COVID-19 – A Malaysian private university's immediate response to provide testing services

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Introduction

On 11 March 2020, when the World Health Organization (WHO) announced the coronavirus disease 2019 (COVID-19) pandemic[1], Malaysia was still in the early phase of the COVID-19 outbreak, with only 161 confirmed cases reported on 13 March 2020.[2] Initially, the Ministry of Health Malaysia's (MOH) public health measures of containment were effective but since then, the number of cases increased daily and continued in an upward trend; thus the MOH had to change its strategy, moving from containment to mitigation.[3] Public health measures during containment include rapid identification of cases, contact tracing, testing of samples, isolation of confirmed and suspected cases, and mobilization of resources where needed.

Malaysia started its pandemic preparedness plan well ahead of time and long before WHO decided to declare the outbreak a pandemic.[4] Several hospitals were identified to handle COVID-19 patients; a rapid real-time polymerase chain reaction (RT-PCR) test to detect SARS-CoV-2 in patients and contacts was developed, used and distributed to several government hospitals and medical laboratories; and management protocols were developed.

Survey on Laboratory Preparedness

As part of the government's early preparations to handle COVID-19 sample testing, on 23 January 2020, a survey on laboratory facilities to handle diagnostic testing on COVID-19 was conducted by the National Public Health Laboratory (NPHL) on selected private laboratories including the International Medical University (IMU). Among important information required from the survey are the following:

1. Information on COVID-19 diagnostic testing, virus identification and culture, and other serology testing
2. Willingness of the laboratory to receive samples for COVID-19 testing
3. Identification of laboratory capability and capacity for sample testing per day
4. Willingness of laboratory to participate in a WHO organized proficiency testing programme for coronaviruses
5. Willingness of laboratory to share viruses isolated from specimens produced in-country or internationally, if permission has been granted by referring country with the global laboratory community if requested by the WHO.

Our Research Laboratory responded to this survey and also specifically mentioned that our University has a biosafety officer in-house and our Research Laboratory is equipped with Biosafety Level 2 (BSL 2) facilities and is able to perform detection of coronavirus and novel coronavirus. However, our Research Laboratory has no capability for isolation of novel coronavirus since this requires higher BSL facilities. It is worthwhile to mention that in 2014, our Research Laboratory had previously participated in a 3-yearly survey on assessment of capacity and capability, quality and safety of laboratory services in Malaysia. The assessment was conducted by NPHL for the purpose of establishing the

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laboratory inventory for the country. This laboratory inventory will be used to plan a strategic capability of diagnostic laboratories in preparing for untoward events such as remerging and emerging diseases. Subsequently after we responded to the COVID-19 survey, our Research Laboratory conducted various discussions and coordination activities with our Institute for Research, Development and Innovation's (IRDI) management and team members in early anticipation of receiving COVID-19 samples. On 6 February 2020 both public and private universities were invited to a COVID-19 laboratory diagnosis training at the NPHL as part of national preparedness and a faculty member from our university was sent for this training.

COVID-19 Sample Testing

On 23 March 2020, the Director of NPHL approached the University's Pro-Vice Chancellor of Research for help to run screening tests for some of its samples as their lab was overwhelmed with the volume of samples it received daily. We were able to respond immediately to this request based on our good practices, staff dedication and preparedness.

