



**THE REPUBLIC OF UGANDA
MINISTRY OF HEALTH**

**Uganda National Health Laboratory
Services Policy II**

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ACRONYMS AND ABBREVIATIONS

AHPC	Allied Health Professions' Council
AIDS	Acquired Immunodeficiency Syndrome
AMR	Anti-Microbial Resistance
APHL	Association of Public Health Laboratories
ASLM	African Society for Laboratory Medicine
CDC	Centers for Disease Control and Prevention
CHAI	Clinton Health Access Initiative
CHEW	Community Health Extension Workers
CPHL	Central Public Health Laboratories
DTS	Dried Tube Specimen
EAPHLNP	East African Public Health Laboratory Networking Project
EQA	External Quality Assurance
EU	European Union
GFATM	Global Fund to fight AIDS, Tuberculosis and Malaria
GHSA	Global Health Security Agenda
GoU	Government of Uganda
HEP	Health Education and Promotion
HIV	Human Immunodeficiency Virus
HLIMS	Health Laboratory Information Management System
HMIS	Health Management Information System
HR	Human Resource
HSSIP	Health Sector Strategic and Investment Plan
IDI	Infectious Diseases Institute
IDSR	Integrated Disease Surveillance and Response
IHR	International Health Regulations
ISO	International Organization for Standardization
JCRC	Joint Clinical Research Centre
JICA	Japan International Cooperation Agency
JMS	Joint Medical Stores
M&E	Monitoring and Evaluation
MCH	Maternal and Child Health
MOH	Ministry of Health
NCD	Non Communicable Diseases
NDA	National Drug Authority
NEQAS	National External Quality Assurance Scheme
NHLSP	National Health Laboratory Services Policy
NHP	National Health Policy
NMS	National Medical Stores
NTLP	National Tuberculosis and Leprosy Program
NTRL	National Tuberculosis Reference Laboratory
PEPFAR	President's Emergency Plan for AIDS Relief

PNFP	Private Not for Profit
POC	Point of Care
POCT	Point of Care Testing
PPPH	Public Private Partnership for Health
SLIPTA	Stepwise Laboratory Improvement Process towards Accreditation
SLMTA	Stepwise Laboratory Management towards Accreditation
SOPs	Standard Operating Procedures
STD	Sexually Transmitted Diseases
TAG	Technical Advisory Group
TAT	Turn Around Time
TB	Tuberculosis
TIG	Technical Implementation Group
UAHPC	Uganda Allied Health Professionals' Council
UBTS	Uganda Blood Transfusion Services
UCMB	Uganda Catholic Medical Bureau
UMDPC	Uganda Medical and Dental Practitioners' Council
UMLTA	Uganda Medical Laboratory Technology Association
UMMB	Uganda Muslim Medical Bureau
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNHL	Uganda National Health Laboratory
UNHLS	Uganda National Health Laboratory Services
UNHRO	Uganda National Health Research Organization
UNMHCP	Uganda National Minimum Health Care Package
UPMB	Uganda Protestant Medical Bureau
UVRI	Uganda Virus Research Institute
VHT/CHEW	Village Health Teams / Community Health Extension Worker
WHO-AFRO	World Health Organisation-African Regional Office

FOREWORD

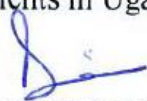
Accurate and reliable diagnosis is the cornerstone of disease management and prevention. Laboratories provide the bulk of available diagnostic techniques and are indispensable in healthcare delivery. A reliable and properly organized laboratory system generates information critical to individual case management, provides utility for disease surveillance and control, operational research towards invention of novel diagnostics and treatment schemes. Maintaining a functional and effective national health laboratory structure and network is a complex undertaking that requires guidance, support and regulation of well laid down policies.

A process to develop the National Health Laboratories Services Policy (NHLSP) was initiated in 2008 by the ministry in collaboration with partners. This initial effort culminated into the first Uganda National Health Laboratory Services Policy document (NHLSP Volume I) in 2009 that has been reviewed and updated into the current NHLSP Volume II.

Developed in the context of the National Health Policy II (NHP II), the Health Sector Strategic and Investment Plan (HSSIP II), the Public Private Partnerships for Health (PPPH) policy, Sustainable Development Goals (SDGs) and the National Development Plan II, the revised NHLSP is geared towards availing the people of Uganda with reliable laboratory services in support of the Uganda National Minimum Health Care Package (UNMHCP). The policy sets direction in 14 key areas that are fundamental towards attaining accessible and sustainable quality laboratory services in the country; organization and management; Laboratory Services delivery; laboratory facilities, biosafety and biosecurity; laboratory equipment and supplies; human resources; quality management systems; information systems; research and development; point of care testing services; partnerships; regulatory and legal framework; monitoring and evaluation; community; financing and accountability. The revised NHLSP II now recognizes point of care testing (POCT) as a critical step towards increasing community access to laboratory services.

For each of the 14 thematic areas, a number of feasible and cost-effective strategies have been outlined. The revised NHLSP II, will form a basis for the development of five year institutional strategic plans for various institutions within the national health laboratory network. This will enable delivery of robust and coordinated laboratory services in the country.

Therefore, I call upon all stakeholders of health laboratory services delivery to embrace the use of this document for planning, implementation and review of laboratory service investments in Uganda.



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Dr. Diana Atwiine
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Finally the Ministry is grateful to all institutions and individuals who have not been specifically mentioned above, but who directly or indirectly contributed to the successful development and finalization of this policy document.



.....
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GLOSSARY OF TERMS

Health Laboratory: In this document, the term 'health laboratory' is used to refer to a 'medical/clinical laboratory'. This is to reserve consistency with policy language used in other health sector policy documents.

Medical/Clinical Laboratory: The International Organization for Standardization (ISO) 15189:2012 defines a Medical/Clinical laboratory as a facility for the biological, microbiological, immunological, chemical, immunohaematological, hematological, biophysical, cytological, pathological, genetic or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, management, prevention and treatment of disease in, or assessment of the health of, human beings, and which may provide a consultant advisory service covering all aspects of laboratory investigation including the interpretation of results and advice on further appropriate investigation.

Laboratory client: These are persons that seek laboratory services either as patients and/or, researchers, clinicians, public health specialists, epidemiologists, students and others who may be seeking testing/clinical/preventive services.

Medical Laboratory practitioner: These are such persons that are trained, qualified, certified and licensed by a relevant body to provide medical laboratory services.

The Uganda National Minimum Health Care Package (UNMHCP): The UNMHCP comprises interventions that address the major causes of the burden of disease in the country. This package is the cardinal reference in determining the allocation of funds and other essential inputs for health in Uganda. It has the following four clusters:

- a) Communicable Disease Control (CDC)
- b) Non-communicable Disease Control (NCD)
- c) Maternal and Child Health (MCH)
- d) Health Education and Promotion (HEP)

Point of Care (POC) or Point of Care Testing (POCT); As used in this policy document, POC/POCT refers to a situation in which efforts are made to bring laboratory testing services closer to the community (for example; field testing, moonlight clinics, blood donor centers) or closer to patient care points within a facility (such as OPD, ANC, PMCT, HCT).

