CDC/IDSA COVID-19 Clinician Call

February 27, 2021

Q&A

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1. **The poll didn't address another method of extended use, which is hours a mask is used. We do this for persons who only need to wear the N95 for a very short part of a day, such as consultants.**

   Thanks for this feedback. We will let the CDC staff know investigation of this method of extended use is advised.

2. **How long are the vaccines effective?**

   We don't yet know the duration of protection of these vaccines, but we are monitoring very closely through vaccine effectiveness studies.

3. **Can or should the J&J vaccine be administered to a patient who had prior severe allergy or anaphylaxis to one of the MRNA vaccines in order to complete the "second shot"**

   It can be administered to a person who had a previous severe allergy to the mRNA vaccine, but it would not be considered a "second" shot, rather, it would be considered starting and finishing the J and J vaccine.

4. **J and J vaccine use in pregnancy? any insight? Thank you**

   The sponsor stated that they will start a vaccine trial in pregnant women in April 2021. Very few pregnancies have occurred in their current trials. No difference in pregnancy outcomes between vaccine and placebo recipients.

5. **Given the data coming out on the efficacy of the Pfizer vaccine after one shot, do you envision the recommendation ever changing regarding the two shots for Pfizer and Moderna? What would you need?**

   The data are interesting. We need to evaluate these post-authorization data carefully, particularly whether a single dose of these vaccines affords long-term immunity.

6. **J& J should be a two-dose regimen - why didn't you wait for the data from the two dose trials? It is obvious that it should NOT be a one dose vaccine.**

   There was discussion on this topic. A number of the committee members including I felt that in the face of a deadly pandemic with insufficient supply of the other two vaccines, this vaccine would be a valuable addition at this time. It also offers the benefit of not needing ultra-cold transportation and storage which is important for making the vaccine available to communities where such storage is not available.

7. **When you say adolescent trial in Japan, what are the age groups being tested?**

   Ages 12-17.

8. **I have had several patients who reported some side effects to the vaccine but when they contacted the site where they received the vaccine, they did not feel their report was accepted or they could not get someone on the phone line. Aside from directing them to the VAERS website or V-safe is there another avenue for them to have their symptoms better assessed to see if it was truly a vaccine side effect. Unfortunately, they are only notifying my office 1-2 weeks later and symptoms have fully resolved.**

   Even if the person's symptoms have resolved, please have them submit a VAERS report or report through V-Safe. For mild or moderate events that did not impact daily activities or require a visit to a health provider, they may not get a follow-up call from V-Safe, but it is still important for us to capture that information.

9. **Regarding the stability, it is reported to be stable for 2 hours of room temp when open and for 6 hours in refrigerated temp when open; does this mean you have to open the vial and draw doses in a refrigerated environment, or can you draw at room temp (and for how long) and then place it back in the fridge?**

   You can draw in a room temp environment and then place back in the refrigerator within 15-30 minutes, but if you are drawing up lots of doses you can also have a cold storage (a container surrounded by cold packs), so the doses do not get to room temperature while out.

10. **Do we know where the DNA encode is synthesized/processed, is it muscle cells? (I assume once expressed, APCs take from there).**

    You are correct.

11. **For Dr. Cohn: In the recent CDC recommendation for fully vaccinated asymptomatic close contacts not needing to quarantine for 3 months, how does CDC recommend vaccination status be verified? What may meet criteria for acceptable evidence of immunity (e.g., immunization)? Thank you!**

    There should be documentation of the vaccine series being complete either through the card, or hopefully through the state vaccine registry, which is capturing all of the vaccines given.

12. **Is this being considered as a "tide over" measure until more 2 dose vaccines are available? Seems like the only plus of the J and J is one dose and easier storage/administration, otherwise effectiveness and potential decreased longevity are distinct issues.**

    Yes. We may also find that single dose vaccines offer adequate immunity.

13. **Please address the thrombi that formed in the vaccine group of J&J which led to cases of PE, Stroke, and MI - did that not concern you?**

    There were 14 TE events in the vaccine arm and 10 in the placebo arm. It needs to be monitored.

14. **What was the discussion of the VE in HIV patients? What are the implications?**

    Only 2% of participants were HIV positive. A study in immunocompromised individuals is planned to start in Q3 of 2021. I am not sure if this will include HIV positive patients.

15. **Does this vaccine formulation include polysorbate or PEG?**

    It does not.

16. **Are the ACIP meetings open to the public and if so, can you please post the link to the invite?**

    https://www.cdc.gov/vaccines/acip/

The webcast will be live and open to the public.

17. **Given the logistical difficulties with getting mRNA vaccines into smaller community settings more accessible to marginalized and minority communities, many have been looking forward to a single dose vaccine with fewer cold/technical requirements. While the mRNA and adeno vector vaccine studies have many differences that preclude making a direct comparison, many people and medical community are making these comparisons. A) Do you think we can truly make such a comparison to say that mRNA is better than Ad26.CoV2. S? B) What is your opinion about how the medical community can maintain trust with minority communities in light of much discussion focusing on the overall vaccine efficacy differences b/w mRNA & Ad26. Thank you**

    I recommend we NOT make these comparisons as the vaccines have not been studied concomitantly. Best to provide accurate information to the audience.

18. **How many breakthroughs have been reported in the clinical use of the mRNA vaccines, at least 2 weeks following the second dose, and are any of them among the new variants?**

    There have been breakthrough cases, I don't know how many but within what we would anticipate, and they are doing further evaluation of these cases, but we do not know the results yet.

19. **Any data on mixing and matching vaccine doses from Pfizer and Moderna vaccines?**

    Not yet!

20. **How much longer before we have data from the 2 doses for J&J and was it so much time that you could not wait?**

    We are unlikely to get 2 dose data for several months.