

# CDC/IDSA COVID-19 Clinician Call

## COVID-19 in Pregnant Individuals; Plus Vaccine Q&A - Hosted in partnership with ACOG

April 13, 2021

### Q&A

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**1. I am going to do IVF; how long do I have to wait after receiving the vaccine?**

There is no waiting period after vaccination to begin IVF. CDC recommends that those who are trying to become pregnant do not need to avoid pregnancy after COVID-19 vaccination. There is no evidence that any of the COVID-19 vaccines affect future fertility.

**2. Vaccine question: Is there a "compassionate use program" or "expanded access" or anything of that sort that would allow a candidate less than 16 years of age to receive the currently available adult vaccine (that is authorized for adults)? For e.g., if the child is in their early teens and may have some immunodeficiencies or immunological issues, and the child/parents wish for the child to receive the currently available version of the Pfizer or Moderna vaccine - based on the current known safety/efficacy info in adults (and as we await the results of the trials and EUA) in order to receive protection against COVID-19 - and are willing to accept any risks associated with it and take that chance. Thanks a lot!**

There is currently no program to authorize that children less than 16 years of age receive a COVID-19 vaccine. However, pediatric and adolescent vaccines are on the horizon -- Pfizer just submitted their EUA application to FDA yesterday for vaccination in adolescents aged 12-15 years, and pediatric studies are ongoing. (Sarah Mbaeyi)

**3. I had a family with COVID-19 this week. The father had been fully vaccinated with Pfizer in January. The mother had one dose of Pfizer on 23 March. The daughter had not been vaccinated. On Friday, the daughter became symptomatic. Today all three are positive for COVID-19. The daughter has moderate disease, the father moderate to severe. The mother is asymptomatic. The PCR data shows that the father (fully vaccinated) has extremely high viral loads. How common is this situation?**

There is accumulating real-world evidence on the effectiveness of Pfizer vaccine, with studies in the UK, US, and Israel showing high effectiveness of after 2 doses (mid-80 to upper 90% vaccine effectiveness depending on population, as summarized in this Science Brief from CDC:

<https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html>).

However, no vaccines are 100% effective, and thus unfortunately there will still be fully vaccinated as well as partially vaccinated people who become infected. (Sarah Mbaeyi)

**4. Are CDC fully vaccinated guidelines applicable only for 90 days post second shot? Or up to 6 months? Or longer?**

There is currently no time limit on how long after vaccination. This will be reassessed as more data on duration of protection become available. Of note, this is a change from the first version of the guidance around quarantine which stated 90 days after completion of vaccination. (Sarah Mbaeyi)

**5. I am curious about the CDC decision to drop the 90-day post-complete vaccination qualification for “fully vaccinated” individuals.**

There are a few reasons for this change: 1) We know that vaccines are likely protective longer than 3 months (and Pfizer and Moderna have presented data now through 6 months). 2) The public was misinterpreting this to think that the vaccines only last 3 months, so there was a sentiment "why bother getting vaccinated". 3) When the CDC guidance was expanded from just being for quarantine to a broad set of activities, it no longer made sense to have such a threshold (especially such a narrow threshold). For example, it's very difficult to say that a vaccinated grandma can hug her grandkids within 90 days of her second dose but not afterwards. (Sarah Mbaeyi)

**6. What will likely be the timing/recommendation for re-vaccination or booster?**

This will depend on a few factors, including duration of protection and any need for adapted vaccines due to variants that may emerge that the current vaccines do not protect well against. (Sarah Mbaeyi)

**7. Are you seeing chronic fatigue in pregnant women post COVID-19?**

There is not a lot of data regarding this. The PRIORITY study showed that symptoms persisted for  $\geq 8$  weeks in 25% of participants. Our epi team on the CDC response is actively monitoring it. (Titilope Oduyebo)

**8. For individuals less than 50 years and had received one dose of AstraZeneca. Should they get Pfizer as second dose (Germany, UK, France: are advising 2nd dose to mRNA)? Pfizer is available in our country (Kuwait).**

