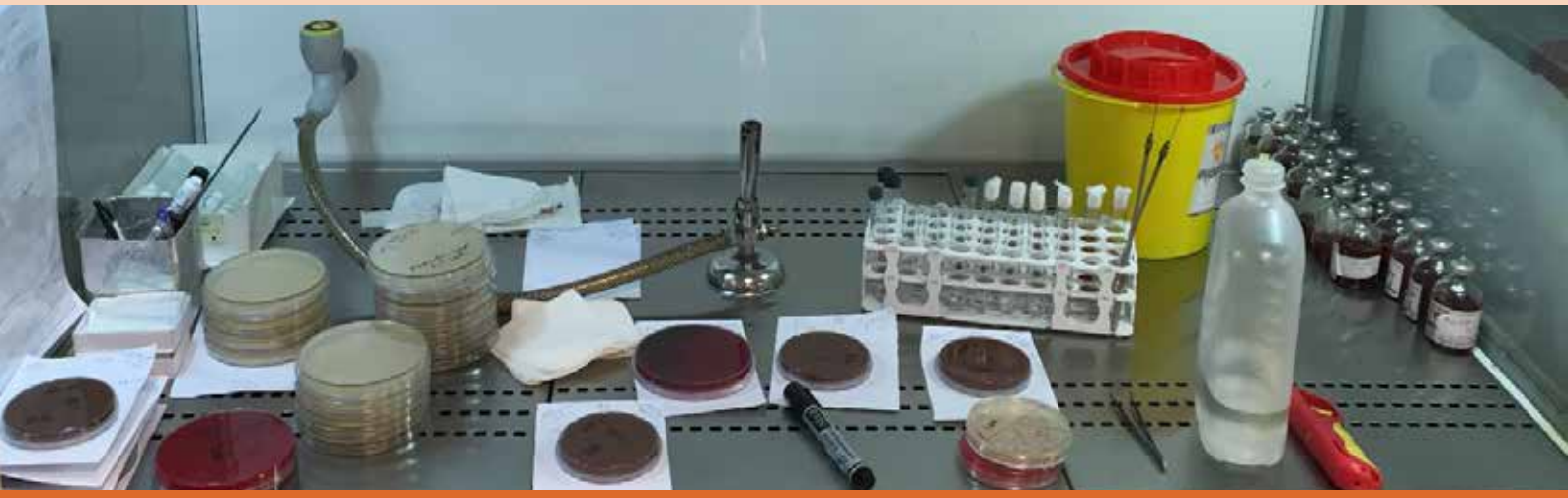
WHO-EM/LAB/390/E

Strategic framework for strengthening health laboratory services



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Foreword

Laboratories are an essential and fundamental part of health systems and contribute directly to the improvement of health services. Reliable and timely results from laboratory investigations are critical elements in decision-making in all aspects of health services. 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 the International Health Regulations (IHR) 2005, depend upon laboratory results.

The modern world is threatened with growing outbreaks of known, emerging or unknown diseases. Poliomyelitis, meningitis, measles, influenza (H1N1, H5N1 and H7N9), Middle East respiratory syndrome coronavirus (MERS-CoV), Ebola virus disease, and lately Zika virus disease are some of the diseases that the international community has been dealing with. In our preparedness and response to these threats, the role of public health laboratories is crucial.

Within the WHO Eastern Mediterranean Region, there has been progress in strengthening laboratory capacity. 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 protocols. These enormous challenges are compounded by the fact that performance of laboratory services are not monitored at the national level and laboratories are not given due priority and recognition in national health systems.

In early October 2016, the 63rd session of the WHO Regional Committee for the Eastern Mediterranean endorsed the strategic framework for strengthening health laboratory services 2016–2020. The strategic framework will guide Member States in developing and improving sustainable national health laboratory systems. It will also provide regional and global partners with a guiding framework with which to align their financial and technical support for health laboratory services. Finally, it will serve as a blueprint for the monitoring and evaluation of progress towards strengthening health laboratory systems at the regional and country level.

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

Ala Alwan
WHO Regional Director for the
Eastern Mediterranean

Executive summary

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). Universal health coverage requires continuous strengthening and quality improvement to ensure equitable access to safe, secure, quality-assured and cost-effective laboratory services.

Within the WHO Eastern Mediterranean Region, despite steady progress towards strengthening laboratory capacity to support certain disease-specific programmes, substantial challenges remain. In particular, IHR requirements for laboratory core capacities have not yet been met in many Member States, and there are issues related to weak or non-existent regulatory frameworks for laboratory services, insufficient funding and inadequate access, quality of testing, equipment and supplies, and competence of the workforce. Laboratories are given low priority and recognition in most national health care systems. These challenges notwithstanding, demand for laboratory services continues to grow and is accompanied with overutilization of laboratory services placing an ever increasing burden of health care expenditure on national budgets.

The strategic framework for strengthening health laboratory services 2016–2020 has been developed to address these issues and improve the health status of the populations of Member States in the Region. The strategic framework is the culmination of extensive consultation with representatives of Member State governments, donors, development partners, laboratory practitioners and other stakeholders through peer review of draft strategy documents, meetings and working group discussions.

