



REPUBLIC OF UGANDA
MINISTRY OF HEALTH

**DEPARTMENT OF NATIONAL HEALTH LABORATORY
AND
DIAGNOSTIC SERVICES**

**National Health Laboratory Services Strategic Plan III
(2021-2025)**

CONTENTS

1. Foreword.....	4
2. Acknowledgments.....	5
3. Abbreviations and Acronyms.....	6
4. Executive Summary	8
5. Background.....	10
1.1 Introduction.....	10
1.2 The Ugandan Health Care system.....	11
1.2.1 Laboratory Services in Uganda.....	11
6. Situation Analysis.....	12
1.3 Organization and Management.....	12
1.4 Laboratory Services.....	13
1.5 Health Laboratory Services Network.....	13
1.5.1 Point of Care Testing (POCT) Services:	14
1.5.2 Testing for Non-Communicable Diseases.....	14
1.5.3 Global Health Security	15
1.6 Infrastructure, Biosafety and Biosecurity.....	16
1.7 Laboratory Equipment and Supplies:	17
1.7.1 Laboratory Supplies	17
1.7.2 Laboratory Equipment.	18
1.8 Human Resources.....	18
1.9 Quality Management System.....	19
1.10 Health Laboratory Information Management Systems	20
1.9 Research &Development.....	20
1.10 Health Laboratory Systems Strengthening through Partnerships.....	21
1.11 Legal and Regulatory.....	21
1.12 Monitoring and Evaluation	22
2.12 Financing, Resource mobilization and management	23
1.13 Community Health Promotion for Lab Services.....	23
7. The Strategic plan.....	24

1.14	Vision:.....	24
1.15	Mission.	24
1.16	Strategic objectives.....	24
8.	Strategies.....	25
1.17	Strategic objective 1: (Leadership and Governance).....	25
1.17.1	Organization and Management.....	25
1.17.2	Human Resources.....	25
1.17.3	Regulatory and Legal Framework.....	25
1.17.4	Financing, Resource mobilization and Management.....	25
1.17.5	Health Laboratory Systems Strengthening through Partnerships.....	26
1.18	Strategic objective 2: (Accessibility to Quality of Laboratory Services).....	26
1.18.1	Laboratory Services Network.....	26
1.18.2	Infrastructure, Biosafety and Biosecurity.....	26
1.18.3	Equipment and Supplies.....	27
1.18.4	Quality Management Systems.....	27
1.18.5	Community Health promotion for Lab Services.....	27
1.19	Strategic objective 3: (Information Management and Utilization).....	28
1.19.1	Health Laboratory Information Management Systems.....	28
1.19.2	Monitoring and Evaluation.....	28
1.20	Strategic objective 3: (Promoting Research).....	28
1.20.1	Research & Development.....	28
9.	Frame work for the lab strategic plan III (2021/25).....	30

FOREWORD

This National Health Laboratory Services Strategic Plan (NHLSSP 2020-2025), builds on two previous strategic plans and seeks to strengthen the achievements registered so far in providing equitable access to quality laboratory services.

The ministry of health recognizes the importance of laboratory services in its efforts to accelerate movement towards Universal Health Coverage (UHC). Laboratory services can only efficiently contribute to the realization of this goal if they are well managed, coordinated, resourced and responsive to knowledge and technological advancements.

The management and coordination of laboratory services, though still suboptimal has improved over the past 5 years, however the funding of laboratory services has remained inadequate. This compromises the functionality of laboratory services leading to increased health care costs and poor quality of life resulting from poor/delayed diagnosis, irrational use of medicines as well as poor case and outbreak management. Vertical funding for particular diseases/programs such as HIV, TB Malaria and others has led to fragmented implementation resulting in inefficient use of resources availed for laboratory services. The MOH, together with development and implementing partners

appreciate the benefits of an integrated health laboratory services and will advocate for centralized as opposed to vertical funding for laboratory service.

This strategic plan provides a framework to guide investments in the national health laboratory services and implementation of National Health Laboratory Services Policy (NHLSP II) for financial years 2020/2021 to 2024/2025. Development of this strategic plan has been informed by a wide range of stakeholders including MOH leadership, clinicians, academicians, private sector, AHPC, Laboratory professionals as well as formal desk reviews and empirical evaluations of the performance against the NHLSSP II.

The Ministry of Health remains committed to strengthening equitable access to quality health laboratory services. All stakeholders and partners are encouraged to consult this strategic plan to inform their contribution to the delivery of laboratory services.



Dr. Diana Atwine
PERMANENT SECRETARY
MINISTRY OF HEALTH

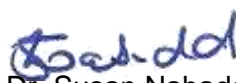
ACKNOWLEDGMENTS

The National Health Laboratory Services Strategic Plan (NHLSSP) 2020/2021 – 2045/2025 has been developed by the Ministry of Health (MOH), department of national Health laboratory and diagnostic services in collaboration with several stakeholders, health development partners, implementing partners and individual experts. The process involved a series of desk reviews, consultative meetings/workshops, individual and institutional engagements.

The Ministry of Health would therefore like to extend sincere appreciation to the Health Development Partners, especially Centers for Disease Control and Prevention (CDC) for providing financial and technical assistance, World Health Organization (WHO) Country Office, Professional Councils especially Uganda Medical Laboratory Technology Association, Academia from various universities, clinicians at the various levels of healthcare delivery, professionals in public and private practice for the technical assistance during 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, the

various units of the Department of National Health Laboratory and Diagnostic Services (NHLDS), Top and Senior Management teams of UNHLDS. 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 third national health laboratory services strategic plan.



Dr. Susan Nabadda

**COMMISSIONER, LABORATORY &
DIAGNOSTIC SERVICES
MINISTRY OF HEALTH**

ABBREVIATIONS AND ACRONYMS

AHPC	Allied Health Professionals Council
AMR	Antimicrobial Resistance
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
GHSA	Global Health Security Agenda
GoU	Government of Uganda
HIV	Human Immunodeficiency Virus
HLMIS	Health Laboratory Management Information Systems
HMIS	Health Management Information Systems
HIC	High income countries
HSD	Health Sub-District
HSSP	Health Sector Strategic Plans
IDI	Infectious Diseases Institute
JCRC	Joint Clinical Research Center
JEE	Joint External Evaluation
JMS	Joint Medical Store
LMICs	Low and medium income countries
LIMS	Laboratory Information Management Systems
LTC	National Health Laboratory Technical Advisory Committee
MDGs	Millennium Development Goals
MJAP	Mulago-Mbarara Teaching Hospitals' Joint AIDS Program
MOH	Ministry of Health
MRC	Medical Research Council
NCC	National Coordination Centre
NCDs	Non-communicable Diseases
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
NMRL	National Microbiology Reference Laboratory
NPEAP	National Poverty Eradication Action Plan
NPHL	National Public Health Laboratory
NPO	National Professional Officer

NLTP	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
POEs	Border Points of Entry
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 second National Health Laboratory Services Strategic Plan (NHLSSP II) guided the implementation of the second National Health Laboratory Services Policy (NHLSP II) for the period 2016-2020. There has been notable though suboptimal (below 50%) achievements against the targets set out in the NHLSSP II partly due to inadequate funding and fragmented implementation dictated by the different funding mechanisms.

This plan (NHLSSP III) shall guide the implementation of the NHLSP II for the period 2021-2025. It recognizes regional and global health initiatives, has been aligned with the Second Health Sector Development Plan (HSDP II), takes advantage of technological advancements and addresses the increasing demand and complexity of delivering laboratory services routinely and under emergency situations. The sectors contribution to the overall MOH goal of accelerating movement towards universal coverage shall be guided by for strategic objects i.e.: -

- I. To strengthen the leadership and governance structures for effective and sustainable laboratory service delivery at all levels.

- II. To provide quality and equitable laboratory services at all levels to support clinical care, public health services and research
- III. To strengthen laboratory information management and utilization for performance monitoring and decision making
- IV. To create enabling environment to promote research and innovations

The Plan provides a roadmap and identifies activities across (14) thematic areas for the realization of the strategic objectives as summarised in Table 1. The plan shall be implemented in a collaborative manner with relevant MDAs, Local Governments, development partners, Implementation partners as well as local international NGOs.

The projected annual cost of implementing this strategic plan is 1.4 trillion. More than half of this 860 billion (62%) is for equipment and supplies while the remaining 535 billion (48%) goes to health systems strengthening.

Funding is expected from GOU, Development partners and cost recovery through private laboratory services in public facilities.

Table 1: National Health Laboratory Services Strategic Plan III 2020-2025 summary.

National Health Laboratory Services Strategic Plan - 2021-2025			
Vision			
Quality health laboratories services available and accessible to all people in Uganda.			
Mission			
To Provide quality, cost-effective and sustainable health laboratory services to the people in Uganda and to support health care delivery regionally and internationally.			
Strategic Focus			
1. Leadership and Governance	2. Equitable Access to Quality Laboratory Services	3. Information Management and Utilization	4. Promotion of Research and implementation science
Objectives			
1. Establish and maintain an appropriate organizational structure to coordinate and manage National Health Laboratory Services.	1. Provide quality laboratory services to all people in Uganda	1. To implement an integrated HLIMS in the laboratory network.	1. Undertake research of public health importance.
2. Ensure adequacy of laboratory professionals (numbers and Skills)	2. Ensure appropriate laboratory infrastructure.	2. To create and implement mechanisms to effectively measure performance of the health laboratory subsector for decision making.	
3. Ensure the national standards are enforced.	3. Ensure availability of supplies and functional equipment.		
4. Establish resource mobilization and accountability mechanisms all levels.	4. Establish and maintain a national laboratory quality management system.		
5. Strengthen Partnerships.	5. Promote community engagement and utilization of laboratory services.		
Performance Indicators			
1. National and sub national laboratory coordination structure established and functionalized. 2. Proportion of positions filled as per established staffing norms. 3. Proportion of staff meeting national CPD requirements, 4. Proportion of operating laboratories that are licensed as per national standards/guidelines. 5. Percentage of national health laboratory budget that is funded.	1. Proportion of labs implementing the test menu appropriate for the level without interruption. 2. Proportion of facilities reached by the hub rider as per schedule. 3. Proportion of laboratories meeting national health laboratory standards. 4. Number of laboratories achieving international accreditation. 5. Number meeting National Laboratory Infrastructure guidelines. 6. Proportion of laboratories passing the safety audits. 7. Reduction in Equipment downtime 8. Reduction in Stockouts of critical supplies.	1. An integrated HLIMS to support the national health laboratory network, 2. Proportion of laboratories able to effectively utilizing the national HLIMS. 3. Proportion of indicators reported through the HLIMS 4. Percentage of program reports published within agreed time lines.	1. Approved research agenda. 2. Number of research publications. 3. Research dissemination meetings (conferences/workshops).

