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Lessons Learned from Setting up COVID-19 Testing Services for Provincial Hospital Laboratories During the Pandemic in Cambodia

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ABSTRACT

Coronavirus has imposed many difficulties across the globe, with infected cases emerging everywhere, leaving countries devastated. Developing countries such as Cambodia are facing problems when dealing with COVID-19 due to the lack of resources for elongating the diagnostic setup processes. Subsequently, the National Institute of Public Health has worked side by side with the Ministry of Health (MOH) and development partners to ensure the complete and proper laboratory facilities specializing in screening and diagnosing COVID-19. The testing room arrangement procedures were aligned with the Laboratory Quality Management System (LQMS) assessment tool to guarantee an ideal working environment for laboratory technicians and scientists with reliable results for patients.

This process of conducting trials for the GeneXpert PCR lab setup requires the following 5 steps: 1) LQMS assessment, 2) staff training, 3) infrastructure preparation, 4) information management system, and 5) equipment validation to reach its full potential. This strategy will respond to the outbreak, prevent and lessen death caused by COVID-19, as citizens will have access to better testing sites.

The success of setting up for COVID-19 testing is strongly affected by the commitment of the laboratory personnel. Having a strong commitment and clear understanding of the testing process would help speed up the setup of the COVID-19 testing service. Strong technical and financial support from MOH and development partners could also facilitate the readiness of the laboratory in providing COVID-19 testing services. During the pandemic, additional support should be allocated to the laboratory, especially at the early stage of the emergency, so that the laboratory could have enough time and resources to expand its services.

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Background

Novel coronavirus disease 2019 (COVID-19) causes millions of deaths worldwide. In Cambodia, on 27 January 2020, the Ministry of Health (MOH) with the World Health Organization (WHO) confirmed the first case of COVID-19 in Sihanoukville (a seaport province, southwest of Cambodia, approximately 230 km from Phnom Penh). As of 29 November 2021, the total reported COVID-19 was 120,134 cases [1]. Testing for COVID-19 has been one of the key strategies to tackle the pandemic; therefore, expanding COVID-19 testing capacities and facilities at national and subnational laboratories is one of the government's priorities. Reversed transcriptase-polymerase chain reaction (RT–PCR) is the recommended testing method for SARS-CoV-2; however, only major laboratories located in the capital city of Phnom Penh have this capacity. As a result, samples were collected from all provinces and then packed and transported daily to the Institut Pasteur du Cambodge (IPC) and National Institute of Public Health (NIPH) for testing, in which it was overwhelming and stretched the resources and central lab capacities resulted in longer waiting times, and the lab results were mostly available in the next 24 hours.

In response to this challenge, the NIPH, which serves as the national reference medical laboratory of the MOH, is working closely with the IPC, WHO, and United States Centers for Disease Control and Prevention (US-CDC) to expand the testing capacity at the laboratory at the subnational level. As planned, 14 provincial laboratories have been established with PCR testing capacity for COVID-19 using the GeneXpert platform. Most of these provincial laboratories are located along the border where imported cases are frequent. This paper aims to share all steps needed for expanding COVID-19 testing services at subnational laboratories during emergency responses, as well as its challenges and best practices.

Steps in expanding the lab facilities for COVID-19

We described in detail various steps in expanding the COVID-19 laboratory since chosen laboratories for the COVID-19 test are not at a similar level in terms of quality, infrastructure, and human resources. These steps included laboratory quality management systems (LQMSs), capacity building for laboratory staff, preparation of lab infrastructures, establishment of lab information management systems and validation, followed by challenges and lessons learned documented by the authors who were directly involved and responsible for expanding the COVID-19 lab in Cambodia.

1. Conducting Laboratory Quality Management System Assessments

This was the imperative first step to ensure that all target laboratories could maintain good quality of their testing services, and LQMS assessment needs to be conducted to have a clear understanding of the existing quality management status of the laboratories. An assessor team who had experience in quality management plays an important role in identifying gaps and the root causes of each laboratory so that they could propose a practical plan for setting up COVID-19 testing capacity at each laboratory.

