2024-2025 Respiratory Season Immunization Updates and Recommendations

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Disclosures

I have nothing to disclose concerning possible financial relationships with ineligible companies that may have a direct or indirect interest in the subject matter of this presentation.

Objectives

- Describe the influenza vaccination recommendations for the upcoming season.
- Describe the recommendations for COVID-19 vaccination.
- Describe the RSV prevention products that are available and understand their recommendations for use.

Make-up of 24/25 influenza vaccines

- No confirmed detections of wild-type influenza B/Yamagata lineage viruses in global surveillance since March 2020
- 2024–25 U.S. influenza vaccines will not include an influenza B/Yamagata component
- All influenza vaccines available in the United States during the 2024–25 season will be trivalent vaccines

https://www.cdc.gov/flu/media/pdfs/2024/08/acip-2024-25-summary-of-recommendations.pdf
https://www.immunize.org/wp-content/uploads/catg.d/p4072.pdf

Depending on Source 24/25

U.S. egg-based influenza vaccines

- An influenza A/Victoria/4897/2022 (H1N1)pdm09-like virus
- An influenza A/Thailand/8/2022 (H3N2)-like virus
- An influenza B/1359417/2021 (Victoria's lineage)-like virus

U.S. cell culture-based (ccIIV3) & recombinant (RIV3)

- An influenza A/Wisconsin/67/2022 (H1N1)pdm09-like virus
- An influenza A/Massachusetts/18/2022 (H3N2)-like virus
- An influenza B/Austria/1359417/2021 (Victoria's lineage)-like virus

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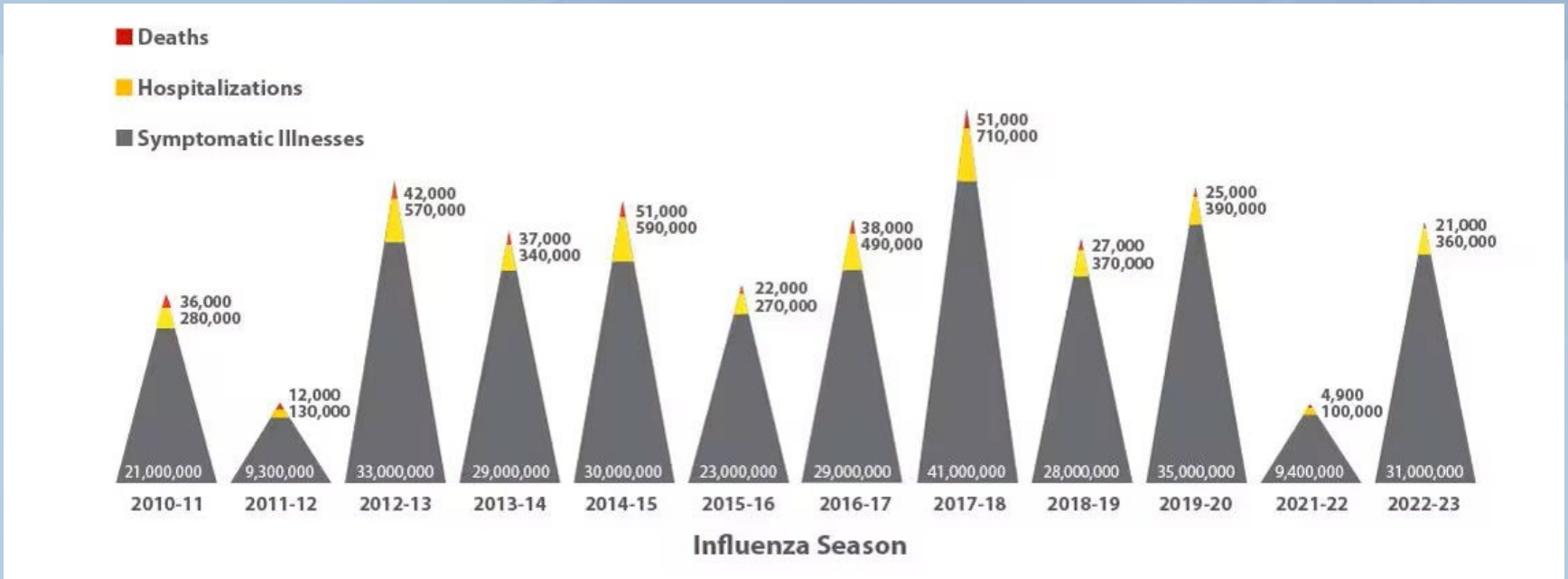
Flu Burden



Estimated U.S. Flu Burden, By Season CDC

Who is at greatest risk from influenza?

- Children under 5 years
- Adults 50 years and older
- Pregnant people
- Alaska Natives and American Indians
- Residents of nursing homes or other long-term care facilities
- Medical conditions that increase a person's risk of severe influenza include: chronic pulmonary (including asthma), cardiovascular (excluding isolated hypertension), renal, hepatic, neurologic, hematologic, or metabolic disorders (including diabetes mellitus)
- Immunocompromising conditions due to any cause (including, but not limited to, immune suppression caused by medications or HIV);
- Extreme obesity (body mass index of 40 or greater for adults);
- Chronic use of aspirin- or salicylate-containing medications in children through age 18 (due to the risk of Reye syndrome after influenza infection)

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Who is recommended to get vaccinated against influenza?

- ACIP/CDC recommends annual vaccination for all people ages 6 months and older who do not have a contraindication to influenza vaccination
- ACIP now recommends high-dose inactivated influenza vaccine (HD-IIV) or adjuvanted inactivated (aIIV) influenza vaccine (each licensed by FDA for people age 65 years or older) as acceptable options for influenza vaccination of solid organ transplant recipients 18 through 64 years who are on immunosuppressive medication regimens. There is no preference for aIIV or HD-IIV over any other age-appropriate inactivated or recombinant influenza vaccine in this group.
- The HD-IIV vaccine, which is now trivalent, is given at a dose of 0.5 mL

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What influenza vaccines products are available for the 24/25 season?

