THE REPUBLIC OF UGANDA
MINISTRY OF HEALTH

Uganda National Health Laboratory Services Strategic Plan

(2016-2020)
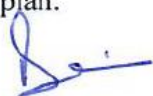
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Foreword

The National Health Laboratory Services Strategic Plan (NHLSSP) 2016-2020, is a major milestone in the journey towards quality, responsive, accessible and cost effective laboratory services. A well-developed laboratory sector is a fundamental and crucial component of any health system. It enhances timely and accurate disease detection, reporting, management and control.

The health system in Uganda aims to deliver quality, accessible and affordable health services to the Ugandan population. To achieve this, laboratory services must be well managed, coordinated and resourced. Laboratory sub sector in Uganda, has for long not received adequate support required to fulfill its role. This has often resulted into increased healthcare delivery costs due to inadequate disease identification, missed diagnoses, poor case monitoring and management as well as delays in disease outbreak investigation and control. This strategic plan therefore provides a framework for funding and implementation of health laboratory services as provided for in the National Health Laboratory Services Policy (NHLSP) II.

The NHLSP II outlines the vision, goals, and strategies for strengthening key thematic areas of laboratory services in the country towards achieving the UNMHCP. In the past decade, laboratory services have registered remarkable improvement through vertical funding for priority diseases namely HIV, Tuberculosis, and Malaria. The Ministry, together with development and implementing partners recognize the significance of a holistic approach towards health laboratory sector investment. Thus the MOH endorsed a review of the NHLSSP to ensure its alignment to the most recent National Health Sector Development Plan (NHSDP), the regional and international health care initiatives; Universal Health Care Access, One Health Concept, Global Health Security Agenda (GHSA), UNAIDS 90-90-90 goals and the International Health Regulations (IRH) – 2005.

Development of this NHLSSP involved a countrywide stakeholder's engagement through consultative meetings, formal desk reviews and imperical evaluations (GHSA assessment 2016) of the first policy document. The document provides a national framework to guide implementation and investments into the national health laboratory services for the public, as well as the private sector. The Ministry of Health is committed to strengthening accessibility to quality and affordable laboratory services for all people in Uganda to achieve excellent health status as we strive to achieve a middle-income status. All stakeholders and partners are encouraged to examine the strategic plan, assess their involvement in the delivery of laboratory services, and thereafter align their activities with the guidelines laid out in the plan.

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Acknowledgments

The National Health Laboratory Services Strategic Plan (NHLSSP) 2016 -2020 has been developed by the Ministry of Health (MOH) in collaboration with several stakeholders, health development partners, implementing partners and expert individuals. The process involved a series of desk reviews, consultative meetings/workshops, individual and institutional engagements.

The Ministry of Health would like to acknowledge and extend sincere appreciation to the President's Emergence Plan for Aids Relief (PEPFAR) for funding the review process through the US Centers for Disease Control and Prevention (CDC). The Association of Public Health Laboratories (APHL) is highly appreciated for providing technical oversight in the review process. Special acknowledgements go to the World Health Organization (WHO) Country Office and the African Regional Office (WHO AFRO) for providing the guiding framework and technical assistance for the development and review process.

The Ministry extends special thanks to the following teams who formed a technical working group to compile and proof read the document; the CDC – Uganda team, Central Public Health Laboratories (CPHL) Uganda National Health Laboratory Services (UNHLS), Top and Senior Management teams. Finally, MOH is grateful to all those institutions and individuals who have not been specifically mentioned above, but who directly or indirectly contributed towards the successful development and finalization of the national health laboratory services strategic plan.

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Dr. Susan Nabadda
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Abbreviations and Acronyms

AFB	Acid-Fast Bacilli
AHPC	Allied Health Professionals Council
AMREF	African Medical and Research Foundation
CDC	Centers for Disease Control and Prevention
CHEW	Community Health Extension Workers
CPHL	Central Public Health Laboratories
DHO	District Health Officer
DHS	District Health Services
DLFPs	District Laboratory Focal Persons
F&A	Finance and Accountability
FIND	Foundation for Innovative New Diagnostics
GoU	Government of Uganda
HIV	Human Immunodeficiency Virus
HLMIS	Health Laboratory Management Information Systems
HMIS	Health Management Information Systems
HSD	Health Sub-District
HSSP	Health Sector Strategic Plans
IAVI	International AIDS Vaccine initiative
IDI	Infectious Diseases Institute
JCRC	Joint Clinical Research Center
JMS	Joint Medical Store
LIMS	Laboratory Information Management Systems
LTC	National Health Laboratory Technical Advisory Committee
MDGs	Millennium Developmentnt Goals
MJAP	Mulago-Mbarara Teaching Hospitals'Joint AIDS Program
MOH	Ministry of Health
MRC	Medical Research Council
NDA	National Drug Authority
NDC	Department of National Disease Control
NEQAs	National External Quality Assessment Scheme
NGOs	Non-Governmental Organizations
NHLSP	National Health Laboratory Services Policy
NHP	National Health Policy
NHRL	National HIV Reference Laboratory
NMS	National Medical Stores
NPEAP	National Poverty Eradication Action Plan
NPHL	National Public Health Laboratory
NPO	National Professional Officer
NTLP	National Tuberculosis and Leprosy Program
NTRL	National Tuberculosis Reference Laboratory
PEPFAR	President's Emergency Plan for AIDS Relief
PHP	Private Health Providers
PNFP	Private not for Profit
POCT	Point of care testing
PPPH	Private Public Partnerships for Health

RLC	Regional Laboratory Coordinators
RLCC	Regional Laboratory Coordination Committees
SWOT	Strength, Weakness, Opportunities and Threats
TB	Tuberculosis
UBTS	Uganda Blood Transfusion Service
UHC	Universal Health Care
UMLTA	Uganda Medical Laboratory Technology Association
UNCST	Uganda National Council for Science and Technology
UNMHCP	Uganda National Minimum Health Care Package
USAID	United States Agency for International Development
UVRI	Uganda Virus Research Institute
VHT	Village Health Team
WHO	World Health Organization

Executive Summary

The National Health Laboratory Services Strategic Plan II (NHLSSP II) provides a frame work to guide the government of Uganda, the private sector, private not for profit institutions, health development and implementing partners towards the allocation of investments to the national health laboratory sub-sector. The plan aims at strengthening coordination, implementation and management of the health laboratory services to achieve transparency, effectiveness and responsiveness to the country's health needs.

The development of the document went through highly consultative processes involving many stakeholders. Situational analysis of laboratory services in the country was conducted with reference to the accomplishments and challenges of the NHLSSP I (2010-2015). Concerted efforts were made to align the plan with the national, regional and global policy guiding frameworks

The Ministry recognizes that an effective and efficient laboratory system is critical towards the achievement of universal access to the Uganda National Minimum Health Care package (UNMHCP). Laboratory services provide a rich source of data for early diagnosis, prevention and control of disease, a cornerrstone to an effective health care response.

Taking advantage of strategies designed by the Ministry of Health and development partners to strengthen national health services, the NHLSSP gives direction and provides a framework for health laboratory services delivery in the 14 thematic areas namely: 1) Organization and Management of the health laboratory system; 2) Laboratory services; 3) Infrastructure, Biosafety and Biosecurity; 4) Laboratory Equipment and Supplies; 5) Human Resources for laboratories; 6) Laboratory Quality Management Systems; 7) Laboratory Information Management Systems; 8) Research and Development; 9) Point of Care Testing Services; 10) Multi-Sectoral Partnerships and Networking; 1 1) Legal and Regulatory Framework; 1 2) Monitoring, and Evaluation; 13) Financing and Accountability for laboratory services; and 14) Community Engagement. For each of these thematic areas, a situation analysis has been done, and strategically represented as one objective with several strategies and sub objectives alongside targets, performance indicators, funding source and timeline for accomplishment. All stakeholders of health services delivery are urged to utilize the NHLSSP II in the formulation of realistic annual operational work plans for implementation.

1. Introduction

1.1. Background

Communicable diseases account for 54% of the country's disease burden (MOH-AHSPR, 2015/16). Malaria, HIV/AIDS and tuberculosis are the leading causes of death. For example, in 2015/16, there were 408 malaria cases per 1000 persons reported with 18 deaths per 100,000 persons. In addition, 45,268 TB cases were reported in FY 14/15 (MOH-AHSPR, 2015/16) and 64,000 new cases of HIV/AIDS are reported every year (UNAIDS, 2009). Outbreaks of other diseases such as cholera, typhoid, VHFs, dysentery and meningococcal meningitis have been common over the years. While dracunculiasis has been virtually eliminated, other neglected tropical diseases including onchocerciasis, schistosomiasis and trypanosomiasis remain major problems (Kolaczinski, 2007). There is also a growing burden of non-communicable diseases such as trauma, diabetes, cardiovascular diseases and cancers.

Health laboratories constitute a critical component of the health care system. They generate information for timely and accurate diagnosis of disease and for monitoring efficacy and potential toxicity of therapy. Laboratory data such as antimicrobial susceptibility profiles form the basis for designing and regularly updating empirical treatment regiments. In addition, laboratories play a key role in protecting the health of the population as a whole through disease surveillance, providing essential data for health systems planning, and disease prevention and control. Lack of reliable laboratory services results in delayed and inaccurate diagnosis of disease, leading to avoidable morbidity and mortality, drug wastage, high expenditure for government/organizations and individuals as well as loss of confidence in the health care system.

This NHLSSP has been aligned to the Health Sector Development Plan (HSDP) 2016 to 2020, whose goal is to accelerate movement towards Universal Health Coverage (UHC) with essential health care and related services needed for promotion of a healthy and productive population. These plans set key objectives to be attained during the 5 year period. These include: (i) contributing to the production of a healthy human capital for wealth creation through provision of equitable, safe and sustainable health services; (ii) increasing financial risk protection of households against impoverishment due to health expenditures; (iii) addressing the key determinants of health through strengthening inter-sectoral collaboration and partnerships; and (iv) enhancing health sector competitiveness in the region and globally. This strategic plan in cognizance of the HSDP goal, sets direction in 14 key thematic areas that are fundamental towards attaining accessible and sustainable quality laboratory services in the country. These include: organization and management; laboratory services; 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; regulatory and legal framework; monitoring and evaluation; community; financing and accountability.

The HSSP II (2005-2009) which preceded the HSSIP (2010-2015) recognized laboratory services as integral to the delivery of UNMHCP and attainment of the country's health goals. It prescribed the development of a National Health Laboratory Policy, establishment of effective leadership for national health laboratory services, strengthening of quality assurance, upgrading of staff and improving their competencies, and

provision of adequate supplies and equipment at all levels. It recommended that the National Public Health Laboratory operates as a semi-autonomous entity spearheading the coordination and strengthening of laboratory services nationwide.

1.2. Core Functions of Laboratory Services in Uganda

This strategic plan aims to strengthen the laboratory services to execute the listed core functions as well as to raise the quality of services to acceptable national and international standards through certification and accreditation. The functions include:

1. Routine, reference, and specialized testing to confirm etiology of health events
2. Disease diagnosis, prevention, control, and surveillance
3. Emergency response to public health events
4. Environmental health monitoring
5. Food safety monitoring
6. Development of laboratory policy, guidelines and standards
7. Public health related operational research

Accordingly, each core function is facilitated by the following 14 thematic areas:
1. Organization and Management
2. Laboratory Services
3. Infrastructure, Biosafety and Biosecurity
4. Equipment and Supplies
5. Human Resources
6. Quality Management Systems
7. Health Laboratory Information Management Systems
8. Research and Development
9. Point of Care Testing Services
10. Partnerships
11. Regulatory and Legal Framework
12. Monitoring and Evaluation
13. Financing and Accountability
14. Community

1.3. Organization of National Health Laboratory Services.

Laboratory services in Uganda are currently coordinated by the Central Public Health Laboratories (CPHL), a unit under the department of National Disease Control (NDC) of the Ministry of Health. Established in1983 as a national reference laboratory to support the Epidemiological Surveillance Division (ESD) in disease surveillance and outbreak investigation, CPHL was assigned additional role of coordination and stewardship of laboratory services in 1999 following a structuring process at the Ministry of Health.

