Centers for Disease Control and Prevention National Center for Immunization and Respiratory Diseases



Recommendations and Clinical Guidance for Use of RSV Vaccines in Older Adults and Pregnant People and Use of Nirsevimab in Infants and Young Children

Current Issues in Immunization

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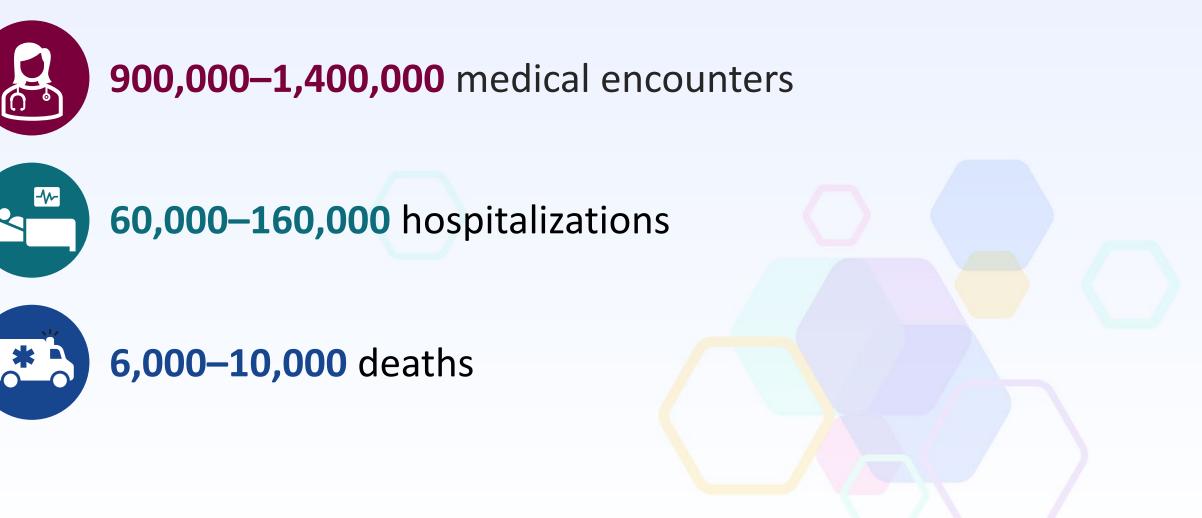
Recommendations and clinical guidance for use of RSV vaccines in older adults

Clinical Presentation in Adults

- Usually mild or no symptoms
- Older adults are at increased risk for becoming seriously ill
- This includes:
 - -Lower respiratory tract infection
 - -Exacerbation of existing conditions



Annual RSV Burden Among Adults Ages 65 Years and Older



https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2023-02/slides-02-23/RSV-Adults-04-Melgar-508.pdf

In June 2023, CDC's Advisory Committee on Immunization Practices (ACIP) recommended the first two RSV vaccines for older adults.

RSVPreF3 (Arexvy, GSK) is a 1-dose adjuvanted (ASo1_E) recombinant prefusion F protein (preF) vaccine.
 Approved for use <u>ONLY</u> in people ages 60 years and older

RSVpreF (Abrysvo, Pfizer) is a 1-dose recombinant preF vaccine.
 Approved for use in people ages 60 years and older <u>AND</u> pregnant people

RSV Vaccination Recommendations for Older Adults

 ACIP and CDC recommend that adults ages 60 years and older may receive a single dose of RSV vaccine using shared clinical decision making.



Chronic Underlying Medical Conditions Associated with Increased Risk of Severe RSV Disease in Older Adults



increase the risk for severe disease

Other Factors Associated with Increased Risk of Severe RSV Disease in Older Adults

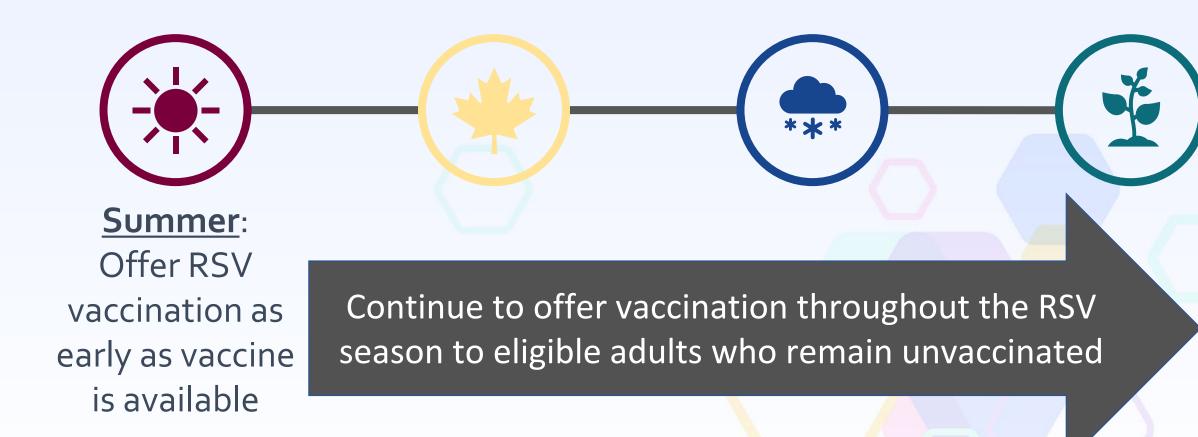


Residence in a nursing home or other long-term care facility (LTCF)





RSV Vaccination Timing for Older Adults: 2023-2024 Season



Coadministration of RSV vaccine in older adults

- Coadministration with all other adult vaccines is acceptable.
- If vaccines are NOT administered the same day, there is no required interval between vaccines.



