

Strategic framework for strengthening health laboratory services in the WHO Eastern Mediterranean Region, 2024–2029



World Health
Organization

Eastern Mediterranean Region

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Organization**

Eastern Mediterranean Region

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Foreword

Laboratories play a vital role in the diagnosis, management, epidemiological surveillance, control and prevention of both communicable and noncommunicable diseases. Detecting emerging infectious diseases such as COVID-19 and multidrug-resistant and extensively drug-resistant tuberculosis has demonstrated the indispensable role that laboratory services play in the health system.

The value of laboratory services is often overlooked, however, despite their vital contribution to the provision of cost-effective quality health care. Laboratory results provide the only scientific approach to patient management, enabling the clinician to make an accurate diagnosis and rationalize drug use. Globally, it is estimated that 70% of all diagnoses depend on a laboratory report.

A lack of diagnostic facilities contributes to a high incidence of nonspecific and false diagnoses. This situation in turn affects treatment strategies and the length of hospital stays, ultimately increasing the cost of health care delivery and stretching already scarce resources. As a result, an improvement in a country's laboratory services is ultimately expected to lead to a reduction in its national health expenditure, while improving the quality of patient care and the health status of the nation, of the Region and globally.

WHO recognizes the importance of laboratory services and that they are an integral part of a universal health system. The overall objective of this strategic framework is to provide both a road map to strengthen laboratory services delivery in the Eastern Mediterranean Region and a foundation for the development of a resilient and sustainable health system.

WHO calls on all stakeholders to support its implementation.

Acknowledgements

The development of this strategic framework for strengthening health laboratory services in the WHO Eastern Mediterranean Region involved the participation of stakeholders at different stages of the consultative process. In particular, the consultative process included planning meetings and a review of key documents with Member States and regional and global partners, under the coordination of the Public Health Laboratories programme of the WHO Regional Office for the Eastern Mediterranean.

WHO would like to acknowledge the contributions of all representatives from Member States and partner organizations.

Executive summary

The COVID-19 pandemic had a major impact on public health systems. In 2020, the need for rapid expansion of diagnostic capacity led to a spectacular increase in this area, particularly in polymerase chain reaction diagnosis capacity. In 2021, the emergence of variants led to a similar expansion of sequencing capacity. However, sustaining the gains of the COVID-19 response was challenging. Bottlenecks remained around governance and leadership, as well as around the implementation of a sustainable laboratory quality management system. For countries, the absence of a central unit/department within their Ministry of Health to coordinate, oversee and monitor the performance of laboratory services at all levels further compounded these challenges.

To capitalize on the progress achieved during the COVID-19 response and to build upon lessons learned since 2016, the vision for this strategic framework for strengthening health laboratory services in the WHO Eastern Mediterranean Region throughout the 2024–2029 period will be to ensure that the Region's health laboratory services are comprehensive, well-coordinated, integrated and sustainable. Such services will obtain and report safe, accurate and reliable test results in a timely manner for use in clinical and public health settings. This will be achieved through seven strategic goals relating to the following topics:

1. leadership and governance of the national laboratory systems;
2. laboratory quality management systems;
3. sustainable, sufficient and competent human resources for laboratory service delivery;
4. laboratory biosafety and biosecurity;
5. coordinated, effective, tiered and integrated national and international laboratory referral networks;
6. rational and evidence-based use of integrated laboratory services; and
7. research and development of and access to new and innovative technologies.

For each strategic goal, the strategic framework provides guiding objectives, key activities and proposed outcomes to support national health authorities to address gaps and challenges faced by their laboratory systems. The strategic framework also outlines principles for monitoring and evaluation (M&E). WHO will continue to support efforts towards attaining sustainable health laboratory services by providing technical support and partner coordination at the regional and country levels.

Introduction

Well-functioning laboratories are one of the core capacities that countries must develop to support the diagnosis and treatment of communicable diseases and to implement the International Health Regulations (IHR 2005) (1). They are central to the detection, assessment, response, notification and monitoring of disease. Their provision of timely and accurate information for use in patient management and disease surveillance makes laboratory services essential for disease control and prevention programmes (2), as well as for achieving the other health-related targets of the United Nations Sustainable Development Goals. Achieving universal health coverage calls for continuous strengthening and quality improvement to ensure equitable access to safe, secure, quality-assured and cost-effective laboratory services. In addition to the health and well-being of individuals, critical public health decisions concerning health security, national development and meeting the international obligations of the IHR (2005) all depend upon laboratory results. While high-income countries have organized routine laboratory systems and services, these are often neglected in low- and middle-income settings (3,4), with gaps remaining.

In 2016, the 63rd session of the Regional Committee for the Eastern Mediterranean Region endorsed the *Strategic framework for strengthening health laboratory services 2016–2020*, through resolution EM/RC63/R.4 (5,6). This strategic framework guided the development 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 communicable diseases, in line with the IHR (2005). In 2020, the 67th session of the Regional Committee for the Eastern Mediterranean further extended the time frame for implementation of the framework by three years, until 2023 (7). Because the extension of the resolution came to an end in 2023, the WHO Regional Office for the Eastern Mediterranean convened its Member States in December 2022 to assess progress made towards implementation of the 2016–2023 strategic framework, with a focus on the 2016 strategic goals, limited progress and opportunities to build on COVID-19 response achievements.

