

# THE NATIONAL HEALTH LABORATORY SERVICES POLICY

2021 - 2025

BANJUL, THE GAMBIA May

Ter

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



# CONTENTS

FOREWORD iv
ACKNOWLEDGEMENTSvi
LIST OF ABBREVIATIONS
CHAPTER 1: INTRODUCTION
1.1 Role of the health system administration1
1.2 Role of laboratory services in the healthcare delivery system1
1.3. Policy rationale2
1.4 Policy context2
1.4.1 Global policy context
1.4.2 Regional policy context
1.4.3 National policy context
CHAPTER 2: HEALTH SERVICE DELIVERY
2.1 The health sector5
2.1.1 The public health sector
2.1.2 The private health sector
2.2 Health policy and the Strategic Plan 2021–20306
CHAPTER 3: SITUATION ANALYSIS OF LABORATORY SERVICES
3.1 The National Health Laboratory Service structure and networking7
3.2 Organization and management of the National Health Laboratory Service structure and network7
3.3 Laboratory services: the major constraints8
3.3.1 Organization and management
3.3.2 Laboratory services
3.3.3 Infrastructure, biosafety and biosecurity10
3.3.4 Laboratory support systems: equipment and supplies10
3.3.5 Laboratory support systems: human resources11
3.3.6 Laboratory quality management system12
3.3.7 Laboratory information management systems12
3.3.8 Research and development (R&D)12
3.3.9 Point-of-Care Testing (POCT) Services13



3.3.10 Networking and collaboration13
3.3.11 Legal and regulatory framework13
3.3.12 Monitoring and evaluation (M&E)14
3.3.13 Financing and accountability14
3.3.14 Laboratory service ethics and community engagement14
CHAPTER 4: POLICY FRAMEWORK
4.1 Vision
4.2 Mission
4.3 Goal15
4.4 Core values and guiding principles15
4.5 General policy statement16
4.5.1 General policy objective
CHAPTER 5: COMPONENTS OF this policy
5.1 The process
5.2 Thematic areas
5.2.1 Organization and management
5.2.2 Laboratory Services
CHAPTER 6: IMPLEMENTATION OF POLICY
6.1 The National Health Laboratory Services24
6.2 The implementation process
6.3 Conclusion
List of contributors

# FOREWORD

Information provided by medical laboratory services underpins the practice of modern medicine within the incidence and prevalence of the 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, improve management of disease, essential public health information, and assist with surveillance of diseases such as meningitis, measles, rubella, tuberculosis, HIV, malaria, Ebola, COVID-19 and various multidrug-resistant pathogens.

This is the first time a National Health Laboratory Services (NHLS) Policy has been developed to guide the delivery of health laboratory services in The Gambia. The country has lacked a comprehensive framework for the collection of public health laboratory data to inform disease prevention and provide strategies for the Ministry of Health (MoH). In coordination to help maintain quality standards, this policy becomes even more critical in an environment where there is a decrease in participation by the private sector and traditional medicine in healthcare delivery. It is hoped that this policy will help laboratory stakeholders, especially traditional medicine practitioners, strike a balance to fulfil the clientele's satisfaction who visit public and private laboratories and minimize their risk exposure. This policy provides a framework for the government to establish optimum National Health Laboratory Services and monitor the delivery of quality services at all healthcare system levels.

The participation by the private sector during the development of this policy will play a crucial role in promoting public-private partnerships in the laboratory sector and in harnessing private resources and expertise for public health interventions on a level playing field. The introduction of new and revised health legislation will provide a regulatory framework that both public and private laboratories can operate while maintaining the same standards.

The World Health Organization – African Regional Office (WHO AFRO) Regional Committee meeting held in Yaoundé, Cameroon, in September 2008, committed member states to formulate their own National Health Laboratory Policies and increase the representation of National Laboratory Services at the decision-making level of their respective Ministries of Health. An assessment necessitated the development of this policy during Stepwise Laboratory Management Towards Accreditation (SLIPTA) audits, Health Technology Assessments (HTAs) and a WHO Joint External Evaluation (JEE) report. Based on these and other more recent recommendations, emerging new health challenges and the implementation of the International Health Regulations (IHR) (2005), the MoH of The Gambia, in collaboration with the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM), Foundation for Innovative New Diagnostics (FIND), WHO, and other stakeholders, has developed this National Health Laboratory Services Policy.

This policy clearly defines how the laboratory services in The Gambia should be organized and managed and adopts an integrated public health laboratory service approach while also taking on board the private sector. This policy calls for the development of an integrated laboratory information system; the nurturing of high standards of biosafety, biosecurity and adherence to national standards of quality; ensuring the continued professional development of laboratory staff and the sustenance of a competent and motivated workforce.



The policy is structured into 14 thematic areas that address laboratory management systems issues and aims to contribute to delivering accessible and quality services. It will be implemented through a National Health Laboratory Services Strategic Plan together with Annual Operational Plans. There will also be monitoring and mentorship guidelines from the National Laboratory Technical Working Group (NLTWG) and Senior Management Teams (SMT) to advise the Directorate of National Health Laboratory Services to attain set goals. Besides establishing the medical laboratory council responsible for the licensing of laboratory staff and premises and the maintenance of code of conduct.

Therefore, the Ministry of Health calls upon all stakeholders in both the public and private sector to continue the collaboration and increase efforts in promoting the improvement of laboratory services in The Gambia. It is anticipated that the same spirit of collaboration shown during the development of this policy will also prevail during its implementation.

