

CDC/IDSA Clinician Call
COVID-19 New Booster Vaccines and Variants Update:
Plus Updates on RSV, Influenza and Pneumococcal Immunizations
September 14, 2023
Q&A

This is the Q&A transcript from the Zoom webinar held on September 14, 2023. 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. What is the interval between the last dose of Bivalent COVID vax and the new Monovalent COVID vax?

Dr. del Rio: I tell people at least 3 months but remember this is not a "booster".

2. I practiced Pediatrics for almost 46 years and retired 2 years ago—Will I need the RSV vaccine?

Dr. Britton: The RSV vaccines are recommended for adults ages 60 years and older based on shared clinical decision-making. This means if you are 60 or older we recommend discussing with your healthcare provider whether you would benefit from vaccination. In particular, adults over 60 who have other underlying medical conditions (such as COPD, CHF, and immune compromise) that increase the risk of severe RSV disease are likely to benefit most from vaccination.

3. CDC page for Covid vaccine has some discrepancies in regards to covid vaccination. is it intentional and CDC did not embrace all recommendations or just the team did not have time to update.

Dr. Link-Gelles: Yes, please keep an eye on the CDC website. Updates will be made to various pages over the next couple of days with the new recommendations.

4. Still recommending waiting 3 months after recovery from COVID to get the vaccine?

Dr. Link-Gelles: People who recently had SARS-CoV-2 infection may consider delaying a COVID-19 vaccine dose by 3 months from symptom onset or positive test (if infection was asymptomatic). Studies have shown that increased time between infection and vaccination might result in an improved immune response to vaccination. Also, a low risk of reinfection has been observed in the weeks to months following infection. Individual factors such as risk of COVID-19 severe disease or characteristics of the predominant SARS-CoV-2 strain should be taken into account when determining whether to delay getting a COVID-19 vaccination after infection.

5. What is the sensitivity and specifics of rapid COVID tests with current COVID variants?

Dr. del Rio: As good as with previous variants. No change there.

6. How long after COVID infection should we get the new booster?

Dr. del Rio: At least 8 - 12 weeks.

7. If a Nirsevimab-eligible infant/young child has an RSV infection during the season before they receive Nirsevimab, should they still receive a dose? Does it matter if diagnosis was clinical vs lab-confirmed?

Dr. Jones: Yes, they should take a dose. Nirsevimab recommendations are the same regardless of prior RSV infection or RSV-associated hospitalization.

8. Can we co-administer RSV with flu and/or covid vaccines at the same visit? The CDC FAQ website and RSV vaccine PIs state is it "permissible" but heard there may be some controversy.

Dr. del Rio: I am fine with doing Flue and COVID together (different arms if possible) but like to do RSV separate.

9. We are testing everyone for RSV because it's part of our covid panel, and almost no one is positive. Is there really a new problem?

Dr. Britton: We are just starting to see increases in RSV activity across some parts of the Southeastern United States in recent weeks, suggesting a continued shift toward seasonal RSV trends observed prior to the COVID-19 pandemic. Historically, such regional increases have predicted the beginning of RSV season nationally, with increased RSV activity spreading north and west over the following 2–3 months.

10. Is there a preference for RSV prevention between maternal vaccination of the Pfizer vaccine vs. Beyfortus?

Dr. Jones: Currently, there are no ACIP recommendations for the Pfizer maternal RSV vaccine. Please tune in to the ACIP meeting on 9/22 during which ACIP will discuss this vaccine.

11. For the (rare) unvaccinated individual, with the updated 2023-24 mRNA vaccines, will a complete primary series be just one single dose?

Dr. del Rio: I say yes. Hard to believe there is someone unvaccinated and uninfected! Have then been living in the Space Station?

12. What tests can be done to determine if an immunocompromised patient has formed a response to a Covid vaccine and has some protection against Covid?

Dr. Talbot: Unfortunately, there is not a test for this at this time. We currently do not know the correlates of immunity for COVID-19. Hence test results for any immunity test is not interpretable. We do know that patients with immunocompromised do have improved immune responses with repeat immunizations.

