

# Guidance for Development of National Laboratory Strategic Plans

Helping to Expand Sustainable Quality Testing to Improve the Care and Treatment of People Infected with and Affected by HIV/AIDS, TB and Malaria

- World Health Organization – Geneva
- World Health Organization Regional Office for Africa
- United States Centers for Disease Control and Prevention
- Association of Public Health Laboratories



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| <b>TABLE OF CONTENTS</b>  |    |
|---|----|
| INTRODUCTION  | 6  |
| EXECUTIVE SUMMARY   | 7  |
| PURPOSE OF DOCUMENT   | 8  |
| Scope of document   | 8  |
| Intended audience   | 8  |
| Introduction  | 8  |
| How to use this document  | 8  |
| Strategic objectives of this document   | 9  |
| Table 1: Central Core Group Leading Development of National Laboratory Strategic Plan | 10 |
| BACKGROUND  | 11 |
| The need for comprehensive, quality laboratory services                               | 11 |
| HIV/TB/malaria as a vehicle for integrated laboratory service                         | 12 |
| PLANNING CONSIDERATIONS   | 13 |
| Defining a vision and mission   | 13 |
| Setting objectives  | 13 |
| Principles  | 14 |
| Leadership  | 15 |
| Resources to assist the development of National Laboratory Strategic Plans            | 15 |
| Analysis of the national laboratory system  | 15 |
| Structure of the national laboratory system   | 16 |
| Different levels of service – a tiered system   | 16 |
| Table 2: Review of Current System Structure   | 17 |
| Committees required   | 18 |
| Standard operating procedures and referral processes                                  | 19 |
| Standardization   | 19 |
| Tests to be performed   | 20 |
| Quality management  | 20 |
| Management and business systems   | 21 |
| Training  | 21 |
| Career paths delineated   | 22 |
| Financing the Plan  | 22 |
| Current global role players in laboratory support                                     | 23 |
| Guidelines for involvement of development players                                     | 23 |
| Communications plan   | 24 |
| Data management   | 24 |
| Monitoring and evaluation (M&E)   | 25 |
| Legal considerations  | 25 |

|  |    |
|--|----|
| PROPOSED ROADMAP   | 26 |
| Where to start   | 26 |
| Appropriate expectations regarding staging   | 26 |
| Consultation steps   | 26 |
| 1: Initial core leadership   | 26 |
| 2: Engagement with national stakeholders   | 27 |
| 3: Engagement with key global development partners   | 27 |
| Table 3: National Plan Development Stakeholders  | 28 |
| Table 4: International Partners  | 29 |
| 4: Large consultative forum  | 30 |
| 5: Providing sufficient detail to the draft Plan through a series of smaller task group meetings | 30 |
| 6: The final draft Plan  | 31 |
| Adoption and inclusion in National Health Plans  | 31 |
| Fundraising and implementation   | 31 |
| CONCLUSION AND REFERENCES  | 32 |
| APPENDICES   | 33 |
| Acronyms and Glossary  | 33 |
| Maputo Declaration   | 34 |
| National Laboratory Strategic Plan Development Checklist   | 36 |
| Laboratory Services National Strategic Plan  | 37 |

# Introduction

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At a consensus meeting of major stakeholders, held 22-24 January 2008 in Maputo, Mozambique, participants agreed to recommendations for laboratory standardization and harmonization that were published as “Consultation on Technical and Operational Recommendations for Clinical Laboratory Testing Harmonization and Standardization (The Maputo Declaration.)” Energized by the strong agreement found among the international laboratory community at the Maputo meeting, new initiatives to strengthen laboratory infrastructure have begun, such as laboratory networking and accreditation. With the growing interest and commitment for supporting laboratory infrastructure, countries and international agencies also have recognized the need to develop and maintain current, comprehensive national laboratory policies and strategic plans to guide the effective development and continual improvement of laboratory organization, capabilities, capacities, workforce and resources.

This document is based on sound theoretical principles tempered by the practical experience of working with national health authorities in the development of comprehensive national laboratory strategic plans. As with the Maputo Declaration, a broad array of major stakeholders provided input into the final version of this “Guidance for Development of National Laboratory Strategic Plans.”

As the international laboratory community has become more collaborative, the role of laboratory services has been made clearer and the importance of laboratory testing services for improved health is now more appreciated. The national leaders who have pledged their commitment to the strengthening of laboratory systems in a coordinated and standardized approach have enabled the many committed international partners to work together effectively on shared goals that support national health plan priorities. This guidance document is another forward step following the Maputo Declaration. It is a tool that can aid further progress in the development of strong, sustainable laboratory infrastructures for all countries so that all citizens can have access to quality laboratory services.

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# Executive Summary

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This document provides guidance for the development of a national laboratory strategic plan (NLSP), a necessary tool for strengthening laboratory services. Laboratory capability and capacity is critical to effective primary care, treatment and prevention. Laboratory testing identifies the cause of disease, and provides data for surveillance of diseases and early detection of emerging problems to guide an effective response to health threats. The importance of access to quality laboratory services to promote health is well recognized and the goal to establish laboratory-based surveillance in all WHO member countries was established by the International Health Regulations of 2005.

Recent consensus meetings (Maputo Declaration on Strengthening of Laboratory Systems and the WHO/AFRO Regional HIV/AIDS Public Health Laboratories Network Dakar Report) have provided advocacy and strategies for effective means to strengthen national laboratory networks. With increased demands for quality laboratory services and growing international donor support, the development of current, comprehensive NLSP is ever more essential for management of resources and guiding annual operating plans to achieve sustainable laboratory capacity as an integral part of a national health plan.

There are many important considerations for the development of NLSPs. Issues to be addressed include technical, legal, quality, financial and logistical matters. Logically, NLSPs will differ among countries because of fundamental differences in and varying levels of infrastructure, human capacity, financial resources, and levels of engagement by the international community.

This document is a guidance tool for country leaders for the development of a NLSP and provides information on organizations available to support countries with technical expertise and funding. This document is not prescriptive, but rather provides options and suggestions for a process to facilitate buy-in that is important for success in development of a plan that can form the basis for harmonized planning and realistic annual operational plans. A politically supported NLSP is a crucial component of efforts to improve laboratory support for clinical facilities and public health needs, and thereby improve health care and health. This document exploits the recent experience gained in the use of strategic planning tools developed in support of the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) in countries in sub-Saharan Africa.

# Purpose Of Document

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## **Scope of document**

The scope of this document is broad given that the development of laboratory capacity within developing countries is a long-term endeavor that requires the support of many sectors of society and government.

The document provides direction on the complex matrix of influences at the national and international level required to build laboratory capacity, including in-country stakeholders, multilateral agencies, donors, the private and public sectors, communities, and others.

## **Intended audience**

This document is designed to support and offer guidance to the national core group leading the efforts to strengthen laboratory systems, and the wide-ranging and large number of individuals and organizations within the country who are stakeholders in the process.

## **Introduction**

Adequate, quality laboratory services are essential to ensuring that communities receive appropriate and effective clinical care and government agencies have sufficient data and information to prevent disease and advance health. Despite recent major efforts to improve laboratory services, the laboratory systems of most developing countries remain inadequate to meet priority needs. There is an urgent need to develop effective National Laboratory Strategic Plans to provide a logical basis for effectively using limited resources to strengthen laboratory systems, as an integral part of strengthening overall health systems of resource limited settings. This document is a direct response to a recommendation of the January 2008 "Consensus Meeting on Harmonization and Standardization of Laboratory Tests and Equipment for HIV/AIDS, Tuberculosis and Malaria" and the call to action to advocate for adequate laboratory capacity in resource limited settings (Appendix–Maputo Declaration).

## **How to use this document**

1: This document can be used as a guide to develop or update a National Laboratory Strategic Plan. It should be used as one of the resources in a national process that involves participation of all stakeholders. Sections of the document identify global partners and organizations involved in laboratory work that can offer assistance, including valuable collaborations and funding support.

2: The senior health official should appoint a national laboratory leader, who will chair the small core leadership team and associated secretariat to drive the process of developing the National Laboratory Strategic Plan (hereinafter, the Plan or NLSP). The leadership may come from any one of the groups described below, but typically is chaired by a senior government official or national laboratory leader within the country. The leadership driving the development of the Plan may choose to use an expert laboratory management consultant to manage the overall process and provide experience on development of NLSP laboratory practice and management as well as insights into global partnerships.

Importantly, the chosen leader and leadership team responsible for developing the NLSP should have the support of involved sectors, and access to key decision makers. Leadership must involve as many stakeholders as possible during the Plan development.

3: The Plan should be a document that matures, evolves and is updated at least annually to respond to such issues as:

- Changes in disease burden
- New technology
- Cost benefit of technology advancements
- Government and donor support levels
- Clinical indications for diagnosis and monitoring
- Human resource requirements and HR capacity development
- Degree of testing that occurs outside of the traditional laboratory setting, for example VCT and mobile clinics

### **Strategic objectives of this document**

This document:

- Describes a general process for developing a consensus Plan.
- Defines possible roles and responsibilities of the different sectors within the country in developing the Plan.
- Identifies organizations that can assist the process.
- Provides insights into key considerations that are relevant to the Plan.

This document is not meant to prescribe how countries develop a Plan, nor is it a complete information package on the state-of-the-art requirements for laboratories. This document offers options and general overviews of specific areas and strategic considerations for development of a sound plan. It does not provide guidance on implementation of the Plan. However, planning for how strategic initiatives will be implemented in annual operating plans and through other means is a responsibility of the core leadership team that is essential to success of the Plan's goals and objectives.

| <b>TABLE 1: CENTRAL CORE GROUP LEADING DEVELOPMENT OF NATIONAL LABORATORY STRATEGIC PLAN</b>   |
|--|
| <b>REPRESENTATIVES OF GOVERNMENT</b>   |
| <b>MINISTRY OF HEALTH</b>  |
| The Ministry of Health should be the lead agency for development of the Plan.  |
| National directorate (if any) managing the existing service laboratories   |
| National commissions (if any) on major diseases and programs, such as HIV, tuberculosis (TB), malaria, Expanded Program for Immunization, diarrheal diseases and food safety   |
| Heads of bodies set up to register and monitor notifiable diseases   |
| Heads of clinical divisions within the Ministry  |
| Heads of relevant administrative departments including finance, procurement, supply chain management, and human resources  |
| <b>MINISTRY OF EDUCATION</b>   |
| The Plan must engage the higher education sector that governs training of the laboratory, medical and allied health workforce.   |
| <b>MINISTRY OF FINANCE/TREASURY</b>  |
| The Plan requires high-level support from Treasury to develop a financial plan that integrates the national budget and donor funds.  |
| <b>MINISTRY OF DEFENSE</b>   |
| The Ministry of Defense is often a major service provider of health care for the armed forces and their dependents.<br>The Defense Force may also be involved in health care provision for the broader community and have access to donor funding. |
| <b>OTHER MINISTRIES</b>  |
| Depending on the organizational and political environment, other ministries may be included such as foreign affairs or transportation.   |
| <b>REPRESENTATIVES OF PUBLIC SECTOR LABORATORIES</b>   |
| The head (or representative) from the National Reference Laboratory  |
| Each tier should be represented and consideration given to geographical/regional representation.   |
| <b>REPRESENTATIVES OF PRIVATE SECTOR LABORATORIES</b>  |
| Involve key players to leverage potential public-private synergy.  |
| <b>REPRESENTATIVES OF CLINICAL HEADS OF HOSPITALS</b>  |
| The laboratory's clinical counterparts who are the primary users of services   |
| Knowledgeable clinical practitioner leaders who through experience understand the true clinical needs of the country   |
| <b>REPRESENTATIVES OF MISSION HOSPITALS/LABORATORIES</b>   |
| <b>REPRESENTATIVES OF NON-GOVERNMENTAL ORGANIZATIONS</b>   |
| <b>REPRESENTATIVES OF RESEARCH GROUPS AND PRACTITIONERS</b>  |
| <b>A GOOD NATIONAL LABORATORY SERVICE WILL ENGAGE WITH, AND SUPPORT RESEARCH AIMED AT IMPROVING CLINICAL OUTCOMES.</b>   |
| Laboratory research groups concerned with defining laboratory quality indicators (safety, effectiveness, efficiency, and timeliness)   |
| Clinical research groups interested in accessing laboratory services   |
| Contract research organizations, clinical and public health laboratories, and data management groups   |
| <b>REPRESENTATIVES OF REGULATORY OVERSIGHT BODIES</b>  |
| <b>NATIONAL REGULATORY BODIES ARE VITAL TO THE DEVELOPMENT OF A NATIONAL LABORATORY STRATEGIC PLAN.</b>  |
| Regulators who give approvals for diagnostic and prognostic tests and regulate use within country  |
| Institutional review committees (ethics committees) that authorize research protocols involving human subjects   |
| Biosafety committees that deal with waste disposal.  |
| If there are gaps and weaknesses in the existing regulatory infrastructure, the core leadership team should seek advice from consultants so that objective strategic actions to address gaps are included in the Plan.                             |

# Background

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## **The need for comprehensive, quality laboratory services**

Many countries have a significant endemic disease burden, with HIV/AIDS, TB, malaria, diarrheal and respiratory diseases contributing the majority of morbidity and mortality. The effectiveness of clinical care is improved by adequate access to quality laboratory testing. Treatment and prevention of the majority of significant illnesses can be improved by laboratory confirmation of the diagnosis, laboratory monitoring of the patient after the diagnosis has been made and surveillance to monitor trends in morbidity and mortality. Without appropriate, high quality laboratory support to patients and laboratory-based surveillance for public health, significant illnesses cannot be managed optimally and public health programs cannot be maximally effective.

Laboratory services for clinical medicine and public health functions in resource-limited settings carry a double burden of administering to communities with a very high burden of diverse diseases requiring varying levels of laboratory sophistication and functioning with sub-optimal resources. Resource-constrained laboratories often have to make compromises that limit access to best-practice testing services for treatment, and reduce the effectiveness of the fight against the burden of human diseases including HIV/AIDS, TB, and malaria.

While TB and malaria have long been a major problem for health care systems, HIV/AIDS has added an additional level of suffering, and it is clear that many laboratories cannot adequately address the increased need for diagnosis and monitoring of HIV infection. In addition, as greater access to adequate treatment is achieved, the management of many other chronic diseases becomes ever more important. Communities are affected by many chronic non-communicable diseases, such as hypertension, cerebrovascular accidents, diabetes, pulmonary disease, and neoplastic diseases. Life-saving drugs are enabling people living with HIV/AIDS to have longer productive lives and require increased laboratory monitoring of patients over many years. Although these diseases have major consequences for individuals and the healthcare system, countries find that raising interest from international development partners for funding to support clinical and laboratory infrastructure for these chronic diseases is difficult.

Further, the introduction of drugs requires laboratory monitoring for drug resistance as well as adverse reactions to the treatments. Laboratory services are necessary to assure efficacy and safety of treatments such as promoted by the WHO Collaborating Centre for International Drug Monitoring.

### **HIV/TB/malaria as a vehicle for integrated laboratory service**

It is evident that diagnosing and treating the high prevalence communicable and infectious diseases, namely HIV/AIDS, TB and malaria, requires significant laboratory support that is not widely available in most resource limited settings. Integrated laboratory support for all diseases should be country-wide and accessible to all communities.

These three major diseases have attracted significant donor funding streams, and it is possible in many countries to put a comprehensive package of support, treatment and care in place to serve highly affected communities.

Proper management of HIV/AIDS, TB, and malaria requires a comprehensive network of supporting laboratories, and access to a range of laboratory tests, including microbiology, virology, immunology, and clinical chemistries. Because building capacity for these laboratory tests is not necessarily specific for HIV, TB or malaria care, a Plan should look at funding streams for HIV, TB and malaria care as a legitimate and cost-effective basis for leveraging improvements to the entire laboratory infrastructure to support management of other diseases. Laboratory resources, especially advanced instrumentation, should be used across disease-specific programs, not designated for single disease use.