In Uganda, laboratories are essentially based in healthcare facilities with their complexity increasing with the level of the facility. The lowest level of fixed facilities are the health centre II at parish level of which

the country has 5,418. A few HCII facilities have laboratories given that the national health policy targets HCIII and above for laboratories. There are 1,289 HCIIIs at sub-county level of which 86% have laboratories. All health facilities above HC III have laboratories. Next to the HCIII in the tier are the 197 HC IVs at county/constituency level, constituting the Health Sub-district which play administrative and supervisory roles over lower facilities. The country also has 144 general hospitals, 14 Regional referral and 2 National Referral Hospitals. In addition, there are PNFP and private health facilities that complement the public health service delivery.

While all facilities at the level of health centre IV and above have laboratories, very few of the laboratories are fully functional and capable of performing all tests on their recommended menus. At national level are a number of standalone reference laboratories including CPHL, the National Tuberculosis Reference Laboratory, the Vector Borne Diseases Laboratory, the Uganda Blood Transfusion Services, the National STI/STD reference laboratory and the Uganda Virus Research Institute.

The complexities of laboratories in the 56 PNFP and 9 private hospitals as well as 263 PNFP/private health centers are comparable to those of the equivalent government facilities. There are also a number of standalone laboratories, particularly in the private sector and numerous side laboratories in small private clinics.

In addition, medical training institutions, research institutions and specialized HIV/AIDS care institutions offer a significant range of healthcare related laboratory services. The Makerere University College of Health Sciences and Mbarara University of Science and Technology are the major providers of histopathology and cytopathology with the National Cancer Registry housed within the Makerere College of Health Sciences. The Joint Clinical Research Centre and other HIV care organizations offer advanced HIV related tests that are not often available in many other facilities.

Because laboratory services require huge investments and yet Uganda has limited resources, most of these vast number of laboratories have been operating at sub-optimal level. This prompted Ministry of Health to choose 100 of them strategically located within 40km radius of each other and worked with partners to enable them operate optimally in terms of infrastructure, equipment, human resources, and quality management systems. These laboratories, called hubs, are equipped to handle large volumes of tests. They therefore receive samples from the lower health facilities, analyze them and send results through the established sample and results transport network which operates throughout the country. The complex tests that the hubs are not able to perform are referred to higher level reference laboratories within the national laboratory network and results sent back through the same transport network.

1.4. Purpose of the Strategic Plan

The National Health laboratory Services has reached the end of its 2010-2015 strategic plan implementation period and is embarking upon the implementation of strategies in its next 5-year strategic planning. This new 2016-2020 strategic plan is being developed to guide the implementation of the National Health Laboratory Services Policy II (NHLSP II) in line with the National Health Policy and the HSSIP. It will provide the frame work to guide investment and development of health laboratory services by the Government of Uganda, health development partners and other stakeholders over the next 5 years.

1.5. Vision of National Health Laboratory Services

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

1.6. Mission of the National Health Laboratory Services

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

1.7. Core Values and Guiding Principles of Laboratory Services

- Quality laboratory services
- Accessibility and affordability for laboratory testing services
- Adequacy and competency of laboratory workforce
- Confidentiality of client information
- Transparency and accountability
- Equity of services

2. Situational Analysis: Achievements and Challenges

In June 2016, a gap analysis of the national health laboratory services was conducted in order to identify achievements and challenges carried over from the previous Strategic Plan of 2010-2015, as well as to highlight strengths, weaknesses, opportunities and challenges associated with the national laboratory services as the Ministry aspires to fulfilling the national health laboratory policy and the national health policy. This analysis was conducted with a focus on the following thematic objectives of the strategic plan framework.

2.1. Organization and Management

Significant progress was made during the past 5 years to strengthen and define the organizational structure and management of the National Health Laboratory Services, culminating in the submission of the Uganda National Health Laboratory Services (UNHLS) Bill 2016 that is currently under parliamentary approval processes. Leadership of the laboratory services at the national level through the UNHLS institutional framework has been strengthened by establishment of MOH guided and partner-supported leadership and governance trainings for laboratory professionals at national and sub-national levels. Importantly, there is a great deal of political will within the MOH and the Ugandan government in general, to improve the health laboratory services in the country and to support current initiatives such as the International Health Regulation (IHR), UNMHCP and Global Health Security Agenda (GHSA), all of which are geared towards strengthening health laboratory systems.

A number of challenges remain to be addressed by the revised national health laboratory strategic plan in order to strengthen laboratory services through organization and management. First, an established national laboratory services structure with capacity to coordinate laboratory services is not yet in place at all tiers within the national health laboratory network. As a result, the coordination of laboratory services across all tiers of service delivery remains weak. Second, the development of leadership and management competen-

cies that has occurred at the national level has not yet been significantly rolled-out to the sub-national levels. Finally, despite the support from leadership, there have been delays in the enactment of the UNHLS Bill which may delay the reorganization and effective coordination of functions across the laboratory network. Thus the next 5 years will be dedicated towards delivering on the above mentioned challenges.

2.2. Laboratory Services

Laboratory services are designed to support the delivery of the national minimum healthcare package (UN-MHCP), and the complexity of tests conducted increase with the level of care. Significant progress was made toward this goal during the implementation of the last strategic plan. Specialized laboratories have gained the technical capacity to detect diseases that threaten population health and laboratory services have markedly improved at the hubs level. In addition, a functioning network has been established for referral and transport of clinical specimens for testing, with results being reported back to the originating facilities within good turn-around-times (TAT). Overall, access to, and equity of, laboratory testing services has improved significantly.

However, a number of challenges to the effective delivery of laboratory services remain. Linkages among the laboratories within the national network are weak in many instances and the roles and responsibilities of the national reference laboratories have not yet been fully defined. Despite improvement in access to laboratory services, the utilization of these services remains sub-optimal. The offering of laboratory testing services is hindered by supply chain issues for laboratory consumables and equipment maintenance. Point of care testing services remain uncoordinated and lack quality and technical support from laboratory professionals. Other major challenges faced include; sub-national laboratories lack adequate capacity to respond to public health emergencies, inadequate staffing at all levels due to outdated staffing norms for laboratory cadres and staff attrition among others.

To meet these challenges, laboratory services will need to take advantage of opportunities presented by the political and professional interests in laboratory services both at national and international levels to enact the UNHLS Bill, and also obtain resources from initiatives such as the Global Fund for HIV/AIDS, Tuberculosis and malaria, Global Health Security Agenda (GHSA), Presidents Emergency Pan for Aids Relief (PEPFAR) and others to build a strong laboratory system and structures that respond to emergency public health threats, infectious disease surveillance, anti-microbial resistance surveillance and control among others.

2.3. Infrastructure, Biosafety and Biosecurity

While the majority of health facilities in the country were constructed several decades ago and most have not undergone regular routine maintenance, progress has been made during the previous strategic plan period in this area. Guidelines for infrastructure, biosafety and biosecurity in health laboratories have been developed, and more than 70% of regional hub laboratories have been remodeled in accordance with the national infrastructure guidelines. In addition, a baseline assessment of the laboratory system for the Global Health Security Agenda (GHSA) priorities has been completed.

However, implementation of the new biosafety and biosecurity guidelines, including hazardous and infectious waste management, has been very limited and is weak throughout the system, and formal policies on

biosafety and biosecurity in health laboratories have not been developed for the country. Most laboratories have no safety equipment available and there is slow response by many laboratory managers to the standardization efforts in these areas. In addition, the cost of biosafety, biosecurity and other facility infrastructure improvements is significantly high, but the GHSA initiative as well as an international recognition and demand for improved laboratory practices provide opportunities in this area.

2.4. Equipment and Supplies

The Ministry of Health fully embraces the new Policy (Vote 116-NMS) on the procurement and supply of medicines and Health supplies and is looking forward to working with all stakeholders in minimizing medicines/supplies stock outs countrywide. The National Medical Equipment Policy (2009) stipulates that medical equipment represents a substantial asset in the healthcare delivery system and needs to be managed efficiently and that their appropriate daily, periodic corrective maintenance are key to achieving safe and cost-effective management.

Laboratory equipment and supplies are procured and distributed mainly by the Government owned National Medical Stores, a private not for profit (PNFP) Joint Medical Store (JMS) and a number of private companies. For government and PNFP facilities, a credit line exists at NMS and JMS where each facility is allocated a sum of money from which they draw an equivalent of supplies.

Based on the recommended tests for each level, a national standard list of equipment for each level has been developed. Acquisition, use, maintenance and disposal of all medical equipment are guided by the National Medical Equipment policy, last revised into the 4th Edition in 2009. In addition, the Ministry established a National Advisory Committee on Medical Equipment (NACME) to formulate policy on medical equipment management and to continually review the country's medical equipment needs.

During the implementation period of the previous strategic plan (2010-2015), a number of foundational elements were put in place to improve the procurement and uninterrupted flow of laboratory testing supplies to the network laboratories. To strengthen the laboratory supply chain system, the position of Laboratory Logistics Coordinator, and Laboratory Logistics Technical Advisors were established and operationalized in NMS, JMS and NDA. In addition, DLFPs have been designated and a functional LTC has been established. Guidelines and procedures for the procurement of laboratory equipment and supplies have been developed and implemented throughout the laboratory system and an essential laboratory supply list was developed and an inventory system established. Monthly reporting to the MOH occurs, allowing for regular national quantification. Furthermore, The national laboratory logistics system has been integrated into the health supply chain system and an M&E mechanism has been implemented to monitor the success of this operation. To address equipment issues, a laboratory equipment inventory was established and a Biomedical Engineers are being recruited for regional equipment workshops.

While the infrastructure division of the MOH is mandated to maintain all medical equipment in the country through its central and regional maintenance workshops, the capacity of these workshops is limited by inadequate numbers of skilled technicians, lack of tools/ equipment and inadequate funding. Several other specific challenges remain that must be addressed if the network laboratories are to be able to provide their full range of testing without interruption. With regard to laboratory supplies, laboratory logistics advisors

are not facilitated to conduct their duties and the M&E of the logistics chain is weak. DLFPs lack administrative support to perform their duties due to lack of formal appointments to the position. At present, the equipment inventory is not regularly updated to ensure its accuracy. Preventive maintenance programs for equipment are not well developed, so equipment malfunction which results into interruption of testing services is common. Inadequacy of Biomedical Engineers at the MOH and NDA and at the regional workshops further compromises the ability to keep the equipment functional. Finally, there are no clear guidelines or procedures on equipment evaluation or decommissioning and disposed.

2.5. Human Resources

The health sector development plan (HSDP 2015-2020) notes that health workforce is still a key bottleneck for the appropriate provision of health services, with challenges in adequacy of numbers and skills, retention, motivation, and performance challenges. There has been significant increase in the number of laboratory professionals employed in the public sector, with 81% of the current staffing norms filled (MoH HRH Biannual Report December 2015). During the previous strategic planning period, internship training for laboratory students at all levels within the system was established and implemented and a draft scheme of services for laboratory personnel was developed, now in the approval process. The national initiative to certify and accredit testing laboratories provides the justification and opportunity to continue to make progress on the training of laboratory personnel.

Some of the remaining challenges to the development of a high quality workforce in the laboratories include the slow pace to approve and implement the scheme of service for laboratory cadres and the harmonized implementation of career development and retention strategies for laboratory staff in "hard-to-reach" areas. There is very poor occupational health support for laboratory personnel. Current MOH staffing norms continue to result in work overload as the recommended laboratory staff do not match the current work load and do not cater for cadres like bachelor's degree holders and post graduate qualifications.

2.6. Quality Management Systems

The Health Sector Ministerial Policy Statement (2016/17) pledges the Ministry's commitment to providing high quality healthcare as a means to facilitate the attainment of a good standard of health for all people of Uganda thereby meaningfully contributing towards achievement of Uganda Vision 2040. Quality in healthcare can only be achieved if there is a strong laboratory system that ensures accurate and reliable laboratory services across all tiers of healthcare. This is because laboratory contributes the bulk of diagnostic tests used in both clinical and public health decision making. Current national and international certification and accreditation initiatives and requirements within the country make the development of robust laboratory quality management systems a critical objective.

From 2010-2015, significant foundational work was completed towards the goal of establishing a quality management system throughout the health laboratory services system in Uganda. During this period, Uganda adopted the world Health Organization's (WHO) Stepwise Laboratory quality Improvement Process towards Accreditation (SLIPTA) initiative. The country also adopted Strengthening Laboratory Management towards

Accreditation (SLMTA), a task-based, hands-on training program directly linked to and therefore facilitating implementation of the SLIPTA initiative.

