

Guidance for Development of National Laboratory Strategic Plans

**World Health Organization – Regional Office for
Africa and United States Centers for Disease
Control and Prevention (CDC), Atlanta**

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Glossary and Acronyms

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
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
CEO	Chief Operating Officer
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 <u>information systems</u> , particularly software applications and computer hardware.
JICA	The Japan International Cooperation Agency is an independent governmental agency that coordinates <u>official development assistance</u> 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 <u>supplier</u> to <u>customer</u> .
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>U.S. Agency for International Development</u> , the <u>Department of Health and Human Services (Centers for Disease Control and Prevention)</u> , the <u>Department of State</u> , the <u>White House</u> , 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 <u>bank</u> that provides financial and technical assistance to developing countries for development programs. www.worldbank.org

EXECUTIVE SUMMARY

The development of greater laboratory capacity in developing countries is an urgent need, as defined in the Maputo Declaration on Strengthening of Laboratory Systems of 2008. Each country is encouraged to have a National Laboratory Strategic Plan as part of its national health plan. National efforts aimed at the development of increased laboratory capacity require policy adoption and strategic planning and implementation of activities appropriate for each country. This document provides guidance for the development of National Laboratory Strategic Plans in developing countries.

There are many important considerations for the development of National Laboratory Strategic Plans. These include logistical matters as well as financial, technical, legal, and quality issues. Naturally, National Laboratory Strategic Plans will differ between countries, because of varying levels of infrastructure, human capacity, financial resources, and levels of engagement by the international community.

This guidance document provides country leaders with a suggested road map for the development of a National Laboratory Strategic Plan, as well as 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 that facilitates easier adoption of a National Laboratory Strategic Plan. Such plans are a crucial part of the process to improve laboratory support to clinical facilities, and therefore improve the lives of those requiring health care.

SECTION 1 – PURPOSE OF DOCUMENT

Introduction

Adequate laboratory services are critical to ensuring that communities receive good clinical care. Despite recent major efforts to improve global laboratory services, the national laboratory systems of most developing countries are inadequate to meet priority needs. There is an urgent need to develop effective National Laboratory Strategic Plans to strengthen laboratory systems, as an integral part of strengthening overall health systems of developing countries.

This document, a reference guide for developing a National Laboratory Strategic Plan, 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”*.

The meeting in Mozambique ended with the *“Maputo Declaration on Strengthening of laboratory Systems ,”* which is a call to action to advocate for increased laboratory capacity in developing countries. (Appendix).

How to use this document

1: This is a guidance document **meant to assist in** the development of a National Laboratory Strategic Plan or updating of a current plan. As such, it should be used as one of many resources in a national process that involves participation of all stakeholders. Sections of the document identify global partners/organizations involved in laboratory work that can offer assistance, including valuable collaborations and funding support.

2: This document **provides** advice about **the development process of the plan**, not just the development of a document. As described in Section 4, it is recommended that there be a small leadership core and an associated secretariat to drive the process of developing the **National Laboratory Strategic Plan** (hereinafter, the Plan). This 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, including ensuring timelines are met and providing experience and insights into laboratory practice, management, as well as insights into 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 also make it a priority to involve as many stakeholders as possible during the plan development.

3: The **Plan should be a document which matures and evolves** and responds to such issues as:

- Changing burden of disease
- Availability of new technology
- Cost of technology advancements
- Government and donor support levels
- Automation

- Clinical indications for diagnosis and monitoring
- Training requirements

Strategic objectives of this document

This document provides guidance in several areas that are important in the development of an effective Plan. Specifically, 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.

Scope of document

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

The document also 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.

Who should use this document

This document is designed to support and offer guidance to the central core group leading the efforts to strengthen laboratory systems, and the broad group of individuals and organizations within the country who are stakeholders in this process.

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, such as AIDS, tuberculosis (TB) and malaria • 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 appropriate staff.
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. The Ministry of Defense may also have access to donor funding.

