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EDITORIAL

When Should Asymptomatic Persons Be Tested for COVID-19?

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ABSTRACT On 24 August 2020, the Centers for Disease Control and Prevention (CDC) updated its website to highlight that asymptomatic individuals, even those with exposure to a COVID-19-positive contact, do not necessarily need to be tested unless they have medical conditions associated with increased risk of severe illness from COVID-19. The CDC subsequently updated its guidance on 19 September 2020 to support testing of asymptomatic persons, including close contacts of persons with documented SARS-CoV-2 infection. In this editorial, the American Society for Microbiology Clinical and Public Health Microbiology Committee's Subcommittee on Laboratory Practices comments on testing of asymptomatic individuals relative to current medical knowledge of the virus and mitigation measures. Specific points are provided concerning such testing when undertaking contact tracing and routine surveillance. Limitations to consider when testing asymptomatic persons are covered, including the need to prioritize testing of contacts of positive COVID-19 cases. We urge the CDC to consult with primary stakeholders of COVID-19 testing when making such impactful changes in testing guidance.

KEYWORDS COVID-19, SARS-CoV-2, asymptomatic testing, contact tracing, surveillance

In March 2020, at the beginning of the COVID-19 pandemic in the United States, the limiting factor to testing suspected cases was access to tests. The delay in the rollout of the test from the Centers for Disease Control and Prevention (CDC) to public health laboratories, coupled with requirements for Food and Drug Administration (FDA) Emergency Use Authorization for laboratory-developed tests in CLIA-certified laboratories, resulted in limited test availability and left public health authorities, clinicians, and laboratories with no choice but to prioritize testing to symptomatic individuals. The inability to test broadly and rapidly early in the U.S. pandemic likely contributed to the undetected spread of the virus in many communities and ignited the U.S. epidemic. Figure 1 shows the average daily number of tests in the United States by month (1). From April to October, the average daily number of tests conducted in the United States has increased less than 5-fold. Even with >100 million tests performed since March, less than 25% of the U.S. population has been tested for COVID-19 (each test does not represent a unique individual). While there are many factors contributing to the persistence of the COVID-19 epidemic in the United States, undertesting is undoubtedly one of them.

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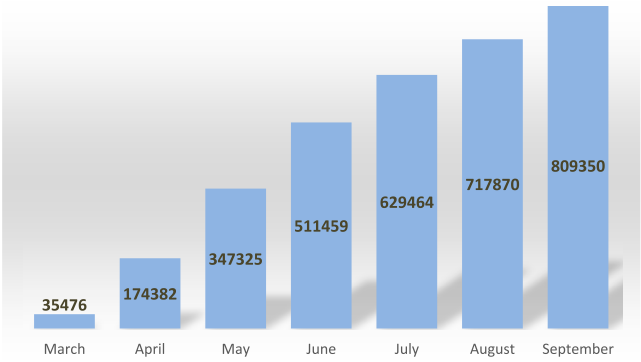

FIG 1 Average daily number of tests by month from data at https://covidtracking.com/data/national (1).

Another contributing factor to the continued, undetected spread of SARS-CoV-2 is viral transmission from asymptomatic persons and the relatively long incubation period of up to 14 days (2). Individuals who are asymptomatic (or have subclinical disease) and those who are presymptomatic are significant sources for ongoing viral transmission (3, 4). A number of described outbreaks in skilled nursing facilities, airplanes, cruise ships, and social gatherings have demonstrated the substantial role of asymptomatic transmission in the current pandemic (5–10). Testing individuals without symptoms should be a cornerstone of the concerted effort to curb SARS-CoV-2 transmission and, therefore, prevent unnecessary morbidity and mortality and allow for the reopening of schools and businesses.