Manufacturer	Trade Name (vaccine abbreviation)[1]	How Supplied	Mercury Content (mcg Hg/0.5mL)	Age Range	CVX Code	Vaccine Product Billing Code[2] CPT
AstraZeneca	FluMist (LAIV3)	0.2 mL (single-use nasal spray)	0	2 through 49 years	111	90660
GSK	Fluarix (IIV3)	0.5 mL (single-dose syringe)	0	6 months & older[3]	140	90656
	FluLaval (IIV3)	0.5 mL (single-dose syringe)	0	6 months & older[3]	140	90656
Sanofi	Flublok (RIV3)	0.5 mL (single-dose syringe)	0	18 years & older	155	90673
	Fluzone (IIV3)	0.5 mL (single-dose syringe)	0	6 months & older[3]	140	90656
		0.5 mL (single-dose vial)	0	6 months & older[3]	140	90656
		5.0 mL multi-dose vial (0.25 mL dose)	25	6 through 35 months[3]	141	90657
		5.0 mL multi-dose vial (0.5 mL dose)	25	6 months & older	141	90658
	Fluzone High-Dose (HD-IIV3)	0.5 mL (single-dose syringe)	0	65 years & older[4]	135	90662
CSL Seqirus	Afluria (IIV3)	5.0 mL multi-dose vial (0.25 mL dose)	24.5	6 through 35 months[3]	141	90657
		5.0 mL multi-dose vial (0.5 mL dose)	24.5	3 years & older[5]	141	90658
		0.5 mL (single-dose syringe)	0	3 years & older[3]	140	90656
	Fluad (aIIV3)	0.5 mL (single-dose syringe)	0	65 years & older[4]	168	90653
	Flucelvax (ccIIV3)	0.5 mL (single-dose syringe)	0	6 months & older[3]	153	90661
		5.0 mL multi-dose vial (0.5 mL dose)	25	6 months & older[3]	320	90661

NOTES

1. All 2024–2025 seasonal influenza vaccines are trivalent. IIV = egg-based inactivated influenza vaccine (injectable); where necessary to refer to cell culture-based vaccine, the prefix "cc" is used (e.g., ccIIV); RIV = recombinant hemagglutinin influenza vaccine (injectable); aIIV = adjuvanted inactivated influenza vaccine.
2. An administration code should always be reported in addition to the vaccine product code. Note: Third party payers may have specific policies and guidelines that might require providing additional information on their claim forms.
3. Dosing for infants and children age 6 through 35 months:
   - Afluria 0.25 mL
   - Fluarix 0.5 mL
   - Flucelvax 0.5 mL
   - FluLaval 0.5 mL
   - Fluzone 0.25 mL or 0.5 mL
4. Solid organ transplant recipients age 18 through 64 years who are on immunosuppression medication regimens may receive HD-IIV influenza vaccine as options for influenza vaccination, without a preference over other age-appropriate IIVs or RIVs.
5. Afluria is approved by the Food and Drug Administration for intramuscular administration with the PharmaJet Stratis Needle-Free Injection System for persons age 18 through 64 years.

https://www.immunize.org/wp-content/uploads/catg.d/p4072.pdf

Who should get what flu vaccine?

- Age 6 month to 64 years CDC recommends any available age-appropriate influenza vaccine product
- Age 65 years and older CDC preferentially recommends:
  - Fluzone High-Dose (HD-IIV, Sanofi), Flublok recombinant (RIV, Sanofi), and Fluad adjuvanted (aIIV, CSL Seqirus)
- Solid organ transplant recipients (SOTRs) age 18 years through 64 years have the option of receiving HD-IIV or aIIV, both of which are licensed for people age 65 years or older, however, not preferential

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When should flu vaccination be offered?

- Most groups should be offered vaccination in September and October and continue vaccinating as long as influenza is circulating
- Specific groups to consider:
  - Most adults and pregnant persons in 1st/2nd trimester, avoid immunization in July/August unless later vaccination might not be possible
  - Children 6 months – 8 years who need 2 doses can be vaccinated as soon as a dose is available
  - Pregnant in 3rd trimester can be vaccinated in July/August

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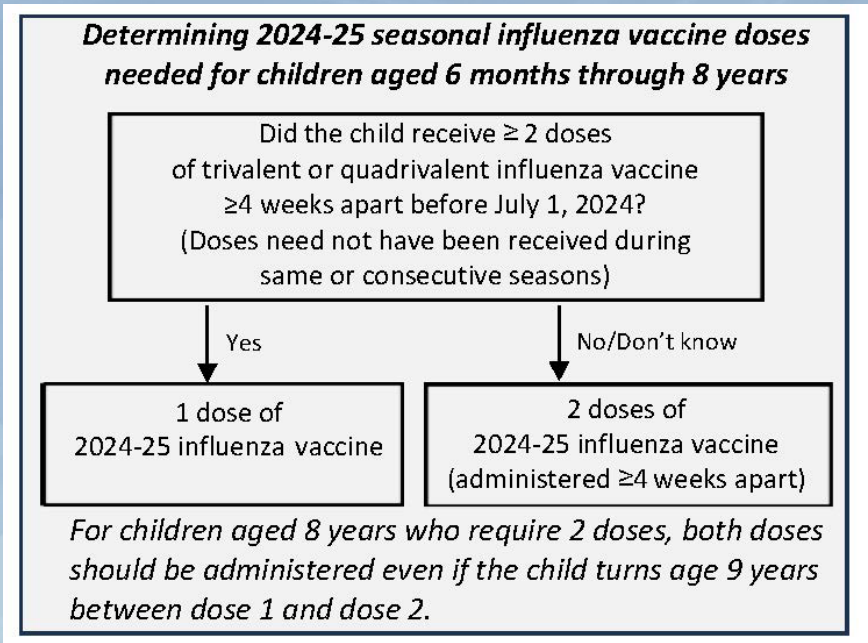
Who needs 2 doses of influenza vaccine?