Representatives of PUBLIC SECTOR LABORATORIES

	<ul style="list-style-type: none"> • From all tiers
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Representatives of PRIVATE SECTOR LABORATORIES

	<ul style="list-style-type: none"> • Involve as many as possible to leverage potential public-private synergy.
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Representatives of CLINICAL HEADS OF HOSPITALS

	<ul style="list-style-type: none"> • The laboratories need to service their clinical counterparts
	<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

A good national laboratory service will engage with, and support research aimed at improving clinical outcomes.

- 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

National regulatory bodies are crucial to the development of a National Laboratory Plan.

- Regulators give approvals for diagnostic and prognostic tests.
- and determine the cost applied to tests in public and private settings.
- Institutional review committees (ethics committees) authorize research protocols involving human subjects
- Biosafety committees deal with waste disposal.

Representatives of BODIES SET UP TO REGISTER AND MONITOR NOTIFIABLE DISEASES

SECTION 2 – BACKGROUND

The need for comprehensive, quality laboratory services

African countries have a significant disease burden, with HIV/AIDS, TB and malaria making up the majority of the disease and death rates. The provision of clinical care requires adequate access to quality laboratory support. The majority of significant illnesses require laboratory confirmation of the diagnosis, and laboratory monitoring of the patient after the diagnosis has been made.

Therefore, without appropriate, high quality laboratory support to patients, many cases of significant illnesses cannot be managed optimally.

Laboratory support to clinical medicine in developing countries suffers the double burden of functioning in a resource-poor 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 which ultimately affect the health of patients. In some environments, these compromises deny access to laboratory diagnosis/monitoring of many diseases, thereby reducing 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 African health care, AIDS has added a new level of suffering, and it is clear that African laboratories cannot adequately address the need for diagnosis and monitoring of HIV infection. In addition, as greater access to adequate treatment is achieved in Africa, the management of many other chronic diseases becomes ever more important. Life saving drugs are enabling people infected with HIV to have longer productive lives. However, the access to increased levels of treatment also demands increased laboratory monitoring of patients over many years.

African communities are affected by many chronic diseases, such as hypertension, diabetes, lung diseases, and neoplastic diseases. These diseases have a high impact on the individual and on the healthcare infrastructure.

However, many countries find that raising international donor money for the support of 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 major diseases in Africa, namely HIV/AIDS, TB and malaria, requires significant laboratory support, and that this is not currently available in most developing countries. 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 cases to put a comprehensive package of support, treatment and care in place to serve highly affected communities. The same levels of funding are not available for other diseases, even though care of these patients is equally important.

Proper management of HIV/AIDS, TB, and malaria requires a comprehensive network of supporting laboratories, and access to a suite of laboratory tests, including access to microbiology, virology, immunology, and chemistry. These laboratory tests are not specific for HIV/AIDS, TB or malaria care. One consideration of a Plan should be to look at how funding streams for HIV/AIDS, TB and malaria care might be used as a legitimate basis for improving the entire laboratory infrastructure to support management of other diseases, staffing and supplies.

SECTION 3 – PLANNING CONSIDERATIONS

This section deals with a variety of activity areas and themes that should be considered by country participants 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, the field of laboratory management is constantly evolving, and investigators should keep abreast of all relevant developments.

Setting objectives

The importance of defining appropriate country 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 between countries, as they will in part be influenced by the available in-country capacity, infrastructure, and systems.

The careful negotiation of a limited number of country objectives takes time and skill. Each sector will attempt to influence the Plan to its own best interest. This phenomenon is natural, and can be positive, provided that it is 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 productivity. Three to five overarching objectives 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 on reality on the ground.
- The objectives should be based on what is possible, not aspirations, and should stimulate progress.

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

- Infrastructure development and organizational structure
- Training and retention

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

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 what 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 an integral part of the Ministry of Health. The organization should carefully articulate the vision and mission, as the success or failure of the Plan will to an extent depend on what is contained in these statements.

Generally A vision statement shows what the organization aspires to, and gives an overarching definition of where the future lies for the entity. It is normally short, and does not include much detail.

