CDC/IDSA COVID-19 Clinician Call:

COVID-10 Vaccine Boosters, the Immune Compromised & Protecting the Most Vulnerable October 23, 2021

Q&A

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1. What would your recommendation be for a healthy 31-year-old male with history of one J and J in March? Should he get another J and J or mRNA vaccine. Risk of clots vs myocarditis vs young healthy male with no underlying history?

CDC is including guidance in our clinical considerations around the individual risk-benefit for these types of situations. The risk of either of these outcomes are rare, however, to put it in context the risk of TTS is highest in women aged <50 years, and the risk of myocarditis is highest in males 12-30 years. So this could be taken into account as well as the patient preference and vaccine availability. (Dr. Mbaeyi)

2. Even though the authorized booster for Moderna is half the usual dose, would you consider a full dose for those who've received J&J, since that's what we've seen in the immunogenicity studies? Particularly for immunocompromised patients, I am inclined toward the full dose. Any recommendations?

The only authorized dose for a Moderna booster is the 50 ug dose. Therefore, CDC recommends that anyone getting a Moderna booster dose, including recipients of J&J and immunocompromised persons, receive the 50 ug dose. (Dr. Mbaeyi)

3. Do we have any recommendations for patients who had COVID then J&J or other vaccine do we know yet if they would benefit from Moderna or other boosters?

CDC's recommendation is to offer primary and booster vaccination to eligible individuals, regardless of their prior infection history. After natural infection, there is some heterogeneity in the immune response. Serologic testing is also not recommended to determine if someone previously infected is protected, because the existing antibody tests are not authorized for this purpose, there is variable sensitivity/specificity, and no correlate of protection. We have data on immune responses for the primary series in previously infected people, but not for booster vaccination. For all of these reasons, CDC continues to emphasize that vaccination (primary and booster for recommended groups) is the best way to ensure protection. (Dr. Mbaeyi)

- 4. Thoughts about 16–17-year-olds that would qualify for a booster given a chronic medical condition who are now >6 months from their 2nd dose?
 - People under the age of 18 are not currently recommended to receive a booster dose, given lack of data in this group. (Dr. Mbaeyi)
 - Data were not presented to VRBPAC by any of the sponsors in this population. (Dr. Chatterjee)
- 5. Why is there a need of third dose and booster doses drops Ollie who get third dose 28 days after second dose also then get booster dose after 6 months of first dose? Was it essential to use the third and booster dose rather than just booster dose only?

If I'm understanding the question, it relates to recommendations for immunocompromised people. We currently recommend that immunocompromised people receive a 3rd mRNA dose because there is evidence for incomplete protection after 2 doses. This is different from a booster dose, where individuals are initially protected after the first two doses but protection wanes over time. CDC is currently considering recommendations for booster vaccination in immunocompromised persons who have already received an additional dose. (Dr. Mbaeyi)

6. Could healthcare workers who got a Pfizer booster qualify for a Moderna booster in 6 months? Since the neutralizing antibody counts appeared to be more robust with Moderna?

Yes. Any of the vaccines could be used to boost. The sample size was too small to compare between the different groups with regard to more robust responses. (Dr. Chatterjee)

- 7. In regard to time interval between Covid infection and getting COVID vaccine, as we need to wait for 90 days for individuals who received monoclonal antibody, why is this not the same for natural infection and probably interaction between natural antibody and vaccine?
 - The recommended 90 day deferral between mAb and vaccination is a precautionary measure because we do not currently have data on whether there is immune interference. We will adjust our recommendations as needed once data become available. For natural infection, there are a number of studies now that demonstrate people who have had natural infection and then are vaccinated have a very strong immune response. While we don't necessarily have data on specific intervals between infection and vaccination in these studies, we have no evidence that there is immune interference; on the contrary, immune responses are very good for people who have natural infection and then get vaccinated. (Dr. Mbaeyi)
 - Investigators at CoV-PN and Lilly are completing work on the administration of bamlanivimab followed by vaccination with mRNA vaccines in residents of nursing homes. This study was conducted when the alpha variant was dominant. I would expect the results to appear before the end of the year, and to better inform the "risk" or "limitations of vaccinating AFTER administration of a monoclonal antibody or mAb combination. Conversely, vaccination is not a contraindication for mAb treatment for high-risk patients. (Dr. Cohen)

8. Why are we hearing that the best booster is Moderna vaccine for those who received the Janssen vaccine? I am concerned that the basis for the Moderna recommendation is limited by the analysis at only 4 weeks after the booster. What about clinical correlation and what about durability of the booster response?