- Persons aged 9 years and over only need one dose.
- Determine the number of needed doses based on the child's age at the time of the first dose and the number of doses of influenza vaccine received in previous seasons.



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Persons with Egg Allergies

- Studies indicate that egg-allergic persons are NOT at increased risk of severe allergic reaction to egg-based influenza vaccines
- Therefore, any age-appropriate influenza vaccine can be used for a person with an egg allergy
- No additional safety measures are recommended as all vaccines should be administered in settings which have appropriate personnel and equipment to handle rapid recognition and treatment of acute allergic reactions

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https://www.immunize.org/wp-content/uploads/catg.d/p4072.pdf

Flu vaccine and travelers

- All travelers should ensure vaccination at least 2 or more weeks prior to departure
- Travel to Southern hemisphere may not be covered by Northern hemisphere flu vaccine and the southern hemisphere vaccine may not be available in U.S.

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Contraindications/Precautions for Specific Flu Vaccines

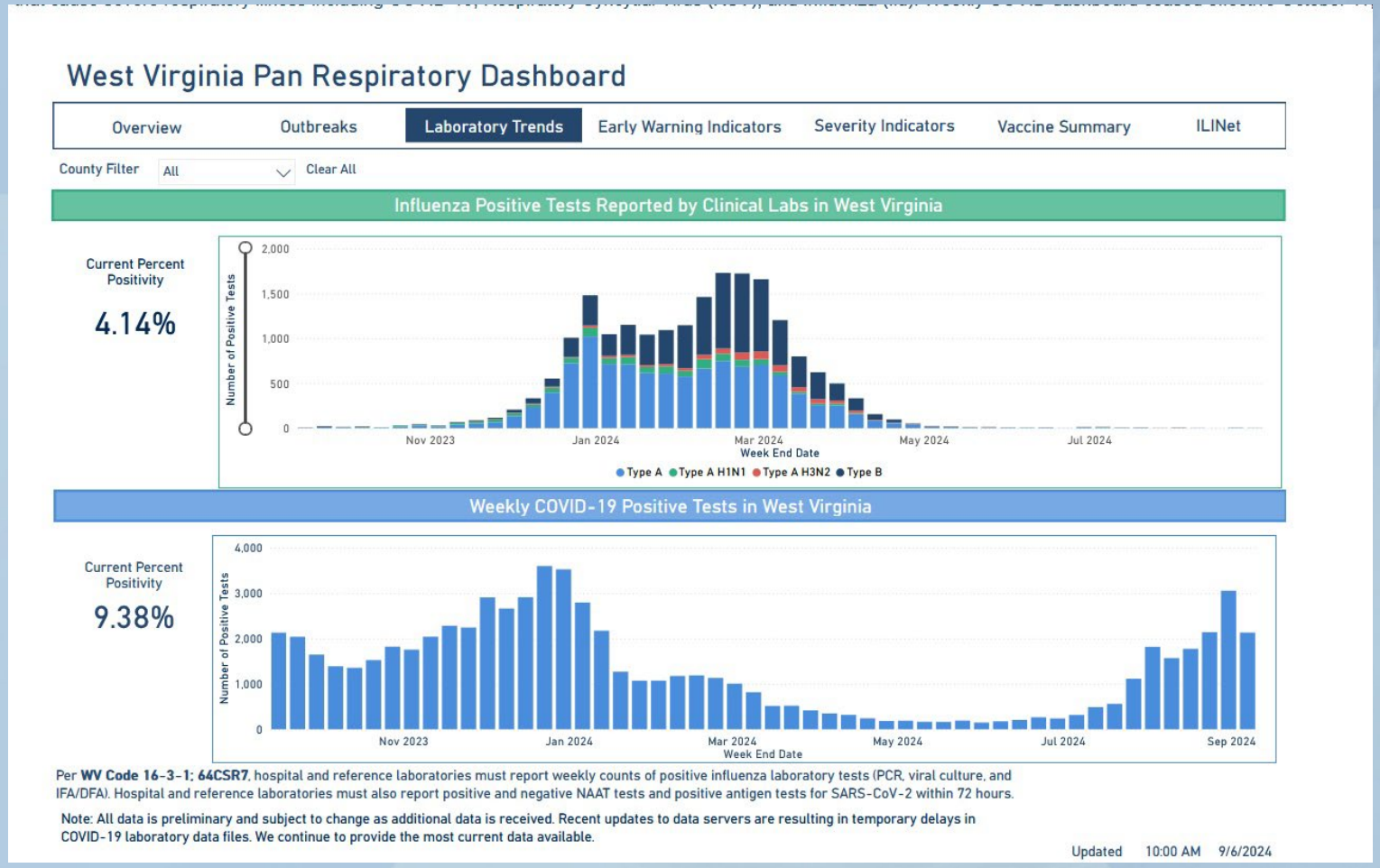
Influenza Vaccine Contraindications and Precautions	
Egg-based IIV3	C: History of severe reaction (anaphylaxis) to any influenza vax P: Moderate/Severe illness; Hx of GBS within 6 weeks of influenza vaccine
ccIIV3	C: History of severe reaction (anaphylaxis) to ccIIV of any valency or vax component P: Moderate/Severe illness; Hx of GBS within 6 weeks of influenza vaccine; History of severe reaction (anaphylaxis) to any influenza vax
RIV3	C: History of severe reaction (anaphylaxis) to RIV of any valency or vax component P: Moderate/Severe illness; Hx of GBS within 6 weeks of influenza vaccine; History of severe reaction (anaphylaxis) to any influenza vax
LAIV3	History of severe reaction (anaphylaxis) to any flu vax; concomitant aspirin of salicylate in children or adolescents; children 2-4 yrs with asthma; children or adults who are immunocompromised; close contacts of severely immunocompromised; persons with active communication with CSF & the oropharynx, nasopharynx or any other CSF leak; Persons with cochlear implants; Receipt of antiviral medication within the previous 48 hours (oseltamivir/zanamivir) or 5 days (peramivir) 17 days (baloxavir) P: Moderate/Severe illness; Hx of GBS within 6 weeks of influenza vaccine; Asthma in person≥ 5 years; other medical condition that could predispose complications from influenza

