominent DHIS is such an example [21] meeting secondary roles not the primary role of patient care continuity [20]. (ii) Implementation of health information systems that are not interoperable to each other [24] and thus cannot aid decision making [16, 23] and continued integrated primary healthcare. Sandiford [60] once noted that improvements in information processing does not automatically guarantee rational decision making. Therefore, to improve primary healthcare installed HIS ought to be comprehensive [33-35] and interoperable [61] with ability to exchange information and use it [62]. Furthermore, HIS implementation challenges ought to be addressed to improve future HIS implementations in regards achieving PHC.

5 Conclusion and Future Studies

This paper has provided an analysis of the propensity of current health information systems towards integrated primary healthcare in developing countries. The practical implication to healthcare professionals is to increase awareness that integrated primary healthcare can be enhanced by implementing comprehensive HIS that are capable of meeting both secondary and primary care roles. The paper proposes an integration of the prominent DHIS with other patient health information systems in order to promote both secondary and primary care roles for improved primary healthcare delivery. For future research, the paper proposes a focus on how health information systems can be further interoperated and integrated into

comprehensive systems, and how HIS implementation challenges particular to developing countries can be overcome.

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Towards Universal Healthcare Coverage Through Adoption Of Blockchain Technology: A Literature Review

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Countries in low and middle income countries (LMICs) are embarking on a path to achieve universal healthcare coverage (UHC) for its populace. The growth is evidenced by the renewed commitment by governments, both from a policy and implementation perspective, to providing affordable healthcare for all of its citizens by increasing financial risk protection through the National Health Insurance Funds (NHIF), even adding more benefits targeting informal sector households and adjusting outpatient cover; to improve access to health and improve the national health outcomes.

Despite these commendable efforts, there are still several challenges facing the health provision in LMICs. High poverty levels, increased unemployment rates, high cost of care, disparate information systems and weak data use culture, inadequate funding, inadequate tax collection system, corruption, weak management and oversight by regulator, insufficient skilled personnel and difficulties in identifying and reaching the most vulnerable citizens, are all challenges that have impacted negatively on health.

The potential uses of blockchain technology in healthcare are multiple; blockchain technologies have advanced and have matured to hold the promise to unite the disparate processes in the pharmaceutical industry and healthcare ecosystem, reduce costs, improve regulatory compliance, increase data flow, and improve patient experience and outcomes.

The objectives of this paper is to present a review of published articles and journals that discuss the applications of blockchain technology in healthcare in order to gain knowledge about methodologies used and findings obtained from the implementation of blockchain solutions in healthcare settings.

Literature review included critical assessment of 19 papers to identify studies that examine the use case for blockchain technology in healthcare.

The findings show that Blockchain proves to be key in building a global precision-medicine ecosystem that optimally connects patients, clinicians, researchers, insurers and clinical laboratories to one another. Blockchain can improve patient data security, data sharing, interoperability, patient engagement, big data analytics, health information exchange, fighting counterfeit drugs, R&D processes, AI-based diagnostics and fostering vertical business models. Other potential breakthroughs in the healthcare ecosystem are not limited to cost reduction, improve regulatory compliance, increase data flow, and improve patient experience and outcomes.

Keywords: Blockchain, NHIF, UHC, LMICs, FHIR, smart contracts

1 Introduction

Blockchain is a network of distributed databases or public records of transactions which do not need permissions in a chronological order. It is shared and maintained by multiple parties that secure all the records that are added to it. Each transaction contains a timestamp and secure links to the previous one. Records can only be added to the database and cryptographically linked to all previous one and can never be deleted. Addition of new records is done once the parties managing the databases are on the synchronous

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agreement or “distributed consensus”. It is hard for one individual to manipulate cryptographically linked past records without breaking the overall consistency of the database.

Blockchain technology entails having an infrastructure that creates decentralized digital public records of transactions that are secure, anonymous, unchangeable and tamper proof. This has attracted technology giants such IBM Watson and Microsoft who are already working to provide Blockchain-as-a-Service (BaaS) products where developers can create and test a blockchain on the cloud.

Bitcoin was the first blockchain implementation as a digital financial asset in widespread use.[2] It is an electronic payment system based on cryptographic proof instead of trust. Although Bitcoin seemed to be a suitable technology for preventing data tampering in medical arena, it is currently not appropriate for following reasons: (1) it is an open network that anyone can join, (2) it needs massive computing power to guarantee tamper resistance and (3) it deals with currency which is only one-dimensional data. [3]. Nevertheless, in private network blockchain system, that prerequisite permission to join has been developed; this system can handle multidimensional data and does not require massive computing power for effective tamper resistance[4]

Blockchain can maintain endlessly growing lists of data records and secured transactions and has the power to potentially transform health care and revolutionize the way data is processed in areas as health data interoperability, revenue cycle management, and validation of supply chain, blockchain has the potential to dramatically reduce back-office data input and maintenance costs and improve data accuracy and security according to the industry experts.[5]

2 Application of Blockchain technology in healthcare

The following is a summary of blockchain capabilities that make it a potentially useful technology tool for healthcare data interoperability; creating secure and trusted health record data; linking identities while preserving the anonymity of patient encounter and other transactional data, and recording patient consent.

2.1 Secure patient data access

Blockchain technology can provide a patient with a security key that matches that of their provider’s allowing them to access their longitudinal care records. A typical patient care workflow for this includes a scenario where a patient with a private key, and an address that provides the codes to unlock their patient data, is matched with a healthcare provider universal signature. When the two are combined, the required authentication to unlock the patient’s data is established. The patient defines in their profile, the access rules required to unlock their medical records. In this case, preventing unauthorized access to patient data becomes very easy.

Blockchain provides the authentication to enable access (identification and authentication) to the requested data and also offers a non-reputable audit trail which guarantees the records’ validity, and that a patient record was authentically signed and certified. Blockchain would enable peer-to-peer interoperability among participants within transactions using smart contracts and fully auditable history. The advantage of blockchain transactions being cryptographically and unchangeable safeguards privacy across parties. The patient using keys (either public or private) would be able to designate by whom the access the data.[11]

2.2 Health data exchange and interoperability using blockchain technology.

The adoption of digital health solutions and particularly electronic medical records (EMRs) in Africa has also been on the rise over the past decade. Both primary and secondary health care facilities, that traditionally recorded patient records manually, have embraced digital health systems for recording patient data and overall patient management.

At the same time, EMRs store highly sensitive patient data for diagnosis and treatment, which needs to be distributed and shared frequently among peers such as healthcare providers, insurance providers, pharmacies, researchers, patient’s families, among others, to realize their true potential. Ensuring the patient’s medical history is up-to-date is a challenge. Patient’s treatment process gets complicated when multiple entities are involved in storing and sharing data.

Patients suffering from serious ailments like cancer or HIV/AIDS, need to have a well-maintained history of their treatment processes. Having access to a complete history is paramount to ensure treatment and continuation of care. [7] states that a patient has right to information; every patient is entitled to receiving and access full and accurate information concerning their health and health care. This also limits who has access to their health information. If patients need to share their health information with another healthcare provider they need to consent, despite this a security risk when the patients' information is in transit.

Depending on the centralized entity that would store and manage the patients' data, access control policies means having a single point of failure, which could be a bottleneck for the whole framework. It also requires either conducting all the operations (such as search, or anonymization) over encrypted data or choosing a fully trusted entity that will have access to sensitive information about the patients.[8]

It is possible to overcome issues mentioned above by having a ledger - an open, immutable, and transparent record of all the activities happening in the network (such as a patient modification, a physician uploading new data and disseminate them for research). It is by having mutual agreement among distributed entities without trusting any party, that blockchain technology will guarantee security, control over sensitive data, and will smoothen healthcare data management for the patient and stakeholders in the medical domain.[8]

Blockchain can support interoperability across systems and organizations. This is crucial for advancement in our current health ecosystem which consists of disparate IT legacy systems which do not communicate with each other. Blockchain can provide a single system that offers interoperability to replace these disparate systems with.

2.3 *Automated health claims adjudication*

Another blockchain revolution is to verify the claim transactions to support health care financing tasks (i.e., health plan claims), such as preauthorization payment, alternative payment models, automated claims using Fast Healthcare Interoperability Resources (FHIR) and smart contracts.[14]

A smart contract structure enables a node to perform a transaction for the contract. This logic guarantees correct completion of claims and supports compliance audits using business rules [17]. Some positive strides have been taken by different individuals to explore the possibilities of blockchain technology.

Blockchain provides a decentralized management where real-time claim processing happens without intermediaries. This feature will replace the health plan intermediation by having claims adjudication in real-time using transparent blockchain technologies.[15] Based on Blockchain immutability there is improved claim auditing and fraud detection: "Payer, private and government insurers, and individual payers have the benefits of audits facilitation and better fraud detection"[16]

3 **Materials and methods**

A literature review was conducted for published research studies and articles on application of blockchain technology in healthcare. The search for the related material started in January 2018 and finished in April 2018. Journal of Medical Informatics, Research Gate and directory of open access journals (DOAJ) and the internet at large, were some of the databases used to access articles and papers on this subject. The keywords used to search for the articles were: blockchain, blockchain in healthcare, smart contracts in healthcare, digital health, health information management, patient data security, secure access to patient data. The review was limited to articles and papers published between 2000 and 2018 and in English. We hit 19 articles.

4 **Conclusion**

Further research is suggested to focus on the cost associated with the deployment of blockchain technology, the capacity of systems integrators to adapt to changing technology and ongoing maintenance of systems. In addition to that, it is suggested that deployment of blockchain applications be incremental in nature as with any emerging technology.[11] A project such as MedRec has led to demonstrate how we can lead to

interoperable and secure EHR systems using decentralization and blockchain architectures. They are prioritizing open APIs and network structure transparency.[12] Other studies such as the tamper-resistant mHealth solution based on blockchain technology which was able to confirm that mHealth data is compatible with blockchain technology, need to be further examined and replicated across the numerous mhealth solutions used in LMICs.

There are fears with vulnerability around the blockchain system, the implementations around it can be attacked despite it known for tamper-resistance. Poorly maintained and out-of-date codes in an incident involving a decentralized autonomous organization made it vulnerable.[18]

Blockchain technology is envisaged to enable near real-time transactions and faster, however, the cost of operating such as system is not yet known. there are scarce blockchain solutions in complete operation, and with this in mind, it is hard to forecast the possible costs of operating a blockchain at scale. Consequently, there should be targeted experiments and common blockchain solutions to iteratively assess the technology with a view to scale and understand the possible cost of the fully scaled blockchain.[19]

Regulatory consideration is crucial to blockchain advancement; this should also fit within the existing regulatory frameworks. Despite regulations like the Health Insurance Portability and Accountability Act (HIPAA), it is still evident that healthcare organizations still aren't doing enough to protect themselves from cyber-attacks.[1] They need to take a step to prevent future incidents and one possible way is in the decentralization of healthcare data through blockchain

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Towards Effective Healthcare Information SMS Model

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Problem: The healthcare sector uses SMS to disseminate healthcare information to a large population of people. Maternal and post-natal healthcare information is widely delivered through SMS messaging. Evidence of a structure used when sending the healthcare information via SMS, ensuring that the message received is effective, remains very limited.