However, in a surprise move, on 24 August 2020, the CDC updated its website to highlight that asymptomatic individuals, even those with exposure to a COVID-19-positive contact, do not necessarily need to be tested unless they also have underlying medical conditions that could render them at high risk of severe COVID-19 infection (11). The update to these testing recommendations, approved by the White House Coronavirus Task Force, occurred without an accompanying rationale for the change. Within a few days, many professional organizations, including the American Society for Microbiology (ASM) and the Infectious Diseases Society of America (IDSA), spoke out against this abrupt change by announcing that this modification to testing guidelines was inconsistent with current knowledge of the virus and proven mitigation measures necessary to contain the pandemic. After outspoken protests by many in the scientific and medical communities, the CDC subsequently reversed its guidance on 19 September 2020, to support testing of asymptomatic persons, including close contacts of persons with documented SARS-CoV-2 infection (12). Clinical and public health microbiologists, physicians, and the general population have relied on the CDC for decades to guide us through public health crises and times of uncertainty. While abrupt shifts in practice are expected during a pandemic as new data emerge, the initial notification announced in August by the CDC restricting testing for asymptomatic persons was not supported by literature and was made without consultation of many primary stakeholders. We agree with the current, updated guidance by the CDC which encourages testing of persons without symptoms and urge primary stakeholders in our fight against COVID-19 to work together when making changes in guidelines that have widespread effects.

When should asymptomatic persons be tested as a component of contact tracing? Contact tracing is a valuable tool in the interruption of chains of infection transmission during outbreaks and has been used successfully to curb disease spread in past epidemics (13, 14). The key aim of contact tracing is to capture potential transmission events before they occur. Large-scale contact tracing and testing of asymptomatic individuals have been successfully used in countries such as Singapore and Taiwan to stem the spread of SARS-CoV-2 (15, 16). While some reports have demonstrated identification of asymptomatic COVID-19 cases by prospective screening of exposed

individuals, others have failed to identify additional cases through screening of asymptomatic individuals (17). Although the reasons for these discrepancies are likely multifactorial, background disease prevalence may play a role. Although most testing efforts during contact tracing to date in the United States have focused on testing symptomatic exposed individuals, testing of asymptomatic exposed persons is also a crucial part of the process.

The asymptomatic and presymptomatic phases of SARS-CoV-2 infection make it impossible to rely on symptom-based contact tracing alone. Published studies suggest that up to 45% of individuals infected with SARS-CoV-2 can be asymptomatic (18, 19). Symptomatic individuals with COVID-19 and asymptomatic individuals without known exposure may have similar levels of detectable virus, suggesting equal infectivity (20, 21). In asymptomatic individuals, infectivity can start as early as 12.3 days (confidence interval [CI] 5.9 to 17 days) before symptom onset (22–24). Thus, health authorities have relied heavily on emphasizing quarantine and isolation as a key component in curbing viral transmission. Unfortunately, such guidance is difficult to enforce and is variably followed, as evidenced by studies demonstrating extensive issues in persons adhering to self-isolation and quarantine during contact tracing efforts (25).

The IDSA recommends that testing of asymptomatic exposed individuals is applicable in certain settings in which substantial transmission is expected to have occurred, including but not limited to household clusters and nursing home outbreaks, and for hospital employees with close contact with COVID-19 individuals (conditional recommendation with very low certainty of evidence) (26). The IDSA also emphasizes that testing of asymptomatic individuals postexposure is especially important when defining risks for other potentially vulnerable individuals within congregate or household settings, or when considering potential hospitalization of that individual. Consideration should also be given to the testing of asymptomatic exposed health care workers during contact tracing efforts when appropriate personal protective equipment (PPE) was not worn.

In their updated guidance, the CDC provides recommendations for testing of asymptomatic individuals as a component of contact tracing (12). They state that asymptomatic persons who have been in close contact with a person with documented SARS-CoV-2 infection (meaning within 6 feet of an infected person for at least 15 min) should be tested due to the potential for asymptomatic transmission. Asymptomatic persons who have not been in close contact with infected persons do not need a test unless recommended or required by their health care provider or public health official. It should be noted that some states require mandatory testing for specific circumstances. In summary, testing of asymptomatic exposed individuals as part of contact tracing measures is recommended by both the IDSA and CDC and endorsed by ASM.