C=Contraindication P=Precaution GBS= Guillain-Barre syndrome

https://www.cdc.gov/flu/media/pdfs/2024/08/acip-2024-25-summary-of-recommendations.pdf

COVID-19 24/25 Vaccines

Current Respiratory Trends WV



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COVID-19 2024/2025

- Three products were approved for the 2024/2025 season
- mRNA vaccines
  - Moderna COVID-19 Vaccine (2024–2025 Formula) is authorized for children ages 6 months–11 years; SPIKEVAX is the licensed Moderna product for people ages 12 years and older. These vaccines are hereafter referred to as 2024–2025 Moderna COVID-19 Vaccine.
  - Pfizer-BioNTech COVID-19 Vaccine (2024–2025 Formula) is authorized for children ages 6 months–11 years; COMIRNATY is the licensed Pfizer-BioNTech product for people ages 12 years and older. These vaccines are hereafter referred to as 2024–2025 Pfizer-BioNTech COVID-19 Vaccine.
- Protein subunit vaccine
  - Novavax COVID-19 Vaccine, Adjuvanted (2024–2025 Formula) is authorized for people ages 12 years and older. It is hereafter referred to as 2024–2025 Novavax COVID-19 Vaccine

CDC Interim Clinical Considerations for COVID-19 Vaccines https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html
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https://www.fda.gov/media/167211/download?attachment

Composition of COVID-19 24/25 vaccines

- Monovalent vaccine based on the Omicron JN.1-lineage of SARS-CoV-2, as follows:
- Moderna and Pfizer-BioNTech: KP.2 strain
- Novavax: JN.1 strain

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https://www.fda.gov/media/167208/download?attachment
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Pfizer BioNTech COVID-19 2024/2025 Vaccine

- How Supplied:
  - COMIRNATY (30 mcg/0.3mL glass pre-filled syringe presentation) is indicated for individuals 12 years of age and older.
  - Pfizer-BioNTech COVID-19 Vaccine is indicated for individuals 5 through 11 years of age (via a 10mcg / 0.3mL single-dose vial presentation) and for individuals 6 months through 4 years of age (via a 3mcg / 0.3mL multi-dose vial (3 doses per vial) presentation).
- Storage:
  - Multi-dose and Single dose vials: store frozen ultra-cold temperatures; once the vials are thawed, the multi-dose and single-dose vials must be stored refrigerated
  - Glass single dose prefilled syringes: ages 12 and older must be stored refrigerated (between 2°C and 8°C); DO NOT FREEZE. The total time out of refrigeration (at temperatures between 8°C and 25°C) must not exceed 12 hours
- Only the 6 month- 4 year requires dilution with 1.1 mL of sterile 0.9% Sodium Chloride Injection, USP. Reconstitution is required only for the Pfizer-BioNTech COVID-19 Vaccine for individuals 6 months through 4 years of age in multi-dose vials

https://www.cdc.gov/vaccines/php/info-by-product/pfizer-covid-19-summary.html#cdc_generic_section_3-storage-requirements

Pfizer BioNTech COVID-19 2024/2025 Vaccine Shelf-life

Shelf Life	6 months through 4 years	5 years through 11 years	12 and older
Unopened, frozen vaccine	Once received, frozen vials may be stored in an ultra-low temperature freezer at -90°C to -60°C until the expiration date printed on the vials and cartons. Do not store vials at -25°C to -15°C. Once vials are thawed, they should not be refrozen.		DO NOT FREEZE.
Unopened, refrigerated vaccine	Once received, frozen vials may be immediately transferred to the refrigerator [2°C to 8°C], thawed and stored for up to 10 weeks, not to exceed the expiration date printed on the vial and cartons. If vials and cartons are received at 2°C to 8°C, they should be stored at 2°C to 8°C. Check that the carton has been updated to reflect the 10-week refrigerated expiry date, not to exceed the expiration date printed on the vial and cartons.		The vaccine may be stored at 2°C to 8°C until the expiration date printed on the carton and syringe labels (not to exceed 8 months). DO NOT FREEZE.
Opened, refrigerated vaccine	If not previously thawed at 2°C to 8°C, allow multi-dose vials or single dose vials to thaw at room temperature [up to 25°C (77°F)] for 30 minutes. Multi-dose or single dose vials may be stored at room temperature [8°C to 25°C] for a total of 12 hours prior to the first puncture. After dilution, multiple dose vials should be held between 2°C to 25°C. Multi-dose vials should be discarded 12 hours after dilution.		After removing the tip cap and attaching an appropriate needle, the glass prefilled syringe should be used immediately. If it cannot be used immediately, it must be used within 4 hours. DO NOT FREEZE.
Opened, room temperature vaccine	If not previously thawed at 2°C to 8°C, allow multi-dose vials or single dose vials to thaw at room temperature [up to 25°C (77°F)] for 30 minutes. Multi-dose or single dose vials may be stored at room temperature [8°C to 25°C] for a total of 12 hours prior to the first puncture. After dilution, multiple dose vials should be held between 2°C to 25°C. Multi-dose vials should be discarded 12 hours after dilution.		After removing the tip cap and attaching an appropriate needle, the glass prefilled syringe should be used immediately. If it cannot be used immediately, it must be used within 4 hours. DO NOT FREEZE.