Considerations for Coadministration for RSV vaccine in older adults



Whether the patient is **up to date** with currently recommended vaccines



Likelihood of **returning**



Risk for acquiring vaccine-preventable disease



Vaccine **reactogenicity** profiles



Patient preferences

Respiratory Syncytial Virus (RSV) Immunization Recommendations to Protect Infants and Children



Annual RSV Burden Among Infants and Children in U.S.



58,000–80,000 hospitalizations among children age <5 years; 79% of those hospitalized <2 years had no underlying medical condition



100–300 deaths among children age <5 years



Preterm infants experience higher hospitalization and ICU admission rates

Suh et al, J Infect Dis (2022): doi: 10.1093/infdis/jiac120. Hall et al, N Engl J Med (2009): doi: 10.1056/NEJMoa0804877 McLaughlin et al, J Infect Dis (2022): doi: 10.1093/infdis/jiaa752 Hansen et al, JAMA Netw Open (2022): doi: 10.1001/jamanetworkopen.2022.0527 Thompson et al, JAMA (2003): doi: 10.1001/jama.289.2.179 Hall et al, Pediatrics (2013): doi: 10.1542/peds.2013-0303 McLaurin et al, J Perinatol (2016): doi: 10.1038/jp.2016.113

Maternal RSV Vaccine and Infant Nirsevimab

Two products are available to protect infants from severe RSV disease

- To protect infants in their first season:
 - -Maternal vaccine
 - OR
 - -Nirsevimab
- To protect eligible infants in their second season: —Nirsevimab

Nirsevimab (Beyfortus[™])

- Monoclonal antibody
- Immunization, but not a vaccine
- Provides passive immunity





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Nirsevimab Safety

- Most reported adverse reactions were injection site reactions and rash
- Incidence of serious adverse events not significantly different between nirsevimab and comparators (placebo or palivizumab)

Maternal RSV Vaccine, Abrysvo (Pfizer)

- Recombinant prefusion F protein (preF) vaccine
- Single dose
- 0.5mL
- Requires reconstitution
- Intramuscular injection
- Abrysvo (Pfizer) is the <u>ONLY</u> RSV vaccine approved for pregnant people
 - Approved for use in people ages 60 years and older AND pregnant people
- Arexvy (GSK) is <u>NOT</u> approved for pregnant people
 - Approved for use ONLY in people ages 60 years and older

Vaccine Safety: Maternal RSV Vaccine, Abrysvo (Pfizer)

- Side effects tend to be mild or moderate, temporary, and like those experienced after other vaccinations.
- More preterm births and reports of hypertension during pregnancy, including pre-eclampsia were seen in the vaccine group than placebo group in clinical trials, but it is not known if this was related to the vaccine or simply due to chance.
 - Vaccination during 32 to 36 weeks gestation reduces the potential risk of preterm birth.
- ACIP determined benefits of maternal vaccination outweigh potential risks.

Maternal Vaccination Recommendations

Maternal Vaccine Recommendations

- Maternal vaccine is recommended for pregnant people during 32 through 36 weeks gestation, with seasonal administration.
 - During **September through January** in most of the continental United States
 - In jurisdictions with seasonality that differs from most of the continental United States (e.g., Alaska, jurisdictions with tropical climates), providers should follow state, local, or territorial guidance on timing of administration*
- Maternal Pfizer vaccine can be simultaneously administered with other indicated vaccinations.

*The timing of maternal RSVpreF vaccination might vary in these jurisdictions because the historic timing of RSV circulation differs from the rest of the United States. As maternal RSVpreF vaccination should start 1–2 months before the anticipated start of the RSV season and continue through 2–3 months before the anticipated end of the RSV season, it is not feasible to change maternal RSVpreF vaccination timing based on year-to-year variations in RSV circulation. Thus, in most of the continental United States, maternal RSVpreF vaccination should be given in September–January, regardless of year-to-year variation in RSV circulation. Thus, in most of the continental United States, maternal RSVpreF vaccination should be Fleming-Dutra KE, Jones JM, Roper LE, et al: https://www.cdc.gov/mmwr/volumes/72/wr/mm7241e1.htm

Maternal Vaccine Recommendations

- Pfizer maternal RSV vaccine is recommended as a one-time dose at this time.
- Currently, no data are available on either the efficacy of the first lifetime dose to protect infants born after subsequent pregnancies or the safety of additional doses given in subsequent pregnancies.
- Additional data are needed to determine whether additional seasonal doses in subsequent pregnancies would be indicated, and ACIP might update recommendations in the future, as data become available.