A mission statement is more detailed, but still concise and outlines what the organization hopes to achieve. A mission statement often includes the objectives and activities set out to meet the objectives of the Plan and perhaps some of the most important work areas.

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 government by a process of continuous improvement.

Leadership

The Plan should address the leadership structure and culture of the laboratory system. The leadership 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 rest of the leadership 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 is 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 “CEO-like” 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 leadership structure, leadership styles should be addressed in the Plan. While leadership styles differ, the characteristics expected of those in senior positions can be delineated. This ties in with 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. If the main leadership’s style is contradictory to that of the laboratory system, major human resource hurdles will emerge.

Resources to assist the development of national laboratory strategic plans

The development of an effective Plan is a process which will take the lead persons a significant amount of effort, 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

Table 2: Review of Current System Structure	
Structure	
	<ul style="list-style-type: none"> • Current governance structure and desired structure, if different • Delineation of different levels within the tiered laboratory network, including referral structures, centers of excellence and national reference bodies • Laboratory management

Infrastructure	<ul style="list-style-type: none"> • What is available, and what is needed • Buildings, capital equipment • 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"> ○ quality ○ temperature regulation ○ test equipment ○ reagents and consumables ○ general laboratory supplies ○ sample transport and storage ○ data management ○ office space ○ staff compliment ○ organograms ○ training records
Human resources	<ul style="list-style-type: none"> • Current and required • Capacity development and retention strategies • Salary structures • Relationship with universities and technical colleges
Finances	<ul style="list-style-type: none"> • 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 routine laboratories vs. those at referral centers • Recommendations of tests that should be available and hierarchy (as below)
Quality Assurance and Quality Control	<ul style="list-style-type: none"> • Assess existing QA, laboratory schemes and proficiency testing programs
Systems	<ul style="list-style-type: none"> • Business • Supply chain management • Laboratory IT 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 laboratory system within country

The Plan should address the issue of how well-structured the laboratory system is currently, and what is required to improve service to the population.

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.

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.

Primary care laboratory service tier

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, or simple automated assays, can be carried out by technologists, 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 at these primary care laboratories must be carefully described in the Plan.

Secondary and tertiary laboratory service tiers

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 delineate. However, rules will be required to guide when tests are requested, and when to “escalate” a laboratory test from one tier to a higher level.

Public Health Reference Laboratories

All countries should consider the formation of a national reference laboratory.

This laboratory will perform a variety of tasks, among others;

- Tests that are required infrequently
- Tests that are not cost-effective to run at multiple centers
- 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
- Development of new assays, as new technology becomes available
- Setting of national standards and norms
- Assisting nationally with issues such as quality assurance and training
- National tracking of disease epidemiology
- National outbreak 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 very well linked to the other regional and local facilities to ensure easy access and support. International support and linkages are crucial.

Testing algorithms and escalation

The laboratories will be able to offer the clinical colleagues a much better service if the Plan delineates testing algorithms for each clinical condition at all clinics. For example, a blood sample arriving for analysis for chronic hepatitis, HIV, anemia, etc. should be processed according to a standard algorithm, irrespective of laboratory used. This allows a pathologist to order, subsequent set of tests to be performed outside of the initial algorithm. 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 escalating a laboratory request to a higher level.

- Certain tests will not be performed at lower level clinics (e.g., nucleic acid based tests), and escalation 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 escalation.
- 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 may automatically be done at a more sophisticated laboratory.

Standardization

Issues of test standardization are critical and important because:

- Certain tests from different suppliers have very different sensitivities and - specificities, and therefore are difficult to compare.
- Different tests require test-specific training, which has a human capacity implication.
- Equivalent tests for the same clinical indication may cost more.
- 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.
- Automation with certain suppliers has positive cost and staff benefits.

In resource-poor 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 liability. Therefore a balance has to be

struck between having a limited but sufficient number of suppliers that still allow 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, etc.

The list of available tests should be guided by a committee of senior clinicians and pathologists which is 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.

