Development of National Health Laboratory Policy and Plan

World Health Organization
South-East Asia Region Western Pacific Region

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WHO Library Cataloguing-in-Publication data

Development of national health laboratory policy and plan.

1. Laboratory Techniques and Procedures – manpower – standards.
2. Clinical Laboratory Information Systems. 3. Equipment and Supplies.
4. Guidelines. I. World Health Organization, Regional Office for South-East Asia. II. World Health Organization, Regional Office for the Western Pacific.

ISBN 978-92-9022-396-2 (NLM classification: QY 25)

Printed in India

Contents

Acknowledgements

We gratefully acknowledge the contributions of Dr Jane Carter, Technical Director, Clinical and Diagnostics, African Medical and Research Foundation, Nairobi, Kenya for preparing the first draft of this document.

The contributions made by several experts (Annex 2) in finalization of this document are also acknowledged.

Preface

Laboratory services are an essential and fundamental part of all health systems. Their purpose is to improve the health status of the population by providing the evidence base for detection, management and prevention of diseases. The Asia Pacific Strategy for Strengthening Health Laboratory Services (2010–2015) was developed to guide and encourage all Member States in the South-East Asia and Western Pacific Regions of the World Health Organization (WHO) to develop appropriate, scientifically sound, evidence-based, practical and sustainable national strategies for strengthening health laboratory services within their national health systems. Since it is acknowledged that "one size does not fit all", each country's strategy for developing and strengthening laboratory services should be planned according to that country's unique health system, ensuring integration with other health system components and existing national health policies, strategies and resources.

Recognizing that strong health systems are the foundation for health programmes to improve performance, and that laboratory services are a critical component of health systems, the Sixtieth session of the WHO Regional Committee of the Western Pacific (2009) endorsed strengthening of health laboratory services and through resolution WPR/RC60.R6, urged Member States:

- to guide the development of coherent national frameworks for health laboratory services;
- to provide adequate human, material and financial resources to strengthen local and national capacities for the implementation of national plans or equivalents;
- to establish country-specific minimum standards for health laboratories at different levels.

The key challenge for countries is to ensure that the recommendations are implemented and monitored so that individuals and communities will benefit from improved laboratory services at all levels of care. This requires ownership by all relevant stakeholders and a firm commitment by ministries of health, and may require the establishment of appropriate regulatory and legal support structures.

Establishing a national laboratory policy and national laboratory strategic plan provides the framework for the coordinated development and delivery of quality and accessible national laboratory services. The policy and plan should systematically outline the major issues that need to be addressed, including organizational and management structure, human resources, laboratory infrastructure, care and maintenance of equipment, provision of laboratory supplies, a functional information management system, a quality management system and adequate financial support.

WHO has prepared this guidance document to provide technical support to Member States in the South-East Asia and Western Pacific Regions on the steps required to develop and effectively implement a national laboratory policy and national laboratory strategic plan. The document provides a structure for developing a comprehensive policy and regulatory framework for establishing, operating and monitoring the health laboratory services, and promoting better coordination of activities among health programmes and institutions.

This document has been developed through the collaborative efforts of many stakeholders in the laboratory services, and relied heavily on their inputs and contributions in terms of material and technical support.

Introduction

Reliable and timely results from laboratory investigations are critical elements for decision-making in almost all aspects of health care, and are essential for the surveillance and control of diseases of public health importance. Improved disease recognition also improves the accuracy of health information and promotes effective national health planning. However, laboratory services are often fragmented and accorded low priority, compounded by inadequate allocation of resources. There is often no national laboratory policy or strategic plan to deliver comprehensive and integrated quality laboratory services to those who need them.

The health laboratory services include all those laboratories that provide support to preventive, promotive, rehabilitative and curative health services. The effective implementation of the Asia Pacific Strategy for Strengthening Health Laboratory Services requires a systematic approach to establishing a coherent national framework for laboratory services. This includes developing a national laboratory policy and strategic plan; defining managerial, oversight and regulatory mechanisms; and establishing the required support services within the context of each country.