Following resolution EM/RC63/R.4, Member States in the Eastern Mediterranean Region began to make strides towards universal health coverage as they worked towards continuous strengthening and quality improvement to ensure equitable access to safe, secure, quality-assured and cost-effective laboratory services. However, there has been limited progress in inducing countries to finalize their policies, and the need to build on progress made during the COVID-19 pandemic remains.

Overview of regional capacities

The WHO Eastern Mediterranean Region comprises 22 countries and territories with a diverse range of socioeconomic conditions and demographic characteristics. The provision of health and other services in the Region remains challenging due to acute and protracted humanitarian emergencies, poverty, lack of political commitment and fragile health systems. During the COVID-19 pandemic, countries and territories in the Region made efforts to respond through strengthening health systems. They realized the need to invest in personnel, risk communication, training of essential health care workers for surge capacity, and equipment. For laboratory services, challenges identified included governance and leadership and the implementation of laboratory quality management systems, with a particular focus on sustainability. The absence of performance monitoring for laboratory services at the national level prevents documentation of the investments made so far (7).

In 2019, the laboratory strengthening team of the WHO Lyon office undertook a global review of the published joint external evaluation (JEE) reports (8),ⁱ focusing on the national laboratory system and

biosafety and biosecurity technical areas (the two out of the 19 technical areas that are most directly related to the public health laboratory systems and their activities) (9). The assessment addressed national laboratory system indicators. Annual self-reporting and regular JEE monitor IHR implementation at the country level. JEE scores range from 1 to 5 (from no capacity to sustainable capacity).

Data are publicly available in JEE reports for 17 countries in the Region that have undergone evaluation since the release of the first JEE tool in 2016. These data strongly support the need for continued development, with the highest cumulative score in the laboratory-related technical areas at 69% (national laboratory system). The results demonstrate that countries require firmer governance to support their national laboratory policies, with respect to cross-sector coordination and monitoring and the provision of quality laboratory services; that there is unmet need for trained human resources for laboratory service delivery, as well as for stronger mechanisms to manage biorisk in terms of legislation, personnel training and procedures for the handling of biological and infectious substances; and that there is widespread need in countries to ensure appropriate specimen testing, referral, reporting, and sharing of information among stakeholders, as well for countries to strengthen their tiered, integrated laboratory networks.

In 2022, the WHO Regional Office for the Eastern Mediterranean developed a matrix to assess country/territory progress in implementing the regional framework for strengthening health laboratory services (Table 1). The Regional Office collected data through the respective WHO country offices and analysed gaps in the Region's laboratory performance. Scores ranged from 1 to 4 (no capacity to demonstrated capacity). From 5 to 7 December 2022, the fourth laboratory directors meeting of the Eastern Mediterranean Region provided an opportunity to validate the results. Member States further elaborated on the strengths, weaknesses and opportunities identified (Annex A).

Table 1. Scorecard analysis to assess country-level implementation of the regional Strategic framework for strengthening health laboratory services, 2016–2023

Leadership, legislation and governance including laboratory networks	Availability of fully implemented laboratory policy	3	1	3	2	3	1	1	3	1		3	1	1	4	4	1	2	1	1	4	2	4
	Fully implemented integrated national laboratory strategic plan	3	1	3	4	3	1	1	4	1		1	2	2	4	3	1	2	1	1	4	2	4
	Re-licensing of all laboratories in the public and private sectors	4	2	1	3	3	1	3	4	3		3	3	3	2	3	3	4	3	3	4	3	4
	National laboratory coordination with multiple ministries and private sector	1	2	2	2	2	1	1	4	3		4	4	4	3	3	2	4	3	2	4	4	3
	Dedicated national laboratory budget completely covering intersectoral functions with defined operational plans	2	2	2	2	2	1	1	4	2		2	3	2	4	3	2	4	3	4	4	4	4
	Dedicated laboratory budget at all levels of the human health networks	2	1	2	4	2	1	4	4	4		2	4	3	2	4	2	4	4	4	4	4	4
	Presence of laboratory networks for all functions with clearly defined tier-specific roles	4	3	2	3	4	1	2	4	4		3	3	4	4	3	2	4	2	4	4	3	4
	All types of laboratories integrated into a laboratory network	1	2	2	3	2	1	2	3	2		1	1	4	3	2	2	4	1	4	3	1	2
	Defined minimum testing package based on a current list of national priority diseases	3	2	1	3	2	1	2	4	4		3	3	3	4	2	1	3	1	4	4	3	3
	Designated national reference laboratory coordinating public health functions of the entire national laboratory network	3	2	2	4	4	1	4	3	4		4	2	2	4	4	1	4	2	4	4	3	
Human resources for laboratory service delivery	Competency-based training curricula are in line with national standards	1	1	1	4	2	1	1	4	4		1	3	1	4	2	2	4	2	3	4	3	3
	Quality and safety management are offered as topics in pre-service laboratory training curricula	1	1	3	4	3	1	1	4	3		1	2	3	4	3	2	4	1	4	4	3	4
	Training programme for laboratory management is in place	1	1	4	3	2	1	1	4	4		3	1	2	4	1	1	4	1	4	4	2	2
	Licensing of laboratory workers is based on education, training and competency	2	2	2	2	2	1	2	2	2		1	2	2	3	2	2	4	2	2	4	4	4
	National staffing plan for the laboratory network in place based on workload forecasting	1	1	1	1	1	1	1	1	1		1	1	1	4	2	1	4	2	4	4	2	3
	All available positions filled	2	2	1	1	2	1	2	2	2		2	2	2	4	2	1	4	2	4	4	3	2
	Presence of human resource development strategy addressing laboratory workers and fully implemented	1	1	2	1	2	1	2	3	1		2	1	1	3	2	1	4	1	3	3	4	2
	Standardized and competency-based job descriptions are available at all levels of the laboratory network	2	2	1	3	3	1	2	4	2		3	3	2	4	4	2	4	2	4	4	3	4

