

National Public
Health Laboratory

POLICY

(Establishing a strong Public
Health Laboratory System)

October 2012



Ministry of Health
and Social Services

FOREWORD

This is the first time in Namibia that a National Public Health Laboratory Policy has been developed to guide the development and delivery of health laboratory services in Namibia. This policy becomes even more critical in an environment where there is increasing participation of the private sector in health care delivery. The policy will hopefully help laboratory stakeholders strike a balance between commercial interests and public good.

For a long time the country has lacked a framework for the collection of public health laboratory data to inform disease prevention and control strategies of the Ministry of Health and Social Services (MOHSS). This policy provides the framework for the government to establish a National Public Health Laboratory System (NPHLS) and to monitor delivery of quality services. If successfully implemented the country will see a more informed and focussed public health laboratory intervention programme.

I am glad to note that many stakeholders, including the private sector participated in the formulation of this policy. It is my hope that this will play a crucial role in promoting public-private partnerships in the laboratory sector and in harnessing private resources and expertise into public health interventions.



.....
DR RICHARD NCHABI KAMWI, MP
MINISTER

PREFACE

This policy has been developed in recognition of the need to have a framework for the development and delivery of integrated laboratory services in the country. The development of the policy has benefited from the input of many experts in laboratory medicine and systems from within and outside Namibia. The development has borrowed significantly from experiences and structures in other countries within the region and WHO recommendations. In addition, the policy has been aligned to the National Health Policy Framework 2010-2020 and existing policies of the MOHSS disease programmes.

The policy defines the organisation and management of the laboratory system in the country and in particular expands the scope to include an integrated public health laboratory service beyond the public sector. It calls for the development of an integrated laboratory information system, maintenance of national standards of quality and employment of competent professionals.

The policy is organised and structured into thematic areas that address laboratory management issues, systems and technical operations areas that will contribute to the overall goal of delivery of accessible and quality services. It will be implemented through a National Public Health Laboratory Strategic Plan and Annual Operational Plans.

It is hoped that with the support and participation of stakeholders Namibia, will see the development of a National Public Health Laboratory service of international repute and that meets the needs of the country.

I wish to thank all those who were involved in the development of the policy and especially our partners who have provided not only technical but also financial support. The Ministry of Health and Social Services would like to acknowledge the contributions made by the following Directorates and Institutions; Tertiary Health Care and Clinical Support Services, Directorate of Special Programmes, Primary Health Care Services, Namibia Institute of Pathology, Blood Transfusion Services of Namibia, University of Namibia, Polytechnic of Namibia, Centre for Diseases Control and Prevention, Association of Public Health Laboratories, Military Laboratory, Supply Chain Management Systems (SCMS), Ministry of Agriculture Water and Forestry (Veterinary Services), Fisheries, Nam Water, Private Laboratories: Caprivi Pathology Centre, J Hagstrom, Maxi med, High Care and Clinpath and many other stakeholders for their invaluable inputs into this document.



MR ANDREW N. NDISHISHI
PERMANENT SECRETARY

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LIST OF ABBREVIATIONS

AFRO	Africa Regional Office
CDC	Centres for Disease Control and Prevention
CPC	Caprivi Pathology Centre
CPD	Continuous Professional Development
DDNPHLS	Deputy Director National Public Health Laboratory System
DNPHLS	Director National Public Health Laboratory System
EQA	External Quality Assurance
EQAP	External Quality Assurance Programme
HIV/AIDS	Human Immunodeficiency Virus/Acquired Immuno-Deficiency Syndrome
HPCNA	Health Professions Council of Namibia
HRD	Human Resource Development
HRM	Human Resource Management
IHR	International Health Regulations
IPHL	Integrated Public Health Laboratory Committee
LIS	Laboratory Information System
MOHSS	Ministry of Health and Social Services
NAMBTSS	Namibia Blood Transfusion Service
NIP	Namibia Institute of Pathology
NPC	National Planning Commission
NPHL	National Public Health Laboratory
NPHLS	National Public Health Laboratory System
NSI	Namibian Standards Institution
PHLN	Public Health Laboratory Network
PMDRC	Policy Management Development Review Committee
POC	Point of Care (Testing)
QA	Quality Assurance
SLMTA	Strengthening of Laboratory Management Towards Accreditation
SLIPTA	Stepwise Laboratory Quality Improvement Towards Accreditation
SOP	Standard Operating Procedure
THC&CSS	Tertiary Health Care and Clinical Support Services
UNAM	University of Namibia
WHO	World Health Organisation

CHAPTER 1: INTRODUCTION

An efficient laboratory system is critical for the correct diagnosis of clinical conditions and the detection and identification of the cause of disease outbreaks in the shortest possible time. These two laboratory functions - diagnostic patient services and public health surveillance & response services - are essential to provide sufficient information for treatment, prevention and health improvement.

In many countries in Africa, clinical laboratories perform timely, accurate diagnostic testing services and disease reporting to Ministries of Health for surveillance, prevention, control and outbreak response. However, resource limitations and high demand for diagnostic testing services often limit the contribution of clinical laboratory data for surveillance purposes. Test result reporting may be delayed, may not be accurate and may not provide information on priority health issues.

It is the responsibility of the Ministry of Health and Social Services to provide leadership through regulation, policy and collaboration as well as direct service provision to assure that within resource limitations the most appropriate mix of laboratory services - diagnostic, surveillance and outbreak response - is developed to achieve the best outcomes in health for all. Lack of adequate infrastructure and operations are barriers to providing access to adequate services for clinical and public health functions. Resource limitations can result in a lack of or delay in laboratory diagnostic results with the consequence of less effective patient management and poorer health outcomes. Weak reporting systems and lack of or delays in providing timely testing and response to disease outbreaks results in increased morbidity and mortality for major disease of public health concern such as TB, malaria, cholera and HIV/AIDS. The National Public Health Laboratory Policy is designed to guide best choices in achieving health.

