

Guidance for Establishing a National Health Laboratory System

**The World Health Organization
Regional Office for Africa**

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Foreword

Laboratories are an essential and fundamental part of all health systems and their goal to improve health. Reliable and timely results from laboratory investigations are crucial elements in decision-making in almost all aspects of health services and disease prevention and control programmes. Critical decisions dependent on laboratory results concern health security, national economies and meeting obligations such as the International Health Regulations (IHR) as well as the health and well-being of individuals.

Despite this central role, strengthening nationally coordinated laboratory services has, until recently, received little or inadequate attention in many countries. This has resulted in laboratory services having a very low national priority in respect to financing, planning and service delivery.

Given the growing importance of health laboratories and emphasis on evidence-based medical and public health practices, it is imperative that health laboratories are strengthened to provide critical inputs to making informed decisions.

To bring the laboratory capacity building agenda as a central component of national health system strengthening, Resolution AFR/RC58/R2 on Public Health Laboratory Strengthening was adopted by Member States in the WHO African region during the 58th session of the Regional Committee in September 2008 in Yaoundé, Cameroon.

The WHO AFRO strategic direction priorities for 2010–2015 highlighted the importance laboratory quality services through partnerships and harmonization of technical support to countries in building capacity to respond to diseases of public health importance such as HIV/AIDS, malaria, tuberculosis and other non-infectious diseases. The development of this document is one of the outcomes of these important initiatives.

In order for laboratories to provide high quality test results, the following systems must be in place: human capacity, infrastructure and management of quality systems.

Competent staff who are adequately trained, effective supervision by managerial staff, and recruitment and retention programmes are required to maintain trained laboratory personnel. Formal, pre-service training programmes as well as orientation, performance appraisals and in-service training systems must also be available.

A safe and suitable physical environment with adequate space, power, climate control, water and transport access is a necessity. There should be uninterruptible power supply (UPS) supporting laboratory equipment in case of power surges. Sufficient light, bench space, mains or bore hole water, and distilled water are also required. In place must be high quality, functioning laboratory equipment and a supply chain management system to provide adequate supplies of reagents, consumables and quality control (QC) materials. The laboratory environment should have enough space to perform day-to-day operations safely and efficiently and to store cold chain and non-cold chain supplies.

Effective laboratory quality systems, including well written policies and procedures, a quality control (QC) system, quality improvement (QI), external quality assessment (EQA), and accreditation standards should exist. Standard operating procedures (SOPs) must be understood and implemented to ensure overall test reliability, which includes test accuracy and precision. Laboratory professionals should routinely perform QC testing to guarantee that test methods and equipment perform according to established standards. Laboratory professionals must participate in EQA/proficiency testing (PT) programmes in order to demonstrate that acceptable systems are in place and that specimens are collected and processed appropriately.

All the above requirements for the laboratory to operate and function are well detailed and explained in the **“Guidance for Establishing a National Health Laboratory System”**.

This document will help countries in their efforts to move away from a disease-specific laboratory focus towards an integrated, coordinated health laboratory system, promotes efficient use of resources and improved laboratory service delivery, builds laboratory capacity country-wide, and ensures laboratories at all levels of the health system contribute to national disease surveillance and control.

This document, the **“Guidance for Establishing a National Health Laboratory System”**, is a tool and resource for strengthening or establishing a national health laboratory system and developing a national laboratory policy and plan.

I recommend the use of such an integrated and coordinated approach to the countries in developing the laboratory component of their national health policy and strategic plan.

Dr Luis Gomes SAMBO
Regional Director

A handwritten signature in black ink, appearing to read "Luis Gomes Sambo", is centered below the text. The signature is fluid and cursive.

Preface

In the African Region, many cases of significant illnesses and preventable diseases remain unmanaged because appropriate, high quality laboratory support is not available at all levels of the health care system. While considerable effort has gone into improving laboratory services in many African countries, much of the focus has been on specific disease control programmes, leaving general laboratory services fragmented and without adequate resources. Many countries in Africa still lack a national health laboratory system policy and strategic plan, and place national investment in planning, financing, and delivery of comprehensive and integrated quality laboratory services as a very low priority within their national health systems.

In 2008, during the 58th session of the Regional Committee, WHO-AFRO Member States adopted Resolution AFR/RC58/R2 [1], which emphasises the urgent need to strengthen public health laboratories in the African Region at all levels of the health care system. The Resolution calls for major investment in strengthening national policy, capacity-building and infrastructure development to improve contributions of National Health Laboratory Services in patient management, and in disease surveillance, prevention and control. The Resolution urges the Regional Director to provide technical support to countries in their efforts to develop national health laboratory policies, norms, standards and plans, and to promote the establishment and networking of national and regional public health laboratories.

In 2011, Member States ratified a second resolution, AFR/RC59/R11 [2] to strengthen laboratory capacity to address antimicrobial resistance in Acquired Immune Deficiency Syndrome (AIDS), Tuberculosis (TB) and Malaria. In addition, Resolution AFR/RC59/R4 [3] requests technical support for development of a regional network of “Centres of Excellence” as reference centres for disease surveillance, including the establishment of public health reference laboratories. This Resolution also advocates for additional resources at national and international levels for the establishment of centres of excellence for disease surveillance and public health laboratories, among others.

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Abbreviations

AFRO	WHO Regional Office for Africa
AIDS	Acquired Immune Deficiency Syndrome
APHL	Association of Public Health Laboratories
BLT	Blood Safety, Laboratories and Technologies
CAREC	Caribbean Epidemiology Centre
CDC	Centers for Disease Control and Prevention
CLSI	Clinical and Laboratory Standards Institute
CLT	Clinical Laboratories and Technologies
EHT	Essential Health technologies
EMRO	WHO Regional Office for the Eastern Mediterranean
EQA	External Quality Assessment
HIV	Human Immunodeficiency Virus
HSS	Health Systems & Services Cluster (WHO/AFRO)
IATA	International Air Transport Association
IDSR	Integrated Disease Surveillance and Response
IHR	International Health Regulations (2005)
IP	Institut Pasteur
IQLS	Integrated Quality Laboratory Services
ISO	International Organization for Standardization
IVE	Immunization, Vaccines and Emergencies Cluster
LAT	Laboratory Assessment Tool
LIMS	Laboratory Information Management System
LMIS	Logistics Management Information System
PAHO	Pan American Health Organization
PIP	Pandemic Influenza Preparedness
PPP	Public Private Partnership
QMS	Quality Management System
SEARO	WHO Regional Office for South-East Asia
SLIPTA	Step-Wise Laboratory Improvement Process Towards Accreditation
SOP	Standard Operating Procedure
TB	Tuberculosis
UN	United Nations
USAID	United States Agency for International Development
WHO	World Health Organization
WPRO	WHO Regional Office for the Western Pacific

Executive Summary

Health laboratory services are a critical component of strong national health systems, yet they are often neglected in resource-limited countries. Laboratories play a central role in individual patient diagnosis and care, in disease surveillance and control, and in provision of accurate health data for national planning and resource mobilisation. In spite of this, many millions of people, particularly those in rural and under-served areas on the African continent, still do not have access to basic reliable diagnostic laboratory services.