Objective: This paper presents a study which was aimed at proposing a model, presenting salient factors, which can be used to effectively send healthcare information via SMS.

Methods: A total of 80 people were initially recruited. However, 63 out of the 80 people, all residing in Nairobi participated in this study. 52 respondents were interviewed over the phone using semi-structured scripts, six of them participated in a focus group discussion carried out at a Hospital in the Eastern part of Nairobi. Five respondents responded to questionnaires issued to them.

Results: Through review of literature and data analysis, five factors emerged which influence effectiveness of healthcare messages sent via SMS. The factors include: the time of day in which respondent has most access of their phone, the day of the week most preferred to receive the SMS, frequency of receiving the healthcare messages, topics of interest to the receiver and preferred language.

Conclusions: This study shows that to ensure healthcare messages sent over SMS are effective, it is important that information is sent to the recipient subject to their availability and preferences. Healthcare institutions need to consider these factors when sending healthcare information, to ensure information sent is relevant and convenient to the receiver thus resulting in expected behavior change.

The model can be adopted in other sectors which rely on SMS to send information to its beneficiaries.

Keywords : MS, mhealth, TotoHealth, MNCH

ACM Classification Keywords H.5.m. Information interfaces and presentation (e.g., HCI): Miscellaneous

1 Introduction

Technology advances have seen the use of mobile devices increase significantly in the recent years in African and the whole world at large. Studies affirm that smart phones and other high-end technology gadgets appear to be increasingly used by healthcare workers [1].

The use of mobile and wireless technologies to support the achievement of health objectives (mHealth) has the potential to transform [2] the face of health service delivery across the globe. To this extent, many health organizations are designing projects that use mobile technology to support health services and health education [3].

Some of these models largely use Short Message Service (SMS) as their main communication technology.

Health information systems communicate to their intended users via various communication channels such as text messaging, calls, interactive voice response (IVR), and emails among others, to enhance medication adherence, improve health literacy and ensure appointment attendance [4].

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This paper describes a model for effectively sending healthcare information via short messaging system (SMS). We describe factors emerging from a research conducted in Nairobi, that influence effectiveness of healthcare messages sent via SMS by making the receiver at ease with the initiative. This is mainly done through choosing the correct parameter values for the SMS communication.

1.1 SMS Technology

Short messaging service (SMS) (a.k.a. text messaging) in particular is greatly preferred because it provides an opportunity to improve health knowledge, behaviors, and clinical outcomes, particularly among hard-to-reach populations. Text messaging is also easy to use and affordable.

SMS messages have a number of characteristics that make them very appropriate for use in a healthcare setting including: direct patient communication, privacy, confidentiality, swift delivery of messages and receipt of responses, convenience for health providers and patients. SMS messaging technology also allows the dispatching of substantial numbers of messages simultaneously, so reducing labor expenditure [5].

1.2 Maternal and newborn child healthcare

Each year, at least 1.16 million African babies die in the first 28 days of life – and 850,000 of these babies do not live past the week they are born. This is largely attributed to poor post-natal clinic attendance [6] [7].

Mortality in children under the age of five has been reported to have fallen from an average rate of 90 per 1000 live births in 1990 to 43 per 1000 in 2015. Maternal mortality however, has declined by 45% [8].

A number of efforts have attempted to map the state of the evidence relating maternal, newborn and child health (MNCH) in lower and middle income countries (LMIC), to technology. Numerous examples of mHealth interventions, mostly SMS-based, have been used to support mothers through safe pregnancy and childbirth and to facilitate neonatal and infant health. However, we found that there has been no rigorous systematic documentation of what structures were used to send the healthcare information via SMS. A review of most SMS based initiatives showed that various providers or initiatives have their different SMS structures with no empirical evidence of their suitability.

This study was conducted in Nairobi, Kenya, through the support of TotoHealth Limited [www.totohealth.net]. TotoHealth is a social enterprise committed to revolutionizing the maternal and child health industry in Kenya. It uses an SMS-based platform to allow parents and caregivers to record milestones in their child's physical development, which helps with the timely detection of abnormal growth in children below the age of five. To achieve their objectives, TotoHealth sends life-saving information to mothers and caregivers in Kenya particularly among rural low-income populations. The contribution of TotoHealth in our study was that they provided the participants. These participants used to receive messages every Monday on maternal and newborn health care.

1.3 Problem Statement

The key problem which this study was concerned with is the evidence of a working SMS structure. The healthcare sector uses SMS text messaging to disseminate healthcare information to a large population of people due to its low cost. Maternal and post-natal healthcare information is widely delivered using SMS text messages. Evidence of a structure used to send the healthcare SMS ensuring that the message received is effective remains very limited [9] [10].

This study was aimed at proposing a model to be used to send healthcare information using SMS, to ensure that the message sent is effective.

1.4 The organization of the paper

The rest of the paper is structured as follows: Section Two presents related work in this area, Section Three describes the process of gathering information where a mix of both qualitative and quantitative research methods were employed. Section Four presents the results from the data collected. Section Five presents a

discussion of the results of the data collected while in section Six we conclude with the current state of our work and our recommendations.

2 Related work

There are several mHealth solutions in the healthcare space, adopting SMS solutions to disseminate healthcare information. But as we had mentioned, there is very limited evidence of studies supporting the need to have a common and standardized model which ensures that healthcare information sent over SMS is effective. This section highlights some of the mHealth initiatives in the healthcare landscape and the models used to send information via SMS.

2.1 The current mHealth Landscape: Review of interventions supported by SMS applications in healthcare

There are numerous ways SMS is being used in the healthcare sector globally. Some of its uses include broadcasting of urgent and important information across a wide geographical area, increased efficiency in monitoring patient progress and condition, diet and health tips, emergency toll-free telephone services, managing emergencies and disasters, mobile telemedicine, appointment reminders, community mobilization and health promotion, treatment compliance, mobile patient records, information access, patient monitoring, health surveys and data collection, surveillance, health awareness raising, and decision support systems [11].

In 2014, the US department of health and human services conducted an environmental scan to highlight a number of text messaging initiatives that address various health issues. [<http://www.hrsa.gov/healthit/txt4tots/environmentalscan.pdf>] The scan represented text messaging initiatives in maternal and child health, tobacco control, emergency response and preparedness among others. The initiatives focused on health promotion and disease prevention. The use of SMS was seen to positively result to behavior change.

In a study conducted by the Center for Population Health to determine the impact of text messaging for sexual health promotion for young people, text messaging was found to be an effective method and improvement in sexual and health knowledge was observed [10]. This was largely attributed to the messages being short, catchy, and informative, and where possible, tied into particular events (e.g., Valentine's Day, Mother's Day).

2.2 Evidence of use of SMS to support maternal and newborn child healthcare

This section provides a summary of some of the SMS based mhealth solutions in the MNCH space that have been developed to address some of the gaps in MNCH such as patient identification, ANC reminders etc. and the models used in sending the SMS.

Wired Mothers.

Wired Mothers is a mHealth project that seeks innovative ways to ensure access to ANC and skilled attendance at delivery, and to examine the beneficial impact mobile phones can have on maternal and neonatal morbidity and mortality. It was designed with the aim of linking pregnant women to their primary health care providers throughout their pregnancy, childbirth and post-partum period [12].

During the pilot study conducted in 2009-2013, nearly 1300 pregnant Zanzibar women registered their mobile phones with the local health clinic upon their first antenatal visit. The women received a number of benefits, such as what kinds of foods to eat, how to prepare for the arrival of their babies and reminders on when to attend the next antenatal checkup. They were also given a nurse's cell phone number in case of any questions or emergencies.

Wired Mothers sends two SMS in Kiswahili, every month before 36 weeks of pregnancy; one reminding the pregnant woman of her next ante-natal care visit and another on health education. After the woman gives birth, she is put on post-pregnancy health information, where she receives reminders for her baby's vaccinations.

Interactive Alerts .

The biggest IT challenge in the health and medical fields continues to be the ability to identify patients. As mobile phone availability becomes ubiquitous around the world, the use of Near Field Communication (NFC) with mobile phones has emerged as a promising solution to this challenge. Interactive Alerts offers child tracking and referral via general packet radio service (GPRS) using NFC mobile phones and radio frequency identification (RFID) tags. A child's caregiver first enrolls onto a system during a visit to an immunization center. The care giver then receives SMS reminders about vaccination appointments. To assure each child completes the scheduled vaccines on time, health workers also individually track enrolled children using the mobile phone-based RFID system. The amount of cash the caregiver is compensated is dependent with each subsequent vaccine their child completes.

Caregivers receive higher cash amounts for vaccinations that are administered at the recommended age. Interactive alerts enrolled more than 14,000 infants over a period of 6 months [13]. IRD's Interactive Alerts application sends SMS reminders about vaccination appointments to caregivers.

M-chanjo.

M-chanjo is a mobile based system that creates awareness on child immunization schedules and provides basic health facts. It is a mobile based system that seeks to reduce the rate of child mortality especially in the developing world.

The idea was born out of the realization that out of the 8.1 million children under 5 years of age who die every year, a large percentage dies from preventable diseases such as pneumonia, measles and diarrhea. These diseases can be prevented by administering vaccinations which are given free for all children under five years. Still, the rate remains high. The millennium development goal 4 was geared towards reducing the rate of child mortality by two-thirds by the year 2015 [14].

The M-chanjo system works by sending automated reminders via SMS to parents to keep them informed on any future immunization dates and appointments for their children. The text messages also include basic health care tips to manage common diseases.

M-chanjo banks on the negligible costs in sending text messages and on the high mobile phone penetration rate. The use of mobile phones and SMS is thus efficient and in the long run reduces costs on outreach and treatment of diseases that could otherwise have been prevented. [<http://healthmarketinnovations.org/program/m-chanjo>]

ChildCount+.

ChildCount+ is a mHealth platform developed by the Millennium Villages Project aimed at empowering communities to improve child survival and maternal health. The main program goal is to register every child under 5 and pregnant woman and record the MUAC indicators of every child from 6 months to 5 years every 90 days for malnutrition. The child is also monitored for diarrhea, malaria and pneumonia, the three major preventable causes of death in children under 5.

The program uses SMS messages to facilitate and coordinate the activities of community-based healthcare providers, and to register patients and their health status on a central web dashboard that provides a real-time view of the health of a community. Automated alerts help reduce gaps in treatment. [<http://healthmarketinnovations.org/program/childcount>]

WelTel Kenya.

WelTel Kenya conducted a randomized controlled trial to test the clinical effectiveness of text message support for HIV treatment adherence in Kenya. This trial showed that patients receiving text message support had significantly improved treatment adherence and viral suppression, than patients who received standard care alone [15].