Good points - we do not have clinical correlation data or durability data yet. Also, each of the groups was fairly small in number. (Dr. Chatterjee)

9. Is mixing and matching only for boosters, or can this apply to primary series as well?

No data were presented on "mixing and matching" for the primary series. (Dr. Chatterjee)

10. Is there an immunological advantage in boosting mRNA with Janssen?

Not that I know of (Dr. Chatterjee)

11. Have any of the three authorized booster dose vaccines shown evidence of reducing viral load and/or infectiousness/risk of spread by the COVID-19 vaccine recipient, in addition to preventing severe outcomes in the COVID-19 vaccine recipient?

These data were not presented. (Dr. Chatterjee)

12. As a young, male healthcare worker who was fully vaccinated with Moderna, what evidence exists that I would benefit from a booster, compared to my risk of vaccine-associated myocarditis?

CDC has conducted a benefit-risk analysis for Pfizer booster dose, and even with the rare risks of myocarditis, the benefits outweigh the risks. Please see for more details: <u>https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html</u> (Dr. Mbaeyi)

13. What is the evidence to support the Moderna booster dose at 50 mcg following a primary J&J?

From the "mix and match" study - Dr. Marks will show the data shortly. (Dr. Chatterjee)

14. Should those with primary one-time dose of J&J have second dose of J&J and then a booster with mRNA vaccine for best boost?

No data presented for this option. (Dr. Chatterjee)

15. In the trial presented, did patients who received J&J vaccine and received Moderna booster receive full dose Moderna or half dose? Which is recommended?

The J and J vaccine recipients received a full 100 mcg dose. Data using 50 mcg are currently being generated. However, since 50 mcg of Moderna gets a bit over 75% of the immune response of 100 mcg, this is probably a reasonable extrapolation, given how high the boost was with 100 mcg (75 fold increase in GMT). (Dr. Marks)

16. Myocarditis sounds to be transient as a side effect and long COVID could last for months or potentially years, which we don't know yet. It might help if this is communicated better. Agree! (Dr. Chatterjee)

17. Why did the VRBAC committee believe that not all of those in the US will have access to the vaccine they received in the primary series?

This was of particular concern for the Janssen recipients. This vaccine was used in populations such as the homeless who may not return to the same vaccination site to get their booster dose.

18. What is the guidance for those who have previously received two doses of J&J? Should they receive a 3rd dose?

If the second dose of Janssen vaccine was given at least 2 months after the first, the vaccine efficacy should be close to 95%. We do not know the durability of protection from this regimen yet. (Dr. Chatterjee)

19. Should the third dose of the Pfizer/BioNTech vaccine be regarded as part of the primary series?

Only for those who are immunocompromised. (Dr. Chatterjee)

20. Do we expect that the booster will offer protection in the way of preventing transmission? For example, if someone were to get the booster, does it offer protection against transmitting to unvaccinated or even vaccinated household members?

Indirectly, yes. Higher antibody titers should reduce the chance of infection, which should reduce the risk of transmission. (Dr. Chatterjee)

21. Is there reason to believe that doing a Moderna booster after 2 Pfizer primary series 8 months out offers more or better protection than another Pfizer?

The NIAID study was not powered to make such comparisons. (Dr. Chatterjee)

22. Has there been any discussion of using J and J booster for under 18s young males when it comes time to boost them? Some of them will be coming up on 6 mos. already if they got vaccinated at first opportunity in mid-May. (for the 12 to 15s)?