Establishment of a comprehensive National Health Laboratory System provides the framework for coordinated development and delivery of accessible, quality laboratory services countrywide. This “Guidance for Establishing a National Health Laboratory System” provides technical guidance for the steps required to develop a National Laboratory Policy and National Laboratory Strategic Plan, and effectively implement all the key elements of a comprehensive National Health Laboratory System. These include the organisational and management structure, the regulatory framework, a laboratory human resources plan, laboratory infrastructure, care and maintenance of equipment, provision of laboratory supplies, a functional information management system, laboratory quality and biorisk management systems and overall resource and financial management.

The document also proposes a structure for better coordination of activities among health programmes, institutions and partners at all levels of the health system.

The document provides examples of resource materials from various countries and suggestions for further reading to support implementation of the recommendations.

Introduction

Rationale for developing a National Health Laboratory System

Laboratory services influence the efficiency and effectiveness of both clinical and public health functions, including diagnosis, treatment, health promotion, disease prevention, surveillance and response, and research. Laboratory services are essential to guide decision-making processes by clinicians, public health specialists, and health policy makers [4, 5]. The diagnosis of disease based on clinical symptoms alone, without the support of diagnostic tests, leads to inappropriate treatment and increased patient morbidity and mortality, and promotes the development of drug resistance. Inaccurate clinical data lead to poor national planning and misallocation of resources [6]. Laboratory information gathered through implementation of national Integrated Disease Surveillance and Response (IDSR) programmes is used to direct effective prevention and control of priority diseases, and to manage potential public health emergencies of international concern, according to requirements of the International Health Regulations (IHR) [7].

While vertical programmes provide opportunities for laboratory strengthening, they may also lead to inadequate organization of national laboratory services and neglect of other components of the laboratory system. Other factors that may impact on laboratory services include diverse funding sources, inappropriate use of resources, ineffective aid coordination, and most importantly, lack of a robust and coherent national health policy and strategic plan that incorporates a strong laboratory component. Failure to implement the national strategic plan and fragmentation of laboratory services leads to inefficiencies in the health system, and ultimately suboptimal health outcomes.

The laboratory system must be seen as an integral part of the national health system, and a major contributor to its overall efficiency and effectiveness. A strong laboratory system reflects the commitment by the Ministry of Health to provide comprehensive health services through effective use of available resources in the country including those provided by international partners. It is vital that the laboratory system is appropriately integrated in its development and implementation with other government sectors that impact on human health, such as the agricultural, veterinary and environmental sectors.

Moving away from a disease-specific laboratory focus towards an integrated, coordinated health laboratory system promotes efficient use of resources and improved laboratory service delivery, builds laboratory capacity country-wide, and ensures laboratories at all levels of the health system contribute to national disease surveillance and control [8, 9].

Purpose of the Guidance document

This “Guidance for Establishing a National Health Laboratory System” is intended to support Member States of the WHO African Region in their efforts to develop and implement an effective national health laboratory system. This Guidance document is directed primarily at policy makers in the Ministry of Health, as policies, strategies, regulations and management practices necessary to strengthen the national health laboratory system and coordinate laboratory networks can only be achieved through strong national leadership and governance.

The document guides development of a comprehensive National Laboratory Policy and Strategic Plan, which are the vital first step towards organising, operating and monitoring a national health laboratory system. Laboratory systems comprise a number of inter-dependent elements, which frequently overlap and interconnect; for example, biorisk management requires a strong regulatory component, as well as being part of the laboratory quality

management system, and can also be addressed through human resources development. This document employs a systematic approach to addressing all the key elements of a national health laboratory system.

Finally, the document promotes an integrated approach to establishing a national health laboratory system for the most effective use of available human, logistical, and financial resources, and to enhance networking amongst health programmes and institutions. The document does not describe all possible ways of achieving success in strengthening national health laboratory systems, but presents a set of principles to guide national leadership in decision-making. Each country needs to define the most appropriate path to developing its own national health laboratory system within the context of local variables and influences.

Establishment of a national health laboratory system

Health laboratory systems are an essential component of strong national health systems. The World Health Organization has described diagnostic services, including laboratory services (Medical Products and Technologies), as one of the six essential building blocks of an effective health system (see Figure 1 below). Although the building blocks are managed by different sections of the health system, they all relate to each other and require a strong coordinating mechanism at central level to enable the health system to function effectively as a whole.