13. When do we expect to have post-marketing data regarding the safety of adult RSV vaccines with respect to the rare neurological AEFI observed in both the GSK and Pfizer vaccine trials?

Dr. Britton: Safety monitoring has already begun and CDC plans to share early safety data as soon as it is available. However, the timing will depend on the rate of uptake of the vaccine. If uptake is limited in this first season it may take some time to have a large enough sample size to evaluate rare events.

14. Can a person get the Novavax vaccine after getting an mRNA booster this fall? If so, how long would they have to wait between the vaccines?

Dr. Link-Gelles: Novavax COVID-19 Vaccine is currently authorized to be given as a booster dose in limited situations to people ages 18 years and older who previously completed primary vaccination using any FDA-approved or FDA-authorized COVID-19 vaccine; have not received any previous booster dose(s); and are unable (i.e., mRNA vaccine contraindicated or vaccine not available) or unwilling to receive an mRNA vaccine and would otherwise not receive a booster dose. The Novavax booster dose is administered at least 6 months after completion of any primary series.

15. What is the recommended time interval after birth for Beyfortus?

Dr. Jones: Infants younger than 8 months and born shortly before or during the RSV season: administer 1 dose of nirsevimab within 1 week of birth either in hospital or outpatient setting.

Infants younger than age 8 months not born during RSV season, and now entering their first RSV season: administer 1 dose of nirsevimab shortly before start of RSV season.

Infants younger than age 8 months with prolonged birth hospitalization (e.g., for prematurity) discharged shortly before or during the RSV season: administer 1 dose of nirsevimab shortly before or promptly after discharge.

16. Has the new COVID vaccine actually been studied in pregnant women, or is it being approved for use during pregnancy based on the safety experience of the prior COVID mRNA vaccines? Also, if a woman has the flexibility, is there any preference for delaying receiving the vaccine until they are past the first trimester of pregnancy?

Dr. Talbot: Safety for pregnant women has been extrapolated from prior COVID-19 vaccines. Women need to be protected at the time COVID-19 is circulating so immunization should occur now and not wait for a particular trimester.

17. What is the recommendation for COVID 19 vaccination for unvaccinated infants less than 1 year of age who became infected with COVID 19 during the summer 2023?

Dr. Link-Gelles: Those infants should complete the initial series (2 or 3 doses, depending on manufacturer) with the updated vaccine. They can follow advice previously posted about potentially waiting 3 months after their infection.

- 18. Patient in his 60's who develop new onset vestibular neuritis, persistent (14 month and counting). Started around 24 hrs. after fourth vaccination last July. Other risk factor being HTN and aortic insufficiency. Recommend continuing taking SARS-CoV-2 vaccinations?**

Dr. Talbot: This is a fantastic question for a group that addresses specific vaccine adverse event questions. The group is CISA and can be reached at <https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html>

- 19. Will infants of mothers who received the Pfizer RSV vaccine be recommended to receive nirsevimab as well?**

Dr. Jones: Currently, there are no ACIP recommendations for the Pfizer maternal RSV vaccine. Please tune in to the ACIP meeting on 9/22 during which ACIP will discuss this vaccine.

- 20. There was a slight increase in pre-term deliveries compared to placebo in women who received the RSV vaccine, although I do not think this difference reached statistical significance. I also believe that women who were felt to be at increased risk for pre-term deliveries were mostly excluded from the study. If a woman is felt to be at increased risk for pre-term delivery, is there any reason for her to avoid receiving the RSV vaccine, or does the potential benefit of receiving the vaccine outweigh the risk?**

Dr. Jones: Currently, there are no ACIP recommendations for the Pfizer maternal RSV vaccine. Please tune in to the ACIP meeting on 9/22 during which ACIP will discuss this vaccine.

