MoH

THE NATIONAL HEALTH LABORATORY SERVICES STRATEGIC PLAN

2021 – 2025

BANJUL, THE GAMBIA,
May, 2021

"Striving towards the attainment of high-quality laboratory services in the context of Universal Health Coverage"

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FOREWORD

Information provided by medical laboratories underpins the practice of modern medicine; by defining the incidence and prevalence of disease, it allows government and other agencies to plan the provision of healthcare services and monitor their effectiveness. An efficient laboratory service is an essential part of a functional health service. Laboratories provide confirmatory diagnosis and improve management of disease, enable timely detection, and share essential public health information for disease surveillance. Laboratory assessments and other reports have revealed that the Directorate of National Health Laboratory Services (DNHLS) lacks the policies and strategic plans to comprehensively govern and coordinate its services to achieve better healthcare, as has been envisaged in the National Health Policy and Strategic Plan of the Gambia Ministry of Health, the Sustainable Development Goals and the Global Health Security Agenda.

The Ministry of Health and partners, together with assistance from the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM), the Foundation for Innovative New Diagnostics (FIND), and the World Health Organization (WHO), have developed a five-year National Health Laboratory Service Strategic Plan (NHLSSP) 2021–2025, to address evidence-based gaps in the delivery of quality laboratory services. To help maintain quality standards, this NHLSSP will play a critical role in creating an environment where there is increasing participation of the public and private sector in healthcare delivery towards the attainment of universal health coverage, health insurance demands initiatives, Sustainable Development Goal (SDG) 3 and the Global Health Security Agenda, in addition to a Ministry of Health strategic plan. Thus, the NHLSSP will support the delivery of quality laboratory services at all levels.

The Ministry of Health is committed to assist in the implementation of the NHLSSP to complement the National Health Strategic Plan, with prudent use of available funding and to solicit from other donor's assistance towards the provision of better health for all Gambians. I also hope that all donors and other collaborators will align their activities towards achieving the targets set in the NHLSSP. My Ministry will establish a Laboratory Technical Working Group (NLTWG) to advise the Directorate of National Health Laboratory Services towards attaining the objectives laid out in the NHLSSP.

Honourable Dr Ahmadou Lamin Samateh
Minister of Health
May, 2021

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Sheriffo Jagne
Director, National Public Health Laboratory Services
May, 2021

EXECUTIVE SUMMARY

The Ebola outbreak in West Africa during 2014, the COVID-19 pandemic in 2020, and other potential public health challenges have led to calls for the immediate strengthening of the healthcare system, especially the laboratory component, for the early detection of such disease outbreaks and better management of patients. These phenomena reminded the governments of developing countries and The Gambia specifically about the World Health Organization Africa Regional Office (WHO-AFRO) Regional Committee meeting held in Yaoundé, Cameroon, in September 2008, where member states committed to formulating National Health Laboratory Policies and Strategic Plans. The development of this National Health Laboratory Services Strategic Plan (NHLSSP) is underpinned by reports from a health system analysis, notably the National Health Laboratory Services (NHLS) Policy, Stepwise Laboratory Quality Improvement Process towards Accreditation SLIPTA audits, Health Technology Assessments and WHO Joint External Evaluation reports. These plans aim to facilitate the development and strengthening of national laboratory systems and support the health system in surveillance, prevention and control of diseases. Therefore, in line with these and other more recent recommendations and the implementation of International Health Regulation (IHR) (2005), the MoH of The Gambia, in collaboration with Global Fund, FIND, WHO and other stakeholders, has developed this NHLSSP as a tool to facilitate the implementation of the NHLS policy through Annual Operational Plans. This NHLSSP will strengthen the NHLS to effectively and efficiently support the health system in The Gambia.

The NHLSSP has been formulated with a view to having a framework for the development and delivery of an integrated laboratory service in The Gambia. The development of the NHLSSP has benefited from the input of many experts in laboratory sciences and other related fields from within The Gambia, under the supervision of an international consultant. This development borrowed considerably from the experiences and structures in other countries within the African region and broadly followed WHO, Centres for Disease Prevention and Control (CDC) and Association of Public Health Laboratories (APHL) recommendations for the key elements of an NHLSSP. In addition, the NHLSSP has been aligned to the National Health Policy Framework 2021–2030 and the National Health Sector Strategic Plan 2021–2025 of the Gambia.

The Ministry of Health, through the Directorate of National Health Laboratory Services will coordinate the implementation, monitoring and evaluation of this strategic plan. Government directorates and departments involved in the delivery of laboratory services will complement DNHLS. Development partners and national stakeholders will contribute to the implementation of this strategic plan by working with ministries, directorates and departments. There will also be monitoring and mentorship guidelines from the National Laboratory Technical Working Group (NLTWG) to advise the Directorate of National Health Laboratory Services on the attainment of set goals.

The implementation of the NHLSSP will ensure the establishment of a functional laboratory council, which will regulate laboratory staff and practices in both public and private institutions. The oversight function of the NLTWG will facilitate the Directorate of National Public Health Laboratory Services to achieve set health goals as described by the Ministry of Health, SDG 3, WHO, WAHO, the Global Health Security Agenda and in its policy. The creation of functional laboratory networking, sample transportation systems and laboratory quality and biosafety systems will enhance attainment of universal health coverage, provide a laboratory test menu for the Essential Health Package, facilitate

the implementation of healthcare insurance schemes, catalyse the resource-based financial scheme, and enable the prompt detection of pathogens of global security threat.

ABBREVIATIONS AND ACRONYMS

AMR	Antimicrobial resistance
ASLM	African Society for Laboratory Medicine
AIDS	Acquired immunodeficiency syndrome
BF	Blood film
BL	Biosafety level
CDC	Centres for Disease Prevention and Control
CEO	Chief Executive Officer
CMD	Chief Medical Officer
CEmONC	Comprehensive Emergency Obstetrics and Neonatal Care
DNHLS	Directorate of National Health Laboratory Services
DNPHLS	Directorate of National Public Health Laboratory Service
DHIS2	District of Health Information Software 2
EDCTP	European-Developing Countries Clinical Trial Partnership
EFSTH	Edward Francis Small Teaching Hospital
EQA	External quality assessment
FETP	Field Epidemiology Training Programme
GF	Global Fund
IATA	International Air Transport Association
IDSR	Integrated disease surveillance and response
Hb	Haemoglobin
HMIS	Health management information system
HIV	Human immunodeficiency virus
IATA	International Air Transport Association
LIMS	Laboratory information management system
LIS	Laboratory information system
LMIC	Low- and middle-income country
LS	Laboratory services
LQMS	Laboratory quality management systems
NLTWG	National Laboratory Technical Working Group
M&E	Monitoring and evaluation
MoFEA	Ministry of finance and Economic Affairs
MRCG	Medical Research Council The Gambia
MoH	Ministry of Health and Social Welfare
NBTS	National Blood Transfusion Service
NHLS	National Health Laboratory Service
NHLSSP	National Health Laboratory Service Strategic Plan
NHP	National Health Policy
NHSP	National Health Strategic Plan
NPHRL	Neglected tropical disease
NTD	National Public Health Reference Laboratories
NTRL	National Tuberculosis Reference Laboratory
PS	Permanent Secretary
PCR	Polymerase chain reaction

PCU	Project Coordinator Unit
PoCT	Point-of-Care Test(ing)
PPE	Personal protective equipment
PPPH	Public–Private Partnership for Health
R&D	Research and development
RCH	Reproductive and Child Health
RDT	Rapid diagnostic test
RHD	Regional Health Directorate
OIC	Officer-in-Charge
SLIPTA	Stepwise Laboratory Quality Improvement Process Towards Accreditation
SOP	Standard operating procedure
STI	Sexually transmitted infection
SWOT	Strengths weaknesses opportunities and threats
TB	Tuberculosis
UNDP	United Nations Development Programme
UNICEF	United Nations Children Emergency Fund
UNFPA	United Nations Family Planning Agency
WAHO	West African Health Organization
WHO	World Health Organization

CHAPTER 1: PURPOSE OF THE STRATEGIC PLAN

1.1 Introduction

Laboratory services are an integral component of health service delivery. They play a key role in disease surveillance, providing essential data for health systems planning, case management, research, and disease prevention and control. National Health Laboratory Service is faced with numerous challenges, including weak quality management systems, inadequately trained staff, weak biosafety and waste management systems, no regulation of laboratory personnel and premises, high rate of attrition of critical staff and intermittent stock-outs of supplies and reagents.[1],[2] Therefore, there is an urgent need for the development and implementation of a functional National Health Laboratory Services Strategic Plan (NHLSSP) to resolve these issues.

1.2 Strategic objective

The objective of this NHLSSP 2021–2025 is to guide the implementation of the National Health Laboratory Services Policy 2021–2025, which is geared towards the attainment of high quality and accessible laboratory services at all levels of healthcare service delivery. The NHLSSP should provide a framework to guide investment from government, donors and other partners towards the development of an efficient laboratory service within the 5 years.

[1] Health Technology Assessment report,2019
[2] World Health Organization Mission Report, 2017: Joint External Evaluation of IHR Core Capacities of the Republic of The Gambia

CHAPTER 2: BACKGROUND AND INTRODUCTION

2.1 Country profile

The Gambia, in Western Africa, has an area of 11,300 sq. km, of which 10,000 sq. km borders either side of the River Gambia, forming a narrow enclave into the Republic of Senegal, except for a short seaboard on the Atlantic coastline. It has an estimated population of 2,348,000[3], a Human Development Index ranking of 174 out of 189 countries, and had a gross national income per capita of $710 in 2018.[4] The country has a population density of 176 individuals per km^2,[4] one of the highest population densities in Africa; this imposes extreme pressure on productive land and the provision of social services and healthcare in particular.

2.2 Health financing landscape for healthcare services

The healthcare sector is mostly funded by external donors; National Health Account reports for 2016 and 2017 show donors contributed 28.83% and 45.49% of the total health funding, respectively, while government health expenditure as a percentage of total health expenditure dwindled from 38.60% in 2016 to 30.65% in 2017.[5] According to a Health Technology Assessment (HTA) conducted in 2019, external donors contributed to 80% of procured commodities for laboratory services.[1] In addition, the cost of providing healthcare continues to rise, due to increasing demand, changes in diagnostic and therapeutic technologies, inflation, and currency fluctuations. Although there is an impressive revenue collection system enacted by The Gambia Revenue Authority, and opportunities for progressive economic development through local government and civil service reforms as well as attracting investment from the private sector, funding to the health sector is still below the Abuja Declaration of 15% of annual budget allocations.[6]

2.3 Legislative context of health services

The Ministry of Health (MoH) is mandated to oversee and implement health services through its policies and strategic plan. The Directorate of National Health Laboratory Services (DNHLS) was established in 2007 to coordinate and supervise laboratories to complement healthcare management. However, since the inception of DNPHL there has been no regulatory system for laboratory services, which is a great concern for the quality of the services and could be responsible for dishonest, frauds laboratory services.[1] Therefore, there is an urgent need to establish a Medical Laboratory Council which will be mandated with registering all laboratory practitioners and laboratories. There are a few laboratories in the private sector that are associated with private clinics and which are registered with the Medicines Board. Given the importance of health laboratories in making medical decisions that depend on laboratory results, the need for a Medical Laboratory Council cannot be overemphasized.

[1] Health Technology Assessment report,2019
[3] The Gambia Census report,2013
[4] https://countryeconomy.com/countries/gambia
[5] The Gambia Health Account reports for 2016 and 2017
[6] https://www.who.int/healthsystems/publications/Abuja10.pdf

2.4 Health system administration

The MoH is responsible for overall policy formulation, planning, organization and coordination for health in The Gambia. Bodies the MoH oversees include directorates, technical programme units, hospital administrations, health professional councils and other bodies that help the MoH in the execution of its roles and functions. Among the directorates is the Directorate of National Public Health Laboratories (DNPHL), which is tasked with overseeing and providing leadership for all laboratory activities and services in the country (both public and private), including blood transfusion services.[2]

2.5 National healthcare system

A. The public health sector

The public health laboratories serve at a national level, providing overarching support and instituting quality control systems. Key functions include the establishment of norms and standards, emergency and outbreak responses, high-end technology testing that is not cost effective at other levels of the healthcare system, targeted training to improve and strengthen human resources, surveillance, and operational research.

