LETTER TO THE EDITOR

SEARCH FOR RAPID AND LESS EXPENSIVE COVID-19 TESTS FOR LOWER MIDDLE-INCOME COUNTRIES-ANTIGEN BASED IMMUNOASSAYS REMAINS A NEGLECTED TOOL

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Dear Editor,

The Coronavirus Disease 2019 (COVID-19) continues to infect masses globally and the situation is worse in resource-constrained lower middle-income countries (LMIC) including Pakistan and neighbouring South East Asia.[1] Biochemical and molecular diagnostic assays detect affected subjects, especially the vast majority of asymptomatic, but capable of viral shedding leading to local spread. Moreover, diagnostic modalities also identify those who have recovered from the disease and prove beneficial for surveillance and epidemiological studies.

The expensive real time polymerase chain reaction (PCR) based tests are considered the current gold standard for COVID-19. Owing to the cost and scarce availability most LMIC have tested less than 5% of their population till now. For LMIC an ideal candidate biochemical test for the diagnosis will be the one that is cheap, accurate, user friendly, does not require specialized laboratory setup and highly trained technologists and pathologists.[2]

From a laboratorian's perspective, for LMIC antigen-based tests can serve as the best alternative, a test whose merits and limitations are aligned with what a population needs and can afford. Recently the U.S. Food and Drug Administration has issued the first emergency use authorization (EUA) for a few COVID-19 antigen tests *Sofia 2 SARS Antigen* from QUIDEL, a new category of tests for use in the ongoing pandemic. This test utilizes the principle of Fluorescent Immunoassay based lateral flow technology in a sandwich design for the qualitative detection of nucleocapsid protein from the novel severe acute respiratory syndrome virus (SARS-CoV-2).[3] It can be utilized for point of care testing on an automated platform and have a turnaround time of fewer than 15 minutes.

Antigen tests can generally be produced at a relatively lower cost than PCR tests and once various manufacturers start producing the assays, can potentially scale up to test millions of individuals per day due to their simpler design, helping LMIC better identify infection rates closer to real time.

The few limitations hindering the current widespread development and use of antigen tests are their relatively lower sensitivity. The above-mentioned test has reportedly a sensitivity of 85% relative to PCR tests. From a financial perspective, the often not widely discussed reason is that these tests are considered a comparatively less attractive long-term investment for in vitro diagnostics companies as they are prone to become obsolete early, once the pandemic is over. While on the contrary, the PCR based assays which are being sold and researched more amidst the outbreak, provide consumables and mechanical infrastructure which can be utilized even post COVID-19.

Despite the advice of a cautious approach by the regulatory bodies, the development, scholarly insight and validation/verification of antigen-based tests for COVID-19 diagnostics must continue as they have the potential to achieve maximum testing targets for resource limited set ups including Pakistan.

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