Laboratory biosafety and biosecurity	Available up-to-date laboratory biosafety manual in all facilities	2	4	1	4	2	1	3	4	3		1	1	1	4	2	1	4	3	4	4	3	4
	All safety equipment available to all laboratory workers at all levels	2	3	3	4	3	1	4	4	4		3	1	3	4	4	2	4	4	4	4	4	4
	A designated safety officer in place in public and private sector laboratories	1	2	2	3	3	1	3	4	2		2	1	1	2	2	2	4	4	4	4	3	4
	Biosafety cabinets are regularly serviced at all relevant tiers by a certified body	3	1	1	2	1	1	1	3	4		3	1	2	2	4	2	4	3	4	4	4	4
	Available regulated system of biobanking for all tiers of the laboratory network	2	2	1	1	1	1	1	3	3		3	1	1	2	2	1	3	1	2	1	3	3
	Waste management conformance is fully monitored in accordance with level-specific biosafety and biosecurity requirements	2	2	1	4	1	1	4	3	4		2	2	3	4	2	1	4	3	4	4	3	4
	All laboratories have access to incinerators that comply with national standards	3	3	2	4	1	1	4	3	4		3	3	1	4	3	1	4	4	4	4	2	4
Quality of laboratory services	Internal quality control procedures are standardized throughout the network for all tests	2	4	2	4	3	1	2	4	4		1	1	3	3	4	1	4	4	4	4	4	4
	External quality assessment programme for all 10 priority diseases is in place at all tiers, with feedback of results and action for improvement	2	1	3	3	1	1	2	3	3		3	1	2	2	2	2	4	3	4	4	4	4
	Reference laboratories participate in international external quality assessment programmes	2	4	2	2	3	1	4	1	4		3	1	2	4	4	2	4	2	4	4	4	4
	Laboratory quality officer positions filled in all public sector laboratories	1	1	2	2	4	1	2	2	4		2	2	1	2	3	1	4	4	4	4	3	4
	Quality management activities are implemented in all laboratories	1	1	2	2	3	1	2	4	3		2	1	2	2	3	1	4	3	3	4	3	4
	Available mandatory certification and accreditation standards for laboratories	1	1	1	2	2	1	3	4	4		2	2	2	3	3	3	3	3	3	4	3	4

Notes: Country/territory names have been anonymized. 1: No capacity; 2: Limited capacity; 3: Developed capacity; 4: Demonstrated capacity; blank cells indicate no data available.

As shown in Table 1, of the 21 countries/territories for which data were collected, four (19%) have fully implemented their laboratory policies, and eight (38%) have partially implemented their policies. Five (24%) have fully implemented strategic plans, and eight (38%) have finalized the development process for a strategic plan but have not yet implemented it. Eleven countries/territories (52%) have internal quality control procedures standardized throughout the network for all tests. Five (24%) have an external quality assessment 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 external quality assessment programme. Seven countries/territories (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. 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.

Potential challenges across all intervention areas include lack of resource allocation and management (personnel, equipment, reagents and infrastructure), insufficient recognition of the need to support laboratory quality management system implementation at a higher level, resistance to change management, and fragile health systems in some countries/territories that lead to operational disruptions.

Rationale for updating the strategic framework

In 2022, the WHO Regional Office for the Eastern Mediterranean decided to update the strategic framework, based on the above analysis and considering the following points. First, pre-COVID-19, countries and territories in the Eastern Mediterranean Region had aimed for universal health coverage, including laboratory services. However, the laboratories were underprioritized and not fully functional. Second, the COVID-19 pandemic stressed laboratories, diverting focus and leading to short-term investments, including rapid growth in molecular diagnosis. Third, a new strategy to strengthen laboratory services could provide new opportunities through focusing on leadership, governance, quality management systems, human resources, and biosafety and biosecurity. Fourth, adopting sustained approaches for the implementation of laboratory quality management systems, such as the Stepwise Laboratory Improvement Process Towards Accreditation (known as SLIPTA), are an opportunity to enhance quality services with limited resources to build a future-ready laboratory systems capability in the Region.

Development process

Updating the strategic framework for the 2024–2029 period has entailed the following steps.