# Planning Considerations

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This section deals with a variety of activity areas and themes that should be considered by a country when developing the Plan. The section does not provide an exhaustive list of topics nor a complete description of each aspect. More complete descriptions of the issues addressed in this section can be found in various other documents, journals, and publicly available publications. In addition, it is prudent to keep abreast of changes in the constantly evolving field of laboratory medicine, management, and policy.

## **Defining a vision and mission**

The Plan should define a vision and mission for the national laboratory system. The manner in which these are developed depends on which structure is proposed. For example, if there is a separate structure proposed for the national laboratory infrastructure and operations, the vision and mission will be worded differently than if the laboratories are integrated throughout each tier of the clinical laboratory system of the Ministry of Health. The organization should carefully articulate the vision and mission, as the success or failure of the Plan will depend on the clarity of these statements and the ability of leaders to advocate and influence both those within the laboratory system to work in harmony and external stakeholders to support and use the system.

Generally, a **vision statement** expresses what the organization aspires to, and gives an overarching definition of where the future lies for the entity. It is a longer narrative than the mission statement and provides a cogent explanation of the future for the laboratory system.

A **mission statement** is concise and succinctly describes what the organization does, why it exists, who it serves and how it does its work. A mission statement must be understood at all levels of the system and provide a compelling explanation of the greater purpose of the organization.

## **Setting objectives**

The importance of defining appropriate country strategic objectives for the Plan cannot be over-emphasized. Agreement on objectives is a critical early step, as the entire process should flow from these objectives. The objectives will vary among countries, as they will in part be influenced by disease prevalences and the current situation of the available in-country capacity, infrastructure, and systems.

Major components or themes of laboratory systems for which objectives have been developed in previous country Plans include:

- Infrastructure development and organizational structure
- Training and retention
- Quality management systems

- Supply chain management of commodities and standardization of testing/test and equipment maintenance
- Referral systems for sample transportation
- Regulatory framework

The careful negotiation of a limited number of country objectives for each theme area is key to successful implementation but takes time and skill. Each sector will attempt to influence the Plan to its own best interest. This behavior is typical and can be positive, provided that it is understood and moderated by the Ministry of Health to ensure that the Plan favors the best overall interests of the country.

The setting of objectives must be based on certain considerations.

- Too many objectives can be a hindrance to effective implementation. Three to five objectives for each major component or theme of the laboratory system are usually adequate. These become the basis for all that is to follow. It is crucial that participants understand the difference between an objective and its associated work plan.
- The objectives should be rigorously scrutinized to ensure that they are based in reality “on the ground.”
- The objectives should be feasible within the timeline of the Plan, not be long-term aspirations, and should stimulate progress on major issues that will make a difference in health.

## **Principles**

There are two sets of discrete but overlapping principles to consider in the planning process. As core principles these should be developed by consensus with the broadest possible involvement of stakeholders. The two are;

- Principles that guide the development of the Plan.
- Principles that guide implementation of the Plan.

Principles chosen for the development of the Plan should consider unique aspects of the country as well as the universal values of:

- **Inclusiveness** – All stakeholders are involved.
- **Participation** Every relevant group participates meaningfully throughout the process.
- **Consultation** – Relevant individuals, government departments, national and international organizations are meaningfully consulted in the process.

Principles established for the implementation of the Plan are also critical to success, and these include:

- **Commitment** – The Ministry of Health should approve, and other government agencies should support consensus recommendations that evolve in the planning process for policy, institutional organization of the national laboratory system and priority goals.
- **Continual process** – The Plan should be governed by a process of continuous improvement.

## **Leadership**

The Plan should address the organizational structure and culture of the national laboratory system. The organizational structure discussion must start within the Ministry of Health. In addition to political leadership offered by the Minister, there should be a dedicated directorate (or division) within the Ministry led by an experienced individual knowledgeable of laboratory issues, who is responsible for the laboratory system. The organizational structure should ensure that each area of the country has an adequate number of knowledgeable and competent personnel. Heads of major laboratories should have access to decision makers within the laboratory directorate of the Ministry of Health. Well-structured leadership and management are critical to ensuring a properly functioning laboratory system.

The leadership structure should identify the major areas of the laboratory system that require oversight. In addition to a Ministry-level leader, there should be leadership levels with well-defined roles and responsibilities at all levels of the national laboratory system. The tiered structure of the entire national laboratory service should be reflected in the management structure.

Along with the organizational structure, leadership should be addressed in the Plan. While leadership styles differ, the characteristics expected of those in senior positions can be delineated to support the organizational culture that is sought for a national laboratory system. A Plan should accommodate different cultures, such as those associated with service delivery, education, and business models of the country in relationship to their intersection with the laboratory system. The integration of these cultures will require negotiation.

## **Resources to assist the development of national laboratory strategic plans**

The development of an effective Plan is a process that will take a significant effort by the core leadership, and will require considerable financial and administrative support. The later sections of this guidance document provide suggestions on possible development processes.

The Government, most often the Ministry of Health, is best positioned to provide financial and administrative support for the NLSP as any Plan developed must be part of the National Health Programs. However, the government should also leverage existing relationships with international health and development agencies with a vested interest in providing financial and technical assistance to develop and implement a Plan that results in improved laboratories.

## **Analysis of the national laboratory system**

The development of a Plan requires the organization of a significant amount of technical detail. A crucial step is to conduct a thorough review of the current system in the form of a SWOT—strengths, weaknesses, opportunities, and threats. The SWOT analysis should include descriptions of what already exists within the country and projections for many areas, including the list contained in Table 2. The technical analysis will almost certainly require the input of full-time staff and consultants. Each involved professional or

team of professionals will need precise terms of reference to ensure completion and limited overlap. Each team may be considered as a technical committee supporting development of the Plan.

The technical details should be developed in committees that are established for this purpose, or generated by outside consultants working in conjunction with technical committees and in-country stakeholders. It is crucial that accurate technical details are available for determining the future systems and structures.

### **Structure of the national laboratory system**

The Plan should address the issue of how well structured the national laboratory system is currently, and what is required to improve service delivery. This requires an analysis of user needs in the clinics, and an assessment of what the major diseases are within the country. The analysis should also include other diseases that are important to diagnose and monitor. Results of the assessments will be used to determine an optimal tiered laboratory system that reflects varying levels of service sophistication according to a predetermined schedule and to provide the Ministry of Health (MOH) with sufficient information to implement, monitor, and evaluate public health programs and the health of the public.

### **Different levels of service – a tiered system**

The Plan should describe a well-structured laboratory system with multiple tiers of laboratory service. In this system, regional laboratories attend to local clinics that perform simple and more regularly requested sample analyses, while referral centers have a higher level of laboratory structure and perform more specialized tests, or those tests which are requested less frequently. Attention must be given to the transport of samples, tracking of samples referred in the system and return of test results to the correct site for patient management.

#### ***Primary care level***

The vast majority of primary care laboratory tests conducted on blood (or urine) can be performed in laboratories that are run from peripheral health centers where rapid tests can be carried out by non-laboratory trained healthcare workers who report results back to clinical colleagues.

The laboratory tests that are conducted and required at these primary care laboratories must be carefully described in the Plan.

| <b>TABLE 2: REVIEW OF CURRENT SYSTEM STRUCTURE</b>   |                                  |                                  |
|--|----------------------------------|----------------------------------|
| <b>STRUCTURE</b>   |                                  |                                  |
| Current governance structure and desired structure, if different. Organizational structure and reporting relationships (organogram)                            |                                  |                                  |
| Delineation of different levels within the tiered laboratory network, including referral structures, centers of excellence and national reference laboratories |                                  |                                  |
| Laboratory management  |                                  |                                  |
| <b>INFRASTRUCTURE</b>  |                                  |                                  |
| What is available, and what is needed  |                                  |                                  |
| Buildings, capital equipment   |                                  |                                  |
| Electricity, water sources, ventilation, etc.  |                                  |                                  |
| Waste disposal   |                                  |                                  |
| How well aligned to public health care needs   |                                  |                                  |
| Full assessments of laboratories, which should include but not necessarily be limited to:  |                                  |                                  |
| » organograms  | » general laboratory supplies    | » quality systems                |
| » physical conditions  | » sample transport and storage   | » staffing                       |
| » equipment and maintenance  | » data management                | » education and training records |
| » reagents and consumables   | » office space                   | » information systems            |
|  | » education and training records |                                  |
| <b>HUMAN RESOURCES</b>   |                                  |                                  |
| Current and required laboratory and non-laboratory staff   |                                  |                                  |
| Managerial knowledge, skills, abilities of laboratory heads  |                                  |                                  |
| Salary structures  |                                  |                                  |
| Relationship with universities and technical colleges  |                                  |                                  |
| <b>FINANCES</b>  |                                  |                                  |
| Current funding, sources and process for requests and allocations  |                                  |                                  |
| Funding required to implement the Plan   |                                  |                                  |
| Financial systems for supporting a new National Laboratory Strategic Plan  |                                  |                                  |
| Fiscal oversight   |                                  |                                  |
| <b>TEST REQUIREMENTS</b>   |                                  |                                  |
| Tests currently available at all tiers of the national laboratory system   |                                  |                                  |
| Recommendations of tests that should be available and hierarchy (as below)   |                                  |                                  |
| <b>QUALITY MANAGEMENT SYSTEMS INCLUDING QUALITY ASSURANCE AND QUALITY CONTROL</b>  |                                  |                                  |
| Provision of Quality Management Systems  |                                  |                                  |
| Assess existing QC, QA, laboratory schemes and proficiency testing programs  |                                  |                                  |
| <b>SYSTEMS</b>   |                                  |                                  |
| Business   |                                  |                                  |
| Supply chain management  |                                  |                                  |
| Laboratory information management systems  |                                  |                                  |
| Monitoring and evaluation frameworks   |                                  |                                  |
| IT systems and how well they link between the tiers  |                                  |                                  |
| Communication systems  |                                  |                                  |
| <b>LEGAL AND POLICY REVIEW</b>   |                                  |                                  |
| Investigate laws, statutes, and government policies  |                                  |                                  |

### **Committees required**

Each country needs to put in place a set of committees for the development of a Plan. These committees need to have very specific terms of reference and address the core themes of a laboratory strategic plan including governance, infrastructure, testing services, quality management systems, human resources and legal and regulatory issues.

- 1: In the first instance, the committees need to be directed at acquiring the necessary information for the generation of the Plan itself. They should be tasked with finding the facts surrounding the current systems, structures, etc., usually done with a SWOT analysis (see Analysis of the National Lab System, page 15).
- 2: In addition, the committees should be empowered to make recommendations for which systems and structures should be put in place within the Plan.
- 3: Decisions on the committees can be informed by experienced laboratory experts and the experiences of other countries.

The issues surrounding human capital development and retention of skilled individuals are many, and this guidance document does not attempt to cover all the areas. It is recommended that each country put in place a dedicated team of human resource experts to guide the Plan's development. The human resources experts should cover two main areas: evaluation of the current situation relating to human resources and making recommendations regarding strategic initiatives in the Plan for developing and sustaining human resources.

With regard to managing human resources, specific recommendations consistent with the national HR policy will need to be formulated for:

- 1: The required expertise to run each level/area of the laboratory service.
- 2: Entry-level jobs and relevant career paths for all levels /types of staff.
- 3: Capacity retention strategies.
- 4: Strategies to attract some of the many professionals living outside of their country to return.

### ***Secondary and tertiary laboratory service tiers***

The delineation between the next levels will depend on what types of service the country wants to offer. Review of the "Consensus Meeting on Clinical Laboratory Testing Harmonization and Standardization" (Maputo, January 2008) can be used as a guide. The Plan will need to define the structure of the national laboratory system.

### ***National Reference Laboratories (NRL)***

All countries should consider the formation of a national reference laboratory. This NRL will perform a variety of tasks, among others;

- National outbreak response and control capabilities

- National tracking of disease test results
- Conduct and coordinate quality assurance and training nationwide
- Setting of national standards and norms
- Validation and optimization of new assays, as new technology becomes available
- Tests that require rare skills or a set of special conditions that are available in a limited number of laboratories, e.g., BSL 3 laboratories
- Tests that are not cost-effective when performed in a decentralized manner
- Tests that are required infrequently

The national reference laboratory should be funded at levels that are adequate. The reference laboratory must be well linked to the major laboratories that support local facilities to ensure easy access and support for all levels. International support and linkages through the WHO regional network to the global surveillance and reference laboratories are necessary to meet requirements of the International Health Regulations.

### **Standard operating procedures and referral processes**

The laboratories will be able to offer clinical colleagues a much better service if the Plan includes appendices that describe standard operating procedures and where possible a validated testing algorithm for each clinical condition at all clinics. For example, a blood specimen arriving for analysis for chronic hepatitis, HIV, anemia, etc. should be processed according to a standardized testing algorithm, irrespective of tier of laboratory used. Subsequent additional testing would be based on the algorithm or clinical recommendation based on initial results. The issues of standardization are discussed later in this document.

For testing algorithms to work properly, there needs to be a structured set of links and rules for referring a laboratory request to a higher level.

- Certain tests will not be performed at lower level clinics, and referral will be automatic. If required, the test is done through a process of specimen or patient referral.
- In other situations, a preliminary set of tests may be performed at a local level, and based on the results (positive, negative, or indeterminate), the next assessments including confirmatory testing, may automatically be done at a higher level laboratory with increased capacity and/or sophistication.
- The relationship and interaction of the public laboratory system with private laboratories must be addressed for both clinical care and public health purposes.

### **Standardization**

Issues of test standardization are critical and important because:

- Tests from different suppliers can have different performance characteristics and are not interchangeable.

- Different tests may require test-specific training, which has a human capacity implication.
- Clinically equivalent tests for the same clinical indication may have widely different costs when considering factors such as unit test cost, standards, QC and reproducibility, so cost-effectiveness analyses must be performed.
- Standardizing tests across the country will allow the government to negotiate better supply costs.
- Standardization allows for more simple supply chain management of consumables.
- Standardization allows for movement of staff among clinics without the need for additional training.

That standardization is preferable is not an absolute in laboratory systems. The Ministry should establish a laboratory advisory committee (LAV). The terms of reference, membership, and support resources of the LAV should be defined in the Plan. Decisions must be vetted by the laboratory advisory committee with the goal of maximum standardization but variability or exception to address needs, robustness of the system and responsiveness to unexpected or extraordinary events. In resource-constrained environments these issues are even more important, as levels of test standardization will have many direct and indirect cost implications for the country. There is no single answer as to how much standardization there should be. However, single-source suppliers for all or almost all tests are a significant potential risk. Therefore a balance has to be struck between having a limited but sufficient number of suppliers that still allows for achieving high levels of standardization.

### **Tests to be performed**

Each country needs to make decisions about which laboratory tests will be provided. This list of assays should be guided by various factors, such as disease burden, clinical requirements, costs, technical realities, donor support and training resources.

The list of available tests should be recommended by a sub-committee of the LAV that includes senior clinicians, pathologists, and laboratory professionals. The sub-committee should meet regularly to review the assays that are required, as well as new technology and funding that may become available to support increased services.

Accurate and reliable laboratory services are expensive, and each country should have a test hierarchy to ensure appropriate use of resources, so that expensive and difficult-to-perform tests are only requested when truly required, rather than as a first-line investigation. Guidelines for appropriate use of tests must be put in place and widely distributed. These guidelines will need to be updated on a regular basis, so as to reflect new developments.

### **Quality management**

This guidance document cannot stress enough the importance attached to ensuring that the Plan has sufficient attention given to issues of quality management (QM) and establishment of a national quality manager role at the national reference laboratory.

A major component of a QM system is quality assurance (QA), the systematic process of actions taken to ensure that specific standards and procedures are adhered to, and that delivered products or services meet the specified performance requirements. Giving attention to QA means allocating adequate resources to QA processes and oversight, and employing a team of skilled individuals specifically responsible to address quality issues.