Public health service in The Gambia is delivered at one of three different levels:

- Primary level (village health services and community clinics)
- Secondary level (minor and major health centres and district hospitals)
- Tertiary level (general, teaching and specialised hospitals and the national Public Health Reference Laboratories)

Primary level

This level is the first point of contact and comprises village clinics, Reproductive and Child Health (RCH) tracking stations and minor health centres. This is the lowest level of healthcare, where basic laboratory services are offered, including urinalysis, blood film (BF) microscopy for malaria, stool microscopy, haemoglobin (Hb) estimation, blood glucose measurement, sickle cell testing, and rapid diagnostic tests (RDTs) for malaria, syphilis and HIV. All of these tests are performed at minor health centres, with the exception of RDTs, which are mainly offered at village clinics.

Secondary level

This level consists of major health Centres and district hospitals, also referred to as Comprehensive Emergency Obstetrics and Neonatal Care (CEmONC). In addition to the services provided at the primary level, secondary level facilities provide haematology and blood transfusion services, basic microbiology and clinical chemistry.

Tertiary level

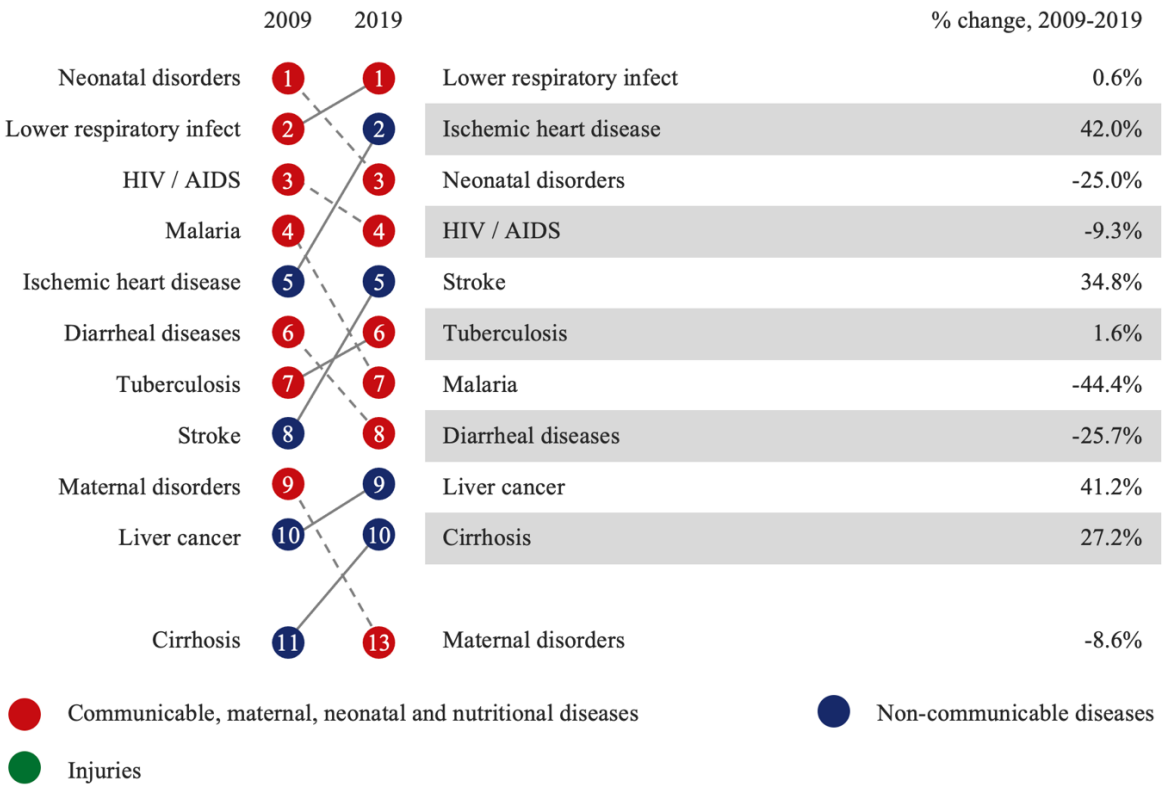
This level consists of general, specialized and teaching hospitals. These hospitals provide more advanced health and laboratory services, including a full range of haematology, blood transfusion, histology, cytology, clinical chemistry and medical microbiology services to name but a few. In addition, teaching hospitals serve as a training centre for healthcare professionals, including laboratory personnel. The National Public Health Reference Laboratories (NPHRL) conduct quality control and assurance for HIV, syphilis, tuberculosis (TB), and malaria RDTs, provide foodborne disease and antimicrobial resistance surveillance, food chemistry testing and in-service training.

B. The private health sector

This category of healthcare providers includes private-for-profit and private-not-for-profit providers and practitioners of traditional medicine, which are not integrated with the government system and provide services for fees paid by patients. Some of these facilities offer laboratory services. There are also several stand-alone private laboratories and Universities laboratories, private research laboratories (Medical Research Council Laboratories at London School of Hygiene and Tropical stations at Fajara, Keneba and Basse) across the country. These provide a range of laboratory tests, depending on the financial status of the service provider.

2.6 Epidemiology profile of leading causes of mortality

What causes the most deaths?



	% change, 2009-2019
Lower respiratory infect	0.6%
Ischemic heart disease	42.0%
Neonatal disorders	-25.0%
HIV / AIDS	-9.3%
Stroke	34.8%
Tuberculosis	1.6%
Malaria	-44.4%
Diarrheal diseases	-25.7%
Liver cancer	41.2%
Cirrhosis	27.2%
Maternal disorders	-8.6%

Figure 1. Trends in the major causes of mortality in The Gambia, 2009 to 2019
(*Courtesy of http://www.healthdata.org/gambia*)

2.6.1 Non-communicable diseases

A ten-year (2009–2019) analysis report on mortality revealed significant increases related to non-communicable diseases in The Gambia (Figure 1). Ischemic heart disease increased from being ranked fifth among all causes of mortality in 2009 to second in 2019, while stroke-associated deaths increased from being ranked eighth in 2009 to fifth in 2019. Other non-communicable diseases associated with an increased number of deaths from 2009 to 2019 include cirrhosis and cancer. Following investment to improve maternal management, deaths associated with maternal disorders have decreased from being ranked ninth in 2009 to thirteenth in 2019.[7] This shows that there has been a progressive shift in national disease burden from communicable to non-communicable diseases; hence, there is need for a functional laboratory policy and strategic plan to ensure timely diagnosis to better inform treatment and management of such diseases.[7]

2.6.2 Communicable diseases

Some communicable diseases have shown a declining trend in total associated mortality, such as malaria, which went from being the fourth-ranked cause of mortality in 2009 to seventh in 2019, a change of -42%. HIV associated deaths decreased slightly, from being ranked third in 2009 to fourth in 2019, a change of -9.3%. Furthermore, with national integrated investment to reduce deaths linked with neonatal disorders, these deaths have decreased from being rank first in 2009 to third in 2019, a change of -25.0%. The introduction of rotavirus vaccination, along with other improvements to disease management, resulted in a reduction in associated mortality from 2009 to 2019.[7] However, despite investment to control, prevent and better manage TB and lower respiratory tract infections, deaths from TB have increased slightly, from being ranked seventh to the sixth leading cause of death, while lower respiratory tract infections increased from being ranked second to the leading cause of deaths in 2019, with changes of 0.6% and 1.6%, respectively. Therefore, there is a need to align the NHLSSP to strengthen the gains made in reducing diseases such as malaria, HIV and diarrhoea. The diagnosis, management and prevention to improve outcomes from lower respiratory tract infections must be addressed, while intensifying testing for sexually transmitted infections (STIs), skin infections, fevers of unknown origin and neglected tropical diseases (NTDs) should be prioritized.

2.7 HIV/TB/malaria/COVID-19 programmes– a vehicle for integrating laboratory services

The Global Fund has actively supported the strengthening of laboratory services capacity, mainly to support the surveillance and management of diseases such as malaria, TB and HIV, for the last two decades. The national public and private health laboratories have been strengthened to respond to and monitor COVID-19 since WHO declared the epidemic and subsequently the pandemic and more concerted efforts are needed to scale-up testing in provincial laboratories.[8] These funded programs exist in silos within the national laboratory system because of the lack of a well-designed laboratory network. Disease-specific reference laboratories conduct parallel supervisory visits and training, as planned in their intervention strategies. However, other disease conditions without assured sustainable funding, such as non-communicable diseases, are the most vulnerable to supply stock-

[7] http://www.healthdata.org/gambia
[8] http://www.moh.gov.gm/wp-content/uploads/2020/07/The-Gambia-Revised-COVID-19-Plan-June-2020.pdf

outs when trying to confirm diagnosis. Therefore, significant consideration was made with this NHLSSP to better inform the development of a laboratory network that will harmonize all of the work on these diseases supported by the Global Fund. In addition, COVID-19 funding can be used to leverage the opportunity for holistic disease laboratory testing systems to maximize the prudent use of government and donor resources. Regional laboratories will be strengthened to supervise minor laboratories, while the reference laboratories will oversee the regional laboratories for all disease conditions.

2.8 The role and need for comprehensive quality laboratory services and their essential components

The National Health Policy 2021–2030 advocates the *"provision of quality and affordable Health Services for All"*.[2] to achieve this goal, laboratory services should function effectively and efficiently. Laboratory services are an essential component in the delivery of quality and affordable health services, yet laboratory services in The Gambia receive less attention in terms of budgetary allocation than vaccines and essential medicines.

A well-functioning public health laboratory service should include the following attributes:

1. Provides vital information needed for proper planning and utilization of health resources;
2. Enhances evidence-based diagnosis, patient management and prevents/eliminates diagnosing patients based on clinical symptoms alone;
3. Contributes immensely towards health research, disease surveillance, disease outbreak detection and management, and pathological and forensic investigations; and
4. Monitors the efficacy of antibiotics and the detection of antimicrobial resistance (AMR).

Globalization, cross-border diseases and the ever-increasing risk of bioterrorism have thrown the spotlight on the need to have quality assured clinical and diagnostic services alongside integrated disease surveillance and response strategies capable of effective containment of outbreaks before they become a national or global emergency.

Without diagnostics, the management of medical conditions/diseases is blind and yet diagnostics receive much less attention than vaccines and drugs. Despite recent investments in global health diagnostics, the potential for diagnostics to generate value for patients and health systems has not been met across all settings; particularly in low- and middle-income countries (LMICs) where disease burdens are high and diagnosis remains a big gap within the healthcare domain. This NHLSSP aims to strengthen laboratory services to execute their core functions and deliver quality assured laboratory services acceptable at both national and international standards.

[2]World Health Organization Mission Report, 2017: Joint External Evaluation of IHR Core Capacities of the Republic of The Gambia

CHAPTER 3: SITUATIONAL ANALYSIS: ACHIEVEMENTS AND CHALLENGES

In 2017, the MoH senior management team, together with other partners, conducted a comprehensive situational analysis; which is being used as the main baseline in the development of this strategic plan. These findings were updated using the HTA report of 2019 and the SLIPTA assessment report of 2020.[1],[9]

The central team, used a pretested questionnaire to collect data from all public health facilities as well as offices of the Regional Health Directorates. Furthermore, the team carried out in-depth discussions on the issues/challenges affecting the delivery of laboratory services at the various levels of service delivery. Table 1 shows a summary of this SWOT analysis.

Table 1: Results of the strengths, weaknesses, opportunities and threats analysis of National Public Health Laboratory Services

Thematic area	Strength	Weakness
Organization and management	1. Collaborations and support from the MoH 2. Establishment of a DNHLS 3. Existence of a tiered laboratory system 4. Support from development partners (GF, WHO, UNICEF, UNFPA, UNDP, WAHO, CDC, EDCTP, MRCG, Africa CDC, ASLM)	1. Weak organizational structure 2. Insufficient number of qualified staff 3. Weak linkage among public and between public and private health sector laboratories 4. Limited implementation capabilities 5. Lack of an organizational chart depicting lines of communication and roles and responsibilities of key laboratory staff 6. Weak supervision of the overall laboratory system 7. Inadequate finances and human resources
	Opportunity	Threat
	Collaboration with development partners (GF, WHO, UNICEF, UNFPA, UNDP, WAHO, CDC, EDCTP, MRCG, Africa CDC, ASLM)	1. Indequate quality of laboratory service delivery 2. Donor fatigue 3. No laboratory policy or strategic plan 4. No Medical Laboratory Council Act

[1] Health Technology Assessment report, 2019
[9] SLIPTA assessment of National Public Health Reference Laboratories report, November 2020.

