

Progress report on the strategic framework for strengthening health laboratory services 2016–2020

Introduction

1. In October 2016, the 63rd session of the Regional Committee adopted resolution EM/RC63/R.4, endorsing the strategic framework for strengthening health laboratory services 2016–2020 as a tool to help countries meet laboratory core capacity obligations under the International Health Regulations (IHR) (2005). The framework recognizes the critical role of health laboratories in patient diagnosis and treatment, and surveillance of and response to infectious diseases. The Committee urged Member States to adapt the framework to their specific situation, and requested WHO and partners to support countries in implementation.

2. In 2020, the COVID-19 pandemic has highlighted the critical role of health laboratories in public health as well as in infectious disease surveillance and control.¹ The pandemic is a real-life check on laboratory services and demonstrates that national health laboratory systems need to be capable of rapidly scaling up testing during outbreaks. The six strategic goals of the framework (i.e. regulatory frameworks, quality, workforce, biosafety and biosecurity, networking, and rational use of laboratory services) guide the establishment of laboratory systems that can achieve this objective.

3. In 2018, the 65th session of the Regional Committee reviewed progress in implementing the strategic framework for strengthening laboratory services (EM/RC65/INF.DOC.4). Progress was reported in the areas of laboratory quality and biosafety, and new initiatives related to laboratory workforce and laboratory surveillance for antimicrobial resistance were presented. However, the report stressed that development of national laboratory policies needed to be re-emphasized. This updated report summarizes the further progress made by WHO and Member States since the 65th session of the Regional Committee, including challenges and the way forward.

Progress update

4. National laboratory policies guide the establishment and strengthening of national laboratory services. A national laboratory policy signals political commitment to address priority areas and optimize the use of resources. From 2016 to 2020, the number of countries in the Region that officially endorsed national policies increased from two to eight. Morocco is in the final stage of policy development and the process is due to start in Iraq and Tunisia; however, these three countries are facing delays because of the COVID-19 pandemic. More Member States in the Region should be aiming to strengthen their laboratory system leadership and governance through national laboratory policies.

5. External quality assessment (EQA) independently ensures that a laboratory is providing quality testing. Laboratories in the Region have participated in global EQA programmes for vaccine-preventable and emerging infectious diseases including influenza, arboviral diseases and COVID-19. For example, 13 national laboratories in 11 countries participated in WHO's 2018 EQA for arboviral diagnostics and reported scores of 77% or higher.² WHO has evaluated its regional EQA scheme in microbiology, which is coordinated by laboratories in the Islamic Republic of Iran and Oman. The EQA has been running since 2005, with scores of 80% or higher for 75% of the 36 laboratories registered across 20 countries. The evaluation indicated corrective actions that would further strengthen the programme, including establishing a technical advisory

¹ Konings F, Barakat A, Hutin Y, Hajjeh R. COVID-19 highlights the need for a strong health laboratories foundation for infectious disease surveillance and control in the Eastern Mediterranean Region. *East Mediterr Health J.* 2020;26(6):633-5.

² Squires RC, Oxenford CJ, Cognat S, Konings F. Performance of Eastern Mediterranean Region laboratories in the World Health Organization external quality assessment programme for arbovirus diagnostics. *East Mediterr Health J.* 2020;26(5):616–9.

committee to improve governance, communication with stakeholders, data management and tracking. WHO has supported evaluations of national EQA programmes in Jordan and Pakistan which generated similar findings. WHO is taking steps to align these EQAs with the objectives of the Global Antimicrobial Surveillance System (GLASS).

6. Simulation exercises are a key voluntary instrument in the validation of IHR (2005) core capacities. In 2019, WHO, the United States Centers for Disease Control and Prevention and the Pakistan National Institute of Health jointly organized a two-day national exercise to assess the performance of Pakistan's public health laboratory system during a simulated viral haemorrhagic fever outbreak. Almost 60 participants from six provinces tested existing plans through a table-top and laboratory performance skill drill exercise. The exercise indicated that mitigation plans were in place to detect outbreaks and to collect and transport specimens, but that areas for improvement remained. This was the first such large-scale laboratory exercise in the Region, setting the stage for its reproduction in other countries.