This guidance document outlines the steps for developing a national health laboratory policy and a guide to developing a national health laboratory plan. Countries that already have a national health laboratory policy and plan could use this guidance document to review and revise their existing national health laboratory policy and plan. The national health laboratory policy and national health laboratory plan must be consistent with the national health policy and national health plan of the country, receive full endorsement from the Ministry of Health, and be approved through the appropriate government channels. The

existence of a national health laboratory policy and national health laboratory plan are an indication of the commitment of a government to provide quality health services to its people by ensuring that systems are established for the management and operation of laboratory services, and adequate and sustainable financing is available.

This document is divided into two main sections: national health laboratory policy and plan; and essential elements of the national health laboratory policy and national health laboratory plan. The first section outlines the role and responsibilities of the laboratory services within the national health system, and the principles, processes and steps involved in developing a national health laboratory policy and national health laboratory plan. This section also provides an approach to monitoring and evaluating the implementation and impact of the national health laboratory policy and national health laboratory plan.

The second section describes in detail the essential individual elements of the national health laboratory policy and national health laboratory plan, and the issues that should be addressed and included within each element.

1 National policy and plan for health laboratories

1.1 Role of laboratory services in the health system

Laboratory services are an essential component of a comprehensive health-care system. They provide the required diagnostic support to curative and preventive health services, health promotion activities and research. These are essential to guide appropriate treatment and rational use of essential drugs, and for surveillance and control of diseases of public health concern. Laboratory services may be utilized effectively at every level of health care including the primary level, where many common diseases and diseases with outbreak potential may be diagnosed using basic laboratory tests.

Laboratory services need to be considered as an integrated programme, and not fragmented with only parts of the system strengthened to support specific disease control initiatives. A vertical approach may lead to disorganization of the laboratory and neglect of other components of the laboratory services.

Laboratory services should be recognized as a vital and integral part of a quality health service at all levels of the health system. This requires all stakeholders to undertake operational planning and allocate adequate and sustainable resources.

1.2 Developing policy guidelines and setting priorities

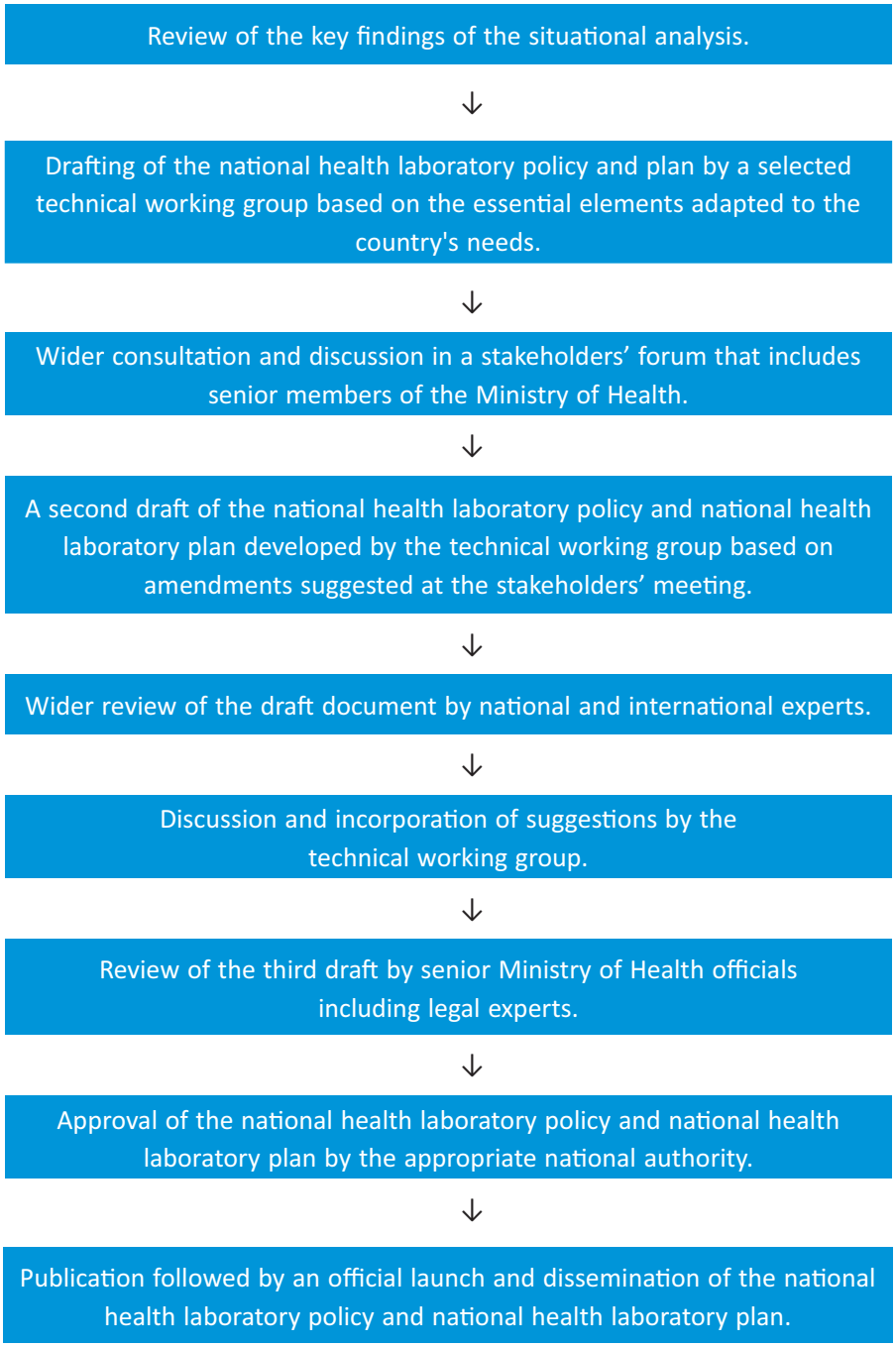
The approach to establishing an effective national health laboratory service requires addressing essential services at each level, including clinical and public health needs, required resources, staffing, equipment and supplies. The following steps are required:

- A detailed countrywide **situational analysis** to determine the current status of the health laboratory services and requirements based on clinical and public health activities;
- Establishment of a **national health laboratory policy** outlining the structure and function of the laboratory services, including the structure of laboratory management and support systems;
- Development of a long-term (5–10 years) **national health laboratory plan** outlining priorities, timelines and indicative budgets;
- Development of **annual operational plans** detailing clear timelines, costs and responsibilities of implementing partners, including the contribution of the private sector.

The responsibility and leadership for conducting the countrywide situational analysis, developing the national health laboratory policy, the national health laboratory plan, and annual operational plans lie with the **national laboratory focal point**. The national laboratory focal point works through a consensus-building process involving a wide range of stakeholders, including government and nongovernmental decision-makers, service providers, health development partners, professional users, patients, training institutions and financers. A diverse group of technical experts, including laboratory scientists, clinicians, pathologists, public health experts, health economists and biomedical engineers, should be involved in the process.

The situational analysis should be conducted using a structured checklist that includes all the elements to be addressed in the national health laboratory policy and national health laboratory plan. These essential elements are outlined in Section 2 of this document. Based on the findings of the situational analysis, the national health laboratory policy and national health laboratory plan are drafted through a consensus-building process.

This process may include the following steps:


Review of the key findings of the situational analysis.
Drafting of the national health laboratory policy and plan by a selected technical working group based on the essential elements adapted to the country's needs.
Wider consultation and discussion in a stakeholders' forum that includes senior members of the Ministry of Health.
A second draft of the national health laboratory policy and national health laboratory plan developed by the technical working group based on amendments suggested at the stakeholders' meeting.
Wider review of the draft document by national and international experts.
Discussion and incorporation of suggestions by the technical working group.
Review of the third draft by senior Ministry of Health officials including legal experts.
Approval of the national health laboratory policy and national health laboratory plan by the appropriate national authority.
Publication followed by an official launch and dissemination of the national health laboratory policy and national health laboratory plan.