1 BACKGROUND

1.0 Introduction

Quality, effective and equitable laboratory services play a critical role in the overall improvement of health services. Laboratories provide information necessary for efficient use of medicines and for disease prevention. Laboratory testing as part of routine diagnostics or through surveillance programs provides data necessary for early detection of health threats thereby guiding effective responses to, minimizing effects of and promoting the life, wellbeing and productivity of citizens. The need to strengthen laboratory services functionality as part of overall health systems improvement has been the basis for several global and regional accords/declarations such as the Maputo and Yaoundé, declarations (2008).

The national aspirations of a “Transformed Ugandan Society from a Peasant to a Modern and Prosperous Country” (Vision 2040), and the Ministry of Health’s vision of “A healthy and productive population that contributes to economic growth and national development.” cannot be realized without a strong and effective laboratory system. Strengthening laboratory systems requires appropriate strategic plans guided by national health laboratory policies.

Uganda’s first National Health Laboratory Services Policy (NHLSP I, 2009) which was implemented through the first national health laboratory strategic plan (NHLSSPI, 2010) was updated in 2017 (NHLSP II) to address advances in health technology globally, including GHSA, SDG, UNAIDS 90-90-90, IHR, UHC among others. The revision of the NHLSP II, was followed by the development of the second National health Laboratory services strategic Plan (NHLSSP II, 2016) which guided implementation of the policy for the period 2016-2020.

The NHLSSP III has been developed to guide investments in the health laboratory sub-sector for the next five years (2021-2025). The plan is guided by the NHLSP II (2017) and is in alignment with the MOH strategic plan (2020/2021-2024/2025). The plan seeks to contribute to the implementation of NDP III, the attainment of Uganda’s vision 2040 and the global agenda (SDGs) 2030.

1.2 THE UGANDAN HEALTH CARE SYSTEM

The Ministry of health provides overall stewardship of the health sector in which health care is provided through public, private not for profit (PNFP) and Private health facilities. Public health facilities constitute approximately 66% of all health outlets in a tiered network comprising of National referral hospitals (4), regional referral hospitals (16) covering 14 health Regions, General hospitals (112) Health Centre IVs (197) Health Centre IIIs (1,289), Health Centre II (XX) and community health extension workers who provide basic health care services at the village level.

Some services are provided through specialized autonomous national institutions such as the Uganda blood transfusion services, Uganda Heart Institute, National Medical Stores among others.

The PNFP health care facilities which are largely run by faith based medical bureaus (UCMB, UPMB, UMMB, and UOMB) mirror the tiered public health care facilities. There are also several private health facilities including hospitals and health centers/clinics that provide a wide range of health care services.

2.1 Laboratory Services in Uganda

The department of National Health Laboratory and Diagnostic Services (NHLDS) responsible for overall stewardship of health laboratory services in the country.

Established laboratories exist in all public health facilities starting from HC III. The range and complexity of testing services increases with level of health facility as defined in the

national Test menu with each level serving as a reference laboratory for the levels lower than it except for laboratory hubs which serve as referrals for same level and below due to enhanced facilities at hubs. Testing also happens in mobile laboratories and outside laboratories at HC II and community levels by trained non-laboratory health workers using point of care technologies.

There are specialized laboratories serving as national referral centers providing specialized testing services. Such laboratories include Central Public Health Laboratories (CPHL) which provides reference testing services for bacterial diseases and antimicrobial resistance, HIV/ Hepatitis B viral load, HIV Early Infant Diagnosis (EID) testing, among others. Other specialized reference laboratories include the Supra/National Tuberculosis Reference Laboratory (S/NTRL), the National STD Reference Laboratory, the Uganda Virus Research Institute (UVRI), the Joint Clinical Research Centre (JCRC), Uganda Cancer Institute (UCI), Mulago Histopathology Laboratory, Uganda Heart Institute (UHI), Uganda Blood Transfusion Services (UBTS) and Entomology Reference Laboratory.

In the private sector, PNFP and Private Health facilities run laboratories as part of the diagnostic services. The range of services provided in private sector laboratories varies widely as influenced by market forces and/or technical expertise/interests of the proprietors.

In addition to laboratories established for the purpose of providing diagnostic services, there are several other laboratories in universities and other training institutions that complement the national health laboratory services.

In 2019, an evaluation of the status of NHLSSP II implementation was undertaken. The evaluation took stock of progress, identified challenges and informed the development of the third Health laboratory strategic plan.

The assessment was structured along the 14 thematic areas of Organization and Management, Health Laboratory Services Network, Infrastructure, Biosafety and Biosecurity, Equipment and Supplies, Human Resources, Quality Management Systems, Health Laboratory Information Management Systems, Research and Development, Point of Care Testing Services, Partnerships, Regulatory and Legal Framework, Monitoring and Evaluation, Financing and Accountability and Community as identified in the NHLSSP II.

Although the overall achievement was below 50%, major achievements were registered during the past five years. The low performance was largely due to inadequate funding for priority areas within the strategic plan other than HIV services, weak coordination mechanisms at regional and sub-national levels and inadequate M&E systems.

2.1 Organization and Management

The success of any health system hinges on a strong and efficient management and governance structure. A functional laboratory governance structure ensures that laboratory services are efficiently coordinated and regulated.

The National Health Laboratory & Diagnostic Services (NHL&DS) is the department in the

Ministry of Health (MOH) that is responsible for overall stewardship and governance of health laboratory services. It coordinates a tiered network comprising of National and Regional referral Laboratories, General Hospital Laboratories, HCIV and HCIII laboratories as well as POCT testing outside designated laboratories. The department also collaborates with specialized and research laboratories e.g., the UBTS, UVRI, UCI. The Laboratory Technical and Advisory Committee (LTC) supports the department in the technical review of policies, guidelines and plans.

During the past five years of the second national health laboratory services strategic plan, considerable efforts were made to streamline the organization and management structures of the national health laboratory services.

The 2018 restructuring of the MOH created the department of National Health Laboratory and Diagnostic Services (NHLDS) which has improved leadership and governance for Laboratory service delivery at the central level. However, the increasing demand on laboratory services to meet clinical, diagnostics, public health, surveillance, epidemic management and research demands requires higher level of organization and coordination that is difficult to attain within the department organizational structures. Furthermore, sub national coordination and management structures are not very clearly defined and remain obscure. All coordination roles at subnational levels are designated positions as opposed to substantive employment, which compromises their ability to coordinate at that level.

Additionally, implementation of regional and global initiatives such as the International Health Regulation (IHR), and Global Health Security Agenda (GHSA) requires multisectoral collaboration and demands for better coordination of health laboratory services at all levels of healthcare delivery system.

The prevailing national and global health threats such as Ebola and COVID-19 outbreaks have prompted the Ministry of Health to initiate creation of the National Institute of Public Health (NIPH) to ensure proper coordination of the emergency disease response. The department of National Health Laboratory Services (NHLDS) will work with the institute to establish Laboratory a system for outbreak investigations and early disease detection.

This strategic plan seeks to strengthen Laboratory services coordination at both national and sub national levels by elevating the Department to directorate level, clearly defining linkages between the department and other MDA as well as Private Health Laboratory Providers. Mechanisms for proper coordination of laboratories at subnational levels are also proposed.

2.2 Laboratory Services

2.2.1 Health Laboratory Services Network

Health laboratory services in Uganda are delivered through a network of laboratories within public, private (including PNFP) health facilities, universities as well as stand-alone public and private laboratories. Within the public health facilities, the range and complexity of services provided increases with the level of care as defined by the national standard test menu and this is mirrored in

PNFP facilities. The range and complexity of laboratory services in private health facilities, private stand alone laboratories and university laboratories are highly varied reflecting the interests of the founding body, available technical expertise and/or Market forces. At the national level, specialized laboratories such as CPHL, UVRI, UBTS, provide specialized testing services.

Significant progress has been made in the provision of quality laboratory services during the implementation of the strategic plan 2015 - 2020. Specialized laboratories such as viral load EID reference labs (VL/EID), National microbiology reference lab (NMRL), and National TB reference lab (NTRL), Abovirology lab at UVRI among others have enhanced the technical capacity in the detection of diseases of public health interest. Furthermore, laboratory services have markedly improved at the regional referral hospitals (RRH), general hospitals, and lower health facilities. Of particular interest over 100 laboratory hubs have been improved to serve a designated catchment area with provision of technical capacity, modern equipment and human resource.

In addition, the sample transport network has been strengthened to support referral of clinical specimens from lower health facilities for testing, with results being reported back to the originating facilities within good turn-around-time (TAT) via electronic dispatch. Overall, access and equity of laboratory testing services for the major diseases such as malaria, HIV and TB has also improved significantly.

However, a number of challenges to the delivery of effective and sustainable health laboratory services remain. The disease specific programming has resulted into suboptimal utilization of laboratory resources. For example some equipment e.g. GeneXpert used for TB testing, Flow cytometers (CD4), and Real Time PCR systems (HIV Viral Load &

HIV DNA PCR) that can perform several other tests has been used to perform only tests specific for the program that placed them in facilities. The integration of program specific staff into routine health facility laboratory services has been a challenge. Guided by the UNMHCP, testing within these programs is narrow largely focusing on infectious diseases e.g. HIV, TB and malaria.

Gaps still exist in the sample referral network including long TAT of sample transportation due to limited number of facility visits, poor specimen and results tracking, limited cold chain capacity at the hubs, and weak referral at the hub level.

While points of entry (POE) Laboratories are critical in mitigating risks resulting from infectious diseases across the borders, only 3 POE laboratories have been established to support Covid-19 sample collection, testing and reporting. These POE laboratories however lack the functional capacity to provide other tests for emerging and re-emerging infectious diseases of Public health interest. There is need to officially establish coordination structures for POE laboratories working together with PoE surveillance activities at the MOH level.

To address these challenges, and in line with the HSDP 2020/21 – 2024/25, this strategic plan advocate for increased financing for laboratory services, provision of equitable quality laboratory services, promotes efficient utilization of equipment, and the proper integration of laboratory surveillance into clinical care. Special attention will be given to tests for risk stratification, diagnosis, and monitoring of non-communicable diseases (NCDs) and the use of point of care technologies.