Should asymptomatic individuals be tested as part of routine surveillance? General surveillance testing of asymptomatic persons is more nuanced than that of testing asymptomatic contacts of known infected individuals. Situational awareness, one of the most crucial components of a pandemic response, may be defined in the context of an ongoing public health crisis as the ability to maintain accurate and real-time data of the current state of an ongoing issue affecting the well-being of a population (27). Policymakers and other stakeholders rely on situational awareness to assess the dynamics of disease transmission in the community and the effectiveness of preventive and interventional measures, which would allow for proper allocation of resources needed to tackle the spread of the disease and guide decisions with high economic consequences such as enforcement of confinement restrictions (28). One of the most crucial strategies to maintain situational awareness during a pandemic is having an effective infectious disease surveillance program. Surveillance testing among asymptomatic individuals has been suggested to be one of the key strategies to control the spread of COVID-19 in the community (19). Surveillance screening for acute infections is especially impactful in certain populations including health care workers, those living in congregate or incarcerated settings, students and campus staff, and other populations made vulnerable by social inequities (8, 29, 30, 31). In addition to

acute disease control, surveillance testing among asymptomatic individuals is instrumental in epidemiological studies, including those that evaluate dynamics of acute disease transmission and genomic epidemiology. Data generated by these studies provide a more accurate estimation of critical disease indicators such as reproduction number and population attack rate (32, 33).

IDSA's COVID-19 diagnostic guidelines released on 6 May 2020 provide situational surveillance testing suggestions for asymptomatic individuals with no known exposure including testing of immunocompromised individuals admitted to the hospital, persons undergoing immunosuppressive procedures, and patients admitted for major surgeries or aerosol-generating procedures, such as bronchoscopy, if PPE for health care providers is limited (26). Furthermore, thresholds suggested by IDSA for testing asymptomatic individuals before hospital admission vary based upon community prevalence rates of COVID-19. These recommendations further underscore the importance of community surveillance studies.

Surveillance testing of students on college and university campuses has received much attention, as testing approaches vary across institutions. While some universities did not require testing prior to on-campus activities, others instituted robust systems that included both testing prior to arrival on campus and routine surveillance testing. Insufficient data are available at this time to assess whether mass testing of asymptomatic college students provides significant benefit. It is also unclear whether testing is necessary for on-campus success in maintaining low rates of transmission, as testing is coupled with other mitigation strategies including contact tracing and dedensifying campuses and dormitories. At the University of North Carolina at Chapel Hill, where entry COVID-19 testing was not required, cases increased dramatically within 2 weeks of students returning, necessitating the return of the majority of on-campus students back home (34, 35). However, in the same geographic area, Duke University required entry testing but found only 0.3% of students were positive, and subsequent surveillance tests have identified only 29 additional positive students (36). The University of Illinois at Urbana-Champaign has a large student population and requires twice-weekly testing for students. They have performed over 450,000 tests in an effort to quickly identify positive persons on campus, and yet, during the week of August 31, they reported 100 to 200 new positive tests daily, which quickly declined with the implementation of strict mitigation strategies (37). Surveillance testing on campuses is still an experiment with unknown impact, but it will be important to analyze data to determine the potential benefit, or lack thereof, of widespread surveillance testing in this setting. Although there are no data yet for K-12 school testing, the accessibility of high-quality, rapid point-of-care testing may allow for the role of surveillance testing to be assessed in a variety of settings.

What are the limitations associated with testing asymptomatic individuals? One of the strongest arguments against testing asymptomatic individuals has been the limited availability of testing resources, including specimen collection materials, test reagents, and consumables; skilled staff to collect specimens; and laboratory staff to run the tests. When considering asymptomatic testing, supply chain constraints must be evaluated to ensure laboratories can support such testing endeavors without delaying the time to results for symptomatic individuals who need results for clinical management. If supplies are limited, symptomatic patients should be prioritized above testing asymptomatic persons.

