



Answers to Your Questions

Question:

A Summary by Dr. Wilbur Chen of the pandemic and vaccines at the end of January.

Answer:

Wrap-Up for January 2021

Since about the second week of January, new hospitalizations for COVID-19 have been on a slow but steady decline. However, the burden of managing COVID-19 patients continues to strain the medical system throughout the U.S. There are local and regional shortages of medical oxygen and trained medical personnel. There are still high levels of transmission of the virus with high amounts of hospitalizations and deaths. It is not time to relax vigilance with physical distancing measures.

Variant viruses have increasingly been detected throughout the U.S. The U.K. variant (B.1.1.7) demonstrates efficient transmission globally. The U.K. variant was first detected in a case from Colorado on Dec. 29, 2020, and since then has been confirmed in 315 cases in 28 states, among which four cases have been identified from Marylanders. With the sequencing of biobanked viruses in the U.S. from September 2020, there is evidence that the U.K. variant has been in the U.S. since early November 2020. The first cases of the South Africa variant (B.1.351) were just detected in South Carolina on Wednesday, Jan. 27, 2021, in two people with no history of travel or contact with each other. The first case of the Brazil variant (P.1) was detected in Minnesota on Monday, Jan. 25, 2021, in a person who recently traveled from Brazil and had illness in early January.

What do these variant viruses mean? Any time a virus replicates, there can be the rare introduction of random mutations in the genetic code — this also happens with influenza, HIV, hepatitis viruses, etc. Some of these random mutations can cause an amino acid change or an amino acid deletion — amino acids are what make up proteins, such as the important “spike” protein of SARS-CoV-2. So, these changes or deletions may have no effect on the virus or may make the virus less or more successful in “fitness.” The mutations that confer better “fitness” to the virus are the ones that will be more successful in circulating; the mutations that confer worse “fitness” probably don’t go on to circulate much more — they die off. As more mutations accumulate in variant viruses, there is the risk for higher transmissibility, higher severity of disease, and for our diagnostic tests, therapies, and vaccines to perform less well. So far, the three variant viruses that I have discussed have been found to be more transmissible and perhaps slightly more severe (this is not yet clear, but it is not significantly more severe according to existing data). There is concern for both the South Africa and Brazil variant viruses to be associated with lower efficacy with the mRNA vaccines from Pfizer and Moderna. Let’s be clear that this is a slightly lower efficacy and not no efficacy, so vaccination continues to be very important.

The rolling out of vaccines has been confusing and frustrating for nearly everybody. There has been a lack of clarity with knowing how much vaccine is being allotted from week to week from the federal to the state level. This impacts how local jurisdictions and medical systems plan for deploying vaccines. There was the assumption that federal stockpiles of vaccine were being maintained to ensure that second doses of vaccines would have a guaranteed supply. On Jan. 12,

then-Health and Human Services Secretary Alex Azar announced that the Trump administration would be “releasing the entire supply for order by states, rather than holding second doses in reserve.” Yet, on Jan. 15, it was announced that “states will not be receiving increased shipments of vaccines from the national stockpile next week, because there is no federal reserve of doses” (as Oregon Gov. Kate Brown tweeted). And so, please be patient as there is the need to better coordinate the national vaccination program under President Biden.

Yesterday, Jan. 28, 2021, we heard great news from Novavax regarding efficacy observed in their vaccine trials in the U.K. and South Africa — remember these are the two countries that are concurrently dealing with their own variant viruses. The efficacy in the U.K. was 89.3 percent and in South Africa was 49 percent. Why was the efficacy lower in South Africa? There is much more HIV in South Africa, and the immunocompromised typically have poorer immune responses to vaccination. Also, the South Africa variant virus (B.1.151) is already anticipated to be able to slightly decrease the vaccine efficacy. Third, there may be other factors in the population that may decrease the efficacy of the vaccine, such as malnutrition, comorbidities, occupational risk, etc. Moreover, let’s concentrate on the Novavax vaccine’s effect on preventing severe disease — it demonstrated near 95 percent efficacy for preventing severe disease!

Today, Jan. 29, 2021, we finally heard the interim analysis of the Johnson & Johnson/Janssen vaccine. The broad geographic locations for the evaluation of efficacy were performed and efficacy was 72 percent in the U.S., 66 percent in Latin America, and 57 percent in South Africa — a cumulative efficacy of 66 percent. If only examining effect on preventing severe disease, the efficacy is 85 percent. This is a GAME CHANGER. Although you may be looking at these numbers as “the glass half-full,” I will remind you that this is a single-dose vaccine that can be stored in normal refrigeration. This is the vaccine that can be easily deployed to low- and middle-income countries and very-difficult-to-reach populations throughout the world. This is what is needed to end this pandemic — to successfully vaccinate the world. Perhaps we’ve been lulled into expecting that all vaccines should show 95 percent efficacy, but let’s acknowledge that the original expectation set by the Food and Drug Administration and scientists many months ago was for vaccines to demonstrate >50 percent efficacy. Another reason for my extreme enthusiasm for this vaccine is that there is another study being conducted (named Ensemble-2) that is evaluating efficacy for two doses separated by 56 days (eight weeks). The data from Ensemble-2 will pave the way for the possible administration of a booster dose (second dose) of the Janssen vaccine, if needed. I expect that this second dose would confer very high levels of protection — potentially reaching or exceeding 95 percent efficacy. Nonetheless, one dose throughout the world is all that is needed to achieve high levels of community immunity.

With the closure of this first month of the new year, this nation has observed the peaceful transfer of power, the ebb and flow of viral infections, the introduction of variant viruses, and exciting new data supporting two more vaccines for the fight against COVID-19. I personally received the second dose of the Pfizer vaccine this month, but I continue to maintain strict adherence to the 3 W’s: wear masks, watch my distance, and wash hands! Stay safe, everyone.

About the Author: Dr. Wilbur Chen is an adult infectious disease physician-scientist with a specific interest in clinical vaccinology. He is Professor of Medicine at the University of Maryland School of Medicine (UMSOM), Chief of the Adult Clinical Studies section within the Center for Vaccine Development and Global Health (CVD, an organized research center of UMSOM), and Director of the University of Maryland, Baltimore (UMB) Travel Medicine Practice. Dr. Chen has served in a pivotal role in the COVID-19 pandemic as a member of Maryland Governor Larry Hogan’s COVID-19 taskforce. He is advising the state on vaccine development and distribution as well as COVID-19 safety initiatives. During the 2009 H1N1 pandemic, Dr. Chen was the principal investigator of the NIH--sponsored national H1N1 vaccine trials. Within the present COVID-19 pandemic, Dr. Chen is also co-leading the Maryland Department of Health (MDH) state-wide serological surveillance program of COVID-19, and is co-principal investigator of a CDC-funded COVID-19 syndromic

surveillance program which is being implemented through the University of Maryland Medical System.

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