

# Asia Pacific Strategy for Strengthening Health Laboratory Services (2010–2015)



World Health  
Organization

South-East Asia Region    Western Pacific Region



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## PREFACE

Health laboratory services are an integral component of the health system. Efficiency and effectiveness of both clinical and public health functions including surveillance, diagnosis, prevention, treatment, research and health promotion are influenced by reliable laboratory services. 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 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 in making informed decisions.

This biregional strategy addresses policy and technical issues for strengthening health laboratory services. It calls for each Member State to develop a national laboratory policy and strategic plan, and emphasizes various components that are critical for providing appropriate infrastructure, expertise, quality, safety and technologies to assure efficient laboratory support.

The Asia Pacific Strategy for Strengthening of Health Laboratory Services (2010–2015) aims to assist Member States in providing comprehensive laboratory services to contribute to improved health outcomes in the South-East Asia and Western Pacific Regions of WHO. It provides guidance and impetus to the countries to view laboratory services not as a small component of a vertical health programme but as a critical cross-cutting support service that needs to become an integral component of the health system at all levels.

WHO is committed to providing normative and technical support to all its Member States in implementation of this strategy and strengthening of health systems.



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## EXECUTIVE SUMMARY

Efficient and reliable health laboratory services are an essential and fundamental component of any strong and effective health system and its goal to improve health. Reliable and timely results from laboratory investigations are crucial in decision-making in almost all aspects of health services.

While considerable effort has gone into improving health laboratory services in the Asia Pacific Region, much of the focus has been on specific disease control programmes such as polio, measles, HIV/AIDS, tuberculosis (TB) and malaria. As a result, laboratory services are often fragmented and other parts of the laboratory system are accorded low priority with inadequate allocation of resources. There is often no national laboratory policy or strategic plan to deliver comprehensive and integrated quality laboratory services to all those who need them.

The Asia Pacific Strategy for Strengthening Health Laboratory Services (2010–2015) presents a brief overview of the major challenges in assuring reliable laboratory services and offers a health systems perspective in dealing with them. The objective of this strategy is to assist Member States in providing comprehensive laboratory services to contribute to improved health outcomes in the Asia Pacific Region. In acknowledging that “one size does not fit all”, it suggests an approach that national authorities can adapt to their country or regional contexts and integrate with their existing national health policies, strategies and resources.

The strategy advocates establishment of a sustainable and coherent national framework for laboratory services encompassing a national laboratory policy, national regulatory mechanisms, and a national laboratory plan, with a designated focal point and an oversight mechanism, in order to deliver safe and quality laboratory services.

The strategy articulates the need for sufficient resources and appropriate financing mechanisms to promote rational use of services and avoid conflicts of interest. It proposes using cost-effectiveness tools, de-linking provider income from tests requests and moving toward prepaid pooled funding mechanisms rather than user-fees.

The strategy emphasizes building capacity for laboratory services including design of a tiered laboratory network with each level having appropriate physical infrastructure, human resources, procurement and supply management, referral networks and information system. It promotes quality, biosafety, occupational health, and rational use of laboratory services and operational research to assure use of appropriate technology.

The document provides some practical examples and references throughout the text and annex, and outlines broadly how WHO can assist Member States in each of the strategic elements.

# 1. Introduction

Progress towards achieving the Millennium Development Goals (MDG) to reduce morbidity and mortality related to HIV/AIDS, malaria and other major diseases has been slow, partly because of the lack of access to quality medicines and health technologies, in particular diagnostics and laboratory services.

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. 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.

The spectrum of laboratory investigations ranges from sophisticated and expensive to simple, familiar and inexpensive. Overall, medicines, vaccines and health technologies consume approximately 50% of recurrent health budgets of Member States; however, there is significant opportunity for improvement because well over half of this expenditure is wasted on poor planning and management.<sup>1</sup> Taking into consideration that laboratory science is rapidly evolving, a continuous process of evaluating and adopting relevant new methods is imperative for any efficient health system.

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<sup>1</sup> Capacity Development Workshop on Health System Development (Cairo, Egypt, 8–12 June 2008). Cairo, World Health Organization, 2008.

The Asia Pacific Strategy for Strengthening Health Laboratory Services (2010-2015) encourages all Member States in the South-East Asia and Western Pacific Regions of WHO to develop an appropriate, scientifically sound, evidence-based, practical and sustainable national strategy for strengthening health laboratory services within their national health systems. The Asia Pacific Strategy provides guidance concerning the essential elements of a national laboratory strategy and the key activities that need to be performed to meet the specific needs of countries. It is acknowledged that “one size does not fit all” and that each country’s strategy for laboratory services should be integrated with its existing national health policies, strategies and resources.

## 2. Background

### 2.1 Health systems strengthening and laboratory services

The right to health is recognized as a basic human right in the WHO Constitution ratified in 1946. This right was reaffirmed in the *Declaration of Alma-Ata on Primary Health Care* in 1978.<sup>2</sup> Access to strong and effective health systems is necessary to achieve continued improvement in health outcomes in an efficient and equitable manner.

Efficient and reliable health laboratories are an essential part of any strong and effective health system. Countries often lack a national laboratory policy and strategic plan. Many health systems are underfunded and even the well-funded ones are under economic pressure due to increasing demand and cost inflation. In these scenarios, laboratory services are often accorded low priority and inadequate allocation of resources.

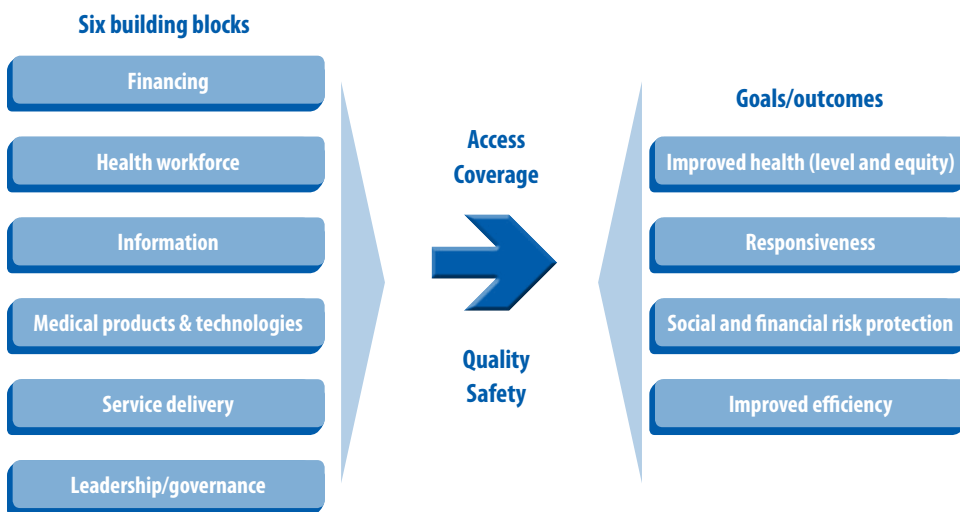
Increasing fragmentation of health systems, including health laboratory services, leads to inefficiencies and suboptimal health outcomes. Pressures that contribute to fragmentation include poorly implemented decentralization, privatization and commercialization, the proliferation of diverse funding sources, ineffective aid coordination, inappropriate use of resources, ineffective communication, and, in many cases, the lack of a robust and coherent national health strategy and plan to guide the health system, including laboratory services. Moving away from disease-specific laboratory services to a more integrated approach would result in more efficient use of resources and better laboratory service delivery. Governments can play crucial leadership and stewardship roles in coordinating and ensuring standards in health services delivery, even where they are not the provider or the financier of services.

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2 Declaration of Alma-Ata, 1978 ([http://www.who.int/hpr/NPH/docs/declaration\\_almaata.pdf](http://www.who.int/hpr/NPH/docs/declaration_almaata.pdf)).

WHO proposes using a single framework (Figure 1) composed of six building blocks when analysing health systems. The building blocks are: (1) service delivery, (2) health workforce, (3) financing, (4) medical products and technologies, (5) information, and (6) leadership and governance. These building blocks are often managed by different units within the health sector, but the key concept is for the health system to be analysed in its totality and for the building blocks to relate to each other.

**FIGURE 1: THE WHO HEALTH SYSTEM FRAMEWORK**



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

Diagnostic services, including laboratories, are part of the building block for medical products and technologies. However, they also relate to other building blocks as they have to be funded and staffed, they use and produce information, they depend on good equipment, and they aim to provide quality services in an efficient manner — all these require appropriate policies, strategies, regulation and management through effective leadership, governance and political will.

Major public health crises, such as severe acute respiratory syndrome (SARS) or the emergence of a new influenza strain, would become even more serious and difficult to control without prompt and accurate detection by peripheral health workers and the laboratory network. Similarly, an essential component for successful eradication of poliomyelitis is a laboratory network capable of

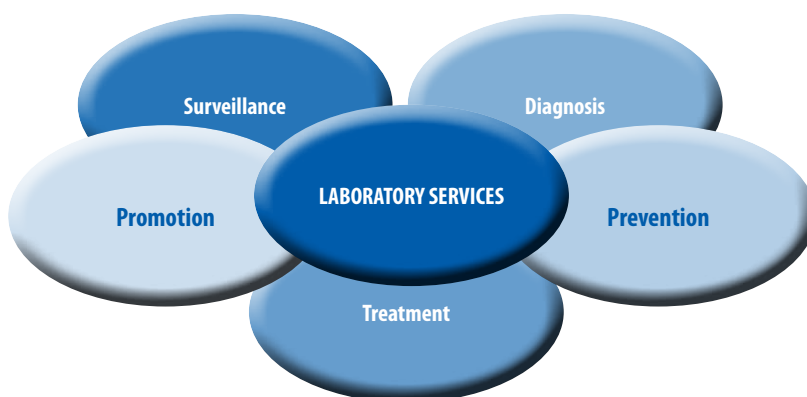


analysing specimens and providing timely responses to local health workers and to national health authorities.<sup>3</sup> To further illustrate the point, one of the weak links in tuberculosis (TB) control remains the need for appropriate, affordable and sustainable laboratory services, especially in light of the pressing need for an accelerated and extensive scale-up of multidrug-resistant tuberculosis (MDR-TB) programmes.<sup>4</sup>

## 2.2 Overview of laboratory services in the Asia Pacific Region

The role of laboratory services, as integral and important to both clinical and public health functions, is increasingly recognized. As indicated in Figure 2, surveillance, diagnosis, prevention, treatment and health promotion all rely on laboratory services, with an estimated 70% of health decisions involving laboratory results.<sup>5</sup> Laboratories provide vital support and facilitate the initiation and monitoring of appropriate clinical and public health interventions. Despite this central role, strengthening laboratory services has, until recently, received little or inadequate attention in many countries.

**FIGURE 2:** ROLE OF LABORATORY SERVICES



3 WHO/EPI/GEN/95.4 and USAID Polio Eradication Initiative.

4 Policy guidance on drug-susceptibility testing (DST) of second-line antituberculosis drugs. Geneva, World Health Organization, 2008.

5 Forsman RW. Why is the laboratory an afterthought for managed care? *Clinical Chemistry*, 1996, 42(5):813-816.

In the Asia Pacific Region, considerable effort has gone into improving health laboratory services; however, much of the focus has been on specific disease-control programmes such as poliomyelitis, measles, HIV/AIDS, TB and malaria, where funding has been available through global health initiatives. This assistance has built considerable capacity in Member States and sometimes has had a positive spill-over effect into other parts of health services. Frequently, however, the connection between the various laboratory initiatives has not been strong, especially between the public health-oriented services and the clinical services, and the focus has been more on short-term results than on long-term capacity-building. As a result, inefficiency has been introduced in some areas (and duplication in others), some aspects have been neglected, long-term sustainability has been put at risk, and health laboratory services have been further fragmented.

Even though countries in the Asia Pacific Region are in varying stages of development, their health systems are facing common major issues that impact adversely on laboratory services (see Table 1).