Ministry of Health has implemented the SLIPTA/SLMTA initiative in over 100 laboratories throughout the country since 2010, and there have been tremendous improvements in the Laboratory quality management system particularly in the hub laboratories. Two government health laboratories, notably the National Tuberculosis Reference Laboratory (NTRL) and Early Infant Diagnosis/Viral Load Laboratories at CPHL were accredited to International Standards (ISO 15189) through South African National Accreditation System (SANAS), while others, especially hospital-based laboratories, are now preparing to apply for International Accreditation.

However, there still remains critical challenges in the implementation of laboratory quality management system in the country: There are limited number of laboratory professionals within the country with knowledge and experience in laboratory quality management system that can guide the laboratories to accreditation. The lack of appreciation of the importance of laboratory quality by both the laboratory workers and their clinical colleagues who use their services contributes to poor implementation of the quality initiatives in the laboratories. Most managers at all levels of healthcare do not understand the need for quality and therefore allocate limited or no resources to critical supplies like quality control materials.

There is no clearly developed and well coordinated system for external quality assessment (EQA).A number of EQA proficiency testing schemes exist in the country including CPHL's National External Quality Assessment Scheme (NEQAS), NTRL's tuberculosis smear microscopy and Gene Xpert schemes, AMREF's Regional East African Quality Assessment Scheme (REQAS),the UK-NEQAS scheme for CD4 and complete blood count testing, and the UVRI's Dry Blood Spot (DTS) HIV rapid testing scheme. However, these schemes are limited in scope and coverage, are irregular in timing, and do not usually provide timely feedback to participating laboratories. Besides, all these panels with exception of UK-NEQAS which in itself is very expensive, are produced by laboratories that are not accredited for production of quality EQA panels. To crown it all, the poor coordination between the different EQA providers often leads to duplication of efforts, inefficiencies and ineffectiveness of EQA schemes.

2.7. Health Laboratory Information Management Systems

Over the past five years, the health laboratory sub-sector has made a number of advances toward its goal of establishing and strengthening laboratory information systems to promote laboratory performance, quality patient care, surveillance, evidence-based planning, policy formulation and research. A LIMS sub-committee was established within the MOH and a national LIMS master plan has been put in place, as well as national guidelines for data dissemination, record confidentiality and data archiving. HMIS tools are being distributed to facilities in the laboratory system, a national health reporting system has been created that will utilize LIMS data to guide health policy formulation, planning and decision-making. Currently, 40% of laboratory data needs are reported by 60% of public and PNFP laboratory facilities. An electronic LIMS for EID and VL is operational at the national reference laboratory and the on line dissemination of EID and VL results is being piloted. On line ordering of laboratory supplies for HIV testing is now possible in the laboratory system.

Despite these achievements, there are still significant issues that must be addressed in order to achieve the LIMS goals. Relating to the overall foundational elements required for a functional LIMS within the laboratory system, human resources are, at present, inadequate to fully implement the LIMS master plan for laboratories- in the areas of development, management and maintenance- and funding is inadequate to establish the IT infrastructure at laboratory facilities. HMIS tools for reporting notifiable disease conditions by the laboratories are not universally available across laboratories and are under utilized by the laboratories in the tiered system. There is a lack of network infrastructure at hub facilities which prevents the deployment of an electronic HLIMS at these facilities. The coordination of laboratory infrastructure and personnel training is weak at the district and regional levels and adherence to data management guidelines varies across the system. Another weakness of the system relates to the on line purchase of supplies/commodities; at present, the ability is limited to materials for HIV testing- no other laboratory commodities can be procured via this system. Other challenges faced by the heath laboratory sub-sector in its drive to implement a robust LIMS for health laboratories as they move towards a One Health Approach to population health is the absence of guidelines to govern the mechanisms and limitations of data sharing and data confidentiality across sectors (health, agricultural, etc.).

2.8. Research and Development

Well-designed and conducted applied research is necessary within the health laboratory services in order to improve cost effective service delivery to the public and to evaluate test kits and new technologies for their appropriateness and suitability for the Ugandan population setting. Recognizing this, there are a growing number of research grant opportunities with partners to investigate innovations in health-related research relating to approaches to delivery of laboratory and POCT testing services. Having recognized the importance of this type of research to Uganda, CPHL is in the process of establishing a Research Ethics Committee (or Institutional Review Board) to review and oversee research activities within the national laboratory services system. Fortunately, there already exists an established infrastructure across laboratory tiers for conducting this type of research as well as a number of laboratory practitioners who have both the qualifications and the capacity to conduct research.

However, the National Laboratory Services faces several challenges that impede its progress in this objective. At the moment, there are neither coordinated mechanisms for prioritizing, funding and conducting operational research geared at improving laboratory service delivery nor a defined national laboratory services research agenda to guide applied research conducted by health laboratory services. For research that is conducted within the laboratory system, there is no database to track research activities or to disseminate findings throughout the laboratory system to apply the research findings to service delivery. In addition, research if not well planned or regulated, may divert human and other laboratory resources from routine care work.

2.9. Point of Care Testing Services

The effective, efficient and equitable delivery of health care testing services to the public is critical for implementation of the Uganda National Minimum Health Care Package (UNMHCP). Implementation of this package and the achievement of the goal of Universal Health Care (UHC), in addition to impacting laboratory-based testing activities, will necessitate the development and employment of novel point-of-care testing (POCT) technologies and strategies in certain situations. In the 5 year period of the previous national health

laboratory services strategic plan, great strides were made in the expansion of quality POCT for HIV in Uganda, a strategy that has increased detection rates and resulted in expansion of treatment numbers. More recently, POCT technologies have been approved for diagnosis of tuberculosis using the Gene Xpert technology. This trend will certainly continue as new technologies appear in the market that offer cost-effective POCT testing that increases population access to diagnostics and the acceptance by clinicians and program managers of the POCT approach and trust in its benefits. UNHLS has already developed policy guidelines and protocols for the evaluation, verification and approval of new POCT technologies before being adopted in the country.

However, the anticipated growth of POCT will pose a number of challenges to the MOH and to the national health laboratory services in their oversight role as they act to ensure the quality of POCT. UNHLS will have to establish standard operating procedures for persons conducting POCT, quality control/quality assurance protocols strategies and programs for POCT, set training curricula and competency assessment strategies for POCT testers who are not trained laboratory staff. UNHLS will also have to determine reporting standards and processes for POCT data.

2.10.   Partnerships

Multi-sectoral laboratory partnerships are becoming more important as a strategy for both implementing a One Health approach to population health and to achieve Universal Health Care (UHC). The multi-sectoral approach includes both public-private collaboration and partnerships as well as multi-sectoral collaborations and partnerships among public laboratories in different Ministries Departments and Agencies of Government.

The National Policy on Public Private Partnerships in Health (March 2012) provides a framework that enables the public and private sectors in health to work together to improve service delivery by exploiting the comparative advantages that each has while focusing on the common health goals being pursued. The private sector is actively involved in the implementation of the Health sector development plan and participates in the Health Policy Advisory committee of MOH. Through the PPP Sector working group Government has recognized the role of PNFP in delivery of laboratory services by including them in the credit line for the provision of laboratory supplies, training of personnel and inclusion in EQA programs.

The Ministry of Local Government is responsible for management of Health Services within districts and is critical to running of laboratory services throughout the country. Development partners including WHO, CDC, USAID and Global Fund among others provide technical assistance and fund priority areas. The PNFPs often serve hard to reach areas of the country, thus promoting equity in service delivery. Some of standalone PHP laboratories offer testing that is not routinely currently available in the Government systems there by complementing services delivered by Government.

2.11.   Regulatory and Legal Framework

A fully functional and efficient national laboratory services system is characterized by a strong and stream-

lined legal and regulatory framework to guide and enforce its activities in the areas of licensing, registration and control of all health laboratory services. Laboratory services in the country are regulated under the Allied Health Professionals Act of 1996. The act empowers the Allied Health Professional's Council (AHPC) to register all laboratory professionals before they can practice in the country and renew the registration on an annual basis.   As such, the council, in consultation with UNHLS, approves laboratory training courses within the country to ensure that their graduates qualify for registration. During the strategic plan implementation period from 2010-2015, national laboratory services have been well represented at the AHPC- both national and regional levels - and a database for private laboratories and laboratory professionals was established. Training standards for laboratory professionals were reviewed and harmonized. These initiatives have resulted in improved capacity of the council to perform its regulatory role.

The initiation of the UNHLS 2016 Bill and the creation and utilization of a national health laboratory strategic plan will facilitate the streamlining and strengthening of the legal and regulatory framework in which laboratories operate. These initiatives, as well as the move toward laboratory certification and accreditation, e.g. the SLIPTA program, have increased the medico-legal awareness of laboratory leaders and managers throughout the laboratory system.

However, the strengthening and streamlining of the regulatory and legal framework in which health laboratories operate is hindered by the fact that the AHPC has a limited mandate, in that it cannot penalize non-compliance, particularly in public sector facilities. Furthermore, the AHPC has a limited capacity to regulate laboratory operations throughout the entire country and linkages between regulatory bodies is weak and/or is spread across multiple ministries (MOES regulates laboratory training institutions and schools) or overlaps across jurisdictions (regulatory and service delivery; DLFPs act on behalf of the AHPC). A code of ethics has not been customized for laboratory professionals. The revised NHLSSP 2016-2021is aimed at strengthening the legal regulatory framework through collaboration with professional associations.

2.12.   Monitoring and Evaluation

A robust Monitoring and Evaluation (M&E) framework aligned to the National Health Laboratory Services Policy (NHLSP) and the National Health Laboratory Services Strategic Plan (NHLSSP) is critical to the effective achievement of quality laboratory services delivery. The M&E framework has been developed to aid the tracking of progress towards quality, responsive, accessible and cost effective delivery of national health laboratory services in Uganda. In line with the goals, strategic objectives and targets stipulated in the national health laboratory services strategic plan; the M&E framework will measure the effectiveness of the strategies for delivering national health laboratory services.

Indeed, the M&E framework will form a basis of strengthening understanding around the many multi-layered factors underlying national health laboratory services. The M&E framework will be used to demonstrate whether national health laboratory services strategic plan has had a measurable impact on the expected outcomes and whether it has been implemented as planned. In the same vain, the M&E framework will support different stakeholders (managers, planners, implementer, policy makers and donors) acquire the information and understanding they need to make informed and strategic decisions about delivery and quality of laboratory services. Finally the M&E will not only help with identifying the most valuable and efficient use of resources but also provide data for strategic planning, designing and implementing innovative ways of de-

livering quality laboratory services.

During the period of the previous 2010-2015 national health laboratory services strategic plan, progress was made towards establishing a substantive M&E program; UNHLS has made efforts towards establishing a mechanism for coordinating M&E activities in the health laboratory sub-sector. The major progress made towards the goal of enabling data collection for M&E purposes via the LIMS and DHIS2 platform.

Challenges which need to be addressed include the fact that the M&E coordinator position that was established in UNHLS is not in the government scheme of service. In addition, M&E focal persons have not been established at the District level to work with the M&E coordinator. M&E practitioners have not been trained on the M&E implementation or data management processes; suggesting that the national and sub-national M&E program is not fully functional. In order to implement the M&E program, UNHLS will have to take advantage of the e-health systems, donor funding and training opportunities.

The next five years will be dedicated to further strengthening M&E data collection platforms through the country wide roll out of LIMS and subsequent review of DHIS2 tools to enable detailed data capture. The M&E unit at UNHLS will be empowered than ever, to take on more tasks aimed at collection and management of nation-wide data needs to keep progress of quality lab services delivery in check.

A robust Monitoring and Evaluation (M&E) framework aligned to the National Health Laboratory Services policy (NHLSP) and the National Health Laboratory Services Strategic Plan (NHLSSP) is critical for the effective achievement of quality laboratory services delivery. An M&E framework has been developed to aid the tracking of progress towards quality, responsive, accessible and cost effective delivery of national health laboratory services in Uganda. In line with the goals, strategic objectives and targets stipulated in the national health laboratory services strategic plan; the M&E framework will measure the effectiveness of the strategies for delivering national health laboratory services.