#### Honourable Dr Ahmadou Lamin Samateh

Minister of Health

May, 2021

# ACKNOWLEDGEMENTS

This policy has been formulated to develop and deliver an integrated health laboratory service in The Gambia. The development of the policy has benefited from the input of many experts in laboratory sciences from within The Gambia, under the supervision of an international consultants. This development has borrowed significantly from experiences and structures in other countries within the African region and broadly followed WHO recommendations on key elements needed for a National Health Laboratory Services Policy. In addition, the policy has been aligned to the National Health Policy Framework 2021–2030. We wish to thank all those involved in the development of the policy, especially our partners who have provided technical and financial support: GFATM, FIND, and WHO. We recognised the immense contribution of Dr. Mamading Cham, Dr. Haddy Bah, Dr Abdul Karim Ceesay Mr Haruna S Jallow, Mr Alphonse Mendy, Mr Alieu Faal, Mr Abdoulie M. Sanyang, Musa Ceesay, Mariama Jammeh, and Mariama Drammeh. We appreciated the leadership and mentorship of Dr Juliana Ndasi (FIND consultant) and Lali Zira (WHO consultant). We thank Mr Bakary Sanneh, Mr Sheriffo Jagne and Mr Ignatius Baldeh (former Director of NPHL) for their leadership, stamina and firmness to walking this document to the end. This could not have happen without the contribution of the following stakeholder who are well appreciated: Department of Livestock Services, Ministry of Agriculture, Ministry of Higher Education, Research, Science and Technology, the Ministry of Finance and Economic Affairs, the Personnel Management Office, Medical Research Council at London School of Hygiene Tropical Medicine The Gambia, Afrimed Clinic Laboratory, Jobot Laboratories, Pakala Clinic, West Africa Holistic Medical Centre Laboratories, and BIO-MED Laboratories. Finally, I would like to acknowledge the contributions made by the Directorate of Planning and Information and all staff in the Ministry of Health during the development of the policy.

#### Sheriffo Jagne

Acting. Director, National Public Health Laboratory Services

May 2021



# LIST OF ABBREVIATIONS

AIDS	Acquired immunodeficiency syndrome	
AIUWA		
AIUWA	American International University of West Africa	
AMR	Antimicrobial resistance	
BF	Blood film	
BLIS	Basic Laboratory Information System	
CEO	Chief Executive Officer	
CMD	Chief Medical Director	
COVID-19	Coronavirus disease 2019	
CPD	Continuing professional development	
DHIS2	District Health Information System Version 2	
DHS	Director of Health Services	
DNHLS	Directorate of National Health Laboratory Services	
DPI	Directorate of Planning and Information	
DPS	Directorate of Pharmaceutical Services	
DSW	Directorate of Social Welfare	
ECOWAS	Economic Community of West African States	
EFSTH	Edward Francis Small Teaching Hospital	
EHCP	Essential Health Package	
FIND	Foundation for Innovative New Diagnostics	
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria	
GLP	Good laboratory practice	
HIV	Human immunodeficiency virus	
HMIS	Health management information system	
HTA	Health Technology Assessment	
ICT	Information and communication technology	

IDSR	Integrated disease surveillance and response
IHR	International Health Regulation
ISO	International Standard Organization
JEE	Joint External Evaluation
LIMS	Laboratory information management system
LMIC	Low- and middle-income country
NLTWG	National Laboratory Technical Working Group
LQMS	Laboratory Quality Management System
M&E	Monitoring and evaluation
MoH	Ministry of Health
MRCG	Medical Research Council, the Gambia
NARI	National Agricultural Research Institute
NBTS	National Blood Transfusion Services
NDP	National Development Plan
NEQAS	National External Quality Assessment Scheme
NHLS	National Health Laboratory Services
NHLSP	National Health Laboratory Services Policy
NPHL	National Public Health Laboratories
NPHRL	National Public Health Reference Laboratories
PHL	Public Health Laboratory
PMO	Personnel Management Office
POCT	Point of Care Testing
PPE	Personal protective equipment
PSC	Public Service Commission
QA	Quality assurance
QMS	Quality Management System
R&D	Research and Development
RCH	Reproductive and child health
RDT	Rapid diagnostic test
RHD	Regional Health Directorate
SDG	Sustainable Development Goal
SMT	Senior Management Team
SLIPTA	Stepwise Laboratory Improvement Process towards Accreditation
SOP	Standard Operating Procedure
ТВ	Tuberculosis
ToR	Terms of Reference
UHC	Universal Health Coverage
WBC	White blood cell
WHO	World Health Organization
WHO-AFRO	World Health Organization-African Regional Office



WHO-QMS

# CHAPTER 1: INTRODUCTION

# 1.1 Role of the health system administration

The Ministry of Health (MoH) is responsible for overall policy formulation, planning, organization and coordination for health in The Gambia. The MoH oversees directorates, technical programme units, hospital administrations, health professional councils and other bodies that help the ministry execute its roles and functions. Among the directorates is the Directorate of National Public Health Laboratories (NPHL), tasked to oversee and provide leadership to all laboratory activities and services in the country (both public and private), including blood transfusion services.

# 1.2 Role of laboratory services in the healthcare delivery system

The National Health Policy 2021–2030 advocates the "*provision of quality and affordable Health Services for All*".<sup>1</sup> 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; however, laboratory services in The Gambia receive less attention in terms of budgetary allocation than vaccines and essential medicines.<sup>2</sup> Despite recent investments in diagnostic for global health, the potential for diagnostics to generate value for patients and health systems alike has not been met across all settings, particularly in low- and middle-income countries (LMICs), where disease burdens are high and diagnosis remains a large gap in the cascades of care.

A well-functioning health laboratory service should:

- 1. Provide vital information necessary for proper planning and utilization of health resources;
- 2. Enhance evidence-based diagnoses and patient management and prevent/eliminate making diagnoses based on clinical symptoms alone;
- 3. Contribute immensely towards health research, disease surveillance, disease outbreak detection and management, and pathological and forensic investigations; and
- 4. Monitor the efficacy of antibiotics and detect antimicrobial resistance (AMR).

<sup>&</sup>lt;sup>1</sup>National Health Policy, Republic of the Gambia 2021-2030

<sup>&</sup>lt;sup>2</sup>Health Technology Assessment report,2019

# 1.3. Policy rationale

Since the establishment of the Directorate of National Public Health Laboratories in 2007, it was only designated a Directorate in 2014. There has been no national laboratory policy to guide laboratory service delivery and management in The Gambia<sup>2</sup>. This lack of a national laboratory policy has:

- 1. Adversely affected governance of and resource allocation to laboratory services, which has negatively impacted the coordination and availability of quality laboratory service delivery across the country;
- 2. Hindered efforts to control the opening of laboratories (either stand-alone or as part of conventional or traditional health settings); thus, there is a proliferation of unlicensed laboratories;
- 3. Affected the availability of necessary laboratory tests (essential or otherwise) and failed to make certain tests mandatory at various levels of health facilities/health delivery systems; and
- 4. Posed a formidable challenge nationally to the structural development of laboratories, career development of laboratory professionals, biosafety, waste management, and biosecurity<sup>2</sup>.