Laboratory infrastructure	Strength 1. Peripheral laboratories upgraded 2. Provision of a biosafety level (BSL) III laboratory 3. Existence of laboratory structures	Weakness 1. Unsuitable and substandard national reference laboratory facilities 2. Inappropriate operational environment e.g. uncontrolled ambient temperature, intermittent power failure, inadequate water supply 3. Culture of periodic maintenance of laboratory facilities no longer in place 4. Inadequate investments in laboratory infrastructure 5. Limited of monitoring of laboratory environmental controls 6. Absence of a national standard for laboratory infrastructure 7. inadequately ventilated laboratories at primary and secondary levels 8. Lack of a National Blood Transfusion Service Centre
	Opportunity 1. Availability of donor/partner supported model laboratories 2. Availability of local partnership in infrastructural development (GAMWORKS)	Threat 1. Inadequate funding to address laboratory infrastructure 2. Inadequate safety and security for personnel in working environments 3. Frequent interruption in water and electricity supplies from the national grid
Laboratory services	Strength 1. Availability of an array of routine tests at the peripheral laboratories 2. Availability of some specialized tests at regional and reference laboratories 3. A functional National Blood Transfusion Service (NBTS) 4. Availability of the IDSR guideline and list of diseases 5. Availability of a national reference laboratory	Weakness 1. No national list of at least 10 priority diseases (JEE 2017) 2. Inadequate reports from regional laboratories 3. Lack of or non-functional equipment for specialized tests 4. Inadequate funding for laboratory consumables 5. Weak biomedical engineering servicing to support maintenance of equipment

		6. Inadequate coordination of laboratory services across the three healthcare tiers 7. Insufficient resources to support specialized testing services 8. Prolonged turnaround times 9. Weak of a sample referral system 10. Indeaquate cold chain system in place
	Opportunity	Threat
	1. Partner support and funding for equipment, training and supplies	1. High rate of staff attrition 2. Improperly maintained laboratory equipment leading to increased equipment downtime 3. Insufficient number of trained staff at all levels and a compromised staff to workload ratio resulting in delayed treatment 4. Intermittent stock-outs for testing of diseases with epidemic potential
Laboratory support systems: Equipment and supplies	Strength	Weakness
	1. Involvement of laboratory management in the procurement of equipment and supplies 2. Existing budget line on government estimates 3. Equipment user manuals available for training purposes	1. Inadequate presence of up-to-date technology to meet current needs 2. Unreliable supply of reagents and consumables, resulting in frequent stock-outs 3. Limited budget for procurement of equipment and supplies to match national health demands 4. Inadequate and inappropriate basic laboratory equipment at all levels 5. Weak inventory management 6. Weak of established preventative maintenance programmes 7. Weak of equipment management systems 8. Lack of equipment user maintenance training 9. Lack of equipment standardization

	Opportunity 1. External partnerships and support programmes from Regional Reference Laboratories (MRCG (Medical Research Council Gambia), Dakar, Accra and Abidjan) 2. Ability to establish service contacts with equipment vendors	Threat 1. Limited government support 2. Few biomedical engineers to address in-country equipment maintenance needs 3. Service interruption due to lack of spares 4. Limited budget line to purchase equipment and maintenance 5. Inaccessible budget line for government estimates
Point-of-Care Testing (POCT) Services	Strengthen 1. Availability of sustainable point of care test nationally for malaria,HIV, TB, etc 2. Established of Medical Control agency for regulation medical products and devices 3. Availability MoH budget to procure point of care test	Weakness 1. No policy and validated guideline for the use of point of care test 2. No guideline and protocol for validation of point of care test 3. No laboratory based task shifting policy and guideline for the use of point of care test 4. Limited NEQA system for point of care test
	Opportunity 1. Willing of donor such as GF,WHO,WB UNICEF to procure point of care test 2. Engagement of MRCG and other research institute for the evaluations of point of care test 3. Availability of WHO requalified list of Point of Care test	Threat 1. Weak regulation of the point of care test 2. No NEQAS programme for point of care test 3. Limited training programme for the use of point of care test
Laboratory support systems: human resources development and management	Strength 1. Qualified laboratory professionals 2. Availability of different cadres of laboratory professionals (medical/scientific) 3. Existence of trainable personnel 4. Availability of a Field Epidemiology Training Programme (FETP) 5. Refresher training at DNHLS	Weakness 1. Low remuneration of staff 2. High rates of staff attrition and an insufficient number of qualified staff 3. Unavailability of specialist training in biomedical sciences locally 4. Limited in-service training 5. Limited accommodation arrangements at the regional level

		6. Lack of competency assessments 7. Lack of professional development and continuing education programmes 8. Weak of maintenance of personnel records (education, qualifications and experience) 9. Lack of staff retention strategies 10. No appraisal and work job description system
	Opportunity 1. Availability of partner support 2. Training of laboratory staff at the University of The Gambia and America International University of West Africa	Threat 1. Limited motivation 2. Unqualified personnel working in laboratories 3. No human resources for laboratory plan
Laboratory quality management system	Strength 1. Availability of a national quality unit at the MoH	Weakness 1. Inadequately trained staff 2. Lack of a laboratory quality management system (LQMS) 3. Limited participation in international EQA 4. Inadequate supporting infrastructure and equipment
	Opportunity 1. Availability of partner support to strengthen LQMS	Threat 1. High costs of implementation of quality programmes
Biosafety and biosecurity	Strength 1. Existing biosafety manual	Weakness 1. Lack of laboratory health and safety officers and committees 2. Occasional stock-outs of PPE 3. Inadequate waste management facilities (incinerators) 4. Inadequate training and compliance with safety and security measures 5. Absence of safety inspections 6. Inadequate training and procedures for the safe transport of infectious materials

		7. Lack of defined roles and responsibilities related to bio-risk management 8. Inadequate funding for biosafety 9. Lack of biosafety and biosecurity protocols
	Opportunity	Threat
	1. Existing programmes to support laboratory biosafety and training: African Society for Laboratory Medicine (ASLM), CDC 2. Availability of external funding sources for training on biosafety	1. Lack of awareness of bio-risk management 2. Exposure to highly pathogenic organisms
Ethics and community	Strength	Weakness
	1. Existence of a national ethics committee that oversees scientific research proposals	1. Lack of an ethics committee that oversees the ethics of laboratory practice 2. Poor awareness of good ethical practice 3. Lack of a mechanism for the enforcement of ethics regulations 4. Lack of a national code of conduct for laboratory personnel 5. Lack of in-service ethics training
	Opportunity	Threat
	1. Ethics training opportunities for accreditation of laboratories 2. Sanctions for breaches of ethics at a professional level 3. Continuing professional development and training regarding ethics	1. Compromised professional conduct through cover-ups of ethical breaches
Laboratory information management system	Strength	Weakness
	1. Existing laboratory information management information system (LIMS) and health management information system (HMIS) within the MoH 2. Existence of IDSR	1. Lack of IT infrastructure in laboratories for the efficient management of laboratory data, supplies and equipment 2. Poor internet connectivity and other utilities 3. Inefficient dissemination of information

		4. Lack of laboratory data management guidelines and data collection tools 5. Weak LIMS system
	Opportunity	Threat
	1. Opportunity to improve existing LIMS 2. Existing programme to support LIMS and HMIS 3. LIMS as part of continuing professional development	1. No back-up system to prevent loss of laboratory data 2. No data security mechanisms
Research and development	Strength	Weakness
	1. Ongoing R&D activities 2. Existence of research institutions	1. Low number of trained scientific staff at postgraduate level with research experience 2. Inadequate facilities to conduct research 3. Difficulty in retaining qualified staff 4. Limited resources to conduct research 5. Few R&D activities undertaken 6. Lack of a laboratory research database 7. Lack of NPHLS and EFSTH laboratories getting accreditation 8. No budget line for operational research
	Opportunity	Threat
	1. Existence of national training institutions 2. Existence of a research directorate 3. Networking among researchers 4. National and international involvement and support for R&D	1. Lack of translation of research findings into national policies 2. PhD graduates are tempted to quit their jobs
Networking and collaboration	Strength	Weakness
	1. Existence of scientific and professional organizations that support meetings 2. Opportunities for networking and collaboration (WAHO, UN bodies and MRCG)	1. Poor communication between public and private sector laboratories 2. Minimal linkages with other relevant ministries, such as Agriculture, Fisheries, Higher Education, etc.

	3. Laboratory staff participation in central, regional and facility meetings 4. Existence of surveillance networks	3. Existing surveillance networks are not comprehensive and focus on endemic diseases surveillance 4. Existing surveillance networks not adequately integrated with the laboratory system 5. Poor communication among health laboratories
	Opportunity	Threat
	1. Existence of a monthly national seminar organized by MRCG	1. Delayed IDSR 2. Communication challenges
Legal and regulatory framework	Strength	Weakness
	1. Reference laboratories participate in national quality control activities	1. Absence of legislation to regulate the operation of laboratories 2. Lack of licensing of laboratories 3. Lack of registration and licensing of laboratory personnel 4. Non-conformity to policies and regulations 5. No laboratory is accredited to any international standard 6. No laboratory is participating in quality audits
	Opportunity	Threat
	1. Political will for regulatory and licensure apparatus establishment 2. Growing country ownership of integrated laboratory programmes 3. Collaboration and support from national and international organizations to promote 4. accreditation, quality management and training	1. Deception leading to misdiagnosis and high levels of antimicrobial resistance
Monitoring and evaluation	Strength	Weakness
	1. Partner support for specific diseases 2. Small country with a good road network	1. Lack of core M&E tools specific to laboratories 2. Weak supervision and inadequate knowledge of M&E 3. Lack of qualified M&E personnel specific to laboratories

	Opportunity 1. Availability of partner funding	Threat 1. Inability to measure progress
Financing and accountability	Strength 1. Government funding available to support laboratory services 2. Donor and private sector funding	Weakness 1. Inadequate government budget for laboratory services 2. Inadequate cost recovery mechanism in all public health facilities 3. Inadequate funding allocated for laboratory capacity building, staff education and training 4. Insufficient funding to support surveillance networks and other public health activities
	Opportunity 1. Additional sources of funding becoming available	Threat 1. Unregulated pricing systems for costing laboratory tests 2. Overdependence on external support

Subsequently, the situational analysis was complemented by a desk review of normative documents of the MoH; key documents reviewed were:

1. Ministry of Health and Social Welfare Banjul, The Gambia, 2012/2020: National Health Policy

2. Ministry of Health and Social Welfare Banjul The Gambia, 2014/2020: National Health Sector Strategic Plan

3. Ministry of Health Social Welfare Directorate of Planning and Information, 2016: Annual Report: Service Statistics Report

4. The Gambia Health Sector Investment Case for Accelerating Progress towards the SDGs, 2013–2015

5. National Strategic Plan for HIV/AIDS, 2015/2019

6. Ministry of Health and Social Welfare Banjul, The Gambia; 2017–2030: Health Financing Policy: Resourcing the Pathway to Universal Health Coverage

7. WHO Consultant Report, 2018: The HRH Assessment Report; For Input into the Comprehensive Health System Assessment of The Gambia

8. The Gambian National AIDS Secretariat, 2019: Health Technology Assessment

9. Ministry of Health and Social Welfare Banjul, The Gambia; 2018: Gambia Health Information System and Monitoring and Evaluation Report

10. World Health Organization Mission Report, 2017: Joint External Evaluation of IHR Core Capacities of the Republic of The Gambia

11. Africa Society of Laboratory Medicine Report (ASLM), 2015: Country Summary Landscape Report The Gambia

12. National Nutrition Agency (NaNA)-Gambia, UNICEF, Gambia Bureau of Statistics (GBOS), Ground Work. Gambia National Micronutrient Survey 2018. Banjul, Gambia; 2019

13. National Health Policy, Republic of the Gambia 2021–2030

3.1 The National Health Laboratory service structure and networking

Currently, most health facilities across the nation have laboratories that render services ranging from the most basic at a minor health centre level to the most specialized laboratory services at teaching hospital laboratories, private research laboratories and the National Public Health Reference Laboratories.

A comprehensive National Health Laboratory Services Policy, along with the Medical Laboratory Council Act, will enhance the establishment of a Medical Laboratory Council.1 the council shall implement the regulation and licensing of laboratory personnel and premises in both public and private laboratories for assured quality and reliable service delivery in the country.

Some laboratories operate in silos, as the network in practice exists without official mandate/policy, terms of reference (TORs), guidelines and a medical laboratory council, hence the urgent need to better position the laboratory services. The development of a holistic National Health Laboratory Service Policy would encompass all of these laboratories and facilitate the decentralization of laboratory services.