Figure 1: The WHO health system framework

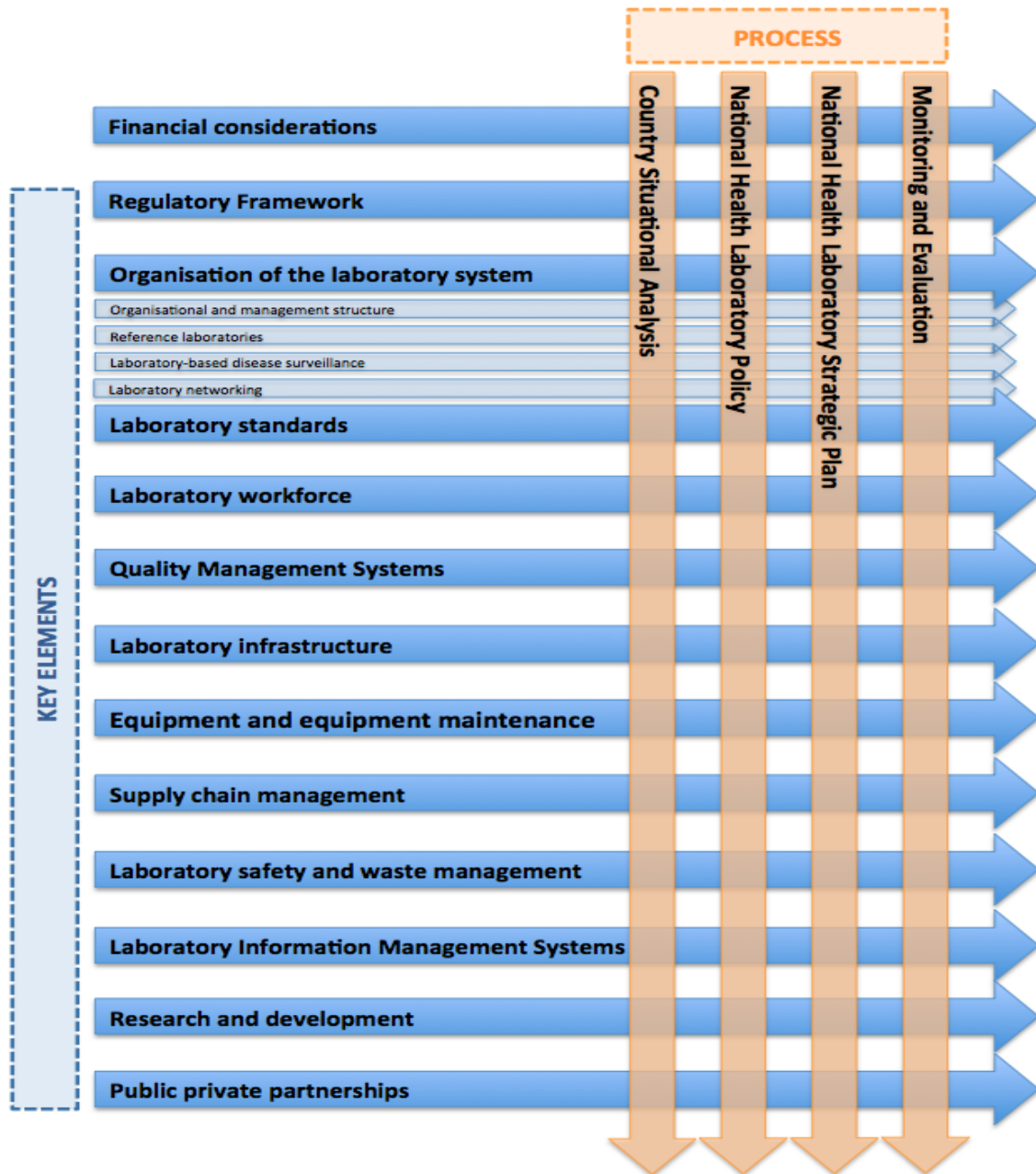


Source: *Everybody's Business: Strengthening Health Systems to Improve Health Outcomes*. Geneva, World Health Organization, 2007 [4].

Strong national health laboratory systems provide timely, high quality, cost-effective diagnostic and informative services to their customers, which include national and local health authorities, health care providers, patients and communities. Laboratory systems need to employ state-of-the-art procedures appropriate for different settings to diagnose, monitor, prevent and control diseases, and provide accurate information for national and local health monitoring and planning. Laboratory systems need to place emphasis on excellence, complete customer satisfaction and continuous quality improvement.

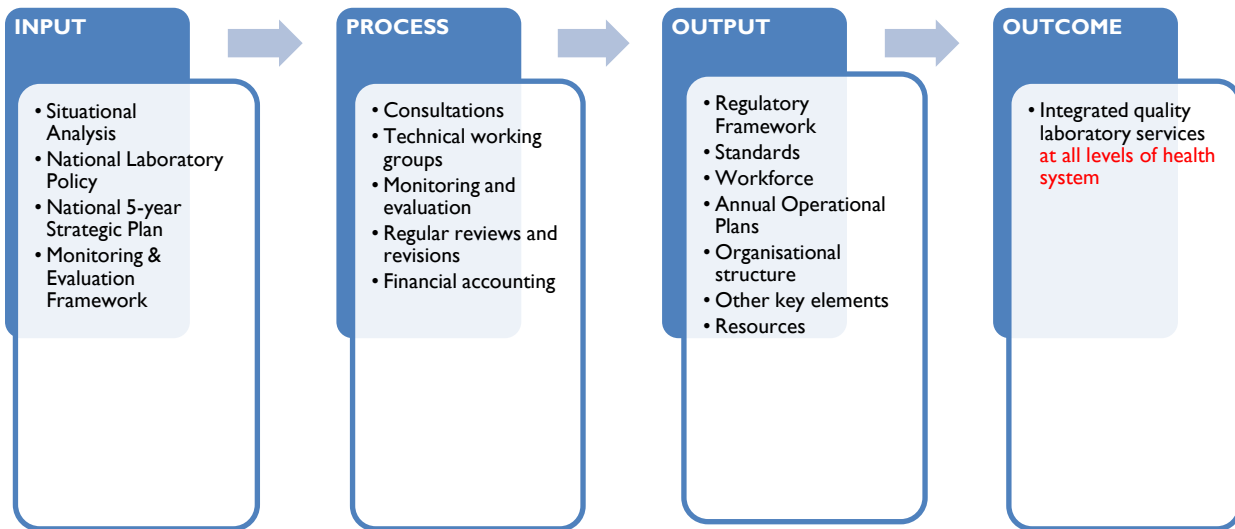
As shown in the figure 2, the health laboratory system comprises a number of key elements that are cross-cutting across most of its functions. It is vital that all key elements are adequately addressed to enable the laboratory system to function efficiently and effectively. Weaknesses in any of the key elements affect the smooth operations of the complete laboratory system, and constrain its ability to provide quality services in support of the national health system at every level.

Figure 2: Key cross-cutting elements of a National Health Laboratory System



As shown in the figure 3 below, the development of a national health laboratory system can be considered in three main phases: Inputs, Processes and Outputs to reach the final Outcome. Inputs include conducting a situational analysis, drawing up the National Laboratory Policy and Strategic Plan, and establishing the monitoring and evaluation framework. Processes include undertaking consultations, establishing technical working groups, carrying out monitoring and evaluation, conducting regular reviews and revisions, and financial accounting. These lead to key Outputs such as the regulatory framework, management and administrative structures and national standards addressing all key elements of the national health laboratory system, including the laboratory workforce, laboratory infrastructure, the equipment and supply management system, information management, safety, and the overall quality management system. These Outputs are conducted through Annual Operation Plans that set out clear targets and indicators, responsibilities and required resources, and are measured through the monitoring and evaluation framework. The Outcome of the overall process is an integrated, quality laboratory service.

Figure 3: Establishing and implementing a National Health Laboratory System



PART ONE

National Laboratory Policy

The National Laboratory Policy provides the overall framework and direction for establishing, strengthening and maintaining the national health laboratory system. The National Laboratory Strategic Plan provides the framework for the operations of the national health laboratory system, including establishing measurable indicators to monitor performance over time [10].

The National Laboratory Policy defines minimum standards of diagnostic services in support of essential clinical and public health services at each level of a tiered health care system; and addresses the organisational and management structure, regulatory mechanisms, human resource requirements, and all required support services, within the context of each country's national health priorities and health care delivery system.

The National Laboratory Policy includes the following:

1. **A Vision statement:** The vision defines the desired long-term future of the health laboratory system. For example: Affordable, accessible, equitable, quality health laboratory services for the people of a country.
2. **A Mission statement:** The mission articulates the overall goal of the health laboratory services and provides a guide towards achieving the vision. For example: To establish and maintain an effective, accessible and equitable health laboratory system in the country that supports clinical care of patients and the prevention, control and surveillance of diseases and public health events of national and international importance.
3. **Objectives:** The overall goal of the National Laboratory Policy is to guide the establishment of a safe, reliable quality health laboratory system that meets national health priorities. Objectives outline major areas of focus and guide planning and strategic activities and may include the following:
 - a. To develop and implement national policies, supportive regulatory frameworks and effective organisational and management structures;
 - b. To establish systems to assure quality of the national health laboratory services, including minimum standards at each level of the health system and national accreditation processes;
 - c. To build the capacity of the health laboratory system through enhanced human and financial resources, effective support systems and functional networks;
 - d. To establish systems for monitoring and evaluation of the health laboratory system for maximum efficiency and effectiveness;
 - e. To support research and development to continually inform and improve the national health laboratory system.