1.1 BACKGROUND

The Ministry of Health and Social Services (MOHSS) has overall responsibility and authority for providing direction over the national health programme. The MOHSS structure has four Departments (three technical and one administrative) and nine Directorates. The Laboratory Services is a Sub Division under the Tertiary Health Care and Clinical Support Services (THC/CSS) Directorate. This Sub Division is tasked to oversee laboratory services in the country including the Namibia Institute of Pathology (NIP) and the Blood Transfusion Service of Namibia (NAMBTS). The newly established Integrated Public Health Laboratory Committee (IPHLC) provides advisory and coordination functions for laboratory services.

The Government of the Republic of Namibia is a signatory to several of WHO resolutions that call for the strengthening of the Public Health Laboratory System and the establishment of a functional National Public Health Laboratory (NPHL). The revised IHR (2005) require countries "To develop, strengthen and maintain capacities of laboratories to detect, assess, notify, and report events". In addition to the IHR requirement, WHO/AFRO has urged member countries for commitment to laboratory strengthening in line with the following declarations and resolutions:

- Maputo declaration on strengthening of laboratory systems: Maputo **January 2008**.
- Resolution AFR/RC58/R2: Strengthening Public Health Laboratories in the WHO African region: Yaoundé, Cameroon **September 2008**
- 5th Meeting of the Regional HIV/AIDS Public Health Laboratory Network, Dakar, Senegal, **September 2008**.
- Resolution AFR/RC59/WP/3: Policy orientations on the establishment of centres of excellence for disease surveillance, public health laboratories, Food and medicines regulation Kigali, Rwanda **September 2009**
- Resolution AFR/RC59/R2 – Drug Resistance related to AIDS, Tuberculosis and Malaria: Issues, Challenges and the Way Forward Kigali, Rwanda **September 2009**.

In showing its commitment to implement these resolutions, GRN in the National Health Framework 2010-2020, has proposed the establishment of a strong NPHL to provide technical support to the disease prevention and control initiatives.

1.2 PURPOSE OF THE POLICY

Laboratory services are critical for proper delivery of health care services. They are also critical in providing data for policy formulation and informed decision making. However laboratory services need to be organised and properly regulated at the national level in order to meet the priority needs of the healthcare and public health systems and assure the quality of testing public as well as private laboratories. The national public health laboratory policy supports priority goals as defined by the MOHSS. Therefore, a need was identified for a national policy to establish the necessary environment for setting of comprehensive standards for public and private laboratories. These regulatory standards are important in the establishment of public and private laboratories, in the training and certification of laboratory personnel and in quality laboratory practice.

This policy defines the laboratory governance, coordination and collaboration structures and provides an environment and infrastructure that will assure the delivery of quality laboratory services to all and support the priority health initiatives of the national health plan. The National Public Health Laboratory Policy is a key element of the MOHSS operational resources for supporting effective national health priorities.

1.3 PROCESS

A team consisting of Ministry of Health and Social Services and the Namibia Institute of Pathology personnel visited Ethiopia, Kenya and South Africa on a fact finding mission to get an idea of how best a Public Health Laboratory System could be run in Namibia. The three countries were selected because of their unique systems of operations of the Public Health Laboratory Systems which could be borrowed and incorporated in to the establishment of the National Public Health Laboratory Systems locally. Each of the countries has developed a system to respond to their unique health structure. The Public Health Laboratory System is run as an autonomous unit in South Africa; while in Kenya the clinical and Public Health Laboratory System are separate at national level but integrated at primary levels. In Ethiopia one unit runs both the clinical and public health laboratory functions. These findings have informed the development of this policy.

These policy requirements were developed by MOHSS in collaboration with experts drawn from the laboratory and academic sectors. The process was driven by the Laboratory Sub-Division of the MOHSS with technical assistance from CDC and the Association of Public Health Laboratories (APHL) and the Integrated Public Health Laboratory Committee (IPHLC), comprising experts from public, private and academic sectors. Several meetings and consultations involving the wider stakeholders were held to finalize the policy.

1.4 THEMES

The policy addresses several thematic areas. For each of the themes, a background highlighting the major issues and challenges is provided along with an objective 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 as follows:

- Organisation and infrastructure
- Human Resources (HRD and HRM)
- Laboratory Services (Test Menu)
- Laboratory Support Systems (equipment, and supplies)
- Quality Management System including Bio-safety and Bio-security
- Laboratory Information Management System
- Legal and Regulatory Framework
- Research and Development
- Networking and Collaboration

CHAPTER 2: SITUATIONAL ANALYSIS

2.1 NAMIBIA INSTITUTE OF PATHOLOGY

According to Act no. 15 of 1999, the Namibia Institute of Pathology (NIP) was established to provide and sustain quality medical laboratory diagnostic services throughout Namibia. NIP operates a laboratory system through a network of 38 laboratories that extends up to district level.

NIP is managed by a Board of Directors, appointed by the Minister of Health and Social Services and answerable to the MOHSS. The Board is responsible for ensuring NIP management maintains current and adds new testing services in order to increase accessibility; provides testing services at reasonable and affordable tariffs that will enable all Namibians access to laboratory services; assures quality in the delivery of its services; provides MOHSS statistical and other information on infectious and communicable diseases and epidemiological trends that are of public health interest; provides financial reports and protects its assets.

The NIP operates a good system for specimen referral to ensure countrywide coverage for laboratory services. However, the referral system faces challenges of specimen collection, transportation and long turn-around times for test results.

2.2 OTHER LABORATORIES

Namibia has a network of 58 clinical laboratories in both the public and private sectors. The public sector laboratories under NIP account for 38 of these laboratories. The rest are shared by six main laboratory chains (Path Care, Clinpath, CPC, Oshana, High Care and Maxi med). The Blood Transfusion Service is organized and managed under NAMBTS, an institution not for gain. In addition, there are quasi-government laboratories offering a mixture of research and specific testing relating to the mandates under their respective ministries (Veterinary, NamWater, Marine, Forensics and Dairy).

There is currently no established system to capture data and information from this network of laboratories for public health use. The network has not been organized nor incorporated into the MOHSS disease outbreak response structures. The National Public Health Laboratory System (NPHLS) will provide the framework for the Integrated Laboratory Data Management Systems and establishment of Public Health Laboratory Network (PHLN) to address the issues cited above.