CDC does not have any recommendations around this, as AstraZeneca is not a currently authorized vaccine in the United States. We would recommend that individuals follow the guidelines in their country. (Sarah Mbaeyi)

**9. Any newer data regarding the more highly transmissible and possibly more aggressive variants in pregnancy?**

Not at this time; this is an area of great interest and we are actively monitoring this. (Titilope Oduyebo)

**10. When approximately is the Pfizer vaccine expected to be available for age 12-15 after EUA? Will it be about a month till we receive the EUA and have it actually available to administer? Or some other duration?**

This will depend on FDA's review process, I cannot provide a more specific timeline but it's important for providers to start preparing to vaccinate now so that we are ready on time, including for pediatricians to enroll to become a COVID-19 vaccine provider. (Sarah Mbaeyi)

**11. Vaccine question – Is there a statement from CDC about the use of fetal cell lines in the testing, development, and production of vaccines and also specific to COVID-19 vaccines? I heard the former was available and the latter was being developed in early March but can't find anything online. It would be useful to address concerns and vaccine hesitancy, especially for J&J vaccine**

I will need to check and can get back to the organizers. I also was unable to find a statement on CDC's website. (Sarah Mbaeyi)

**12. When will vaccines be available for children? Timeline? Will they be vaccinated before the school year?**

If FDA authorizes the vaccines, we can expect to start vaccinating adolescents before the next school year. Pfizer submitted their EUA application yesterday to FDA for adolescents aged 12-15 years. Clinical trials are still ongoing for younger children. (Sarah Mbaeyi)

**13. Why do you refer to pregnant “people/persons” rather than “women”?**

CDC's COVID-19 Response strives to use terms that are inclusive of all gender identities if the content does not refer to a specific sex. Therefore, in our COVID-19 messages and recommendations for healthcare providers and the public, we use the term 'pregnant people' to communicate and help providers communicate to all pregnant people including those who do not identify as female. When referring to surveillance data and findings from those data, we use the term 'pregnant women' because data on pregnancy are based on self-reported female sex. (Titilope Oduyebo)

**14. Is there any data on outcomes in woman who have completed their COVID vaccinations shortly before getting pregnant?**

Hello, not at this time. The v-safe pregnancy registry is also capturing pregnancies that occur within 30days of vaccination and most of these pregnancies are ongoing. As soon as we have information regarding this, we are committed in releasing it in a timely manner. (Titilope Oduyebo)

**15. Can you comment on any known safety data from the Ebola vaccine campaign (adenovirus platform) regarding pregnant women?**

The adenovirus vector platform used in the Janssen COVID-19 vaccine has also been used for other Janssen vaccine development programs that have included pregnant people vaccinated during any trimester, including in a large-scale Ebola vaccination trial. No adverse pregnancy-related outcomes—including infant outcomes—were determined to be related to the vaccine in these trials. (Titilope Oduyebo)

**16. Trap should be given 2 weeks after the COVID shot or COVID series of shots?**

Yes, CDC's current recommendation is to not routinely administer COVID-19 vaccines within 14 days of other vaccines. Our guidance includes some potential exceptions: However, COVID-19 and other vaccines may be administered within a shorter period in situations where the benefits of vaccination are deemed to outweigh the potential unknown risks of vaccine coadministration (e.g., tetanus-toxoid-containing vaccination as part of wound management, rabies vaccination for post-exposure prophylaxis, measles or hepatitis A vaccination during an outbreak) or to avoid barriers to or delays in to COVID-19 vaccination (e.g., in long-term care facility residents or healthcare personnel who received influenza or other vaccinations before or upon admission or onboarding). (Sarah Mbaeyi)

**17. My co-worker has a family member who received AstraZeneca vaccine x1 2-3 weeks ago in Ghana but is now in the US where AstraZeneca is not available. Any recommendation for completion of vaccination in this patient while remaining in US?**

CDC is working on guidance for this, which should be published soon. However, in the interim when we receive this question, we advise that a person who has been partially vaccinated with AZ (or other non-