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, serves as a tool for coordination of national authorities, donors and development partners at the 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 for health laboratory services as an integral part of their portfolio.

The vision of the strategic framework is to ensure that within the 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. This vision will be achieved through six interrelated strategic goals:

- 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 laboratory referral networking (in-country and among countries) and enhance coordination; and
- promote rational and evidence-based use of laboratory services.

For each strategic goal, the strategic framework sets out a guiding rationale, objectives, proposed activities and expected outcomes that should help national health authorities to address gaps and challenges faced by their laboratory systems. The strategic framework also outlines the implementation process and principles for monitoring and evaluation.

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).

1. Introduction

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 clinical as well as public health settings. 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.

For the purposes of case management and disease control and prevention, laboratories can be grouped into two broad categories: clinical (or medical) laboratories and public health laboratories. Public health laboratories are responsible for providing results primarily for the purpose of disease control and prevention. At the same time, public health laboratories are often used for confirmation of clinical diagnosis of some infectious diseases (such as HIV) as they usually have access to more sophisticated equipment and advanced diagnostic techniques. Clinical laboratories, on the other hand, are responsible for providing results for diagnosis and case management of infectious and noncommunicable diseases. Even though clinical laboratories are mostly focused on individual patient care, they often serve as sentinel sites for surveillance and early detection of events of public health importance. Hence, data generated from both are essential in clinical as well as public health settings. Moreover, principles and approaches for achieving safety and quality of reported results are very similar for both categories of laboratories, and therefore their inclusion in the same strategic framework is justified.

The modern world continuously faces outbreaks of known and emerging diseases, such as poliomyelitis, meningitis, measles, influenza (H5N1, H1N1 and H7N9), dengue, chikungunya, Middle East respiratory syndrome coronavirus (MERS-CoV) and Ebola and Zika virus diseases that not only jeopardize national and regional economies but have the potential to become national security threats. Accidental or deliberate release of dangerous pathogens, such as anthrax, from unsafe or unsecured laboratories, can also be the origin of outbreaks.

Under the revised International Health Regulations (IHR 2005), countries have agreed, and are required to develop, the capacity to detect, investigate and report to the international community, through WHO, potential public health emergencies of international concern. This can only be achieved through a credible, reliable, accessible and sustainable laboratory service that is capable of early detection and

characterization of epidemic and pandemic-prone pathogens, safely containing and handling those pathogens, and producing high quality results in a timely manner.

Furthermore, achieving universal health coverage requires continuous strengthening and quality improvement to ensure equitable access to safe, secure, quality-assured and cost-effective laboratory services. This in turn requires strong political will and committed leadership, managerial skills, personnel awareness and buy-in at all levels of the laboratory system, building human and institutional capacity of laboratory organizations, and establishing and strengthening national regulatory frameworks for laboratory services, including national laboratory policies and strategic plans, national laboratory quality standards and, where appropriate and feasible, national legislations for laboratory licensing and accreditation.

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, have 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 national health agendas. As a result, such services suffer from inadequate financing, low attention paid to recruitment of human resources and training, and poor infrastructure.

These trends are accompanied by overutilization of laboratory services, with a large number of unnecessary and unjustified tests that further increase the burden of health care expenditure on national budgets. There is therefore an urgent need to rationalize the use of laboratory services in accordance with evidence-based principles of test ordering and test result interpretation.

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.

To provide Member States with guidance for improvement of their clinical and public health laboratory services, the strategic framework for strengthening health laboratory services 2016–2020 was developed. At the core of the strategic framework is nurturing countries' political will and leadership commitment, human and institutional capacity-building, and the development of national regulatory frameworks for laboratory services.

The strategic framework for strengthening health laboratory services 2016–2020 is the culmination of extensive consultations involving representatives of Member State governments, donors, development partners, laboratory staff and other stakeholders, through peer review of draft strategy documents, meetings and working group discussions. Following a review and analysis of the findings of a 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. Finally, in early October 2016, the 63rd session of the WHO Regional Committee for the Eastern Mediterranean endorsed the strategic framework for strengthening health laboratory services 2016–2020.

The strategic framework for strengthening health laboratory services 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.

2. Situation in the Region

The Eastern Mediterranean Region contains 22 countries with a population over 560 000 000 (ranging 850 000 to 177 000 000). Government annual expenditure on health, at an average exchange rate (US$), ranges from US$ 4 to US$ 1153 per capita. The adult literacy rate for both sexes in the Region is highly variable, ranging 25–96%. More than 55% of the world's refugees originate from the Region. Thirteen of the Region's 22 countries are currently experiencing complex humanitarian emergencies, affecting more than 40 million people, with massive damage to health systems and infrastructure and impeded access to basic public health functions and basic health services, and with substantial economic implications.

The Region is currently going through a period of rapid socioeconomic development, and demographic and epidemiological transition. Despite substantial improvement in the health status of some countries, significant disparities persist among countries. Within countries, inequities in health represent one of the most important challenges. General regional trends and challenges are reflected in the status of health laboratory services in Member States. In particular, laboratory diagnostic capacities are unevenly distributed, both on a population basis and among different sectors and units.