1.0 INTRODUCTION

1.1 Policy Rationale

Health laboratory services are essential for the delivery of quality health care and should be accessible to all the people in Uganda. Poor health laboratory services subject patients to inappropriate treatment, chronic ill-health, and catastrophic health expenditures, loss of incomes and ultimately loss of confidence in health services. Poor laboratory services are also costly in terms of high wastage of scarce public resources on ineffective treatment, loss of economic productivity of the population due to chronic illness and loss of life.

The National Health Laboratory Services Policy volume one (NHLSP I) was launched in 2009 to provide a regulatory framework for ensuring that the health laboratory services in Uganda are standardized and controlled to adequately support effective and efficient delivery of the Uganda National Minimum Health Care Package (UNMHCP). However the NHLSP I, has been overtaken by new health developments and global initiatives such as; OneHealth concept, Global Health Security Agenda, International Health Regulations, Universal Health Access, UNAIDS 90-90-90 goals for HIV response and the Point of Care (POC) testing strategies aimed at extending health laboratory services to the people. The NHLSP I has therefore been revised into NHLSP II to take into consideration the current health care development strategies.

The development and review of the previous NHLSP I involved extensive consultations with representatives from several stakeholder institutions, development partners, laboratory staff drawn from all levels of the tiered laboratory network, as well as review and analysis of several policy documents dealing with health issues in Uganda, in the African region and globally.

1.2 Roles and Responsibilities of the Health Laboratory Services

The government, together with development partners, have made commendable efforts towards improvement of health for the people of Uganda through the development of policies and establishment of appropriate programs to ensure implementation. The National Health Policy volume two (NHP II) advocates for "attainment of a good standard of health by all people in Uganda, in order to promote a healthy and productive life". To achieve this, all levels within the tiered laboratory network need to function coherently and effectively in order to provide quality laboratory services. This includes point of care (POC) services that provide increased access to essential diagnostic services.

Indeed, POC testing services not only reduce the therapeutic turnaround time (TAT), but also provide a basis for a correct diagnosis, rather than relying only on clinical symptoms. This promotes better management of diseases and faster recovery of patients. Reliable diagnostics services enhance trust between clinicians and laboratory practitioners, creating confidence in the overall health system.

Apart from the routine diagnosis and management of disease conditions, information derived from health laboratories immensely contributes towards health research, surveillance for priority diseases, identification of notifiable infections and anti-microbial resistance (AMR), management of disease outbreaks and forensic investigations. Health laboratories enhance adequate and timely health interventions, contribute towards early disease detection, response and prevention of infections of global importance. The latter heightens compliance to the Global Health Security Agenda (GHSA), Integrated Disease Surveillance and Response (IDSR), International Health Regulations (IHR) and the One Health concept.

1.3 Vision, Mission, Principles and Values, Objectives

1.3.1 Vision

Quality health laboratory services available and accessible to all people in Uganda

1.3.2 Mission

Provide quality, cost-effective and sustainable health laboratory services to the people in Uganda and to support health care delivery regionally and internationally.

1.3.3 Principles and Values

Implementation of the National Health Laboratory Services policy II (NHLSP II) will be guided by the following principles:

- a) **Quality** laboratory services
- b) **Accessibility** and **affordability** for laboratory testing services
- c) **Adequacy** and **Competency** of Laboratory workforce
- d) **Confidentiality** of patient information
- e) **Transparency** and **Accountability**
- f) **Equity** of services

1.3.4 Major Objectives

- a) To establish organizational and management structures for the effective coordination of laboratory services
- b) To develop, recruit, deploy, motivate, and retain adequate numbers of human resources for laboratory services
- c) To mobilize financial and logistical resources required to support the delivery of quality laboratory services

- d) To establish a robust and sustainable tiered laboratory network and a strong referral system with adequate testing capacity to provide equitable access to quality laboratory services.
- e) To establish a system for monitoring and evaluation of laboratory services, as well as support public health research and development
- f) To improve utilization of laboratory services through improved demand creation, community engagements and extension of point of care testing (POCT) technologies
- g) To strengthen partnerships by embracing global health initiatives such as One Health Approach, Sustainable Development Goals, UNAIDS, GHSA, IHR, Universal Health Access, IDSR and other global health initiatives for sustainable development
- h) To increase access to highly specialized health laboratory testing so as to reduce referral of patients and specimens outside Uganda.

To achieve the above objectives, the policy document highlights 14 thematic areas of laboratory systems strengthening namely: organization and management; Laboratory Services delivery; laboratory infrastructure, biosafety and biosecurity; laboratory equipment and supplies; human resources; quality management systems; information systems; research and development; point of care testing services; partnerships and development; regulatory and legal framework; monitoring and evaluation; community; financing and accountability. For each of the thematic areas, a situation analysis that clearly defines the status quo is provided and policy statements have been developed to guide the government and stakeholders towards strategic investments in the national health laboratory services delivery systems.

2.0 POLICY CONTEXT

The revised NHLSP II was formulated within the context of the following National, Regional and Global policies:

2.1 National Health Policy Context

The overall goal of the National Health Policy is "the attainment of good standards of health for all the people in Uganda, in order to promote a healthy and productive life". This will be achieved via an integrated approach to testing services and patient care. The main focus of this policy is delivery of a defined Uganda National Minimum Health Care Package (UNMHCP) through primary health care, equity, quality services and universal health access. Strengthening collaboration/partnerships with multiple stakeholders at both public and private sectoral levels is a key strategic approach for this policy. Development and implementation of the National Health Laboratory Services Strategic Plan (NHLSSP II) and

the national health laboratory standard guidelines will support effective implementation of the revised NHLSP II in Uganda.

The National Hospital Policy aims at providing equitable access to cost-effective hospital services on a sustainable basis for all people in Uganda, through improvement of the organization, capacity and management of the hospital and health facility network.

The Human Resources for Health Policy emphasizes the need to develop and maintain a health workforce that will equitably, effectively and efficiently support the delivery of the UNMHCP.

Other policies that guide the prevention and management of diseases such as malaria, TB, and HIV/AIDS all aim at supporting and promoting the health development agenda, and thus the overall development of the nation.

Review of the NHLSP I ensured that the NHLSP II document does not conflict with standing policies within the health environment and other service delivery sectors in Uganda.

