Mount Sinai Health Partners
March 2021 COVID-19 Town Hall
Your Questions, Answered

Thank you to all who participated recently in the MSHP March 2021 COVID-19 Town Hall. Some of you asked questions during the meeting that required further clarification. Here are the answers to your questions from the meeting's presenters on COVID-19 vaccines, variants, and telehealth.

COVID-19 Immunity, Vaccines, and Variants

Q: If a patient has a positive COVID-19 test, how long should they wait in order to receive the COVID-19 vaccine? In addition, do they need two doses or one dose of the vaccine?

A: The official guideline is that you need two doses of the vaccine. However, most countries in Europe have already changed their guidelines to one dose, but right now; the recommendation really is two doses. From an immunological perspective, if someone is positive and infected with SARS-COVID 2, wait for 4 weeks until the person receives the vaccine to get the B-cell and T-cell components down to resting state again before you reactivate them.

Additionally, somebody who was just infected with SARS-COVID 2 has considerable protection against reinfection. There is no rush to get that person vaccinated unless you know that the person will not come back if you wait. Therefore, wait for the levels to go down and then vaccinate.

Q: Is there any suggestion that the Johnson & Johnson vaccine may be safer for young people as compared with the mRNA vaccines? Is the J&J vaccine similar to traditional vaccines used in the past?

A: It is currently not clear yet if the J&J vaccine is safer for young people. We see side effects with the vector vaccines and with the mRNA vaccines. Both Pfizer and Moderna are currently conducting studies in children and they will have safety data. Therefore based on the safety data, these vaccines will be licensed for kids or not. The data so far seems to indicate that these clots do NOT occur in people over 50 – but stay tuned.

The J&J vaccine is more similar, not to traditional vaccines, but vaccines that have been used in the last few years in Europe and it is relatively similar to a vaccine that the US Army has been using since 1971 against Adenovirus 4 and Adenovirus 7. However, the standards for the US Army's vaccine might be a little bit different from the standard that we have for the remaining part of the population.

Q: Is one vaccine better than another in immunocompromised or patients with autoimmune or inflammatory bowel disease?

A: Right now, the vaccine that gives you higher efficacy might be better in those patients, partially if you have patients who have a compromised immune system to various degrees**.** It is not an official recommendation, but it is better to have a vaccine that is given twice.

We know that there are efficacy differences and differences in the magnitude of the immune response so the mRNA vaccines are currently better inducing stronger immune responses and giving better protection than the J&J vaccine. Therefore, use those for people who already have issues with the immune response, but again I do not think there is an official CDC recommendation.

Q: Does B.1.526 have any age propensity? I am seeing a shift in younger patients who are minimally symptomatic.

A: Not that we know of. Specifically B.1.526 does not have the N501 Y mutation, which is usually associated with high receptor binding. There have been hypotheses that viruses with the N501 Y mutation have high infection rates in kids. However, this is not proven yet as there is no solid data for the New York variance.

Q: What if you have a patient who gets COVID-19 after the first dose of the vaccine? Do you delay the second dose?

A: Yes, wait a few weeks so the immune system cools down.

Q: Why aren't a person's COVID-19 antibodies who was infected with COVID-19 as strong or long lasting as a person who got the vaccine?

A: When we see people who had COVID-19 there is a lot of variability in how high their antibodies go and how strong the immune response was, so there is a lot of heterogeneity. With the mRNA vaccines, we do not necessarily see that. We see a very strong response in almost everybody, so that is the main difference. Be careful because the vaccine is only inducing systemic immune responses against one viral protein while the infection is inducing monoclonal responses and T-cell responses again from many different proteins that the virus expresses. We are seeing from large studies that the vaccine is protecting against reinfection too.

Q: I have a few patients who came down with COVID-19 about the same time they got the COVID-19 vaccine. Should they wait to get their second shot?

A: They should not wait too long, because you typically have to wait between the two shots at least 3-4 weeks depending on the vaccine. Wait 4 weeks until they are no longer symptomatic and then get the second shot if that is possible.

Q: Will a combination of different vaccines with different monoclonal antibodies be recommended in the future?

A: This is still unknown. There could be a scenario where the monoclonal antibody enhances the immune response, but there could also be a scenario hypothetically where it suppresses the immune response. Typically, if you get monoclonal antibody it means you had an infection, so wait for some time until being vaccinated.

