BRIEF REPORT

Shifting Coronavirus Disease 2019 Testing Policy and Research to Include the Full Translation Pipeline

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The current severe acute respiratory syndrome coronavirus 2 testing policy and practice limits testing as a prevention tool. Radical shifts are required to increase the scale of rapid testing strategies and improve dissemination and implementation of venue-based and self-testing approaches. Attention to the full translation pipeline is required to reach high-risk segments of the population.

Keywords. dissemination; reach; SARS-CoV-2; testing; translation.

OVERVIEW

The current paper discusses the importance of understanding severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) self-testing in the broader context of translating testing innovations to real-world settings. Our perspective is that self-testing should be an integral part of a larger venue-based testing system; self-testing is not a replacement for venue-based testing, it is an enhancement that increases system reach to include individuals who desire testing but have limited or no access to venue-based testing (eg, clinic or drive-through sites). We recognize that there are segments of the population who, for a variety of reasons, are resistant to testing just as they deny the existence of a pandemic or espouse antivaccine beliefs. Our discussion does not address this latter population segment.

Service [1] summarized expert opinion and recent studies in concluding that stemming the spread of SARS-CoV-2 requires a radical change in testing policy and practice including the following: (1) substantial increases in support for scaling up test production, (2) using tests that produce results more rapidly, and (3) increasing the frequency of testing (eg, testing every 2–4 days) to allow for the use of less sensitive, but more available tests, and to reduce the spread of SARS-CoV-2 by shortening the length of time between initial infection, test results, and preventive action. Although we concur with these proposed policies, it is critical to more fully address the translation pipeline including test dissemination and consumer implementation with attention to reaching high-risk populations (eg, Latinos, African Americans, American Indian/Alaska Native, Native Hawaiian/Pacific Islander, low literacy adults, adults with poor mobility, and low healthcare access) [2, 3]. Furthermore, we agree that SARS-CoV-2 self-testing has the potential to (1) augment prevention efforts by increasing the frequency of repeat testing over short periods of time, (2) reduce access barriers to testing (eg, for low income, elderly, mobility challenged; ie, transportation barriers significantly reduce healthcare seeking) [4, 5], (3) decrease health risks associated with venue-based testing (eg, viral exposure from/to others), (4) reduce SARS-CoV-2 healthcare costs by reducing the need for contact with trained providers, and (5) improve linkage to care through earlier detection.

SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2 SELF-TESTS: STRENGTHS AND LIMITATIONS

There is considerable precedence for self-testing as a mechanism for increasing monitoring (eg, blood pressure, blood glucose self-testing) and for strengthening primary/secondary prevention efforts (eg, human immunodeficiency virus [HIV], pregnancy home testing). Past work suggests that self-testing has the greatest potential for widespread adoption when the costs are low, tests are widely available and easy to access, tests are simple and/or painless to self-implement, and results are rapidly obtained [6–9].

Currently, there are 3 ways to test for SARS-CoV-2: antibody, antigen, and ribonucleic acid (RNA)-based tests. Antigen and RNA-based tests provide information on active infections. Both are highly specific, but RNA-based tests are more sensitive. The RNA-based polymerase chain reaction (PCR) tests are considered to be the gold standard for providing definitive results on active infections. There are multiple SARS-CoV-2 RNA-based PCR self-testing strategies [10–13] that allow for home self-collection of oral or nasal specimens, which are returned to a laboratory for analysis. Past work suggests that RNA-based tests may generate errors in identifying active infection because the test is unable to discriminate between live and dead virus [14]. Moreover, RNA-based tests do not provide information on past infection.

From a dissemination implementation perspective, the major limitations of RNA-based PCR self-tests are their expense (>$100) and associated delays in obtaining results. The overall process requires 3 steps: (1) the test is ordered and delivered, (2) the consumer performs the test and mails it back to the laboratory, and (3) the laboratory performs the testing procedures and returns the test results. This 3-step process may take 4–6 days to complete. In some rare circumstances, this process may take longer due to delays in acquiring or returning specimen collection kits. Processing of self-test specimens typically occurs at national laboratories. Manufacturers (eg, LabCorp) [10] estimate that laboratory specimen analysis alone will take 1–2 days. Moreover, specimens that are delayed in arriving at the laboratory may be rejected, which requires a new specimen collection by the consumer.