Nirsevimab Recommendations

Nirsevimab Recommendations

- Infants younger than age 8 months born during or entering their first RSV season are recommended to receive 1 dose, if:
 - -The mother did not receive RSV vaccine during pregnancy.
 - -The mother's RSV vaccination status is unknown.
 - -The infant was born within 14 days of maternal RSV vaccination.
- Children ages 8–19 months who are at increased risk of severe RSV disease and entering their second RSV season are recommended to receive 1 dose.
- Age ranges represent the infant's or child's age at the time of immunization.

Jones JM, Fleming-Dutra KE, Prill MM, et al. <u>https://www.cdc.gov/mmwr/volumes/72/wr/mm7234a4.htm</u>

Children Ages 8–19 Months at Increased Risk



Children with chronic lung disease of prematurity who required medical support any time during the 6-month period before the start of the second RSV season

Children with severe immunocompromise

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Children with cystic fibrosis who have manifestations of severe lung disease or weight-for-length <10th percentile

American Indian and Alaska Native children

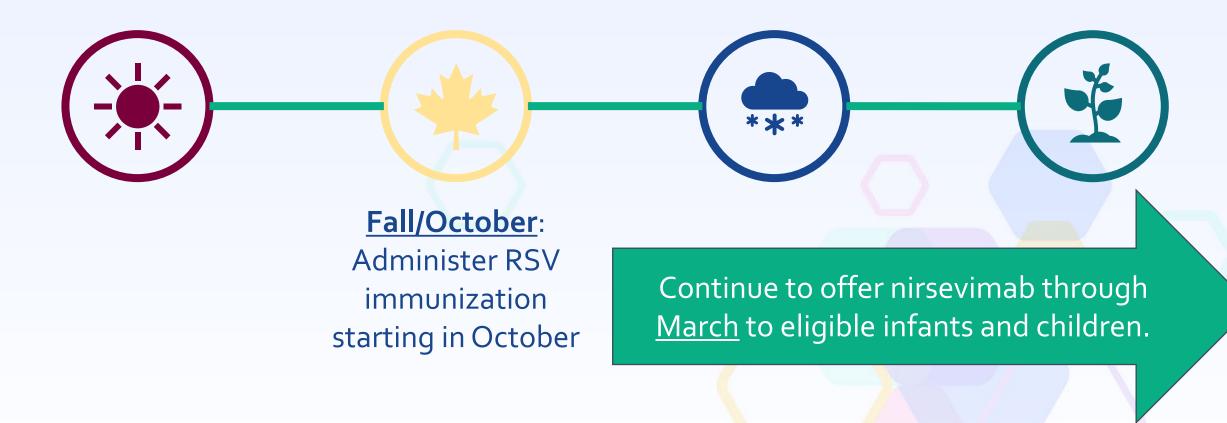
Jones JM, Fleming-Dutra KE, Prill MM, et al. https://www.cdc.gov/mmwr/volumes/72/wr/mm7234a4.htm

Timing of nirsevimab

- Providers should target administration¹:
 - In the first week of life for infants born shortly before and during the season
 - Shortly before the start of the RSV season for infants aged <8 months
 - Shortly before the start of the RSV season for children aged 8–19 months who are at increased risk of severe RSV disease

¹While optimal timing for nirsevimab administration is shortly before the season, nirsevimab may be given at any time during the RSV season for ageeligible infants and children who have not yet received a dose

Nirsevimab Timing: 2023-2024 Season



Jones JM, Fleming-Dutra KE, Prill MM, et al. <u>https://www.cdc.gov/mmwr/volumes/72/wr/mm7234a4.htm</u>

Nirsevimab Timing: 2023-2024 Season

Local guidance:

Administration schedules can be adjusted based on local epidemiology. Nirsevimab can be given outside of October through March, when appropriate. Follow local guidance, when provided.

Jones JM, Fleming-Dutra KE, Prill MM, et al. https://www.cdc.gov/mmwr/volumes/72/wr/mm7234a4.htm

Nirsevimab Timing: 2023-2024 Season

Local guidance:

Areas with less predictable seasonality may include, but are not limited to: Florida, Hawaii, Guam, Puerto Rico, U.S. Virgin Islands, U.S.-affiliated Pacific Islands, and Alaska.

Jones JM, Fleming-Dutra KE, Prill MM, et al. https://www.cdc.gov/mmwr/volumes/72/wr/mm7234a4.htm

Coadministration and nirsevimab

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

- Based on limited numbers, the safety profile of nirsevimab given simultaneously with routine vaccines and that of vaccines given alone was similar in trials.
- Coadministration is not expected to interfere with immune response.

https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761328sooolbl.pdf Esposito S, Abu-Raya B, Bonanni P, et al. <u>https://doi.org/10.3389/fimmu.2021.708939</u> Jones JM, Fleming-Dutra KE, Prill MM, et al. <u>https://www.cdc.gov/mmwr/volumes/72/wr/mm7234a4.htm</u>

Considerations for Maternal Vaccine or Nirsevimab

Maternal RSV Vaccine and Nirsevimab Recommendations

- Either maternal vaccination or use of nirsevimab in the infant is recommended to prevent RSV lower respiratory tract infection, but administration of both products is not needed for most infants.
- Healthcare providers of pregnant people should provide information on both products and consider patient preferences when determining whether to vaccinate the pregnant patient or to not vaccinate and rely on administration of nirsevimab to the infant after birth.

