Adult Immunization Update

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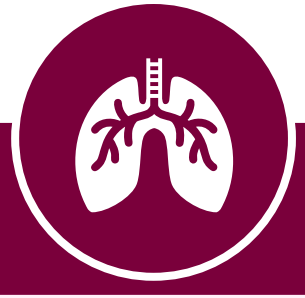
Outline

Fall Respiratory Viruses	RSV, Influenza, COVID-19
New Recommendation	Polio
Updates	MMR, hepatitis
Co-Administration	RSV, Influenza, COVID-19, live vaccines, nirsevimab, orthopoxvirus vaccines

RSV: Older Adults

About Respiratory Syncytial Virus (RSV)



Common respiratory virus

Causes mild, cold-like symptoms

Seasonal epidemics

Spread through respiratory droplets, direct contact, fomites

Annual RSV Burden Among Adults Ages 65 Years and Older

900,000–1,400,000 medical encounters

60,000–160,000 hospitalizations

6,000–10,000 deaths

RSV Vaccines for Adults Ages 60 Years and Older

RSVPreF3-AS (Arexvy, GSK)

RSVpreF (Abrysvo, Pfizer, Inc.)

There is no preferential recommendation; give whichever vaccine is available.

Characteristics of Both RSV Vaccines

- Recombinant prefusion F protein (preF) vaccine
- Single dose
- 0.5mL
- Require reconstitution
- Intramuscular injection

Vaccine Efficacy (VE)

- **Vaccines had similar and high VE against RSV-associated lower respiratory tract disease.**

- **Case definitions for primary outcomes were not aligned across trials.**

Vaccine Efficacy (VE): GSK

- **One primary outcome: RSV lower respiratory tract disease (LRTD)**
  - At least **two** lower respiratory **symptoms** or **signs**, including at least one **sign**, OR
  - At least **three** lower respiratory **symptoms**

Symptoms
- Sputum
- Cough
- Dyspnea

Signs
- Wheezing
- Crackles/rhonchi
- Tachypnea
- Hypoxemia
- Oxygen supplementation

Vaccine Efficacy (VE): GSK

- **Randomized, double-blinded, placebo-controlled phase 3 clinical trial**
  - 17 countries
  - 24,973 participants
- **VE against RSV-associated lower respiratory tract disease (LRTD):**

Vaccine Efficacy (VE): Pfizer

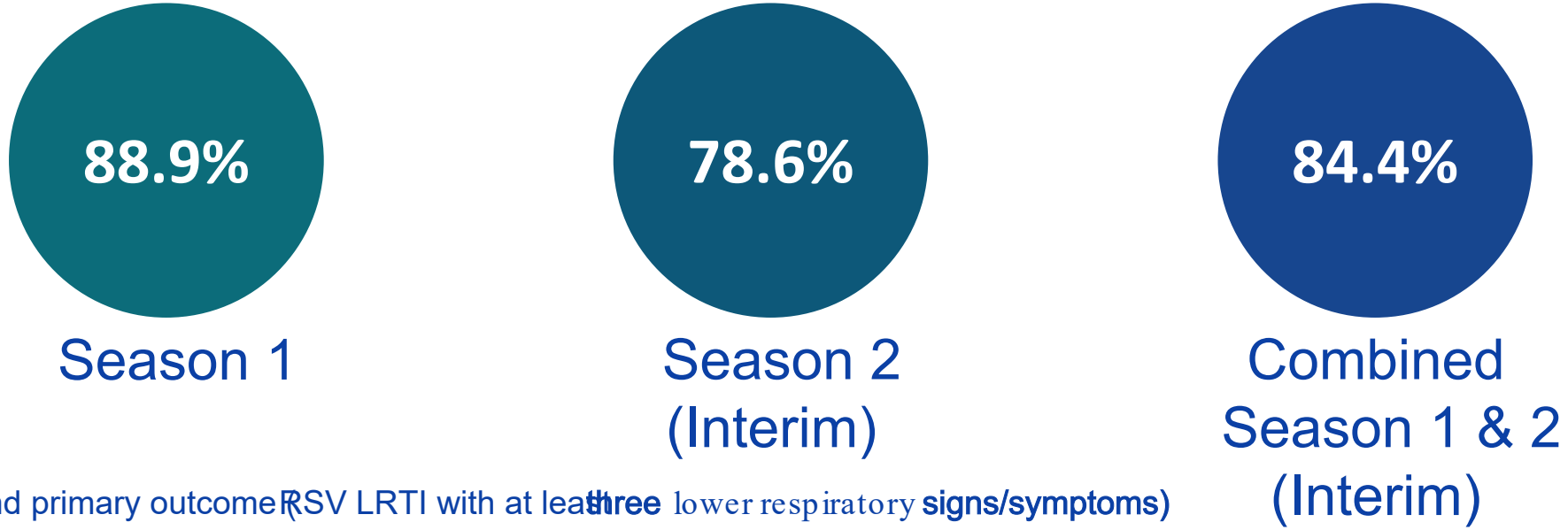
- **Two primary outcomes**
  - RSV lower respiratory tract infection (LRTI) with at least **two** lower respiratory **signs/symptoms**
  - RSV LRTI with at least **three** lower respiratory **signs/symptoms**