2.3 ACADEMIC INSTITUTIONS

The Polytechnic of Namibia and UNAM have started schools for training laboratory personnel at basic level. It is hoped that in the near future Namibia will be able to meet its needs for basic level laboratory personnel, but will continue to rely on outside expertise for specialised testing but eventually train specialised staff in the country.

2.4 REGIONAL PUBLIC HEALTH LABORATORIES

At the inception of the establishment and strengthening of the Public Health Laboratory System in Namibia, a team from the Directorate of Tertiary Health Care and the Namibia Institute of Pathology visited regional Public Health Laboratories on a fact finding mission on how best to come up with a system that would fit in the Namibian set up.

Three countries namely Kenya, South Africa and Ethiopia were visited, because of their unique Public Health Laboratory set ups which would later be helpful in deciding the best model and practice. All three countries were found to have different but effective Public Health Laboratory System that if combined and borrowed, would help in charting the first step forward in establishing a Namibian Public Health Laboratory System.

CHAPTER 3: POLICY FRAMEWORK

3.1 VISION

To provide laboratory services of the highest standard of quality that will contribute to the overall health of all Namibians.

3.2 MISSION

The National Public Health Laboratory System will provide and assure quality testing services where and when needed for all, support clinical care providers in the treatment and prevention of disease and support the MOHSS in its disease surveillance and response, planning and policy development to prevent unnecessary disease and advance continual health improvements.

3.3 CORE VALUES

In order to assure that the National Public Health Laboratory initiatives provide appropriate quality laboratory services. The following have been defined to support correct actions by all professionals who work in the laboratory system.

- **Equity:** Laboratory resources and services are distributed equitably throughout the country.
- **Accessibility:** Services are affordable and within reach of all.
- **Relevance:** Laboratory services are appropriate for the purpose and address the needs of the community.
- **Partnership:** Promote teamwork and team spirit among all laboratory personnel and 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 public good.
- **Quality testing:** Ensuring that test results are accurate and reliable.

3.4 POLICY OBJECTIVES

The objective of the National Public Health Laboratory Policy is to establish authority and direction for the development of required capacity of laboratory services, and define standards for all aspects of health laboratory practice in the country.

3.4.1 MAJOR POLICY OBJECTIVES

- a) To establish a NPHLS for the coordination of public health testing, disease surveillance and integrated public health data management.
- b) To establish a functional NPHL for Namibia.

3.4.1.1 STRATEGIES

- a. Ensuring reference and specialised testing for tests not routinely provided by clinical or other laboratories.
- b. Ensuring a functional and effective sample referral system.
- c. Developing, coordinating and implementing a national quality assurance programme.
- d. Providing laboratory back up in outbreak investigation and control.
- e. Providing an organisational and management structure for the oversight and coordination of Public Health Laboratory Service and network.
- f. Ensuring public health laboratory testing in support of disease prevention, control and public health intervention.
- g. Developing an integrated public health laboratory data collection and management system for disease prevention and control programmes.
- h. Develop strategies and interventions that are evidence-based.

3.4.2 SPECIFIC OBJECTIVES

3.4.2.1 ORGANISATION

The Laboratory Directorate shall provide oversight on all laboratory services in the country including policy direction and regulations of testing facilities.

3.4.2.1.1 OBJECTIVES

To establish an organisational and laboratory management system that provides good governance, coordination, access and accountability at all levels.

3.4.2.1.2 POLICY STATEMENTS

- a) A National Public Health Laboratory (NPHL) shall be established in the country to provide technical oversight and development of public health laboratory related activities.
- b) A Director for National Public Health Laboratory System (DNPHLS) shall be appointed with authority to supervise the NPHL and to coordinate the NPHLS.
- c) The Director, shall advise the MOHSS on all major public health laboratory related policies and decisions.
- d) The Permanent Secretary, MOHSS or his delegate shall be accountable for the implementation of this policy.
- e) There shall be a clear line of authority and accountability between MOHSS and all laboratories within the system.
- f) There shall be an IPHLC appointed by the Permanent Secretary, MOHSS to provide technical advice to the ministry. The committee shall be representative of all relevant public and private agencies having a role or interest in laboratory services and all major stakeholders.
- g) There shall be a Service Level Agreement (SLA) between the MOHSS and other stakeholders that shall stipulate the authority, responsibility and accountability of the NPHL.

3.4.2.2 INFRASTRUCTURE

In some instances laboratory infrastructure is inadequate and is not appropriately designed to meet the requirements of safe laboratory practice, extensive renovation and development of new laboratories will have to be undertaken to address these challenges.

3.4.2.2.1 OBJECTIVE

- a) To establish a National Public Health Laboratory facility designed to national standards.
- b) To provide laboratory facilities designed to national standards at each level of health care that are appropriate for the services provided at the level.

3.4.2.2.2 POLICY STATEMENTS

- a) The MOHSS shall provide infrastructure for the establishment of the NPHL.
- b) The location and design of each laboratory shall conform to established national standards.
- c) The Director of each laboratory shall be involved in the oversight of design, building and equipping of laboratories.
- d) An annual inspection of all laboratory facilities shall be conducted by the body responsible for such inspections.

3.4.2.3 HUMAN RESOURCES

Like many other countries, Namibia has a shortage of qualified and skilled laboratory personnel. It is therefore necessary that the country develops the necessary policies to guide the development of a sufficient and appropriately trained human resource. There must be guidelines for the continued professional development of the staff in post. Although three training institutions have now been established, they do not yet have the capacity to meet the country's needs, especially in specialised skills.

3.4.2.3.1 OBJECTIVE

To ensure the development of adequate numbers of skilled and competent laboratory personnel to meet the country's requirements and provide comprehensive laboratory services.