7. WHO and partners are developing the Global Laboratory Leadership Programme (GLLP), which will help countries work towards sustainable, sufficient and competent human resources for laboratory services. The GLLP consists of a mix of face-to-face and on-the-job assignments, with a concluding project under the guidance of a mentor. WHO and partners proposed Pakistan for the first in-country validation of the GLLP, in three phases, in line with their national laboratory policy. Phase 1 ended in October 2019 and focused on leadership and communication competencies with participants from both human and animal health sectors (a One Health approach). The summative evaluation based on pre- and post-examinations indicated a 41% increase in knowledge among participants, while formative evaluation on different indicators was satisfactory. Phase 2 is scheduled for 2020, initially through remote sessions.

8. Joint external evaluations are a voluntary, multisectoral activity to assess progress towards IHR (2005) core capacity targets. Member States consistently scored poorly in biosafety and biosecurity, highlighting the need for more investment in these laboratory areas. Most countries in the Region face an ongoing challenge in regular certification of their biological safety cabinets. WHO now has two trainers to support the Region with certification of shippers of infectious substances, which can improve safe referral and transport of specimens by air.

9. In 2019, WHO continued its ongoing mapping of laboratory capacities to support antimicrobial resistance detection in national reference laboratories (NRLs) in Bahrain, Egypt and the Islamic Republic of Iran. NRLs in Jordan, Pakistan, Sudan and Tunisia have already been assessed. WHO provided technical support for implementation of laboratory quality management systems in Jordan, Pakistan and Tunisia. In addition, in Jordan, WHO worked with donors and WHO collaborating centres to provide additional on-site training to strengthen the national EQA programme in bacteriology of the NRL. WHO also developed and adapted guidance on terms of reference, specimen retesting in EQA and detection of emerging resistance, to assist NRLs in Member States to carry out their designated functions and activities.

10. The Region is in dire need of regional reference laboratories and centres for excellence. In February 2019, WHO designated the Department of Experimental Pathology, Immunology and Microbiology and the Center for Infectious Diseases Research, Faculty of Medicine, American University of Beirut, as a WHO collaborating centre for reference and research on bacterial pathogens. The WHO Secretariat would encourage other laboratories with expertise that could benefit others to apply to become a WHO collaborating centre.

Challenges

11. Despite notable progress in the past two years, some challenges remain in implementation of the strategic framework:

- there is insufficient recognition of the importance of health laboratory services, with 14 countries in the Region still lacking a national laboratory policy;
- technical and operational challenges in generating and maintaining regional expertise in biological safety cabinet certification and shipping infectious substances must be addressed to support biosafety and specimen referral;

- the number of WHO collaborating centres and reference laboratories in the Region should be increased to support a variety of laboratory-related areas and activities;
- emergencies such as COVID-19 highlight the need to build resilient and flexible laboratory systems that can adapt to surge situations and scale up capacities in emergencies, while still meeting population health needs and infectious disease surveillance and control functions during normal times.

The way forward

12. Member States, with support from WHO and partners, should continue to implement the strategic framework to meet IHR (2005) core capacities, supported by the Global Health Security Agenda. Outcomes of laboratory-related assessments including joint external evaluations, after-action reviews and simulation exercises need to be incorporated in national action plans for health security. This requires ongoing advocacy, commitment, resources and efforts from all stakeholders.

13. Although progress has been made, 2020 is the final year of the strategy and the five-year time frame may have been too ambitious for its full implementation. In particular, normative work such as developing national policies and implementing quality systems requires long-term commitment and investment. Furthermore, COVID-19 threatens a whole year's worth of work, draining country resources and hampering trainings, travel for on-site workshops and other technical support. An extension of the timeline for the strategy with an additional three years and its alignment with national action plans for health security should be considered.

14. The WHO Secretariat, international partners and national counterparts need to complete in-country validation of the GLLP and adapt the associated learning package to countries in the Region in order to contribute to strengthening the laboratory workforce at national and subnational levels.

15. Each large-scale public health emergency underlines the importance of laboratories, but attention quickly wanes when the crisis is over. COVID-19 is an unprecedented opportunity to convey that successful response depends on investment in laboratory systems and preparedness beyond the stop-gap measures that characterize emergencies, such as procurement of test kits. Strong policies need to build systems that will have the flexibility and resilience to meet future challenges. These should connect national laboratory networks with epidemiological surveillance sites using integrated information systems. Including a laboratory diagnosis component that takes this comprehensive perspective as part of the evaluation of countries' response to COVID-19 will ensure that this aspect receives the attention it requires.