



**Government of Malawi
Ministry of Health**

Digital Health Strategy

2020-2025

MAY 2020



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Dr. Charles Mwansambo
Secretary for Health
March, 2021


Preface

The goal of the health sector in Malawi is to move towards Universal Health Coverage (UHC) by ensuring that everyone – irrespective of their ability-to-pay gets the health services they need in a timely fashion without suffering any undue financial hardship because of receiving the care. Due to its ability to transform the high quality of health services, increase and access to health services, digital health is at the centre of attaining UHC. Consequently, global institutions such as the United Nations and the World Health Organization have moved to influence the delivery of health services using digital health solutions.

To show its commitment to digital health leadership, the Ministry of Health has designated the Directorate of Planning and Policy Development to lead and coordinate the implementation of Digital Health in the health sector. At national level, the Government designated the Ministry of Information with representation at Cabinet level to champion digital governance. Through this commitment the Government has embarked on a drive to create a conducive environment for e-government by improving the digital infrastructure, inclusive digital policies and legislation, tax reduction on digital products and a drive to extend access to digital services to rural communities.

Notwithstanding this commitment from Government, for the health sector to fully utilize digital health there is more to be done; First is harmonization of investments in digital health to increase efficiencies and effectiveness. Harmonization is key to ensure finances, time and efforts are not duplicated through parallel initiatives; Second is to ensure that digital health solutions respond to the needs of service providers through adopting a human centered approach by emphasizing adoption of the principles for digital development in any digital health initiative.

This Strategic Plan highlights the Ministry's approach to attain the UHC by implementing selected activities in the next five years. It is a tool that will help the Ministry provide leadership and coordinate effort towards improving digital health in support of health service delivery. All stakeholders are, therefore, obligated to align their plans and strategies with this national digital health strategy.



Honorable Khumbize Kandodo Chiponda, MP
Minister of Health
March 2021

Key Acronyms

CDC	Disease Control and Prevention
CMED	Central Monitoring and Evaluation Division
CHAM	Christian Health Association of Malawi
CHT	Community Health Team
DHAMIS	Department of HIV and AIDS Management Information System
DHIS2	District Health Information System
DPPD	Department of Planning and Policy Development
EMRSA	Electronic Medical Record Systems Assessment
EMR	Electronic Medical Record
EHR	Electronic Health Record
HIS	Health Information System
HMIS	Health Management Information System
HAS	Health Surveillance Assistant
ICT	Information Communication Technology
IFMIS	Integrated Financial Management Information System
IHRMIS	Integrated Human Resource Management Information System
IOT	Internet of Things
LIMS	Laboratory Information Management System
LMIS	Logistics Management Information System
MDAs	Government Ministries, Departments and Agencies (MDAs)
MDGs	Millennium Development Goals
MFL	Master Facility List
MMR	Malawi's Maternal Mortality Rate
NMR	Neonatal Mortality Rate
PAMIS	Physical Assets Management Information System
PACs	Picture Archiving and Communication System
SDGs	Sustainable Development Goals
SOP	Standard Operating Procedure
TWG	Technical Working Group
UHC	Universal Health Coverage
WHO	World Health Organization

Glossary of Terms

Client	Beneficiary of a health service.
Digital Health	Use of ICT and computer enabled medical devices in health service delivery.
mHealth	Delivery of health services using ICTs available on mobile digital devices.
Big Data	Collection, processing, analysis and use of large data sets in sizes of more than one Terabyte.
Electronic Medical Records	Systems that digitize vertical disease programs.
Electronic Health Records	Systems that digitize all clinical health services and provides a longitudinal and holistic view of the patient health records.
Telehealth	Includes provision of remote clinical services (telemedicine) and other additional non-clinical services such as provider training, administrative meetings, continuing medical education, Surveillance, health promotion, public health functions etc.
Telemedicine	Is a component of telehealth and includes remote delivery of healthcare services, such as health assessments or consultations, over the telecommunications infrastructure. Telemedicine focuses only on clinical health services.
Digitization	The process of transitioning from paper based to electronic systems.
Digitalization	Using ICTs to transform the way health services are delivery by, among other ways, re-engineering health business processes.
User	A person or system that interacts with a digital solution.
Internet of Things (IoT)	A system of interrelated computing devices, mechanical and digital machines, objects, animals or people that are provided with unique identifiers (UIDs) and the ability to transfer data over a network without requiring human-to-human or human-to-computer interaction.
Hybrid Power Systems	Combine two or more modes of electricity generation together, usually using renewable technologies such as solar and wind.
Interoperability	Linking of two or more digital health systems to share data and information.

Executive Summary

Introduction

Digital Health is broadly defined by World Health Organization (WHO) as the application of Information and Communication Technologies in the health sector to improve the flow and use of information in support of the delivery and management of healthcare services. Increasing demands on healthcare systems call for a change in the organization and management of health services, including the integration of digital solutions that support timely and accurate decisions.

Among others, the key benefits for digital health include: Improved visibility into health data and health program performance to inform managerial action; Greater opportunity to improve patient-focused healthcare provision; Increased space to inform resource allocation and prioritization with evidence in the face of increasing pressure and competing needs; Greater opportunity to integrate patient data and allow informed patient health care from any service delivery point; Improved capacity to plan, deliver and manage high-quality healthcare service.

The prioritization of digital health service delivery is not isolated to Malawi. The United National Sustainable Development Goal #9 provides a clear focus on technology to promote good health and well-being. This SDG goal is preceded by a number of World Health Assembly (WHA) resolutions which provided initial encouragement to countries to develop digital health strategies and increased focus on national standards, strategies and Internet for health. These WHA resolutions are an attempt by WHO to encourage member states to integrate innovation in the delivery of health services.

Key global trends and experiences have also influenced the development of this strategy. Advances in information technology and computer sciences have predisposed emerging trends including the principles for digital development in Health; paradigm shift of health services model; population health, big data and artificial Intelligence; telehealth/telemedicine; mobility and Internet of Things (IoT)-based devices; health systems interoperability; renewable and hybrid energy sources; E-Learning; privacy and confidentiality. This strategy has integrated these emerging areas in the action plan.

Current Status of Digital Health in Malawi

The situation analysis has articulated the progress that was made with the 2011 – 2016 E-Health Strategy. In terms of applications, the analysis has noted the successful implementation of DHIS 2 as the national aggregate data warehouse; the successful implementation of drug and essential supply logistics management information systems using the OpenLMIS; the scale up of stock as a last mile drug management tool at the community level. In terms of infrastructure, analysis has noted the progress that government has made both in the health sector and at national level. The Government has extended the fiber backbone network to all districts, has established two fiber links to the sea for Internet access and has gazetted a number of legislations to improve digital governance. ICT penetration continues to rise steadily although the access to Internet and other digital services remains low compared to the rest of SADC countries.

While appreciating the progress that has been made, the situation analysis recognizes the following key challenges:

- i. High dependence on paper based approach to health service delivery
- ii. Lack of Sustainability of digital health Solutions

- iii. Inadequate coverage of digital health solutions e.g., Electronic Medical Records Systems (EMRs)
- iv. Lack of Interoperability between digital systems
- v. Lack of trust in Data Quality and lack of Data Use
- vi. Poor coordination of Digital Health Efforts

Digital Health Overall Agenda

VISION

To attain sustainable and harmonized country led digital health system that covers all areas of service provision and enables efficient delivery of health services to beneficiaries at all levels of the health system.

MISSION

To improve the delivery of health services by providing digital health solutions that are harmonized, sustainable, reliable, interoperable, secure and comply with standards in order to increase efficiency and enable provision of quality services at the point of service.

OBJECTIVES

- i. Establish a reliable ICT infrastructure that enables utilization of digital health systems
- ii. Build the capacity of clients, communities, health care workers, and IT personnel to participate in and benefit from digital health interventions
- iii. Leverage technology to increase access to and quality of service delivery
- iv. Improve security of information and ICT Systems
- v. Promote interoperability of digital health solutions to enable information sharing for continuity of care.
- vi. Strengthen the sharing and accessibility of data across systems to enable use.

Within these objectives the MoH has prioritized the provision of adequate ICT gadgets and infrastructure such as computers, tablets etc to all health facilities; the deployment of connectivity infrastructure to all health facilities to enable access to key resources; the implementation of a hospital wide EHR to allow digitalization of all clinical services; the delivery of telehealth services to address the challenge of shortages in specialized health personnel; the delivery of continuous professional development (CPD) through e-learning and improvement in the digital health human resources availability.

Digital Health Financing

The total resource envelop required for digital health implementation in the next five years is MK40,468,279,697 (US\$55,436,000). Key cost drivers include the hospital wide EHR and the shared health record, Connectivity, drug and essential supply dispensation system, laboratory information management system, unique identification and scale up of existing EMR solutions.

CHAPTER 1

Background / Introduction

CHAPTER 1

Background /Introduction

A. Social, economic, and health situation

Malawi has an actual enumerated population of 17.6 million people (Malawi Census report (2018)), reflecting an average annual growth rate of 2.9% from previous census. Given that preliminary Malawi Census report (2018) has not provided projected population figures beyond 2018, the current average growth rate of 2.9% per annum implies that Malawi population is likely to grow to 20.3 million people by the year 2023. With a predominantly youthful population, it is anticipated that the current population distribution pattern will continue to reflect on the previous distribution patterns: 64% under the age of 15, 18% under the age of 5 and only 3% above 65 years. In addition, it is estimated that majority of the population will continue to live in rural areas, despite current urbanization.

Malawi has made strides to address gender gaps in key social areas including education and health with literacy in men at 83% and women at 72%. Additionally, estimated percentage of women involved in decisions about their health care increased from 55% in 2010 to 68% in 2015-16 and women's involvement in decisions about major household purchases increased from 30% to 55% over the same period.

At a Gross Domestic Product (GDP) per capita of USD327 in 2017 the economy is predominantly agricultural-based with agriculture, forestry and fishing contributing to 28% of GDP. Development aid plays a key role in the economy and in the health sector it accounts for on average 62% of total funding.

Life expectancy at birth is estimated at 63.9 for both sexes in 2017. Malawi's maternal mortality rate (MMR) and neonatal mortality rate (NMR) are among the highest in Sub-Saharan Africa despite a decline in MMR which was estimated at 439/100,000 live births in 2016, down from 675/100,000 in 2010. Acute respiratory Infections (ARIs) are still significant causes of morbidity and mortality especially among children under five years. Despite progress over the period of the last HSSP, Malawi continues to hold a high burden of disease with HIV and AIDS, respiratory infections, malaria, diarrheal diseases, and perinatal conditions as the leading causes of death.

Health services in Malawi are provided by the private not-for-profit Christian Health Association of Malawi (CHAM) and the rest by individual private-for-profit health practitioners. The public sector includes all health facilities under the Ministry of Health and Population (MoH), district, town and city councils, Ministry of Defense, Ministry of Homeland Security (Police and Prisons) and the Ministry of Forestry and Natural Resources. Health services in the public sector are free-of-charge at the point of use. The PFP sector consists of private hospitals, clinics, laboratories, and pharmacies. Traditional healers are also prominent and would be classified as PFP. The PNFP sector comprises of religious institutions, non-governmental organisations (NGOs), statutory corporations and companies. The major religious provider is the Christian Health Association of Malawi (CHAM) which provides approximately 29% of all health services in Malawi. Most private and private-not-for-profit providers charge user fees for their services.

Malawi's health system is organized at four levels namely: community, primary, secondary, and tertiary. These different levels are linked to each other through an established referral system. Community, Primary and Secondary level care falls under district councils. The District Health Officer (DHO) is the head of the district health care system and reports to the District Commissioner (DC) who is the Controlling Officer of public institutions at district level. At community level, health services are provided by health surveillance assistants (HSAs), health posts, dispensaries, village clinics, and maternity clinics. At primary level, health services are provided by health centres and community hospitals. Health centres offer outpatient and maternity services and are meant to serve a population

of 10,000. The secondary level of care consists of district hospitals and CHAM hospitals of equivalent capacity. Secondary level health care facilities account for 9.5% of all health care facilities. They provide referral services to health centres and community hospitals and also provide their surrounding populations with both outpatient and inpatient services. The tertiary level consists of central hospitals. They ideally provide specialist health services at regional level and also provide referral services to district hospitals within their region.

B. Definition for digital health

The term 'digital health' is broadly defined by World Health Organization (WHO) as the application of Information and Communication Technologies in the health sector to improve the flow and use of information in support of the delivery and management of healthcare services. The European Society of Cardiology (ESC) defines digital health as “the use of information and communication technologies (ICT) to treat patients, conduct research, educate healthcare professionals, track diseases and monitor public health”.

C. Rationale for digital health

Increasing demands on healthcare systems call for a change in the organization and management of health services, including the information systems that support timely and accurate decisions.

Adopting digital health in Malawi promises a number of dividends for the health sector:

- Improved visibility into health data and health program performance to inform managerial action;
- Greater opportunity to improve patient-focused healthcare provision;
- Increased space to inform resource allocation and prioritization with evidence in the face of increasing pressure and competing needs;
- Greater opportunity to integrate patient data and allow informed patient health care from any service delivery point;
- Improved capacity to plan, deliver and manage high-quality healthcare service.

D. Alignment with Global and National Goals and Priorities

While the UN has included Sustainable Development Goal Number 3 to ensure health life and to promote well-being of all at all ages, it has also included Goal Number 9 which focuses on building resilient infrastructure, promoting inclusive and sustainable industrialization and fostering innovation. Goal 9 provides a clear focus on technology to promote good health and well-being.

The SDG Goals are preceded by a number of World Health Assembly (WHA) resolutions as follows: Resolution WHA58.28 (2005) set the direction and encouraged countries to have digital health strategies; Resolution WHA66.26 (2013) focused on national standards, strategies and Internet for health; and World Telecommunications Development Conference Resolution WTDC-65 (2010) calls for development of national digital health strategies. Since 2016 the World Health Assembly Executive Board has focused discussions on mHealth as an appropriate digital technology for public health. Highlighting a fundamental shift from digital health to digital health WHA 71.7 has recalled both WHA58.28 (2005) on digital health and WHA66.24 (2013) on digital health standardization and interoperability. These WHA resolutions are an attempt by WHO to encourage member states to integrate innovation in the delivery of health services.

Similarly, to assure success of digital programs, global partners have developed and endorsed the Principles for Digital Development which are nine living guidelines that are designed to help integrate best practices into technology-enabled programs⁶ Building on the Principles for Digital Development in place, development partners further collaborated to develop the Principles for Donor Alignment for Digital Health. These are to enable countries to pursue an integrated approach to strengthening health systems by aligning donor investments to country digital health strategies that are in support of national health strategies. Additionally, the roadmap for Health Measurement and Accountability for

Health Results and a 5-Point Call to Action outlines a shared strategic approach and priority actions and targets that countries and development partners can use to put effective health monitoring plans in place to strengthen health information systems. At the centre of the 5-Point Call to Action is the need for development partners to harmonize efforts by investing in country-led platform for information and accountability.

At the national level, the Ministry of Health launched the Health Sector Strategic Plan II in 2017. The HSSP II, as the national health sector medium term strategy, contributes to the national development strategy under the Malawi Growth and Development Strategy (MGDS III) which is the final medium-term strategy under the Vision 2020. The implementation of HSSP II is supported by policies and governance tools. The HSSP II is complemented by the national Community Health Strategy which has full focus on improving service delivery at the community level. Through the Ministry of Information, the government has a comprehensive national ICT Policy (2013), the Access to Information Act (2015), the e-Transactions and Cyber Security Act (2016) and various standards and guidelines. In addition, the Ministry of Information is implementing a flagship ICT Infrastructure improvement Project under the name Digital Malawi. At Ministerial level, the MoH has the National Health Information Systems Policy (2015) and the Monitoring, Evaluation and Health Information Systems Strategy (2017).

E. 2011 – 2015 digital health Strategy Implementation Review

The 2011 – 2015 Digital Health Strategy key achievement is the establishment of a foundation for digital health in Malawi. The Strategy acted as a tool to promote ICT use in the health sector. It increased attention and rallied support to the role of digital systems among stakeholders in health service delivery. As a result, the level of investment and commitment of resources towards digital health has generally increased between 2012 - 2018 (Table 1, MoH 2018). Notably, there has been increased investment in computing infrastructure at national, district and facility levels. More healthcare workers continue to get access to end user computing devices, connectivity, training, and digital systems to support health service delivery. The table below summarizes the progress in the implementation of the 2011 – 2016 Digital Health Strategy:

Table 1: 2011-2015 digital health strategy implementation review

Key Achievements	Key Outstanding Issues
<ol style="list-style-type: none"> 1. Review of national minimum (core) health data set for different health programs through the national health indicators 2. Update standards of clinical coding of disease conditions – conditions in the OPD register revised 3. Develop and implement national health data collection and storage standards (standardize data collection and storage infrastructure for each levels of health care facilities/providers) – HIS Policy approved 4. Update and publish national unique identification codes for all levels of health service providers – On line web service for Master Health Facility Registry in place 5. Update and publish the GIS coordinates for all levels of health care providers. List updated and published 	<ol style="list-style-type: none"> 1. Develop, review and implement national health data dictionary/Terminology Registry 2. Design national digital health connectivity architecture for all levels of health service providers; Harmonize connectivity plans among stakeholders implementing digital health solutions in health facilities 3. Incorporate the national ID from the National Registration Bureau into the national health identification system 4. Extend the existing EMR solutions to increase coverage within and across health facilities 5. Identify/develop a facility wide low-cost patient management health information system 6. Implement a functional electronic health record 7. Enable Interoperability and data exchange

Key Achievements	Key Outstanding Issues
<ol style="list-style-type: none"> 6. Support the development of the health sector data policy – HIS Policy approved 7. Input into the Access to Information Bill and Malawi National Health Bill to ensure that issues of health data protection are included 8. Improve patient management at the OPD and Wards by ensuring that the Clinician, Physician, Order Entry (CPOE) for the OPD; and Admission, Discharge and Transfer (ADT) for the Ward are computerized for all high burden health facilities – OPD EMR extended to more than 70 health facilities within the period 9. Review, design and implement electronic maternal, neonatal, child health health information system – Maternity and ANC EMR modules developed within this period 10. Strengthen the drug Logistics Management Information System (LMIS) through design and implementation of an electronic system – OpenLMIS in place 11. Other patient management systems developed and implemented in selected facilities within this period include NCDs, LIMS, Pilots for Village Clinic; cStock piloted and scaled up; 	<ol style="list-style-type: none"> between patient level and aggregate health information systems 8. Implement digital health care solution where technology such as email, telephone, telemetry, video conferencing, digital imaging, web and digital television are used to support clinical consultations between professional to professional, clinicians and patients, or between groups of clinicians. 9. Identify and prioritize professional development areas to be supported through e-learning

f. Strategy development process

The development of this Digital Health Strategy followed a consultative process throughout. First, the Ministry appointed a taskforce with high representation from both Government and implementing partners. Government representation included various departments within the Ministry of Health and from the Ministry of Information through the department of E-Government. The Taskforce was the major coordinating mechanism driving the different steps for developing the strategy with the Directorate of Quality Management and Digital Health as the Secretariat continuing from the effort that started with the Directorate of Planning and Policy Development.