Laboratory QA starts at the bedside where a test is requested and ends at the point where the result is returned to the patient's hospital/clinic folder and entered into the national disease surveillance records. It involves ensuring timely processing of specimens within a controlled, documented environment that ensures reliability at all times. Where there are problems, the QA system should identify, document, and correct them. The QA issues faced by developing countries are substantial, but there are many groups and consultants who are skilled in this area and available to analyze existing situations and recommend options for improvement.

### **Management and business systems**

All Plans should be detailed in their descriptions of the laboratory and business management systems that will be employed. These include supply chain management, billing, human resources, finance, and other important management tools necessary for a comprehensive laboratory service.

The Laboratory Information Management System (LIMS) needs to be adapted to suit specific environments. However, systems can be modified to accommodate multi-tiered laboratory structures. The systems used should be based on industry standards that enable electronic communication between the laboratory and other health information and relevant management information systems.

### **Training**

The Plan will need to address training, both in terms of developing new graduates for placing within the laboratory systems, as well as ongoing professional career development for those already working in the laboratories.

#### ***Pre-service training***

The Plan should include initiatives to establish excellent relationships with the universities and technical colleges, so as to ensure that proper training skills are developed for the laboratory positions. These could be skills in areas such as technical training, scientific, medical/pathology, management, business, IT support, systems analysis, among others. This is critically important and formal links between the various stakeholders or government departments may need to be facilitated through formal inter-ministerial agreements.

### *In-service training*

Training for staff members within the laboratory system should be an ongoing process with additional career development curricula adopted to ensure that staff training responds to changes in technology.

If the infrastructure and capacity exist, career development training may be formalized into a system where practitioners will have to participate in a required amount of training every year.

### **Career paths delineated**

There is much emphasis correctly placed on capacity development in resource-limited settings. However, in the absence of enough jobs linked to adequate career paths for existing and new staff in the sector, it will be difficult to retain that capacity within the public sector. Highly trained individuals tend to move to more highly remunerated (and available) jobs in the private sector, the NGO sector, as well as international organizations .

The establishment of career paths is a huge task, and this document does not intend to do justice to such an important area. However, the Plan should give consideration to the following:

- Open existing posts which were frozen due to budgetary constraints
- Establish new posts with associated budgets
- Set up a clear hierarchy structure allowing staff to see the possibility of progress based on experience and training
- Establish a staff performance monitoring system and transparent salary scales for different levels
- Establish guidelines for and agreements among partners to recognize the goal of supporting staff retention within the public system

The career path issues have significant financial implications that need to be considered under the finance section of the Plan.

### **Financing the Plan**

The Plan should have a section that outlines financing of the entire national laboratory infrastructure. This is a complex part of the development process and discussions with the financial decision makers should be started in parallel with the Plan development. The generation of the financial sections of the Plan requires in-depth analysis by both business experts and accountants. Therefore, obtaining the services of an appropriately skilled business consultant with insights into the field of laboratory medicine, as well as an accountant (or team thereof) is critical. The business consultants need to analyze the systems required (human, infrastructure, consumables, IT, training, etc.) and integrate these into a format that can be quantified.

The financial sections of the plan may be a significant basis for decisions on whether or not to allocate resources. Where appropriate, the financial projections should include as many co-funding opportunities

as possible. As described elsewhere in this document, developing countries will find that there are multiple donor channels available from which to seek co-funding. Financial commitments to the program from global donors may well support approval of a plan that might not be possible otherwise. The Plan should allow for and facilitate coordination of multiple sources of funding for the laboratory system. The World Bank and WHO Health Systems Division can provide technical assistance in developing such projections.

### **Current global role players in laboratory support**

Developing countries have significant opportunities to engage with the global players involved in laboratory development and support. There are many multilateral and unilateral donors that have laboratory support as a key component of their outputs.

Examples of these are the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), the Global Fund for AIDS, TB and Malaria (GF), United Nations agency programs and the many bilateral country donor initiatives. These programs contribute significant resources to developing countries for preventive measures as well as clinical and laboratory interventions. There are current opportunities for developing countries to engage with such programs to raise revenues for both development and implementation of a Plan.

The area of increased laboratory infrastructure and activities also falls within the broader area of development, as defined by the United Nations Millennium Development Goals (MDGs). Three of the MDG's have direct application to health and therefore laboratory functioning. The achievement of these MDGs is supported by the wealthy first world nations as well as other development agencies. Developing countries have significant opportunities to achieve their MDGs by having NLSPs funded by international development agencies.

### **Guidelines for involvement of development partners**

There are many multilateral, bilateral, and other funding bodies that want to have a positive effect on resource limited settings' healthcare, and funding the development and running costs of laboratories is one avenue for such bodies. An NLSP can ensure that donor funding achieves maximum effectiveness, and document that funding is well aligned with the national priorities.

The Plan should consider how to effectively engage international agencies to support laboratory systems within the country. This should spell out the nature of the assistance required, the process required of donor agencies to engage with in-country stakeholders, and how best to be aligned with national structures/systems. The guidance may well include how best to demonstrate outcomes and further develop the established national monitoring and evaluation systems.

## **Communications plan**

To ensure the success of the Plan, an effective communications strategy is essential. An excellent communications platform is a key part of change management. This communications plan should aim to inform, on an ongoing basis, all stakeholders - internal and external, on all levels - on the developments in the project via bulletins, advisories, e-mail and websites. It is essential to obtain participant feedback and buy-in throughout the process.

It is important to recognize that a Plan will have major effects on many peoples' lives and careers. As such, while some will welcome the proposed changes, others will resist the changes. A structured program of communication will minimize chances for misunderstanding.

## **Data management**

The development of an appropriate data management plan is crucial. There are many systems and IT support structures to assist in this. However, these tools must complement the activities proposed in the Plan. An adequate data management plan is essential for the proper evaluation and continual improvement of the national laboratory system. Without an adequate data set that has the features set out below, it is impossible to have adequate monitoring and evaluation and more difficult to attract donor funding.

Data management is a specialist area, within which detailed plans need to be constructed as to how data are captured, compiled, analyzed, utilized and archived. There are a series of checks and balances that need to be put in place to ensure that the data are of a high quality. Thus the data management plan will have to address issues such as:

- data validity (has the right thing been measured)
- data reliability (accuracy, precision and consistency)
- data timeliness (can decisions be made in a timely manner)
- data precision (free from bias and error)
- data integrity (truthfulness of the data set)
- data storage and back-up (are the data secure)

The process of developing the Plan will need to acknowledge the importance of data management, and appoint specialists to assist and ensure that this critical area is robust, and that enough resources are made available within the Plan to sustain data management.

## **Monitoring and evaluation (M&E)**

No Plan will be complete without a comprehensive M&E component. M&E is linked to the data management plan (and dependent on it), but is separate. The M&E discipline is one that is recurrently undervalued and underfunded. Many donors often consider spending up to 8% of an overall budget on M&E.

The discipline of M&E is put in place to do two things: The monitoring component is performed during the course of the program, and is intended to ensure that all targets (performance and quality) are being achieved as planned. The evaluation component is the aspect which looks at outcomes.

To perform adequate M&E, it is necessary to design a program with realistic targets as well as specific indicators of success/failure. Relevant “inputs,” “outputs” and “outcomes” will need to be linked to these indicators. The M&E plan will need to describe how data is accrued, reviewed, interpreted and used. The M&E framework needs to make specific plans on how targets will be modified during the course of the program, and under what conditions this will be required. The M&E team will need to be empowered to make recommendations about program changes, if during the course of implementation it becomes clear that targets are not going to be met.

## **Legal considerations**

It is important that due consideration be given to the legal implications of the proposed Plan, and therefore the involvement of legal bodies/legal counsel is essential. The involvement of the State legal advisors (in whatever form the country structures this) is important, as these specialists are able to draft legislation with due consideration to the policy frameworks that already exist within the relevant Ministries (Health, Education, Treasury, Science and Technology, etc.). There exists the possible need for changes to the law and the drafting of laws to create possible new structures that will require legal opinion and policy guidelines.

# Proposed Roadmap

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## **Where to start**

There is no prescribed way to start the development of a Plan, and each country needs to have its own unique process. The development of this Plan will also differ from country to country depending on the existing medical, regulatory, and laboratory infrastructure, as well as the current involvement of government, researchers, communities, and other stakeholder groups. Thus, while it will be of significant benefit to consult with, and gain the insights of other countries that have already developed such a Plan, each country must define its own appropriate path within the context of local variables and influences.

The Plan is most often given initial informal leadership by senior laboratory personnel within the public health structures, and by representatives of government. It is these individuals who drive the initial processes before a more structured set of committees and systems are put in place by the National Health Ministry to drive the development of the Plan. In this early phase it is important to ensure that senior government decision makers become aware of the issues, and that their endorsement is obtained to assure success of the planning effort.

## **Appropriate expectations regarding staging**

It is important that everyone involved in the planning process has realistic and accurate expectations. The planning process is focused on the **development** of a Plan – not **implementation**.

Although implementation is an entirely different process, the Plan must be developed with an awareness and consideration of how the strategic initiatives will be implemented in an effective and timely way. The Plan must be a living document, implemented through continual annual operational plans that are linked back to the Plan's goals and objectives and updated as needed to reflect successes and lessons learned.

## **Consultation steps**

### *1: Initial core leadership*

The Health Ministry should appoint a core leadership team made up of individuals from within the country with a deep knowledge of the current national structures, systems, strengths, and challenges.

The initial core leadership will map out a process for including the various national stakeholders in the first set of consultations. It is critically important that all relevant individuals and organizations be consulted and included in the development process.

The initial core leadership group will make proposals to government for an adequate budget for the development of the Plan. These funds should come from the Ministry of Health, but significant support for this may be obtained from outside stakeholders as well. There will need to be a budget that supports the employment of dedicated persons and an administrative support unit to facilitate and drive the process. A consultant may be hired to manage the process, as most other individuals are normally over-committed in their usual jobs.

A budget for planning will include capital equipment, as well as a budget for consumables, meetings, flights, and consultations.

Once government support and a budget are secured, the designated leadership assisted by a consultant or dedicated Ministry of Health staff member should move to perform the subsequent steps in Plan development.

### ***2: Engagement with national stakeholders***

The process of engaging with the national stakeholders is critically important. This Plan is a national plan that must have local ownership, local involvement and local buy-in. As a result, significant efforts need to be expended to ensure broad involvement through a large consultative forum preceded by a sequence of consultations with individual or groups of stakeholders

It is important to involve as wide a group as possible and to have representatives arrive to the consultative forum understanding their role and prepared to participate. Table 3 is a description of many of the main in-country stakeholders typically involved.

### ***3: Engagement with key global development partners***

Each country needs to decide what level of international community engagement is needed for the development of the Plan. This will be determined, in part, by the existing levels of capacity and funding available within the country. Those countries with more developed infrastructures, and higher levels of human capital and funding may elect to have less involvement of the international agencies. For those countries with limited capacity, the involvement of the international community is critical.

The international agencies are often already engaged with supporting the country health infrastructure, either through:

- a) being a normative agency, e.g., WHO,
- b) direct implementation of programs,
- c) other donor relationships, or
- d) organizations critical to a significant area of laboratory practice, e.g., external QA.

In many cases, development partners already are active stakeholders.

Table 4 lists many of the key international players.

| <b>TABLE 3: NATIONAL PLAN DEVELOPMENT STAKEHOLDERS</b>  |
|---|
| <b>GOVERNMENT</b>   |
| The Ministry of Health  |
| Ministry of Education   |
| Ministry of Finance / Treasury  |
| Ministry of Defense   |
| <b>PUBLIC SECTOR LABORATORIES</b>   |
| All tiers of the laboratory services are included. If there is no formal delineation between the different tiers, make sure that there is a good overlap of representatives from laboratories with diverse locations and capacities, as each will give a different perspective on what should be prioritized.   |
| <b>PRIVATE SECTOR LABORATORIES</b>  |
| Involve representatives of private sector laboratories to explore synergies between the private and public sectors. Private laboratories may have access to technologies and skills not found elsewhere in the country. Seek to establish public-private partnerships where there is benefit.   |
| <b>NON-GOVERNMENTAL ORGANIZATION AND MISSION HOSPITALS/LABS</b>   |
| The medical and laboratory services of many countries are supported (or run in part) by the NGO sector and mission hospitals. These are often critical links to rural and under-served communities.   |
| <b>CLINICAL HEADS OF HOSPITALS</b>  |
| The laboratories need to align their services to meet the needs of the clinical care services.  |
| <b>PROFESSIONAL BODIES (SUCH AS THE HEALTH PROFESSIONALS COUNCIL) AND BODIES WHICH REGULATE STANDARDS FOR TRAINING</b>  |
| Major changes in the structures which govern laboratory staff may need to be instituted by the professional bodies.   |
| <b>RESEARCH GROUPS AND PRACTITIONERS</b>  |
| A good laboratory service will need to engage with, and support research to improve clinical outcomes. These include laboratory research groups, clinical research groups interested in accessing laboratory services, contract research organizations, clinical and public health laboratories and data management groups. These groups can offer technical assistance to public laboratories and provide capability and capacity which can be used by the laboratory and clinical services. |
| <b>WORKERS UNION</b>  |
| Workers' unions and organizations play an important advocacy, lobbying and protective role for their members, including senior staff, in a regulated environment. The National Laboratory Plan may recommend (or stipulate) changes that require a collective bargaining process involving the unions, and their early involvement is therefore important.  |
| <b>LEGAL AND POLICY EXPERTS</b>   |
| Legal and policy experts need to be closely engaged with the process, as the implementation of a National Laboratory Plan will have significant policy and legal implications. Some developing countries have had to enact new legislation through Parliament to facilitate implementation of new initiatives.  |
| <b>REGULATORY OVERSIGHT BODIES</b>  |
| Regulatory oversight bodies give approvals for diagnostic and prognostic tests; those which determine the cost applied to tests in public and private settings; institutional review committees (ethics committees) which authorize research protocols involving human subjects; and biosafety committees.  |

| <b>TABLE 4: INTERNATIONAL PARTNERS</b>                                    |
|---|
| <b>NORMATIVE AGENCIES</b>   |
| World Health Organization (WHO)   |
| The United Nations Joint Programme on HIV/AIDS (UNAIDS)                   |
| <b>FUNDING AND IMPLEMENTING PARTNERS</b>                                  |
| The U.S. President's Emergency Plan for for AIDS Relief (PEPFAR)          |
| The Global Fund for AIDS, Tuberculosis and Malaria (GFATM)                |
| The U.S. Centers for Disease Control and Prevention (CDC)                 |
| U.S. President's Malaria Initiative                                       |
| The World Bank  |
| African Development Bank  |
| Clinton Health Access Initiative (CHAI)                                   |
| Japan International Cooperation Agency (JICA)                             |
| U.K. Department for International Development (DFID)                      |
| The European and Developing Countries Clinical Trials Partnership (EDCTP) |
| Deutsche Gesellschaft für Technische Zusammenarbeit (GTZ)                 |
| <b>INTERNATIONAL NGOS</b>   |
| CARE  |
| African Medical Research Foundation (AMREF)                               |
| Family Health International (FHI)   |
| International Red Cross/Red Crescent                                      |
| Medecins san Frontieres (MSF)   |
| Partners in Health (PIH)  |
| Oxfam International   |
| Population Services Council (PSI)   |
| Many others   |
| <b>PUBLIC SECTOR LABORATORY ORGANIZATIONS</b>                             |
| Association of Public Health Laboratories (APHL)                          |
| United Kingdom National External Quality Assessment Service (UK NEQUAS)   |
| College of American Pathologists (CAP)                                    |
| Public Health Agency of Canada (PHAC)                                     |
| <b>DATA MANAGEMENT SPECIALISTS</b>  |
| Private, in-country companies and universities                            |
| Independent standards setting bodies, e.g., HL-7, LOINC and SNOMED        |

#### *4: Large consultative forum*

Once preliminary individual and focus group meetings have taken place to inform participants of the process, a large national consultative forum should be organized by the group leading the development of the Plan.

