Prolongation of the Pandemic

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January 2021!!! In one year's time the SARS-CoV-2 virus has changed all of our lives—globally. Such is the power of a pandemic. Looking back, there was naivete at first and then a lot of missed opportunities—especially with testing. As a physician, I kept scouring my emails and websites to see how we would test people for the virus: here in the office? Send them to a big lab with a prescription? Look for public health department testing somewhere? Send patient samples to the CDC? I actually thought my investigating skills were to blame because, despite the media telling us that "the COVID-19 virus is deadly, spreading fast, and containment will rely on widescale testing," I could find no clinical protocol for testing. Testing how? By whom? We now know that the CDC insisted on making it's own complicated test, refusing to employ the WHO test that the rest of the world was using. The CDC-developed test was approved by the FDA and, in early February 2020, the CDC sent out this new SARS-CoV-2 test kit to 100 public health departments. It had a 33% failure rate and they had to go back to the drawing board. That's why I felt helpless and ignorant. There was no information on our country's testing strategy as we had no test!!! For several weeks there was no surveillance testing of people in potential hot spots. This was the start of the virus taking the lead and our public health strategy trying to catch up. With only 15 confirmed cases in the US at that time, the virus was circulating undetected in communities across the country.

By March 2020, federal health officials began to allow universities and commercial labs to perform their own tests, but they had to validate them through Centers for Medicare and Medicaid Services (CMMS). Initially CMMS set the quality bar quite high—such that the test would not detect MERS or SARS by mistake (but there have been no SARS and only 2 MERS cases in the US since 2014). The new FDA commissioner emphasized that independent scientific review was as important as timely test availability. Makes sense. The FDA established Emergency Authorization Use guidelines. Still no innovative deviations from the test manufacturing protocols or reduction in onerous paperwork was forthcoming. Few applicants meant that the bureaucratic regulatory environment was creating more delays. At the end of March, the FDA loosened the EUA regulations and more university and commercial labs began to apply. During the month of March 2020 we started to see testing become available but, because of the paucity of kits, testing was limited to people with symptoms. And the virus continued to circulate undetected in asymptomatic people across the country.

350,000 deaths later (2,000 - 3,000 per day), the United Stated leads the world in cases (20.5 million) and deaths. We have never caught up to this virus. And just when many people are looking to vaccines as "the light at the end of the tunnel," the virus is mutating. Authorities suggest that the vaccines will still be effective, but there is no guarantee. As well, the virus can continue mutating. It's like a bad science fiction movie—it seems like it is always one step ahead of us. Holiday gatherings with families, pandemic fatigue of mask wearing and isolation, much more time spent indoors and we are in for a helluva winter. And the vaccines are rolling out slower and with more obstacles than expected. Another score for the virus.

Meanwhile we have poured $18 billion dollars into Operation Warp Speed (OWS) for vaccine development. The vaccine producers are protected from any liability for these vaccines because vaccines are "inherently risky" and this is a pandemic. The government has a Countermeasures Injury Compensation Program that will pay for serious vaccine injury if compelling evidence exists. From May to August 2020, executives from one of the OWS vaccine companies, Moderna, netted a profit of $115.5 million from selling shares in their company. Emergent BioSolutions, a vaccine manufacturing facility contracted by the US Department of Health and Human Services, AstraZeneca, and J&J with $1.5 billion of assets protected from clinical trial risk, sold shares during this summer as well. Executives netted $5 million and the executive chairman netted $8.1 million. Eli Zupnick, a spokesman for Accountable Pharma, described the companies contracted with Operation Warp Speed as a perfect business. "Their downside is covered by taxpayers, and their upside is already in their pockets."

So what's my point? Having an underfunded and underutilized public health system in this country means we treat a public health crisis like a disease—because we know how to do that. We wait until the disease is established enough to have an expensive test or drug that can mitigate symptoms. So when this new infectious and deadly health threat appeared, the NIH poured $98.35 million into RADx (Rapid Acceleration of Diagnostics) initiative for novel COVID-19 testing technologies. All, so far, are point-of-care tests (none are complete at-home tests) and emphasize a way of linking test results with a reporting system for tracking. The tests that are in development are not inexpensive, designed to give immediate results, or scalable for daily use. Even Dr. Fauci, head of the National Institute of Allergy and Infectious Diseases said that the coronavirus testing debacle had exposed deep structural problems in the nation's public health system.

An effective public health testing strategy has been withheld from the people.

If you are in a hospital with rapidly progressing shortness of breath and fever, you want an accurate diagnostic test for SARS-CoV-2 so that you get the right medications that can save your life. You may have COVID-19 or you may have bacterial pneumonia. The medication choices would be different. This is acute care medicine. The US healthcare system is really good at this. But this same highly accurate diagnostic test given to an asymptomatic or mildly symptomatic person is expensive and so cannot be used frequently. It often gives results that are meaningless eg, a positive result received 3 days later is not helpful if you have been out in the community spreading the virus.

Imagine waking up in the morning and swabbing inside the lower part of your nose, rubbing it on a small piece of paper and dropping it in a small tube of saline. You then go and dry your hair and come back 15 minutes later and check the paper. As the liquid from the tube saturates up the paper it leaves lines: one line (the control) and you're negative; two lines and you're positive. The virus in your nasal secretions matched up with an antibody imprinted on the paper. If they match, you'll see the second line and you're positive. If you are positive, you quarantine for 2 weeks – as does the rest of your immediate "pod". This test has not been given EUA by the FDA because it does not meet their high standards. They require it to be 80% as accurate as the current COVID-19 RT RNA PCR diagnostic test. Dr. Michael Mina of Harvard University's TH Chan School of Public Health has done modeling to suggest that Paper Tests are 80 - 90% sensitive in capturing people who are transmitting the virus while a PCR test used every 3 weeks is only 5% sensitive in capturing transmitters. He uses this example: Let's say the highly accurate PCR test detects virus at 1,000 particles; and the paper tests detects virus at 100,000 particles; most people, by the time they are transmitting virus, have about 1 million – 1 trillion particles. The rapid test finds the people who, at the time of testing, are at greatest risk of transmitting virus; His modeling (and common sense) reveals that the frequency of testing (daily testing vs. every 3 weeks testing) is much more important than the sensitivity of the test. The PCR tests are so accurate that they find strands of RNA in a person for weeks after they have resolved the infection. This means we are putting many people in quarantine for no reason. This is a false positive test result meaning that it detects viral RNA but not the presence of the complete virus, the disease, or the ability to transmit the disease.) Here is where reporting the Ct (cycle threshold) value of the PCR test would be useful. The Ct value indicates the relative amount of RNA detected. Knowing this would allow a strategy to determine a person's place in the course of infection. Having a Ct value of 37 indicates very little RNA was detected and that person would not need contact tracing to see who they were around 2 days prior because they probably got the virus 2 weeks ago. Labs are not allowed to report Ct values for the SARS-CoV-2 PCR test. Really?

Contrast the RADx approach with the "rapid paper at-home" tests that are cheap ($ 1 - 2 a piece vs $50 - 200 for point-of-care tests), more accessible, and with faster turn-around times, eliminating the need for contact tracing. These can be easily and quickly manufactured to increase testing capacity much more than any point of care test. The whole strategy (putting a pack of these strips in every household) would cost about 10 billion dollars and could potentially end the spread of the virus in a matter of weeks.

We are tired of wearing masks and being in lock-downs. We're hungry for a cheap test that will tell us how we can contribute to the end of the pandemic. Several countries are piloting rapid tests now but the US is not one of them. I hope President Biden gets on board with this strategy right away.

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