Additional challenges include: high rates of out-of-pocket payments in many low- and middle-income countries; lack of regulatory mechanisms for health services and practice in either the public or private sector; lack of evidence-based strategic health workforce planning with high attrition rates and related shortage of qualified health care personnel; and fragmented health information systems, with major gaps in reporting of cause-specific mortality and health facility records, conducting regular health surveys, and routine and other data collection activities. Lack of access to reliable health information makes it extremely difficult to develop, implement and evaluate national and sub-sectoral health policies and plans.

A situation analysis conducted recently in a number of countries identified serious gaps in areas such as organization and management of laboratory services, human resources management, document and record control, procurement and supply chain management, biorisk management, information systems, and laboratory monitoring and evaluation mechanisms. Laboratory services are given low priority in most countries and there is a lack of ownership by national authorities, leading to inadequate financing of laboratory services and low attention given to recruitment and training, procurement of supplies, maintenance of equipment and other

complex problems. Many countries in the Region do not have national laboratory policies and strategic plans. Laboratories in some countries still use expired reagents on a regular basis. Poorly structured laboratory information management systems are rarely, if ever, integrated with health information systems. Mechanisms for monitoring and evaluation of laboratory performance are poor or non-existent. In particular, no quality indicators are monitored and no internal audits are conducted in many countries, while poor internal quality control programmes and lack or partial coverage by external quality assessment schemes is common. Many countries have deficient, if any, arrangements for laboratory equipment maintenance, service and repair, and regional mechanisms for this do not exist. Quality system documentation, such as quality manuals, policies and standard operating procedures, where they exist, are rarely reviewed and updated. Inadequate infrastructure and poor compliance with biosafety and biosecurity requirements, especially in countries with ongoing war, conflict or civil unrest, lead to unacceptably high levels of biological risk.

Most countries have diagnostic facilities at their central public health laboratories, although some depend on laboratories outside ministries of health (such as teaching hospital laboratories) or abroad (regional reference laboratories or WHO collaborating centres). While this is acceptable in terms of IHR, individual countries may wish to achieve national laboratory excellence rather than remaining dependent on international service providers.

Within the Region, the oversight of health laboratories is often fragmented within the health system. Ineffective donor coordination, lack of robust national laboratory policies and strategic plans, and diversity of funding sources have contributed to the development of uncoordinated health laboratory services in many countries. Many disease-specific programmes have been very effective in developing their laboratory component. These initiatives should definitely continue, and national health authorities should feel encouraged to expand them in a more cross-cutting manner, while trying to avoid detriment to existing national laboratory systems.

3. Strategic framework for strengthening health laboratory services 2016–2020

Goal

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 concerns and other potential emergencies of public health concern.

Scope

The strategic framework recognizes that the development of laboratory systems is a long-term endeavour that requires the support of governments and multiple national and international stakeholders, including in-country stakeholders, multilateral agencies, donors, the private and public sectors, communities and others. The strategic framework is intended to provide guidance for Member States in setting priorities and formulating, implementing and evaluating national policies and strategic plans for their laboratory services. It proposes planning actions to help national health authorities address the gaps and challenges faced by their laboratory systems.

Intended audience

The strategic framework is designed to support and offer guidance to national health authorities and national health laboratory focal points in their efforts to strengthen laboratory systems, and to the wide-ranging and large number of national, regional and international organizations who are stakeholders in the process.

Vision

Within the Eastern Mediterranean Region, health laboratory services are comprehensive, well-coordinated, integrated and sustainable to obtain and report

safe, accurate and reliable test results in timely manner for use in clinical and public health settings.

Strategic goals and objectives

It is proposed to achieve the vision through the following six interrelated strategic goals and corresponding strategic objectives.

Strategic goal 1: Strengthen leadership and governance of the national laboratory systems

- Strategic objective 1.1: Strengthen national coordination and supervision of laboratory services.
- Strategic objective 1.2: Establish an independent intersectoral oversight mechanism for health laboratory services.
- Strategic objective 1.3: Conduct a situational analysis for laboratory service delivery in every country.
- Strategic objective 1.4: Build advocacy among senior management and administrators of the ministry of health for the importance of health laboratories in cohesive national health systems.
- Strategic objective 1.5: Develop and implement a national health laboratory policy and a national laboratory strategic plan.
- Strategic objective 1.6: Establish a legal and regulatory framework to support implementation of the national laboratory policy.
- Strategic objective 1.7: Create a national organizational structure for development of standards and guidelines and monitoring of their implementation.
- Strategic objective 1.8: Establish a monitoring and evaluation mechanism for performance of health laboratory services.

Strategic goal 2: Strengthen the organization and management of the national laboratory systems towards quality

- Strategic objective 2.1: Streamline the structure and functions of the national laboratory services within health system to meet country needs, especially public health needs.
- Strategic objective 2.2: Establish a quality management office and/or quality manager's/officer's position to oversee all quality-related activities.
- Strategic objective 2.3: Implement quality management system practices.
- Strategic objective 2.4: Ensure sustainable laboratory services through dedicated adequate government budget/funding.
- Strategic objective 2.5: Improve supply chain management, equipment procurement and maintenance processes.