The strategic objectives of this consultative forum are to:

- Review in-depth the current state of laboratories in the country, looking at structures, human resources, management systems and structures, internal testing systems, quality assurance, etc.
- Explain to all stakeholders the vision and mission for the national laboratory system, as an integral part of the Ministry of Health's mission to ensure quality health to all citizens
- Explain the proposed process and introduce the leadership within the Ministry of Health and from among other stakeholders who will lead the process of developing the plan
- Ensure that there is support and buy-in from stakeholders for the development of a Plan
- Hear the expectations and concerns of stakeholders
- Form technical task groups from among stakeholders to drive the technical aspects of the Plan's development
- Propose the steps in Plan development and implementation
- Explain milestones and timeframes to develop and implement the Plan
- Complete a first comprehensive draft of the Plan

This consultative forum should attempt to include all relevant in-country stakeholders as well as representatives of the key international agencies. Inviting representatives of countries that have a viable National Laboratory Strategic Plan is advantageous.

#### *5: Providing sufficient detail to the draft Plan through a series of smaller task group meetings*

From this point, there are two processes that will go forward in parallel tracks:

The core leadership team, guided by the Ministry of Health (and consultants), moves forward to negotiate the process at an administrative and political level, taking into account the resolutions of the large consultative forum. The administrative leadership will act as the drivers of the overall process, and give management oversight and vision to the entire program, including the specialist task groups.

Expert technical task teams research their specific areas and report back to the administrative leadership at predetermined intervals. These reports will inform how the plan should strategize for the future. The technical task teams will develop the detailed analysis and plans to inform the plan. Each committee will have a specific brief and terms of reference. The committees will have appropriate representation from the involved sectors in drafting of the document.

## ***6: The final draft Plan***

The final draft Plan must be scrutinized in-depth by government policy experts to ensure that it is complementary to the other policy frameworks before submitting for approval by the Minister of Health. The leadership should liaise with relevant government agencies or representatives on an ongoing basis throughout the writing of the final draft Plan.

### **Adoption and inclusion in National Health Plans**

After review and approval by the Ministry of Health, the formal introduction of the Plan should be a national meeting that includes all of the national and international stakeholders who contributed to its development.

The meeting should give expression to the vision that has emerged from the consultations. Groups that have contributed to the Plan should be active participants in the meeting, describing the detail of the technical aspects of what will be adopted. The leadership core that has driven the process should give in-depth descriptions of overall vision and mission in the context of national health delivery.

The Ministry of Health should then discuss how the plan will be put in place. It is their responsibility to ensure that the Plan comes to fruition.

### **Fundraising and implementation**

The National Laboratory Strategic Plan should be a practical document with an implementation process mapped out. This should include a fundraising strategy, as well as the tasks that different groups will be expected to perform. The funds required for implementation should be identified, as well as funds required to sustain the improvements in infrastructure and services. Funds, if possible, should be committed at this stage or alternatively the potential funders identified.

# Conclusion

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The development of a National Laboratory Strategic Plan is a key part of a comprehensive National Health Plan to improve clinical care, public health programs and the health of all people. The development process is demanding and lengthy. Many stakeholders must be consulted and diverse perspectives considered and recognized or reconciled in a final plan to assure broad support. Over the course of the Plan's development, the national leadership must remain strong as the commitment of the leadership is an essential factor of success in earning the buy-in of the stakeholders.

The Plan is an important tool that provides a forum for open discussion and transparency in the implementation of programs, linking action to strategic priorities so that the Ministry can make the case for resource support to government and donor agencies.

The implementation of the Plan's initiatives must be accompanied by monitoring and evaluation to demonstrate the value of resource investment and to guide continual adjustment and improvement. The goal of better health outcomes can be achieved with proper planning and implementation, and the public health agencies are responsible for assuring success. And a NLSP is a necessary element of a health agency's resources and means for achieving success.

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| ACRONYMS AND GLOSSARY                   |   |
|---|---|
| ADB                                     | African Development Bank - a multilateral development bank for Africa. <a href="http://www.afdb.org">www.afdb.org</a>   |
| AMREF                                   | African Medical and Research Foundation—a health development organization. <a href="http://www.amref.org">www.amref.org</a>   |
| APHL                                    | Association of Public Health Laboratories—member organization for public health labs. <a href="http://www.aphl.org">www.aphl.org</a>  |
| CAP                                     | College of American Pathologists—Accreditation body. <a href="http://www.cap.org">www.cap.org</a>   |
| CARE                                    | Non-governmental organization engaged in disaster relief and other poverty and health problems worldwide. <a href="http://www.care.org">www.care.org</a>  |
| CDC                                     | U.S. Centers for Disease Control and Prevention. <a href="http://www.cdc.gov">www.cdc.gov</a>   |
| Clinton Health Access Initiative        | Non-governmental charitable foundation. Works with governments through its AIDS initiative to provide care to people in need. <a href="http://www.clintonfoundation.org">www.clintonfoundation.org</a>  |
| DFID                                    | The Department for International Development (DFID)—the part of the U.K. Government that manages Britain's aid to poor countries and works to get rid of extreme poverty. <a href="http://www.dfid.gov.uk">www.dfid.gov.uk</a>  |
| EDCTP                                   | The European and Developing Countries Clinical Trials Partnership aims to accelerate the development of new or improved drugs, vaccines and microbicides against HIV/AIDS, malaria and tuberculosis. <a href="http://www.edctp.org">www.edctp.org</a>   |
| FHI                                     | Family Health International - Non-governmental international public health organization with activities in research, education and family health. <a href="http://www.fhi.org">www.fhi.org</a>  |
| Gates Foundation                        | Bill and Melinda Gates Foundation. Private foundation that works to help all people lead healthy productive lives; involved in global health and global development. <a href="http://www.gatesfoundation.org">www.gatesfoundation.org</a>   |
| Global Fund for AIDS, TB & malaria      | Partnership among donor and recipient governments, civil society, the private sector and affected communities created to address the fight against AIDS, tuberculosis and malaria. <a href="http://www.theglobalfund.org">www.theglobalfund.org</a>   |
| GTZ                                     | The Deutsche Gesellschaft für Technische Zusammenarbeit is an international cooperation enterprise that supports the German government in achieving its development-policy objectives. <a href="http://www.gtz.de">www.gtz.de</a>   |
| IT                                      | Information Technology is the study, design, development, implementation, support or management of computer-based information systems, particularly software applications and computer hardware.  |
| JICA                                    | The Japan International Cooperation Agency is an independent governmental agency that coordinates official development assistance for the government of Japan. <a href="http://www.jica.go.jp">www.jica.go.jp</a>   |
| MSF                                     | Medecins Sans Frontières—an international, independent, medical, humanitarian organization that provides emergency medical assistance to people in danger. <a href="http://www.msf.org">www.msf.org</a>   |
| NGO                                     | Non-governmental Organization: created by private organizations or people with no participation or representation of any government   |
| OXFAM                                   | NGO consortium working in Development, Disaster Relief, Advocacy and Policy Research. <a href="http://www.oxfam.org">www.oxfam.org</a>  |
| PEPFAR                                  | The U.S. President's Emergency Plan for AIDS Relief <a href="http://www.pepfar.gov">www.pepfar.gov</a>  |
| PSI                                     | Population Services International: Non-profit organization with a focus on measurable health impact. Areas of work: Malaria, Child Survival, Reproductive Health and HIV. <a href="http://www.psi.org">www.psi.org</a>  |
| Public-private partnership              | A government service or private business venture which is funded and operated through a partnership of government and one or more private sector companies. Sometimes referred to as PPP or P3.   |
| Stakeholder                             | A person, group, organization, or system who affects or can be affected by an organization's actions.   |
| Supply chain                            | The system of organizations, people, technology, activities, information and resources involved in moving a product or service from supplier to customer.   |
| Synergy                                 | A situation where the final outcome of a system is greater than the sum of its parts; a mutually advantageous outcome.  |
| UK NEQAS                                | United Kingdom National External Quality Assessment Service. Quality service for laboratory medicine. <a href="http://www.ukneqas.org.uk">www.ukneqas.org.uk</a>  |
| UNAIDS                                  | United Nations AIDS is the chief advocate for worldwide action against AIDS; represents ten organizations of the United Nations system which share a common agenda on AIDS. <a href="http://www.unaids.org">www.unaids.org</a>  |
| US President's Malaria Initiative (PMI) | Collaborative U.S. Government effort to fight malaria worldwide, led by the U.S. Agency for International Development, the Department of Health and Human Services (Centers for Disease Control and Prevention), the Department of State, the White House, and others. <a href="http://www.fightingmalaria.gov">www.fightingmalaria.gov</a> |
| WHO                                     | The World Health Organization is the directing and coordinating authority for health within the United Nations system. <a href="http://www.who.int">www.who.int</a>   |
| World Bank                              | An internationally supported bank that provides financial and technical assistance to developing countries for development programs. <a href="http://www.worldbank.org">www.worldbank.org</a>   |

# Maputo Declaration

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## **The Maputo Declaration on Strengthening of Laboratory Systems**

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We, representatives of governments, multilateral agencies, development partners, professional associations, and academic institutions, participated in a Consensus Meeting on Clinical Laboratory Testing Harmonization and Standardization in Maputo, Mozambique, on 22nd - 24th January 2008. The meeting sought to address laboratory challenges that limit the scale-up of services for tuberculosis, malaria and HIV diagnosis and care.

The objectives of the Maputo meeting were:

- To review and agree on a list of supplies and tests needed at each level of an integrated tiered laboratory network;
- To develop a consensus to guide standardization of laboratory equipment at each level of the laboratory network;
- To develop a consensus on key considerations to guide maintenance and service contracts for equipment at various levels of the laboratory network.

**Recognize** the burden of the priority diseases HIV, malaria and tuberculosis. Globally, some 33.2 million individuals are living with HIV but of those just 10% are aware of their sero-status.<sup>1</sup> In spite of efforts to limit transmission, the incidence of HIV infection remains high. Similarly, 8.8 million new cases of tuberculosis occur annually while the prevalence of multi- and extensively-drug resistant tuberculosis continues to increase with only a fraction of cases being detected.<sup>2</sup> Co-infection with HIV and tuberculosis remains a difficult clinical challenge in many settings. In many countries, malaria remains the largest contributor to mortality primarily among infants and children, with about 1 million deaths per year.<sup>3</sup>

**Recognize** the need to expand and further develop quality-assured laboratory services as part of a greater framework of health system strengthening within resource-limited settings. Increasingly, countries and implementing partners have identified that limited laboratory capacity represents a major barrier to implementation and sustainability of prevention, treatment and care programs for HIV, malaria and tuberculosis.

**Recognize** that in resource-limited settings, several challenges have resulted in inadequate laboratory systems to support the scale-up of programs. These include a lack of leadership and advocacy, human resources, career path and retention of staff, national laboratory policy, strategic planning (budgetary concerns), insufficient physical infrastructure, supply chain management, and quality management systems (quality assurance).

**Note** that there has been a substantial increase in funding to fight HIV, tuberculosis, and malaria. For instance, a total contribution of US\$10 billion per annum has been secured from donors towards

prevention, treatment and care programs for the three diseases through funding bodies such as the Global Fund to fight AIDS, Tuberculosis and Malaria, The U.S. Presidents Emergency Plan for AIDS Relief, U.S. President's Malaria Initiative, the World Bank, and the Bill and Melinda Gates Foundation. This represents a significant increase on previous commitments that totaled US\$1 billion in 2001 for disease control programs for high burden diseases in resource-limited settings.

**Recognize** that in order to improve and sustain access to laboratory services, there must be an integration of laboratory support for tuberculosis, malaria and HIV disease programs. The aim of this effort should be to sustain any improvements made to a laboratory as part of the greater health system from a public health perspective.

**Call on** national governments to support laboratory systems as a priority by developing a national laboratory policy within the national health development plan that will guide the implementation of a national strategic laboratory plan. Governments should establish a department of laboratory systems within the Ministry of Health.

**Call on** national governments with support of their donors and partners in resource-limited settings to develop national strategic laboratory plans that integrate laboratory support for the major diseases of public health importance including HIV, tuberculosis, and malaria.

**Call on** donors and implementing partners to ensure that in supporting laboratory strengthening that proper consideration is given to fostering national ownership.

**Call on** countries and all partners to urgently address the broader laboratory human resources agenda for laboratory strengthening including training, recruitment and retention of laboratory workers and their adequate financing.

**Call on** donors and development partners to commit to work collaboratively with each other and with coordination from the national governments to support strengthening of laboratory systems in order to create one unified, integrated national laboratory network. These laboratory strengthening efforts should seek to build public private partnerships.

**Call on** academic institutions and research funders to accelerate efforts to develop new diagnostic tools applicable to resourced-limited settings

*Done in Maputo, Mozambique on 24 January 2008*

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1. Joint United Nations Programme on HIV/AIDS (UNAIDS) and World Health Organization (WHO) 2007 AIDS Epidemic Update. Accessed at [http://data.unaids.org/pub/EPISlides/2007/071119\\_epi\\_pressrelease\\_en.pdf](http://data.unaids.org/pub/EPISlides/2007/071119_epi_pressrelease_en.pdf) on 24 January 2008
  2. WHO factsheet no. 104 - Tuberculosis. Accessed at <http://www.who.int/mediacentre/factsheets/fs104/en/index.html> on 24 January 2008
  3. WHO/GMP frequently asked questions Accessed at <http://www.who.int/malaria/faq.html> on 24 January 2008

# National Laboratory Strategic Plan Development Checklist

- Define a Mission and a Vision
- Identify Leadership

## **Establish Principles**

- To guide development of the plan
- To guide implementation of the plan

## **Set Objectives**

- Identify Resources to assist Plan development

## **Situation (technical) Analysis of Laboratory:**

- Structure
- Infrastructure
- Human Resources
- Finances
- Test requirements at each tier
- Quality Assurance Program
- Sample referral systems
- Legal and Policy Review

## **Key Objectives of Plan:**

- Establish a tiered laboratory network
- Training/Retention
- Standardization of Lab Commodities
- Equipment Maintenance
- Quality Assurance Program
- Sample referral systems
- Laboratory Information Systems
- Monitoring and Evaluation
- Regulatory Issues



# Laboratory Services National Strategic Plan

## MISSION

To improve the health status of the nation through the provision of quality services by advancing the capabilities of all laboratories in laboratory technology, related public health disciplines, training, research and well motivated staff.

**This example is based on the Guyana National Strategic Plan for Laboratories 2008-2012 (Version 2) (Feb 2007) developed by a team led by Dr. Colin Roach, Director, National Public Health Reference Laboratory and Miss Yvette Irving, National Public Health Reference Laboratory.**

# Introduction

## **The Role of medical laboratories**

ISO 15189:2003 defines the medical laboratory (clinical laboratory) as a “laboratory for biological, microbiological, immunological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological or other examinations of materials derived from the human body for the purpose of providing information for the diagnosis, prevention and treatment of disease in, or assessment of the health of human beings, and which may provide a consultant advisory service covering all aspects of laboratory investigation including the interpretation of results and advice on further appropriate investigation.”

Information provided by the medical laboratory underpins the practice of modern medicine and by defining the incidence and prevalence of disease it allows government and other agencies to plan the provision of health care services and monitor their effectiveness.

Over the years the practice of medicine and surgery has become increasingly complex and so have the demands that are placed on laboratories. The direct impact of diseases on the population reinforces the recognition that disease prevention and control are critical to sustainable human development. Laboratories are often the first sites for the detection of disease outbreaks and also serve as a major source for health information. They produce critical and relevant information for patient care and treatment, epidemiology and surveillance. Strong laboratory facilities are therefore essential to health as well as to the national well-being and maintenance of health and economic development.

## **Background**

The Government of SampleCountry is currently engaged in a programme of significant restructuring/ reform of the nation’s health services and the health sector. Over the years, the Ministry of Health (MOH) has remained committed to improving the institutional capacity of the health sector to be able to respond in an adequate and timely manner to the public health care needs of the country within a resource constrained environment. Within this context the Ministry of Health is developing a series of sector specific reform plans such as this for the medical laboratory services.

