



Strategic framework for strengthening health laboratory services 2016–2020

Executive summary

1. Health laboratory services provide vital support for disease prevention, diagnosis, treatment management, screening and surveillance. Laboratory test results have important implications for health outcomes in both clinical and public health settings. Safe, effective and cost-efficient laboratory operations are a cornerstone of any country's capacity to investigate biological events in order to apply evidence-based control of detected diseases and prevent the accidental or deliberate release of pathogens from laboratories.

Despite the ever-increasing demand for health laboratory services, they are still given low priority and recognition by the national authorities in many countries. As a result, such services suffer from inadequate financing, low attention to recruitment of human resources and training and poor infrastructure, as well as other complex problems.

2. Following a review and analysis of the findings of situation analysis by health laboratory stakeholders from Member States and representatives of international development partners at a regional meeting in December 2013, consensus was reached on the need to develop regional strategic guidance to support countries in their efforts to improve health laboratory services. In February 2015, the directors of the public health laboratories of the Eastern Mediterranean Region at their first intercountry meeting discussed and approved a draft strategic framework for strengthening health laboratory services.

3. The strategic framework for strengthening health laboratories is intended to guide countries in developing sustainable national health laboratory systems in order to improve clinical and public health services in a cross-cutting manner and ensure 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 is built around six interrelated strategic goals, each comprising a menu of activities and corresponding desired outcomes, from which Member States can draw based on their national priorities, resources, capacities, regulations, and specific contexts. A monitoring and evaluation framework is also outlined and includes country and regional indicators.

4. Implementation of the regional strategic framework for strengthening health laboratory services 2016-2020 is essential for improvement of quality and safety of health laboratory services and fulfilment of Member States' obligations under the International Health Regulations (2005). The Regional Committee is invited to endorse the strategic framework with a view to mobilizing high-level political commitment and support and ensuring allocation of adequate resources by Member States.

Introduction

5. Laboratories are an essential and fundamental part of all health systems and their goal to improve health. Reliable and timely results of laboratory investigations are crucial elements in decision-making in almost all aspects of health care. Laboratory testing results may greatly affect critical decisions concerning the health and well-being of individuals and populations, health security and cost of health care systems, as well as meeting international obligations such as the International Health Regulations (2005).

6. Within the Eastern Mediterranean Region, despite regular progress towards strengthening laboratory capacity to support certain disease-specific programmes, substantial challenges remain. National assessments, conducted with WHO support, identified a pressing need for development of national policies and strategic plans for laboratory services to address inadequate funding, increase

competence of laboratory staff, improve laboratory infrastructure, maintain or replace old, obsolete or inadequately serviced equipment, provide for uninterrupted supply of essential laboratory reagents and consumables, and ensure appropriate quality assurance and quality control of laboratory examinations. These challenges notwithstanding, demand for laboratory services continues to increase as a result of emerging and re-emerging infectious diseases, the increasing magnitude of noncommunicable diseases, aging populations and rapid introduction of technological innovations leading to new and expensive laboratory techniques. However, there is a stark disconnect between the rising importance of and increasing demand for health laboratory services and the low priority given to them in the national health agendas.

7. As a result of these developments, the national health authorities, WHO and a growing and diverse group of international partners have recognized the urgent need to provide Member States with strategic guidance that will mobilize high-level political commitment and leadership support, ensure allocation of adequate resources, and inform policy decisions for high-quality, safe and sustainable health laboratory services. Following a review and analysis of the findings of situation analysis by health laboratory stakeholders from Member States and representatives of international development partners at a regional meeting in December 2013, consensus was reached on the need to develop strategic guidance to support countries of the Region in their efforts to improve health laboratory services. In February 2015, the directors of the public health laboratories of the Region at their first intercountry meeting discussed and approved a draft. The strategic framework for strengthening health laboratory services 2016–2020 is intended to guide countries in developing sustainable national health laboratory systems in order to improve clinical and public health services in a cross-cutting manner and ensure better preparedness for, surveillance of, and response to, epidemic-prone diseases, health security issues and other potential emergencies of public health concern.

