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Opinion

The United States' SARS-CoV-2 Testing Challenges Underscore the Need to Improve Surveillance Ahead of the Next Health Security Crisis

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The COVID-19 pandemic has underscored the critical role of diagnostics tools in public health responses to health security crises. But persistent gaps in abilities at the national- and sub-national level to adequately diagnose and enumerate infected individuals, identify contagious individuals, and describe changing trends in transmission and the pathogen itself have hindered health officials' abilities to control the spread of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus. These challenges are not necessarily unique to the current pandemic and, absent specific plans to address them, will likely be encountered again in future emerging infectious disease events.

The potential for pathogens like the SARS-CoV-2 virus to spread between people—sometimes before obvious symptoms develop—increases the importance of having adequate tools to diagnose infection. In addition to being needed for clinical management of sick patients, tools that enable identification of contagious individuals can help facilitate disease control efforts. Rapid identification of infected patients enables prompt isolation and the tracing and quarantining of patients' contacts to prevent spread of the virus to others.

Challenges in using diagnostics to support a public health response to COVID-19 have been evident in the US since the beginning of the pandemic. Though some countries were able to quickly build capacities to test patients suspected of being infected with the SARS-CoV-2, the US struggled for months to do so. At the onset of the pandemic, testing persons suspected of having the virus was limited to that which could be conducted at the US Centers for Disease Control and Prevention (CDC). This constrained the total number of patients who could be tested and the timeliness with which test results could be obtained. For months, only patients with a history of travel to China and/or ill enough to be hospitalized could be tested for the virus.

The US's failure to rapidly expand testing to enable the identification of patients infected with the novel virus has been called the "original sin" in its public health response to COVID-19 (1). First, an inability to adequately diagnose and isolate infected travelers enabled the virus to spread within the US. Then, an inability to test patients without a history of travel delayed local transmission of the virus and allowed it to establish itself in US communities. This led to explosive outbreaks in the spring of 2020, which left states with few options but to implement shutdowns and restrict public gatherings. In some parts of the US, public support for future disease control measures weakened after the shutdowns (2).

A mix of technical and regulatory challenges slowed US efforts to implement widespread laboratory-based testing for the SARS-CoV-2 virus. Though some countries adopted testing assays from the World Health Organization, CDC developed the first assay authorized for diagnosing SARS-CoV-2 infection in the US. Quality issues were found, however, in some test kits deployed to state laboratories. This setback delayed the start of decentralized testing. Regulatory constraints also created difficulties in establishing laboratory surveillance. Although the US has a world-class network of public health and clinical laboratories that could have developed their own assays to test for SARS-CoV-2, instead of waiting for CDC to send them test kids, federal restrictions initially prevented these laboratories from doing so. While technical challenges may have been unforeseen, the US should consider whether its regulatory approaches adequately enable an expansion of quality laboratory testing during public health emergencies.

Though confirmatory testing at laboratories will likely remain the foundation of national surveillance programs, the COVID-19 pandemic has demonstrated the need for more rapid and decentralized testing to support disease control efforts. The ability of individuals with SARS-CoV-2 infections to transmit the virus in the absence of distinguishing symptoms, created a case for testing for more than just diagnosing sick patients.

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Testing to support public health efforts requires tools that enable the rapid identification and isolation of individuals likely to be contagious. The development of additional testing technologies, such as antigen-based tests, enable individuals to be rapidly screened outside of a laboratory and provide results quickly enough to isolate individuals who may be contagious. Groups called for the widespread use of these tools for screening in schools and businesses, but limited progress in regulatory standards and production limitations in the US slowed adoption of these tools (3, 4).

Even now, with widespread laboratory testing and other diagnostic tools available, the US still struggles to use testing to guide its public health control efforts. A key reason is the failure to establish testing programs aimed at answering key epidemiological questions, such as whether the pathogen is mutating and how it is spreading between people. There is a need to expand genomic surveillance efforts to characterize pathogens and identify epidemiological links between cases. Since the start of the pandemic, the SARS-CoV-2 virus has demonstrated the potential to mutate. But by the end of December 2020, the US had only sequenced less than a third of a percent of its then more than 17 million COVID-19 cases—a step necessary to track potential mutations (5). In April 2021, the Biden administration provided additional resources to increase US sequencing capabilities (6). This has led to an expansion of sequencing across the US, though the country still lags others it in the overall percentage of cases sequenced (7). Though resources provided by the Biden administration also were intended to establish Centers of Genomic Epidemiology, compared to other countries, the US has published very few genomic analyses of case clusters. Sustained funding will be necessary to ensure that these expanded sequencing capacities are maintained during future health security emergencies.

The US also failed to establish surveillance programs to proactively identify infections and to estimate the incidence of infections occurring in communities. Most jurisdictions' approaches to conducting surveillance rely on individuals who are symptomatic or who have been exposed to a case to self-report for testing. Additional testing may occur if large employers or colleges screen employees or students for the virus. Biases in who is likely to self-report for testing or be tested through workplace- or school-based screening programs mean these surveillance approaches do not enable an estimation of the frequency of infections occurring in many areas, likely contributing to an underestimate of the amount of infection occurring in the overall community and creating missed opportunities to interrupt transmission through isolation and quarantine. In future pandemics, surveillance efforts that actively test representative populations may better enable estimation of the incidence of infection.

Finally, the US has not adequately addressed social and economic barriers that may prevent patients from getting tested. Throughout the pandemic, there have been reports of uneven access to testing among communities (8). Though the numbers of tests conducted within the US has increased over the course of the pandemic, government-run testing efforts declined in many areas once jurisdictions shifted government resources to focus on mass vaccination (9). Though testing is still available through private-sector providers, private providers, such as retail pharmacies, may not serve all communities, including those that may have been hardest hit by the virus.

Even when testing is widely available, there still may be disincentives for patients to get tested, such as fear of losing income from having to isolate after testing positive. While some countries have guaranteed financial support for individuals that need to isolate or quarantine, the US failed to implement comprehensive programs to enable COVID-19 cases and their contacts to comply with public health recommendations to stay home until they were deemed to be no longer at risk of spreading infection (10). Efforts to expand testing in the future must address social and economic barriers to adherence.

While the emergence of new infectious diseases is difficult to forecast, a strong enough pattern has been established for us to expect to see the regular appearance of new infectious diseases. The ongoing pandemic follows a string of highly challenging disease emergencies that have posed threats to the US, such as the emergence and spread of West Nile virus, severe acute respiratory syndrome in 2003, pandemic H1N1 influenza, Middle East respiratory syndrome, and Zika. The frequency with which these events have occurred tracks with findings that, even after accounting for improved surveillance, across the globe the number of emerging infectious disease outbreaks that have involved new diseases emerging in humans for the first time has been increasing since 1940 (11).

It is urgent that we learn from the US surveillance shortcomings during the COVID-19 pandemic and make improvements to national preparedness efforts in advance of future health security crises. Though COVID-19 came as a surprise to many elected officials, the medical and public health community has long been calling on national political leaders to improve preparedness for infectious disease emergencies. Most recently, the Global Health Security Index found that no country—including the US–was fully prepared to respond to a pandemic, such as COVID-19 (12). Before COVID-19, political inattention to the need to bolster surveillance may have been understandable. But after spending

nearly 2 years of bearing witness to the consequences of not being prepared, no more excuses remain.

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