3.4.2.3.2 POLICY STATEMENTS

- a) The MOHSS shall ensure the development and implementation of a HRD plan for laboratory personnel to ensure that all levels of laboratory services have adequate personnel with the required skills and competencies.
- b) The MOHSS, in liaison with the training institutions shall advocate and plan for the pre-service training of adequate numbers of all cadres and categories of laboratory personnel.
- c) The Director of National Public Health Laboratory System (DNPHLS) shall facilitate access for all in-service staff to continue professional development through partnerships with centres of excellence that can provide in-service education and training.
- d) The DNPHLS shall ensure that all laboratory personnel have the required skills and competencies for their assigned duties.
- e) The MOHSS shall develop and implement strategies to retain staff within the service.

3.4.2.4 LABORATORY SERVICES

The DNPHLS shall work to ensure access to a minimum package of laboratory services appropriate to each level of care in the public sector, to ensure equity and access to a functional specimen referral system that will be necessary to allow for services at all levels. Where samples are referred to other laboratories, efforts should be made to ensure quick turn-around times to clinicians and patients.

3.4.2.4.1 OBJECTIVE

To provide quality laboratory services appropriate for each level and to ensure equitable access to a uniform service.

3.4.2.4.2 POLICY STATEMENTS

- a) The NPHL shall be the primary national reference laboratory for the country.
- b) Laboratory tests shall be selected for each level based on their public health and clinical importance, appropriateness, cost and suitability to the work environment and the level of expertise of the service providers and users.
- c) Laboratory investigations shall be fully integrated into clinical and preventive programmes of the MOHSS and other implementers.
- d) The MOHSS shall ensure uninterrupted testing for all tests in the minimum package for the public health sector.
- e) All laboratories shall set turnaround time for all tests performed.

3.4.2.5 LABORATORY SUPPORT SYSTEMS

Laboratory supplies and equipment will be procured according to the Government of Namibia procurement guidelines and according to the standards defined at the national level. Safe and correct handling of equipment and preventive maintenance procedures will be introduced into training curricula at all levels.

3.4.2.5.1 SUPPLIES

A system for proper quantification, specification, procurement and distribution of laboratory reagents and supplies is necessary.

3.4.2.5.2 OBJECTIVE

To provide a framework that ensures availability of quality laboratory supplies are on a timely manner at facility level.

3.4.2.5.3 POLICY STATEMENTS

- a) All laboratories in the NPHLS shall implement systems to ensure adequate and uninterrupted supply of essential commodities.
- b) The NPHLS Directorate shall ensure that all laboratory consumables are appropriately validated before put in place.
- c) All laboratories shall establish guidelines on procurement procedures for laboratory equipment, reagents and supplies.
- d) Distribution of laboratory supplies shall be overseen by personnel trained in purchasing and supplies with adequate knowledge of laboratory supplies logistics.
- e) Adequate storage facilities shall be provided for laboratory supplies at national and facility level and shall conform to such standards of safety and quality as may be prescribed from time to time.
- f) Donor supply systems shall operate consistent with and in coordination with the MOHSS system so that for users the supplies are provided in a single, seamless system.

3.4.2.6 EQUIPMENT

There shall be an equipment policy in place in each laboratory to govern identification, procurement, installation, use and retirement of equipment.

3.4.2.6.1 OBJECTIVE

To provide a policy framework that ensures equipment meets set standards and the needs of the users.

3.4.2.6.2 POLICY STATEMENTS

- a) The MOHSS shall ensure that public laboratory and testing facilities are equipped according to established guidelines to perform the tests relevant to their level.
- b) All laboratories shall define the conditions for the installation, commissioning, training, use, maintenance and de-commissioning of all laboratory equipment. Donations of laboratory equipment shall conform to set standards and guidelines.

3.4.3 QUALITY AND SAFETY (INCLUDING BIOSAFETY AND BIO SECURITY)

3.4.3.1 QUALITY MANAGEMENT SYSTEM

The cost of poor quality is often much higher than any investment made to establish good quality systems in the laboratory. It is therefore important that quality management systems are available and implemented in all laboratory and testing facilities.

3.4.3.1.1 OBJECTIVE

To guide laboratories and testing facilities towards delivery of quality laboratory services and to maintain international standards of practice.

3.4.3.1.2 POLICY STATEMENTS

- a) The National Public Health Laboratory shall participate in at least one External Quality Assurance Programme (EQAP) for each of the tests it performs.
- b) The Director NPHLS shall oversee and provide an EQAP either directly to all laboratories or by defining alternative EQAP that are acceptable substitutions.
- c) All laboratories and Point Of Care (POC) testing sites shall be required to participate in an EQAP for all the tests they perform.
- d) The MOHSS in conjunction with the NPHL shall develop a National QAP appropriate for the country.
- e) The NPHLS shall develop and implement norms, standards and performance indicators for evaluating QA system.
- f) All laboratories shall work to be accredited and compliant with acceptable laboratory standards to a nationally recognised body within a timeframe to be determined by the MOHSS in conjunction with the NPHL.
- g) Internal quality control of test procedures shall be instituted and strengthened in all laboratories and POC testing sites.
- h) Standard Operating Procedures (SOPs) addressing the entire analytical cycle shall be developed and implemented by each laboratory.
- i) All laboratories shall embrace the SLMTA/SLIPTA WHO AFRO Quality Programmes.

3.4.3.2 BIO-SAFETY AND BIO-SECURITY

The risk of laboratory acquired infections is ever present in personnel handling pathogenic organisms. This risk is compounded by low awareness, lack of training and inability to adhere to recognized preventive and precautionary measures. In many countries disposal of medical waste is often not regulated. There is also a potential danger in many laboratories of unauthorised access to highly pathogenic organisms which may expose the country to malicious threats. It is therefore necessary that all laboratories take precautions to protect staff, the environment and control access to the laboratory.

3.4.3.2.1 OBJECTIVE

To develop a policy framework that promotes bio-safety, minimises exposure to pathogenic organisms to personnel, public environment and deters un-authorized access to hazardous biological material.