**TABLE 1: MAJOR ISSUES IN HEALTH LABORATORIES IN THE ASIA PACIFIC REGION**

Health System Framework	Issues in health laboratories
Leadership and governance	<ul style="list-style-type: none"> <li>• Low priority of laboratory services in national health strategy</li> <li>• Absence of national laboratory policy and strategic plan</li> <li>• Inadequate or weak implementation of laboratory regulations</li> <li>• No national laboratory programme and/or focal point or structured responsibility to monitor laboratory services</li> </ul>
Financing	<ul style="list-style-type: none"> <li>• Inadequate resources and infrastructure</li> <li>• Incentives for irrational use</li> <li>• Insufficient cost-effectiveness analysis</li> </ul>
Health workforce	<ul style="list-style-type: none"> <li>• Inadequate number of laboratory professionals and technicians</li> <li>• Inadequate training and supervision programmes</li> <li>• Lack of strategic plan to retain staff</li> <li>• Lack of career structure and opportunities</li> </ul>
Information	<ul style="list-style-type: none"> <li>• Inadequate use of information technology</li> <li>• Inadequate information base to inform development of laboratory services</li> <li>• Inadequate monitoring and evaluation</li> </ul>
Medical products and technologies	<ul style="list-style-type: none"> <li>• Lack of laboratory policy and regulation</li> <li>• Unregulated procurement and management of equipment and material</li> <li>• Lack of effective equipment maintenance systems</li> <li>• Lack of standardization and harmonization of laboratory test schedules</li> </ul>
Service delivery	<ul style="list-style-type: none"> <li>• Fragmentation of laboratory services</li> <li>• Weak or absent laboratory networking</li> <li>• Poor coordination with clinical services</li> <li>• Inappropriate utilization</li> </ul>
Quality and safety	<ul style="list-style-type: none"> <li>• Inadequate quality awareness</li> <li>• Weak quality systems</li> <li>• Inadequate safety measures</li> </ul>

### 3. Objectives

The objective of this document is to assist Member States in providing comprehensive laboratory services to contribute to improved health outcomes in the Asia Pacific Region.



## 4. Key strategic elements for health laboratory services

While this document sets out a range of elements and information that are considered essential to developing coherent and comprehensive laboratory services, it is recognized that “one size does not fit all”. The ideas suggested here are not cast in stone. It is expected that countries will adapt the following strategic elements and plan content to reflect their specific context:

- Establish a coherent national framework for laboratory services.
- Finance laboratory services in a sustainable manner.
- Build capacity for laboratory services.
- Assure the quality of laboratory services.
- Promote the rational use of laboratory services.
- Maintain safe laboratory services.
- Support research and ethics in laboratory services.

### 4.1 Establish a coherent national framework for laboratory services

Too often, laboratory services have had very low national priority in respect to financing, planning and service delivery. This biregional strategy calls for each Member State to establish a coherent national framework for government and nongovernmental laboratory services, which would include developing a national laboratory policy and strategic plan, and to define the managerial, oversight and regulatory mechanisms for laboratory services suitable to their context.

The size, socioeconomic status, political economy and health systems of Member States in the Asia Pacific Region vary extensively. For example, health systems vary from being primarily financed and delivered by the government,

to being predominantly financed and delivered by the private sector. Most Member States have health systems that fall somewhere in between. Health laboratory services should be determined by the size, scale and scope of the country's health system. They should be organized within the existing health system to maximize their efficiency and effectiveness and to promote universal access. The degree to which universal, equitable access to laboratory services is achieved will depend on the overall structure of the entire health sector. The framework needs to be flexible enough to incorporate advances in technologies that may be appropriate for the country.

The following components are essential for a coherent national framework (Table 2):

- national laboratory policy
- national regulatory mechanisms
- national focal point
- national laboratory strategic plan
- national oversight mechanism.

#### **4.1.1 National laboratory policy**

A national laboratory policy should articulate the national commitment to providing comprehensive laboratory support to health services through the harnessing of resources available to the country. It should define the goals and objectives of a national laboratory system and advocate the allocation of appropriate resources.

A national laboratory policy should define who is responsible for health laboratory services at the different levels of the health system and how these services relate to each other in the laboratory network, and to the rest of the health system.

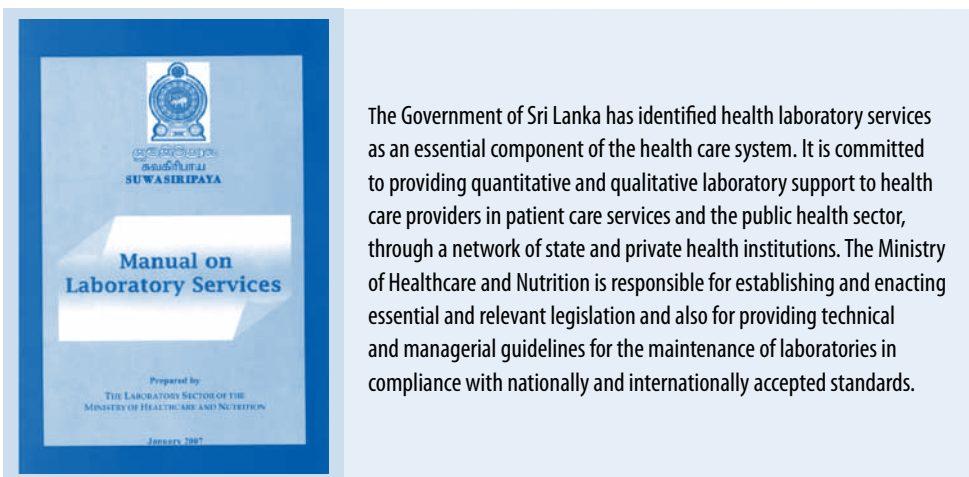


A national laboratory policy should reflect a commitment to ethical values in laboratory practice, including patient confidentiality, adherence to professional codes of conduct, recognition and avoidance of potential conflicts of interest, and ethical conduct in relation to research (refer to 4.7.4)

The ways in which policy and planning processes are interpreted and implemented can vary depending on the setting. The national laboratory policy and planning processes should be consistent with the national health policy and planning processes within a country. The national laboratory policy should be developed through a consensus-building process involving a wide range of stakeholders, including governmental decision-makers, service providers, developmental partners, professional users, consumers (patients) and financiers. A diverse group of technical experts, including laboratory scientists, engineers, clinicians, pathologists, public health experts and health economists, might be called upon in the process.

A national laboratory policy should empower the establishment and implementation of a national laboratory plan. An example of a Member State (Sri Lanka) introducing a national laboratory policy is presented (Figure 3).

**FIGURE 3:** SRI LANKA ADOPTS NATIONAL LABORATORY POLICY AND MANUAL ON LABORATORY SERVICES



The Government of Sri Lanka has identified health laboratory services as an essential component of the health care system. It is committed to providing quantitative and qualitative laboratory support to health care providers in patient care services and the public health sector, through a network of state and private health institutions. The Ministry of Healthcare and Nutrition is responsible for establishing and enacting essential and relevant legislation and also for providing technical and managerial guidelines for the maintenance of laboratories in compliance with nationally and internationally accepted standards.

Source: *Manual on Laboratory Services*. Laboratory Sector, Ministry of Healthcare and Nutrition, Government of Sri Lanka, Colombo, 2007.

### 4.1.2 National regulatory mechanisms

Regulation is the legal means to govern or control laboratory service provision and reporting of essential information to meet required standards. It is a government tool for ensuring competent performance of and confidence in laboratory services. Each Member State will need to identify or establish a regulatory authority or mechanism for its health laboratory services that is appropriate to its existing national structures. Regulatory mechanisms will be responsible for licensing providers, setting standards for different levels of service, monitoring performance and compliance with those standards, and intervening when non-compliance is serious. The national laboratory policy and plan can be used by the regulatory authority to set national standards for laboratory services.

Each Member State will also need to decide whether it will regulate point-of-care testing, e.g. rapid diagnostic tests performed in community, private or clinical care settings, or whether it will only regulate testing undertaken in laboratory settings at a given time and consider including new technologies as and when these become available.

### 4.1.3 National focal point

Assigning a focal point for the development of laboratory services is highly essential. The focal point could be an individual, a department, a standing committee or any other appropriate mechanism that is permanent. The focal point should:

- coordinate various initiatives or proposals to fit them into the broader context of the health laboratory services for the overall health system;
- be the driving force behind the development of the laboratory services policy and plan;



- be responsive to rapid changes in situations and in science, particularly in respect to communicable disease control and epidemiological transition; and
- be willing and capable of evaluating new initiatives and technologies.

#### 4.1.4 National laboratory plan

The national laboratory plan should be an integral part of the national health plan. The laboratory plan should give guidance on the operation of health laboratory services and the relationships between various providers in the laboratory network, all within the broader context and regulation of the health system. The laboratory plan should define the general relationship between public health and clinical laboratories (including government, private and university laboratories, where feasible), define the relationship between the different levels of all systems, and determine who is responsible at each level and to whom they are responsible in the overall health system. The laboratory plan should also define an effective supervisory structure and mechanism.

The national laboratory plan should encourage the setting of minimum standards for laboratory services at each level of the laboratory network, including physical infrastructure, tests, techniques, major equipment and human resource requirements. It should address issues of equipment maintenance and disposal, laboratory management information systems, laboratory quality and safety, research, monitoring and evaluation. In order to guide service providers, a national laboratory plan should include:

- (1) a situation analysis that relates health laboratory services to the needs of the health system, epidemiological situation and health finances of the existing system, e.g. mapping existing laboratory services and identifying the strengths, weaknesses, opportunities and threats (SWOT);
- (2) a realistic review of the existing health laboratory services in governmental (public) and nongovernmental (private and other) sectors as well as vertical programmes and practical mechanisms for their functional or structural integration; and

- (3) a definition of intended laboratory services, elaborating essential minimum functions and structures at the different levels of the health system (e.g. community/primary, secondary, tertiary/reference, public health) which may include:
- (a) tests and methods;
  - (b) infrastructure and equipment;
  - (c) human resources and skills;
  - (d) procurement, maintenance and supply management systems;
  - (e) systems for quality, safety and regulation;
  - (f) laboratory network;
  - (g) sustainability;
  - (h) costing (refer to section 4.2);
  - (i) responsible officers, management and supervisory links; and
  - (j) monitoring and evaluation systems at all levels to include:
    - (i) regulations and licensure procedures
    - (ii) reporting formats and systems
    - (iii) laboratory Information management systems
    - (iv) feedback mechanisms.

The national laboratory plan should be realistic and practical and include a time-frame for implementation with necessary indicators. It can seek to improve and advance the level of service, but it should remain within the domain of possibility and not be pitched at an unachievable level. Each Member State will decide the degree to which they are able to introduce standardization in aspects of health laboratory services. For example, in some circumstances, potential efficiency gains can be made by standardizing methods, reagents, infrastructure, equipment and the entire procurement and supply chain if it can be done without disrupting existing services.

The nature of the health care system will determine the role played by the national laboratory plan. It can serve as a mandatory implementation plan, as



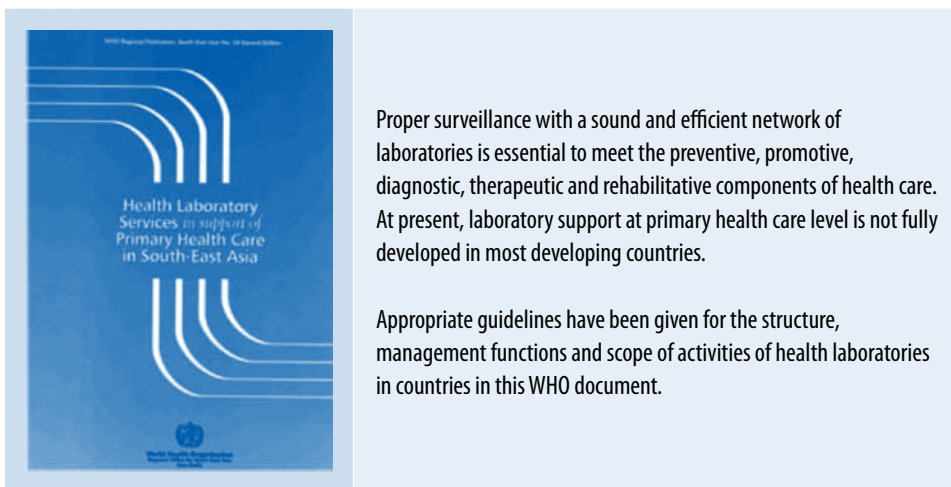
the basis of an accreditation system, as standards for a regulatory system or as aspirational guidelines for those that want to improve and acquire international standards. Where services are predominantly provided by the government, the national laboratory plan will be prescriptive and will determine actual implementation. Where provision is more diffuse, the plan will serve to outline standards and provide guidelines and regulatory safeguards. Periodic reviews of the national laboratory plan should be performed.

