



Progress report on the implementation of the framework for strengthening health laboratory services, 2016–2023

Introduction

1. Laboratories continue to play a critical role in all disease control and prevention programmes by providing timely and accurate information for use in patient management and disease surveillance. Laboratory diagnostic capacity is crucial to reaching the health-related targets of the Sustainable Development Goals by 2030. In addition to the health and well-being of individuals, critical public health decisions concerning health security, national development and meeting international obligations, such as those established in the International Health Regulations (2005), all depend upon laboratory results. However, laboratory systems and services are often neglected in resource-poor settings.

2. To sustainably strengthen national laboratory systems in resource-poor countries, it is necessary to develop national laboratory strategic plans and policies, establish public–private partnerships and ensure effective leadership, commitment and coordination by host governments. Laboratory strategic planning is a means for resource-poor countries to define direction, set standards and make decisions on allocating capital and people to achieve sustainable standards for quality laboratory services. These plans should consider policy, legal and regulatory frameworks, the administrative and technical management structure of the laboratories, human resources and retention strategies, laboratory quality management systems, monitoring and evaluation systems, procurement and maintenance of equipment, and laboratory infrastructure enhancement.

The strategic framework for strengthening health laboratory services 2016–2023

3. At its 63rd session in October 2016, the WHO Regional Committee for the Eastern Mediterranean endorsed the strategic framework for strengthening health laboratory services 2016–2020 in resolution EM/RC63/R.4. At its 67th session in 2020, the Regional Committee extended the timeframe for implementation of the framework by three years, from 2016–2020 to 2016–2023. The overall goal of the strategic framework is to guide the strengthening of sustainable national health laboratory systems to improve clinical and public health services in a cross-cutting manner for better preparedness for surveillance of, and response to, epidemic-prone diseases, health security issues and other potential emergencies of public health concern. The strategic framework guides priority-setting and serves as a tool for the coordination of national authorities, donors and development partners at the global and regional level and facilitates planning and resource mobilization by all stakeholders concerned.

4. The framework has six interrelated strategic goals. These are to: strengthen leadership and governance of the national laboratory systems; strengthen the organization and management of the national laboratory systems towards quality; establish sustainable, sufficient and competent human resources for laboratory service delivery; ensure safe and secure laboratory environments; promote effective, tiered and integrated laboratory referral networks (in-country and among countries) and enhance coordination; and promote rational and evidence-based use of laboratory services.

5. As the extended timeframe for implementing the framework ends in 2023, it is important to make an overall assessment of implementation of the framework, while focusing on strategic goals in relation to current issues.

6. In general, there has been limited progress in inducing countries to finalize their policies, and the need to build on progress made during COVID-19 remains.

7. WHO has developed a matrix for assessing progress in implementing the regional framework. It consists of a scorecard focused on the five key goals of the framework. Specific indicators were not developed for the sixth goal, to promote rational and evidence-based use of laboratory services, as it depends on the implementation of the five goals assessed. Ministry of health laboratory directors, through their respective WHO country offices, were asked to complete the scorecard and return it by email. A total of 21 countries/territories responded to the request to complete the scorecard. The obtained data were analysed and validated at the fourth regional laboratory director's meeting in December 2022. A summary of the results is provided below.

Leadership and governance of national laboratory systems

8. Four countries/territories (19%) have fully implemented their laboratory policies, while 8 (38%) have partially implemented their policies. Five (24%) have fully implemented strategic plans, while 8 (38%) have finalized the development process for a strategic plan but have not yet implemented it. Five (24%) have a programme for relicensing all laboratories in the public and private sectors based on developed national standards, and seven (33%) reported having a dedicated national laboratory budget completely covering intersectoral functions with defined operational plans.

