Dr. Delgado COVID-19 Update 11-09-20

Vaccine Update

Early data **suggests** that Pfizer's coronavirus vaccine is more than 90% effective in preventing an infection with the virus that causes COVID-19.

The vaccine, developed by Pfizer, is currently being tested in a large phase 3 clinical trial — the last and most critical stage of testing in which vaccines must prove to be safe and effective in a large group of people — that began in late July.

The early analysis revealed that among these 94 participants, fewer than 10% of those who received two injections of the
vaccine, 28 days apart, developed COVID-19. In other words, most of the cases, more than 90% of them, were among those who received the placebo. However, this 90% efficacy was announced in a press release, and the companies haven't yet released actual data on the trials. The data has not been peer reviewed or published in a medical journal.

While the final results and conclusions are still pending, if these numbers hold up, they will be much higher than anticipated.

The trial will continue to enroll participants until the final analysis when 164

participants test positive for COVID-19. This specific number was agreed upon by both Pfizer and

the FDA as an additional metric to not only see if it can prevent the novel infection, but if the vaccine also provides protection for those who have been previously infected with COVID-19. It will also provide better accuracy to determine if the vaccine reduces severity in those vaccinated who subsequently develop the infection.

The companies will be eligible to apply for an emergency use authorization (EUA)
once they have gathered two months of safety data after participants received the second dose of vaccine — a milestone that could be reached in the third week of November.

Pfizer's candidate vaccine uses the same technology as Moderna's, another vaccine that's in late-stage testing. It uses a genetic messenger called mRNA to prompt the immune system to recognize the virus. No vaccine that uses this technology has yet been approved for any virus.

Even so, this type of vaccine may have several advantages over traditional vaccines, such as being quicker and easier to manufacture. However, the Pfizer vaccine requires ultra-cold storage at minus 94 degrees Fahrenheit (minus 70 degrees Celsius), which could make distributing and administering the vaccine more challenging.

(Moderna's vaccine requires storage at ordinary freezer temperatures.)

More to follow.

Distribution

As the U.S. edges closer to approving a vaccine for Covid-19, a difficult decision is emerging as a central issue: How should we prioritize access to it?

Frontline health workers, elderly people, nursing home residents and those with chronic conditions that make them especially vulnerable to Covid-19 are likely to be at the head of the line.

The Advisory Committee on Immunization Practices, which gives vaccination guidance to the director of the Centers for Disease Control and Prevention, will not make a decision on who should get a vaccine, and whether to give preference to certain cohorts, until a vaccine is approved.
The group will be guided in part by a framework released last month by the National Academies of Sciences,
Engineering, and Medicine, which advocates taking an equitable approach to vaccine allocation. The National Academies' recommendations are broken down into four phases and set a goal to ensure that every step of the process takes into account the disproportionate public health and economic impact the virus has had on the

elderly and communities of color.

Across all phases, the National Academies says geographic priority should be given to communities that are high on what the CDC calls the Social Vulnerability Index, which identifies communities most endangered and in need of aid during disasters like hurricanes. The index takes into account poverty, unemployment, and health insurance rates, among other socioeconomic, demographic, housing, and transportation vulnerabilities.

It would be quite a challenge to ensure equitable distribution. It will be up to state, local and tribal health agencies to determine who falls into each priority group and how to deliver it to them.

Increasingly, the worry is that if there was explicit racial or socioeconomic priority given to the Covid-19 vaccine, we could be embroiled in litigation that would really undermine any implementation of the vaccine process. According to Lawrence Gostin, who recently published in JAMA as to this specific legal issue, there are real concerns as to legal objections that may arise as to any framework that uses race and ethnicity when determining vaccine allocation and the way it might be interpreted in courts.

There is also concern that some groups, especially Black people, might be hesitant to be among the first to get a vaccine, given the history of mistreatment of Black

patients in medical research. We need to be proceed with caution and sensitivity. We don't want to give certain

groups the perception that they're being experimented upon.

These and many other issues will come to the forefront over the next weeks and months. Regardless of how they play out, a vaccine offers our society the most expeditious avenue to any sense of normalcy.

Local update

The rates continue to dramatically escalate locally (specifically the cases per 100,00k of population which is irrespective of testing volume) and are approaching those not
seen since early April in Blaine County. I am disheartened to see the bars/restaurants and commercial spaces filled with many not wearing masks and with inconsistent social distancing. I support all of our local businesses and an individual's right to operate and congregate, but better enforcement and spacing is clearly necessary.

I don't advocate for another lockdown as I know how crippling economically and socially that would be for our community, but our rates dropped dramatically once that occurred previously and the current curve is worrisome.

A vaccine is many months away, at minimum, in terms of

reaching critical mass in our population to initiate any flattening of this curve. Until then, we have only ourselves to blame for this ongoing public health issue. Tough choices need to be made daily and now is not the time to resign yourself from what needs to be done communally in deference to your individual needs. Doing so imperils all of us. Either travelling or hosting others in your homes during the holidays needs to be seen for what it may portend.

Stay vigilant and connected,

R. Delgado, MD & staff