Situation in the Region

8. Within the Eastern Mediterranean Region, a situation analysis conducted by WHO in a number of countries during the period of 2013–2015, showed the following.

- Policy and planning for health laboratory services are weak or non-existent; only two out of 22 countries have national laboratory policies and/or national laboratory strategic plans officially endorsed by the national authorities.
- Laboratory diagnostic capacities are unevenly distributed, both on a population basis and among different sectors and units, which, in combination with high rates of out-of-pocket payments in many low- and middle-income countries, leads to inequitable access to health laboratory services.
- Evidence-based strategic health workforce planning is not in place; the laboratory workforce situation is characterized by high attrition rates and shortages of qualified personnel.
- Most countries do not have a national external quality assessment programme or other national mechanisms for monitoring and evaluation of laboratory performance.
- Many countries have deficient, if any, arrangements for maintenance, service and repair of laboratory equipment; regional mechanisms to support countries in the regard do not exist either.
- Laboratories in many countries still experience periodic shortages of reagents and supplies; in some countries, expired reagents are used occasionally or on a regular basis.
- Laboratory quality management systems are poorly documented in most countries; quality manuals and standard operating procedures, where they exist, are rarely reviewed and updated; laboratory records are not properly controlled.
- Laboratory information systems are usually poorly structured and rarely, if ever, integrated with hospital information systems; their capabilities to support data collection for surveillance or research purposes are extremely limited.
- Inadequate infrastructure and poor compliance of personnel with biosafety and biosecurity requirements are common and may lead to unacceptably high levels of biological risk, especially in countries with ongoing war, conflict, civil unrest or other kind of humanitarian emergency.

9. Most of the deficiencies and gaps identified are due to the following fundamental underlying factors: a) low priority and recognition given to the health laboratory services at the national level and associated inadequate resource planning and budgeting for health laboratory services; b) absence of, or weak, legislative and regulatory frameworks for health laboratory services; c) lack of robust mechanisms for the evidence-based policy and planning processes at the national level; and d) inadequate governance, coordination, organization and management of health laboratory services. These factors have resulted in inefficient and inappropriate use of scarce resources, duplication of effort in some services and neglect of others, poor sustainability of services, and suboptimal health outcomes.

Purpose and scope of the regional strategic framework

10. The overall goal of the framework is to guide countries in developing sustainable national health laboratory systems in order to improve clinical and public health services in a cross-cutting manner and ensure better preparedness for, surveillance of and response to epidemic-prone diseases, health security issues and other potential emergencies of public health concern. In support of this goal, the aims of the strategic framework are to:

- advocate for health authorities of Member States to mobilize political commitment, build ownership and support for health laboratory services;
- provide guidance for Member States in setting priorities, formulating, implementing and evaluating national policies and strategic plans for their health laboratory services;
- propose planning actions that will help national health authorities to address the gaps and challenges faced by their laboratory systems;
- provide regional and global partners and other relevant stakeholders with a guiding framework, with which to align their financial and technical assistance in support of strengthening health laboratory services;
- provide a blueprint for monitoring and evaluation of progress towards strengthening health laboratory systems on the regional and country level.

11. The strategic framework covers the period of 2016-2020 and is intended to support both national health authorities and national health laboratory focal points in their efforts to strengthen laboratory systems, as well as the wide-ranging and large number of national, regional and international organizations who are stakeholders in the process. The strategic framework is built around six interrelated strategic goals, full implementation of which will allow countries to achieve the vision of comprehensive, well-coordinated, integrated and sustainable health laboratory services capable of obtaining and reporting safe, accurate and reliable test results in a timely manner for use in clinical and public health settings.

12. The strategic goals are as follows:

- 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 environment;
- 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.