However, a significant improvement in RNA-based self-testing has recently occurred (November 17, 2020) with the US Food and Drug Administration (FDA) approval of the Lucira coronavirus disease 2019 (COVID-19) complete all-in-one at-home test kit (ie, home specimen collection, analysis, and results). This is a single-use test kit intended to detect active infection using the loop-mediated isothermal amplification method (LAMP) to detect viral RNA [15]. Although this test could conceivably be a major step forward in home-testing, it requires a prescription from a physician and costs approximately $50 per test. The prescription requirement will potentially reduce the reach of this home test kit to (1) those individuals who are experiencing symptoms and have a physician and (2) those who have insurance coverage. Consequently, low-income individuals without insurance and who do not have a regular physician (eg, rural Latino farmworkers) may have difficulty accessing this test [16].

Full at-home antigen tests are not yet available but are under development [17]. Current antigen tests, such as Abbott's Binax NOW rapid COVID-19 antigen test, are point-of-service tests that require an expensive device to test specimen samples. Consequently, it is not an at-home testing procedure, but a venue-based testing method, although it could be coupled with mobile testing services to improve reach to less mobile communities. The challenge with antigen tests is that specimens collected beyond 5–7 days after the onset of symptoms may reduce sensitivity and produce a higher rate of false negative results.

Antibody testing informs an individual that they have been infected but does not identify persons with active infections who are capable of spreading SARS-CoV-2. Medek has produced the Healgen COVID-19 antibody test, which can generate results at home (ie, specimen collection, analysis, and test results are obtained at home) in approximately 10 minutes [18]. This test has value for surveillance and behavioral epidemiological studies because it helps to identify pathways that SARS-CoV-2 infection has taken in the population.

Research to date on SARS-CoV-2 self-tests has primarily emphasized accuracy and manufacturing capacity [1, 17, 19], with less focus on how to improve dissemination and implementation in high-risk population segments. Current SARS-CoV-2 self-testing strategies are expensive [17], dissemination is primarily internet-based, and may be poorly adapted for low-literacy, non-English speaking adults.

SELF-IMPLEMENTATION CHALLENGES

Self-implemented health practices require that the consumer receive training materials that are easy to comprehend and to use. With respect to SARS-CoV-2 self-testing, implementation fidelity studies need to be conducted with consumers in natural settings rather than clinical settings to verify that the materials being used to train consumers in self-implementation are able to do that correctly (ie, consumers comprehend training materials and perform required test procedures correctly). The SARS-CoV-2 self-tests more often use written and graphic inserts and less frequently use online videos as training materials. These materials need to be examined closely, particularly in low-literacy populations that might have trouble understanding written or graphic instruction materials. Prior investigations [20, 21] have not reported self-test performance fidelity for those who are less likely to perform self-testing correctly (eg, low income, less educated persons) or for high-risk segments of the population (eg, low-income African American or Latino persons) (eg, Tu et al [21] do not report race/ethnicity data; Altamirano [20] reports data for only 2 Latino cases and reports no education data). Moreover, these studies do not examine training materials and self-implementation in natural settings outside of the clinical environment. Parallel literature on implementation fidelity for HIV oral self-testing may be helpful to investigators pursuing SARS-CoV-2 self-testing research (see "Lessons From Human Immunodeficiency Virus Testing" below).

DISSEMINATION CONCERNS

We agree with Service [1] in pointing out how critical it is to reduce the lag time between consumers test-seeking and receiving results; in this context, we believe that improvements in dissemination of at-home testing can reduce lag time [17]. Reducing lag time may have important treatment ramifications. Delays incurred could make a difference in whether life-saving interventions can be administered and may negatively impact clinical outcomes (eg, remdesivir is more effective when oxygenation requirements are minimal) [22].

With regards to dissemination, the majority of current SARS-CoV-2 testing is being conducted through venue-based approaches wherein people need to access a clinic or other venue (eg, drive-through sites) to obtain testing. The limits of venue-based health practices have been documented in other contexts (eg, problems reaching African Americans [6–8] at high risk for HIV infection and limiting vaccine dissemination to Latino

workers whose access is inhibited by the absence of sick leave that would allow them to seek medical services [16]).

As noted earlier, internet dissemination of SARS-CoV-2 self-testing may limit access. Internet-based dissemination strategies require a proactive individual who has access to the internet. Despite the popular myth that everyone has internet access (ie, either computer or cellphone), US census data reveals that access is significantly lower for low-income and ethnic/racial minority persons [23, 24], population segments at high-risk for SARS-CoV-2. With regard to self-testing, we recommend dissemination through commercial sites (eg, pharmacies, grocery stores), community-based organizations (without prescription), and mobile test units (eg, health van delivery of testing to specific neighborhoods, rural areas) that increase reach to high-risk communities. Mobile testing offers a unique advantage in that it has proven to successfully improve access to healthcare for high-risk ethnic minority populations [5], and it would allow dissemination of both venue-based tests and self-test kits. Mobile SARS-CoV-2 testing units are being deployed in some states but, to our knowledge, do not include self-testing options (eg, Texas) [25]. Support is needed at all levels to increase the production and dissemination of mobile van units devoted to SARS-CoV-2 testing.