2.2.2 Point of Care Testing (POCT) Services:

Properly used, POCT can significantly improve access to effective, efficient, and equitable testing services to support the implementation of UNMHCP and promote acceleration towards the achievement of Universal Health Care (UHC). Several POCT technologies have been approved for the diagnosis/management of infectious diseases e.g., malaria, tuberculosis, HIV, and non-communicable diseases. The 48 facilities successfully using POCT for HIV EID, the 3 POE laboratory using POCT for COVID-19 provides credence that even NAT that has been traditionally reserved for highly complex laboratory facilities with highly trained personnel can be conducted at POCT sites. Uganda has a Point of Care Testing Policy and Implementation Guidelines that among other things gives guidance for implementation of POCT. In-country production of EQA materials for selected POCT has been successfully piloted. The major challenge however remains the rollout and implementation of these POCT policy guidelines. This strategic plan therefore aims at ensuring the actualization of proper utilization of POCT through implementation of the POCT policy and guidelines.

2.2.3 Testing for Non-Communicable Diseases

Non communicable diseases are the leading cause of death, accounting for 41 million deaths globally per year. In Uganda, the 4 major NCDs (cardiovascular diseases, cancers, chronic respiratory diseases and type 2 diabetes mellitus) account for 33% of deaths annually. With special attention Uganda has a disproportionately high levels of hemoglobinopathies which laboratory systems play a significant role in screening and diagnosis. Sickle cell disease is one of the two major hemoglobinopathies, the other being thalassemia's. In Uganda it is estimated that

20,000-25,000 babies are born with SCD each year and more than 70% do not celebrate their 5th birthday. For this reason, the MOH has leveraged on the infrastructure of HIV Early Infant Diagnosis (EID) to start the screening and diagnosis of SCD in high burden districts across the country. This strategic plan seeks to improve on the access to screening and diagnosis for all hemoglobinopathies (SCD and Haemophilia's) at selected health facilities.

Uganda recorded 32,617/100,000 new cancer cases in 2018 with 21,829 deaths. Of these, cancer of the cervix accounted for 6,413/100,000 (19.7%), Kaposi's sarcoma 4,238/100,000 (13%), cancer of the breast 2,318/100,000 (7.1%) and cancer of the prostate 2,086 (6.4%). Despite this burden, there is a significant gap in access diagnostic services including pathology services. The lack of services is largely due to limited human resource capacity and infrastructure. This strategic plan supports the strengthening of laboratory capacity to perform tests for NCD through enhancing HR and improving laboratory infrastructure to handle major NCDs including pathology services.

2.2.4 Global Health Security

Addressing Global Health Security requires local, regional and international efforts and the main priority is to develop surveillance systems and capacity to detect, report and conduct surveillance, real time detection and reporting of resistant bugs. The capacity to conduct real-time detection and reporting is a priority in developing countries, where the prevalence of both new and re-emerging infections is high.

Globally, bacterial infections cause acute and chronic life-threatening infections and have become so difficult to treat due to antimicrobial resistance since the discovery of antibiotics almost over seven decades ago. This challenge of antibiotic resistance is not only in one sector but cuts across all the key sectors with serious drivers and threats originating

from human health, animal health, environment, food chain and the economic sector Gelband, et, al. (2015). Although antimicrobial resistance is a natural phenomenon, it is easily accelerated by misuse and overuse of antibiotics WHO (2018). If not addressed, antimicrobial resistance will cost the global economy over 100 trillion USD by 2050 LSMTH, (2016).

To this end, AMR surveillance is considered a high yield investment that countries must undertake to combat this global threat. Through surveillance and implementation science, countries can monitor trends and detect the magnitude of the emerging resistance to priority antibiotics. This evidence can inform local policies both at national and sub-national level in areas of treatment guidelines and infection prevention and control strategies.

The increasing cross-border migrations in concert with emerging novel and re-emerging resistant infectious diseases possess a global health security thus global threat. Understanding the epidemiology of these infectious diseases at a global scale is now a priority for controlling them. Increasing antimicrobial resistance (AMR) in humans, animals, and the environment alongside other infectious disease outbreaks like zoonoses, rationalizes the need to implement the Global Health Security Partnerships (GHSP), which aims at strengthening national and international capacities for all countries and global agencies to prevent, detect and respond to infectious disease threats.

On the other note, the increasing resistance to antimicrobial agents at a global scale in humans, animals and the environment, threatens our abilities to treat even minor conditions – thus we are running out of options. Addressing AMR requires local, regional and international collaborations and partnerships. The main priority is to develop surveillance systems and capacity to conduct in-depth research with an understanding of the drivers of resistance, real time detection and reporting

of resistant bugs. These surveillance systems are a priority in developing countries, where the prevalence of both new and re-emerging infections is high.

Therefore, in this strategic plan, much emphasis shall be put in strengthening national and facility level microbiology capacity in relation to AMR surveillance systems and structures. This will provide accurate and reliable data for country representation of the magnitude of resistance. The AMR-NAP is a strategic document with five key strategic objectives that address areas of; Laboratory based surveillance for Antimicrobial Resistance; Surveillance for Optimal Use access and stewardship of antimicrobials; Infection Prevention and Control as well as surveillance for HCAs; Public awareness, training and education and Antimicrobial resistance research and innovation.

With support from our partners, Centers for Disease Control under the Global Health Security Agenda and the United Kingdom support through the Fleming Fund, in the last five years, Uganda has established five AMR sentinel sites and these have generated resistance data that has been shared globally and also used locally to influence policy and practices. These sites are; Arua, Mbale, Kabale and Mubende RRH laboratories as well as the National Microbiology Reference Laboratory at CPHL. The establishment of the AMR National Coordination Centre (NCC) for coordination of AMR related activities in all the laboratories in the network has also boosted the coordination of arm of NMRL/NHLDS to strengthen microbiology services in the network. In the last five years, Uganda published its action plan as well as other key documents to enable surveillance activities. These include; Human Health AMR Surveillance Plan, Human Health Antimicrobial Use and Consumption Surveillance plan, Diagnostic Stewardship Manual for AMR Site surveillance and clinical protocols,

In-service Microbiology Training Curriculum, Facility based Microbiology tools to capture patient level data; Draft architecture of National Microbiology Dashboard to link surveillance data of all microbiology facilities in the network.

The Uganda National Policy for Bio-banking and achieving of microbiology isolates. Twelve sets of Standard Operation Procedures (SOPs) which can be harmonized and adopted by the all microbiology laboratories in the network with inclusion of animal health, environment and food and beverages laboratories.

However, there is need to strengthen these efforts by increasing the scope of surveillance sites to have data that is representative of the country's magnitude of resistance to also capture other microbial agents like antiviral resistance among HIV patients. Involving other key players like the private sector, address the challenges of microbiology supplies and commodities, improve the laboratory infrastructure to address biosafety and biosecurity, as well as improve the human resource capacities in microbiology bench skills so that the antimicrobial susceptibility data generated is of quality.

2.3 Infrastructure, Biosafety and Biosecurity

Laboratory testing procedures may expose lab personnel, environment and community to infectious and non-infectious hazards which negatively impact on the quality of lab services. Improvements in Bio-risk Management (BRM) coordination has been strengthened through the establishment of biosafety biosecurity coordination office at UNHLS as well as multi-sectorial partnership and engagements under the one Health program. During the previous strategic plan implementation period, national biosafety biosecurity performance progressed from 33% in 2017 to 44% in 2020. Equally,

progress has been registered in capacity building efforts for example, 80 national BRM trainers- 25 (30%) attained International Federation of Biosafety Association certification, over 1000 laboratory personnel and 30 auditors for Biosafety and Biosecurity were trained with support from the regional implementing partners. More than 300 health and veterinary laboratories were audited as part of annual BRM program monitoring and evaluation. National pathogen inventory was established under Uganda national council of science and technology as well as regulation and establishment of biobanks at UNHLS. Several policies, and guidelines (BRM manual, national checklist, infrastructure, waste management) were developed under the one health program and distributed to about 70% of the facilities including the revision of the training and auditing curriculum. All the 100 Hubs, Regional and General Hospitals have been remodeled to meet the infrastructure standards and partial remodeling of other laboratories has been done by the different partners. There has been a gradual improvement in the provision of emergency and general safety equipment including Biosafety cabinets. Servicing and Certification of Biosafety cabinets have been rolled out across the country.

However, there remain many challenges that need to be addressed; the policy and many other documents (biosecurity bill and policy, review of BRM manual: 2015, infrastructure guideline) still remain in draft form at various levels of approval. The overall management support/commitment for Biosafety biosecurity program remains at 28%. The other outstanding challenges include lack of a dedicated budget for supporting biosafety biosecurity national activities, absence of occupational safety and health (OSH) programme for laboratory personnel, inadequate infrastructure at national level, regions and hubs to accommodate expanded

scope of tests due to emerging and re-emerging diseases for both clinical and public health, substandard infrastructures in some non-hub and private laboratories, inadequate capacity for fire, chemical and waste management, and inadequate capacity for containment of and response to emerging and reemerging infectious diseases.

This strategic plan lays strategies for addressing the gaps above bearing in mind challenges caused by diseases such as COVID-19 and many others yet to be encountered in future. Emphasis will be put on infrastructure designs, expansion and construction of infrastructure at national and subnational levels to address increased laboratory services scope for both clinical and public health, ensuring availability of up-to-date guidelines for control and mitigation of effects arising from handling various pathogens and hazardous materials in the laboratories in line with guidance from ISO 35001 2019 and ISO 15190 2020. Efforts shall be made to obtain Management commitment and resource allocation towards Biorisk management interventions.

2.4 Laboratory Equipment and Supplies:

2.4.1 Laboratory Supplies

Effective supply chain and equipment management is the key for provision of quality laboratory services. A lot of efforts have been made to strengthen lab supplies chain systems at all levels to ensure uninterrupted services at all tiers of health care. Tremendous improvements have been noted across the different components of logistic cycle, including the development of standardized test menu, techniques and list of harmonized equipment, periodic quantification of lab commodities and supply plans, improvement in web-based ordering and inventory management systems and the implementation of Lab SPARS to strengthen capacity of lab staff in supplies.

Outstanding challenges include inadequate funding for procurement, weak tracking and

distribution system, inadequate Human Resources for lab logistics, inadequate storage facilities at national and facility level, poor data management at facility level that affects the quality of forecasts.

UNHLS will advocate for increased funding of lab commodities, strengthen logistics management systems, maintain an updated national laboratory test menu and institute mechanisms for pre- and post-market surveillance.

2.3.1 Laboratory Equipment

Adequate and appropriately managed equipment are essential in the delivery of health laboratory services.

Clinical laboratory instrumentation has undergone marked increase in sophistication and complexity. In the previous strategic plan, laboratory equipment procurement was streamlined through development of equipment procurement and placement guideline, establishment of equipment calibration center, attaining international accreditation for the equipment calibration center, incorporating maintenance in the reagents purchased as markup, reagent rental for high volume facilities and Public private partnerships. Additionally, the Ministry with Development Partners has strengthened equipment maintenance for non-automated equipment using Regional Medical Equipment Maintenance workshops where Biomedical Engineers/Technicians were recruited and trained to provide preventive maintenance and repair on laboratory equipment across the laboratory network with support from implementing partners.

