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Assessment of Laboratory Network in Armenia: Experience of Scale-up During COVID-19 Pandemic

Brief Report

December 2021

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Disclaimer: This study is made possible by the generous support of the American People through the United States Agency for International Development (USAID). The contents of this study are the sole responsibility of the American University of Armenia Fund and do not necessarily reflect the views of USAID or the United States Government

Project Description

The Support to Control COVID-19 and Other Infectious Disease Outbreaks Activity strengthens the national capacity to control COVID-19 and other communicable disease outbreaks and emergencies of potential public health concern, advancing the Public Health Emergency Preparedness and Response strategy in Armenia. The activity is funded by the United States Agency for International Development (USAID) and is implemented by the American University of Armenia Fund, in collaboration with the Ministry of Health (MoH) of Armenia.

The project focuses on the following spheres:

1. To strengthen the capacity of the Government of Armenia to formulate and implement public policies and services to prevent and respond to emergencies of potential public health concern
2. ***To advance health sector capacity for the surveillance, detection, assessment, early notification, and response to disease outbreaks and other emergencies of potential public health concern***
3. To improve literacy on COVID-19 and other communicable diseases among the Armenian population

Objective 2 of the activity focuses on advancing the capacity of the primary healthcare (PHC) system for appropriate response to public health emergencies. The team of the American University of Armenia conducted comprehensive assessments of the PHC system and laboratory network to identify existing gaps, and develop an action plan for strengthening the capacity of the health system to balance the demands for responding directly to public health emergencies, while simultaneously maintaining the delivery of essential health services.

Assessment of laboratory network in Armenia: experience of scale-up during COVID-19 pandemic

Introduction

The study was conducted in the spring of 2021 by the Turpanjian College of Health Sciences, the American University of Armenia, as part of the USAID-funded "Support to control COVID-19 and other infectious diseases outbreaks in Armenia" project.

The study aimed to:

- Investigate the process of laboratory participation in the nationwide surveillance efforts on the novel coronavirus SARS-CoV-2 and other communicable disease pathogens.
- Identify gaps in quality improvement, biohazard management, and biosafety assurance.

Brief methodology

The research team utilized a qualitative research technique through in-depth interviews (IDIs) with key informants conducted through the online Zoom platform. The key informants (n=15) were policymakers/experts involved in decision-making regarding the scale-up, as well as laboratory managers, and laboratory physicians involved in the national laboratory network for COVID-19 testing. Private and public laboratories were chosen from the official list of laboratories that provide COVID-19 testing available on the MoH website.

The research team developed semi-structured IDI guides for each type of key informant, based on the WHO laboratory assessment system-level tool. The study team utilized purposeful and convenience sampling approaches to recruit the study participants. The team utilized directed content analysis to reveal and summarize the findings.

The study team applied to the American University of Armenia Institutional Review Board to approve the research procedures prior to data collection.

Findings

The study results are presented using the main themes below:

Structure and Organization - According to the study participants, there was no unified laboratory network in Armenia, and the existing one was perceived as a complex system, in which the private and state laboratories, as well as the infectious disease control laboratory

networks, have been developed disproportionately to each other. The participants highlighted the importance of a common legislative framework for building a proper unified network in the country.

According to the participants, the network of state laboratories under the jurisdiction of the NCDC served as a basis for the relative preparedness and response to the pandemic. The participants agreed that as the demand for laboratory services increased, so did the supply of relevant diagnostic services. The latter was implemented by involving other state and private laboratories. The widespread accessibility of COVID-19 testing services was also achieved through the expansion of the network of sampling sites. At the beginning of the pandemic, there were issues associated with proper implementation of specimen collection, packaging, and transportation (e.g. labeling, container packing, cold chain maintenance). Specimen handling was strengthened continuously by the everyday efforts of laboratory personnel as well as guided by various governmental decisions, documents, and continuing educational activities.

Other challenges raised by the participants were the scarcity of human and technical resources. However, the participants noted that the laboratories of the NCDC network were generally provided with the necessary resources.

Prior to introducing COVID-19 testing services, each laboratory underwent an initial assessment of readiness to perform the test, focusing particularly on biosafety measures. According to the participants, the evaluated results showed that a number of laboratories did not comply with the requirements, but taking into account the emergency situation, they were able to quickly correct the deficiencies, and main discrepancies, and institute of COVID-19 PCR testing.

In general, the participants noted that despite numerous challenges, the scale-up was successful in terms of rapid establishment of sampling, PCR testing, and human resource capacity.

Coordination and Management - The policymakers highlighted that in the past there was no uniformly coordinated laboratory system in place, and that the coordination mechanisms specific to the network model existed only within the NCDC and other vertical disease-specific networks. Some policymakers even stressed that poor coordination was one of the major weaknesses in the

field, and that there was no specific unit responsible for the coordination of the laboratory system.

Initial licensing of laboratories and inspection visits were mentioned as the only existing coordination mechanisms. Moreover, the visits of the inspection bodies merely focused on the evaluation of the laboratories' compliance with the newly issued orders and lacked support and guidance for further improvement. Some participants also raised their concerns regarding the overall quality and effectiveness of those inspection visits as the legislative requirements/norms for the laboratories are vague, and contain repetitions and contradictions. Moreover, the inspection visits do not comply with the international standards (ISO, etc) and the specialists conducting those visits lacked proper training and specialization in laboratory services.

