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Commentary

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The coronavirus disease 2019 (COVID-19) pandemic has pushed the public health laboratory to the forefront of

epidemic preparedness and has highlighted the critical role of these laboratories for a robust and timely response. Enormous pressures have been imposed on the laboratories over the last few months to keep up with the increasing demands of testing and “PCR test” (polymerase

chain reaction test) has become a common household term. Public health authorities have been pushing for years about the importance of the laboratory, and the need for governments to devote more attention to develop a strong laboratory foundation and networks in the Region.

Laboratories are the nexus of all infectious disease diagnosis and management as well as public health response, ranging from diseases such as HIV/AIDS, tuberculosis and malaria, to emerging infectious diseases such as cholera, Middle East respiratory syndrome and diphtheria. Recently, the microbiology laboratory was also recognized as a pillar of major global initiatives such as control of antimicrobial resistance (AMR). Furthermore, the revised International Health Regulations (IHR, 2005) require countries to be able to identify, investigate and report potential public health emergencies of international concern (PHEICs) (1). A well-governed and organized nationwide health laboratory system serves as a foundation for safe, reliable and timely detection, confirmation and reporting of public health events.

In late 2019, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) causing COVID-19 emerged in Wuhan, China. On 30 January 2020, the Director-General of the World Health Organization declared the outbreak a PHEIC and on 11 March a pandemic (2). Globally, the number of confirmed cases is in the millions with large numbers of deaths. The Eastern Mediterranean Region has been heavily affected with the majority of cases and deaths in the Islamic Republic of Iran (3). This novel virus required new diagnostic tests to be developed, validated and made widely available quickly. International shortages of laboratory supplies along with questions about who and how to test are additional challenges discussed even in the mass media. COVID-19 is a real-life check of our laboratory systems that underlines the essential role of laboratories in public health.

The Eastern Mediterranean Region consists of 21 countries and the Occupied Palestinian Territories. The Region is diverse in terms of geography, culture, income, education, political stability and health system development. This diversity is reflected in the countries' laboratory systems which range from basic to advanced. Countries experiencing protracted emergencies face additional difficulties due to loss of infrastructure and resources while embargoes complicate international procurement and specimen referral of select countries.

As an important component of the IHR (2005) monitoring and evaluation framework (4), the joint external evaluation (JEE) provides peer-to-peer expert external evaluations of IHR capacities, including for laboratories. A 2018 analysis of 14 JEEs completed in the Region indicated intermediate to high mean scores for their national laboratory systems (5). Biosafety and biosecurity as well as laboratory quality systems had low and intermediate mean scores, respectively, highlighting the need for more investments in these areas. For example, most of

the countries are facing an ongoing challenge in validating their Class 2 Biosafety Cabinets (BSC Class II) and are struggling with the implementation of laboratory quality management systems. The sparsity of national laboratory policies is another challenge: in 2020, only eight countries in the Region have developed such policy. Bacteriology laboratory capacities in the Region are especially poor, negatively impacting AMR surveillance and response efforts. Overall, there are not enough sufficiently trained human resources for the laboratory. Those who want to become laboratory leaders have very limited educational options. Countries struggle to navigate the abundance of new laboratory technologies on the market. Finally, there is a lack of reference laboratories that are based in and support the Region.

Interactions between laboratories in the Region and globally are crucial for infectious disease surveillance and control. Disease-specific laboratory networks, especially the global influenza surveillance and response system, have facilitated establishing laboratory capacities for the detection of several epidemic diseases (6), including COVID-19. The optimal performance of such disease-specific networks requires a well-established nationwide health laboratory system capable that can scale up rapidly the testing during outbreaks. While much attention has been paid to national-level laboratories, there is a lack of decentralization of supporting laboratory infrastructure at the sub-national level.

For the laboratory foundation to be developed, it is not enough to focus only on the physical structure of the laboratory, equipment and technical capacity. A comprehensive strategy to build a solid system with adequate governance, financial and human resources, as well as strong evaluation and monitoring systems ensures quality and safe services. In October 2016, the 63rd session of the Regional Committee for the Eastern Mediterranean Region endorsed the Strategic Framework for Strengthening Health Laboratory Services, 2016–2020 (resolution EM/RC63/R.4) (7). The strategic framework helps address the challenges in the Region through its six strategic goals that emphasize regulatory frameworks, quality, workforce, biosafety and biosecurity, networking and rational use of laboratory services. 2020 will be the final year of the strategy and while progress has been made, such as increasing the number of laboratory policies from two to eight, the five-year time frame may have been too ambitious to fully implement it. In particular, the normative work, such as policies and implementing quality systems, requires long-term commitment and investment because there is no ‘quick fix’. An extension of timeline and alignment with national action plans for health security (NAPHS) may accelerate implementation of IHR core capacities.

Improving our national health laboratory systems takes time, effort, dedication, perseverance and adequate funding, but we will be able to reap the benefits during emergencies such as the COVID-19 outbreak. Below are the six goals of the Strategic Framework for Strengthening Health Laboratory Services and their current priorities:

Regulatory frameworks

The development of a national laboratory policy is a step towards strengthening a country's laboratory services, including for COVID-19. It offers a long-term vision, signals political commitment, empowers the government, and can be used to advocate for funding (8).

Quality

Managing the COVID-19 pandemic requires reliable test results. Implementation of laboratory quality management system (LQMS) and, where possible, work

towards accreditation to ensure that quality is the cornerstone of any laboratory aiming for accuracy in all tests it performs.

Workforce

Laboratory workers are at the heart of COVID-19 testing. Increasing the attractiveness of a career in health laboratories stimulates the recruitment and retention of the best staff. The Global Laboratory Leadership Programme will give more attention to the next generation of laboratory leaders (9).

Biosafety and biosecurity

A practical, risk- and evidence-based approach to biosafety and biosecurity keeps laboratory staff and the public safe while working with pathogens, including COVID-19. A cadre of professionals certified to validate BSC Class II urgently needs to be trained in the Region.

Networking

An expanded regional roster of laboratory experts allows us to make optimal use of regional resources for COVID-19 laboratory support. Such experts need training, orientation and field exposure. The Region is in dire need to have regional reference laboratories and centers for excellence. WHO would encourage laboratories with expertise that could benefit others to apply to become collaborating centres.

Rational use of laboratory services

Already there is an abundance of new COVID-19 diagnostics (10). Molecular techniques and

sequencing start to play a bigger role. Periodic review and sharing of experiences allow countries to be aware of emerging laboratory technologies and their potential use in the laboratory, in the field or at the point-of-care. This ensures timely introductions that take into account country contexts.

The importance of laboratories captures the attention each time there is a large emergency but this quickly wanes when the crisis is over. We need to seize this opportunity to convey that success depends on investments in laboratory systems and preparedness rather than ad-hoc procurement of test kits only. A well-organized health laboratory system with a clear vision and adequate numbers of trained and committed staff is necessary. Health laboratory services need to remain a priority at the national level and well financed to ensure their operations.

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