In March 2003 the Ministry of Health published the National Health Plan 2003- 2007 (NHP) document which provided a strategic framework for the health sector over that period. This reform strategic plan focuses on the health priorities of the government and is premised on the millennium development goals, the poverty reduction paper and the national development strategy. The NHP provides the overall framework and the overarching frame of reference for the National Strategic Plan for Laboratories 2008-2012.

In addition, this Plan is consistent with the findings and recommendations of the following:

- Strengthening of Medical Laboratory Services in the Region – A European Union Funded Project.
- SampleCountry’s National Laboratory Strategic Planning Workshop Draft Report – January 2005.

- Consultation with key stakeholders in the public and private medical laboratory services through the National Laboratory Advisory Steering Committee now referred to as the National Laboratory Oversight Committee.

The central purpose of this Plan is to provide a chartered course or road map for improvement and strengthening the provision and delivery of laboratory services to ensure equitable access to quality services based on the adequacy and availability of skilled human and other resource inputs – financial and material. The objective is to improve, strengthen and promote the institutional and operational capacities of laboratories that will improve their diagnostic and monitoring capabilities.

## Situational Analysis – Strategic Assessment of the Laboratory Sector

The Public Health Laboratory services in SampleCountry consist of a network of diverse institutions and public laboratories that work in undefined collaboration with private clinical laboratories. Since the 1980s, the HIV epidemic has emphasized the Public Health Laboratory's critical role in assessing, leading, and developing health policies. The public laboratory system has recognized the need for established laboratory priorities for bio-terrorism, emerging and re-emerging pathogens, e.g., anthrax (2001), Severe Acute Respiratory Syndrome (SARS) (2003), avian influenza (2005).

### **The Existing Laboratory Services**

#### ***Public Facilities***

Clinical Laboratory Services within the public system are provided through the Central Medical Laboratory (CML) of the Sample Public Hospital Corporation (SPHC), four Regional Hospitals with functioning medical laboratories and nine (9) district hospitals

The SPHC provides anatomical and clinical laboratory services. The SPHC is the only Tertiary Care facility where the highest level of specialization in Clinical Medicine is practiced. The CML is the main referral hospital laboratory. The Medical Technologist, who works in specialized areas, is the mainstay in respect of staffing at this facility. However, there is great scope for scientific officers as well as several categories of support staff. This laboratory possesses the highest level of medical technology available in the Public Health system for clinical care.

The CML provides a range of services in biochemistry, hematology, serology/immunology and microbiology. Histo-and cytopathology laboratory services are offered by the anatomical pathology laboratory.

The main focus of the Regional Hospital is to provide secondary health care to the population. They operate on a 24-hour basis and the laboratory service is available at all times. This category of laboratory provides the highest level of service in the region. They are served by Medical Technologists, Multi Purpose technicians and Phlebotomists. The following services are offered:

- Basic biochemistry
- TB diagnosis
- Malaria
- Basic haematology
- Urinalysis
- Basic serology (VDRL, HepB, HIV)

There are also seven (7) district hospitals, which offer varying degrees of testing in their laboratory departments; these are Sample Hospital 1 (Region 8), Sample Hospital 2 (Region 5), Sample Hospital 3 (Region 9), Sample Hospital 4 (Region 2), Sample Hospital 5 (Region 7) and Sample Hospital 6 and Sample Hospital 7 (Region 10). These hospitals provide the following services

- TB diagnosis
- Limited Biochemistry and Hematology
- Malaria
- Basic serology (HIV, VDRL)

There are a seven (7) other district hospitals, A, B, C, D (Region 1), E (Region 9), F (Region 3) and G (Region 6) that have infrastructure to house laboratory facilities. However, there is need for structural alterations to make them more suitable for fulfilling their laboratory functions.

Point-of-care testing is done in some Health Centers, e.g., HIV testing and blood sugar tests.

### ***The National Blood Transfusion Service (NBTS)***

There is one specialized laboratory; the National Blood Transfusion Service. It is the only free-standing blood collection facility in the country and was established in 1989. Blood collection facilities in the Regions are located within the Regional Hospital facility. In addition to providing specifically for the blood transfusion service the laboratory also provides infectious disease testing for private and public health facilities.

**Testing:** All blood collected by Blood Transfusion Centres in SampleCountry is screened for HIV, Hepatitis B (HBV), HCV, syphilis and malaria. In August 2006 testing became available for HTLV 1 & 2. At NBTS screening for HIV, HBV and HCV is done by use of commercially available enzyme linked immunosorbent-assay (ELISA) kits. All testing is conducted in accordance with manufacturer's protocols and international guidelines for quality assurance. Screening for malaria and filaria is done by smear-microscopy and that for syphilis by RPR and TPFA.

Regional Centres screen blood for HIV HBV and syphilis using rapid tests. Testing for HCV and other confirmatory ELISA testing is carried out at the NBTS. This arrangement has created an informal programme of Quality Assurance among the Regional Centres in SampleCountry. Discordant test results found between the rapid tests and the ELISA tests have been statistically insignificant.

NBTS also provides proficiency test (PT) samples to the Regional Centres on a regular basis. The laboratory staff participates in external PT programmes for immuno-haematology (NEQAS), syphilis (Health Canada) and ELISA-based testing (Q-panel). They also participate in the Model Performance Evaluation Programme (MPEP) from the Centres for Disease Control and Prevention (CDC).

### ***Private Facilities***

Laboratory services are also provided within the private sector. There are currently 15 known private laboratories in operation of which two are certified by the SampleCountry NBS. They provide a range of general clinical laboratory services.

### ***Private/Public Collaborative Efforts***

The quality of both public and private sector laboratory services vary widely. This requires an established mechanism for standardising, monitoring and controlling the quality of medical laboratory services available to the public. Important advances have already been made in this regard in recent years.

They include:

- Establishment of a National Laboratory Advisory Committee through the EU Lab Strengthening Project in 2003. The Minister of Health is the Chairman with stakeholders from both private and public sectors.
- Establishment of a national certification system for laboratory operations by the SampleCountry National Bureau of Standards, fulfilling the requirements of the SYS 170:2003.
- Adoption of the Southern Regional Standards for Blood Banks.
- Adoption of the ISO 15189 International Standards for Clinical Laboratories.
- Donor support for several aspects of laboratory service development, particularly in the areas of HIV/AIDS and TB care, treatment and support.
- Establishment of a network of public and private laboratories such as the SampleCountry Lab Link founded in 2004 (through the EU Project) and the SampleCountry NBS Clinical Subcommittee.
- Implementation of a number of training initiatives which started through Southern Region and was strengthened by the EU Project.
- Implementation of a proficiency testing programme for monitoring laboratory quality nationally.
- Development of a Health Facilities Act which is currently under parliamentary review.

## **Strengths and Challenges to Service Delivery**

**Overview:** Delivery of high-quality laboratory services is essential in our health-care system both for providing the foundation for clinical decisions and as an objective means to measure and monitor biological and environmental markers. Accurate and timely laboratory analyses are critical to identify, track, and limit public health threats which ultimately will reduce rates of preventable morbidity and mortality. Optimal functioning of the public health system to meet these threats is dependent on uniform and high-quality laboratory testing.

A key precept for public health is recognizing that a significant amount of testing for public health is either performed in private laboratories or is dependent on private laboratories for referral and reporting. Therefore, a function of public health and specifically of the Public Health Laboratory system is to ensure the availability, quality, and reporting of laboratory testing performed in the private sector.

A minimal association exists between public and private (i.e., hospital and independent) laboratories, and this limited association has led to limited communication and coordination of the laboratory testing that is necessary to support public health interventions.

### **Strengths**

A guaranteed package of services to be delivered at each level of Laboratory service has been defined and a strategic plan for the strengthening of the National Blood Transfusion Services and improvement of blood safety has been developed and accepted.

The National Certification of laboratories programme is coordinated by the SNBS and was implemented in 1995.

A number of training opportunities for laboratory personnel have been utilized in the following areas: Laboratory Quality Management, STIs and OIs, TB, Flow Cytometry and CD4 Testing.

Closer collaboration between the laboratories and the Ministry of Health in the following areas –

- Increased awareness of the laboratory profession by other health care providers
- Creation of the Network of Medical Laboratory Professionals and the increased participation of laboratory personnel in this network
- The acquisition of new technologies for use in both public and private laboratories
- The proficiency testing scheme available to all medical laboratories
- Open door management style that exists in some medical laboratories

## **Challenges**

### ***Internal***

Each member of staff should have the opportunity to update his or her knowledge on laboratory testing. However, opportunities for laboratory technologists to obtain additional education in some areas of laboratory technology are urgently needed. Standardised training for other levels of staff is almost non-existent. Currently the NBTS offers one blood safety training module routinely to donor nurses employed there or at regional centres. The only other training provided regularly by NBTS or SOUTHERN REGION covers testing procedures for HIV, HBV, HCV, syphilis and quality assurance. This training is limited to laboratory personnel. Current resources do not permit external training opportunities for medical or administrative personnel.

The Ministry of Health facilitates and coordinates with other international organisations to convene workshops and training sessions for lab personnel country-wide:

- Laboratory quality assurance
- General lab services

Other challenges include:

- Balancing the capacity of new technology with current needs
- Unreliable supply of reagents
- Preventive maintenance and repair of biomedical equipment
- Rapid staff turn-over and shortage of qualified/specialised staff
- Lack of updated and enforced regulations
- Poor remuneration of staff

### ***External***

- Non availability of a constant supply of the utilities (water, electricity)
- Meeting the demands of international standards
- Utilising donor resources for the maximum benefits of the Medical Laboratory Services Network

## **Opportunities**

Significant technical and financial support for laboratory services is being provided by our development partners – PAHO/WHO, CDC, CIDA/CSIH, EU, Global Fund, USAID, World Bank, and SOUTHERN REGION. Many of the technical and financial inputs are already en train and it is hoped that the strategic plan – NSLP – will further streamline and strengthen these collaborative links.

Consistent with the policy of the Government to stimulate and encourage private sector involvement in health development, it is envisaged that there will be increased public/private sector partnership and collaboration in the provision of quality laboratory services. Such a partnership will assist in maximizing the use of resources.

Health sector reform activities will provide the environment for improving efficient and effective delivery of the laboratory services.

The implementation of national standards will improve the quality of laboratory testing and the level of performance by all stakeholders. The introduction of new and revised health legislation will provide a regulatory framework within which both public and private laboratories can operate while maintaining the same standard. The development of the National Public Health Reference Laboratory (NPHRL) will provide a nucleus for the defined functions of the National Laboratory System.

## National Laboratory Services: Vision and Mission

### **The Vision**

A network of highly efficient laboratories, public and private, functioning according to national standards and guidelines, well staffed with appropriately trained personnel, technically and financially sound. This will require the expansion of the range of services – diagnostic and confirmatory tests. Such a network will be supported by a centralized management information system (MIS).

In the past certain diseases were managed based on clinical diagnosis because of the lack of laboratory diagnostic capability to carry out confirmatory testing. Such testing had to be accessed overseas. The time is now right for such capabilities to be developed in SampleCountry. Thus the vision includes the establishment of a Centre of Excellence for Laboratory Performance in the form of a National Public Health Reference Laboratory (NPHRL). This laboratory will serve as the nucleus of the National Laboratory Services and provide a combination of selected laboratory services that support specific programs such as HIV, TB, STIs, and Malaria. This laboratory will have the flexibility and capability to assist with the management of disease outbreaks such as leptospirosis; special investigations and surveys related to specific issues of concern for example filariasis, anemia, avian influenza, and West Nile virus and drug resistance. In addition, the NPHRL, certified in accordance with current international standards, will be the centre for many of the National Laboratory Services core functions.

It will play a key role in ensuring private laboratories meet a minimal standard of quality and reporting. This will guarantee that information used for the management of individual patient care and treatment is both accurate and reported to the Ministry of Health when it is of ‘public health importance.’

### **Mission of the Laboratory Services**

To improve the health status of SampleCountry through providing quality service by advancing the capabilities of all laboratories in laboratory technology, related public health disciplines, training, research and well motivated staff.

# Core Functions

In the next five years the Ministry of Health projects that its National Laboratory Service will execute the listed core functions with the NPHRL providing leadership and specialized services, as well as having all laboratories and testing sites certified and licensed to the National Standard (GYS:170:2003):

- disease prevention, control, and surveillance;
- integrated data management;
- reference and specialized testing;
- environmental health and protection;
- food safety;
- laboratory improvement and regulation;
- policy development;
- emergency response;
- public health-related research;
- training and education; and
- partnerships and communication.

## **Disease Prevention, Control and Surveillance**

- Provide timely, accurate and precise analytical results for different diagnostic and analytical functions for the assessment and surveillance of infectious, communicable, genetic, and chronic diseases, and environmental exposures.
- Serve as a first line of defense by rapidly recognizing and preventing the spread of communicable diseases by
  - » examining specimens for identifying disease outbreaks;
  - » isolating and identifying the causative agents;
  - » determining the sources of infection;
  - » identifying carriers; and
  - » locating sources of infection in the environment.
- Serve as a centre of expertise for the detection and identification of biologic agents of significance in human disease; as such, ensure access to laboratory expertise and capabilities in the disciplines of
  - » bacteriology;
  - » virology;
  - » parasitology;
  - » molecular microbiology;
  - » immunology and serology;
  - » chemistry
  - » mycology; and
  - » hematology and immuno-hematology

- Provide specialized tests for low-incidence, high-risk diseases, detect epidemiologic shifts; and detect newly emerging pathogens, including but not limited to
  - » testing specimens from suspect cases of tuberculosis to identify *Mycobacterium tuberculosis* infections and determine effective antibiotic treatment;
  - » assisting public and private health-care providers in investigating and controlling communicable or environmental related health conditions.
- Provide population surveillance for conditions of interest to the public health community, including screening for inherited neonatal metabolic disorders, environmental toxins, immune status, risk factors, chronic blood diseases, blood lead, and antibiotic resistance.
- Perform tests to meet specific program needs of public health agencies.

### **Integrated Data Management**

- The NPHRL will serve as the focal point for accumulating, blending, and disseminating scientific information in support of public health programs, including
  - » capturing laboratory data essential for public health analysis and decision-making;
  - » ensuring the ability to maintain and communicate laboratory data by using standardized data formats;
  - » ensuring rapid dissemination of laboratory information to assist in identification, understanding, and controlling disease outbreaks;
  - » providing primary data necessary to provide information for and implement policy and planning; and
  - » providing a countrywide disease reporting network, with centralized facilities for receipt, storage, retrieval, and analysis of data.
- The NPHRL will serve as nucleus in the national database system to collect, monitor, and analyze laboratory data, as the primary data link with SOUTHERN REGION and CDC for surveillance of diseases of national, regional and global concern.
- Serve the data needs of country epidemiologists, laboratories, and practitioners in identifying trends and sentinel events which indicate emerging health problems.

### **Reference and Specialized Testing**

- The NPHRL will serve as the country's primary reference to
  - » test for, and aid in the diagnosis of unusual pathogens;
  - » confirm atypical laboratory test results;
  - » verify results of other laboratory tests;
  - » provide oversight for quality assurance;
  - » test epidemiologically significant specimens with potential public health implications;
  - » provide reference diagnostic testing to private sector laboratories that might not have the capability to fully identify disease agents of public health significance;

- » test for diseases of public health consequence that are rare or unusual for other laboratories to maintain capacity for testing, including human genetic markers of disease; and
- » provide toxicology testing, including drug, alcohol, poison, and trace metal analyses.

### **Environmental Health and Protection**

- Conduct scientific analyses of environmental samples (air, water, and soil) to identify and monitor potential threats to human health and ensure compliance with environmental regulations.
- Analyze environmental and biological specimens and detect, identify, and quantify toxic contaminants (e.g., lead, pesticide residues, and heavy metals).
- Ensure laboratory services that support assurance of clean water in the county by analysing water for synthetic organic chemicals, pesticides, inorganic chemicals, and micro-organisms.

