Dr. Delgado COVID-19 Update 01-22-21

Vaccine update

A seismic shift in federal engagement appears to be formulating with the recent change in our leadership. A more science-based consortium of policy makers have clearly delineated an emphasis on a federal mobilization and the formulation of a more cogent and uniform strategy that will hopefully undo the current vaccine morass.

The disparate state rollouts and continued delays continue to frustrate our population and create clear angst. Israel, with an early and centralized emphasis on education, planning and infrastructure put in place prior to the arrival of any actual vaccine, continues to lead the world in the per capita vaccination rate. It has already reached its next cohort of 40 years of age or older and is on track to complete the vaccination of its entire country with its first dose by the end of March.

With the Johnson & Johnson (J&J) vaccine candidate expected to present its clinical studies to the FDA for review in the next few weeks and the Oxford/AstraZeneca (OAZ) candidate likely to closely follow, it will offer the hope of a major acceleration in the volume of vaccine entering distribution portals.

These newer offerings to the vaccine pool offer several notable advantages. Foremost, neither vaccine is formulated with an excipient. Excipients are the inactive substances, such as preservatives, fillers, etc., that serve as the vehicle or medium for most vaccines. These lead to the common and mild reactions seen with the Pfizer and Moderna formulations, but it is anticipated that both of the new candidates should be free of any notable side effects. Secondly, they can both be stored indefinitely without any temperature requirements. This will allow a more rapid distribution directly to MD offices/clinics or vaccination sites and should benefit poorer countries with compromised medical infrastructures. The current mRNA vaccines degrade rapidly and this is why strict and sustained storage requirements at appropriate temperatures prior to usage are necessary. Lastly and most importantly, the J&J offering is only one shot so any level of vaccine will double the level of recipients in comparison to the other candidates.

The data on the two current mRNA vaccine options clearly shows that they greatly reduce clinically significant infections and hence decrease the rates of hospitalizations, ventilatory requirements and by doing so overall death. This effect is noted to become statistically significant 10 days after your first vaccine administration. The efficacy from the initial injection appears to confer 50-70% immunity. It remains paramount that everyone receives their second vaccination as this pushes likely immunity up to 95%.

The current level of concern with these expected "viral mutations" is whether their frequency and the effectiveness of the permutations—a virus has the capacity to change its genome or genetic code by 1% just overnight — to mutate into strains that can circumvent our vaccine's efficacy to confer immunity. This appears a bit premature at this point. It certainly is a possibility over time, but it should not be absolute and render our current vaccine efforts as ineffective. Most likely it will only lead to some minor diminishment in the efficacy of the vaccines.

Viral mutations are the norm and explain why the yearly influenza

vaccination is modified a bit each year. Scientific extrapolations show this is likely the course for Covid-19 and a "booster" dosing will likely be necessary at some point.

One of the benefits of mRNA vaccines is that they allow faster "customization" for any nuances that occur with possible variants that may compromise efficacy. Encoding changes to tweak a vaccine accordingly will offer a counter moving forward to any compromising viral mutations and appear to be the future of vaccine technology. If appropriate molecular surveillance is in place in the near future, this will allow for a targeted response via lockdowns and boosters in noted hot spots as they arise.

In addition, prior vaccination yields usually involved a laborious and timely production process which generally limited the ability to rapidly ramp up production to any degree. mRNA processing will exponentially improve adoption in the scales of production into the future.

If we are able to attain 70-80% vaccination levels, we should start to see a precipitous decline in the burden to our health care system. Some current projections estimate this is a possibility by July. If this occurs, we can expect to see normalization in our lives several months thereafter and we then may begin to be able to safely remove our masks.

As to vaccine side effects, normally when a vaccine is submitted for FDA review and approval, the manufacturer stops active data collection. In contrast, the current use of V-safe — an application that allows you to use your smartphone to report any information as to side effects — is now collecting this data in real time and we are over 10 million plus at this juncture with the Covid-19 vaccines. Irrespective of the anecdotal reports, major side effects are essentially zero. Historically, significant and unexpected vaccine side effects appeared in the first month of usage and we have now crossed that threshold. The vaccine appears safe.

Availability

Some trickling in of vaccines locally continues, but it remains uneven and unpredictable. My office is registered with the state to receive vaccine at some point, but it's anyone's guess as to when and more importantly in what quantities.

I will continue to keep you informed to the best of my

abilities.

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