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Editorial

Is One Diagnostic Test for COVID-19 Enough?

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Abstract: There is no doubt about the importance of diagnostic testing in an emergency; specifically, which range of tests is available, where and when they are dispensed, and who might be tested using laboratory-developed tests, or other diagnostic tests including experimental tests. This includes testing for the SARS-CoV-2 virus that causes the COVID-19 disease. Testing is essential to "flatten the curve" of the number of confirmed positive cases of the disease, in addition to handwashing, isolation, and social distancing, among other essential measures. Is one diagnostic test enough to obtain the correct decision about a confirmed positive outcome?

Keywords: COVID-19; SARS-CoV-2; diagnostic testing; confirmed positive outcomes

JEL Classification: C12; C18; C22

1. Introduction

One of the most important and topical issues confronting the international community is the SARS-CoV-2 virus that causes the COVID-19 disease. Much has been written on COVID-19 in the media, and important research about the virus and the resulting disease has been reported in leading medical journals, such as the *Journal of the American Medical Association (JAMA)*, the *New England Journal of Medicine*, and *The Lancet*.

Interesting discussions regarding risk management of COVID-19 have been reported in Yang et al. (2020) on risk management of COVID-19 by universities in China, and by McAleer (2020) on prevention being better than the cure.

Recent important research results have been published in *JAMA* by Wu and McCoogan (2020), Del Rio and Malani (2020), Wang et al. (2020), Wu et al. (2020), Paules et al. (2020), Parodi and Liu (2020), Hopman et al. (2020), Gostin et al. (2020), Merchant and Lurie (2020), and Yu et al. (2020), including prescient comments on false diagnoses and reinfection; characteristics of and important lessons from the outbreak of the virus and disease in China; the known unknowns of the disease; the fast and furious response to the outbreak in Taiwan; the risk factors for and conditioning sets of the disease; prescient caution about the coronavirus and the common cold; the failed containment of the disease in the USA, with the only available option being responsible management; financial markets and government action against the disease in Lower and Middle Income Countries (LMICs); the proverbial "with great power comes great responsibility" relating to presidential power, and the slow and inept management of the disease; social media (mis)information and (mis)handling of COVID-19, and the connection of the coronavirus to the seasonal flu; and comorbidities of cancer patients.

Sharfstein, Becker, and Mello (Sharfstein et al. 2020) provide an important discussion regarding diagnostic testing for COVID-19, and suggest a number of tests that might be used in trying to mitigate

its spread, as distinct from discovering a vaccine to provide immunity against the disease. The next section examines whether one diagnostic test for COVID-19 is enough.

2. Discussion

The informative and invaluable paper by Sharfstein, Becker, and Mello (Sharfstein et al. 2020) makes clear the critical importance of diagnostic testing in an emergency; specifically which range of tests is available, where and when they are dispensed, and who might be tested using laboratory-developed tests, or other diagnostic tests including experimental tests. This includes testing for the SARS-CoV-2 virus that causes the COVID-19 disease. Testing is essential to "flatten the curve" of the number of confirmed positive cases of the disease, in addition to handwashing, isolation, and social distancing, among other essential measures.

The authors discuss a range of tests that includes:

(1) "the first test developed by the ... CDC"; "own laboratory-developed tests";
(2) "non-FDA-approved drug or device to respond to a declared emergency";
(3) "test developed ... by the Robert Koch Institute in Germany and adopted by the ... WHO" (which had some inconclusive and invalid outcomes!);
(4) "laboratories were encouraged to develop tests but could not use them for clinical diagnosis";
(5) "state laboratories asked FDA for permission to develop and use their own tests";
(6) "laboratory-developed tests without prior agency approval".

More recent investigations have considered variations of malaria-related vaccines and treatments of other coronaviruses, including HIV.

The question remains as to what tests are the most likely to lead to a correct diagnosis, namely a correct positive outcome. The purpose of this note is to provide commentary on the following critical statement by Sharfstein, Becker, and Mello (Sharfstein et al. 2020):

> "It is important to balance two concepts: remedying testing gaps is imperative; yet more testing is not always better."

The issue of "more testing" is fundamental to the application of any diagnostic testing. A test is of a null hypothesis, which in the case of testing for the SARS-CoV-2 virus that causes the COVID-19 disease, is as follows:

Null Hypothesis (H_0). *No confirmation of the virus.*

that is, a negative test outcome is presumed.

The null hypothesis may be correct (sometimes called true) or false. Rejection of a correct null hypothesis, which leads to a false positive diagnosis, involves the probability of a type I error, with an associated level of significance that is fixed at an arbitrary level (such as 1%).

The primary purpose of any diagnostic test is to maximize its power, namely rejection of a false null, such that a patient is diagnosed correctly as having the virus. Such a finding gives an accurate positive outcome of a viral infection, leading to a true positive. The power of a test is affected by the significance level and sample size, among other factors.

In the absence of a specific optimal test, the use of more (joint, simultaneous, or sequential) tests can increase the power of a test of the null hypothesis, and lead to a more accurate diagnosis.

The cost of diagnostic testing cannot be ignored, but it would seem prudent to consider more testing, and on many more patients, in order to immunize as many individuals as possible.

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