The WelTel intervention involved sending weekly SMS using the WelTel Kenya1 model and an automated text-messaging platform (WelTel and Vertical Labs). Each week for 6 months during the study period (January to December 2012), enrolled participants were sent a text message asking, "How are you?" Responses were categorized into those that were reassuring and those that required follow-up by clinic staff. Participants who indicated a problem or question were either texted or called. If participants had not responded within 48 hours of the first text, a second text was sent asking, "Haven't heard from you ...how's

it going?" Mobile phones and phone plan support were provided to participants without a phone: 15 participants owned a mobile phone at baseline and 10 were provided with phones and phone plans. In addition, 4 participants who had their own phones had their plans upgraded for unlimited texting.

Table 1 provides a summary of the models used in sending healthcare messages from the review of literature listed above. The table confirms that there exist many versions of models used when sending healthcare information over SMS. There is therefore the need to have a common and standardized model which considers all the relevant factors thus ensuring that healthcare information sent over SMS is effective.

Intervention	Frequency	Type of SMS	Preferred Language
Wired Mothers	2	Health Education, Ante-natal visit reminders, baby vaccination reminders	Kiswahili (predominantly native language)
Interactive Alerts		Vaccination	English
WelTel	Weekly	Follow up on ART medication, Reminders for next ART visit	Kiswahili
ChildCount		CHWs receive SMS notifications to conduct follow-up visits and to remind women and children in their catchment area of upcoming clinic visits	

Table 1. Summary of models used

This therefore brought about our need to find out the factors that make up an SMS model that would be effective in meeting the intended objectives.

3 Methods

3.1 Information Gathering

A mix of both qualitative and quantitative research methods were used to verify the hypothesis that sending healthcare information via SMS requires certain parameters to ensure effectiveness. These methods are briefly described next.

3.2 Sampling

Sample Size

The population in this study are all people who have been receiving TotoHealth maternal and child care SMS for more than 6 months. They were selected from a population of 600 people within the TotoHealth database. To determine the sample size, we use Slovincs formula [16].

$$n = \frac{N}{1 + N(e)^2}$$

Where:

n = sample size

N = population size

e = margin of error 10.41%

n= 600/ (1+600(0.104²) = 80.11

Sample size for the study was 80 respondents; consisting of 11 males and 69 females from Nairobi's urban center and low resource setting areas such as Kibera, Mukuru wa Njenga and Embakasi. These areas are regarded as either low or medium income earning sections within Nairobi city.

3.3 Data Collection Techniques

A preliminary review and study of literature on existing models used to send healthcare messages using SMS was conducted. This process helped to inform the design of data collection tools. The data collection tools contained questions on time of day in which participants had most access of their phone, day of the week most preferred to receive the SMS, frequency of receiving the healthcare messages, topics of interest to the receiver and preferred language of receiving the healthcare messages among other questions.

Interviews: 52 respondents were interviewed over the phone using semi-structured scripts. Interview topics included time of day in which respondent has most access of their phone, day of the week most preferred to receive the SMS, frequency of receiving the healthcare messages, topics of interest to the receiver, preferred language, education level and general demographic of the receiver such as age, cadre (father, mother, young mother). Interviews were conducted over the phone due to of the geographical location of the respondents who were in various places around the city. Each interview lasted approximately 10 - 20 minutes, were tape recorded and transcribed verbatim. The interviews were conducted in either English or Swahili. The interview consisted of 34 mothers between the ages of 25 and 40, 11 young mothers between the ages of 16 and 24 and 8 fathers.

Focus Group Discussions: A focus group discussion consisting of six participants was held at Kayole II Hospital Center in Kayole, Nairobi. The discussion topics included time of day in which participants had most access of their phone, day of the week most preferred to receive the SMS, frequency of receiving the healthcare messages, topics of interest to the receiver and preferred language of receiving the healthcare messages. Participants received Kshs 200 as a compensation for their time.

Questionnaires: Questionnaires were used to collect demographic characteristics, respondent's access and use of mobile phones and general perception of the SMS intervention. Questionnaires were filled at the Kayole II Hospital Center. Just like in our focus group discussions, the participants were given Kshs 200 (approximately 2 USD) as a compensation for their time.

Observations - The researcher subscribed to TotoHealth service to receive the SMS' containing healthcare information. This was done in order to gauge the messages received and understand their effect to the recipient.

3.4 Data Analysis and Interpretation.

The analysis framework was based on the factors identified during the literature review and discussions that included favorable day and time to receive healthcare information via SMS, how frequently they would like to receive the SMS, preferred language and which topics of interest. The quantitative data was statistically analyzed using Microsoft Excel. For the qualitative data, obtained from the interviews, focus group discussions and observations, the data was coded and themes identified, grouped, analyzed and interpreted.

3.5 Ethical issues

The study reported here was carried out under the umbrella of TotoHealth. As a result, all the ethical issues were dealt with by TotoHealth. Being an already established organization, they extended the permission already obtained to use the respondent's details to our study. Respondents were informed that their participation was voluntary, that they could withdraw at any time and that all information provided/used was going to be confidential.

4 Results

The structure of the existing TotoHealth system captured the preferred language of the recipient, the names of the users and expected delivery date. We therefore set to assess the factors that needed to be considered to ensure the messages sent were effective.

From the sample of 80 selected, only 63 participants responded to the study, which is approximately 79%. The other 21% were not available to take the interview due to lack of availability.

Even though 100% of the respondents owned a personal cell phone, only 21% of the 63 respondents contacted for this study, had access to their phones in the morning hours only, while 29% had access to their phones in the evening.

On selecting the best time during a day when respondents would like to receive the healthcare SMS, 46% of the respondents preferred to receive the messages in the morning hours between 8:00am – 12:00 noon, 4.8% preferred to receive the messages in the afternoon between noon and 5:00 PM. 28.5% preferred receiving the SMS in the evening, between 5:00 PM and after 7 PM. 20.6% preferred to receive the messages anytime.

On selecting which day of the week the respondents preferred to receive the healthcare message, 58.7% of the respondents preferred receiving the healthcare messages on Monday, 7.9% on Tuesday, 4.8% on Wednesday and Friday, 0% on Thursday, 9.5% on Saturday and 3.2% on Sunday.

44.4% of the respondents prefer to receive healthcare messages once in a week, while 29% preferred to receive the messages at least twice in a week. 22.2% preferred to receive the SMS as frequently as possible. Data from the young mothers interviewed showed that they preferred to receive the messages as frequently as possible. This can be explained by the fact that they needed a lot of information given that they were new mothers and felt that they knew very little regarding motherhood.

On finding out which topics the respondents were interested in receiving SMS on, 77.8% of the respondents were interested in receiving SMS on child development and stimulation. 71.4% were interested in SMS on breastfeeding and nutrition. It was however noted that the respondents were least interested in health pregnancy and safe delivery information.

Young mothers were interested in receiving information on child development and stimulation, breastfeeding and nutrition and parenting by 91.7%.

Six out of the eight fathers interviewed were seen to be interested in receiving messages on first aid, child development and stimulation, immunization reminders and parenting.

When the language the respondents preferred to receive the healthcare messages from TotoHealth was assessed, 60% of the participants preferred to receive the messages in English while 40% preferred to receive the messages in Swahili. No respondent selected a native language as their preferred language.

5 Discussions

The TotoHealth system which was under study sends messages to its users but does not send when the recipient is most available. During the registration process, the system only captures the preferred language and the names of the users amongst other things, which do not contribute to the quality of the message.

The new solution extends the structure of the messages send by TotoHealth system, to enable the user to

- *Propose day of the week*

The system enables the user to select which day of the week they would like to receive the messages. This enables the user to create a habit of expecting the healthcare message on a particular day when he/she is most available.

- *Propose the time of day*

This function enables the user to select which time of day selected they had most access to their phones and preferred to receive the message. This is the time the recipient is most free with little or no distractions.

- *Propose frequency of receiving the messages*

This function enables the user to determine how frequently they would like to receive the healthcare messages. According to the data collected, new and young mothers preferred to receive the healthcare messages as frequently as possible compared to older and more experienced mothers.

- *Propose topics of interest*

Although the topics covered by TotoHealth were all important, young mothers and fathers were seen to prefer receiving specific messages compared to experienced mothers.

6 Conclusion and recommendations

6.1 Contribution to the study

It has become clear in this study that several versions of models have been used to send healthcare information over SMS. This was seen from review of literature. There is need to have a common and standardized model which considers all the relevant factors which ensure that healthcare information sent over SMS is effective. From the data collected in this study, the following model was derived.

The table 2 below shows the factors that need to be considered when sending healthcare information via SMS and compares preferences and availability of a young mother and a working mother.

Factors to be considered	Young Mother	Working mother
Best Time of Day	Prefers to receive the SMS at 2:00pm probably because that's when the child is asleep and she is relaxing at home	Prefers to receive the message in the evening at 8:00pm – after feeding her child and preparing to watch 9:00pm news. TotoHealth can target to send the healthcare messages just before 9pm news with the intention of catching many viewers when ready to watch
Best Day (s) of the week	Wednesday	On Saturday when she is not working
Frequency	Twice a week because she is a new mom	Once a week
Topic (s) of Interest	child development and stimulation	immunization reminders
Language	Swahili	English

Table 2. Factors considered when sending healthcare information via SMS

6.2 Recommendations for future work

The parameters identified in this research are generic and potentially recognizable in any other healthcare environments. However, upon close inspection, it is apparent that other factors need to be considered to ensure that healthcare information sent over SMS is effective. These additional factors include persons reading level, reader's level of comprehension, use of simplified messaging, understandability of the healthcare information and presentation of the message; i.e. have a clear organizational structure and follow the grammar and spelling rule, consideration to disability. These, we propose as future work.

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A Scalable Low-Cost Multi-Hospital Tele-Radiology Architecture in Kenya

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In LMIC, radiology image studies are transported across distant geographical locations in an attempt at seeking radiologist's reporting services. This often leads to delayed care, poor patient outcomes and negative monetary implications. The landscape is rapidly changing with improved internet connectivity and availability of advanced radiology equipment. Tele-radiology holds great promise in solving this problem. We describe a tele-radiology architecture that uses the global virtual radiology service model, its implementation, success, challenges and its promise with wide adoption.

Implementation involved several policy, stakeholder, security and workflow integration considerations. Over a 1-year period of implementation from January to December 2017, 80 X-rays (CR studies), 150 MRIs and 1,335 CT Scans were processed and delivered for reporting within a period of three (3 ± 1.4) minutes. There was image size variability depending on modality. The total cost of implementation of the architecture was \$7,540.

The system demonstrated that it is possible to implement a scalable, low-cost, sustainable, secure and robust tele-radiology architecture in low resource settings. This would help alleviate some of the constraints associated with the sparse number of radiologists.

1 Introduction

There is a general shortage of radiologists in the world [4,5]. This shortage is more marked in the developing countries despite the increasing demand for radiology services. In Kenya, for example, the number of qualified radiologists is only 13-38% of those needed to serve the country's population [6]. The few radiologists tend to be concentrated in urban areas compared to rural areas where a majority of the population lives [5]. To help address the deficiency in radiologists, tele-radiology has been identified as a potential solution to improving the reach and timeliness of radiology services in low- and middle-income countries (LMICs) [3]. Tele-radiology is defined as the exchange of radiological images and patient-related data between geographically separate locations for purposes of primary interpretation, expert consultation and/or clinical review by digital transmission [1].