https://www.cdc.gov/vaccines/php/info-by-product/pfizer-covid-19-summary.html#cdc_generic_section_3-storage-requirements

Moderna COVID-19 2024-2025 Vaccine

- How supplied:
  - Spikevax: Carton of 10 single dose pre-filled syringes, each syringe containing
  - 1 dose of 0.5 mL
  - Moderna COVID-19 2024/2025: Carton of 10 single dose pre-filled syringes, each syringe containing 1 dose of 0.25 mL
- Storage:
  - Store frozen between -50°C to -15°C (-58°F to 5°F). After thawing, may be stored refrigerated between 2°C to 8°C (36°F to 46°F) for up to 60 days or up to the expiration date printed on the carton, whichever comes first. After thawing, may be stored between 8°C to 25°C (46°F to 77°F) for up to 12 hours.
- No reconstitution

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https://www.fda.gov/media/155675/download?attachment

Novavax COVID-19 2024/2025

- Authorized under Emergency Use Authorization
- Administer the 0.5 mL dose of Novavax COVID-19 Vaccine, Adjuvanted intramuscularly
- Ages 12 years and up
- Similar Side effects to mRNA; Evidence of GBS
- Supplied: Carton containing 10 single-dose pre-filled syringes. Each pre-filled syringe (NDC 80631-107-01) contains 1 dose of 0.5 mL
- Store single-dose pre-filled syringes in a refrigerator between 2 to 8°C (36 to 46°F).

https://www.fda.gov/media/159897/download?attachment

Recommendation for those NOT immunocompromised

Initial Vaccination

- Ages 6 months–4 years
  - 2 doses of 2024–2025 Moderna **OR**
  - 3 doses of 2024–2025 Pfizer-BioNTech
- Ages 5–11 years
  - 1 dose of 2024–2025 Moderna **OR**
  - 1 dose of 2024–2025 Pfizer-BioNTech
- Ages 12 years and older
  - 1 dose of 2024–2025 Moderna **OR**
  - 1 dose of 2024–2025 Pfizer-BioNTech **OR**
  - 2 doses of 2024–2025 Novavax

Received a previous COVID-19 vaccine dose

- Ages 6 months–4 years
  - 1 or 2 doses of 2024–2025 mRNA vaccine from the same manufacturer as administered for initial vaccination, depending on the vaccine and the number of prior doses
- Ages 5–11 years
  - 1 dose of 2024–2025 Moderna **OR**
  - 1 dose of 2024–2025 Pfizer-BioNTech
- Ages 12 years and older
  - 1 dose of 2024–2025 Moderna **OR**
  - 1 dose of 2024–2025 Pfizer-BioNTech **OR**
  - 1 dose of 2024–2025 Novavax

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COVID-19 Vaccine recommendations for not immunocompromised ages 6 month-4 years

Pfizer-BioNTech

Individuals 6 Months Through 4 Years of Age by Pfizer-BioNTech COVID-19 Vaccination Status

Number of Previous Doses of Pfizer-BioNTech COVID-19 Vaccine(s)[a]	Pfizer-BioNTech COVID-19 Vaccine, (2024-2025 Formula) Vial Cap and Label Border Color	Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula) Dosing Regimen, Dose and Schedule[b]
0[c]	Yellow	3 doses[d], 0.3 mL each Dose 1: Week 0 Dose 2: Week 3 Dose 3: ≥8 weeks after Dose 2
1	Yellow	2 doses[d], 0.3 mL each Dose 1: 3 weeks after receipt of the previous dose of Pfizer-BioNTech COVID-19 Vaccine[a] Dose 2: ≥8 weeks after Dose 1
≥2	Yellow	Single dose, 0.3 mL ≥8 weeks after receipt of the last previous dose of Pfizer-BioNTech COVID-19 Vaccine[a]

a. Previous dose refers to a dose of any prior Pfizer-BioNTech COVID-19 Vaccine that is no longer authorized for use in the United States.
b. For individuals with certain kinds of immunocompromise previously vaccinated with Pfizer-BioNTech COVID-19 vaccines, see text below tables for dosing information.
c. Not previously vaccinated with any COVID-19 vaccine.

Moderna

Individuals 6 Months Through 4 Years of Age by Moderna COVID-19 Vaccination Status (2.3)

Number of Previous Doses of Moderna COVID-19 Vaccine(s)[a]	Moderna COVID-19 Vaccine (2024-2025 Formula) Dosing Regimen, Dose and Schedule[b]
0[c]	2 doses,[d] 0.25 mL each Dose 1: month 0 Dose 2: month 1
1	Single Dose, 0.25 mL One month after receipt of a previous dose of Moderna COVID-19 vaccine[a]
≥2	Single dose, 0.25 mL ≥2 months after receipt of the last previous dose of Moderna COVID-19 vaccine[a]

[a] Previous dose refers to a dose of any prior Moderna COVID-19 Vaccine that is no longer authorized for use in the United States.
[b] For individuals with certain kinds of immunocompromise previously vaccinated with a Moderna COVID-19 vaccine, see text following the tables for dosing information.
[c] Not previously vaccinated with any COVID-19 vaccine.
[d] Individuals turning from 4 years to 5 years of age during the vaccination series should receive both doses with Moderna COVID-19 Vaccine (2024-2025 Formula).

