

**CDC/IDSA COVID-19 Clinician Call:
Summer Update: Plus the Latest on COVID-19
Vaccination for Children Under 5
June 25, 2022
Q&A**

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- 1. Are we seeing increased hospitalizations with increased time from 2 vaccine doses + 1 booster or is it just waning antibody levels?**

I believe any increase in hospitalizations is more likely related to the emergence of new virus variants. (Dr. Chatterjee)

- 2. When will there be a recommendation as to repeat dosing of Evusheld now that it has been about 6 months since the first administration was given?**

It's a great question. We'll check with our FDA, ASPR, and NIH colleagues, as they're the leads on therapeutics issues. (Dr. Jackson)

- 3. When can we expect guidance around re-dosing for Evusheld?**

It's a great question. We'll check with our FDA, ASPR, and NIH colleagues, as they're the leads on therapeutics issues. (Dr. Jackson)

- 4. The Evusheld trials done in 2021 showed that .6% of those getting Evusheld had a serious cardiac event (all of them had previous cardiac concerns). Has there been any updated data since then?**

I'm not fully up to speed on the latest Evusheld data. I'd welcome input from other panelists or attendees and can follow up with colleagues at other agencies who lead work on therapeutics. (Dr. Jackson)

- 5. What is the current thinking about efficacy of Evusheld, etc., and how long treatment lasts?**

I'm not fully up to speed on the latest Evusheld data. I'd welcome input from other panelists or attendees and can follow up with colleagues at other agencies who lead work on therapeutics. (Dr. Jackson)

- 6. Will our government mandate that public schools upgrade their ventilation and support that. Our grassroots movement to petition our school board to support and apply for funding for that was met with significant hurdles. While our school allowed for units to be donated to individual teachers some schools were told outright they would not be allowed to bring the air filters in.**

Those types of mandate would likely have to come through legislation given funding considerations. The federal government has made hundreds of millions of dollars for ventilation improvements as well as other public health measures. CDC is working with other agencies to promote the importance of and provide relevant info on indoor air quality, including in schools. For example, <https://www.cdc.gov/coronavirus/2019-ncov/community/schools-childcare/interactive-ventilation-tool.html> (Dr. Jackson)

- 7. Still seeing severe influenza A although it is the end of June. Also severe post-influenza bacterial and Aspergillus pneumonia. Anyone else seeing this?**

You might be interested in the weekly influenza surveillance report.

<https://www.cdc.gov/flu/weekly/index.htm>

Flu levels have been elevated later in the season than usual, likely a product of pandemic behavior changes. As aside, my non-COVID job is in fungal diseases and we'd be glad to connect on Aspergillus pneumonia: fungaloutbreaks@cdc.gov (Dr. Jackson)

- 8. Prevention of transmission does not seem to be prevented by any of the vaccines. Is that still the case or has it never really been examined? It is felt that children may be a continuous reservoir, so it is of interest.**

We have known from the beginning that these vaccines have modest efficacy in preventing transmission. The best that they can do is to reduce the disease burden and prevent transmission in that way. (Dr. Chatterjee)

- 9. How do you address the lower vaccine effectiveness with parents when discussing risks and benefits for kids 6 mos to 5 yrs and trying to convince families to get their younger kids vaccinated?**

While there is lower effectiveness with the newer variants, there is still significant benefit is preventing severe disease, MISIC, hospitalization, ICU admission, etc. (Dr. Chatterjee)

- 10. Is there any difference in efficacy of the vaccine in infants if the injection is given in the thigh as opposed to the arm?**

We have no data on this. (Dr. Chatterjee)

- 11. How do you evaluate benefit risks in a declining rate of Covid cases? If it keeps declining, how that would affect the benefit/risk ration?**

It is difficult to do with the "moving target" that the pandemic is. Clinical trials determine benefit vs. risk over a specific period in time. (Dr. Chatterjee)

12. If there's any evidence showing that lower vaccine efficacy against Omicron variant in children? What's the vaccine efficacy of Moderna and Pfizer BNT among children under 5 year-old?

There is lower efficacy against Omicron, but the data are limited. VE for Moderna - 40-50% in <5 yo; Pfizer - 76% for 6-23 mo. and 82% for 2-4 yo. (Dr. Chatterjee)

13. Please define effectiveness. Is it prevention of any disease or prevention of symptomatic illness?

It was prevention of symptomatic illness. (Dr. Chatterjee)

14. Any difference in side effect between Moderna (1/4 adult dose) and Pfizer (1/10 adult dose)

The studies were not conducted with "head-to-head" comparison, so not possible to evaluate. (Dr. Chatterjee)

15. What is the average time from symptom onset to rapid test negativity? Does Paxlovid prolong this time period? Is it safe to stop self-quarantining in the home once rapid test is negative without infecting an in home spouse who is vaccinated and boosted?

