

Dr. Delgado COVID-19 Update 4-1-20

Getting tested for the coronavirus in the U.S. has been difficult to impossible for many people, starting with technical difficulties with the kits initially developed by the CDC and continuing with shortages in swabs, reagents and other parts of test kits. After this failure, the Food and Drug Administration issued an Emergency Use Authorization for private labs and hospitals to develop their own coronavirus PCR tests. Large companies are currently ramping up production of these tests.

Two main barriers persist in regards to current testing. One, although these tests take just a few hours to complete, transporting samples to central labs takes time, as does preparing the samples to be run. Two, current testing only detects active infections and fails to identify those whom have previously contracted the coronavirus and have recovered.

How do we make coronavirus testing faster?

Some companies are rolling out point-of-care tests (PCT's), which are tests that can be done entirely within clinics, doctors offices or at mobile drive-through testing sites.

These tests quickly copy the genetic material in a sample so that any viral genes consistent with coronavirus are detectable. They only require a proprietary processor, which generates temperature fluctuations to facilitate the necessary chemical reactions, and the cartridges in which the nasopharyngeal samples are placed. Results can return within an hour.

One company, Abbott, claims it can return positive results in 5 minutes and rule out coronavirus in 13 minutes. It issues proteins to amplify the coronavirus genetic material without the temperature changes of most current systems. The company will start shipping 50,000 tests daily today.

PCT tests can be helpful for letting medical professionals know right away if a patient has COVID-19, which might save valuable hospital space and personal protective equipment (PPE). In addition, a negative test means that a person might be sent home without concern for infecting others. Quick testing might also help a sick doctor or nurse know whether they must self-isolate for 14 days.

While the reduced timing of results will be beneficial, it won't lead to increasing overall testing volume. Traditional machines at central labs can run up to 96 samples at one time. Thus, a PCT might be able to provide quicker answers to individual patients, health care workers or clinical scenarios, but they won't be able to handle the large numbers of tests needed to get a clearer picture of the pandemic.

Serologic Testing Update

As my previous email (3/30) explained, getting a handle on the pandemic will require a serologic test to determine who has ever been exposed, even if they were without showing symptoms.

It typically takes around 8 days for the body to mount an antibody response to a virus. Serological testing may also be useful in some cases where someone has been sick for more than 8 days without access to a test for active infections, but it

may miss those burgeoning infections if obtained too early in the disease course.

Once developed, it will help immensely. Foremost, it will allow health care workers return to work more quickly with the assurance of their safety. Two, it will ease the need to provide PPE for all presumed Covid encounters if positive. Three, as it becomes more available to the general population, it allows those showing immunity to care for others and begin to return to work.

Many companies are working to develop this mode of testing. One has even set up a website to share their data and processing techniques for others to use them. There are also efforts to import already developed tests from other countries.

The city of Telluride in Colorado started testing all of its 8000 residents last week with a new serologic test. This strategy, funded by United Biomedical which developed the test, will provide a litmus test as to how mass testing can be used to detect and contain community spread. The information will help officials make decisions about whether quarantines or other restrictions are needed, and how widespread these restrictions should be in a given area.

This approach to community-wide testing was used in Vo Euganeo, a small Italian town that tested all of its residents, albeit for an active infection, and was able to reduce transmission by 90%.

Vaccine Update

Multiple companies and academic institutions are racing to create a vaccine and larger scale human trials appear imminent. Normally this process can take many years, but several factors have allowed for an acceleration of this curve.

Because coronaviruses have caused two recent epidemics, Sars and Mers, the groundwork on potential vaccines was begun and may now be repurposed against the current circulating strain. Sars and Covid-19 fortuitously share over 80% of their genetic material. In addition, China was able to unlock the genetic sequence of Covid-19 and share it with researchers in early January thereby allowing them to grow the virus and study avenues to pursue in vaccine development.

Clinical trails will determine efficacy, but just as importantly assess the safety of the vaccines. Ideally, vaccines introduce the pathogen, in this case the coronavirus, to the body in a weakened or inactivated state to produce an immune response. This allows the body to produce antibodies that will offer protection if the same virus tries to invade once again.

Besides potentially infecting those administered the vaccine, many unknown or unexpected side effects can arise. No vaccines made from genetic material, hence engineered by scientists, has been approved to date. While we all want expediency in regards to availability, clinical trials and their stepwise approach, remain vital to assess efficacy and ensure safety. Any modification of this process should be with utmost judiciousness and should entail a general consensus within the scientific community.

Masks Update

The groundswell of evidence in relation to recommending masks be worn whenever you venture into public continues to grow. Many researchers are now urging global health authorities to reconsider the decision to not recommend wider use of face masks in people who don't feel ill to limit the transmission of the coronavirus.

Several reasons exist as to why this recommendation was not made earlier in this crisis. Foremost, the projected insufficient supply of masks for providers or those who are ill and the fear of progressive shortages led to this logical initial guideline. Second, more data continues to be culled as to the level of asymptomatic carriers of the virus and the apparent prolongation of viral shedding that may be occurring while they venture into the public. Several recent studies in Iceland and China have shown that 50% or more of those testing positive showed no or minimal symptoms and may be the primary drivers in the spread of the illness.

Social distancing continues to be the most impactful measure. Some droplets may exceed the 6 feet criteria currently used and droplets are produced and expectorated even when only speaking. Masks are not necessary at home with those whom you have been isolating over the last few weeks.

If you have masks, it would be prudent to consider wearing them when interacting with any others when your situation prompts you to leave your home for supplies or other issues.

How long can someone transmit the virus?

Some new studies suggest that the current CDC recommendations for self isolation for three full days after the

resolution of any symptoms may be premature. A recent analysis from China, though limited in scope, revealed that more than half of the patients they tested kept shedding virus up to 8 days after the resolution of their symptoms. The authors suggest we extended this parameter to two weeks post symptoms to ensure no viral shedding persists.

Social isolation guidelines in place at this time should address this matter. The key will be to determine if this data is reproducible in the U.S. and erring on the side of caution as to any recommendation moving forward as we ease restrictions on social interaction.

When will this end?

The key remains obtaining a serologic test and initiating a coordinated campaign to distribute it on a mass scale. Anyone who has remained essentially asymptomatic is at risk if no immunity has been conferred and may further contribute to the viral spread if they circulate.

After the rate of new cases had been reportedly essentially controlled in China and Singapore via stringent restrictions, it appears a new surge in cases is now occurring as foreign nationals return from overseas and are infecting those without immunity. This has led to a tightening of recent activity which had been allowed and portends to what may occur here. It would be wise to follow these situations closely and use them to guide us as to the easing of social restrictions once the acute phase appears to be abating.

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