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https://www.fda.gov/media/167211/download?attachment
CDC Interim Clinical Considerations for COVID-19 Vaccines https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html

COVID-19 Vaccine recommendations for not immunocompromised ages 5 -11 years

Pfizer-BioNTech

Individuals 5 Years Through 11 years of Age Irrespective of COVID-19 Vaccination Status

Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula) Vial Cap and Label Border Color	Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula) Dosing Regimen, Dose and Schedule[a]
Blue	Single dose, 0.3 mL (If previously vaccinated, administer the dose ≥2 months after receipt of the last previous dose of COVID-19 vaccine)[b]

a. For individuals with certain kinds of immunocompromise, see text below tables for dosing information.
b. Previous dose refers to a dose of any prior COVID-19 vaccine that is no longer authorized for use in the United States.

Moderna

Individuals 5 Years Through 11 Years of Age Irrespective of COVID-19 Vaccination Status (2.3)

Moderna COVID-19 Vaccine (2024-2025 Formula) Dosing Regimen, Dose and Schedule[a]
Single dose, 0.25 mL (If previously vaccinated, administer the dose ≥2 months after receipt of the last previous dose of COVID-19 vaccine[b])

[a] For individuals with certain kinds of immunocompromise, see text below tables for further dosing information.
[b] Previous dose refers to a dose of any prior COVID-19 vaccine that is no longer authorized for use in the United States.

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https://www.fda.gov/media/167211/download?attachment

Transitioning from a younger age group to an older age group during

- Receive the age-appropriate vaccine product and dose based on their age the day of the vaccination
- the option to administer a lower dosage is no longer authorized

CDC Interim Clinical Considerations for COVID-19 Vaccines
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https://www.fda.gov/media/167211/download?attachment

Who is considered moderate to severely immunocompromised?

- Including but not limited to:

- Active treatment for solid tumor and hematologic malignancies
- Hematologic malignancies associated with poor responses to COVID-19 vaccines regardless of current treatment status (e.g., chronic lymphocytic leukemia, non-Hodgkin lymphoma, multiple myeloma, acute leukemia)
- Receipt of solid-organ transplant or an islet 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., common variable immunodeficiency disease, severe combined immunodeficiency, DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced HIV infection (people with HIV and CD4 cell counts less than 200/mm^3, history of an AIDS-defining illness without immune reconstitution, or clinical manifestations of symptomatic HIV) or untreated HIV infection
- Active treatment with high-dose corticosteroids (i.e., 20 mg or more of prednisone or equivalent per day when administered for 2 or more weeks), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor necrosis factor (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory (e.g., B-cell-depleting agents)

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Multiple Vaccine Administration

- COVID-19 vaccines may be administered without regard to timing of other vaccines. This includes simultaneous administration of COVID-19 vaccine and other vaccines on the same day.
  - Providers may simultaneously administer COVID-19, influenza, and respiratory syncytial virus (RSV) vaccines to eligible patients; the Health Alert Network (HAN) published on September 5, 2023 may be consulted for additional information about simultaneous administration of these vaccines.
  - Simultaneous administration of COVID-19 vaccine and nirsevimab (a long-acting monoclonal antibody for certain infants and young children for prevention of RSV) is recommended
  - Coadministration of COVID-19 and RSV vaccine for older adults is acceptable
  - There are additional considerations if administering an orthopoxvirus vaccine and COVID-19 vaccine
- If multiple vaccines are administered at a single visit, administer each injection in a different injection site, according to recommendations by age.
  - Separate injection sites by 1 inch or more.
  - For older children (≥11 years), the deltoid muscle can be used.
  - For younger children, if more than 2 vaccines are injected in a single limb, the vastus lateralis muscle of the anterolateral thigh is the preferred site because of greater muscle mass.

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Considerations for Revaccination

- Recipients of HCT or CAR-T-cell therapy \
- Revaccination may also be considered for patients who received 1 or more doses of COVID-19 vaccine during treatment with B-cell-depleting therapies
- Case by case basis for those with on-going immunocompromising therapy

CDC Interim Clinical Considerations for COVID-19 Vaccines https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html
https://www.fda.gov/media/167208/download?attachment
https://www.fda.gov/media/167211/download?attachment

Interchangeability of COVID-19 Vaccines

- For ages 5 years and over no special consideration is needed.
- Any of these situations it is acceptable to administer vaccines from different manufacturers:
  - Same vaccine not available at the time of the clinic visit
  - Previous dose unknown
  - Person would otherwise not receive a recommended vaccine dose
  - Person starts but unable to complete a vaccination series with the same COVID-19 vaccine due to a contraindication

CDC Interim Clinical Considerations for COVID-19 Vaccines https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html
https://www.fda.gov/media/167208/download?attachment
https://www.fda.gov/media/167211/download?attachment

Interchangeability of COVID-19 Vaccines

- mRNA
  - *Children ages 6 months–4 years*
    - The second dose is administered 4–8 weeks after the first dose.
    - The third dose of either 2024–2025 Moderna vaccine or 2024–2025 Pfizer-BioNTech vaccine is administered at least 8 weeks after the second dose.
  - *People ages 6 months and older who are moderately or severely immunocompromised*
  - The second dose is administered 4 weeks after the first dose.
  - The third dose of either 2024–2025 Moderna vaccine or 2024–2025 Pfizer-BioNTech vaccine is administered as follows:
    - Ages 6 months–4 years: at least 8 weeks after the second dose
    - Ages 5 years and older: at least 4 weeks after the second dose
- Novavax
  - 12 years and older who initiate vaccination with Novavax should receive a 2nd Novavax dose to complete the series. However, if more than 8 weeks have passed since the initial dose, any 24/25 COVID-19 vaccine can be administered