However, there are still gaps in laboratory equipment management in Uganda including fragmented equipment maintenance system, low funding, inadequate human resource,

limited capacity of regional maintenance workshops.

Over the next five years, efforts will be focused on strengthening the national health laboratory equipment management mechanisms, building human resource capacity improving the functionality of the regional equipment maintenance workshops.

2.4 Human Resources

A highly trained and skilled laboratory work force is essential for the provision of quality laboratory services. The health sector development plan two (HSDP II, 2020/21-2024/25) notes that Human resources for health (HRH) is the most critical factor in provision of quality preventive, promotive and curative services.

The Ministry of Health human resources for health audit report 2017/18 shows that positions for Laboratory cadre are over filled at 102%. However, this audit was conducted against a staffing structure that was developed over 30years ago when the population of the country was 8million and disease burden was low. The advancement of technology and the new disease trends require a more diverse and skilled human resource the address the current public health needs. In this new strategic plan, we aim at ensuring we have the right human resource is put in place at all levels. In order to achieve this the strategic plan will ensure that; the new laboratory scheme of service 2018 is fully functionalized and the Pathology sub-specialties are incorporated in the current structure. There is also need for laboratory support function human resource capacity to ensure the smooth and efficient delivery of services like data and IT support.

This strategic plan will ensure that there is adequate Human Resources in terms of qualification, skills and numbers. Efforts will be made to implement strategies for continuous

skills improvement and retention of skilled Laboratory professionals in the service.

2.5 Quality Management System

Implementation of quality management system (QMS) in the Health Laboratory subsector in Uganda will be underpinned on the premise of the Strategic objective 4 of the Health Sector Development Plan II (HSDPII) which states thus: “To strengthen the health system and its support mechanisms to optimize delivery of quality health care services”.

QMS will improve the accuracy and reliability of laboratory services across all tiers of healthcare delivery system, thereby building confidence in the clinicians and public health practitioners to use the laboratory diagnostic tests more in both clinical and public health decision making, and for research. 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.

In the 2016-2020 strategic period, the Uganda Laboratory subsector achieved significant milestones in QMS implementation. During this period, Uganda continued to implement the World Health Organization’s (WHO) Stepwise Laboratory quality Improvement Process towards Accreditation (SLIPTA) initiative; 49 SLIPTA auditors were trained and certified, and presented cumulatively up to 83 Laboratories for international audit by the African Society for Laboratory Medicine (ASLM) on behalf of WHO, 73 of which were certified at various star levels. A number of ASLM certified Laboratories were fast-tracked for international accreditation, 18 of which attained accreditation to ISO 15189 Standards, one in the private sector, 4 in the private not for profit subsector while 13 were purely government health facilities, bringing to 25 the total number of Laboratories accredited to ISO15189 Standards in the country.

On the other hand, the National Tuberculosis Reference Laboratory (NTRL) obtained additional accreditation to ISO17043 for production of Proficiency Testing (PT) Panels particularly for TB microscopy, Nucleic Acid Test (NAT)/Gene Xpert and Diagnostic Sensitivity Testing (DST), and the Early Infant Diagnosis/Viral Load Laboratory at CPHL was certified by WHO for prequalification of HIV and Hepatitis B invitro diagnostics.

Uganda’s External Quality Assessment (EQA) system was boosted by initiation of local panel production for 5 proficiency testing schemes for both conventional and POC, including HIV NAT and Hepatitis B serology by the CPHL EID/VL Laboratory, Serum CRAG and Gram by the National Microbiology Reference Laboratory (NMRL), and HIV-Syphilis duo serology testing by Uganda Virus Research Institute (UVRI) which were all successfully piloted, bringing to 10 the total number of schemes with panels produced locally, a huge boost to the country’s quality management systems programming.

However, there still remains critical challenges in the implementation of laboratory quality management system in the country including limited capacity in the areas of audit and mentorship, high attrition of staff at facilities, majority of tests still lack EQA schemes with a few tests having PT panels imported from other countries, fragmented implementation of the available schemes (both imported and locally produced), high cost of accreditation due to use of accreditation bodies from other countries. Other challenges are stockout of laboratory reagents and supplies for essential tests in the accredited facilities.

This strategic plan will focus on strengthening the existing efforts in quality management systems towards accreditation of more laboratories through; harmonizing the National External Quality Assurance (EQA) schemes, strengthening capacity development efforts for more Laboratory professionals on Quality

Management System, Establishing a National Accreditation system for laboratories and sustenance of Laboratory accreditation efforts through development of a cost recovery process that will ensure availability of testing commodities as well as engaging anatomical laboratories in all quality assurance stratagems.

2.6 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 largely by paper-based LIMS. Over the period of the strategic plan the drive is to electronic data capture for purposes of utilizing it for efficient decision making.

At the national level, electronic databases have been established and are currently being used to host electronic HIV EID, VL and COVID-19 LIMS. All the 100 hubs and more than 350 high volume non hub facilities are electronically accessing and printing results from the LIMS. Online ordering of laboratory supplies for HIV testing is now possible through the inventory management system.

Advocating for the use of electronic information systems across the health laboratory network will increase the utilization laboratory

generated data. Over the past five years, NHLDS has coordinated stakeholders in development and review of the national laboratory data tools to address clinical and public health requirements. Considerable efforts have been made to establish interoperability of the health laboratory information system (HLIMS) with Electronic Medical Records (EMRs) to enable linkage of national referral laboratories to lower-level health facilities. This will facilitate efficient sample and results relay and effective monitoring of laboratory operations for timely decision making.

Despite these achievements, limitations to achieving the LIMS goals still exist. 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, 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 other challenge limiting the implementation of a robust LIMS with capacity to support other sectors (one health approach) is the absence of guidelines to govern data sharing.

This plan will therefore promote the implementation of a robust LIMS that facilitates data capture and utilization across sectors at national and sub-national-levels. and support.

2.7 Research & Development

Research plays a very important role in generating information to guide practice in

addition to facilitating planning and policy formulation. While there are laboratories established purposely for research, data generated as part of routine disease diagnosis and monitoring can yield important information beyond the intended clinical use which if properly managed compliments research laboratories in generation of information. National reference laboratories such as UVRI and CPHL perform both research and diagnostic functions.

The capacity of laboratories to conduct research tremendously improved during the last strategic planning period; a National Biorepository was established at CPHL, the CPHL research and ethics committee/institutional review Board was accredited by the UNCST and the National Health laboratory research agenda drafted. Working with partners and the LTC subcommittee on research and development, some operational research undertakings have been completed.

Outstanding challenges include the lack of an approved research agenda which is partly responsible for the low-level engagement in research activities within the network and underutilization of the Biorepository. Mechanisms for supporting, management and coordination of research activities within the network need to be strengthened.

Through this strategic plan, the department of national health laboratory and diagnostic services shall take advantage of the growing number of research grant opportunities in health-related research, improved technical capacity among laboratory professionals, support from other government MDAs and partners to promote research within the Health laboratory network. Efforts will be directed towards innovation and technology adaptation.

2.8 Health Laboratory Systems Strengthening through Partnerships

Both the National Development Plan III (NDP) and the HSDP II emphasize the importance of collaboration and partnerships between MOH, Health Development Partners, the private sector and between Ministries, Departments and Agencies (MDAs) among others. Partnerships have been pivotal in achieving the improvements registered in Laboratory services in the previous strategic planning period. Several development partners e.g. CDC, USAID, WHO and global fund have provided technical and financial assistance to laboratory services. Ministry of local government has continued to run and support laboratories through the district health services. A number of standalone laboratories and those within health facilities are run by the private sector. Government has continued to provide logistical and technical support to PNFP and PHF e.g., by providing them with selected reagents, technical support and training.

Given the strategic importance of partnerships in health services delivery in general, and laboratory services delivery in particular, this plan seeks to strengthen partnerships even further. Efforts will be made to develop integrated health laboratory systems at national and subnational levels as opposed to disease focused funding. Robust crosscutting national laboratory systems and networks shall be developed to harness all partner contributions ensuring they effectively and efficiently contribute to national and health sector Plans.

2.9 Legal and Regulatory

Attainment of quality laboratory services and protection of the health laboratory professionals simultaneously, the public Implementation of national health laboratory standards requires strong and dedicated regulatory system supported by appropriate

laws and resources to perform their duties. In Uganda, this function is vested in the Allied health professionals' council (AHPC) by the Allied Health Professionals Act, Cap 268 of 1996. The council is mandated to register and license (laboratories and professionals) and to control the practice of medical laboratory services. The council also approves laboratory training courses and institutions within the country in consultation with the ministries of education and sports and the ministry of health so that their graduates qualify for registration and practice in Uganda. The health mechanisms have increased the interaction between veterinary and human health laboratories with both samples and professionals crossing sectors.

During the strategic plan implementation period from 2016-2020, national laboratory services has worked closely with AHPC at both national and regional levels. A database for laboratory professionals and private laboratories was established. There has been concerted have been made to harmonize Training standards for laboratory professionals. Guidelines for licensing human and veterinary laboratories have been developed and undergoing approval.

Limited funding, inadequate staff numbers, limited mandate over public sector facilities, weak linkages between regulatory bodies (MOH, MAAIF, MOES, AHPC) remain serious challenges to AHPC exercising its mandate.

The revised NHLSSP 2021-2025 is aims at strengthening the AHPC to perform its functions by registering, licensing and supervising laboratories, professionals, training schools and programs. Tools to aid AHPC in performing its functions shall be developed/updated.

2.10 Monitoring and Evaluation

Effective and efficient M&E systems are

necessary to ensure that national health laboratory services strategic and annual plans are implemented properly to generate information to drive policy, future plans and to ensure that allocated resources achieve the intended results.

During the last five years, UNHLS has made considerable efforts to improve M&E systems through establishment a Result-Based M&E system, strengthening mechanisms, Human and infrastructural capacity to collect and utilize data at the national level. Routine monitoring has been done through the ministry of health's HMIS/dhis2 as well as vertical programs e.g., HIV EID, HIV VL health information system (HIS). Midterm evaluation of the NHLSSPII was done albeit towards the end of the implementation period. The suboptimal performance against targets of the NHLSSPII was partly due to poor M&E systems including poor definition of indicators. Dashboards, national/regional, departmental performance review meetings and quarterly newsletters have been the major routes for dissemination of M&E data.

