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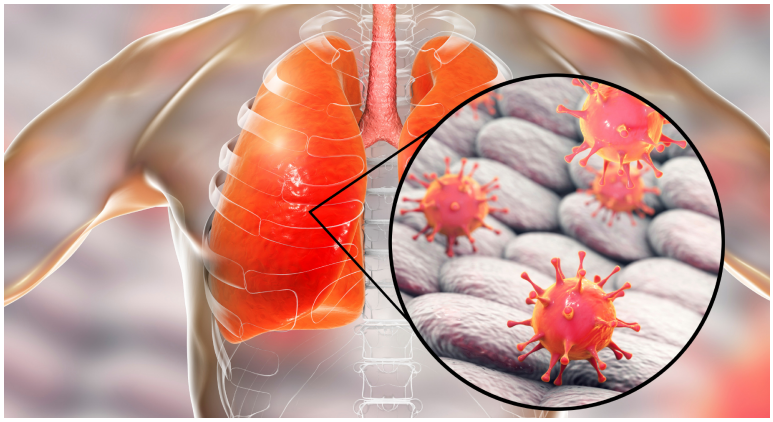

Self-Service Diagnosis of COVID-19—Ready for Prime Time?

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As the world grapples with the novel coronavirus (COVID-19), experts have called for increased access to health care resources, including diagnostic testing, particularly in light of the recent expansion of the Food and Drug Administration's Emergency Use Authority to make such testing more widely available in the United States.[1] Despite rapid expansion, there are significant barriers to testing in ambulatory clinics, emergency departments, and hospitals, which are likely to see a substantial increase in demand. Such access points also pose risks due to overcrowding and nosocomial transmission.

Current policy solutions are trying to eliminate financial barriers as well as facilitate additional points of access through increased use of telemedicine. However, telemedicine itself has limitations, because patients still need to go to a health facility to have a specimen collected and sent for processing.

In the wake of this epidemic, **other countries** have expanded testing through "testing drive-thrus," which have also been employed in **limited settings** in the United States. Self-testing for COVID-19 **has been proposed** in the United States in a limited setting. We propose expanding access more widely with a self-service diagnostic pathway for COVID-19 using at-home nasopharyngeal swab collection.

New Delivery Model

Use of an at-home nasal swab enables a diagnostic pathway for COVID-19 to be delivered remotely using widely available tools:

- Step 1: Individuals experiencing symptoms would access a telemedicine service and be advised by a qualified clinician who would triage them and determine whether testing is appropriate per the latest **CDC guidelines**.

- Step 2: Individuals able to be safely tested at home would receive a test kit through home delivery from a local distribution site; pickup at a local clinic, pharmacy, or public health center; or by mail; and then swab their nasopharynx themselves or with the help of caregivers.

- Step 3: The test kit would then be delivered or mailed to a local laboratory, which would provide results to the individual and their ordering clinician.

Benefits

There are several benefits to a self-service model, including wider availability with lower costs and mitigated risk of exposure to the virus. Home testing would also decentralize care and promote social distancing, particularly for older adults who have already been identified as high risk because of the increased mortality for adults over 50 years of age. Decreased use of health care facilities during an epidemic also has the advantage of allowing scarce resources to be allocated appropriately. Simply put, teams in hospitals, emergency departments, and clinics can focus on the patients with the highest-acuity health care needs and minimize nosocomial risks.

At-home testing could also promote health equity and patient-centeredness. Providing access to such testing could reduce language, cultural, or logistical barriers to seeking care at a clinic, emergency department, or hospital and reach rural communities where innovations such as drive-thru testing may not be feasible. Many individuals, particularly hourly workers and those without reliable childcare or ready access to transportation, may be better able to obtain testing if necessary.

Evidence Base

COVID-19 is a new pathogen, and so research and experience with self-collection of nasal swabs is limited. Nasal swab testing for COVID-19 has recently been assessed with emerging data on the performance of the available reverse transcriptase–polymerase chain reaction tests.[2] Self-testing for viral respiratory illnesses itself is not new and has been described in influenza, where there is more experience. A recent meta-analysis showed a pooled sensitivity of 87% (95% CI, 80%-92%) and specificity of 99% (95% CI, 98%-100%) compared with professional-collected swabs in the diagnosis of influenza.[3] In another study, participants were asked to self-collect swabs in an emergency department, which were compared with swabs collected by health care professionals in the opposite nostril.[4] Results were comparable; 90% of participants found self-collection to be easy or very easy, and only 21% preferred health care professional collection vs self-collection. Notably, a self-testing strategy would be offered only at the direction of a clinician with an understanding that no test is perfect, much like many of our available tests for other illnesses.

Policy Considerations

In response to the COVID-19 pandemic, more than a dozen US states have declared states of emergency, and national policy makers are considering following suit. Critical shortages of testing supplies and kits **remain a major concern**. A key policy question is whether and when the US will have enough testing kits for wide-scale rollout of self-testing. In the interim, a rapid study to assess the efficacy of self-testing is warranted.

We recommend that health care providers be allowed to develop and evaluate self-testing programs while calling on the federal government to mobilize the following actions in short order:

1. Accelerate health services research to establish and identify comparative effectiveness of various interventions, including self-testing, drive-thru testing, telemedicine for purposes of triage alone, and traditional face-to-face clinic- or facility-based visits. Key populations, such as those with higher risks, limited mobility, and language barriers, should be considered.

2. Identify how a self-directed testing strategy can be paired with a more robust monitoring mechanism to identify which states or regions may need more testing supply (eg, self-testing requests can be paired with the ability to monitor testing capacity as more academic and commercial labs are increasing capacity).

3. Issue guidance to health information vendors certified through the US Department of Health and Human Services Office of the National Coordinator for Health Information Technology to collaborate and develop a mechanism to rapidly share de-identified health information for the purpose of learning more about positive results, clinical presentation, treatment course, and outcomes.

4. Consider self-testing as a recommended strategy in hot-spot areas with particular concern for reliability of self-quarantine in asymptomatic cases with a confirmed likely COVID-19 contact.

5. Continue to press public and private payers to cover self-directed testing without any out-of-pocket costs.

Conclusion

Self-service diagnosis for COVID-19 as a new clinical pathway would need to be proactively monitored and assessed for effectiveness. But given the present limited state of access to testing for far too many individuals, the risk of inaction may be even greater.

Article Information

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