1. **Literature review:** We reviewed the literature focusing on laboratory services, diagnostics and public health emergencies in the Eastern Mediterranean Region. This review encompassed relevant publications, reports and policy documents.

2. **Consultations:** We engaged key stakeholders involved in laboratory services within the Region in consultations. Stakeholders included representatives from ministries of health, public health agencies, academic institutions, development partners and international organization. This engagement occurred in December 2022 and March and August 2023.
3. **Capacity-building initiatives:** Member States agreed that they needed to develop capacity-building initiatives at the national and subnational levels, based on identified priorities. These initiatives should include training programmes, technical assistance, and resource mobilization efforts to strengthen laboratory systems and networks.
4. **Advocacy and networking:** We leveraged a platform with Member States for advocacy and networking purposes that will continue to advocate for increased investment in laboratory services and improved policy frameworks to support their development, while fostering collaborations with regional and international partners to exchange expertise and resources.
5. **M&E:** We have established mechanisms for monitoring and evaluating the impact of technical working group activities on laboratory systems strengthening in the Eastern Mediterranean Region. We will regularly assess progress towards objectives and outcomes and adjust as needed to ensure effectiveness and sustainability.

Strategic framework for strengthening health laboratory services in the WHO Eastern Mediterranean Region, 2024–2029

Vision

Ensure that within the Eastern Mediterranean Region, health laboratory services are comprehensive, well-coordinated, integrated and sustainable, and can obtain and report safe, accurate and reliable test results in a timely manner for use in clinical and public health settings.

Goal

Increase the infrastructure and capabilities of national health laboratory systems, with the aim of advancing both clinical practice and public health initiatives. By augmenting laboratory capacity, the strategic framework aims to support comprehensive disease control and surveillance endeavours, focusing particularly on communicable diseases. Additionally, the framework seeks to prioritize preparedness for the surveillance of and response to epidemic-prone diseases, health security concerns and other potential emergencies of public health concern.

Strategic goals and respective objectives

To achieve the overall vision of the Eastern Mediterranean Region’s strategic framework, countries and territories must implement the following seven strategic goals and related strategic objectives (see Annex B).

Strategic goal 1: Leadership and governance of the national laboratory systems

This framework prioritizes leadership and governance for national laboratory systems. It recommends a central entity within ministries of health, together with the development and implementation of laboratory strategy, ongoing advocacy by senior management, and a structured approach for standards development and implementation monitoring. The “One Health” strategy emphasizes coordinated leadership across sectors for holistic public health impact.

Strategic goal 2: Laboratory quality management systems

The framework involves setting up a quality management office or appointing a quality manager for overseeing the implementation of quality management systems at specific sites to ensure standardized practices. Emphasis will also be placed on securing supply chain management and optimizing equipment processes to enhance overall laboratory quality and efficiency.

Strategic goal 3: Sustainable, sufficient and competent human resources for laboratory service delivery

To ensure robust human resources for laboratory service delivery, policies for sustainable and competent staff must be developed. These include strengthening management, establishing licensing mechanisms, and implementing strategies for staff attraction and retention. Educational programmes will be aligned with the needs of laboratory services, and continuous professional development systems are to be put in place for all personnel, covering both public and private laboratories.

Strategic goal 4: Laboratory biosafety and biosecurity

Ensure a safe and secure laboratory environment by establishing national regulatory frameworks for biosafety and biosecurity management. This includes maintaining secure facilities to prevent accidental or intentional release of infectious agents, protecting both laboratory workers and the community. Additionally, policies for biobanking and waste management will be implemented.

Strategic goal 5: Coordinated, effective, tiered and integrated national and international laboratory referral networks

Create tiered, coordinated laboratory networks nationally to ensure access to testing capacity for public health concerns by supporting regional and global networks. Additionally, resource-limited countries will be assisted to develop or strengthen their networks to meet diagnostic needs. In parallel, strengthen external partnerships for technical and financial support.

Strategic goal 6: Rational and evidence-based use of integrated laboratory services

Encourage the evidence-based use of integrated laboratory services by implementing testing programmes, guiding health care providers in test selection and interpretation. Focus on proper specimen handling and enhance laboratory personnel capacity for advisory services and improved communication.

Strengthen bacteriology laboratories to provide accurate, reliable and timely evidence-based antimicrobial resistance data to use in planning, implementing, monitoring and evaluating public health intervention programmes. Focus on assessing existing capacity to provide an evidence-based plan of action for improving laboratories' capacities, including training and the sustainability of service.

Strategic goal 7: Research and development of and access to new and innovative technologies

Support research through regulatory processes and frameworks to foster the development and accessibility of new and innovative technologies. In addition, identify gaps and challenges in laboratory systems' efficiency and effectiveness through research, providing solutions to enhance access to these technologies.

Implementation

At the regional level

- Establish a regional laboratory technical working group to advise on pragmatic approaches to advance laboratory services for public health and clinical care.
- Support the strengthening of laboratory services across the health system through policies, governance and investment in sustainable laboratory systems.
- Foster collaborations with various stakeholders to promote a community of practice for peer-to-peer learning between Member States.
- Establish partnerships to strengthen regional supply chain mechanisms for laboratory consumables and reagents.