2.2 International Policy Context

Concerted efforts to strengthen health laboratory systems and networks in Uganda have been made by the government in collaboration with various development partners; the World Health Organization (WHO), US President's Emergency Plan for AIDS Relief (PEPFAR), Global Fund to fight AIDS, Tuberculosis and Malaria (GFATM), the East African Public Health Laboratory Network (EAPHLN), Clinton Health Access Initiative (CHAI) and the World Bank. Uganda continues to benefit from these, and many more partnerships like; the Foundation for Innovative New Diagnostics (FIND), Bill and Melinda Gates Foundation, the Wellcome Trust, the European Union (EU), the British Department for International Development and the Japan International Cooperation Agency (JICA). With national and international implementing partners on the ground, the country has registered tremendous improvement in the extent and quality of laboratory service delivery.

PEPFAR II advocated for joint investments in health to achieve shared goals and objectives, mutual contributions, measurable outcomes and country ownership. The African Society for Laboratory Medicine (ASLM) advocates for laboratory strengthening initiatives on the continent. Uganda is a beneficiary through the Stepwise Laboratory Management (Improvement Process) Towards Accreditation (SLMTA/SLIPTA) programs.

Thus, revision of the Uganda National Health Laboratory Services Policy volume one (NHLSP I) has facilitated integration of the current international and regional policy initiatives towards health systems strengthening while cognizant of the One Health concept, and other International health and security drivers to which Uganda subscribes as a member state, for example; Global Health and Security Agenda (GHSA), the Maputo declaration (WHO 2008), International Health Regulations (IHR), Universal Health Access, and the

UNAIDS 2020 ambitious goals. The policy affirms strong commitment towards support for robust national, regional and international health care service delivery networks and systems of sharing knowledge.

3.0 SITUATIONAL ANALYSIS

3.1 National Health Laboratory Services

Appendices I and II illustrate key stakeholder agencies and groups that work harmoniously towards delivering quality health laboratory services in Uganda. An overview on the major role of key stakeholder groups is given below.

The delivery of health laboratory services in Uganda is through a tiered network of laboratories from HC III, IV, General Hospital, Regional Referral Hospital, National Referral Hospital, up to National specialized Reference Laboratories. Testing also happens outside laboratories at HC II and community levels by trained health workers using point of care technologies.

At the national level there are specialized laboratories serving as national referral centers such as the Central Public Health Laboratories (CPHL), Supra/National Tuberculosis Reference Laboratory (S/NTRL), the National STD Reference Laboratory, the Uganda Virus Research Institute (UVRI), the Joint Clinical Research Centre (JCRC), Uganda Cancer Institute (UCI), Mulago Histopathology Laboratory, Uganda Heart Institute (UHI) and the Uganda Blood Transfusion Services (UBTS), Entomology Reference Laboratory. In addition, the National Referral Hospitals at Mulago and Butabika have extended clinical laboratory reference facilities. At the sub national level there are 16 Regional Referral Hospitals, 112 general hospitals, 197 Health Centre IVs, and 1,289 Health Centre IIIs. To increase access to laboratory services, the country has created and equipped 100 laboratory hubs to facilitate testing and coordination of samples and results transport through the national sample and results transport referral network (NSRTN)

Anti-Microbial Resistance (AMR) is increasingly becoming a global threat impacting on the clinical outcomes of patient care and management thus increased cost of treatment and limited options with antibiotics. WHO has called upon member states to take necessary steps to address this threat. The recent WHO and GHSA Joint External Evaluation (JEE) for IHR-2017 revealed that Uganda still has limited capacity in the areas of antimicrobial resistance detection and surveillance of infections caused by AMR pathogens. To increase Uganda's capacity in AMR surveillance, five sentinel sites have been identified, namely; Arua, Mbale, Kabale and Mubende RRH laboratories as well as the national microbiology laboratory at CPHL as the reference center. The National Coordination Centre (NCC) for data on AMR surveillance is based at CPHL National Microbiology Reference Laboratory (NMRL). CPHL/NMRL works with Infectious Diseases Institute (IDI) on the Global Health Security Partner Engagement Project in Uganda. This project focuses on strengthening laboratory systems in areas of AMR, Biorisk Management, Infection Prevention and Control practices (IPC), and Antimicrobial stewardship at national and sub-national levels.

To bridge the gaps identified in the JEE, the GOU embraced the “One Health” concept and established a Multi-sectoral National AMR Task Force to strengthen country efforts against public health threats in the areas of zoonoses, food safety and AMR under the International Health Regulations (IHR) and the World Health organization.

In addition to the laboratories under the public system, there are private health laboratory service providers. These include Private not for Profit (PNFP) laboratories run by NGOs and faith-based organizations such as Uganda Catholic Medical Bureau (UCMB), Uganda Protestant Medical Bureau (UPMB), and Uganda Muslim Medical Bureau (UMMB) as well as those in private health facilities and stand-alone laboratories. There are also laboratories within various medical and laboratory training institutions.

3.2 Organization and Management

The management, coordination and supervisory responsibility for the various health laboratories is not under one entity:

- a) Health laboratories fall under the department of Integrated Curative Services
- b) Laboratory activities related to surveillance and public health emergence management are coordinated under the department of National Disease Control (NDC)
- c) Research laboratories are governed by the Uganda National Health Research Organization (UNHRO)

CPHL currently provides stewardship for the national laboratory network to guide the prevention of disease and promotion of health in Uganda through early detection of disease burden in order to achieve overall sustainable development. It is the technical focal point of laboratory services in the Ministry of Health which also provides reference testing. However, its present status as unit under NDC constrains its ability to effectively handle its dual role. The revised MOH structure (2016) positioned laboratories in the department of integrated curative services.

Efforts are under way to establish the Uganda National Health Laboratory Services (UNHLS) by a parliament Bill (UNHLS Bill, 2016) to offer coordination, management and stewardship of all health laboratory services. The UNHLS is meant to coordinate all health laboratories including specialized reference laboratories such as CPHL and S/NTRL as well as all lower level health laboratories in the tiered health care system.

The Uganda Virus research institute (UVRI), Uganda Cancer institute (UCI), Tropical Diseases Institute (TDRI) and the Natural Chemotherapeutic Research Institute (NCRI) shall continue to be governed and controlled by the Uganda National Health Research Organization. These laboratories are mandated by the UNHRO ACT (2009, 2011) to conduct health related research in specified areas. Laboratories under UNHRO shall continue to collaborate with UNHLS to provide laboratory testing capacities that have not yet been established within the UNHLS network.

3.3 Infrastructure, Biosafety and Biosecurity

Draft national infrastructure guidelines have been developed to guide the designing, construction and remodeling of laboratory infrastructure. In the past five years, considerable efforts have been made towards the improvement of laboratory infrastructure in selected hubs and lower level facilities. The GOU together with development partners has improved infrastructure at National Reference Laboratories (NTRL and CPHL), and the National Referral Hospital (Mulago), Regional Referral Hospitals (50%), General hospitals (11%) have been improved. Despite these achievements, the majority of laboratory facilities are still in need of infrastructure upgrade to meet the nationally recommended infrastructural standards for ideal biosafety and biosecurity practices. Some facilities, especially those that have been recently upgraded from HC II to HCIII and IV, have not realized substantive improvement in their laboratory infrastructure to meet the increased level of service delivery.