US vaccine) can be offered to restart the series with one of the vaccines authorized in the US. (Sarah Mbaeyi)

**18. Any thoughts regarding causes or proportion of breakthrough infections in fully vaccinated? And how much to be concerned about variants in the context of breakthrough infections?**

CDC is currently analyzing breakthrough cases that have been reported, and this will be shared once available. I don't have any specific data to share at this time since it is still being analyzed, but just want to again put a plug in to clinicians to report breakthrough cases to their health department. The health departments are coordinating with CDC so that these cases can be accurately characterized. (Sarah Mbaeyi)

**19. Maybe I missed it but what proportion of maternal antibodies are passed to the baby? Is it 1:1, higher, lower?**

The study by Prabhu on April 6 showed 1:1 or higher depending on the time since the 2nd dose. (Linda Eckert)

**20. Dr. Mbaeyi, could you please comment on what was thought to be the cause of the symptoms that caused the mass vaccination site in Colorado to pause? Could you also please comment on what was thought to be the cause of death in the female in Kansas?**

I am including CDC's statement on these events in CO (and elsewhere) below. I do not have any information to share on the death in KS. CDC is aware of several incidents of vaccine recipients experiencing dizziness, light headedness, feeling faint, rapid breathing, and sweating (vasovagal or anxiety-related) symptoms following COVID-19 vaccines in Iowa, Colorado, Georgia, and North Carolina. CDC is working closely with each of the state and local health departments to evaluate these incidents. CDC has performed vaccine lot analyses and has not found any reason for concern. Currently CDC and FDA are not recommending health departments stop administering any lots of COVID-19 vaccine. COVID-19 vaccines are safe and effective. Many people don't have any side effects after COVID-19 vaccines, but some people will have pain or swelling at the injection site or fever, chills, or a headache. These typically don't last long and are signs that your body is building protection. (Sarah Mbaeyi)

**21. Are there any "bad" things from the Covid vaccine that can be transferred to the fetus? If no research yet, is there any areas of concern not being fully validated yet but under priority studies? Thank you.**

The components of the vaccine degrade very quickly. And pregnant individuals being excluded from Phase 3 studies is not new, and not based on any particular concerns with Covid vaccines but has been a longstanding practice. (Linda Eckert)

**22. Have any deaths been reported in breakthrough infections after fully vaccinated?**

CDC is analyzing the information on breakthrough infections in those that are fully vaccinated and will share the information when available. Just wanted to remind people that if you have patients with a breakthrough infection, please make sure to report these cases to your health department. They will coordinate with CDC to review these cases. (Sarah Mbaeyi)

**23. How to answer a pregnant lady question regarding safety for their babies? The answer no data is not convincing any.**

We have animal data that is reassuring, we have initial CDC Vsafe data that is reassuring, and we have data that antibody transfers well. We also have data that Covid in pregnancy is of increased risk for

poor pregnancy and maternal health outcomes. So, I think we have a lot of data actually. Just not Phase 3 trial data. (Linda Eckert)

- 24. Does a person one week out from their vaccine who is exposed to someone who had a first dose then one week later Ag tested positive with COVID need to be quarantined the person's exposure occurred 6 days before the positive Ag COVID test PCR pending currently. Also, the person who Ag tested positive one week after mRNA vaccine had extended exposure to children but again 6 days prior to the pushover Ag test and none sense.**

Anyone who is not fully vaccinated (at least 2 weeks out from their 2nd dose in a 2-dose series, or 2 weeks out from a single-dose vaccine [J&J]) need to quarantine. Thus, the patient you mention does need to quarantine because the person is only 1 week out from their 1st dose. (Sarah Mbaeyi)

- 25. Is pregnancy a 1b indication for covid 19 vaccine?**

That depends on your state prioritization. (Linda Eckert)

- 26. Can you mix the Pfizer and Moderna vaccines if that's what's available? Any advantage to doing so with respect to antibody response?**