The major outstanding challenges is lack of positions for laboratory services M&E officers within the public services structures both at national and subnational levels. UNHLS leveraged on the vertical program M&E officers to create programmatic M&E systems to support national reporting. As a consequence, there was fractured and inconsistent reporting since national M&E activities had to be tailored to vertical programs' plans resulting into, unplanned data collection, non-uniform data collection points, and failure to properly implement the national laboratory services M&E plan.

In order to address the outstanding challenges, UHNLS will advocate for a strengthened M&E HR and systems. UNHLS will continue to leverage on existing systems and/or mechanisms to create a technical working group that will support the definition,

monitoring and reporting of both activity and outcome indicators against a preapproved M&E plan.

2.11 Financing, Resource mobilization and management

Public spending on the health sector remains suboptimal, with national Health spending as a proportion of Gross Domestic Product (GDP) approximately 7%, but only 8.7% of the GoU's National Budget- below the Abuja Declaration target of 15% of the national budget for health. WHO also provides a government spending benchmark for LICs like Uganda of estimated \$34 per capita as the minimum for a generic essential package, although GoU spends approximately \$ 11 – 15 per capita, implying a major gap in domestic financing of health programs.

Given the low funding for health in Uganda, laboratory services tend to disproportionately suffer due to lower prioritization amidst the many needs. This chronic under funding of laboratory services affects not only availability of laboratory services, but also the quality of lab services. Consequences of poor or nonexistent laboratory services include drug misuse, poor patient management, increased morbidity and mortality, increased costs of patient management, poor health outcomes, and the resultant drug resistance.

Health development partners fund and provide technical assistance in selected priorities leading to disease specific programs e.g. Malaria, TB, HIV/AIDS. This weakens the resolve for systems reform and complicates coordination.

In order to improve patient management and disease surveillance, we need to come up with robust strategies that harness support from GOU, grants, Development partners and private services. Resources need to be allocated to all components of the laboratory

services chain including personnel, equipment, equipment servicing and maintenance, infrastructure, quality management system, data management, sample management and transport, reagents and supplies.

Funding all these components calls for increased funding from government, leveraging donor funding that is usually disease/program specific to build over hatching systems that support beyond the programs/diseases that are funded. Private wing services at some public facilities should be encouraged, such that able patients can be able to pay for the required diagnostic services and funds generated used to improve overall laboratory services. Research should be encouraged as another way of increasing funding to laboratory services.

2.12 Community Health Promotion for Lab Services

Community involvement is essential in facilitating efforts to expand clinical laboratory services, outbreak response and for enhancement of health promotion. Critical to the community extension of diagnostic services, is the deployment of novel point-of-care testing (POCT) technologies. Both rapid diagnostic kits and portable diagnostic devices that complement conventional testing services are available in the market.

Community awareness of health laboratory services is however low which limits the utilization of laboratory services in the prevention, control and management of diseases.

This strategic plan promotes creation of awareness about laboratory services in communities through engagement of opinion leaders (cultural, religious, political, schools etc.) and CHEWS in the planning, monitoring and delivery of health laboratory services.

3

THE STRATEGIC PLAN

This Strategic plan (NHLSSP III) provides the framework for implementing the Second National Health Laboratory Services Policy (NHLSP II) for the period 2020/2021-2024/2025. It takes over from NHLSSP II, which was the first NHLSSP under the revised NHLSP II. The implementation period of the NHLSSP II was cut by one year to allow for the alignment with National and sector development plans. The strategies in this strategic plan are guided by the Vision, Mission and policy objectives of the national health laboratory services policy which provides policy objectives in 14 thematic areas as well as the Sector development (HSDP) and are influenced by the aspirations of the parent ministry, clinicians and the laboratory fraternity.

3.1 Vision:

Quality health laboratories services available and accessible to all people in Uganda.

3.2 Mission.

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

3.3 Strategic objectives.

Over the next five years, NHLDS will peruse four strategic objectives:

- I. To strengthen the leadership and governance structures for effective and sustainable laboratory service delivery at all levels.

- II. To provide quality and equitable laboratory services at all levels to support clinical care, public health services and research
- III. To strengthen laboratory information management and utilization for performance monitoring and decision making
- IV. To create enabling environment to promote research and innovations for improved lab service delivery.

The fourteen (14) thematic area objectives identified in NHLSP II will form the basis for the activities undertaken to achieve the four strategic objectives.

3.4 Implementation of the Strategic Plan.

The plan shall be implemented by the department of national health laboratory and diagnostic services through the laboratory services network and in collaboration with relevant MDAs, Local Governments, development partners, Implementation partners as well as local international NGOs.

The projected annual cost of implementing this strategic plan is 1.4 trillion. More than half of this 860 billion (62%) is for equipment and supplies while the remaining 535 billion (48%) goes to health systems strengthening.

Funding is expected from GOU, Development partners and cost recovery through private laboratory services in public facilities.

5

STRATEGIES

Repentance

5.1 Strategic objective 1: (Leadership and Governance)

5.1.1 Organization and Management

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

Strategies

5.1.1.1 Strengthen the national and sub-national laboratory organizational structures.

5.1.1.2 Strengthen functionality of the National laboratory Technical and Advisory Committee (LTC) to provide oversight for the laboratory services.

5.1.1.3 Strengthen the coordination of the tiered laboratory network.

5.1.2 Human Resources

Policy Objective:

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

Strategies

5.1.2.1. Operationalize the approved scheme of service through recruitment of adequate laboratory staff to fill vacant and new positions at all levels

5.1.2.2. Retain adequate laboratory staff at all levels in line with the revised scheme of service

5.1.2.3. Equip the laboratory workforce with skills and competencies essential for quality service delivery

5.1.3 Regulatory and Legal Framework

Policy Objective:

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

Strategies

5.1.3.1. Ensure that all health laboratories meet the required standards for registration and licensing

5.1.3.2. Ensure that all practicing laboratory professionals are registered and licensed

5.1.4 Financing, Resource mobilization and Management

Policy Objective:

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

Strategies

5.1.4.1 Advocate for increase in the budget dedicated for laboratory services in the Ministry of Health and in district health budgets.

5.1.4.2 Strengthen coordination of partner funding activities for laboratory services

5.1.4.3 Mobilize funds to meet laboratory budget needs

5.1.4.4 Establish a transparent system to ensure programmatic and financial accountability of laboratory services

5.1.5 Health Laboratory Systems Strengthening through Partnerships Policy Objectives

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

Strategies

5.1.3.1. Establish system of sharing information, testing capacity and resources between sectors towards One-Health Strategy (Zoonotic, AMR, Notifiable, Outbreaks)

5.1.3.2. Establish mechanisms to out-source specialized laboratory services to increase efficiency and effectiveness in service delivery

5.1.3.3. Promote public private partnership for provision of health laboratory services in accordance to with PPPH Policy

5.1.3.4. Support the establishment of laboratory services in under-served areas by providers outside the public system.

5.1.3.5. Establish a partnership forum through which all laboratory partners/ stakeholders meet to draw strategies to improve laboratory services across all sectors

5.1.3.5. Develop partnerships strengthen the sample transport system as a way of increasing access to laboratory services across the country

5.2 Strategic objective 2: (Accessibility to Quality of Laboratory Services)

5.2.1 Laboratory Services Network

Policy Objective:

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

Strategies

5.2.1.1 Review the minimum package of testing services at all laboratory tiers in line with the health sector development plan 2020/1 - 2024/5, to include NCD

5.2.1.2 Strengthen laboratory services for surveillance, public health emergency investigations and management at all laboratory tiers

5.2.1.3 Strengthen safe specimen collection, packaging and transportation within the laboratory referral network

5.1.5.1 Develop private lab services in public labs in order to promote access to affordable sustainability services

5.1.5.2 Expand infant screening for SCT& SCD to all districts with high SCD burden in Uganda.

5.1.5.3. Establish screening for hemophilia

5.1.5.4. Improve risk screening and testing for major NCDs

5.1.5.5. Promote clinical Forensic testing services

5.1.5.6. Improve waste management in Anatomic labs (including wastes related to oncology)

5.1.5.7. Develop strategies to increase community access to equitable quality testing services

5.2.2 Infrastructure, Biosafety and Biosecurity

Policy Objective:

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

Strategies

5.2.2.1 Strengthen national laboratory biosafety system, fire and radiation, Chemical safety programme.

5.2.2.2 Ensure that construction and renovation of health laboratory facilities

conform to national infrastructure guidelines and standards

5.2.2.3 Establish maintenance program for Biosafety and biosecurity equipment

5.2.2.4 Establish an effective occupational health and safety program for laboratory personnel

5.2.2.5 Strengthen the co-ordination of Biosafety and Biosecurity activities through effective management at all levels

5.2.2.6 Strengthen the co-ordination of Biosafety and Biosecurity activities through effective management at all levels

5.2.3 Equipment and Supplies

Policy Objective:

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

Strategies

5.2.3.1 Strengthen the coordination of laboratory supply chain management system across the network

5.2.3.2 Strengthen supply chain management.

5.2.3.3 Establish pre- and post- market surveillance systems for laboratory commodities

5.2.3.4 Strengthen capacity building in laboratory logistics management

5.2.3.5 Develop and implement guidelines for equipment procurement and placement across the laboratory network

5.2.3.6 Strengthen Equipment maintenance and management at all levels.

5.2.4 Quality Management Systems

Policy Objective:

To establish and maintain a national laboratory quality management system that will lead to

national/international certification and accreditation.

Strategies

5.2.4.1 Strengthen national laboratory standards

5.2.4.2 Strengthen the implementation of laboratory quality management Systems

5.2.4.3 Strengthen the National External Quality Assessment (EQA) schemes

5.2.4.4 Strengthen the coordination and management of quality assured laboratory services.

5.2.4.5 Expand the scope of WHO prequalification laboratory capacity to support quality evaluations, verifications, pre-market and post-market surveillance.

5.2.4.6 Establish a national medical laboratory certification, inspection and accreditation unit

5.2.5 Community Health promotion for Lab Services

Policy Objective:

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

Strategies

5.2.5.1 Engage the media (telecommunication companies, radio and TV stations) to build support for efforts that reach out, communicate, and partner with community leaders and organizations within communities on laboratory services promotion and delivery.

5.2.5.2 Encourage participation of community members and to build community capacity to access and utilization of lab services.

5.2.5.3 Build capacity of community health workers such as VHTs on laboratory services promotion and delivery.

5.2.5.4 Sensitize the communities on the availability of laboratory services in the country.

5.2.5.5 Engagement of other community organizations/structures such as churches, cultural leaders among others in creating awareness and utilization of the laboratory services.

5.2.5.6 Strengthen community involvement and partnerships to implement laboratory services.

5.2.5.7 Expand clinical and laboratory services to promote access to and use of high-quality care by people at community level.