Symptomatic patients should be tested with a highly sensitive molecular test since testing informs both infection control/public health and immediate patient management. Decisions on the testing platforms to use in testing of asymptomatic persons are considerably more complex. The FDA has stated that health care providers should consider using a highly sensitive test with rapid turnaround times for screening asymptomatic individuals (38). While we support use of rapid, highly sensitive tests when available, real-world data to support this recommendation are lacking. Some have advocated for the use of less sensitive test methods, such as antigen testing, for asymptomatic testing, citing rapid turnaround time, scalability, and reduced costs (39).

There are also significant limitations to consider with this approach, including the test availability, positive and negative predictive values of results, and issues with adherence to testing (40).

While there are no outcome-driven data, when testing resources are limited, persons with a known exposure should take priority over less-targeted asymptomatic screening, such as low-risk presurgical screenings. When contact tracing is required after a known exposure or outbreak, a strategy should be developed whereby asymptomatic testing is used either for direct patient impact or through more urgent public health initiatives to curb SARS-CoV-2 transmission. For asymptomatic screening for public health or infection control initiatives, testing should be prioritized to frontline exposed health care personnel, those employed in essential jobs, and exposed individuals.

In addition to the relevance of large-scale testing or frequent asymptomatic testing, providers and laboratories remain confused about the appropriateness of different specimen types, timing of specimen collection, and test materials. Data on the accuracy and performance of alternative specimens tested using different assay methodologies in asymptomatic patients are lacking but are urgently needed. Specifically, the role of saliva in testing asymptomatic individuals is unclear and deserves wider study prior to endorsement. IDSA guidelines state that nasopharyngeal (NP) swabs are preferred over other sample types for symptomatic patients but do not comment on what sample type is preferred for asymptomatic testing. To date, few data exist on the accuracy of alternative sample types such as saliva and anterior nares for asymptomatic screening, and that raises the question if an NP swab sample is required for accurate detection of asymptomatic and presymptomatic carriers. Additional studies are necessary to determine the validity of non-NP sample types, the frequency of false negatives, and the impact they have during a time of a public health emergency.

What is the path forward? It is concerning that the CDC guidance for asymptomatic testing was initially altered in August 2020 without input from the primary stakeholders of COVID-19 testing—notably, clinical and public health microbiologists and infectious disease clinicians and epidemiologists. Also absent were public discussions and a stated rationale based on the currently available scientific evidence. Although consistency is challenging in a time of rapidly evolving data, it is imperative to adopt the practices of applying consistent transparent messaging and incorporating the scientific rationale behind decisions. Only scientifically driven guidance will optimize the use of scarce testing resources and maintain public trust. When conflicting guidance exists among and within federal entities and professional societies, this results in confusion for laboratories, health care providers, hospital leadership, and the public. This has left a door of uncertainty open for scientifically unfounded approaches, misinformation, and theories that may have negative consequences.

The testing goals of each institution and/or community will depend upon many factors and will likely even vary over time as resources fluctuate. Focusing attention on appropriate testing practices rather than decreasing availability or frequency of testing is the most effective approach. The supply of laboratory tests will remain limited for the near future, and choices regarding lab testing will become increasingly complex as new tests with widely disparate performance characteristics become available. CDC should urgently convene a panel of experts, including clinical and public health microbiology laboratory directors and other critical experts and stakeholders, for consultation to develop guidance for asymptomatic screening, to include:

1. prioritization of populations who should receive testing when resources are limited
2. a strategy based on local positivity rates below which screening of defined populations (e.g. preprocedure, congregate settings, schools, etc.) should not be performed
3. appropriateness of different testing modalities and levels of sensitivity and specificity for different populations, with guidance for interpretation and confirmatory testing

4. definition of sample types to be used (or not used) in specific asymptomatic settings and associated limitations
5. recommendations for frequency of testing based on disease prevalence.

As members of the ASM Clinical and Public Health Microbiology Committee's Subcommittee on Laboratory Practices, we support widespread testing of asymptomatic individuals, with prioritization of contacts of positive cases when needed. We urge the CDC to call upon the collective wisdom and experience of clinical and public health microbiologists before implementing guidance measures which may be misconstrued or inappropriately applied.

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