From the Facilities Biorisk Management Assessment 2016, Laboratory space was not adequate in all NRHs and HCIIIs as well as 50% of RRHs, GHs and HCIVs. In 75% of the facilities assessed, the buildings were secure but 80% could not profile the risk of the organisms they were handling. Reporting of incidents and response to chemical exposures was weak at most facilities. Overall, biosafety and biosecurity manuals, policy and guidelines were lacking in most facilities, however, there was improved power supply (80%) and back up (60%).

The enhanced capacity of laboratory hubs to serve as centralized testing points and specimen referral centers has improved the quality of laboratory services delivery in the country, however, the large volume of samples handled at hub laboratories creates greater risks to health workers. This compromises the safety of laboratory personnel, laboratory users and the community.

Biosafety and biosecurity needs have received nationwide attention and support from various stakeholders. Nevertheless, most laboratories especially at GHs, HCIVs and HCIIIs remain inadequate in terms of biosafety and biosecurity systems, occupational health and safety strategies, safe waste disposal mechanisms, and infection prevention and control mechanisms. Biosafety and biosecurity measures in many health facilities are not robust enough to meet requirements for occupational health and safety programs. The GHSA assessment (MOH unpublished report, April 2016) for biosafety biosecurity performance indicated that many facilities were still below average at 41%.

Despite the fact that the national biosafety and biosecurity program has conducted refresher trainings of over 700 laboratory personnel and 56 trainers of biosafety and biosecurity have been assigned in all health regions, there is still limited knowledge and skills on biorisk management, procurement of safety supplies and equipment, safety auditing of facilities and incident management responses by personnel and managers.

3.4 Human Resource

Human Resource (HR) is the most valuable resource in the national health laboratory system. The Laboratory workforce is comprised of a number of cadres including laboratory managers, phlebotomists, technicians, scientists, pathologists and laboratory support staff. The laboratory workforce interfaces with a range of professionals including clinicians, public health officers, nurses, managers, staff working in the support services as well as the community. The World Health Organization (WHO) has recognized the critical shortage of laboratory professionals on the African continent. This has been attributed mainly to staff migration across sectors and countries as a result of poor remuneration and motivation. Institution of measures to attract and retain qualified, competent staff appropriate for all levels of the National Health Laboratory systems has been recommended to mitigate this challenge.

At the national level, the Ministry of Health Policy on Human resources for health acknowledges the importance of Human Resource, including the health laboratory workforce, and advocates for due prominence to be given to it and its related functions. The Policy also emphasizes that an efficient and effective health care system largely depends on the availability of carefully planned, effectively trained, equitably distributed and optimally utilized health workers. Laboratory services in Uganda are provided by pathologists, scientists, technologists, technicians and laboratory assistants. Microscopists and laboratory attendants who in the recent past, formed a significant proportion of the laboratory workforce were phased out during implementation of the 2010-2015 national health laboratory services strategic plan.

There are public and private institutions that train laboratory professionals at certificate, diploma, undergraduate and postgraduate levels. Despite the existence of the laboratory training institutions and the seemingly large number of different cadres of laboratory work force produced every year, staffing of laboratory units continues to remain poor due to restrictive wages, inappropriate staffing norms and outdated scheme of service. Training of high level laboratory specialists such as immunologists, toxicologists, mycologists and histo-chemists is very limited, hence the lack of many of the specialized laboratory services in the country. Only a small portion of the laboratories in the national laboratory network meet the recommended staffing norms. Moreover, the staffing norms currently being followed have not been reviewed for a long time and therefore are not in line with current demands. Due to this acute shortage of human resource, Implementing Partners, with support from PEPFAR and other development partners have filled the gap by recruiting higher level cadres at various levels of service delivery.

There is a pertinent need to absorb the trained pool of specialists in key areas to provide the capacity necessary for the National Health Laboratory Services. Although the National Scheme of Service is under review to address this concern, there is need to fast track its approval and adoption to absorb all the available laboratory professionals. In addition, there is need to plan and implement a national scheme for continuous professional development of laboratory cadre-ship. In-service training programs and their co-ordination have greatly

improved over the last couple of years. A training master plan was developed in 2013 and this has guided stakeholders fairly well in implementing their training programs. Standard curricula have been developed in many thematic areas e.g. HIV testing, TB microscopy, Integrated Disease Surveillance and Response, SLMTA, Logistics management, but similar curricula are yet to be developed in a few other critical areas like biorisk management, diagnosis of opportunistic infections, ethics and professional code of conduct and global health security agenda. There is also need to intensify provision of courses in laboratory management and leadership for laboratory managers at all levels.

3.5 Equipment and Supplies

Laboratory supplies and equipment are procured according to the national procurement guidelines. There is a stakeholders' quantification exercise that annually determines nationwide procurement needs usually based on supply chain rationalization. Following standardization of laboratory tests, supplies and equipment, a list of the requirement for laboratory supplies and equipment at the different levels of care is put in place for facilities to use while placing orders at the respective warehouses. Laboratory supplies are procured through the National Medical Stores (NMS) for public facilities and Joint Medical Stores (JMS) for Private Not for Profit (PNFP) facilities and the warehouses have a streamlined distribution system based on orders from respective facilities.

The Government of Uganda (GoU) has stepped up health financing to meet the Uganda national minimum health care package (UNMHCP). However laboratory commodity budgeting has not been increased to match current demands. There is inconsistent supply of laboratory commodities and interruption of lab services due to stock outs especially for items that are not empowered by development partners. Logistics management training and mentorship to build capacity for the lab staff to effectively manage stocks has been an area of focus in the last 5 years. However these efforts have been frustrated by poor infrastructure for lab commodity storage making it difficult for proper storage and inventory management. Even though a harmonized laboratory equipment list exists to guide procurement and donation of equipment in the country, laboratory reagents and general supplies have not been harmonized. Efforts to build capacity of regional equipment maintenance workshops have been made but the challenge is inadequate staffing and lack of facilitation for the maintenance engineers to visit lower level facilities. Automated equipment are not covered within the scope of work for the regional workshops as the majority do not have service contracts with MOH. Thus automated equipment maintenance has remained donor dependent and vertically skewed towards the control of HIV and TB. The current strategy is to build capacity for the biomedical engineers to maintain automated equipment, certify biosafety cabinets and to cascade these skills to lower level laboratories.