This National Health Laboratory Service Policy (NHLSP) has been developed to address the above challenges and to pave a new path for laboratory services delivery and management in The Gambia.

## 1.4 Policy context

This NHLSP is formulated in consistent with the global, regional and national context and is informed by situational analysis and assessment reports.

## 1.4.1 Global policy context

Laboratory service delivery is a key component in health systems development and, most importantly, enhancing effective and efficient healthcare delivery. The global context within which this policy has been conceived is as follows:

1. World leaders, including those of The Gambia, committed themselves to the attainment of *"Sustainable Development Goal (SDG) 3: Good Health and Wellbeing"*. This SDG includes reductions in child and maternal mortality, the fight against tuberculosis (TB), HIV/AIDS, malaria and other communicable diseases, and the surging endemicity of non-communicable diseases such as diabetes and hypertension.<sup>3</sup> To achieve this, SDG will require, among other things, a functional national health system, including laboratory services;

 $<sup>^{3}\</sup> https://www.gm.undp.org/content/gambia/en/home/sustainable-development-goals/goal-3-good-health-and-well-being.html$ 

- 2. In line with our International Health Regulations (IHR) obligations, The Gambia has a responsibility to have an effective and well-functioning laboratory service at all levels to facilitate healthcare delivery;<sup>4</sup>
- 3. Improving national health laboratory services is an important step towards the attainment of Universal Health Coverage (UHC).<sup>5</sup> The government of The Gambia has declared it is committed to the attainment of UHC;
- 4. The fight against AMR is top of the global agenda, and The Gambia is playing its role. General Assembly resolution 70/183, of 17 December 2015, involved the Assembly's decision to hold a high-level meeting in 2016 on AMR.<sup>6</sup> This effort requires a functional network of health laboratories across the country; and
- 5. The Gambia has, over the years, increased efforts to combat neglected tropical diseases (NTDs). The World Health Assembly (WHA) Resolutions on NTDs: 1948–2019 requires functional health laboratories to be in place.<sup>7</sup>

## 1.4.2 Regional policy context

The government of The Gambia subscribes to regional and sub-regional efforts aimed at improving health and development, including laboratory services, in Africa and the Economic Community of West African States (ECOWAS) region in particular. Among the resolutions The Gambia is committed to be:

- 1. The Maputo declaration of January 2008 on the "*Strengthening of laboratory systems in Africa*"<sup>8</sup> recognizes the challenges towards the scale-up of services for malaria, TB and HIV/AIDS. This calls on national governments, donors, and partners to join together in pooling resources and supporting efforts to improve laboratory systems;
- 2. The Gambia is also committed to WHO-AFRO Resolution AFR/RC58/R2: "*Strengthening Public Health Laboratories in the WHO African region*", which was arrived at in Yaoundé, Cameroon, in September 2008;<sup>9</sup>
- 3. The 5th Meeting of the Regional HIV/AIDS Public Health Laboratory Network, held in Dakar, Senegal, in September 2008.<sup>10</sup>

<sup>&</sup>lt;sup>4</sup>WHA58.3, Revision of the International Health Regulations, The Fifty-eighth World Health Assembly

<sup>&</sup>lt;sup>5</sup> https://undocs.org/A/RES/67/81

<sup>&</sup>lt;sup>6</sup> https://www.un.org/pga/71/event-latest/high-level-meeting-on-antimicrobial-resistance/

<sup>&</sup>lt;sup>7</sup> https://www.who.int/neglected\_diseases/mediacentre/resolutions/en/

<sup>&</sup>lt;sup>8</sup> https://www.who.int/diagnostics\_laboratory/procurement/Maputo-Declaration\_2008\_2.pdf?ua=1

<sup>&</sup>lt;sup>9</sup>WHO AFRO Resolution AFR/RC58/R2: "Strengthening Public Health Laboratories in the WHO African region", Yaoundé, Cameroon in September 2008;

<sup>&</sup>lt;sup>10</sup> 5th Meeting of the Regional HIV/AIDS Public Health Laboratory Network, held in Dakar, Senegal, in September 2008

4. WHO-AFRO Resolution AFR/RC59/WP/3: "Policy orientations on the establishment of Centers of *Excellence for Disease Surveillance, Public Health Laboratories, Food and Medicines Regulation*", arrived in Kigali, Rwanda, in September 2009.<sup>11</sup>

In demonstrating her commitment to the implementation of these resolutions, The Gambia's National Health Policy 2021–2030 proposed the establishment of a strong laboratory service to provide technical support to disease prevention and control initiatives in The Gambia.<sup>1</sup>

## 1.4.3 National policy context

The national context within which this policy has been conceived is as follows:

- 1. Access to healthcare services in The Gambia has been clearly articulated in the National Development Plan (NDP) (2018–2021).<sup>12</sup> During the lifespan of the NDP, the government will priorities boosting investment in our people to build the requisite human capital for improved living standards and power the economy. The NDP goal for human capital development is "quality health, education, and basic social services accessible and affordable to all and improved social and child protection systems in place for the most vulnerable".
- 2. As articulated in the "National Health Policy," the government of The Gambia aims for the "*provision of quality and affordable Health Services for All*". Achieving this goal will require correspondingly functional laboratory services instituted through a well-thought-out laboratory policy.
- 3. The 2019 MoH and partners' *"Health Technology Assessment Report"* strongly recommended strengthening health laboratory services nationally.<sup>13</sup>
- 4. In 2017, the MoH and WHO conducted the country's first-ever Joint External Evaluation (JEE).<sup>14</sup> The report from that exercise highlighted key gaps in the country's national laboratory systems and strongly recommended strengthening the health laboratory services nationwide.
- 5. The Essential Health Package (EHCP) for The Gambia, published in 2020, identified laboratory services as a key component of healthcare delivery across all levels of care.<sup>15</sup>
- 6. The government of The Gambia has expressed strong political will and commitment to the attainment of UHC and has also called for general health service delivery, including health laboratory services, nationally.