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

- Strategic objective 3.1: 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.
- Strategic objective 3.2: Strengthen management of laboratory services.
- Strategic objective 3.3: Establish mechanisms for registration or licensing of all categories of laboratory workers, including those in private laboratories, based on mandatory minimum qualification requirements (standards).
- Strategic objective 3.4: Develop a system for attraction and retention of staff in laboratory services.
- Strategic objective 3.5: Ensure that pre-service education and training programmes teach knowledge and skills that meet the needs of country's laboratory services.
- Strategic objective 3.6: Develop a system for in-service continual professional development and competence building for all categories of laboratory workers, including private laboratories.

Strategic goal 4: Ensure safe and secure laboratory environments

- Strategic objective 4.1: Develop/improve national regulatory frameworks to systematically manage biorisk in laboratory settings.
- Strategic objective 4.2: 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.
- Strategic objective 4.3: Develop and use appropriate training/competence development programmes and associated materials to understand, adopt and implement biorisk management strategies.

Strategic goal 5: Promote effective, tiered and integrated laboratory referral networks (in-country and among countries) and enhance coordination

- Strategic objective 5.1: 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.
- Strategic objective 5.2: Improve cross-sectoral communication and coordination with national authorities for effective control of zoonotic diseases by using the "One Health" approach.
- Strategic objective 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.

- Strategic objective 5.4: Strengthen external partnerships for technical and financial assistance.

Strategic goal 6: Promote rational and evidence-based use of laboratory services

- Strategic objective 6.1: 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.
- Strategic objective 6.2: Build capacity of laboratory personnel to provide consultant advisory service and improve communication.

4. Rationale, objectives, activities and expected outcomes for each of the strategic goals

Strategic goal 1: Strengthen leadership and governance of the national laboratory systems

Rationale: Support to laboratories is often fragmented, scattered across vertical disease-specific control programmes or health care facility management programmes and suffers from lack of proper coordination. This results in duplication of effort (such as separate supervision visits or procurement systems), strengthening of certain type of laboratory to the detriment of others (for example, virology versus bacteriology laboratories) and poor financing of services. A national laboratory policy should address laboratory services in a holistic way as a complete cross-cutting system and should provide a vision of laboratory services that fully satisfy the health needs of the population. A strategic plan should be developed to implement the national policy and should identify ways of making the services operationally and financially sustainable. The strategic plan should serve as the basis for discussions between a country and its development partners interested in building laboratory capacity and in strengthening health systems capacity in general. The implementation of the policy's initiatives should be accompanied by monitoring and evaluation to demonstrate the value of the resource investment and to guide continual adjustment and improvement, with the ultimate goal of achieving better health outcomes for the population.

Strategic objectives	Activities	Outcomes
1.1 Strengthen national coordination and supervision of laboratory services	Engage WHO in advocacy to support establishment of the focal point for national laboratory services Determine the mechanism of the national health laboratory focal point, such as an individual, a unit, a standing committee, or other Develop generic (model) terms of reference for the national health laboratory focal point outlining scope of responsibility and authority; adjust terms of reference to the specific country context Establish a focal point at the ministerial level for national laboratory services	Governance of health laboratory services streamlined under unified clear leadership Improved advocacy and liaison for laboratory services within the ministry of health Intersectoral dialogue between health laboratory services and other relevant services and stakeholders established and coordinated Process for development and implementation of the national regulatory framework for laboratory services properly coordinated

Strategic objectives	Activities	Outcomes
1.2 Establish an independent intersectoral oversight mechanism for health laboratory services	Define the oversight mechanism to best suit specific country context and needs, such as oversight or advisory body, intersectoral organizational committee or other Define membership and representation level of oversight mechanism Develop terms of reference for oversight mechanisms	National health authorities independent review of and advice on various aspects of laboratory services structure, operations and regulation conducted
1.3 Conduct a situational analysis for laboratory service delivery in every country	Conduct a thorough assessment of the current laboratory system and key individual laboratories, where feasible, in the form of a SWOT (strengths, weaknesses, opportunities, and threats) analysis Communicate the results of the assessment to all relevant stakeholders	Gaps, weaknesses and needs of the current laboratory system identified Stakeholder awareness of laboratory services needs enhanced (stakeholders sensitized)
1.4 Build advocacy among senior management and administrators of the ministry of health for the importance of health laboratories in cohesive national health systems	Establishment of national laboratory committee in the country, chaired by minister and with involvement of relevant stakeholders Laboratory-related items included in the agenda of ministerial meetings Develop and distribute advocacy materials, including printed and multi-media materials	Policy dialogue with the national health authorities regarding the role and needs of national laboratory services established Participation of relevant stakeholders in the advocacy for national health laboratory services ensured Commitment of senior management to laboratory quality obtained Support for the strengthening of national health laboratory services mobilized
1.5 Develop and implement a national health laboratory policy and a national laboratory strategic plan	WHO to provide guiding documents, tools and technical support to assist Member States in development and implementation of national laboratory policies and strategic plans Member States to develop and officially endorse/enact their national laboratory policies and strategic plans through: establishment of a national laboratory working group or an equivalent policy development mechanism; conducting an appropriate consultative process and consensus building with relevant stakeholders; and endorsement/enactment of policy/plan document through appropriate country mechanisms/channels	National commitment to providing comprehensive and quality laboratory services clearly articulated Vision, mission, guiding principles, values, goals and objectives of the national health laboratory services defined Evidence-based resource allocation mechanisms for laboratory services established for the medium- and longer-term
1.6 Establish a legal and regulatory framework to support implementation of the national laboratory policy	Develop/update and enforce national legislation and regulations on: diagnostic capacity, including reference laboratories for priority diseases; notifiable diseases and mechanisms for reporting; registration or licensing of health laboratory personnel; licensing and (where feasible) certification and accreditation of health laboratories; and professional code of ethics	Effective legal and regulatory framework in place to ensure access to quality laboratory services Regulatory mechanisms in place for continuous monitoring of performance of health laboratories
1.7 Create a national organizational structure for development of standards and guidelines and monitoring of their implementation	Establish or designate a national body responsible for development of national laboratory standards of best practices, including testing standards and guidelines on quality management, testing strategies and external quality assessments Develop national laboratory quality and testing standards and guidelines	Standards and guideline development bodies in place to nationally recognize best practices, standards and guidelines National quality and testing standards developed and implemented

