

CDC/IDSA COVID-19 Clinician Call:

The Latest on COVID-10 Vaccination on Children Ages 5-11

*Hosted in partnership with the American Academy of Pediatrics
& the Pediatric Infectious Diseases Society*

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Q&A

This is the Q&A transcript from the Zoom webinar. The views and opinions expressed here are those of the presenters and do not necessarily reflect the official policy or position of the CDC or IDSA. Involvement of CDC and IDSA should not be viewed as endorsement of any entity or individual involved.

- 1. Given the lower dose of mRNA and the data emerging regarding differences in the durability of protection from Moderna vs. Pfizer, is there concern for the durability of the protection elicited by the lower dose of the Pfizer/BioNTech vaccine in 5- to 11-year-olds?**

We simply don't yet know the duration of protection or whether a booster will be needed. This is being evaluated in ongoing clinical trials, and we will just need to see the results. (Marks, Peter)

- 2. I'd like to understand better the vaccine content for 5-11 yo & how this is different from the 12+ vaccine, inc. buffer, lipid-particle, glycerol, excipients etc.**

A full list of ingredients included in each FDA approved or authorized vaccine can be found here: <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#Appendix-C> (Kate Woodworth)

- 3. Do these 5-11 Pfizer vaccines contain different ingredients compared to other age group vaccines 12-15 and >16 yrs? There has been some concern circulating among parents on social media - that pediatric 5-11 vaccines contain "different ingredients". How do we counsel them about the different buffer/inactive ingredients in different formulations that may not matter safety-wise?**

The only difference is that the prior formulation for adults used phosphate buffered saline as the buffer and the new pediatric and adult formulation uses tromethamine (tris), which is a better buffering agent that allows the vaccine to be stored in the refrigerator for 10 weeks instead of 2. Tris buffered products have been used extensively in children and adults, and FDA has no concerns with this change. (Marks, Peter)

- 4. What is the change in formulation in 5-11 yr vaccine? Is it the addition of tromethamine? Patient mother extremely upset by misinformation. What response to her would be helpful?**

This change is in an inert ingredient that just allows the vaccine to be stored longer in the fridge. A number of other biologic products given to children contain this buffer. FDA would not have allowed this change if we had any concerns about the safety or efficacy of the vaccines. (Marks, Peter)

- 5. I understand that a different buffer solution has been used in the children's product, for improved stability and to allow longer refrigeration compared to the adult dose. Are there any theoretical concerns about this being a slightly different product? Has the new formulation been studied for safety?**

There are no concerns that this inert buffer changes the safety or effectiveness of the product. There both other vaccines and other biologic products that are formulated using this buffer, which simply represents the use of a more modern effective inert buffering ingredient. (Marks, Peter)

- 6. TROMETHAMINE: instead of the Salt/potassium ingredient. How do we tell the vaccine hesitant families about the change of the ingredients and whether this different ingredient is "safe"....it's all about convincing them it's safe.. as we are questioned on EVERY single issue?**

Tromethamine is a very commonly used buffering agent in medical products, including other vaccines used in children. It is inert and does not affect the safety or effectiveness of the mRNA vaccine. The reason for the change was to improve the stability of the vaccine for storage - this buffer works better for this than the original phosphate buffered saline one. (Marks, Peter)

- 7. <https://www.bmj.com/content/375/bmj.n2635> Covid-19: Researcher blows the whistle on data integrity issues in Pfizer's vaccine trial - Should this prove more pervasive, what then?**

FDA has investigated this complaint thoroughly. In addition, we performed bioethics research monitoring at a number of sites. FDA has no concerns whatsoever about the integrity of the data underlying the COVID-19 vaccine approvals (or any others for that matter). Quite unfortunately, BMJ did not check with the agency prior to publishing. (Marks, Peter)

- 8. Which of the data presented on # of MIS-C is up to date and correct? Dr Oliver gave 2,316 MIS-C while Dr Shane showed CDC site stating there had been 5,526 cases of MIS-C.?**