Circumstances for which nirsevimab can be considered when mother has received RSV vaccine ≥14 days prior to birth

- Nirsevimab can be considered in rare circumstances when, per the clinical judgment of the healthcare provider, the potential incremental benefit of administration is warranted. These include but are not limited to:
 - Infants born to pregnant people who may not mount an adequate immune response to vaccination (e.g., people with immunocompromising conditions) or who have conditions associated with reduced transplacental antibody transfer (e.g., people living with HIV infection)¹
 - Infants who might have experienced loss of maternal antibodies, such as those who have undergone cardiopulmonary bypass or extracorporeal membrane oxygenation²
 - Infants with substantial increased risk for severe RSV disease (e.g., hemodynamically significant congenital heart disease, intensive care admission and requiring oxygen at discharge)

1 Palmerira Clin Dev Immunol 2012. 2 Feltes J Pediatr 2003.

Fleming-Dutra KE, Jones JM, Roper LE, et al: <u>https://www.cdc.gov/mmwr/volumes/72/wr/mm7241e1.htm</u>

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Centers for Disease Control and Prevention National Center for Immunization and Respiratory Diseases



Updates to COVID-19 Vaccine Policy

2023 – 2024 (Monovalent, XBB Containing) COVID-19 Vaccine

Dr. Megan Wallace October 18, 2023

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Summary and Work Group Interpretation: Public Health Burden

- The burden of COVID-19 varies by age and underlying condition status with those ages ≥65 years and those with multiple underlying conditions having the highest risk of severe outcomes due to COVID-19
- COVID-19 burden is currently lower than at previous points in the pandemic, however there are still thousands of hospitalizations and hundreds of deaths each week
- Children and adults ages 5 49 years had the lowest hospitalization rates overall
 Severe outcomes occur in this age group, including in people with no underlying medical conditions
- Although hospitalization rates are currently low, we have seen rates increase in recent weeks and anticipate further increases as we enter respiratory virus season
- Majority of U.S. population has some level of immunity due to infection, vaccination, or both
 - Vaccine and infection-induced immunity wane and new variants have emerged, suggesting that susceptibility remains and may increase over time
- Racial and ethnic minority groups have been disproportionately affected by COVID-19

Summary and Work Group Interpretation: Benefits and Risks

- Monovalent XBB containing COVID-19 vaccines increase the immune response against the currently circulating variants
- Last year's updated vaccine was effective at preventing medically attended COVID-19, hospitalization due to COVID-19, and death due to COVID-19
- COVID-19 vaccines have a high degree of safety
 Unlikely that updating the formulation would increase adverse event rates
- Benefits are anticipated in all age groups; benefits of COVID-19 vaccines vary by age, and incidence of COVID-19 hospitalizations
- Benefits outweigh risks in age groups for which there is a risk of myocarditis
- Modeling projects more hospitalization and deaths averted when updated doses are universally recommended compared to no recommendation or recommended only for persons ≥65 years

Key changes from bivalent mRNA recommendations

2022 – 2023 bivalent recommendations	2023 – 2024 vaccine recommendations	Rationale		
Everyone ages 6 years and older recommended for a single bivalent dose	Everyone ages 5 years and older recommended for a single 2023 – 2024 dose	Eliminates complex recommendations for 5-year- olds		
Two Moderna dosages authorized for 6 months – 5 years, depending on vaccination history and immune status	All Moderna doses in ages 6 months – 11 years are now 25 µcg	Reduces the number of COVID-19 vaccine products in use		
Optional 2 nd bivalent dose for those ages 65 years and older	No additional dose recommendation at this time	Will monitor epidemiology and vaccine effectiveness to determine if additional doses are needed		

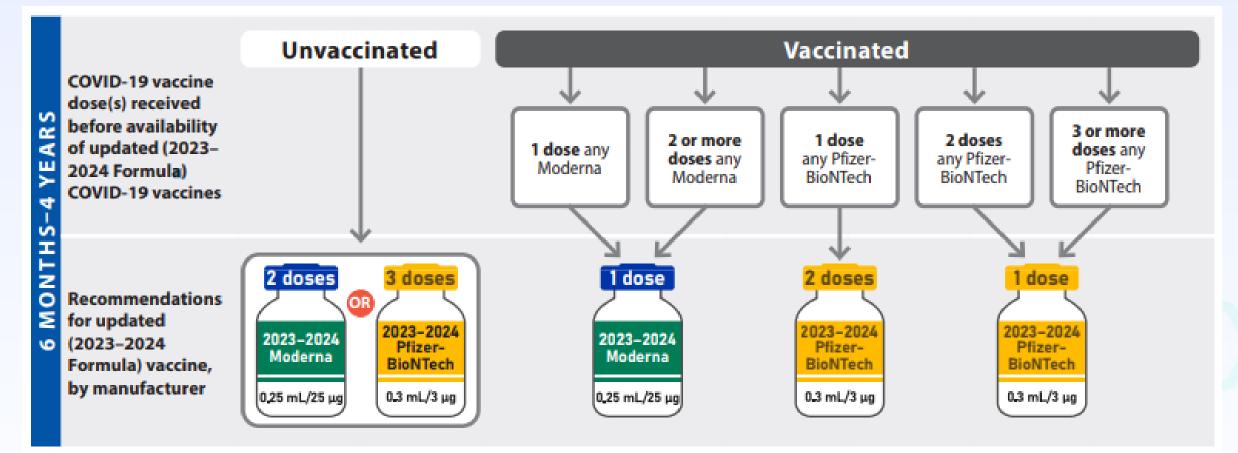
Recommendations for children aged 6 months – 4 years <u>without</u> immunocompromise