No data yet on under 18 for Janssen's vaccine. (Dr. Chatterjee)

23. At some point will we all need full doses again? Not only a booster?

No way to know that yet (Dr. Chatterjee)

24. So is there evidence that immune compromised mounted enough immunity after 3rd dose and if so what levels are enough levels? I am still not able to understand what scientific basis is being used to make these confusing third dose and booster dose recommendations. Many are confused on these recommendations.

Please wait for the second segment of today's webinar for answers to your questions. (Dr. Chatterjee)

25. Can you discuss the mechanism behind the results of boosting in particular when you are mix and matching with the same platform (e.g., with mRNA vaccines)?

Since the target for all the vaccines is the spike protein, it probably triggers a boost, irrespective of the priming dose(s). (Dr. Chatterjee)

26. 2 weeks after third dose of Moderna COVD vaccine my heart rhythm converted from atrial fibrillation which had been chronic for 20 years, to regular sinus rhythm with p waves. Could this have been a positive cardiac effect of the vaccine?

No data to base this on, but good for you! (Dr. Chatterjee)

27. If we are looking at effectiveness just based on clinical presentation, are we including the effect of no masking and lack of social distancing for the past many months?

I did ask this question, particularly around the Israeli data. No way to really answer the question, other than in Israel, they did not change any of their mitigation measures. (Dr. Chatterjee)

28. Do we know when this data for under 18 for Janssen vaccine is expected?

We do not know at this time. (Dr. Marks)

29. In retrospect, should the original spacing of mRNA doses been closer to 2 months to provide longer duration of protective immunity?

This has been speculated on. Important to keep in mind that the clinical trials were set up very shortly after the pandemic began, and given the potential for fatality, earlier protection was considered important to achieve. (Dr. Chatterjee)

30. Does the CDC provide information on the percentage of residents in nursing homes who have received booster doses?

CDC provides data on vaccination of residents and staff of nursing homes at this link: <u>https://www.cdc.gov/nhsn/covid19/ltc-vaccination-dashboard.html#anchor 1594393306</u> At this point, the data shown are for primary series vaccination, not for booster doses. (Dr. Fox)

31. Will there be stronger recommendations for the public regarding getting an mRNA booster if they received J&J initially based on evidence of improved response?

Currently, CDC's recommendation is that any of the vaccines can be used. There is no preferential recommendation for an mRNA booster dose. (Dr. Mbaeyi)

32. What are pregnant females considered? Moderately high risk or not.

Pregnant women are included in the 'may receive' booster group. Pregnancy is considered a condition that increases risk of COVID-19, so they are in the same risk group as others aged 18-49 with an underlying condition. (Dr. Mbaeyi)

33. This is more a comment than a question. It seems the piecemeal approach we are taking of slow increments is creating confusion even among experts. Is it time to slow down, get better data and be consistent across vaccines? It seems we are mainly basing our recommendations using data from Israel and with Pfizer vaccine (and then extrapolating to other vaccines). In terms of heterologous regimens, it is true they all boosted well; that said, those that contained Moderna at some point were the ones with the highest GMT at the end, and those with J&J had the lowest: that is what the numbers show!

You are correct regarding the raw numbers. However, the NIAID study was not powered to make comparisons between groups. The "piecemeal" approach as you call it, depends primarily on the availability of data from the sponsors. (Dr. Chatterjee)

34. Why recommend Janssen booster at all, given lower efficacy?

The booster with Janssen does restore protection to 95% or so. (Dr. Chatterjee)

35. What are the recommendations to BOOST the immunocompromised who received an additional 3rd dose?

Recommendations for this group are currently under consideration-please stay tuned! (Dr. Mbaeyi)

36. Dr. Mbaeyi/CDC: Any estimated timeline for when CDC's 1) Clinical Considerations page and2) standing order templates will be updated to reflect this week's updated booster dose recommendations?

We hope to get these posted on Monday. (Dr. Mbaeyi)

37. Are there recommendations for those who qualify for booster doses who developed COVID-19 after their primary vaccination series?

