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Editorial

Testing Testimonial

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Running head: Improving COVID-19 Testing

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A review of our nation's response to the pandemic reveals a collective failure to implement a sufficient testing system. Comprehensive, systematic COVID-19 testing was arguably the most important weapon we had to prevent avoidable deaths and the devastating economic repercussions caused by this virus. Instead, the fight against the virus was largely dedicated to Operation Warp Speed (OWS), an initiative designed to accelerate the development and distribution of a COVID-19 vaccine. News of a vaccine inspires hope for a return to pre-pandemic normalcy, but it is our belief that had America shifted a fraction of the resources devoted to OWS to early and efficient diagnostic COVID-19 testing, many of the negative outcomes of this pandemic could have been avoided.

In this editorial, we will examine COVID-19 testing in 4 segments: (1) a brief background on testing basics and efficacy, (2) a review of mishaps in development resulting in a shortage of tests, (3) a proposal for an effective testing strategy, and (4) a look at new, promising testing efforts and innovations. We have reviewed the predominant literature on COVID-19 testing and conducted interviews with several key thought leaders to supplement the rapidly evolving literature. The purpose of this editorial is to explain the value of COVID-19 testing and argue that increased funding for testing would have prevented avoidable deaths and accompanying shutdowns. A system using frequent, asymptomatic at-home testing would control spread by giving people access to tests that are capable of immediately informing them whether they are contagious and, if so, preventing them from inadvertently spreading the virus to others.

COVID-19 Diagnostic Testing and Its Ability to Reduce Viral Transmission

COVID-19 diagnostic testing can be broadly categorized into molecular tests and antigen tests. Molecular tests, such as reverse transcription polymerase chain reaction (RT-PCR), nucleic acid amplification test, and loop-mediated amplification tests, detect the presence of the virus's genetic material and generally provide a result within 48 hours, although turnaround times for some Rapid PCR tests have improved to mere hours. In comparison, antigen tests rapidly identify specific proteins from the virus and generate a result within 30 minutes.¹

The purpose of an efficient test is to identify cases to reduce viral spread. Viruses can be described by a time-varying effective reproduction number (R_e) that “quantifies the transmissibility of a virus, representing the average number of secondary infections generated by one infected person.”² A contributor to the development of this pandemic is COVID-19's highly infectious R_e value, estimated between 2 and 4. The goal of interventions—such as wearing masks, social distancing, and implementing early, widespread testing and contact tracing—is to slow viral transmission, resulting in the reduction of R_e . When the R_e value of a virus is reduced to below 1, then each infected individual is expected to infect less than 1 person, thereby slowing the spread of the virus.

In a recent global observation study comparing the relationship between R_e and common interventions against viral spread, testing intensity was found to be the most influential intervention ($P < 10^{-16}$).² By using test-to-case ratio (TCR) to quantify PCR testing intensity, researchers demonstrated that a 10-fold increase in TCR would reduce the R_e

by roughly 8.6%²; a 100-fold increase in TCR would reduce the R_e by approximately 16.4%. Though all other interventions, including school closures, mask use, time spent at home, and age, were associated with reductions in transmissibility, the relationship never reached statistical significance. Further simulations indicated that an increase in testing intensity to TCR levels of 60+ would have reduced the R_e below 1, thereby effectively controlling the virus.² Newer studies have shown statistically significant reductions in transmissibility through mask use.²

Problems with Testing Development Resulting in a Shortage of Effective Tests

The Centers for Disease Control and Prevention's (CDC's) initial delay with testing development stems from a commitment to designing a novel COVID-19 test rather than using the technique already provided by the World Health Organization (WHO). WHO released specific instructions for designing a COVID-19 test on January 13, 2020, yet the CDC did not release a universal test until 46 days later because of technical difficulties and disagreements about inclusion criteria.³ Stephen A. Morse, a retired microbiologist with experience assisting public health labs with rapid responses to disease outbreaks, criticized the CDC's approach for being too narrow: "It would have been prudent to use the WHO test that was already available...see if you could improve on it with a second-generation test."³ A broader approach to testing development would have afforded more opportunity for error in additional test development while concurrently using a known working test.