3.6 Quality of Services

The quality of Laboratory service delivery is based upon structures, processes and outcome. Inadequacy in laboratory performance systems such as the infrastructure, human resource, equipment and supplies compromise the quality of services delivered at many facilities. This

has caused loss of trust from laboratory customers at clinician and patient levels. Guidelines and standard operating procedures (SOPs) are not fully disseminated and implemented in many facilities including the private sector, and very few laboratories get regular technical support supervision due to limited capacity of the supervisory bodies. Only facilities involved in vertical programs such as TB and HIV/AIDS get regular in-service training and supervision.

There is no clearly developed and well-coordinated system for internal controls and external quality assessment scheme or established secretariat. The National External Quality Assessment (NEQAS) guidelines are still in development. Capacity to prepare panels locally is still low and restricted to a few vertical programs like Dried Tube Specimen (DTS) for HIV by UVRI, TB microscopy by NTRL and GeneXpert EQA by NTRL all coordinated in silos.

The majority of Laboratory tests on the national test menu are not monitored through EQA. Additional roles of the reference Labs in executing their roles as Technical Implementation/Advisory Groups (TIG/TAG) are not well defined as the NEQAS guidelines are still at the developmental stage. There is no national health laboratory accreditation body to set and promote improvement of quality and standards of laboratory services, although some measures are being undertaken in this area. The government together with development partners have rolled out a SLIPTA/SLMTA program to guide laboratories through a Stepwise quality improvement process towards accreditation. A national quality management master plan is also under development to guide quality and assurance and control operations country wide.

3.7 Health Laboratory Information Management System

The national primary data collection and reporting tools for laboratory data are paper based. While paper based health Management Information System (HMIS) data collection is affordable in the national health system, there is always a tradeoff between the size of the tool and the amount of information needed to satisfy clinical and public health needs. Review processes for paper based HMIS tools usually becomes lengthy and roll out is costly due to print, distribution and reprint requirements. The national specimen referral network as an innovation to bring services close to the people has presented an urgent need for timely, accurate and reliable data transfer systems to overcome the inconsistencies associated with paper based tools and reduce turnaround time (TAT).

Making use of electronic information systems across the health laboratory network will address these challenges. Over the past five years, CPHL has coordinated stakeholders in development and review of the national laboratory data tools to suit clinical and public health requirements. Ongoing efforts in the development of a national health laboratory information system (HLIMS) will enable linkage of national referral laboratories to lower level health facilities. The move will facilitate efficient sample and results relay and effective monitoring of laboratory operations for timely decision making.

3.8 Regulatory Framework

Regulation provides the legal framework to ensure safe, quality laboratory operations and to protect the people from sub-standard and unethical laboratory practices. A national regulatory framework establishes requirements for registration and licensing of laboratory facilities and the laboratory workforce. The purpose of the regulation is to ensure that the right practitioners deliver laboratory services and their environment meets acceptable standards and that the delivery of the services is ethical.

Laboratory services in Uganda are regulated under the Allied Health Professionals Act of 1996. The Act mandates the Allied Health Professionals Council (AHPC) to register and license all laboratory professionals before they can practice. The council is also empowered under the same Act to register and license all laboratories, public, private as well as private not for profit facilities.

However, pathologists registered under the Uganda Medical and Dental Practitioners Council (UMDPC) operate laboratories which are not registered by AHPC. There are also private clinics registered by UMDPC that house laboratories not registered by AHPC. This relaxed mechanism of registration and licensing of laboratories, encourages quack laboratory practices.

Currently, CPHL as the technical arm of the Ministry of Health on laboratory services, has provided technical support to AHPC to deliver its mandate as by law established. However, CPHL is a national specialized reference laboratory. Therefore, establishment of Uganda National Health Laboratory Services (UNHLS) with the mandate to provide nationwide stewardship for laboratory services will strengthen the regulatory framework of laboratory services and enable AHPC to effectively perform its mandate.

The Uganda Medical Laboratory Technology Association (UMLTA) has continued to provide capacity building and advocacy for laboratory professionals and bridging the gap between the professionals and their regulatory body.

The National Drug Authority (NDA) plays a role in regulating laboratory supplies and reagents, equipment and diagnostic devices but its ability to effectively operate in the medical laboratory sector has been hindered by lack of expertise, inadequate human resources and absence of operational policies and guidelines to influence regulation.

3.9 Monitoring and Evaluation

Currently there is no effective system or measurable indicators to assess the laboratory system's performance on whether it is effectively supporting the delivery of the UNMHCP. The monitoring and evaluation (M&E) system is being established with efforts from MOH and support from development partners.

Efficient and effective implementation of the NHLSP II will depend on quality laboratory testing, data generation and utilization for use in disease prevention and treatment. Establishment of a functional M&E system for health laboratory services in the country will enhance monitoring and evaluation of the indicators set in the NHLSP II and operational plan throughout the national health laboratory network.

3.10 Financing

The health laboratory services are grossly under-funded. There is no dedicated budget line for laboratory services at the national or district levels and this affects laboratory performance. National health laboratory services are hugely funded by development partners through grants to institutions and implementing partners. This has led to vertical funding based on priority diseases in the partnerships and sustainability is a threat. Funding through the government is insufficient and usually generalized to all medical reagents and supplies, a practice that leaves laboratory priorities marginalized. Therefore, there is need to establish a dedicated budget line by government, and to coordinate laboratory financing from all sources.

3.11 Community

Interface of laboratory services with the community remains an important factor to the access and utilization of laboratory services. Community has unrestricted access to drugs beyond facility-based health care, and thereby rendering self-medication and self-testing a common practice. Self-testing is being proposed as a strategic approach towards increasing diagnostic services. Community awareness of health laboratory services is limited, yet this is a requirement for effective disease prevention and control. All fevers are treated as malaria and coughs as acute respiratory tract infections in community and there is low community awareness of the importance to confirm etiology of a health event before starting medication. Therefore, community involvement in this policy is cognizant of the above situation and is motivated by the following developments in healthcare delivery: (a) the change in policy on management of malaria in 2012 that demands confirmation of etiology before starting treatment; (b) the VHT/ CHEW strategy that engages community in health care; (c) the new global Universal Health Coverage (UHC) that Uganda is adopting to replace the UMHCP; among others. This policy intends to increase community awareness and engagement in relation to laboratory services.

3.12 Partnerships

The National Policy on Public Private Partnerships for Health (September 2010) recommends the promotion and development of public-private partnerships as an effective strategy towards achievement of economic growth, health and wellness. By establishing a multi-sector health advisory committee, the ministry recognizes the strength of partnerships for effective health service delivery. The government acknowledged the role of public not for profit (PNFP) institutions in the delivery of laboratory services and included them in the credit line for laboratory supplies, personnel training and quality assurance programs.

