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**Guidance for Development of
National Laboratory Strategic Plans**

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EXECUTIVE SUMMARY

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, provides data for surveillance of diseases and early detection of emerging problems to guide 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.

SECTION 1 – PURPOSE OF DOCUMENT

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 3 - 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. This document **should be used with the direction of a national laboratory leader appointed by the senior health official and 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 and insights into laboratory practice and management, as well as information on global partners that are operating in the field.

Importantly, the chosen leader or leaders responsible for developing the Plan should have the support of involved sectors, and access to key decision makers. Leadership should make it a priority to 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 i.e. VCT, mobile clinics, etc.

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 on how strategic initiatives will be implemented in annual operating plans and through other means is a responsibility of the core leadership team, and that is essential to success.

Table 1: Central Core Group Leading Development of National Laboratory Strategic Plan

Representatives of GOVERNMENT	
Ministry of Health	<ul style="list-style-type: none"> • 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 associated with finance, procurement, supply chain management, human resources, etc.
Ministry of Education	<ul style="list-style-type: none"> • The Plan must engage the higher education sector that governs training of the laboratory, medical and allied health workforce.
Ministry of Finance/ Treasury	<ul style="list-style-type: none"> • The Plan requires high-level support from Treasury to develop a financial plan that integrates the national budget and donor funds.
Ministry of Defense	<ul style="list-style-type: none"> ■ The Ministry of Defense is often a major service provider of health care for the armed forces and their dependents. The Defense Force may also be involved in health care provision for the broader community and have access to donor funding.
Other Ministries	<ul style="list-style-type: none"> ■ Depending on the organizational and political environment, other ministries may be included such as foreign affairs or, transportation.
Representatives of PUBLIC SECTOR LABORATORIES	
	<ul style="list-style-type: none"> • The head (or representative) from the National Reference Laboratory • Each tier should be represented and consideration given to geographical/regional representation

Representatives of PRIVATE SECTOR LABORATORIES	
	<ul style="list-style-type: none"> • Involve key players to leverage potential public-private synergy.
Representatives of CLINICAL HEADS OF HOSPITALS	
	<ul style="list-style-type: none"> • The laboratories need to service their clinical counterparts who are the primary users of services.
	<ul style="list-style-type: none"> • Knowing the true clinical needs is critical
Representatives of MISSION HOSPITALS/LABORATORIES	
Representatives of NON-GOVERNMENTAL ORGANIZATIONS	
Representatives of RESEARCH GROUPS AND PRACTITIONERS	
<p>A good national laboratory service will engage with, and support research aimed at improving clinical outcomes.</p>	<ul style="list-style-type: none"> ■ Laboratory research groups concerned with defining laboratory quality indicators, e.g., safety, effectiveness, efficiency, and timeliness ■ Clinical research groups interested in accessing laboratory services ■ Contract research organizations, clinical and public health laboratories, data management groups, etc.
Representatives of REGULATORY OVERSIGHT BODIES	
<p>National regulatory bodies are crucial to the development of a National Laboratory Plan.</p>	<ul style="list-style-type: none"> • Regulators give approvals for diagnostic and prognostic tests and regulate use within country • Institutional review committees (ethics committees) authorize research protocols involving human subjects • Biosafety committees 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 objectives strategic actions to address gaps are included in the Plan.

SECTION 2 – BACKGROUND

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 require 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 support to clinical medicine in resource limited settings suffers a double burden of functioning in a resource-constrained environment and administering to communities with a very high burden of diverse diseases requiring varying levels of laboratory sophistication. Resource-constrained laboratories often have to make compromises that limit access to testing services required for proper treatment and cure 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. 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.

In addition, communities are affected by many chronic non-communicable diseases, such as hypertension, cerebrovascular accidents, diabetes, pulmonary disease, and neoplastic diseases. 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.

HIV/TB/malaria – 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 access to microbiology, virology, immunology, and clinical chemistries. Because building capacity for these laboratory tests is not neces-

sarily 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.

SECTION 3 – PLANNING CONSIDERATIONS

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, publicly available standard operating procedures, and policy publications. In addition, it is prudent to keep abreast of changes in the constantly evolving field of laboratory management.

