Dr. Delgado COVID-19 Update 09-30-20

Vaccine forthcoming?

The process of deciding when a vaccine appears to be safe and effective isn't as straightforward as the general public might believe. But it's important to understand it if we are to have confidence in it for helping to curb the pandemic.

A clinical trial is actually monitored by what is known as a data and safety monitoring board, or DSMB, a group of independent experts hired to make sure volunteers in the study are safe. The DSMB has the ability to recommend stopping a study not only if a treatment is unsafe, but also if it is so clearly effective that continuing just wouldn't be ethical.

The DSMB's will conduct what's called an interim analysis after a certain number of people have been infected with Covid-19 and shown symptoms. Each of these cases is considered an "event," and each vaccine maker has set a different number of events as a threshold to conduct an interim analysis as part of their trial protocols.

Currently, anywhere from 26 to 53 "events" compromise the range of events necessary by most of the current manufacturers to perform their first interim analysis as to

the efficacy of their vaccine. If and when a company believes its vaccine is safe and effective, it will then submit its data to the Food and Drug Administration.
Should a vaccine be approved, potentially for millions of people, after its efficacy has been shown based on as little as 26 cases of Covid-19 vaccinations?

No Covid-19 vaccine is likely to be fully approved by the FDA in the near term, because of current requirements for manufacturing and follow-up that could take years. The FDA is expected instead to use a different authority by granting what is known as an emergency use authorization, or EUA. The challenge for the FDA will be to make sure that it brings its usual standards for a vaccine to the much more flexible emergency use authorization process.

Reviewing data on a drug or vaccine candidate normally takes years. Even a truncated review should take months. So even if data for vaccines becomes available for consideration in mid to late October, an emergency authorization by either Election Day or even by the end of the year is difficult to imagine.

In the interim analyses that most people who follow these trials are used to, as soon as there is a clear result, the trial stops and everyone is immediately vaccinated if it appears efficacious. But the plan for Covid-19 vaccines is

slightly different. Data from an interim analysis may be released if a vaccine is deemed inarguably effective — but volunteers may not be immediately told whether they are receiving a vaccine or placebo. Participants receiving a placebo will not be switched immediately to the vaccine.

The reason is that there is a need to assess efficacy in smaller subgroups, such as teenagers, the elderly, ethnic minorities, those with severe infections, etc. This will also allow further study and analysis on long term safety.

More to follow on this subject.

Rapid Antigen Testing

A potentially potent tool could also arrive in the coming weeks to months: rapid, at-home coronavirus tests, akin to pregnancy tests. This type of antigen test, which could use a saliva sample, is not as accurate as the current PCR diagnostics (which detect the virus' genetic material). But the vision is that it could offer individuals a pretty good clue as to whether they have infectious Covid-19 within minutes — information that would allow them to go about their lives (with continued precautions) or isolate themselves.

The tests detect specific proteins — known as antigens — on the surface of the virus, and can identify people who

are at the peak of infection, when virus levels in the body are likely to be high.
Proponents argue that this could be a game changer. Antigen tests could help to keep the pandemic at bay, because they can eventually be rolled out in vast numbers and can spot those who are at greatest risk of spreading the disease. These tests are a key element in the testing strategies of other countries, such as India and Italy.

Antigen assays are much faster and cheaper than the gold-standard tests that detect viral RNA using a technique called the polymerase chain reaction (PCR). But antigen tests aren't as sensitive as the PCR versions, which can pick up minuscule amounts of the SARS-CoV-2 virus that causes COVID-19.

This difference raises some concerns as some worry that antigen tests could miss infectious people and result in new outbreaks. Others view the lower sensitivity as an attribute, because some people who receive positive PCR test results are infected, but are no longer able to spread the virus to others. So antigen tests could shift the focus to identifying the most infectious people.

Antigen-based testing could help to rapidly identify people who have high levels of virus — those who are most likely to be infectious to others — and isolate them from the community, but it's still unclear what viral load is the

threshold below which a person is no longer contagious? This is a major concern because the moment you get that wrong, the whole idea and benefit of antigen testing may implode.

This can be mitigated by frequent testing — done multiple times per week. This could quickly identify infected people, even if the assays are less sensitive than a PCR-based test, because the amount of virus in their noses and throats rises within hours.

At the end of August, the FDA granted emergency use authorization to a new credit-card-sized testing device for the coronavirus that costs $5, gives results in 15 minutes and doesn't require a laboratory or a machine for processing. The federal government spent $760 million on the initial supply of 150 million of these tests from healthcare company Abbott Laboratories. They also have the first option on the next 150 million produced. How the federal government will allocate these tests remains a bit nebulous, but they appear earmarked for schools and other "special needs populations" such as nursing homes.

Unfortunately, this purchase agreement has limited both hospital systems and physicians from acquiring these tests for a more rapid distribution within the general population. Other rapid tests (3 others have received EUA) are only sporadically available, produced on much

smaller scales and don’t appear to be as accurate as Abbott’s version.

Beyond concerns about costs and availability, researchers worry that, with an over-the-counter test, people who get positive results might not follow up with public health authorities, so their contacts won’t be traced or employment compromised. Another risk would be people getting someone else to take their test — so they can be sure of a negative result and avoid quarantine.

Another concern is that people will get a false sense of security from tests. There’s a risk that the moment these tests become widely available, people will use them and determine that if the test is negative they are clear to resume at-risk behaviors. Testing cannot and must not replace the basic control measures that need to remain in place to keep this virus controlled.

Local update

Since the beginning of May, Blaine County had averaged mostly 0-1 new cases daily through mid September (the 13th to be exact). Since that time, the average daily rate has steadily risen and over the last three days 4 positive cases have been recorded daily in our county with the curve appearing to continue its upward trend. This is also being seen throughout the state with 229 total positive cases recorded in Idaho September 9th and now 402

positive cases reported on September 29th.
I reiterate that this is not cause for alarm, but a reminder to continue minimizing your risk with appropriate measures.

R. Delgado, MD & Staff