In applying testing as a prevention strategy, it is also important to consider translation with regards to dissemination capacity. In discussing testing as a prevention tool, Service [1] reviewed work by Paltiel et al [26] which shows that university settings would need to test everyone every 2–3 days to achieve a successful prevention strategy. This type of strategy would require a large workforce to rapidly and repeatedly disseminate point-of-service tests or field workers to administer tests in students' residences (eg, 133 full-time staff to test 20 000 students in 3 days). Full at-home self-testing may reduce workforce problems by allowing students to test themselves frequently, assuming that a sufficient volume of tests are available.

LESSONS FROM HUMAN IMMUNODEFICIENCY VIRUS TESTING

Human immunodeficiency virus testing has evolved from a clinic-based testing model to one that encompasses community-based test sites (eg, churches, street fairs, service organizations) and self-testing. Although this system has developed over the past 30 years, the movement from venue-based testing to self-testing was slow (ie, self-testing was available for almost 1 decade [6, 9], but Centers for Disease Control and Prevention/state health departments were slow to adopt the tests [7, 8, 27]). Questions were raised concerning the utility of self-testing to reach high-priority populations, the ability of individuals to self-test correctly, and whether self-testing would inhibit or facilitate clinical diagnosis, linkage to care, and counseling. Concerns regarding HIV self-testing persisted, and venue-based HIV testing continued to be a priority for prevention and/or linkage

to care [28, 29] despite research identifying the limitations of this approach in reaching high-risk populations [6, 30].

A major goal of self-testing is to improve the reach of the testing system to population segments that have difficulties or are reluctant to seek testing from public venues. Evidence that approximately 15%–20% of new HIV cases were previously unaware of their HIV status [29, 31, 32] suggests that venue-based testing resources in the United States have limited reach in some population segments. In particular, venue-based testing has been demonstrated to have poor reach into high-risk populations in which self-testing is more acceptable [6, 30, 33]. In this regard, self-implemented HIV testing has gained global acceptance and has significant potential to extend the reach of HIV testing among priority populations [6–8, 14, 34].

Until recently, oral-HIV self-testing was primarily being disseminated through commercial sites such as pharmacies [6]. Because of this limited distribution process and high commercial costs (>$40 per unit), oral-HIV self-testing had poor dissemination unless underwritten by public funding [6]. Before the COVID-19 pandemic, HIV self-testing was primarily recommended as a screening test. Since the COVID-19 pandemic internet dissemination of free oral-HIV self-tests has become commonplace [27, 35], with departments of public health offering oral-HIV home test kits as a primary test with the proviso that if individuals test positive and seek pre-exposure prophylaxis, then they would need additional testing [27].

Another criticism of self-testing is that consumers may not use it even if it is more widely available. A substantial body of work has shown that oral-HIV self-testing is preferred by consumers over venue-based testing and finger-stick HIV self-testing [6, 14, 27, 35–38]. In this context, we suspect that SARS-CoV-2 self-testing that involves saliva samples will show a higher consumer preference over nasal or oral swabs, which can be uncomfortable.

Studies examining the sensitivity and specificity of oral-HIV self-testing in community settings have been mixed. Some studies have found lower sensitivity for oral-HIV self-test kits compared with blood-based tests [14, 39], but several other studies suggest that oral and blood-based tests are equivalent [9, 40–44]. Catania et al [45] have suggested the challenge is not with the test itself, but with consumers' ability to implement the test with high fidelity. We suspect that COVID-19 self-testing will also show higher variability in diagnostic accuracy across samples, in part because of differences in tests, but also because tests differ in the challenges they pose for self-implementation.

Another criticism of SARS-CoV-2 self-testing is that people will not faithfully test themselves [17]. However, such criticisms are somewhat vague and unsubstantiated. The ability of self-testing to identify COVID-19 cases to facilitate earlier quarantine or treatment is an empirical question to which we do not currently have an answer. However, from the experience of people working in the field of HIV, we have found that

individuals can overcome their reluctance to get tested as well as overcome barriers to venue-based testing through access to self-testing [7, 8]. Large-scale dissemination studies have shown the ability of HIV self-testing to reach never-tested populations [7, 8]. Nevertheless, we assume that there remains a population segment that cannot be reached with either venue-based or at-home self-tests. From this perspective, we believe that individuals who are resistant to COVID-19 prevention messages and disbelieve the presence of a COVID-19 pandemic will probably not get tested, just as they are unlikely to get vaccinated. However, it is specious to argue that we should not widely disseminate COVID-19 self-tests because some population segments will not participate.