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.

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.

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 region of the country has an adequate number of knowledgeable and competent personnel. Heads of regional 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 second and third tier leadership levels with well-defined roles and responsibilities. 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 a Plan as any Plan developed must be part of the National Health Programs including the HIV/AIDS Control Plan of the country. 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.

Technical analysis

The development of a Plan requires the organization of a significant amount of technical detail. A crucial first step is to conduct a thorough review of the current system and identify any gaps. A SWOT analysis – strengths, weaknesses, opportunities and threats – is often a good approach. 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. These technical analysis committees or teams will need precise terms of reference to ensure completion, and limited overlap between committees.

Table 2: Review of Current System Structure

Structure	<ul style="list-style-type: none">• 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
Infrastructure	<ul style="list-style-type: none">• 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:<ul style="list-style-type: none">• physical conditions• equipment and maintenance• reagents and consumables• general laboratory supplies• sample transport and storage• data management• office space• education and training records

Human resources	<ul style="list-style-type: none"> • Current and required -both laboratory and non-laboratory staff • Capacity development and retention strategies • Salary structures • Relationship with universities and technical colleges
Finances	<ul style="list-style-type: none"> • Current funding, sources and process for requests and allocations • Funding required to implement the plan • Financial systems for supporting new National Laboratory Strategic Plan • Fiscal Oversight
Test requirements	<ul style="list-style-type: none"> • Tests currently available at all tiers of the national laboratory system • Recommendations of tests that should be available and hierarchy (as below)
Quality Management Systems including Quality Assurance and Quality Control	<ul style="list-style-type: none"> • Provision of Quality Management Systems • Assess existing QC, QA, laboratory schemes and proficiency testing programs
Systems	<ul style="list-style-type: none"> • Business • Supply chain management • Laboratory information management systems • Monitoring and evaluation frameworks • IT systems and how well they link between the tiers • Communication systems
Legal and Policy Review	<ul style="list-style-type: none"> • investigate laws, statutes, and government policies

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

Structure of national laboratory system within country

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 burden of diseases is within the country. The analysis should also include other diseases which 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 MOH with sufficient information to implement, monitor and evaluate public health programs 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 attending to local clinics will perform simple and more regularly requested sample analyses, while referral centers will have a higher level in the laboratory structure and perform more specialized tests, or those tests which are performed 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 within peripheral health centers. These rapid tests can be carried out by non-laboratory trained healthcare workers, including the reporting back of results to the clinical colleagues. There is seldom a need for a pathologist to be on site, although telephonic access to such a person should be possible for any cases which prove to be more complicated.

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

District and regional/provincial levels

The delineation between the next levels will depend on what types of service the country wants to offer. There is no standard way of determining at which point a laboratory test becomes a secondary or tertiary level assay. This is something that the Plan will need to define. However, rules will be required to guide when tests are requested, and when to refer a specimen or individual from one tier to a higher level.

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;

- Tests that are required infrequently
- Tests that are not cost-effective in a decentralized manner
- 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
- Validation and optimisation of new assays, as new technology becomes available
- Setting of national standards and norms
- Conduct and coordinate quality assurance and training nationwide
- National tracking of disease test results
- National outbreak response and control capabilities

The national reference laboratory should be funded at levels which are far higher per test performed than normal, when compared with the other laboratories in the country. The reference laboratory must be well linked to the other regional and local facilities to ensure easy access and support. International support and linkages through the WHO regional network to the global surveillance and reference laboratories are necessary.

Standard operating procedures and referral processes

The laboratories will be able to offer the 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. In some instances a pathologist may need to determine if a test required at all. 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 be referred for further testing at a higher level laboratory with increased capacity and/or sophistication.

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 between clinics without the need for additional training.

That standardization is preferable is not an absolute in laboratory systems. Decisions must be vetted by a 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 inappropriate 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 is 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, and too many suppliers.

Tests to be performed

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

The list of available tests should be guided by a committee of senior clinicians and pathologists appointed by the Ministry of Health. The 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 service to clinicians.