Doses recommended:

- Initial series of 2 Moderna vaccine doses OR 3 Pfizer-BioNTech vaccine doses
- At least 1 dose of 2023–2024 COVID-19 vaccine

- All doses should be homologous (i.e., from the same manufacturer)
- All Moderna doses in ages 6 months 11 years are now 25 μcg

Recommended 2023–2024 COVID-19 mRNA vaccines for people who are NOT immunocompromised, aged 6 months–4 years*[†]



*For information about administration intervals and children who transition from age 4 years to age 5 years, see Table 1 in the Interim Clinical Considerations for Use of COVID-19 Vaccines

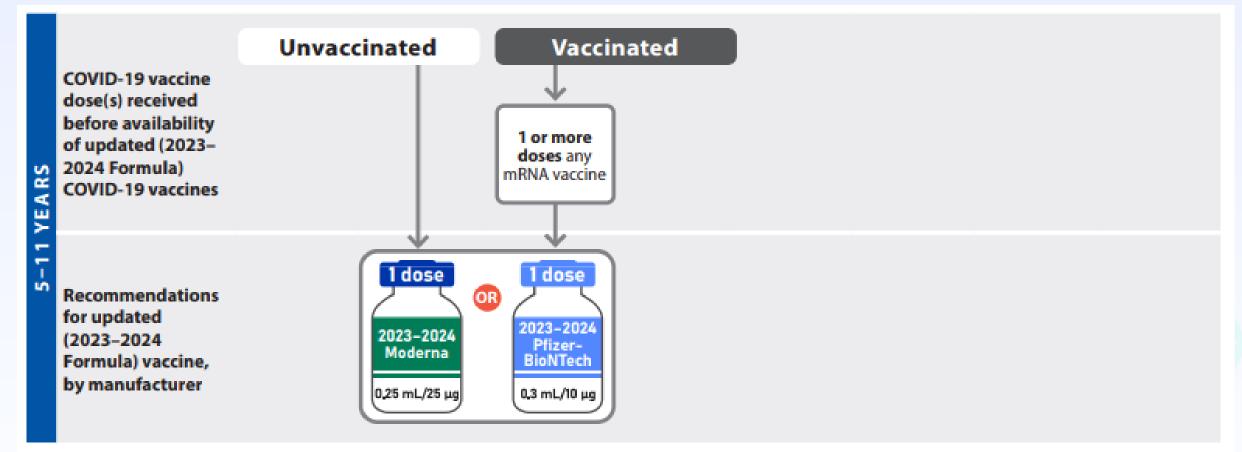
Recommendations for people aged 5 years and older <u>without</u> immunocompromise

Doses recommended:

• 1 dose of 2023–2024 COVID-19 vaccine

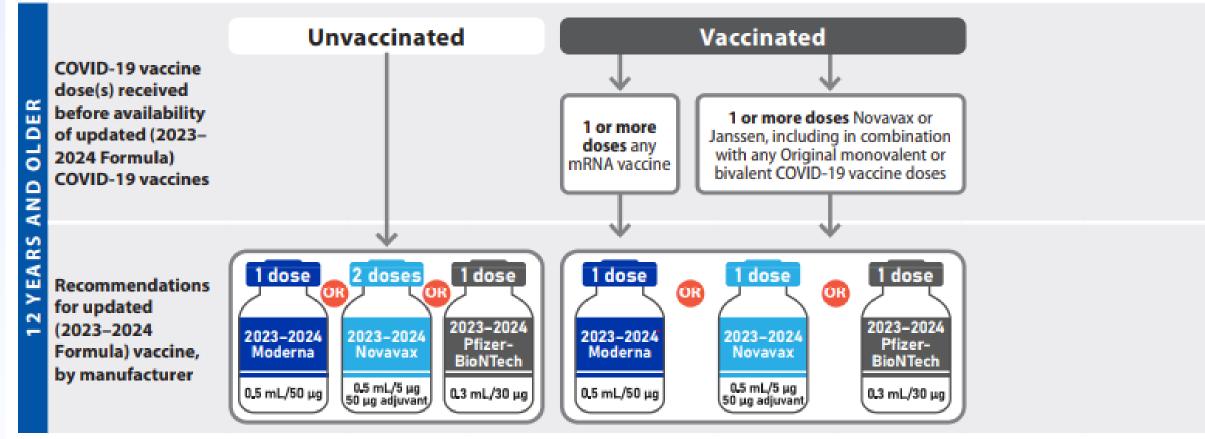
- mRNA COVID-19 vaccines authorized or approved for ages ≥6 months and Novavax COVID-19 vaccine authorized for ages ≥12 years
- Unvaccinated persons receiving Novavax COVID-19 should complete a 2-dose initial series
- New harmonized age cutoff for recommendations for young children for Moderna and Pfizer-BioNTech COVID-19 vaccines resulting in simplified recommendations for 5-year-olds
- All Moderna doses in ages 6 months 11 years are now 25 μcg
- 2023–2024 COVID-19 vaccine dose is recommended at least 2 months after receipt of the last COVID-19 vaccine dose