- 21. Is there a recommendation for timing of the new COVID vaccine with regards to infection (e.g. if someone was positive in early August with symptomatic disease - should we wait 3, 4, 6 months to vaccinate)?**

Dr. Link-Gelles: People who recently had SARS-CoV-2 infection may consider delaying a COVID-19 vaccine dose by 3 months from symptom onset or positive test (if infection was asymptomatic). Studies have shown that increased time between infection and vaccination might result in an improved immune response to vaccination. Also, a low risk of reinfection has been observed in the weeks to months following infection. Individual factors such as risk of COVID-19 severe disease or characteristics of the predominant SARS-CoV-2 strain should be taken into account when determining whether to delay getting a COVID-19 vaccination after infection.

- 22. Immunocompromised patients (especially HCT/ CART) are typically given 4 injections of COVID19 mRNA vaccine. Do they need to re-do the entire series with monovalent mRNA COVID vaccine or just 1 injection will suffice?**

Dr. Talbot: They should receive one dose of the 2023-2024 vaccine. If needed, a second dose may be administered 2-months later.

23. What genomic/antigenic surveillance is being done for RSV at this time? If there is an antigenically important change in circulating isolates, what is the process to update the vaccines?

Dr. Jones: RSV differs from influenza and SARS-CoV-2 in that there is not as much antigenic change to the targeted antigen (F protein for RSV). While there are several platforms that look at genomic sequences of detected RSV and will look for immune escape mutation, there is not an expected need to update vaccines or monoclonal antibodies on a yearly basis.

24. What are the current national requirements for State reporting of COVID 19 data? Is reporting arbitrary? How much confidence can we have in State data to the CDC?

Dr. Kirking: Hi Marc, there were some COVID-19 surveillance changes that occurred with the end of the COVID-19 public health emergency in May 2023. Case-based reporting from states (i.e. counting and reporting every single case to CDC) transitioned to a surveillance strategy in which we instead now rely on other indicators including the proportion of PCR tests completed that are positive (lab-based reporting), ED visits for COVID-19, and hospitalizations for COVID-19. This transition is described in more detail in this MMWR in case you have more questions.

https://www.cdc.gov/mmwr/volumes/72/wr/mm7219e2.htm?s_cid=mm7219e2_x

25. These are important slides. Can this report be shared across the network so we can report accurately on national trends?

Dr. Kirking: Hi James, yes, I think these slides will be shared or available on the website. Additionally, most of my slides are pulled from CDC's public websites/COVID-19 Data Tracker (and I put links on them to designate where this data is in case you want to trend them into the future).

26. Are there any planned effectiveness RCT studies of the XBB.1.5 COVID-19 vaccines in the coming weeks?

Dr. Talbot: These studies will be done as observational studies producing vaccine effectiveness estimates.

27. If a patient aged 6mo-5 years received 1 dose of Pfizer, should the patient receive all 3 doses of 2023-2024 Pfizer or would it be 2 doses?

Dr. Link-Gelles: The initial series should be completed with the updated vaccine, no need to start over.

28. Is there human response data (not just animal) we can share with patients re: vax efficacy with new preparations?

Dr. Talbot: Yes. The data for human administration was presented at ACIP on Tuesday. Here is the website where you can review the data for both vaccines.

29. Since the covid vaccines for adults are no longer under the EUA, will insurance companies still cover the vaccine and admin costs when it is given at pharmacies (as opposed to clinics and provider's offices)? Insurance companies, Medicare, Medicaid, etc.

Dr. Link-Gelles: Vaccines will remain free or low cost for most U.S. residents through the Vaccines for Children Program, Children's Health Insurance Program, most commercial insurance, Medicare, and Medicaid programs, as well as the CDC Bridge Program for COVID-19 Vaccination

30. Is it recommended for IC, specifically sotr, to wait for Novavax since now are basically unprotected by vaccination since last dose, or get other manufacturers now?

Dr. Talbot: Please do not wait and use the currently authorized vaccines to prevent infection and the complications of COVID-19 infection.

31. Novavax was covered at the ACIP meeting, but was it recommended by the committee, it appeared that only the mRNA's were recommended.

Dr. Talbot: Yes. Novavax does not currently have an FDA approved 2023-2024 COVID-19 vaccine. Hence ACIP could not vote on the use of the vaccine until FDA authorization has been given.