Pathology services are expensive, and each country should have a test hierarchy to ensure appropriate use of resources, where 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 pathology 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 Assurance

Quality Assurance (QA) is a 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.

This guidance document can not stress enough the importance attached to ensuring that the Plan has sufficient attention given to issues of QA. 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 point where the result is returned to the patient's hospital/clinic folder. 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 appropriately.

This guidance document can not do justice to the large field of quality management. 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 that are required for the development of a Plan. These committees need to have very specific terms of reference.

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. (see Technical Analysis – Section 3).
2. In addition, the committees should be empowered to make recommendations around what 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. There are many such commercial

systems available which integrate the day-to-day laboratory activities with business management aspects. These include supply chain management, billing, human resources, finance, and other important management tools necessary for a comprehensive laboratory service.

The laboratory management IT systems all need to be adapted to suit a specific environment. However, systems can be modified to accommodate 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 massive, 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 will cover these two main areas:

1. Evaluating the current situation relating to human resources.
2. Making recommendations regarding the best way forward in the PLAN for managing human resources.

With reference to managing human resources, specific recommendations will need to be formulated about many areas, including:

1. Developing the required expertise to run every level/area of the laboratory service.
2. Opening jobs and creating relevant career paths for all levels /types of staff.
3. Developing capacity retention strategies.
4. Developing strategies to convince some of the many Africans living outside of the continent to return to work within the new 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.

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

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 all staff training responds to developments in technology and equipment in the field. Refresher courses should be offered to staff to give them broader insights into recent developments.

If the infrastructure and capacity exist, career development training may be formalized into a point system where practitioners will have to achieve a certain number of points every year.

Career paths

There is much emphasis correctly placed on capacity development in developing countries. 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 stable (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:

- Opening 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.
- Establish a staff performance monitoring system and transparent salary scales for the different levels.

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 delineates financing. This is a complex process which should be started as soon as the initial process starts. 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 are what Treasury will use to make its final decision 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 allow

Treasury to sign-off on a plan that might not be possible under other conditions. Treasury will expect that the business plan factors in all aspects of the overall plan, as well as increases due to inflationary pressures, new technologies, growth of the service, as well as considerations on how best to limit financial liability over time.

Current global role players in laboratory support

Developing countries have significant opportunities to engage with the global role 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.

The most prominent of these are the President's Emergency Plan for AIDS Relief (PEPFAR) and the Global Fund for AIDS, TB and Malaria. Both of these programs contribute billions of US dollars (or equivalent) to developing countries for preventive measures as well as clinical and laboratory interventions. There are great opportunities for developing countries to engage with such programs to raise revenues for both the generation of the 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) - <http://www.un.org/millenniumgoals/goals.html>. Three of the MDG's have direct application to health and therefore laboratory functioning. The achieving 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 such plans funded by international development agencies.

In addition, there are foundations and charitable groups that may be interested in funding Plans to achieve the same goals.

Guidelines for involvement of global role players

There are many multilateral, bilateral, and other funding bodies which want to have a positive impact on developing countries' healthcare, and funding the development and running costs of laboratories is one avenue for such bodies. These bodies invariably want to ensure that their funding achieves maximum impact, and see that the work performed with that funding is well aligned with the national priorities and systems. International funders do not support setting up of unnecessary parallel structures.

Thus, the Plan should consider how to engage international agencies to support laboratory systems within the country. This should spell out the nature of the assistance required by each country, the process required of donor agencies to engage with in-country stakeholders, and how best to be well aligned with national structures/systems. The guidance may well include how best to demonstrate impact within the already 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, websites, etc. and may need to be facilitated by a professional communications consultancy. 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 and may use communication deficiencies to discredit the Plan. A structured program of communication will minimize opportunities for misunderstanding.

Data management

The development of an appropriate Data Management Plan for the 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 (see below). Without monitoring and evaluation systems in place it is 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 accrued, compiled, analyzed and utilized. There are a myriad 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)

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 plan. 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. Donors often consider it appropriate to spend up to 8% of the overall budget on M&E.