At the country level

- Establish a central unit within the Ministry of Health to drive the laboratory service agenda and priorities.
- Catalyse investment and resource mobilization towards multiyear strengthening of health laboratory services.
- Increase access to quality testing in clinical and public health laboratories across the health system.
- Strengthen integrated specimen referral and specimen collection transport systems.
- Introduce diagnostic stewardship and strengthen linkages to clinical services for improved clinical management.
- Establish national quality assurance programmes and national biorepositories to catalogue samples for research and development and diagnostic test evaluations.
- Facilitate learning for continuous improvement of public health laboratories.

M&E of the strategic framework

Continued concerted efforts and collaboration between all countries and territories of the Region, WHO, other United Nations agencies, donors and development partners will allow for the implementation of the Eastern Mediterranean Region strategic framework at the regional and country levels. The M&E framework includes a number of identified indicators (see annex B) that will be monitored at the regional and country levels to enable a systematic and real-time understanding of the implementation of this strategic framework and its effectiveness in achieving the strategic goals.

These indicators were selected from various frameworks, including the IHR (2005), the Integrated Disease Surveillance Programme, and communicable disease programmes such as those for HIV and tuberculosis, and will be used to monitor progress in the implementation of IHR core capacities and programme performance in countries and territories in the Region. Countries and territories may also wish to consider referring to these indicators as the basis for a national tool to monitor capacity-building. Whenever possible, M&E indicators from relevant existing programmes will be utilized to reduce the burden of data collection (7).

Annex A: Strengths, weaknesses and opportunities identified towards implementation of the regional framework

Priority intervention areas	Strengths	Weaknesses	Opportunities
Leadership, legislation and governance	<ul style="list-style-type: none"> National strategy and plans in some countries Some national laboratory services departments with established budget line National laboratory technical working groups in some countries Integrated laboratory electronic system in some countries Partially integrated laboratory systems and platforms, including the multiplex and specimen referral systems, available in some countries Establishment of a tiered laboratory network in some countries 	<ul style="list-style-type: none"> Poor coordination of clinical and public health services due to lack of a specific unit/department in the Ministry of Health (MOH) Lack of laboratory policies and strategic plans Poor coordination of One Health programmes Fragmentation of health care system Limited training opportunities for leaders 	<ul style="list-style-type: none"> Advocate for well-established structure of laboratory services at the MOH level to oversee laboratory services and advocate for funding Support development and implementation of laboratory policies and strategic plans Integrate laboratory services, platforms, specimen referral and data management system Initiate and implement the One Health concept Capitalize on COVID-19 investments
Laboratory quality management systems (QMS)	<ul style="list-style-type: none"> Established laboratory QMS in some countries in which they are partially implemented Presence of functional laboratory accreditation/certification bodies in some countries Presence of the Regional External Quality Assessment Programme for serology, bacteriology, mycology and antimicrobial resistance 	<ul style="list-style-type: none"> Suboptimal implementation of laboratory QMS due to lack of quality manual, quality assurance programmes, laboratory mentors, laboratory quality auditors and funding Inadequate national accreditation bodies Existence of parallel data systems No key performance indicators for monitoring quality Inadequate and irregular availability of supplies and reagents 	<ul style="list-style-type: none"> Designate a focal point to follow laboratory quality management and biosafety and biosecurity at the national level Support the establishment and/or implementation of laboratory QMS through the adoption of existing approaches such as the Stepwise processes, especially in resource-poor countries Support the establishment of a regional accreditation body Support the establishment of a national essential diagnostic list Support the establishment of vertical and horizontal collaborations (e.g. twinning and peer laboratory auditing and mentoring initiatives)

Priority intervention areas	Strengths	Weaknesses	Opportunities
Human resources for laboratory services	<ul style="list-style-type: none"> Establishment of education and training programmes for laboratory workforce (pre-service training and in-service training) Established WHO Global Laboratory Leadership Programme Licensing and registration of laboratory workforce is in place in some countries Established integrated task-shifting service delivery models in some countries 	<ul style="list-style-type: none"> High turnover of laboratory workforce Inadequate number of technical and laboratory managers Lack of funding for training and scholarships for laboratory personnel to achieve a high level of education in bioinformatics, sequencing, etc. 	<ul style="list-style-type: none"> Recruit qualified laboratory staff Establish national training programmes Establish laboratory leadership curriculum in universities Establish pre-service training on safety and QMS Scale up Global Laboratory Leadership Programme
Biosafety and biosecurity	<ul style="list-style-type: none"> Partial availability of adequate and maintained physical infrastructure Processes and procedures for risk assessment and risk minimization are partially in place Systems and procedures for transporting biological specimens and infectious substances are partially in place System of inventory of infectious agents and substances partially in place Some countries have companies for biosafety cabinet certification National biobanking system infrastructure modified/established in some countries to enable long-term sample storage Availability of WHO Biosafety Manual Risk management committees in place Biosafety officer in some laboratories 	<ul style="list-style-type: none"> No established biosafety and biosecurity legislation Absence of national biosafety cabinet certification system in most countries Lack of national biobanking policy Poor waste management and lack of protocols Insufficient personal protective equipment Poor capacity for equipment maintenance (biosafety cabinet certification; non-standardized equipment) 	<ul style="list-style-type: none"> Establish a national biosafety and biosecurity legislation and management system Develop and implement a national biobanking policy and waste management policy Establish systems for equipment maintenance, including safety equipment and biosafety cabinets Establish a list of priority pathogens Standardize tool kit for risk assessment and risk management