<sup>15</sup> The Essential Health Care Package (EHCP),2020



<sup>&</sup>lt;sup>11</sup>WHO AFRO Resolution AFR/RC59/WP/3

<sup>&</sup>lt;sup>12</sup> National Development Plan (2018 - 2021)

<sup>&</sup>lt;sup>13</sup> The Gambian National AIDS Secretariat, 2019: Health Technology Assessment

<sup>&</sup>lt;sup>14</sup> World Health Organization, Joint External Evaluation, Report, 2017, The Gambia

# CHAPTER 2: HEALTH SERVICE DELIVERY

The health system of The Gambia comprises the public health sector complemented by the private health sector, which includes traditional medicine practitioners and faith-based healers.

## 2.1 The health sector

## 2.1.1 The public health sector

The public health sector comprises three levels:

- 1. Primary level (village health services, community clinics and minor health centres).
- 2. Secondary level (major health centres and district hospitals).
- 3. Tertiary level (general, teaching and specialized hospitals and national Public Health Reference Laboratories).

The laboratory services available at these levels are different.

#### **Primary level**

This level is the first point of contact for health-seeking and consists of village clinics, Reproductive and Child Health (RCH) trekking stations and minor health centres. This is the lowest level of healthcare, where essential laboratory services are offered, such as 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 diagnosis. All of these tests are performed at minor health centres, except for 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. In addition to the services provided at the primary level, secondary level facilities provide haematology, blood transfusion, basic microbiology and basic clinical chemistry services.

#### **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 training centres for healthcare professionals, including laboratory personnel. The National Public Health

Reference Laboratories conduct quality control and assurance for HIV, syphilis, TB and malaria testing, and surveillance on foodborne disease, food chemistry testing, antimicrobial resistance and in-service training.

### 2.1.2 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.

## 2.2 Health policy and the Strategic Plan 2021–2030

The current National Health Policy was developed to provide strategic direction to the health sector. The plan is guided by Gambia National Health Policy, which aims to attain the highest level of health for the Gambian population by the year 2030. The plan defines the programmes to be implemented more clearly and the results to be achieved by the year 2030. Its focus is to scale up health service delivery and human capital development to contribute to poverty reduction. Both the health policy and health strategic plan documents address issues regarding laboratory services in The Gambia. Policy strategies include but are not limited to the following:

- Strengthen the capacity of the laboratory programme for improved service delivery.
- Expand laboratory services to meet the service demands of the population in the context of decentralization.
- Expand and strengthen the laboratory surveillance programme.
- Strengthen quality control and quality assurance for laboratory services.
- Promote research in laboratory services.



# CHAPTER 3: SITUATION ANALYSIS OF LABORATORY SERVICES

There is general public awareness about the role of laboratory services; this is evident by the large number of people who seek medical laboratory services daily at health facilities across the country. However, there is a need to develop both the profession and facilities to support the delivery of quality healthcare to citizens more effectively. None of the public laboratories has yet been accredited as International Organization for Standardization (ISO) 15189 and none has yet been awarded any stars by the WHO Stepwise Laboratory Improvement Process towards Accreditation (WHO SLIPTA) approach. There is only one ISO 15189 accredited laboratory in The Gambia, a private laboratory at the Medical Research Council at the London School of Hygiene and Tropical Medicine in The Gambia.

## 3.1 The National Health Laboratory Service structure and networking

Most health facilities across the nation have laboratories that offer services ranging from the most basic at the 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 Service Policy and the Gambia Medical Laboratory Council Act will enhance the establishment of a Gambia Medical Laboratory Council. The council shall implement the regulation and licensing of laboratory personnel and premises in public and private laboratories for assured quality and reliable service delivery in the country.

Some laboratories exist in silos, as the network in practice exists without official mandate/policy, terms of reference, guidelines or a laboratory council, hence the urgent need to better position the laboratory services. This policy intends to encompass this array of laboratories and facilitate the decentralization of laboratory services.

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

A Director oversees the National Public Health Laboratories, which houses the National Blood Transfusion Service (NBTS); HIV, TB, malaria and bacteriology reference laboratories; and the remaining laboratories of the National Health Laboratory Services. The Directorate coordinates the employment, training and deployment of laboratory staff, mainly to health facilities at minor and major health centres and district hospitals. The teaching and general hospitals are semi-autonomous and thus employ their laboratory staff. The Director of NHLS, in consultation with the Directorate of Pharmaceutical Services, procures laboratory equipment, reagents and consumables for all laboratories under the MoH and private laboratories supported by the Global Fund. This policy will address the mandate and terms of references of the Directorate of National Health Laboratory Services (NHLS) to extend beyond the NPHL and explains how autonomous and semi-autonomous laboratories will interface with the network. The policy also gives autonomy to the Directorate of

NHLS to procure laboratory equipment, reagents and consumables, in consultation with senior management of the MoH. Besides delineating clear terms of references for each laboratory, the different laboratory levels will be linked to laboratory test menus, a sample referral system, and ultimately a laboratory quality management system to avoid duplication of work.

# 3.3 Laboratory services: the major constraints

The major constraints against the effective contribution to healthcare delivery by the laboratory sector include:

- No mandate, term of references or guidelines that clearly explain the components of the laboratory network.
- No flow chart of the laboratory network that can describe sample collection sites, average sample testing volumes, and the relationships between labs that dictates flow of sample referrals throughout the system.
- No guidelines or systems for sample transportation.
- Weak laboratory governance and coordination.
- A low number of qualified laboratory personnel across all levels of the healthcare sector.
- The absence of an efficient capacity building and continuous professional development system through a clearly defined professional development strategic plan.
- The lack of national standards for the establishment of medical laboratories and the absence of a comprehensive laboratory quality management system.
- Inadequate essential components are necessary for the effective functioning of medical laboratories and efficient service delivery. These components include basic physical infrastructure, laboratory equipment and supplies, and the unreliable supply of essential 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.
- A poor monitoring system for laboratory supplies.
- No regulation, policy and guidelines for introduction and monitoring the use of point of care devices



- There is a low level of preparedness for specimen collection and transport during outbreaks, nor an explanation of routine sample flows to support surveillance activities.
- No National Blood Transfusion Centre.
- No molecular-based screening for blood-borne infections.
- Limited standard operating procedures (SOPs) in place at all levels of the laboratory service.
- Limited policy or guidelines for reporting and archiving laboratory results.
- Limited 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.
- A lack of specialized laboratories, such as toxicology laboratories, forensic science laboratories, and biobanks for the storage of tissues/isolates.