Health services in Uganda have been decentralized. The Ministry of Local Government is

responsible for management of health services within respective districts. Development partners provide technical assistance and fund priority areas through grants, cooperative agreements, donations and/or contracts to institutions, local governments, central government and/or implementing partners. Faith based organizations and PNFPs institutions often complement government through delivery of quality services in hard-to-reach areas. Private for profit institutions often offer quality health services and their compliance to national programs such as immunization, HIV/AIDS interventions and national health data management systems is critical for the success of such programs. Attempts have been made to partner with private for profit facilities which provide a big percentage of laboratory services to the community. These attempts have not been very successful resulting in uncoordinated centralized monitoring in areas such as data sharing and utilization.

The GOU subscribes to the Global Health Security Agenda (GHSA) in a bid to strengthen partnerships towards prevention and control of diseases, outbreak investigations and detection of environmental threats to human and animals. MOH has since embraced the “One Health” approach to strengthen country efforts against public health threats in the areas of zoonoses, food safety and AMR. A coordination desk has been established at Emergence Operation Center (EOC) of MOH to coordinate partners under the “One Health” approach.

The current laboratory policy will ensure streamlining and consolidating partnerships towards effective delivery of quality laboratory services. This policy underscores the significance of partnerships framework through a dedicated centralized coordination mechanism.

3.13 Research and Development

Applied research within the health laboratory services network is a requirement aimed at solving local public health problems. Research innovations have the potential of delivering cost effective, reliable, accurate and quality diagnostic services. Applied research and implementation science in the Uganda National Health Laboratory Network is limited. There is no coordinated mechanism to prioritize research and development through adequate funding, training, coordination and management of the research agenda. Efforts are underway to streamline data collection through the national health laboratory information system and to promote the research agenda across the laboratory network. This policy is intended to address the gaps identified. Specific strategies such as the training of human resources, recruitment of higher-level cadres and infrastructure development will boost applied research and implementation science at all levels of the health laboratory network.

3.14 Point of care testing

The effective, efficient and equitable delivery of diagnostic testing services to the public is essential for implementation of the Uganda National Minimum Health Care Package (UNMHCP). Critical to the community extension of diagnostic services, is the development and employment of novel point-of-care testing (POCT) technologies. Both rapid diagnostic kits and portable diagnostic devices complement conventional testing services. Point of care

testing services increase access to quality diagnostics in resource constrained healthcare settings characterized by inadequate power supply, limited human resource capacity and poor infrastructure.

In the last decade, health laboratory services have experienced remarkable increase in the variety of point of care diagnostics on the market. A number of POCT technologies have been approved by WHO for diagnosis of malaria, tuberculosis, HIV and other diseases. However, many POCT technologies on the market have not been validated for use in-country. In addition, more efforts are needed to increase the scope of POCT in diagnosis of sophisticated tests like HIV and hepatitis B viral load, multi-drug resistant TB testing and other infections critical to the control of HIV/AIDS.

The development of the POCT policy, guidelines, standards and protocols to evaluate, verify and approve new POCT technologies and reagents for use in Uganda has been finalized. The POCT policy and implementation guidelines will create a framework for effective adoption of POCT technologies in Uganda.

3.15 Summary of key challenges

From sections 3.1 to 3.14, below are the key challenges:

- a) Lack of clear organizational structure and management that encompasses all the health laboratories, with clear roles and responsibilities, and leadership at the appropriate level within the Ministry of Health
- b) Poor infrastructure in public sector laboratories and lack of clear guidance on minimum infrastructural requirements
- c) Inappropriate scheme of service for the recruitment, deployment and retention of the current cadres of laboratory professionals in the public sector
- d) There is a weak mechanism for validation of laboratory equipment and supplies
- e) Weak laboratory quality management systems (LQMS) across laboratory network
- f) Weak and ineffective regulatory framework for laboratories
- g) Inadequate financing of health laboratory services
- h) Unregulated point of care testing
- i) Weak mechanism for coordinating partners
- j) Inadequate national health laboratory information management system
- k) Limited accessibility to quality laboratory services

4.0. POLICY STATEMENTS

4.1 Laboratory Services

Policy Objective:

To provide quality laboratory testing services to all the people in Uganda to support clinical, public health services and operational research.

Strategies:

- 4.1.1 Laboratory services shall be defined at each level in the tiered health care delivery to facilitate implementation of the Uganda National Minimum Healthcare Package
- 4.1.2 Each healthcare facility level and specialized centers shall display the list of tests performed which shall be supported by available testing capacity or approved referral mechanisms
- 4.1.3 A system for safe and secure specimen referral shall be established for the laboratory network
- 4.1.4 National reference laboratories shall provide specialized laboratory services in accordance with their mandate
- 4.1.5 Laboratory services at all tiers, including private sector, shall meet IHR and GHSA requirements by providing necessary support for disease/events surveillance, investigation and management of public health threats.
- 4.1.6 Laboratory services delivery shall be guided by the principles of quality and equitable access
- 4.1.7 There shall be a mechanism to improve utilization of laboratory services by both health workers and the community
- 4.1.8. Laboratory services shall enable the generation of adequate and reliable data that can guide policy actions to combat public health threats.

4.2 Organization and Management

Policy Objective:

To establish a clear organizational structure with appropriate authority to coordinate and manage the provision of comprehensive health laboratory services in the country.

Strategies:

- 4.2.1 An organization structure for the laboratory sub-sector shall be established under one clear UNHLS leadership at National, Regional and District levels
- 4.2.2 UNHLS shall provide stewardship, coordination and management for laboratory services
- 4.2.3 There shall be a well-defined and coordinated tiered laboratory network with clear roles and responsibilities at all levels
- 4.2.4 Collaborative networks shall be established among laboratories within the national health system and other sectors at both the national and international levels

4.3 Infrastructure, Biosafety and Biosecurity

Policy Objective:

To provide appropriate laboratory infrastructure to ensure the safety of personnel, community and the environment, and provide for security of materials and information.

Strategies:

- 4.3.1 There shall be a national health laboratory biosafety and biosecurity policy and guidelines based on accepted international standards
- 4.3.2. Health laboratories shall comply with the national biosafety and biosecurity guidelines
- 4.3.3 All health laboratories shall be constructed/renovated in accordance with the national infrastructure guidelines and standards
- 4.3.4 Laboratory services shall have procedures to respond to emergencies and there shall be linkage to emergency response centers
- 4.3.5 There shall be regular trainings of personnel in bio-risk management and equipment maintenance
- 4.3.6 Occupational health and safety services shall be available for all health workers and support staff.
- 4.3.7 All testing sites shall have procedures to protect clients, community and the environment.

4.4 Human Resource

Policy Objective:

To ensure that laboratory services have the required number of staff with the necessary competencies, remuneration and motivation to deliver quality laboratory services at all designated levels.