As part of developing this framework, during the period of the previous 2010-2015 national health laboratory services strategic plan, progress was made towards improving data collection and management where the goal of enabling data collection for M&E purposes via the LIMS and DHIS2 platform was achieved. The next five years will now be dedicated to further strengthening M&E data collection platforms through the country wide roll out of LIMS and subsequent review of DHIS2 tools to enable detailed data capture. The M&E unit at UNHLS will be empowered to conduct Continuous Data Quality Assessments (DQAs) to ensure data quality of lab services delivery.

Indeed, the M&E framework will form a basis of strengthening understanding around the many multi-layered factors underlying national health laboratory services. The M&E framework will be used to demonstrate whether national health laboratory services strategic plan has had a measurable impact on the expected outcomes and whether it has been implemented as planned. In the same vain, the M&E framework will support different stakeholders (managers, planners, implementer, policy makers and donors) acquire the information and understanding they need to make informed and strategic decisions about delivery and quality of laboratory services. Finally, the M&E will not only help with identifying the most valuable and efficient use of resources but also provide data for strategic planning, designing and implementing innovative ways of de-

livering quality laboratory services.

2.13.   Financing and Accountability

In the 2010-2015 strategic plan, initiatives were undertaken to improve the financing and accountability of the UNHLS, which was grossly under-funded with no dedicated budget line for laboratory services and lacking the adequate systems and personnel with the skills to conduct fiscal planning and accounting for the laboratory. This largely prevented the ability of many laboratories to optimize the mobilization and utilization of their resources. Since that time, principles of financing and accountability have been included in refresher trainings for management staff, and laboratory leaders have rationalized the use of support from partners to improve the utilization of resources. Cost recovery mechanisms have been put in place in some public facilities to recover costs for lab services performed for the private facilities. At a higher level, advocacy for increased allocation of funds for laboratory services has been conducted and finance and accountability has been included as a theme in the national laboratory policy.

A major challenge remaining in this area is that limited numbers of staff have been trained on finance and accountability concepts and practices, so there is a lack of personnel competent to manage budgets. Partners and donors have offered to make such trainings available, which may offer a solution to this. Another challenge is that managerial tools for planning, costing, inventory consumption monitoring have not been developed for use in the laboratories. For those individuals attempting to manage their laboratory budget and optimize the efficiency and use of resources, they are hampered because criteria and guidelines for subsidized programs have not been developed. The significant dependence upon donor funding for the laboratory will continue to make it difficult for long range planning of for financial resources.

2.14.   Community

Interface of laboratory services with the community remains an important factor to the access and utilization of laboratory services. Developments in healthcare delivery such as the change in policy on management of malaria in 2012 that demands confirmation of etiology before starting treatment; the VHT/ CHEW strategy that engages community in health care; the new global Universal Health Coverage (UHC) that Uganda is adopting to replace the UMHCP and the self-testing which is being proposed as a strategic approach towards increasing access to diagnostic services require equitable access to and utilisation of quality laboratory services . Community awareness of health laboratory services is however low which limits the utilisation of laboratory services in the prevention, control and management of disease. Syndromic management of fevers as malaria and coughs as acute respiratory tract infections in the community is common which can be expensive, life threatening and is partly the reason for other secondary effects like AMR. To overcome these challenges; the laboratory sub sector shall have to increase community awareness of the importance to confirm aetiology of health events before starting medication using appropriate diagnostic tools, remain responsive and accountable to the community.

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3. The Strategic Plan Framework (2016-2021)

Uganda National Health Laboratory Network Strategic Plan Framework: 2016/17 -2020/21

OBJECTIVE 1. Organization and Management: To establish a clear organizational structure with appropriate authority to coordinate and manage the provision of comprehensive health laboratory services in the country

Strategies	Sub-Objectives	Targets	Performance Indicators	Funding Source and Approx. Cost	Y1	Y2	Y3	Y4	Y5
1.1 Establish national laboratory organizational structure with clearly defined roles and responsibilities	1.1.1 Enact the UNHLS Bill 2016 to provide mandate for UNHLS to coordinate laboratory services in Uganda	UNHLS Bill enacted	UNHLS bill implemented	MoH	X	X	X	X	X
	1.1.2 Appoint the Board of Directors of Uganda National Health Laboratory Services (UNHLS) to provide administrative oversight and guide operations of UNHLS	BOD of UNHL appointed	BOD appointed and functional	MoH	X	X	X	X	X
	1.1.3 Define and implement roles and responsibilities for the different stakeholders in the tiers of the network to facilitate effective coordination of laboratory services	Roles and responsibilities defined	Roles and responsibilities implemented at all levels	MoH	X	X	X	X	X
	1.1.4 Develop a structural organogram including sub national coordinators and corresponding Job descriptions of UNHLS to ensure clear reporting relationships	Structural organogram developed	Structural organogram functional	MoH	X				
	1.1.5 Strengthen functionality of the National laboratory Technical and Advisory Committee (LTC) to provide technical oversight for laboratory services.	Quarterly meetings held	Number of meeting held by the the National laboratory Technical and Advisory Committee (LTC)	MoH/partner	X	X	X	X	X
1.2 Strengthen the coordination of the tiered laboratories	1.2.1 Establish regional coordination offices and provide staff to improve coordination of laboratory services at regional level	14 regional coordination offices with regional officers established	14 functional regional coordination offices available	MoH/partner	X	X	X	X	X
	1.2.2 Update the supportive supervision checklists for each tier in the network	supportive supervision checklists updated	Supportive supervision checklists utilized	MoH/partner	X	X	X	X	X

Strategies	Sub-Objectives	Targets	Performance Indicators	Funding Source and Approx. Cost	Y1	Y2	Y3	Y4	Y5
	1.2.3 Streamline the structure of the hub laboratories to align with the UNHLS structure.	Hub structure aligned with UN-HLS	No of Hubs aligned with UNHLS structure	MoH/partner	X	X	X		
	1.2.4 Train RLC, DLFP and hub coordinators in supportive supervision to improve their supervisory capacity	100% trained	% of Regional Lab Coordinators and DLFPs trained in supportive supervision	MoH/partner	X	X			
	1.2.5 Strengthen regional laboratory coordination committees (RLCC) to improve services within the regions	Quarterly RLCC meetings held	Number of meeting held by the regional laboratory coordination committees (RLCC)	MoH/partner	X	X	X	X	X
	1.2.6 Establish full time positions of district laboratory focal person via local government councils for all districts	100% positions of DLFPs established	Number of full time DLFP positions filled.	Ministry of Local Government	X	X	X	X	X

OBJECTIVE 2. Laboratory Services: To provide quality laboratory testing services to all the people in Uganda to support clinical, public health services and operational research.

Time-line

Strategies	Sub-Objectives	Targets	Performance Indicators	Funding Source and Approx. Cost	Y1	Y2	Y3	Y4	Y5
2.1 Establish a minimum package of testing services at all laboratory tiers	2.1.1 Define and disseminate national test menu to ensure standardization of testing services at each laboratory tier	100% of laboratories have test menu.	Proportion of laboratories tiers with an updated test menu	MoH, Partners	X	X			
2.2 Strengthen laboratory services for surveillance, public health emergency investigations and management at all laboratory tiers, including private sector	2.2.1 Develop and disseminate the list of notifiable diseases/events to all laboratories and implement standardized reporting system at all laboratory tiers	100% laboratories have list of notifiable diseases	% of laboratories that are reporting notifiable diseases/events	MoH, Partners	X	X	X	X	X
	2.2.2 Develop and implement guidelines for multi-sector and inter-laboratory collaboration to facilitate collaborative testing capacity	Guidelines developed and implemented	multi-sector and inter-laboratory collaboration guidelines available	MoH, Partners	X	X	X	X	X
			Multi-sector and inter-laboratory collaboration guidelines implemented	MoH, Partners					

Activity	Target	Indicator	Responsible					
2.2.3 Map the outbreak/event response capacity for the national and sub national reference laboratories in MOH and other sectors under the One Health Approach to guide in the specimen referral across the laboratory network for disease confirmation	20 MOH, 4 university and 5 MAAIF laboratories mapped	Number of specialised laboratories mapped	MoH, Partners	X	X			
2.2.4 Develop guidelines for implementation of laboratory-based surveillance (for AMR, disease/event surveillance, food safety, environmental safety, zoonotic agents) to provide guidance for notification/reporting	4 guidelines developed	Number of laboratory-based surveillance guidelines developed	MoH, Partners	X	X			
	4 guidelines implemented	Number of laboratory-based surveillance guidelines implemented						
2.2.5 Develop a plan and budget to support laboratory public health emergency responses	Plan and Budget approved	A plan to support laboratory public health emergency responses available	MoH, Partners	X				
		An approved budget to support laboratory public health emergency responses avialable						
2.2.6 Develop plans and procedures for real time surveillance, public health emergency and incident response	Approved emergency plan	Emergency plan in use	MoH, Partners	X	X	X	X	X
2.2.7 Develop human resource competencies for the specialized and clinical laboratories at national and regional level for detection of agents of public health importance under the One Health Approach.	All staff trained at national, regional levels	% of staff competent in detecting agents of public health importance	MoH, Partners	X	X	X	X	X

					X	X	X	X	X
2.3 Strengthen safe and secure specimen collection, packaging and transportation within the laboratory network	2.3.1 Develop and implement an integrated guideline for specimen collection, packaging and transportation to ensure safe and effective referral of samples	Guidelines approved	Guidelines implemented	MoH, Partners	X	X	X	X	X
	2.3.2 Develop an electronic specimen tracking system for samples in transit.	Electronic tracking system developed	Electronic tracking system for samples in transit available	MoH, Partners	X	X			
	2.3.3 Initiate and follow up the Procurement and distribution of appropriate specimen packaging materials at all tiers of laboratory services	Appropriate packaging materials provided at all laboratory tiers	% of laboratories with appropriate specimen packaging materials by laboratory tiers	MoH, Partners	X	X	X	X	X
	2.3.4 Institutionalize specimen referral services into the UNHLS budget	Specimen referral services incorporated in the UNHLS/ MoH budget	Budget line for specimen referral services available	MoH, Partners	X	X	X	X	X
	2.3.5 Develop and implement skills development plan for safe and secure shipment of specimens	Skills development plan developed and implemented	Number of health workers trained in safe and secure shipment of specimen	MoH, Partners	X	X	X	X	X
2.4 Strengthen national laboratory testing capacity to support effective implementation of UHC	2.4.1 Update laboratory test menus and technologies at all levels to increase accessibility to laboratory services to support implementation of UHC	Laboratory test menus and technologies updated for all levels	An updated laboratory tests menu and technologies at all levels available	MoH, Partners	X	X	X	X	X
	2.4.2 Improve access to laboratory services by vulnerable and most at risk populations	All vulnerable/ most at risk groups accessing laboratory services	% of vulnerable and most at risk groups accessing laboratory services	MoH, Partners	X	X	X	X	X
	2.4.3 Determine cost of laboratory testing services at all levels for effective implementation of UHC	Cost of laboratory services established for all levels	Cost of laboratory testing services for all levels available	MoH, Partners	X	X	X	X	X

Strategies	Sub-Objectives	Targets	Performance Indicators	Funding Source and Approx. Cost	Y1	Y2	Y3	Y4	Y5
	2.4.4 Identify laboratory tests and technologies that have potential of leading to catastrophic expenditure and impoverishing house hold incomes for inclusion in the MOH health insurance package	Laboratory tests with potential for catastrophic expenditure identified	Number of laboratory tests with potential for catastrophic expenditure at household level included in health insurance package	MoH, Partners	X	X	X	X	X

OBJECTIVE 3. Infrastructure, Biosafety and Biosecurity: To provide appropriate laboratory infrastructure to ensure the safety of personnel, community and the environment, and provide for security of materials and information.   Time-line