The strategy development started with a comprehensive situation analysis, then development of the draft vision, mission, goals and the digital health strategies. This was followed by development of the M&E framework and costing for the full strategy. At each of these stages which involved an iterative process, digital health stakeholders were engaged in consultation meetings. The first digital health stakeholder meeting was to review the draft situation analysis. There were two meetings to review the vision, mission, objectives and strategies. A Taskforce workshop was organized, which also included participation outside the regular taskforce members, to draft the M&E framework and to cost the strategy. Finally, a Digital Health Steering Committee was convened to provide input into and approve the strategy for further submission to Senior Management.

Three key assessments and consultations provided input into the strategy development process. First was the Electronic Medical Record Systems Assessment which was independently conducted by the

VitalWave with leadership from the Ministry. The sole purpose of this assessment, which was funded by the Bill and Melinda Gates Foundation, was to inform the development of the Digital Health Strategy. Additionally, with support from UNICEF, the Ministry organized a digital health end user workshop where participants were drawn from the districts and health facilities. The aim of this workshop was to gain perspectives of the key challenges and demand for digital health at the implementation level of the health system. The third input came from the assessment conducted by the WHO mission to scope the digital health landscape in Malawi and identify key areas of focus to improvement to integrate digital health in the delivery of health services. The report from the scoping mission provided a number of recommendations to the Ministry. These assessments have been integrated and have been vital to strengthen the final digital health strategy.

b. Conclusion

In conclusion, the ever-growing pressure to provide high quality healthcare services in a fast-growing population, increasing demand for visibility into program performance, shifts in global trends toward patient-driven healthcare and the need for integrated healthcare systems (among other factors) have increased the need for Malawi health sector to increase its investments in digital health. The context provided in this Chapter has described an ecosystem in which government is working to provide an enabling environment for the implementation of digital health in Malawi. However, the World Economic Forum Information Technology Readiness Index puts Malawi on position 132 out of 139 developed and developing countries.

Malawi as a developing country need to adopt ICT's and associated business processes and management skills in order to remain competitive in the constantly changing and increasingly global economies.

The positive effect of ICT in a developing country depends on a national enabling ICT environment that relies on multiple factors such as accessibility, infrastructure, governance issues and human capacity. Malawi needs the accessibility of the ICT to all levels of the society in order to get the maximum benefit of it.

CHAPTER 2

Situation Analysis

CHAPTER 2

Situation Analysis

1. Global Trends and Experience

Amid the digital era evolving from previous digital health arena, the global society recognizes the potential of digital technologies to advance the Sustainable Development Goals, and in particular to support health systems in all countries. While Malawi has its own key areas to focus in strengthening digital health developments, there is need to ensure the process takes into account global trends. This section summarizes the key trends and experiences in digital health to inform and support present and future development strategies. These trends provide a high-level view of the current global state to guide Malawi's digital health strategy.

i. Principles and Guidance for Digital Development in Health

In order to develop suitable digital health solutions, while considering the sustainability of innovations, and their feasibility, scale-up and inclusivity; principles for development partners and donors were established in the past decade.

There are two major guidance adopted by global community: Digital Investment Principles and Principles for Digital Development. According to the Digital Investment Principles, it is essential and urgent for donors to align their investments to country digital health strategies. Both principles highlight the importance of being collaborative to attain the common goals.

Amongst important items in the Principles for Digital Development is "Design With the User". The user-centered design approach can foster successful digital initiatives which are rooted in an understanding of user characteristics, needs and challenges. Thereafter, WHO developed the Digital Health Interventions Classification to address needs from different categories of users in supporting health system needs and guiding relevant digital solution developments.

ii. Paradigm shift of health services model

Addressing the goal of Universal Health Coverage underpinned in SDG3, WHO urged member states to reform its health care services toward integrated, people-centred health services. The adopted Framework on Integrated, People-centred Health Service includes strategic approach on innovating and incorporating new technologies. Since new information and communication technologies allow new types of information integration, they can assure continuity of information, track quality, facilitate patients' empowerment and reach geographically isolated communities. The framework also includes approach in strengthening information systems and knowledge management. Practical activities on development of information systems and an organizational culture that supports monitoring and evaluation, knowledge sharing and using data in decision-making is also a prerequisite for transformational change.

iii. Transitioning from EMR to shared EHR

Within the Health Information Systems domain distinction has emerged between Electronic Health Record Systems (EHRs) and Electronic Medical Records Systems (EMRs). An EMR is a narrower view of a patient's medical history, while an EHR is a more comprehensive report of the patient's overall health. EMRs are limited in that they often computerize isolated disease areas and patient visits are not consolidated into a single longitudinal file. On the other hand, Electronic health record systems (EHRs) offer a more comprehensive view of a patient's medical history versus EMRs and real-time data that enables more precise and informed patient care.

As digital health matures, one of the major value propositions of electronic patient management is the ability to offer healthcare providers a complete view of a single patient's medical history. However,

patients often move between several providers and service points (e.g., pharmacies) within a health system. Having a complete, shared view of a patient's medical history help coordinate and facilitate the exchange of clinical information among health providers. This has resulted in a shift from EMRs to EHRs. This shift requires multiple systems to efficiently exchange patient data in a secure and timely manner with the appropriate governance and management standards. In countries with large private sector healthcare markets, the move to EHRs has been slow due to lack of interoperability, regulations, and data/technology standards. In healthcare markets supported by more public-sector funding such as Malawi, there has been a more gradual transition to EHRs, but gaps still persist.

iv. Population health, big data and Artificial Intelligence

'Big data' is massive amounts of information that can work wonders. It has become a topic of special interest for the past two decades because of a great potential that is hidden in it. Various public and private sector industries generate, store, and analyze big data with an aim to improve the services they provide. In the healthcare industry, various sources for big data include hospital records, medical records of patients, results of medical examinations, and devices that are a part of internet of things.

There is a push moving patient health records from a paper-based system to an electronic, the opportunities to aggregate, analyze, and pull insights from large pools of clinical data expand. Real-world data (RWD) are data that come from sources other than traditional clinical trials and are becoming increasingly important to today's healthcare decisions. The ability to pool clinical data within and across individual points of care has also enabled individual healthcare providers to understand and manage their population health with tools that allow them to identify and stratify their patient populations based on risk factors, costs, outcomes, etc. Management of data at the population level means the ability to take information and decision-making to a new level. Population health approaches now support the transition from fee-for-service delivery models to more value-based-care delivery models, which incentivize quality of care over quantity of services. Applying analytical tools such as predictive analytics or artificial intelligence allow individual healthcare providers to obtain more meaningful insights into how to treat or prevent diseases while minimizing cost and maximizing outcomes for the health system.

v. Telehealth/Telemedicine

Telehealth/Telemedicine is another potential tool to advance universal healthcare in emerging economies. With inadequate trained health personnel, most rural health facilities lack the personnel and equipment to provide necessary level of consultation and treatment to patients. With the aging of the global population, more patients are increasingly immobile and do not have access to appropriate care. Digital health has expanded to understanding how to increase coverage of essential health services while taking advantage of lower-cost information and communication technologies. The ability to remotely share information, employ video-conferencing or other tools to indirectly interact with patients in remote locations is viewed as a big opportunity for health systems with limited reach but geographically dispersed patient population pools. Through network medicine and population screening programs, e-health tools could provide the means to centralize clinical decision making and leverage the most experienced health professionals across the system in a cost-effective manner.

vi. Mobility and Internet of Things (IoT)-based devices

The mobile-enabled technology has been applied to and transformed industries from banking to transportation. Mobile-based services disrupted many industries, and they are expected to transform healthcare delivery models in the future. Mobile devices and internet-of-things (wirelessly connected, personal devices) are expected to contribute to and shape how healthcare is delivered in the future. The need for real-time data and continuous patient engagement could be extended beyond traditional points of care in the healthcare systems with insights vast amounts of data collected outside of the traditional healthcare settings. For example, personal health trackers could enable providers to remotely monitor patient outcomes, treatment adherence, and adverse effects. This presents a real

opportunity to augment current care delivery models, enrich data around continuous care management, and serve as a means to collect more reliable data to inform patient care and care delivery.

vii. Health Systems Interoperability

As coverage of electronic Health systems has increased, and most countries have shifted the focus from deployment of the digital health systems to the use of data which is facilitated by the ease of sharing of data among these systems. Interoperability has, therefore, become a key issue in most countries. The role of interoperability is to facilitate Health Information Exchange (HIE) between systems. To achieve this, the global community has supported the process through development of standards around interoperability culminating into the Open Health Information Exchange (OpenHIE) framework.

viii. Renewable and hybrid energy sources

Due to rising costs, inadequacy and the environmental impact of existing power systems there is a global shift to harness the power of renewable energy sources. These include energy sources such as the sun, wind, geothermal, ocean and biomass as sustainable, cost-effective and environment friendly alternatives for conventional energy sources. However, the lack of reliable year-round availability of these renewable energy resources has led to research in the area of hybrid renewable energy systems. Hybrid power systems combine two or more energy conversion devices, or two or more fuels for the same device that when integrated, overcome limitations inherent in either. Renewable and hybrid energy sources are particularly attractive to promote in Malawi due to the unreliability of main grid power in the last 15 years

ix. E-Learning

Traditional healthcare training comes with a number of challenges. Healthcare professionals are overwhelmed by work, making it difficult for them to find time to attend to training sessions. The challenge is even bigger with health systems worldwide facing shortages in health professional workforce. Additionally, attending these courses is also expensive for healthcare employers because it often involves travel and takes valuable employees away from their jobs. To address this shortage, e-Learning is increasingly being adopted in health professionals' education.

x. Privacy and confidentiality

The integrity of the health system relies on the protection of privacy and confidentiality. Health professional must 'maintain the confidentiality of the patient's personal information including their medical records, disclosing their information to others only with the patient's express up-to-date consent or as required or authorized by law. Health privacy has become increasingly important due to the rapid rate of technology integration in healthcare. New technologies (e.g., mobile apps and devices) can track substantially larger amounts of information about a patient than ever before and put it in an easy to access place such as a cloud-based service.

The misuse of these insights can implicate the core values and principles which privacy protection seeks to promote, such as individual autonomy, equality and free speech, and this may have a broader impact on society.

2. The Status of digital health in Malawi

i. Leadership and Governance

e-government, the Malawi government began implementing the initiative in order to enhance service delivery to the citizens, the private sector and improve general information sharing among government departments. The Ministry of Information has a decentralized structure for the management of ICT with its staff seconded to each Ministry and Government Departments. At the Ministry of Health, the structure is represented by an ICT Section headed by a Deputy Director and has staff to support the infrastructure, services, and applications. At the district level, there is at least one Systems Analyst and Programmer at central hospitals and a Programmer stationed at each District Health Office. With decentralization and the upcoming functional review of the Ministry of Information, the governance structure and scope are likely to change. Figure 1. Shows the human resources structure for digital health in the MoH.

In a greater awakening and consciousness, the Ministry of Health has strategically repositioned the governance of digital health to harmonize implementation of initiatives and strengthen coordination among related Departments and Sections. The Ministry has, therefore, extended the roles of the Department of Planning and Policy Development to also include Digital Health. In this respect DPPD is working closely with the following

- (1) MoH's ICT Section which is responsible for managing the technology.
- (2) The Central Monitoring and Evaluation Division (CMED), which is responsible for data governance and the Health Management Information System (HMIS).
- (3) The Department of e-Government which works closely with the MoH's ICT section as its mother body in providing ICT support in various MDAs.

The department provides policies, strategies, acts and standards on ICT for the government. Additionally, MoH Departments and Programs have been particularly useful in implementation of digital health solutions by providing programmatic and subject matter leadership to the design and deployment of solutions. MoH has also used Government/Partner consultative forums such as the mHealth Sub TWG & National Health Data Standards Sub TWG, which are also part of the governance structure in implementation of digital health solutions.

While Government procures and supports some of the ICT technologies, most of the digital health solutions are financed by donors and partners. Although Government contribute officers to support deployment of the digital systems, most projects have time frame of basically five years demonstrating a strong link with donor project funding cycles. Consequently, the government fails to sustain such projects due to financial challenges and poor incorporation of sustaining strategies in projects.

MoH ICT Section Organogram

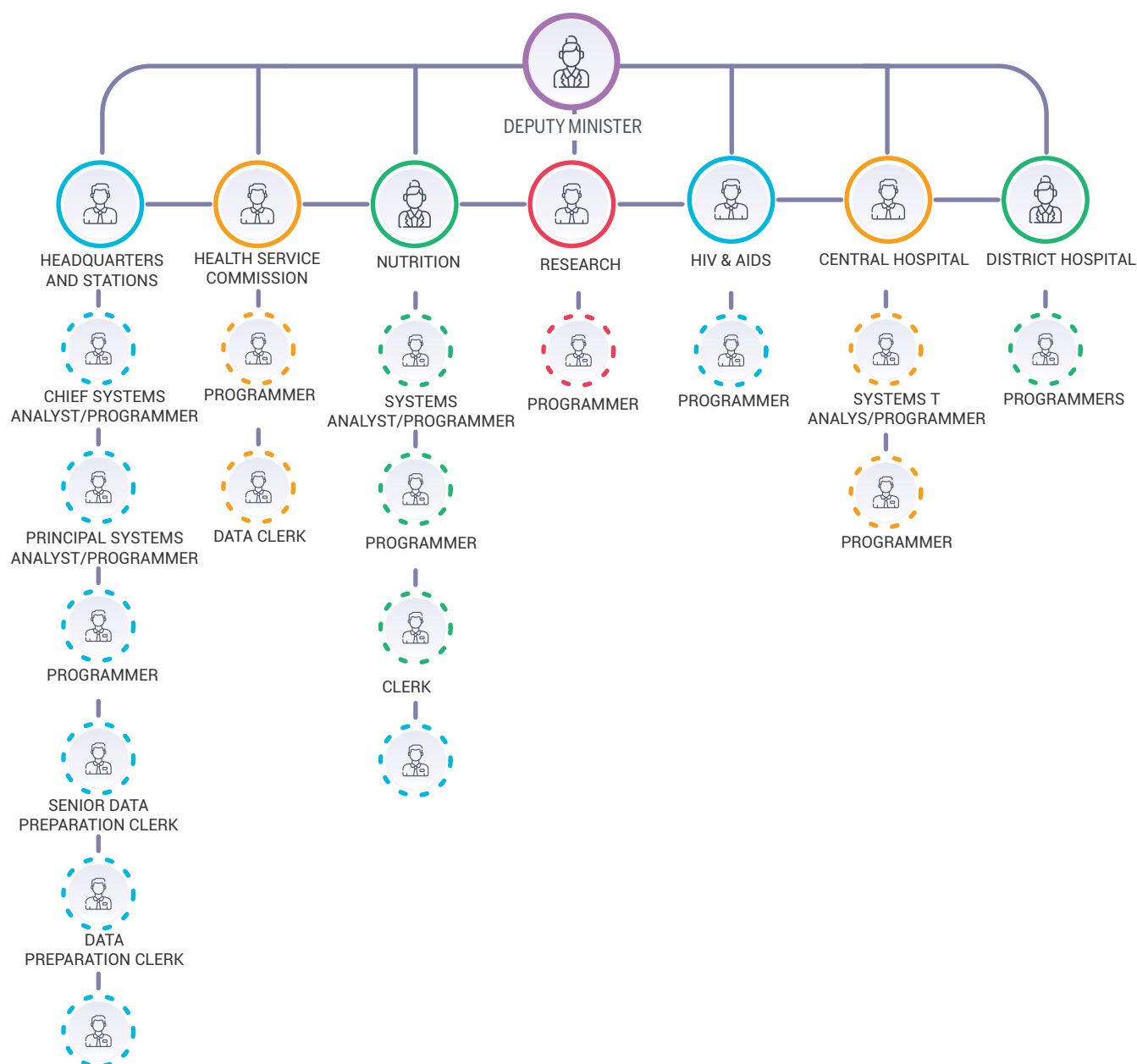


Figure 1: MoH ICT Section Organogram

ii. Legislation, Policy and Compliance

- At national level, the Government through the Ministry of Information and the Ministry of Health has put in place various regulations, laws, policies and standards to guide the implementation of the digital systems. The following documents provide a framework and vision for ICT in the country:
 - The e-Transactions and Cyber Security Act (2016), which aims to provide a framework for digital transactions and to protect individuals from digital fraud
 - The Access to Information Act (2017) which provides guidelines for access to public data
 - The National ICT Policy (2013). The aim of the policy is to support the national goal of wealth creation and reduction of poverty through sustainable economic growth and infrastructure development
 - The National ICT Master Plan and the ICT Standards & Guidelines.

- The Health Information Systems Policy (2015) is available.
- The Malawi National Registration Act (2009). Records births, deaths, and marriages at the village, traditional authority, district, and national levels. Also establishes a registry of everyone in Malawi who is 16 years or older and is a Malawian citizen or has a permanent residence permit, a temporary employment permit, or a business residence permit
- The Malawi Health Sector Monitoring, Evaluation and Health Information Systems Strategy (2017)
- Monitoring and Evaluation Health Information System 2018 (MEHIS)

Additionally, the Government also mandated the Malawi Communications Regulatory Authority (MACRA) to provide regulatory oversight to all developments in the communications sector.

iii. Human Resources for digital health

In supporting the delivery of health services, digital health solutions intersect with an array of stakeholders depending of context. Such stakeholders can be health care workers, patients or clients or they can be technical staff to design and support the digital solutions. All these sets of stakeholders may interface with the digital health solutions. Consequently, the implementation and use of digital health solutions requires availability of skilled personnel to design and manage the technology, to provide leadership and coordination and promote usage of the deployed technologies. Additionally, healthcare workers need skills and knowledge to apply the solutions in the provision of health service delivery. Patients and clients need the ability to access and use the digital solutions as part of receiving care.

For the digital health professionals, the education sector has moved to provide academic training in medical engineering, computer sciences, information technology, and health informatics. While this pool of trained personnel is available, the Ministry of Health continues to struggle in hiring and retaining adequate numbers of staff to strengthen the delivery of its services. At national level, the ICT Section continues to have high vacancy rates as struggles to fill positions due to the freeze on hiring of new staff by the government. Although e-Government took steps to address human capacity challenges at sub national levels by seconding Programmers to Central Hospitals and District Health Offices, most of the seconded staff have either been moved to other Ministries without replacement or have resigned and moved on to other jobs. This has created a significant gap in staffing levels.

In addition to the capacity gaps for the ICT personnel, there are still gaps in the skills of end users to enable utilization of existing digital health solutions. In light of this, introduction of new technologies requires an upgrading of skills for end users who are consumers of the technologies. Such end users include health workers and patients or clients. The e-Government has proposed for a structure review on ICT common service to increase the number of IT staff in MDAs.

iv. Services and Applications

Services and applications are the means to address the needs of individuals, health-care providers, managers and administrators in the health system. These components enable stakeholders to access, use and share health information, and deliver health services in new ways. Table 2 below provides common services and applications in the health sector.