Others can quote the data better than me, but people are often rapid test positive through days to 5-7. CDC recommends isolating after a positive test for 5 days followed by 5 days of masking (a part people sometimes forget). More info in this link about using a testing strategy:

<https://www.cdc.gov/coronavirus/2019-ncov/your-health/quarantine-isolation.html#iso> .

On rebound after Paxlovid, we can discuss live, but will point you to this health alert.

<https://emergency.cdc.gov/han/2022/han00467.asp>

If you experience COVID-19 rebound, you should follow CDC's isolation guidance. Isolate again and restart the recommended 5-day isolation period at the time of recurrence of symptoms or a new positive COVID-19 test result. You can end re-isolation after 5 days if you are fever-free for 24 hours without the use of fever-reducing medication and your symptoms are improving. You should also wear a mask for 10 days after rebound. (Dr. Jackson)

16. Many parents are expecting a third dose of Moderna will be made available and are preferring starting with a 2 dose of Moderna because they ARE paying attention to the nuances.

Good! (Dr. Chatterjee)

17. Is Moderna now authorized for 12years of age and older?

Yes (Dr. Chatterjee)

18. What is the rate of severe morbidity in this age group from the vaccine?

They differed a little bit in the different trials, but Grade 3 or 4 reactions were mostly zero to <1%. (Dr. Chatterjee)

19. I think the real question here is should we trying to "talk parents into" this vaccine with such a paucity of data. Previous Covid infection recommendation for vaccine based on what data?

While the data are limited, they are compelling in showing protection from severe disease. These authorizations give parents and guardians as well as those who provide care to children an opportunity to vaccinate them. (Dr. Chatterjee)

20. Is Pfizer going to provide updated clinical efficacy data to the FDA when they have more data points? Or will VE for the Pfizer vaccine in patients 6 mo through 4 years be assessed in the different platforms that are looking at this (VISION, PROTECT and others)?

CDC will monitor VE for post-authorization effectiveness for infection (ICATT, PROTECT) and hospitalization (VISION, Overcoming COVID). Timing of estimates will depend on incidence of COVID and uptake of the vaccine, but we will share publicly as soon as we have estimates. (Dr. Oliver)

21. Is there any data for those 11 y/o booster and vaccine efficacy compared with 12 y/o? Is there a difference in the Ve with the boosters with different doses?

VE is difficult to determine at different booster doses because of changes in the virus over time. The important thing to note is that booster doses restore waning antibody titers. (Dr. Chatterjee)

22. In a non-immunocompromised 2 year old child who develops COVID infection, how long would you wait before administering a primary COVID vaccination series? Thank you.

There is no minimal interval where you have to wait (once the immediate isolation period is over). However, we do have guidance that you can chose to wait 3 months after SARS-CoV-2 infection as that may result in an improved immune response. Guidance is in the Interim Clinical Considerations from CDC. <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#infection> . People who recently had SARS-CoV-2 infection may consider delaying a primary series dose or their first or second COVID-19 vaccine booster dose by 3 months from symptom onset or positive test (if infection was asymptomatic). Studies have shown that increased time between infection and vaccination may result in an improved immune response to vaccination. Also, a low risk of reinfection has been observed in the weeks to months following infection. (Dr. Oliver)

23. CAN THE BOOSTER in the 5 years and up switch to Moderna as the primary at this time IS PFIZER??

We do not yet have data on "mix-and-match" for this age group. (Dr. Chatterjee)

24. Do you have more data on Plaxovid and possibly Lagevrio rebound COVID?

We'll address live if time. In short, several studies have not suggested severe disease with rebound. Possibility of rebound should not prevent antiviral use. Viral Load Rebound in Placebo and Nirmatrelvir-Ritonavir Treated COVID-19 Patients is not Associated with Recurrence of Severe Disease or Mutations. 2022 Jun 21 [cited 2022 Jun 22]; Available from: <https://www.researchsquare.com>

Ranganath N, O'Horo JC, Challener DW, Tullidge-Scheitel SM, Pike ML, Michael O'Brien R, et al. Rebound Phenomenon after Nirmatrelvir/Ritonavir Treatment of Coronavirus Disease-2019 in High-Risk Persons. *Clinical Infectious Diseases*. 2022 Jun 14;ciac481.