Recommended 2023–2024 COVID-19 mRNA vaccines for people who are NOT immunocompromised, aged 5–11 years*[†]



*For information about administration intervals and children who transition from age 4 years to age 5 years, see Table 1 in the Interim Clinical Considerations for Use of COVID-19 Vaccines

Recommended COVID-19 vaccination schedule for people who are NOT moderately or severely immunocompromised, aged ≥12 years^{*†}



*For information about administration intervals and children who transition from age 4 years to age 5 years, see Table 1 in the Interim Clinical Considerations for Use of COVID-19 Vaccines

Recommendations for people aged ≥6 months who are moderately or severely immunocompromised

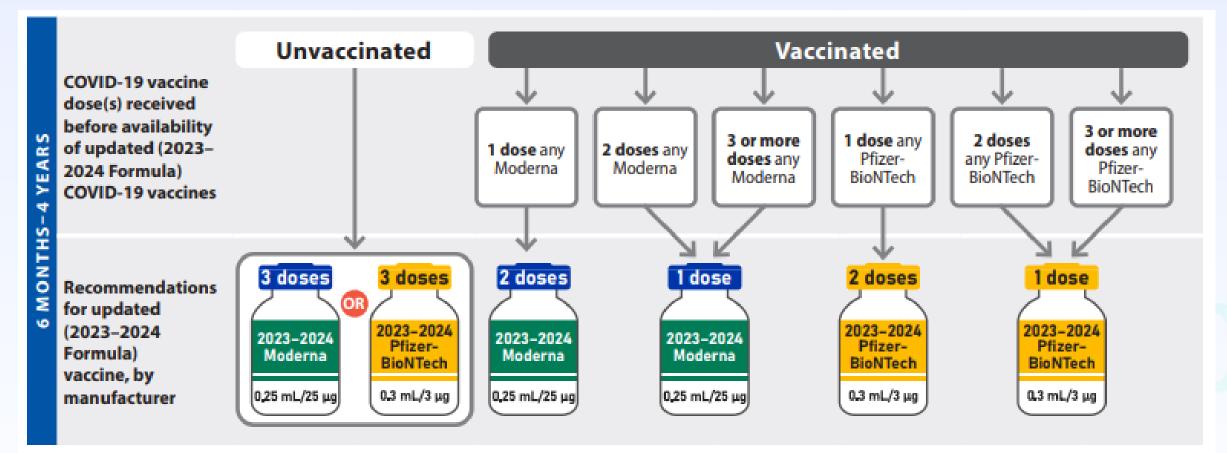
Doses recommended:

- Initial COVID-19 vaccine series*
- At least 1 2023–2024 COVID-19 vaccine dose
- May receive 1 or more additional 2023-2024
 COVID-19 vaccine doses**

*Series of 3 homologous mRNA COVID-19 vaccine doses or 2 homologous Novavax COVID-19 vaccine doses at time of initial vaccination. This could also include a history of receipt of 1 or more doses of Novavax or Janssen, including in combination with mRNA vaccine dose(s).

**Further additional dose(s) may be administered, informed by the clinical judgement of a healthcare provider and personal preference and circumstances. Further additional doses should be administered at least 2 months after the last 2023-2024 COVID-19 vaccine dose.

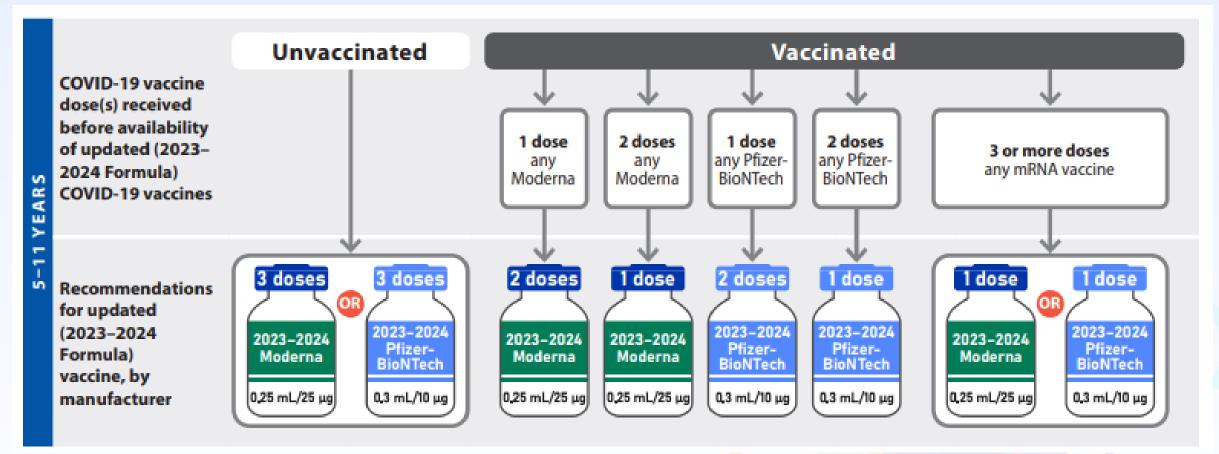
Recommended 2023–2024 COVID-19 vaccines for people who ARE moderately or severely immunocompromised, aged 6 months–4 years^{*†}