The mRNA vaccines are not interchangeable, and people who start the series with one vaccine should complete the series with the same vaccine. However, CDC states that in exceptional situations where the person cannot complete the series with the same product, they may be given another mRNA product. In terms of advantages, we currently do not have any data for a mixed mRNA series. There is a study ongoing in the UK to look at a mixed mRNA and viral vector vaccine. (Sarah Mbaeyi)

- 27. Do CDC or ACOG have any educational material, ad campaigns, or counterprogramming to directly address the misinformation circulating widely on social media incorrectly linking the vaccine to infertility risks? Perhaps Dr. Eckert's great slide on "Fertility Concerns" could be made into an ad and promoted in social and broadcast media? Anecdotally, I'm hearing of many women including female HCP who are vaccine hesitant due to this misinformation. Thank you for the excellent presentations!**

Yes, please refer to our one stop shop toolkit. <https://www.cdc.gov/coronavirus/2019-ncov/communication/toolkits/pregnant-people-and-new-parents.html>. (Titilope Oduyebo)

- 28. For pregnant women with Covid-19, any recommendations on use of monoclonal antibodies, Remdesivir, and/or dexamethasone?**

NIH has guidelines regarding your question: <https://www.covid19treatmentguidelines.nih.gov/special-populations/> (Titilope Oduyebo)

- 29. Any considerations regarding vaccination after receiving a blood transfusion**

CDC does not have any recommendations to defer vaccination after receiving a blood transfusion. (Sarah Mbaeyi)

- 30. As a pediatrician, I have lactating mothers wondering about the duration of the IgA from the vaccine, in order to know how long to continue breastfeeding. And also, if there is utility to providing pumped milk to her non-breastfed children such as toddlers, and young children.**

This is not known yet. (Linda Eckert)

- 31. Do the V-safe and manufacturer registries combine data from pregnant females?**

No, we don't; however, it is possible that some women might participate in both registries.

**32. Pregnant women in the country where mRNA vaccine is not available, what will be the suitable vaccine?**

Adenovirus vector vaccines have been used for Ebola in pregnant women- I am not able to speak to specific vaccines. (Linda Eckert)

**33. @DrEckert - Thank you. Due to the complete lack of safety data on COVID-19 vaccination of the pregnant mother on infant and child development, would you recommend for the pregnant person (low risk, isolating/working from home/spouse vaccinated) to wait until after birth to receive the vaccine, so that IgA is transferred through breastmilk instead of getting vaccinated 2nd/3rd trimester?**

I talk with my patient about that decision. What we are seeing so far is that the IgG antibody concentration in the cord blood is robust, and we do not have clinical data to know how the IgA versus IgG protects the infant. (Linda Eckert)

**34. Vaccine Q: Is there any detailed data about predisposing factors in the 30 people who developed blood clots after AstraZeneca? Thank you!**

Based on their review of the cases, both the European Medicines Agency and the United Kingdom regulatory agency have stated that no specific risk factors have been confirmed. (Sarah Mbaeyi)

**35. Is it better to get the vaccine earlier in pregnancy? What about 1<sup>st</sup> trimester?**

ACOG does not advise waiting for a certain gestational age, but to consider receiving the vaccine as soon as feasible. (Linda Eckert)

**36. What are your thoughts on the likelihood of the vaccines causing birth defects?**

Birth defects happen at a background rate of 3-5% per pregnancy, independent of any vaccine use. So far, we have no indications that these vaccines are causing any problems. We have reassuring animal data (DART data), and we will be continuing to monitor outcomes. (Linda Eckert)

**37. There is no data on COVID-19 vaccination during pregnancy on infant/child development later (not birth defects). In this light, is it safer for the infant/child that the pregnant person to wait until after giving birth to receive the vaccine instead of getting vaccinated during pregnancy?**

There is a risk of acquiring COVID-19 during pregnancy that could negatively impact the fetus (preterm labor for instance, death, or ICU care for the pregnant individual) so it is a risk/benefit discussion that I have with my patient. I cannot tell my patients what to choose. It depends on many factors that I mentioned in my talk. (Linda Eckert)