In the UK, there is a trial running where they give someone a vector vaccine, like the AstraZeneca vaccine, and then follow up with the mRNA vaccine and this could potentially be something that might be happening with some of your patients. For example, someone may have gotten the first Moderna shot and then did not get the second one, but then they got a Pfizer vaccine. What we very often see in research and clinical trials where we look at new vaccination regiments is that combining different

vaccine platforms let us say a vector first then a protein-based vaccine later, actually gives superior immune responses. However, right now there is no data to support that in terms of safety.

We did have people who dropped out of AstraZeneca clinical trial who had a vaccination there, and took the mRNA vaccine because they could then get it. Do not be very alarmed if that were to happen, there is just not enough data now about this.

Q: With past vaccines, many people do not get so severely ill from them. What is it about the vaccines that make so many people so ill?

A: There might be different mechanisms. For the vector vaccine, such as AstraZeneca, the first shot gives you these flu like symptoms, COVID-19 like symptoms, and for the mRNA vaccines, it's usually the second shot. It is probably a combination of a strong innate immune response to the mRNA vaccines in general and then for the second time, there is probably an additive effect of an already existing adaptive immune response.

Q: Is there any value to getting antibody testing after vaccination?

A: Not recommended, as it would not accurately reflect whether immunity is or is not present. Most of the current Serum Antibody tests check for antibodies against the Nucleocapsid component of the virus. Since the vaccines are against the Spike Protein and not the Nucleocapsid component, it would not be helpful to draw serum antibody levels after vaccination.

Q: Is it currently recommended that the vaccine be administered to women who wish to conceive or to pregnant women? If so, is there a preference for any one vaccine vs. another?

A: The current recommendations from the WHO and the CDC are that a pregnant woman have a conversation with her provider to determine if getting the COVID-19 vaccine is right for her. Although there were, no clinical trials specifically conducted on pregnant women, at this time over 30,000 pregnant women have received either the Moderna or Pfizer vaccines. No serious adverse effects have been reported to the CDC Vaccine Safety Datalink.

As the vaccines will soon be made available to anyone over the age of 16 who would like one, women of child-bearing age should also receive the vaccine to protect them from COVID-19. As per the CDC site: COVID-19 in pregnancy is associated with an increased risk for serious illness (such as ICU admission) and increased risk of adverse pregnancy outcomes (such as preterm birth) compared to pregnant women without COVID-19.

There is no preference of one vaccine over another for women of childbearing age.

Q: What Monoclonal Antibody Treatment is currently being utilized at Mount Sinai against COVID-19?

A: Monoclonal Antibodies available for treatment have shown decreased efficacy against the variants and the FDA has removed the EUA for the single component formulation (Bamlanivimab alone). At this time, Mount Sinai is only using the combination of Bamlanivimab + Etesivimab for both outpatient and (limited) inpatient use.

Q: What are the current rules of health care workers returning from non-contagious states with regard to quarantine and testing if they have been vaccinated?

A: Recently, New York State Department of Health issued new guidance on travel and health care workers. Effective immediately, all asymptomatic health care workers may return to work after domestic travel without quarantine or testing.

Telehealth

Q: Did the recent COVID relief package (The American Rescue Plan of 2021) provide any funding for small medical practices?

A: The Act allocated an additional $7.25 billion in funding for small businesses under the Paycheck Protection Program. For the most up to date information on how to apply, we recommend monitoring the Small Business Administration website or contacting your lender. The Small Business Associate is currently offering Paycheck Protection Program loans until May 31, 2021.

Q: How long do we expect the Public Health Emergency (PHE) and related flexibilities around telehealth billing and reimbursement to remain in effect?

A: The current PHE declaration is in effect until July 19, 2021. In January, HHS indicated that the PHE would likely remain in effect through the end of 2021. While that is not a guarantee, it is a good indication that Medicare telehealth access and reimbursement will likely remain in effect until then. If we learn of any updates on planned end dates or extensions of these policies, we will share that information with you as quickly as possible.

Q: Is POS 02 now required for all telemedicine services?

A: POS 02 has always been required for Telemedicine services. However, the only adjustment made on the professional side was to add a site of service location, “Telehealth POS 11” to obtain the Non-facility reimbursement for those payers who were following CMS’s payment parity affirmation. This was declared in April 2020 and required us to send POS 11 for their systems to process at the higher rate. For those payers that didn’t require the site of service location logic we submitted with the standard POS 02 and monitored if they reimbursed at the non-facility rate.