Developing a national health laboratory policy

A **national health laboratory policy** is a document that provides the overall direction for establishing and strengthening the national laboratory services. It should include the following:

- **A vision statement**, for example: affordable, accessible, sustainable, equitable, quality health laboratory services for the people of a country;
- **A mission statement**, for example: provide accessible and equitable quality health laboratory services that contribute to improved health outcomes for the people of the country;
- **Objectives** of the national health laboratory policy:
  (1) To affirm government commitment and support for the organization and management of efficient, cost-effective and sustainable health laboratory services;
  (2) To strengthen laboratory services for supporting diagnosis, treatment, surveillance, prevention and control of diseases;
  (3) To establish national standards for laboratory quality systems;
  (4) To ensure the quality of the health laboratory through an established quality system;
  (5) To empower the establishment, implementation and monitoring of the national health laboratory plan;
  (6) To ensure adequate financial and human resources to meet the requirements of the health laboratory services;
  (7) To commit to ethical values in laboratory practice, including patient confidentiality, adherence to professional codes of conduct and ethical research practices;
  (8) To encourage research and collaboration to inform and improve the quality of health laboratory services.

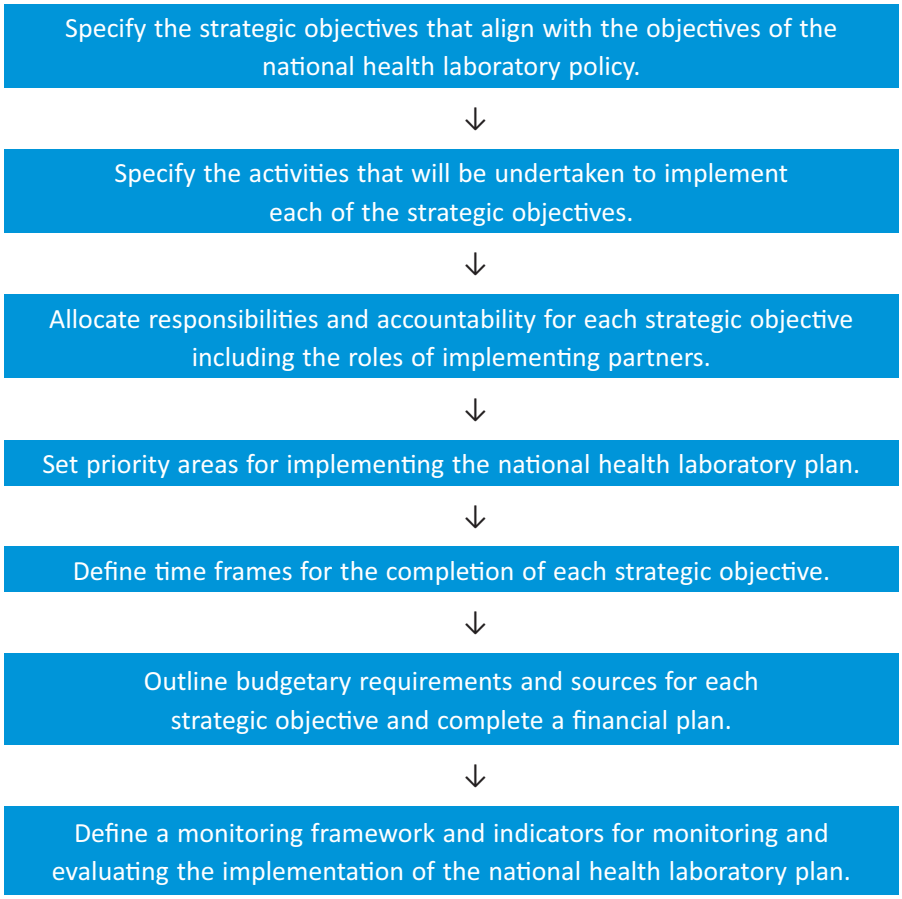
Developing a national health laboratory plan

The national health laboratory policy provides the framework for developing the national health laboratory plan, and addresses the key elements mentioned in Section 2. The national health laboratory plan provides the framework for

developing the strategies and activities required to achieve the components defined in the national health laboratory policy. Each key component of the national health laboratory policy becomes a strategic objective and a number of planned activities are developed for its implementation.

The national health laboratory plan should be carefully designed, realistic and practical, and include a time frame for implementation with the necessary indicators, budgetary allocations and designated partners. A step-wise approach to development is more likely to be sustainable and capable of contributing to the achievement of health system goals.

The process of developing a national health laboratory plan should include the following steps:



Once the national health laboratory plan is developed, annual operational plans need to be drawn up, detailing activities, time frames, implementing partners, budgetary allocations and annual funding sources, taking into consideration the contribution of the private sector.