### **Food Safety**

In collaboration with the food and drug department, the NPHRL will:

- Test specimens from persons, food, and beverages implicated in food borne illness outbreaks to identify causes and sources. Testing might include assays to identify organisms (e.g., staphylococcus, bacillus, salmonella, shigella, vibrio, listeria, and clostridium).
- Analyze food specimens to detect, identify, and quantify toxic contaminants, e.g., pesticide residues, and heavy metals.

### **Laboratory Improvement and Regulation**

- Coordinate and promote quality assurance programs for private clinical and environmental laboratories through training, consultation, certification, and proficiency testing.
- Serve as the standard of excellence for local and private laboratory performance.
- Exercise leadership and authority as the agency responsible for laboratory regulation and training in the clinical and environmental areas.
- Develop and oversee countrywide quality assurance and laboratory improvement programs to ensure the reliability of laboratory data used for communicable disease control and environmental monitoring.
- Oversee the licensure, certification, and accreditation of laboratories to ensure medical, environmental, and food safety, laboratories fulfill national and legal mandates.

### **Policy Development**

- Provide scientific and managerial leadership in developing public health policy and in developing, promoting, and integrating public health laboratory science into practice.
- Participate in developing standards for all health-related laboratories, including food, environmental, clinical, and research standards.

## **Emergency Response**

- Provide laboratory support as part of national disaster preparedness plans for environmental or health emergencies, including
  - » rapidly identifying and investigating analyses of biological, chemical, and radiological agents, regardless of the source of exposure (i.e., unintentional, terrorist or natural disaster);
  - » ensuring the capacity to quickly and accurately handle a substantial volume of tests during an emergency situation; and
  - » providing a rapid response system for hazardous contaminants waste spills (air, water, and soil) and in food borne disease outbreaks.

## **Public Health-Related Research**

- Evaluate and implement new technologies and analytical methodologies to ensure laboratories provide state-of-the-art, cost-effective, and timely analytical diagnostic services and support the public health care professionals in the country by
  - » identifying the need for new laboratory methodologies for disease detection and prevention;
  - » conducting research to improve laboratory tests for more effective disease surveillance; and
  - » conducting research to develop rapid methods for laboratory diagnosis.
- Collaborate with academic, private sector researchers and other government agencies to adapt emerging technologies in public health laboratory techniques and information systems.
- Conduct applied studies into new and improved analytical methods and services which are necessary to meet changing public health surveillance and environmental regulatory requirements.
- Provide advice to the private sector regarding newly marketed and validated tests.

## **Training and Education**

- Sponsor training opportunities to improve scientific and technical skills of public health laboratory staff.
- Provide, or facilitate, training courses and workshops for laboratory staff in private and public sectors to continually upgrade the knowledge and skills essential for providing quality services in medical, environmental, and public health laboratories.
- Provide short- and long-term training opportunities to prepare scientists for careers in public health laboratory practice.
- Provide continuing education in management and leadership development for those in administrative positions.
- Participate in training of medical scientists.

## Partnerships and Communication

- Develop and strengthen partnerships among countrywide public health leaders, academia, and private industry to advance understanding of the critical role played by public health laboratories in supporting the core functions of public health.
- Emphasize the role and value of the public health laboratory to national public health programs.
- Participate in strategic policy planning and development processes.
- Maintain strong communication networks among
  - » public health doctors/private doctors;
  - » city council officials;
  - » epidemiologists;
  - » directors of various public health programmes;
  - » legislators;
  - » state health budget personnel; and
  - » other laboratory management staff.

The definition of laboratory core functions provides a basis for assessment of laboratories against appropriate standards and guidelines for the improvement of laboratory activities, followed by policy development and quality assurance.

Another key continuation of the definition of laboratory services core functions is the need to develop performance standards. Performance standards are critical for public health and provide potential benefits of improved accountability; better resource deployment; enhanced capacity building for community, and national public health systems; widespread use of best practices; and increased focus on mission and goals. The same premise is true for benefits of performance standards for laboratories. Work is in progress to create performance standards for the nation's laboratories through collaborative efforts with SOUTHERN REGION and CDC.

# The Plan

## **Over-arching Goal:**

A coordinated Public Health Laboratory Service established and functioning according to agreed upon standards.

## **Specific Objective:**

To strengthen and enhance the planning, management and operational/service capacity of the Laboratory Services – including Blood Transfusion Services and the NPHRL for the provision of efficient and quality services.

## **General Strategic Objectives of the Laboratory Services over the next five years:**

1. Network laboratory structure, system, roles and responsibilities defined and operational.
2. A framework within which planning and development of an integrated Laboratory Services Delivery System will be established.
3. Operational standards and guidelines established and implemented.
4. Laboratory services well staffed and managed.
5. Quality Assurance (QA) and Continuous Quality Improvement (CQI) Programmes for laboratory services developed and implemented.
6. A centralised management information system (MIS) for the laboratory service network established.
7. To advocate for an efficient and effective procurement and maintenance system to be established and implemented.
8. A marketing, advocacy and promotional programme designed and implemented to ensure quality laboratory services nationally.
9. New/revised legislation and regulations in support of laboratory service reform and accreditation of laboratories developed.

## **MANAGEMENT OF THE NETWORK OF LABORATORY SERVICES**

The efficient and effective management of the network of laboratories requires that there be a clearly defined technical and administrative relationship between the Ministry, the Regions, the public facility level and the private sector. The main areas for consideration in the public sector are appointment, training and supervision of staff, procurement of equipment, supplies and maintenance of equipment.

In general the Ministry will be responsible for defining policy and determining standards for the entire system - procurement of equipment and reagents; assessing and evaluating the need for new technologies; advising on the types of service contracts required on the purchase of equipment, investment in a biomedical equipment maintenance unit and overall monitoring and evaluation of the services.

In terms of biomedical equipment maintenance it is felt that service contracts need to be established with the suppliers, maintenance manuals must be provided and training in day-to-day maintenance provided to the users. Given the paucity of biomedical equipment maintenance services available in the public domain the Ministry should invest in the training of biomedical equipment maintenance personnel.

The Regional level should be responsible for ensuring policies are carried out, standards enforced, and for general supervision of all staff working in the regional facilities. In the case of vertical programmes such as Malaria and TB technical oversight should be carried out by the vertical program but day-to-day supervision by the relevant senior officer within the regional services of the laboratory in which the technician works. Issues related to program management will be dealt with at the level of the Medical Superintendent and the (vertical) Program Director.

At the Regional level the Chief Technologist will be responsible for the hospital laboratory management and technical supervision of staff of the lower level laboratory services and will report to the Medical Superintendent of the hospital. All staff working within the laboratory will report to and be supervised by the Chief Technologist.

**Objective: Network laboratory structure, system, roles and responsibilities for laboratories defined and operational**

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*Indicators:*

1. An efficient and effective procurement and maintenance system established and implemented as demonstrated by uninterrupted quality services to all users by the end of 2010.
2. Legislation and regulations in support of laboratory service reform and accreditation of laboratories developed by 2009.

*Activities:*

- Develop a document detailing the roles and responsibilities of each level of the network, central, regional, district and facility.
- Conduct training programmes for regional laboratory and administrative staff on roles, responsibilities and collaboration in the efficient functioning of the service.
- Conduct training in the use of information systems in laboratory service management
- Ongoing monitoring and evaluation of the various programmes and activities.

**Objective: Laboratory services reformed and facilities equipped, staffed and functioning at a level that provides accurate, reliable results in a timely fashion.**

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**Indicators:**

1. 75% of laboratories at all levels equipped as defined in the levels of care by the end of 2009.
2. 75% of laboratories with the categories and number of each category of personnel defined for their level of care by the end of 2009.
3. All public laboratories (Levels 1-4) certified to GYS 170:2003 by the end of 2009.
4. All level 5 laboratories (SPHC, NBTS and NPHRL) accredited to the ISO 15189 by the end of 2009.
5. Quality Assurance (QA) and Continuous Quality Improvement (CQI) Programmes for laboratory services validated by the number of laboratories in compliance with the relevant standards for operation.

**Activities:**

- Survey all laboratory facilities to determine space, equipment and staffing needs on a quarterly basis.
- Prepare a five-year programme based on a yearly budget for filling these needs.
- Conduct a gap analysis followed by a work plan to prepare laboratories for the certification and accreditation processes.

**HUMAN RESOURCES:**

Human resources for the provision of laboratory services are comprised of Medical Technologists, Multi-Purpose Technicians, Laboratory Aides and Phlebotomists. The medical technologist has undergone a three year university programme, the multipurpose technician an eighteen month programme sponsored by the Ministry of Health, which includes pharmacy and X-Ray technology, and the phlebotomist in-service training in withdrawing blood. The Laboratory aide is not required to undergo any defined training programme.

There is almost a crisis situation in relation to the categories of staff. The current situation is that the National Health Service is not benefiting from the training of laboratory technologists at the University of SampleCountry. Graduates either enter the private sector or migrate. Furthermore, with the advent of the National Public Health Reference Laboratory technologists with higher levels of training will be required.

Specialized training of technologists in the field of microbiology and chemical pathology is available at the University of SampleCountry. However, the un-availability of lecturers has curtailed the training of Medical Technologists in the specific areas of haematology and blood banking. As such, there have been no graduates in the programme of the University for the past three years. This has resulted in a chronic shortage of specialised staff in this area.

The NBTS conducts limited in-service training but does not have enough staff to meet current training requests from other laboratories. The Ministry of Health currently provides training in all areas with emphasis on quality management systems whilst the CML, SPHC offers regular in service training.

The degree programme in laboratory technology is to be instituted at the start of the 2007-2008 academic year. This programme will be offered instead of the current Associate degree programme. It is necessary that links with training institutions be formalized to ensure the provision of appropriately trained personnel. For example the tri-partite forum on training matters – MOH, SPHC, and UG – should be reinstated to ensure that the curriculum meets the needs of the health services and that the appropriate ‘hands on’ experience is being provided.

The solution to the shortage of human resources would be to establish a proactive, innovative and appropriate mechanism to encourage technologists to enter the public service, provide incentives to retain them and in the interim make use of other levels of personnel according to the needs of the service.

In terms of recruitment this may include offering scholarships to and contracting an agreed upon number of technologists every year and establishing training programme for medical laboratory technicians (with students coming from all regions especially the rural areas).

In terms of retention it is recommended that well-defined career paths be developed for all categories of staff through the introduction of standardized continuing education. Opportunities must be created for technologists to specialize in different fields – hematology and blood banking, microbiology and chemical pathology since level 4 and 5 services require these three (3) specialties. A technologist should have at least a BSc degree and be certified to become a Head of Department or a Chief Technologist so that post graduate training should be made available.

It is necessary that the various curricula and job descriptions be reviewed. There is also need to institute basic training for laboratory attendants. Senior laboratory personnel including management must be involved in this exercise.

Human resource policies will also need to be reviewed to define the categories of staff required in light of the redefined laboratory services, to redefine the requirements for personnel to move from one level to the next in the system, and the new categories of staff to be added to the establishment.

**Objective: To provide and retain appropriately trained personnel in adequate quantities to staff the laboratory network within the framework of the Workforce Development Strategy**

*Indicators:*

1. Five-year training plan for pre service and in-service training for all categories of laboratory technical staff developed
2. 80% of target reached in the number of persons of each category of staff to be trained annually

*Activities*

- The NLOC will address the requirement of human resources necessary to provide quality laboratory services.

- Conduct a skills-needs analysis in relation to the defined network functions.
- Develop a training plan based on the human resource needs/skills ensuring that sustainability strategies are a major focus.
- Design an appropriate common approach for the delivery of training, both pre-service and in-service, and the monitoring of the training outcomes and impact.
- Conduct internal and external evaluation of all training programmes to ensure that they remain relevant to the services being provided.
- Develop criteria for:
  - » recruitment that reflect the skills appropriate to the organizational structure and function, develop targeted recruitment strategies; and
  - » promotion from one level to the next.
- Develop a tool for the evaluation of staff in terms of proficiency and readiness for promotion or in grade increases in salary.
- Develop and implement relevant and effective orientation programmes for recruits in terms of their role, their reporting relationships, and functioning of the facility.
- Design and conduct a series of in-service training modules to prepare each category/level of personnel to enter the programme of the level above.
- Reconstitute the tri-partite forum on training (MOH, SPHC and UG).

## DATA MANAGEMENT

The National Laboratory Services of the Ministry of Health will be the central repository for management data and will be linked to the Ministry of Health MIS unit. This unit will be responsible for design, acquisition and storage of all forms required for data collection, analysis and for utilizing the data for decision making.

### **Objective: To establish a centralized interactive database and electronic communication links for the laboratory service network**

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#### *Indicators:*

1. Data management system developed to address the type of data to be collected, frequency, flow, analysis, and use designed, for both disease surveillance and programme management by the end of 2009.
2. 75% of laboratory facilities utilizing and reporting according to agree upon data needs, flow and timelines by the end of 2010.
3. All laboratories at level 3 and higher equipped with computers by the end of 2008.

#### *Activities:*

- Convene meeting of all stakeholders to determine data needs, reason needed, utilization frequency, etc.
- Design information system, including standardized data formats and user manuals.
- Conduct training programmes for relevant staff in data collection, compilation, utilization and reporting.
- Conduct training in data entry and the use of relevant software.
- Issue contract for printing of data forms and manuals.
- Procure IT equipment and service contracts.

## MONITORING AND EVALUATION

The functioning of the entire system of laboratories needs to be carefully monitored so as to maintain a high level of service. This includes evaluation (internal and external) of all training programmes to ensure that they remain relevant to the services being provided -

- evaluation of services in relation to certification
- evaluation of staff in terms of proficiency and readiness for promotion or in grade increases in salary
- development of instruments to carry out the evaluation of laboratories
- services and staff

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**CHAPTER 1: LABORATORY INSTITUTIONAL AND MANAGEMENT FRAMEWORK**


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|        |  |
|--------|--|
| 1.1    | <p><b>Strategic Objective</b></p> <p>Develop the administrative and technical management structure of the National Public Health, Regional and District Laboratories</p>   |
| 1.2    | <p><b>Challenges</b></p> <ul style="list-style-type: none"> <li>• No organizational or coordinating structure</li> <li>• Weak national management system</li> <li>• Lack of strong national reference laboratory</li> <li>• Lack of qualified human resource</li> </ul>  |
| 1.3    | <p><b>Planned activities</b></p>   |
| 1.3.1  | <p>Establish linkages between the National Public Health, Regional and District Laboratories to the Ministry of Health</p>   |
| 1.3.2a | <p>Designate the following positions at:</p> <ul style="list-style-type: none"> <li>• NPHL – Director , Head of Sections, Administrative Officer, executive Secretary, Senior Medical Technologist, Medical Technologist, Medical Laboratory Technician</li> <li>• Regional Laboratory – Supervisor, Senior Medical Technologist, Medical Technologist, Multi Purpose Technician and Phlebotomist</li> <li>• District Laboratory – Medical Technologist, Multi Purpose Technician</li> </ul> |
| 1.3.2b | <p>Develop and organizational chart for the NPHL, regional and District Laboratories</p>   |
| 1.3.3  | <p>Establish the location and physical offices of the:<br/>Director, Respective Head of Departments, Administrative Officers – NPHL and the Supervisor and Medical Technologist for the Regional and District Laboratories respectively</p>  |
| 1.3.4  | <p>Revise the roles and responsibilities of the Regional and District Laboratories and implement the defined roles and responsibilities of the NPHL</p>  |
| 1.3.5  | <p>Revive the National Laboratory Oversight Committee (NLOC) to provide linkages to programs and partners to support the National Strategic Plan for laboratories</p>  |
| 1.3.6  | <p>Appoint standing Technical Advisory Committee(s) as required supporting the functions of the NLOC</p>   |
| 1.3.7  | <p>Include representatives from the regional and district laboratories at the NLOC meetings</p>  |