* For information about administration intervals and children who transition from age 4 years to age 5 years or age 11 years to age 12 years during an mRNA vaccination series, and administration of additional dose(s), see Table 2 in the Interim Clinical Considerations for Use of COVID-19 Vaccines

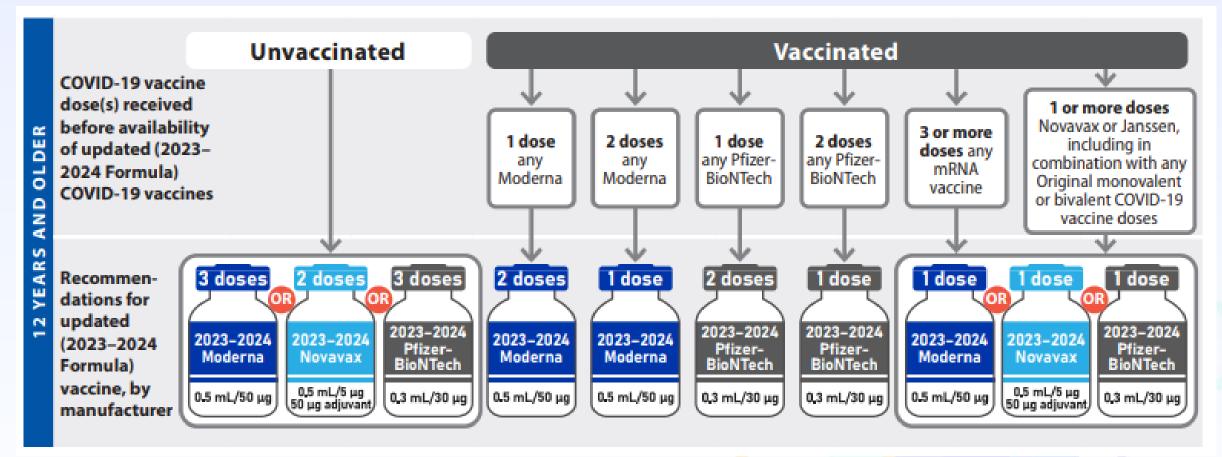
+ COVID-19 vaccination history refers to previous receipt of doses of Original monovalent mRNA or bivalent mRNA vaccine or a combination of the two; for people ages 12 years and older, Original monovalent Novavax COVID-19 Vaccine doses, alone or in combination with any mRNA vaccine doses; and for people ages 18 years and older, Janssen COVID-19 Vaccine doses, alone or in combination with any mRNA or Original monovalent Novavax COVID-19 Vaccine doses, alone or in combination with any mRNA vaccine doses; and for people ages 18 years and older, Janssen COVID-19 Vaccine doses, alone or in combination with any mRNA or Original monovalent

Recommended 2023–2024 COVID-19 vaccines for people who ARE moderately or severely immunocompromised, aged 5–11 years*[†]



* For information about administration intervals and children who transition from age 4 years to age 5 years or age 11 years to age 12 years during an mRNA vaccination series, and administration of additional dose(s), see Table 2 in the Interim Clinical Considerations for Use of COVID-19 Vaccines

Recommended COVID-19 vaccination schedule for people who ARE moderately or severely immunocompromised, aged ≥12 years^{*†}



* For information about administration intervals and children who transition from age 4 years to age 5 years or age 11 years to age 12 years during an mRNA vaccination series, and administration of additional dose(s), see Table 2 in the Interim Clinical Considerations for Use of COVID-19 Vaccines

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2023-24 ACIP Influenza Vaccination Recommendations Update

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October 18, 2023

ACIP Influenza Vaccination Recommendations, 2023-24

- Annual vaccination of all ages 6 months and older who do not have contraindications continues to be recommended.
- Vaccination is recommended ideally by the end of October, but should continue as long as influenza viruses are circulating.*
- High-dose inactivated, recombinant, and adjuvanted inactivated influenza vaccines are preferentially recommended for people ages 65 years and older.
- Changes for the 2023-24 season include:
 - The updated U.S. influenza vaccine composition for the 2023-24 season.
 - Based on a review of safety data concerning influenza vaccination of people with egg allergy, there are no longer recommendations for specific vaccination settings for people with severe allergy to eggs.
 - * See the ACIP 2023-24 Influenza Statement for information concerning July/August vaccination for specific groups. https://www.cdc.gov/mmwr/volumes/72/rr/rr7202a1.htm