Table 2: Digital Health Services and Applications

Component	Description	Examples
Individual electronic health information	Services that support the collection and storage of health information for an individual.	<ul style="list-style-type: none"> • Electronic health records (EHR) • Electronic medical records (EMR) • Personal health records (PHR)
Health care communications and collaboration	Services that enable health care providers electronically to communicate and share information with other such providers as part of providing care to an individual.	<ul style="list-style-type: none"> • Electronic referrals and specialist letters • Electronic health event summaries, prescribing and test • ordering • Access to an individual's EHR and test results • Health-care provider and service directories • Care plan management • Appointment booking and management
Health care service delivery tools	Services that support health care providers in making diagnosis and treatment decisions, and in managing the delivery of care to an individual, whether electronically or in person.	<ul style="list-style-type: none"> • Medications management • Prescription and test ordering decision support • Clinical decision support • Alerts monitoring and management • Chronic disease management • Real-time clinical data access and analysis • Telemedicine (tel digital health) and mobile health (mHealth)
Health Information and Knowledge	Services that enable individuals and health-care providers to access trusted and verified health information and knowledge.	<ul style="list-style-type: none"> • Consumer health knowledge sources • Health-care provider knowledge sources • Distance learning and electronic resources
Healthcare Management and Administration	Services that enable health-care managers and administrators to manage effectively the delivery of care to individuals and monitor the health of the broader population.	<ul style="list-style-type: none"> • Adverse event monitoring • Risk analysis • Compliance monitoring • Surveillance and At-Risk Identification • Health-care operations management • Clinical practice improvement • Health programme design and optimization • Health policy development • Health care and clinical research

The Ministry has made progress in the implementation of services and applications in the sector. Telemedicine was successfully piloted at Kamuzu Central Hospital with complementary efforts from other partners such as the DREAM Project which is using telemedicine services in its health facilities. Other services such as the Chipatala Cha Pa Foni are actively improving health information and knowledge through sharing of trusted and verified health messages. To digitize and harmonize the implementation of the Health Management Information System, especially aggregate data reporting, the Ministry has implemented the DHIS 2 as a single source for accessing aggregate health information. Although anecdotal evidence suggests that more than 90% of service delivery and data management is paper based, the Ministry has made progress in computerizing key HMIS sub systems at aggregate data management level. The key subsystems under HMIS include integrated Human Resource Management Information System (iHRIS), Logistics Management Information System (LMIS), Laboratory Information Management System (LIMS), Physical Assets Management Information Systems (PAMIS), Integrated Financial Management Information System (IFMIS) and the various patient level systems implemented at facility and community levels (Chaulagai et al., 2005). Each of these sub systems is represented by electronic systems that are used to support service

delivery. As noted in Table 3 below, these systems are not interoperable with each other. Additionally, these sub systems are all part of the one system, the national health management information system (HMIS) as such they are incomplete when considered individually as they need to input into each other.

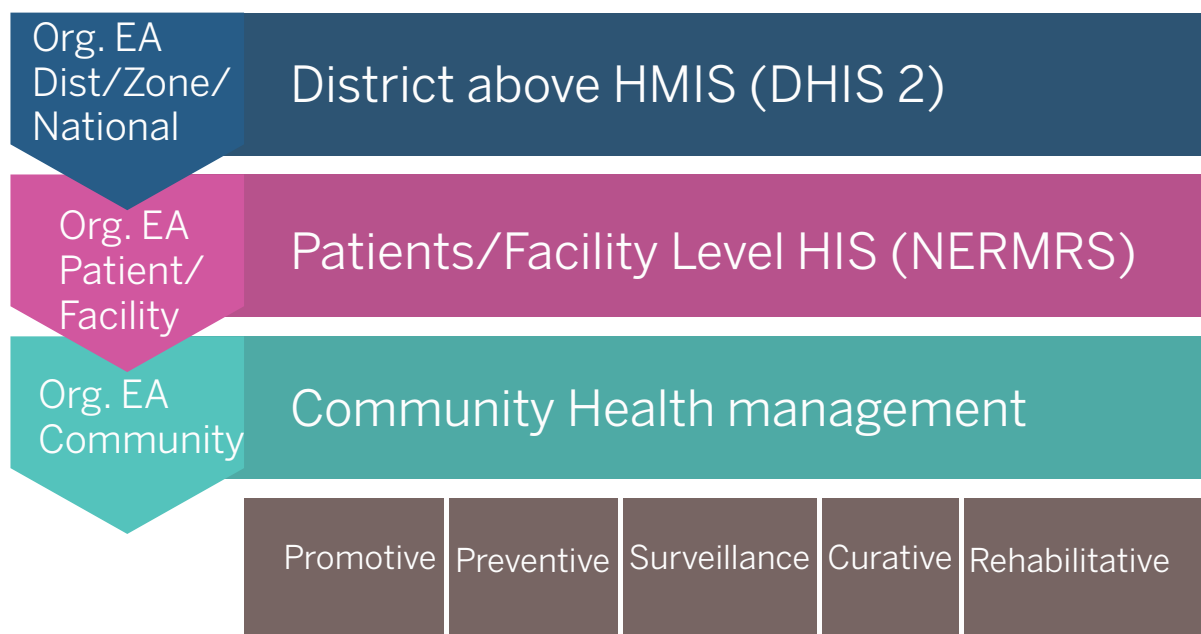
Table 3: Health Information System Subsystems.

Data Sources	Scopes
HMIS	Complete information on preventive, promotive, curative, and rehabilitative health services.
LIMS	Complete information on medical laboratory and diagnostic services.
LMIS	Complete information on medicine and medical supplies.
IHRMIS	Complete information on human resource planning, production, recruitment, and administration.
IFMIS	Complete information on budget, expenditure, revenue by major program component and cost centers.
PAMIS	Complete information on building, medical equipment, vehicles and all other durable supplies and their management.
Rapid Assessments	Information on providers and consumers satisfaction. Data quality assessment and adjustment.
Annual Health Facility Census	All detailed data that are not captured by any of the routine data systems shall be captured in the annual health facility census. Age and gender disaggregated data shall also be captured in the census.
Surveys	Surveys (such as MDHS MICS, SPA) shall cover information on all impact indicators
Vital Registration	Complete information on births and deaths.
Census	Complete population data with a breakdown of target group for various health programs.

Source: Malawi National Health Information System Policy.

Services and applications follow a cascade of solutions provided at various levels of health service delivery including community, facility and national level. This cascade is represented in the architecture shown in Figure 2 below.

Figure 2: Malawi National HIS and CHIS Architecture



Note: mHealth artifact building blocks are categorized according to HSSP2, National Community health Strategy and CHWs Tasks List

v. Standards and Interoperability

A standard is an agreed specification, format or definition on how something can be implemented. Standards are defined for both hardware devices and software systems. Hardware standards usually relate to interfaces, electrical design, ergonomics, input methods, display standards etc. A common classification of hardware is whether it is digital or analogue. Digital hardware or appliances provide more flexibility in improving health service delivery. Hardware standards are necessary to ensure compatibility and interchangeability of hardware devices and components. On the other hand, software standards relate to messaging formats, data formatting and protocols. Examples of software standards include HTML, TCP/IP, SMTP, POP and FTP, SOAP, FHIR etc. Software standards are useful to enable exchange of data between systems.

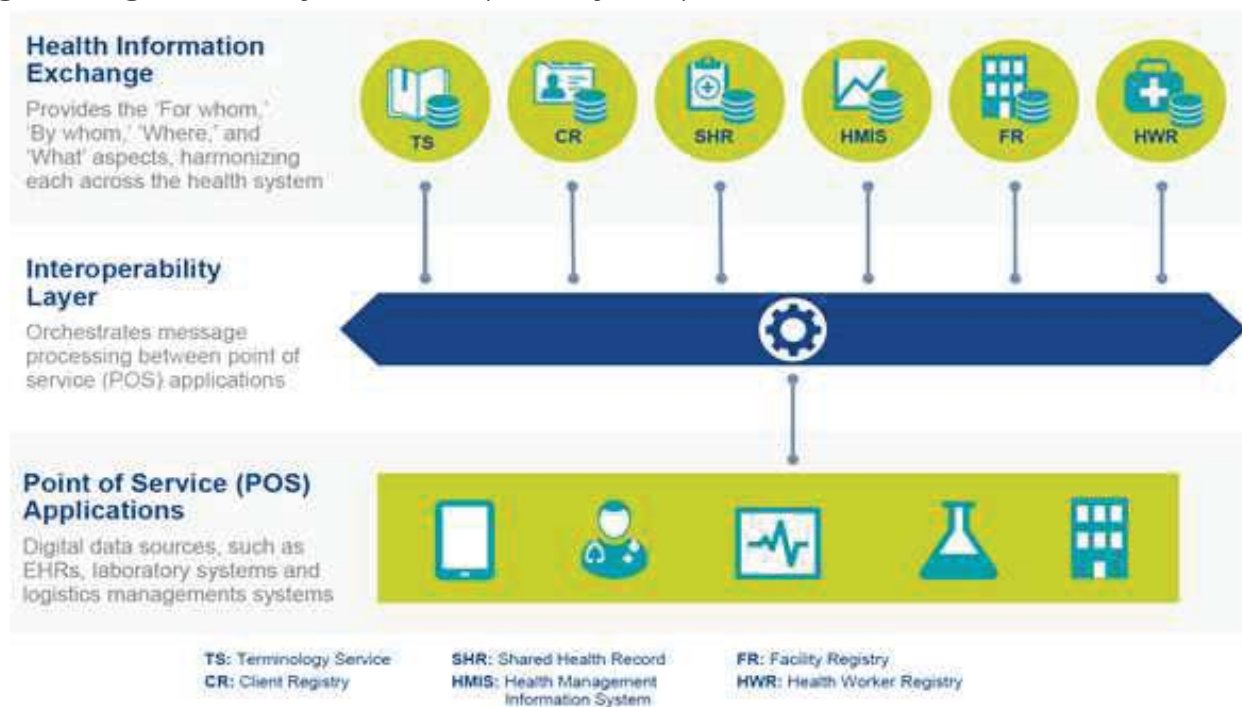
Standards are therefore integral to the implementation of digital health solutions. The Ministry of Information has a set of ICT standards to be used in deployment and use of ICT products. The Ministry of Health has adopted various standards to support the implementation and use of health information systems. Such standards include national handbook of indicators, the Master Health Facility Registry, the Terminology Registry etc. In addition, the implementation of digital health solutions has incorporated the use of standards including the HL7, FHIR, SOAP etc.

As special type of standards that Ministry of Health (MoH) has developed are the Standard Operating Procedures (SoPs) and Guidelines to support implementation of digital health solutions. These include SoPs and guidelines for the following: HIS Security Guidelines; Interoperability of Systems; Introduction of New Systems; Disaster Recovery and Data Breach; User Support and User Account Management; among others. Notwithstanding, there is need to develop and implement digital health Standards and Guidelines document. Furthermore, as a basis for implementation of digital health solutions, the Ministry of Health has standardized data collection and reporting tools. A new set of

revised selected registers was released in 2018. The Ministry has also finalized the development of National Health Indicators Handbook and as of 2018 the development of Program level indicators was in progress. The MoH through the Central Monitoring and Evaluation Division was finalizing the definition of diagnoses based on ICD-10 coding as of 2018.

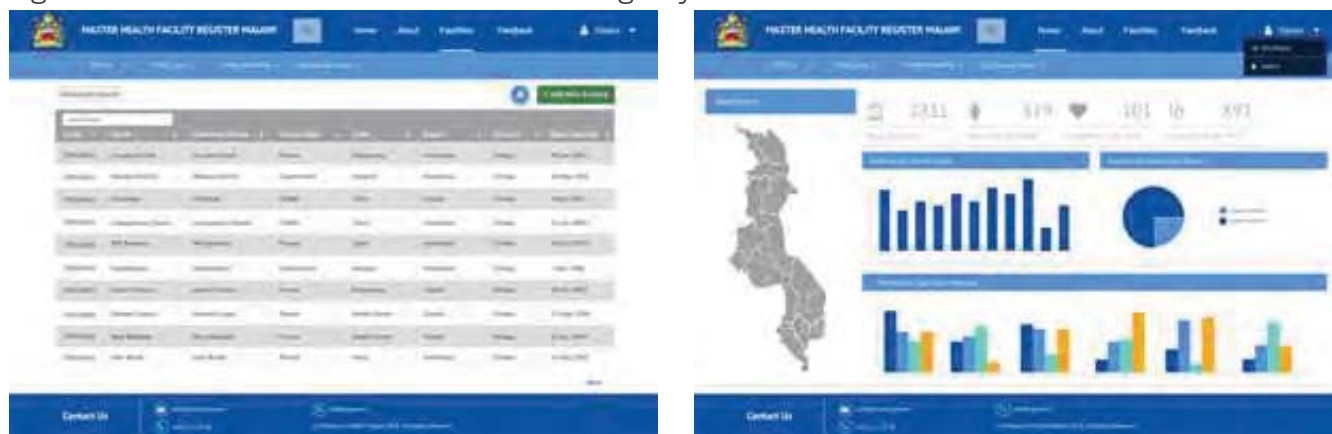
In terms of Interoperability, the MoH is following a standards based approach to Interoperability with the development of key interoperability components based on the Open Health Information Exchange (OpenHIE) framework as shown in Figure 3 below. As such the Ministry has developed the Master Facility Registry and as of 2018 work was under way to develop the Interoperability Layer and the Terminology Registry which comprises definitions for both disease diagnosis and treatment.

Figure 3: Digital Health Systems Interoperability Components



The Master Health Facility Registry (MHFR) which is the national registry of all facilities maintained by the Ministry of Health, was completed in 2018. Figure 4 shows some screenshots from the MHFR. Other key components for interoperability slated for development include the terminology service and demographic data exchange (DDE) as the client registry.

Figure 4: Screenshots of the Malawi Health Registry Infrastructure



I. Infrastructure

The key issues related to infrastructure include Connectivity, central repositories, end-user computing devices, server farms, data centers, support systems and power.

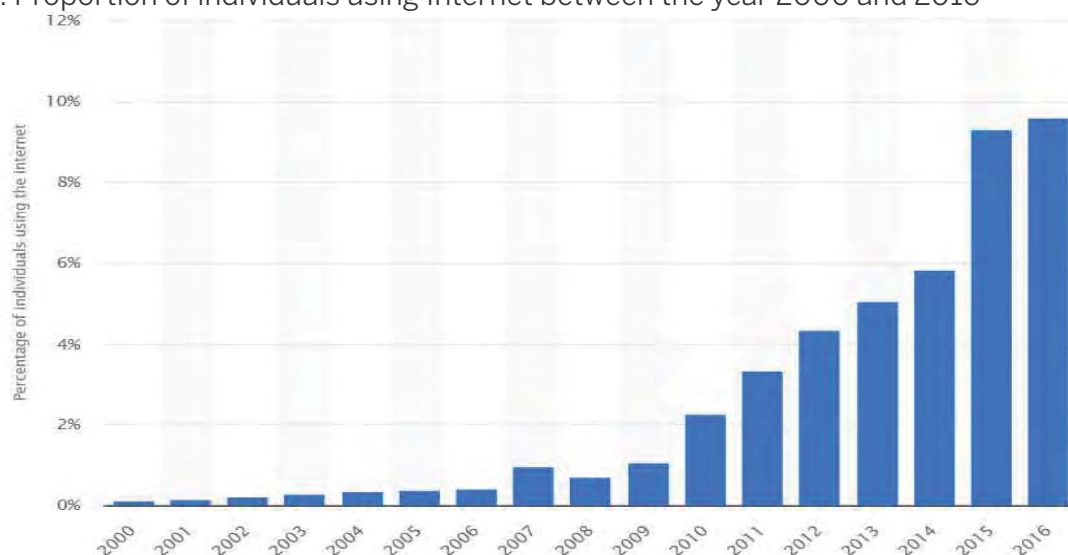
Connectivity: Connectivity is a key factor to support continuity of care. With the aim of moving towards a digital economy Government has embarked to improve ICT infrastructure, mainly connectivity and access to ICT devices. To date, the Malawi Government has laid more than 2086Km of the fiber backbone across the country's 28 districts with drop off points at each and every DCs office. As a result, Government offices in Lilongwe, Mchinji, Salima, Nkhotakota and Rumphi including selected health facilities have been connected to the Government Wide Area Network (GWAN). The overall goal of the Government is to connect all public institutions in the country to the GWAN through the high-speed backbone with an aim of modernizing public service. In addition, partners such as Baobab Health Trust have deployed a network backbone connecting districts and facilities to wide area network through a virtual private network.

Digital Infrastructure: Primary physical infrastructure are the computing devices. Contrary to the situation 5 years ago, computing devices such as desktop computers, laptops, tablets, and mobile phones are more visible at all levels of healthcare. In a recent study on data use incentives among healthcare workers at all levels it was found that health workers own an average of 1.44 mobile phone per person with 63.5% of these being smartphones while 55% were running on Android, which is a modern mobile phone platform. In addition to computing devices, other critical infrastructure is the National Data Centre which has not been implemented yet; hence Government Systems are hosted in different server sites resulting in high management cost. Plans are underway to establish a national Data Centre.

Power and Energy Sources: The main source of power in Malawi is electricity grid provided by the Electricity Supply Corporation of Malawi. However, the country has been facing constant and prolonged power interruptions. This has made it difficult to progress in implementation of reliable digital health systems. As a solution the health sector has slowly been moving to alternative sources of energy including renewable and hybrid energy sources. For example, the country is using solar energy for vaccination refrigerators and Electronic Medical Records systems deployment, among others. However, the utilization is at a smaller scale although it can be expanded.

Internet: Internet services are a key part of connectivity. Until 2016, the proportion of individuals using Internet has been increasing as shown in Figure 5. although cost is a key barrier to access. MACRA's 2014 Survey on Access to ICT and Computer Services established that at community level 56% of individuals perceive cost as the key barrier to Internet access. High costs for mobile phone usage might be a key contributor to this perception as some studies have suggested that the use of mobile phone is very expensive in Malawi considering that the mobile phone is the most common end user computing device in Malawi.

