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Short Communication

Two Pandemics: Experience In A Clinical Laboratory

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Two Pandemics: Experience In A Clinical Laboratory

During a public health emergency, laboratories play a lead role in detection and response to infectious diseases. They must meet increasing testing demands. The laboratory professionals have had a unique pandemic experience since 2009 H1N1 influenza pandemic. The common problems were deciding which test to do, to give fast and accurate results as for the other common diseases. When the pandemic begins, using PCR which is the most sensitive is the first choice at the beginning; but then using the validated rapid antigen test with the desired sensitivity and specificity in certain settings caused uncertainty at every time. The misinformation about testing among the public always caused a problem between the patients and the microbiologists and clinicians. The most important issue in the laboratory, is the difficulty to convince the clinician and patient for the test results if it is not reported as assumed. Especially collection of sample because of not collecting according to the rules causes time consumption especially in the pandemics because of the necessity for demanding a new appropriate sample. Mostly the laboratory is used to make another test of different method. So PCR is demanded although only rapid antigen tests work in certain settings. Sometimes this may go to legal process leading the laboratory defending itself.

On 30 January 2020, the World Health Organization (WHO) declared the outbreak and a global health emergency, and on 11 March 2020, WHO declared a pandemic [1]. It was the coronavirus disease-2019 (COVID-19) pandemic originating from Wuhan, China. Since the H1N1 2009 influenza virus (formerly known as swine flu) first appeared in Mexico and the United States in March and April 2009 this was the second pandemic of 21st century.

Diagnostic tests for SARS-CoV-2 are of two broad categories: antigen tests and realtime reverse transcription polymerase chain reaction (RT-PCR) tests. First of all PCR testing was considered as the laboratory reference standard for COVID-19 diagnosis although later the laboratories met with some limitations. The experienced staff and automated platforms were required. The shortage of reagents and swabs were the other limitations for this testing [2-6]. In February 2020, the World Health Organization (WHO) identified point-of-care (POC) testing as a number one priority to address the COVID-19 pandemic [7]. The test delays could impact the value of isolation to reduce the spread of SARS-CoV-2 [8]. The false positives or negatives prevented early identification and the spread of disease [9].

Rapid antigen tests reduce turnaround time with some processes like the sample collection [10-11]. Considering these advantages, rapid antigen tests were used worldwide for rapid COVID-19 diagnosis. The issue for this testing is a deficiency of data transmission for surveillance [12].

COVID-19 will not be the only pandemic that laboratorians will face. Clinical laboratories play a central role in pandemic response for diagnostic testing, monitoring, and research activities. Increased testing capacity, sample collection and transportation, data management and reporting should be the first step to be taken for the other pandemics [13].

The choice of testing should be decided as soon as the diagnostic tests are accepted by the worldwide and national authorities. As it was experienced during the influenza pandemic, in some countries forcing the laboratories to use only PCR tests although there were rapid antigen tests might be misleading. The tests should be chosen according to the laboratories' facilities and workload. In certain setting a simple algorithm starting with antigen test and when it is negative going on with PCR with the interpretation added to the report would be appropriate. Although there are limited articles about the laboratory personnel's burden, workload and burnout especially in COVID pandemic should be one of the most

important issues to be considered. Decisions about test's choice in certain settings should be planned as a national policy and after that it should be applied.

As CDC implements its 'Moving Forward Strategy', it will be important to continue to elevate laboratory sciences within the agency and address the urgent need for a strategy for national laboratory coordination or rather, a national laboratory system. As we look ahead, there is an urgent need for a national laboratory coordination strategy that clearly outlines a public–private laboratory system or network poised to detect the next threat [14].

As experienced in this second devastating pandemic of COVID-19, US as a developed country, in search for accurate, rapid and easy-to-use tests required for the nation's safely return to normal life, launched a national initiative to speed innovation in the development, commercialization, and implementation of technologies for the new virus. Rapid Acceleration of Diagnostics (RADx®) Tech established by The National Institutes of Health has succesfully created a new model for rapidly translating diagnostic tests from the laboratory to widely use. ECDC is another good example publishing guides and recommendations that EU Member States should perform independent and setting-specific validations of rapid antigen tests before their implementation and use in the algorithms of laboratory tests. Unfortunately the disadvantage for such validated international kits for Covid-19 diagnosis was their high price, therefore rapid antigen tests even when they were necessary they were not successfuly and widely used or not perfectly validated rapid antigen tests were used and mostly not properly. Therefore considering these experiences one of the important lessons to be learnt by developing countries is not only build up strategies to improve development and commercialization of newrapid diagnostic tests but also establish independent bodies and settings-specific validations of rapid antigen tests before their implementation in colloboration with universities and professional organizations to be able to combat emerging infectious diseases [15-16].

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