Strategies	Sub-Objectives	Targets	Performance Indicators	Funding Source and Approx. Cost	Y1	Y2	Y3	Y4	Y5
3.1 Strengthen national laboratory biosafety system, fire and radiation safety programme	3.1.1 Develop national health laboratory Biosafety Policy for effective implementation of safety of personnel, environment and community	National Biosafety policy developed	A national health laboratory Biosafety Policy available	MoH/partner	X	X	X	X	X
	3.1.2 Develop standards to ensure effective implementation of Biosafety Plan into laboratory practices via Biosafety Manual	Biosafety standards developed	% of laboratories implementing the Biosafty manual based on the standards.	MoH/partner	X	X	X		
	3.1.3 Develop SOPS to operationalize national Biosafety Manual for use in all tiers of laboratory	# SOPs for biosafety developed at all levels	Number of laboratories using SOPs to operationalize the national Biosafety Manual	MoH/partner	X	X	X		
	3.1.4 Develop and implement guidelines for national biosafety audits of health laboratories	Biosafety audit guidelines developed and implemented in all laboratories	% of health laboratories audited using the national biosafety guidelines.	MoH/partner	X	X	X	X	X
	3.1.5 Establish fire and radiation safety programme	Fire and radiation safety programme established	A Fire and radiation safety programme established	MoH/partner	X	X	X		
3.2 Establish national laboratory biosecurity system	3.2.1 Develop national health laboratory Biosecurity Policy to ensure safe and secure custody and protection of biological materials at all levels	National biosecurity policy for health laboratories developed	A national health laboratory Biosecurity policy available	MoH/partner	X				

	Activity	Output Indicator	Outcome Indicator	Responsible	Y1	Y2	Y3	Y4	Y5
	3.2.2 Develop standards to ensure effective implementation of Biosecurity Plan into laboratory practices via Biosecurity manual	Biosecurity standards developed	% of laboratories implementing the Biosecurity manual based on the standards.	MoH/partner	X				
	3.2.3 Develop SOPS to operationalize national Biosecurity manual for use in all tiers of laboratory	# Biosecurity SOPs developed	SOPs to operationalize the biosecurity manual developed.	MoH/partner	X	X			
	3.2.4 Develop a policy to regulate the storage and access to the usage of chemicals, infectious agents and other harmful materials against malicious use.	Policy developed for access and store of dangerous agents available by year 2	Policy to regulated access and store of dangerous agents available	MoH and Partners	X	X			
	3.2.5 Develop and implement plan for national biobanking of infectious agents	Plan developed	Plan implemented	MoH and Partners	X	X			
3.3 Ensure that construction and renovation of health laboratory facilities conform to national infrastructure guidelines and standards	3.3.1 Review and disseminate laboratory infrastructure guidelines and standards	National laboratory infrastructure guidelines reviewed and disseminated	National infrastructure guidelines and standards reviewed	MoH/partner	X	X			
	3.3.2 Assess the status of laboratory infrastructure to identify gaps and non- conformities	Infrastructure assessment performed in all laboratories	% of laboratories that conform to national infrastructure guidelines and standards	MoH/partner	X	X	X	X	X
	3.3.3 Construct/ renovate/refurbish and maintain laboratories in conformity with national guidelines and standards.	All laboratories identified in assessment constructed/ renovated /refurbished	Number of laboratories constructed/ renovated/ refurbished in conformance to national guidelines and standards	MoH/partner	X	X	X	X	X
	3.3.4 Advocate for adequate budget for infrastructure improvement	Budget calculated and approved	Proportion of the Budget allocated to infastructure improvement	MoH/partner	X	X	X	X	X

3.4 Establish maintenance program for Biosafety and biosecurity equipment	3.4.1 Develop and implement guidelines for maintenance and servicing of biosafety and biosecurity equipment at all levels to enhance safety of personnel and infectious materials.	Guidelines developed and all lab biosafety equipment serviced/ properly maintained	Guidelines for maintenance and servicing of biosafety and biosecurity equipment at all levels available	MoH/partner	X	X	X	X	X
			% of laboratories implementing guidelines for maintenance and servicing of biosafety and biosecurity equipment by level						
	3.4.2 Plan and implement certification of biosafety and biosecurity equipment for optimum performance	Certification plan available with all laboratory biosafety and biosecurity equipment certified	% of laboratory biosafety and biosecurity equipment certified	MoH/partner	X	X	X	X	X
	3.4.3 Develop and update a national list of biosafety and biosecurity equipment and kits necessary at each laboratory tier	List of safety equipment and kits developed	An updated list of Biosafety and biosecurity equipment and kits necessary at each laboratory tier available	MoH/partner	X				
3.5 Establish an effective occupational health and safety program for laboratory personnel	3.5.1 Develop and disseminate guidelines for monitoring health of laboratory personnel to improve management of personnel safety.	Guidelines for personnel safety and health monitoring developed	Occupational health and safety guidelines for monitoring health of laboratory personnel developed	MoH and Partners	X	X			
			% of laboratories implementing occupational health and safety guidelines to improve management of personal safety of their personnel						

	3.5.2 Develop and implement a plan for effective monitoring of health laboratory personnel for appropriate intervention and deployment.	national laboratory health monitoring system Plan developed	A national health laboratory personnel monitoring Plan in place	MoH and Partners	X	X			
			Number of interventions and deployments implemented based on the national health laboratory personal monitoring plan						
3.6 Strengthen the co-ordination of Biosafety and Biosecurity activities through effective management at all levels	3.6.1 Revitalize the sub-committee of Biosafety and Biosecurity in the LTC Committee	Biosafety and biosecurity committee in place	Committee functional with documentation of meeting frequency, minutes, and document reviews	MoH and Partners	X	X			
	3.6.2 Create a biosafety and biosecurity unit at national level for coordination of national biosafety and biosecurity program	unit established with approriate staff.	proportion of biosafety and biosecurity staff hired and unit functional	MoH and Partners	X	X	X	X	X
	3.6.3 Develop biosafety and biosecurity unit within the regional office with staff to coordinate biosafety and biosecurity in each region	Regional office includes safety unit with 2 staff hired	Number of staff hired in regional office biosafety and biosecurity unit	MoH and Partners	X	X	X	X	X
3.7 Strengthen human resource capacity for biosafety and biosecurity Program through trainings for improved practices.	3.7.1 Develop and regularly update database for national biosafety and biosecurity trainings to determine the skill levels of personnel.	national biosafety and biosecurity training database developed	An updated national biosafety and biosecurity trainings database in place	MoH and Partners	X	X	X	X	X
	3.7.2 Review Biosafety and biosecurity training plan for laboratory workers, managers and non technical laboratory personnel in both Public and private laboratories.	Plan reviewed	A revised Biosafety and biosecurity training plan in place	MoH and Partners	X	X	X	X	X
	3.7.3 Conduct TOT for biosafety and biosecurity training to increase capacity of trainers	100 laboratory trainers, 10 manager trainers	Numbers of TOTs in biosafety and biosecurity trained	MoH and Partners	X	X	X	X	X
	3.7.4 Finalize biosafety and biosecurity training curricula	Curricula developed	Biosafety and biosecurity training curriculum finalized	MoH and Partners	X	X	X	X	X
	3.7.4 Train officers using the biosafety and biosecurity curricula	4,000 officers trained	Number of officers trained	MoH and Partners	X	X	X	X	X

OBJECTIVE 4. Equipment and Supplies: To ensure availability of supplies and functional equipment that are appropriate at all levels to support uninterrupted routine and emergency laboratory services.					Time-line				
Strategies	**Sub-Objectives**	**Targets**	**Performance Indicators**	**Funding Source and Approx. Cost**	**Y1**	**Y2**	**Y3**	**Y4**	**Y5**
4.1 Strengthen the coordination of laboratory supply chain management system across the network	4.1.1 Designate the position of laboratory logistics officers at all laboratory levels	126 designated positions (14 at Regional and 112 at District levels)	Number of designated laboratory logistics positions filled.	MoH/partners	X	X	X	X	X
	4.1.2 Conduct quarterly logistics coordination meetings at regional level to review performance of logistics activities	4 meetings per region per year	Number of performance review meetings conducted	MoH/partners	X	X	X	X	X
	4.1.3 Define roles and responsibilities of stakeholders in supply chain management to avoid duplication.	Roles and responsibilities of stakeholders defined	Defined roles and responsibilities of stakeholders in supply chain management in place	MoH/partners	X	X			
4.2 Establish pre- and post-market surveillance systems for laboratory commodities	4.2.1 Develop and implement guidelines for pre-and post market surveillance to ensure product quality	Pre- and post- market surveillance guidelines developed with reports generated	Guidelines for pre-and post market surveillance developed	MoH/partners	X	X	X	X	X
			Pre and post market surveillance reports available						
	4.2.2 Strengthen the quality assurance laboratory to effectively coordinate Quality Control, batch testing/lot to lot of new laboratory commodities at UNHLS, in collaboration with NDA and UNBS	UNHLS Quality Control testing facility for lab commodities established	A functional quality assurance unit for laboratory commodities established at UNHLS	MoH/partners	X	X			
	4.2.3 Perform pre and post market surveillance of laboratory commodities in the system	Pre- and post-market surveillance report disseminated bi-annually	Number of Pre- and post-market surveillance reports of laboratory commodities	MoH/partners	X	X	X	X	X

Strategy	Activity	Output	Indicator	Responsible	Y1	Y2	Y3	Y4	Y5
4.3 Strengthen supply chain management to quantify, procure, distribute and monitor laboratory commodities across the network	4.3.1 Review and update laboratory supply list and catalogues	A reviewed supply list and catalogues available	A reviewed supply list and catalogues in place	MoH/partners	X			X	
	4.3.2 Conduct annual national laboratory supply quantification with quarterly reviews to assess and address the ongoing needs at all tiers of laboratory service	Quarterly reviews and annual quantification report generated	Annual national laboratory supply quantification report available	MoH/partners	X	X	X	X	X
	4.3.3 Prepare and implement guidelines for procurement and distribution of laboratory commodities for facilities to avert stock outs (including donations)	Guidelines prepared and distributed	Guidelines for procurement and distribution of laboratory commodities developed	MoH/partners	X				
			Number of stakeholders implementing guidelines for procurement and distribution of laboratory commodities						
4.4 Strengthen the ordering, storage and inventory management systems at all levels.	4.4.1 Revise, update and harmonise the laboratory supplies request form across the national stores	Request forms updated	A harmonised laboratory supplies request form across the national stores in place	MoH/partners	X	X	X	X	X
	4.4.2 Provide adequate storage capacity for laboratory commodities in accordance with infrastructure standards at all levels	Enough storage space at all levels	% of laboratories with adequate storage capacity for laboratory commodities in accordance with infrastructure standards at all levels	MoH/partners	X	X	X	X	X
	4.4.3 Procure cold storage facilities for laboratory commodities at national, district and health facility levels for maintenance of reagent potency in collaboration with national ware houses	100 hubs by Year 2 & 90% at all levels by Year 5	Number of laboratories across all tiers with cold storage facilities for laboratory commodities	MoH/partners	X	X	X	X	X

	4.4.4 Develop and disseminate guidelines for proper storage of laboratory commodities and ensure easy access and retrieval of supplies	Guidelines developed and disseminated	Guidelines for proper storage of laboratory commodities developed	MoH/partners	X	X	X	X	X
			Number of laboratories implementing guidelines for proper storage of laboratory commodities to ensure easy access and retrieval of supplies		X	X	X	X	X
	4.4.5 Develop and implement inventory management system for laboratory commodities across the network to avoid stock out and expiries of vital commodities.	Facility stock out less than 10%	Percentage stockout of vital laboratory commodities	MoH/partners	X	X	X	X	X
			Percentage expiries of vital laboratory commodities		X	X	X	X	X
4.5 Strengthen data management systems for laboratory logistics to meet routine and emergency services delivery	4.5.1 Revise, update and harmonise logistic data management tools for system strengthening	Logistics data tools harmonized	Number of Logistics data tools harmonized	MoH/partners	X	X			
	4.5.2 Print and distribute data management tools to all facilities	Data tools printed and distributed	Number of data management tools printed.	MoH/partners	X				
			Number of data management tools distributed.		X				
	4.5.3 Conduct training in logistics data management and reporting at all levels to ensure compliance to national standards	logistics and data management trainings done	% of laboratories at all levels trained in logistics data management and reporting	MoH/partners	X	X	X	X	x
4.6 Strengthen capacity in laboratory logistics management including SPARS	4.6.1 Review and update laboratory SPARS training curriculum	Finalise laboratory Curriculum and SPARS	Laboratory SPARS Curriculum updated	Partners	X	X			
	4.6.2 Conduct ToT for laboratory SPARS	12 ToTs conducted	Number laboratory SPARS ToTs conducted	Partners	X	X			
	4.6.3 Conduct facility training for laboratory SPARS	90% facilities trained	% of facilities trained in laboratory SPARS	MoH/partners	X	X			
4.7 Establish M&E system	4.7.1 Establish a system for M&E of labora-	M&E system established	Developed and Opera-	MoH/partners	X	X	X	X	X