The LQMS assessment tool consisted of 12 quality contents: 1) Document and Records, 2) Management Review, 3) Organization & Personnel, 4) Client Management & Customer Service, 5) Equipment, 6) Evaluation and Audits, 7) Purchasing & Inventory, 8) Process Control, 9) Information Management, 10) Identification of nonconformities, Corrective and Preventive actions, 11) Occurrence/Incident Management & Process Improvement, and 12) Facilities and Biosafety. This LQMS tool has also been used for assessing various laboratories in Cambodia [2].

Conducting LQMS assessment requires substantial efforts. On average, each lab required a 3-day assessment performed by 4 LQMS assessors. The assessment was conducted using various methods consisting of direct observation, interviews with lab staff, and document review. Then, the assessor team shared the results of the assessment and proposed a plan for COVID-19 lab setup to the hospital and provincial health directors for further discussion **(Figure 1)**.

From October to December 2021, 14 provincial laboratories were assessed with an average score of 61% **(Figure 2)**. Laboratories that received low scores in the assessment received more feedback on the plan to improve their capacity before they could set up COVID-19 testing services at their facilities.

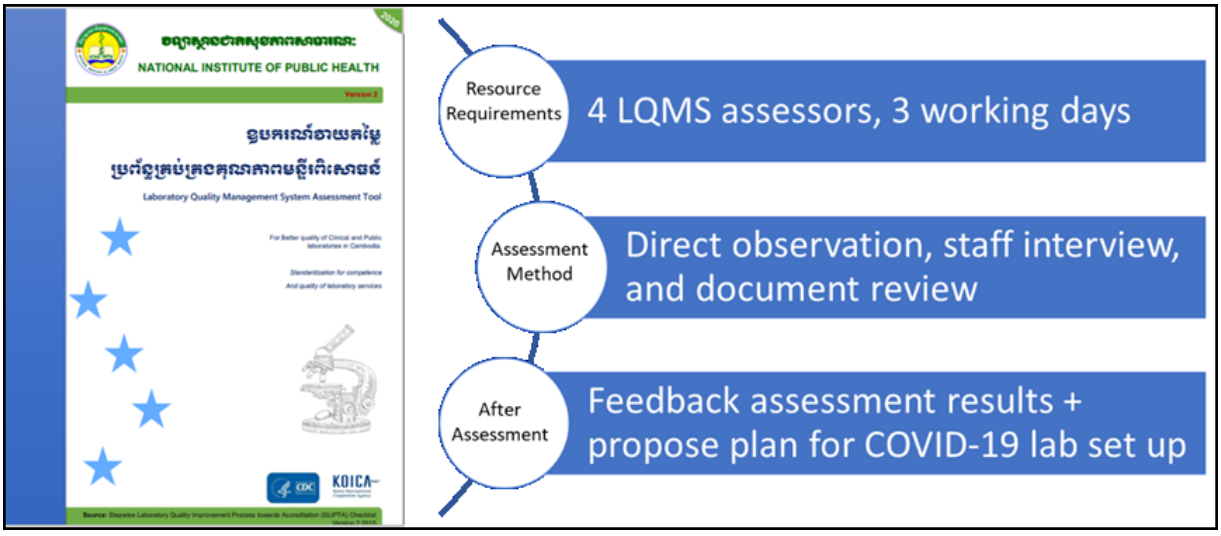

Figure 1: Assessment process summary using Lab Quality Management System tool

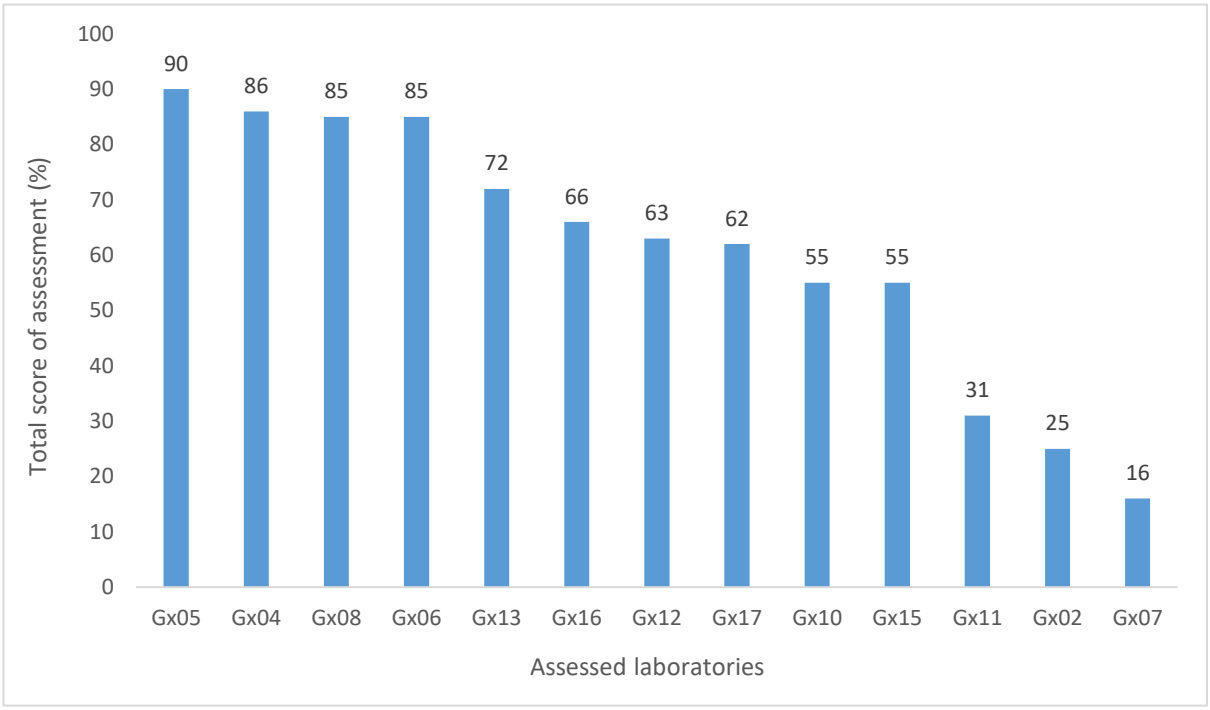

Figure 2: LQMS assessment score (Average: 61%, Min: 16%, Max: 90%)

2. Building the testing capacity of lab staff