Figure 4 shows an example of WHO guidelines that countries can use in developing their national laboratory plans and laboratory standards.

All decisions made for the national laboratory framework and related key strategic elements need to consider not only the country context, but also sustainability issues. Sustainability means being able to continue a desired level of functioning into the future within accessible resources. Therefore, a carefully designed and integrated national laboratory plan that incorporates a step-wise development approach is more likely to be sustainable and capable of contributing to the achievement of health system goals. All the components discussed in this biregional strategy are interlinked, and decisions in one area will impact others. Sustainability requires not only adequate financing, but also a carefully thought-out network design, human resources plan, quality and safety systems and research programme.

The sustainability of laboratory services is at risk where they are highly dependent on external funding sources. National authorities need to monitor all externally funded laboratory developments for two key policy and sustainability issues: (1) externally funded improvements benefit the laboratory network broadly rather than narrowly; and (2) government funding will be available to ensure continued laboratory service provision when external funding ceases or is reduced.

**FIGURE 4.** HEALTH LABORATORY SERVICES IN SUPPORT OF PRIMARY HEALTH CARE IN SOUTH-EAST ASIA



Source: *Health Laboratory Services in Support of Primary Health Care in South-East Asia*. New Delhi, World Health Organization, 1999.

#### 4.1.5 National oversight mechanism

A national advisory or oversight body, comprising representation from a range of stakeholders, will provide national health authorities with independent reviews and technical advice, including guidance on aspects of the work of the national focal point. The advisory or oversight body must be separate from the focal point mechanism, particularly if the national focal point is directly involved in financing, regulation or accreditation, as there may be a conflict of interest.

In addition, the oversight function is performed through the regulatory agency as well as the establishment of an accreditation mechanism for health laboratories. These two aspects have been described elsewhere in this document.



**TABLE 2:** STRATEGIC ELEMENT: A COHERENT NATIONAL FRAMEWORK FOR LABORATORY SERVICES

Strategy components	Key points to consider	Role of WHO
4.1.1 National laboratory policy	<ul style="list-style-type: none"> <li>• National commitment</li> <li>• Stakeholder involvement</li> <li>• Goals, objectives and allocation of resources</li> <li>• Responsibilities and networks</li> </ul>	<ul style="list-style-type: none"> <li>• Advocate through Regional Committee resolutions</li> </ul>
4.1.2 National regulatory mechanism	<ul style="list-style-type: none"> <li>• Licenses providers</li> <li>• Sets minimum standards for human resources, materials, machines, methodologies</li> <li>• Monitors and enforces standards</li> </ul>	<ul style="list-style-type: none"> <li>• Develop a step-by-step approach to assist Member States in developing a national policy and plan</li> </ul>
4.1.3 National focal point	<ul style="list-style-type: none"> <li>• Advises national authorities</li> <li>• Guides all laboratory initiatives in line with national policy and plan</li> <li>• Responsive to rapid changes</li> </ul>	<ul style="list-style-type: none"> <li>• Support regional consultation</li> </ul>
4.1.4 National laboratory plan	<ul style="list-style-type: none"> <li>• Setting standards</li> <li>• Financing</li> <li>• Structure and functions at different levels of services</li> <li>• Networking and links between different levels of service and programmes</li> <li>• Human resources plan</li> <li>• Infrastructure and equipment maintenance</li> <li>• Laboratory information systems</li> <li>• Laboratory quality and safety,</li> <li>• Monitoring and evaluation</li> <li>• Research</li> <li>• Reporting to health systems</li> </ul>	<ul style="list-style-type: none"> <li>• Develop and disseminate generic laboratory functions and minimum requirements at different levels of health service delivery</li> <li>• Provide technical support in implementation of national laboratory plan</li> </ul>
4.1.5 National oversight mechanism	<ul style="list-style-type: none"> <li>• Separate national oversight body</li> <li>• Regulatory mechanism</li> <li>• Accreditation body</li> </ul>	<ul style="list-style-type: none"> <li>• Technical support to help establish appropriate models of accreditation</li> </ul>

## 4.2 Finance laboratory services in a sustainable manner

Financing of health laboratory services is frequently given low priority and should receive more attention. The national laboratory plan should include a financing plan designed to reduce inappropriate out-of-pocket payments and ensure equitable access and coverage. The financing plan for laboratory services should be part of the country's overall health budget and should encourage public-private partnerships.

The following components are necessary for financing health laboratory services (Table 3):

- evidence-based planning and management
- capacity for cost-effectiveness analysis
- a financing strategy and plan.

### 4.2.1 Evidence-based planning and financing

Decision-making on the planning and financing of laboratory services is frequently done on an ad hoc basis with incomplete information. The costs and benefits of laboratory services and other comparative information need to be part of the national health financing information base. Information on financing and expenditure of diagnostic services, including laboratory services, needs to be part of national health accounts. The information base should include sources and uses of external financial assistance to laboratory services.

### 4.2.2 Capacity for cost-effectiveness analysis

Cost-effectiveness analysis is important for the selection of appropriate laboratory technologies and methods. With accurate evidence and information, countries can decide which tests are best for specific health interventions, while making the most of available financial resources. Each Member State needs to build capacity to perform (or obtain) and interpret this type of analysis. In some cases, out-of-country referrals of laboratory tests may be more cost-effective



than establishing complex and expensive testing capacity within the country. Further, people who request laboratory services need to understand the evidence base behind the range and limitations of services that are agreed to be available at each level and are part of the laboratory network in order to promote rational use and universal coverage.

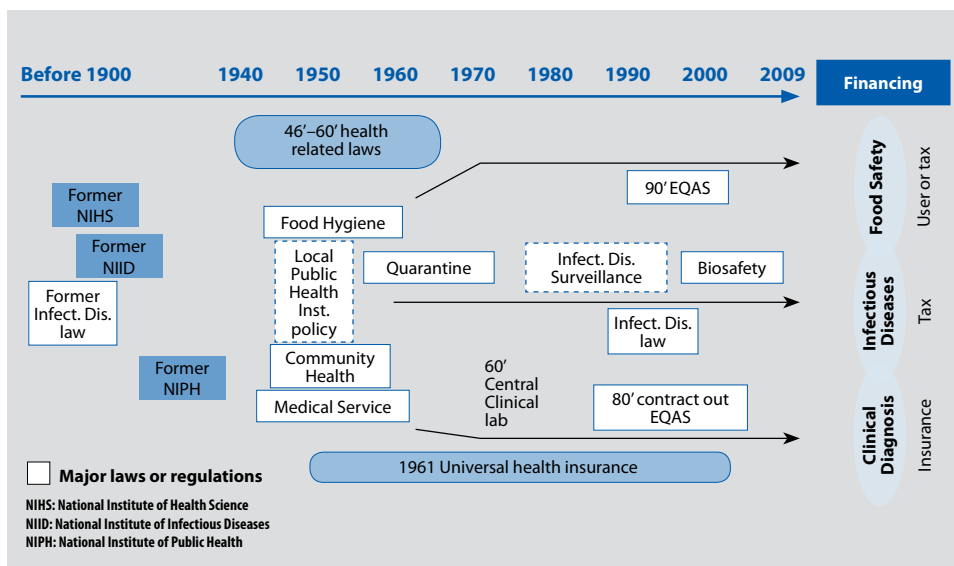
### **4.2.3 Financing strategy and plan**

The financing of health laboratory services must be part of the overall health financing plan and all national, sub-national and institutional budgeting processes.

Financing mechanisms and incentives should ensure adequate financial resources for laboratory services in countries and areas of the Asia Pacific Region. They should encourage rational laboratory use, enhance equity in access to services and protect the public from inappropriate out-of-pocket payments, whether for public or private laboratory services.

Where laboratory examinations are paid for out of pocket, fees for services form an important part of health care financing. These mechanisms should be explored so that there is no misuse, underuse or overuse of laboratory services. In terms of incentives, the income of the health care provider ordering laboratory examinations should not depend on the number of examinations requested. Prepaid pooled options are the financing mechanisms most likely to limit the misuse, underuse and overuse of tests and to curb incentives, provided they do not limit equity of access to laboratory services. An example from Japan (Figure 5) shows how funds for laboratories are generated from various sources, including insurance, taxes and user fees on different types of laboratory services.

**FIGURE 5: TRENDS OF HEALTH POLICY RELATED TO LABORATORY**



All costs associated with providing laboratory services, including those of effective procurement and supply management, implementing quality assurance, ensuring laboratory safety, maintenance of equipment and infrastructure, staff training and supervision, salaries and incentives, occupational health, staff insurance, communication, specimen transport, supervisory outreach and other related activities across the laboratory network, must be included in budgets at all levels of the health system. All sources of funding, including the government, global health initiatives and multilateral and bilateral donors, should be coherently planned and ideally reflected in the national expenditure plan or budget. The financing strategy should be continuously monitored and regular timely updates should be made available to laboratory managers.



**TABLE 3:** STRATEGIC ELEMENT: FINANCE LABORATORY SERVICES IN A SUSTAINABLE MANNER

Strategy components	Key points to consider	Role of WHO
4.2.1 Evidence-based planning and financing	<ul style="list-style-type: none"> <li>Laboratory expenditure in national health accounts and budgets</li> <li>Comparative cost information</li> <li>Sources and use of external funding</li> </ul>	<ul style="list-style-type: none"> <li>Build capacity for cost-effective analysis</li> </ul>
4.2.2 Cost-effectiveness analysis	<ul style="list-style-type: none"> <li>Evidence base for selection of examinations</li> <li>Needs to be understood by those who request laboratory services</li> </ul>	<ul style="list-style-type: none"> <li>Assist in mobilization of funds from international partners and bilateral and/or donor agencies</li> </ul>
4.2.3 Financing strategy and plan	<ul style="list-style-type: none"> <li>Part of overall health financing plan</li> <li>Include all costs associated with laboratory service provision</li> <li>Risk pooled, pre-paid financing</li> <li>Incentives to encourage rational use of laboratory services</li> <li>Ensure equitable access and protect public from inappropriate out-of-pocket expenditures</li> <li>Coordinated donor aid (ideally reflected in budget)</li> <li>Timely financial updates</li> </ul>	<ul style="list-style-type: none"> <li>Advocate for best possible impact on overall laboratory system from available financing</li> <li>Advocate for equitable access to laboratory services</li> </ul>

### 4.3 Build capacity for laboratory services

Efficient and effective implementation of the national framework for laboratory services must be based on sufficient capacity. The national laboratory policy, regulations and plan should ideally be implemented and reviewed within existing capacity, but if this is not possible, implementation capacity may need to be expanded. Any increase in capacity is most likely to succeed if it is incremental, consistent, and fits well within the rest of the health system (planned and resourced).

The following components are necessary for capacity-building and should be elaborated in the national laboratory plan (Table 4):

- physical infrastructure (building and design) and equipment
- human resources
- procurement and supply management
- laboratory networks
- transportation of specimens
- information systems and communication.

For each of these components, Member States will need to decide and clarify whether the requirements specified in their national laboratory plan are presented as aspirational guidelines, accreditation standards or regulatory requirements that the service provider must follow.

In the framework of IHR (2005),<sup>6</sup> by June 2009, countries should have completed a self- or in-depth assessment of their surveillance and response capacities, leading to the drafting of an action plan, including laboratory capacity-building programmes (national laboratory policy and national laboratory plan) by 2012. Laboratory assessment tools have been drafted by WHO and may be used, when available, to assist these processes.