While services hold great promise in low- and middle-income countries (LMICs), implementation of these systems has been slowed down by several challenges. These challenges include poor internet connectivity, poor understanding of the technology, vendor lock-in, and lack of state of the art equipment. Additionally, there is paucity of data on an appropriate infrastructure setup that would be affordable and scalable to implement without disrupting the workflow of hospitals and radiologists. The demand for services has also been limited by the fact that most of the radiology equipment were initially only available in urban areas, which tended to have radiologists. Rural areas, that could benefit best from tele-radiology services, given lack of radiologists, often also lacked radiology equipment.

However, things are rapidly changing in several LMICs. In Kenya for example, recent developments have increased the demand for tele-radiology services. In 2015, the government invested heavily in equipping at least all county and national referral hospitals with advanced medical imaging equipment [8].

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It involved deploying more than 585 units of diagnostic imaging equipment including digital radiography (X-ray), Computed Tomography (CT) Scan and Magnetic Resonance Imaging (MRI) machines across the country's hospitals. At the same time, the country has experienced significant increase in broadband internet penetration over the last decade after arrival of the undersea fiber optic [7].

Despite these positive developments, Kenya has found itself in the situation where many imaging studies continue to be physically transported across distant geographical regions for interpretation by radiologists. In scenarios where the imaging studies are not transported, the radiologists must shuttle between multiple hospitals to report on the studies. These constraints often lead to delayed care with negative impact on patient outcomes, and negative monetary impact on hospitals and patients.

The chronic shortage of radiologists in the country coupled with rising Internet connectivity rates, ubiquity of computers and accepted communication standards in digital imaging (such as the Digital Imaging and Communications in Medicine [DICOM] standard) have meant that Kenya is in a unique position to benefit greatly from tele-radiology. In this article, we describe the development of a scalable low-cost multi-hospital tele-radiology architecture in Kenya. We also describe its implementation, successes, challenges and the promise of this implementation with broad adoption.

2 Materials and Methods

2.1 Setting

The tele-radiology architecture and service was implemented among four private facilities in western Kenya in January until December 2017. The private facilities have a combined capacity of 364 beds (i.e. 24, 90, 100 and 127 beds). Radiology equipment within these facilities included: (a) Computed Tomography (CT) scanner in three facilities, (b) a Magnetic Resonance Imaging (MRI) machine in two facilities, and (c) a digital radiography (x-ray) machine in all the facilities. Internet connectivity to each of the hospitals was an upload speed and download speed of 6 megabytes per second (MBps). Before the implementation, none of the hospitals had resident radiologists. The all shared from the same pool of radiologists. The hospitals are situated within a 5-kilometer radius of each other.

2.2 Tele-Radiology Architecture

The goal of the tele-radiology architecture was to: (a) allow images from the various facilities to be efficiently and securely transmitted to a central server accessible to radiologists; (b) allow for notification of relevant radiologists assigned to interpret the image; (c) save the radiology report; and (d) allow for notification and viewing of generated report by facilities.

(a) Policy and Stakeholder Considerations

Development and implementation of the system was done in close collaboration with key stakeholders from the four care facilities. Particular attention was paid to ownership of radiology data files, to ensure that each facility retained ownership of their radiology images at all times, and that other facilities could not have unauthorized access to these images. In essence, the infrastructure established acted as a secured repository for each facility, ensure confidentiality of the patient information. Policies on who could access the images (e.g. radiologists allowed to review images for a hospital) were determined by each individual facility. Mechanisms were also put in place on how to manage space within the central server, delete old studies, manage duplicate studies based on a matching algorithm and to optimize responses to different modalities. Acquisition of images was via Digital Imaging and Communications in Medicine (DICOM) compliant modalities in each of the hospitals. The modalities include a CT scan in three facilities, an MRI in two facilities and a digital radiography machine in all four facilities.

(b) Architecture and Implementation

Existing equipment at the facilities often take digital images that are stored within the equipment and are available for printing. Images are acquired using DICOM standard. We implemented an architecture that allowed for the acquired images to be securely transmitted to a central server. To do this, we set up a central

DICOM server that was hosted on a HP Proliant ML310e-G8 Intel XeonE3-1220v2 (3.1GHz/4-core) with 4GB random access memory and 2 terabytes of hard-disk space. The server was connected to an uninterrupted power supply (UPS) device capable of sustaining 30 minutes of use without electricity. A power generator was also available on standby and we had power-surge protection functionality. The connection speed to the server was 25 MBps regulated by a Mikrotik router with an advanced firewall and port forwarding configured.

The central server ran the ClearCanvas DICOM Server v13.2.19401.1661 software by Synaptive Medical. This server application is available under an opensource license and can be downloaded for free. With this software, the central server could receive and process DICOM images from distinct types of modalities including but not limited to: Computed Radiography (CR), CT, MRI, Nuclear Medicine (NM), Ultrasound (US), Endoscopy (ES), Positron emission tomography (PET), radiographic imaging (conventional film/screen) and X-Ray angiography among others.

The server was configured so that there was a separate partition for images originating from each facility. At each facility, the radiology equipment was also configured to connect to the DICOM central server. With this configuration, the acquisition of an image by an equipment at the facility automatically triggered a storage command to the central server. This allowed the image to be automatically uploaded. The central server processed each incoming image using a set of criteria before storage. As an example, Lossless compression was applied if uncompressed images were received. Each image was then saved to its appropriate partition based on source facility. The images were then available for view by authorized radiologists within minutes of storage into the central server. Figure 1 gives an outline of the architecture implemented.

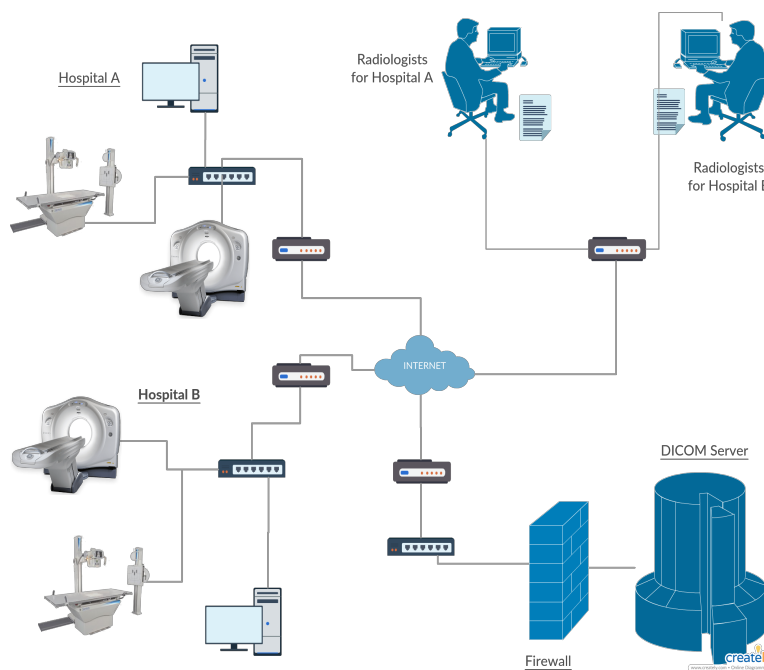


Figure 1. The architecture implemented to interconnect hospitals and radiologists

(c) Workflow Integration

To ensure little interruption to the existing interaction between the radiologists and the hospitals, we implemented a separate workflow tool that was developed using Java and Spring framework. The interface for this tool enabled users with various privileges to log in and monitor the status of the images. The workflow tool actively alerted users on items that needed their attention based on predetermined triggers. As an example, Radiologists assigned to Hospital A would get alerts for new images sent from Hospital A that needed interpretation and reporting. Alerts were pushed to providers and users using verified email addresses in the system. Similarly, hospitals got email alerts for new reports submitted by radiologists. The

workflow tool had added functionality such as customizable templates for reports and the ability to generate PDF versions of signed reports.

(d) Security Considerations

Several security measures were implemented given the sensitivity of handling patient-level data. First, the central DICOM server was kept behind a two-tiered firewall - one implemented on the router to only accept traffic through specified ports and a second firewall within the server itself. Second, access to the radiology studies stored on the central server could only be permissible through a virtual private network (VPN). Third, at the application level, the partitions only accepted storage command requests and could not be queried by external applications. The partitions additionally only accepted storage command requests from specified modalities e.g. the partition assigned to Hospital A only accepted commands from the hospitals modalities and rejected those from other modalities.

The system also implemented user-level authentication mechanisms. Secure logins were required for one to be able to view images, create a report or view reports. User level restrictions and privileges for hospital users also ensured that users were only able to view radiology reports and images that they have rights to. Radiologists on the other hand could only view images if they satisfied set criteria. They had to be in the specific hospitals panel of approved radiologists and be certified by the Kenya Medical Practitioners and Dentists Board (KMPDB) as a radiologist allowed to practice in the country for them to be given privileges within the system. Once a radiologist with relevant privileges logged into the secure system and selected an image for interpretation and reporting, the specific study got locked from access and interpretation by other users. Only then were they allowed to view and report on the images. The security measures implemented are summarized below in Table 1.

Table 1. Summary of security measures

Security implemented in the architecture
Router level firewall
Server level firewall for port restriction
Partition restriction to each hospital/facility
Secured user logins
User resource restrictions
Only certified board radiologists can report images
Locking of images for availability for reporting
Image studies accessible only through a virtual private network (VPN)

3 Results

The tele-radiology system went live in January 2017. The studies that were received and processed from January to December 2017 included 80 x-rays (CR studies), 150 MRIs and 1,335 CT Scans. The breakdown per institution is as shown in Table 2.

Table 3. Number of studies processed over a 1-year period in 2017

Institutions	Hospital A	Hospital B	Hospital C	Hospital D
CR studies	1	15	6	58
MRI studies	-	-	-	150
CT studies	4	-	37	1294

The number of images (or series) sent per patient for each study modality varied based on the modality. On average, CR studies had 2 series, MRI studies had 176 images, while CT scan study had 160 images in each patient study. The number of the images/series also varied depending on the type of equipment used by study type (e.g. 16 slice vs 64 slice CT), the type of study (abdominal CT vs head CT) and study settings.

100% of the studies were fully transferred to the central DICOM server within three (3 ± 1.4) minutes of initiation of transfer and were then immediately available for reporting by radiologists. All studies were compressed using the lossless technique. The summary of stored image sizes per modality is shown in Table 3.

Table 3. Image sizes in megabytes (MB) per study

Modality	Minimum size	Maximum size	Average size	Standard deviation
CR studies	7.0	34.0	13.6	8.7
MRI studies	21.0	242.0	81.9	52.6
CT studies	16.0	1150.0	294.0	260.0

CR studies pushed in the least size of images and needed less storage resources while CT studies required bigger storage needs per study. There was a large variability in image size for CT studies compared with other modalities. This was contributed by the fact that CT images of the abdomen were significantly larger. The significantly smaller image sizes were contributed by incomplete image transfer from the modalities to the server.