Strategy	Activity	Target	Indicator	Responsible					
for laboratory logistics activities	tory commodities to inform forecasting and ascertain their quality		tional M&E						
	4.7.2 Develop indicators and checklists for laboratory logistics monitoring	National list of Indicators and checklist developed	Indicators for monitoring laboratory logistics in place	MoH/partners	X	X	X	X	
			Checklists for laboratory logistics monitoring in place		X	X	X	X	
	4.7.3 Conduct M&E training for all laboratories	All laboratories trained	% of laboratories trained in M&E	MoH/partners	X	X	X	X	X
4.8 Develop and implement guidelines for equipment procurement and placement across the laboratory network	4.8.1 Conduct equipment harmonization review every three years	to have a harmonised list every 3 years	Equipment harmonised list in place	MoH/partners	X			X	
	4.8.2 Develop equipment specifications and standards for all laboratory equipment across the laboratory network	Equipment standards developed	Laboratory equipment specifications developed	MoH/partners	X	X			
	4.8.3 Establish and harmonise guidelines for regulation of equipment in collaboration with UNBS, NDA and NACME	Regulation on laboratory equipment	Harmonised guidelines on equipment regulation available	MoH/partners				X	
4.9 Strengthen Equipment maintenance and management at all levels.	4.9.1 Establish positions for laboratory equipment biomedical engineers at national and regional workshops.	16 positions established	Number of positions for laboratory equipment biomedical engineers esterblished at national and regional workshops.	MoH/partners	X	X	X	X	X
	4.9.2 Establish positions for laboratory equipment biomedical supervisors at national level to oversee laboratory equipment maintenance	2 positions established	Number of positions for laboratory equipment biomedical supervisors esterblished at national level	MoH/partners	X	X	X	X	X
	4.9.3 Procure spare parts for preventive maintenance and repair of laboratory equipment	90% of identified needed spare parts are procured	% of spare parts procured	MoH/partners	X	X	X	X	X
	4.9.4 Support biomedical engineers to conduct preventive and curative maintenance of medical laboratory equipment	All laboratory equipment has down time less than 10%	% of laboratory equipment maintained	MoH/partners	X	X	X	X	X

					Y1	Y2	Y3	Y4	Y5
	4.9.5 Develop guidelines for laboratory equipment verification and calibration	Guidelines developed and implemented	Guidelines for laboratory equipment verification and calibration available	MoH/partners	X	X	X	X	X
	4.9.6 Establish a calibration centre for laboratory equipment at National level	National Calibration Centre established	A functional national Calibration Centre established	MoH/partners	X	X	X	X	X
4.10 Establish a system for monitoring equipment functionality and managing the disposal of laboratory equipment and supplies	4.10.1 Develop and implement guidelines for reporting equipment breakdown at all levels	Guidelines developed	Guidelines for reporting equipment breakdown at all levels developed	MoH/partners	X	X	X	X	X
			Number of laboratories utilizing the guidelines to report equipment breakdown		X	X	X	X	X
	4.10.2 Review and update national guidelines for laboratory equipment and laboratory supplies disposal in line with PPDA guidelines.	Disposal guidelines developed	Disposal guidelines in place	MoH/partners	X	X	X	X	X
	4.10.3 Train health workers at national, regional and district levels on procedure for proper disposal of obsolete laboratory equipment and expired reagents	95% of laboratory staff trained	Percent of health workers trained on procedure for proper disposal of obsolete laboratory equipment and expired reagents	MoH/partners	X	X	X	X	X

OBJECTIVE 5. Human Resources: To ensure that the laboratory sub-sector has adequate workforce with the necessary competencies, remuneration and motivation to deliver quality laboratory services at all designated levels

Time-line

Strategies	Sub-Objectives	Targets	Performance Indicators	Funding Source and Approx. Cost	Y1	Y2	Y3	Y4	Y5
5.1 Review and update current scheme of service for laboratory work force	5.1.1 Fast track the review of the Scheme of Service for laboratory professionals	To have the Scheme of service reviewed	Reviewed scheme of service available	MoH/partners	X				
	5.1.2 Review and conduct stakeholder consultation on the reviewed scheme of service	Stakeholder consensus on scheme of service	Stakeholder consultation report on the reviewed scheme of service available	MoH/partners	X				
	5.1.3 Engage with Ministry of Public Service & Ministry of Finance to approve and operationalize the revised scheme of service	Approved scheme of service	Approved scheme of service in place	MoH/partners	X	X			

	5.1.4 Engage the PNFP & PFP sector to adopt the revised laboratory scheme of service	Approved scheme of service shared with all PNFP & PFP service provider	% of PNFP & PFP who have adopted the scheme of service	MoH/partners /PFP/PNFP	X	X	X	X	X
5.2 Recruit adequate laboratory staff to fill vacant and new positions at all levels in line with the revised scheme of service for laboratory professionals	5.2.1 Fill the vacant laboratory posts at the various tiers of lab network	To have all vacant posts filled	Percentage of vacancies filled	MoH, PNFP & PFP	X	X	X	X	X
5.3 Retain adequate laboratory staff at all levels in line with the revised scheme of service	5.3.1 Establish a well defined career progression within the laboratory scheme of service	A national laboratory career progression plan	Career progression plan in the revised scheme of service implemented	MoH/HR/partners	X	X	X	X	X
	5.3.2 Develop and operationalize a reward/sanction system to foster laboratory staff retention	Reward/ sanction system developed	A rewarding/sanctioning system in place	MoH/partners	X	X	X	X	X
5.4 Equip the laboratory workforce with skills and competencies essential for quality service delivery	5.4.1 Ensure cadres from certified educational institutions are licensed and registered to practice	All working laboratory professionals are registered & licensed by the appropriate authorities/ bodies	Percent of laboratory professionals who are registered & licensed	MoH/partners	X	X	X	X	X
	5.4.2 Advocate for review of pre-service training curricula with the training schools/institutions to meet the needs of laboratory services	Pre-service Training curricula reviewed	Revised Pre-service Training curricula in place	MoH/partners/MOE	X	X			
	5.4.3 Adopt and implement the national in-service training plan	Annual in-service training plans developed	Number of trainings conducted based on the national in-service training plan	MoH/partners	X	X	X	X	X
	5.4.4 Develop guidelines and criteria for accrediting professional bodies to conduct CPDs for laboratory professionals	Guidelines/ criteria developed	Guidelines to conduct CPDs for laboratory professionals available	MoH/partners	X				
	5.4.Develop guidelines and criteria for certification of Non laboratory personnel involved in testing	Guidelines/ criteria developed	Guidelines for certification of Non laboratory personnel available	MoH/partners	X	X	X	X	X

OBJECTIVE 6. Quality Management System: To strengthen national laboratory quality management system in order to ensure quality service delivery that leads to national/ international laboratory certification and accreditation				Time-line					
Strategies	**Sub-Objectives**	**Targets**	**Performance Indicators**	**Funding Source and Ap-prox. Cost**	**Y1**	**Y2**	**Y3**	**Y4**	**Y5**
6.1 Establish national labor-atory standards	6.1.1 Develop a comprehensive national minimum standards of laboratory packages for laboratory compliance and certification	Comprehensive stand-ards developed	National minimum stand-ards of laboratory pack-ages for laboratory com-pliance and certification available	MoH & Partners	X	X	X	X	X
	6.1.2 Develop guidelines and procedures for effective implementation of Quality Man-agement Systems at all laboratory ti-ers/levels	Guidelines and proce-dures developed	Quality Management Systems guidelines and procedures available	MoH & Partners	x	x			
			Percentage of laborato-ries at all levels adhering to the quality manage-ment systems guidelines and procedures	MoH & Partners	x	x			
	6.1.3 Formulate standardized laboratory indicators for monitoring performance	laboratory indicators formulated	Laboratory performance monitoring indicators available	MoH & Partners	x	x	x	x	x
6.2 Standardize and strengthen the coordination of activities for implementa-tion of laboratory Quality Management Systems	6.2.1 Strengthen the QA Units and QA committees at national, regional and district levels for effective coordination	QA units fully functional at all levels	Number of fully function-al QA units	MoH & Partners	x	x			
	6.2.2 Strengthen the capacity of laboratory work force at facility level to implement laboratory quality management system	90% of laboratory work-force strengthened in QMS	% of laboratory work force trained/mentored on qaulity management systems	MoH & Partners	x	x	x	x	x
6.3.Strenghthen National External Quality Assessment schemes (NEQAS)	6.3.1 Establish a TWG for effective coordina-tion of EQA Schemes	NEQAS coordination committee functional	NEQAS coordination committee in place	MoH & Partners	x	x			
	6.3.2 Develop National EQA guidelines	NEQA guidelines devel-oped	NEQAS guidelines availa-ble	MoH & Partners	x				
	6.3.3 Strengthen national EQA capacity	7 additional PT schemes developed	Number of additional PT schemes added	MoH & Partners	x	x	x	x	x

	6.3.4 Increase number of laboratories participating in EQA Schemes	Attain 50% coverage of laboratories in Uganda	Percentage of laboratories participating in the NEQAS	MoH & Partners	x	x	x	x	x
6.4 Strengthen the national capacity for implementation of quality management systems towards laboratory certification and/or accreditation	6.4.1 Establish a national laboratory certification/accreditation unit	National Lab accreditation & certification established	A functional national Laboratory accreditation & certification unit available	MoH & Partners	x	x	x	x	x
	6.4.2 Train and certify SLMTA Trainers to facilitate effective implementation of laboratory quality management system	20 SLMTA trainers certified	Number of SLMTA trainers certified	MoH & Partners	x	x			
	6.4.3 Train and certify SLIPTA auditors to help in assessment and mentorship of laboratories for accreditation readiness	200 auditors trained	Number of trained auditors	MoH & Partners	x	x	x	x	x
		200 laboratories implementing SLMTA/SLIPTA program	Number of laboratories implementing SLMTA program	MoH & Partners	x	x	x	x	x
		200 Laboratories certified according to national/international standards	Number of laboratories certified according to national/international standards	MoH & Partners	x	x	x	x	x
		25 laboratories accredited to ISO 15189	Number of laboratories accredited to 15189	MoH & Partners	x	x	x	x	x
		5 blood banks accredited to ISO 9000	Number of blood banks accredited to ISO 9000	MoH & Partners	x	x	x	x	x
	6.4.4 Develop mentorship capacity for LQMS at all levels.	300 mentors trained	Number of LQMS mentors trained		X	X	X	X	X
	6.4.5 Develop and implement a database for Laboratory Quality Management System with respect to HLIMS frame work.	LQMS database developed	A functional LQMS database available	MoH & Partners	x	x	x	x	x
	6.4.6. Implement LQMS at lower health facilities not enrolled on SLMTA	30% of labs not enrolled on SLMTA	% of lower health facilities implementing LQMS		x	x	x	x	x
OBJECTIVE 7. Health Laboratory Information Management System: To implement an integrated HLIMS in the laboratory network for management and utilisation of patient data and other data on laboratory services in order to facilitate evidence based decision making and operational research					**Time-line**				

Strategies	Sub-Objectives	Targets	Performance Indicators	Funding Source and Approx. Cost	Y1	Y2	Y3	Y4	Y5
7.1.Develop and implement an electronic integrated HLIMS at all hubs in the network to improve laboratory data and information management	7.1.1 Scale-up the implementation of an electronic HLIMS in a phased approach in all 100 hubs to improve data quality for effective monitoring of laboratory services	Electronic integrated HLIMS implemented at 20 hubs per year	Number of hubs using the integrated electronic HLIMS per year	MoH, Partners	X	X	X	X	X
	7.1.2 Develop and conduct training on guidelines for laboratory data management	Conduct trainings on guidelines for HLIMS at 50 hubs per year	Number of hubs receiving trainings per year	MoH, Partners	X	X	X	X	X
	7.1.3 Conduct annual reviews of laboratory data management guidelines to improve on system performance	4 annual reviews of laboratory data management guidelines	Annual reviews of laboratory data management guidelines conducted	MoH, Partners		X	X	X	X
	7.1.4 Establish network infrastructure at all hubs to support electronic HLIMS	Network infrastructure for supporting electronic HLIMS established at 100 hubs	Number of hubs with established Network infrastructure for supporting electronic LIMS	MoH, Partners	X	X	X	X	X
	7.1.5 Establish the HLIMS central administration unit to effectively manage HLIMS initiatives	Established HLIMS central administration unit for managing and maintaining LIMS	Functional HLIMS central administration unit for managing and maintaining LIMS esterblished	MoH, Partners	X	X	X	X	X
	7.1.6 Build HLIMS human resource capacity at the hubs to manage HLIMS activities at hubs.	Trained and deployed HLIMS human resource at all hubs in the laboratory network	Number of hubs with trained HLIMS human resource.	MoH, Partners	X	X	X	X	X
	7.1.7 Establish and implement a national laboratory data warehouse to archive electronic laboratory data	Established national laboratory data warehouse	Functional and maintained laboratory data warehouse	MoH, Partners	X	X	X	X	X