Human resources for laboratory service delivery

9. Six countries/territories (29%) have competency-based training curricula that are in line with national standards, while seven (33%) offer quality and safety management as topics in pre-service laboratory training curricula and seven (33%) have pre-service and in-service training programmes for laboratory management. Four (19%) license laboratory workers based on education, training and competency assessment. Four (19%) have a national staffing plan for the laboratory network based on workload forecasting and have all their available laboratory positions filled. Two (10%) have a fully implemented human resource development strategy addressing laboratory workers.

Quality of laboratory services

10. Eleven countries/territories (52%) have internal quality control (IQC) procedures standardized throughout the network for all tests. Five (24%) have an external quality assessment (EQA) programme for all priority diseases at all tiers with feedback of results and action for improvement, and 10 (48%) have reference laboratories participating in an international EQA programme. Seven (33%) have laboratory quality officer positions filled in all public sector laboratories, four (19%) have implemented quality management activities in all laboratories and four (19%) have implemented mandatory certification and accreditation standards for laboratories.

Effective, tiered and integrated laboratory referral networks and enhanced coordination

11. Seven countries/territories (33%) have a well-established laboratory coordination mechanism at their ministry of health including multiple ministries and the private sector, while 10 (48%) have laboratory networks for all functions with clearly defined tier-specific roles, but only three (14%) have all types of laboratories integrated in their laboratory networks.

Laboratory biosafety and biosecurity

12. Eight countries/territories (38%) have an up-to-date laboratory biosafety manual in all facilities, 12 (57%) have basic safety equipment available to all laboratory workers at all levels, six (29%) have designated safety officers in place in public and private sector laboratories, and seven (33%) have biosafety cabinets regularly serviced at all relevant tiers by a certified body. None have a regulated

system of biobanking at any level of their laboratory system. Eight (38%) have a waste management policy in place in conformance with level specific biosafety and biosecurity requirements, and nine (43%) have access to incinerators that comply with national standards in all laboratories.

Key challenges

13. There has been progress in strengthening laboratory capacity within the Region. However, substantial challenges remain. These challenges include a lack of national policy and strategic planning for laboratory services, insufficient funding, inadequately trained laboratory staff, weak laboratory infrastructure, old and inadequately serviced equipment, a lack of essential reagents and consumables, weak biorisk management, and limited quality assurance and quality control implementation.

14. These enormous challenges are compounded by the fact that the performance of laboratory services is not monitored at the national level and laboratories are not given due priority and recognition in national health systems.

Way forward

15. WHO will continue to support efforts towards attaining sustainable health laboratory services through the provision of technical support and partner coordination. There has been significant progress since the endorsement of the regional framework for strengthening health laboratory services in 2016 and the investments made in laboratories to respond to the COVID-19 pandemic.

16. The next framework should focus on the following areas.

- Strengthening laboratory leadership and governance, prioritizing the development and implementation of laboratory policies and costed strategic plans. WHO will work with countries/territories and partners to advocate for laboratory resources (financial and human) from domestic sources and partners.
- Implementing laboratory quality management systems using existing approaches such as strengthening laboratory management towards accreditation and coordinating regional accreditation schemes with Member States.
- Training human resources for the laboratory at pre-service level to ensure the availability of competent human resources for laboratories, including biomedical engineers.
- Strengthening biosafety and biosecurity in laboratories, including the development and implementation of waste management policy, and coordinated specimen biobanking.
- Creating an integrated public health laboratory system that services multiple diseases, including SARS-CoV-2, HIV, tuberculosis, hepatitis, malaria, sexually transmitted diseases and other infections to help improve universal health coverage delivery and pandemic preparedness. Strategies to overcome these include greater implementation of policies that support multidisease testing and treatment systems, diagnostic network optimization, bundled test procurement and a more rapid spread of innovation and best practices across disease programmes.

17. Delivering a diagnostic test result requires not only a test itself, but also a range of supportive health systems such as data, sample logistics, quality assurance, instrument maintenance, supply chain and training. This will require test operators and clinicians to be cross-trained on the use and interpretation of multiple assays, and for clinicians to be able to routinely order tests and provide an integrated package of follow-on care and treatment where needed.