Strategies:

- 4.4.1 There shall be a scheme of service and scope of practice for all cadres of laboratory professionals to facilitate forecasting, recruitment, and retention.
- 4.4.2. The needs for staff training, continuing education, and career development shall be identified and addressed.
- 4.4.3 All laboratory staff shall adhere to professional code of conduct and other regulations.
- 4.4.4 All laboratory professionals shall be registered and licensed by the professional council.

4.5 Equipment and Supplies

Policy Objective

To ensure availability of supplies and functional equipment that are appropriate at all levels to support uninterrupted routine and emergency laboratory services.

Strategies:

- 4.5.1. There shall be an effective and demand driven supply chain management system implemented with respect to national standards.
- 4.5.2 All laboratories shall adhere to the National Inventory Management System
- 4.5.3 All equipment and supplies shall conform to national specifications and standards
- 4.5.4 All equipment shall be routinely monitored and maintained according to manufacturer's requirements and national protocols
- 4.5.5 There shall be a mechanism for pre- and post-market surveillance of supplies and equipment.
- 4.5.6 All donations and/or procurements of equipment and supplies shall comply with the national standards and guidelines
- 4.5.7 A system shall be put in place for relocation of equipment and for the safe disposal of obsolete equipment and expired supplies for all health laboratories

4.6 Quality Management System

Policy Objective:

To establish and maintain a national laboratory quality management system that will lead to national/international certification and accreditation.

Strategies:

- 4.6.1 There shall be a national master plan for quality assurance of both public and private health laboratories
- 4.6.2 All laboratories shall adhere to established national quality standards and guidelines
- 4.6.3 There shall be effective country wide technical support supervision programs within the tiered public and private laboratory system
- 4.6.4 Laboratories shall be certified and/or accredited according to national/ international standards
- 4.6.5 A National External Quality Assessment Scheme (NEQAS) shall be established to monitor the performance of laboratory services at public and private laboratories

4.7 Health Laboratory Information Management System

Policy objective:

To implement an integrated HLIMS in the laboratory network for management and utilization of patient results, other laboratory data, and operational research data

Strategies:

- 4.7.1 There shall be a robust and sustainable health laboratory information management system within the tiered laboratory network
- 4.7.2 Where possible, electronic health laboratory information management system shall be put in place to collect, report, and store data at all levels of the laboratory network
- 4.7.3 All laboratories shall adhere to the standardized and approved national laboratory information system that supports connectivity of all equipment including POCT technologies.
- 4.7.4 All laboratories shall be committed to sharing data in order to support a multi-sectoral approach of managing public health threats.
- 4.7.5 The national health laboratory information management system shall collect and report data on all thematic areas of health laboratory services.
- 4.7.6 Mechanisms shall be established to effectively manage HLIMS initiatives at all levels in the laboratory network, according to the requirements set by Ministry of Health.

4.8 Regulatory and Legal Framework

Policy Objective:

To ensure that the national health laboratory legal and regulatory framework is enforced within the entire health laboratory network

Strategies:

- 4.8.1 All public and private health laboratories, including those in clinics and hospitals, shall meet the required standards for registration and licensing
- 4.8.2 Penalties shall be applied to laboratories which fail to comply with required standards in accordance with regulatory guidelines
- 4.8.3 All practicing laboratory professionals shall be registered and licensed by their relevant professional councils
- 4.8.4 All registered and licensed laboratory professionals shall be graduates of accredited local and/or international training institutions
- 4.8.5 Mechanisms shall be established to strengthen the bodies regulating laboratories and laboratory personnel

4.9 Monitoring and Evaluation

Policy Objective:

To create and implement mechanisms to effectively measure performance of the health laboratory subsector to facilitate management, planning, learning and policy formulation in the country.

Strategies:

- 4.9.1 Implementation of National Health Laboratory policy shall be effected through national strategic plans and annual operational plans
- 4.9.2 Measurable performance indicators shall be developed, monitored and evaluated to ensure the successful implementation of National Health Laboratory Services Strategic Plans
- 4.9.3 There shall be periodic reviews of the laboratory subsector performance at pre-determined intervals with stakeholders across all levels in the laboratory network.

4.10 Financing and Accountability**Policy Objective:**

To establish resource mobilization and accountability mechanisms at national and subnational levels to ensure availability and accessibility of adequate resources for the provision of sustainable laboratory services

Strategies:

- 4.10.1 There shall be a dedicated budget line for laboratory services at national and subnational levels.
- 4.10.2 Partner support for laboratory services shall be harmonized and coordinated by UNHLS
- 4.10.3 A mechanism shall be established to recover costs of providing private services in public health laboratory facilities
- 4.10.4 A transparent system shall be established to ensure programmatic and financial accountability of the laboratory services
- 4.10.5 Financial incentives and/or other forms of support shall be extended to private health facilities for laboratory services in accordance with Public Private Partnership for Health (PPPH) policy

4.11 Community**Policy objective:**

Laboratory services shall be an integral part of the health services responsiveness to the community needs and shall adhere to ethical and environmental standards.

Strategies:

- 4.11.1 Health promotion shall be used to inform the communities about the role and use of laboratory services.
- 4.11.2 Communities shall be informed about their right to appropriate laboratory diagnostic testing.
- 4.11.3 Laboratory staff shall treat clients with respect and shall safeguard confidentiality and privacy according to the National Patient Charter.
- 4.11.4 Laboratories shall provide services to the community while adhering to environmental safeguards.

4.12 Partnerships**Policy Objective:**

To strengthen multi-sectoral national, international, public, and private partnerships to promote equitable access to quality laboratory services.

Strategies:

- 4.12.1 Mechanisms shall be established for sharing information, building testing capacity and ensuring adequate resources between and within sectors.
- 4.12.2 Mechanisms shall be developed to enable private health providers establish laboratories in underserved areas to improve access to laboratory services.
- 4.12.3 All partnerships shall comply with the applicable national and international regulations.