The recommendations for boosters are irrespective of prior natural infection history. Please see other responses in the Q&A for a more detailed rationale! (Dr. Mbaeyi)

38. Dr. Mbaeyi - could you please comment on the definitive CDC guidance on whether the choice of type of vaccine given as a booster dose is based patient preference and healthcare provider preference (or if providers should consider the same brand first, then default to the patient and healthcare provider's preference)?

CDC's guidance is that any of the three vaccines can be used. There is no preference to use the same brand in our recommendations. (Dr. Mbaeyi)

39. Are additional doses after the first dose of the Janssen vaccine boosters or part of the primary series?

A second dose of Janssen is considered a booster dose (not part of the primary series). (Dr. Mbaeyi)

40. Does speaker mean J + J where Janssen is listed?

Yes - Janssen is the vaccine arm of J&J. (Dr. Chatterjee)

41. Dear Dr Chatterjee, i was unclear in my question, the question is why we are seeing such an INCREASE in boosting effect when we mix and match. Of course, we all know that the portions of the spike form the peptides that the MHC are showing to T cells, the question I have is "what is the underlying reason for a HIGHER boost from mixing than from non-mixing. Please let us know what data we have on that effect.?

There appear to be numeric differences, but please keep in mind that the NIAID study was not powered to make comparisons between groups. I think this is a fascinating question that could perhaps be answered through a larger study. (Dr. Chatterjee)

42. What will be the plan for the 12 to 17s who will be coming to 6 mos soon if they started the series of Pfizer right when it became available in May?

Data on this population for booster doses have not been made available yet. (Dr. Chatterjee)

43. The third dose of Moderna is full dose or that is also 50 Microgram?

The additional dose of Moderna for immunocompromised persons is a full 100 ug dose. (Dr. Fox)

44. If someone got additional (3rd dose) due to being moderate/severely immunocompromised, are they also recommended to get the booster dose (which would be their 4th dose)? If yes - when can they receive it?

CDC is currently working on guidance around this - please stay tuned! (Dr. Mbaeyi)

45. Moderna Booster = 50 micrograms Moderna Additional dose = 100 micrograms?

Yes. (Dr. Chatterjee)

46. In the mix and match studies, where a Moderna vaccine was given for a booster, was it always the 50 microgram dose given as a booster? Just wondering why the recommendation for someone who received Janssen initially, which Moderna booster dose should they receive?

In the Mix & Match study, the 100 ug dose of Moderna was used to boost. (Dr. Chatterjee)

47. Are we recommending booster doses in immunocompromised patients 6 months after the initial 3 dose series of Moderna or Pfizer?

CDC is working on developing guidance around this, please stay tuned! (Dr. Mbaeyi)

48. Is there any known advantage to following an initial mRNA series with the Janssen vaccine as a booster?

No specific advantage. (Dr. Chatterjee)

49. If a person had COVID infection and then received full series of vaccine, do they need a booster also?

CDC's recommendation is to offer primary and booster vaccination to eligible individuals, regardless of their prior infection history. After natural infection, there is some heterogeneity in the immune response. Serologic testing is also not recommended to determine if someone previously infected is protected, because the existing antibody tests are not authorized for this purpose, there is variable sensitivity/specificity, and no correlate of protection. We have data on immune responses for the primary series in previously infected people, but not for booster vaccination. For all of these reasons, CDC continues to emphasize that vaccination (primary and booster for recommended groups) is the best way to ensure protection. (Dr. Mbaeyi)

50. Can a person with acute COVID-19 infection who subsequently developed GBS be vaccinated thereafter?

Yes - People with a history of GBS can receive any currently FDA-approved or FDA-authorized COVID-19 vaccine. However, given the possible association between the Janssen COVID-19 vaccine and an increased risk of GBS, a patient with a history of GBS and their clinical team should discuss the availability of mRNA COVID-19 vaccines to offer protection against COVID-19. (Dr. Mbaeyi)

51. What is CDC's definition of fully vaccinated for those who received the Astra Zeneca vaccine, for the purposes of international travel?