Strategic objectives	Activities	Outcomes
1.8 Establish a monitoring and evaluation mechanism for performance of health laboratory services	Develop and implement national quality standards for health laboratories Develop and update quality system documentation, including quality manuals and standard operating procedures, along with procedures for document and record control Develop and implement quality indicator measurement programmes to continuously monitor performance of laboratory services Conduct regular internal and (where feasible) external assessments to evaluate overall performance of laboratory services Analyse and use the data generated by monitoring and evaluation activities for decision-making to continuously improve the quality of health laboratory services Communicate or make available the results of monitoring and evaluation activities to all users of health laboratory services	Performance of health laboratory services properly documented and continuously monitored to identify opportunities for improvement Evidence-based decision-making is facilitated by the availability of data Continual improvement process for health laboratory services in place

Strategic goal 2: Strengthen the organization and management of the national laboratory systems towards quality

Rationale: The laboratory should be organized and managed in such a way as to create conditions conducive to the establishment and maintenance of a quality management system. Implementation of a quality management system addressing pre-analytical (e.g. specimen collection and transport), analytical (i.e. specimen processing and testing) and post-analytical (result reporting and interpretation) stages have a direct impact on the reliability of laboratory results and the contribution of the laboratory to national public health goals. Stepwise implementation of laboratory quality management systems was one of the main recommendations made at the joint WHO-CDC conference on health laboratory quality systems, held in Lyon, France on 9–11 April 2008, and also at the regional workshop on strengthening health laboratory quality systems held in Amman, Jordan on 7–9 October 2012. Countries were urged to implement laboratory quality standards in a stepwise manner, with accreditation to internationally recognized standards, such as the International Organisation for Standardization's standard ISO 15189 on medical laboratories' requirements for quality and competence, as the ultimate goal for those laboratories with sufficient resources.

Strategic objectives	Activities	Outcomes
2.1 Streamline the structure and functions of the national laboratory services within the health system to meet country needs, especially public health needs	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	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
2.2 Establish a quality management office and/or quality manager's/officer's position to oversee all quality-related activities	Establish composition and develop terms of reference of the quality management office Create position description for quality manager/officer and promote recruitment of quality officers in laboratories Determine appropriate staffing	Quality management offices established and available to institutions Quality officers available in laboratories
2.3 Implement quality management system (QMS) at targeted sites	Perform baseline QMS assessments at targeted laboratories using standardized structured tools Provide training in QMS to selected staff at targeted sites Conduct supervisory coaching and mentorships in QMS at targeted laboratories Train selected staff to become QMS trainers and created national and regional pools of trainers Cascade QMS training to all categories of laboratory worker using regional and/or national pool of QMS trainers Establish mechanism for continuing development of laboratory management in advanced QMS topics Conduct ongoing monitoring and evaluation of QMS implementation	Continuing quality improvement process in place QMS implementation continually monitored and evaluated Regional and national pools of QMS trainers established
2.4 Ensure sustainable laboratory services through dedicated adequate government budget/funding	Ensure laboratory services form part of the ministry of health's national health budget and support referral networks, surveillance and response capacities Develop a business case model for laboratory funding that incorporates costs for meeting national laboratory priorities, supports tiered services and ensures successful stepwise implementation of changes	Public health laboratory activities are funded in an adequate and sustainable manner Technology improvement and access to appropriate technologies ensured
2.5 Improve supply chain management, equipment procurement and maintenance processes	Implement WHO pre-qualification of diagnostic kits/regulation of diagnostics Establish a standardized process for acquisition of equipment, validated reagents and supplies that incorporates specifications of need and quality Assure proper importation and storage and adequate distribution of diagnostic materials 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 Identify ownership and responsibilities for equipment selection, purchase and maintenance Strengthen regional capacity for equipment maintenance and repair	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: Establish sustainable, sufficient and competent human resources for laboratory service delivery

Rationale: The laboratory workforce consists of a wide range of positions with equally wide skillset requirements ranging from the laboratory director or manager to administrative staff and various technical positions to auxiliary/support positions. Laboratory workforce needs and expected skills mix are often poorly assessed compared to other medical professions. There are considerable differences among countries in terms of the training and competence of the health laboratory workforce. A commonly-identified training gap is a lack of leadership and management skills among laboratory directors and managers that can have a significant impact on the efficiency of the operations of the laboratory. Adequate numbers of appropriately qualified and motivated staff are an essential component of a laboratory service, but many countries are facing significant challenges in preparing, recruiting, training and retaining competent and sufficient staff.