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. The committee of senior clinicians and pathologists should put in place guidelines for appropriate use of tests. This will need to be updated on a regular basis, so as to reflect new developments. The test hierarchy described earlier should also be guided by this committee.

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 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 of 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 points 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 which ensures reliability at all times. Where there are problems, the QA system should identify, document, and correct them.

This guidance document cannot do justice to the large field of quality management. As an example, 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.

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 Technical Analysis – Section 3).
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.

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.

Human capital

The issues surrounding human capital development and retention of skilled individuals are great, 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 will need to be formulated for:

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

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 may need formal links between the various stakeholders or government departments be facilitated through formal inter-ministerial agreements.

In-service training In addition, training for staff members within the laboratory system should be an ongoing process with additional career development curricula being 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 at a required amount of training every year.

Career paths delineate

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, because 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 the existing posts which were frozen due to budgetary constraints,.
- Establish new posts with associated budgets
- Set up a clear hierarchy structure where staff can see that there is a possibility to progress based on experience and training.
- Establish a staff performance monitoring system and transparent salary scales for the 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 which 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 process in 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 which 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 the equivalent of many billions of US dollars 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 (MDG's). Three of the MDG's have direct application to health and therefore laboratory functioning. The achievement of these MDG's is supported by the wealthy first world nations as well as other development agencies. Developing countries have significant opportunities to achieve their MDG goals 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 impact on resource limited settings' healthcare, and funding the development and running costs of laboratories is one avenue for such bodies. A NLSP can ensure that donor funding achieves maximum impact, 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 impact 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 impacts 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 opportunities 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 is 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 is 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 which 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 the 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 what should be considered, if during the course of the program 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.

SECTION 4 – PROPOSED ROADMAP

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 a 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 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.

Table 3: National Plan Development Stakeholders

<p>Government</p>	<ul style="list-style-type: none"> • The Ministry of Health • Ministry of Education • Ministry of Finance / Treasury • Ministry of Defense
<p>Public sector laboratories</p>	<p>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.</p>
<p>Private sector laboratories</p>	<p>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.</p>
<p>Non-governmental organization and mission hospitals/labs</p>	<p>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.</p>
<p>Clinical heads of hospitals</p>	<p>The laboratories need to align their services to meet the needs of the clinical care services.</p>
<p>Professional bodies, such as the Health Professionals Council, and those bodies which regulate standards for training</p>	<p>Major changes in the structures which govern laboratory staff may need changes to be instituted by the professional bodies.</p>

<p>Research groups and practitioners</p>	<p>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.</p>
<p>Workers Union</p>	<p>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 which require a collective bargaining process involving the unions, and their early involvement is therefore important.</p>
<p>Legal and Policy experts</p>	<p>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.</p>
	<p>Some developing countries have had to enact new legislation through Parliament to facilitate implementation of new initiatives.</p>
<p>Regulatory oversight bodies</p>	<p>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.</p>

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.

Table 4: International Partners

Normative agencies	<ul style="list-style-type: none">• World Health Organization (WHO)• UNAIDS
Funding and implementing partners	<ul style="list-style-type: none">• The US President’s Emergency Plan for AIDS Relief (PEPFAR)• The Global Fund for AIDS, Tuberculosis and Malaria (GFATM)• The US Centers for Disease Control and Prevention (CDC)US President’s Malaria Initiative• The World Bank• African Development Bank• Clinton HIV/AIDS Initiative (CHAI)• J.I.C.A• D.F.I.D• E.D.C.T.P.• G.T.Z.
International NGOs	<ul style="list-style-type: none">• CARE• African Medical Research Foundation (AMREF)• Family Health International (FHI)• International Red Cross/Red Crescent• Medecins san Frontieres (MSF)• Partners in Health (PIH)• OXFAM• Population Services Council (PSI)• Many others

Public sector laboratory organizations	<ul style="list-style-type: none"> • United Kingdom National External Quality Assessment Service (UK NEQUAS) • College of American Pathologists (CAP) • Association of Public Health Laboratories (APHL) • Public Health Agency of Canada
Data management specialists	<ul style="list-style-type: none"> • Private, in-country companies • Independent standards setting bodies, e.g., HL-7

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 within 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 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 groups 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 on-going 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 which incorporates 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 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.