7.2. Strengthen a standard-ized paper-based HLIMS at sites without electronic HLIMS to facilitate data capture and reporting	7.2.1 Update and harmonise paper-based HLIMS to accommodate all laboratory data needs	Updated and standard-ised paper-based HLIMS available at all tiers in the laboratory network	% of laboratory facilities at all tiers that have ade-quate/steady supply of updated and standard-ised paper-based HLIMS	MoH, Partners	X	X	X	X	X
	7.2.2 Conduct training on utilization of up-dated and standardised paper-based HLIMS to improve data capture and reporting	All facilities in the labor-atory network trained and utilizing updated and standardised paper-based HLIMS.	Number of facilities trained in using updated and standardised paper-based HLIMS for report-ing notifiable diseases and other laboratory pro-grammes	MoH, Partners	X	X	X	X	X
7.3. Develop and implement an electronic mobile, web-based platform for effective specimen tracking across the national sample transport network	7.3.1 Conduct a needs assessment to de-termine system and hardware needs for the specimen tracking system	Designed system for electronic mobile, web-based platform for ef-fective specimen track-ing across the national sample transport net-work.	Specimen tracking needs assessement report avaialable	MoH, Partners	X				
			Approved design for specimen tracking	MoH, Partners	X				
	7.3.2 Implement the mobile and web-based platform for specimen tracking to improve sample referrals	Transported specimens in network are tracked via electronic platform	Number of hubs using mobile and web-based platform for real-time specimen tracking im-plemented throughout network	MoH, Partners		X	X	X	X
7.4. Establish a system for standardized collection, analysis, and reporting of patient data to improve data use.	7.4.1 Develop and implement a comprehen-sive mechanism for collection, analysis, and reporting of all data including data on drug resistance, laboratory-based disease surveil-lance, notifiable diseases and outbreak in-vestigation to improve data use	Quality laboratory data generated for decision making at all levels.	Number of laboratories with quality data for decision-making.	MoH, Partners	X	X	X	X	X

	7.4.2 Build capacity among laboratory personnel at all levels on data usage to improve evidence-based planning and decision making amongst stakeholders.	All facilities in the laboratory network have staff using laboratory data in evidence based decision making	Number of facilities with staff trained on evidence based decision making	MoH, Partners	X	X	X	X	X
	7.4.3 Develop a laboratory data communication plan to streamline data reporting and feedback	Standardised laboratory data and information communication plan for reporting and feedback developed	Number of laboratories with standardised laboratory data and information communication plan for reporting and feedback	MoH, Partners	X	X	X	X	X
7.5 Establish a forum for multi-sectoral data sharing among all laboratories and agencies with activities affecting human health to enhance collaboration to implement One-Health model	7.5.1 Conduct advocacy for data sharing among all sectors including laboratories undertaking activities that affect human health to promote One-Health	Advocacy meetings on data sharing conducted with all laboratories and agencies with activities affecting human health	Number of advocacy meetings on data sharing conducted with all laboratories and agencies with activities affecting human health	MoH, Partners	X	X	X	X	X
	7.5.2 Develop a harmonized framework of data needs in accordance with multi-sectoral guidelines to achieve One-Health	A multi-sectoral framework of data needs towards achieving one-health	Availability of multi-sectoral framework of data needs towards achieving one-health	MoH, Partners	X	X	X		
	7.5.3 Implement and maintain a forum for multi-sectoral data sharing to achieve One-Health	Established forum for multi-sectoral data sharing	Functional forum for multi-sectoral data sharing; proportion of stakeholders operating within multi-sectoral data sharing	MoH, Partners	X	X	X	X	X
7.6 Establish an integrated database for managing non-clinical laboratory data to improve coordination of	7.6.1 Develop standards and implement an integrated database to manage non-clinical laboratory data	Developed integrated database at national level to monitor non-clinical laboratory data	Functional integrated database at national level to monitor non-clinical laboratory data	MoH, Partners	X	X	X	X	X

Strategies	Sub-Objectives	Targets	Performance Indicators	Funding Source and Approx. Cost	Y1	Y2	Y3	Y4	Y5
laboratory services	7.6.2 Implement a web-based system to improve logistics and equipment management	Developed web based ordering system for all types of laboratory commodities and equipment management at 100 hubs	Number of hubs with functional web based ordering system for laboratory commodities; a functional inventory and equipment management system	MoH, Partners	X	X	X	X	X
7.7 Develop and implement telemedicine in laboratory service delivery to improve patient care and build capacity	7.7.1 Conduct needs assessment for the telemedicine platform of laboratory services to guide the development and implementation of the platform	Defined needs and standards of telemedicine platform to support laboratory services	Availability of requirements document for a telemedicine platform to support laboratory services	MoH, Partners		X	X	X	X
	7.7.2 Develop and implement the telemedicine platform for laboratory services to improve accuracy and interpretation of laboratory results	Telemedicine implemented to support laboratory services	Number of laboratories with functional telemedicine platform for supporting laboratory services	MoH, Partners			X	X	X
7.8. Develop enterprise architecture for Lab services cordination function at UNHLS.	7.8.1 Conduct needs assessment for the coordination function of the UNHLS enterprise architecture	Developed requirements for segment B of the UNHL enterprise architecture	Requirements document for the UNHL enterprise architecture for coordination functions available	MoH, Partners	X				
	7.8.2 Design UNHLS enterprise architecture for coordination function inorder to specify system and technology needs for this function	Designated UNHL enterprise architecture for coordination functions	A designated UNHL enterprise architecture for coordination functions designed	MoH, Partners	X				
	7.8.3 Integrate architectures for UNHLS coordination function and for lab service delivery function across the laboratory network	Integrated UNHL enterprise architecture	Consolidated architecture description document for the integrated UNHL enterprise architecture	MoH, Partners	X				
	7.8.4 implement components in the intergrated UNHLS enterprise architecture	All components of LIMS developed	Functional components of LIMS developed	MoH, Partners	X	X	X	X	X

OBJECTIVE 8. Research and Development: To undertake research of public health importance according to the research priorities of the National Health Sector							Time-line		
Strategies	Sub-Objectives	Targets	Performance Indicators	Funding Source and Approx. Cost	Y1	Y2	Y3	Y4	Y5

Objective	Activity	Output indicator	Outcome indicator	Responsible	Y1	Y2	Y3	Y4	Y5
8.1 Develop a research agenda for laboratory sub sector	8.1.1 Establish a research and development unit with competent human resource to undertake roles of research operationalization in laboratory sub sector	Established unit for research and development of laboratory services	Existance of Operational unit for research and development of laboratory services	MoH, Partners	X	X			
	8.1.2 Establish a research and ethics committee (REC) at UNHLS	Functional research and ethics committee	A research and ethics committee established				X		
	8.1.3 Establish a national laboratory research plan to outline priority areas and identify collaborating partners	Approved national laboratory research plan with priorities	A national research plan with priorities in place.	MoH, Partners	X	X	X		
	8.1.4 Develop operational framework for research on laboratory services to guide research efforts	Approved operational framework for research on laboratory services developed.	Operational framework for research on laboratory services in place.	MoH, Partners	X	X			
	8.1.5 Implement the operational framework for research on laboratory services to generate information for better patient care and policy formulation	Operational framework for research on laboratory services in all national and regional laboratories	Number of national and regional laboratories operating within the research framework for laboratory services	MoH, Partners			X	X	X
8.2. Build capacity of laboratory personnel in operational research.	8.2.1 Develop training materials for operational research	Operational research materials developed	Operational research materials in place	MoH, Partners			X		
	8.2.2 Conduct regional trainings on undertaking operational research	4 regional trainings per year	Number of Regional Trainings conducted	MoH, Partners		x	x	x	x
8.3. Develop and implement a national laboratory research database to track and disseminate research findings	8.3.1 Establish collaborations and partnerships between academic and private sector partners, research institutions, and service delivery institutions to encourage multi-disciplinary and multi-sectoral research	Research collaborations and partnerships functional	Number of collaborative research initiatives established	MoH, Partners			X	X	X
	8.3.2 Implement the national laboratory research database to track and disseminate research findings on laboratory services	National laboratory research database tracks and disseminates all research by laboratory services	Functional national laboratory research database for tracking and disseminating research efforts on laboratory services	MoH, Partners		X	X	X	X

Strategies	Sub-Objectives	Targets	Performance Indicators	Funding Source and Approx. Cost	Y1	Y2	Y3	Y4	Y5
	8.3.3 Promote the utilisation of research findings to inform decision making at all levels, policy revision and improve practice	Research results from the national laboratory research database are shared	Number of research findings utilized to inform decision making at all levels, policy revision and improve practice	MoH, Partners				X	X

OBJECTIVE 9. Point of Care Testing (POCT) Services: To increase access to testing services by complementing conventional laboratory testing services with approved and appropriate point of care technologies — **Time-line**

Strategies	Sub-Objectives	Targets	Performance Indicators	Funding Source and Approx. Cost	Y1	Y2	Y3	Y4	Y5
9.1. Strengthen coordination mechanism for POCT to improve provision of POCT services	9.1.1 Establish the POCT Technical Working Group (TWG) to guide POCT implementation activities	POCT TWG established	Number of quarterly stakeholders meetings conducted by the POCT Technical Working Group (TWG) to guide POCT implementation activities	MoH, Partners	X	X			
	9.1.2 Develop and implement a POCT master plan	Approved POCT master plan to guides services	A POCT master plan developed	MoH, Partners	X	X	X	X	X
			Number of sites providing POCT services		X	X	X	X	X
	9.1.3 Define roles and responsibilities of stakeholders to improve coordination of POCT activities	Clearly defined roles and responsibilities of POCT stakeholders	Number of POCT Coordination activities conducted	MoH, Partners	X	X	X	X	X
9.2 Develop capacity for Point of Care Testing (POCT)	9.2.1 Conduct training and mentorship of health workers on POCT at all levels to build capacity for POCT services	Health workers trained and mentored on POCT	Number of health workers trained on POCT	MoH and Partners	X	X	X	X	X
			Number of health workers mentored on POCT		X	X	X	X	X
	9.2.2 Strengthen facilities to implement POCT and increase access to laboratory services	facilities empowered to implement POCT	Proportion of facilities that implement POCT services	MoH, Partners	X	X	X	X	X
9.3 Develop and implement policy and guidelines for all aspects of POCT to standardize POCT services	9.3.1 Develop POCT policy guidelines to guide implementation of POCT activities	laboratory POCT policy guidelines developed	POCT policy guidelines developed to guide implementation of POCT activities	MoH, Partners	X				
	9.3.2 Conduct evaluation of new POCT technologies to guide appropriate roll out of	All new POCT technologies evaluated	Number of new POCT technologies evaluated	MoH, Partners	X	X	X	X	X

					Y1	Y2	Y3	Y4	Y5
	POCT								
	9.3.3 Develop and implement integrated information management mechanism for POCT to improve data capture, analysis and reporting	An integrated information management mechanism for POCT manages data	An integrated information management mechanism for POCT to improve data capture, analysis and reporting available	MoH, Partners	X	X	X	X	X
	9.3.4 Develop and implement monitoring and evaluation guidelines for POCT	Monitoring and evaluation guidelines for POCT developed	Monitoring and evaluation guidelines for POCT in place	MoH, Partners	X	X			
	9.3.5 Conduct operational Research on POCT to guide policy formulation and service delivery	POCT operational research conducted at all levels	Number of sites conducting POCT operational research	MoH, Partners	X	X	X	X	X
9.4 Develop and implement POC communication strategy to improve access to POCT services at national, regional, district and community levels	9.4.1 Develop and disseminate POCT communication strategy to improve access to POCT services	POCT Communication strategy developed and disseminated	POCT Communication strategy in place	MoH, Partners	X				
			Number of stakeholders meetings held to disseminate POCT communication strategy		X				
	9.4.2 Translate POCT key messages in the local languages for community sensitization	Key messages translated into local languages	Number of local languages with key POCT messages translated	MoH, Partners	X	X	X		
	9.4.3. Disseminate POCT key messages to stake holders to enhance clinical adherence	POCT communication strategy disseminated to stakeholders	Number of stakeholders meetings held to disseminate POCT key messages to enhance clinical adherence	MoH, Partners	X	X	X		
9.5 Develop QA mechanism for POCT to improve quality of POCT services	9.5.1 Develop guidelines for QA-POCT to streamline the implementation of POCT services	QA-POCT guidelines developed. for implementation	QA-POCT guidelines developed.	MoH, Partners	X	X	X	X	X