Strategic objectives	Activities	Outcomes
3.1 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	Review existing best practices and procedures in human resources management 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 Assess existing capacity against needs through skill needs analysis Prepare a staff recruitment plan Promote and support local recruitment	More effective and efficient personnel management Improved staff competency Improved needs assessment and matching
3.2 Strengthen management of laboratory services	Identify appropriate roles and responsibilities of management in relation to laboratory services Identify specific needs in management (gap analysis) Identify available resources and programmes for building managerial capacity for laboratory services	Improved effective and efficient management of laboratory services
3.3 Establish mechanisms for registration or licensing of all categories of laboratory workers, including those in private laboratories, based on mandatory minimum qualification requirements (standards)	Review/improve/define minimum qualification standards/requirements Establish procedures for periodic registration and/or licensing of laboratory workers Require minimal qualifications for all categories of laboratory worker as a condition of employment as well as for licensing, certification or accreditation of laboratories in all sectors, including for private laboratories Promote elevation of the position of laboratory staff to their appropriate place in the public health system	All laboratories are operated by registered/licensed personnel fully qualified for their jobs
3.4 Develop a system for attraction and retention of staff in laboratory services	Set up a clear career structure with visible possibilities for career advancement based on training, experience and performance Establish a staff performance monitoring system, including annual performance appraisal and ongoing competency	Improved staff motivation and career plans Improved staff retention and morale

Strategic objectives	Activities	Outcomes
	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	Improved staff competency
3.5 Ensure that pre-service education and training programmes teach knowledge and skills that meet the needs of country's laboratory services	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 inter-ministerial agreements where appropriate Evaluate existing educational curricula, programmes and courses in laboratory sciences, technology and medicine to align them with pre-service training/recruitment criteria	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 worker, including private laboratories	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 Develop technical guidance for training curricula Establish individual continuing professional development plans for all staff Resources and capacity permitting, consider formalizing continuing professional development programmes, requiring a minimum amount of training every year and linked to promotion/career advancement Design processes and tools for the monitoring of training outcomes and impact	Improved quality of in-service training and relevance to laboratory services being provided Improved staff competency

Strategic goal 4: Ensure safe and secure laboratory environment

Rationale: The new field of biorisk management is progressing rapidly and providing new insights and understanding to the laboratory community in terms of containment, biosafety and biosecurity. Several biorisk management training opportunities for trainers in the Region have started a cascade of national training activities with the goal of raising awareness on the need to carry out laboratory biorisk assessments to ensure appropriate local biorisk mitigation measures are implemented, regularly revised and improved. While these training activities are maintained and expanded, effective regulatory and oversight mechanisms to further encourage the implementation of biorisk management systems still need to be introduced. Basic information relating to laboratory design and operating parameters is often confusing, with a lack of evidence to underpin many commonly-used controls, and developing countries in particular often struggle to implement solutions that have been designed for use in other parts of the world where different working conditions prevail. A better understanding of the issues will allow more stakeholders to contribute to the development and further improvement of regulatory requirements. As a consequence of increased knowledge and understanding, an increasing number of adequate support services to operate

laboratories will develop, and effective supplier networks, maintenance provision capacity and other basic measures that are currently unavailable to those most in need will be strengthened.

Strategic objectives	Activities	Outcomes
4.1 Develop/improve national regulatory frameworks to systematically manage biorisk in laboratory settings	Ensure national laboratory policy and national laboratory strategic plan address need for biorisk management Review/develop national policies and procedures/guidelines and update/establish biorisk management regulation accordingly, drawing on the expertise of institutional biosafety initiatives Establish and endorse biorisk management body, complete with appropriate terms of reference and distribution of responsibilities Establish standardized laboratory biorisk manager position, complete with appropriate position description	National biorisk management policies and procedures/guidelines established and/or updated Biorisk management systems are in place including biorisk management bodies and biorisk manager/officer positions Improved national regulatory frameworks for the implementation of biorisk management approaches
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	Ensure adequate physical infrastructure is in place and maintained Develop systems and procedures for, and systematically conduct, risk assessment, risk mitigation and biorisk management performance evaluation activities at each facility level Establish systems and procedures for transporting biological specimens and infectious substances at different levels Establish a system of inventory of infectious agents and substances categorized according to country	Laboratory physical infrastructure is adequate to minimize biorisk Processes and procedures for risk assessment and risk minimization are improved and systematically implemented Infectious substances are transported safely
4.3 Develop and use appropriate training/competence development programmes and associated materials to understand, adopt and implement biorisk management strategies	Ensure biorisk management principles addressed in pre- and in-service training for laboratory workers Assess competence development needs across the entire spectrum of roles and responsibilities relating to biorisk management (such as regulators, assessors, managers, scientists, students, support staff, first responders and the general public) Meet competence development needs through the provision of appropriate trainings, continuing professional development materials, tools and communication channels Transfer the required knowledge and skills to ensure competence development and local capacity-building; Support development of capacity and capability through local, regional and global knowledge sharing and networking in the area of biorisk management Define, recognize and value biorisk management duties in job descriptions Develop advocacy and awareness programmes for all personnel at all service levels, as well as all concerned stakeholders	Biorisk management education/awareness raised Staff at various service levels has necessary competences to address and mitigate biorisks