The total cost to setup the initial infrastructure capable of supporting the tele-radiology architecture is shown in Table 4. The infrastructure can support an unlimited number of hospitals and modalities with the major limitation being storage, and this can be easily overcome. The business model employed for sustaining this tele-radiology service included the addition of a 10% fee on top of the radiologist's fee for every study that was reported. The resources were used to sustain the architecture through payments for internet and wages to maintain and improve the system.

Table 4. Cost implication of setting up the tele-radiology infrastructure

Component	Amount (USD)
Server - HP Proliant	1,000
Additional storage for images - 2 terabytes	120
MikroTik router	120
Uninterrupted power supply	300
Server internet connectivity 1 year	600
Design and development of workflow tracking tool	2,500
Server and modality configuration costs	500
Tele-radiology support staff wages	2,400
TOTAL	7,540

4 Discussion

We describe an implementation of a tele-radiology solution in a network of four private hospitals in Western Kenya, as a demonstration of a scalable and sustainable health information technology-based approach to improve efficiency and effectiveness of radiology services in settings with limited numbers of radiologists. We demonstrate that this system improves the timeliness to radiologists accessing images from remote sites, enables radiologists to manage their time more effectively by alleviating the need to shuttle between different facilities, and allows for efficient monitoring of turnaround times for reporting on images. The implementation of radiology information systems and picture archiving systems (RIS/PACS) in the western world has been well documented and been shown to be largely beneficial [13,12]. In resource constrained settings the literature is not as comprehensive, and our work adds to the growing body of evidence around the implementation of these technologies within LMICs.

There are four types of business models described in literature for tele-radiology systems: the standalone tele-radiology, the nighthawk/on-call coverage, solo radiologist practice, second opinion tele-radiology and the global virtual radiology [10]. This implementation closely matches the global virtual radiology service model and making it feasibly to alleviate radiology human resource constraints by leveraging approved professionals globally. The attractiveness of this approach is in its ability to potentially allow for cost-reductions for radiology services, and quality monitoring over time. We also demonstrate that through innovative use of open source application, the cost of implementation can be substantially reduced. The cost of obtaining an out of box tele-radiology system is upwards of 20,000 USD [9]. However, the licenses increase exponentially as more modalities are added. The total cost of implementation of this tele-radiology architecture was 7,540 USD, with the infrastructure able to support virtually an unlimited number of facilities and modalities, once storage considerations are accommodated.

In our implementation we demonstrate the importance of using health informatics standards. The architecture implemented is reproducible in different settings with minimal effort. The ubiquity of DICOM standard made it easy to integrate with radiology equipment from different vendors. DICOM use also ensures interoperability with other systems in future e.g. E-learning systems [2], electronic health or personal health records. Most importantly, DICOM is a much more secure standard when combined with the recommended VPN technology as was implemented. Our system also makes use of freely available open source systems, which not only makes the cost of implementation low but also improves on interoperability. Further, we provide evidence of importance of fitting into the users' workflow as a proven way to improve acceptance and utilization of a system [11]. Finally, we highlight the need for multimodal security approaches to protect patient-level information in tele-radiology systems.

This work is the initial stage of a multi-stage implementation. Our manuscript is descriptive, but in the future, we intend to conduct more rigorous evaluation on impact of the system on patient and provider satisfaction, efficiency in care, impact on outcomes and cost effectiveness.

5 Conclusion

In low resource settings where human resources for health are limited, scalable, secure, low cost, sustainable and robust tele-radiology systems promise to alleviate some of the constraints associated with limited numbers of radiologists. We demonstrate the feasibility of such a system using the global virtual radiology service model in the resource limited setting of Western Kenya.

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Background Factors Associated with Willingness to Use *mHealth* for Tuberculosis Treatment Adherence in Kisumu, Siaya and Homa-Bay Counties of Kenya

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Background and Purpose: Poor adherence to the antimicrobial regimen has been cited as one of the most challenging problems for TB treatment as this provides favourable conditions for the maintenance of disease transmission, high mortality and the development of resistant strains. *mHealth* has been advocated as an innovative tool for improving both access to and quality of health care in underserved and remote locations. However, there remains limited evidence on patients' willingness to adopt it for TB treatment adherence.

Methods: A semi-structured questionnaire was used to collect data from 522 eligible patients seeking TB care at study sites.

Results: The predictors of willingness to use *mHealth* include residing in rural settings, earning monthly income of at least Ksh 10,000, travelling more than 5KM to access a health facility, using a text function sometimes/oftenly and preference for *mHealth* intervention at night-time/evening. The others are Turn-around-Time of 21 –30 days from the time they first reported to the public facility till first diagnosis as TB case, believing that stopping treatment before completing the full course was harmful to one's health and taking the medication in the afternoon.

Conclusion: There are several factors influencing patients' willingness to use *mHealth*, which should be considered when rolling out *mHealth* interventions for medication adherence and other desired health outcome

Keywords: *mHealth*, TB, Willingness

1 Introduction

TB is ranked alongside HIV as the leading cause of death from infectious diseases worldwide (WHO, 2015). A major barrier to better results is the high number of new smear-positive cases that voluntarily interrupt treatment. Low cure rates and a high treatment default rate provide favourable conditions for the maintenance of disease transmission, high mortality and the development of resistant strains (Volmink and Garner, 2006). However, widespread progress at controlling TB is restricted by poor infrastructure and increasing health-system costs. *mHealth* has been advocated as an innovative tool for improving both access to and quality of health care in underserved and remote locations in low and middle-income countries. *mHealth* is defined by the WHO (2011) as the "medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistances and other wireless devices". Mobile phone access has risen dramatically, creating significant opportunities for creative and cost-effective implementation of *mHealth* interventions. However, despite the growing interest in *mHealth*, there remains limited evidence on TB patients' willingness to use the technology. Absence of such information hampers efforts to capitalize on expanding successful *mHealth* pilot projects and hence the need for this study. The objective of the study was to determine the level of willingness to use *mHealth*

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intervention on Tuberculosis treatment adherence and related factors in Kisumu, Siaya and Homa-Bay Counties of Kenya.

2 Methodology

This cross-sectional study was conducted in selected hospitals in the Nyanza North TB control region which covers, Siaya, Kisumu and Homa-Bay Counties. The study population was the newly diagnosed TB patients and those beginning re-treatment phases. A total of 522 participants were recruited for the study as they initiated TB treatment until the desired sample size was attained. All study participants were required to provide a written informed consent at enrolment. A semi-structured questionnaire was used to obtain participant demographic, socio-economic and willingness to use mHealth data which was then analyzed using Statistical Package for Social Sciences (SPSS) software. Both descriptive and inferential statistics were utilized.

3 Results

3.1 Willingness to use *mHealth* in relation to selected socio-demographic characteristics

There was a significantly increased proportion of willingness to use mHealth among patients from Siaya County (57.3%) (OR=2.34; 95% CI: 1.52 – 3.60; $p<0.001$) when compared to those patients from Homa Bay (36.5%) (Table 1). The proportion of those willing to use mHealth was significantly higher among patients from rural settings (54.0%) (OR=1.96; 95% CI: 1.38 – 2.78; $p<0.001$) than those who reside in urban areas (31.8%). In addition, the level of willingness to use mHealth, was significantly higher among the participants from the age category of 33-37 years (51.8%) (OR=1.85; 95% CI: 1.04 – 3.31; $p=0.037$) and 28-32 years 51.8%) (OR=1.85; 95% CI: 1.04 – 3.31; $p=0.037$) compared to those who were above 42 years (36.7%). The proportion of willingness to use mHealth was significantly less among those who didn't have a specific main occupation (36.5%) (OR=0.49; 95%CI: 0.28 - 0.87; $p=0.014$) compared to those who were employed/ Salaried workers (53.8%). Willingness to use of mobile phones for health was significantly higher among patients whose income were less than KSh10,000 (47.8%) (OR=1.55; 95% CI: 1.03 – 2.33; $p=0.037$) and with income of KSh10,000-20,000 (OR=1.92; 95% CI: 1.11 – 3.35; $p=0.020$) than those who were without any income or dependent (37.2%). Respondents who indicated that they didn't know the distance from place of residence to the public health facility were significantly less likely to accept using mobile phone (16.7%) (OR=0.27; 95% CI: 0.08 – 0.95; $p=0.041$) compared to those patients with less than 2 KM (40.0%).

3.2 Willingness to use *mHealth* in relation to mobile phone Access and usage

TB patients who indicated that they own mobile phones were significantly more willing to use mHealth (52.9%) (OR=2.37; 95% CI: 1.56 – 3.61; $p<0.001$) compared to those patients sharing mobile phones (32.1%) (Table 2). Also, the willingness to use mHealth was significantly higher among respondents who rarely used mobile phone, rarely used text function and those who considered night-time or Evening to be the ideal time for mHealth intervention (56.4%) (OR=3.19; 95%CI: 2.14- 4.75; $p<0.001$) and at any time (61.8%) (OR=3.98; 95%CI: 1.87- 8.50; $p<0.001$) compared to those who indicated in the morning time (28.9%) respectively.

3.3 Willingness to use *mHealth* in relation to TB Treatment and Turn-Around-Time (TAT) Among the Study Participants

Greater willingness to use mHealth was noted among patients who took 21 –30 days from the time first reported to the public facility till first diagnosed as TB cases (60.8%) (OR=2.39; 95% CI: 1.55 – 3.68; $p<0.001$) than to those who took 1 - 10 days (39.4%) (Table 3). The type of TB, treatment outcomes and any experience of side effects did not have any association with willingness to use mHealth intervention for TB treatment adherence.

3.4 Willingness to use *mHealth* in relation to TB treatment Adherence

Respondents who believed that stopping treatment before completing the full regimen will be harmful to health had significantly increased proportion of willingness to use mHealth intervention (51.4%) (OR=9.68; 95% CI: 4.08 – 22.93; $p<0.001$) than to those who had contrary view (9.8%) (Table 4). This was also reported by TB patients who reported taking the medication in the afternoon.

3.5 Multivariate Analysis of Factors Associated with willingness to use *mHealth*

After Multivariable analysis, eight out of fifteen factors were independently associated with willingness to use mHealth (Table 5). Respondents from rural setting were 2 times more willing to use mHealth (AOR=2.02; 95% CI: 1.23 – 3.32; $p=0.005$) when compared to those respondents from urban setting. Willingness to use mHealth was 1.7 times more among patients whose monthly income were less than KSh10,000 (47.8%) (AOR=1.68; 95% CI: 1.00 – 2.83; $p=0.049$), about 2 times among those with monthly income of KSh10,000-20,000 (AOR=2.22; 95% CI: 1.11 – 3.35; $p=0.020$) and 10.8 times among those with monthly income of KSh 40,000-50,000 (AOR=10.81; 95% CI: 1.53 – 76.55; $p=0.017$) than those who were without monthly income. Other factors are as shown in table 5.