In our interview, Chris Tomlinson, MBA and Enterprise Vice President for the clinical laboratory and pathology service lines at Jefferson Health, a leading integrated delivery system in Philadelphia and parts of New Jersey, pointed to unpredictable supply chain issues as another limiting factor in early testing capability. Tomlinson explained the following:

Many commercial testing platforms were unable to meet their commitments in terms of allocations to health systems. Hospitals using only one or two test platforms were often faced with running out of reagent or consumable supplies leading to unacceptably long delays in receiving test results.

Using 7 different testing platforms, Jefferson Health was able to ensure adequate testing through redundancy, despite the regular shortages of reagents and other necessary consumables. This approach to testing development established Jefferson Health as a local and national leader in COVID-19 testing, eclipsing 300,000 processed tests by early December 2020.

In our interview, Wendi Mader, Quest Diagnostics Executive Director and Commercial Leader, noted that “testing is here to stay in efforts to help sort out rules and regulations for employers and to keep places open.” As of December 2020, Quest Diagnostics continued to lead the testing industry by providing more than 200,000 tests per day nationally—a rapid increase from its first testing initiative 9 months earlier in March. Despite these efforts, a recent Quest Diagnostics Health Trends study found that an alarming 74% of Americans who believed they needed a COVID-19 test chose not to get one or delayed getting one because of concerns about further exposure to the virus (30%),

doubts about COVID-19 (21%), fears of quarantine (15%), and questions about cost (15%).⁴ Inability to address these issues demonstrates the continued lack of a cohesive, large-scale COVID-19 testing strategy necessary to control the spread of the virus.

Proposal for an Effective Testing Strategy

An effective system using frequent, asymptomatic at-home antigen testing would control spread by giving people access to tests that are capable of immediately informing them whether they are contagious and, if so, preventing them from inadvertently spreading the virus to others. For this testing system, antigen testing is preferable because of low costs per test and scalability, ease of use by the individual, and 30-minute turnaround times that generate results in time to act.⁵ Government distribution to participating households with additional availability in schools and workplaces would allow a people-centric approach rather than the current medical community-centered one with testing available only at health care-run testing sites.^{5,6}

Though the establishment of a nationwide at-home testing program appears intricate, a program such as this does not require the entire population to participate for effectiveness.⁶ Michael Mina, MD, PhD, and assistant professor of epidemiology at the Harvard T.H. Chan School of Public Health, estimates that even if only 50% of the population tested themselves every 4 days using this method, then the R_e would drop below 1, resulting in an effective control of the spread of the virus.⁶⁻⁸ Mina has drawn attention advocating for accurate, rapid, at-home COVID-19 testing as a means to fight this pandemic. Mina is among many public health experts nationwide who have argued that

“widespread and frequent rapid antigen testing (public health screening to suppress outbreaks) is the best possible tool we have at our disposal today—and we are not using it.”⁶ New data evaluating the significance of testing continue to strengthen Mina’s argument for at-home testing—an antigen-based test described by him as similar in user friendliness to a pregnancy test.

Critics of widespread, national at-home testing programs as a means of controlling the virus focus on analytical test sensitivity at the complete expense of test effectiveness.

Mina explains the following:

*Antigen tests are ‘contagiousness’ tests. They are extremely effective >98% sensitive compared to the typically used PCR test in detecting Covid-19 when individuals are most contagious. Paper-strip antigen tests are inexpensive, simple to manufacture, give results within minutes, and can be used within the privacy of our own home.*⁶

Though Mina argues for the affordability of paper-strip antigen tests, some critics still argue that the price of testing is too great. These individuals fail to understand the economic savings that effective population testing would provide. In addition to the estimated 100,000 lives that projections estimate could have been saved from June through December 2020, the economic benefit is enormous. “The U.S. government can produce and pay for a full nation-wide rapid antigen testing program at a minute fraction (0.05% – 0.2%) of the cost that this virus is wreaking on our economy.”⁶ A cost-benefit economic evaluation by a group of Harvard economists of a nationwide antigen testing

plan from June to December 2020, estimated \$28 billion in total cost and increased the gross domestic product by a conservative estimate of between \$395 billion and potentially upward of \$1 trillion or more by the prevention of outbreaks.⁶