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| TABLE 1: LABORATORY INSTITUTIONAL AND MANAGEMENT FRAMEWORK  |                        |    |    |    |    |   |  |
|---|------------------------|----|----|----|----|---|--|
| STRATEGIC OBJECTIVE<br>PLANNED INTERVENTIONS  | TIME FRAME (YEAR 2000) |    |    |    |    | RESPONSIBLE<br>PARTNERS                   | OUTCOMES AND<br>PLANNED RESULTS                              |
|   | 08                     | 09 | 10 | 11 | 12 |   |  |
| 1.1. Strategic Objective<br>Develop the administrative and technical management structure of the National Public Health, Regional and District Laboratories   | X                      | X  | X  | X  | X  |   |  |
| 1.2 Challenges<br><ul style="list-style-type: none"> <li>No organizational or coordinating structure</li> <li>Weak national management system</li> <li>Lack of strong national reference laboratory</li> <li>Lack of qualified human resource</li> </ul>  | X                      |    |    |    |    | MOH Regional Health Services and partners | Organogram developed   |
| 1.3.1 Establish linkages between the National Public Health, Regional and District Laboratories to the Ministry of Health   | X                      | X  |    |    |    | MOH<br>CDC<br>RHS                         | Organogram<br>Job Descriptions developed/reviewed            |
| 1.3.2a Designate the following positions at:<br><ul style="list-style-type: none"> <li>NPHL – Director , Head of Sections, Administrative Officer, Executive Secretary, Senior Medical Technologist, Medical Technologist, Medical Laboratory Technician</li> <li>Regional Laboratory – Supervisor, Senior Medical Technologist, Medical Technologist, Multi Purpose Technician and Phlebotomist</li> <li>District Laboratory – Medical Technologist, Multi Purpose Technician</li> </ul> | X                      | X  |    |    |    | MOH<br>CDC<br>RHS                         | Completed<br>Organogram                                      |
| 1.3.2b Develop and organizational chart for the NPHL, regional and District Laboratories  | X                      | X  |    |    |    | MOH<br>CDC<br>RHS                         | Package of services used at the various levels               |
| 1.3.3 Establish the location and physical offices of the: Director, Respective Head of Departments, Administrative Officers – NPHL and the Supervisor and Medical Technologist for the Regional and District Laboratories respectively  |                        |    | X  | X  |    | MOH<br>Partners<br>Stakeholders           | Functional committee to strengthen linkages and partnerships |
| 1.3.4 Revise the roles and responsibilities of the Regional and District Laboratories and implement the defined roles and responsibilities of the NPHL  |                        | X  | X  |    |    |   |  |
| 1.3.5 Revive the National Laboratory Oversight Committee (NLOC) to provide linkages to programs and partners to support the National Strategic Plan for laboratories  | X                      | X  | X  |    |    |   |  |
| 1.3.6 Appoint standing Technical Advisory Committee(s) as required supporting the functions of the NLOC.  | X                      | X  | X  |    |    |   |  |
| 1.3.7 Include representatives from the regional and district laboratories at the NLOC meetings  | X                      | X  | X  |    |    |   |  |

**CHAPTER 2: LABORATORY SERVICES**

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**2.1 Strategic Objective**

To strengthen and enhance the planning, management and operational/service capacity of the Laboratory services – including Blood Transfusion Services and the NPHRL for the provision of efficient and quality service

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**2.2 Challenges**

- Balancing the capacity of new technology with current needs
  - Unreliable supply of reagents
  - Preventative maintenance
  - Rapid staff turn-over and shortage of qualified/specialist staff
- 

**2.3 Planned activities**

2.3.1 Develop a network laboratory structure with systems, roles, and responsibilities defined and established; Establish a comprehensive surveillance, preparedness and disease outbreak response system: Develop guidelines for capabilities, planning and SOPs for disaster/outbreak response in the lab at each health care level.

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2.3.2 Establish and implement national operational standards and guidelines for laboratory services  
Ensure Laboratory facilities are well staffed and managed

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2.3.3 Develop and implement a quality assurance programme for the laboratory service  
Establish a centralized management information system within the Laboratory network

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2.3.4 Advocate for an efficient and effective procurement and maintenance system to be established and implemented; Revise existing legislation and regulations in support of laboratory service reform.

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2.3.5 Campaign for Laboratory Certification and Accreditation  
Use audit results to identify current gaps within the laboratory services and develop strategies for closing these gaps

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2.3.6 Create a National Public Health Reference Laboratory (NPHRL) within the MOH Laboratory network; Establish an External Quality Assessment Scheme (EQAS) within the National Laboratory Network

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2.3.7 Revise and possibly increase the scope of testing at the different levels of care

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| TABLE 2: LABORATORY SERVICES  |                        |    |    |    |    |                                   |  |
|---|------------------------|----|----|----|----|-----------------------------------|--|
| STRATEGIC OBJECTIVE<br>PLANNED INTERVENTIONS  | TIME FRAME (YEAR 2000) |    |    |    |    | RESPONSIBLE<br>PARTNERS           | OUTCOMES AND<br>PLANNED RESULTS  |
|   | 08                     | 09 | 10 | 11 | 12 |                                   |  |
| 2.1 Develop a network laboratory structure with systems, roles, and responsibilities defined and established  | X                      | X  |    |    |    | M.O.H<br>R.H.S<br>Partners        | A developed Laboratory network, with its system, roles and responsibilities clearly defined and established reflecting the levels of care. |
| 2.3.1 Establish a comprehensive surveillance, preparedness and disease outbreak response system: Develop guidelines for capabilities, planning and SOP's for disaster/outbreak response in the lab at each health care level. | X                      | X  | X  | X  | X  | M.O.H<br>CML<br>R.H.S<br>Partners | A developed and functioning surveillance, preparedness and outbreak response system  |
| 2.3.2 Implement national operational standards and guidelines for laboratory services   | X                      | X  | X  | X  | X  | M.O.H<br>R.H.S<br>Partners        | Clearly defined guidelines and standards for Laboratory operation  |
| 2.3.2 Ensure Laboratory facilities are well staffed and managed   | X                      | X  | X  | X  | X  | M.O.H<br>R.H.S<br>Partners        | Lab facilities well staffed and managed  |
| 2.3.3 Develop and implement a quality assurance programme for the laboratory service  | X                      | X  | X  | X  | X  | M.O.H<br>R.H.S<br>Partners        | A functional quality assurance system in laboratories  |
| 2.3.3 Establish a centralized management information system within the Laboratory network   | X                      | X  |    |    |    | M.O.H                             | A M.I.S that is developed and functional   |
| 2.3.4 Advocate for an efficient and effective procurement and maintenance system to be established and implemented  | X                      | X  | X  | X  | X  | M.O.H<br>R.H.S<br>Partners        | A procurement and maintenance system that is efficient and effective   |
| 2.3.4 Revise regulations in support of laboratory service reform  | X                      |    |    |    |    | M.O.H                             | Laboratory regulations mandatory   |
| 2.3.5 Promote Laboratory Certification and Accreditation  | X                      | X  | X  | X  | X  | M.O.H<br>GSCP<br>Partners         | Labs certified and accredited  |
| 2.3.6 Establish an External Quality Assessment Scheme (EQAS) within the National Laboratory Network   | X                      | X  | X  | X  | X  | M.O.H<br>RHS<br>Partners          | Scheme established and revised   |
| 2.3.7 Revise scope of testing to reflect the levels of care   | X                      | X  |    |    |    | M.O.H<br>R.H.S                    | A revised level of care document with an increased scope of service  |

## CHAPTER 3: HUMAN RESOURCES

|        |   |
|--------|---|
| 3.1    | <p><b>Strategic Objective</b></p> <p>To provide and retain appropriately trained personnel in adequate quantities to staff the laboratory network within the framework of the Workforce Development Strategy</p>  |
| 3.2    | <p><b>Challenges</b></p> <ul style="list-style-type: none"> <li>• Poor retention of qualified staff resulting from migration or move to private sector</li> <li>• Unavailability of specialist training in hematology &amp; blood banking at the University of SampleCountry</li> <li>• Limited in-service training at NBTS and other institutions</li> <li>• Absence or poorly defined job descriptions along with staff development framework with predictable staff progression</li> </ul> |
| 3.3    | <p><b>Planned activities</b></p>  |
| 3.3.1  | NLOC to address the requirement of human resources necessary to provide quality laboratory services   |
| 3.3.2  | Conduct a skills/needs analysis in relation to the defined network functions  |
| 3.3.3  | Development of a human resource skills/needs training plan with major focus on sustainability strategies  |
| 3.3.4  | Design and conduct a series of in-service training modules to prepare each category/level of personnel to enter the next level in the organization  |
| 3.3.5  | Design an appropriate pre-service and in-service delivery of training including the monitoring of the training outcomes and impact  |
| 3.3.6  | Conduct internal and external evaluation of all training programmes to ensure that they remain relevant to the services provided  |
| 3.3.7  | <p>Develop Criteria for;</p> <ul style="list-style-type: none"> <li>• recruitment that reflect the skills appropriate to the organizational structure &amp; function, develop targeted recruitment strategies, and</li> <li>• evaluation of staff in terms of proficiency and readiness for promotion or in grade increases in salary</li> </ul>  |
| 3.3.8  | Develop and implement relevant and effective orientation programmes for recruits in terms of their role, their reporting relationships and functioning of the facility  |
| 3.3.9  | Reinstitute the tri-partite forum on training (MOH, SPHC and UG)  |
| 3.3.10 | Development of Medical Laboratory Technician Training Programme   |
| 3.3.11 | Development of Training Committee within the department of Standards & Technical Services   |
| 3.3.12 | Develop a Human Resources database  |

| TABLE 3: HUMAN RESOURCES                     |  |                        |    |    |    |    |  |   |
|--|--|------------------------|----|----|----|----|--|---|
| STRATEGIC OBJECTIVE<br>PLANNED INTERVENTIONS |  | TIME FRAME (YEAR 2000) |    |    |    |    | RESPONSIBLE<br>PARTNERS                      | OUTCOMES AND<br>PLANNED RESULTS   |
|  |  | 08                     | 09 | 10 | 11 | 12 |  |   |
| 3.1  | NLOC to address the requirement of human resources necessary to provide quality laboratory services  | X                      | X  | X  | X  | X  | NLOC<br>MOH – Standards & Technical Services | Regular updates of Laboratory Services  |
| 3.2  | Conduct a skills/needs analysis in relation to the defined network functions   | X                      |    | X  |    | X  | MOH-HRD,<br>HSE, DSTS, UG                    | Level of skills available   |
| 3.3  | Development of a human resource skills/needs training plan with major focus on sustainability strategies   | X                      | X  |    |    |    | MOH, HSDU, HSE,<br>HRD, SPHC, UG             | Availability of training plan. Implementation of training programs                              |
| 3.4  | Design and conduct a series of in-service training modules to prepare each category/ level of personnel to enter the next level in the organization (i.e. career path)   | X                      | X  | X  | X  | X  | MOH, HSDU, HSE,<br>HRD, Partners             | Provision of Training Modules   |
| 3.5  | Design an appropriate pre-service and in-service delivery of training including the monitoring of the training outcomes and impact   | X                      |    |    |    |    | MOH, HSDU, HSE,<br>HRD, SPHC                 | Five year training plan for all categories of laboratory technical staff developed              |
| 3.6  | Conduct internal and external evaluation of all training programmes to ensure that they remain relevant to the services provided   | X                      | X  | X  | X  | X  | MOH, DSTS, HSDU,<br>HSE, HRD, SPHC           | 80% of target reached in the number of persons in each category of staff to be trained annually |
| 3.7  | Develop Criteria for;<br>• recruitment that reflect the skills appropriate to the organizational structure & function, develop targeted recruitment strategies, and<br>• evaluation of staff in terms of proficiency and readiness for promotion or in grade increases in salary | X                      |    | X  |    | X  | MOH, DSTS, HSDU,<br>HRD, SPHC                | Recruitment plan developed<br><br>Evaluation & Promotion scheme designed and developed          |
| 3.8  | Develop and implement relevant and effective orientation programmes for recruits in terms of their role, their reporting relationships and functioning of the facility   | X                      | X  | X  | X  | X  | HRD, DSTS                                    | All staff correctly indoctrinated to the organization   |
| 3.9  | Reinstitute the tri-partite forum on training (MOH, SPHC and UG)   | X                      |    |    |    |    | MOH, SPHC, UG                                | Reformation of the training forum   |
| 3.10   | Development of Medical Laboratory Technician Training Programme  | X                      |    | X  |    | X  | HRD, DSTS, HSE                               | Train an agreed-upon number of MLTs in every batch  |
| 3.11   | Development of Training Committee within the department of Standards & Technical Services  | X                      |    |    |    |    | DSTS   | Formation of committee<br>Development of Training Schemes                                       |
| 3.12   | Develop a Laboratory Human Resources database  | X                      |    |    |    |    | HRD  | Generation of personnel capacity  |

## CHAPTER 4: LABORATORY SUPPORT SYSTEMS

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### 4.1 Strategic Objective

Ensure each level of lab service is submitting regular standardized reports to the Ministry of Health

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### 4.2 Challenges

- Absence of accurate and regular reports from decentralized labs
  - Inadequate or inappropriate laboratory infrastructure
  - Lack of or non-functional laboratory equipment
  - Non-functional procurement procedure
  - Non-standardized equipment and reagents at all levels of service
- 

### 4.3 Planned activities

4.3.1 Establish and implement a National Laboratory Information System (NLIS)

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4.3.1a1 Determine information needs of NLIS

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4.3.1a2 Procure IT equipment and service contracts

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4.3.1a3 Printing of data forms and manuals

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4.3.1b Develop and implement manual laboratory data procedure and tools

---

4.3.1c Conduct training in the use of the laboratory information tools and relevant software

---

4.3.1d Pilot an electronic NLIS in selected sites and roll on a national scale

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4.3.2 Improve the physical infrastructure at prioritized laboratories at all health care levels

---

4.3.2a Develop an implementation plan for laboratory physical structure upgrading and maintenance

---

4.3.3 Provide essential equipment, reagents and supplies according to the needs assessment

---

4.3.3a Develop mechanisms for procurement of standard equipment

---

4.3.3b Develop regular laboratory equipment maintenance schedules

---

4.3.3c Develop a procurement and supply plan for laboratory supplies and reagents integrated with the NLIS.