Strategic goal 5: Promote effective, tiered and integrated laboratory referral networks (in-country and among countries) and enhance coordination

Rationale: Effective networking is important for laboratories in developing countries with limited resources. Laboratory networks exist as a platform for sharing information and expertise and as a system for sharing clinical specimens and other biological material for testing. In addition, effective links between laboratories and surveillance and response systems are vital for the timely transfer of the accurate and consistent information needed for an appropriate public health response. Networking between the public health, veterinary, food safety and environmental laboratory sectors will also play an important role in the timely detection of outbreaks and emerging pathogens. However, while international networks are established to identify specific diseases (for example, poliovirus, influenza), more efforts are needed to strengthen subnational networks that should be flexible enough to cope with the emergence of novel pathogens and link with international networks, as needed.

Strategic objectives	Activities	Outcomes
5.1 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	Map existing laboratory assets and capacities at national level, including linkages between laboratories and structures of existing networks Establish tiered, integrated national networks, with clear and detailed roles and responsibilities at each level of the network and effective referral and reporting mechanisms, with a particular emphasis on the importance of a regulated and functional/modernized/systematized specimen transportation system 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 (LIMS) within laboratories and improve communications across laboratories and surveillance systems Promote functional integration between laboratories of the network through use of modern information technologies Make use of successful networks for other activities	Improved quantity and quality of resources available to strengthen public health laboratory networks in resource-limited countries Strengthened and functional existing networks Improved diagnostic capacity
5.2 Improve cross-sectoral communication and coordination with national authorities for effective control of zoonotic diseases by using the “One Health” approach	Communicate, coordinate and cooperate with relevant ministries and other governmental bodies responsible for zoonoses	Improved cross-sectoral communication and coordination for zoonoses

Strategic objectives	Activities	Outcomes
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	Identify testing capacities at regional and global level Establish regional referral systems Develop streamlined regulatory process for material transfer Promote technology transfer Facilitate access to reagents and testing protocols Support specimen-sharing across networks, through pre-agreed memorandums of understanding (MoUs) Explore establishment of a regional network for diseases not covered by existing networks	Strengthened regional and global networks Reliable and timely results available
5.4 Strengthen external partnerships for technical and financial assistance	Identify needs and gaps within the national laboratory system and map capacities and contributions of existing partners at national, regional and global levels Identify potential partnerships and stakeholders to address gaps in: workforce development; supply chain management; specimen management and transport; diagnostic technologies including commercial IVD testing; and referral and reference networks, and quality management including proficiency testing programmes. Engage laboratory directors in all aspects of planning and implementation (total process) Wherever feasible, formalize collaboration between partners and the participating laboratories through MoUs or equivalent documents, to assure mutual understanding and stability Identify twinning partners (such as national and state laboratories, universities) and develop twinning mechanisms Ensure coordination of partners by the ministry of health/WHO, promote information-sharing for transparency and mutual trust	Partners facilitate work of the public health laboratories

Strategic goal 6: Promote rational and evidence-based use of laboratory services

Rationale: While use of laboratory services has been increasing steadily over recent years, patient outcomes are not improving at a similar pace. Studies show that the test selection and ordering behaviour of physicians varies widely for seemingly similar indications. This may be explained by several factors, including physician inability to estimate test performance characteristics, inaccurate interpretation of test results, and lack or inadequacy of advisory services from the laboratory to help physicians with evidence-based test ordering and results interpretation. Both overutilization and underutilization can jeopardize equity of, and access to, laboratory services and have negative impact on the health status of the population and finances of the health system. The rational use of laboratory services depends on both health care providers and laboratory personnel. It can be achieved by improving health care providers' understanding of laboratory services and improving their communication with laboratory services, including provision of timely and competent advice by laboratory staff on test selection and result

interpretation. Laboratory staff should have adequate capacity for provision of consultant advisory services to clinicians.