13. Each strategic goal is supported by associated strategic objectives and comprises a menu of activities and corresponding desired outcomes, from which Member States can draw based on their national priorities, resources, capacities, regulations and specific contexts. A monitoring and evaluation framework is also outlined and includes country and regional indicators (Annex 1).

Key country actions

14. The implementation of the strategic framework at the country level is a collective endeavour that will require concerted and coordinated actions by a wide range of national and international stakeholders under the leadership of the Ministry of Health. These actions should be adapted to and aligned with each country's specific context, political and socioeconomic environment, available resources and capacities, and overarching health and development strategies, laws and regulations.

15. The following actions will have a critical role for implementation and are common for most of the countries regardless of the country context.

- Conduct a thorough assessment of the current laboratory system and key individual laboratories.
- Use the results of the assessment to mobilize high-level political commitment and cross-sectoral support for the strengthening of health laboratory services.
- Establish an independent intersectoral oversight mechanism for health laboratory services to provide national health authorities with independent review of, and advice on, various aspects of laboratory services structure, operations and regulation, ensure effective collaboration and coordination across government departments and with various nongovernmental actors, including the private sector and civil society, and monitor implementation progress.
- Develop a national health laboratory policy and national laboratory strategic plan through an inclusive consultative process and consensus-building with relevant stakeholders and officially endorse/enact the policy and plan through appropriate country mechanisms and channels.
- Mobilize the necessary resources, including human, technical and financial resources;
- Establish a national mechanism for monitoring and evaluation of the performance of health laboratory services and the implementation of the national laboratory policies and strategic plans.

16. Engagement, ownership and commitment on the part of the national authorities are of critical importance for successful implementation. Key national stakeholders and potential partners include: ministries of education, finance, labour, environment, justice and defence; border and custom authorities; academic, training and research institutions; professional associations; relevant business entities, insurance companies and private sector; civil society, nongovernmental organizations and community representatives; donors and development partners. The extent and nature of participation of various stakeholders will greatly depend on the country context, traditions of cross-sectoral collaboration, institutional relations between the various constituencies concerned, and existing coordination mechanisms, if available.

Way forward

17. Ministries of health are in the best position to assume a steering, brokering and stewardship role in managing an inclusive and meaningful policy dialogue leading to development of coherent national laboratory policies and national laboratory strategic plans, without which laboratory strengthening efforts cannot be systematic and effective. Policy dialogue can be enriched by investing in country-level institutional and individual capacities, such as policy or planning units within the ministries. Policy dialogue can, and should, be broadened to go beyond the public sector and beyond the health sector, aligning national laboratory policies and national laboratory strategic plans with laboratory strategies and plans of other sectors such as agriculture, animal health, and environmental testing. Ministries of health will play a critical role in fostering the dialogue with a wide range of stakeholders and constituencies, both within the country and internationally.

18. The national policy and strategic planning process for health laboratory services should be built on a sound situation analysis and inclusive priority-setting. Good situation analysis should be broad enough to take into account the comprehensive range of current and projected trends in socioeconomic development, health and population dynamics and encompass a systematic analysis of demand for health

laboratory services under various scenarios, including infectious disease outbreaks and other public health and humanitarian emergencies.

19. One of the essential functions of the ministries of health is to ensure availability of adequate resources (in terms of funding, people, infrastructure, equipment, etc.) for implementation of national laboratory policies and strategic plans through a robust resource planning and programme budgeting process. The ministries should combine the available tools and technical expertise (both domestic and international) to translate national priorities into evidence-based and detailed resource plans and further into budgetary implications. This will greatly facilitate strategic financial negotiations and increase the chances of mobilizing the needed funds from either domestic or external sources.

20. Ministries of health can significantly improve the outcomes of health laboratory strengthening efforts through a focused investment in monitoring and evaluation of laboratory performance and the progress towards implementation of national laboratory policies and strategic plans. This will necessarily require an investment in the establishment of effective and integrated laboratory information systems. When properly designed and implemented, this will also improve contribution of health laboratories to surveillance programmes as well as allow for learning, continuous improvement of planning and implementation process, and timely corrective action.