Additionally, heads of private laboratories stated that during the COVID-19 response the NCDC introduced some new coordination mechanisms in terms of oversight and enforced self-monitoring mechanisms. Eventually, some participants concluded that the established COVID-19 testing network could potentially serve as a foundation for the further expansion of the laboratory network throughout the country, to become a nationwide laboratory network also covering other laboratory services.

Interviews with heads of laboratories that provide state-assured COVID-19 testing revealed that the supply management, including procurement, was adequately organized by the NCDC, which facilitated uninterrupted. preventing any interruptions. However, one head of a private laboratory reflected that the timely procurement of the necessary supplies was one of the challenging aspects of response to the COVID-19 outbreak. The participants also mentioned the periodic elevated prices of PPE as a financial barrier for their laboratories.

Regulations and Laboratory Information Management - The regulatory mechanisms of the laboratory system in Armenia lack requirements for mandatory certification and accreditation. In addition, the national accreditation body of Armenia has not introduced international accreditation standards. As a result, there is no nationally accredited laboratory in Armenia. As such, there is a gap in the regulatory mechanisms for PCR laboratories, and the absence of required licensing of PCR laboratories is problematic for proper quality control. With the

COVID-19 scale up, however, new decisions and orders partially regulated the operations of the PCR laboratories performing COVID-19 testing.

The interviews revealed that laboratories have had various electronic data management practices in place such as hardcopies, WHO-recommended Laboratory Information Management System (LIMS), or Excel databases, and all of these are not interconnected and/or interoperable. However, with the COVID-19 outbreak, some changes happened because a single data management systems was established. Currently, all laboratory data related to COVID-19 is being entered into the National e-health operator – ArMed – which assures the standardization of collected information throughout the country.

Human and Technical Resources - Laboratory managers discussed about the ongoing monitoring of testing demand against the laboratories' capacities and making corresponding adaptations, such as additional personnel, equipment, and stock of supplies. When asking the managers of laboratories how they were addressing the lack of staff, some mentioned compensating for overtime work and night shifts, others adapted work schedules and involved additional experienced laboratory personnel, repurposed other laboratory professionals, or involved operators to be responsible for the entry of the results. Some others mentioned concentrating their efforts on learning PCR testing methods on their own before the specialists became available. For some participants, the lack of laboratory professionals specializing in PCR testing was a particular challenge during the COVID-19 response. Many of the participants highlighted the importance of continuous education and various training/ workshops organized by the NCDC. The latter helped lab staff to gain the skills necessary to perform PCR testing.

When discussing the possibility of future scale-up, the participants mentioned the need to involve additional laboratory personnel since, according to them, a potential challenge for future scale-up could be the shortage of adequate human resources. In addition, participants also mentioned the importance of continuous education of existing laboratory specialists to ensure that their knowledge is always in line with modern practices. Furthermore, the policymakers specified that there is no unified registry of all laboratory specialists along with their specialization. This is fundamental to tracking the human resource capacity, and for ensuring country-wide coordination and rapid mobilization.

Quality of laboratory system - One of the challenges revealed in the laboratory system was weak quality control. Before the pandemic, there were no national general quality norms or sets of standards mandated by a health authority. In fact, laboratories were left to decide and implement quality control activities based on their own priorities and their own perceptions of the importance of quality control. The response to COVID-19 introduced positive changes in quality control measures. Participants described that they conducted internal quality control and external quality assurance practices, as well as equipment and reagent management as parts of quality control and assurance.

The interviews revealed that one of the important components of quality assurance in the laboratories, i.e. validation and verification of new batches of materials and reagents, is not properly implemented.

The external quality assessment (EQA) in the country is being conducted on three main levels: on-site quality assessment, retesting of tested samples, and testing of blinded samples. The participants had contradicting opinions regarding the EQA program. Some of them mentioned a lack of supportive supervision from the organization that leads the EQA program, whereas others noted a positive experience in this regard.

Biosafety control - The biosafety of laboratory procedures is regulated through various legislation, ministerial orders, and guidelines (based on the WHO guideline) which need to be updated. According to the participants, though the biosafety guideline is in place, it is not properly enforced: appropriate training, guidance, and coordination are still missing. The laboratories use the national regulations to develop local SOPs, and laboratory-level guidelines that guide biosafety. According to a policymaker, with the outbreak of COVID-19, new SOPs for quality and biosafety management were developed and enforced within the NCDC network. According to the interviews, the introduction of COVID-19 testing was not associated with major changes in the laboratories' waste management practices. To manage the increased volume of waste generated as a result of high testing demands, separate areas were for waste collection and processing.

In fact, the assessment did not reveal any biosafety coordination unit in the laboratory sector. Waste management in Armenia is guided by various documents such as national strategy,

legislation, ministerial orders, SOPs, etc. A policymaker stated that in contrast to other legislative documents in the laboratory sphere, the ones guiding waste management in Armenia are mostly in line with international recommendations.

Readiness for future outbreaks - The participants agreed that the laboratory system is ready for future challenges, however, the development of a coordination unit for the laboratory system is a priority. The participants also emphasized the need to expand technical capacity and infrastructure.

Conclusion

The assessment revealed the successes and challenges that the laboratory system of Armenia witnessed while scaling up to combat the COVID-19 pandemic. Urgent changes are required to increase the response capacity for future outbreaks of infectious diseases. The improvements should address several aspects of the laboratory system as the study findings showed: a) the enhancement of coordination and networking mechanisms and expansion over other laboratory services, b) the continuous development of human resources including strengthening the managerial capacity, training of laboratory personnel on quality improvement, biosafety, and waste management, and c) the improvement and revision of policy papers which regulate the laboratory system functioning.