3.2 Organization and management of the National Health Laboratory Service structure and network

A director currently oversees the National Public Health Laboratories (NPHLs), which house the HIV, TB, malaria and bacteriology reference laboratories, the NBTS, and the remaining National Health Laboratory Service (NHLS) laboratories. The director coordinates the employment, training and deployment of laboratory staff, mainly to health facilities at minor and major health centres and district hospitals. Teaching and general hospitals are semi-autonomous and thus employ their own laboratory staff. The director of the NHLS, in consultation with the Directorate of Pharmaceutical Services, procures laboratory equipment, reagents and consumables for all laboratories under the MoH and other private laboratories supported by the Global Fund. This policy will address the mandate and TORs of the director of the NHLS to extend beyond the NPHL and how autonomous and semi-autonomous laboratories will interface with the network. It will also give autonomy to the director of the NHLS to procure laboratory equipment, reagents and consumables, in consultation

with senior management. Besides delineating clear TORs for each laboratory, the different laboratory levels will be linked to laboratory test menus, a sample referral system and ultimately the laboratory quality management system to avoid conflicts of interest.

3.3 Laboratory services: the major constraints

The major constraints to the laboratory sector effectively contributing to healthcare delivery include:

- No mandate, ToRs or guidelines that clearly explain how the components of the laboratory network should work together
- No flow chart of the laboratory network exists that could dictate sample collection and transportation/referral for more advanced testing
- No guidelines or weak systems for sample transportation
- Weak laboratory governance and coordination
- Low number of qualified laboratory personnel across the various levels of the health sector
- The absence of an efficient capacity building and continuous professional development system using a clearly defined professional development strategic plan
- The lack of national standards for the establishment of medical laboratories and the absence of a comprehensive quality management system
- Inadequate basic components necessary for effective functioning and efficient service delivery by medical laboratories, including basic physical infrastructure, laboratory equipment and supplies and the unreliable supply of utilities such as electricity and water
- Limited participation by and communication with laboratory management in the procurement of equipment, reagents and consumables, leading to frequent stock-outs and a lack of spare parts at all laboratory levels
- Limited systems for monitoring laboratory supplies
- Low level of preparedness for epidemic specimen management
- No National Blood Transfusion Centre
- No molecular-based screening for blood-borne infections
- Limited SOPs in place at all levels of the laboratory service
- No policy or guidelines for reporting and archiving laboratory results

- Weak laboratory information management system
- Weak biosafety and biosecurity systems throughout the national laboratory network
- Inadequate funding support for continuous services of the Essential Health Package at all levels of the laboratory system
- Lack of specialized laboratories, such as toxicology, forensic science and bio-bank laboratories for the storage of tissues/isolates

These inadequacies hinder effective clinical care and do very little to inform positive public health decisions.

3.3.1 Organization and management

The NPHL provides laboratory support by acting as a national reference laboratory. It also carries out coordination and supervision functions for all clinical laboratories providing diagnostic services within all public and private health facilities, including stand-alone laboratories. There is thus a need to provide a comprehensive organogram, including standardized term of references, for all jobs under the NPHL and other clinical laboratories. This would help to clearly define and separate the roles and functions of these laboratories within the NHLS network. It is envisaged that one principal laboratory scientist should be posted at each Regional Health Directorate (RHD) to facilitate coordination of activities, oversee the operations of all satellite laboratories and report to the central level, which is the Directorate of the National Public Health Laboratory Service (DNPHLS), which shall be housed at the National Public Health Reference Laboratories (NPHRLs). Currently, this system is not functional due to a lack of policy for effective human resources distribution across the country and motivation for retention in service. There is weak national laboratory governance, an inadequate number of qualified laboratory personnel, and generally non-existent linkage among public and private health sector laboratories.[1]

3.3.2 Laboratory services

The Directorate of the NPHLS has not ensured access to a minimum package of laboratory services appropriate to each level of care in the public and private sectors. This should be ensured for equity and access to a functional specimen referral system that provides services at all levels. Where samples are referred to other laboratories, efforts are not made to ensure quick turn-around times for clinicians and patients. There exist the integrated disease surveillance and response guideline wherein 42 diseases of public health importance have the highlight for the national surveillance system and notably, diseases such as measles, rubella, yellow fever, meningitis, polio, malaria, HIV, TB and COVID 19 had a well-established laboratory surveillance system and all the report. Although according WHO joint external evaluation report, there is no laboratory-based list of at least ten priority diseases[14], limited regular reports from regional laboratories, and inadequate coordination of laboratory services across the three health care tiers. Laboratory services within both the public and private sectors are not audited to ensure standardization in service delivery to improve the quality of services rendered to the general public.

3.3.3 Infrastructure, Laboratory biosafety and biosecurity

The infrastructural capacity of several laboratories has been improved with support from development partners. However, many facilities that were built some decades ago are now dilapidated and in need of renovation or upgrading to meet current recommended infrastructural standards. There is inadequate investment in laboratory infrastructure, with unreliable sources of utilities such as water and electricity, uncontrolled ambient temperature, and no effective mechanisms for fire safety and infection control system structures. There are no standard regulations for laboratory infrastructure.

The risk of laboratory-acquired infections is ever present among personnel handling pathogenic organisms. This risk is compounded by low awareness, inadequate training and an inability to adhere to recognized SOPs. In many countries, including The Gambia, the disposal of medical waste is often not regulated. There is also a potential danger in many laboratory premises due to unauthorized access by non-laboratory staff. This can lead to exposure to highly pathogenic organisms (e.g. the virus that causes COVID-19). It is therefore essential that all laboratories take precautions to protect staff and the environment and control access to the laboratory. Most facilities do not have designated safety officers, sufficient personal protective equipment (PPE), safe waste-disposal mechanisms, infection prevention and control mechanisms, adequate waste-management facilities (incinerators), or adequate training and compliance with SOPs. Hence, there is a need to recruit and train a health and safety officer who will advise employers on the measures needing to be taken in the interests of safety and health at a place of work. The safety officer should also inspect places of work, to determine whether there are any hazards liable to cause bodily injury, and investigate any accidents, near misses, dangerous occurrences, or occupational poisoning or disease. The safety officer shall ensure that staff receive adequate training on health and safety at work, strictly adhere to rules, and safely manage the disposal of waste. Laboratory staff currently have no access to health insurance schemes for themselves and their families, thus making the profession insecure and risky.

3.3.4 Laboratory support systems: equipment and supplies

Laboratory consumables and equipment are procured by the MoH through the procurement unit. Development partners also procure laboratory consumables and equipment for the MoH. The storage and distribution of these consumables and equipment are coordinated by the Directorate of Pharmaceutical Services (DPS). Generally, higher-level facilities are relatively better equipped than lower-level facilities. Non-government sector facilities are usually better equipped and better stocked with reagents and supplies, but in general there are weak and poorly coordinated inventory and procurement systems to ensure uninterrupted supply and service delivery. Many facilities experience regular stock-outs of essential reagents as well as equipment downtime, limiting their ability to carry out basic tests.

Laboratories at all levels are ill-equipped, with most lacking up to date equipment required to provide basic microbiology, haematology and clinical chemistry services. Equipment in some facilities lacks

either skilled users or is not adequately maintained, thus leading to wastage of resources. This is usually due to the limited inclusion of maintenance agreements in purchase contracts and the limited of training programmes for users in the use and basic maintenance of equipment. There is a limited budget for the procurement of equipment, replacement parts and supplies to match national health demands. The Biomedical Unit is poorly furnished and therefore should be well-equipped in order to maintain other available equipment. Generally, laboratory users are not actively involved in the procurement process.

3.3.5 Laboratory support systems: human resources

The shortage of human resources to work in diagnostic laboratories is serious and is affecting the quality of healthcare at our facilities. There is a huge challenge in providing and retaining adequate numbers of laboratory professionals in public sector healthcare laboratories, especially in rural and remote areas. A countrywide tour to conduct a comprehensive assessment of the status of public health laboratories was performed by a consultant in 2019, and the biggest challenge highlighted was the shortage of appropriately trained staff.[1] Thus, many laboratories do not meet the recommended staffing norms and instead resort to employing unqualified personnel, referred to as laboratory attendants. This cadre of staff has no formal technical training and therefore are a cause for concern in terms of the quality of service they can provide. Currently, in The Gambia, there are limited institutions where biomedical scientists can be trained. The University of The Gambia and the American International University, West Africa (AIUWA) only train laboratory technicians.[10] Although the former also trains biologists, these trainees only graduate with a BSc in biology and hence fall short of the requisite training to become a biomedical scientist. There are limited highly qualified personnel to fill the available positions at both the technician and scientist levels.

There is widespread dissatisfaction among laboratory practitioners, with complaints of low pay and poor working conditions. This leads to high rates of staff attrition and a shortage of qualified staff, which further worsens the human resources crisis in the country's health sector. Simply addressing the absolute number of laboratory professionals without dealing with career progression and continued opportunities for education or in-service training will not result in developing and maintaining key personnel. All these factors result in demotivation, which further compromises the quality of services delivered. There are limited highly qualified personnel available who are able to fill vacant positions at the technician and scientist levels.

3.3.6 Laboratory quality management system

There is no clearly developed and well-coordinated quality management system for internal and external quality assessment that could lead to the continuous quality improvement of standard laboratory services; resulting in accreditation.[2] The establishment of a quality management system for every laboratory is essential to ensure quality testing services.

Inadequacies in the infrastructure, human resources, equipment, supplies and other aspects compromise the quality of laboratory services delivered at all facilities.[2]

[10] Human Resources for Health, Assessment report, 2019.

Standard laboratory guidelines, manuals, and standard operating procedures (SOPs) are absent in most facilities, and a number of laboratories receive no technical support or supervision due to limited capacity and resources for the supervision and monitoring team. Only facilities involved in vertical programmes, such as those related to TB, malaria and HIV/AIDS, receive some periodic in-service training and supervision.

3.3.7 Laboratory information management systems

The laboratory is often a valuable source of data for patient management and public health interventions. Data that are accurate, complete and timely are critical for public health interventions, including planning and outbreak responses. It is therefore important that a laboratory information management system (LIMS) be established nationally, and that all laboratory personnel are trained in IT to support clinical and public health programmes. Data collected at healthcare facility level are often incomplete and inaccurate. Currently, information is manually managed at the peripheral level and is not effectively used at many levels. The transfer of laboratory data among different levels and sectors is also not very effective. The use of modern computerized systems is limited, and systems for keeping laboratory records and collating data from testing laboratories are not standardized. This is due to limitations in laboratories in the IT infrastructure for efficient management of laboratory data, supplies and equipment; poor/lacking internet connectivity and other utilities; and a lack of laboratory data management guidelines and data collection tools. Therefore, the opportunity to introduce the LIMS system link to the District of Health Information Software 2 (DHIS2) for the management and reporting of COVID-19 results could be exploited to expand it for all laboratory services.

3.3.8 Research and development (R&D)

R&D is an important pillar of any progressive laboratory service and is essential for any country that seeks to understand and find solutions to its problems. Laboratory scientists should be trained to initiate and conduct research activities. The potential exists to build on the available capacity to enhance laboratory-based research activities in the country in conjunction with the Directorate of Health Research, Medical Research Council, Directorate of Research under the Ministry of Higher Education and Research and other relevant partners. However, there is currently inadequate funding and facilities to conduct research, hence R&D is often neglected.

3.3.9 Point-of-Care Testing (POCT) Services

The discovery and introduction of the point of care test has increase access and turnaround in the diagnoses and management of patients. This success stories has drastically increased to the access of testing and management for malaria, HIV and TB in the Gambia. Point of care tests are the mainstay test for blood screening for transfusion transmission infection nationally, though; it is ideal to introduce molecular-based diagnostic capacities for such services. There are no and weak regulation of use of point of care devices national and these devices may of dependable on their sensitivity and specificity for the desired result to be ascertain. Beside there no standardize external quality assurance programme for such devices such that their performance are ensured to be reliable. Therefore for the quest of laboratory service in the context of universal health coverage, it

paramount to embrace the used of WHO prequalified point of care tests which has to be locally regulated and dependable

3.3.10 Networking and collaboration

Networking and collaboration are essential components in delivering quality laboratory services, due to the different categories of laboratories (e.g. diagnostic and reference laboratories). It is sometimes necessary to refer tests to other laboratories within or outside the country. It is now recognized and proven that a country can successfully organize a disease-specific or general laboratory network within the country to provide many patients with access to a range of tests. Networks are also important for sharing information and experience, strengthening the referral system, and training laboratory personnel.

There is limited equipment and trained personnel to provide higher-level testing throughout the country. This leads to an alarmingly high rate of patient referrals, just because of the lack of on-site laboratory testing with no national sample referral system guidelines. This greatly hinders the timely management of clinical cases. There is also poor communication between public and private sector laboratories and weak linkages with other relevant ministries, such as Agriculture, Fisheries, Higher Education etc.14 Hence, the implementation of the National Public Health and Emergency Response Plan, which had all the structures for the implementation of One Health, would create a structure for inter- and intra-ministerial linkages for responses and coordination for diseases and other public events.[11]

3.3.11 Legal and regulatory framework

There is no Medical Laboratory Council Act to regulate the operation of laboratories or the registration and licensing of laboratory personnel.[2] Therefore, there is an urgent need to establish a Medical Laboratory Council, which will be mandated with registering and licensing all laboratory practitioners and laboratories. Besides council shall support the development and implementation of a code of conduct and maintenance of laboratory ethics and execution of disciplinary for the NHLS. Further, it will be strengthened to support the continuous professional development of the cadre. This unit shall be semi-autonomous and could liaise with the Directorate where relevant.