#### **4.3.1 Physical infrastructure and equipment**

Buildings and equipment are necessary parts of a health laboratory system. When deciding on a building and its location, consideration must be given to the country context, number and distribution of human resources, utilities such as electricity, water supply, maintenance and replacement of equipment and other recurrent costs. Appropriate building space, design, utilities and equipment are essential to deliver safe and effective services. The use of appropriate technology at different levels of the laboratory network is cost-effective and enhances efficiency. When equipment is not appropriately

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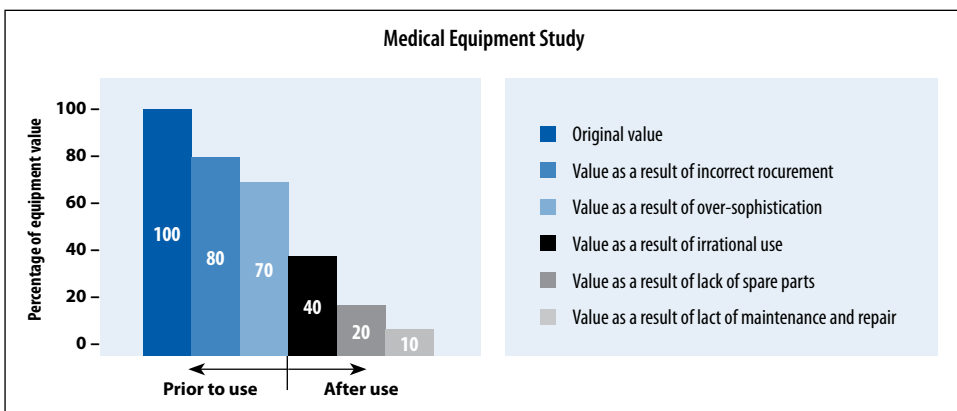
<sup>6</sup> *International Health Regulations (2005)*, second edition. Geneva, World Health Organization, 2008.



purchased, maintained or used, its value decreases. Several factors influence the value of equipment, as shown in a recent Swiss study (Figure 6).

The national laboratory plan must specify the appropriate building and equipment requirements and overall development plan for different levels of service irrespective of source of funding. Decisions on purchase and acceptance of donated equipment should always include considerations of running and maintenance costs.

**FIGURE 6:** HEALTH TECHNOLOGY ASSESSMENT AND UTILIZATION OF RESOURCES



**Source:** Swiss Center for International Health, Basel, 2005

### 4.3.2 Human resources

Each Member State should have a comprehensive human resources plan that proposes how to meet the projected requirements. The human resources plan should not only address the supply component of human resources, but also guide teaching institutions and universities in educating the future workforce.

Adequate numbers of qualified personnel are needed to implement the national laboratory plan. Ensuring consistency with its overall health workforce plan, each Member State must decide what numbers and types of health workers are best suited to implement the laboratory plan from the peripheral level to the reference and/or national laboratory level (Figure 7). The plan must also indicate what kinds of training requirements and laboratory tests can be done at each

level by village volunteers, nurses, medical assistants and doctors, and at what levels trained laboratory personnel must be introduced to perform, supervise, interpret and validate laboratory analysis. As with all other health workers, the human resources plan for laboratory personnel should include issues of basic and in-service training, continuing professional development, motivation and incentives, retention, remuneration, and career development, comparable to the best in the corresponding echelons in the health system.

Good management of a laboratory facility covers all aspects of laboratory functions: quality and compliance with nationally recognized standards, safety, procurement and supply management, communication in the laboratory network, rational use of services, reporting results, etc. The national plan will indicate at what level or size of service provision the laboratory management functions should be undertaken by a designated head of laboratory, or by the overall health facility manager. In all arrangements, it is important that managers and other staff clearly understand their roles and responsibilities in relation to the laboratory services and the requirements outlined in the national laboratory policy and plan.

Effective supervisory systems, set up to monitor work productivity and quality, are essential for effective laboratory services. The national laboratory plan can outline supervisory approaches to improving laboratory performance. The most effective supervisory systems combine on-site evaluation, teaching, mentoring, monitoring, quality assurance and supportive feedback.



### 4.3.3 Procurement and supply management

Procurement and supply management is another key component of laboratory services that requires appropriate capacity. The selection of laboratory tests and methods (as outlined in the national laboratory plan) should appropriately reflect the country's capacity to manage the supply chain. Procurement decisions should be based on the quality of supplies and equipment, e.g. pre-validation, expiry dates and shelf-life. Supply decisions should take into account issues such as centralized or decentralized purchasing, bulk or small purchase. These decisions also apply to donated equipment and supplies. Decisions on procurement and supply management cannot be over-ruled without adequate consultation between the suppliers and end-users.

Expected standards and approaches to building capacity in procurement and supply management can be outlined in the national laboratory plan using WHO guidelines where applicable.<sup>7</sup>

### 4.3.4 Laboratory networks

The national laboratory plan can describe the structure, functioning and capacity of the laboratory network, outlining the extent and limitations of the roles and responsibilities, communication and referrals, coaching and mentoring, and monitoring and evaluation required at and between each level of service.

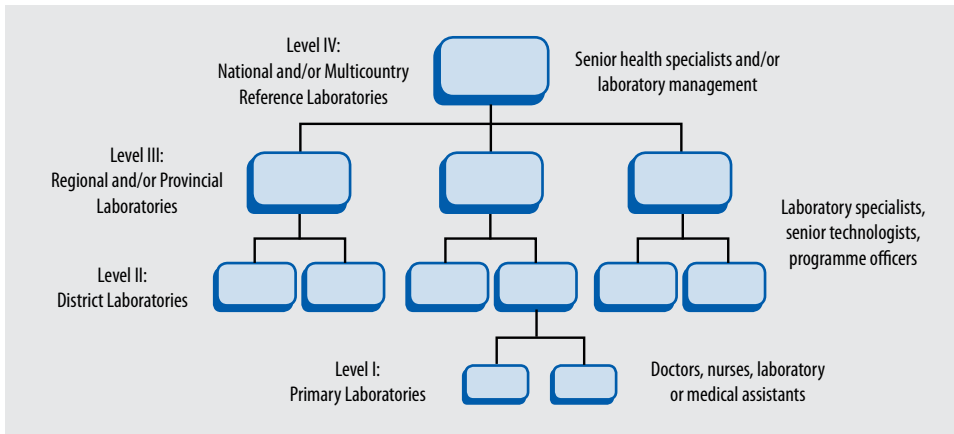
Not all laboratory investigations can be available at every facility or at every level of the health system. An organized network (as shown in Figure 7) ensures that complex test methods are referred to the appropriate level (see also Annex 1). The transport of specimens or referral of patients is usually more cost-effective than developing sophisticated capacity in every facility. In some countries, patients or specimens may be referred out.

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<sup>7</sup> *Handbook of Supply Management at First-level Health Care Facilities* - 1st version for country adaptation. Geneva, WHO and partner organizations, 2006.

In some cases, point-of-care testing may be non-laboratory based and decisions about capacity, supervision, quality control and regulations will need to be made at the national level.

**FIGURE 7: THE TIERED, INTEGRATED LABORATORY NETWORK**



Source: Consultation on Technical and Operational Recommendations for Clinical Laboratory Testing, Harmonization and Standardization (Maputo, 22–24 January 2008). Consultation

Every laboratory service (regardless of size or location) should know where it stands within the national or regional laboratory network, and to whom to refer specimens or patients for different specialized investigations.

A formalized network facilitates the exchange of knowledge and expertise among experienced laboratory specialists and practitioners, thus facilitating timely and appropriate laboratory support for patient management, surveillance, disease prevention and control.

At present, some Member States may have disease- or programme-specific laboratories that primarily undertake diagnostic services. Unfortunately, there is often weak collaboration between the laboratory components of these programmes and other laboratories (e.g. national referral laboratories, clinic- and hospital-based laboratories, and private laboratories). Global financing instruments and disease-specific bilateral projects have increased the “verticality” of some laboratory systems, thus contributing to their fragmentation. Each has its own budget, human resources, procurement



and supply chain, information network and technical programmes, which often leads to duplication of efforts, omission of locally required essential components and waste of resources. The aim is to ensure that all laboratories can work together in an effective, practical and functional way, with clear patterns for referral, confirmation of certain types of results, and efficient provision of supplies and procurement. The expertise available with the specialized laboratories supporting the vertical disease programmes (e.g. TB, HIV/AIDS) should be harnessed to support other laboratories in the country.

One of the roles of the national focal point for health laboratories would be to explicitly define both the vertical (between levels) and horizontal (across programmes) connections between health laboratory services to strengthen the network. Even when laboratories remain separate, functional integration can improve efficiency, quality and health outcomes. In many settings, improved information technology, such as Internet and mobile phones, can make this functional integration more feasible.

#### **4.3.5 Transportation of specimens**

Human error, poor laboratory techniques and misuse of equipment cause the majority of laboratory injuries and work-related infections. In addition, improper collection, transport and handling of specimens carry a risk of infection to the personnel involved.

The transport of infectious and potentially infectious materials is subject to strict national and international regulations. These regulations call for the proper use of packaging materials, as well as other shipping requirements, in accordance with the basic triple packaging system.

Compliance by laboratory personnel with the transport regulations will:

- reduce the likelihood that packages will be damaged and leak, and thereby
- reduce the possibility of exposure and probable infection, and
- improve the efficiency of package delivery.

International model regulations are not intended to supersede local or national requirements. However, in countries where national requirements do not exist, international model regulations should be followed. It is important to note that international transport of infectious substances is also dependent on and subject to national import/export regulations.

#### **4.3.6 Information systems and communication**

Laboratory test results are a vital part of a patient's health record and provide health care professionals with data to support decision-making and case management at the point of care. Implementation of laboratory information systems will reduce duplication of tests and help accelerate diagnosis and appropriate care. By ensuring results are correctly linked to patients, safety will be enhanced and health care providers will have a more complete and accurate medical profile to assess patient needs.

Laboratories need to be supported by an information system that can provide quality and timely information to: (1) support appropriate patient information; (2) support laboratory management; (3) on a broader scale, contribute to disease surveillance, prevention and control. Thus, the information processes for a laboratory information system and manual documentation—from data collection, transmission, processing and analysis including an early warning system—are designed to meet these three functions. Establishing standards to manage data and to facilitate exchange of information across the laboratory network is of prime importance. In some countries, electronic solutions may be appropriate.

To support laboratory management, the laboratory information system needs to be designed to accurately log patients' information and examination results, to track the use of reagents, to facilitate inventory management, to assist in quality assurance, and to meet accreditation requirements. Oftentimes, the laboratory information system must interface with instruments and other information systems such as hospital information systems. Health services in charge of epidemiological surveillance should be able to access data to



maintain subnational and national epidemiological database. At all times, individual patient confidentiality should not be compromised.

Support is needed to build the capacity of laboratory staff to analyse and disseminate laboratory information in order to facilitate early detection of new health problems or outbreaks and provide evidence-based data for policy-making and planning.

Regular communication with customers as well as with other laboratory professionals should be maintained to keep abreast of new developments and the needs of the users of laboratory services.