Table 1. Willingness to use *mHealth* in relation to Socio-demographic characteristics

Variables	Full Willingness, N=235		Partial Willingness (N=287)		OR ^ψ	95% CI ^φ		χ ² test
	n	%	n	%		Lower	Upper	P value*
County								
Siaya	82	57.3	61	42.7	2.34	1.52	3.60	<0.001
Kisumu	72	45.9	85	54.1	1.48	0.97	2.24	0.067
Homa Bay	81	36.5	141	63.5	Reference			
Residence								
Rural	129	54.0	110	46.0	1.96	1.38	2.78	<0.001
Urban	106	37.5	177	62.5	Reference			
Age in years								
18-22	29	44.6	36	55.4	1.39	0.74	2.60	0.302
23-27	43	51.8	40	48.2	1.85	1.04	3.31	0.037
28-32	43	51.8	40	48.2	1.85	1.04	3.31	0.037
33-37	52	45.6	62	54.4	1.45	0.85	2.47	0.177
38-42	28	41.2	40	58.8	1.21	0.65	2.25	0.551
> 42	40	36.7	69	63.3	Reference			
Main Occupation								
Employed	56	53.8	48	46.2	Ref.			
Farmer	40	41.7	56	58.3	0.61	0.35	1.07	0.086
Business	67	43.8	86	56.2	0.67	0.41	1.10	0.114
None	35	36.5	61	63.5	0.49	0.28	0.87	0.014
Others	37	50.7	36	49.3	0.88	0.48	1.60	0.678
Monthly income								
>10,000	118	47.8	129	52.2	1.55	1.03	2.33	0.037
10,000-20,000	41	53.2	36	46.8	1.92	1.11	3.35	0.020
20,000-30,000	10	35.7	18	64.3	0.94	0.41	2.17	0.882
30,000-40,000	0	0.0	2	100.0	UD	UN	UN	0.999
40,000-50,000	4	66.7	2	33.3	3.38	0.60	19.03	0.167
Over 50,000	4	66.7	2	33.3	3.38	0.60	19.03	0.167
None	58	37.2	98	62.8	Ref.			
Distance from place of residence to the public health facility								
Less than 2KM	107	42.8	143	57.2	Reference			
2-5KM	86	47.8	94	52.2	1.22	0.83	1.80	0.306
> 5+ KM	39	52.7	35	47.3	1.49	0.89	2.51	0.134
Don't know	3	16.7	15	83.3	0.27	0.08	0.95	0.041

^ψ Odds ratio; ^φ95% Confidence Interval; UN= Undefined; Ref= Reference

Table 2. Willingness to use *mHealth* in relation to Mobile Phone Access and usage

Variables	Full Willingness N=235		Partial Willingness (N=287)		OR ψ	95% CI ϕ		χ^2 test
	n	%	n	%		Lower	Upper	P value*
Mobile phone Access								
Owens	184	52.9	164	47.1	2.37	1.56	3.61	<0.001
<i>Shares</i>								
without Household	8	27.6	31	72.4	0.81	0.33	1.97	0.636
within Household	43	32.1	91	67.9	Ref.			
Mobile phone Usage								
Seldom	44	41.1	63	58.9	5.89	2.46	14.09	<0.001
Daily	184	52.7	165	47.3	9.40	4.18	21.15	<0.001
Unreported	7	10.6	59	89.4	Ref.			
Frequency of using text function								
Rare	67	44.4	84	55.6	2.93	1.59	5.39	<0.001
Sometimes	83	55.3	67	44.7	4.54	2.46	8.38	<0.001
Often	67	48.9	70	51.1	3.51	1.89	6.52	<0.001
Always	18	21.4	66	78.6	Ref.			
When would you consider as the ideal timing of the SMS or phone call?								
Morning	56	28.9	138	71.1	Ref.			
Noon	17	38.6	27	61.4	1.55	0.79	3.07	0.207
Night / Evening	141	56.4	109	43.6	3.19	2.14	4.75	<0.001
Any time	21	61.8	13	38.2	3.98	1.87	8.50	<0.001

* Significant at p<0.05 bolded; ψ Odds ratio; ϕ 95% Confidence Interval; Ref.=Reference

Table 3. Willingness to use *mHealth* in relation to TB Treatment and Turn-Around-Time

Variables	Full Willingness N=235		Partial Willingness (N=287)		OR ^ψ	95% CI ^φ		χ ² test P value*
	n	%	n	%		Lower	Upper	
Turn-Around-Time from first visit to the public facility till TB diagnosis								
1 - 10 days	80	39.4	123	60.6	Ref.			
11 - 20 days	33	37.9	54	62.1	0.94	0.56	1.58	0.813
21 - 30 days	90	60.8	58	39.2	2.39	1.55	3.68	<0.001
Over 30 days	32	38.1	52	61.9	0.95	0.56	1.60	0.836
Turn-Around-Time during sputum examination								
1 day	36	45.6	43	54.4	Ref.			
2 days	90	45.9	106	54.1	1.01	0.60	1.71	0.958
3 days	52	35.4	95	64.6	0.65	0.38	1.14	0.135
Over 3 days	57	57.0	43	43.0	1.58	0.87	2.87	0.129
Treatment Outcome								
Cured	213	45.9	251	54.1	1.39	0.79	2.43	0.250
Relapse	22	37.9	36	62.1	Ref.			
Type of TB								
Pulmonary TB	188	43.9	240	56.1	Ref.			
Extra pulmonary TB- EPTB	47	50.0	47	50.0	1.28	0.82	2.00	0.284
Are you currently experiencing any side effects?								
Yes	46	45.5	55	54.5	1.03	0.66	1.59	0.906
No	189	44.9	232	55.1	Ref.			

* Significant at p<0.05 bolded; ^ψ Odds ratio; ^φ95% Confidence Interval

Table 5. Willingness to use *mHealth* in relation to TB treatment Adherence

Variables	Full Willingness, N=235		Partial Willingness (N=287)		OR ψ	95% CI ϕ		χ^2 test
	n	%	n	%		Lower	Upper	*P value
Are you confident you will finish the entire treatment?								
Agree	230	45.7	273	54.3	2.36	0.84	6.65	0.104
Not sure	5	26.3	14	73.7	Ref.			
Do you believe stopping treatment before full course will harm your health?								
Agree	228	51.4	216	48.6	9.68	4.08	22.93	<0.001
Not sure	1	5.9	16	94.1	0.57	0.06	5.11	0.618
Disagree	6	9.8	55	90.2	Ref.			
Where do you keep your medications?								
HandBag	45	42.9	60	57.1	1.11	0.63	1.98	0.713
cupboard	60	46.2	70	53.8	1.27	0.74	2.21	0.389
container at home	55	44.7	68	55.3	1.20	0.69	2.10	0.518
bedside table	30	54.5	25	45.5	1.78	0.90	3.53	0.097
Under the pillow	10	45.5	12	54.5	1.24	0.48	3.18	0.657
Elsewhere	35	40.2	52	59.8	Ref.			
When do you take your medications?								
Morning	63	51.2	60	48.8	1.56	0.98	2.49	0.061
Afternoon	41	69.5	18	30.5	3.38	1.80	6.36	<0.001
Evening	61	36.7	105	63.3	0.86	0.56	1.34	0.510
At bed time	70	40.2	104	59.8	Ref.			
How do you take your medications?								
With food	87	51.2	83	48.8	Ref.			
Without food	104	45.0	127	55.0	0.78	0.53	1.16	0.223
Other	44	36.4	77	63.6	0.55	0.34	0.88	0.013
How do you remember to take your medications?								
By Family member	47	45.2	57	54.8	0.92	0.44	1.93	0.818
visible medications	64	47.4	71	52.6	1.00	0.49	2.06	0.997
Tie to a daily routine	66	44.0	84	56.0	0.87	0.43	1.78	0.709
Wait for <i>mHealth</i>	40	42.1	55	57.9	0.81	0.38	1.72	0.581
Other	18	47.4	20	52.6	Ref.			
In the last 7 days, did you miss any of your TB medications?								
Yes	22	43.1	29	56.9	0.92	0.51	1.65	0.776
No	213	45.2	258	54.8	Ref.			
Have you ever missed your clinic appointments?								
Yes	15	36.6	26	63.4	Ref.			
No	220	45.7	261	54.3	1.46	0.76	2.83	0.260
Adherence to TB treatment								
Non-Adherent	95	42.4	129	57.6	Ref.			
Adherent	140	47.0	158	53.0	1.20	0.85	1.71	0.299

* Significant at $p < 0.05$ bolded; ψ Odds ratio; ϕ 95% Confidence Interval; Ref=Reference

Table 6. Factors Associated with Willingness to Use *mHealth*

Predictors	AOR ^ψ	95% CI ϕ		p value*
		Lower	Upper	
Reduced model				
Residence				
Rural	2.02	1.23	3.32	0.005
Urban	Reference			
Monthly income				
Less than 10,000	1.68	1.00	2.83	0.049
10,000-20,000	2.22	1.11	4.46	0.024
20,000-30,000	0.85	0.31	2.33	0.757
30,000-40,000	UD	UD	UD	0.999
40,000-50,000	10.81	1.53	76.55	0.017
Over 50,000	2.79	0.43	18.12	0.282
None/Dependent	Reference			
Distance from place of residence to the public health facility				
Less than 2KM	Reference			
Between 2-5KM	1.00	0.62	1.60	0.989
More than 5+ KM	2.29	1.16	4.53	0.017
Don't know	0.23	0.06	0.93	0.039
Frequency of using text function				
Unreported/Very Rare	1.78	0.80	3.96	0.159
Sometimes	3.20	1.40	7.32	0.006
Often	2.44	1.04	5.70	0.040
Always	Reference			
When would you consider as the ideal timing of the SMS or phone call?				
Morning	Reference			
Noon	0.98	0.45	2.16	0.968
Night time/ Evening	2.39	1.45	3.93	0.001
Any time	3.53	1.38	9.00	0.008
Turn-Around-Time from first visit to health facility till TB diagnosis				
1 - 10 days	Reference			
11 - 20 days	1.04	0.56	1.93	0.893
21 - 30 days	2.77	1.62	4.74	<0.001
Over 30 days	1.73	0.88	3.41	0.112
Do you believe stopping treatment full course will harm your health?				
Agree	6.23	2.03	19.13	0.001
Not sure	0.25	0.02	2.66	0.250
Disagree	Reference			
When do you take your medications?				
Morning	1.27	0.72	2.26	0.412
Afternoon	2.77	1.30	5.92	0.008
Evening	0.62	0.36	1.05	0.077
At bed time	Reference			

* Significance at $p < 0.05$ bolded; ψ Adjusted odds ratio; ϕ 95% Confidence Interval