3.3.12 Monitoring and evaluation

There are limited monitoring and evaluation (M&E) systems for the comprehensive assessment of laboratory performance for effectiveness and efficiency in the delivery of quality, affordable and timely health services in accordance with the National Health Policy 2021–2030. This system needs strengthening to track the progress and achievement of laboratory-based health outcomes on a regular basis. There is a limited, core M&E tool specific to laboratories, inadequate supervision and knowledge of M&E at the central level, and a lack of qualified M&E personnel specific to laboratories. Most of the parallel funded disease monitoring and evaluation programme will be oriented to cover other diseases.

[2]World Health Organization Mission Report, 2017: Joint External Evaluation of IHR Core Capacities of the Republic of The Gambia

[11] National Public Health and Emergency Response Plan, 2019

3.3.13 Financing and accountability

The NHLS is grossly underfunded.[2] there is a dedicated budget line for National Health Laboratory Services but this is not easily accessible and well below the amount required to guarantee equipment availability and no stock outs of reagents, test kits and laboratory supplies. There is also limited cost recovery mechanism for laboratory services in public health facilities. This must be urgently addressed via a laboratory policy, a clear organizational structure, and leadership at the appropriate level within the MoH to develop a laboratory business plan in the quest for cost recovery to sustain the continuity of laboratory services. Besides, it will be prudent to explore implementing a resource-based financing scheme paid for improving health care services in piloted health facilities in rural Gambia. Thus, facilities under such funding could include the cost of replenishment of reagents and consumables to reduce stock out and total dependence on limited NHLS budget lines.

3.3.14 Laboratory service ethics and community engagement

There are currently no protocols or guidelines that comprise a laboratory code of conduct. The Medical Laboratory Council should enforce such codes, which will guarantee client respect, confidentiality, privacy and safety. There is no swearing of such a code of conduct when laboratory staff graduate; hence, weak regulations and limited guidance for laboratory ethics prevail in the system. There is a need to sensitize the wider community about the role played by laboratories in healthcare, as well as their rights and the rights of service provider. They could be sensitized on how to launch complain in case of any malicious practice for redress.

CHAPTER 4: STRATEGIC PLANNING

4.1 Context and rationale of the National Laboratory Strategic Plan

The national laboratory strategic plan was developed to implement the National Health Laboratory Services Policy (NHLSP) 2021–2025, and is aligned with the following:

- The National Health Policy (2021–2030), which recognizes the National Public Health Laboratory Service as the institution coordinating the services of a network of medical laboratory services

- The Gambia National Health Sector Strategic Plan, 2021–2025, which proposed two strategic objectives: (1) availability of well-functioning laboratory services in all hospitals and all major and minor health centres by 2025, and (2) increasing access for all to quality laboratory services and blood transfusion services by 2025

- The National Monitoring and Evaluation Plan for the National Health Sector Strategic Plan (NHSSP), 2021–2025 recognizes the need to strengthen the quality assurance/quality control systems for laboratory services and a linkage to a reference laboratory at the national level which needs further strengthening

- Technical Guidelines for Integrated Disease Surveillance and Response in The Gambia; the Public Health Emergency Operation Centre, and the Health insurance scheme, which are all geared towards attainment of the following objectives for strengthening laboratory preparedness and responses to health emergencies:
    - Improve laboratory capacity for identifying pathogens and monitoring drug sensitivity
    - Strengthen the involvement of laboratory personnel in epidemiological surveillance

The strategic plan is also aligned with regional and global initiatives focused on improving the quality of health laboratory services in Africa, notably:

1. Maputo Declaration, January 2008: the Maputo Declaration calls for the strengthening of laboratory systems in Africa and for scaling-up of services for improving laboratory support for TB, malaria and HIV/AIDS

2. Yaoundé, Cameroon Declaration; Resolution AFR/RC58/R2, September 2008: The Yaoundé, Cameroon Declaration calls for the strengthening of public health laboratories (PHLs) as centres of excellence for outbreak management in the WHO/AFRO sub region

3. Dakar, Senegal, September 2008, 5th Meeting of the Regional HIV/AIDS Public Health Laboratory Network; this meeting called for the strengthening of national HIV/AIDS testing for improved quality assurance services

4. Kigali, Rwanda, September 2009; Resolution AFR/RC59/WP/3: Policy orientations on the establishment of centres of excellence for disease surveillance, public health laboratories, and food and medicines regulation

5. Sustainable Development Goal 3

6. Universal Health Coverage

The implementation of this national laboratory strategic plan will take 5 years and will provide a national framework to guide investment in health laboratory services by the Government of The Gambia, health development partners and other stakeholders.

4.2 Vision statement, core values and guiding principles

Vision
Provision of high quality and accessible laboratory services at all levels of healthcare service delivery.

Mission
To provide high quality laboratory testing services where and when needed; support clinical care providers in the management of diseases and support disease surveillance systems and public health research.

Goal
To put in place high quality health laboratory service at all levels of healthcare delivery across the country.

Core values and guiding principles
The following core values and guiding principles shall apply in the management and delivery of laboratory services in the country.

Quality testing: Ensuring quality assurance and management systems to guarantee that test results are accurate, reliable and timely.

Equity: Laboratory resources and services are distributed equitably throughout the country.

Accessibility: Laboratory services are affordable and within reach of all.

Relevance: Laboratory services are appropriate for the purpose and address the needs of individuals, families and communities.

Partnership: Promote teamwork and team spirit among all laboratory personnel and afford networking and collaboration with stakeholders.

Confidentiality: Promote professionalism and ethical practice among all staff and in their relationships with patients.

Timeliness: Ensure laboratory results reach the caregiver and the patient on time and contribute to appropriate patient management.

Customer focus: Always bearing in mind who we are serving. The customer may be the community, patient, clinician, individual or the public.

Ethics: Respect for autonomy, non-maleficence, beneficence and justice.

Accountability: Decision-makers in laboratory services are accountable to the public and institutional stakeholders in the delivery of services.

Effectiveness and efficiency: Processes and institutions should produce results that meet population needs and influence health outcomes, while making the best out of available resources.

4.3 Objectives of the strategic plan

General objective statement
The objective of this National Health Laboratory Strategic Service Plan is to establish authority and direction for the development of the required capacity of laboratory services and define standards for all aspects of health laboratory practice in the country.

General strategies
To establish a functional National Health Laboratory Service (NHLS) for the coordination of standardized and high-quality laboratory testing, disease surveillance, health research and data management.

General sub-objectives

1) To restructure/transform the Directorate of NPHL to the Directorate of NHLS, with the capacity to effectively and efficiently manage laboratory services across The Gambia in the context of decentralization.

2) To provide the required number of staff with the necessary qualifications, skill sets, competence and motivation to deliver high-quality laboratory services across The Gambia.

3) To promote integrity, dignity and appropriate conduct in laboratory practices at all times and all levels.

4) To provide appropriate, functional laboratory equipment and sufficient consumables and supplies to guarantee uninterrupted laboratory service delivery at all levels of healthcare.

5) To have quality laboratory services at all health system levels to support effective patient management, disease surveillance, epidemic investigation, research, and other specialized services.

6) To provide outstanding contributions to key research outcomes to improve patient management, laboratory performance and disease control in line with the national health policy and strategy.

7) To institute appropriately designed and standardized laboratory structures that meet the specific needs of each level of health facility.

8) To mobilize and advocate the provision of sufficient financial and logistical resources required to facilitate the delivery of continuous and high-quality health laboratory services.

9) To establish a quality management system in health facilities towards the accreditation of laboratories.

10) To establish a system for monitoring and evaluating laboratory service delivery at all levels of healthcare.

11) To establish the Gambia Medical Laboratory Council for the regulation of laboratory personnel and institutions across the country.

12) To put in place appropriate mechanisms that will guarantee laboratory personnel, users, visitors and the immediate environment.

13) To adopt best practices that comply with relevant and appropriate national and international laboratory information management systems (e.g. IDSR/HMIS).

14) To establish a National Laboratory Technical Working Group that advises the Directorate of the NHLS towards the attainment of policy objectives.

15) Promote networking among health facilities and public and private laboratories and all other relevant stakeholders.

16) To establish and maintain a robust legal framework for the regulation of all medical laboratories.

17) To institute a committee to ensure the accountability and transparency of laboratory services across all levels of healthcare in liaison with the project coordination unit and National Laboratory Technical Working Group

18) To establish policies and guidelines for laboratory biosafety, biosecurity and waste management.

19) To establish a National Blood Transfusion Centre that has molecular-based blood testing facilities.

20) To review and update national blood transfusion policies, guidelines and strategies.

21) To establish antimicrobial resistance (AMR) policies and strategies for the surveillance and control of AMR.

22) To develop mechanisms to ensure the availability of laboratory financial protocols and guidelines for financial management and accountability.

23) To establish and maintain regulations and policies for introducing and monitoring the performance of the point of care test.

4.4 Strategic directions of the plan

1. Organization and management

Objective: Strengthen an organizational structure with appropriate authority to coordinate and manage the provision of comprehensive health laboratory services across the country.

Strategies

1.2 Transform the Directorate of NPHL to the Directorate of NHLS with the capacity to effectively and efficiently manage laboratory services

1.3 Implement effective communication and representation of laboratory services at the seven Regional Health Directorates (RHDs)

1.4 Establish a technical oversight body (NLTWG) to coordinate and establish direction and standards for the NHLS

1.5 Provide training support for supervisors throughout the tiered laboratory network

2. Laboratory Services

Objective: Provide quality laboratory testing services to all people

Strategies

2.1 To have quality laboratory services at all levels of the health system that will support effective patient management, disease surveillance, epidemic investigation, research and other specialized services

2.2 Strengthen safe and secure specimen collection, packaging and transportation within the laboratory network and at the international level

2.3 Strengthen national laboratory testing capacity to support effective implementation of UHC

2.4 Conduct mapping of the outbreak response capacity of the national and regional reference laboratories in public and other sectors under the One-Health approach to guide specimen referral across the laboratory network for disease confirmation

2.5 Review/adapt, validate and print guidelines for the implementation of laboratory-based surveillance of AMR, vaccine preventable diseases, foodborne diseases and non-communicable diseases in the mainstream IDSR, One-Health context

2.6 Develop a plan and budget to support laboratory public health emergency responses, which is mainstreamed with the national health emergency response plan for early warning system

2.7 Develop and implement human resource competencies for specialized and clinical laboratories at the national and regional levels for the detection of agents of public health importance under the One-Health approach

3. Infrastructure, Biosafety and Biosecurity

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

Strategies

3.1 Strengthen national laboratory biosafety and biosecurity system
3.2. Ensure that construction and renovation of health laboratory facilities conform to national infrastructure guidelines and standard
3.3 Establish maintenance programme for biosafety and biosecurity equipment
3.4 Establish an effective occupational health and safety programme for laboratory personnel in liaison with the occupational health unit of the MoH
3.5 Strengthen the coordination of biosafety and biosecurity activities through effective management at all levels
3.6 Strengthen human resource capacity for biosafety and biosecurity Program through trainings for improved practice

4. **Equipment and Supplies**

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

Strategies

4.1. Strengthen the coordination of the laboratory supply chain management system across the network in liaison with National Pharmaceutical Services (NPS)
4.2 Establish pre- and post- market surveillance systems for laboratory commodities
4.3 Strengthen supply chain management to quantify, procure, distribute and monitor laboratory commodities across the network
4.4 Strengthen the ordering, storage and inventory management systems at all levels
4.5 Strengthen data management systems for laboratory logistics to meet routine and emergency services delivery
4.6 Strengthen capacity in laboratory logistics management, including BLIS
4.7 Develop and implement guidelines for equipment procurement and placement across the laboratory network
4.8 Strengthen equipment maintenance and management at all levels
4.9 Establish a system for monitoring equipment functionality and managing the disposal of laboratory equipment and supplies

5.0 **Human Resources**

Objective: Ensure that the laboratory sub-sector has an adequate workforce with the necessary competencies, remuneration and motivation to deliver quality laboratory services at all designated levels