Signs/symptoms

- Sputum
- Cough
- Shortness of breath
- Wheezing
- Tachypnea

Vaccine Efficacy (VE): Pfizer

- **Randomized, double-blinded, placebo-controlled phase 3 clinical trial**
  - 7 countries
  - 36,862 participants
- **VE against RSV-associated lower respiratory tract disease (LRTD)*:**



*Based on second primary outcome (RSV LRTI with at least three lower respiratory signs/symptoms)

RSV Vaccination Recommendations for Older Adults

- **Adults ages 60 years and older may receive a single dose of RSV vaccine using shared clinical decision making**

Shared Clinical Decision Making

- **There is no default decision to vaccinate**
- **Recommendations are individually based and informed by a decision process between the health care provider and patient**

Best available evidence

Patients' risk for disease, characteristics, values, preferences

Clinical discretion

Characteristics of the vaccine

https://www.cdc.gov/vaccines/acip/acip-scdm-faqs.htm

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

- Lung disease
- Cardiovascular disease
- Moderate or severe immune compromise
- Diabetes Mellitus
- Neurologic or neuromuscular conditions
- Kidney disorders
- Liver disorders
- Hematologic disorders

Other conditions that might increase the risk for severe disease

Other Factors Associated with Increased Risk of Severe RSV Disease

- Residence in a nursing home or other long-term care facility
- Frailty
- Advanced age

Vaccination Timing: 2023-2024 Season

Summer/July: Offer RSV vaccination as early as vaccine is available

Continue to offer vaccination throughout the RSV season to eligible adults who remain unvaccinated

GSK/Arexvy: Storage and Handling

BEFORE Reconstitution

Store **refrigerated** between 2°C and 8°C (36°F and 46°F)

Do **NOT freeze**

Protect from **light**

VS

AFTER Reconstitution

Store **refrigerated** between 2°C and 8°C (36°F and 46°F) OR at **room temperature** [up to 25°C (77°F)]

Do **NOT freeze**

Protect from **light**

Use within **4 hours**

https://www.fda.gov/media/167805/download

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Pfizer/Abrysvo: Storage and Handling

BEFORE Reconstitution

Store **refrigerated** between 2°C and 8°C (36°F and 46°F)

Do **NOT freeze**

VS

AFTER Reconstitution

Store at **room temperature** [15°C to 30°C (59°F to 86°F)]

Do **NOT refrigerate**

Do **NOT freeze**

Use within **4 hours**

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GSK/Arexvy: Preparation

- **Supplied in two vials**

Vial of lyophilized antigen component

Vial of diluent adjuvant suspension component

https://www.fda.gov/media/167805/download

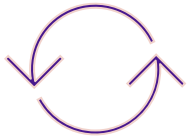
GSK/Arexvy: Preparation

Step 1

Cleanse vial stoppers and **withdraw** contents of the diluent.

Step 2

Transfer the diluent into the lyophilized antigen component vial.