Figure 5: Proportion of individuals using Internet between the year 2000 and 2016

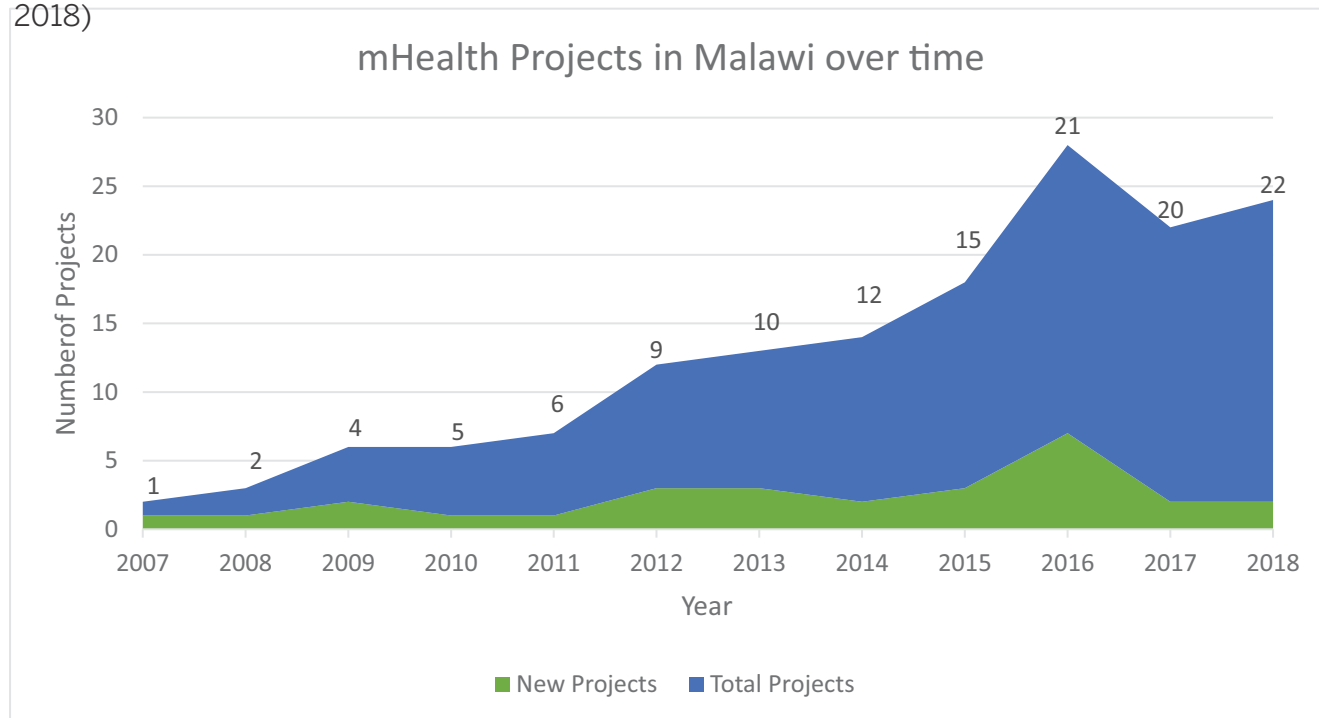


vii. Mobile Technology

With mobile phone coverage by population of 80% and the proportion of households with mobile phones at 36% (MACRA, 2014), the mobile phone is the most common method of connectivity in Malawi. More people including health care workers are finding platforms provided by the mobile phone, including messaging, whatsapp etc, more relevant for both individual and work related communication.

The health sector has contributed significantly to the development of the mobile phone sector with the number of mHealth Projects increasing each year as shown in Figure 6 below. As of 2018, the health sector has at least 31 mHealth applications in use (Figure 6). This trend highlights the significance of the mobile phone in health service technology.

Figure 6: Number of mHealth projects in Malawi: Malawi Report (Ministry of Health and Population, 2018)



From the national registration of mHealth projects, several key findings on the breadth of mHealth experience and consistent trends in mHealth. These key findings included:

- 31 mHealth projects were registered in the MOH registration
- mHealth projects have been active in Malawi since at least 2007
- The average mHealth project lifespan is 5 years
- An average of 2 new mHealth projects have launched each year with 2016 peaking at 7 new projects
- 22 live mHealth projects in Malawi in 2018
- There are an average of 8 mHealth projects per district
- Blantyre and Zomba Districts each have 13 mHealth projects, the highest density per district

The National Health Information System (HIS) designates mHealth for the community level. The strategy includes a target that by 2022, 50% of Community Health Teams (CHTs) should be using mHealth for integrated service delivery, data collection, and supervision.

At community at least 31 different applications are in use providing access to almost 45% of HSAs currently active.

The National Community Health Strategy outlines the strategic objective to “Promote a harmonized community health information system with a multi-directional flow of data and knowledge.”

In a recent survey of 328 healthcare workers at different levels (community, facility, and district), only 1 did not own a phone. 63.5% of staff surveyed owned a smartphone, with 55.2 of those smart phones

were android phones. Staff averaged 1.44 per person and 81% of phones were purchased by the individual survey. This demonstrates the widespread availability of mobile technology within the workforce.

Of the 15,000 HSAs set forth by the National Community Health Strategy to be, the target to be achieved by 2022 of 50% would be 7,500 HSAs. Currently, approximately 1,823 HSAs are using mHealth for data collection, supervision, and integrated service delivery.

viii. National ID and Unique Identification Systems for Health Users

The key challenge in enabling continuity of care is to uniquely identify each user of the health system. In the absence of a national unique identifier the MoH introduced the national Unique Health Identifier through the implementation of EMRs. Other programs such as HIV also introduced other unique identifiers in order to improve tracing of patients. However, for national unique identification the Ministry of Homeland Security through the National Registration Bureau (NRB) has the mandate to register all citizens over 16 years with a national ID number and card. At the end of a mass registration campaign in December, 2017 over 9 million (48% of total population) Malawians aged 16 and above had registered for the national ID card. The national ID card contains a chip, which also contains the biometric details of the individual. The NRB has provided for space on the chip to be used for electronic health passport based on the Health Service applet CWA 15974, commonly known as the electronic European Health Insurance Card. The electronic health passport will be used for storage of individual health information. The roll out of the National ID registration has provided potential for continuity of health service delivery for each individual. The National ID came at a time when the health sector had implemented the Demographic Data Exchange (DDE). Through the DDE, health service beneficiaries are able to get a unique number although there is a possibility for a beneficiary to get duplicate numbers within or across health facilities. Efforts are underway to utilize the National ID in the health sector.

The country is implementing Civil Registration and Vital Statistics through registration of births and deaths. Birth registration is available at all health facilities providing maternity services. Children under 16 years are to be registered through birth registration and receive a birth certificate with their national ID number, but at the moment only a small percentage of children has actually been registered, leaving a gap of 8-9 million children that are not legally registered with a national ID number. Following a meeting between NRB and MOH on the issue of reducing the gap of child registration, a task force was formed also with the Ministry of Education involved, to develop a concept document on a possible mass birth and ID registration of children for the benefit of all the different departments. As of 2018, this concept was to be presented to the cabinet for endorsement and once they have approved it, the wider stakeholder community would be engaged and resources would be mobilized.

For Unique Identification to be effectively implemented in the health sector the following considerations are key;

- There is need to ensure that all children under the age of 16 are provided with a National Unique ID. Since this population comprises more than 50% of the total population and the most of users of the health system, implementing Unique ID with only adults may not be feasible.
- The National ID is only available to eligible Malawians and selected groups of non-nationals who achieve a certain criteria. However, the health system continues to be accessed by non-nationals who are not eligible for the Malawi National ID especially through the borders of Mozambique, Zambia and Tanzania.
- There are ethical and security concerns about directly matching patient records with the national ID as any one who knows the ID can attempt to look up a person's medical history.

The issue of non eligible non-nationals for the National ID and the issue of security concerns necessitate the implementation of a complementary health sector Unique ID.

3. Key Challenges and Barriers to digital health

i. High dependence on Paper based approach to health service delivery

The majority of data collection in Malawi is paper based. Patients move through the health system with a paper based personal health passport, which “contains their key personal health details which shall freely be taken home by the patient for ease of reference and personal monitoring of their health matters, in addition to the patient records kept in the facility.” Paper based registers and monthly reporting forms are the common data capture and reporting tools in the health facilities. Having many paper-based data recording and reporting tools at the point of service delivery leads to problems such as difficulty in retrieving patient records, data inconsistency, inadequate storage, costly maintenance of the paper forms, less security and confidentiality, inability to access the paper forms from different points of care, poor integrity of patient information and lack of continuity of patient care. Additionally, health facilities have cited other challenges associated with the paper-based approach which includes insufficient paper forms and untimely delivery of the data collection tools.

Despite these challenges, the key issues with paper-based data management are reflected through the work culture and on availability of human resources in the health system. In terms of work culture, structural issues, paper-based approach give health care workers flexibility to deploy shortcuts in patient assessment and documentation that does not strictly adhere to protocols step by step. The absence of these short cuts in most digital solutions alienate health care workers who in turn perpetuate the paper-based system. Structural arrangements also proliferate paper-based approach. Key among this is lack of complete digital work flows leading to same patients supported through digital solution in part of the facility and paper approach in another section of the same facility. For example, reports to the digital DHIS2 system are often pulled from digital sources such as the EHR or mobile application databases, filled out into paper forms and re-submitted into a different digital system. This introduces potential errors and slows down the process of service delivery. On the other hand, paper-based data management exert enormous pressure on the few health care workers as same information has to be recorded or reported more than once and significant time has to be spent on summarizing and reporting this information.

ii. Lack of Sustainability of digital health Solutions

Due to the level of investment required to develop and implement a useful digital health solution, value for money can be realized if the solutions are functional and operational in the long term. Building for sustainability is principle number four of the Principles for Digital Development and focuses on long-term impact of digital health solutions. Although the meaning of sustainability can vary based on the environment, key areas include donor alignment of investments as covered by the Principles for Donor Alignment in Digital Health Investments, local government led coordination and ownership, and capacity building.

In terms of donor harmonization, a recent mHealth Assessment found that the average lifespan of mHealth applications or solutions is 5 years. With most donor funded projects lasting within the same period, it is evident that the survival of mHealth solutions is linked to the time a donor funded project is active. This means that once donor funding is gone, implementation ceases. Coincidentally, when such projects die, the data they might have collected over a period of time also becomes inaccessible.

In terms of Government led coordination, lack of centralized coordination has led to the proliferation of many small uncomplimentary digital health solutions that cover narrower perspectives in the broader health spectrum. This has resulted in duplicate efforts and lack of harmonization of expenditures through reusing and building on existing efforts. Existence of too many initiatives has also resulted in lack of Government ownership of these systems to ensure continuity. Continuity of systems transferred to Government has been affected by the tendency to transfer such systems without accompanying financial and technical resources. A similar phenomenon could also be observed for

other digital solutions where there is uncertainty regarding deployment and maintenance of these systems. Additionally, there is lack of transition of these solutions across projects to government when the project period expires. While lack of Government ownership could be linked to financial sustainability when projects are designed and implemented to the end period without integrating government finance systems, the other key element is transfer of skills and general capacity building. Most projects use technical experts outside Government system and tends to transfer ownership without transferring or building adequate technical capacity.

iii. Inadequate coverage of digital health solutions e.g. Electronic Medical Records Systems (EMRs)

Up to now, the Ministry has no digital health solution which can cover all services provided at a health facility. This has led to a mixed approach of digital and paper in facilities where digital health solutions are implemented. While there are various initiatives to implement digital health solutions at health facilities there are no standard guidelines to design and implement such solutions including Electronic Health Records (EHRs). As a result, until now the MOH has no digital health solution which can cover all services provided at a health facility. This has led to a mixed approach of digital and paper systems in facilities where digital solutions such as EMRs are implemented. The EMR implemented through Baobab, for example, is deployed in different disease specific modules (i.e. HIV, ANC, OPD) resulting in some sections of the facility with no coverage to assist service provision. This is the result of disease specific donor funding strategies and the absence of a concrete national HIS architecture to guide the implementation of EMR modules. However, deploying modules that cover all section in each facility may improve the use and ownership of systems as well as work towards a more cohesive system along the continuum of care.

iv. Lack of Interoperability between digital systems **Figure 7: Electronic Health Information Landscape (HIS) for HIV and AIDS in Malawi: Vital Wave Assessment 2019**

Within health domains there are multiple databases, digital systems, and applications that are not interoperable, disconnected and are unable to talk to one another. This affects the ability of the systems to share information securely and timely, ultimately affecting the quality of information. This leaves data users unable to match data across systems and frustrated with a wealth of information that cannot be merged together for analysis and decision making. Also, multiple systems store information in their own format and using their own standards making it more difficult to link with other systems. From a 2019 analysis that looked at HIV systems, there were many different systems across various departments within the ministry where HIV data was stored as shown in Figure 7, yet none of them were connected in a way to make it easy for users to share information and/or perform analyses. At the point of care, lack of interoperable systems affects the linkage between care providers, sharing of clinical information between the care providers as well as the provision of smooth and uninterrupted

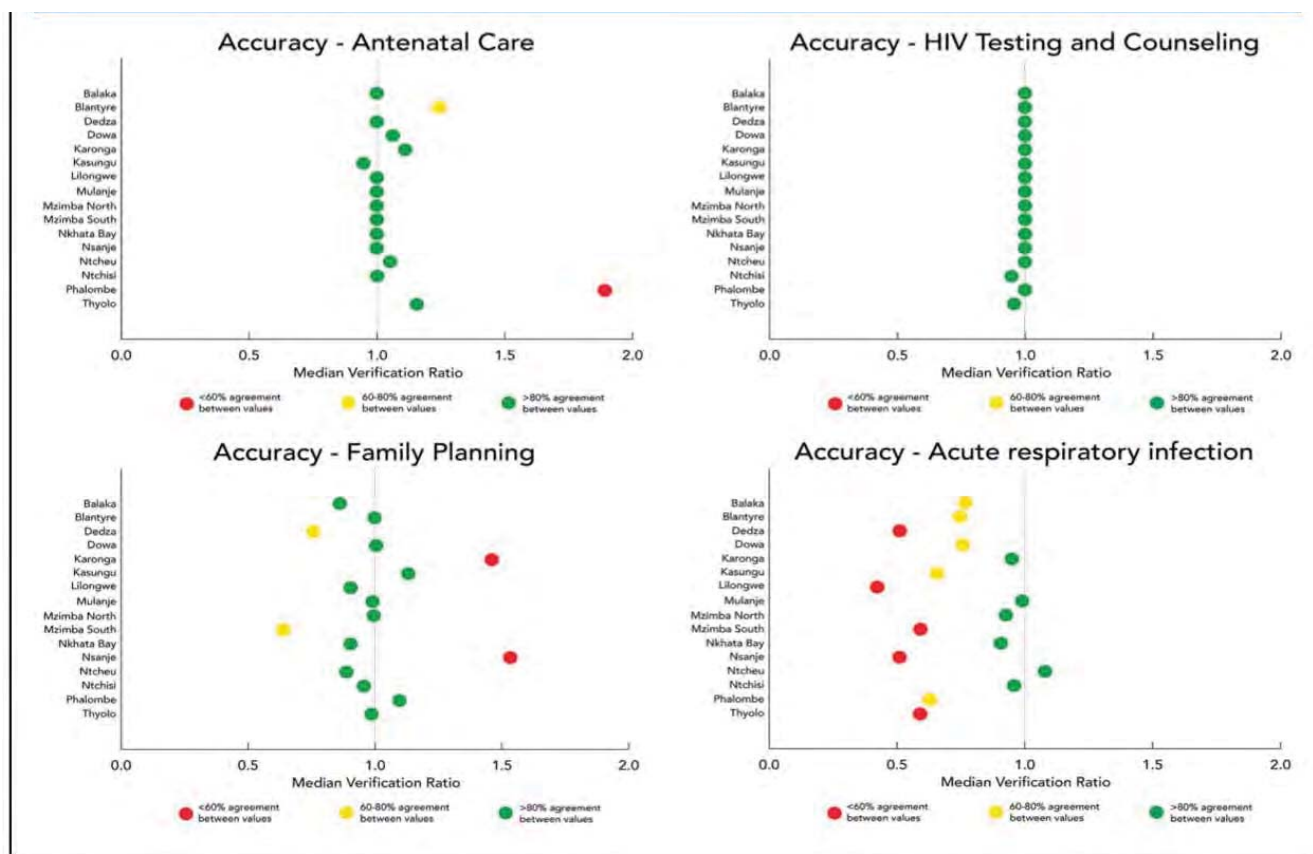
Figure 7: Electronic Health Information Landscape (HIS) for HIV and AIDS in Malawi: Vital Wave Assessment 2019



i. Lack of trust in Data Quality and lack of Data Use

With heavy reliance on manual data processing, data quality is still a challenge. Various factors contribute to data quality in the health system. Such factors include inadequate human resources leading to poor timeliness and availability of data; inadequate skills in data management, more especially due to task shifting resulting in less skilled personnel taking up data management roles in health facilities; poor data documentation practices, unavailability of data recording and reporting tools, among others. Figure 8 below highlights some of the accuracy issues in data quality as identified during a data use study among healthcare workers. Related to poor data quality is the lack of adequate data use in decision making at all levels of healthcare. Although it is argued that data use can help improve data quality. While digital health solutions have the potential to increase both data quality and data use, usage of such systems have been partial among some healthcare workers who either completely disregard the electronic systems or keep changing between paper and electronic systems leading to poor or incomplete data that cannot be used.

Figure 8: Data Accuracy Verification Ratios



i. Inadequate and Unskilled Workforce

In order to maintain, update, and provide technical support for the current systems being managed by external partners, the Ministry of Health and Population will need an assessment of the skills required and a significant investment in the necessary skills to manage the health informatics system. In the most recent training needs assessment, 40% of facilities did not have staff who formally provided IT/systems support. At facilities that did, they lacked the training and mastery levels in key areas of competency for such a role. Addressing staff shortage and equipping them with the skills to provide basic troubleshooting and user support for electronic systems at the facility level will be critical to having a capable workforce. At a broader level, most health care workers lack necessary skills in digital health systems including some of the common ones like DHIS 2, EMRs etc. For example, in the Training Needs Assessment conducted by the Ministry only 64% of health care workers with decision making responsibilities at health facility level demonstrated adequate knowledge in digital health concepts. While these challenges can be addressed through in-service training there is also need to focus on strengthening the capacity of pre-service training to impart knowledge and skills in digital health.

ii. Coordination of Digital Health Efforts

The situation analysis has covered issues of leadership and governance and Legislation, Policy and Compliance which are vital in the coordination of digital health investments. However, gaps still exist as evidenced by lack of harmonization in the implementation of digital health investments. For example, the recent mHealth assessment identified more than 30 mHealth applications to be implemented in the health sector. Some of these are implemented in the same geographical area. Additionally, there has been lack of consultative decision-making processes with key departments in the Ministry or other government departments and ministries in the introduction or deployment of digital health systems as some departments and programs have unilaterally initiated and deployed solutions without including other departments in the decision process. Furthermore, lack of a minimum set of standards with criteria against which EHRs can be measured has made difficult the coordination effort to harmonize effort around HER implementation. These challenges point to inadequate policy and regulatory framework for the management and coordination of digital health implementations.