A template for developing a national health laboratory plan and a financial plan are given in **Annex 1**.

1.3 Monitoring and evaluation

Implementation of the national health laboratory plan and annual operational plans requires regular, careful monitoring to ensure that agreed activities are properly implemented and financial expenditures are accounted for. The following should be considered:

(1) Establish mechanisms for monitoring the implementation of activities, including identifying responsible persons, establishing regular reporting mechanisms, and holding regular review meetings with stakeholders to assess progress.

(2) Review progress through the measurement of indicators, as follows:

  (a) Activity indicators: measurement of activities conducted

  (b) Outcome indicators: measurement of outcomes and performances.

(3) Prepare timely reports addressing the review of indicators as well as challenges and constraints.

(4) Adjust activities, objectives and timelines according to the results of the review.

(5) Conduct periodic audits, both internal and external, to evaluate performance and activities, based on the essential elements.

2 Essential elements of the national health laboratory policy and national health laboratory plan

The essential elements of the national health laboratory policy and national health laboratory plan should include the following:

(1) Laboratory organizational and management structure

(2) National standards for infrastructure, tests, techniques and equipment

(3) Human resource management

(4) Quality management systems

(5) Procurement and supplies management

(6) Laboratory equipment management

(7) Laboratory information management system

(8) Safety and waste management

(9) Laboratory financing.

2.1 Laboratory organizational and management structure

A coherent national framework for health laboratory services includes a well-organized and managed structure, the important components of which are as follows:

(a) National laboratory focal point and national laboratory coordinating committee

(b) National regulatory mechanism

(c) Laboratory structure and network.

(a) National laboratory focal point and national laboratory coordinating committee

A national laboratory focal point or department and national laboratory coordinating committee should be established. The terms of reference for the national laboratory focal point, and the composition and terms of reference for the national laboratory coordinating committee should include responsibility and accountability for steering and monitoring the health laboratory services.

The national laboratory coordinating committee should comprise key individuals in the Ministry of Health and other relevant government departments, the national laboratory focal point, national regulatory authorities and other key stakeholders, including representatives of donors and partner agencies such as WHO, professional bodies, clinical and public health physicians, disease programme managers, representatives of relevant professional societies, research and training institutions, legal advisers, health administrators and representatives from the laboratory network, including nongovernmental and private laboratories.

The principal functions are as follows:

National laboratory focal point or department

(1) To develop the national health laboratory policy and national health laboratory plan, including costing, and identification and allocation of financial resources for implementation of the plan;

(2) To take overall responsibility for the coordination and guidance of the laboratory services in accordance with the plan;

(3) To coordinate the establishment of national standards for health laboratory quality systems;

(4) To ensure that the quality of laboratory services is maintained.

National laboratory coordinating committee

(1) To advise the Ministry of Health on national health policies, and relevant medical and technical developments in relation to the laboratory services;

(2) To coordinate various initiatives or proposals in which the health laboratory services can contribute to the overall health systems strategy;

(3) To contribute to the development of legislation and regulations, as required;

(4) To regularly review and, where necessary, propose revision of the national health laboratory plan with respect to communicable diseases including emerging infections, and noncommunicable disease control;

(5) To evaluate new laboratory initiatives and technologies;

(6) To provide a forum for discussion on national issues relating to the laboratory services;

(7) To provide technical inputs through expert groups on various issues concerning the health laboratory services.

(b) National regulatory mechanism

Regulation is the legal means of governing or controlling health service provision, including laboratories, laboratory staff, equipment, test kits and reagents, and reporting of essential information to meet the required standards. Regulation is a tool for ensuring competent performance as well as confidence in the laboratory services. It is important for the country to identify or establish a regulatory authority and mechanism, and to formulate appropriate laws or regulations to govern its health laboratory services, addressing both the public and private sectors. Regulations incorporate a code of ethics that defines appropriate and proper conduct.. They are also responsible for licensing providers, setting national standards, monitoring performance and compliance with those standards, and intervening, including taking disciplinary action for non-compliance.