People who received a vaccine that is listed for emergency use by the WHO (but not authorized/approved) in the United States are considered 'fully vaccinated' based on CDC's definition. More information can be found in the guidance document, including in the Annex for more details: <u>https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated-guidance.html</u> (Dr. Mbaeyi)

52. Speaker is saying we recommend coadministration. Does she mean to say it is ok to do so, or it is actually recommended?

Ok to do so. (Dr. Chatterjee)

53. For patients > 65 yo and who received Sinovac from another country, do we recommend a booster or revaccination with Pfizer/Moderna/Janssen or complete re-vaccination?

For persons who received a vaccine that is listed for emergency use by WHO but not authorized/approved by FDA (including Sinovac), our current recommendations are to offer them a primary series of a US-authorized/approved vaccine.

54. Any data on mix & match booster with Vaxzevria?

Not that I am aware of. (Dr. Chatterjee)

55. How robust do you feel is the data that a 50 microgram dose of Moderna is comparable to 100 micrograms.

The sample sizes were small, but no difference in immunogenicity was noted with the lower dose booster. (Dr. Chatterjee)

56. Does mixing of vaccines protect better against variants?

We do not know if there is better protection against variants. Limited data currently indicate protection against current variants. (Dr. Chatterjee)

57. Recommendations for people who got the AZ vaccine? (similar to the question above re Sinovac)

CDC does not yet have booster recommendations for this group. (Dr. Mbaeyi)

58. Apologies for re-asking, but I am still concerned about the immunogenicity of mRNA vaccine, particularly half-dose Moderna, in immunocompromised recipients of J&J. While the lower dose is as immunogenic (in normal hosts?) as 100 mcg, per Dr. Marks, I am not convinced that will apply to IC hosts, given their poor responses overall. I understand the recommendation, but am concerned about the lack of evidence in this population. Some patients have of course figured out how to get the one they want. I hope we'll get more information on boosting in this group.

For a third dose given to an immunocompromised individual the dose should most certainly be 100 mcg. This is a complexity here to remember with implementation. (Dr. Marks)

59. What should we recommend and offer to US citizen who got AstraZeneca or Novavax, either in a study in the US or if they were living overseas?

CDC does not yet have guidance for these groups, please stay tuned! (Dr. Mbaeyi)

60. Any data show if children under 12 years old will have risk of myocarditis /pericarditis if they receive mRNA vaccine?

We don't know the answer to this yet. The data that are now posted on line for the Pfizer vaccine in 5 to 11 year olds did not see myocarditis in 2000 or so vaccinated children. We will need to follow this using large databases once the vaccine is deployed.

61. If someone had COVID, then got fully vaccinated, should they then get the booster dose if eligible?

Booster doses are recommended (for the eligible/recommended groups) regardless of history of prior natural infection. Please see other responses in the Q&A for more details! (Dr. Mbaeyi)

62. If someone got 2 Pfizer, do they get "more total vaccine" if they get a Moderna booster (even at half dose) then another Pfizer? Or does the math not work in a direct comparison like that between the two?

It does not appear to be a mathematical equation. (Dr. Chatterjee)

63. Why are we equating (or seeming to anyhow) Ab-levels with needing to boost/not boost? Are there not other factors that should go in? (not that anyway we yet have definite correlates of protection).

The Israeli data is quite compelling that waning antibody titers are associated with breakthrough infections resulting in hospitalizations. (Dr. Chatterjee)

64. Why was the NIAID study so small?

The NIAID study was designed to show that the principles of mix and match worked, not to determine the best regimen. To the extent that everything boosted everything else, it was successful. It is likely that there will be larger follow up studies. (Dr. Marks)

65. What is the maximum time that booster should be received? and will we need to start all over with vaccination if we did not receive the booster within certain time?

There is a minimum but not a maximum time for the booster dose. Since the immune response is so readily boosted, there should not be a need to "start over". (Dr. Chatterjee)

66. Why did we not study (or are we studying) a modified mRNA booster tailored for Delta variant? Is it likely there will be need for a 4th shot now as the virus evolves?