32. After recent COVID 19 illness not requiring ER visit or hospitalization, how long to wait for the current vaccine administration? Is there a problem with not waiting to get the vaccine once fully recovered from illness?

Dr. Link-Gelles: People with known current SARS-CoV-2 infection should defer any COVID-19 vaccination at least until recovery from the acute illness (if symptoms were present) and criteria to discontinue isolation have been met.

People who recently had SARS-CoV-2 infection may consider delaying a COVID-19 vaccine dose by 3 months from symptom onset or positive test (if infection was asymptomatic). Studies have shown that increased time between infection and vaccination might result in an improved immune response to vaccination. Also, a low risk of reinfection has been observed in the weeks to months following infection. Individual factors such as risk of COVID-19 severe disease or characteristics of the predominant SARS-CoV-2 strain should be taken into account when determining whether to delay getting a COVID-19 vaccination after infection.

33. Is the interval between last dose of Bivalent vax and new COVID monovalent vax, the same for Moderna and Pfizer?

Dr. Link-Gelles: Yes, at least 2 months since last dose for both Moderna and Pfizer.

34. Can we get RSV vaccine covered for patients less than 60 but high risk such as COPD or asthma?

Dr. Talbot: The RSV vaccine has not been authorized to be used in patients less than 60 years. The data is being collected and will be reviewed by the FDA soon.

35. Clarification: Wait 2 months after COVID infection to vaccinate with 23-24 vaccine?

Dr. Link-Gelles: People with known current SARS-CoV-2 infection should defer any COVID-19 vaccination at least until recovery from the acute illness (if symptoms were present) and criteria to discontinue isolation have been met.

People who recently had SARS-CoV-2 infection may consider delaying a COVID-19 vaccine dose by 3 months from symptom onset or positive test (if infection was asymptomatic). Studies have shown that increased time between infection and vaccination might result in an improved immune response to vaccination. Also, a low risk of reinfection has been observed in the weeks to months following infection. Individual factors such as risk of COVID-19 severe disease or characteristics of the predominant SARS-CoV-2 strain should be taken into account when determining whether to delay getting a COVID-19 vaccination after infection.

36. Why the 2 month wait interval for COVID vaccine after prior vaccine or prior COVID illness instead of 1 month or less interval? What's the physiology for the 2 month interval?

Dr. Talbot: There is a better and longer lasting immune response when viral respiratory vaccines are spread out (ideally 6 months). We have also seen fewer adverse events when the vaccine timing is spread out. The one month was used at the beginning of the pandemic to increase immunity as quickly as possible.

37. I see 2 months between vaccines. What was the recommendation from infection to vaccine?

Dr. Link-Gelles: People with known current SARS-CoV-2 infection should defer any COVID-19 vaccination at least until recovery from the acute illness (if symptoms were present) and criteria to discontinue isolation have been met.

People who recently had SARS-CoV-2 infection may consider delaying a COVID-19 vaccine dose by 3 months from symptom onset or positive test (if infection was asymptomatic). Studies have shown that increased time between infection and vaccination might result in an improved immune response to vaccination. Also, a low risk of reinfection has been observed in the weeks to months following infection. Individual factors such as risk of COVID-19 severe disease or characteristics of the predominant SARS-CoV-2 strain should be taken into account when determining whether to delay getting a COVID-19 vaccination after infection.

38. Please say why RSV vaccine is not recommended for pregnant people? It's only because it hasn't yet been considered by ACIP. It is to be considered by ACIP next week.

Dr. Britton: Yes, incredibly important point. It will be considered by ACIP next week on 9/22. Thank you.

39. What are the intervals between 3 doses in unvaccinated, immunocompromised hosts (not in the infographic)?

Dr. Link-Gelles: This varies by age and product, so would refer to CDC's Interim Clinical Considerations website for specifics (will be updated by Monday). Generally, the first 2 doses of Pfizer are 3 weeks apart and first 2 doses of Moderna are 4 weeks apart, with the third dose at least 4 weeks later.