Strategies	Sub-Objectives	Targets	Performance Indicators	Funding Source and Approx. Cost	Y1	Y2	Y3	Y4	Y5
	9.5.2 Establish facilities at national and reference laboratories for production of POCT PT panels	National and regional facilities for POCT panel preparations established	Number of facilities at national and reference level established for production of POCT PT panels	MoH, Partners	X	X	X	X	X
	9.5.3 Implement QA-POCT activities across all levels to assess performance and improve quality of POCT services	QA-POCT activities conducted across all levels	Number of sites implementing QA- POCT activities across all levels	MoH, Partners	X	X	X	X	X
	9.5.4. Develop and implement a corrective action plan for QA-POCT to improve performance of POCT services	Corrective action plan for QA-POCT developed	Corrective action plan for QA-POCT developed	MoH, Partners	X	X	X	X	X
			Number of facilities implementing corrective action plan for QA-POCT to improve performance of POCT service		X	X	X	X	X
	9.5.5 Develop and implement POCT EQA plan	POCT-EQA plan developed	Number of POCT sites participating in POCT-EQA	MoH, Partners	X	X	X	X	X
	9.5.6 Develop and implement a plan for POCT site supervision	plan for POCT site supervision Developed	Number of POCT sites supervised	MoH, Partners	X	X	X	X	X

OBJECTIVE 10. Partnerships: To strengthen multi-sectoral, national, international, public, and private partnerships to promote equitable access to quality laboratory services.

Time-line

Strategies	Sub-Objectives	Targets	Performance Indicators	Funding Source and Approx. Cost	Y1	Y2	Y3	Y4	Y5
10.1 Establish system of sharing information, testing capacity and resources between sectors towards One-Health Strategy (Zoonotic, AMR, Notifiable, Outbreaks)	10.1.1 Establish a laboratory multi-sectoral TWG to oversee implementation of One-Health Strategy	Multi sectoral TWG constituted	Number of multi-sectoral TWG meetings conducted to oversee implementation of One-Health Strategy	MoH	X				
	10.1.2 Determine testing capacities and ensure adequate resources to facilitate inter-sectoral referral services	Status of testing capacities for laboratories established	Number of facilities with capacity to facilitate inter-sectoral referral services	MoH/partners	X				
	10.1.3 Develop and implement mechanisms for information sharing to facilitate collabo-	Criteria / mechanisms for One-Health Strategy	Mechanisms for One-Health Strategy available	MoH/partners	X				

Strategies	Sub-Objectives	Targets	Performance Indicators	Funding Source and Approx. Cost	Y1	Y2	Y3	Y4	Y5
	ration and One-Health Strategy (for zoonotic agents, AMR, Notifiable, Outbreaks, Food safety)	in place	Number of sectors sharing information to facilitate collaboration and One-Health Strategy	MoH/partners	X				
10.2 Establish mechanisms to out-source specialized laboratory services to increase efficiency and effectiveness in service delivery	10.2.1 Review National laboratory Test Menu to define the tests to be out-sourced.	List of tests to be out-sourced	List of tests to be out-sourced available	MoH/partners	x	x			
	10.2.2 Develop MOUs to commit national and international specialized laboratories to perform the identified tests to be out-sourced.	MOU's signed for all identified areas	MOU to commit national and international specialized laboratories to perform the identified tests to be out-sourced in place	MoH/partners	x	x	x	x	x
10.3 Promote public private partnership for provision of health laboratory services in accordance to with PPPH Policy	10.3.1 Develop criteria for identifying underserved areas to be supported by providers outside the public system.	Criteria for identifying underserved HSDs developed	Criteria for identifying underserved areas available	MoH/partners	x	x			
	10.3.2 Identify alternative funding mechanisms and devise incentives for partners to support under-served areas and disciplines	List of underserved areas and alternative funding identified	Number of underserved areas supported by alternative funding mechanisms	MoH/partners	x	x			
10.4 Support the establishment of laboratory services in under-served areas by providers outside the public system.	10.4.1 Identify priority underserved HSDs where providers outside the public system can provide laboratory services	List of priority underserved HSDs	Number of underserved HSDs identified	Partners	X				
	10.4.2 Establish MOUs to commit providers outside the public system.	MOU's signed between MOH and service provider	Number of outside providers that signed the MOU	MoH/partners	X	X	X	X	X
	10.4.3 Link under-served HSDs to service providers outside the public system.	Priority underserved HSDs linked to support	Number of underserved HSDs linked to support	Partners	X	X	X	X	X
OBJECTIVE 11. Regulatory and Legal Framework: To ensure that the national laboratory legal and regulatory framework is enforced within the entire health laboratory network in collaboration with relevant regulatory bodies.					**Time-line**				
Strategies	**Sub-Objectives**	**Targets**	**Performance Indicators**	**Funding Source and Approx. Cost**	**Y1**	**Y2**	**Y3**	**Y4**	**Y5**

Strategies	Sub-Objectives	Targets	Performance Indicators	Funding Source and Approx. Cost	Y1	Y2	Y3	Y4	Y5
11.1 Ensure that all health laboratories meet the required standards for registration and licensing	11.1.1 Review and update the existing laboratory registration and licensing standards to identify and address gaps	100% Updated laboratory registration and licensing standards	Laboratory registration and licensing standards revised to identify and address gaps	MoH/partners	X	X			
	11.1.2 Disseminate updated standards to ensure all the laboratories comply with the standards	100% of the laboratories in the network with the standards	% of laboratories with a copy of the registration and licensing standards	MoH/partners/Regulatory Bodies		X			
	11.1.3 Support regulatory bodies to assess all laboratories for compliance to standards	100% of the laboratories assessed	% of laboratories that comply with the laboratory registration and licensing standards	MoH/partners/Regulatory Bodies		X			
	11.1.4 Support the regulatory bodies to review and update the current provisions for deterrent action and address the gaps identified.	Regulatory body Act updated	Regulatory body Acts reviewed	MoH/partners/Regulatory Bodies			X		
11.2 Ensure that all practising laboratory professionals are registered and licensed	11.2.1 Conduct sensitization meetings for training institutions on the importance of registration and licensing	100% training institutions sensization	% of training institutions sensitized on the importance of registration and licensing	MoH/partners/Regulatory Bodies	X	X	X	X	X
	11.2.2 Develop guidelines on CPD/CME requirements for licensing laboratory professionals	Guidelines available and distributed	CPD/CME guidelines developed	MoH/partners/Regulatory Bodies	X	X			
	11.2.3 Conduct regional sensitization meetings on the new CPD/CME regulatory guidelines	Regions sensitized	Number of regional sentization meeting held on the new CPD/CME regulatory guidelines						
	11.2.4 Develop guidelines on the process of administering the laboratory personnel oath at graduations.	Guidelines developed and distributed	Guidelines on the process of administering the laboratory personnel oath at graduations available	MoH/partners/ Regulatory Bodies	X	X			

OBJECTIVE 12. Monitoring and Evaluation: To create and implement mechanisms to effectively measure performance of the Health Laboratory sub-sector to facilitate management, planning, learning and policy formulation in the country.

Time-line

Strategies	Sub-Objectives	Targets	Performance Indicators	Funding Source and Approx. Cost	Y1	Y2	Y3	Y4	Y5

					Y1	Y2	Y3	Y4	Y5
12.1 Strengthen the M&E system to monitor and evaluate the implementation of the National Health laboratory Strategic Plan	12.1.1 Establish a mechanism for monitoring and evaluation of the National Health laboratory Strategic Plan at all levels of laboratory service delivery	A functional M & E mechanism at UNHLS	Functional M & E mechanism established	MoH/partners	X				
	12.1.2 Develop and implement a M&E plan to guide the implementation of the National Health laboratory Strategic Plan and Annual Operational Plans	M&E Plan completed and finalised	M&E Plan available	MoH/partners	X	X	X	X	X
			Number of units reporting on the performance indicators		X	X	X	X	X

OBJECTIVE 13. Finance and Accountability: To establish resource mobilisation and accountability mechanisms at national and sub-national levels to ensure availability and accessibility of adequate resources for the provision of sustainable laboratory services

Time-line

Strategies	Sub-Objectives	Targets	Performance Indicators	Funding Source and Approx. Cost	Y1	Y2	Y3	Y4	Y5
13.1 Ensure a dedicated budget for laboratory services in the Ministry of Health and in district health budgets	13.1.1 Ensure that the laboratory services have a dedicated vote in the MOH and at the local government budget to facilitate timely and consistent implementation of laboratory plans	Laboratory specific budget at the MOH	Existence of the laboratory services' vote at MOH	MoH	X				
13.2 Coordinate partner funding activities for laboratory services	13.2.1 Establish a finance and accounting unit at the UNHLS to mobilise, coordinate and monitor government and partner funding opportunities	A fully fledged finance unit at the UNHLS	A functional finance unit established at UNHLS	MoH	X				
	13.2.2 Establish a finance forum between funding partners and the UNHLS to monitor funding of laboratory activities	A functioning forum	Number of meetings held by the Finance Forum	MoH/partners		X			
	13.2.3 Build capacity of laboratory managers at all levels, in budgeting, finance and accountability to improve their management skills for proper planning	100% of laboratory Managers trained	% of laboratory Managers trained in budgeting, finance and accountability to improve their management skills for proper planning	MoH/partners	X	X	X	X	X
13.3 Mobilize funds to meet laboratory budget needs	13.3.1 Develop and implement a plan of resource mobilization for delivery of laboratory services at all levels	Plan functional	Existence of a budgetline to support the delivery of laboratory services at all levels	MoH	X				

	13.3.2 Ensure implementation of cost recovery program to facilitate uninterrupted provision of laboratory services	100% of laboratory units engaged in cost recovery	% of laboratories providing uninterrupted laboratory services guided by the cost recovery program	MoH	X	X	X	X	X
13.4 Establish a transparent system to ensure programmatic and financial accountability of laboratory services	13.4.1 Adopt the established Ministry of Finance Guidelines on Financial Management and Accountability to ensure effective management of laboratory resources	All laboratory units adopt the MOF guidelines	% of laboratory units implementing the Ministry of Finance guidelines on Financial Management and Accountability to ensure effective management of laboratory resources	MoH	X	X	X	X	X
	13.4.2 Build capacity of laboratory managers at all levels to plan and monitor budgets in line with MOFPED guidelines to ensure effective accountability	100% of laboratory managers able to use the MOFPED guidelines	% of laboratory managers trained in MOFPED guidelines to ensure effective accountability	MoH	X	X	X	X	X
OBJECTIVE 14.COMMUNITY: Laboratory services shall be an integral part of the health services responsiveness to the community needs and shall adhere to ethical and environmental standards.									
14.1 Develop strategies to increase community access to equitable quality testing services	14.1.1 Develop plan for community awareness and feedback to ensure understanding of testing services by the population	Community awareness plan developed	Community awareness and feedback plan available	MoH, Partners	X	X	X	X	X
	14.1.2 Conduct outreach programs to provide quality testing services to communities to ensure equal access	500 outreaches conducted	Number of outreaches conducted	MoH, Partners	X	X	X	X	X
	14.1.3 Develop the information, education and communication (IEC) materials for community awareness program on laboratory services	IEC Materials developed	IEC materials for community awareness program on laboratory services developed	MoH, Partners	X	X	X	X	X
	14.1.4 Implement community awareness plan to ensure access to information on laboratory services.	50% of network laboratories implementing community awareness plan by year 5	% of laboratories implementing community awareness plan	MoH, Partners	X	X	X	X	X