3.4.3.2.2 POLICY STATEMENTS

- a) The safety of the worker shall be the collective responsibility of both employer and employee.
- b) It is the responsibility of the employer to provide a safe working environment including safety equipment to all employees.
- c) All laboratory workers shall be trained and proficient in the safe handling and disposal of hazardous materials.
- d) The international laboratory safety code of practice shall be implemented at all levels of laboratory practice.
- e) It is mandatory to wear appropriate Personal Protective Equipment when handling infectious materials.
- f) Disposal of laboratory waste and hazardous products shall be regulated as stipulated in the National Waste Management Policy. Appropriate international health regulations shall be enforced concerning the import and export of food, animals, animal products, and biological products.
- g) Each laboratory shall designate a person to be in-charge of safety who shall ensure implementation of safety procedures including Post Exposure Prophylaxis.
- h) Laboratories handling highly infectious pathogens and organisms shall have systems of access control and containment that meet internationally acceptable standards.

3.4.4 LABORATORY INFORMATION SYSTEM (LIS)

The laboratory is often a source of data for patient management and public health intervention. Data that is accurate, complete and timely is critical to public health interventions including planning and outbreak response. It is therefore important that LIS is strengthened nationally to ensure support to clinical and public health programmes. Data collected at facility level is often not complete and accurate. It is important that systems are put in place to strengthen data collection, use, and management at all levels.

3.4.4.1 OBJECTIVE

To define the framework for the collection, management and dissemination of data and its use by all relevant stakeholders.

3.4.4.2 POLICY STATEMENTS

- a) The NPHL in conjunction with MOHSS shall spearhead the development of a strategic plan for the development and implementation of an integrated laboratory information and data management system.
- b) The relevant Ministries/agencies/offices shall define the data to be collected and NPHL shall develop appropriate national tools for capturing the data.
- c) All laboratory managers shall be trained and be conversant with simple data analysis for local use in planning and management.
- d) The generation, use, archiving, retrieval, access and disposal of data shall be governed by laws of the country and such regulations as determined by the MOHSS.
- e) Laboratory personnel shall be expected to maintain strict confidentiality in respect of all data.
- f) Laboratory data and information that are of public health importance (diseases, condition or events) according to the Integrated Disease Surveillance and Response (IDSR) guidelines and International Health Regulations must be communicated to the relevant authorities within the stipulated time from the time the information becomes available.
- g) A National Data Warehouse shall be established to coordinate, disseminate and share data with relevant MOHSS Departments/Divisions and other stakeholders.
- h) Hardware shall be procured and maintained according to the standards and guidelines set by the government of Namibia.

3.4.5 LEGAL AND REGULATORY FRAMEWORK

The Health Professions Council of Namibia (HPCNA) is mandated by Act of Parliament no. 20 of 1993 to regulate training, professional registration and laboratory practice for all laboratories, public and private, that test human specimens for the diagnosis of disease.

3.4.5.1 OBJECTIVE

To provide a regulatory framework for the training and professional registration of laboratory personnel, laboratory practice and observance of professional ethics in all public and private laboratories.

3.4.5.2 POLICY STATEMENTS

- a) The HPCNA shall regulate the training of medical laboratory professionals and laboratory practice.
- b) All medical laboratory professionals shall be registered and deregistered by the HPCNA.
- c) The HPCNA shall enforce and implement a code of professional ethics for all laboratory staff.
- d) There should be a national laboratory certification authority in the MOHSS to put into effect laboratory standards, regular inspections and certification of all laboratories that perform diagnostic testing of human specimens.
- e) The IPHLC will review and recommend national laboratory standards for laboratory certification that are approved for adoption by the Minister of Health and Social Services.

3.4.6 RESEARCH

Research is important to any country that seeks to understand and find solutions to its problems. However, because of competing priorities and low funding health research has often been neglected. The capacity for laboratory based research is limited to very few laboratories centrally. There are few trained laboratory scientists to support research activities. However the potential exists to build on the available capacity and enhance research activities in the country.

3.4.6.1 OBJECTIVE

To put in place an environment that will promote research and development that addresses the health priorities of the country and directly contributes to improved health care service delivery.

3.4.6.2 POLICY STATEMENTS

- a) The MOHSS in conjunction with NPHL shall promote and strengthen laboratory based research in harmony with national goals and priorities.
- b) The government shall mobilise resources for laboratory based research activities.
- c) Conduct, use and dissemination of research findings should be in conformity with National Research and Ethics Policies.

3.4.7 NETWORKING AND COLLABORATION

It is not feasible for the government to equip all laboratories to perform all the range of tests. It will be sometimes necessary to refer some tests to other laboratories within the country or outside the country. It is now recognised and proved that a country can successfully organise a disease specific or general laboratory network within the country to provide access to a range of tests to many patients. The network is also important for information and experience sharing and can be used for training laboratory personnel.

Namibia should develop a plan to provide accurate, reliable and timely laboratory testing for all national needs by laboratories within Namibia. Referral of laboratory testing outside Namibia should be necessary only in cases of previously unrecognised diseases or pandemics, no local capacity in the country or for further testing. Collaboration and linkages among laboratories within Namibia can be exploited to the mutual benefit of all. Improving the networking of laboratories will maximize the utilisation of resources, and provide support for technical and human development.

3.4.7.1 OBJECTIVE

To promote national and international networking and collaboration that will improve access to laboratory services and maximise on resource mobilisation and utilisation.