5.3 Strategic objective 3: (Information Management and Utilization)

5.3.1 Health Laboratory Information Management Systems

Policy Objective:

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

Strategies

5.3.1.1 Advocate for IT infrastructure that includes Internet and Local Area Network development at all levels

5.3.1.2 Advocate for IT personnel at national, regional and district level to support IT initiatives.

5.3.1.3 Establish an integrated database for managing nonclinical laboratory data to improve coordination of laboratory services

5.3.1.4 Implementation of facility and client registries to support inter-operability & longitudinal tracking

5.3.1.5 Design and implement health laboratory information exchange for data sharing

5.3.1.6 Increase hosting capacity of national data center

5.3.1.7 Scale up of electronic HLIMS to 100 hub laboratories and the sub-national laboratories from the current 40 laboratories

5.3.1.8 Scale up implementation of electronic mobile, web-based platform from 48 hubs and 38 POEs to 100 hubs and 53 POEs.

5.3.1.9 Establish an integrated database for managing non-clinical laboratory data to improve coordination of laboratory services i.e waste management, quality assurance, Biosafety biosecurity, M&E database (activity modules)

5.3.2 Monitoring and Evaluation

Policy Objective:

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

Strategies

5.3.2.1 Strengthen the organizational structure required to support implementation of the functional results based M&E system

5.3.2.2 Obtain national, regional and health facility capacity to implement the national laboratory services M&E results framework.

5.3.2.3 Manage national and sub national databases for data quality and accurate performance review and reporting.

5.3.2.4 Support strategic and programme improvement through QI, Performance Review, and Evaluations.

5.3.2.5 Build accountability, transparency and collaboration among health lab services partners through information sharing and data use.

5.4 Strategic objective 4: (Promoting Research)

5.4.1 Research & Development

Policy Objective: To undertake research of public health importance according to the research priorities/agenda of the Ministry of Health.

Strategies

5.4.1.1 Complete the draft National Laboratory Research Agenda for the health and strengthen it.

5.4.1.2 Build capacity of laboratory personnel in operational research.

5.4.1.3 Develop and implement a national laboratory research database to track and disseminate research findings

5.4.1.4 Improve the utilization of stored specimen in the national bio repository

5.4.1.5 Sensitize researchers and academic and research institution on the national bio repository

5.4.1.6 Strengthen local and international research collaborations

5.4.1.7 Promote innovations and research grants writing

STRATEGIC OBJECTIVE 1: (LEADERSHIP AND GOVERNANCE)							
Sub-Objective 1: Organisation and Management: To strengthen the leadership and governance structures for effective and sustainable laboratory service delivery							
Strategy	Activities	Performance Indicators	Target				
			Y1	Y2	Y3	Y4	Y5
1.1 Strengthen the national and sub-national laboratory organizational structures	1.1.1. Review current structure of UNHLS and advocate for elevation to directorate to provide an appropriate structure for stewardship of national health laboratory services.	Revised Structure Approved.			X		
	1.1.2. Streamline leadership, governance and reporting mechanisms for the lab network at subnational levels.	Functional Sub-national organogram.			X	X	X
1.2 Strengthen functionality of the National laboratory Technical and Advisory Committee (LTC) to provide oversight for the laboratory services.	1.2.1. Transform the LTC into a Technical Working Group (TWG) responsible for Laboratory Services.	Functional LTC	X	X	X	X	X
	1.2.2. Hold Regular LTC meetings to review and approve Reports, Standards, Policies, Plans etc.						
1.3 Strengthen the coordination of the laboratory Services Network.	1.3.1. Establish Sub national coordination offices.	% of subnational coordination offices established.		40	60	100	
	1.3.2. Update Support supervision framework, tools and Check lists.	% of laboratories successfully completing targeted CQI projects.	100	100	100	100	100
	1.3.3. Implement skills development for management and governance across the health laboratory network to improve coordination.	% of targeted officers trained in leadership and management.		100	100	100	100

Sub-Objective 2. Human Resources: To ensure that laboratory services have the required number of staff with the necessary competencies, remuneration and motivation to deliver quality laboratory services at all designated levels.							
Strategies	Activities	Performance Indicators	Targets				
			Y1	Y2	Y3	Y4	Y5
2.1. Operationalize the approved scheme of service through recruitment of adequate laboratory staff to fill vacant and new positions at all levels	2.1.1 Engage the Ministry of Public Service, MOF, Health Service Commission, Districts Local Government and Partners to implement the Approved staffing norms for laboratory cadres	1. % of facilities implementing the approved scheme of service.			40	100	100
	2.1.2 Engage the PNFP & PHP sector to adopt the revised laboratory scheme of service.	2. % of posts filled inline with the Approved scheme of service.			60	100	100
	2.1.3 Support restructuring of laboratory positions to much work load with required skill set and staff numbers.	3. Appropriate structure Approved.			X		
2.2. Retain adequate laboratory staff at all levels in line with the revised scheme of service	2.2.1 Support laboratory professionals career development to build a pool of desired knowledge and skill set.	1. No of professionals attaining higher qualifications.	X	X	X	X	X
	2.2.2 Support the Provision of continuous professional development(CPD) for Laboratory Professionals.	1. Guidelines/ criteria to conduct CPDs for laboratory professionals approved. 2. % of Targeted CPD training conducted	X				
	Develop and operationalize a reward/sanction system to foster laboratory staff retention.	Renumeration and Reward System Approved.	100	100	100	100	100
2.3 Equip the laboratory workforce with skills and competencies essential for quality service delivery	2.3.1 Ensure that only cadets from certified educational institutions are registered and licensed to practice.	% of working laboratory professionals that are registered and licensed to practice.	100	100	100	100	1000
	2.3.2 Develop and implement the national laboratory in-service training plan	1. Annual In-service training plans developed and implemented.	X	X	X	X	X
		2. % of targeted Laboratory professionals trained.	100	100	100	100	100

	2.3.4 Develop E-learning laboratory program for all levels of service.	E-learning training program developed and implemented		X	X	X	X
	2.3.5 Review of pre-service training curricula with the training schools/institutions to ensure continued relevancy to National needs.	Bi Annual Pre-service training curriculum reviews conducted.		X		X	
	2.3.6 Review guidelines and criteria for certification of Non laboratory personnel involved in testing.	Guidelines for certification of Non laboratory personnel developed and implemented		X	X	X	X
Sub-Objective 3. 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 body.							
Strategies	Activities	Performance Indicators	Targets				
			Y1	Y2	Y3	Y4	Y5
3.1 Ensure that all health laboratories meet the required standards for registration and licensing	3.1.1. Develop national health laboratory standards that mirror international standards for clinical laboratory practice.	National Health Laboratory Standards Developed.	X				
	3.1.2. Conduct a national Health Laboratory Census to establish the status of Health Laboratories in Uganda.	National database of all laboratories in the country established and continuously Monitored.		X	X	X	X
	3.1.3. Perform periodic Laboratory inspections to ensure compliance to the standards.	% of laboratories that comply with the laboratory registration and licensing standards		50	60	80	100
3.2 Ensure that all practicing laboratory professionals are registered and licensed	3.2.1. Continously Monitor the registration and licensure status of practicing professionals.	% of Practicing Professional with valid practicing licences.	100	100	100	100	100
	3.2.2. Engage Training schools/insititutions to promote students and Alumini understading of national guidelines, standards and procedures related to regulation of laboratory services in the country.	% of training institutions engaged .	100	100	100	100	100

Sub-Objective 4. Resource Mobilization, Financing and Accountability: Effective financing mechanisms will be in place centrally and at local government levels to ensure availability of and accessibility to adequate resources for the provision of sustainable laboratory services.							
Strategy	Activities	Performance Indicators	Target				
			Y1	Y2	Y3	Y4	Y5
4.1. Actively mobilise resources to meet laboratory services budget.	4.1.1. Advocate for increased allocation to the laboratory vote at national and district levels.	%of Laboratory Budget funded by GOU	8	20	40	60	80
	4.1.2. Implement a cost recovery mechanism (Private laboratory services in public laboratories)	% of laboratory units implementing cost recovery.	10	30	60	60	60
	4.1.3. Undertake routine stakeholders engagement activities to create awareness, raise resources and plan for laboratory services.	% of Laboratory Budget that is realised.	65	80	90	90	90
4.2. Consolidate donor funding from disease specific to laboratory sector wide strengthening.	4.2.1. Coordinate donor funding for laboratory services to avoid duplication and redundancy.	% of disease specific funding supporting the entire sector through centralised coordination.	80	80	80	80	80
	4.2.2. Establish a partnership forum to support coordination and monitoring of laboratory investments.	Functional partnership Forum	X	X	X	X	X
4.3. Strengthen Pragmatic and financial accountability.	4.3.1. Strengthen respective institutional capacities for planning, Monitoring and evaluation of laboratory programs as per their mandate.	Proportion of program objectives/goals accomplished within budget and time.	100	100	100	100	100
	4.3.2. Implement GOU/Donor approved financial management policies and procedures.	Unqualified audit reports.	X	X	X	X	X
Sub-Objective 5. Partnerships and Collaborations: To strengthen multi-sectoral, national, international, public, and private partnerships to promote access to quality laboratory services.							
Strategies	Activities	Performance Indicators	Targets				
			1	2	3	4	5
5.1 Establish system of sharing information, testing capacity and resources between sectors towards	5.1.1 Establish a laboratory multi-sectoral TWG to oversee implementation of the laboratory aspects under the One-Health Agenda.	1. Functional Multi sectoral TWG.	X	X	X	X	X

actualising One-Health concept.	5.1.2 Determine testing capacities and promote intersectoral referral services.	1. Laboratory testing capacities across sectors established.		X			
		2. Functional inter-sectoral referral mechanisms.	X	X	X	X	X
	5.1.3 Develop and implement mechanisms for information sharing to facilitate collaboration across sectors.	Functional information sharing platform..	X	X	X	X	X
5.2 Establish a mechanism for the National Sample Transport Network (NSTN) to serve the one health platform.	5.2.1 Establish an integrated mechanism for sample movement across sectors.	Functional multi sectoral NSTN.	X	X	X	X	X
5.3 Promote public private partnership for provision of health laboratory services in accordance to with PPPH Policy	5.3.1 Conduct mapping of private laboratories and their capacity across the country.	List of private laboratories and their relative capacities established.		X			
	5.3.2. Engage the private sector laboratories to complement the public sector in providing laboratory services.	Increase in number of private laboratories complementing service delivery to address unmet testing needs.	X	X	X	X	X
	5.3.3 Devise incentives for partners to support underserved areas and disciplines	Increase in private sector support in underserved areas/disciplines.	X	X	X	X	X
STRATEGIC OBJECTIVE 2: (ACCESSIBILITY TO QUALITY LABORATORY SERVICES)							
Sub-Objective 1: Laboratory Services Network: To provide quality laboratory testing services accessible to all the people in Uganda to support clinical, public health services.							
Strategy	Activities	Performance Indicators	Target				
			Y1	Y2	Y3	Y4	Y5
1.1 Review the minimum package of testing services at all laboratory tiers in line with with emerging health issues.	1.1.1. Conduct laboratory Network optimisation to identify testing capacities at various levels of service delivery and address identified gaps.	DNO Report.		X			
	1.1.2. Review and implement the national test menu to guide in the implementation of testing	Test Menu reviewed and disseminated		X			
		% of laboratories implementing the test menu appropriate for the level.	100	100	100	100	100