National Strategic Plan

The National Laboratory Policy provides the framework for developing the National Strategic Plan for the Health Laboratory Services. The National Strategic Plan identifies the strategies and activities required to achieve the objectives defined in the National Laboratory Policy over a designated time frame, such as 3 to 5 years.

Process for developing the National Laboratory Policy and National Strategic Plan

The development and implementation of the National Laboratory Policy and National Strategic Plan is the responsibility of the designated laboratory department or unit in the Ministry of Health, which provides the leadership function. The National Laboratory Policy and National Laboratory Strategic Plan are developed in line with National Health Sector Policies and the overall country National Health Sector Strategic Plan. A carefully designed National Laboratory Strategic Plan that is realistic, practical and integrated with other relevant national health programmes is most likely to be sustainable and successful in the long-term. The National Laboratory Policy and National Laboratory Strategic Plan are living documents that require regular review based on a well-structured Monitoring and Evaluation System.

The process for developing the National Laboratory Policy and National Laboratory Strategic Plan is as follows:

1. Country Situational Analysis

The National Laboratory Policy is guided by a detailed country Situational Analysis. The Situational Analysis is a baseline assessment of the current status of laboratory services at all levels of the tiered health system, and explores the key elements required for an effective National Health Laboratory System addressing clinical and public health requirements. The Situational Analysis identifies major gaps and constraints, and is used as the basis for outlining requirements to improve all elements of the health laboratory system, prioritise essential actions and establish indicators against which improvements can be measured.

Standard assessment tools are available to assist countries to conduct baseline assessments in a selected number of laboratories at all levels of the health system [11, 12]. Examples of tools to assess National Health Laboratory Systems are available [13, 14].

2. National Laboratory Policy

The National Laboratory Policy states the Vision, Mission and Objectives for the National Health Laboratory System. The National Laboratory Policy defines the major components of the system and establishes activities and minimum standards of operation appropriate for laboratories at each tiered level of the health system. Each major component of the policy requires a policy statement and a number of broad strategies.

Examples of national laboratory policies developed in countries in Africa are available [15, 16, 17]. Other WHO guidance documents for development of a national laboratory policy are also available [18].

3. National Laboratory Strategic Plan

The findings and recommendations from the country Situational Analysis and the broad strategies outlined in the National Laboratory Policy are used to develop a 3 – 5 year National Laboratory Strategic Plan. Each broad strategy within the National Laboratory Policy becomes a Strategic Objective, and a number of planned activities are developed for its implementation. Activities are grouped into priorities across the time frame of the Strategic Plan, each with measurable indicators and designated responsible units and partners. The Strategic Plan contains a detailed budget that forecasts annual financial requirements for priority activities for at least the first 3 years of the Plan, including administrative costs, and indicates confirmed or possible sources of funding.

Once the National Laboratory Strategic Plan is developed, Annual Operational Plans are drawn up, detailing activities, time frames, implementing partners, budgetary allocations and annual funding sources.

4. Monitoring and Evaluation

Monitoring and evaluation is an essential component of the implementation of the National Laboratory Strategic Plan. Monitoring and Evaluation is systematic and supportive, and evaluates and measures the progress of implementation of the Strategic Plan. A strong Monitoring and Evaluation system:

- a. Establishes measurable indicators, including output, outcome and impact indicators
- b. Monitors implementation of agreed activities
- c. Ensures regular reporting and review processes
- d. Identifies the need for additional action points
- e. Suggests possible changes and improvements to policy statements and strategic planning
- f. Accounts for all financial expenditures.

5. National Coordinating Mechanism

The National Laboratory Policy and National Strategic Plan are developed through a consultative and consensus building process. A National Laboratory Technical Working Group is constituted to provide support to the development of the National Laboratory Policy and National Strategic Plan, including establishment of national standards, and to regularly review their implementation. The National Laboratory Technical Working Group requires clear Terms of Reference and an operating budget.

The National Laboratory Technical Working Group includes a diverse group of stakeholders with various types of expertise at different levels of the national health system. These include representatives from other government sectors such as ministries responsible for the environment (on matters relating to water-borne diseases, environmental events of public health importance); agriculture (on matters relating to human-animal contact and disease); education, including universities and technical colleges (on matters relating to human resource development); finance and donor support (on matters relating to financial resources); non-governmental agencies and the private sector; and technical experts such as clinicians, pathologists, public health experts, health economists and biomedical engineers.

PART TWO

Key elements of a National Health Laboratory System

The key elements that are taken into consideration when developing the National Health Laboratory System are:

1. Financial considerations
2. Regulatory framework
3. Organisation of the laboratory system
4. Laboratory standards
5. Laboratory workforce
6. Quality Management System
7. Laboratory infrastructure
8. Equipment and equipment maintenance
9. Supply chain management
10. Laboratory safety and waste management
11. Laboratory Information Management Systems (LIMS)
12. Research and development
13. Public private partnerships

I. Financial considerations

The financing of the National Health Laboratory System is part of the overall national health financing plan as outlined in the National Health Sector Strategic Plan. The National Health Laboratory System requires a dedicated, integrated budget covering the time frame of the National Laboratory Strategic Plan, utilising all available sources. Sources of funding include: government budgetary provisions, vertical programmes, user fees, partner organisations and other donors.

Key considerations

- A dedicated national budget for the National Health Laboratory System, based on detailed costing estimates, with adequate financing mechanisms to implement the Strategic Plan.
- Mobilisation and coordination of required resources by the Ministry of Health, using key funding mechanisms, such as global public health programmes, epidemic alert and response programmes, and disease prevention and control programmes such as Polio, TB, HIV and Malaria. Governments may explore internal mechanisms of funding, including cost recovery and insurance schemes.
- An efficient, user-friendly, transparent record-keeping and reporting system involving laboratory managers at all levels of the laboratory network, with regular evaluations and clear lines of accountability. Laboratory managers at least at central level of the health system require training in financial administration.

2. Regulatory framework

Regulation provides the legal framework to ensure safe, quality laboratory operations and to protect the public from substandard and unethical laboratory practices. The national regulatory framework establishes requirements for registration and licensing of laboratory facilities and the laboratory workforce. Registration is the official recognition that laboratories and laboratory workers have complied with the legal requirements to operate within a country. Licensure is documented permission from the regulatory authority to carry out specific laboratory functions within a designated time period. The processes and the standards used to register and license laboratories may be adjusted according to the type of laboratory and level of operation.