CDC Interim Clinical Considerations for COVID-19 Vaccines https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html
https://www.fda.gov/media/167208/download?attachment
https://www.fda.gov/media/167211/download?attachment

Expected Adverse Effects Covid-19 Vaccines

It is recommended that everyone ages 6 months and older stays up-to-date on COVID-19 vaccination

Anticipated side effects (children, adolescents, and adults):

- Local: pain, swelling, erythema at the injection site
- Systemic: fever, fatigue, headache, chills, myalgia, arthralgia, lymphadenopathy

- Younger children (6 months to 5 years):
  - Local: pain, tenderness at the injection site
  - Systemic: fatigue, irritability/crying and drowsiness/sleepiness

https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2023-09-12/11-COVID-Wallace-508.pdf
https://www.fda.gov/media/151707/download?attachment

Adverse Effects

- Myocarditis/Pericarditis
  - Seen most frequently in males ages 12-39 years within 7 days after receiving the 2nd dose
  - Risk estimates of myocarditis/pericarditis in 18–39-year-olds during days 0-7 after 2 doses were modestly higher after Moderna than after Pfizer
- Guillain-Barre After COVID-19 Vaccination
  - No evidence of association between GBS and mRNA-based COVID-19 vaccines
  - Findings were consistent with an association between increased risk of GBS and Janssen COVID-19 vaccine

https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2023-09-12/07-COVID-Klein-508.pdf

Respiratory Syncytial Virus(RSV) Vaccines

Who is most at risk for RSV?

- Very young and the very old (esp over 75 years)
- Older adults: U.S. adults age 65 and older, RSV is responsible for approximately 60,000 to 160,000 hospitalizations and 6,000 to 10,000 deaths each year
- Infants: 50,000–80,000 RSV-associated hospitalizations and 100–300 RSV-associated deaths occur each year among U.S. infants and children younger than age 5 years

3 Current RSV Vaccines Approved in US

- All 3 have indication for prevention of RSV-associated lower respiratory tract disease (LRTD) in adults 60 age years and older
  - RSVPreF3 (Arexvy, GSK) – recombinant protein vaccine
  - RSVpreF (Abrysvo, Pfizer) - recombinant protein vaccine
    - licensed for use during pregnancy (during 32 through 36 weeks and 6 days' gestation) September through January; currently only initial pregnancy not upon repeated pregnancy
  - mRNA RSV (mResvia, Moderna)

RSVPreF3 (Arexvy, GSK)

- A single-dose vial of lyophilized antigen component (powder) and a single-dose vial of adjuvant suspension component, includes an AS01adjuvant, (liquid)
- Must be reconstituted
- Before reconstitution: Store vaccine and diluent refrigerated between 2°C and 8°C (36°F and 46°F) in original packaging
- Administer immediately or store in the refrigerator between 2°C and 8°C (36°F to 46°F) or at room temperature [up to 25°C (77°F)] for up to 4 hours prior to use.

RSVpreF vaccine (Abrysvo, Pfizer)

- consists of a recombinant RSV F protein antigen (based on both the RSV-A and RSV-B subtypes)
- a single-dose vial of 120 µg of lyophilized preF antigen component (60 µg from RSV-A, 60 µg from RSV-B) to be reconstituted with the accompanying vial of sterile water diluent component
- Pfizer's vaccine is supplied in a kit with three components:
  - Vial of Lyophilized Antigen Component (a sterile white powder)
  - Prefilled syringe containing Sterile Water Diluent Component
  - Vial adapter: Refer to the manufacturer's package insert for specific instructions on reconstituting the vaccine: Package Insert – ABRYSVO (fda.gov)
- Before reconstitution: Store vaccine and diluent refrigerated between 2°C and 8°C (36°F and 46°F) in original packaging
- After reconstitution: Immediately administer the vaccine; you should prepare the vaccine only when ready for use. If you do not immediately administer the vaccine, there are some minor differences in storage: Store the reconstituted vaccine ONLY at room temperature (15°C to 30°C / 59°F to 86°F).Do NOT refrigerate.
- Once you've reconstituted the vaccine, you have 4 hours to use the vaccine before it must be discarded

Healthcare Providers: RSV Vaccination for Pregnant People https://www.cdc.gov/vaccines/vpd/rsv/hcp/pregnant-people.html#:~:text=CDC%20recommends%20one%20dose%20of,32%20through%2036%20weeks%20pregnant.

RSVpreF vaccine (Abrysvo, Pfizer)

- Administration: intramuscular injection in the deltoid
- Sufficient evidence does not exist at this time to determine the need for additional doses in subsequent pregnancies.
- Pregnant people can receive RSV, Tdap, COVID-19, and influenza vaccines at the same clinic visit when the vaccines are recommended.
- Contraindication: history of severe allergic reaction, such as anaphylaxis, to any component of this vaccine
- Precaution: Moderate or severe acute illness, with or without fever, vaccination should generally be deferred until the patient improves

Healthcare Providers: RSV Vaccination for Pregnant People https://www.cdc.gov/vaccines/vpd/rsv/hcp/pregnant-people.html#:~:text=CDC%20recommends%20one%20dose%20of,32%20through%2036%20weeks%20pregnant.