Influenza Vaccines by Age Indication, United States, 2023–24 Influenza Season

	Vaccine type	0 through 6 months	6 through 23 months	2 through 17 years	18 through 49 years	50 through 64 years	≥65 years		
IIV4s	Standard-dose unadjuvanted inactivated (IIV4)		Afluria Quadrivalent Fluarix Quadrivalent FluLaval Quadrivalent Fluzone Quadrivalent						
	Standard-dose unadjuvanted cell culture-based inactivated (ccIIV4)		Flucelvax Quadrivalent						
	Standard-dose adjuvanted inactivated (allV4)		Fluad Quadrivalent* Fluzone High-Dose Quadrivalent*						
	High-dose inactivated (HD-IIV4)								
RIV4	Recombinant (RIV4)		Flublok Quadrivalent*						
LAIV4	Live attenuated (LAIV4)			FluMist Qu	adrivalent				
IIV4=quadrivalent inactivated influenza vaccine RIV4=quadrivalent recombinant influenza vaccine LAIV4=quadrivalent live attenuated influenza vaccine									
	Not approved for age group Egg-based Not egg-based 5								

* Preferred for those aged \geq 65 years

U.S. Influenza Vaccine Composition, 2023-24

- All vaccines available in the U.S. are quadrivalent.
- The 2023-24 composition includes updated influenza A(H1N1)pdm09 components.
- All U.S.-licensed influenza vaccines will include hemagglutinin derived from:
 - An influenza A/Victoria/4897/2022 (H1N1)pdm09-like virus (egg-based vaccines) or an influenza A/Wisconsin/67/2022 (H1N1)pdm09-like virus (cell-based and recombinant vaccines)
 - An influenza A/Darwin/9/2021 (H3N2)-like virus (egg-based vaccines) or an influenza A/Darwin/6/2021 (H3N2)-like virus (cell-based and recombinant vaccines)
 - An influenza B/Austria/1359417/2021-like virus (B/Victoria lineage)
 - An influenza B/Phuket/3073/2013-like virus (B/Yamagata lineage)

Egg Allergy—Background

- Affects approximately 1-3% of children by age 3 years.
- Resolves for many in later childhood/adolescence (~68% by age 16 years).
- Severe allergic reaction to any vaccine component is listed as a contraindication in package inserts for egg-based influenza vaccines.
- However, ACIP has recommended previously that all with egg allergy should receive any influenza vaccine appropriate for age and health status (egg based or non-egg based).
- Up until this season, those with severe egg allergy recommended to be vaccinated in a medical setting if an egg-based vaccine used.

Influenza Vaccines and Egg Allergy: AAP, AAAAI, ACAAI

- American Academy of Pediatrics
 - Since 2016-17, no additional measures recommended for persons with egg allergy.¹
 - "Children with egg allergy can receive any influenza vaccine without any additional precautions beyond those recommended for all vaccines."²
 - Measures related to use of specific vaccines, observation periods, or restricting vaccination to specific medical settings not warranted and constitute a barrier to vaccination.³
 - Not necessary to inquire about or screen for egg allergy prior to influenza vaccination.³
- Joint Task Force, AAAAI/ACAAI
 - "No special precautions beyond those recommended for the administration of any vaccine to any patient are necessary for administration of influenza vaccine to egg allergic individuals."⁴

^{1. &}lt;u>Recommendations for Prevention and Control of Influenza in Children, 2016–2017 | Pediatrics | American Academy of Pediatrics (aap.org)</u>

^{2.} Recommendations for Prevention and Control of Influenza in Children, 2022–2023 | Pediatrics | American Academy of Pediatrics (aap.org).

^{3.} AAP. Technical Report for the 2022-23 Recommendations for the Prevention and Control of Influenza in Children, 2022-23

^{4.} Greenhawt M et al. Ann Allergy Asthma Immunol 2018;120:49-52.

General Best Practices Guidelines for Immunization

- From chapter titled "Preventing and Managing Adverse Reactions":
 - "Although allergic reactions are a common concern for vaccine providers, these reactions are uncommon and anaphylaxis following vaccines is rare, occurring at a rate of approximately one per million doses for many vaccines. Epinephrine and equipment for managing an airway should be available for immediate use."

Review of Influenza Vaccines in Egg Allergy

- Among 31 studies describing administration of seasonal and monovalent H1N1pdm09 influenza vaccines to people with egg allergy, there were no instances of anaphylaxis.
- Less severe reactions involving cardiovascular symptoms, respiratory symptoms, angioedema, or generalized urticaria, or which involved treatment with medications or outpatient/emergency department attention occurred with low frequency (≤1.5%).

Egg Allergy—Update for 2023-24

- As previously, all people aged ≥6 months with egg allergy should receive influenza vaccine.
 - Any influenza vaccine (egg based or non-egg based) that is otherwise appropriate for the recipient's age and health status can be used.
- New: Following a review of safety data, previous recommendations for vaccination setting for those with severe egg allergy have been removed.
- Egg allergy in and of itself necessitates no additional safety measures for influenza vaccination beyond those recommended for any recipient of any vaccine, regardless of severity of previous reaction to egg.
 - All vaccines should be administered in settings in which personnel and equipment needed for rapid recognition and treatment of acute hypersensitivity reactions are available.

Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023– 24 Influenza Season | MMWR (cdc.gov)

Thanks!

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