The data (limited as they are) do demonstrate activity of the booster against the delta variant. (Dr. Chatterjee)

67. What is the data about mRNA vaccines in diabetic patients- is there a peer reviewed paper?

The data are on the FDA website. Initial effectiveness following the two dose primary series of Pfizer or Moderna is 95 to 100% - no different from the general population. (Dr. Marks)

68. If a person had a natural infection with COVID and then was fully vaccinated, do they need an additional/booster dose?

CDC recommends primary and booster vaccination (for eligible and recommended groups) regardless of history of infection. Please see other responses in the Q&A for a more detailed explanation on rationale. (Dr. Mbaeyi)

69. Even though the authorized booster for Moderna is half the usual dose, would you consider a full dose for those who've received J&J, since that's what we've seen in the immunogenicity studies? Particularly for immunocompromised patients, I am inclined to.

Monoclonal antibodies clearly do not provide long-term protection. Neither do they induce the full repertoire of immune responses that vaccines and natural infection do. (Dr. Chatterjee)

70. The Moderna vaccine in the mix and match was 100ug not 50ug dose, correct? In such, would we expect a linear response with the 50ug Moderna boost so that it is equivalent to getting a boost with Pfizer?

You are correct about the Moderna dose in the Mix & Match study. It is not possible to tell whether the 50 ug dose of Moderna would be equivalent to the 30 ug Pfizer dose. (Dr. Chatterjee)

71. Will there be guidance for the public in terms of someone who is say, late 40s, early 50s, healthy, not high exposure, but it has been more than 6 mos, if it is a good idea to get booster.

Please stay tuned over the next month or so for updates on this situation. (Dr. Marks)

72. Is there any thoughts that patients who are poor responders to other vaccines (eg Hep B) would be poor responders to the covid vaccines?

No data to answer this question. (Dr. Chatterjee)

73. Are there new data to guide decision-making for adolescent patients (<18 years) who developed myocarditis/pericarditis after their 1st Pfizer dose regarding 2nd dose?

Please see CDC's guidance on this: <u>https://www.cdc.gov/vaccines/covid-19/clinical-</u> considerations/covid-19-vaccines-us.html#underlying-conditions (Dr. Mbaeyi)

74. Any guess when a 2nd booster may be necessary hopefully should be based on ab data and not only clinical data like the Israel study because it might result in unnecessary deaths

Would be a pure guess, so would not want to speculate on this. (Dr. Chatterjee)

75. Persons who have received boosters have tested positive with rapid test but negative with PCR is it because it was a false positive or did the neutralizing antibodies prevent replication and a detectable viral load to PCR? (shouldn't have had PCR I know but got it done elsewhere). Repeat PCR 3 days later was still negative, so I presumed false positive though had very high risk exposure (indoor meal unmasked, hug and kiss on cheek from infected person, though all persons vaccinated)

Likely false positive rapid test. (Dr. Chatterjee)

76. How long should defined immunosuppressed patients who become infected (regardless of vaccination status) be isolated? Until negative test?

Great question. We do not know. And we are constrained in tools to STOP replication. I suspect the least you can do is an NP PCR, and it may need to be repeated. What should you do if PCR remains positive? This is topic of a broader discussion. (Dr. Cohen)

77. Thank you, Dr Chatterjee, I suspect that there may be a subtle differences when the (very similar) mRNA sequences in Moderna versus Pfizer/BioNTech peptide forms intracellularly (or how the Spike on the Adenovirus26 of Janssen vaccine) and how those spike proteins are then broken down intracellularly. This would in theory form slightly different peptides. Those slightly different peptides that are then presented by MHC-II molecules would be more likely to lead to new Naive T CD4 cell activation with slightly different TCRs from the clones that formed from the prior vaccine. These slightly different TCRs on Tfh may lead to slightly different B cell clones developing. The net effect being a higher level of boost.

Interesting theory. (Dr. Chatterjee)

78. If the 50mcg dose of the Moderna vaccine is not readily available, is there any disadvantage to administering the 100mcg dose as a booster?