PCR techniques are one of the new skills lab staff need to master before they can provide COVID-19 testing services. The principle of performing the COVID-19 test is based on minimizing the risk of COVID-19 infection and ensuring the quality of the testing service. Therefore, laboratory staff should be well trained to handle each step related to the handling of biological samples and performing COVID-19 tests.

First, the key training on floor plans and PCR methods using GeneXpert usually took 3 days. The major objectives of this training were 1) to guide lab staff drawing their floorplan and workstation setup for SARS-CoV-2 testing, 2) to enable lab staff to safely handle SARS-CoV-2 specimens, including transportation, 3) to manage waste and disinfect unclean areas, and 4) to perform real-time RT–PCR for SARS-CoV-2. Training for the lab staff was critically important since they had to clearly understand the laboratory floorplan from pre to post analysis to avoid any unexpected biohazard caused by bad specimens and infectious waste.

In addition to classroom training, lab staff should have opportunities to visit an existing COVID-19 lab to deepen their understanding of the process of COVID-19 testing. During the visit, trainees should be exposed to the whole process of COVID-19 testing, ranging from the preanalytical to the postanalytical phase of the testing process, including specimen reception, aliquoting, analysis, the results reporting, and waste disinfection and disposal. Trainees should participate in a simulation exercise on COVID-19 testing using "Xpress Xpert SARS-CoV-2 testing by GeneXpert DX System". During each simulation, each participant should be evaluated by the trainer on their competency. Each laboratory should have at least four trained staff or more depending on laboratory capacity. Trainees could receive the certificate of participation at the end of the training if they pass the assessment.