Conclusions and recommendations

21. Laboratories are an essential and fundamental part of all health systems and their goal to improve health. Reliable and timely results of laboratory investigations are crucial elements in decision-making in most aspects of health services. The improvement of health laboratory services is therefore a development imperative and will be critical to the successful achievement of the Sustainable Development Goals, including the targets for universal health coverage and International Health Regulations (2005). This regional strategic framework is intended to guide and support Member States in their efforts to strengthen health laboratory services.

22. The framework promotes partnership and collective action across the Region towards a common goal of ensuring equitable access to safe, secure, quality assured and cost-effective laboratory services for better preparedness for, surveillance of, and response to epidemic-prone diseases, health security issues and other potential emergencies of public health concern. It guides priority-setting; serves as a tool for coordination of national authorities, donors and development partners at the country- and regional level; facilitates planning and resource mobilization by all concerned stakeholders, and advocates among Member States to build ownership and support within ministries of health and other relevant government agencies for health laboratory services as an integral part of their portfolio.

23. The following recommendations are proposed for Member States.

- Implement the proposed actions as outlined in the strategic framework for action, adapted to national priorities, regulations and specific contexts through a broad-based cross-sectoral partnership with national and international partners and stakeholders. Use the strategic framework to guide the policy dialogue and develop or further strengthen national laboratory policies and national laboratory strategic plans, based on the findings of a sound situation analysis and inclusive of priority-setting, aligned with the overarching national health plan and national development strategy, and synchronized with national financial policy cycles.
- Ensure provision of adequate financial, human, infrastructural, and technical resources for implementation of national laboratory policies and national laboratory strategic plans through sound resource planning and program budgeting, leveraging the support available from domestic and international sources.

- Build and expand the mechanisms and institutional base for monitoring and evaluation of laboratory performance and the progress towards implementation of national laboratory policies and national laboratory strategic plans.

24. Overall, the proposed strategic framework for action informs the collaborative interventions needed to strengthen health laboratory services across the Region for the period of 2016–2020.

25. WHO will continue to provide support to Member States at regional and country level in their efforts to strengthen health laboratory services in a cross-cutting and comprehensive manner.

26. The Regional Committee is invited to endorse the strategic framework for strengthening health laboratory services 2016–2020.

Annex 1. Framework of action for strengthening health laboratory services 2016-2020