4. SWOT Analysis

Strengths	Weaknesses
<ul style="list-style-type: none"> Existing ICT infrastructure and solutions driven by the health sector and Government at large Ongoing Government Projects targeting to improve infrastructure in the health sector Availability of key innovations in the mobile and financial sectors which can be leveraged by health e.g. mobile money, mobile insurance, short code services Improved Internet and connectivity services Increased number of people owning and accessing computing technologies Availability of governance structures and tools like acts, policies and guidelines Increased awareness and appreciation of benefits of ICT solutions within MOH Existing assessment reports for MOH to understand the digital health ecosystem in country Availability of government ICT staff in supporting digital health interventions Existing platform (TWG) for knowledge and experience sharing among digital health initiatives Availability of e-waste disposal standard 	<ul style="list-style-type: none"> Inadequate human resources capacity to effectively support digital health Inadequate ICT infrastructure in health facilities Duplication of digital health efforts resulting in competing solutions. Lack of an interoperability of systems resulting in inability to timely access integrated data for improved decision making at various levels of service delivery. Inadequate implementation of standards and guidelines to guide the implementation of digital health Solutions Lack of sustainability plan for implemented digital health solutions Lack of prioritization of funding towards digital health solutions Weak coordination of digital health interventions including reuse of software, hardware, infrastructure, etc. Inadequate user-centered design in existing digital health interventions Delays in procurement processes resulting in delays in implementation and loss of funding especially for donor driven digital health projects Inadequate rigorous evaluation on digital health interventions Inadequate policies on security, privacy and data governance at national level Inadequate compliance to e-waste disposal policy set by eGovernment Inadequate coverage of integrated digital health solutions across all service areas in community and facility
Opportunities	Threats
<ul style="list-style-type: none"> Political will and leadership from Government to improve digital health Donor willingness and commitment to invest in digital health Increase in data demand resulting in push towards improvement in digital health solutions Availability of local digital professions including developers, implementer and designers Existing digital health solutions are in line with Open Standards and Open Source Availability of National ID for enabling continuum care 	<ul style="list-style-type: none"> Strong dependency on unsustainable donor support on funding digital health Solutions Inadequate power supply Low penetration of communications infrastructure and utilization Proliferation of partner driven digital health initiatives Inadequate network coverage at point of health service delivery

CHAPTER 3

Digital Health Overall Agenda

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Digital Health Overall Agenda

1. Vision, Mission and Objectives

Our Vision

A sustainable and harmonized country led digital health system that covers all areas of service provision and enables efficient delivery of health services to beneficiaries at all levels of the health system

To improve the delivery of health services by providing digital health solutions that are harmonized, sustainable, reliable, interoperable, secure and comply with standards in order to increase efficiency and enable provision of quality services at the point of service.

Our Mission

Objectives

The situation analysis provides the status quo of digital health environment in Malawi. The challenges and the SWOT analysis, particularly, provide a highlight of areas that need to be addressed in terms of digital health in Malawi. Based on this analysis the following are the objectives designed to improve health service delivery in Malawi using digital health solutions.

Objectives

Objective 1: Improved coordination of digital health investments to increase efficiency.

Objective 2: Establish a reliable ICT infrastructure that enables utilization of digital health systems

Objective 3: Build the capacity of clients, communities, health care workers, and IT personnel to participate in and benefit from digital health interventions

Objective 4: Leverage technology to increase access to and quality of service delivery

Objective 5: Improve security of information and ICT Systems

Objective 6: Promote interoperability of digital health solutions to enable information sharing for continuity of care.

Objective 7: Strengthen the sharing and accessibility of data across systems to enable use.

2. Guiding Principles

In order to best address the vision, mission and the objectives identified, the implementation of this strategy will be underpinned by certain key principles. These principles represent fundamental values that will guide decision-making by the Ministry of Health and its development partners.

These principles are:

- i. National ownership and government leadership: The digital health strategy is a national health sector strategy with government through the Ministry of Health leading implementation.
- ii. Principles of Digital Development:
 - Design with the User
 - Understand the existing ecosystem
 - Design for Scale
 - Build for sustainability
 - Be Data Driven
 - Use Open Standards, Open Data, Open Source and Open Innovation
 - Reuse and Improve
 - Address Privacy and Security
 - Be Collaborative
- iii. Digital Investment Principles
- iv. Ethical Considerations: Implementations of digital health solutions shall adhere to the principles of confidentiality, privacy, safety and efficacy.
- v. Implementation of digital health solutions shall take an incremental approach where new solutions are required to build on what already exists in both the public and private sectors and fill the gaps where necessary.
- vi. Look for sustainable early wins in implementations and benefits to build the confidence of health professionals, patients and the public in digital health.

CHAPTER 4

Strategies to Strengthen Digital Health

CHAPTER 4

Strategies to Strengthen Digital Health

The Malawi digital health situation analysis described in the first chapter and includes thorough presentation on the global digital trends and experience, the status of digital health in Malawi, key challenges and barriers to digital health and the SWOT analysis provides a detailed view of gaps and areas that need to be focused on in the design of strategies and activities that are needed to improve digital health in Malawi. This Chapter, therefore, presents the strategies and activities under each objective.

Objective 1: Improved coordination of digital health investments to increase efficiency

Rational: Coordination is identified as a primary digital health element incorporating leadership and governance; legislation, policy and compliance. Coordination challenges have been evidenced through lack of harmonization in the implementation of digital health solutions, lack of consultative decision-making processes when implementing digital health solutions, lack of standards, inadequate policy and regulatory framework for digital health solutions. The strategies under this objective are meant to address these key challenges.

Expected Outcome:

Improved harmonization and adherence to established tools and processes in the implementation of digital health interventions

Strategy 1.1 Strengthen leadership and governance structures for management of digital health interventions

In order to strengthen leadership and governance, the following activities are expected to be implemented:

Activity	Deliverables
<p>1.1.1. Establish governance structures and processes for digital health</p> <ul style="list-style-type: none"> ○ Institute digital health governance structures in the health sector <ul style="list-style-type: none"> ▪ Digital Health TWG and its Sub TWGs ▪ Certify/licensing authority ▪ High level, multisectoral steering committee ○ Review, update and create human resource requirements for digital health ○ Develop and maintain a register for digital health solutions ○ Conduct review and approval of all digital health technologies according to standards ○ Develop standards and guidelines for digital health solutions <ul style="list-style-type: none"> ▪ EMR and EHR standards ▪ mHealth standards ▪ Telemedicine standards ▪ Software & hardware standards ▪ Connectivity standards ▪ Hosting standards ▪ Guidelines to manage transitions between systems ▪ Standards for offline data capturing ▪ Interoperability standards 	<p>Digital Health TWG and Sub TWGs instituted and meeting regularly;</p> <p>Initiation of new technologies following an agreed approval process.</p>

Activity	Deliverables
<ul style="list-style-type: none"> ▪ Change management guideline ▪ Data security guideline ▪ Maturity model for digital health intervention deployment 	
1.1.2. Conduct quarterly updates on the progress of the digital health strategy implementation	Quarterly Progress Report
1.1.3. Facilitate harmonization of digital health systems <ul style="list-style-type: none"> ○ Conduct functional review of all existing systems ○ Streamline existing systems to comply with applicable standards 	Aggregated system functionalities from many systems into fewer manageable number of systems
1.1.4. Facilitate digital health change management <ul style="list-style-type: none"> ○ Sensitization of key decision-makers on digital health systems <ul style="list-style-type: none"> ▪ Assess sensitization needs ▪ Addressing technology and cultural issues ▪ Develop package of data and materials for digital health sensitization - Communication Plan ▪ Conduct sensitization to facilitate readiness for digital health intervention ○ Facilitate health business process reengineering <ul style="list-style-type: none"> ▪ Conduct workflow analysis before introducing digital tools ▪ Redesign and implement business process with introduction of digital tools 	Sensitization sessions conducted; Key stakeholders involved in key digital health meetings Redesigned health service delivery processes for implementation of digital tools.

Strategy 1.2 Create an enabling environment for effective implementation of digital health solutions through appropriate legislation, policies and compliance mechanisms

Activity	Deliverables
1.2.1 Disseminate digital health related standards	Standards document published, awareness meetings conducted with stakeholders
1.2.2 Enforce adherence to the digital health standards	System audits conducted
1.2.3 Support implementation of Standard Operating Procedures (SOPs) <ul style="list-style-type: none"> ○ Relevant SOPS <ul style="list-style-type: none"> • Data privacy • Data Ownership • Data access and release • Introduction of new systems • Disaster recovery 	Dissemination meetings on SOPs conducted, System audits conducted

Activity	Deliverables
<p>1.2.4 Facilitate accessible design for people with physical challenges</p> <ul style="list-style-type: none"> Facilitate inclusion of disability compliance in digital health solutions e.g. web solutions 	<p>Disability guidelines for digital health solutions developed, audits conducted to check adherence to disability guidelines</p>

Strategy 1.3 Strengthen Sustainability mechanism for digital health solutions

Activity	Deliverables
<p>1.3.1 Develop and enforce sustainability measures for digital health solutions</p> <ul style="list-style-type: none"> Enforce compliance with sustainability readiness requirement stipulated in the SOP of introducing new systems Lobby for coordinated, sustained and increased funding for digital health solutions (donors and government) Lobby for inclusion of funding for internet and equipment maintenance in district budgets Provision for sustainability resources (utilities, infrastructure, financial, maintenance, human resource, governance) Develop and implement technology transfer plan 	<p>Compliance assessment report on sustainability</p> <p>Increased resources for digital health systems,</p> <p>Technology transfer plan in place</p>
<p>1.3.2 Develop a common and coordinated investment framework for digital health interventions</p> <ul style="list-style-type: none"> Develop a mapping of digital health partner investments Prioritize digital health intervention activities Lobby for the inclusion of cost center and budget line for Digital Health in the ORT annual budget 	<p>Common investment framework developed; digital health interventions prioritized.</p>
<p>1.3.3 Continuity of digital health interventions in light of donor transitions</p> <ul style="list-style-type: none"> Guide new investments to focus on strengthening existing systems 	<p>New funding investments aligned with existing interventions</p>
<p>1.3.4 Collaborate with innovation hubs and research institutions to incubate solutions for digital health</p> <ul style="list-style-type: none"> Introduce platform for sharing health problems to digital health innovators Promote funding for digital health researches and innovations Collaborate with innovation hubs and research institutions to identify potential innovations for support Support innovation hubs and research institutions to identify 	<p>Platform for sharing digital health problems in place; Signed and operational MoUs between MoH and innovation hubs and research institutions</p>

Objective 2: Establish a reliable ICT infrastructure that enables utilization of digital health systems (Also refer to MEHIS Activity 2.9)

Rational: The delivery of health services through digital applications will require that health care workers and communities in urban, rural and remote areas have access to the appropriate computing infrastructure, networked with a high-speed data connection and with appropriate software. This objective, therefore, focusses on ensuring that computing devices, connectivity and energy sources are available. Until now the country has relied on hydro energy as the main source of power, but with increase in demand this source of power has become significantly unreliable. Addressing energy sources is therefore a key area within this objective.

Expected Outcome:

Enable electronic access to appropriate health services for health care workers and communities in urban, rural and remote areas.

Strategy 2.1 Improve capability of connectivity in poorly covered areas (i.e. areas with no or intermittent connectivity)

To improve connectivity, emphasis is made on health facilities in both urban, rural and remote communities. A national approach to connectivity in the health sector would leverage existing initiatives by both government and the private sector. In terms of the private sector, most common, affordable and scalable source of connectivity are the Mobile Network Providers MNP such as Airtel, TNM, Access. However, in areas where these providers have a point of presence regardless whether it is urban or rural there are cases of inadequate coverage in the health facilities around or near the point of presence. This is sometimes due to the orientation or alignment with the microwave dishes or antennae at the point of presence. Additionally, MNPs focus on return on investment and are therefore not attracted to invest in point of presence in low income areas where health facilities are also available. The activities around this strategy are therefore aimed at mobilizing resources and support to extend the operation of MNPs to cover health facilities. In terms of public sector, extending the connectivity for the health sector intends to leverage the connectivity infrastructure that government has established through e-Government. This means extending the government fiber network and connectivity to district health offices and health facilities. The activities below are therefore meant to address connectivity by addressing these issues:

Activity	Deliverables
2.1.1 Engage government departments and Mobile Service Providers about increasing ICT Infrastructure in off-grid or poorly connected areas <ul style="list-style-type: none"> • Adopt and implement infrastructure standards from eGovernment • Lobby eGovernment on the prioritization of health sector in the Digital Malawi Project and Government Wide Area Network (GWAN) • Lobby Ministry of Information on implementation of connectivity in remote areas • Lobby for use of universal access fund with MACRA to support digital health services in remote areas 	Meetings conducted with eGovernment, MACRA, Mobile Service providers; More connectivity resources allocated to MACRA, eGovernment and MNOs
2.1.1 Facilitate internet and network connectivity in all health facilities <ul style="list-style-type: none"> • Develop a comprehensive network plan for the health sector • Install local area networks in health facilities in a phased approach starting with central and district hospitals • Engage with eGovernment to extend GWAN from the DC office to all health facilities • Consolidate fragmented connectivity in health instructions and health facilities • Extend the health wide area network to offer last-mile connectivity 	60% of the health facilities connected to GWAN

Strategy 2.2 | Extend coverage of renewable and hybrid power solutions

Addressing power challenges to enable utilization of digital health solutions will focus on standardizing the power solution to be deployed at each health facility. This will also involve the scale up of deploying the solutions to all relevant health facilities.

Activity	Deliverables
<p>2.2.1 Define specifications for renewable and hybrid power solutions</p> <ul style="list-style-type: none"> Engage with Ministry of Energy and MERA on renewable and hybrid power solutions implementation standards Develop a summary of specifications 	Specifications for renewable and hybrid power solution developed and adopted
<p>2.2.2 Deploy hybrid power solutions in health facilities</p> <ul style="list-style-type: none"> Coordinate deployment of renewable power solutions for digital health application to health facilities and institutions Lobby for deployment of renewable and hybrid power systems for digital health applications in health facilities and institutions 	60% of health facilities with hybrid power solutions

Strategy 2.3 | Extend coverage of renewable and hybrid power solutions

Healthcare workers need technological devices for them to access and provide health services through digital solutions. Ensuring that health care workers have access to technological devices is therefore a priority for the strategy. A localized data hosting center is also a priority to ensure the continuity of delivery of health services. Making available this data center at a national level will ensure protection of patient information. The activities under strategy are designed to address these issues.

Activity	Deliverables
<p>2.3.1 Facilitate local hosting of health data</p> <ul style="list-style-type: none"> Develop and implement guidelines for local hosting Implement short-term solutions for local hosting Support the eGovernment on deployment of national data center 	<p>Guidelines for local hosting developed,</p> <p>Data hosted locally</p>
<p>2.3.2 Facilitate availability of computing devices in health facilities</p> <ul style="list-style-type: none"> Provide digital end-user devices (e.g. desktop, laptop, tablet and other devices) Adopt the use of digital medical equipment Provide support on maintenance of ICT equipment Manage inventory of computing devices in the health sector 	Computing devices available in all health facilities
<p>2.3.3 Maintain standard specifications for computing devices</p> <ul style="list-style-type: none"> Collaborate with eGovernment to regularly update standard specifications for computing devices Adapt eGovernment standard specifications for digital health Disseminate standard specifications for digital health 	Updated standard specifications developed and adopted

Objective 3: Build the capacity of consumers, communities, human resources for health to participate in and benefit from digital health interventions

Rationale: Successful implementation of digital health solutions rely on the ability of users to embrace and adopt these solutions. This ability can manifest in form of knowledge and skills; enabling resources such as human capital, change management processes and tools that provide platforms for users to engage the health system. Knowledge and skills are necessary for both health care workers, consumers including patients and communities who are interested in understanding and participating in conversations on general health issues.

Expected Outcome:

Increased adoption and use of digital health solutions by consumers in accessing health service delivery and health care workers at the point of service delivery. 90% of health care workers, more specifically clinicians and nurses, will have access to digital solutions by 2023.

Strategy 3.1 Increase capacity of health workforce to implement and utilize digital health interventions

The health workforce including health care workers and ICT personnel require both skills and knowledge to strengthen their ability utilize or deploy and support digital health solutions. Adequate numbers for ICT personnel are also required to support the implementation and maintenance of these digital solutions. The activities under this strategy are intended to address these issues.

Activity	Deliverables
3.1.1 Train health care workers and IT personnel in digital health solutions <ul style="list-style-type: none"> Facilitate inclusion of digital health modules (from HIS training materials) in CPD of health workers <ul style="list-style-type: none"> Number of health workers trained in digital health modules Deliver digital health modules to ICT personnel 	Digital health module delivered to all healthcare workers and ICT staff
3.1.2 Facilitate increased numbers of skilled ICT personnel to support implementation of digital health solutions <ul style="list-style-type: none"> Lobby with Government through eGovernment to fill vacant positions in the ICT section in MoH Lobby for structural review of DPPD to include positions for digital health staff Lobby for structural review of ICT section to increase number of staffs Lobby for training institutions to include digital health modules within the curriculum for pre-service training 	ICT Section Vacancies filled; DPPD digital health functional review done
3.1.3 Introduce an eLearning platform for CPD <ul style="list-style-type: none"> Identify and customize eLearning platform Customize modules in the eLearning platform Dissemination and training on the eLearning platform 	CPD eLearning platform developed and operational

<p>3.1.4 Introduce capacity building and skills transfer to government as part of implementation of new and existing digital health solutions</p> <ul style="list-style-type: none"> ○ Include this requirement in SoP for introducing new digital health solutions ○ Disseminate this requirement to all stakeholders: government, development and implementing partners ○ Enforce and monitor adherence to this requirement 	<p>Skills transfer included in budgets as part of implementing any new digital solution</p>
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Objective 4: Leverage technology to increase access to and quality of service delivery

Rationale: The Health Sector Strategic Plan 2017-2021 objective one aims to increase equitable access to and improve quality of health care services. Currently, service delivery is limited to the formal setting of the health facility with occasional outreach services. The primary tenet of universal health coverage is to ensure that certain segments do not unfairly suffer or get impoverished by the process of seeking health services. Due to limited availability of qualified health personnel some patients cover long distances to access specialized personnel or better medical equipment. Technology can be used to lessen this burden and facilitate equity in access to health services. This objective, therefore, focusses on advances in technology such as teledigital health, machine learning (predictive analytics) and digital diagnostics interventions, among others.

Expected Outcome:

Increased access to health services and diagnostics using digital interventions. 50% of rural and remote health facilities have access to specialized medical personnel. All secondary level health facilities have diagnostics equipment linked with the computerized hospital health information system

Strategy 4.1 Use innovative digital health technologies to increase access and quality of health (Also refer to MEHIS Activity 3.6)

Digital technologies have the capability to dramatically increase access to health services and improve the quality of health service delivery.