3. Investing in infrastructures, equipment, and supplies

To ensure the good flow of COVID-19 testing, the floorplan for RT–PCR using the GeneXpert system required 4 compartments (**Figure 3**), namely, (1) specimen reception and testing area, (2) personal protective equipment (PPE) donning area, (3) data entry area, and (4) PPE doffing and waste sterilization area. The principal equipment required for the GeneXpert system is GeneXpert, a biosafety cabinet (BSC) and an autoclave, and its reagents and consumables.

The lack of infrastructure to support COVID-19 testing is one of the major barriers to establishing a COVID-19 lab in Cambodia. After having floorplan for COVID-19 lab development, lab staff and lab managers need to discuss the floorplan with the hospital management team to plan for the renovation of their existing laboratory facility or to build additional space for the laboratory. In Cambodia, 3 regional labs (with negative pressure rooms) were newly built to expand its COVID-19 testing service, and it took an average of approximately 10 months to complete the construction. Other labs required some renovation, which took an average of 6 months.

Each lab should establish a reliable supply system for the reagents and consumable for COVID-19 testing. The purchase of reagents and consumables is time consuming since Cambodia needs to import all reagents and consumables for COVID-19 testing. Therefore, the laboratory should start providing COVID-19 service only if its supply system is functional.

4. *Setting-up Laboratory Information Management System*

The COVID-19 lab not only provides the results to the patients but also shares the test results with the national response team, who could use data for contact tracing, quarantine and treatment purposes. To share laboratory results effectively, each COVID-19 lab should have an effective electronic information management system for storing, managing and sharing the COVID-19 test results. In fact, in Cambodia, a laboratory information management system named the Cambodia Laboratory Information System (CamLIS) was developed by the Department of Hospital Services (DHS) in collaboration with the WHO in 2012. Currently, CamLIS has been expanding to some national, subnational laboratories. CamLIS has been standardized patient data, mainly on history and laboratory data, and reports were quickly generated from the system.

In 2020, under the management of the Department of Communicable Disease Control (CDC), all COVID-19 testing data were consolidated from different sources and generated into national reports through the CamLIS. Recently, the WHO has continued to support MoH in upgrading the CamLIS web based on managing and harmonizing COVID-19 laboratory data from all COVID-19 laboratories, both public and private, in Cambodia (**Figure 4**).