**TABLE 4:** STRATEGIC ELEMENT: BUILD CAPACITY FOR LABORATORY SERVICES

Strategy components	Key points to consider	Role of WHO
4.3.1 Physical infrastructure and maintenance	<ul style="list-style-type: none"> <li>• Norms for establishing laboratories</li> <li>• Appropriate laboratory design</li> <li>• Appropriate equipment (purchased or donated)</li> <li>• Electricity, water and support services</li> <li>• Appropriate biosafety infrastructure</li> <li>• Waste disposal</li> <li>• Maintenance and upkeep</li> </ul>	<ul style="list-style-type: none"> <li>• Develop infrastructure and maintenance norms for laboratories at different levels</li> <li>• Assist in upgrading skills of human resources</li> <li>• Facilitate linking of national networks with international and/or regional networks</li> <li>• Provide technical assistance in prequalification of diagnostics and equipment</li> <li>• Assist in setting up a laboratory information system (hardware and software)</li> <li>• Provide minimum standards/guidelines for different levels of service</li> </ul>
4.3.2 Human resources	<ul style="list-style-type: none"> <li>• Human resource planning</li> <li>• Training</li> <li>• Technical competence</li> <li>• Managerial functions</li> <li>• Supportive supervision</li> </ul>	
4.3.3 Procurement and supply management	<ul style="list-style-type: none"> <li>• Range of tests and methods to be used at each level</li> <li>• Validation of equipment</li> <li>• Decentralized vs. centralized systems</li> <li>• Small vs. bulk procurement</li> <li>• Maintenance of donated equipment and supplies</li> <li>• Laboratory inputs in purchase decisions</li> </ul>	
4.3.4 Laboratory networks	<ul style="list-style-type: none"> <li>• Roles and responsibilities</li> <li>• National or regional approach</li> <li>• Functional and structural integration between existing laboratories</li> <li>• Referral networks</li> <li>• Collaboration between disease-specific programmes and other laboratories</li> <li>• Oversight of non-laboratory-based point-of-care testing</li> </ul>	
4.3.5 Transportation of specimens	<ul style="list-style-type: none"> <li>• Timely and efficient</li> <li>• Shipping and handling of biological and chemical specimens (as per national and international regulations)</li> </ul>	
4.3.6 Information systems and communication	<ul style="list-style-type: none"> <li>• Patient management</li> <li>• Laboratory management</li> <li>• Disease surveillance</li> <li>• Outbreak investigation and management</li> <li>• Networking of laboratories (hardware and software)</li> <li>• Patient confidentiality</li> <li>• Regular communication with peers and users of laboratory services</li> </ul>	



## 4.4 Assure the quality of health laboratory services

The importance of quality in the functioning of health laboratories is undeniable. Laboratories that provide accurate, timely and reliable services for diagnosis, treatment and monitoring, whether in public health or clinical services, is the aim of every efficient health laboratory system. Monitoring of quality and its continuous improvement is a feature of well-managed laboratories. Quality is achieved by establishing an efficient quality system.

The following components of a quality system in health laboratories are essential (Table 5):

- management commitment and quality policy
- quality standards
- training of human resources
- documentation and its control
- assessment and accreditation.

Considerable resources are needed for continuous quality improvement. However, the costs of developing, implementing and monitoring quality are much less than the costs of the adverse consequences of poor quality in terms of misdiagnosis, repeating tests unnecessarily, lost time and ultimately poorer health outcomes. Expensive technologies are not always necessary to ensure quality, but trained staff, standards and effective feedback mechanisms are always required.

***Quality costs: poor quality costs more***

#### 4.4.1 Management commitment and quality policy

Laboratory management needs to be firmly committed to quality assurance and allocation of adequate resources. A laboratory quality policy should reflect the intention and commitment of the organization to provide quality services. The policy can be implemented through a quality plan, which in turn needs to be documented in the form of a quality manual. The overall responsibility for the design, implementation, maintenance, updating and improvement of the quality system rests with those managing the laboratory. Quality is the responsibility of all the staff members of the organization, supported by relevant training, standards, procedures and documentation.

Laboratory management should also articulate standards and mechanisms for the control of:

- purchased materials and equipment;
- supplier evaluation and approval;
- proper sample collection, request preparation, identification, receipt and processing;
- pre-approved, version-controlled analytical test methods;
- equipment maintenance and operations;
- results, interpretation, reporting, filing and delivery; and
- specimen archiving.

#### 4.4.2 Quality standards

Quality standards are an integral part of the quality system. They are designed to help laboratories meet regulatory requirements, including local health regulations, and monitor laboratory functions, thereby ensuring laboratory safety and consistency of performance.

A national health laboratory plan will specify quality standards for laboratories at each level and define the bodies responsible for establishing and monitoring those standards. Minimum standards are mandatory and efforts should be



made to ensure that they are met by all facilities. There can also be higher standards which are desirable but not mandatory.

Quality standards should be developed in consultation with all stakeholders. To be useful, standards must not only be realistic, but also be up to date with the latest scientific advances. A dynamic balance between the two is necessary in most situations. All countries should aspire to adopt existing international standards; however, each country will have to decide what standards fit their situation. For some countries, a regional approach to developing standards may be appropriate. A widely acclaimed Thai model (Figure 8) for introducing quality standards at different levels of the health system is available as a practical example.

**FIGURE 8:** *QUALITY STANDARDS IN HEALTH LABORATORIES IN THAILAND*



**Source:** *Quality Standards in Health Laboratories: Implementation in Thailand*. New Delhi, World Health Organization, 2005 ([http://www.searo.who.int/LinkFiles/Publications\\_SEA-HLM-386\\_\\_a4\\_\\_2\\_.pdf](http://www.searo.who.int/LinkFiles/Publications_SEA-HLM-386__a4__2_.pdf)).

#### 4.4.3 Training of human resources

A laboratory quality system is only as good as the staffs who work with it. No matter how good a quality system is on paper, if it is not carried out consistently in daily practice, high quality cannot be achieved.

Laboratory staff must be properly trained on all aspects of the quality system. Laboratory management is responsible for identifying and outlining training needs and for ensuring adequate resources for training purposes. Training should be competency based and should be imparted using approved training materials. Training received by each staff member should be recorded and followed up to ensure that learning is put into practice.

#### **4.4.4 Documentation and its control**

Documents are hard-copy or electronic records of information or instructions, which may include policy statements, quality manuals, procedures, worksheets, tests reports, job descriptions and documents of external origin such as regulations and standards. Documentation control is an essential component of the laboratory quality system and involves creating, regularly reviewing and updating, distributing and maintaining all documents and information (from internal and external sources).

Standard operating procedures (SOPs) are approved, controlled and reviewed periodically by management to promote quality and safety in the daily work of laboratory staff. A laboratory quality system should define, document, maintain and update SOPs for documentation control. All relevant documents, in their most current forms, should be available at all locations that contribute to or impact on effective functioning of the laboratory services.

#### **4.4.5 Assessment**

Quality can also be assessed through audits (internal or external), internal quality control, and participation in external quality assessment schemes (EQAS), the results of which should guide management in further improving the quality of laboratory services delivery.

Laboratory management should develop relevant quality indicators to systematically monitor and evaluate the laboratory's performance and contribution to the overall health services and health outcomes. A system should be implemented to evaluate complaints, turnaround time for critical



tests, and timeliness of important operations and error management. When results on indicators identify needs for improvement, laboratory management should take corrective and preventive steps to address them.

EQAS, formerly known as proficiency testing, is a powerful tool for assessing laboratory quality in a schematic way through an external agency. EQAS challenges the internal quality control measures used by laboratories and assesses the entire testing process, including the quality of results generated by a particular laboratory. Specimens of undisclosed but known content are used for processing and for measuring the accuracy of the results.

All laboratory services would benefit from a more comprehensive external quality assessment plan sustained through national resources. In some Member States, external quality assessment is provided within the laboratory network, e.g. national laboratories serving subnational laboratories; in others, it is provided on a regional basis, e.g. the regional EQAS for Pacific island countries.

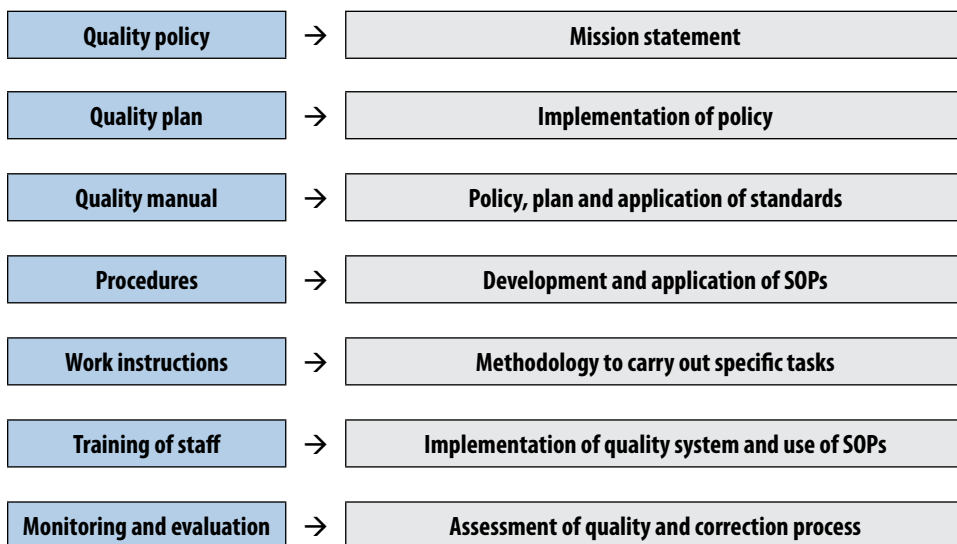
“Accreditation” (national or international) is a voluntary process to confirm that standards have been met. Accreditation serves as a marker of quality to consumers and can have significant benefits in increasing confidence in laboratory services.

#### **4.4.6 Development of a quality system**

A quality system can be developed in a step-wise approach as shown in Figure 9.



**FIGURE 9:** DEVELOPMENT OF A QUALITY SYSTEM



**TABLE 5:** STRATEGIC ELEMENT: ASSURE THE QUALITY OF LABORATORY SERVICES

Strategy components	Key points to consider	Role of WHO
4.4.1 Management commitment and quality policy	<ul style="list-style-type: none"> <li>• Supportive working environment</li> <li>• Quality policy</li> <li>• Training of human resources</li> </ul>	<ul style="list-style-type: none"> <li>• Develop training on the national standards</li> <li>• Develop guidelines for the accreditation of laboratories</li> <li>• Facilitate regional EQAS</li> <li>• Support national EQAS</li> </ul>
4.4.2 Quality standards	<ul style="list-style-type: none"> <li>• Consensus on national or regional quality standards</li> <li>• Step-wise approach to implement standards</li> <li>• Aspire to international standards</li> </ul>	
4.4.3 Training of human resources	<ul style="list-style-type: none"> <li>• Training needs</li> <li>• Training materials</li> <li>• Conduct training courses</li> <li>• Review impact of training</li> </ul>	
4.4.4 Documentation and its control	<ul style="list-style-type: none"> <li>• Standard operating procedures</li> <li>• Worksheets</li> <li>• Records</li> <li>• Quality manual</li> <li>• Job descriptions</li> </ul>	
4.4.5 Assessment	<ul style="list-style-type: none"> <li>• Audits</li> <li>• Internal quality control</li> <li>• External quality assessment</li> <li>• Accreditation (national, international)</li> </ul>	



## 4.5 Promote the rational use of laboratory services

Equity and access issues are critical and should be considered when designing and strengthening the national laboratory network. Laboratory investigations need to be carried out for the right reasons, on the right specimens, at the right times and in the right places, and the results need to be interpreted and used appropriately. If not, resources are wasted and other needed services cannot be provided, reducing both coverage and equity and jeopardizing access.

Laboratory services can be either underused or overused, both of which can be detrimental to the health and/or finances of the public. If necessary tests are not done, appropriate treatment or infection control might not be administered, resulting in harm to the patient and community. On the other hand, unnecessary tests are costly to the public, whether paid for directly by patients or indirectly through third party payers (government or insurance) and leads to waste of resources.


The methods used to promote the rational use of laboratory investigations include efforts to influence the following (Table 6):

- health service providers
- appropriate development of laboratory services
- community awareness.

### 4.5.1 Health service providers

Health service providers, including clinicians, epidemiologists, laboratory personnel and other health professionals, can request laboratory services. Ways to promote the appropriate use of laboratory services by health personnel include: (1) improving understanding of laboratory services, and (2) de-linking examination requests from income of health providers.

Health services providers who order laboratory examinations need to know how to provide relevant clinical information; select appropriate tests; properly collect, store and ship specimens; interpret laboratory results using reference



ranges; initiate correct patient management based on laboratory results; and understand the public health implications of laboratory results so that notification is done promptly. In the context of outbreaks, subsequent testing is rational and guided by epidemiological and pathological causes.

Where individual or facility-based service providers gain direct income by ordering laboratory examinations, there is a potential conflict of interest with the ethics of rational use of services. Wherever feasible, efforts should be made to design payment mechanisms to avoid this conflict of interest.

The proper use of laboratory examinations should be included in clinical practice guidelines. Audits and review committees could be established in both the clinical and public health sectors. An inventory of available tests, indications, limitations, costs and type of specimen required could be compiled, kept up to date and made easily available to all those ordering laboratory services.