Finally, critics point to a possible privacy invasion with mandatory reporting and the rebound effect of increased activity following a negative test. Mina argues that reporting can and should remain voluntary, with simple 1-click reporting structures built into iPhones, androids, emails, and text messaging services that allow for more public health data.⁶ He dismisses concerns about increased activity following a negative test as both old and paternalistic, comparing them to past perceptions about pregnancy tests, HIV tests, and seat belts.⁶⁻⁸ Although human behavior is complicated and unpredictable, test results allow for better informed decisions compared to the alternative.

Variations of the asymptomatic surveillance testing program have been instituted across various college campuses nationwide. We will use Duke University as an example. A Fall 2020 study of Duke's testing program included 10,265 students who received 68,913 tests with only 84 positive results.⁹ This asymptomatic testing program, using RT-PCR tests, included testing for residential undergraduates twice weekly and demonstrated efficacy in isolating contagious yet asymptomatic individuals. Innovations, such as pooled sampling for those students in shared residences, allowed 120 primary samples to be run in 24 tubes in just over 13 minutes (33 seconds per pool).⁹ Positive pools were flagged for follow-up by deconvolution—individual testing of the specimens in the positive pool allowing for identification and isolation of contagious individuals. Similar

asymptomatic testing programs have been instituted at Cornell University and Boston University; they have increased in popularity across universities and other institutions throughout the country.

Given the success in these samples, asymptomatic testing has gained traction on a larger scale. Worldwide, countries are exploring these testing programs as an alternative to strict lockdowns. In Slovakia, for example, the government started using rapid COVID-19 tests on a massive scale on October 31, 2020, testing two thirds of its population and mandating a quarantine period for anyone who was infected.¹⁰ “Within a week—truly, within a week—they stopped the virus from growing exponentially on a country level, to dropping incidence by half.”¹⁰ By the middle of November, the R_e in the country had fallen to between 0.7 and 0.9.¹¹

Current Innovations to Testing Efforts

Because the coveted vaccines will not be widely available to the greater population for many more months, thousands of Americans continue to die of the virus each day and the country is still enduring economically-devastating lockdowns. Widely available, inexpensive home-based testing offers a quick and alternative solution to this dire situation.⁸ New testing efforts include the recent Food and Drug Administration (FDA) Emergency Use Authorization (EUA) for the Ellume Ellume COVID-19 Home Test, the first over-the-counter fully at-home diagnostic test for COVID-19.¹² Preliminary data suggest that this new at-home test correctly identified 96% of positive samples and 100% of negative samples in people with symptoms, and 91% of positive samples and 96% of negative

samples in patients without symptoms.¹² Estimations indicated that more than 3 million Ellume tests had been produced by the end of January, with the ability to connect the analyzer to a software application on a smartphone generating results in 20 minutes.¹²

In conjunction with Purlab, GoPuff, a grocery delivery business, announced the first EUA for at-home saliva testing in December 2020. The test costs \$145, which most insurance companies will cover, and can provide results 24-72 hours after the Rutgers laboratory receives the testing kit.¹³ Jeff Shuren, MD, JD, and director of the FDA's Center for Devices and Radiological Health, announced on December 16, 2020, that the BinaxNow Antigen Card Home Test received a similar EUA, meaning there now are at least 3 FDA-approved tests that can be used completely at home.¹⁴