	services at each level of health care.							
	1.1.3. Optimise equipment usage through multiplexing to support the revised test menu and DNO recommendations.	Proportion of testing gaps identified for for multiplexing closed.			50	80	100	
1.2. Implement an effective Specimen referral and result handling system within the tiered network.	1.2.1 Review and implement the specimen referral and result handling guidelines to intergrate global health security , one health needs and other emerging issues at PFP, PNFP and public facilities.	Revised guidelines implemented.			X			
	1.2.2. Implement an effectice specimen and results tracking system across the network.	Functional Specimen and Result tracking system.		X	X	X	X	X
	1.2.3. Cotinously review the performance of the National Laboratory services network to identify gaps and implement recommendations.	Proportion of recommendations implemented.	100	100	100	100	100	100
1.3. Support the establishment of private services in public laboratories to promote sustainability.	1.3.1. Develop National guidelines for establishment of private lab services in public facilities.	Guidelines approved.		X				
	1.3.2. Develop and implement a business plan for operationalising the Private laboratory services.	Business plan developed and approved.		X				
		% of targeted public laboratories offering private survices.	10	20	40	60	80	
1.4 Strengthen laboratory testing facilities at Point of entry to handle Emerging health issues.	1.4.1 Develop and implement guidelines for operating lab testing facilities at POEs.	Guidelines Approved		X				
		Propotion of targeted POEs functional in line with the approved guidelines.			50	80	100	
1.5 Increase access to laboratory testng services through Point of Care (POC) technologies	1.5.1. Review and update the national POCT guidelines.	Updated POC guidelines.			X			
	1.5.2. Promote the use of POCT in disease diagnosis and management.	Increase in adoption of POCTs		X	X	X	X	X
	1.5.3. Incorporate POC in all Laboratory Surport Functions,	% of laboratory surport functions, policies. Guidelines , standards etc that embed POCT.		100	100	100	100	100

	Policies, guidelines, standards etc.							
	1.5.4. Review national Testing algorithims to priotise POCT usage.	National algorithims reviewed.			X			
1.6 Strengthen laboratory services for surveillance, public health emergency investigations and management at all laboratory tiers	1.6.1. Strengthen survailance reportng system at all lab tiers	Reporting tools, Reporting SOP, Training and mentorship meetings	X	X	X	X	X	X
	1.6.2 Strengthen multi-sectoral inter-laboratory collaboration to facilitate collaborative testing for disease survailance and hadling.	Evidence of multisectoral/inter laboratory collaborations.	X	X	X	X	X	X
	1.6.3 Stregthen 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.	% of targeted laboratory proffessionals competent in detecting agents of public health importance		40	80	100		
1.7. Strengthen lab capacity to conduct screening and diagnosis for NCDs.	1.7.1. Asses current national capacity for screening and diagnosis of selected NCDs.	Report on current laboratory capacity to surport NCDs screening and diagnosis.		X				
	1.7.2. Equip health workers with skills and knowledge for screening and diagnosis of selected NCDs	Prportion of targeted health workers equiped with knowledge and skills to diagonise selected NCDs.		100	100	100	100	100
	1.7.3 Conduct surveys to establish burden of selected NCDs	Survey reports for Selected NCDs				X	X	
	1.7.4. Expand current national NCDs screening programs to include additional key NCDs identified as serious risks.	Proportion of the selected NCDs screening programs that are implemented.	100	100	100	100	100	100
	1.7.5. Intergrate NCDs in all mainstream laboratory programing.	Prportion of laboratory programs, policies , standards and guidelines that incorporate NCDs.	100	100	100	100	100	100
Sub-Objective 2. Community Health Promotion for Laboratory Services: Increase community engagement in the delivery and access to quality laboratory services.								
Strategies	Activities	Performance Indicators	Targets					
			Y1	Y2	Y3	Y4	Y5	

2.1. Increase laboratory engagement with the community for improved acces to laboratory testing services.	2.1.1. Develop and implement laboratory community engagement guidlines.	Laboratory community engagement guidelines developed and implemented.		X			
	2.1.2. Run Media campaigns to promote comuunity understanding of laboratory services.	Proportion of targeted media engagements implemented.	100	100	100	100	100
	2.1.3. Conduct community based laboratory screening and diagnosis for priority diseases.	Proportion of laboratories participating in comuunity outreach programs.	100	100	100	100	100
		Proportion of targeted community based laboratory outreaches conducted.	100	100	100	100	100
	2.1.4. Develop IEC materials to promote awareness about laboratory services services.	Targeted IEC materials distributed.	X	X	X	X	X
	2.1.5. Implement client based approaches to testing and results delivery.	% of targeted labotory staff trained in customer care.		40	100		
		Improved customer satisfaction survey ratings.	X	X	X	X	X
	2.1.6 Conducting a pilot/ survey to determine national uptake and progress of screening for priority NCDs	Pilot / survey reports .			X		
Sub-Objective 3: Infrastructure, Biosafety and Biosecurity: To provide appropriate laboratory working Environment, and ensure safety of personnel, community and environment, and pomote global health security through containment of pathogens, materials and Information.							
Strategy	Activities	Performance Indicators	Target				
			Y1	Y2	Y3	Y4	Y5
3.1. Strengthen national laboratory biosafety biosecurity coordination and capacity through hiring human resource, policy development, training, evaluation and certification	3.1.1 Setting up National, subnational and facility level BRM Strucures.	Functional BRM comitees at National ,sub-National and facility level .	X	X	X	X	X
	3.1.2 Revise current national BRM 2015 manual to adress emerging issues.	Approved National BRM manual		X			
	3.1.3 Revise the national BRM training materials and Audit checklists inline with the updated BRN manual.	Updated National BRM training curriculum and Checklists		X			

	3.1.4 Conduct national biorisk management training of trainers	Number of national BRM TOTs	40				
	3.1.5 Conduct annual biorisk management auditors trainings and certifications	Number of trained and certified BRM auditors.	40	25			
	3.1.6 Conduct annual BRM trainings for Administrative, Technical and Support staff based on the revised national training curriculum	Number of staff trained	2000	2000	2000	2000	2000
	3.1.7 Conduct regional BRM support supervision and mentorship	% of targeed support supervision visits conducted	100	100	100	100	100
	3.1.8 Conduct annual national BRM audit	Annual BRM Audit Report.	X	X	X	X	X
3.2. Continously improve laboratory infrastructure across the laboratory services network.	3.2.1 Have national infrastructure Guidelines approved and disseminated	Approved infracture Guidelines		X			
	3.2.2 Formation and functionalisation of regulatory structure to oversee the implementation of laboratory Infrastrature guidelines	Functional infrastructure committee	X	X	X	X	X
	3.2.3 Conduct National laboratory infrastruture assesment	National Laboratory infrastructure assesment report.	X	X	X	X	X
	3.2.4Conduct Laboratory infrastructure improvement as per infrastruture assesment report .	Number of targeted laboratory infrastructure improved.	30,000,000	30,000,000	20,000,000	20,000,000	10,000,000
	3.2.5 Expand / construct infrastructure at national and subnational levels to address increased laboratory services scope for both clinical and public health.	Number of targeted laboratory infrastructure expanded and furnished at national and subnational levels Number of targeted laboratory infrastructure constructed and furnished at national and subnational levels					
3.3 Establish an effective occupational health and	3.3.1 Develop National guidelines for Laboratory occupational safety and Health.	Approved national OHS guidelines			X		

safety surveillance program for laboratory personnel	3.3.2 Conduct Occupational Health and Safety training and mentorship for Laboratory professionals	Number of Laboratory persons trained in OHS nationally	400	400	400	400	400
	3.3.3 Conduct regular audits and inspections to assess implementation of OHS programs	National occupational health audit Report.	X	X	X	X	X
3.4 To establish an effective biosecurity management system for mitigation and containment of high consequence pathogens through risk assessment, training, equipment and repository management	3.4.1. Develop and implement a maintenance plan for biosafety and biosecurity equipment	Annual biosafety and biosecurity equipment maintenance report.	X	X	X	X	X
	3.4.2 Establish a monitoring dashboard for functionality Biosafety and biosecurity equipment and inventory	Biosafety and biosecurity equipment functionality reports.	X	X	X	X	X
	3.4.3 Strengthen the National agent inventory and accountability program	Updated National Biological agent inventory database	X	X	X	X	X
	3.4.4. Equip laboratories with appropriate biosafety and biosecurity equipment.	% of facilities with appropriate functional biosafety biosecurity equipment.	100	100	100	100	100
	3.4.5 Conduct BRM risk assesment for all health care levels to establish the risk level of each Laboratory and support improvement	BRM Assesment Report.	X	X	X	X	X
3.5 To strengthen health laboratory waste management.	3.5.1 Review the current HCW mangement plan.	Revised HCW mangement plan			X		
	3.5.2 Establish HCW regional disposal centres	Number of regional final disposal/ incineration centres established	5	5	5	5	5
	3.5.3. Provide appropriate waste handling equipment to all facilities.	Proportion of laboratories with appropriate waste handling facilities.	100	100	100	100	100
	3.5.4 Continue to build the capacity on proper health care waste management	Number of facilities trained and mentored on proper waste management procedures.	500	500	500	500	500

Sub-Objective 4. Equipment and Supplies: To ensure that laboratories have appropriate functional equipment and adequate, continuous and timely supplies to support routine and emergency laboratory services							
Strategies	Activities	Performance Indicators	Targets				
			Y1	Y2	Y3	Y4	Y5
4.1 Strengthen the coordination of laboratory supply chain management system across the network	4.1.1. Conduct laboratory Supply chain optimization.	Optimization report		X			
	4.1.2. Build capacity in supply chain management.	%r of targeted profesionlas trained.		100	100		
	4.1.3 Conduct Periodic logistics coordination meetings at at all levels .	Logistics performance review reports.	X	X	X	X	X
4.2 Strenghten supply chain management.	4.2.1 Review and update laboratory supply list, specifications and catalogues	Updated Lab equipment and supplies List		X		X	
	4.2.2. Conduct Periodic quantification for laboratory comodities.	Updated Comodity Quantification.	X	X	X	X	X
	4.2.3 Review the Laboratory equipment harmonization guideline to streamline the procurement and placement of equipment in the country	Updated guidelines		X			
	4.2.4. Implement electronic inventory managemet systems.	Number of facilities implementing electronic management systems.					
	4.2.5 Prepare supply plan and funding gap analysis for procurement and advocacy for funding	Supply chain gap analysis report.	X	X	X	X	X
4.3 Establish pre- and post-market surveillance systems for laboratory commodities	4.3.1 Develop guidelines for pre- and post market surveillance to assure product quality	Guidelines Developed			X		
	4.3.2. Perform pre-and post Market survaillance as per guidelines.	Survailance reports.	X	X	X	X	X
4.4 Strengthen capacity building in laboratory logistics management	4.4.1 Review and update laboratory SPARS training curriculum	SPARS curriculum reveiwed.		X			
	4.4.2. Asses laboratory logistics handling at facilities.	% facilities with aproprate stock management practices.					