Professional organizations and laboratory professionals play an important role in promoting professional ethics, use of clinical practice guidelines and rational use of laboratory services. Health professionals could be made aware of methods, such as cost-effectiveness analysis, that are used to select laboratory investigations and methods for inclusion in the national laboratory plan.

Operational research may provide for continuous guidance on the rational use of laboratory services (refer section 4.7.1)

#### **4.5.2 Appropriate development of laboratory services**

Another mechanism that can be used to promote rational use of services is the national laboratory network. As discussed in section 4.3.4, all types of laboratory investigations will not be available at every facility or at every level of the health system. In many instances, transporting specimens or referring patients to other laboratories is more rational than developing capacity in every facility, or in every small country. Therefore, coordination mechanisms should be in place to facilitate access to techniques or examinations that are complex or expensive and undertaken in selected facilities. Guidelines on appropriate collection,



storage and transportation of specimens must be developed and made available. Effective communication and safe transport have to be available for such a system to function effectively.

With increasing globalization, referrals or outsourcing may need to go beyond national boundaries. When this occurs, licensing and transportation requirements and legal implications need to be defined.

### 4.5.3 Community awareness

Public awareness of the importance of laboratories and the benefits of the proper use of examinations should be promoted. Public education should be provided on the role and value of laboratory tests in screening and early detection of both communicable and noncommunicable diseases. Civil society organizations and professional bodies may play an important part in promoting informed public awareness on rational use of resources.

**TABLE 6:** STRATEGIC ELEMENT: PROMOTE THE RATIONAL USE OF LABORATORY SERVICES

Strategy components	Key points to consider	Role of WHO
4.5.1 Health service providers	<ul style="list-style-type: none"> <li>• Payment mechanisms to de-link income from volume of tests ordered</li> <li>• Adequate patient evaluation</li> <li>• Proper collection, storage and shipment of specimens</li> <li>• Interpretation of results</li> <li>• Public health implications of laboratory results</li> <li>• Laboratory tests in clinical practice guidelines</li> <li>• Professional ethics</li> <li>• Role of professional organizations</li> <li>• Role of research in keeping clinical practice guidelines up to date</li> </ul>	<ul style="list-style-type: none"> <li>• Develop training materials on selection of laboratory tests</li> <li>• Develop training materials on specimen collection, storage and shipment</li> <li>• Set up a model institution laboratory committee</li> </ul>
4.5.2 Appropriate development of laboratory services	<ul style="list-style-type: none"> <li>• Network of laboratories including private sector, national and international reference laboratories</li> <li>• Sharing of complex tests and methodologies</li> <li>• Transportation of specimens</li> </ul>	
4.5.3 Community awareness	<ul style="list-style-type: none"> <li>• Importance of laboratories in health care</li> <li>• Involvement of professional bodies and civil society</li> <li>• Public education</li> </ul>	



## 4.6 Improve laboratory safety

“First, do no harm” remains a core tenet of any health system. Health laboratory services should be free from recognized hazards that may cause serious harm to its employees, the general public, or the environment. Occupational safety and health standards should be established and compliance should be mandatory. The public expects laboratories to be safe and to protect the community from biorisks. Staff are expected to follow safe working practices (biosafety), to keep their work and materials secure (biosecurity) and to follow an ethical code of conduct (bioethics). Despite advances in technology, the availability of more sophisticated instruments, increasingly effective techniques and the use of personal protective equipment (PPE), human error remains one of the most important contributory factors in breaches of biosafety. Inadequate training, low staff numbers, unpredictable workload, inadequate supply of PPE and other infection control materials, poor concentration, denial of responsibilities, inappropriate accountability, incomplete record-keeping and labelling of reagents, suboptimal facility infrastructure, and lack of ethical conduct may all contribute to laboratory-acquired infections, loss of material and inappropriate use.

Ensuring safety in the laboratory involves (Table 7):

- biosafety
- biosecurity
- occupational health and safety
- waste management including environmental protection.

### 4.6.1 Biosafety

Biosafety involves good staff training, the availability of standard operating procedures, staff competence in risk management, appropriate containment equipment, proper facility design, correct operation and maintenance, and administrative considerations to minimize the risk of worker injury or illness (Figure 10). Biosafety practices must be engaged at every step — from



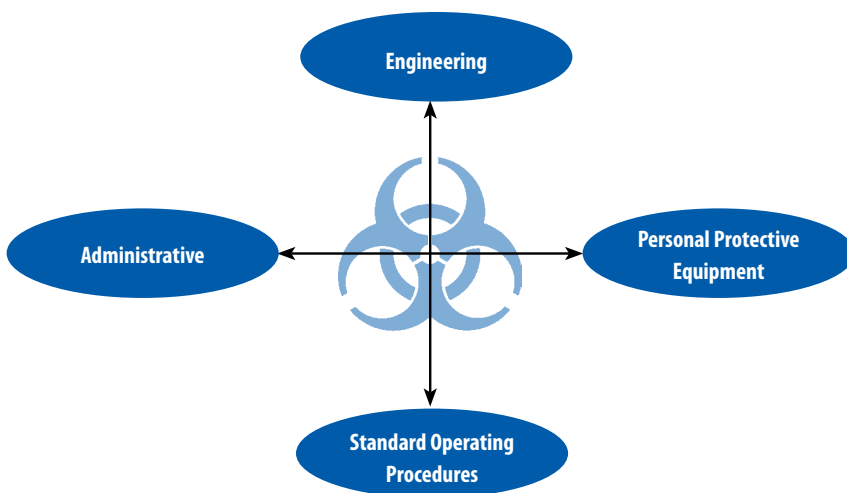
sample collection, transportation, processing and testing to storage or waste management. Errors in any one part of the chain will result in risks to biosafety.

Biosafety requires appropriate physical infrastructure, including engineering controls and equipment maintenance. Physical infrastructure should be upgraded where necessary. Personal protective equipment and procedures are essential: right kit, right use and right disposal. Techniques that require the handling of highly pathogenic transmissible agents should not be introduced unless biosafety can be assured. Laboratory workers should never be asked to perform examinations for which their training and skill level are not adequate to assure biosafety.

Monitoring and medical surveillance of health laboratory workers is an essential component. All laboratories should have a waste management policy and guidelines to investigate and rectify breaches of biosafety and related incidents.

Continuous training of laboratory personnel and good management practices can help to establish a “no blame” environment so that problems are quickly identified and staff can learn from mistakes and near-miss incidents.

**FIGURE 10: ESSENTIAL CONTROLS OF BIOSAFETY**



**Source:** Biosafety and Biosecurity in Health Laboratories: Report of a Regional Workshop (Pune, India, 8–11 July 2008). New Delhi, World Health Organization, 2008.

## 4.6.2 Biosecurity

Effective biosafety practices are the foundation of laboratory biosecurity. Risk assessments should be conducted to document the type of organisms, their physical location and personnel who have access to them, including whether an institution possesses biological materials that may be used inappropriately. Member States should develop national standards that recognize protocols set forth by the International Health Regulations, including the need to protect specimens, pathogens and toxins from misuse. An appropriate laboratory biosecurity programme must be developed and implemented for each facility. Documentation (see 4.4.4) is required to ensure compliance of biosecurity measures.

## 4.6.3 Occupational health and safety

The employing authority, through the laboratory manager, is responsible for ensuring adequate surveillance of the health of laboratory personnel to monitor for occupationally acquired diseases. Appropriate activities to achieve these objectives include:

- documented evidence of training in safety and biosafety procedures of all laboratory personnel;
- emphasis on preventive action and provision of necessary immunization for staff, e.g. pre-exposure prophylaxis;
- provision of active or passive immunization for post-exposure prophylaxis where indicated;
- facilitation of the early detection of laboratory-acquired infections; and
- provision of effective personal protective equipment and procedures.

## 4.6.4 Waste management including environmental protection

Waste can be a potential health hazard for laboratory staff as well as communities. Standard operating procedures for waste disposal and spillage,



in accordance with prevailing scientific concepts and national regulations,<sup>8</sup> should be developed, implemented and reviewed regularly. Prior to disposal, all biohazardous waste should be stored separately from the general waste stream and from other hazardous wastes. The containers used to store biohazardous waste should be leak-proof, and any biohazardous sharps, such as infectious needles and scalpels, must be placed in containers that are puncture-resistant, leak-proof and closable.

Staff responsible for cleaning, laundry and maintenance should be afforded the same protection as laboratory staff.

Many countries have developed regulations for environmental protection. Laboratories must follow these regulations.

**TABLE 7:** STRATEGIC ELEMENT: IMPROVE LABORATORY SAFETY

Strategy components	Key points to consider	Role of WHO
4.6.1 Biosafety	<ul style="list-style-type: none"> <li>• Management commitment</li> <li>• Engineering controls</li> <li>• Facility management and maintenance</li> <li>• Waste management equipment</li> <li>• Standard operating procedures</li> <li>• Training in biosafety practices</li> <li>• Reporting of adverse events</li> <li>• Risk management</li> </ul>	<ul style="list-style-type: none"> <li>• Establish guidelines on biosafety and bioethics practices</li> <li>• Establish guidelines and standards for pre- and post-exposure prophylaxis (including vaccination) in laboratories and health care settings</li> <li>• Provide technical support in establishing biosafety engineering controls, waste management and bioethics practices</li> </ul>
4.6.2 Biosecurity	<ul style="list-style-type: none"> <li>• Risk assessment – what is being done, who has access</li> <li>• Physical security and control</li> </ul>	
4.6.3 Occupational health and safety	<ul style="list-style-type: none"> <li>• Immunization</li> <li>• Pre- and post-exposure prophylaxis</li> <li>• Early detection of laboratory-acquired infections</li> <li>• Personal protective equipment and procedures</li> </ul>	
4.6.4 Waste management including environmental protection	<ul style="list-style-type: none"> <li>• Potential health hazard for the laboratory and support staff and communities</li> <li>• Standard operating procedures for waste disposal</li> </ul>	

<sup>8</sup> Each country should define “highly hazardous organisms”.

## 4.7 Support research and ethics in laboratory settings

The Millennium Development Goals will not be attained without new research addressing health system constraints to delivering effective interventions. Laboratory technologies are rapidly advancing and Member States need to have defined processes for continuous evaluation to determine if technologies are appropriate to the country context.

Relevant activities include (Table 8):

- operational research
- evaluation of appropriate technology
- developing new methods and tools
- research ethics.

### 4.7.1 Operational research

An enabling work environment that encourages creativity and the need to conserve resources can lead to new and effective ways of working that should be tested in operational research.

Member States should develop an operational research programme and protocols appropriate to their setting, which may be national or regional. Research and technological development should contribute to improve local health needs. Methods of sustainable quality improvement, cost-effectiveness analysis, ease of implementation, and interpretability and/or usability of results should be tested under real conditions.

### 4.7.2 Appropriate technology

Technology is appropriate only when it is scientifically sound, affordable, sustainable, culturally acceptable to patients and user friendly for service providers. New materials continually offer opportunities for less costly, better and novel biomedical devices, equipment and facilities. Appropriate



opportunities should be identified and assessed, and if criteria are met, new technology should be implemented.

However, over recent decades, many countries have experienced a widespread introduction of expensive technology without assessing the following: the technology's effectiveness and relevance; maintenance support and utilities; technology needs at different levels; recurring costs; and alternative options. Consequently, there have been unnecessary cost implications, frequent breakdowns of equipment, and diversions of resources from other priority areas.

Even though technology can be a major driver of costs, appropriate technology is important for enhancing laboratory performance for improved patient management. Each Member State should strive to evaluate both new and old technologies against a set of criteria to assess their appropriateness at different levels of the laboratory network.

### **4.7.3 Developing new methods and tools**

Research is needed to develop new laboratory tests and methods and to assess their potential value. The goal is to evaluate new diagnostic tools as rigorously as other health interventions using well-designed research protocols. The findings of such research should lead to improved quality of care with consequent improvements in the uptake of cost-effective treatments. Understanding the underlying science of new technologies is also essential for sustainable implementation. Thus, where feasible and practical, individual or groups of Member States should be encouraged to develop the capacity for innovative research on laboratory methods and technologies. Efforts should be made to focus some of this research on neglected diseases and conditions of national relevance with high burden of disease.