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

## 3.3.1 Organization and management

The National Public Health Laboratories (NPHL) provides laboratory support by acting as a national reference laboratory. It also carries out coordination and supervisory functions for all clinical laboratories providing diagnostic services within all public and private health facilities, including stand-alone laboratories. Thus, there is a need to provide a comprehensive organogram, including standardized TORs, for all jobs under the remit of the NPHL and other clinical laboratories 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 of the seven Regional Health Directorates (RHD) to facilitate the coordination of activities, oversee the operations of all satellite laboratories, and report to the central level. The Directorate of National Health Laboratory Services shall be housed at the National Public Health Reference Laboratories (NPHRL). Currently, this system is not functional due to the lack of a policy for the effective distribution of staff across the country and motivation for retention in service.<sup>2</sup> 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.<sup>2, 18</sup>

### 3.3.2 Laboratory services

The Directorate of NPHLS has not ensured access to a minimum package of laboratory services appropriate to each level of care in public and private sectors for equity and access to a functional specimen referral system necessary to allow services at all levels. Where samples are referred to other laboratories, efforts are not made to ensure quick turnaround times to 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<sup>14</sup>, 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, 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 are inadequate investments in laboratory infrastructure, unreliable sources of utilities such as water and electricity, uncontrolled ambient temperatures, and no effective mechanisms for fire safety or infection control systems structures. There are also no standard regulations for laboratory infrastructure.

The risk of laboratory-acquired infections is ever-present among personnel who handle pathogenic organisms. This risk is compounded by low awareness of the risks, 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 on many laboratory premises due to unauthorized access by non-laboratory staff. This can lead to exposure to highly pathogenic organisms (e.g. SARS-CoV-2, the virus that causes COVID-19). Therefore, all laboratories must take precautions to protect their 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 for each laboratory who will advise employers on the measures needed to be taken in the interest of health and safety in the workplace. The safety officer will also inspect workplaces to determine if there are any hazards liable to cause bodily injury and will investigate any accidents, near misses, dangerous occurrences, occupational poisonings or disease. Moreover, the safety officer shall ensure that all staff receives adequate training on health and safety at work, strictly adhere to rules, and practice safe management and disposal of waste.

## 3.3.4 Laboratory support systems: equipment and supplies



The MoH procures laboratory consumables and equipment 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; generally, however, there are weak and poorly coordinated inventory and procurement systems to ensure uninterrupted supplies and service delivery. Many facilities experience regular stock outs of essential reagents and equipment downtime, limiting their ability to carry out basic tests.

Laboratories at all levels are ill-equipped, with most of them lacking the up-to-date equipment necessary to provide basic microbiology, haematology and chemistry services. Equipment in some facilities either lacks 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 engineering unit is poorly furnished and needs to be well-equipped to maintain other available equipment subsequently. Generally, laboratory staff are not actively involved in the procurement process.

## 3.3.5 Laboratory support systems: human resources

The shortage of suitably qualified human resources to work in diagnostic laboratories is severe and affects the quality of healthcare at our facilities. There is a huge challenge in providing and retaining adequate laboratory professionals in public sector health laboratories, especially in rural and remote areas. During 2019, a consultant undertook a countrywide tour to conduct a comprehensive assessment of the status of public health laboratories, and the most significant challenge highlighted by this assessment was the lack of the required number of appropriately qualified staff.<sup>2, 16</sup> Many laboratories do not meet recommended staffing norms. This cadre of staff has limited formal technical training and is a cause for concern regarding the quality of service they render. 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.<sup>16</sup> 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, leading 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 ongoing education opportunities or inservice training will not develop and maintain the necessary key cadre of personnel. Together, these factors result in the demotivation of staff, which further compromises the quality of services delivered. Laboratory staff also currently have no access to a health insurance scheme for themselves and their families, making the profession insecure and risky.

<sup>&</sup>lt;sup>16</sup> Human Resources for Health, Assessment report, 2019.

### 3.3.6 Laboratory quality management system

There is no developed and well-coordinated quality management system for internal and external quality assessment that could result in continuous quality improvements of standard laboratory services and lead to accreditation.<sup>2</sup> The establishment of a quality management system for every laboratory is essential to ensure quality testing services.

Inadequacies in laboratory infrastructure, human resources, equipment, supplies and other aspects compromise the quality of laboratory services delivered at all facilities.<sup>2</sup> Standard laboratory guidelines, manuals and SOPs are absent in most facilities, and some laboratories receive no technical support supervision due to the limited capacity and resources of the supervision and monitoring team. Only facilities involved in programmes, such as TB, malaria and HIV/AIDS, get some periodic in-service training and supervision and thus there is urgent need to the Ministry Of Health increase the budget line for procurement of the laboratory supplies

### 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 healthcare planning and outbreak responses. Therefore, it is important that a laboratory information management system (LIMS) be established nationally and that all laboratory personnel are trained in information and communication technology (ICT) to support clinical and public health programmes. Data collected at the facility level are often incomplete and inaccurate. Currently, a paper-based system is used to enter information at the peripheral levels. The transfer of laboratory data among different levels and sectors is also not very effective. Modern computerized systems are limited while keeping laboratory records and collating data from testing laboratories is not standardized. This is due to limitations in the ICT infrastructure in laboratories for the efficient management of laboratory data, supplies and equipment; poor or lacking internet connectivity and other utilities; and a lack of laboratory data management guidelines and data collection tools. Therefore, the opportunity of introducing a LIMS to link to the District Health Information System Version 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. However, it requires trained laboratory scientists 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, the Medical Research Council, the Directorate of Research under the Ministry of Higher Education and Research, universities, and other relevant partners. However, there is currently inadequate funding and few facilities to conduct research; hence R&D is often neglected.