Strategies

5.1 Review and update current scheme of service for the laboratory work force
5.2 Recruit sufficient laboratory staff to fill vacant and new positions at all levels, in line with the revised scheme of service for laboratory professionals
5.3 Retain sufficient laboratory staff at all levels, in line with the revised scheme of service
5.4 Equip the laboratory workforce with the skills and competencies essential for quality service delivery

6. Quality Management System
Objective: Strengthen the national laboratory quality management system to ensure quality service delivery that leads to national/ international laboratory certification and accreditation

Strategies
6.1 Develop and establish national laboratory standards for laboratory quality
6.2 strengthen the coordination of activities for the implementation of the laboratory quality management system (QMS)
6.3 Strengthen National External Quality Assessment Schemes (NEQAS)
6.4 Strengthen the national capacity for implementation of quality management systems towards laboratory certification and/or accreditation
6.5 Provide training support for supervisors throughout the tiered laboratory network

7. Laboratory Information Management System
Objective: Implement an integrated LIMS in the laboratory network for the management and utilization of patient data and other laboratory services data to facilitate evidence-based decision-making and operational research

Strategies
7.1 Develop and implement an electronic, integrated LIMS in all laboratories in the network to improve laboratory data and information management
7.2 Strengthen standardized, paper-based LIMS at sites without electronic LIMS to facilitate data capture and reporting
7.3 Develop and implement an electronic, mobile and web-based platform for effective specimen tracking across the national sample transport network
7.4 Establish a system for the standardized collection, analysis and reporting of patient data to improve data use
7.5 Establish a forum for multi-sectoral data sharing among all laboratories and agencies with activities affecting human health, to enhance collaboration for implementing the One Health model
7.6 Establish an integrated database for managing non- clinical laboratory data to improve the coordination of laboratory services

8. Research and Development
Objective: Undertake research of public health importance according to the research priorities of the National Health Sector

Strategies
8.1 Develop a research agenda for the laboratory sub-sector
8.2 Build capacity of laboratory personnel involved in operational research
8.3 Develop and implement a national laboratory research database to track and disseminate research findings

9.0 Point-of-Care Testing (POCT) Services
Objective: To increase access to testing services by complementing conventional laboratory testing services with approved and appropriate point-of-care technologies

Strategies
9.1 Strengthen coordination mechanism for POCT to improve provision of POCT services
9.2 Develop capacity for POCT as a means of increasing access to laboratory services
9.3 Develop and implement POCT communication strategy to improve access to POCT services at national, regional and community levels
9.4 Develop QA mechanism for POCT to improve quality of POCT services

10. Networking and Collaboration
Objective: to Strengthen multi-sectoral, national, international, public and private partnerships to promote equitable access to quality laboratory services

Strategies
10.1 Establish a system for sharing information, testing capacity and resources among sectors towards the One-Health strategy (e.g. for AMR, zoonotic and notifiable diseases, outbreaks, and food safety)
10.2 Establish mechanisms to outsource specialized laboratory services to increase efficiency and effectiveness in service delivery
10.3 Promote public–private partnerships for the provision of health laboratory services in accordance with PPPH policy
10.4 Support establishment of laboratory services for underserved areas by providers outside the public system

11. Regulatory and Legal Framework
Objective: Ensure that the national laboratory legal and regulatory framework is enforced within the entire health laboratory network, in collaboration with relevant regulatory bodies

Strategies
11.1 Establish and maintain a robust legal framework for the regulation of medical laboratories and laboratory personnel
11.2 Ensure that all health laboratories meet the required standards for registration and licensing
11.3 Ensure that all practising laboratory professionals are registered and licensed

12. Monitoring and Evaluation
Objective: Create and implement mechanisms to effectively measure performance of the health laboratory sub-sector to facilitate management, planning, learning and policy formulation in the country

Strategies
12.1 Establish an effective program to monitor and evaluate the implementation of the National Health Laboratory Strategic Plan
12.2 Establish M&E for laboratory logistics activities
12.3 Ensure regular assessment of the overall performance of laboratory services

13. Finance and Accountability

Objective: Establish resource mobilization and accountability mechanisms at national and sub-national levels to ensure availability and accessibility of adequate resources for the provision of sustainable laboratory services

Strategies

13.1 Ensure a dedicated budget for laboratory services in the MOH
13.2 Coordinate partner funding activities for laboratory services
13.3 Mobilize funds to meet laboratory budget needs
13.4 Establish a transparent system to ensure programmatic and financial accountability of laboratory services

14. Ethics and Community

Objective: Laboratory services shall be an integral part of the health service's responsiveness to community needs and shall adhere to ethical and environmental standards

Strategies

14.1 Promote integrity, dignity and appropriate conduct in laboratory practices and responses to community needs at all times and at all level
14.2 Develop strategies to increase community access to equitable quality testing services

CHAPTER 5: IMPLEMENTATION FRAMEWORK

5.1 Institutional framework

The strategic plan matrix (below) details the strategic objectives; activities and implementation timeframe; performance indicators; and responsibility and sources for resources that would need to be deployed to implement the National Health Laboratory Service Strategic Plan; 2021–2025.

5.2 System of planning and implementation framework

The MoH, through the Directorate of the NHLS, will coordinate the implementation, monitoring and evaluation of this strategic plan. Government directorates and departments involved in the delivery of laboratory services will complement the DNHLS. Development partners and national stakeholders will contribute to the implementation of this strategy by working with line ministries, directorates and departments.

5.3 Monitoring and evaluation

The monitoring and evaluation (M&E) of laboratory services was not given adequate consideration in the National Health Strategic Plan 2015–2020,[12] making it a critical component to monitor the implementation of the NHLSSP for The Gambia 2021–2025.

The methodology and framework developed to evaluate the progress and impact of the overall strategic goals are defined in this Monitoring and Evaluation (M&E) Plan. The M&E indicators will measure the degree to which activities achieve results, as defined in the M&E framework. The results the NHLSSP expects to achieve in particular focus areas are clearly presented in the M&E framework. The M&E plan will act as a tool for the routine tracking of laboratory performance. It will also serve as a guide for managing laboratory resources, enabling stakeholders to change goals and approaches, with the comprehensive data and information flows needed at each stage to assess impact.

To ensure the implementation of M&E activities as outlined in the NHLSSP, strategic information and guidance on the progress of implementation of laboratory services should be provided. Also, the accomplishment of targets, measure impact, and timely feedback for decision making and planning are also needed.

[12] Ministry of Health and Social Welfare Banjul The Gambia, 2014/2020: National Health Sector Strategic Plan

1. Organization and management **<u>Objective:</u> Strengthen an organizational structure with appropriate authority to coordinate and manage the provision of comprehensive health laboratory services across the country.**			**Timeline**				
Strategies	Sub- Objectives	Funding Source	Y1	Y2	Y3	Y4	Y5
1.1 Transform the Directorate of NPHL to the Directorate of NHLS with the capacity to effectively and efficiently manage laboratory services	1.1.1 Enactment of DNHLS reform policy	MoH	X				
	1.1.2 Define and institute an organogram which includes national and regional coordinators and their corresponding job descriptions that ensure clear reporting lines within DNHLS and mainstream private laboratory linkages	MoH, WHO, GF	X				
	1.1.3 Define and implement roles and responsibilities for the different stakeholders in the tiers of the network to facilitate effective coordination of laboratory services in The Gambia	MoH, WHO, GF	X				
1.2 Implement effective communication and representation of laboratory services at the Regional Health Directorates (RHDs	1.2.1 Institute regional coordination offices and provide staff to coordinate laboratory services at regional level, mainstreaming into the Regional Health Directorates	MoH,PMO,PSC		X	X		

	1.2.2 Institute and implement annually retreat of the NHLS meeting of national and regional coordinators	MoH,GF,WB		X	X	X	X
1.3 Establish a technical oversight body (Laboratory Technical Working Group) to coordinate and establish direction and standards for the NHLS	1.3.1 Establish a Laboratory Technical Working Group (LTWG) to provide linkages to programmes, partners and other stakeholders to support the National Strategic Plan for Laboratories	GF, FIND, MoH	X	X	X	X	X
1.4 Provide training support for supervisors throughout the tiered laboratory network	1.4.1 Institute training for Laboratory Head, coordinators and supervisors in the lab network for lab oratory management course	GF, FIND, MoH		X		X	
2. Laboratory services **<u>Objective:</u> Provide quality laboratory testing services to all people**			**Timeline**				
Strategies	Sub-Objective	Funding Source	Y1	Y2	Y3	Y4	Y5
2.1 To have quality laboratory services at all levels of the health system that will support effective patient management, disease surveillance, epidemic investigation, research and other specialized services	2.1.1 Institute the Essential Health Package of test services at all laboratory tiers to suit the MoH-approved standards public and private laboratories	MoH, WHO, WAHO, Afro CDC	X				
	2.1.2 Strengthen laboratory services for surveillance and public health emergency investigations and management at all laboratory tiers, including the private sector	MoH, WHO, WAHO, Afro CDC		X	X	X	X

2.2 Strengthen safe and secure specimen collection, packaging and transportation within the laboratory network and at the international level	2.2.1 Institute and implement integrated guidelines for specimen collection, packaging and transportation to ensure safe and effective referral of sample	MoH, GF, FIND	X	X	X	X	X
	2.2.2 Develop an electronic specimen-tracking system for samples in transit	MoH, GF, FIND, WHO			X		
	2.2.3 Initiate and follow up the procurement and distribution of appropriate specimen packaging materials at all tiers of national health laboratory service	MoH, GF, FIND, WHO	X	X	X	X	X
	2.2.4 specimen referral services into the DNHLS MoH budget	MoH, GF		X	X	X	X
	2.2.5 Institute training to build a skills development plan for safe and secure shipment of specimens and facilitating IATA certification of staff in the laboratory network	MoH, WHO, WAHO		X		X	
2.3 Strengthen national laboratory testing capacity to support effective implementation of UHC	2.3.1 Update laboratory test menus and technologies at all levels to increase accessibility to laboratory services to support the implementation of UHC	MoH, WB, GF			X	X	X
	2.3.2 Improve access to laboratory services for vulnerable and most at-risk population	MoH, WB, GF			X	X	X
	2.3.3 Determine the cost of laboratory testing services at all levels for effective implementation of UHC	MoH, WB, GF			X	X	X

	2.3.4 Identify laboratory tests and technologies that have the potential of leading to catastrophic expenditure and impoverishing household incomes for inclusion in the MOH health insurance package	MoH, WB, GF			X	X	X
2.4 Conduct mapping of the outbreak response capacity of the national and regional reference laboratories in public and other sectors under the One-Health approach to guide specimen referral across the laboratory network for disease confirmation	2.4.1 Hire consultants to conduct mapping and development of laboratory based costed strategic plan and guideline for response to outbreak in the context of Onehealth	MoH, WHO, WAHO, Afri CDC		X	X		
2.5 Develop, validate and print guidelines for the implementation of laboratory-based surveillance of AMR, vaccine preventable diseases, foodborne diseases and non-communicable diseases in the mainstream IDSR, One-Health context	2.5.1 Develop and implement a cost plan and guideline for laboratory- based implementation of the Surveillance infectious diseases using the strategy of the IDSR	MoH, WHO, WAHO, Afri CDC	X	X			
2.6 Develop a plan and budget to support laboratory public health emergency responses, which is mainstreamed with the national health emergency response plan for early warning system	2.6.1 Hire a consultant to develop costed laboratory public health emergency responses plan	MoH, WHO, WAHO, Afri CDC	X				

Develop and implement human resource competencies for specialized and clinical laboratories at the national and regional levels for the detection of agents of public health importance under the Onehealth approach	2.7.1 Develop training plan to strengthen the capacity of laboratory staff with specialized diagnostic technique for the detect and response to pathogens and other aetiological agents of public health importance	MoH, WHO, WAHO, Afri CDC		X			
3. Infrastructure, Biosafety and Biosecurity **Objective: Provide appropriate laboratory infrastructure to ensure the safety of personnel, community and the environment, and provide for security of materials and information.**			**Timeline**				
Strategies	Sub-Objectives	Funding Source	Y1	Y2	Y3	Y4	Y5
3.1 Strengthen national laboratory biosafety and biosecurity system	3.1.1 Establish a national laboratory biosafety and biosecurity program	MoH, WB	X	X	X	X	X
3.2 Ensure that construction and renovation of health laboratory facilities conform to national infrastructure guidelines and standard	3.2.1 Develop, validate and disseminate laboratory infrastructure guidelines and standards	MoH, Gambia Standard Bureau, GAMWORKS		X	X		
	3.2.2 Assess the status of laboratory infrastructure to identify gaps and non-conformities	MoH, WB	X	X	X	X	X
	3.2.3 Construct/ renovate/ refurbish and maintain laboratories in conformity with national guidelines and standard	MoH		X	X	X	X
	3.2.4 Advocate for adequate budget for infrastructure improvement	MoH		X	X	X	X
3.3 Establish maintenance programme for biosafety and biosecurity equipment	3.3.1 Develop and implement guidelines for maintenance and servicing of biosafety and biosecurity equipment at all levels to enhance the safety of personnel and infectious material	MoH, WB	X	X	X	X	X