Annex B: Strategic actions, activities and outcomes indicators to be monitored at country and regional levels

Strategic goal 1: Leadership and governance of the national laboratory systems		
Objectives	Key activities	Qualitative outcome indicators
1.1 Advocate for strengthening national coordination and supervision of laboratory services and call for a central entity in the MOHs to supervise and coordinate laboratory services	<ul style="list-style-type: none"> Establish a directorate/unit to oversee health laboratory services at the MOH 	<ul style="list-style-type: none"> Laboratory directorate/unit established at the MOH Health laboratory services coordinated at MOH level Sustainable laboratory services ensured through dedicated adequate government budget/funding
1.2 Analyse the situation of laboratory service delivery in every country to develop an informed national laboratory policy	<ul style="list-style-type: none"> Conduct a thorough assessment of the current laboratory system Communicate the results of the assessment to all relevant stakeholders 	<ul style="list-style-type: none"> Gaps, weaknesses and needs of the current laboratory system identified Stakeholder awareness of laboratory services needs enhanced (stakeholders sensitized)
1.3 Develop a national health laboratory policy to implement a national laboratory strategic plan	<ul style="list-style-type: none"> Conduct an appropriate consultative process and consensus building with relevant stakeholders Establish a national laboratory working group or an equivalent policy development mechanism Develop national laboratory policy and national laboratory strategic plan Include an M&E mechanism for the performance of health laboratory services in national strategic plans Member States to officially endorse/enact their national laboratory policies and strategic plans through appropriate country mechanisms/channels 	<ul style="list-style-type: none"> Integrated national laboratory strategic plan in place and implemented National laboratory working group for policy development mechanism in place National laboratory policies in place and implemented Performance of health laboratory services properly documented and continuously monitored to identify opportunities for improvement Defined evidence-based resource allocation mechanisms for laboratory services established for the medium and longer term
1.4 Create a national organizational structure for development of standards and guidelines and the monitoring of their implementation	<ul style="list-style-type: none"> Develop/update and enforce national legislation and regulations on diagnostic capacity, including reference laboratories for priority diseases; notifiable diseases and mechanisms for reporting; licensing and certification and accreditation of health laboratories; and professional code of ethics 	<ul style="list-style-type: none"> Effective legal and regulatory framework in place to ensure access to quality laboratory services Standards and guidelines development bodies in place to nationally recognize best practices, standards and guidelines
1.5 Organize mechanisms to coordinate a One Health multisectoral approach	<ul style="list-style-type: none"> Establish a multisectoral collaboration mechanism to implement a One Health approach 	<ul style="list-style-type: none"> A multisectoral collaboration mechanism to implement a One Health approach is in place

Strategic goal 2: Laboratory QMS		
Objectives	Key activities	Qualitative outcome indicators
2.1 Establish a quality management office and/or quality manager's/officer's position to oversee all quality-related activities	<ul style="list-style-type: none"> • Create position description for quality manager/officer and promote recruitment of quality officers in laboratories 	<ul style="list-style-type: none"> • Quality management offices established at the MOH • Quality officers available in all laboratories
2.2 Implement laboratory QMS at all levels of laboratory services	<ul style="list-style-type: none"> • Adopt the Stepwise approach in implementing QMS at selected laboratories • Perform baseline QMS assessments at targeted laboratories using standardized structured tools • Provide training in QMS to selected staff at selected laboratories • Conduct supervisory coaching and mentorships in QMS at selected laboratories • Cascade QMS training to all categories of laboratory worker, using regional and/or national pool of QMS trainers • Conduct ongoing M&E of QMS implementation 	<ul style="list-style-type: none"> • QMS implementation continually monitored and evaluated • Regional and national pools of QMS trainers established • Regional laboratory accreditation process established • M&E of QMS implementation in place
2.3 Secure supply chain management, equipment procurement and maintenance processes	<ul style="list-style-type: none"> • Develop and implement a national laboratory diagnostic list • Establish a standardized process for acquisition of equipment, validated reagents and supplies that incorporates specifications of need and quality • Establish a standardized stock control and inventory management system in all laboratories • Establish standardized and sustainable mechanisms for procurement of service/maintenance contracts for automated equipment, biosafety cabinets and microscopes 	<ul style="list-style-type: none"> • National laboratory diagnostic list established and implemented • Proper, functioning equipment and adequate quantities of validated reagents and supplies available at all times to support uninterrupted provision of services • Processes and ownership clearly defined in relation to procurement, maintenance and repair of equipment, and associated supplies and reagents