Activity	Deliverables
<p>4.1.1 Increase coverage of existing digital health solutions</p> <ul style="list-style-type: none"> ○ Perform a situation analysis of existing tel e-digital health systems in Malawi ○ Define the standard and requirements for tele-digital health solutions ○ Identify and implement the tel e-digital health interventions based on the standard ○ Coordinate and/or scale -up tel e-digital health systems to increase coverage 	<p>60% of health facilities providing telehealth services</p>
<p>4.1.2 Extend use of Picture Archive and Communication System (PACS) to more facilities</p> <ul style="list-style-type: none"> ○ Perform a situation analysis of existing PACS in Malawi ○ Define the standard and requirements for PACS solutions ○ Implement PACS compliant to the Digital Imaging and Communication in Medicine (DICOM) standard in facilities on prioritized access points ○ Facilitate development of medical image processing, visualization tools 	<p>All district and central hospitals fitted with PACS</p>

Activity	Deliverables
4.1.3 Implement a drug and essential commodity dispensation management system <ul style="list-style-type: none"> ○ Perform a situation analysis of existing dispensation systems in Malawi ○ Define the standard and requirements for dispensation solutions ○ Develop and deploy dispensation system Facilitate 	Dispensation management system scaled up to 50% of health facilities
4.1.4 Implement a Laboratory Information Management System <ul style="list-style-type: none"> ○ Perform a situation analysis of existing LMIS in Malawi ○ Define the standard and requirements for LMIS solutions ○ Develop and deploy LMIS Facilitate 	LMIS scaled up to 50% of health facilities
4.1.5 Facilitate coordinated implementation of mHealth Solutions <ul style="list-style-type: none"> ○ Define the standards and requirements for mHealth solutions ○ Identify mHealth solutions compliant to standards and requirements ○ Expand functionality and scale up existing mHealth solutions 	mHealth solutions scaled up based on defined standards and requirements
4.1.6 Improve performance of the current EMRs <ul style="list-style-type: none"> ○ Define the standards and requirements for enhanced EMRs ○ Upgrade and/or identify alternative software platforms for running EMRs ○ Upgrade and/or identify alternative hardware for running EMRs ○ Establish client support systems to promote EMR use 	EMR standards and requirements developed and operational
4.1.7 Saturate EMR functionality to already installed facilities <ul style="list-style-type: none"> ○ Expand network, hardware and power coverage within the facility ○ Install additional modules to current EMR in all facilities ○ Integrate modules ○ Improve and scale out Demographic Data Exchange (DDE) 	Additional EMR modules deployed to 140 facilities already with EMR
4.1.8 Scale out EMRs to non EMR facilities <ul style="list-style-type: none"> ○ Assess non EMR sites for readiness ○ Install power and backup solutions ○ Install network and hardware infrastructure ○ Deploy the EMR solutions 	EMR installed to additional 200 facilities
4.1.9 Increase accessibility of data from digital health solutions <ul style="list-style-type: none"> ○ Build portal for users to access patient level data <ul style="list-style-type: none"> ● Create dashboards for reports generation ○ Enforce privacy and confidentiality policies in the use of patient data through digital health intervention 	Secure data use portal developed and operational
4.1.10 Strengthen management of health research and data <ul style="list-style-type: none"> ○ Perform a situation analysis of digital research management system ○ Define the standard and requirements for digital research management system ○ Develop and implement the digital research management system 	Digital research management system developed and operational

Strategy 4.2 Leverage use of predictive analytics and big data to improve health service delivery

The Ministry of Health is generating huge repositories of data either through direct health service delivery systems or through auxiliary and proxy systems such as the social media both in real time or retrospectively. These sets of data are generally referred to as “big data”. On top of big data it is possible to run complex analysis such as predictive analytics. Predictive analytics is an area of statistics that deals with extracting information from data and using it to predict trends and behavior patterns. Predictive analytics uses statistical techniques that include data modeling, machine learning, artificial intelligence, deep learning algorithms and data mining. Because big data and predictive analytics can help provide insights by answering questions into better ways to provide health service delivery through treatment, increased accuracy and early detection of diagnosis, planning and management, and control among others, this strategy has provided focus to leverage this emerging field of data science.

Activity	Deliverables
4.2.1 Mobilize resources to perform predictive analytics <ul style="list-style-type: none"> ○ Identify a central repository to consolidate, aggregate and store data ○ Identify methods and tools to perform predictive analysis ○ Acquire technical assistance to provide training as well as perform predictive analytics ○ Train staff to have required data science skills to perform predictive analytics 	Patient level central repository implemented and operational; At least 30 staff trained in advanced data science
4.2.2 Identify questions that need to be answered with predictive analytics	A set questions and use cases identified
4.2.3 Utilize predictive analytics for proactive and accurate health service delivery <ul style="list-style-type: none"> ○ Develop models with predictive analytics to inform decision-making ○ Train decision-makers to use the developed models in making decisions ○ Leverage predictive analytics at the point of service 	Models incorporated in digital health solutions

Strategy 4.3 Align digital health interventions with comprehensive digital health architecture

Digital health solutions have emerged in the Ministry at different paces and with focus on particular areas of health service delivery. Demand has therefore driven the fast tracking of certain components of the digital health landscape. As such there is need to ensure alignment between these systems with focus on a broader national digital health design and implementation. This strategy has therefore put focus on developing a national digital health architecture and ensuring that any digital systems are aligned with this architecture.

Activity	Deliverables
4.3.1 Update national HIS architecture to a comprehensive digital health architecture based on the government national ICT architecture <ul style="list-style-type: none"> ○ Review and update the organizational architecture ○ Review and align data architecture with the OpenHIE framework ○ Review and update the application architecture with required standard and requirement from relevant stakeholders ○ Define the technical architecture with required standard and requirement 	Updated Architecture available
4.3.2 Disseminate national comprehensive digital health architecture to relevant stakeholders <ul style="list-style-type: none"> ○ Publish national comprehensive digital health architecture on MOHP website ○ Disseminate architecture to relevant stakeholders through events 	Architecture document published; Dissemination sessions conducted

Objective 5: Improve security of information and digital health systems

Rationale: In digital health systems security extends the privacy of the individual. Privacy is defined as the right of an individual to keep his/her individual health information from being disclosed. This is typically achieved through policies and procedures. Privacy encompasses controlling who is authorized to access patient information; and under what conditions patient information may be accessed, used and/or disclosed to a third party. On the other hand, security is defined as the mechanism in place to protect the privacy of health information. This includes the ability to control access to patient information, as well as to safeguard patient information from unauthorized disclosure, alteration, loss or destruction. Security is typically accomplished through operational and technical controls within a covered entity. International legal instruments such as the US's Health Insurance Portability and Accountability Act (HIPAA) and Europe's recent General Data Protection Regulation (GDPR) highlight key issues to ensuring security in digital health solutions. Learning from this, this strategy seeks to strengthen the security management framework for digital health solutions in Malawi.

Expected Outcome:

Digital health solutions are compliant with security guidelines and standards. 100% digital health solutions will be compliant by the mid year of the strategy implementation.

Strategy 5.1 | Ensure continuity of service delivery in all service delivery points in cases of disasters and loss of property

Disaster recovery is a key component in ensuring the security of digital health systems. This strategy is focusing on implementing a disaster recovery mechanism.

Activity	Deliverables
5.1.1 Conducting a risk analysis to assess risk areas and interventions <ul style="list-style-type: none"> ○ Liaise with ICT Section to produce annual security risk analysis report 	Risk analysis conducted Annually
5.1.2 Enforce implementation of Disaster Recovery SOP <ul style="list-style-type: none"> ○ Perform regular backups and store in separate multiple locations based on a comprehensive disaster recovery plan at each facility 	Disaster Recovery Sites Operational
5.1.3 Conduct Annual Security Audit of digital health solutions	Audit Reports

Strategy 5.2 Develop and deploy standardized security management process in health sector to promote acceptable use of data and related tools, including hardware and software

The way digital health solutions including hardware and software are used have the potential to render the digital health systems vulnerable. Better security management processes can therefore help address these challenges and improve secure digital health solutions.

Activity	Deliverables
5.2.1 Implement security management process standard within the health sector <ul style="list-style-type: none"> Develop and implement security checklist in all service delivery points. Orient system suppliers/developers and implementing partners on the security policies and guidelines Provide training to all health staff regarding security for digital health systems Implement audit logs in all electronic system to monitor system usage 	Security management process standard developed and operational
5.2.2 Deploy digital health interventions security breach response system <ul style="list-style-type: none"> Define roles for security contact person Identify and orient security contact person Implement and enforce Data Breach SOP 	Security response system operational

Strategy 5.3 Address ethical issues in digital health in order to promote privacy and security of clients data

Ethics are a moral obligation on how to ensure privacy and security of digital solutions including data. This strategy is focusing on ensuring that ethics are adhered to in implementation of digital health solutions.

Activity	Deliverables
5.3.1 Implement and enforce Data Access and Release SOPs	SoPs disseminated and operational
5.3.2 Develop a tracking system of all authorized data accesses and disposal policy for ease follow up	Tracking system developed and operational
5.3.3 Conduct targeted orientation on privacy and confidentiality ethical issues (Partners as well as researchers)	Orientation sessions conducted

Strategy 5.4 Ensure that digital health information and users are protected from undesirable threats including physical threats(fraud and theft), malwares, breach of privacy, misuse of information

Threats to security can be dealt with by among other ways having a comprehensive prevention mechanism in place. These ensure that systems are protected before the damage is done. This strategy therefore focusses on ensuring that digital systems are prepared to address threats.

Activity	Deliverables
5.4.1 Enhance physical security controls in all digital <ul style="list-style-type: none"> Enforce password policy in all digital health systems 	SoPs disseminated and Operational
5.4.2 Enhance physical security controls in all digital health systems <ul style="list-style-type: none"> Implement physical access control system to digital health systems Install physical security controls in all buildings housing electronic equipment (e.g. lock, authentication processes, alarm system, burglar bars, etc.) 	Additional physical Access control measures deployed and operational
5.4.3 Implement and adhere to security measures in line with Public Service ICT Standards	ICT standards dissemination sessions conducted; Implementation of action plans from security audits monitored

Objective 6: Promote continuity of care through the shared health record (Also refer to MEHIS Activity 3.6 and Activity 3.7)

Rationale: The Shared Health Record (SHR) facilitates the sharing of clinical information between health information systems to enable better patient care thus improving health outcomes. In order to have the shared health record systems should be able to provide both diagnosis and treatment information as part of patient updated history. This objective is therefore focused on ensuring continuity of care by addressing strategies to enable the shared health record.

Expected Outcome:

Patients are able to access their health record from any health facility or at any point of service.

Strategy 6.1 Lead efforts to ensure that longitudinal and cross-sectional patient health records are accessible at the point of service delivery

In order to achieve the shared health record, key components need to be addressed. Such components include standards and specifications, terminology services and most importantly a digital health solution that can be accessed at any section of the health facility.

Activity	Deliverables
6.1.1 Define and adopt minimum specifications and framework for EHRs <ul style="list-style-type: none"> Gather information to understand the minimum requirements for an EHR (data and system) Develop specifications for minimum allowable functionality and non-functionality features of EHR 	Specifications and framework developed and implemented
6.1.2 Implement national terminology service <ul style="list-style-type: none"> Implemented the national terminology service Enforce utilization of national terminology service Review and update terminology service as needed 	National terminology service developed and operational
6.1.3 Implement comprehensive and integrated, user centered and secure EHR system <ul style="list-style-type: none"> Identify and implement comprehensive and integrated EHR system(s) Roll out the integrated EHR system(s) Implement SOP on introduction of new systems and features 	Secure HER system designed and deployed in 20% of health facilities
6.1.4 Implement shared electronic health records	

Strategy 6.2 Strengthen the identification of clients and staff across the health system

Without the ability to uniquely identify each client, it is impossible to provide continuity care. This strategy therefore focuses on ensuring that we are able to uniquely identify each service beneficiary.

Activity	Deliverables
<p>6.2.1 Leverage the National ID for clients unique identification in the health sector</p> <ul style="list-style-type: none"> ○ Link the National ID with health identification systems ○ Define unique health user identification ○ Customize health systems to incorporate National IDs ○ Liaise with NRB to create a strategy for identification of Under 16s ○ Liaise with NRB to register all groups not eligible for national IDs ○ Implement the national health identification model 	National ID is used to identify health service beneficiaries
<p>6.2.2 Develop a system for professional IDs for health workers</p> <ul style="list-style-type: none"> ○ Develop regulatory mechanism to uniquely identify all health workers ○ Create and deploy a secure health worker registry system to identify, track, and authenticate health workers ○ Implement security SOPs at every health facility ○ Enforce authentication mechanisms at all points of care 	System developed and operational

Objective 7: Strengthen the sharing and accessibility of data across systems to enable use (Also refer to MEHIS Activity 3.5)

Rationale: The Ministry has ended with some functions implementing digital systems specialized for those particular functions. For example, the OpenLMIS is a drug and medical supplies logistics management system and DHIS 2 is a disease statistics management system. Data from these systems need to be brought together for triangulation to support service delivery. These systems therefore, need to be able to share data. In order to achieve this there is need for other software components and governance frameworks to be implemented. This objective is focusing on interoperability which is the term used to describe the ability of systems to standardize and share data.

Expected Outcome:

Digital systems are able to share data with each other based on the Open Health Information Exchange Framework.

Strategy 7.1 Facilitate alignment of systems to the interoperability framework

For interoperability to happen there is need to standardize how data is going to be shared between systems. This strategy is therefore focusing on governance and digital components to standardize the data sharing.

Activity	Deliverables
7.1.1 Facilitate training in international systems interoperability frameworks and standards <ul style="list-style-type: none"> Identify trainings on interoperability standards - (Certifications, workshops and short courses) provide certification trainings on interoperability framework standards Orient health managers on interoperability framework standards Orient health workers on data sharing across systems 	ICT staff attended specialized training on interoperability; Data sharing training sessions conducted
7.1.2 Develop data dictionary in line with recommended standards for all digital health interventions (All digital health systems must have its data dictionary) <ul style="list-style-type: none"> Define the standard of data dictionary for digital health interventions to compliant Develop holistic and enhance data dictionary Review and update data dictionaries as needed 	Data dictionaries developed and operational for all digital health interventions
7.1.3 Define and implement guidelines and SoPs on interoperability of systems <ul style="list-style-type: none"> Finalize guidelines and SoPs on interoperability Facilitate approval of the interoperability SoP Disseminate interoperability SoP <ul style="list-style-type: none"> Print and distribute SoPs Print and distribute SoPs Publish SoP on the MoH website 	SoPs published and disseminated
7.1.4 Facilitate the implementation of interoperability using the OpenHIE framework <ul style="list-style-type: none"> Design interoperability standard components Develop and deploy the interoperability layer, Health facility registry, Health worker registry, Terminology registry, and shared health records. 	Interoperability components developed and operational

Strategy 7.2 | Implement interoperability among priority systems

Once the standards and components are defined and deployed there is need to implement the actual data sharing between actual systems. This strategy is therefore focusing on interoperability between priority systems.

Activity	Deliverables
7.2.1 Facilitate alignment of systems to the interoperability framework <ul style="list-style-type: none"> Assess existing systems to determine requirements for interoperability Collaborate with system custodians to incorporate interoperability standards into the identified systems 	Interoperability standards incorporated in existing systems
7.2.2 Roll-out interoperability among systems in a phased approach <ul style="list-style-type: none"> Develop interoperability between DHIS II and Open LMIS, ISS, IHRIS, LIMS, DHAMIS, EMRs, CRVS and mHealth applications 	Selected systems are interoperable with DHIS 2

CHAPTER 5

Digital Health Strategic Priorities

CHAPTER 5

Digital Health Strategic Priorities

Implementing the strategies for digital health requires a coordinated approach that identifies the priorities that determine the segments to be implemented in an incremental approach as building blocks for strong and sustainable digital health environment. Such building blocks should be attributed to catalytic or foundational capabilities that enables realization of the strategies in the preceding chapter. This section highlights these building blocks and priorities and describes how each building block will be implemented to enable strong foundations for digital health in Malawi. Among these priorities are: Leadership and Governance; Computing devices for the end users; Connectivity; Health Information Exchange/Interoperability Framework; Hospital Information System; and Human Resources for Digital Health.

1. Leadership and Governance

A vital component in the successful implementation of this strategy and the improvement of digital health in Malawi is strong leadership and governance. Consequently, Objective 1 is focusing on improved coordination of digital health investments to increase efficiency. Among the challenges facing digital health in Malawi are lack of harmonization in the implementation of digital health solutions, lack of digital health standards, inadequate policy and regulatory framework for digital health solutions and lack of consultative decision-making processes when implementing digital health solutions. Leadership and governance, therefore, becomes the priority for government in the implementation of digital health as follows:

Priority #	Description	Deliverables
Digital Health Priority 1	Institute governance structures for managing, registering, reviewing, and certifying all digital health solutions and for developing sustainability measures	legislation, policies, standards and compliance mechanisms for implementation of digital health solutions
	Harmonize digital health investments through development and implementation of a Digital Health Roadmap which highlights a Common Investment Framework	Digital Health Common Investment Framework

2. Computing Infrastructure

Strategy 2.3 is focusing on improving the availability of computing infrastructure and devices to end users at health facility and community levels. The Ministry realizes that for digitalization to happen healthcare workers need to have access to technological devices such as desktop computers, laptop computers, tablets and smart phones. While some devices can be personal in nature, there is need to look at the opportunities to empower the whole facility rather than individuals. As such the nature of devices to be made available to facilities should primarily be those that support group activities than individual. These include desktop and laptop computers. At community level, however, there is need to consider usability due to the requirements for an individual to provide mobile services, for example, at the village clinic or in patients homes. As such more personalized devices such as tablets and smart phones are ideal for community services.

Most diagnostic equipments in health facilities are analogue meaning that readings and other outputs are manually processed. This compromise quality of service delivery through inaccuracies in recording and forcing patients to carry diagnostic documents around the hospital. In preparation for a

digitalized diagnostic service the Ministry direction is to advocate for digital diagnostic devices replacing existing equipment or any new installations. Based on this the Ministry, therefore, has the following digital health priority:

Priority #	Description	Deliverables
Digital Health Priority 2	Improve availability of desktop computers and laptops at health facility level	all health facilities should have one desktop or laptop per 4 healthcare workers
	Improve the availability of tablet computers and smartphones at community level	Every Village Clinic should have at least one tablet or smart phone
	Improve medical diagnostics through deployment of digital enabled diagnostics equipment	Every district and referral hospital have digitally enabled diagnostics equipment only

3. Connectivity

Strategy 2.1 is focusing on improving capability of connectivity. Connectivity is in two aspects. First is the link between health facility and the next point of a service provider. Second is the local area network (wired or wireless) within the health facility. For the health facility to be digitally enabled, connectivity is the key. There are different sources of connectivity including Mobile Network Operators who are private service providers and the public network through the Government Wide Area Network (GWAN). Leveraging the effort that government is making to connect all government departments through the national fiber backbone is the most sustainable approach. Government is already paying for Internet cost under GWAN. The Ministry of Health and Population therefore intends to take advantage of this government driven initiative and connect all health facilities to the GWAN.