Key components

The responsibility of a national regulatory mechanism may include:

(1) Drawing up appropriate legislation governing health laboratory practices;

(2) Establishing mechanisms to strengthen training of staff to carry out the functions of the national regulatory authority;

(3) Licensing of laboratory service providers;

(4) Monitoring compliance with standards for human resources and competence;

(5) Setting requirements for pre-service training and continuing professional development for health laboratory personnel.

(c) Laboratory structure and network

A well-defined laboratory structure must be established, which identifies key management and technical roles and responsibilities at each level, and establishes a functional laboratory network and referral system. The laboratory network should include a disease monitoring and response system.

Key components

These may include:

(1) Identification of the roles and responsibilities, including both management and technical responsibilities, at each level of the laboratory;

(2) Establishment of systems for coordination and communication, such as referral of specimens to reference laboratories and within the network. The necessary guidelines and resources for specimen referral and return of results should be provided;

(3) Identification of and support to national reference laboratories for specific diseases, and surveillance and response mechanisms;

(4) Establishment of mechanisms for procurement and distribution of laboratory equipment and supplies to all laboratories in the health-care system.

2.2 National standards for infrastructure, tests, techniques and equipment

National standards for competence, essential infrastructure, equipment, tests and techniques should be established for laboratories at each level of the network.

Key components

These may include:

(1) Establishment of a physical laboratory infrastructure of appropriate size, location, and with essential utilities, to provide a safe environment for workers, patients and visitors;

(2) Establishment of essential tests and techniques required at each health facility level;

(3) Establishment of the required competency of staff for each level of laboratory throughout the network;

(4) Selection of standardized equipment appropriate for the tests performed at different levels of laboratories, with clear technical specifications;

(5) Availability of standard operating procedures (SOPs) in every laboratory for transportation of specimens, use of equipment, test procedures, reporting formats and guides to interpretation, including normal reference ranges for quantitative results;

(6) Provision of up-to-date inventories to all laboratory users of the available tests, their indications and limitations, costs and types of specimens required;.

(7) Continual review of the cost-effectiveness and appropriateness of recommended standards.

2.3 Human resource management

Adequate numbers of qualified personnel are needed to implement the national laboratory plan. The number and types of health workers required from the peripheral to the reference and/or national laboratory levels need to be defined. A comprehensive national human resources plan may involve coordination with other government departments, such as the Ministry of Education, and should therefore be developed to meet the projected requirements for the health laboratory services, in conformity with the overall health workforce plan.

Key components

These may include:

(1) Laboratory services to be provided only by staff with recognized qualifications or relevant training;

(2) Development of job descriptions for all laboratory personnel working at different levels of the health system;

(3) Establishment of a scheme of service for laboratory workers with clear structures and opportunities for career advancement;

(4) A system of incentives to encourage staff to work in remote and underserved areas;

(5) Periodic competency assessments of staff to verify individual demonstration of necessary skills, knowledge and correct work practices;

(6) Establishment of a staff record for each laboratory worker, including personal and employment details, resumé (CV), posts held and dates, authorized areas of testing, terms and conditions of employment, job description, continuing professional development, competency assessments, disciplinary actions and work injury records;

(7) Performance of annual appraisals by the immediate supervisor, using a standard appraisal tool to provide feedback to individual staff on work performance and guide career development;

(8) Organization of appropriate in-service training programmes for all categories of staff. In-service training programmes may be linked to the annual registration process, to specific disease initiatives or/and address overall staff competency in areas including quality processes, safety, procurement and supply management, and reporting of results. Training programmes may include distance learning and intra- and intercountry exchanges;

(9) Development of effective supervisory systems to monitor work performance and quality using a structured checklist. Supervision should be of sufficient duration and frequency and include on-site evaluation, teaching, mentoring, monitoring, quality assurance and supportive feedback. Training and evaluation programmes for supervisors should also be established;

(10) Involvement in national and/or regional professional associations to promote professional development and ethical practices.

2.4 Quality management systems

Quality laboratory services are achieved by establishing and maintaining a quality management system for all aspects of the laboratory services. Monitoring quality and its continuous improvement is an essential component of a well-managed laboratory service.