Regulations are applicable to all laboratory and testing facilities (public, private not-for-profit, and private-for-profit), staff, equipment, in-vitro diagnostic medical devices, procurement and supply, testing methods, data management, sample transportation, biosafety measures, laboratory networks and ethical issues. Regulatory systems maintain the confidence of health workers and the public in the laboratory services.

Key considerations

- Identification of relevant regulatory authorities, either within the Ministry of Health or appointed by the Minister of Health and operating independently from the Ministry of Health. Regulatory authorities are responsible for drawing up relevant regulatory and licensing statutes, including setting standards for laboratory operations, requirements for pre-service and in-service laboratory training institutions and courses, registering and licensing of laboratories and laboratory workers, and regulation of laboratory equipment and in-vitro diagnostic medical devices.
- Linkages with regional and international regulatory authorities, such as the Pan-African Harmonization Working Party that was launched in December 2012 [19].
- Linkages with relevant institutions and bodies, such as laboratory training institutions, and the national environmental protection agency, in drawing up the regulations.
- Establishment of mechanisms for the regulatory authorities to monitor performance and compliance with standards, and recommend disciplinary guidance for non-compliance to the Ministry of Health. Clearly defined procedures and documentation controls are required to enable the regulatory authorities to fulfil their functions.
- Administration by the national regulatory authorities of a system of continuing education credits as a requirement for annual registration of laboratory workers. Continuing education is provided through national training institutes and other approved institutions, such as professional associations and other implementing partners.
- Establishment of a Code of Ethics that defines standards of conduct of laboratory workers.
- Adequate training of staff involved in regulatory functions, including laboratory inspectors, and members of the regulatory authorities.
- Creation and maintenance of a National Laboratory Directory including health facility names and addresses, contact information, facility categorisations, and facility locations. This information may be shared with the Ministry of Health and other partners, as required.

3. Organisation of the laboratory system

3.1. Organisational and management structure

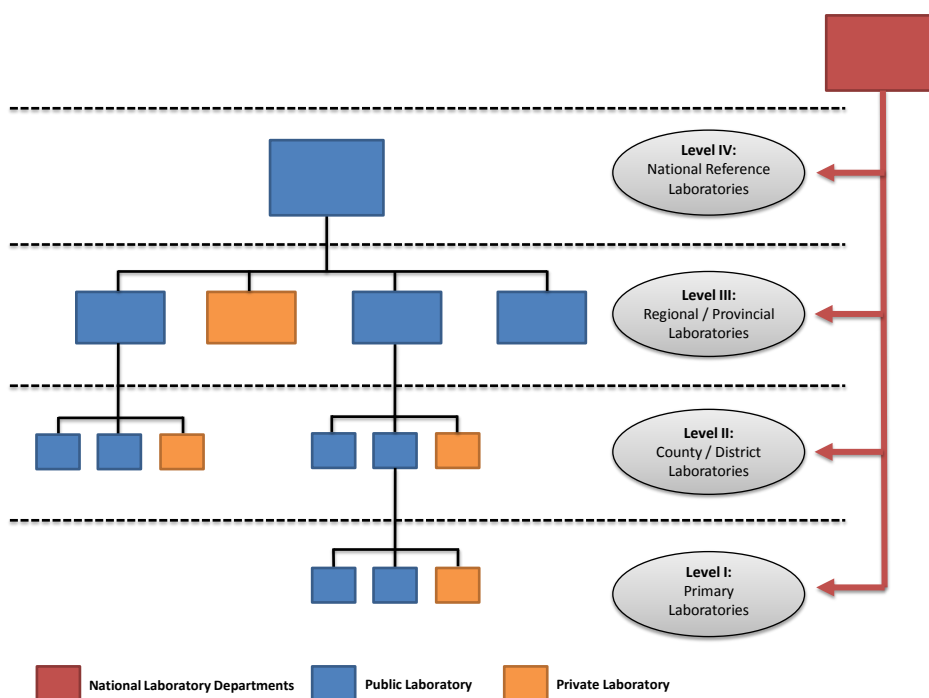
The organisational and management structure of the health laboratory services clearly defines the leadership and management functions at every level of the national health laboratory system. Strong laboratory leadership at national level ensures that the laboratory system is recognised as an essential component of the national health system.

Key considerations

- Establishment of a laboratory department or unit within the central Ministry of Health with a designated head responsible and accountable for managing and coordinating the national health laboratory system. The department or unit requires clear Terms of Reference including:
 - Responsibility for developing, implementing and monitoring the national laboratory policy and strategic plan.
 - Technical support and oversight to laboratories in the public sector performing clinical and public health functions, including national prevention, surveillance and disease control programmes.
 - Communication, coordination, collaboration, joint planning and networking with stakeholders, including disease-specific vertical programmes, national regulatory authorities and private not-for-profit and private-for-profit sectors.
 - Collaboration with the national blood transfusion services to ensure an adequate supply of safe blood for transfusion, and to promote its rational use.
 - Collaboration with the national medico-legal system to ensure adequate support for medico-legal functions from the national health laboratory system.
 - Collaboration with other ministries on cross-cutting areas of public health importance, such as water and sanitation, animal health and the environment,
- Establishment of a tiered laboratory organisational structure, with clear leadership and well articulated roles and responsibilities at each level of the national health laboratory system, including management and technical responsibilities. At most levels of the national health laboratory system, laboratories are expected to carry out clinical as well as public health functions.
- Adequate financial and logistical support for the functions of the national laboratory department or unit, and effective operations of the laboratory services at every tier level of the national health system.

An example of a tiered laboratory system is shown in **Figure 4**.

Figure 4: Example of a tiered laboratory system



3.2 National reference laboratories

National reference laboratories are the highest level laboratories within the national health laboratory system and provide specialised referral laboratory testing within specific disciplines. Reference laboratories communicate and interact as required with sub-regional and regional or international networks, WHO Collaborating Centres and networks, and other international collaborating centres.

Key considerations

- Establishment of criteria for the selection and nomination of national reference laboratories according to the required disciplines within the country [8, 22].
- Establishment of Terms of Reference and approved budgets for the safe operation of quality reference laboratory services.
- Periodic review of the performance of reference laboratories against established standards, including compliance with international quality standards.
- Establishment of links with regional reference laboratories and networks for purposes of providing access to highly specialised testing that may not be available in country, and for quality assurance purposes.
- Establishment of links between the national reference laboratories
- Establishment of twinning projects between resource limited laboratories and specialized institutions

3.3 Laboratory-based disease surveillance

Surveillance is the primary strategy for tracking diseases in the population, and for directing prevention and control measures for both communicable and non-communicable diseases of clinical and public health importance. Disease surveillance is of vital importance for implementing the International Health Regulations (IHR) [7, 9]. Member States in the African Region recommended that IHR be implemented in the context of the Integrated Disease Surveillance and Response (IDSR) strategy. A comprehensive disease surveillance programme requires multi-sector collaboration with policy makers, laboratories, and clinical and epidemiology units at all levels of the health system.