	4.4.3 Conduct facility training for laboratory logistics SPARS.	% of targeted facilities trained	100	100	100	100	100
4.5 Develop and implement guidelines for equipment procurement and placement across the laboratory network	4.5.1 Conduct equipment harmonization review.	harmonised list in place			X		
	4.5.2 Develop equipment specifications and standards for all laboratory equipment across the laboratory network	Equipment standards developed and distributed			X		
	4.5.3 Establish and harmonise guidelines for regulation of equipment in collaboration with UNBS, NDA and NACME	harmonised guidelines on equipment regulation			X		
4.6 Strengthen Equipment maintenance and management at all levels.	4.6.1 Establish positions for laboratory equipment biomedical engineers at national and regional workshops.	% of positons established and filled at national and regional levles			100	X	X
	4.6.2 Establish positions for laboratory equipment biomedical supervisors at national level to oversee laboratory equipment maintenance	% positions established			100	X	X
	4.6.3 Suppport biomedical engineers to carry out maintenance and repare of medical laboratory equipment.	% reduction in equipment downtime.					
	4.6.4 Develop guidelines for laboratory equipment verification and calibration.	Equipment verified and/or calibrated in accordance with guidelines	X	X	X	X	X
	4.6.5 Develop and implement guidelines for reporting equipment breakdown at all levels	Guidelines implemented			X		
Sub-Objective 5: Quality Management Systems: To establish and maintain a national laboratory quality management system that ensures delivery of quality laboratory services.							
Strategies	Activities	Performance Indicators	Targets				
			Y1	Y2	Y3	Y4	Y5

5.1. Strengthen the implementation of laboratory quality management Systems	5.1.1 Develop/review guidelines and procedures for effective implementation of Quality Management Systems at all laboratory tiers/levels	Quality Management Systems guidelines and procedures available.			X		
	5.1.2. Build Capacity for QMS trainers, mentors and auditors to facilitate effective implementation of laboratory quality management system	% of Mentors, Trainers and Auditors Retrained.		100			
		No of New Trainers		25			
		Number of New Mentors		30			
		Number of New Auditors		51			
	5.1.3. Improve the capacity of laboratory work force at facility level to implement laboratory quality management system	% of facility staff trained. In Quality management Systems			20	30	
	5.1.4. Support accredited Laboratories to maintain accreditation.	% of accredited laboratories maintaining accreditation.	100	100	100	100	100
5.1.5. Build capacity of more laboratories towards accreditation	Number of new laboratories accredited.	5	5	5	5	5	
5.1.6. Monitor the QA performance across the network.	QA performance reports.	X	X	X	X	X	
5.2. Strengthen the National External Quality Assessment (EQA) schemes	5.2.1. Finalize National EQA guidelines.	EQA guidelines approved		X			
	5.2.2. Increase EQA schemes produced locally	Number of Additional EQA schemes developed.			5	5	
	5.2.3. Continually improve existing EQA schemes	% of EQA Schemes Running Effectively.	50	80	100	100	100
	5.2.4 Support local panel production laboratories to attain and maintain accreditation to ISO 17043.	% of of schemes whose panels are produced from local accredited panel production laboratories.				80	
	5.2.5 Increase number of laboratories participating in EQA Schemes	Percentage of laboratories participating in appropriate EQA schemes	100	100	100	100	100
	5.2.6 Support panel producing laboratories to enroll on an international EQA provider	Percentage of panel producing laboratories enrolled in an EQA program	100	100	100	100	100

	5.2.7. Coordinate EQA from external providers	% EQA schemes that are managed through the national EQA system.	100	100	100	100	100
5.3. Strengthen laboratory accreditation and certification system	5.3.1 Establish a national laboratory certification/accreditation unit	A functional national Laboratory accreditation & certification unit.			X		
	5.3.2 Increase the number of accredited and certified laboratories	Number of laboratories getting accredited.				16	16
		Number of laboratories getting certified				40	50
	5.3.3 Develop a cost recovery process that will ensure sustainability of accreditation unit	% of budget realised through cost recovery mechanisms.			20	60	80
STRATEGIC OBJECTIVE 3: (INFORMATION MANAGEMENT AND UTILIZATION)							
Sub-Objective 1: Health Laboratory Information Management Systems: To implement an integrated HLIMS in the laboratory network for management and utilization of patient results, other laboratory data, and operational research data							
Strategies	Activities	Performance Indicators	Targets				
			Y1	Y2	Y3	Y4	Y5
1.1. Expand HLIMS modules and increase coverage across the laboratory network for improved laboratory data and information management.	1.1.1 Scale-up the implementation of an electronic HLIMS across the laboratory services network.	Number of Laboratories implementing HLIMS.	20	50	70	90	120
	1.1.2 Establish and implement a national HLIMS data warehouse to archive electronic laboratory data	Functional and maintained laboratory data warehouse		X	X	X	X
	1.1.3 Conduct annual reviews of laboratory data management guidelines to improve on system performance	Annual reviews of laboratory data management guidelines conducted	X	X	X	X	X
	1.1.4. Establish an integrated database for managing nonclinical laboratory data to improve coordination of laboratory services	Functional non clinical laboratory data database.		X	X	X	X
	1.1.5 Establish network infrastructure at targeted laboratories to support electronic HLIMS	Number of Laboratories with established Network infrastructure for supporting electronic LIMS	20	50	70	90	120

	1.1.6. Build additional modules to address the all aspects of clinical laboratory data needs.	% of targeted modules developed.	100	100	100	100	100
	1.1.7 Establish the HLIMS central administration unit to effectively manage HLIMS initiatives	Functional HLIMS central administration unit for managing and maintaining LIMS established	X	X	X	X	X
1.2 Design and implement health laboratory information exchange	1.2.1 Implement inter-operability platform for ALIS and other HIS	Data exchange with partner systems through ALIS, EMR, RECDTS, EIDSR, IHMIS and other lab health systems	X	X	X	X	X
	1.2.2 Scale up of VL exchange	Data exchange between EMR and CPHL databases	X	X	X	X	X
	1.2.3 Develop portable applications to promote patient and clinician accessibility to records	Portable information systems hosted at CPHL on mobile devices	X	X	X	X	X
1.3. Increase hosting capacity of data center	1.3.1 Conduct a needs assessment of data center and end user equipment	A needs assessment report of data center and end user equipment needs	X				
	1.3.2 Procure equipment identified in needs assessment	% of identified equipment installed at targeted facilities.	20	60	100		
	1.3.3 Procure systems licenses for established in needs assessment	Renewed and or upgraded licenses for data center such HPE Nimble, VM ware, Cisco, 3CX, MS Office 365	X	X	X	X	X
Sub-Objective 2: Monitoring and Evaluation: To create and implement mechanisms to effectively measure performance of the health laboratory subsector to facilitate management, planning, learning and policy formulation in the country .							
Strategies	Activities	Performance Indicators	Targets				
			Y1	Y2	Y3	Y4	Y5

2.1 Strengthen the M&E structures of the laboratory network	2.1.1. Institute and operationaize the Laboratory services M&E thematic working group	Functional M&E thematic working group.	X					
	2.1.2. Develop the National M&E Laboratory Services Manual and training curriculum	National M&E Laboratory Services manual and ciriculum developed		X				
	2.1.3. Establish national M&E cordination unit and designate subnation M&E officers.	% of targeted M&E officers assigned.	20	40	60	80	100	
2.2. Effectively measure status of the laboratory subsector through periodic performance reviews, monitoring and evaluation activities.	2.2.1. Develop M&E Frameworks and Plans	NHLDS strategic plan 2020 - 2025 M&E framework developed	X					
	2.2.2. Conduct NHLDS Strategic Plan III Mid-Term evaluation	NHLDS Strategic Plan III mid-term evaluation Report			X			
	2.2.3. Conduct NHLDS Strategic Plan III end-term evaluation	NHLDS Strategic Plan end-term evaluation Report					X	
	2.2.4. Monitor progress of performance improvement (QI projects) against indicated gaps	Proportion of indicated QI projects concluded succesfully	100	100	100	100	100	
	2.2.5. Conduct targeted DQA for national and sub national databases and information systems, notably HMIS / dhis2, A-LIS, VL, EID, SCD, etc	QCA Reports.	X	X	X	X	X	
	2.2.6. Develop a National Laboratory Services M&E Portal/Website Module to disseminate status of each of the national, regional, and facility KPIs	NHLDS M&E Dashbaord developed and updated	X					
STRATEGIC OBJECTIVE 4: To create an enabling environment for promoting research								
Sub-Objective 1: Research & Development: To undertake research of public health importance according to the research priorities/agenda of the Ministry of Health								
Strategies	Activities	Performance Indicators	Targets					
			Y1	Y2	Y3	Y4	Y5	

1.1. Strengthen the research function within the lab network services to promote operational research	1.1.1. Establish and operationalize a research unit within NHL&DS department to coordinate operational research across the network.	Existence of Operational unit for research	X				
	1.1.2. Develop a national laboratory operational research plan and framework	Developed national research plan and frame work in place	X	X			
	1.1.3. Conduct operational research to generate information for better patient care and policy formulation	Number of operational research reports disseminated and or published	X	X	X	X	X
	1.1.4. Create an enabling enviroment for national and international collaborative reaserch including the use of the national biorepository.	No of collaborative research Projects conducted.	X	X	X	X	X
	1.1.5. Surport active participation in operational research activities	% of targeted research related trainings conducted.	100	100	100	100	100
		Annual Research dessemination conferences.	X	X	X	X	X
	No of Research publications in peer reviwed Journals.	X	X	X	X	X	