3.4.7.2 POLICY STATEMENTS

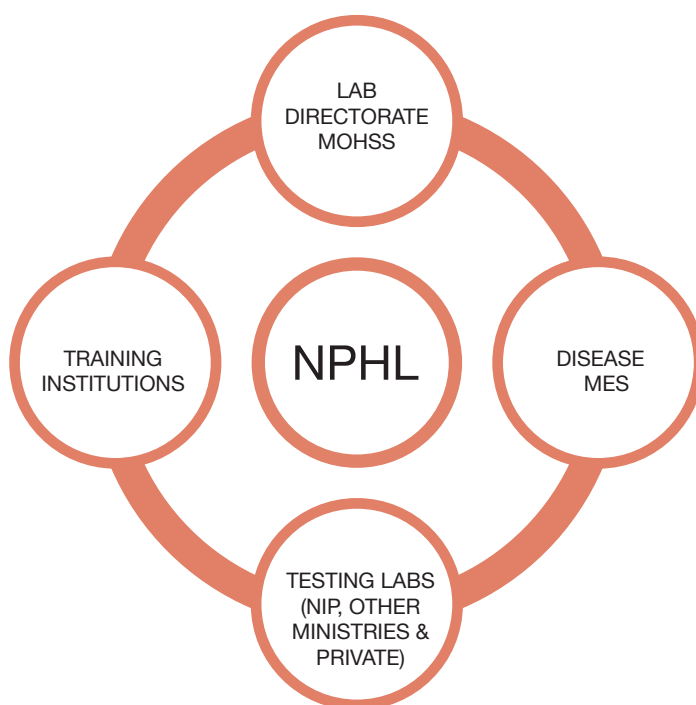
- a) The NPHL shall encourage and expand on the existing laboratory networks in order to improve access to laboratory services.
- b) MOHSS shall strengthen existing collaboration between government and local partners, private, regional, development partner agencies for the implementation of laboratory policies and standards.
- c) NPHL shall ensure that tests that can be cost-effectively performed in Namibia should not be referred outside the country for testing.

CHAPTER 4: INSTITUTIONAL FRAMEWORK FOR POLICY IMPLEMENTATION

4.1 THE NATIONAL PUBLIC HEALTH LABORATORY SYSTEM

The MOHSS, recognizing the need for strong and integrated disease prevention, control and surveillance has proposed the establishment of a National Public Health Laboratory (NPHL) in the draft Public Health Bill and has included this in the current five year strategic plan. The NPHL sitting at the centre of a National Public Health Laboratory System (NPHLS) shall provide reference testing, Quality Assurance (QA) and Continuous Professional Development (CPD) of staff. The NPHL shall be the technical arm of the Laboratory Directorate of the MOHSS in coordinating public health laboratory testing and providing reference testing facilities to district laboratories. The NPHL will coordinate the referral of samples to other laboratories outside of Namibia.

Figure 1: National Public Health Laboratory System



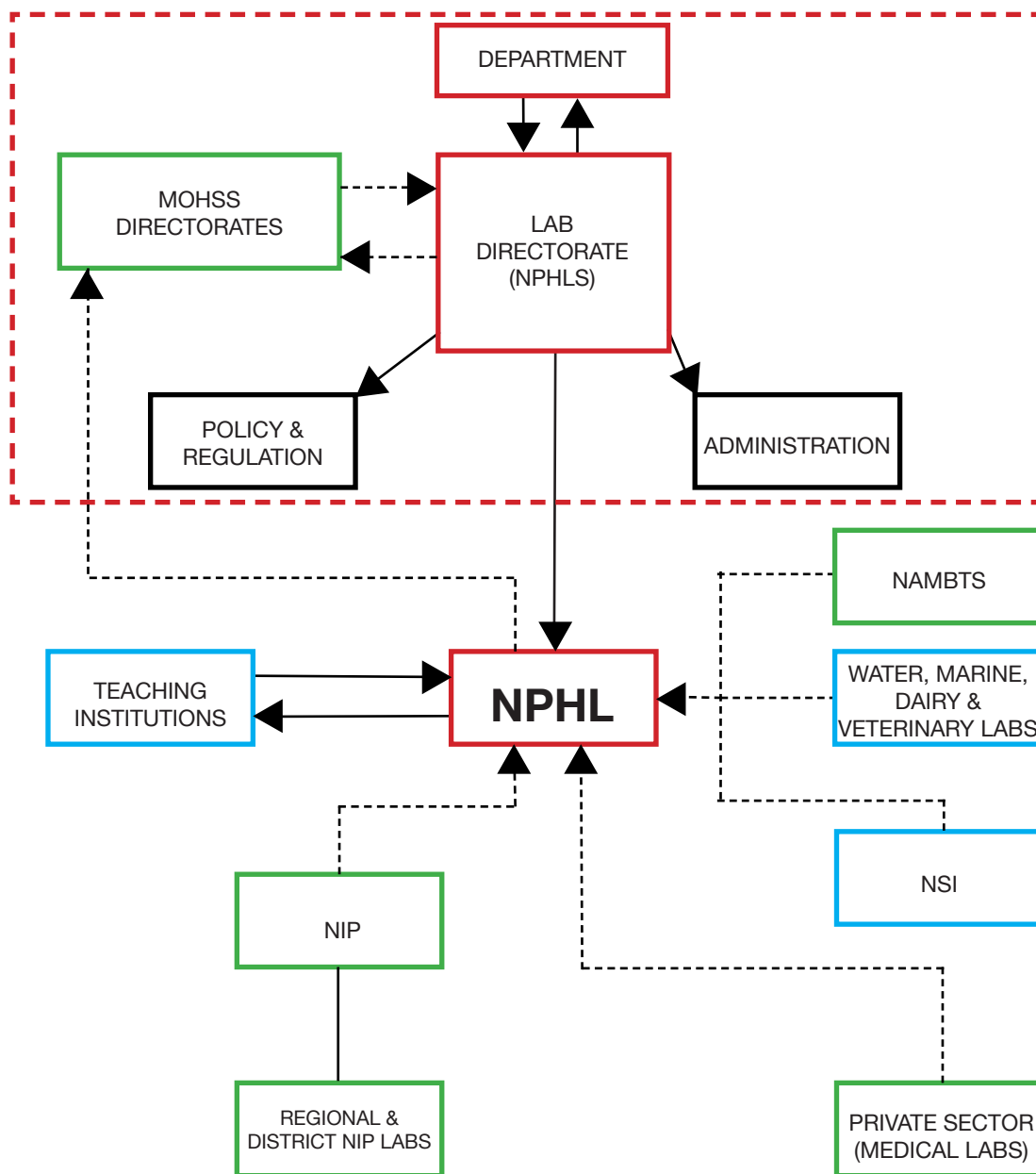
4.2 NPHLS STRUCTURE

Currently the Laboratory Sub-Division of the MOHSS has indirect oversight over NIP which operates clinical laboratories and NAMBTS. There are no structures for a coordinated and Integrated Public Health Laboratory system. This policy seeks to establish a NPHL that will be the central pillar of the system. The Laboratory Directorate will oversee the development of this system. The Permanent Secretary, with advice from the directorate, will deploy a focal person with the requisite experience in laboratory system development to drive this process. The proposed structure is as given in Fig: 2 on the next page.