Key components

These may include:

(1) Developing a national laboratory quality statement. The laboratory quality statement should reflect the intention and commitment of the national authorities to ensure that quality laboratory services are provided at all levels of health facilities;

(2) Provision of adequate and sustainable financial resources for establishing and maintaining quality laboratory systems;

(3) Creation of a network of quality managers among various institutional laboratories under the office of the national laboratory focal point to coordinate all activities relating to the quality system;

(4) Development, implementation and monitoring of quality standards in all laboratories;

(5) Training of all laboratory staff on all aspects of the quality system;

(6) Development, maintenance and updating of SOPs;

(7) Ensuring that internal quality control (IQC) is practised in all laboratory procedures;

(8) Organization of appropriate external quality assessment schemes (EQAS) for each level of laboratory, and ensuring mandatory participation;

(9) Assessment of laboratory performance through audits (internal or external);

(10) Development of relevant quality indicators to consistently monitor and evaluate laboratory performance;

(11) Development of a national system of step-wise accreditation and support laboratories to achieve accreditation (national or international);

(12) Ensuring effective communication between laboratory staff, professional laboratory users, health administrators, technical support services, health development partners, government and nongovernmental decision-makers, patients, training institutions and donors.

2.5 Procurement and supplies management

The selection and standardization of laboratory supplies and reagents must be based on the types of tests performed and equipment used at every level of laboratory across the health system. Standardization promotes efficiency in inventory control, storage and distribution, quantification and procurement procedures; and increases economies of scale and reduces procurement costs. The national laboratory procurement and supplies management system should be in line with the national medical supply and distribution system.

Key components

These may include:

(1) Establishment of an effective national laboratory procurement and supplies management system, with appropriate storage facilities and timely distribution systems;

(2) Evaluation and validation of laboratory consumables and reagents to be conducted by qualified, competent laboratories using standard guidelines or reference to reliable evaluations and validations such as peer-reviewed publications, WHO, etc. Consumables and reagents should be subject to regular checks. Those that do not meet required standards will not be procured;

(3) Identification of a national centre for independent quality assurance and pre-qualification of consumables and reagents;

(4) Development of clear guidelines for accepting and receiving donated supplies to ensure that they meet the required specifications and are appropriate for the laboratory;

(5) Establishment of a standardized system for inventory and stock control in every laboratory;

(6) Development of appropriate systems for receipt, quality checking and storage of consumables and supplies by the laboratory;

(7) Training of laboratory managers in procurement and supply management and logistics, including planning, quantification, costing, budgeting, storage, stock-keeping, inventory control and rational use of supplies;

(8) Establishment of standard procedures to identify laboratory chemicals and supplies for safe disposal.

2.6 Laboratory equipment management

A national equipment management policy must be in place. Major items of laboratory equipment are expensive to purchase, operate and maintain, and constitute the largest capital expenditure of the laboratory. The national laboratory equipment management system should be in line with the national medical equipment management system.

Key components

These may include:

(1) Evaluation and validation of new/donated equipment by authorized testing centres, using standard guidelines;

(2) Establishment of a national database of equipment including information on instrument type, operational status and service contract providers;

(3) Establishment of standard procedures for equipment purchase, using a structured checklist as required;

(4) Development of clear guidelines for accepting and receiving donated equipment to ensure that the equipment meets the required specifications, can be supported by local service agents, and is appropriate for the laboratory;

(5) Ensuring that all equipment is supplied with appropriate service and operation manuals in the language understood by the users, along with spare parts and service tools. Maintenance service contracts including after-sales service should be drawn up for all analytical equipment, whether purchased or donated;

(6) Ensuring that all major equipment is installed by suppliers, and training on equipment use, maintenance and trouble-shooting is provided to relevant personnel at the time of installation or when put into use;

(7) Development of SOPs for equipment use, care and maintenance, and disposal of obsolete or unserviceable equipment.

2.7 Laboratory information management system

The national laboratory information management system (LIMS) database is used to generate relevant information, and provide data for evaluating and planning quality health laboratory services. The national LIMS must be in line with the national health information management system (HIMS), and may be electronic or paper-based.