An early concern regarding HIV self-testing was whether it would improve or inhibit identification of HIV cases and, in turn, if it would be possible to link people to care and/or counseling if they were self-testing at home. In this context, it is important that people self-test frequently to increase the chance that they can identify a new infection and, in turn, take reasonable action. With HIV self-testing, the FDA required that at-home self-tests provide the consumer with a link (telephone/internet) to counselors to aid in the interpretation of test results, provide necessary prevention information, and direct individuals to treatment sites geographically proximal to their home residence. Similar comprehensive services should be attached to SARS-CoV-2 self-testing strategies. This type of proactive service will help produce a potentially seamless link between self-testing and prevention and/or treatment. In this regard, we would assume that individuals who seek self-testing will also be motivated to engage in prevention activities and/or seek treatment advice.

With regards to improving identification of COVID-19 cases as noted, it is important to increase the frequency of testing [17]; self-testing can help accomplish this goal. Extensive work within the field of HIV has shown that high accessibility and low cost will increase self-testing frequency, earlier detection of new infections, and facilitate linkage to care [6–8, 33, 34, 46–51]. A diagnostic criticism is that only symptomatic individuals will seek self-testing, and, therefore, it cannot be useful as a true preventative strategy in that asymptomatic persons who are infected and capable of spreading SARS-CoV-2 will not be identified. From the field of HIV, it has been clear for some time that asymptomatic individuals will test themselves for HIV given public health messages that motivate asymptomatic persons to get tested. Self-testing works best in combination with public health campaigns designed to motivate test uptake [52–54].

A final criticism of self-testing strategies is that people may have significant challenges implementing at-home self-test kits. We agree based on our work in HIV that there are some population segments that may have problems. However, the problem is not with the tests per se, but with the instructional or training materials that accompany self-tests. For instance, OraSure's oral-HIV self-test combines graphic and written instructions along with video instruction that facilitates good training comprehension and performance fidelity, even among less-educated populations [30, 45, 55]. Video training components need to be culturally and linguistically appropriate and have been shown to significantly improve implementation fidelity (vs graphic instructions) among populations with low literacy [56]. The video component is critical because it supplants the need for reading and understanding written or graphic instructions. We strongly recommend more extensive self-implementation studies for SARS-CoV-2 self-tests in a wider range of populations, particularly those at highest risk for severe COVID-19 outcomes and for individuals least likely to understand written or graphic instructions.

CONCLUSIONS

Translation studies are needed in the field of public health to understand how to improve dissemination and implementation of evidence-based programs or technology in everyday settings across diverse populations [57]. The present SARS-CoV-2 venue-based and self-testing system has challenges with respect to dissemination, implementation, and reach. There is an urgent need to conduct studies that examine these issues particularly among those who are at high-risk for SARS-CoV-2 infection and severe outcomes (eg, low income, elderly persons, African American, Indigenous, and other people of color) [2, 3]. We need to expand the testing policy-practice framework to encompass the entire translation pipeline within a multilevel perspective (ie, multiple dissemination and implementation pipelines).

We recommend large-scale dissemination of both SARS-CoV-2 venue-based testing and self-testing, with the specific goal of reaching those persons who are unable to obtain venue-based testing but are motivated to get tested for COVID-19. This process should include increased information dissemination on availability and where to access self-tests to better inform individuals who are unaware of self-testing strategies. Along these lines, an elimination of the need for prescriptions to obtain self-testing is fundamentally necessary; currently, prescriptions add an additional access barrier. In addition, research is needed to examine COVID-19 self-testing training materials that rely too heavily on graphic and written instructions and test the cultural appropriateness of these materials for low-income Latino, American Indian/Alaska Native, Native Hawaiian/Pacific Islander, or African American populations. Lastly, expensive tests that require mailing specimens to a laboratory for processing have reduced utility because individuals may not take necessary preventative precautions while they are awaiting their test results. Full at-home self-tests that are available at relatively low costs are required. Ideally, these costs should be underwritten with by the US government.

Limitations of full at-home test kits may include (1) the failure to report results to public health authorities and (2) the inability of antibody-based tests to identify recent active infections. Despite these potential limitations, self-testing is not a trivial convenience, it is a necessity. Understanding the entire translation pipeline from test production to dissemination and implementation in real-world settings is required for testing systems to be successful [6].

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