The immediate tasks for the focal person, working with technical assistance, will be to;

- Develop and implement an integrated public health laboratory data management system.
- Conduct an in-depth human resource analysis for the proposed NPHL and prepare a detailed human resource development plan.
- Conceptualise and oversee the implementation of the project for the establishment of a functional NPHL.

Figure 2: NPHL Structure



4.3 CORE FUNCTIONS OF THE PUBLIC HEALTH LABORATORY

- **Treatment and Monitoring:** Provide clinicians with accurate and timely laboratory results for initiation of appropriate treatment and monitoring of treatment outcomes (NIP and Private Laboratories).
- **Disease Prevention and Control:** Provide accurate and timely laboratory results to identify disease causative agents and guide effective public health interventions.
- **Surveillance:** Facilitate better understanding of disease, microbial and other outbreak patterns and trends to guide public health planning, policies and programme initiatives.
- **Laboratory Information Systems:** Support data management that will provide timely, sound evidence based data sets from epidemiological surveys, health information systems, and monitoring of an integrated laboratory delivery reporting system to support decision making, programming and formulation and implementation of policy in a cost-effective manner.
- **Disease Outbreaks:** Identification and characterisation of unusual disease occurrences to facilitate appropriate and timely response and the implementation of prevention and control measures.
- **Research and Development:** Undertake operational research and support research in health sector by providing laboratory based evidence and data.

- **Forensic and other Laboratory Investigative Services:** Providing medico-legal expert advice in understanding the causes of unexplained death.
- **Human Resource Management:** Supporting national strategies with innovative approaches to work force planning and development, use of human resource information systems, pre-service and in-service professional training, leadership and management development, task-shifting, performance assessment and quality improvement and the development of effective recruitment and retention policies.
- **Health and Safety:** Maintaining the health and safety of personnel directly involved and the public at large with a safe handling and disposal strategy and processes that protect the environment and prevent any improper or illegal use of biological agents.
- **Food, Water and Environment:** Monitoring food, water and the environment to ensure they meet national and international quality and standards and are free from any contaminants injurious to human health.

4.4 ROLES/FUNCTIONS OF NPHLS COMPONENTS

In order to make the NPHLS functional each of the identified components of the system shall play the following roles and functions. These roles and functions shall be expanded as the system matures and is fully developed. In particular the functions of the National Public Health Laboratory (NPHL) shall be expanded to cover its full scope as defined in this policy.

4.4.1 MOHSS

- Strengthen the Laboratory Directorate to develop and manage the NPHL System.
- Mobilise resources for the development and operations of the NPHL System.
- Facilitate interdepartmental coordination within the Ministry of Health and Social Services.
- Facilitate the establishment of an Inter-Ministerial coordination mechanism for all Ministries undertaking public health laboratory related activities.

4.4.2 LABORATORY DIRECTORATE

- Establish the NPHL.
- Organise, manage and coordinate the NPHL System.
- Disseminate laboratory data and information to relevant arms and programmes of the MoHSS and stakeholders.
- Provide policy and strategic direction for the development and operations of the NPHL System.
- Implement the Laboratory Policy and Strategic Plan.
- Set standards for the regulation, inspection and licensing of laboratory facilities.
- Oversee the introduction and use of Point of Care testing in the country.

4.4.3 INTEGRATED PUBLIC HEALTH LABORATORY COMMITTEE

- Provide technical advice and support to the Medical Laboratory Division.
- Act as a coordinating body for stakeholders involved in public health laboratory activities.
- Advocate for the promotion and resource mobilisation for the NPHL System.

4.4.4 TRAINING INSTITUTIONS

- a. Provide pre-service training of laboratory staff.
- b. Develop training programmes for laboratory staff.
- c. Provide Continuous Professional Development (CPD).
- d. Conduct public health laboratory related research.
- e. Provide specialised testing services on request from NPHL.

4.4.5 NAMIBIA INSTITUTE OF PATHOLOGY

- a. Provide diagnostic testing for the public sector.
- b. Develop and provide diagnostic services and routine testing at district laboratories.
- c. Provide a system for referral and transportation of samples from their laboratories to NPHL.
- d. Collect and transmit public health laboratory data to the central repository.
- e. Provide specialised testing services on request by the NPHL.
- f. Support Continuous Professional Development (CPD) of laboratory professionals.

4.4.6 NATIONAL STANDARDS INSTITUTE (NSI)

- a. Provide calibration services to the NPHLS.
- b. In collaboration with the NPHL set standards relevant to laboratory operations.
- c. Inspect and certify laboratory equipment and apparatus.

4.4.7 PRIVATE SECTOR LABORATORIES

- a. Collect, collate and transmit public health laboratory data to the central depository.
- b. Refer relevant public health laboratory specimens to the NPHL for further testing.
- c. Provide specialised testing on request by the NPHL.

CHAPTER 5: POLICY ANALYSIS

5.1 RISK ASSESSMENT

There are no risks or conflicts that are immediately discernible resulting from the approval of this policy. In particular:

- a) This policy has not dealt with regulatory issues that are clearly addressed under the relevant Acts establishing the NIP and the Allied Health Professions Council of Namibia.
- b) The policy provides general overarching statements that are adaptable to changing political, economic and technological circumstances. The policy directs the establishment of standards and norms to be implemented. It is envisaged that the development of these standards will take cognizance of the economic and technological situation in the country.
- c) The policy has been aligned to the Health Policy Framework (2010-2020) and seeks to create a framework that supports the implementation of all health sector policies. The policy is amenable to continuous evaluation and review to address emerging issues and changing circumstances.
- d) The policy has been made broad enough to include all stakeholders involved in laboratory service delivery while ensuring that laboratory practice meets the minimum standards for quality and safety and is accessible to all.