The discipline of M&E is put in place to do two things:

1. The monitoring component is performed during the course of the program, and is intended to ensure that the all targets are being achieved as planned.
2. The evaluation component is the aspect which looks at “impact” in the relevant community.

To perform adequate M&E, it is necessary that specialists in the field 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 (if required) 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 legal implications may be small if what is proposed in the Plan aims to improve service delivery within the current structures and does not alter the current. Conversely, the legal implications may be very substantial if new systems, structures, contracts, and employment conditions are considered.

In any event, even if major changes are not envisaged in the Plan, it is important that legal opinions be sought early on in the process, as there will invariably be a set of scenarios available to any country, each of which will have legal implications.

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 is 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 3 – 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. Without active support and involvement at a ministerial level, there is a real danger that the masses of technical input may be wasted and not implemented.

Appropriate expectations regarding staging

It is important that everyone involved has an appropriate expectation. This process is focused on the **development** of a Plan – not the **implementation** of that Plan.

The people driving the development of the Plan might not be the same people that implement the Plan. Implementation of the Plan is an entirely different process.

Consultation steps

1: Initial core leadership

The initial core leadership of the initiative to develop the Plan should be made up of individuals from within the country with a deep knowledge of the current national structures, systems, strengths, and challenges. They should be appointed by the Health Ministry to lead the effort. They should preferably not be seen as partisan towards one or another outcome, and be individuals with unquestionable integrity. The emphasis on these personal attributes is based on the fact that if this initial process is perceived as partisan or misguided, the remainder of the development of the plan will likely be fraught with challenges or impossible to undertake.

The initial core leadership needs to map out a process for including the various national stakeholders in the first set of consultations. It is critically important that the above principles are adhered to, and that as many relevant individuals and organizations be consulted. These individuals will need to be included within the development process and structures to be formed.

The initial core leadership group needs to 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 lead the process, as most other individuals are normally over-committed in their usual jobs. On completion of the process to develop the Plan this team will hand over to the tenured staff. There will need to be a capital equipment budget, as well as a budget for consumables, meetings, flights, and consultations.

Once government support and a budget are secured, the interim leadership led 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.

This step can be achieved either as:

1. An extensive sequence of consultations with the major stakeholders, followed by a large consultative forum, or
2. A large consultative forum after limited individual stakeholder engagement.

What is important is that as wide as possible a group should be involved. The following contained in Table 3 are a description of the main in-country stakeholders, among others :

Table 3: National Plan Development Stakeholders

Table 3: National Plan Development Stakeholders	
Government	<ul style="list-style-type: none">• The Ministry of Health• Ministry of Education• Ministry of Finance / Treasury• Ministry of Defense
Public sector laboratories	<ul style="list-style-type: none">• It is important that representatives from 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.

Private sector laboratories	<ul style="list-style-type: none"> It is important to involve as many private sector laboratories as possible, to explore synergies between the private and public sectors laboratories as possible In many developing countries, the private laboratories are well funded through the medical insurance sectors, and thus frequently have technologies and skills which are not found elsewhere in the country. There are significant opportunities to leverage this within the public sector, through the establishment of public-private partnerships where there is benefit which is leveraged by multiple parties.
Non-governmental organization and mission hospitals/labs	<ul style="list-style-type: none"> 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. Government should aim to include these within the process.
Clinical heads of hospitals	<ul style="list-style-type: none"> The laboratories need to align their services to meet the needs of their clinical counterparts. Knowing the true clinical needs is critical
Professional bodies, such as the Health Professionals Council, and those bodies which regulate standards for training	<ul style="list-style-type: none"> Major changes in the structures which govern laboratory staff may need changes to be instituted by the professional bodies.