Priority interventions	Action by countries	Progress indicator
<p>Strengthen leadership and governance of the national laboratory systems</p>	<p>Establish an independent intersectoral oversight mechanism for health laboratory services</p> <p>Conduct a situation analysis for laboratory service delivery</p> <p>Build advocacy among senior management and administrators of the Ministry of Health for the importance of health laboratories in cohesive national health systems</p> <p>Develop and implement a national health laboratory policy and a national laboratory strategic plan</p> <p>Establish a legal and regulatory framework to support implementation of the national laboratory policy</p> <p>Create a national organizational structure for development of standards and guidelines and monitoring of their implementation</p> <p>Establish a monitoring and evaluation mechanism for performance of health laboratory services</p>	<p>Governance of health laboratory services streamlined under unified clear leadership</p> <p>Inter-sectoral dialogue between health laboratory services and other relevant services and stakeholders established and coordinated</p> <p>Gaps, weaknesses and needs of the current laboratory system identified</p> <p>Commitment of senior management to laboratory quality obtained</p> <p>Process for development and implementation of the national regulatory framework for laboratory services properly coordinated</p> <p>Standards and guidelines development bodies are in place to nationally recognize best practices, standards, and guidelines</p> <p>Evidence-based decision-making is facilitated by the availability of data</p>
<p>Strengthen the organization and management of the national laboratory systems towards quality</p>	<p>Streamline the structure and functions of the national laboratory services within the health system to meet country needs, especially public health needs</p> <p>Establish a quality management office and/or quality manager's/officer's position to oversee all quality-related activities</p> <p>Implement a quality management system (QMS) at targeted sites</p> <p>Ensure sustainable laboratory services through dedicated adequate government budget/funding</p> <p>Improve supply chain management, equipment procurement and maintenance processes</p>	<p>A tiered laboratory services referral system that provides public health functions of surveillance, detection and response and supports clinical and research needs of the country</p> <p>Quality management offices are established and available to institutions</p> <p>Public health laboratory activities are funded in an adequate and sustainable manner</p> <p>Reagents and supplies are available at all times to support uninterrupted provision of services</p>
<p>Establish sustainable, sufficient and competent human resources for laboratory service delivery</p>	<p>Develop human resources policies (where necessary and feasible, as part of the national laboratory policy) for sustainable, sufficient and competent staff to manage and operate laboratory services</p> <p>Strengthen management of laboratory services</p> <p>Establish mechanisms for registration or licensing of all categories of laboratory workers, including those in private laboratories, based on mandatory minimum qualification requirements (standards)</p> <p>Develop a system for attraction and retention of staff in laboratory services</p> <p>Ensure that pre-service education and training programmes teach knowledge and skills that meet the needs of country's laboratory services</p> <p>Develop a system for in-service continual professional development and competence building for all categories of laboratory workers, including private laboratories</p>	<p>More effective and efficient personnel management</p> <p>Improved staff competency</p> <p>Improved effective and efficient management of laboratory services</p> <p>All laboratories are operated by the registered/licensed personnel fully qualified for their jobs</p> <p>Improved staff motivation and career plans</p> <p>Improved staff retention and morale</p> <p>Improved quality of in-service training and its relevance to laboratory services being provided</p>

Priority interventions	Action by countries	Progress indicator
Ensure safe and secure laboratory environments	<p>Develop/improve national regulatory frameworks to systematically manage biorisk in laboratory settings</p> <p>Ensure safe and secure working environment and facility to prevent accidental or deliberate release of infectious agents and protect laboratory workers, patients, community and the environment</p> <p>Develop and use appropriate training / competence development programmes and associated materials to understand, adopt and implement biorisk management strategies</p>	<p>National biorisk management policies and procedures/ guidelines established and/or updated</p> <p>Biorisk management systems are in place including biorisk management bodies and biorisk manager/officer positions</p> <p>Improved national regulatory frameworks for the implementation of biorisk management approaches</p> <p>Processes and procedures for risk assessment and risk minimization are improved and systematically implemented</p> <p>Infectious substances are transported safely</p> <p>Staff at various service levels has necessary competences to address and mitigate biorisks</p>
Promote effective, tiered and integrated laboratory referral networks (in-country and among countries) and enhance coordination	<p>Ensure that diagnostic capacity meets national needs, especially public health needs, by assisting resource-limited countries to establish or strengthen nationwide tiered, integrated health laboratory networks</p> <p>Improve cross-sectoral communication and coordination with national authorities for effective control of zoonotic diseases by using the "One Health" approach</p> <p>Support regional and global networks to ensure access to testing capacity when local or domestic capacity is not available, especially for diseases or events of public health concern</p> <p>Strengthen external partnerships for technical and financial assistance</p>	<p>Improved quantity and quality of resources available to strengthen public health laboratory networks in resource-limited countries</p> <p>Strengthened and functional existing networks</p> <p>Improved cross-sectoral communication and coordination for zoonoses</p> <p>Partners facilitate the work of the public health laboratories</p>
Promote rational and evidence-based use of laboratory services	<p>Ensure that health care providers are familiar with evidence-based test selection and interpretation of results and have sufficient information on proper collection, storage and shipment of specimens</p> <p>Build capacity of laboratory personnel to provide consultant advisory service and improve communication</p>	<p>Health care providers have a good understanding of laboratory services and adequate knowledge of evidence-based principles of laboratory test ordering and results interpretation</p> <p>Improved equity and access to laboratory services</p> <p>Improved communication between laboratory services and other health care providers</p>