5.2 RESOURCE IMPLICATIONS

The establishment and operation of a NPHLS, including a Public Health Laboratory Network (PHLN) is normally a resource intensive undertaking because the immediate results of a public health laboratory, when compared to a clinical laboratory, are not immediately discernible there is a tendency to neglect investment in PHLN in favour of the clinical laboratories.

5.3 FINANCIAL RESOURCES

Funding for the PHLN, often externally sourced, is directed to meet the needs of disease programme management and aligned to meet international disease reporting obligations. This skewed investment is more pronounced where a NPHLS does not exist or is weak resulting in lack of policy direction, coordination and monitoring:

- a) The setting up of an integrated Laboratory Information Management System that responds to the needs of the laboratory and other MOHSS programmes.
- b) The construction of the NPHL, procurement of equipment and laboratory supplies.
- c) The training and retention of skilled laboratory professionals and their deployment to rural facilities.

The decision for Namibia to set up a NPHL is informed by this need and will seek to redirect existing and future resources towards meeting the NPHLS priorities and needs. While the NPHL may directly mobilise resources for its operations, it shall be the responsibility of the MOHSS to ensure the NPHL has adequate funding to meet its national obligations.

The Director of the NPHL shall be given authority to expend any funds according to an approved budget and following government guidelines on the use and accounting of public funds.

5.4 HUMAN RESOURCES

Presently, there exist within the NIP and in some private laboratories technical skills for some of the diseases of public health importance. These skills range from simple microscopy and POC testing to more complex molecular testing techniques. However, these skills are currently fully engaged in providing diagnostic services at their facilities and are unlikely to be available to the NPHL.

The NPHL will require both technical and managerial skills in developing, coordinating, managing and providing testing services for the public health system. Some of these skills can be acquired locally while for some skills there will be need for training outside Namibia. A more comprehensive Human Resource (HR) analysis for the NPHL will be undertaken to determine the needed human resources and skills over time till the NPHL is fully functional. A programmed development of these human resources will then be implemented.

5.5 INFRASTRUCTURE RESOURCES

The NPHL, which does not currently exist, will have to be developed. This will require the construction of purposely designed infrastructure and the equipping of the laboratories.

Over the next two years several activities will be undertaken to ensure the realisation of a functional NPHL. These activities will include:

- a. Project proposal submission and approval by the National Planning Commission (NPC).
- b. Allocation of land for the construction of the NPHL.
- c. Project design and costing.
- d. Identification and earmarking of financial resources for the design and construction of the NPHL.
- e. The identification, procurement and installation of required laboratory equipment.

This policy seeks to provide a structured framework to ensure that implementation produces the desired effects. The required resources (financial, infrastructural and human) will be quantified in the strategic and operational plans of the NPHL.

CHAPTER 6: MONITORING AND EVALUATION

This policy seeks to create a functional NPHLS that supports appropriate patient management and timely public health interventions. The successful implementation of this policy should result in quality laboratory testing and generation of data for use by disease prevention and control programmes of the MOHSS. The NPHLS will therefore have impact on the general health of the population and in particular reduce morbidity and mortality.

The implementation and monitoring of this policy will depend on the stewardship provided by the MOHSS. The leadership required to oversee the policy will therefore need to be of a sufficiently high and strategic position within the MOHSS to provide the leverage necessary to interact with and support several ministry divisions and the private sector. A leadership at the directorate level will be an appropriate position to produce any impact. The establishment of the NPHLS Directorate with sufficient resources and authority will be an indicator of success as will be the certification of competence of all laboratory practitioners.

The Health Laboratory Strategic Plans with accompanying Operational Plans that will be the vehicles for the implementation of the policy that will be monitored using agreed national indicators. The following milestones will provide indication on the progress of implementation:

- a. Establishment of NPHLS Directorate.
- b. Establishment of an Integrated Data and Quality Management Systems.
- c. Establishment of a fully functional NPHL.
- d. Development and establishment of National PHLN.

CHAPTER 7: KEY IMPLEMENTATION PHASES

PROPOSED BUDGET FOR THE NPHLS 2013/2014 FINANCIAL YEAR					
ACTIVITY	Q1	Q2	Q3	Q4	ESTIMATED COST N\$
Development of architectural engineering plans for NPHL design and management	X	X			1,630,000.00
Identify and renovate existing laboratory space - Referral and Database Management		X	X	X	10,800,000.00
Establish qualifications of NPHL Director, recruitment of highly qualified Public Health Scientists			X	X	4,000,000.00
Establish organisation, recruitment of laboratory technical and support human resources, equipment and supplies, and identify vehicle needs			X	X	3,500,000.00
Operations	X	X	X	X	400,000.00
PHASE (2) 2014/2015 FINANCIAL YEAR					
	Q1	Q2	Q3	Q4	
Operations	X	X	X	X	400,000.00
Land purchase, develop and implement plan for construction	X	X	X	X	14,200,000.00
Establish drug sensitivity testing capacity	X	X			4,260,000.00
Design and implement a Lab Information System and Database that enables real time tracking of disease events			X	X	2,100,000.00
Stepwise implementation of core functions finalisation of human resource recruitment and equipment procurement				X	2,500,000.00
TOTAL					43,790,000.00

GLOSSARY

Laboratory – Any facility where health laboratory analysis and investigations, ranging from simple to complex, are carried out and may include training facilities.

Public Health Laboratory – Any laboratory that analyses samples (human, animal, food, water, drinks, environment or other sources) whose results will be used to safeguard the health and safety of the population including the prevention, management, control of diseases and outbreaks including other public health events.

Point of Care (POC) – Any medical laboratory testing done, often close to the patient, to provide test results, for immediate clinical management decisions.

Testing Facility – Any facility in which laboratory analysis is carried out to provide test results for a clearly defined task such as Voluntary Counselling and Testing (VCT), surveillance etc.

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