#### 4.7.4 Research ethics

Advances in science open doors to infinite possibilities for researchers to make use of acquired knowledge and techniques. National authorities should establish a legislative and/or regulatory framework that defines legitimate use of biological specimens and ethical research projects, and laboratory managers must maintain oversight of all laboratory activities. Systems and controls should be in place to avoid illegitimate use of biological specimens or unethical research. A code of conduct could include an evaluation of the purpose of the proposed research.

**TABLE 8:** STRATEGIC ELEMENT: SUPPORT RESEARCH AND ETHICS IN LABORATORY

Strategy components	Key points to consider	Role of WHO
4.7.1 Operational research	<ul style="list-style-type: none"> <li>• Cost-effective tests</li> <li>• Cost-effective treatments</li> <li>• Ease of application</li> <li>• Readily interpretable</li> </ul>	<ul style="list-style-type: none"> <li>• Set research priorities</li> <li>• Coordinate the exchange of research approaches and results among Member States</li> <li>• Promote and support appropriate technology</li> <li>• Develop tools and technical assistance for technology assessment</li> </ul>
4.7.2 Evaluation of appropriate technology	<ul style="list-style-type: none"> <li>• Scientifically sound, affordable, able to be used and maintained, culturally acceptable</li> <li>• Identify opportunities but avoid inappropriate purchase or excessive costs and waste</li> </ul>	
4.7.3 Develop new tools and methods	<ul style="list-style-type: none"> <li>• Rapid diagnostic tests</li> <li>• Focus on neglected diseases and conditions with high burden of disease</li> </ul>	
4.7.4 Bioethics	<ul style="list-style-type: none"> <li>• Oversight and selection of research and use of findings</li> <li>• Code of practice</li> </ul>	

## THE WAY FORWARD

The intention of this biregional strategy is not to duplicate the strategic components of laboratory policies and plans developed by specific disease-control programmes, but to enhance nationally coordinated laboratory services and to assist Member States in providing comprehensive laboratory services to contribute to improved health outcomes in the Asia Pacific.

There are some key stages:

- (1) Government commitment and leadership
  - (a) Government commitment and leadership will be essential to reinforce and strengthen the vital contributions that all health laboratories make to safe and effective health service delivery.
  - (b) This commitment should be supported, with relevant evidence-based data, by implementers, financiers, providers of technical assistance and other stakeholders.
- (2) Planning
  - (a) A temporary planning committee should be formed to assist in the development of the national laboratory policy and strategic plan. The committee should consist of key individuals in the Ministry of Health, the national laboratory focal point, the advisory or oversight body and other key stakeholders, including donors and partner agencies such as WHO, professional bodies, clinical and public health physicians, disease programme managers, and representatives from throughout the laboratory network, including nongovernmental laboratories.
  - (b) The national laboratory focal point and/or planning committee will lead and drive the change process.
  - (c) A detailed mapping and situation analysis of the laboratory services in the country should be carried out to provide evidence about the strengths, weaknesses, opportunities and threats, and the issues

and challenges that need resolution to achieve more integrated and effective laboratory services.

- (d) A national laboratory policy should be prepared to cover the entire laboratory network. Priorities should be: to address the issues and challenges as identified through the situation analysis; and to strengthen laboratory capacity and performance for equity, access and universal coverage.
- (e) Key goals, objectives and measurable indicators should be developed.
- (f) A plan of action should be prepared.

### (3) Implementation

- (a) Implementation of the plan should be budgeted
- (b) Identify human resources. Involve the HR, finance and planning sections of the Ministry of Health.
- (c) Identify financial resources. Harmonize donor and national resources.
- (d) Prepare a communication and advocacy strategy aimed at: (i) professional bodies, (ii) subnational leadership, (iii) end-users to promote rational use of laboratories, and partners, including nongovernmental organizations, private sector, academia, and non-health partners.
- (e) Draft legal and regulatory parameters which will cover the health laboratories
- (f) Document required national structures related to different elements discussed in the strategy, e.g. equipment, building design, human resources, supply management.

### (4) Monitoring and evaluation

- (a) Indicators should be monitored.
- (b) Health laboratory services should be evaluated periodically to measure the degree to which individual laboratories have implemented recommended changes, and to assess the degree of impact on the overall health system from the strengthened laboratory network.



(5) Financing

- (a) Allocation of resources from national budgets
- (b) Donor coordination. Almost all major donor agencies have signed on to the aid effectiveness agenda.<sup>9</sup> A robust national health laboratory services policy and plan could be the basis for improved aid coordination and effectiveness for the national laboratory network.

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<sup>9</sup> Paris Declaration on Aid Effectiveness, 2005 ([http://www.searo.who.int/LinkFiles/GAVI\\_ParisDeclaration.pdf](http://www.searo.who.int/LinkFiles/GAVI_ParisDeclaration.pdf)).



# INDICATORS

Measurement of progress, resistance and impact will be required throughout the process of strengthening laboratory services. This can be facilitated by each Member State carefully selecting and defining a small set of indicators. Indicators should be objective and capable of measuring progress towards achieving the objectives in the laboratory services policy and strategic plan. They are a means to ensure transparency and accountability for results and potentially to guide national and donor funding for laboratory services. For credibility of measurement, once established, indicators should not be changed retroactively and within a defined planning period.

The important characteristics of validity, reliability and sensitivity should be considered when selecting indicators. In addition, the indicators should be well accepted, easy to measure and interpret, and useful in decision-making.

Before implementing the plan, it is important to establish a baseline that reflects the situation as well as realistic targets to be reached by the end of a set period. Most indicators will need to be developed at national level, and whatever indicators a Member State chooses to use will need to be carefully defined and data sources identified. The following examples could be considered.

## Examples of country indicators

- (1) Existence of a coherent national health laboratory policy and strategic plan based on a robust situation analysis
- (2) Proportion of laboratories meeting nationally approved standards for each level
- (3) Number of disciplines in which national EQAS are available
- (4) Proportion of laboratories participating in the national EQAS



- (5) Proportion of laboratories reaching acceptable performance levels in the national EQAS
- (6) Proportion of laboratory equipment purchased that meets specifications as outlined in the national laboratory plan
- (7) Proportion of laboratories experiencing a shortage of essential reagents (based on agreed national standards and time-frames for monitoring)
- (8) Existence of a biosafety management plan for health laboratories and the percentage of facilities complying with those standards
- (9) Proportion of laboratory examinations that meet the criteria for rational use as established by the national laboratory plan
- (10) Proportion of laboratories with a functional manual recording system or electronic laboratory information system
- (11) Number of operational research projects pertaining to laboratory services completed in one year
- (12) Proportion of tests for which generic standard operating procedures are available
- (13) Proportion of laboratories with documented quality management systems
- (14) Proportion of laboratories with documented standard operating procedures for public health and IHR (2005) obligations

### **Proposed regional indicators**

- (1) Number of countries with a coherent national health laboratory policy and strategic plan based on a robust situation analysis
- (2) Number of countries with an identified and active national laboratory focal point

- (3) Number of countries and proportion of facilities participating in an acceptable laboratory EQAS that is comprehensive enough to assess proficiency in commonly used tests
- (4) Number of countries with a biosafety management plan for health laboratories and the percentage of facilities in countries complying with those standards
- (5) proportion of laboratories participating in laboratory based surveillance
- (6) proportion of events of public health importance reported with laboratory participation and confirmation

# GLOSSARY

## **Cost-effectiveness analysis**

A form of economic evaluation where costs are expressed in money terms, but consequences are expressed in physical units. It is used to compare different ways of achieving the same objective.

## **Access to service**

The extent to which people, particularly those from disadvantaged groups or areas, can utilize the health services that they need. Access can be considered in terms of physical access, financial access, and social or cultural access or acceptability.

## **Accreditation**

The process by which an independent and authorized agency accredits the quality system and competence of a laboratory on the basis of certain predefined standards (e.g. ISO 15189).

## **Asia Pacific**

comprises countries and areas from both the South-East Asia and Western Pacific Regions of WHO.

## **Bioethics**

The study of the ethical and moral implications of biological discoveries, biomedical advances, and their applications, as in the fields of genetic engineering and drug research.

## **Biosafety**

Laboratory biosafety describes the containment principles, technologies and practices that are implemented to prevent unintentional exposure to, or accidental release of, pathogens and toxins.

### **Biosecurity**

Institutional and personal security measures designed to prevent the loss, theft, misuse, diversion or intentional release of pathogens and toxins.

### **Containment facility**

A facility that is equipped and experienced to handle exotic, dangerous, and potentially life-threatening pathogens.

### **Decentralization**

The process of dispersing power, authority and responsibility for political, economic, fiscal and administrative systems from the central level to the lower levels. The focus here is on administrative decentralization for health policy, health systems management, health financing and service delivery.

### **Equity**

The absence of systematic disparities in health between social groups that have different levels of underlying social advantages or disadvantages, that is, different positions in a social hierarchy. Inequalities in health systematically put groups of people who are already socially disadvantaged, such as by virtue of being poor, female and/or members of a disenfranchised racial, ethnic or religious group at further disadvantage with respect to health.

### **Engineering controls**

Controls used to remove a hazard or place a barrier between the worker and the hazard. Well-designed engineering controls can be highly effective in protecting workers and will typically be independent of worker interactions to provide a high level of protection.

### **Fee for service**

Payment to a provider for items or services provided.

### **Health laboratory services**

Providing support for informed decision-making in curative and public health services.



### **Health promotion**

Series of activities to promote wellness, especially of body or mind, as well as freedom from disease or abnormality.

### **Health service provider**

Organization or individual that provides direct treatment or support services to an individual, family or community.

### **Health system**

The people, institutions and resources, arranged together in accordance with established policies, whose primary tenet is to improve the health of the population they serve, while responding to people's legitimate expectations and protecting them against the cost of ill-health. Health systems fulfil three main functions: (1) health care delivery, (2) fair treatment to all, and (3) meeting non-health expectations of the population.

### **Health workforce plan**

A plan for the future workforce needs of the health system, based on projected epidemiology, demographics and burden of disease, which may involve preparing:

- an overall vision of the future health workforce;
- guiding principles for health workforce policy; and
- health workforce priorities that are expected to require strategic action (over the next five to 10 years), which recognize, and respect, that jurisdictions and stakeholders have specific roles and responsibilities within the health system.

### **Medical surveillance**

The monitoring of individuals who may have been exposed to a pathogen or something noxious in the environment, or detection of the early symptoms of disease.

### **National laboratory policy**

National commitment to provide comprehensive laboratory support to health services, define the goals and objectives of a national laboratory

system, advocate the allocation of appropriate resources, and empower the establishment and implementation of a national laboratory plan.

### **Operational research**

Research conducted to elicit a best possible solution to a problem mathematically to improve or optimize the performance of a system.

### **Out-of-pocket payment**

Payment made directly by a patient to a health service provider without reimbursement.

### **Personal protective equipment (PPE)**

Protective clothing, helmets, goggles or other garments designed to protect the wearer's body from exposure to biological, chemical and radioactive hazards

### **Point-of-care testing**

Any type of testing performed by a hospital or clinic employee outside of the central laboratory. Point-of-care testing may be used as a screening and/or diagnostic tool by primary care providers to enhance the quality of care offered to the community. It is accomplished through the use of transportable, portable and handheld instruments.

### **Pre-validation**

The process of determining whether or not the products of a given phase in the life-cycle fulfil a set of established requirements.

### **Professional body and/or organization**

Many professional bodies perform professional certification to indicate a person possesses qualifications in a subject area, and sometimes membership in a professional body is synonymous with certification. Many professional bodies also act as learned societies for the academic disciplines underlying their professions.



### **Quality assurance**

Covers all activities from design, development, production, installation, servicing and documentation. Quality assurance calls on laboratories to be “fit for purpose” and to “do it right the first time”.

### **Quality control**

The operational techniques and the activities that sustain the quality of a product or service in order to satisfy given requirements. Quality control is a major component of total quality management and is applicable to all phases of the product life-cycle: design, development, manufacturing, delivery and installation, and operation and maintenance.