Key considerations

- Coordination of the national laboratory-based disease surveillance programme through the national health laboratory system to address priority diseases of clinical and public health importance in the country.
- Optimal use of the national health laboratory system for laboratory confirmation at each level of the tiered system, with referral of samples to national or regional reference laboratories for specialised testing.
- Establishment of mechanisms for surge capacity testing, including involvement of the non-government laboratory sector.
- Mandatory participation by the private laboratory sector in essential public health functions, such as submitting disease notification reports.

3.4 Laboratory networking

Laboratories at every tier level of the health system are part of the national network in support of clinical management and public health functions. Laboratory networking at national, sub-regional, regional and international levels is essential for the delivery of quality clinical care, for disease surveillance, for detection and response to events that may be of national and international importance, such as influenza surveillance or food safety, for quality monitoring, and for continuous improvement of the laboratory services.

Key considerations

- Establishment of national leadership in planning, coordinating and financing of national laboratory networks; and establishment of linkages to sub-regional, regional and international laboratory networks, including membership and terms of reference.
- Establishment of procedures for correct and safe collection [23] and safe and secure transport of infectious and potentially infectious specimens and materials in accordance with national and international legal requirements for the transport of dangerous goods, and in line with the United Nations (UN) and International Air Transport Association (IATA) recommendations for the Transport of Dangerous Goods [24, 25, 26].
- Establishment of functional linkages and channels of communication between laboratories at each level of the tiered health system, central ministry departments, disease control units, health information units and other offices for exchange of information, and other interactions.
- Establishment of mechanisms for timely feedback to clinicians and public health officers to guide patient care and interventions of public health importance.

4. Laboratory standards

Minimum packages of essential tests and services are established to meet national clinical and public health needs in accordance with clinical, laboratory and public health capacities at each tier level of the health system [27, 28]. Efficient specimen referral systems ensure that patients can access specialised and confirmatory testing, as required.

Key considerations

- Establishment of minimum standard packages for laboratory services, including laboratory infrastructure and utilities, tests, techniques, equipment and staffing requirements, for each level of the tiered laboratory system, through a consultative process involving relevant stakeholders from the Ministry of Health, other ministry departments, non-governmental organisations and agencies, and the private sector.
- Addressing clinical diagnostic and public health functions, including surveillance of diseases of public health importance, complexity of testing procedures and clinical and laboratory skills, when developing minimum packages for each tier level of the health system [5].
- Recognition of the need for customised packages for selected clinical and public health laboratories, especially laboratories at central and reference levels that provide specialised services or laboratory training.
- Provision of guidance on appropriate use of minimum diagnostic packages to promote rational and effective use of laboratory testing by clinicians and other health care workers.

5. Laboratory workforce

The laboratory workforce is the most valuable resource in the national health laboratory system. The laboratory workforce comprises a number of cadres including laboratory managers, phlebotomists, technicians, laboratory scientists, pathologists and laboratory support staff. The laboratory workforce interfaces with a range of professionals including clinicians, nurses, public health workers, health authorities and staff working in the support services, as well as community members.

There is a critical shortage of laboratory professional staff with appropriate training to meet the clinical and public health demands on the African continent. Staff migration across sectors and countries is a recognised challenge in all African countries, and measures to attract and retain qualified, competent staff appropriate for all levels of the national health laboratory system are vital for the delivery of quality health services [29].

Key considerations

- Development of a comprehensive national laboratory human resources plan to meet projected requirements, taking into consideration minimum staffing requirements for each tier level of the national health laboratory system; required cadres of laboratory workers including supervisors and laboratory auditors; distribution of laboratory workers in urban, rural and remote settings; and laboratory worker production, recruitment and attrition rates.
- Inclusion in the national laboratory human resources plan of adequate numbers of non-laboratory cadres essential for the operation of the laboratory services, in conjunction with other ministry departments and units, including logisticians, equipment maintenance engineers, information technologists and data managers.
- Identification of adequate financial resources to meet the national laboratory human resources plan.
- Rational distribution of qualified laboratory workers to peripheral levels of the health system as part of the process of decentralisation of health services to provide access to quality health care to all the population.

- Establishment of schemes of service, career progression and optimal working conditions for laboratory workers of all cadres.
- Establishment of measures for retention and motivation of laboratory workers, especially for staff working in remote and under-served areas, including appropriate benefits, opportunities for career advancement, continuing education programmes, and special recognition.
- Coordination with universities, colleges and laboratory training institutions to maintain standards of pre-service training of the laboratory workforce through regular updating of tutors, training curricula and facilities, to ensure laboratory graduates are adequately prepared for laboratory practice.
- Establishment of appropriate training courses for ancillary laboratory workers including phlebotomists, information technologists, data managers and equipment maintenance engineers; and for non-laboratory health workers conducting point of care laboratory testing.
- Identification, establishment and coordination of continuing professional development programmes for laboratory workers of all cadres, including distance learning programmes. Laboratory workers at every level of the health system and in all geographical locations require access to continuing professional development programmes, which may be provided by national training institutions, professional associations and other implementing partners.
- Establishment of continuing professional development programmes to address special training needs such as laboratory and financial management for laboratory heads, and for quality managers and safety officers.
- Establishment of a staff record system including regular appraisal of staff performance, and mandatory participation in continuing professional development programmes, linked to annual registration through a credits system.
- Establishment of an effective supervisory strategy, including plans for regular, integrated supervision to laboratories at every level of the tiered health system, the use of comprehensive structured checklists, training of supervisors, effective reporting systems and mechanisms for providing adequate feedback, remedial action and required resources. Supervision may be planned in collaboration with vertical disease control programmes and partners.
- Strengthening the clinical and laboratory interface, including promoting the rational use of laboratory services to increase efficiency, reduce costs and improve the quality of health care.

6. Quality Management Systems

A Laboratory Quality Management System (QMS) is a coordinated approach to directing and controlling laboratory functions with the aim of ensuring accurate, reliable results for clinical and public health purposes [49, 50]

Quality and competence in laboratory services are defined by standards established to guide all laboratory functions. Standards for specific aspects of laboratory work may be internationally recognised, such as the standards set by the International Organization for Standardization (ISO), including ISO 15189 for Quality and Competence for Medical Laboratories, ISO 17043 for General Requirements for Proficiency Testing, and standards set by the Clinical Laboratory Standards Institute (CLSI) for Quality Management Systems for Medical Laboratories. Countries may develop their own national laboratory standards to meet their own specific needs. In 2011, the World Health Organization Regional Office for Africa (WHO AFRO) introduced the WHO Guidance for the Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA) which outlines a framework for a phased laboratory quality improvement process towards achieving accreditation [30-33]. A number of tools for implementing laboratory quality improvement at all levels of the national health laboratory system are available free of charge [31, 32, 34, 35].

