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A Commonsense Approach for Testing in a Pandemic

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KEY TAKEAWAYS

As researchers work to develop a vaccine and effective therapies for COVID-19, it is essential that states deploy appropriate testing to protect Americans.

States should focus on diagnostic tests to determine who has COVID-19, antibody tests to determine who had it, and random sampling tests to find disease prevalence.

Public buy-in is critical for testing programs to succeed. Officials should clearly outline goals, logistics, and candidates for testing.

After initial delays rooted in a flawed pre-existing federal regulatory regime,[1] the United States is rapidly ramping up mass testing for the SARS-CoV-2, which causes the COVID-19 disease. From the outset, the central challenge for federal and state public officials has been to strike a prudential balance between the primary need to protect the lives and safety of American citizens with the necessity of allowing them to work—and thus avoid the manifold damages to their livelihood, as well as their health, from negative consequences of long-term unemployment and economic and social deprivation.

We do not yet have a vaccine, nor are there well-established therapeutics to treat the coronavirus. Thus, a crucial part of managing our response to this pandemic and its aftermath is testing, both diagnostic (determining who *has* the infection) and serological (determining who *has had* the disease). But at least

some forms of testing are labor-intensive, time-consuming, and reliant on chemical agents that may or may not be readily available. Therefore, it is paramount that state officials utilize testing resources in the most efficient and cost-effective manner possible.

Parameters and Public Policy

Parameters for a successful testing program should be targeted to the facts and need of a particular location and population. Any program should offer maximum feasible accuracy, scalability, manageable cost, appropriate availability, and public information so the general public can easily understand the strategy.

Public policy is sound when it addresses concrete reality, the particular conditions on the ground. Obviously, these conditions will not be the same in every state, thus state policies will differ. But whatever such conditions are, both common sense and patriotism should encourage all stakeholders to engage constructively in creating an optimal testing matrix that citizens can generally embrace.

Creating a Matrix for COVID-19 Testing: Five Key Components

State and local public health authorities should use both clinical and environmental testing and clarify the goals of their testing program, the persons who should be tested, the timing of the testing program, and the number of persons that should be tested. The federal Centers for Disease Control and Prevention (CDC) should work with them to support their testing and publicize their findings.

The Types and Goals of Clinical Testing. There are two main types of clinical testing with different goals:

1. **Diagnostic testing.** Diagnostic testing identifies who has an infection. Its main goals are to verify, monitor, and treat infection in individuals and populations and to support the efforts of public health officials to mitigate and eliminate the virus. Diagnostic testing provides vital information to public health officials to conduct surveillance, contact tracing, and/or implementation of isolation or quarantine protocols. Monitoring active and recovered cases as well as the number of tested and the number of positive cases can inform decision making by public health and government officials.

2. **Serological testing.** Serological testing determines who has had the disease. It is also sometimes referred to as antibody testing. Its main goal is to provide a more accurate picture of the spread of COVID-19 in the U.S. and provide individuals and health care providers better knowledge of exposure and immunity status.

   Unfortunately, the CDC, as well as some states, have been "conflating" the diagnostic and serological in their reporting—thus distorting the public information and painting an inaccurate picture of the prevalence of the coronavirus. As reporters for *The Atlantic* observe, "These results damage the public's ability to understand what is happening in any one state. On a national scale, they call the strength of America's coronavirus response into question."[2] Obviously, going forward, state public health officials must not make the same damaging mistake.

The Candidates for Clinical Testing. While ideally everyone could have access to a test, in places where prioritization is required, policymakers should consider this framework:

1. **Diagnostic testing.** Anyone with symptoms of COVID-19 should be tested. Because it is possible to have a co-infection of influenza, once the flu season returns, individuals with flu-like symptoms should be tested for typical flu strains and COVID-19.

   To monitor and control asymptomatic spread of the disease, those working with high-risk populations in nursing homes, prisons, and in health care settings or emergency response should be tested frequently.

   In locations that have significant COVID-19 infections, those working in businesses and manufacturing in which social distancing is not feasible should also be tested for asymptomatic disease. Students arriving from hot spots should be tested prior to returning to campus unless an outbreak occurs, requiring more frequent surveillance or the student is symptomatic.[3]

   A plan for contact tracing and isolation and quarantine of students testing positive will require a collaborative effort by school health officers, diagnostic testing centers, and public health authorities. While mass testing for students and employees at K–12 schools, colleges, and universities may seem advisable, testing capacity, student and parent

willingness, and financial cost will likely prevent this level of testing which, based upon current data, may be unwarranted.[4]

2. **Serological testing.** Priority candidates include those who have been in hot spots and/or who have had symptoms of COVID-19 since December 2019, health care workers, those working in high-risk environments such as nursing homes and prisons, and emergency responders. People who are known to be exposed, such as those informed via contact tracing that they have been in contact with someone with the virus, should be given both a diagnostic test and an antibody test to know whether the person should be cleared or encouraged to voluntarily self-isolate.

   Once testing is readily available, any individual that wishes to obtain a test should be provided the opportunity to do so to determine exposure. At the federal level, the Food and Drug Administration should prioritize authorization of new innovative tests that can be conveniently distributed and administered. Centers for Medicare and Medicaid Services should ensure Medicaid and Medicare patients can afford and access these tests.