Boucau J, Uddin R, Marino C, Regan J, Flynn JP, Choudhary MC, et al. Virologic characterization of symptom rebound following nirmatrelvir-ritonavir treatment for COVID-19 [Internet]. *Infectious Diseases (except HIV/AIDS)*; 2022 May [cited 2022 Jun 16]. Available from:

<http://medrxiv.org/lookup/doi/10.1101/2022.05.24.22275326>

<https://www.cdc.gov/mmwr/volumes/71/wr/mm7125e2.htm> (Dr. Jackson)

25. A 13-year-old had extreme fever and a few days of hives after 2nd Pfizer dose.

Last week got COVID. Two questions, when get the booster dose, it's been many months since 2nd dose? should she get Moderna for the booster? She will soon be traveling to Europe for the summer.

Since the reactions with mRNA vaccines seem to mostly be related to the lipid delivery particles and these are different in the two vaccines, I think a Moderna booster should be ok. (Dr. Chatterjee)

26. Some practitioners using H1 and H2 blocker a prophylaxis to avoid adverse events: what are the recommendations? What are the impact on immune responses?

I know of no recommendation to use these routinely. (Dr. Chatterjee)

27. Building trust is certainly critical. However, we just don't have enough long-term data to be able to address (long term) concerns and side effects that parents bring up, such as mRNA affecting DNA

The mRNA vaccines never enter the nucleus of the cell, so it can't affect the DNA. We have 1.5 years of experience with over 600 million mRNA COVID vaccines with a closely monitored safety profile. (Dr. Oliver)

28. For ADULTS - is there specific guidance on how long to wait after infection to receive covid vaccine? some pharmacies are still making pt wait at least 90 days after infection (pt did not receive monoclonal ab). Thanks

There is no minimal interval where you have to wait (once the immediate isolation period is over). However, we do have guidance that you can choose to wait 3 months after SARS-CoV-2 infection as that may result in an improved immune response. Guidance is in the Interim Clinical Considerations from CDC. <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#infection>

people who recently had SARS-CoV-2 infection may consider delaying a primary series dose or their first or second COVID-19 vaccine booster dose by 3 months from symptom onset or positive test (if infection was asymptomatic). Studies have shown that increased time between infection and vaccination may result in an improved immune response to vaccination. Also, a low risk of reinfection has been observed in the weeks to months following infection. (Dr. Oliver)

29. What would CDC/FDA/AAP consider moderate to severe?

Information on immunocompromising conditions are listed in the interim clinical considerations: <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#infection>

Moderate and severe immunocompromising conditions and treatments include but are not limited to:

Active treatment for solid tumor and hematologic malignancies

Receipt of solid-organ transplant and taking immunosuppressive therapy

Receipt of chimeric antigen receptor (CAR)-T-cell therapy or hematopoietic cell transplant (HCT) (within 2 years of transplantation or taking immunosuppressive therapy)

Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)

Advanced or untreated HIV infection (people with HIV and CD4 cell counts less than 200/mm³, history of an AIDS-defining illness without immune reconstitution, or clinical manifestations of symptomatic HIV)

Active treatment with high-dose corticosteroids or other immunosuppressive medication (Dr. Oliver)

30. We need to be better communicators to our legislators because the voices of political leaders can drown out the voices of scientists and physicians.

The AAP continues to advocate federal and at the state level through our chapters about the importance of creating a culture of vaccination. One of the best ways that policymakers at the state level can support our effort to provide COVID-19 vaccines to children is to help us create a culture of vaccination. Combatting misinformation about the COVID-19 vaccine and childhood vaccines generally is one of our key challenges right now, and just this week the AAP convened a vaccine misinformation summit to educate our members in effectively countering the onslaught of misinformation that parents, policymakers, and the public at large are receiving. Also critical in the effort to create a culture of vaccination is to reduce the financial barriers of entry for pediatricians and other physicians to fully participate in childhood vaccination program. (Dr. Costello)

31. What if after 2 doses of Pfizer in a 2 year old the child is infected with covid-19?- does this child still need the third dose?

There are no changes to the overall vaccine schedule based on prior infection. In addition, there is no minimal interval where you have to wait (once the immediate isolation period is over). However, we do have guidance that you can chose to wait 3 months after SARS-CoV-2 infection as that may result in an improved immune response. Guidance is in the Interim Clinical Considerations from CDC. <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#infection>

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32. Pediatric offices are refusing to order COVID vaccines in our area because they don't want pushback from families and that they have lost money with offering COVID vaccine to older kids.... how do we get over these hurdles?