4.13 Research and Development**Policy Objective:**

To undertake research of public health importance according to the research priorities/agenda of the Ministry of Health

Strategies:

- 4.13.1 Laboratories at all levels shall conduct operational research in accordance with the national and international guidelines
- 4.13.2 All research conducted in health laboratories shall comply with the approved regulatory and ethical framework
- 4.13.3 There shall be a deliberate mechanism to enhance research activity in laboratory sub-sector

4.13.4 Operational research performed in health laboratories shall be aimed at improvement of public health.

4.14 Point of Care Testing

Policy Objective:

To increase access to testing services through complementing conventional laboratory services by expansion of testing services with approved and appropriate point of care technologies

Strategies:

- 4.14.1 There shall be a national policy and guidelines on point of care testing services
- 4.14.2 UNHLS shall establish and promote point of care testing where appropriate in order to improve access to testing services
- 4.14.3 UNHLS shall provide oversight to ensure quality point of care testing in accordance with national guidelines
- 4.14.4 UNHLS shall oversee the training and competence assessment for all point of care testers
- 4.14.5 A mechanism shall be established for centralizing data capture, analysis, and reporting on point of care services
- 4.14.6 All new point of care technologies to be used in Uganda shall be evaluated and approved in accordance with the national POCT policy and implementation guideline
- 4.14.7. There shall be guidelines for quality, training, safety, supervision and monitoring of point of care and community testing services in non-laboratory settings
- 4.14.8 All Point of Care (POC) testing sites and health laboratories, including private sector laboratories, shall be required to implement quality assurance schemes for all the tests they perform

5.0 IMPLEMENTATION OF THE POLICY

It is the intention of the Ministry of Health to fully translate this policy into practice within the health system. The revised policy Volume II has been developed within the context of the National Health Policy II, the Health Sector Strategic and Investment Plan (HSSIP), the National Development Plan II and regional and international health development goals. Therefore, its implementation will be in the same line and within the existing government, NGO, and private sector structures.

Efforts by Ministry of Health to finalize the National Laboratory Strategic Plan 2016 - 2021 are in advanced stages. The strategic plan will give clear guidance on strategies and

objectives needed to improve laboratory services, as well as insight into policy implementation and budgetary implications for translating policy into practice. The process of establishing UNHLS to oversee the implementation of the strategic plan is under way. UNHLS will spearhead the mobilization of the needed resources and coordinate partners and stakeholders on behalf of the Ministry of Health.

The Ministry therefore, calls upon all stakeholders in both the public and private sector to continue collaboration using a multi-sectoral approach, in the spirit of the One Health Concept, and in compliance with International Health Regulations (IHR). Such collaborative efforts will assist with implementation of the Global Health and Security Agenda (GHSA) initiatives, including building capacity for the detection, response and prevention of infections of national and global importance. It is anticipated that the same spirit of collaboration shown during the development of this policy will prevail during its implementation.

6.0 CONCLUSION

Since the development of the first National Health Laboratory Policy in Uganda in 2009, there has been a gradual improvement in the quality of laboratory services with support from government, development and implementing partners. To achieve acceptable standards of laboratory services delivery and meet set regional and global targets, concerted efforts towards strategic laboratory sector investment and country ownership remains critical.

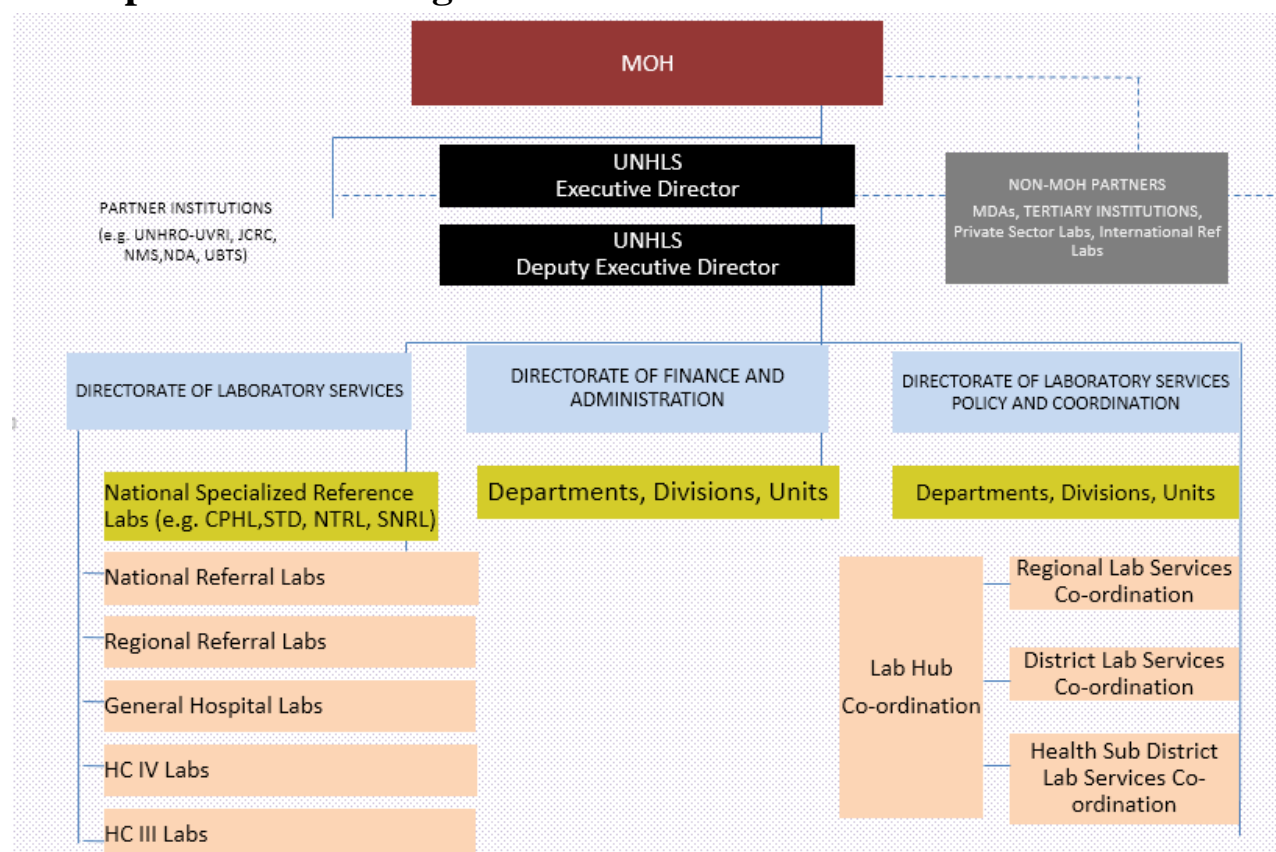
This Policy is directed towards consolidation of what has been achieved and advocating for further investments in the laboratory subsector as part and parcel of a health systems strengthening approach. A clear framework will guide appropriate resource mobilization, allocation and utilization. Priority setting and harmonization of services and processes will reduce duplication and resource wastage, which in turn will make the health system more efficient.

All stakeholders and partners in health are hereby called upon to bring this vision to reality.

REFERENCES

- International Health Regulations (2005), WHO
- Global Health Security Agenda
- The National Health Policy II (NHP II)
- The Health Sector Strategic and Investment Plan (HSSIP II)
- The Public Private Partnerships for Health (PPPH) policy
- The National Development Plan II
- Maputo Declaration 2009
- Abuja Declaration 2001
- Yaounde Declaration 2013
- Kigali Declaration 2009
- UN Sustainable Development Goals

APPENDIX I: Key Stakeholders in Health Laboratory Services and Operational Linkages



APPENDIX II: The National Health Laboratory Network