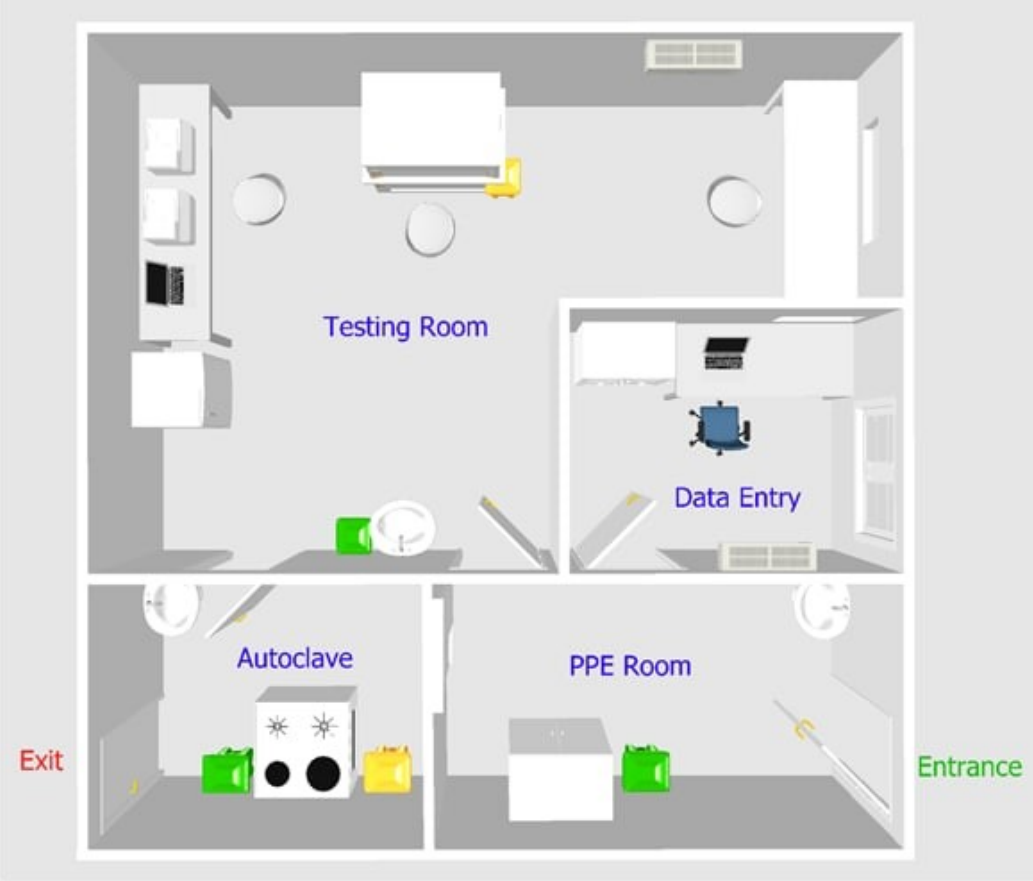

Figure 3: Ideal floor plan for the GeneXpert SARS-CoV-2 testing laboratory

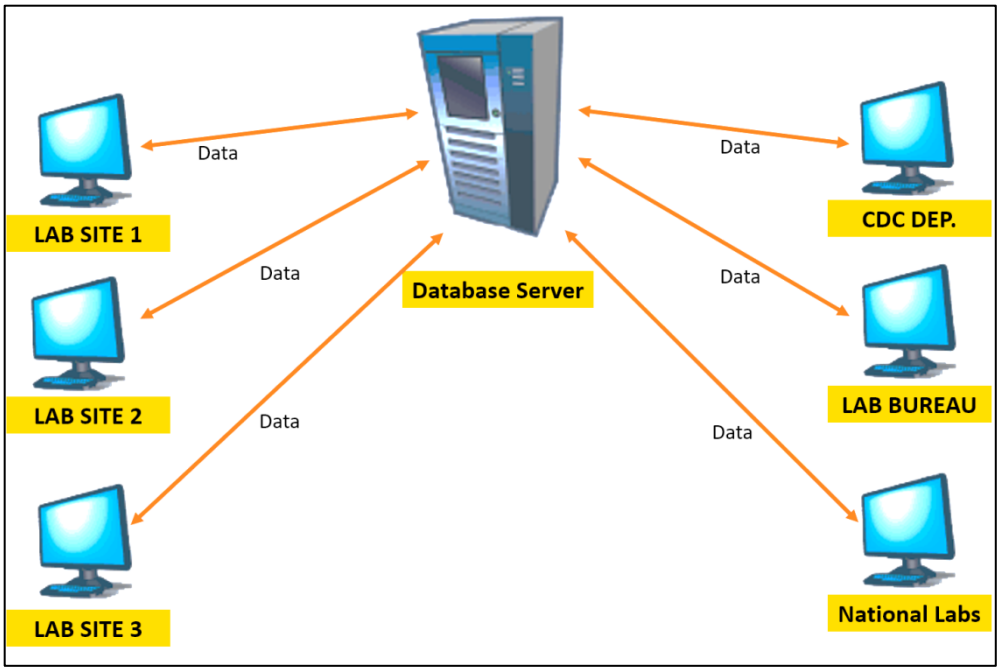

Figure 4: Data transferring method

5. *Conducting Verification of the Quality of COVID-19 Testing Service*

One of the most important steps during setting up a laboratory for COVID-19 testing is the verification process with real samples and follow-up. Each newly set up laboratory needs to pass this stage before receiving official approval for providing COVID-19 testing services from the MOH. The first step is to check the function of the GeneXpert equipment by testing each module of machine with a positive sample (results previously checked by the reference laboratory). The result has to be 100% concordant with the reference to ensure the good performance of the equipment.