Step 3

Swirl vial gently.

Step 4

Administer 0.5 mL.

This slide represents a summary of preparation steps; for complete information see package insert https://www.fda.gov/media/167805/download

Pfizer/Abrysvo: Preparation

- **Supplied in a 3-component kit**

Vial of lyophilized antigen component

Syringe of sterile water diluent component

Vial adapter

https://www.fda.gov/media/168889/download

Pfizer/Abrysvo: Preparation

Step 1	Step 2	Step 3	Step 4	Step 5
Prepare vial and adapter	**Attach** vial adapter	**Remove** syringe cap	**Connect** syringe to vial adapter	**Reconstitute**

Step 6	Step 7	Step 8	Step 9
Withdraw reconstituted vaccine	**Disconnect** syringe	**Attach** needle	**Inspect** visually

This slide represents a summary of preparation steps; for complete information see package insert https://www.fda.gov/media/168889/download

Vaccine Safety

- Six cases of inflammatory neurologic events reported in clinical trials
- It is unknown at this time whether these events occurred by chance, or whether RSV vaccination increases the risk of these events
- Imbalance in the small number of atrial fibrillation events; more cases among vaccine recipients, compared with placebo recipients

Question from NIP-INFO

I have a patient who is 53 years old and they have COPD. They are requesting the RSV vaccine, can I give it to them?

RSV: Pregnant People and Infants

RSV Clinical Presentation in Infants and Young Children

- **Infants more likely to have symptoms than older children and adults**
- **Usually presents as cold-like illness**
- **Can also cause respiratory infections like bronchiolitis and pneumonia**

Annual RSV Burden Among Infants and Children

50,000–80,000 hospitalizations among children age <5 years (RSV is the leading cause of hospitalization in U.S. infants)

100–300 deaths among children age <5 years

Preterm infants experience higher hospitalization and ICU admission rates

Active and Passive Immunity

- **Mechanisms for acquired immunity:**
  - **Active immunity**, i.e., protection that is produced by the person's own immune system (e.g., natural infection, vaccine)
  - **Passive immunity**, i.e., protection is that is produced by animal or human and transferred to another human, usually by injection (e.g., immune globulin, newborn baby acquires passive immunity from mother through placenta)

Two Products for RSV Prevention in Infants

- **Maternal RSV vaccination during pregnancy**
  (Abrysvo, Pfizer, Inc.)

  OR

- **Monoclonal antibody administration during infancy**
  (Nirsevimab [Beyfortus])

Both products are typically <u>not</u> needed for most infants

Maternal RSV Vaccination

- **Maternal RSV vaccine is recommended for pregnant people during 32–36 weeks gestation, using seasonal administration, to prevent RSV lower respiratory tract infection in infants**
  - During September through January in most of the continental U.S.
  - Only the Pfizer vaccine (Abrysvo) is recommended for pregnant people

Maternal RSV Vaccination Timing: 2023-2024 Season

<u>Fall/September</u>: Administer RSV vaccination starting in September

Continue to offer vaccination through <u>January</u> to eligible pregnant people.

Maternal RSV Vaccination Timing: 2023-2024 Season

<u>Local guidance</u>:

Administration schedules can be adjusted based on local epidemiology.

Maternal RSV vaccination **can be given outside of September through January**, when appropriate. Follow local guidance, when provided.

Safety of Maternal RSV Vaccination

- **Imbalance in clinical trials for:**
  - **Preterm labor:** In clinical trials, among people who were vaccinated during weeks 24 through 36 weeks of pregnancy, more preterm births were reported among maternal RSV vaccine recipients than among placebo recipients.
  - **Pre-eclampsia:** hypertensive disorders of pregnancy (including pre-eclampsia) occurred in 1.8% of pregnant people who received the RSV vaccine compared to 1.4% of pregnant people who received a placebo.