	3.3.2 Plan and implement certification of biosafety and biosecurity equipment for optimum performance	MoH, WB	X	X	X	X	X
	3.3.3 Develop and update a national list of biosafety and biosecurity equipment and kits necessary at each laboratory tier	MoH, WB		X			
3.4 Establish an effective occupational health and safety programme for laboratory personnel in liaison with the occupational health unit of the MoH	3.4.1 Develop and disseminate guidelines for monitoring the health of laboratory personnel to improve the management of personal safety in liaison with the occupational health unit	MoH, WB	X	X			
	3.4.2 Develop and implement a plan for effective monitoring of health laboratory personnel for appropriate intervention and deployment	MoH, WB	X	X			
3.5 Strengthen the coordination of biosafety and biosecurity activities through effective management at all levels	3.5.1 Create a biosafety and biosecurity unit at the national level to coordinate the national biosafety and biosecurity programme	MoH	X	X	X	X	X
	3.5.2 Develop a biosafety and biosecurity unit within the regional office with staff to coordinate biosafety and biosecurity in each region	MoH	X	X	X	X	X
3.6 Strengthen human resource capacity for Biosafety and biosecurity Program through trainings for improved practice	3.6.1 Develop and regularly update a database for national biosafety and biosecurity training to determine the skill levels of personnel	DNHLS	X	X	X	X	X

	3.6.2 Develop and validate a biosafety and biosecurity training plan for laboratory workers, managers and non-technical laboratory personnel in both public and private laboratories	MoH, GF	X	X	X	X	X
	3.6.3 Conduct training of trainers (Tot) for biosafety and biosecurity training to increase the capacity of trainers	MoH, GF	X	X	X	X	X
	3.6.4 Finalize biosafety and biosecurity training curriculum	MoH/GF	X	X	X	X	X
	3.6.5 Train officers using the biosafety and biosecurity curriculum	MoH, GF	X	X	X	X	X
4. Equipment and Supplies **Objective: Ensure availability of supplies and functional equipment that are appropriate at all levels to support uninterrupted routine and emergency laboratory services.**			**Timeline**				
Strategies	Sub-Objectives	Funding Source	Y1	Y2	Y3	Y4	Y5
4.1 Strengthen the coordination of the laboratory supply chain management system across the network in liaison with National Pharmaceutical Services (NPS)	4.1.1 Establish focal point for the management and coordination of laboratory supply chain logistic			X	X	X	X
	4.1.2 Conduct quarterly logistics coordination meetings at central and regional levels to review the performance of logistics activities	MoH, GF		X	X	X	X
	4.1.3 Define roles and responsibilities of stakeholders in supply chain management to avoid duplication.	MoH/GF		X			
4.2 Establish pre- and post- market surveillance systems for laboratory commodities	4.2.1 Develop and implement guidelines for pre-and post-market surveillance to ensure product quality using the existing structure of the NPS	MoH, GF		X	X	X	X

	4.2.2 Strengthen the quality assurance laboratory to effectively coordinate quality control, batch testing/lot to lot testing of new laboratory commodities at DNHLS and NPS, in collaboration with MCA, NPS and MRC	MoH, GF		X			
	4.2.3 Perform pre- and post-market surveillance of laboratory commodities in the system	MoH, GF		X	X	X	X
4.3 Strengthen supply chain management to quantify, procure, distribute and storage of laboratory supplies	4.3.1 Review and update laboratory supply lists and catalogues	MoH	X		X		X
	4.3.2 Conduct annual national laboratory supply quantification, with quarterly reviews, to assess and address the ongoing needs at all tiers of laboratory service and mainstreaming into the existing MoH supply quantification structures	MoH	X	X	X	X	X
	4.3.3 Prepare and implement guidelines for procurement and distribution of laboratory commodities for facilities to avert stock-outs, using the MoH procurement and distribution structure	MoH		X			
4.4 Strengthen the ordering, storage and inventory management system at all levels	4.4.1 Revise, update and harmonize laboratory supplies request forms across the national stores	MoH		X	X	X	X
	4.4.2 Provide adequate storage capacity for laboratory commodities, in accordance with infrastructure standards at all levels	MoH		X	X	X	X

	4.4.3 Procure cold storage facilities for laboratory commodities at national, district and health facility levels for maintenance of reagent potency, in collaboration with national warehouses	MoH		X	X	X	X
	4.4.4 Develop and disseminate guidelines for proper storage of laboratory commodities and ensure easy access and retrieval of supplies	MoH		X	X	X	X
	4.4.5 Develop and implement an inventory management system for laboratory commodities across the network, to avoid stock-outs and expiry of vital commodities	MoH		X	X	X	X
4.5 Strengthen data management systems	4.5.1 Revise, update and harmonize logistics data management tools for system	MoH		X			
4.6 Strengthen capacity in laboratory logistics management, including Basic Laboratory Information System	4.6.1 Develop laboratory Basic Laboratory Information System (BLIS) training curriculum	GF	X				
	4.6.2 Conduct Tot for laboratory BLIS	GF	X	X			
	4.6.3 Conduct facility training for laboratory BLIS	MoH, GF	X	X			
4.7 Develop and implement guidelines for equipment procurement and placement across the laboratory network	4.7.1 Conduct equipment harmonization reviews every three years	MoH, GF	X		X		X
	4.7.2 Develop equipment specifications and standards for all laboratory equipment across the laboratory network	MoH, GF		X			

	4.7.3 Establish and harmonize guidelines for the regulation and maintenance of equipment, in collaboration with the Biomedical Unit	MoH, GF		X		X	
4.8 Strengthen equipment maintenance and management at all levels	4.8.1 Increase places for laboratory equipment biomedical engineers and technicians at national and regional workshops	MoH, GF			X	X	X
	4.8.2 Establish positions for laboratory equipment biomedical supervisors at the national level to oversee laboratory equipment maintenance	MoH, GF		X	X	X	X
	4.8.3 Procure spare parts for preventive maintenance and repair of laboratory equipment	MoH, GF		X	X	X	X
	4.8.4 Support biomedical engineers to conduct preventive and curative maintenance of medical laboratory equipment	MoH, GF		X	X	X	X
	4.8. Develop guidelines for laboratory equipment verification and calibration	MoH, GF	X	X	X	X	X
	4.8.6 Establish a calibration centre for laboratory equipment at the national level	MoH/GF		X	X	X	X
4.9 Establish a system for monitoring equipment functionality and managing the disposal of laboratory equipment and supplies	4.9.1 Develop and implement guidelines for reporting equipment breakdown at all levels	MoH, GF	X	X	X	X	X
	4.9.2 Develop and implement national guidelines for laboratory equipment and laboratory supplies disposal in line with PPDA guidelines	MoH, GF		X	X	X	X

	4.9.3 Conduct training of laboratory staff at national and regional laboratories in procedures for the proper disposal of obsolete laboratory equipment and expired reagents	MoH, GF		X		X	
5. Human Resources **<u>Objective:</u> Ensure that the laboratory sub-sector has an adequate workforce with the necessary competencies, remuneration and motivation to deliver quality laboratory services at all designated levels**			**Timeline**				
Strategies	Sub-Objectives	Funding Source	Y1	Y2	Y3	Y4	Y5
5.1 Review and update current scheme of service for the laboratory work force	5.1.1 Fast-track the review of the scheme of service for laboratory professionals	MoH		X			
	5.1.2 Review and conduct stakeholder consultation on the reviewed scheme of service	MoH		X			
	5.1.3 Engage with the Ministry of Public Service and the Ministry of Finance to approve and operationalize the revised scheme of service	MoH		X	X		
5.2 Recruit sufficient laboratory staff to fill vacant and new positions at all levels, in line with the revised scheme of service for laboratory professionals	5.2.1 Engage the sector to adopt the revised laboratory scheme of service	MoH,,PSC, PMO			X	X	X

5.3 Retain sufficient laboratory staff at all levels, in line with the revised scheme of service	5.3.1 Fill vacant laboratory posts at the various tiers of the laboratory network	MoH, PSC, PMO			X	X	X
	5.3.2 Establish a well-defined career progression path within the laboratory scheme of service	MoH			X	X	X
5.4 Equip the laboratory workforce with the skills and competencies essential for quality service delivery	5.4.1 Develop and operationalize an incentive system to foster laboratory staff retention	MoH		X	X	X	X
	5.4.2 Ensure cadres from certified educational institutions are licensed and registered to practice	MoH, WB, GF		X	X	X	X
	5.4.3 Advocate the development and review of preservice training curricula with training schools/institutions, to meet the needs of the laboratory services	MoH	X				
	5.4.4 Adopt and implement the national in-service training plan	MoH		X	X	X	X
	5.4.5 Develop guidelines and criteria for accrediting professional bodies to conduct continuing professional development (CPD) for laboratory professionals	MoH			X		
	5.4.6 Develop guidelines and criteria for certification of non-laboratory personnel involved in testing	MoH			X	X	X
6. Quality Management System			**Timeline**				

Objective: Strengthen the national laboratory quality management system to ensure quality service delivery that leads to national/ international laboratory certification and accreditation							
Strategies	Sub-Objectives	Funding Source	Y1	Y2	Y3	Y4	Y5
6.1 Develop and establish national laboratory standards for laboratory quality	6.1.1 Develop comprehensive national minimum standards of laboratory packages for laboratory compliance and certification	MoH, Gambia Standard Bureau	X	X	X	X	
	6.1.2 Develop guidelines and procedures for effective implementation of quality management systems at all laboratory tiers/levels	MoH	X	X			
	6.1.3 Formulate standardized laboratory indicators for monitoring performance	MoH	X	X	X	X	
6.2 strengthen the coordination of activities for the implementation of the laboratory quality management system (QMS)	6.2.1 Establish the laboratory quality assurance (LQA) units at a central level and focal persons at regional levels for effective coordination	MoH, PMO, PSC	X	X			
	6.2.2 Strengthen the capacity of the laboratory workforce at a facility level to implement the laboratory QMS	MoH	X	X	X	X	
6.3 Strengthen National External Quality Assessment Schemes (NEQAS)	6.3.1 Develop national NEQAS guidelines	MoH		X			
	6.3.2 Strengthen NEQAS capacity	MoH		X	X	X	
	6.3.3 Increase the number of laboratories participating in NEQA Schemes	MoH			X	X	X
6.4 Strengthen the national capacity for implementation of quality management	6.4.1 Establish a national laboratory certification/accreditation unit	MoH			X	X	X

systems towards laboratory certification and/or accreditation	6.4.2 Train and certify Strengthening Laboratory Management Toward Accreditation (SLMTA) trainers to facilitate effective implementation of the LQMS	MoH		X			
	6.4.3 Train and certify SLIPTA auditors to help in assessment and mentorship of laboratories for accreditation readiness	MoH		X	X	X	X
	6.4.4 Develop mentorship capacity for LQMS at all levels.			X	X	X	X
	6.4.5 Develop and implement a database for the LQMS with respect to the LIMS framework	MoH		X	X	X	X
	6.4.6 Implement LQMS at lower health facilities not enrolled in SLMTA	MoH		X	X	X	X
6.5 Provide training support for supervisors throughout the tiered laboratory network	6.5.1 Establish and implement supportive supervision checklists for use by supervisors throughout the tiered laboratory network	MOH, GF, WB		X			
7. Laboratory Information Management System			**Timeline**				
<u>Objective</u>: Implement an integrated LIMS in the laboratory network for the management and utilization of patient data and other laboratory services data to facilitate evidence-based decision-making and operational research							
Strategies	Sub-Objectives	Funding Source	Y1	Y2	Y3	Y4	Y5