40. If someone had a reaction to their 2nd Shingrix, should they avoid the GSK formulation since it uses the same adjuvant?

Dr. Britton: The adjuvant used in the GSK formulation is the same as that used in Shingrix but is half the dose used in Shingrix. If the patient has access to both RSV vaccine products and is concerned about another reaction, it would be reasonable to give the Pfizer product. However, if they would likely benefit from vaccination and the choice is between remaining unvaccinated or using the GSK product, the benefit likely outweighs the risk. The only contraindication to the use of the GSK vaccine is it should not be administered to a person with a history of severe allergic reaction, such as anaphylaxis, to any component of the vaccine.

41. Can you provide an idea of the number needed to vaccinate to prevent one case of LRTD in older adult patients who do NOT have CHF, COPD, chronic lung disease, etc.? Do these patients (a healthy 85 yo for example) really need RSV vaccine?

Dr. Britton: This cost-effectiveness analysis presented at ACIP includes information on NNV in the general adult population. The NNV depends on the outcome of interest. Please see slides 18 and 20: <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2023-06-21-23/04-RSV-Adults-Hutton-508.pdf>

42. If RSV is a particular concern for older adults AND the immunocompromised, why is the RSV vaccine not recommended for immunocompromised under age 60, even 50+?

Dr. Britton: This population (under 60 with risk conditions) is being actively studied in clinical trials currently. As soon as data are available FDA and ACIP/CDC will consider it and if indicated make a recommendation for use in that age group.

43. RSV vaccination in young adult transplant recipient?

Dr. Britton: Adults under 60 with risk conditions are being actively studied in clinical trials currently. As soon as data are available FDA and ACIP/CDC will consider the use of the vaccine in those under 60 and if indicated make a recommendation for use in that age group.

44. As RSV vaccines are introduced, seasonality of RSV may be impacted and use of vaccine or mAb may need to change to year-long instead of seasonal. Any comments?

Dr. Britton: CDC will be monitoring RSV seasonality and changes in epidemiology closely, especially in light of these new prevention products. These data are shared with ACIP to consider in future/changes to current recommendations.

45. Safety of the new COVID vaccines in pregnancy and breastfeeding?

Dr. Talbot: The prior COVID-19 vaccines have been shown to be safe in pregnancy and breastfeeding. We anticipate this to be the same as the vaccine technology has not changed -- only the spike protein mRNA.

46. Is it expected that RSV vaccine reduce transmission in the community?

Dr. Britton: The clinical trials did not study whether transmission was reduced as an outcome, so for the time being we only know that it protects the individual that receives it.

47. Please clarify when ACIP will vote on RSV vaccine for pregnant women. We will have the Pfizer vaccine on hand for older adults. Should we be telling our obstetricians not to start using it yet?

Dr. Talbot: ACIP will meet September 22, 2023 to discuss RSV vaccine for pregnant women.

48. I'd be interested in whether panelists think that newborns of pregnant women who received one of the RSV vaccines should also get the Nirsevimab.

Dr. Jones: Currently, there are no ACIP recommendations for the Pfizer maternal RSV vaccine. Please tune in to the ACIP meeting on 9/22 during which ACIP will discuss this vaccine and this very topic.

49. What is the value or benefit, if any, to checking 'antibody' status? Apologize, in advance, if this was mentioned already in this webinar.

Dr. Talbot: No apology needed. Unfortunately, we do not know a correlate of immunity so we do not know how much antibody is needed for protection. We also do not know how much the cellular immune response impacts protection. Hence, we do not recommend testing antibodies.

50. Can you please address the recommendation for Beyfortus and use of Synagis for this upcoming predicted RSV season in infants/young children? Is the goal to eventually phase out Synagis?

Dr. Jones: AAP has issues considerations: (<https://publications.aap.org/redbook/resources/25379>):

Some considerations for the 2023–2024 RSV season with regard to palivizumab versus nirsevimab administration for high-risk infants during the same RSV season

If nirsevimab is administered, palivizumab should not be administered later that season.