Priority #	Description	Deliverables
Digital Health Priority 3	Connect district health offices and health facilities to the Government Wide Area Network (GWAN)	all health facilities connected to GWAN

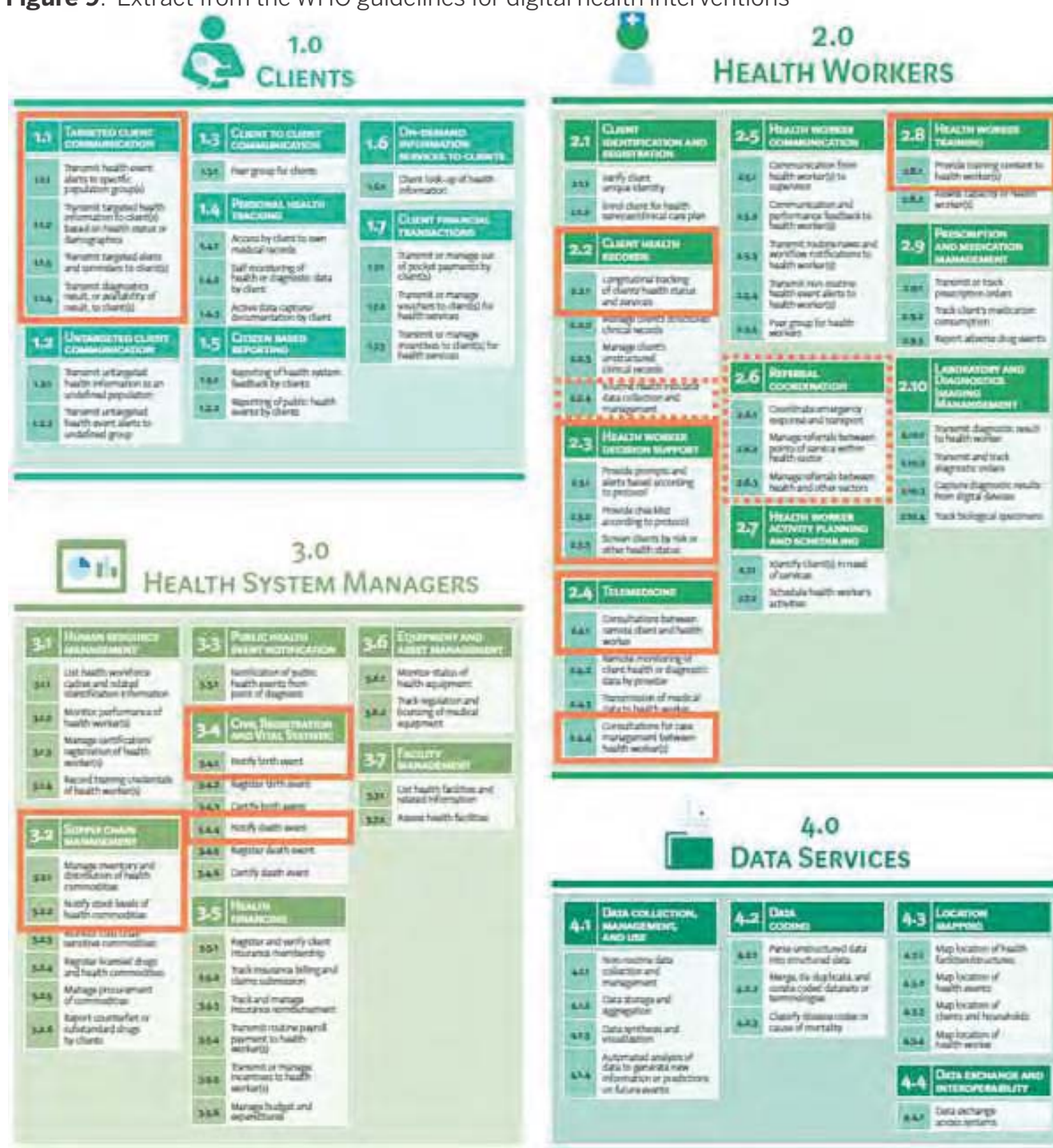
4. Hospital Information System

Delivery of health services currently is mostly through paper based processes. Additionally, for facilities that have a digital solution, some of the sections of the facility are still paper based. As such for the same visit or for subsequent visits a patient has to move between electronic and paper-based service delivery. Transitioning between the two systems add documentation cost and lack of visibility into the services provided in other sections. Feedback from key stakeholders such as district health offices and central hospitals is that the Ministry need to have a hospital wide network solution that enables health workers like doctors and nurses have access to decision support solution at the point of service. This means that the digital solution should focus on how to improve the quality of care at the point of service delivery rather than focus on data collection. The Ministry has, therefore, put high priority on the implementation of a hospital wide network digital health solution.

Priority #	Description	Deliverables
Digital Health Priority 4	Design and implement a hospital wide decision support digital health solution to improve delivery of service at the point of care	50% of health facilities providing services using hospital wide system

The development of a hospital wide network digital system is expected to be an incremental process building on lessons learnt. The WHO has, however, identified key services that should be provided as part digital health interventions at a minimum. These services include longitudinal tracking of client's health status and services; provision of health worker decision support including provision of prompts and alerts based on protocol, provision of checklists according to protocol and screening of clients by

Figure 9: Extract from the WHO guidelines for digital health interventions



risk or other health status; provision of telemedicine services enabling consultation between remote client and health worker and enabling consultations for case management between health workers; referral coordination which includes coordination of emergency response and transport and management of referrals between points of service within the health sector; Supply chain management including management of inventory and distribution of health inventories and notification of stock levels of health commodities. Figure 9 is an extract from the WHO guidelines for digital health interventions showing the full scope of interventions and those prioritized service delivery areas.

The second aspect of the hospital wide system is the adherence to the principals of digital development to ensure a user centered approach in the design of the digital solution. The expectation of the Ministry is that the hospital wide system should revolve around the clinical staff including the nurses and the doctors. To address challenges with implementation of existing systems that are data focused the implementation of the hospital wide system is expected to take into account the work practices of the clinical health workers to ensure that the solution adds value to how they conduct their work.

5. Strengthen Human Resources for Digital Health

For the digitalization of health services to be successful, the Ministry requires adequate numbers of technical personnel within the Ministry to design, deploy and support digital health solutions. Additionally, for the digital health solutions to be used there is need for the healthcare workers who are the primary users of the digital health solutions to have adequate skills in the utilization of these digital solutions. Building capacity for ICT personnel and healthcare workers is needed. The Ministry has, therefore, prioritized the strengthening of human resources as follows:

Priority #	Description	Deliverables
Digital Health Priority 5	Develop capacity for human resources to deploy, support and use digital health solutions at national, district and health facility levels	National level and each district has adequate ICT staff to support with delivery of digital solutions; 50% healthcare workers have received standardized digital health training.

6. Interoperable Health Information Exchange Framework

Interoperability framework enables a structured and efficient data sharing between complementary health information systems. Health information sub systems need to exchange information with each other. Additionally, health systems should draw data from outside sources including sectors commonly seen as the determinants for health such as water, agriculture, education etc. Establishing a solid and comprehensive HIE framework provides a blueprint for all future solutions to follow and conform to.

.	Description	Deliverables
Digital Health Priority 6	Extend the Interoperability Framework to enable exchange of data between health systems	All health systems at a minimum able to share data with the national DHIS 2 instance.

CHAPTER 6

Implementation Arrangements

CHAPTER 6

Implementation Arrangements

1. Risk Analysis

Effective implementation of the digital health strategy will require a functional coordination mechanism and tracking of organizations who have the responsibility to lead on specific activities. Inevitably, the implementation of this strategy is not without risks. When risks overshadow the ability to succeed the attainment of objectives can be constrained. To avoid failure in the implementation it is important to take a strategic approach to anticipate any potential obstacles for implementation and constitute mitigation strategies. Risk is made up of two parts: the probability of something going wrong, and the negative consequences if it does. Preparedness is necessary to mitigate both the probability and the negative consequences. Table 5 below presents the risks identified and mitigation strategies.

Table 5: Digital Health Risk Analysis

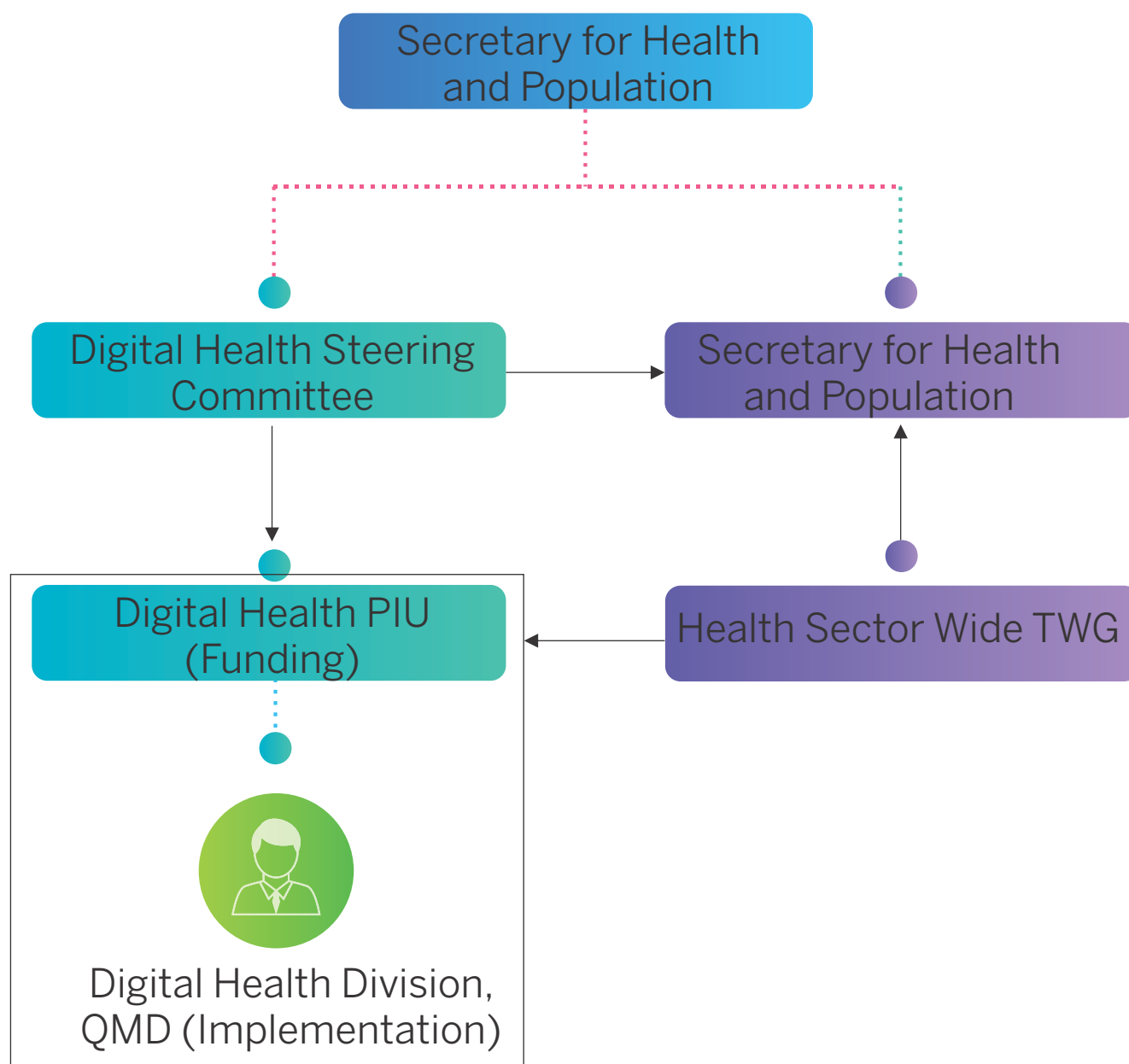
Risk Identification	Risk Analysis			Mitigation Strategy
	Likelihood	Impact/Consequence	Overall Risk	
Depreciation of local currency as related to budgeted costs	5	4	VH	Peg costs to US\$
Weak coordination mechanism	4	4	H	Ensure governance structures are active
Inadequate Human Resources for implementation	5	3	H	Follow up on functional review to incorporate more staff
Inadequate Financial Resources for implementation	5	5	VH	Lobby government and partners for increased funding .
Continued overreliance on external financing for health	5	4	VH	Lobby Government to increase funding towards digital health . Explore public -private partnership in health
Mismanagement of Financial resources	3	5	H	Enforcing adherence to public resources management guidelines through M and E processes.
Misalignment of digital health priorities between donors and government	3	4	H	Adherence to guidelines on introduction of new innovations.
Non compliance to SoPs and digital health standards	3	4	H	Enforce adherence to guidelines on development and use of digital health solutions.

Risk Identification	Risk Analysis			Mitigation Strategy
	Likelihood	Impact/Consequence	Overall Risk	
Inadequate digital health awareness	4	4	H	Sensitization campaigns at all levels of the health system
Rapid changes in digital health developments	4	3	H	Participation in local and International events. Enhance research and development on new technologies.
Low ICT penetration	3	4	H	Investment in infrastructure development.
Digitalizing inefficient health service delivery processes	4	5	VH	Lobby for government to conduct business process re-engineering .
Inadequate (unreliable & inaccessible) main grid power supply	5	4	VH	Invest in alternative power energy sources : renewable and hybrid power systems.
Digital Systems Fragmentation	4	4	H	Strengthen coordination and compliance to digital health guidelines; harmonization of systems.
Resistance /Slow adoption of digital solutions	4	4	H	Development of a change management and capacity building strategy.

2. Coordination

The implementation of digital health shall be lead within the Ministry of Health by the Directorate of Quality Management and Digital Health. While the Director is the primary decision maker, the decision process will be supported by permanent structures and temporally structures will be set up based on need. Figure 10 presents a governance framework for digital health in Malawi. The key structures in this framework are the Directorate of Quality Management and Digital Health, the Digital Health TWG and its sub TWGs and the Digital Health Steering Committee. The steering committee is the high level policy structure while the TWG is a technical implementation guidance team comprising the government, development partners and the private sector. The terms of reference for these structures are articulated separately in a document describing digital health leadership and governance in Malawi. The Steering Committee will meet twice a year while the TWG will meet quarterly. The Directorate of Quality Management and Digital Health is responsible for data to day digital health operations and is the central coordination point for all digital health initiatives.

Figure 10 : Digital Health Leadership and Governance Structure



3. Implementation Roles

For the implementation of the digital health strategy to be successful there is need to clearly identify roles for each stakeholder to ensure ownership of responsibility and accountability. The execution of other activities in the plan falls outside the purview of the MoH due to the nature of those activities. Within the Ministry of Health the primary stakeholders include the Directorate of Quality Management and Digital Health, the Department of Planning and Policy Development through the Central Monitoring and Evaluation Division, the Directorate of Administration through the ICT Section and all the Departments and programs. Outside the MoH, the Department of E-Government in the Ministry of Information, the Malawi Communications Regulatory Authority and the Ministry of Local Government and Rural Development. Table 6 presents the activities and the stakeholder responsible for each activity.

Table 6: Digital Health Roles and Responsibilities

Activity	Primary Responsible	Secondary Responsible
Strategy 1.1: Strengthen leadership and governance structures for management of digital health interventions		
1.1.1 Establish governance structures and processes for digital health	DPPD	IT/CMED
1.1.2 Conduct quarterly updates on the progress of the digital health strategy implementation	DPPD	IT/CMED
1.1.3 Facilitate harmonization of digital health systems	DPPD	IT/CMED
1.1.4 Facilitate digital health change management	DPPD	IT/CMED
Strategy 1.2 Create an enabling environment for effective implementation of digital health solutions through appropriate legislation, policies and compliance mechanisms		
1.2.1 Disseminate digital health related standards	DPPD	IT/CMED
1.2.2 Enforce adherence to the digital health standards	DPPD	IT/CMED
1.2.3 Support implementation of Standard Operating Procedures (SOPs)	DPPD	IT/CMED
Strategy 1.3 Strengthen Sustainability mechanism for digital health solutions		
1.3.1 Develop and enforce sustainability measures for digital health solutions		
1.3.2 Develop a common and coordinated investment framework for digital health interventions	DPPD	DPPD
1.3.3 Facilitate continuity of digital health interventions in light of donor transitions	DPPD	DPPD
1.3.4 Collaborate with innovation hubs and research institutions to incubate solutions for digital health	QMD	IT/CMED
Strategy 2.1: Improve capability of connectivity in poorly covered areas (i.e. areas with no or intermittent connectivity)		
2.1.1 Engage government departments and Mobile Service Providers about increasing ICT Infrastructure in off-grid or poorly connected areas	eGovernment	MACRA
2.1.2 Ensure internet and network connectivity in all health facilities	eGovernment	Health ICT

Strategy 2.2: Extend coverage of renewable and hybrid power solutions		
2.2.1 Define specifications for renewable and hybrid power solutions	PAM	
2.2.2 Deploy hybrid power solutions in health facilities	PAM	
Strategy 2.3: Improve availability of computing infrastructure and devices		
2.3.1 Facilitate local hosting of health data	ICT	CMED/DPPD
2.3.2 Facilitate availability of computing devices in health facilities	DPPD	ICT
2.3.3 Maintain standard specifications for computing devices	ICT	
Strategy 3.1: Increase capacity of health workforce to implement and utilize digital health interventions		
3.1.1 Train health care workers and IT personnel in digital health solutions	ICT/DPPD	HRMD
3.1.2 Facilitate increased numbers of skilled ICT personnel to support implementation of digital health solutions	eGovernment	DPPD/HRMD
3.1.3 Introduce an eLearning platform for CPD	DPPD	ICT
3.1.4 Introduce capacity building and skills transfer to government as part of implementation of new and existing digital health solutions	DPPD	HRMD
Strategy 4.1 Use innovative digital health technologies to increase access and quality of health (Also refer to MEHIS Activity 3.6)		
4.1.1 Increase coverage of existing digital health solutions	DPPD	ICT
4.1.2 Extend use of Picture Archive and Communication System (PACS) to more facilities	DPPD	ICT
4.1.3 Facilitate coordinated implementation of mHealth Solutions	DPPD	
4.1.4 Improve performance of the current EMRs	Implementing Partners	DPPD
4.1.5 Saturate functionality to already installed facilities	Implementing Partners	DPPD
4.1.6 Scale out EMRs to non EMR facilities	Implementing Partners	DPPD
4.1.7 Increase accessibility of data from digital health solutions	DPPD	ICT
4.1.8 Strengthen management of health research and data	Research Unit (NHSRC)	CMED

Strategy 4.2: Leverage use of predictive analytics and big data to improve health service delivery		
4.2.1 Mobilize resources to perform predictive analytics	DPPD	
4.2.2 Identify questions that need to be answered with predictive analytics	DPPD	
4.2.3 Utilize predictive analytics for proactive and accurate health service delivery	DPPD	Clinical/Nursing
Strategy 4.3: Align digital health interventions with comprehensive digital health architecture		
4.3.1 Update national HIS architecture to a comprehensive digital health architecture	ICT	
4.3.2 Disseminate national comprehensive digital health architecture to relevant stakeholders	ICT	
Strategy 5.1: Ensure continuity of service delivery in all service delivery points in cases of disasters and loss of property		
5.1.1 Conducting a risk analysis to assess risk areas and interventions	ICT	
5.1.2 Enforce implementation of Disaster Recovery SOP	ICT	
Strategy 5.2: Develop and deploy standardized security management process in health sector to promote acceptable use of data and related tools, including hardware and software		
5.2.1 Implement security management process standard within the health sector	ICT	DPPD
5.2.2 Strengthen and deploy digital health interventions security breach response system	ICT	DPPD
Strategy 5.3: Address ethical issues in digital health in order to promote privacy and security of clients data		
5.3.1 Implement and enforce Data Access and Release SOPs	CMED	
5.3.2 Develop a tracking system of all authorized data accesses and disposal policy for ease follow up	CMED	
5.3.3 Conduct targeted orientation on privacy and confidentiality ethical issues (Partners as well as researchers)	CMED	Research Unit (NHSRC)
Strategy 5.4: Ensure that digital health information and users are protected from undesirable threats including physical threats (fraud and theft), malwares, breach of privacy, misuse of information		
5.4.1 Implement user account management	ICT	DPPD