7.1 Develop and implement an electronic, integrated LIMS in all laboratories in the network to improve laboratory data and information management	7.1.1 Scale-up the implementation of an electronic LIMS in a phased approach in all 50 laboratories to improve data quality for the effective monitoring of laboratory services	MoH			X	X	X
	7.1.2 Develop and conduct training on guidelines for laboratory data management	MoH	X	X	X	X	X
	7.1.3 Conduct annual reviews of laboratory data management guidelines to improve the system's performance	MoH		X	X	X	X
	7.1.4 Establish network infrastructure at all laboratories to support the electronic LIMS	MoH	X	X	X	X	X
	7.1.5 Establish the LIMS central administration unit to effectively manage LIMS initiatives	MoH	X	X	X	X	X
	7.1.6 Build LIMS human resources capacity in the laboratories to manage LIMS activities	MoH	X	X	X	X	X
	7.1.7 Establish and implement a national laboratory data warehouse to archive electronic laboratory data	MoH		X	X	X	X
7.2 Strengthen standardized, paper-based LIMS at sites without electronic LIMS to facilitate data capture and reporting	7.2.1 Update and harmonize paper-based LIMS to accommodate all laboratory data needs	MoH	X	X	X	X	X
	7.2.2 Conduct training in the utilization of updated and standardized paper-based LIMS to improve data capture and reporting	MoH	X	X	X	X	X

7.3 Develop and implement an electronic, mobile and web-based platform for effective specimen tracking across the national sample transport network	7.3.1 Conduct a needs assessment to determine system and hardware needs for the specimen tracking system	MoH	X				
	7.3.2 Implement a mobile and web-based platform for specimen tracking to improve sample referrals	MoH,		X	X	X	X
7.4 Establish a system for the standardized collection, analysis and reporting of patient data to improve data use	7.4.1 Develop and implement a comprehensive mechanism for the collection, analysis and reporting of all data, including data on drug resistance, laboratory-based disease surveillance, notifiable diseases and outbreak investigation, to improve data use	MoH		X	X	X	X
	7.42 Build capacity among laboratory personnel at all levels on data usage to improve evidence-based planning and decision-making among stakeholders	MoH		X	X	X	X
	7.4.3 Develop a laboratory data communication plan to standardize and streamline data reporting and feedback	MoH	X	X	X	X	X
7.5 Establish a forum for multi-sectoral data sharing among all laboratories and agencies with activities affecting human health, to enhance	7.5.1 Conduct advocacy for data sharing among all sectors, including laboratories undertaking activities that affect human health, to promote One Health	MoH	X	X	X	X	X

collaboration for implementing the One Health model	7.5.2 Develop a harmonized framework of data needs in accordance with multi-sectoral guidelines to achieve One Health	MoH		X	X		
	7.5.3 Implement and maintain a forum for multi-sectoral data sharing to achieve One Health	MoH		X	X	X	X
7.6 Establish an integrated database for managing non- clinical laboratory data to improve the coordination of laboratory services	7.6.1 Develop standards and implement an integrated database to manage non-clinical laboratory data	MoH			X	X	X
	7.6.2 Implement a web-based system to improve logistics and equipment management	MoH		X	X	X	X
8. Research and Development **<u>Objective</u>: Undertake research of public health importance according to the research priorities of the National Health Sector**			**Timeline**				
Strategies	Sub-Objectives	Funding Source	Y1	Y2	Y3	Y4	Y5
8.1 Develop a research agenda for the laboratory sub-sector	8.1.1 Establish a research and development focal point to undertake the role of research operationalization in the laboratory sector in conjunction with the director of health research at the MoH	MoH		X			
	8.1.2 Establish a national laboratory research plan to outline priority areas and identify collaborating Directorates of Research and other collaborators	MoH		X	X		
	8.1.3 Develop an operational framework for research into laboratory services to guide research efforts	MoH		X			
	8.1.4 Implement the operational framework for research into laboratory services to generate information for better patient care and policy formulation	MoH			X	X	X

8.2 Build capacity of laboratory personnel involved in operational research	8.2.1 Develop and implement training program for operational research	MoH			X	X	X
	8.2.2 Ensure that facilities have appropriate personnel, equipment and access to professional databases and publications to enable health research	MoH			X	X	X
8.3 Develop and implement a national laboratory research database to track and disseminate research findings	8.3.1 Establish collaborations and partnerships between academic and private sector partners, research institutions and service delivery institutions to encourage multi- disciplinary and multi-sectoral research	MoH			X	X	X
	8.3.2 Implement the national laboratory research database to track and disseminate research findings on laboratory services	MoH			X	X	X
	8.3.3 Promote the utilization of research findings to inform decision-making at all levels, policy revisions, and improvements to practice	MoH				X	X
9. Point-of-Care Testing (POCT) Services			**Timeline**				
<u>Objective</u>: to Increase access to testing services by complementing conventional laboratory testing services with approved and appropriate point-of-care technologies							
Strategies	Sub-Objectives	Funding Source	Y1	Y2	Y3	Y4	Y5
9.1 Strengthen coordination mechanism for POCT to improve provision of POCT services	9.1.1 Develop and implement a POCT master plan to improve coordination of POCT activities	MoH		X	X	X	X
9.2 Develop capacity for POCT as a means of increasing access to laboratory services	9.2.1 Build physical and human resource capacity for POCT and implement it within the laboratory services	MoH		X	X	X	X

	9.2.2 Develop and implement policy and guidelines for all aspects of POCT, to standardize POCT services	MoH	X				
	9.2.3 Develop and implement integrated information management mechanism for POCT to improve data capture, analysis and reporting	MoH		X	X	X	X
	9.2.4 Develop and implement monitoring and evaluation guidelines for POCT	MoH		X			
	9.2.5 Conduct operational research into POCT to guide policy formulation and service delivery	MoH		X	X	X	X
9.3 Develop and implement POCT communication strategy to improve access to POCT services at national, regional and community levels	9.3.1 Develop and disseminate POCT communication strategy to improve access to POCT services	MoH	X				
9.4 Develop QA mechanism for POCT to improve quality of POCT services	9.4.1 Develop guidelines for QA-POCT to streamline the implementation of POCT services	MoH		X	X	X	X
	9.4.2 Establish facilities at national and reference laboratories to produce POCT PT panels	MoH		X	X	X	X
	9.4.3 Implement QA-POCT activities across all levels to assess performance and improve the quality of POCT services	MoH		X	X	X	X
	9.4.4 Develop and implement a plan for POCT site supervision	MoH	X	X	X	X	X
10. Networking and Collaboration .			**Timeline**				

Objective: to Strengthen multi-sectoral, national, international, public and private partnerships to promote equitable access to quality laboratory services							
Strategies	Sub-Objectives	Funding Source	Y1	Y2	Y3	Y4	Y5
10.1 Establish a system for sharing information, testing capacity and resources among sectors towards the One-Health strategy (e.g. for AMR, zoonotic and notifiable diseases, outbreaks, and food safety)	10.1.1 Establish a multi-sectoral Laboratory Technical Working Group (LTWG) to oversee implementation of the One-Health strategy	MoH		X			
	10.1.2 Determine testing capacities and ensure there are sufficient resources to facilitate intersectoral referral services	MoH		X			
	10.1.3 Develop and implement mechanisms for information sharing to facilitate collaboration and the One-Health strategy (e.g. for AMR, zoonotic and notifiable diseases, outbreaks, and food safety)	MoH		X			
10.2 Establish mechanisms to outsource specialized laboratory services to increase efficiency and effectiveness in service delivery	10.2.1 Review the National Laboratory Test Menu to define which tests should be outsourced	MoH		X			
	10.2.2 Develop memoranda of understanding (MOUs) to commit to national and international specialized laboratories to perform the identified tests to be outsourced.	MoH		X	X	X	X
10.3 Promote public–private partnerships for the provision of health laboratory services in	10.3.1 Develop criteria for identifying underserved areas to be supported by providers outside the public system	MoH			X		

accordance with PPPH policy	10.3.2 Identify alternative funding mechanisms and devise incentives for partners to support under-served areas and discipline	MoH			X	X	
10.4 Support establishment of laboratory services for underserved areas by providers outside the public system	10.4.1 Identify priority underserved HSDs where providers outside the public system can provide laboratory services	Partners			X		
	10.4.2 Link underserved HSDs to service providers outside the public system	Partners			X	X	X
11. Regulatory and Legal Framework **Objective: Ensure that the national laboratory legal and regulatory framework is enforced within the entire health laboratory network, in collaboration with relevant regulatory bodies**			**Timeline**				
Strategies	Sub-Objectives	Funding Source	Y1	Y2	Y3	Y4	Y5
11.1 Establish and maintain a robust legal framework for the regulation of medical laboratories and laboratory personnel	11.1.1 Develop and disseminate laboratory registration and licensing standards	MoH		X			
	11.1.2 Develop specific regulations for the enforcement of the laws	MoH		X			
11.2 Ensure that all health laboratories meet the required standards for registration and licensing	11.2.1 Support regulatory bodies to assess all laboratories for compliance with standards	MoH			X	X	X
	11.2.2 Support the regulatory bodies to review and update the current provisions for deterrent action and address any gaps identified	MoH			X	X	X
11.3 Ensure that all practising laboratory professionals are registered and licensed	11.3.1 Establish The Gambia Medical Laboratory Science Council, which will be responsible regulating, training and practicing of Medical Laboratory Professionals in The Gambia	MoH		X	X	X	X

	11.3.2 Develop guidelines on CPD/CME requirements for licensing laboratory professionals	MoH			X	X	X
	11.3.3 Conduct regional sensitization meetings on the new CPD/CME regulatory guidelines and the importance of registration and licensing for training institutions	MoH			X	X	X
	11.3.4 Develop guidelines on the process of administering the laboratory personnel oath at graduation	MoH,partners, regulatory bodies				X	X
12. Monitoring and Evaluation .			**Timeline**				
Objective: Create and implement mechanisms to effectively measure performance of the health laboratory sub-sector to facilitate management, planning, learning and policy formulation in the country							
Strategies	Sub-Objectives	Funding Source	Y1	Y2	Y3	Y4	Y5
12.1 Establish an effective program to monitor and evaluate the implementation of the National Health Laboratory Strategic Plan	12.1.1 Develop and implement an M&E plan to guide the implementation of the National Health Laboratory Strategic Plan and Annual Operational Plan.	MoH	X	X	X	X	X
12.2 Establish M&E system for laboratory logistics activities	12.2.1 Establish a system for M&E of laboratory commodities to inform forecasting and ascertain their quality	MOH, GF	X	X	X	X	X
	12.2.2 Conduct M&E training for all laboratories	MOH, GF	X	X	X	X	X
12.3 Ensure regular assessment of the overall performance of laboratory services	12.3.1 Conduct M&E on services to assess laboratory system performance in line with the National Health Sector Strategic Plan 2021-2025	MoH	X	X	X	X	X
13. Finance and Accountability			**Timeline**				

Objective: Establish resource mobilization and accountability mechanisms at national and sub-national levels to ensure availability and accessibility of adequate resources for the provision of sustainable laboratory services							
Strategies	Sub-Objectives	Funding Source	Y1	Y2	Y3	Y4	Y5
13.1 Ensure a dedicated budget for laboratory services in the MOH	13.1.1 Ensure the laboratory services have a dedicated vote in the MOH budget to facilitate timely and consistent implementation of laboratory plan	MoH	X	X	X	X	X
13.2 Coordinate partner funding activities for laboratory services	13.2.1 Establish a finance and accounting unit at the DNHLS to mobilize, coordinate and monitor government and partner funding opportunities	MoH		X	X	X	X
	13.2.2 Establish a finance forum among funding partners and the DNHLS to monitor the funding of laboratory activities	MoH		X	X	X	X
	13.2.3 Build capacity of laboratory managers at all levels, in budgeting, finance and accountability, to improve their management skills for proper planning	MoH		X	X	X	X
13.3 Mobilize funds to meet laboratory budget needs	13.3.1 Develop and implement a plan of resource mobilization for delivery of laboratory services at all levels in accordance with the Public-Private Partnership for Health (PPPH)	MoH		X	X	X	X
	13.3.2 Ensure implementation of a cost recovery programme to facilitate uninterrupted provision of laboratory services	MoH		X	X	X	X

13.4 Establish a transparent system to ensure programmatic and financial accountability of laboratory services	13.4.1 Adopt the established Ministry of Finance Guidelines on Financial Management and Accountability to ensure effective management of laboratory resources	MoH		X	X	X	X
	13.4.2 Build capacity of laboratory managers at all levels to plan and monitor budgets in line with the Ministry of Finance and PCU guidelines to ensure effective accountability	MoH		X	X	X	X
14. Ethics and Community							
Objective: Laboratory services shall be an integral part of the health service's responsiveness to community needs and shall adhere to ethical and environmental standards							
Strategies	Sub-Objectives	Funding Source	Y1	Y2	Y3	Y4	Y5
14.1 Promote integrity, dignity and appropriate conduct in laboratory practices and responses to community needs at all times and at all level	14.1.1 Develop and enforce guidelines for laboratory staff to comply with ethical standards	MoH			x		
14.2 Develop strategies to increase community access to equitable quality testing services	14.2.1 Develop a plan for community awareness and feedback to ensure an understanding of testing services among the population	MoH		X	X	X	X

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