### **Quality improvement**

The expectation that an institution has a plan in place to monitor and improve the quality of its programmes. In most cases, quality assurance and accrediting agencies require procedures that ensure ongoing quality improvement.

### **Quality system**

The organizational structure, responsibilities, procedures and resources needed for implementing quality management (ISO definition). A quality system has five key elements: (1) organizational management and structure; (2) quality standards; (3) documentation; (4) training; and (5) assessment.

### **Regulation**

A principle, rule or law designed to control or govern. A governmental order having the force of law.

### **Standard operating procedures (SOPs)**

A set of detailed, written instructions to achieve uniformity of the performance of a specific function.

### **Clinical practice guidelines (or standard treatment guidelines)**

Guidelines that clarify the content of appropriate, high-quality, measurable, cost-effective care that assists a primary care practitioner in decision-making

regarding specific clinical conditions. These guidelines are developed with full practitioner involvement and are based on sound scientific evidence.

### **Standards**

A basis for judging quality, or a level of excellence aimed at, required or achieved. An acknowledged measure of comparison for quantitative or qualitative value; a criterion.

### **Sustainability**

The ability to continue a desired level of functioning into the future within accessible resources.

### **Technical working group (TWG)**

An interdisciplinary collaboration of experts who represent the interests and views of stakeholders and who provide information, knowledge and expertise on a certain subject.

### **Universal coverage (access)**

Access to key health promotion, prevention, curative and rehabilitative health interventions for all, at an affordable cost, thereby achieving equity in access. Incorporates two dimensions: (1) depth, i.e. health care coverage as in adequate health care; and (2) width, i.e. population coverage.

### **Vertical programmes (or specific disease-control programmes)**

Programmes designed for specific diseases, such as HIV/AIDS, malaria and tuberculosis, where the focus tends to be on controlling the disease rather than integrating with other services or strengthening the broader health system.

## ADDITIONAL READING

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# ANNEX 1: An example of examinations at different levels of laboratory service

## ANNEX C

SUMMARY OF WORKGROUP RECOMMENDATIONS FOR TESTS PERFORMED AT EACH LEVEL OF A LABORATORY NETWORK							
Laboratory tests for diagnosis and monitoring (1)	Primary Care Level (2)		District Level (3)		Regional/Provincial Level (4)		National/Multicountry Level (5)
	Send out (6)	On-site	Send out (6)	On-site	Send out (6)	On-site	On-site
HIV antibody testing							
Lab ELISA	X			X		X	X
Rapid point of care 1		X		X		X	X
Rapid point of care 2		X		X		X	X
Rapid point of care 3		X		X		X	X
HIV virological diagnostic testing							
RNA	X		X			X	X
DNA	X		X			X	X
Ultrasensitive p24 antigen	X		X		X		X
HIV viral load measurement	X		X			X	X
Hematology assays							
Hemoglobinometer such as HemoCue		X		X		X	X
WHO color scale		X					
Full blood count and differential	X			X		X	X
CD4							
Absolute count	X			X		X	X
% desirable if available	X			X		X	X
HIV resistance testing (7)			X		X		X (8)
Pregnancy testing							
Urine rapid test		X		X		X	X
Chemistry assays							
Liver function tests		X (if power)		X		X	X
Whole blood glucose (glucometer)		X		X		X	X
Serum glucose				X		X	X
Serum electrolytes	X			X		X	X
Renal function tests		X (if power)		X		X	X
Lipids				X		X	X
Amylase				X		X	X
Lactase				X		X	X

(1) These are generic recommendations and it is recognized that exceptions apply (e.g., some health centers will send out certain tests.) When appropriate, these tests may be used for public health surveillance and QA activities.

(2) Primary health care facilities are those providing first point of contact with the health care system.

(3) District level is defined as hospital at the first referral level that is responsible for a defined geographical area containing a defined population and governed by a politico-administrative organization such as a district health management team.

(4) In some smaller countries, there may not be regional laboratories.

(5) Including the national reference laboratory or public health laboratory, which is usually responsible for QA and surveillance activities.

(6) "Send out" refers to not having the testing capability on site, so samples and/or patients are sent to another site for the tests to be performed.

(7) HIV DR testing is only recommended as part of national efforts for surveillance and monitoring as outlined in the WHO HIV DR laboratory strategy. This testing is usually done by sending out samples to an accredited lab.

(8) May be done at the national level or sent to an accredited lab.

\*Adopted from the WHO publication: Summary of WHO Recommendation on Laboratory Investigations for Clinical Care by Level of Health Care Facility.

Note: test list above is not meant to be all inclusive of the testing performed at each level.

ANNEX C

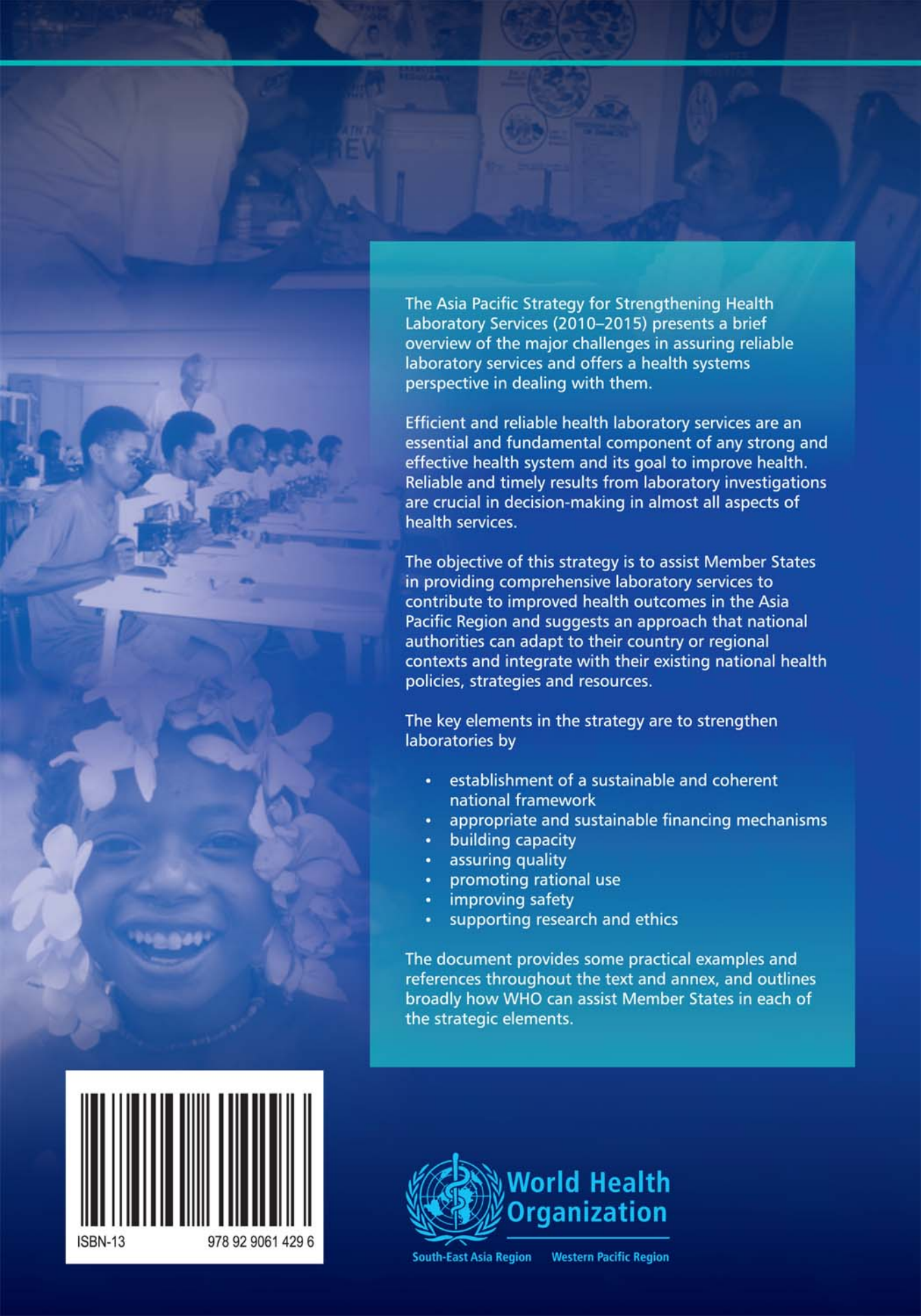
SUMMARY OF WORKGROUP RECOMMENDATIONS FOR TESTS PERFORMED AT EACH LEVEL OF A LABORATORY NETWORK*							
Laboratory tests for diagnosis and monitoring (1)	Primary Care Level (2)		District Level (3)		Regional/Provincial Level (4)		National/Multicountry Level (5)
	Send out (6)	On-site	Send out (6)	On-site	Send out (6)	On-site	On-site
Urine Analysis							
Urine dipstick		X		X		X	X
Urine dipstick with microscopy				X		X	X
Tuberculosis tests							
Microscopy							
Light		X		X		X	X
Fluorescence		X (if high vol)		X		X	X
Culture and ID							
Solid medium	X		X			X	X
Liquid medium	X		X			X	X
Drug susceptibility test							
First-line			X			X	X
Second-line			X		X		X
Malaria tests							
Rapid test for malaria		X		X		X	X
Microscopy for malaria (thick/thin)		X		X		X	X
Microbiology tests							
Gram's stain				X		X	X
Microbiology culture and ID			X			X	X
Blood culture			X			X	X
Microbiology susceptibilities			X			X	X
Wet mounts/preps		X		X		X	
Syphilis tests							
Syphilis rapid diagnostic test		X		X		X	X
Syphilis serological (RPR, FTA, TPPA/TPHA)				X		X	X
Hepatitis tests							
Hepatitis B by EIA				X		X	X
Hepatitis C by EIA				X (if high prev)		X	X
Cerebrospinal fluid (CSF) tests							
CSF microscopy including cell count, India link, Gram's stain and AFB				X		X	X
CSF glucose			X			X	X
Cryptococcal antigen (serum or CSF)						X	X

- (1) These are generic recommendations and it is recognized that exceptions apply (e.g., some health centers will send out certain tests.) When appropriate, these tests may be used for public health surveillance and QA activities.
- (2) Primary health care facilities are those providing first point of contact with the health care system.
- (3) District level is defined as hospital at the first referral level that is responsible for a defined geographical area containing a defined population and governed by a politico-administrative organization such as a district health management team.
- (4) In some smaller countries, there may not be regional laboratories.
- (5) Including the national reference laboratory or public health laboratory, which is usually responsible for QA and surveillance activities.
- (6) "Send out" refers to not having the testing capability on site, so samples and/or patients are sent to another site for the tests to be performed.
- (7) HIV DR testing is only recommended as part of national efforts for surveillance and monitoring as outlined in the WHO HIV DR laboratory strategy. This testing is usually done by sending out samples to an accredited lab.
- (8) May be done at the national level or sent to an accredited lab.

\*Adopted from the WHO publication: Summary of WHO Recommendation on Laboratory Investigations for Clinical Care by Level of Health Care Facility.

Note: test list above is not meant to be all inclusive of the testing performed at each level.





The Asia Pacific Strategy for Strengthening Health Laboratory Services (2010–2015) presents a brief overview of the major challenges in assuring reliable laboratory services and offers a health systems perspective in dealing with them.

Efficient and reliable health laboratory services are an essential and fundamental component of any strong and effective health system and its goal to improve health. Reliable and timely results from laboratory investigations are crucial in decision-making in almost all aspects of health services.

The objective of this strategy is to assist Member States in providing comprehensive laboratory services to contribute to improved health outcomes in the Asia Pacific Region and suggests an approach that national authorities can adapt to their country or regional contexts and integrate with their existing national health policies, strategies and resources.

The key elements in the strategy are to strengthen laboratories by

- establishment of a sustainable and coherent national framework
- appropriate and sustainable financing mechanisms
- building capacity
- assuring quality
- promoting rational use
- improving safety
- supporting research and ethics

The document provides some practical examples and references throughout the text and annex, and outlines broadly how WHO can assist Member States in each of the strategic elements.



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