SECTION 5 – CONCLUSION

The development of a National Laboratory Strategic Plan is a critical part of the process to improve clinical care and public health programs in any country. The process is a demanding, lengthy one within which many stakeholders will be consulted, and a process within which many diverse perspectives will be brought to bear on the leadership. This document is only one tool to guide those who are responsible for the generation of these National Laboratory Strategic Plans. It is the strength of national leadership and commitment that will determine if planning will be effective and result in better health outcomes.

SECTION 6 – APPENDICES, REFERENCES AND RESOURCES

1. Acronyms and Glossary
2. References
3. Maputo Declaration 2008
4. National Strategic Laboratory Plan development checklist
5. Sample National Laboratory Strategic Plan (under separate cover)

6.1 Acronyms and Glossary

ADB	African Development Bank - a multilateral development bank for Africa. www.afdb.org
AMREF	African Medical and Research Foundation - a health development organization. www.amref.org
APHL	Association of Public Health Laboratories. www.aphl.org
CAP	College of American Pathologists - The world leader in laboratory quality assurance. Accreditation body.
CARE	Non-governmental organization engaged in disaster relief and other poverty and health problems worldwide. www.care.org
CDC	Centers for Disease Control and Prevention. www.cdc.gov
Clinton Foundation	Non-governmental charitable foundation. Works with governments through its HIV/AIDS initiative to provide care to people in need. www.clintonfoundation.org
DFID	The Department for International Development (DFID) is the part of the UK Government that manages Britain's aid to poor countries and works to get rid of extreme poverty. www.dfid.gov.uk
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. www.edctp.org
FHI	Family Health International - Non-governmental international public health organization with activities in research, education and family health. www.fhi.org
Gates	Bill and Melinda Gates Foundation. Private foundation which works to help all people lead healthy productive lives; involved in global health and global development. www.gatesfoundation.org
Global Fund for AIDS, TB and malaria	Partnership between European governments, civil society, the private sector and affected communities created to address the fight against AIDS, tuberculosis and malaria. www.theglobalfund.org

GTZ	The Deutsche Gesellschaft für Technische Zusammenarbeit is an international cooperation enterprise which supports the German government in achieving its development-policy objectives. www.gtz.de
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. www.jica.go.jp
MSF	Medecins sans Frontières - Doctors without Borders is a private international humanitarian aid organization that provides emergency medical assistance to people in danger. www.msf.org
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. www.oxfam.org
PEPFAR	The U. S. President's Emergency Plan for AIDS Relief www.pepfar.gov
PSI	Population Services International: Non-profit organization with a focus on measurable health impact. Areas of work: Malaria, Child Survival, Reproductive Health and HIV. www.psi.org
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	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. www.ukneqas.org.uk
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. www.unaids.org
U.S. 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. www.fightingmalaria.gov
WHO	The World Health Organization is the directing and coordinating authority for health within the United Nations system. www.who.int
World Bank	An internationally supported bank that provides financial and technical assistance to developing countries for development programs. www.worldbank.org

References

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2. Medical laboratories – Particular requirements for quality and competence, International standards Organization, International Standard 15189, Second edition, 2007
3. Strengthening National Public Health Laboratory Networks: A Strategic and Practical Blueprint for Public Health Laboratory Services in Resource-Poor Environments, Association of Public Health Laboratories, March 2006, April 2009 (v2)
4. Strategic Orientations To Guide WHO Action In The African Region World Health Organization, Regional Office for Africa, Brazzaville , 2005
5. Developing Laboratory Partnerships to Detect Infections and Prevent Epidemics, World Health Organization, Lyon, 2005
6. Application of a Quality Management System Model for Laboratory Services; Approved Guideline – Third Edition, Clinical and Laboratory Standards Institute, GP26-A3

6.3 Maputo Declaration

The Maputo Declaration on Strengthening of Laboratory Systems

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-status¹. 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 detected². 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 year³.

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).

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 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

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 US Presidents Emergency Plan for AIDS Relief, US 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

6.4 National Strategic Laboratory 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