Strategic goal 3: Sustainable, sufficient and competent human resources for laboratory service delivery		
Objectives	Key activities	Qualitative outcome indicators
3.1 Develop human resources policies for sustainable, sufficient and competent staff to manage and operate laboratory services	<ul style="list-style-type: none"> • Draft human resources policy for laboratory personnel management • Define national competency requirements for various categories of laboratory staff • Review and revise job descriptions for all categories of laboratory workers to align them with the national competency requirements; establish standardized position descriptions • Carry out training needs assessment of laboratory workers via workforce mapping and a continuing review process 	<ul style="list-style-type: none"> • Human resource policy in place • More effective and efficient personnel management • Improved staff competency • Improved needs assessment and matching
3.2 Strengthen management skills of laboratory managers	<ul style="list-style-type: none"> • Identify appropriate roles and responsibilities of management in relation to laboratory services • Identify available resources and programmes for building managerial capacity for laboratory services • Develop and adopt laboratory leadership curriculum in universities 	<ul style="list-style-type: none"> • Increased effective and efficient management of laboratory services • Laboratory leadership curriculum developed and adopted in universities
3.3 Establish mechanisms for registration or licensing of all categories of laboratory personnel	<ul style="list-style-type: none"> • Review/improve/define minimum qualification standards/requirements • Develop minimum qualifications for all categories of laboratory workers as a condition of employment as well as for licensing, certification or accreditation of laboratories in all sectors, including private laboratories • Promote elevation of the position of laboratory staff to their appropriate place in the public health system 	<ul style="list-style-type: none"> • All laboratories are operated by registered/licensed personnel fully qualified for their jobs
3.4 Develop a system to attract and retain staff in laboratory services	<ul style="list-style-type: none"> • Establish a staff performance monitoring system, including annual performance appraisal and ongoing competency assessment mechanisms, linked to promotions/career advancement • Establish transparent salary scales for different levels of laboratory worker • Explore reward/motivation/incentive mechanisms, including in-service training, and introduce staff recognition programmes • Investigate reasons for staff attrition (for instance, with exit interviews) and plan retention measures accordingly 	<ul style="list-style-type: none"> • Improved staff motivation and career plans • Improved staff retention and morale • Improved staff competency
3.5 Ensure that pre-service education and training programmes build competencies (i.e. knowledge, skills and attitudes) that meet the needs of the country's laboratory services	<ul style="list-style-type: none"> • Develop pre-service training/recruitment criteria for a competent laboratory workforce based on qualification requirements/standards • Identify and establish good working relationships with relevant stakeholders, including Ministry of Education, universities, technical schools and colleges, and international institutions, using formal interministerial agreements 	<ul style="list-style-type: none"> • Improved planning to meet human resources needs through the existing educational system
3.6 Develop a system for in-service continual professional development and competence building for all categories of laboratory personnel, including private laboratories	<ul style="list-style-type: none"> • Develop career advancement/promotion criteria • Review in-service training curricula to ensure they are aligned with career advancement/promotion criteria and respond to changes in technology • Formalize continuing professional development programmes, requiring a minimum amount of training every year and linked to promotion/career advancement • Design processes and tools for monitoring training outcomes and impact 	<ul style="list-style-type: none"> • Improved quality of in-service training and relevance to laboratory services being provided • Improved staff competency

Strategic goal 4: Laboratory biosafety and biosecurity		
Objectives	Key activities	Qualitative outcome indicators
4.1 Develop and implement national regulatory frameworks to systematically manage biosafety and biosecurity in laboratory settings	<ul style="list-style-type: none"> Review/develop national policies and procedures/guidelines and update/establish biosafety and biosecurity management regulation accordingly, drawing on the expertise of institutional biosafety initiatives Establish and endorse biosafety and biosecurity management body/committee with appropriate terms of reference and distribution of responsibilities Establish standardized laboratory safety manager position, complete with appropriate position description at all levels of laboratory services 	<ul style="list-style-type: none"> National biosafety and biosecurity regulatory framework in place Biosafety and biosecurity management systems in place, including biosafety and biosecurity management bodies/committee Safety manager/officer positions in place and filled at all levels of laboratory services
4.2 Ensure safe and secure working environment and facility to prevent accidental or deliberate release of infectious agents and protect laboratory workers, patients, the community and the environment	<ul style="list-style-type: none"> Ensure adequate physical infrastructure is in place and maintained Develop systems and procedures for, and systematically conduct, risk assessment, risk mitigation and biosafety and biosecurity management performance evaluation activities at each facility Establish systems and procedures for transporting biological specimens and infectious substances at different levels within the laboratory system Establish a system of inventory of infectious agents and substances categorized according to country 	<ul style="list-style-type: none"> Safe laboratory physical infrastructure Processes and procedures for risk assessment and risk minimization improved and systematically implemented Infectious substances transported safely
4.3 Develop and implement a biobanking policy	<ul style="list-style-type: none"> Develop a list of pathogens to be handled at every level of laboratory in the network Develop and implement biobanking policy and guidelines 	<ul style="list-style-type: none"> Laboratory biobanking policy and guidelines in place and implemented at all levels of laboratory network
4.4 Develop and implement a waste management policy	<ul style="list-style-type: none"> Establish a waste management team Select waste management partners Set targets for waste reduction Develop and implement the waste management policy 	<ul style="list-style-type: none"> Waste management policy in place and implemented