### 3.3.9 Point-of-Care Testing (POCT) Services

The discovery and introduction of point of care tests for HIV, TB, and malaria have increased access and turnaround in the diagnoses and management of patients. This success story has greatly increased 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 regulations to use point-of-care devices national and these devices may depend on their sensitivity and specificity for the desired result to be ascertained. Besides, there is no standardized external quality assurance programme for blood screening services; their performance cannot be assured. Therefore, a key priority for improving laboratory services should be to embrace WHO prequalified point of care tests. Local provisions for the regulatory authority of diagnostic tests are also needed (both for POCT and other diagnostic assays).

### 3.3.10 Networking and collaboration

Networking and collaboration among the different laboratories (diagnostic and reference laboratories) are important components for delivering quality laboratory services. It will sometimes be necessary to refer some tests to other laboratories, either within or outside the country. It is now recognized and proven that a country can successfully organize a disease-specific or general laboratory network in-country to provide many patients with access to various tests. Such networks are also important for information and experience sharing as well as strengthening the referral system and training laboratory personnel.

There is limited equipment and a shortage of trained personnel to provide higher-level testing throughout The Gambia. This situation leads to an alarmingly high rate of patient referrals simply because of the lack of onsite laboratory testing and 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.<sup>14</sup> Therefore, the implementation of the National Public Health and Emergency response plan, which includes all the structures necessary for the implementation of a One Health approach, would enable inter- and intraministerial linkages for the coordination of responses to disease outbreaks and other public events.<sup>17</sup>

## 3.3.11 Legal and regulatory framework

There is no Gambia Medical Laboratory Council Act to regulate the operation of laboratories or the registration and licensing of laboratory personnel.<sup>2</sup> Therefore, there is an urgent need to establish a Gambia Medical Laboratory Council, 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.

<sup>&</sup>lt;sup>17</sup> National Public Health and Emergency Response Plan, 2019

## 3.3.12 Monitoring and evaluation (M&E)

There are limited M&E systems for comprehensive assessments of the effectiveness and efficiency of laboratory performance in terms of delivering quality, affordable, and timely health services according to the National Health Policy 2021–2030. This system needs to be strengthened to track the progress and achievement of laboratory systems outcomes regularly. 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 M&E programme will be oriented to cover the other diseases.

### 3.3.13 Financing and accountability

The NHLS is grossly underfunded.<sup>2</sup> 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 no protocols or guidelines relating to a laboratory code of conduct. The Gambia Medical Laboratory Council will enforce such a code of conduct, which will guarantee client respect, confidentiality, privacy and safety. There is no swearing of such a code of conduct at graduation ceremonies for laboratory students. Hence, weak regulations and guidance of laboratory ethics prevail in the system. There is a need to sensitize the wider community to the role played by laboratories in healthcare and what individuals' rights are and the rights of service providers. The public should be educated around making a complaint and seeking redress in any cases of negative experiences.



# CHAPTER 4: POLICY FRAMEWORK

## 4.1 Vision

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

## 4.2 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.

## 4.3 Goal

To put in place high-quality health laboratory services at all levels of healthcare delivery across The Gambia.

## 4.4 Core values and guiding principles

The following core values and guiding principles shall apply to the management and delivery of health laboratory services in The Gambia.

*Quality testing*: Ensuring quality assurance and management systems that guarantee 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 bear in mind whom 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 available resources.

## 4.5 General policy statement

This National Health Laboratory Service Policy aims 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 Gambia.

## 4.5.1 General policy objective

To establish a functional NHLS to coordinate 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.

# CHAPTER 5: COMPONENTS OF this policy

## 5.1 The process

The MoH developed these policy requirements in collaboration with experts drawn from the laboratory and academic sectors. The processes were driven by the Directorate of the NHLS, with technical assistance from the Directorate of Planning and Information, experts from the public, private and academic sectors, and an international consultant. Several meetings and consultations involving the wider stakeholders were held to obtain a final draft of the policy to be validated.

## 5.2 Thematic areas

The policy addresses several thematic areas. For each of the themes, an objective has been set that the policy seeks to achieve. The relevant policy statements establish the authority to support efforts to achieve the objective. The themes addressed in the policy are listed below:

- Organization and Management
- Laboratory Services
- Laboratory Infrastructure, Biosafety and Biosecurity
- Laboratory Support Systems (Equipment and Supplies)
- Laboratory Support Systems (Human Resources Development and Management)



- Laboratory Quality Management System
- Laboratory Information Management System
- Research and Development
- Point-of-Care Testing (POCT) Services
- Networking and Collaboration
- Legal and Regulatory Framework
- Monitoring and Evaluation
- Financing and Accountability
- Laboratory Service Ethics and Community Engagement

#### 5.2.1 Organization and management

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

#### Strategies

- ✓ Transform the Directorate of NPHL to the Directorate of NHLS with the capacity to effectively and efficiently manage laboratory services
- ✓ Implement effective communication and representation of laboratory services at the seven Regional Health Directorates (RHDs
- ✓ Establish a technical oversight body (NLTWG) to coordinate and establish direction and standards for the NHLS
- $\checkmark$  Provide training support for supervisors throughout the tiered laboratory network

#### **5.2.2 Laboratory Services**

Policy Objective: Provide quality laboratory testing services to all people

#### Strategies

✓ 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

- ✓ Strengthen safe and secure specimen collection, packaging and transportation within the laboratory network and at the international level
- ✓ Strengthen national laboratory testing capacity to support effective implementation of UHC
- ✓ 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
- ✓ 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.
- ✓ Develop a plan and budget to support laboratory public health emergency responses, which is mainstreamed with the national health emergency response plan for an early warning system
- ✓ 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

#### 5.2.3 Infrastructure, Biosafety and Biosecurity

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

#### Strategies

- ✓ Strengthen national laboratory biosafety and biosecurity system
- ✓ Ensure that construction and renovation of health laboratory facilities conform to national infrastructure guidelines and standard
- ✓ Establish a maintenance programme for biosafety and biosecurity equipment
- ✓ Establish an effective occupational health and safety programme for laboratory personnel in liaison with the occupational health unit of the MoH
- ✓ Strengthen the coordination of biosafety and biosecurity activities through effective management at all levels
- ✓ Strengthen human resource capacity for biosafety and biosecurity program through training for improved practice