| TABLE 4: LABORATORY SUPPORT SYSTEMS          |  |    |    |    |    |                         |                                 |   |
|--|--|----|----|----|----|-------------------------|---------------------------------|---|
| STRATEGIC OBJECTIVE<br>PLANNED INTERVENTIONS | TIME FRAME (YEAR 2000)   |    |    |    |    | RESPONSIBLE<br>PARTNERS | OUTCOMES AND<br>PLANNED RESULTS |   |
|  | 08   | 09 | 10 | 11 | 12 |                         |                                 |   |
| 4.1  | Ensure each level of service is submitting regular standardized reports to the MOH                   |    |    |    |    |                         |                                 |   |
| 4.3.1  | Establish and implement a National Laboratory Information System (NLIS)                              | X  | X  | X  | X  | X                       | MOH,RHS, Partners               | NLIS  |
| 4.3.1a                                       | Determine information needs of NLIS  | X  | X  |    |    |                         | MOH,RHS, Partners               | NLIS requirement equipment installed. Forms and manuals printed   |
| 4.3.1a1                                      | Procure IT equipment and service contracts   |    | X  | X  |    |                         | MOH,RHS, Partners               | NLIS requirement equipment installed. Forms and manuals printed   |
| 4.3.1a2                                      | Printing of data forms and manuals   |    | X  | X  |    |                         | MOH,RHS, Partners               | NLIS requirement equipment installed. Forms and manuals printed   |
| 4.3.1b                                       | Develop and implement manual laboratory data procedure and tools                                     |    | X  | X  |    |                         | MOH,RHS, Partners               | Efficient management of laboratory data   |
| 4.3.1c                                       | Conduct training in the use of the laboratory information tools and relevant software                |    | X  | X  | X  |                         | MOH,RHS, Partners               | Efficient management of laboratory data   |
| 4.3.1d                                       | Pilot an electronic NLIS in selected sites and roll on a national scale                              |    | X  | X  | X  | X                       | MOH,RHS, Partners               | Electronic NLIS piloted and extended according to national plan   |
| 4.3.2  | Improve the physical infrastructure at prioritized laboratories at all health care levels            | X  | X  | X  | X  | X                       | MOH,RHS, Partners               | Improved quality of lab testing, improved safety, moral and productivity of lab staff                                   |
| 4.3.2a                                       | Develop an implementation plan for laboratory physical structure upgrading and maintenance           | X  | X  | X  |    |                         | MOH,RHS,                        | Annual planning for facility improvements, time lines and progress made in lab upgrading and maintenance plan schedules |
| 4.3.3  | Provide essential equipment, reagents and supplies according to the needs assessment                 | X  | X  | X  | X  | X                       | MOH,RHS, Partners               | Strengthen provision of quality and standardized lab services   |
| 4.3.3a                                       | Develop mechanisms for procurement of standard equipment   | X  | X  | X  | X  | X                       | MOH,RHS, Partners               | Establishment of priorities and obtaining commitments form MOH and partners for funding lab services                    |
| 4.3.3b                                       | Develop regular laboratory equipment maintenance schedules   | X  | X  | X  | X  | X                       | MOH,RHS, Partners               | Proper function and maintenance of equipment  |
| 4.3.3c                                       | Develop a procurement and supply plan for laboratory supplies and reagents Integrated with the NLIS. | X  | X  | X  | X  | X                       | MOH, SCMS, Partners             | National system for procurement and distribution, inventory reports, NLIS data on tests performed                       |

## CHAPTER 5: LABORATORY QUALITY SYSTEMS

|           |   |
|-----------|---|
| 5.1       | <b>Strategic Objective</b><br>Provide accurate, precise and reliable medical laboratory data for the SampleCountry population   |
| 5.2       | <b>Challenges</b> <ul style="list-style-type: none"> <li>• Lack of trained staff</li> <li>• Absence of legislation</li> <li>• Staff attitudes to implementation of QMS</li> <li>• Lack of supporting infrastructure and equipment</li> <li>• Absence of inbuilt quality culture within the national laboratory system</li> <li>• Lack of support from top management</li> </ul> |
| 5.3       | <b>Planned activities</b>   |
| 5.3.1     | Develop and implement standard training program for Laboratory Quality Management   |
| 5.3.1.a.  | Develop training module and conduct TOT   |
| 5.3.1.b.  | Establish training Committee/Group  |
| 5.3.1.c.  | Develop national roll out plan  |
| 5.3.1.d.  | Develop and manage national QA guidelines (including safety) for different levels, scope of testing supporting program needs  |
| 5.3.1.e   | Implement National Lab QA guidelines and enroll labs in Certification program   |
| 5.3.1.f   | Employ and train Lab QA Managers  |
| 5.3.1.g   | Monitor and evaluate National Lab QA service  |
| 5.3.1. h. | Develop and manage an EQA program nationally  |
| 5.3.2.    | <b>Advocate for legislation promulgation</b>  |
| 5.3.2.a   | Provide regulatory framework for both public and private lab operation  |
| 5.3.3.    | <b>Create and establish quality circles within lab system and include QA indicators in job descriptions and performance evaluations</b>   |
| 5.3.3.a.  | Revise JDs to include quality component and performance management  |
| 5.3.3.b.  | Develop and implement staff advancement program   |
| 5.3.4.    | <b>Develop lab infrastructure improvement program</b>   |
| 5.3.4.a.  | Refurbish and construct suitable laboratory facilities  |
| 5.3.4. b  | Develop policy and guidelines for procurement and maintenance of equipment  |
| 5.3.5     | <b>Strengthen National Laboratory Oversight Committee</b>   |
| 5.3.5.a   | Market and promote quality lab services nationally  |

| TABLE 5: LABORATORY QUALITY SYSTEMS          |  |                        |    |    |    |    |                                  |  |
|--|--|------------------------|----|----|----|----|----------------------------------|--|
| STRATEGIC OBJECTIVE<br>PLANNED INTERVENTIONS |  | TIME FRAME (YEAR 2000) |    |    |    |    | RESPONSIBLE<br>PARTNERS          | OUTCOMES AND<br>PLANNED RESULTS  |
|  |  | 08                     | 09 | 10 | 11 | 12 |                                  |  |
| 5.1.   | Provide accurate, precise and reliable medical laboratory data for the SampleCountry population                                  | X                      | X  | X  | X  | X  |                                  |  |
| 5.3.1  | Develop and implement standard training program for Laboratory Quality Management  | X                      | X  | X  | X  | X  | MOH,UG, Donors, Partners         | All public and private lab staff and University students trained in LQM                                |
| 5.3.1.a.                                     | Develop training module and conduct TOT  | X                      | X  |    |    |    | MOH,UG, Donors, Partners         | LQM Module established and used at the University and by the MOH Trainers available nationally         |
| 5.3.1.b.                                     | Establish training Committee/Group   | X                      | X  |    |    |    | MOH,UG                           | Committee responsible for LQM training nationally  |
| 5.3.1.c.                                     | Develop national QM training roll out plan   |                        | X  | X  |    |    | MOH, UG, Partners Donors         | One year training plan developed   |
| 5.3.1.d                                      | Develop and national QA guidelines (including safety) for different levels, scope of testing supporting program needs            | X                      | X  |    |    |    | MOH, Partners Consultant, Donors | National QA guidelines developed and approved  |
| 5.3.1.e.                                     | Implement National Lab QA guidelines and enroll labs in Certification program  |                        | X  | X  | X  |    | MOH, Partners Lab Staff, Donors  | QA guidelines implemented at all levels of testing and labs enrolled in the SNBS certification program |
| 5.3.1.f.                                     | Employ and train Lab QA Managers   |                        |    | X  | X  | X  | MOH, Partners Donors, Consultant | QA managers employed and working with all labs   |
| 5.3.1.g.                                     | Monitor and evaluate National Lab QA service   |                        |    | X  | X  | X  | MOH, SNBS, QA Managers           | Checklists used for QI in lab service  |
| 5.3.1.h.                                     | Develop and manage an EQA program nationally   | X                      | X  | X  | X  | X  | MOH, Donors                      | EQA Scheme implemented nationally and labs participating   |
| 5.3.2.                                       | Advocate for legislation promulgation  | X                      | X  | X  |    |    | MOH,SNBS                         | Legislation approved and published   |
| 5.3.2.a.                                     | Provide regulatory framework for both public and private lab operation   | X                      | X  | X  | X  | X  | MOH, SNBS                        | National and International standards developed or adopted/adapted                                      |
| 5.3.3.                                       | Create and establish quality circles within lab system and include QA indicators in job descriptions and performance evaluations | X                      | X  | X  | X  | X  | MOH, RHA                         | Lab staff supporting each other QA indicators identified to be used                                    |
| 5.3.3.a.                                     | Revise JDs to include quality component and performance management   | X                      | X  |    |    |    | MOH, RHA                         | JDs revised and used in lab system   |
| 5.3.3.b.                                     | Develop and implement staff advancement program  | X                      | X  | X  | X  | X  | MOH, RHA, Partners, Donors       | Staff development /advancement program developed and implemented, Staff Motivation                     |
| 5.3.4.                                       | Develop lab infrastructure improvement program   | X                      | X  | X  | X  | X  | MOH, RHA Partners, Donors        | Improvement in lab infrastructure nationally   |
| 5.3.4.a.                                     | Refurbish and construct suitable laboratory facilities   | X                      | X  | X  | X  | X  | MOH, RHA, Partners, Donors       | Laboratory facilities refurbished and modernized to support testing needs                              |

| TABLE 5: LABORATORY QUALITY SYSTEMS (CONTINUED)  |                        |    |    |    |    |                                       |   |
|--|------------------------|----|----|----|----|---------------------------------------|---|
| STRATEGIC OBJECTIVE<br>PLANNED INTERVENTIONS   | TIME FRAME (YEAR 2000) |    |    |    |    | RESPONSIBLE<br>PARTNERS               | OUTCOMES AND<br>PLANNED RESULTS   |
|  | 08                     | 09 | 10 | 11 | 12 |                                       |   |
| 5.3.4.b Develop policy and guidelines for procurement and maintenance of equipment and consumables | X                      | X  | X  | X  | X  | MOH, Partners<br>Donors, Consultant   | Policy and guidelines developed and implemented<br>Decrease in stock outs                             |
| 5.3.5 Strengthen National Laboratory Oversight Committee   | X                      | X  | X  | X  | X  | MOH, Partners<br>Donors, Stakeholders | Improved networking of public and private labs<br>Consensus decision making for national lab services |
| 5.3.5.a Market and promote quality lab services nationally   | X                      | X  | X  | X  | X  | MOH, Partners<br>Donors               |   |

| TABLE 6: MONITORING AND EVALUATION OF THE LABORATORY SERVICES  |                        |    |    |    |    |                         |                                 |
|--|------------------------|----|----|----|----|-------------------------|---------------------------------|
| STRATEGIC OBJECTIVE<br>PLANNED INTERVENTIONS   | TIME FRAME (YEAR 2000) |    |    |    |    | RESPONSIBLE<br>PARTNERS | OUTCOMES AND<br>PLANNED RESULTS |
|  | 08                     | 09 | 10 | 11 | 12 |                         |                                 |
| 6.1. Establish a monitoring and evaluation system  |                        |    |    |    |    |                         |                                 |
| 6.3.2 Develop monitoring and evaluation tools to assess Laboratory Services  |                        |    |    |    |    |                         |                                 |
| 6.3.3 Develop an M&E training programme  |                        |    |    |    |    |                         |                                 |
| 6.3.4 Establish a Laboratory Monitoring and Evaluation Training Advisory Committee   |                        |    |    |    |    |                         |                                 |
| 6.3.5 Develop an effective support supervisory system  |                        |    |    |    |    |                         |                                 |
| 6.3.6 Review supervisors job responsibilities in line with the revised scheme of service and establish a clear supervisory chain of command. |                        |    |    |    |    |                         |                                 |
| 6.3.7 Establish and Implement detailed M&E procedures  |                        |    |    |    |    |                         |                                 |
| 6.3.8 Provide applied public health laboratory documentation and collaboration of data.  |                        |    |    |    |    |                         |                                 |
| 6.3.9 Promote collaboration of laboratory personnel in documentation of data   |                        |    |    |    |    |                         |                                 |
| 6.3.10 Procurement of tools needed for the implementation of Monitoring and Evaluation system  |                        |    |    |    |    |                         |                                 |

## CHAPTER 6: MONITORING AND EVALUATION OF THE LABORATORY SERVICES

### 6.1 Strategic Objective

Establish a monitoring and evaluation system to measure the delivery of quality Laboratory Services from Regional and District Laboratories as well as the National Public Health Laboratory and provide the means for continual quality Improvement.

### 6.2 Challenges

- Lack of M&E tools specific to the Laboratory.
- Weak supervision and lack of commitment at the lower level health Facilities.
- Lack of qualified M&E personnel specific to the Laboratories.
- Lack of a relevant Laboratory Monitoring Policy.

### 6.3 Planned activities

6.3.1 Establish a monitoring and evaluation system

6.3.2 Develop monitoring and evaluation tools to assess Laboratory Services

6.3.3 Develop an M&E training programme

6.3.4 Establish a Laboratory Monitoring and Evaluation Training Advisory Committee

6.3.5 Develop an effective support supervisory system

6.3.6 Review supervisors job responsibilities in line with the revised scheme of service and establish a clear supervisory chain of command.

6.3.7 Establish and Implement detailed M&E procedures.

6.3.8 Provide applied public health laboratory documentation and collaboration of data.

6.3.9 Promote collaboration of laboratory personnel in documentation of data.

6.3.10 Procurement of tools needed for the implementation of Monitoring and Evaluation system

**CHAPTER 7: POLICY, LEGAL AND REGULATORY FRAMEWORK**

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**7.1 Strategic Objective**

Strengthen the legal and regulatory framework to support implementation of national laboratory policy

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**7.2 Challenges**

- Weak regulatory and enforcement systems
  - Various agencies engaged in separate training programmes
  - Efficient dissemination of information
- 

**7.3 Planned activities**

7.3.1 Strengthen the capacity of laboratories to certify institutions in accordance to GYS170:2003

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7.3.2 Strengthen the capacity of laboratories to accredit institutions in accordance to ISO 15189

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7.3.3 Develop scheme to evaluate, certify and register laboratory personnel

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7.3.4 Establish and disseminate national standards for laboratory equipment & reagents

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7.3.5 Develop a monitoring system to ensure laboratory equipment, reagents & kits confirm to nationally established standards

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7.3.6 Develop standards for the relevant areas engaged in clinical and surveillance services such as environmental health, food safety and research

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7.3.7 Adoption of any relevant standards by the SNBS in relation to laboratory services

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7.3.8 Develop Quality Assurance (QA) and Continuous Quality Improvement (CQI) programmes for laboratory services validated by a number of laboratories in compliance with the relevant standards for operation

| TABLE 7: POLICY, LEGAL AND REGULATORY FRAMEWORK |  |                        |    |    |    |    |  |   |
|---|--|------------------------|----|----|----|----|--|---|
| STRATEGIC OBJECTIVE<br>PLANNED INTERVENTIONS    |  | TIME FRAME (YEAR 2000) |    |    |    |    | RESPONSIBLE<br>PARTNERS                            | OUTCOMES AND<br>PLANNED RESULTS   |
|   |  | 08                     | 09 | 10 | 11 | 12 |  |   |
| 7.3.1   | Strengthen the capacity of laboratories to certify institutions in accordance to GYS170:2003   | X                      | X  | X  | X  | X  | MOH-DSTS<br>NPHRL<br>SNBS                          | All public & private laboratories certified by the end of 2009  |
| 7.3.2   | Strengthen the capacity of laboratories to accredit institutions in accordance to ISO 15189  | X                      | X  |    |    |    | MOH-DSTS<br>NPHRL<br>NLOC                          | The following laboratories – SPHC, NBTS, GDF, MultiTech, Balwant Singh, Eureka, St. Joseph Mercy – accredited to ISO 15189 by the end of 2009 |
| 7.3.3   | Develop scheme to evaluate, certify and register laboratory personnel  | X                      | X  |    |    |    | MOH-DSTS<br>NPHRL                                  | All staff certified and registered by the end of 2008   |
| 7.3.4   | Establish and disseminate national standards for laboratory equipment & reagents   | X                      |    |    | X  |    | MOH-DSTS<br>NPHRL                                  | Published standards approved by MOH   |
| 7.3.5   | Develop a monitoring system to ensure laboratory equipment, reagents & kits confirm to nationally established standards  | X                      | X  | X  | X  | X  | MOH-DSTS<br>NPHRL<br>Hospital Inspectorate         | Inspection of laboratories & means to address non-conformances  |
| 7.3.6   | Develop standards for the relevant areas engaged in clinical and surveillance services such as environmental health, food safety and research  | X                      |    | X  |    | X  | MOH-DSTS<br>NPHRL<br>Food & Drug Department        | Standards developed, published and available to the national institutions   |
| 7.3.7   | Adoption of any relevant standards by the SNBS in relation to laboratory services  | X                      | X  | X  | X  | X  | SNBS   | Availability of any new standards   |
| 7.3.8   | Develop Quality Assurance (QA) and Continuous Quality Improvement (CQI) programmes for laboratory services validated by a number of laboratories in compliance with the relevant standards for operation | X                      | X  | X  |    |    | MOH-DSTS<br>NPHRL<br>SNBS<br>Relevant Laboratories | QA & CQI programmes established & implemented in all labs by the end of 2009  |



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