5.4.1 Enhance physical security controls in all digital health systems	ICT	DPPD
5.4.2 Implement and adhere to security measures in line with Public Service ICT Standards	ICT	DPPD
6.1: Lead efforts to ensure that longitudinal and cross-sectional patient health records are accessible at the point of service delivery		
6.1.1 Define and adopt minimum specifications and framework for EHRs	DPPD	
6.1.2 Implement national terminology service	CMED	DPPD/Clinical/Nursing
6.1.3 Implement comprehensive and integrated, user centered and secure EHR system	DPPD	Implementing partners
Strategy 6.2: Strengthen the identification of clients and staff across the health system		
6.2.1 Leverage the National ID for clients unique identification in the health sector	DPPD	Implementing partners
6.2.2 Develop a system for professional IDs for health workers	DPPD/Regulatory bodies	HRMD
Strategy 7.1: Implement a standard framework as a national standard for interoperability		
7.1.1 Facilitate training in international systems interoperability	DPPD	ICT
7.1.2 Develop data dictionary in line with recommended standards for all digital health interventions (All digital health systems must have its data dictionary)	Implementing partners	DPPD
7.1.3 Define and implement guidelines and SoPs on interoperability of systems	DPPD	
7.1.4 Facilitate the implementation of interoperability using the OpenHIE framework	DPPD	ICT
Strategy 7.2: Implement interoperability among priority systems		
7.1.5 Facilitate alignment of systems to the interoperability framework	DPPD	ICT
7.1.6 Roll-out interoperability among systems in a phased approach	DPPD	ICT

Activity	2019/20		2020/21		2021/22		2022/23		2023/24	
	H1	H2	H1	H2	H1	H2	H1	H2	H1	H2
Strategy 1.1: Strengthen leadership and governance structures for management of digital health interventions										
1.1.1 Establish governance structures and processes for digital health										
1.1.2 Conduct quarterly updates on the progress of the digital health strategy implementation										
1.1.3 Facilitate harmonization of digital health systems										
1.1.4 Facilitate digital health change management										
Strategy 1.2 Create an enabling environment for effective implementation of digital health solutions through appropriate legislation, policies and compliance mechanisms										
1.2.1 Disseminate digital health related standards										
1.2.2 Enforce adherence to the digital health standards										
1.2.3 Support implementation of Standard Operating Procedures (SOPs)										
Strategy 1.3 Strengthen mechanism for digital health solutions										
1.3.1 Develop and enforce sustainability measures for digital health solutions										
1.3.2 Develop a common and coordinated investment framework for digital health interventions										
1.3.3 Facilitate continuity of digital health interventions in light of donor transitions										
1.3.4 Collaborate with innovation hubs and research institutions to incubate solutions for digital health										

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5. Annual Implementation Plans

The execution of the digital health strategy will follow the activities in the annual implementation plan developed for each year. This plan will be made available to all stakeholders for input and commitment on the areas they will focus on.

CHAPTER 7

Monitoring and Evaluation

CHAPTER 7

Monitoring and Evaluation

Successful implementation of the digital health strategy relies on successful monitoring and evaluation of the activity implementation. Monitoring focuses on what is happening by routinely tracking services and program achievements against targets. Monitoring help ensure adherence to the direction established during strategic planning. With so many partners in the digital health environment, the Ministry need to closely monitor that every effort is aligning and supporting the planned direction through the digital health strategy. Two key areas will therefore be focused on. First is to ensure that activities are kept within the parameters of the agreed strategic aims and objectives. And second, is to ensure that activities are consistent with the strategic vision, mission and values. To ensure successful digital health monitoring the following tools will be used:

- i. **The Annual Implementation Plan.** The Ministry will conduct regular reviews and audits of the annual implementation plans to track implementation progress and adherence.
- ii. **Digital health investment framework.** The Ministry will maintain in collaboration with the DPPD's Aid Coordination Unit a mapping of partners and investments in digital health. This will help track where resources are going and where gaps exist.
- iii. **Semi-Annual Performance Reports.** These will articulate the progress in implementation of specific activities and objectives. The digital health steering committee and TWG will receive these reports.

On the other hand, Evaluation is the periodic assessment of effectiveness focusing on whether the goal or objective was achieved, and why or why not. Key techniques in strategy evaluation include gap analysis which is used to determine the difference between the current position and the desired position; SWOT analysis which analyses strengths, weaknesses, opportunities and threats; bench marking and the balanced score card.

Notwithstanding the approaches highlighted above, the key inputs into monitoring and evaluation are the performance metrics which provide either in quantitative or qualitative form the progress of implementing the strategy. These metrics are also known as indicators. There are five types of indicators categorized as inputs, process, output, outcome and impact indicators. Input indicators measure the level of resources put into programs; process indicators measure the activities and milestones to enable service delivery to be implemented as planned; output indicators measure the volume and percent of people provided with services, and the quality of the services provided; outcome indicators measure the effect on behaviors. In the case of the strategy it will measure the effect of digital health on how work is done; impact indicators will measure and provide evidence that the purported improvement in health service delivery was as a result of the strategy implementation. The process below shows how these types of indicators relate to each other.

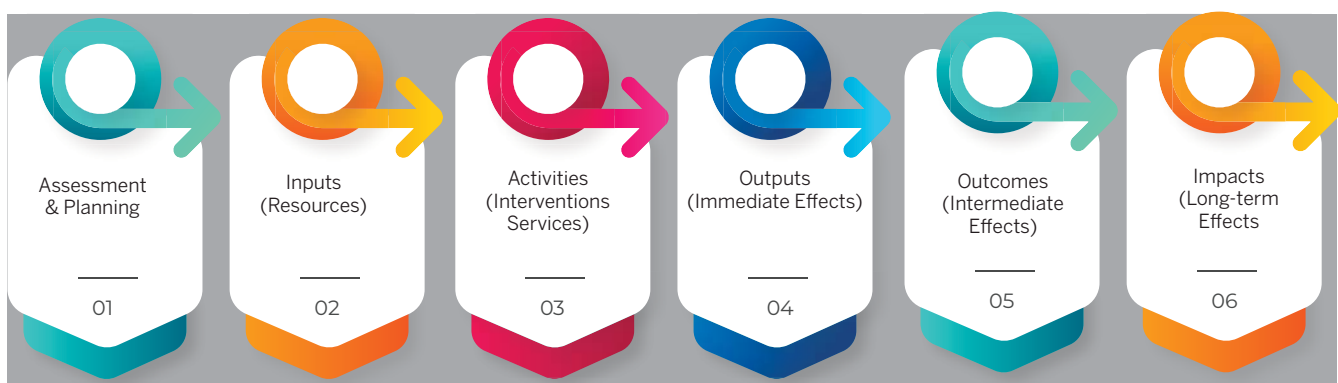


Table 8 below is a listing of the indicators to be used in monitoring the implementation of the digital health strategy.

Table 8: Digital Health Indicator Matrix

Objective	Indicator	Domain/Type	Baseline	Target 2021	Target 2023	Period of Reporting
1.0 Improved coordination of digital health investments to increase efficiency	Proportion of (digital Health) TWG meetings conducted	Process	0	12 (3*4)	20 (5*4)	Annual
	Proportion of digital health SOPs that are being implemented.	Process	0	50%	100%	Annual
	Survival rate for digital health solutions	Outcome	No data	80%	100%	Annual
2.0 Establish a reliable ICT infrastructure that enables utilization of digital health systems	Proportion of health facilities with internet connectivity	Input	TBD	50%	100%	Annual
	Proportion of health facilities with renewable and hybrid power solutions for digital health solutions	Input	TBD	50%	100%	Annual
	Proportion of digital health information solutions that are hosting their data locally.	Process	TBD	80%	100%	Annual
Objective 3: Build the capacity of consumers, communities, human resources for health to participate in and benefit from digital health interventions.	Proportion of health care workers that have undergone CPD per year through eLearning	Output	0	20%	60%	Annual
	Proportion of health care workers and ICT personnel that have undergone digital health module training per year	Output	No data	50%	100%	Annual
	Proportion of ICT positions filled	Input	–	TBD	100%	Annual

	Proportion of health and ICT training institutions that have included digital health modules within the curriculum for pre-service training	Input	TBD	TBD	100%	Annual
Objective 4: Leverage technology to increase access to and quality of service delivery.	Proportion of health facilities with EHRs covering all service areas (hospital wide system)	Input	0	20%	50%	Annual
	Proportion of facilities with tele- health systems	Input	TBD	10%	30%	Annual
	Proportion of digital solutions that are aligned to the ICT architecture	Output	0	50%	80%	Annual
Objective 5: Improve security of information and digital health systems	Proportion of annual security audits conducted	Output	0	40%	100%	Annual
	Proportion of systems that are abiding to the security SoPs	Output	0	50%	100%	Annual
	Proportion of health facilities that pass the data security audits	Output	0	60%	80%	Annual
Objective 6: Promote continuity of care through the shared health record	Proportion of health facilities with EHR System	Input	0%	20%	50%	Annually
	Proportion of health facilities that are able to share Electronic Health Record	Outcome	0%	20%	50%	Annually
	Proportion of health workers with identity cards	Process	0%	50%	100%	Annual

Objective 7: Strengthen the sharing and accessibility of data across systems to enable use	Number of ICT staff that have undergone Interoperability training	Input	0	20	30	Annual
	Proportion of digital solutions that have a data dictionary	Process	TBD	100%	100%	
	Proportion of digital health solutions that are interconnecting using the Interoperability framework	Output	0%	20%	30%	Annual

CHAPTER 8

Financing

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Financing

Financing is at the core of successful implementation of the digital health strategy. The direction of the Ministry is to get maximum value from both existing and future investments by ensuring that funds are leveraged on existing interventions to avoid duplication or repetition. The Ministry is therefore harmonizing all investments from both financing and intervention perspectives. As part of its implementation strategy the Ministry will annually update the digital health investment framework.

Digital Health PIU

The Ministry has established the Digital Health PIU as a central coordination unit and financing mechanism for all investments in digital health. In collaboration with donors, the Ministry will, therefore, take the role of allocating intervention areas to implementing partners based on gaps in the implementation of this strategy.

Digital Health Budget

The financial resource requirements for digital health in the next five years are presented in Table 9 below. The budget was generated through costing the activities identified under each strategy and objective. The Digital Health Strategy Taskforce took a leading role in costing the strategy.

Table 9: Activity Level Budget

	Cost (MK)	Cost (USD)
Objective 1: Improved coordination of digital health investments to increase efficiency		
Strategy 1.1: Strengthen leadership and governance structures for management of digital health interventions		
1.1.1 Establish governance structures and processes for digital health	549,932,283	753,332
1.1.2 Conduct quarterly updates on the progress of the digital health strategy implementation	0	-
1.1.3 Facilitate harmonization of digital health systems	7,166,147	9,817
1.1.4 Facilitate digital health change management	78,367,000	107,352
Strategy 1.2: Create an enabling environment for effective implementation of digital health solutions through appropriate legislation, policies and compliance mechanism		
1.2.1 Disseminate digital health related standards	49,903,000	68,360
1.2.2 Enforce adherence to the digital health standards	44,639,233	61,150
1.2.3 Support implementation of Standard Operating Procedures (SOPs)	51,473,333	70,511
1.2.4 Facilitate accessible design for people with physical challenges	11,132,000	15,249
Strategy 1.3: Strengthen Sustainability mechanism for digital health solutions		
1.3.1 Develop and enforce sustainability measures for digital health solutions	46,396,167	63,556
1.3.2 Develop a common and coordinated investment framework for digital health interventions	70,000	96
1.3.3 Promote continuity of digital health interventions in light of donor transitions	1,952,000	2,674
1.3.4 Collaborate with innovation hubs and research institutions to incubate solutions for digital health	22,122,267	30,304

Objective 2: Establish a reliable ICT infrastructure that enables utilization of digital health systems (Also refer to MEHIS Activity 2.9)		
Strategy 2.1: Improve capability of connectivity in poorly covered areas (i.e. areas with no or intermittent connectivity)		
2.1.1 Engage government departments and Mobile Service Providers about increasing ICT Infrastructure in off-grid or poorly connected areas	17,752,833	24,319
2.1.2 Facilitate internet and network connectivity in all health facilities	2,270,847,300	3,110,750
Strategy 2.2: Extend coverage of renewable and hybrid power solutions		
2.2.1 Define specifications for renewable and hybrid power solutions	85,000	116
2.2.2 Deploy hybrid power solutions in health facilities	1,109,171,050	1,519,412
Strategy 2.3: Improve availability of computing infrastructure and devices		
2.3.1 Facilitate local hosting of health data	420,946,717	576, 639
2.3.2 Facilitate availability of computing devices in health facilities	114,921,967	157,427
2.3.3 Maintain standard specifications for computing devices	54,143,167	74,169
Objective 3: Build the capacity of consumers, communities, human resources for health to participate in and benefit from digital health interventions.		
Strategy 3.1: Increase capacity of health workforce to implement and utilize digital health interventions		
3.1.1 Train health care workers and IT personnel in digital health solutions	30,827,350	42,229
3.1.2 Facilitate increased numbers of skilled ICT personnel to support implementation of digital health solutions	1,076,000	1,474
3.1.3 Introduce an eLearning platform for CPD	71,616,900	98,105
3.1.4 Introduce capacity building and skills transfer to government as part of implementation of new and existing digital health solutions	19,316,000	26,460

Objective 4: Leverage technology to increase access to and quality of service delivery.			
Strategy 4.1: Use innovative digital health technologies to increase access and quality of health (Also refer to MEHIS Activity 3.6)			
4.1.1 Increase coverage of existing digital health solutions	154,733,500		211,964
4.1.2 Extend use of Picture Archive and Communication System (PACS) to more facilities	394,164,800		539,952
4.1.3 Implement a drug and essential commodity dispensation management system	4,104,353,350		
4.1.4 Implement a Laboratory Information management system (LIMS)	4,104,353,350		
4.1.5 Facilitate coordinated implementation of mHealth Solutions	1,929,766,600		2,643,516
4.1.6 Improve performance of the current EMRs	186,425,500		255,377
4.1.7 Saturate functionality to already installed facilities	3,333,198,400		4,566,025
4.1.8 Scale out EMRs to non EMR facilities	2,808,264,000		3,846,937
4.1.9 Increase accessibility of data from digital health solutions	322,470,600		441,741
4.1.10 Strengthen management of health research and data	155,844,150		213,485
Strategy 4.2: Leverage use of predictive analytics and big data to improve health service delivery			
4.2.1 Mobilize resources to perform predictive analytics	52,668,300		72,148
4.2.2 Identify questions that need to be answered with predictive analytics	9,403,000		12,881
4.2.3 Utilize predictive analytics for proactive and accurate health service delivery	178,296,500		244,242
Strategy 4.3: Align digital health interventions with comprehensive digital health architecture			
4.3.1 Update national HIS architecture to a comprehensive digital health architecture based on the government national ICT architecture	10,809,200		14,807
4.3.2 Disseminate national comprehensive digital health architecture to relevant stakeholders	1,700,000		2,329

Objective 5: Improve security of information and digital health systems				
Strategy 5.1: Ensure continuity of service delivery in all service delivery points in cases of disasters and loss of property				
5.1.1	Conducting a risk analysis to assess risk areas and interventions		17,711,067	24,262
5.1.2	Enforce implementation of Disaster Recovery SOP		12,146,667	16,639
Strategy 5.2: Develop and deploy standardized security management process in health sector to promote acceptable use of data and related tools, including hardware and software				
5.2.1	Implement security management process standard within the health sector		10,412,300	14,263
5.2.2	Strengthen and deploy digital health interventions security breach response system		198,897,000	272,462
Strategy 5.3: Address ethical issues in digital health in order to promote privacy and security of clients data				
5.3.1	Implement and enforce Data Access and Release SOPs		198,630,000	272,096
5.3.2	Develop a tracking system of all authorized data accesses and disposal for ease follow up		134,023,400	183,594
5.3.3	Conduct targeted orientation on privacy and confidentiality ethical issues (Partners as well as researchers)		387,820,000	531,260
Strategy 5.4: Ensure that digital health information and users are protected from undesirable threats including physical threats (fraud and theft), malwares, breach of privacy, misuse of information				
5.4.1	Implement user account management SOPs		69,312,667	94,949
5.4.2	Enhance physical security controls in all digital health systems		27,635,333	37,857
5.4.3	Implement and adhere security measures in line with Public Service ICT Standards		18,690,000	25,603

Objective 6: Promote continuity of care through the shared health record (Also refer to MEHIS Activity 3.6 and Activity 3.7)			
Strategy 6.1: Lead efforts to ensure that longitudinal and cross-sectional patient health records are accessible at the point of service delivery			
6.1.1 Define and adopt minimum specifications and framework for EHRs	45,139,017	61,834	
6.1.2 Implement national terminology service	228,002,683	312,332	
6.1.3 Implement comprehensive and integrated, user centered and secure EHR system	9,804,321,700	13,430,578	
6.1.4 Implement shared electronic health records	3,186,155,000	4,364,596	
Strategy 6.2: Strengthen the identification of clients and staff across the health system			
6.2.1 Leverage the National ID for clients unique identification in the health sector	1,283,451,000	1,758,152	
6.2.2 Develop a system for professional IDs for health workers	612,590,667	839,165	
6.2.3 Implement and adhere security measures in line with Public Service ICT Standards	225,699,500	309,177	
Objective 7: Strengthen the sharing and accessibility of data across systems to enable use (Also refer to MEHIS Activity 3.5)			
Strategy 7.1: Implement a standard framework as a national standard for interoperability			
7.1.1 Facilitate training in international systems interoperability frameworks and standards	41,347,883	56,641	
7.1.2 Develop data dictionary in line with recommended standards for all digital health interventions (All digital health systems must have its data dictionary)	51,169,150	70,095	
7.1.3 Define and implement guidelines and SoPs on interoperability of systems	5,563,500	7,621	
7.1.4 Facilitate the implementation of interoperability using the OpenHIE framework	1,358,768,450	1,861,327	
Strategy 7.2: Implement interoperability among priority systems			
7.2.1 Facilitate alignment of systems to the interoperability framework	22,851,700	31,304	
7.2.2 Roll-out interoperability among systems in a phased approach	118,632,050	162,510	
TOTAL	40,468,279,697	55,436,000	