Strategic objectives	Activities	Outcomes
6.1 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	Identify and assess clinician's practices and experiences in using laboratory services, their perception of laboratory quality and knowledge of laboratory examinations-related concepts 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 performance characteristics of laboratory examinations and evidence-based test selection and interpretation of test results Review/revise clinical practice guidelines to include appropriate use of laboratory services	Health care providers have a good understanding of laboratory services and adequate knowledge of evidence-based principles of laboratory test ordering and results interpretation Improved equity and access to laboratory services Improved cost-efficiency of laboratory services Improved patient outcomes
6.2 Build capacity of laboratory personnel to provide consultant advisory service and improve communication	Assess capacity of laboratory personnel to provide consultant advisory services and address gaps identified through continuing a professional development process Conduct regular joint meetings and clinical audits with clinicians to discuss issues related to 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	Laboratory personnel has 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

5. Implementation of the strategic framework

The strategic framework will be implemented through a multi-faceted approach combining complementary regional and country-level activities, and through cooperation between Member States, WHO, other United Nations agencies, donors and development partners. The activities implemented should be consistent with the strategic framework, relevant WHO regional and global strategies, internationally recognized laboratory standards and good laboratory practices. The objectives and proposed interventions of externally funded projects should be consistent with the activities and outputs outlined in the strategic framework. Activities conducted under the strategic framework range from the development of national level policies and strategic plans, guidelines, tools and training materials to their adaptation and implementation at country and institutional level. Synergies and leverage will be sought between donors and development partners to optimize implementation of these activities. The engagement and commitment of national authorities will be key.

The establishment of national strategies will promote a structured approach to capacity-building. Clear timelines and progress indicators should be used to monitor implementation of workplans and the progress of national capacity-building towards IHR (2005) compliance, where appropriate. Country workplans will enable countries to assess their own progress and identify needs and opportunities; an approach that may be particularly useful to facilitate donor coordination for resource-limited countries.

A number of indicators will be identified and monitored at the regional and country level. These indicators will be selected from the IHR core capacity monitoring framework for monitoring progress in the implementation of IHR core capacities in State Parties, supplemented, where needed, by indicators established for areas requiring specific consideration. Countries may also wish to consider referring to these indicators as the basis for a national tool to monitor capacity-building. Whenever possible, monitoring and evaluation indicators from relevant existing programmes will be utilized to reduce the burden of data collection.

Annex 1. Resolution EM/RC63/R.4

REGIONAL COMMITTEE FOR THE EASTERN MEDITERRANEAN

EM/RC63/R4
October 2016

Sixty-third Session

Strategic framework for strengthening health laboratory services 2016–2020

The Regional Committee,

Having discussed the technical paper on the strategic framework for strengthening health laboratory services 2016–2020;

Recalling resolutions EM/RC61/R.2 on global health security and EM/RC59/R.3 on health systems strengthening;

Acknowledging the essential role of health laboratory services in improving health outcomes, achieving universal health coverage and ensuring global health security and the need to improve access to and strengthen national laboratory capacity to generate safe and quality assured results for both clinical and public health use;

Recognizing that the strengthening of health laboratory services is an important component of both the International Health Regulations (2005) and the Global Action Plan on Antimicrobial Resistance;

Recognizing also the importance of intersectoral and cross-country collaboration to support the strengthening of health laboratory services;

1. **ENDORSES** the strategic framework for strengthening health laboratory services 2016-2020 and its framework for action (annexed to this resolution);

2. **URGES** Member States to:

    2.1 Take the necessary steps to strengthen health laboratory services, with particular emphasis on public health laboratories, based on the strategic framework, adapted to national priorities, regulations and specific contexts;

2.2 Develop or further strengthen national laboratory policies and strategic plans, based on situation analysis and aligned with national health policy and planning;

2.3 Ensure provision of adequate financial, human, infrastructure and technical resources for implementation of the national laboratory policies and strategic plans;

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

3. **REQUESTS** the Regional Director to:

3.1 Provide support to Member States in strengthening their health laboratory services based on the strategic framework, with particular emphasis on public health laboratories;

3.2 Encourage national and international partners to support Member States in the implementation of the strategic framework;

3.3 Report on progress in the implementation of the strategic framework to the 65th and 67th sessions of the Regional Committee.

Annex to resolution EM/RC63/R4

Framework for action on strengthening health laboratory services 2016–2020

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

Priority interventions	Action by countries	Progress indicator
Ensure safe and secure laboratory environments	Develop/improve national regulatory frameworks to systematically manage biorisk in laboratory settings 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 Develop and use appropriate training/competence development programmes and associated materials to understand, adopt and implement biorisk management strategies	National biorisk management policies and procedures/ guidelines established and/or updated Biorisk management systems are in place including biorisk management bodies and biorisk manager/officer positions Improved national regulatory frameworks for the implementation of biorisk management approaches Processes and procedures for risk assessment and risk minimization are improved and systematically implemented Infectious substances are transported safely Staff at various service levels has necessary competences to address and mitigate biorisks
Promote effective, tiered and integrated laboratory referral networks (in-country and among countries) and enhance coordination	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 Improve cross-sectoral communication and coordination with national authorities for effective control of zoonotic diseases by using the “One Health” approach 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 Strengthen external partnerships for technical and financial assistance	Improved quantity and quality of resources available to strengthen public health laboratory networks in resource-limited countries Strengthened and functional existing networks Improved cross-sectoral communication and coordination for zoonoses Partners facilitate the work of the public health laboratories
Promote rational and evidence-based use of laboratory services	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 Build capacity of laboratory personnel to provide consultant advisory service and improve communication	Health care providers have a good understanding of laboratory services and adequate knowledge of evidence-based principles of laboratory test ordering and results interpretation Improved equity and access to laboratory services Improved communication between laboratory services and other health care providers

The strategic framework for strengthening health laboratory services 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.