Strategic goal 5: Coordinated, effective, tiered and integrated national and international laboratory referral networks		
Objectives	Key activities	Qualitative outcome indicators
5.1 Establish nationwide tiered, integrated health laboratory networks that will 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	<ul style="list-style-type: none"> Define structure of national laboratory services with clear roles and responsibilities, with an emphasis on public health functions, such as clear policy for designation of national reference laboratories Establish clear networking, referral and reporting mechanisms through a tiered system with a particular emphasis on the importance of a regulated and functional/modernized/systematized specimen transportation system 	<ul style="list-style-type: none"> Tiered laboratory services referral system that provides public health functions of surveillance, detection and response and supports the clinical and research needs of the country
5.2 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	<ul style="list-style-type: none"> Map existing laboratory assets and capacities at national level, including linkages between laboratories and structures of existing networks Develop policy, procedures and testing algorithms, including roles and responsibilities inside the network; referral of specimens/patients and reporting/confirmation of results; communication and sharing of information; training, coaching and mentoring of personnel; monitoring of networking laboratories; and networking with other stakeholders in both government and private organizations Develop guidelines and training materials on specimen collection and transport Use laboratory information management system within laboratories and improve communications across laboratories and surveillance systems Promote functional integration between laboratories of the network through the use of modern information technologies 	<ul style="list-style-type: none"> Improved quantity and quality of resources available to strengthen public health laboratory networks in resource-limited countries
5.3 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	<ul style="list-style-type: none"> Identify testing capacities at the regional and global levels Promote technology transfer Facilitate access to reagents, testing and quality control materials and testing protocols Support specimen-sharing across networks, through pre-agreed memoranda of understanding and material transfer agreements 	<ul style="list-style-type: none"> Regional and global networks are strengthened Reliable and timely results available
5.4 Strengthen external partnerships for technical and financial assistance	<ul style="list-style-type: none"> Identify potential partnerships and stakeholders to address gaps in workforce development; supply chain management; specimen management and transport; diagnostic technologies, including commercial in vitro diagnostics testing; and referral and reference networks and quality management, including proficiency testing programmes Engage national laboratory directors in all aspects of planning and implementation (total process) Identify twinning partners (such as national and state laboratories, universities) and develop twinning mechanisms Promote information-sharing for transparency and mutual trust 	<ul style="list-style-type: none"> Partners facilitate work of the public and clinic health laboratories Information-sharing for transparency and mutual trust promoted

Strategic goal 6: Rational and evidence-based use of integrated laboratory services		
Objectives	Key activities	Qualitative outcome indicators
6.1 Build integrated testing services at all levels of laboratory network	<ul style="list-style-type: none"> • Develop policies for the use of multiplex equipment for multiple diseases • Optimize diagnostic network on specimen referral and multiplex testing platforms, including point of care • Integrate patient pathway and documentation • Adoption of task-sharing policies and cross training on the use and interpretation of multiple assays to non-laboratory health personnel 	<ul style="list-style-type: none"> • Cost-efficiency of laboratory services
6.2 Ensure that health care providers select evidence-based testing, interpret results, and organize proper collection, storage and shipment of specimens	<ul style="list-style-type: none"> • Develop/update primary sample collection manuals (laboratory handbooks, user manuals); make them available to relevant clinical staff • Develop guidelines and training materials on evidence-based test selection and result interpretation • Conduct regular training sessions to familiarize clinicians with the performance characteristics of laboratory examinations and evidence-based test selection and interpretation of test results 	<ul style="list-style-type: none"> • Health care providers have a good understanding of laboratory services and adequate knowledge of the evidence-based principles of laboratory test ordering and results interpretation • Improved equity and access to laboratory services
6.3 Build capacity of laboratory personnel to provide consultant advisory service and improve communication	<ul style="list-style-type: none"> • Conduct regular joint meetings and clinical audits with clinicians to discuss issues related to the use of laboratory services • Establish mechanisms for systematic identification and monitoring of customers' needs and satisfaction with laboratory services through collecting feedback from customers and customer satisfaction surveys 	<ul style="list-style-type: none"> • Laboratory personnel have adequate capacity to provide consultant advisory services to clinicians • Improved communication between laboratory services and other health care providers • Customer needs and satisfaction monitored, and issues documented and addressed

Strategic goal 7: Research and development of and access to new and innovative technologies		
Objectives	Key activities	Qualitative outcome indicators
7.1 Support research through regulatory processes and frameworks	<ul style="list-style-type: none"> • Establish coordination mechanism between laboratories and regulatory authorities • Establish protocols for rapid evaluations/validations of in vitro diagnostics • Develop protocols for post-market surveillance and reporting 	<ul style="list-style-type: none"> • Improved availability and quality of diagnostic tests and devices
7.2 Identify gaps and challenges, and provide solutions for laboratory systems' efficiency and effectiveness through research	<ul style="list-style-type: none"> • Develop training on conducting operational research • Provide resources to increase regional publications • Design processes and tools for the monitoring of outcomes and impact of research 	<ul style="list-style-type: none"> • Reduced systemic challenges, efficient and effective laboratory networks and service delivery

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¹ All references were accessed on 28 September 2024.