#### **5.2.4 Equipment and Supplies**

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

#### Strategies

✓ Strengthen the coordination of the laboratory supply chain management system across the network in

liaison with National Pharmaceutical Services (NPS)

- ✓ Establish pre-and post-market surveillance systems for laboratory commodities
- ✓ Strengthen supply chain management to quantify, procure, distribute and monitor laboratory commodities across the network
- ✓ Strengthen the ordering, storage and inventory management systems at all levels
- Strengthen data management systems for laboratory logistics to meet routine and emergency services delivery
- ✓ Strengthen capacity in laboratory logistics management, including BLIS
- Develop and implement guidelines for equipment procurement and placement across the laboratory network
- ✓ Strengthen equipment maintenance and management at all levels
- Establish a system for monitoring equipment functionality and managing the disposal of laboratory equipment and supplies

#### **5.2.5 Human Resources**

**Policy 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

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

#### **5.2.6 Quality Management System**

**Policy Objective:** Strengthen the national laboratory quality management system to ensure quality service delivery that leads to national/international laboratory certification and accreditation

#### Strategies

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

#### 5.2.7 Laboratory Information Management System

**Policy 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

- ✓ Develop and implement an electronic, integrated LIMS in all laboratories in the network to improve laboratory data and information management
- ✓ Strengthen standardized, paper-based LIMS at sites without electronic LIMS to facilitate data capture and reporting
- ✓ Develop and implement an electronic, mobile and web-based platform for effective specimen tracking across the national sample transport network
- ✓ Establish a system for the standardized collection, analysis and reporting of patient data to improve data use
- ✓ 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
- ✓ Establish an integrated database for managing non-clinical laboratory data to improve the coordination of laboratory services

#### 5.2.8 Research and Development

**Policy Objective:** Undertake research of public health importance according to the research priorities of the National Health Sector

#### Strategies

- ✓ Develop a research agenda for the laboratory directorate
- ✓ Build capacity of laboratory personnel involved in operational research
- ✓ Develop and implement a national laboratory research database to track and disseminate research findings

#### 5.2.9 Point-of-Care Testing (POCT) Services

**Policy Objective:** To increase access to testing services by complementing conventional laboratory testing services with approved and appropriate point-of-care technologies

#### Strategies

- ✓ Strengthen coordination mechanism for POCT to improve the provision of POCT services
- ✓ Develop capacity for POCT as a means of increasing access to laboratory services



- ✓ Develop and implement POCT communication strategy to improve access to POCT services at national, regional and community levels
- ✓ Develop QA mechanism for POCT to improve quality of POCT services

#### 5.2.10 Networking and Collaboration

**Policy Objective:** to Strengthen multi-sectoral, national, international, public and private partnerships to promote equitable access to quality laboratory services

#### Strategies

- ✓ 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)
- ✓ Establish mechanisms to outsource specialized laboratory services to increase efficiency and effectiveness in service delivery
- ✓ Promote public-private partnerships for the provision of health laboratory services following PPPH policy
- Support establishment of laboratory services for underserved areas by providers outside the public system

#### 5.2.11 Regulatory and Legal Framework

**Policy 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

- ✓ Establish and maintain a robust legal framework for the regulation of medical laboratories and laboratory personnel
- ✓ Ensure that all health laboratories meet the required standards for registration and licensing
- ✓ Ensure that all practicing laboratory professionals are registered and licensed

#### **5.2.12** Monitoring and Evaluation

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

#### Strategies

- ✓ Establish an effective program to monitor and evaluate the implementation of the National Health Laboratory Strategic Plan
- ✓ Establish M&E for laboratory logistics activities

✓ Ensure regular assessment of the overall performance of laboratory services

#### 15.2.13 Finance and Accountability

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

#### Strategies

- ✓ Ensure a dedicated budget for laboratory services in the MOH
- ✓ Coordinate partner funding activities for laboratory services
- ✓ funds to meet laboratory budget needs
- ✓ Establish a transparent system to ensure programmatic and financial accountability of laboratory services

#### 5.2.14 Ethics and Community

**Policy 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

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

# CHAPTER 6: IMPLEMENTATION OF POLICY

# 6.1 The National Health Laboratory Services

The MoH, recognizing the need for accurate diagnosis, together with strong and integrated disease surveillance and responses, proposed the establishment of a Directorate of National Health Laboratory Services (DNHLS) in the National Health Policy (NHP) 2021–2030 and has included this in the National Health Sector Strategic plan 2021–2025.

The DNHLS, together with relevant partners, will coordinate public health laboratory testing, reference testing, quality assurance (QA), M&E, and staff CPD.

The MoH intends to translate this policy into practice within the health system fully. The policy has been developed within the National Health Policy, the Health Sector Strategic Plan, and regional and international



health development goals. Therefore, its implementation will align with the existing government, non-governmental organizations (NGOs), and private-sector structures.

To guide this process effectively, the MoH has already embarked on the development of a National Laboratory Strategic Plan. This will give clear guidance on strategic actions needed to improve the laboratory systems and insights into policy, implementation, and budgetary implications for translating the policy into practice. All this will guide the mobilization of the necessary resources, as well as helping the MoH, stakeholders and partners to identify their areas of strength and target their input effectively and efficiently for better outcomes.

# 6.2 The implementation process

The implementation of this laboratory policy will require the full and active participation of all stakeholders. There is an urgent need for a significant infusion of resources to raise standards to a minimum acceptable level; this calls for a coordinated response from the government and cooperating partners to achieve the goals set. The implementation of this policy will be divided into immediate, medium- and long-term activities.

#### Immediate activities include:

- Develop guidelines and term of reference for all laboratory components in the National Health Laboratory Service (DNHLS) network, with a clear organogram of the Directorate National Health Laboratory Service
- Establish a Gambia Medical Laboratory Council.
- Establish a National Laboratory Technical Working Group (NLTWG) with clear Terms of reference.
- Establish a laboratory quality management system (LQMS).
- Establish a Biosafety and Biosecurity Unit.
- Strengthen laboratory information management system

#### Medium-term activities include:

- Improve basic laboratory services (equipment, supplies, human resources, infrastructure and utilities).
- Implement a regulatory system for the training and practice of medical laboratory professionals.
- Enroll all general and district hospital laboratories in the SLIPTA package.