Improving access will continue to be essential to ensure equitable access to the vaccine. Every office evaluates what is feasible for their practice. The AAP has worked to help pediatricians get their practices ready to offer vaccine. Improvement in payment models can help too. • With advocacy on the part of the AAP and recognizing the significant work pediatricians and other clinicians are doing counseling families both on COVID-19 vaccine and all routine childhood immunizations, in December 2021, CMS announced that counseling for childhood vaccination, when done not in the context of vaccine administration, is a service that is part of the EPSDT benefit and covered by Medicaid. For COVID-19 vaccine counseling, this is being fully federally financed. (Dr. Costello)

33. SO can we say data supports that VACCINATIONS PREVENT MISC/ and PASC, / and Post VIRAL Diabetes Mellitus? DO vaccinated people have "less" viral load to spread when they do get symptoms and thus benefit community by not spreading it as much???

Data so far suggest that vaccination reduces the risk of Long COVID/Post-COVID Conditions and certainly for MISC. The exact amount it reduces the risk of Long COVID varies by study and is not yet entirely clear.

<https://www.cdc.gov/coronavirus/2019-ncov/long-term-effects/index.html> (Dr. Jackson)

34. What do you experts think of this? I believe our current surge could be significantly improved with a campaign for the public to understand WHY masks are important, including the evidence. They need to hear it often. The focus has been almost entirely on vaccines, and we know both are necessary to control/reverse this pandemic. This week in Los Angeles two patients reported being bullied to remove their mask and got covid along with at least 100 others at a Florida conference of 550 attendees, four wearing masks.

I appreciate the feedback. I fully agree we need to find ways to make people feel comfortable making choices to wear masks in any setting. (Dr. Jackson)

35. Dr Costello -I had suggested creating a webpage on the AAP site to highlight the work of the PICK TEAMS state chapters who did tremendous work to promote vaccines for kids. Will this be possible?

Thank you for the question/comment, I will share this with our AAP communication/IT teams regarding possibility of such. (Dr. Costello)

36. How long is recommended to wait between primary infection and first vaccine dose in patients under 5 y/o?

There is no minimal interval where you have to wait (once the immediate isolation period is over). However, we do have guidance that you can choose to wait 3 months after SARS-CoV-2 infection as that may result in an improved immune response. Guidance is in the Interim Clinical Considerations from CDC. <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#infection>

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37. Hello, I know off topic, so I apologize. Is there a timeline for Novavax data to be reviewed and publicly discussed in ACIP forum? However, use or availability will be in response to ACIP/ CDC endorsing it, correct?

It was discussed at VRBPAC, and unanimously endorsed. Their deliberations are online (live or recorded) if you want to watch the meeting. Hope that is helpful.

38. A non-vaccine questions Where is it written there is a minimum age requirement to treat with oral antivirals or monoclonal antibodies in a patient with a single risk factor, such as HT, overweight, DM, for severe disease? Our ER pharmacist is citing 65 yo age threshold. I think we should be treating all adults with a risk factor regardless of age. In reviewing the CDC site I found no mention of age requirement.

it is age 12 and older and 40 kg I believe but on the EUA form for healthcare workers it has the exact requirements "The U.S. Food and Drug Administration has issued an EUA for the emergency use of the unapproved PAXLOVID which includes nirmatrelvir, a SARS-CoV-2 main protease (Mpro: also referred to as 3CLpro or nsp5 protease) inhibitor, and ritonavir, an HIV-1 protease inhibitor and CYP3A inhibitor, for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death.

LIMITATIONS OF AUTHORIZED USE

- PAXLOVID is not authorized for initiation of treatment in patients requiring hospitalization due to severe or critical COVID-19.
- PAXLOVID is not authorized for pre-exposure or post-exposure prophylaxis ..."

39. Any recommendations for talking points for families who say what about prior policy of low risk for kids?

The AAP has numerous professional resources to assist with having conversations with families, including talking points: <https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/covid-19-vaccine-for-children/>

Sharing any personal stories of caring for children who had severe disease or complication from COVID-19 can help with the conversation as well. Here is some language to help in bridging that conversation:

It's important for children to receive the protection this vaccine will give. The vaccine has reduced hospitalizations of those infected with COVID from all other age groups and we are eager to see the same protection offered to our youngest children. More than 13.5 million children have tested positive for COVID-19 since the onset of the pandemic. Among children younger than 5, there have been more than 30,000 infections and more than 500 deaths.