The concern would be for potentially enhanced adverse reactions with the higher dose. (Dr. Chatterjee)

79. FYI-The 3ml syringes sent by McKesson/CDC with the Moderna vaccine kits don't accommodate 0.25ml dosing very well. We have purchased tuberculin syringes in anticipation of this dosing.

Now that boosters are recommended, Moderna orders approved after 10:15 AM Eastern time on 10/22 are shipping with double ancillary kits, which should provide enough smaller syringes to use for booster doses. (Dr. Fox)

80. Where is the new CDC booster guidance posted?

It has not been posted yet (check back on Monday) but it will be posted here: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html (Dr. Mbaeyi)

81. Since the mRNA vaccines are pretty similar, isn't 50 ug of Moderna still more than 30 ug of Pfizer? I thought that was one of the reasons for the higher Moderna Ab response (plus the 4 v. 3 week interval)

These are the hypotheses put forward. For proof, we would need comparator trials. (Dr. Chatterjee)

82. How do you monitor immunosuppressives individual post infection? How long do you delay treatment?

There are no hard guidelines on this eg steroids may be necessary re progressive pneumonia clinically and yes there are anecdotal data it is associated with increasing viral replication so it's a difficult issue clinically with no good guidelines; sorry to not be helpfully specific. (Dr. Corey)

83. Do we expect any kind of issue with supply once the vaccine for kids is approved soon coinciding with booster approvals now, or will this be supplied differently and not impact Pfizer supply for adults?

The pediatric vaccine (for ages 5-11 years) is a different product from the one used for ages 12 and older. There is adequate supply of the pediatric product to vaccinate all children in this age group, and there will be on impact on supply of the adult (12+) product. A pause on shipping the adult product for several days, to allow Pfizer to ship pediatric product out widely, has been announced but this is brief and should not affect providers' ability to have ample stock of adult product. (Dr. Fox)

84. If an immunocompromised patient qualifies for pre-exposure prophylaxis, how often should they receive the mAbs?

There are unfortunately no data yet to say are the current doses under EUA sufficient for immunocompromised patients; There is some comfort that the acute levels of antibody immediately post infusion are quite a bit higher than the levels seen with vaccination albeit vaccination is associated with many more epitopes and also T cell responses. So one has to use Pk data which does vary considerably by each manufacturer. (Dr. Corey)

85. Fascinating data Drs. Corey and Cohen - thank you! Do you think we have appropriate study efforts going on to develop valid biomarkers of immunologic correlates for appropriate immunity? Are we creating biomarker correlates in large scale population cohorts/special population pts to answer this question?

We are trying. (Dr. Cohen)

86. Aren't any antibody or drug prophylaxis approaches doomed to force viral evolution?

Maybe. (Dr. Cohen)

87. Can you share any specific data? Short term mild reactions vs moderate or severe? Long term?

mAbs directed against SARS-CoV-2 are very safe. If this is what you are asking? (Dr. Cohen)

88. Comment: Immune compromised patient known not to response well to vaccination (4th dose?!) No strong real-life data to support 3rd/booster dose. We have great data for vaccination (primary series) to control the pandemic. Still we hear a lot about 3rd and booster (every 6 month ??!) but many people not vaccinated at all 😥

I know of no evidence for a benefit of a 4th dose. (Dr. Cohen)

89. For immunocompromised individuals who receive JJ as their primary dose, isn't the instruction to give the Moderna 1/2 dose for these individuals? (This is contrast to an immunocompromised person who received Moderna as a primary series (who would receive the 100 microgram dose as their 3rd dose)?

Yes, that is correct. (Dr. Chatterjee)

90. How is the pharmacist administering the dose supposed to be determining whether a given patient in front of them is to be given the 3rd dose in a primary series or a booster? There is not a physician's prescription involved.

The person requesting the dose should self-identify as eligible for an additional dose (only for immunocompromised) or as eligible for a booster (one of the groups for whom boosters are now available)