The Timing of Testing. Policymakers should work to ensure people have access to tests in time frames tied to the best available science about when to test. Currently, that varies as follows:

1. **Diagnostic testing.** Individuals should be tested when the symptoms present and once the individual is fever- and symptom-free for a minimum of three days to determine when quarantine can end. Preferably, those who have displayed symptoms of active infection should be tested more than once for negative results to ensure they are not spreading the disease once they return to normal activities.

   To monitor for asymptomatic spread, staff that work with high-risk populations, such as those in nursing homes and prisons, should ideally be tested weekly. This will only be possible if quick tests become readily available and distributed that have results within 15 minutes or less. Health care workers and emergency responders should be tested by their employer weekly. If testing capacity does not allow for weekly testing, prioritization should be based on likelihood of exposure and local level of outbreak.

2. **Serological testing.** Serological tests typically are not accurate until a minimum of seven days after exposure.[5] Depending on the antibody being tested, waiting until 14 days or more after exposure may provide more accurate results.[6]

The Number to Be Tested. For both diagnostic and serologic testing, state policymakers should take different approaches based on two goals: treating individuals and conducting random samplings.

1. **Diagnostic testing.** Policymakers cannot rely on a total number of positive tests and the number tested throughout the United States: It does not provide an accurate picture of testing adequacy. Rather, a state-by-state and locational approach provides a much better indication of where the country is facing problems with testing and where the testing is adequate.[7]

   Adequacy is determined by how many people come back positive relative to those tested. The World Health Organization's (WHO's) criteria recommends the positivity rate of tests remain under 10 percent for those tested for COVID-19.[8] If that standard is applied at the state and local level, many states *already* have adequate testing for COVID-19.[9]

2. **Serological testing.** As is recommended for diagnostic testing, antibody testing should be performed on individuals that exhibited symptoms of COVID-19 in the past few months but did not receive diagnostic testing or were unable to receive testing due to testing capacity.

   Antibody testing should also be offered when individuals test negative with diagnostic testing but the clinical picture indicated probable COVID-19. Although antibody testing cannot be performed during the initial phase of the illness, confirmation can take place during recovery, at least 14 days after onset of symptoms to ensure antibodies have had time to present.

   The number of individuals needing to be tested will vary based upon level of exposure in a county, state, or region. When antibody tests become available at a level at which cost-effective mass testing is possible through at-home test kits, this should be considered.

The Use of Alternative Testing Methods. Policymakers should also engage in additional random testing—sampling and environmental—to determine the prevalence and location of the disease.

1. **Random sampling.** Using both diagnostic and serological tests, random-sample testing is done to better determine the prevalence of the disease and provide additional data for immediate and future decision making. Such random sampling can be carried out by federal, state, or local public health officials working together in complementary roles.

   It is neither feasible nor necessary to test the entire population: The task is to ensure that random testing is done with the best methodology to accurately represent the community. The percentage of the population undergoing random testing should be determined by epidemiologists in a local region based upon population numbers, current disease outbreak, and population density.

   Testing should cover a wide range of people and places—both in hot spots and those that are not currently in hot spots, in order to detect emerging hot spots. Large businesses, manufacturers, school districts, and universities may consider working with the local health department to decide whether random sampling of asymptomatic workers and students is appropriate.

   Data from random sampling should be reported at the local, state, and national levels to provide a better picture of the pandemic and the spread of disease. This should be done by medical practitioners, private labs, local public health departments, or state health reporting agencies under the guidance of and reporting to the Centers for Disease Control and Prevention.

   The public will need a clear explanation of the goals of this federalist approach to testing to understand the program, trust the numbers and get an honest assessment of their risk.

2. **Environmental testing.** High-risk environments, such as school districts, universities, nursing homes, and prisons, may want to randomly test surfaces for the virus to determine if additional mitigation and sanitization measures are necessary. Randomly testing surfaces on public transportation and public event spaces may be warranted

to inform decisionmaking and to improve sanitation practices to prevent spread.

Finally, random testing of wastewater to determine probability of community spread could be used to inform the public health response. In the initial SARS outbreak of 2003, Chinese researchers were able to detect the concentration of the virus in sewage.[10] Likewise, there has been some evidence that the current SARS-CoV2 viral particles are shed from the gastrointestinal tract. This method of testing should be validated as soon as possible and, if found useful, deployed immediately. By testing at sanitation substations, public health officials could identify and respond more rapidly to developing hot spots. Colleges and universities could also use this method to monitor for community spread on campus.[11]

To improve population-level data, wastewater-based epidemiology can also be employed to estimate the number of individuals with the virus.[12] These estimations can improve local decision making and secure surveillance at low cost.[13] This information could be collected at the federal, state, and local level.

Conclusion

The work to address COVID-19 requires leadership: America's states, counties, and localities—supported by federal government, as outlined in this paper. Under the U.S. Constitution, state officials have broad authority to protect the health and safety of their citizens.[14] Policymakers should engage in prompt, constructive debate leading to consensus on a sound, well-designed, and targeted testing program that will assist them in their work against this deadly virus.

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Endnotes

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