Key considerations

- A national commitment to establishing and maintaining quality management systems at all laboratory levels, with provision of adequate support, including logistical and financial resources.
- Establishment of laboratory standards for in use in the country with involvement of regulatory authorities, professional bodies and other stakeholders, to avoid co-existence of conflicting standards.
- Development of national Standard Operating Procedures (SOPs) for all laboratory levels to support quality services, including the routine use of internal quality control procedures.
- Participation by all laboratories in appropriate External Quality Assessment (EQA) schemes.
- Appointment of appropriately trained quality managers at all laboratory levels.
- Mandatory compliance by national reference laboratories with internationally recognised quality management standards, including participation in internationally recognised External Quality Assessment (EQA) schemes.
- Inclusion of Quality Management Systems in all pre-service and in-service laboratory training programmes.
- Inclusion of laboratory quality standards as part of national registration and licensing requirements, including private not-for-profit and private for-profit sectors.
- Building national capacity for laboratory assessment, audit, certification and accreditation.

7. Laboratory infrastructure

Adequate laboratory workspace and facilities are essential to enable laboratory functions to proceed without compromising quality of work and safety of laboratory workers, other health care personnel, patients and the community.

Key considerations

- Establishment of standard designs for physical infrastructure appropriate for each laboratory tier level, addressing minimum dimensions of laboratory rooms, ventilation, power and water supply, lighting, drainage, sewage and sanitation, storage including cold storage, waste management and security, in compliance with national or international occupational health, safety and environmental standards.
- Provision of communication tools such as telephones, radios, computers and access to electronic networks.
- Sharing of specialised laboratory infrastructures, such as high containment areas, without compromising quality and safety.
- Provision of adequate logistical and financial resources to develop and maintain required laboratory infrastructure.
- Regular inspections to ensure compliance with standards as part of registration and licensing procedures.

8. Equipment and equipment maintenance

Laboratories require adequate numbers of appropriate, functional equipment to conduct tests required at each level of the national health laboratory system to a high standard. Standardisation of laboratory equipment promotes efficiency in procurement, operability, maintenance and repair, reduces overall costs to the health system, and allows better comparability of performance in quality assessment systems. Major items of laboratory equipment constitute the largest capital expenditure for a laboratory.

Key considerations

- Establishment of standards for equipment selection based on specifications appropriate for each level of the tier laboratory system, capital cost and cost per test, availability, shelf-life and storage conditions of reagents, and availability of user and service manuals in an appropriate language.
- Establishment of national protocols, policies, procedures and checklists for procurement, acquisition, distribution, installation and disposition (retirement) of laboratory equipment, in line with the national medical equipment management system, with provision of adequate logistical and financial resources.
- Establishment of a national medical equipment preventive maintenance and repair system supported by qualified service engineers and availability of adequate tools and spare parts.
- Inclusion of training in user care and preventive maintenance of laboratory equipment in all pre- and in-service training programmes for laboratory workers [34].
- Establishing service contracts with local agents for major items of equipment. Consideration may be given to establishing rental agreements with local agents for large, expensive items of equipment.
- Establishment and adherence to national guidelines for acceptance of donated equipment [36]

9. Supply chain management

Laboratories require a reliable supply of quality reagents, test kits, chemicals and consumables to conduct required tests to a high standard at each tier level of the national health laboratory system. Selection of laboratory supplies is conducted through a consultative process involving laboratory workers, supplies officers, disease control programmes, laboratory national regulatory authorities, central laboratory purchasing agencies, financial partners and other stakeholders. The central laboratory supply unit is tasked with ensuring a timely and sustainable supply of laboratory commodities to adequately support quality laboratory services.

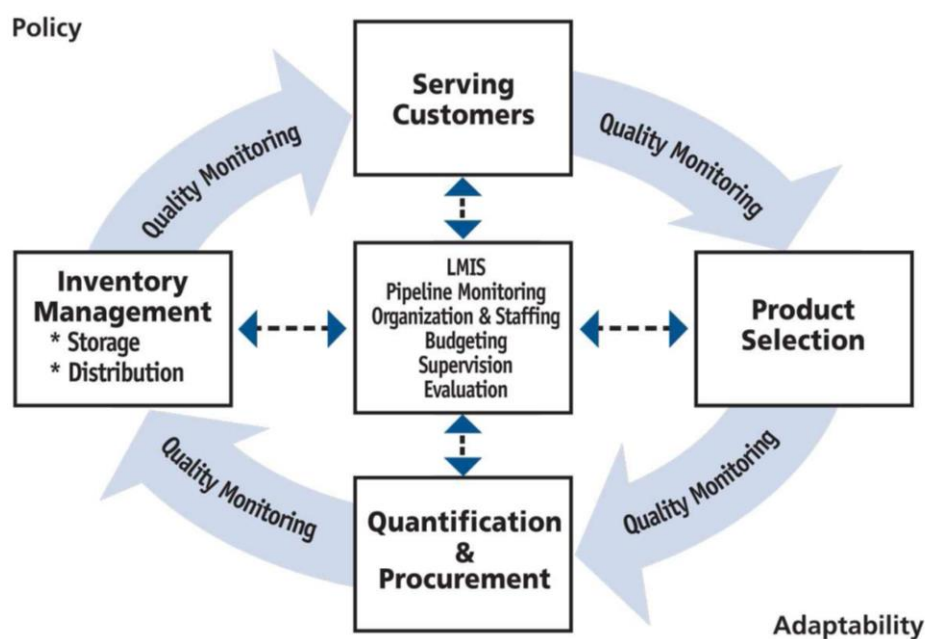
Case studies of national laboratory logistics systems are available [37]. An example of a functional procurement and supply management process is given in figure 5

Key considerations

- Selection and standardisation of reagents, test kits, chemicals and consumables based on specifications appropriate for each tier laboratory level, taking into consideration equipment, methodologies, costs, availability, shelf-life and storage conditions.
- Utilisation of pre-qualification guidance provided by international organisations [38, 39] in selection of specific reagents and test kits.
- Establishment of a national procurement unit [40, 41] with a logistics management system guided by national protocols, policies, procedures and checklists addressing:
 - Quantification
 - Supply planning
 - Selection of vendors
 - Procurement procedures
 - Storage and distribution
 - Pre- and post-market quality monitoring
 - Inventory management at central level
 - Storage and distribution

- Pipeline monitoring
- Supervision and evaluation
- Accurate annual or bi-annual national forecasting of laboratory commodities
- National supply plan
- Disposal or redistribution of expired or surplus reagents and chemicals
- Establishment of a laboratory logistics management system including a Logistics Management Information System (LMIS) overseen by trained laboratory personnel.
- Establishment of a regulatory mechanism for inspecting and approving suppliers of laboratory commodities.
- Establishment of a fair and transparent tender system for bulk procurement to minimise costs.
- Training of laboratory managers in supply management and logistics.
- Establishment of a dedicated budget at central level for the purchase and supply of laboratory commodities.
- Establishment of national guidelines for acceptance of donated laboratory supplies [42].