If palivizumab was administered initially for the season and <5 doses were administered, the infant should receive 1 dose of nirsevimab. No further palivizumab should be administered.

If palivizumab was administered in season 1 and the child is eligible for RSV prophylaxis in season 2, the child should receive nirsevimab in season 2, if available. If nirsevimab is not available, palivizumab should be administered as previously recommended.

51. If the infant is 8 months and 1 day old, the child does NOT qualify to receive Nirsevimab if the child is high risk going in a RSV season?

Dr. Jones: We are developing additional educational materials and FAQ document to answer questions such as these. If at increased risk for severe disease (as defined in the presentation), children at increased risk for severe RSV disease can receive nirsevimab during their first RSV season if 8-11 months. Only one dose of nirsevimab is recommended for each season.

52. In Florida, how to address the conflict of surgeon general Dr lapada stating there were no clinical trials to support use of new Covid vaccine, so it is not recommended in the state.? This will lead to resistance to receive the vaccine-extremely frustrating.

Dr. Talbot: This will be very difficult. There were some small studies of the XxB vaccine that were presented at ACIP. <https://www.cdc.gov/vaccines/acip/meetings/slides-2023-09-12.html>

53. Please clarify if RSV antibody is indicated for all well infants under 6-8 months of age.

Dr. Jones: Yes, nirsevimab is recommended for all infants aged <8 months born during or entering their first RSV season are recommended to receive one dose of nirsevimab.

54. Nirsevimab with other vaccines:

Dr. Jones: Simultaneous administration of nirsevimab with age-appropriate vaccines is recommended.

55. Once a healthy infant is over 8 months old, they cannot receive Beyfortus?

Dr. Jones: ACIP recommendations are for <8 months for healthy infants. Infants and children aged ≥8 months have likely experienced an RSV season and are at decreased risk for severe RSV-associated disease compared with younger infants without previous RSV exposure.

56. According to FDA label, nirsevimab can be given to children up to 2 years of age, yet ACIP recs differ from this. What to do about children age 20 months through 24 months?

Dr. Jones: ACIP recommendations are given when entering their 2nd RSV season. Nirsevimab protection lasts for at least 5 months. Children aged ≥20 months have likely experienced two RSV seasons and are at decreased risk for severe disease compared with younger children who have experienced only one RSV season.

57. If children are hospitalized with RSV during their 1st season, would you give Ab in second season?

Dr. Jones: ACIP recommendations are only to the groups of children defined as increased risk for RSV season as presented for the second RSV season. Recommendations are the same regardless of previous infection or hospitalization history.

58. Re nirsevimab and other vaccines- it is probably not an issue but are we absolutely sure?

Dr. Jones: Little data is available: palivizumab hasn't shown to cause issues and maternal infection-induced antibodies exist and have not shown to cause issues. See doi: 10.3389/fimmu.2021.708939 for a white paper on the issue.

59. What are the recommendations for extreme preterm infants for RSV Ab?

Dr. Jones: Infants with prolonged birth hospitalizations due to prematurity or other causes should receive nirsevimab shortly before or promptly after discharge. If meeting criteria for CLD with medical therapy within 6 months of 2nd season, a dose should be given when entering 2nd RSV season.

60. If a mom receives Abrysvo, when will the infant be able to get Beyfortus or they won't need to receive it? Does it depend on if RSV season is encountered > 6 mo of age and < 8 mo of age since Abrysvo will only protect for 6 mo?

Dr. Jones: Currently, there are no ACIP recommendations for the Pfizer maternal RSV vaccine. Please tune in to the ACIP meeting on 9/22 during which ACIP will discuss this vaccine, including this issue.

61. Download “PneumoRecs VaxAdvisor” free for iOS and Android devices through your APP store - great tool!!!!

Dr. Kobayashi: I am happy to hear that you found the tools to be helpful.

62. Please confirm that PCV means pneumococcal conjugate vaccine and NOT pneumococcal vaccine alone.

Dr. Kobayashi: Whenever I mentioned PCV in the presentation, it referred to pneumococcal conjugate vaccine. Thank you!