4 Discussion, conclusion and recommendations

The willingness to use mHealth for medical intervention has been increasing in a similar pace as its accessibility possibly due to perceived benefits. In a systematic review, Hamine and others (2015) found that the acceptability of mHealth tools for chronic disease management adherence were reported to be generally high among both patients and providers. However, previous studies have documented a number of concerns key among them being the dependence on professional supervision, unnecessary medicalization, and undue anxiety if technology failed (Faridi et al., 2008, Ryan et al., 2012). Among providers, concerns include the amount of time and effort required to review data and provide responses in

time (Halkoaho et al.; 2007). Most of these concerns are reported by studies conducted in developed countries. Perhaps the main barrier to widespread use of mHealth interventions in developing countries may be issues related to cost of implementing the system. Further research is needed to unravel this. A systematic review by Kannisto and others (2014), demonstrated that text message reminders were easy to use, and patients were willing to receive text messages, and satisfied with the text message reminders. This knowledge is essential because patients' views influence the acceptance of the text message intervention and its integration into patients' daily lives (Vervloet et al., 2012). The World Health Organization promotes services similar to those mHealth, since they contribute to a more equitable delivery of care among patients living in low-income countries or in rural areas (Ryu, 2012). In addition, mHealth facilitates more frequent communication with patients and provides the opportunity to deliver health-related messages when they may have the greatest impact (Anglada-Martinez, 2015). At bivariate analysis, the age of the participant was associated with the willingness to use mHealth.. MHealth has been reported to be very feasible and usable among the young people for obvious reasons. For example, in a study on how patients with type 1 diabetes interact with an mHealth tool called "Sweet Talk system" both adolescent patients with diabetes mellitus and their parents perceived that using an mAdherence system increased the adolescent's independence and confidence in disease management (Franklin et al., 2008). In another study, the willingness to accept mHealth in form of text messages was positively associated with being young (Xiao et al., 2014). Among elderly populations, mAdherence was accepted and considered especially useful among older patients living alone and/or with memory issues (Durso et al., 2003). Notably, Burner and others (2013) reported that the use of the mHealth in diabetes self-management was conditioned by gender. Physician providers also favored an mAdherence system that provided patient data and supported clinical decision-making (Worringham et al., 2011). There were county variations in the levels of willingness to use mHealth intervention. TB patients from Siaya County reported significantly higher levels of willingness to use mHealth (57.3%) when compared to those patients from Homa Bay (36.5%). Regional differences in the willingness to use any new intervention are expected due to the varying characteristics of the populations, health facilities and the service provision. In China, living in the middle or north region was a predictor of acceptance of text messages targeted at improving antiretroviral therapy adherence (Xiao et al., 2014).

The proportion of willingness to use mHealth was significantly higher among patients from rural settings (54.0%) than those who reside in urban areas (31.8%). Indeed, research has shown that the ability to improve care and reduce strain on rural healthcare practices will depend on the effective use of technology (Effken & Abbott, 2009). In another study, the willingness to receive short messages for improving antiretroviral therapy adherence in China was positively associated with being a rural resident (Xiao et al., 2014). On the other hand, those who lived within 2 KM had higher levels of willingness to use (40.0%) compared with those who could not estimate the distance (16.7%). This may be linked to the participants' level of interaction with their environment which encompasses social, educational and individual patient characteristics among others. Also, the willingness to use mHealth was significantly higher among respondents who rarely used mobile phone (41.1%) and those who used mobile phone daily (52.7%) compared to those whose mobile phone usage was unknown (10.6%). Similarly, the willingness to use mHealth was significantly higher among respondents who very rarely used text function (44.4%) sometimes used text function (55.3%) and oftenly used text function (48.9%) than those who used the text function always (21.4%). This finding is however contrary to the expectation that those who interact with mobile phones always would have no problem accepting their use for health related purposes. This observation may imply that frequent usage of mobile phones as a tool of communication may not necessarily reflect equal acceptance for health purposes. However this behaviour could be modified gradually through patient education. Further research is needed to fully understand this observation. In addition, the proportion of mHealth acceptance was significantly high among respondents who considered night-time or evening to be the ideal time for mHealth intervention (56.4%) and at any time (61.8%) compared to those who indicated in the morning time (28.9%) respectively. Morning hours are considered "rush" hours when most people are headed for work and might not want to overload the already burdened hours with the tasks of reading text messages or phone call reminders and this may explain the observed phenomenon. On the other hand evening or night-times are considered relaxed and many people may be willing to spare some time for mHealth intervention. Hence the implementation of any mHealth intervention may need to consider the patients' preferred timings in order to increase the effectiveness of the intervention as targeted. Greater willingness to use mHealth was noted among patients who took 21–30 days from the time they first reported

to the public facility till first diagnoses as TB cases. In a similar study, having serious disease condition or disease stage was associated with willingness to accept mHealth (Xiao et al., 2014). Other factors include, taking the medication in the afternoon, pairing medication with substances other than with food or activities not associated with food.

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A Comparative Usability Study of Two Touchscreen Clinical Workstations for Use in Low Resource Settings

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Cost of implementation is one of the biggest barriers to scale up and sustainability of electronic medical record systems in low resource settings. Several approaches can be used to overcome this barrier. In this comparative usability study, we assess whether a lower cost 10-inch touchscreen clinical workstation (TCW) is a suitable alternative to a 14-inch TCW that has been widely deployed in Malawi. A total of 27 participants performed a patient registration task using three different TCWs, a 14-inch device and two 10-inch devices. One of the 10-inch devices used the same size of interface controls as the 14-inch TCW with reduced space between buttons, and the 10-inch device used a modified interface with controls shrunk down to accommodate the smaller screen size. We measured task completion times and error rates as metrics for assessing performance with each workstation. We also captured user perceptions using a usability survey and an exit survey. We compared the mean task completion time, number of errors, and survey scores between the three devices. In addition, a codebook was created to conduct a thematic analysis of the free-text responses to the exit survey. Our results suggest that the 10-inch TCW is a suitable alternative to the 14-inch TCW based on task completion time. Nonetheless, modifications to the user interface are necessary to reduce error rates on the 10-inch TCW before implementation.

1 Introduction

Electronic medical record systems (EMR) have shown potential to improve patient care and outcomes in low-resource settings [1, 2]. However, cost of initial implementation and maintenance remains a significant barrier to the adoption and scaling up of EMRs [3]. Due to the high cost of implementation, the rate of adoption for EMRs has been slow in low-resource settings.

The Center for Health Informatics for the Underserved (CHIU) in the Department of Biomedical Informatics (DBMI) at the University of Pittsburgh and Baobab Health Trust (BHT) have been working towards reducing the cost of health information technology deployments. Since 2001, BHT has deployed low-cost touchscreen workstations in over 100 health facilities in Malawi for various applications including patient registration, managing antiretroviral therapy, and managing chronic non-communicable disease [4, 5]. These implementations have used a 650 USD, 14-inch touchscreen workstation whose cost continues to present a barrier to scaling up into additional health facilities.

One possible approach to reducing this cost is through the use of an alternative hardware platform, such as a Raspberry Pi mini-computer combined with a 10-inch touchscreen display. At a cost of less than 200 USD, this technology solution offers significant cost savings in comparison with the 14-inch TCW currently in use. However, the cost of the workstations is not the only factor that should be considered. Before the existing workstations can be replaced, other factors that affect user satisfaction should also be considered. The most important of these factors is the need for technology to enhance and not hinder the work process. Technology can often be a hinderance if it introduces new errors and is unreliable.

To determine if a Raspberry Pi workstation can replace the 14-inch TCW, we conducted a comparative usability study to assess if users can achieve comparable task performance and efficiency with either workstation. We hypothesized that there will not be a statistically significant difference in task completion

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time or number of errors when using either workstation.

2 Methods

2.1 Setting and Materials

To measure task completion times and errors, we used three TCWs, a 14-inch TCW and two 10-inch Raspberry Pi TCWs. On each workstation, we ran the Baobab Health Trust Patient Registration (BHT-PR) system which is available at no cost as open-source software on GitHub [6]. Two workstations, the 14-inch TCW and one 10-inch Raspberry Pi TCW (10-inch-Normal) used the current user interface configuration for the patient registration task. The size of the buttons and other controls was the same for these two devices but the spacing between them was reduced for the 10-inch workstation due to reduced screen real estate. The third workstation, another 10-inch Raspberry Pi device (10-inch-Resized), used a customized user interface where the button and control sizes were decreased in size to maintain the overall feel and look of the user interface. A screenshot of each of the three workstations is provided in **Supplement 1**. All workstations were set up in an isolated room at DBMI offices for the entire duration of this study.

2.2 Participant Recruitment

A convenience sampling method was used to recruit study participants from DBMI. Participants were required to be adults who had no prior experience using the patient registration application. Familiarity with touchscreen devices was not required for participants to be eligible for the study. Participants in the study were not compensated in any way. The study was approved as non-human subjects research by the Institutional Review Board (IRB) at the University of Pittsburgh.

To determine the number of participants that were required for our study, we performed a power analysis calculation. Due to the limited time we had to perform the study, we opted for a power level of 0.80 and a significance level of 0.10 in our power calculation. We estimated that a 30% increase in task completion time would not significantly increase the total time it takes to register patients over the course of a day. Therefore, we used an effect size of 0.3 in our power calculation, which yielded a required sample size of 30 participants.

2.3 Data Collection

Each participant was required to perform a patient registration task using a standardized task list. The task involved entering demographic information for a simulated patient, including patient name, date of birth, place of origin, and current address. All demographic details for the simulated patient were provided at each workstation. Additional information on the specifics of the task list can be found in **Supplement 2**.

To calculate task completion time for each participant, we logged button presses as the participants performed their task. This was done using an automated process that recorded each button that was pressed and the exact time that it was pressed. In addition to task completion time, we also recorded errors that the participants made while performing the task. This was done through review of screen capture videos that were recorded as participants worked through the patient registration task. In this study, errors are defined as the cases where a user fails to press the right target on the touchscreen. Other literature will refer to this as slips [7]. We did not record cases where the user did not know what action to perform as errors as this was not of interest for our study.

Upon completion of the task on each workstation, the participants completed a 10-question survey that was aimed at gathering user opinions about the workstation they had just finished using (**Supplement 3**). We adapted our survey from the System Usability Scale by modifying it to make sure that the questions were focused on the performance of the touchscreens rather than the system as a whole [8]. Questions were rated using a Likert-scale ranging from 1-5 where 1 was “Strongly Disagree” and 5 was “Strongly Agree”. In addition, participants were given an exit survey after completing the task on all three workstations that asked them to discuss the advantages and disadvantages of the workstations, in addition to general comments about their experience as a whole.

Since study participants performed the task on the three workstations in one sitting, we were concerned about learning effects when using the workstations. To address this concern, we utilized a Latin square design to assign the order in which participants performed tasks on each workstation [9, 10].

2.4 Data Analysis

To test our hypotheses, we first checked whether our data assumed a normal distribution using the Shapiro-Wilk test for normality. If our data was not normally distributed, we performed outlier analysis using a boxplot to identify data points that fell outside the 75th percentile and removed them. If the removal of these outliers resulted in a normal distribution, we ran a repeated measures Analysis of Variance (ANOVA) test to compare the difference among the means of the workstations. Otherwise, we ran the Kruskal-Wallis Ranked Sign test, which is the non-parametric equivalent of the repeated measures ANOVA if the removal of the outliers did not result in a normal distribution.

