Dr. Delgado COVID-19 Update 11-18-20

Rapid at-home testing

U.S. regulators on Tuesday allowed emergency use authorization (EUA) of the first rapid coronavirus test that can be performed entirely at home and delivers results in 30 minutes. However, the test, which is expected to retail for less than $50, will require a prescription, likely limiting its initial use. **In addition, it will not likely hit the national market until early spring 2021.**

The FDA granted emergency authorization to the single use test kit from Lucira Health. The Lucira Covid-19 test grew out of research the company was doing to develop an at-home flu test. Lucira adapted its technology to detect Covid-19 after the outbreak began.

Unlike rapid antigen tests which are currently more readily available and test for viral proteins, the Lucira kit will test genetic material in a method similar to the laboratory tests that have become the standard for detecting the virus.

This will likely provide a higher level of sensitivity and accuracy which is vital so as to limit false negative results and minimize continued spread of the virus.

The kits are currently undergoing additional trials in some

areas and I will continue to follow any reporting on that data and availability as manufacturing ramps up.

Treatment updates

The U.S. Department of Health and Human Services (HHS) will allocate the initial doses of the investigational monoclonal antibody therapeutic, bamlanivimab, which received EUA for the first treatment of non-hospitalized patients with mild or moderate confirmed cases of COVID-19 last week.

Bamlanivimab is authorized for patients with positive results of direct SARS-CoV-2 viral testing and who are at high risk for progressing to severe COVID-19 and/or hospitalization. This includes those who are 65 years of age or older, or who have certain comorbid medical conditions.

While the safety and effectiveness of this investigational therapy continues to be evaluated, bamlanivimab was shown in clinical trials to reduce COVID-19-related hospitalization or emergency room visits in patients at high risk for disease progression within 28 days after treatment when compared to placebo. Bamlanivimab is not authorized for patients who are hospitalized due to COVID-19 or require oxygen therapy due to COVID-19. A benefit of bamlanivimab treatment has not been shown in patients hospitalized due to COVID-19.

The federal government completed a purchase of 300,000 doses of bamlanivimab. HHS will allocate these doses to state and territorial health departments which, in turn, will determine which healthcare facilities receive the infusion drug. The federal government has options to purchase up to 650,000 additional doses if needed through June 30, 2021, for distribution across the country.

A data-driven system will ensure continued fair and equitable distribution of these new products. Beginning immediately, weekly allocations to state and territorial health departments will be proportionally based on confirmed COVID-19 cases in each state and territory over the previous seven days, based on data hospitals and state health departments enter into the HHS Protect data collection platform. An allocation dashboard has been created to allow tracking of the allocation and distribution to each region.

The intravenous administration of therapeutics to non hospitalized patients with confirmed mild to moderate COVID-19 presents unique challenges. To accommodate IV infusions, outpatient facilities must have appropriate healthcare staffing, training and equipment. Additional preparation time may be required for some treatment facilities before they can administer the treatment to patients.

Vaccine update

Excitement continues to build with the announcement of a second vaccine candidate that appears highly efficacious. As per the company's press release, the Moderna vaccine appears to reduce the risk of COVID -19 infection by 94.5%. There were 95 cases of infection among patients who received the placebo arm in the company's 38,000 patients study and only 5 infections in patients who received Moderna's vaccination.

More importantly, Moderna also released data about the number of patients who had severe COVID-19. There were 11 cases of severe disease and they all developed in the placebo group — another clinically significant finding as to the vaccine's efficacy. This has always been a concern as to the primary end point of the trial focusing only on whether it prevents any clinically apparent disease. The fact that no episodes of severe disease were apparent in the vaccine arm are very encouraging. Furthermore, the Moderna vaccine appears to have been protective in important subsets of participants — the elderly and people from racial and ethnic minorities, which made up a significant demographic proportion of the study's participants.

As to safety, Moderna announced no significant safety concerns. Its press release states that severe events occurred in just greater than 2% of the patients and

included fatigue, muscle pain, headache and achiness. They reported these events were short-lived and if accurate are comparable to the influenza vaccination.

Both Moderna's trial and Pfizer's are continuing and efficacy figures could decline by the time the trials are complete. It is often the case that a vaccine performs less well in the real world than it does in clinical trials.

Lastly, the available data from the two trials does not surmise how long the protection afforded by the vaccines lasts. That can only be determined over time as large numbers of people are vaccinated.

The Moderna results, like those from Pfizer, were disclosed in a press release and not in a scientific article that has been peer-reviewed. The details released to the public were limited.

We await the FDA review.

Local update

Cases continue to escalate locally in Blaine County with a 40% increase in the positive rate/100,000K of population tested in just the last week. In addition, the number of hospitalizations in Idaho due to COVID-19 have more than doubled in the past month.

It is apparent that the “winter surge” that was predicted is upon us. Please use your best judgement as to your actions.

To reiterate, our office remains open for your medical needs. If you develop a medical issue that clinically merits an in-person consultation, we remain committed to providing that care as necessary for the foreseeable future.

R. Delgado, MD & staff