Key components

These may include:

(1) Establishment of standard record-keeping systems, and recording and reporting tools. Reporting formats should include patient demographics, type and source of specimen, tests performed, positive and negative results;

(2) Establishment of reporting procedures from across the laboratory network from the peripheral to the central laboratories on a weekly, monthly or quarterly basis;

(3) Analysis of data at district, provincial/regional and central levels to guide support to clinical services, including planning of procurement and supplies, and human resource distribution;

(4) Provision of appropriate data to relevant disease control programmes and national centres as part of national programmes for surveillance and disease control;

(5) Use of national data for health services planning and resource mobilization.

2.8 Safety and waste management

Laboratory managers need to ensure that appropriate safety measures are applied in all laboratory practices. Laboratory safety procedures should be developed in line with national health and safety guidelines, and in collaboration with health facility infection control teams.

Key components

These may include:

(1) Designation of a laboratory safety officer;

(2) Establishment of national safety policies and guidelines;

(3) Provision of adequate protection to laboratory personnel to prevent occupationally acquired diseases, and management in cases of exposure, including post-exposure prophylaxis (PEP);

(4) Establishment of appropriate cleaning, disinfection and sterilization procedures in all laboratories;

(5) Establishment of a biological waste management programme including cleaning, disinfection, sterilization, and disposal of sharps and contaminated material;

(6) Establishment of standard procedures for the safe disposal of chemicals and supplies;

(7) Disposal of laboratory waste in accordance with national environmental protection regulations.

2.9 Laboratory financing

The financing of health laboratory services must be part of the overall health financing plan and all national, subnational and institutional budgeting processes. Laboratory services may be funded through several mechanisms, including government budgetary provision, donations and grants from development partners, health insurance and income-generating activities, and user fees.

Key components

These may include:

(1) Provision of adequate financial resources to sustain all costs associated with quality and reliable laboratory services;

(2) Development of budgets for the national laboratory services taking into consideration all sources of funding, including the government, global health initiatives, and multilateral and bilateral donors, in consultation with the national laboratory focal point;

(3) Development of national health budgets keeping in mind laboratory needs;

(4) Training of laboratory managers in developing annual operational plans;

(5) Continuous monitoring and regular updates of financial expenditure, and making these available to laboratory managers;

(6) Establishment of an efficient, effective, user-friendly and transparent system of financial record-keeping and reporting, in which lines of accountability are established.

Annex 1
Examples

1.a Template for developing a national health laboratory plan

Strategic objective *Planned activities*		Time frame (year)					Responsible partners	Outcomes and planned results
		2011	2012	2013	2014	2015		
	Strengthen provision of standardized quality laboratory services	**X**	**X**	**X**	**X**	**X**		
1	*Establish the national laboratory focal point and national QA committee*	*X*					*MOH*	
2	*Develop/ adapt national laboratory standards*	*X*					*MOH*	
3	Conduct stakeholders' meetings to review documents	*X*	*x*				Partners	National standards documents
4	Disseminate documents	X	X	X			MOH	Documents available in all laboratories
5	*Develop and implement national QA schemes in all laboratories*	*X*	*X*	*X*	*X*	*X*	*MOH, Public Health Laboratory*	
6	Identify and support national / Regional reference laboratories to produce EQA materials	X	X	X	X	X		Capacity established
7	Participate in EQAS	X	X	X	X	X		Conduct national EQA

1.b Template for developing a financial plan

Section 1 (costs in US $ 1000)						
Planned activities	Time frame (year)					Comments
	2011	2012	2013	2014	2015	
1						
2						
3	0.3					
4	10.0	2.0	2.0			Use existing distribution systems, where possible
5	20.0	20.0	20.0	20.0	20.0	Use existing grant for EQA
6	1.0	1.0	1.0	1.0	1.0	
7	10.0	10.0	10.0	10.0	10.0	
Sub-total						

Examples are provided for guidance

Annex 2

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This document provides technical support to Member States in the South-East Asia and Western Pacific Regions on the steps required to develop and effectively implement a national laboratory policy and national laboratory plan in accordance with the Asia Pacific Strategy for Strengthening Health Laboratory Services (2010-2015). The document provides a structure for developing a comprehensive policy and regulatory framework for establishing, operating and monitoring the health laboratory services, and promoting better coordination of activities among health programmes and institutions for efficient support to both clinical and public health services.

ISBN 978 92 9022 396 2