Efficacy of RSVpreF vaccine (Abrysvo, Pfizer)

- Maternal RSV vaccine:
  - reduced the risk of the baby being hospitalized for RSV by 68% and having a healthcare visit for RSV by 57% within 3 months after birth
  - Reduced the risk of the baby being hospitalized for RSV by 57% and having a healthcare visit for RSV by 51% within 6 months after birth
  - reduced the risk of severe RSV disease by 82% within 3 months and by 69% within 6 months after birth

Healthcare Providers: RSV Vaccination for Pregnant People https://www.cdc.gov/vaccines/vpd/rsv/hcp/pregnant-people.html#:~:text=CDC%20recommends%20one%20dose%20of,32%20through%2036%20weeks%20pregnant.

mResvia (mRNA RSV vaccine)

- Comes as a prefilled syringe with frozen suspension to be thawed prior to administration
- contains mRNA that encodes the prefusion form of the RSV F glycoprotein
- Frozen Storage Store frozen between -40°C to -15°C (-40°F to 5°F).

- Storage after Thawing Storage at 2°C to 8°C (36°F to 46°F):
  - Pre-filled plastic syringes may be stored refrigerated between 2°C to 8°C (36°F to 46°F) for up to 30 days prior to use. Storage at 8°C to 25°C (46°F to 77°F):
  - Pre-filled plastic syringes may be stored between 8°C to 25°C (46°F to 77°F) for a total of 24 hours after removal from refrigerated conditions. Discard the pre-filled syringe if not used within this time. Syringes should not be returned to the refrigerator after being thawed at room temperature.
- Total storage at 8°C to 25°C (46°F to 77°F) must not exceed 24 hours.
- Do not refreeze once thawed. Do not shake.

https://static.modernatx.com/pm/6cef78f8-8dad-4fc9-83d5-d2fbb7cff867/36130c97-6fb0-4bea-9f2e-fb5be7a90729/36130c97-6fb0-4bea-9f2e-fb5be7a90729_viewable_rendition__v.pdf

Recommendations for RSV Vaccine (these are changes from last season)

- Single dose of any of the three licensed RSV vaccines for all adults aged 75 years and older
- Single dose of any RSV vaccine for adults aged 60 through 74 years who are increased risk for serious RSV infection due to specific high-risk conditions, frailty, or high-risk living arrangements

https://www.cdc.gov/vaccines/acip/recommendations.html

Who are those in the 60–74-year-old category at increased risk?

- Chronic heart, lung, kidney, and liver disease, diabetes, severe obesity, neurologic and neuromuscular conditions which impair the airway clearance and chronic blood disorders
- Moderate or severe immune compromise
- Overall frailty
- Residence in a nursing home or other long-term care facility
- Other chronic medical conditions or risk factors not specified in this list that a healthcare provider determines might increase the risk of severe disease due to RSV respiratory infection

- People age 60 through 74 years who do not have a medical condition or risk factor that increases their risk of severe RSV disease are not recommended to receive RSV vaccine: they should wait to be vaccinated until a high-risk condition develops or until they turn 75, whichever comes first

https://www.immunize.org/ask-experts/what-conditions-put-older-people-at-the-highest-risk-of-complications-of-rsv/

How long will the RSV vaccine provide protection?

- Currently only one dose of the RSV vaccine is recommended currently. If vaccinated last year, should not receive another dose.
- Global clinical trials for RSVPreF3 (Arexvy, GSK) vaccine indicated reduced symptoms with lab confirmed RSV-associated symptoms by 88.9% the first year and 78.9% through part of the second year
- Global clinical trials for RSVPreF3 (Arexvy, GSK) vaccine showed reduced symptoms with lab confirmed RSV-associated symptoms by 80.9% and efficacy declined to 49.4% 18 months later

https://www.immunize.org/ask-experts/topic/rsv/
https://www.cdc.gov/vaccines/acip/recommendations.html

Nirsevimab-monoclonal antibody

- Injectable, long-acting monoclonal antibody product that gives the recipient direct, immediate protection through passive immunization
- Should NOT be called a vaccine. Can lead to medication errors.
- ACIP recommends one dose of nirsevimab (Beyfortus, Sanofi) preventive antibody for *all* infants less than 8 months and 0 days of age who are born during or are entering their first RSV season. However, if the mother was vaccinated with RSV vaccine, usually not necessary except in limited circumstances

Pneumococcal Vaccine Update*

*A little something extra since a new product was approved in June 2024

Capvaxive (PCV21)

- Approved by FDA 6/17/24
- Indication for the prevention of pneumonia caused by S. pneumoniae serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F and 35B is approved under accelerated approval based on immune responses as measured by opsonophagocytic activity (OPA) in ages 18 years and up

Not just one more serotype covered!

Adult Pneumococcal Vaccines

	1	3	4	5	6A	6B	7F	9V	14	18C	19A	19F	23F	22F	33F	8	10A	11A	12F	15B	2	9N	17F	20	15A	15C	16F	23A	23B	24F	31	35B
PCV15																																
PCV20																																
PPSV23																																
PCV21																																

21-valent pneumococcal conjugate vaccine (CAPVAXIVE™, Merck):

- **Approved by the FDA for adults aged ≥18 years on June 17, 2024[1]**

PCV13=13-valent pneumococcal conjugate vaccine
PCV15=15-valent pneumococcal conjugate vaccine
PCV20=20-valent pneumococcal conjugate vaccine
PPSV23=23-valent pneumococcal polysaccharide vaccine

https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2024-06-26-28/01-Pneumococcal-Loehr-508.pdf

CDC Recommendation Update

- ACIP recommends PCV21 as an option for adults aged ≥19 years who currently have a recommendation to receive a dose of PCV.

https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2024-06-26-28/01-Pneumococcal-Loehr-508.pdf

Summary

- All patients 6months + recommended to get the trivalent influenza vaccine unless specific contraindication.
- COVID-19 vaccines are now available with the 24/25 variant and are monovalent.
- RSV is recommended currently as a one-time dose for those 75 years+ and some 60–74-year-olds. Also, pregnancy indication for one product ONLY
- New update to the pneumococcal vaccine recs…not just another subtype!

Questions and contact info

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