#### Long-term activities include:

- Ensure reference and teaching hospital laboratories are ISO 15189 accredited.
- Upgrade all other laboratory structures to meet acceptable standards.

The implementation is to be guided by a strategic plan that will be implemented over five years. Objectively verifiable indicators and tools will be developed and used to monitor various stages of the implementation process.

## 6.3 Conclusion

Laboratory services in The Gambia have developed slowly over the past few years, which has adversely affected the effective and efficient delivery of health services. In the absence of a guiding framework, several efforts invested have not yielded the expected impact. The adoption of the policy described here represents the beginning of a new era for laboratory and general health systems strengthening. The clear framework will guide the appropriate allocation and utilization of available resources and direct the mobilization of much-needed resources to address weaknesses in the system. Harmonization of services and processes will reduce duplication and resource wastage, making the health system more efficient. To achieve sustainable improvements, concerted efforts, cooperation and collaboration between the MoH and all stakeholders are needed. All of these partners are called upon to bring this vision to reality.

# List of contributors

ſ	No	Name	Designation	Institution/Address



1	Sheriffo Jagne	Acting Director	National Public Health Laboratories, MoH
2	Karamba Keita	Deputy Permanent Secretary- Technical	Ministry of Health
3	Momodou Lamin Jaiteh	Permanent Secretary	Ministry of Health
5	Dr Mustapha Bittaye	Director of Health Services	Ministry of Health
6	Dr Juliana Ndasi	International consultant	Foundation for Innovative New Diagnostics
7	Dr Mamady Cham	Chief Executive Officer	Bwaim General Hospital
8	Dr Haddy Bah	Chief laboratory scientist	Edward Francis Small Teaching Hospital
9	Dr Abdul Karim Ceesay	Head of Genomic Laboratories	Medical Research Council, Gambia
10	Gibril Jarjue	Director	DPI-MoH
11	Alieu Faal	Senior laboratory scientist	National Public Health Laboratories, MoH
12	Dr Sharmila Larreff-Jah	Disease prevention and control (DPC) officer	WHO, The Gambia country office
13	Lali Zira	WHO consultant (laboratory expert)	WHO, Uganda country office
15	Dr Omar Manjang	Acting Director	Directorate of Nursing and Midwifery Services,MoH
16	Dr Makie Taal	Vice Chancellor	American International University, West Africa
17	Dr Fatoumata Jah-Sowe	Deputy Executive Director	Medicines Control Agency
18	Sana M Sambou	Programme Coordinator	Epidemiology Disease Control /MoH
19	Dr Fatoumata Dibba	Program Manager	Quality Assurance Unit
20	Sheriffo Badjie	Deputy Program Manager-	National Aids Control Program
21	Alpha Khan	Deputy Director,	National Aids Secretariat
22	Ignatius Baldeh	Laboratory specialist/Former Director of NPHL	Tujereng
23	Bakary Sanneh	Local consultant/Acting Deputy Director	National Public Health Laboratory
24	Balla Jatta	National Disease Surveillance Officer	Epidemiology Disease Control Unit/MoH
25	Dawda Samateh	Public Health Regional Officer	Directorate of Human Resources for Health /MoH
26	Sainey Cham	Leprosy and Tuberculosis Control officer	National Leprosy Tuberculosis Program

27	Saikou Jawara	Senior planner	Directorate of Planning and Information /MoH
28	Lamin Jawla	M&E officer	Directorate of Planning and Information /MoH
29	Dr Buba Manjang	Director	Directorate of Public Health and Environment
30	Basirou Drammeh	Regional principal nursing officer	Regional Health Directorate-Western Region 2/ MoH
31	Fatou Samateh	Principal pharmacist	National Pharmaceutical Services/MoH
32	Momodou Lamin Jammeh	Head of Laboratory Services	West Africa Holistic Medical Centre
33	Saffie Abia	Deputy Program Manager, NBTS	National Public Health Laboratory
34	Kenbugal Diko	Director of Administration and M&E	Riders for Health
35	Alhagie Papa Sey	Data manager	National Public Health Laboratory
36	Dr Ousman Leigh	Senior Registrar/Pathologist/Head of Laboratory Clinical Services	Edward Francis Small Teaching Hospital
37	Baboucarr Babou	Laboratory manager	Kanifing General Hospital
38	Landing Faal	Head and proprietor of laboratory services	BIO-MED Private Laboratories
39	Abdoulie M. Sanyang	Laboratory scientist	National Public Health Laboratory
40	Dr Davis Nwakanma	Laboratory manager	Medical Research Council The Gambia
41	Baba K Fofona	Principal laboratory scientist	Edward Francis Small Teaching Hospital
42	Dr Ousman Secka	Head of Tuberculosis Laboratory	Medical Research Council The Gambia
43	Mariama Jammeh	Program Manager	National Blood Transfusion Services
44	Momodou Jaye	Lecturer/Retired principal laboratory Science	American International University, West Africa
45	Ramatoulie Secka	Principal laboratory scientist	Edward Francis Small Teaching Hospital
46	Michael Gomez	Biomedical technician	National Public Health Laboratory
47	Musa Ceesay	Senior laboratory scientist	National Public Health Laboratory
48	Alphonse Mendy	Senior laboratory scientist	National Public Health Laboratory
49	Mamadou M Jallow	Laboratory scientist	National Public Health Laboratory
50	Haruna S Jallow	Laboratory scientist	National Public Health Laboratory
51	Biram L Faye	Laboratory scientist	Department of Veterinary Services, Ministry of Agriculture (MoA)



52	Mr Mamodou Bah	Director General	Food Safety Quality Assurance
53	Dr Ousman Ceesay	Deputy Director General	Department of Livestock Services, Ministry of Agriculture
54	Mariama Drammeh	Senior Laboratory Scientist	National Public Health Laboratories
55	Kalifa Sanneh Daboe	Principal Laboratory Scientist	Kanifing General Hospital, Laboratory Department
54	Momodou Lamin Keita	Head of Laboratories	Jobot Laboratory