The second is the verification of the equipment, which was conducted in two further steps. It should start by asking lab staff to confirm the results of samples already tested at the reference lab. If the staff passed this step, they were asked to conduct parallel testing on samples, which were also performed on the same platform (GeneXpert) at the NIPH reference lab.

For the parallel testing stage, if the new setup lab passed with the correct result >80%, the lab could officially provide COVID-19 testing service independently. However, the lab would have to enroll in the COVID-19 external quality assessment (EQA) program offered by the NIPH. If the result from parallel testing fails with < 80% correct results, the laboratory needs to identify errors and conduct corrective actions accordingly. Then, parallel testing was repeated until satisfactory results were obtained.

Challenges

Setting up a COVID-19 testing service between 2020 and 2021 has faced a number of challenges. Lack of lab staff commitment was commonly the biggest challenge, and it could directly determine the success or failure of the laboratory setup, especially during the outbreak, such as COVID-19. Lab staff were overloaded with outbreak response tasks, such as collecting specimens or providing lab services for care and treatment. Second, during the early pandemic, most lab staff feared and were anxious of COVID-19 infection, as it was a new virus. The lab setup technical team has to travel from provinces to provinces during the lockdown period and could be exposed to a high risk of COVID-19 infection because the tasks could be performed virtually. Therefore, all safety measures should be in place before the technical team can travel to a setup lab in high-risk areas.

However, having a good score on LQMS assessment is an advantage for expanding COVID-19 testing capacity [3]. During the pandemic, labs that have lower scores from LQMS assessment could also be transformed to provide COVID-19 testing services. However, more efforts were needed to improve the LQMS scores to ensure the quality of the COVID-19 testing service and sustainability of the service in the long run.

Preparing lab facilities for COVID-19 testing services required technical and budget support to ensure the quality and safety of the service. Good collaboration with development partners and the flexibility of budget and other resource allocation were optimal mechanisms in the emergency response in resource-limited settings. Similar interventions have been applied in Ethiopia during testing capacity expansion [4,5].

The quality of the lab equipment purchased during the pandemic should be strictly assessed, as the process for purchasing equipment is often lengthy due to high demand during the pandemic; therefore, fewer equipment is not up to their required standard specification. For example, failure of the quality of newly purchased biosafety cabinets has delayed COVID-19 testing services at many laboratories across Cambodia.

Lessons learned

The success of setting up for COVID-19 testing is strongly affected by the commitment of the laboratory personnel. Having a strong commitment and clear understanding of the testing process with strong leadership from provincial health departments would help speed up the setup of the COVID-19 testing service. Strong technical and financial support from MOHs and development partners could also positively affect the readiness of the laboratory in providing COVID-19 testing services. During the pandemic, additional support should be allocated to the laboratory, especially at the early stage of the emergency, so that the laboratory could have enough time to expand its required services. This experience could be applied in other laboratories located in resource-limited countries in the case of pandemics.

Conclusions

The five steps for setting up the COVID-19 testing service described in this paper were documented by a team from the National Reference Laboratory, NIPH during the COVID-19 response in Cambodia between 2020 and 2021. The experiences for the expansion of testing capacity of 14 laboratories through building laboratory personal competency, supplying the laboratory with necessary equipment, and introducing the implementation of LQMS program to ensure the quality of the laboratory management in the long run. All interventions implemented in Cambodia are consistent with Pawar et al. published in 2020 [3]. Overall, the quality improvement toward accuracy, reliable results, and error reduction were significantly observed by maintaining LQMS. In addition, external quality assurance should be regularly conducted to monitor the laboratory performance on COVID-19 testing services. We strongly believe that the steps for setting up the COVID-19 testing service in Cambodia could be applied for other resource-limited countries where the expansion of testing capacity is needed during the pandemic.

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