In addition to these tests, we analyzed our 10-question system usability survey by calculating a Cronbach's alpha for each workstation in order to evaluate their reliability. Our exit surveys were analyzed by generating a codebook from the comments in each section of the survey. The codebook compiled a list of main themes in the participants comments with a description and an example. We then used the codebook to go back and code the comments in the exit survey to identify those that came up most often to get an idea of user perceptions of the workstations.

3 Results

3.1 Participant Recruitment

To ensure the viability of our study protocol, we recruited two trial participants to perform the patient registration task on all three touchscreen workstations. These trial participants identified several flaws with our protocol, which we addressed before beginning our data collection. Following this trial run, we recruited 25 participants from DBMI to perform our patient registration task and collected data for each of them. Due to time constraints, we were unable to recruit 30 participants as determined by our power calculation. This reduced the power of our study from 80% to 74% as calculated in our post-hoc power analysis.

3.2 Analysis of Task Completion Times

Completion times were recorded for all 25 participants as they completed tasks across all three touchscreen devices. Table 1 shows the average times and standard deviations for each device.

Table 1. Summary statistics about task completion time for the patient registration task in seconds.

Metric \ Device	14-inch TCW	10-inch-resized	10-inch-normal
Mean	106.97	110.40	109.24
Std. Deviation	28.61	32.40	27.79

We performed a Shapiro-Wilk test for normality to check if task completion times were normally distributed for each device. Table 2 shows the results of this test.

Table 2. Results of test normality for task completion times with Shapiro-Wilk test.

Metric \ Device	14-inch TCW	10-inch-resized	10-inch-normal
P-value with outliers	0.218	0.008	0.263
P-value without outliers	0.292	0.439	0.409

The P-values for the 14-inch TCW and 10-inch-normal devices showed that their data was normally distributed, but this was not the case for the 10-inch-resized device, which returned a P-value of 0.008. Because the distributions were not normal for all three devices, a boxplot was created to perform outlier analysis.

Using the boxplot, we identified three outliers in task completion time. We reviewed the screen capture videos for the outliers to gain an understanding of why they had extreme task completion times. All three outliers were found to have issues with completing the task related to selecting a date from the calendar. Because the issues with the calendar were unrelated to the touchscreens that were being compared in this study, the three outliers were removed and the distributions were re-tested for normality using the Shapiro Wilk test. The results of this test are shown in Table 2.

This test showed that all three distributions were normally distributed following the removal of outliers, so a one-way repeated measures ANOVA test was run to compare the mean task completion time across the three devices. The ANOVA test returned a p-value of 0.977, indicating that there was no statistically significant difference in mean task completion time among the three devices.

3.3 Analysis of Error Rates

Error rates were recorded for 20 of the 25 participants as they performed the required tasks across all three touchscreen devices. We were not able to use data from five of the participants due to issues with the screen capture software. The mean and standard deviation of number of errors for each device is shown in Table 3.

Table 3. Summary statistics about number of errors made during the patient registration task.

Metric \ Device	14-inch TCW	10-inch-resized	10-inch-normal
Mean	2.84	9.20	7.00
Std. Deviation	3.44	3.71	4.23

Before making a statistical comparison of means, we performed the Shapiro-Wilk test for normality. The results of this test are shown in Table 4.

Table 4. Results of Shapiro-Wilk test for normal distribution for number of errors.

Metric \ Device	14-inch TCW	10-inch-resized	10-inch-normal
P-value with outliers	0.00002	0.338	0.006
P-value without outliers	0.031	0.359	0.118

The results of this testing showed that the data from the 14-inch and the 10-inch-normal TCWs are not normally distributed as noted by their low p-values of 0.00002 and 0.006 respectively. On the other hand, data from the 10-inch-resized TCW was normally distributed. Because the number of errors was not normally distributed for all three devices, a boxplot was used to determine if there were any outliers that were affecting the distribution.

Our analysis of the boxplot revealed two outliers, one for the 14-inch device and one for the 10-inch-normal device. These outliers coincided with those identified in the task completion time analysis and were removed for the same reasons. Following the removal of outliers, the Shapiro-Wilk test was performed again to check if the number of errors was now normally distributed.

Despite the removal of outliers, the p-value of the 14-inch TCW remained below the desired level of 0.1. Therefore, we used the Kruskal-Wallis Rank Sum test to compare the means for the number of errors between devices. This test returned a p-value < 0.001 . This indicates that the means number of errors is statistically significantly different among the three devices we tested.

3.4 Analysis of Usability Surveys

Data was collected from 24 of the 25 participants recruited for the study using a 10-question usability survey. One participant did not complete the survey for all three devices. As a result of this, their survey was not included in the data analysis. We first analyzed our survey data by calculating a Cronbach's alpha value. This calculation yielded a value of 0.452, which is considered to be below the acceptable level.

Following this reliability test, we took the survey responses and calculated a total system usability score from them, using a scale from 0-100. System usability scores above 68 are considered to be "above average" and those below 68 are considered to be "below average". The mean and standard deviations for the system usability score for all three devices are shown in Table 5.

Table 5. Summary statistics about number of errors made during the patient registration task.

Metric \ Device	14-inch TCW	10-inch-resized	10-inch-normal
Mean	69.33	62.67	65.17
Std. Deviation	6.94	7.99	9.45

Using the Shapiro-Wilk test, we found that data from all three of the devices was normally distributed at alpha = 0.1 as can be seen in Table 6.

Table 6. Results of Shapiro-Wilk test for normal distribution of usability scores

Metric \ Device	14-inch TCW	10-inch-resized	10-inch-normal
P-value	0.1899	0.7699	0.2002

Since the data was normally distributed, we proceeded to perform a repeated measures ANOVA to compare the mean score for each of the three devices. This test returned a p-value < 0.0001, which is well below the threshold value of 0.1, leading us to the conclusion that the mean system usability score was statistically significantly different among the three touchscreen devices.

3.5 Evaluation of Exit Surveys

Participant responses in the exit survey were categorized into common themes in order to better examine the user's perceptions of the advantages and disadvantages of each device. The most frequently mentioned advantages of the two 10-inch TCWs over the 14-inch TCW were that they had a better brightness level, were easier to use, and they had faster response times. Regarding disadvantages, participants commented that the 10-inch TCWs had a smaller screen size, a lower resolution, a smaller font size, a more delayed response, and a lower screen brightness in comparison to the 14-inch TCW. In the "Additional Comments" section of the exit survey, almost all of the comments were about potential improvements to the interface of the patient registration software (See Supplement 4 for the codebook with descriptions and examples).

4 Discussion

The purpose of our study was to determine whether the 10-inch device is a viable alternative to the 14-inch TCW. To this end, we hypothesized that there would be no statistically significant difference in mean task completion time and number of errors when using either device.

First, we compared the average task completion time across all three devices to determine if participants took roughly the same amount of time to complete the task on any given device. Our analysis showed that there was no statistically significant difference in mean task completion time among the three devices (P-value = 0.977). This supports our hypothesis that the 14-inch TCW could be replaced by a 10-inch TCW without significantly increasing the amount of time it would take for users to perform tasks on a day to day basis.

Next, we compared the number of errors made by participants across all three devices in order to determine if the change in devices had an effect on the number of errors that participants made when

performing the task. This is particularly important in our case because a change from a larger screen to a smaller screen reduces the amount of real estate available to display information. Since the correlation between button sizes, inter-button spacing and the number of errors is well defined, we had to confirm if our alterations to the user interface and the reduction in screen size led to an increase in errors [11].

Our analysis showed there was a statistically significant difference in the number of errors that participants committed across the three devices (P -value < 0.0001). While this is contrary to our hypothesis, it confirms the understanding that button sizes and inter-button spacing have an effect on the number of errors that users make. Despite this finding, we still believe that a 10-inch TCW is a suitable replacement for the 14-inch TCW because simple modifications to the user interface of the patient registration application could significantly reduce error rates on the devices. For example, a lot of errors that were made on the 10-inch TCW involved participants trying to select one letter on the on-screen keyboard and accidentally hitting a letter next to the desired letter. If the size of the buttons on the keyboard or the spacing between the keys were increased, we believe that the error rates of the 10-inch devices would be more similar to those attained by the 14-inch TCW. While these modifications can lead to more of the screen real estate being used for the onscreen keyboard, this is the preferred scenario as opposed to users making more errors and compromising the integrity of the data that is collected.

Another part of our study focused on user perceptions of the three different workstations. We used a system usability survey to identify which workstation participants preferred. This was done to ensure that the 10-inch TCWs were comparable to the 14-inch TCW in terms of both performance and user satisfaction. Our analysis showed that our attempts to modify the system usability scale survey instrument reduced its reliability to 0.452, which is far below the universally acceptable value. This suggests that participants in our study did not understand the questions in the survey to mean the same thing. While this may be a result of different factors, it indicates that our survey may have been poorly designed.

Our comparison of the mean system usability scores derived from the survey showed that devices were not all favored equally and participants preferred the 14-inch TCW to the 10-inch TCW. While the low reliability of the survey urges caution in the interpretation and importance of this finding, we believe that this will not be a problem when the devices are used in real life as users will not be exposed to both devices as was the case in the study.

One interesting outcome of our study was that the exit survey showed contradictory responses from participants. For example, some participants thought the 10-inch TCW had a brighter screen while others thought that the 14-inch TCW had a brighter screen. This was interesting because the lighting in the room and the brightness of the devices were constant throughout the study. We therefore concluded that this could have been a function of different user preference and perceptions.

One of the main limitations of this study is that it was a task-based study, which potentially introduced confounding factors to the study. Since the tasks that participants were asked to perform had a series of activities that involved thinking and locating specific words on the screen, we were measuring both their ability to learn and their ability to perform the task.

For example, participants were asked to select a series of specific names from a list of locations in Malawi. Participants that were unfamiliar with Malawian names struggled to select these locations from the list. Because this did not occur for every participant, this could have artificially inflated task completion times for reasons unrelated to the performance of the touchscreen. Another example is that many participants struggled with the "Enter Date of Birth - 17" task from the task list. In this case, the participants were presented with a calendar with date options presented as buttons from the 1st to the 31st, as seen in Figure 1.



Figure 1. Calendar control used in the BHT patient registration application

Upon review of screen capture videos, we found that many participants spent a lot of time on this screen choosing “1” and “7” over and over again, not realizing that there was a “17” button below. In some cases, participants spent up to a minute doing this. These were the outliers that were removed in our analysis. This potentially introduced confounding to our measurement of task completion times and error rates. In the future, a study with a participant population that is more familiar with both the context and application could help address these issues.

5 Conclusion

In summary, we can say that the 10-inch TCW is a suitable alternative to the 14-inch TCW; however, the two devices should not use the same user interface. Our error rate findings show that modifications to the button size and spacing are necessary before replacing the 14-inch TCW with a 10-inch TCW.

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