Professional sports leagues, such as the NBA and NFL, have implemented asymptomatic testing protocols to continue playing despite the ongoing COVID-19 pandemic. The NBA was able to complete its 2019-2020 season through the formation of a "bubble" that effectively tested as well as isolated players, staff, and employees from outside contact and, therefore, exposure to COVID-19. The "bubble" experienced no outbreaks during the approximately 4 month time line.¹⁵ Since early December, the NFL has used a rapid PCR test developed by Mesa Biotech that delivers accurate results within 30 minutes. The company's initial 917 tests matched perfectly with the standard PCR control, producing 27 positive results and 890 negative ones.¹⁶ From August 1, 2020, through the first week of December, the NFL had run more than 700,000 tests on players and personnel through its daily testing protocols.¹⁶ These testing protocols, with the

addition of the rapid PCR test, have allowed quick game-time decisions for determining whether an athlete can play. In addition, these protocols demonstrate the viability and effectiveness of asymptomatic testing regimens.

Airport testing is another example of practical asymptomatic testing. Jefferson Health opened a testing center at Philadelphia International Airport in December, offering antigen and PCR tests ranging in cost from \$70 to \$130 each for travelers.¹⁷ This program allows the airport to provide testing to passengers with destinations requiring testing before arrival and to decrease exposure to other passengers with the virus. While a negative test is not foolproof due to collection/processing mishaps and the potential for false negatives, testing is generally reliable, giving more information and a safer alternative to not testing. Future efforts may require passengers to use a “digital passport” of a negative test or vaccine to board a flight.¹⁸ While these efforts should be encouraged, more progress can be achieved with a universal testing approach.

Private companies such as Goldman Sachs and Netflix are joining airlines and national sports leagues in essentially taking over testing, using company-sponsored testing to safely return employees to the office.¹⁹ U.C. Davis has made free coronavirus tests available to all 69,500 people in the city of Davis and hundreds of nonresidents who work there.²⁰ Residents can be tested twice weekly with overnight results. In Canada, 12 companies have worked together for 4 months, creating a more than 400-page operating manual on how to run rapid antigen tests in various work settings.²¹ They began piloting the tests in their workplaces this month, and they expect to expand the program

to 1200 small and medium-sized businesses. Private companies and businesses are continually stepping up to fill the testing void that bureaucracy has failed to fulfill.

On January 21, 2021, President Biden’s executive order pledged to respond to the pandemic through “effective approaches guided by the best available science and data, including by building back a better public health infrastructure.”²² The Biden-Harris inauguration proved to be an excellent example of the power of testing as Quest Diagnostics’ ultra-secret “Project Sunrise” tested more 7200 people with no identified outbreaks (unpublished data; H. W. Kaufman, M.D., MBA, FCAP; January 31, 2021). While Quest labs should be lauded for their efforts, imagine if we could deploy similar efforts in every community, each and every day. Funding for testing—specifically a widespread and frequent rapid antigen asymptomatic testing strategy—needs to be at the forefront rather than an afterthought.

Conclusion: Testing Is Here to Stay/Critical Next 6 Months

After our review of the prevailing testing data and interviews with key thought leaders, we believe that COVID-19 testing remains the critical tool to lessen the health and economic burden of the pandemic. Concerns about meeting vaccination goals further support the continued interim use of testing to limit transmission and bridge the gap to herd immunity through vaccination. Current literature and testing experts support frequent, asymptomatic at-home antigen testing as the best data-driven effective strategy for virus containment while future vaccines are developed. This testing system is affordable and scalable, and it can control virus spread by giving people access to tests that are

capable of immediately informing them whether they are contagious and, if so, preventing them from inadvertently spreading the virus to others. Delayed implementation of widespread rapid testing, especially at home and in the workplace, will result in more deaths from the pandemic. Give consumers the power to reduce this terrible toll.

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Author Contribution Statement

Mr. Beiriger and Dr. Nash developed the scope of the manuscript and outlined sources to be included and specific thought leaders to interview. Mr. Beiriger reviewed the prevailing literature on COVID-19 testing and conducted interviews with selected key thought leaders to supplement the rapidly evolving literature. Mr. Beiriger drafted the manuscript with Dr. Nash's consistent input and revisions. All authors contributed to the interpretation of sources, interviews with thought leaders and made critical revisions to the manuscript.

Author Disclosure Statement

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