Figure 5: Example of a functional procurement and supply management process



10. Laboratory safety and waste management

Laboratory workers face a number of risks including bio-hazards (when the source of harm is a biological agent or toxin), chemical risks and fire risks. A risk is a combination of the probability of occurrence of harm and the severity of that harm. Laboratory managers are required to recognise risks, implement measures to minimise risks and respond appropriately to events that may occur [43, 44, 45].

Key considerations

- Establishment of national policies and regulations on laboratory safety and waste management, in compliance with national or international occupational health, safety and environmental standards, using a consultative process, including the national environmental authority.
- Establishment of special biosafety or biosecurity regulations for specific high containment laboratories handling highly dangerous pathogens.
- Promotion of compliance with policies and regulations by ensuring adequate resources for developing and disseminating appropriate safety manuals and guidelines, and supporting infrastructure development.
- Inclusion of laboratory safety and waste management procedures in all pre- and in-service laboratory training programmes.
- Appointment of appropriately trained safety officers at all health facilities.
- Inclusion of compliance with laboratory safety and waste management policies and procedures as part of national registration and licensing requirements, including the private not-for-profit and private for-profit sectors.

11. Laboratory Information Management Systems (LIMS)

A National Laboratory Information Management System (LIMS) comprises specific information generated from laboratories on a regular basis which is used for evaluating the performance and quality of national health laboratory systems, planning and promoting the optimal use of resources, and support to national health services planning [41, 46].

Disease surveillance data is generated using the Integrated Disease Surveillance and Response (IDSR) data management system managed by the disease surveillance unit of the Ministry of Health. Disease surveillance data is also obtained from the national LIMS during routine laboratory reporting.

Key considerations

- Establishment of a standardised national laboratory information management system, addressing both management and operational issues, which may be adapted to meet the current and future needs of the national health laboratory system.
- Harmonisation of the laboratory information management system with the national health information management system and the national laboratory supply chain management system, to guide commodity management.
- Establishment of a designated central unit to manage all aspects of the national laboratory information management system.
- Development of a national data management plan including establishment of policies, procedures and a communication plan to provide feedback to health facilities, laboratories and other stakeholders, to assist in support, evaluation and improvement of the clinical and laboratory services.
- Establishment of appropriate tools and systems to address:
 - Types of data collected, recording systems, frequency of collection

- Reporting lines, formats and intervals
- Analysis, interpretation and usage
- Data storage and retrieval
- Data accuracy and integrity
- Data security
- Deployment of designated, trained staff at all levels of the health laboratory system to manage the national laboratory information management system.
- Provision of adequate reporting materials and means of transmission of reports, including paper-based and electronic systems.
- Inclusion of laboratory data management systems in pre- and in-service laboratory training programmes.
- Continuous review and updating of methods and formats for reporting, recording, analysis and feedback using available tools, such as internet and mobile telephone technology.

12. Research and development

Research is vital to continually inform national policy, improve the functions and quality of the national health laboratory system and address emerging health challenges.

Key components

- Promotion of research at all levels, including strategic collaborations and partnerships between academic and private sector partners, research institutions and the service delivery sector.
- Establishment of a National Research Plan outlining priority areas and collaborating partners. Research may include operational research and laboratory-based research, such as complex laboratory testing in emerging areas of laboratory science including molecular genetics, drug resistance and pathogen discovery.
- Establishment of comprehensive Memoranda of Understanding with research partners addressing shared tasks, ownership and protection of specimens and data, and intellectual property rights. All research on human and animal subjects must adhere to national requirements for scientific and ethical clearance.
- Establishment of a national laboratory research database to track on-going research and promote relevant application of research results into policy and practice.

13. Public–private partnerships

Public–private partnerships (PPPs) are collaborative endeavours that combine resources from the public sector with resources from the private sector to maximise efforts to accomplish laboratory system strengthening goals [47]. Three hallmarks of effective PPPs are helping to ensure sustainability of programmes, facilitating scale-up of interventions, and leverage of significant private-sector resources. Private sector partners include a wide range of organisations such as foundations, in-country and international private businesses, business and trade associations, unions, venture capitalists, and social entrepreneurs. An example of a PPP is the WHO Pandemic Influenza Preparedness (PIP) Framework [48], through which the national health laboratory system can be strengthened.

Key components

- Identifying PPPs to undertake a number of laboratory system strengthening activities, such as quality improvement and training.

- Ensuring partnerships are supported by signed agreements, joint oversight committees and a structured monitoring and evaluation plan.
- Sharing of resources, risks and results during programme implementation.

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Internet Sources: Supplementary Material

The following Websites provide information for implementing comprehensive laboratory policy. Numerous free guidelines, procedures, recommendation can be downloaded from these sites.

WHO

- AFRO
 - Home page: <http://www.afro.who.int/>
 - Laboratory page: <http://www.afro.who.int/en/clusters-a-programmes/hss/blood-safety-laboratories-a-health-technology.html>
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 - Home page: <http://www.who.int>
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 - Diagnostic and laboratory technology home page: http://www.who.int/diagnostics_laboratory/en/
 - Laboratory biosafety programme: <http://www.who.int/ihr/biosafety/en/index.html>
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- SEARO
 - Home page: <http://www.searo.who.int/>
 - Laboratory topics: <http://www.searo.who.int/EN/SectionI0/SectionI7.htm>
- WPRO
 - Home page: <http://www.wpro.who.int/>
 - Laboratory topics: http://www.wpro.who.int/health_topics/laboratory/
- PAHO
 - Home page: <http://new.paho.org/>
 - Laboratory topics: http://new.paho.org/hq/index.php?option=com_joomlabook&Itemid=259&task=display&id=135
- EMRO
 - Home page: <http://www.emro.who.int/>
 - Documentation centre: <http://www.emro.who.int/publications/Series.asp?RelSub=WHO%20EMRO%20Technical%20Publication%20series> (and choose “Laboratory” in the topic drop down list)

CDC: <http://www.cdc.org>

- Division of laboratory systems, home page: <http://www.cdc.gov/nceh/dls/index.html>
- Division of laboratory systems, documents: http://www.cdc.gov/nceh/dls/publications_products.html

CLSI (Clinical And Laboratory Standards Institute): <http://www.clsi.org>

Pasteur Institute

- Website: <http://www.pasteur.fr/ip/index.jsp> (in French)
- Website: <http://www.pasteur.fr/ip/easysite/go/03b-00002j-000/en> (in English)
- Pasteur network website: <http://www.pasteur-international.org/> (in French)

- Pasteur network website: <http://www.pasteur-international.org/ip/easysite/pasteur-international-en> (in English)

Other institutions:

- CARPHA(PAHO)
 - Website: <http://carpha.org/>
 - Laboratory division: http://carpha.org/?page_id=200
- Pacific Public Health Surveillance Network, LabNet: (English)
<http://www.spc.int/phs/pphsn/Services/LabNet/intro.htm>
- Réseau océanien de surveillance de la santé publique, LabNet : (French)
<http://www.spc.int/phs/ROSSP/Services/LabNet/intro.htm>