There have been 5,520 children diagnosed with MIS-C for children of all ages. 2,316 cases of MIS-C diagnosed specifically in children 5-11 years of age. (Those 2316 are a subset of the >5000 children reported to CDC) <https://covid.cdc.gov/covid-data-tracker/#mis-national-surveillance> (Sara Oliver)

9. I have also seen 146 deaths listed in 5-11 years old from FDA. Explain is it 94 or 146?

Different surveillance platforms may use different definitions and methodology. The 94 deaths that Dr. Oliver presented are those that are reported to the National Center for Health Statistics and included children who had COVID-19 reported on their death certificate. This was used to be able to compare to the 2019 top causes of death, which also comes from this data source. More information about NCHS mortality reporting and COVID-19 can be found here: <https://www.cdc.gov/vaccines/covid-19/hcp/pediatrician.html> (Kate Woodworth)

10. Would you recommend to give covid vaccine to a child who already got sick with covid?

CDC recommends COVID-19 vaccine to all persons ages 5 years and older, regardless of a history of SARS-CoV-2 infection. (Kate Woodworth)

11. For children who have had COVID recently- would you recommend waiting 90 days post infection to get the vaccine?

The recommendation to wait 90 days is specific to children with a history of MIS-C, who should wait 90 days after diagnosis to receive a COVID-19 vaccine. For all other children, there is no waiting period, other than to make sure they have completed their recommended isolation period!

12. What is the recommendation for vaccinating children who had MIS-C?

The current recommendation is to offer COVID-19 vaccination 90 days from the date of recovery from MIS-C, provided all symptoms have resolved. Locally we have seen resolution before 90 days and have engaged our cardiologists and pediatric/adult infectious disease clinicians to make a joint recommendation based on the individual circumstances of the patient. Thank you for the question.

13. Is there a recommendation for a booster dose 6 months after third dose for immunocompromised who completed a 3 doses series of Moderna or Pfizer? Any additional doses for immunocompromised who received J and J as a first dose and then got the second dose of a booster will they qualify for a third dose?

Updated clinical considerations for boosters are posted here: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2F covid-19%2Finfo-by-product%2Fclinical-considerations.html#considerations-covid19-vax-immunocopromised - which include guidance for boosters after completion of a primary series (including the additional dose) for immunocompromised individuals. (Sara Oliver)

14. What is a hold up with the Moderna vaccine in children? (if you can comment on this)

Moderna has publicly noted that FDA is taking additional time to assess the myocarditis risk with this vaccine, as countries in Europe and elsewhere have had concerns that there is an elevated risk relative to the Pfizer vaccine. (Marks, Peter)

15. Can you speak to the number of children studied in trial and why this number was chosen and not a larger number? Initially study design had less study participants and asked to increase number of participants.

The number of over 3000 children 5 to 11 studied represents a robust dataset, similar to the number that we like to see for safety datasets of other vaccines. Increasing the size of the trial further by just a few thousand would not likely have been much more informative regarding myocarditis. That said we do have excellent overlapping post-deployment safety monitoring systems in place. (Marks, Peter)

16. How would you make the case to parents that the need this vaccine is comparable to the other vaccines we give them?

We routinely give vaccines in the US, such as the influenza vaccine to prevent illness in fewer children than we are preventing with the COVID-19 vaccines. A bad season of influenza can cause 100-150 pediatric deaths. We know that there have been this many or more per year with COVID-19 in the pediatric age range. No parent should lose a child to a vaccine-preventable infectious disease. (Marks, Peter)

17. Children and young adults all seem to reach the same neutralizing antibody titers of 1100-1200, approximately 3 times the levels reached in adults. The 5-11 year olds reached the same titers as the 12-15 and 16-25 year olds with 1/3 the dose and with fewer adverse reactions. Does this suggest that all adolescents should be given the lower dose?