Research groups and practitioners	<ul style="list-style-type: none"> • A good laboratory service will need to engage with, and support research aimed at improving clinical outcomes. These include laboratory research groups, clinical research groups interested in accessing laboratory services, contract research organizations, clinical and public health laboratories, data management groups, etc. These groups often offer important technical assistance to the routine laboratories. Their involvement in the process adds value. In addition, research groups often build infrastructure and capacity which can be used by the routine laboratory services.
Workers Union	<ul style="list-style-type: none"> • Workers' unions 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.
Legal and Policy experts	<ul style="list-style-type: none"> • Legal and policy experts need to be closely engaged with the process, as the implementation of a National Laboratory Plan will

	<p>have significant policy and legal implications. Some developing countries have had to enact new legislation through Parliament to facilitate the changes. Copies of such legislative changes can be obtained from those countries where this has been enacted.</p>
<p>Regulatory oversight bodies</p>	<ul style="list-style-type: none"> • Regulatory oversight bodies include regulators which 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.

3: Engagement with key international role players

Each country needs to decide what level of international community engagement is needed for the development of the National Strategic Laboratory 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. the 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.

Thus in many cases, they already are active stakeholders.

Table 4 lists the key international players.

Table 4: International Partners

Normative agencies	<ul style="list-style-type: none"> • The 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 Bill and Melinda Gates Foundation • The US Centers for Disease Control and Prevention(CDC) • US Military • US President’s Malaria Initiative • The World Bank • African Development Bank • The Clinton Foundation • 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 • American Medical Research Foundation (AMREF) • Family Health International (FHI) • International Red Cross/Red Crescent • Medecins san Frontieres (MSF) • OXFAM • Population Services Council (PSI) • Many others

Public sector laboratories	<ul style="list-style-type: none"> • United Kingdom National External Quality Assessment Service (UK NEQUAS) • College of American Pathologists (CAP)
Data management specialists	<ul style="list-style-type: none"> • Private, in-country companies

4: Large consultative forum

Once the meetings have taken place, 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.
- To explain to all stakeholders the vision of developing a Plan, as an integral part of the Ministry of Health’s mission to ensure quality health to all citizens
- To 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
- To ensure that there is support and buy-in from stakeholders for the development of a Plan
- To hear the expectations and concerns of stakeholders
- To elect a series of technical task groups from within stakeholders to drive the technical aspects of the plan’s development
- To map a way forward
- Explain timeframes to develop the plan

This consultative forum should attempt to include every relevant in-country stakeholder as well as representatives of the international agencies discussed earlier. Inviting representatives of countries that have a viable National Strategic Laboratory Plan is highly encouraged. The inclusion of knowledgeable representative from other African countries which have already developed such a plan is encouraged.

5: Taking the plan to a new level of detail—A series of smaller task group meetings

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

1. The central administrative leadership led 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. This will almost certainly need a series of consultant-driven reports and processes.

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 group.

2. 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 will have to stick to its terms of reference. The committees will have appropriate representation from the above sectors in drafting of the document. Earlier sections gave details on the technical issues that need addressed.

6: Generation of a final draft of the plan

It is important that a final draft of the policy document be scrutinized in-depth by government policy experts to ensure that it is complementary to the other policy frameworks. The leadership should liaise with relevant government agencies or representatives on an ongoing basis throughout the genesis of the plan.

Adoption and inclusion in National Health Plans

The formal adoption of the plan should be a national meeting which incorporates all of the national and international stakeholders in the field of laboratory service.

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 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 any funds required post implementation. These funds, if possible, should be sourced at this stage. Alternatively, describe the potential funders.

In the absence of an implementation and fundraising plan, it is likely that the plan will be more difficult to make operational. Each new structure or process that is proposed within the plan needs to be cost out and associated with a budget. The country may decide that it needs new (or revised) regulatory review structures, oversight structures or advisory committees.

If no budget is provided for these proposed new structures, they may become a hindrance to the work, rather than a help.

SECTION 4 – CONCLUSION

The development of a National Laboratory Strategic Plan is a critical part of the process to improve clinical care in any country. The process is a grueling, 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 aims to guide those who are responsible for the generation of these National Laboratory Strategic Plans.

SECTION 5 – Appendix

1. Maputo Declaration 2008
2. Sample National Strategic Laboratory Plan
3. National Strategic Laboratory Plan development checklist
4. References
5. Other Resources