How to ensure regulations don’t stymie much-needed COVID-19 point-of-care testing

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The coronavirus disease 2019 (COVID-19) pandemic has raged for more than a year in the United States, upending life as we knew it. Nevertheless, we have seen incredibly rapid advances in vaccines, therapeutics, and diagnostic testing technology. There is tremendous need and economic interest in reopening our businesses and schools and in resuming gatherings for entertainment and sporting events. To accomplish this, we need a strong multifaceted strategy. Already, widespread vaccination is well underway. But those efforts must be coupled with aggressive community-based COVID point-of-care testing so that any case of asymptomatic infection, especially in the most transmissible phase, is rapidly identified (1).

Corporate and federal support of medical diagnostic companies has fueled innovative, easy-to-use, inexpensive, point-of-care COVID-19 viral tests with multiple different technologies. The retail cost of these tests is now as low as $5 per unit, and they have become as easy to use as a home pregnancy test. Unfortunately, it’s not enough.

The US Food and Drug Administration (FDA) has expedited the evaluation and granting of Emergency

We must devise more sensible regulations that meet the moment, allowing for rapid, widespread COVID-19 point-of-care testing. Image credit: Shutterstock/zstock.

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Use Authorizations (EUAs), ensuring that newly developed tests meeting validation criteria come to market promptly. However, similar to COVID vaccine distribution “last mile” barriers, there remain significant challenges to the real-world implementation of rapid, point-of-care testing. These remain despite the FDA, in July 2020, issuing an EUA application template for at-home and over-the-counter (OTC) tests for nonlab settings, such as homes, offices, or schools, which would not require physician prescription (2).

To better develop testing and develop a more effective approach, we must devise more sensible regulations that meet the moment, allowing for rapid, widespread testing. Even as we make progress with vaccines administered across the country, better testing will save lives and aid the economic recovery. Improvements made now will also help ensure a more efficient system for the tests that might be needed in the coming years in the event of a future epidemic or pandemic.

Public Health versus Clinical Care

Traditional diagnostic testing is performed for the benefit of the individual patient, to diagnose or monitor a condition, such as home blood glucose monitoring for diabetes care. But COVID-19 is a highly transmissible viral infection with significant population-based consequences, and point-of-care testing in the community should benefit the collective rather than an individual. The pandemic has clearly demonstrated that we need a different approach.

Consider two illustrative hypothetical case studies to demonstrate these barriers. In the first, imagine that a small performing arts studio, with five employees, wishes to offer regular testing to employees and future patrons. The studio must address the following requirements:

1. A Clinical Laboratory Improvement Amendments (CLIA) waiver: In most cases, companies did not submit tests, even if easy to use, for home/OTC approval. They therefore require CLIA-waiver status for on-site testing, which typically entails a defined laboratory space, a designated medical director, and a relationship with a CLIA-approved clinical laboratory (3).

2. A licensed physician, or equivalent, prescriber: Tests not approved for home/OTC must be prescribed by a licensed prescriber, requiring the arts studio, in this case, to source a state licensed medical physician or provider to develop standing order protocols or prescribe every test.

3. Personal health information (PHI): Test results and the accompanying demographics would classify as PHI, hence requiring a Health Insurance Portability and Accountability Act (HIPPA)-compliant data system to manage and report positive results to public health authorities.

The process is so complex that the studio owner in this case would ultimately need to contract with a third party company to perform the testing, incorporate physician and CLIA-certified laboratory oversight, and perform data management. These requirements greatly increase the costs and make testing economically impractical.

The second case study reflects a real-world scenario. A hotel brand, which the authors worked with, hoped to have employee and patron testing available at properties throughout the United States. The hotel has particular interest in testing to enhance safety for group events (for example, corporate meetings and weddings) and personal services such as spa visits. The hotel central office realized that for CLIA-waiver status, each state has different requirements and approval processes, and each hotel will require a physician authorized in that state to order tests. And there will be further barriers to test distribution, as manufacturers must ship directly to where the test is being performed—as a result, the hotel cannot receive the tests centrally and distribute them.

A Legacy Problem

It is unclear why it remains so challenging for businesses to implement COVID-19 point of care testing and why more tests are not approved for use in nonmedical settings. Businesses, store owners, and organizations obviate many of the above barriers if a test is approved for OTC use. However, to date, there are only two COVID-19 diagnostic tests approved for this purpose, with associated pricing likely prohibiting widespread use (4, 5). This may stem from the economics of opportunity for testing companies; selling to individuals at a higher unit price may be more profitable than lowering the unit price to sell larger numbers to businesses. Vendors may also fear that pricing tests too low may give the public the perception that they are lower quality.

Several things must happen to make this process more feasible and more efficient:

- We need to remove the CLIA-waiver requirement for testing sites, which make the process unnecessarily burdensome and costly.
- We should remove the prescription requirements and reframe workplace and community testing as public health tools to help prevent spread COVID-19 infection. As a result, the employee or guest would not be a “patient” seeking care from a medical provider, and no “patient–provider” relationship would exist. The benefit is to the public as a whole.
- We need innovative data management systems to ensure adequate privacy of test results and personal information, while allowing information to be easily shared with event organizers, businesses, etc. Never before has there been a need to share test results, which may be HIPPA-protected data, outside of the healthcare arena.
- We need quality assurance processes to ensure test sampling, and quality control of testing batches, performed correctly. We should provide correct testing procedures via instructional videos and certify competencies with virtual assessment of employees performing and validating tests and kits.
We need comprehensive public health messaging, including explanations that no test is 100% sensitive or specific and that in many settings negative results do not discount the need for face masks and physical distancing.

Companies need to pursue home/OTC EUA for appropriate tests, and the CLIA and FDA regulations need to be updated to deal with the present pandemic realities and those that may occur in the coming years. COVID-19 infection rates across the United States are decreasing, and we have increasing availability of very effective vaccines. As a result, we have the opportunity to reopen schools and evaluate reopening businesses and communities in a safe manner.

But achieving and maintaining the "new normal" requires widespread testing outside of traditional settings—and, consequently, reform of intrastate barriers, medical practice, and laboratory licensing requirements. Now is the time to make these crucial changes if we hope to continue to make progress against the virus. We cannot sit still.