However, when we first agreed to assist NPHL in screening, our immediate task was to convert one of our laboratories to become a dedicated testing diagnostic lab. We were fortunate as the University had already established an Advanced Microbiology Collaborative Research Laboratory (AMCRL) in the previous year, initially to take on collaborative research with its international partner universities. This laboratory is well designed and equipped with Biosafety Level-2 (BSL-2) cabinets, with its own air-conditioning system which allows a contained testing for infectious agents including SARS-CoV-2, and access to authorised personnel only. There were still challenges as this laboratory was a BSL-2 facility and initially, we did not have sufficient personal protective equipment (PPE) to sort and aliquot samples and perform extraction on a daily basis but we will able to sort this out with NPHL's help. In addition, we needed to move specific equipment e.g. real-time PCR machine, freezer etc. into this dedicated laboratory to reduce the risk of infection. Based on the earlier training provided to our academic staff at NPHL, this staff was tasked to set up working teams comprising of the University's laboratory staff and faculty volunteers. The challenge he faced was to engage Research Laboratory staff and faculty to be volunteers; this was a challenge as they needed to work overtime and even on weekends. But we again were very fortunate to be able to establish our teams immediately due to our Research Laboratory staff and faculty's dedication and deep sense of responsibility and empathy to respond to the nation's call for help and teams were established by 25 March 2020. Of course not all team members were microbiologists or had similar levels of biosafety awareness and training but with further training provided by the NPHL staff on 26 March 2020 to these teams on biosafety and PPE, and data entry into the SIMKA system (web-based portal for COVID-19 test registration process), the University was able to start the testing service at a very short notice. All staff are informed of the risk associated with COVID-19 infection, its symptoms, self-monitoring, reporting procedures and support from the healthcare facility in the event of illness. The University's capability and preparedness to respond to this national need is also due to our good laboratory practices as part of the Research Laboratory has been accredited under ISO 17025:2015 and we are also working towards attaining ISO 45001. The University's Biosafety Committee periodically

conducts training courses to ensure all researchers update their knowledge and adhere to safe laboratory practices. Furthermore, regular team meetings and briefings have been put in place to ensure good communication among all involved. In the initial period of testing, monitoring of the team members' competence was done to ensure the reliability and accuracy of test results.

Compliance to WHO Laboratory Biosafety Manual

Our well trained laboratory staff displayed their talents and innovation in ensuring that the testing was carried out in a very systematic and efficient manner and provided clear instructions to ensure that all team members followed proper Standard Operating Procedures and observed biosafety measures to minimize risk to infection. Donning of PPE is guided with a poster displayed in the laboratory showing the detailed procedure. Upon receiving the samples from NPHL, the samples taken from patients who are suspected or confirmed to be infected with novel SARS-CoV-2 are either safely kept in a dedicated chiller in the AMCRL or processed according to the practices and procedures described under Biosafety Level 2 (BSL-2), as specified in the WHO Laboratory Biosafety Manual (3rd edition). The samples are sorted and identified according to the patient identity in a biosafety cabinet and a small portion (200 µl) of each sample is transferred into a microcentrifuge tube for RNA extraction according to manufacturer's instructions. All the remaining samples are returned to their original packaging or transferred into 2 mL cryovials for storage. The empty sample tubes, wrappers and waste generated during the process are sterilised with alcohol, transferred out of the biosafety cabinet and placed into an autoclave bag and autoclaved before being discarded. All the used PPE are discarded into a biohazard bag placed just outside the exit of the testing area and decontaminated with autoclaving also.

We received the first batch of samples from NPHL and started testing them on 27 March 2020 and since then, we are providing this service on a daily basis. Our ability to assist in providing this testing service is timely and important as we anticipate that the MOH will need both public and private universities to supplement their own testing services in the coming weeks.[5] JP Morgan, an investment banking firm, said in a research paper that it expected the peak of infections to reach in mid-April with about 6,300 cases.[6] Up till April, the MOH has performed about 49,000+ RT-PCR tests with a few hundred more by private labs but this is still far below the ideal.[7] With MOH's capacity of 10,000 tests per day using an automated high throughput system, there is still a need for all universities and private labs to help to deliver another 8,000 tests a day. Since then, the MOH has been increasing their testing capacity with more laboratories providing CoVID-19 testing.

Experience and Lessons Learnt

From this experience, early preparedness in terms of laboratory facilities, staff competencies and training would help an organization to face any unprecedented events and new infectious diseases like COVID-19. We have also learnt a valuable lesson on the importance of teamwork, professionalism, good practices and most importantly, willingness and dedication to serve our nation in times of need.

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