This is an issue that may warrant further research - for now, we would continue to use the 30 mcg dose in those age 12 and up. (Marks, Peter)

18. How do we explain to parents regarding why should a bigger/ heavier 11 yo child get the 5-11 one-third dose and NOT the full dose that is given to 12 yo and above?

Children age 5 to 11 of a variety of weights, including overweight children received the 10 microgram dose in the clinical trial, and the efficacy appeared similar across the population. (Marks, Peter)

19. The volume after dilution in the orange Pfizer vials would allow a total of 12 doses, rather than 10. Is this permissible?

You should use as many full doses as you can extract from the vial. Just don't combine amounts from different vials to make a full dose. (Marks, Peter)

- 20. In NC we have been advised to NOT use 11th doses from the 5-11yo vial since it is against the FDA EUA. It bothers us *deeply* to throw away vaccine- if 11th doses are permissible, can this be issued as a formal opinion ASAP?**

Please have whomever is saying this contact FDA - use of full doses (11th or even 12th) are absolutely permissible. They can email industry.biologics@fda.hhs.gov (Marks, Peter)

- 21. From the boots on the ground, why are 5cc syringes being provided for 1.2ml of diluent? This does not allow accurate diluent measurements.**

Thank you. Yes we are aware of this, and the need to eyeball the correct amount of 1.3ml of diluent. It requires estimation between 1.2 and 1.4ml. We are working this issue for future kits. (Janell Routh)

- 22. Do we have a guideline regarding when and if to continue the vaccine program for a small group of children with severe side effects such as myocarditis?**

Until additional safety data are available, experts advise that people who develop myocarditis or pericarditis after a dose of an mRNA COVID-19 vaccine not receive a subsequent dose of any COVID-19 vaccine. More information about myocarditis can be found here: <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#considerations-pfizer-biontech-moderna> (Kate Woodworth)

- 23. Some 16 year olds who may be higher risk due to underlying conditions so other than their age would be eligible for booster?**

At this time, boosters are not recommended for anyone less than 18 years of age. CDC and ACIP will continue to evaluate data and update interim recommendations as needed. More information about boosters can be found here: <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#considerations-covid19-vax-booster> (Kate Woodworth)

- 24. One of the most common questions our vaccine clinic has heard is whether there is a link to covid pediatric vaccine and growth/fertility issues in the future. Is there any known potential safety risk for these issues?**

While enough time hasn't passed to properly assess fertility/infertility, there is currently no evidence that ANY vaccines, including COVID-19 vaccines, cause female or male fertility problems. There is currently no evidence that vaccine ingredients or antibodies developed following COVID-19 vaccination would cause any problems with becoming pregnant in the future. Similarly, there is no evidence that the COVID-19 vaccine affects puberty. (Kate Woodworth)

25. To our CDC colleagues: Would you be able to let us know when the CDC standing orders for Pfizer COVID-19 vaccine will be available? We in the local health jurisdictions are grateful for these because they ensure consistency in practice across jurisdictions and nationally (including at local pharmacies), without them, multiple organizations end up writing addenda to the existing standing orders. Additionally, the frontline vaccinators use the pages following the CDC Pre-vaccination checklist for COVID-19 vaccination (which is a great summary of clinical guidance). Would you have a timeline from when the update of this also would be available? Both of these help with ensuring consistent clinical quality on the ground level across the nation. Much appreciation to all of you.

They are live! <https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html>
(Janell Routh)

26. Do we give the kids a CDC vaccine card?

Yes, all children will get a CDC vaccine card after their vaccination. (Janell Routh)

27. The v-safe is not allowing to enter kids born after 2005. I was not able to add my child to v-safe.

V-safe has been updated to include those 5-11. We will take this feedback back to our v-safe colleagues if there are issues. (Sara Oliver)

28. Do we know so far the percentage of long covid in breakthrough infections? (adults who has completed the vaccination series)?

The rate of long COVID in breakthrough infections is about half (6-15% vs 16-30%) that of long COVID in the unvaccinated who get infected. (Marks, Peter)