Nirsevimab (Beyfortus™)

- **Administered as IM injection**

Nirsevimab Recommendations

- **Infants younger than age 8 months born during or entering their first RSV season, whose mothers did not receive RSV vaccine at least 14 days prior to delivery**

- **Children ages 8–19 months who are at increased risk of severe RSV disease and entering their second RSV season**

- **Age ranges represent the infant's or child's age at the time of immunization**

Nirsevimab Timing: 2023-2024 Season

Infants at birth

All other infants younger than age 8 months

At-risk children ages 8–19 months

First RSV Season

Second RSV Season

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
- Children with cystic fibrosis who have manifestations of severe lung disease or weight-for-length <10th percentile
- American Indian and Alaska Native children

Nirsevimab Timing: 2023-2024 Season

<u>Local guidance</u>:

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.

Safety Reporting

- **Report suspect adverse reactions following the administration of nirsevimab without coadministration with any vaccine to MedWatch**
  - Reports can be submitted to MedWatch online at www.fda.gov/medwatch or by phone at 1-800-FDA-1088

- **Report suspect adverse reactions following nirsevimab co-administration with any vaccine to the Vaccine Adverse Event Reporting System (VAERS)**
  - Please specify that the patient received nirsevimab on the VAERS form, specifically, in Section 9: 'Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination'

Influenza

Abbreviations

- **IIV = Inactivated influenza vaccine**
- **RIV = Recombinant influenza vaccine**
- **LAIV = Live, attenuated influenza vaccine**
- **Prefixes:**
  - SD = standard dose
  - HD = high dose
  - a = adjuvanted
  - cc = cell-culture-based
- **Numeric suffixes (e.g., RIV3, IIV4) indicate trivalent or quadrivalent, respectively**
  - All currently-available vaccines are quadrivalent

Influenza Vaccines

- **IIV**
  - Contain inactivated virus, split or subunit
    - Standard dose or high dose
    - Unadjuvanted or adjuvanted
    - Egg- or cell-culture-based
    - Many brands, approved for those as young as 6 months of age
    - Intramuscular (IM) administration
- **RIV**
  - Contain recombinant HA
  - Egg-free
  - IM administration
- **LAIV**
  - Live, attenuated virus
  - Attenuated (to not cause clinical illness) and cold-adapted
  - Intranasal (NAS) administration

ACIP Recommendations for Influenza Vaccination: 2023-24

- **Influenza vaccine is recommended for all eligible persons ages 6 months and older**
- **Administer the correct product based on the recipient's age and health status**
  - For example, LAIV (FluMIST) vaccine is approved for persons ages 2 through 49 years
- **All influenza vaccines are administered by intramuscular (IM) injection <u>except</u> LAIV which is administered intranasally**
- **As a live vaccine, LAIV has additional safety considerations**

65 Years and Older: Preferential Vaccines

- **ACIP preferentially recommends higher dose, recombinant, or adjuvanted influenza vaccines for persons ages 65 years old and older**

- **Includes these vaccines:**
  - High-dose influenza vaccine (Fluzone High-Dose)
  - Recombinant Influenza Vaccine (Flublok)
  - Adjuvanted influenza vaccine (Fluad)

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No preference between these 3

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  - Adjuvanted influenza vaccine (Fluad)

No preference between these 3

If none of these are available, vaccinate with another age-appropriate influenza vaccine

Timing of Vaccination

- **Vaccination should occur before onset of influenza activity**
- **For most persons who need only one dose of influenza vaccine, vaccination should ideally be offered during:**
  - September
  - October
- **Vaccination should continue throughout the season as long as virus is circulating**
- **Vaccination in July and August not recommended for most groups**

Influenza Vaccination of Pregnant People

- **Influenza vaccination recommended by ACIP since 2004 for people who will be pregnant during influenza season**
  - Increased risk for severe influenza illness in pregnant people, particularly during second and third trimesters

- **Pregnant people may receive any licensed, recommended, age-appropriate IIV or RIV**

- **LAIV is contraindicated during pregnancy**
  - But can be used post-partum

Influenza Vaccination of Persons with Egg Allergy

- **Persons who have experienced only hives after exposure to egg may receive any licensed, recommended vaccine that is otherwise appropriate**
- **Egg allergy 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**
- **Severe and life-threatening reactions to vaccines can occur with any vaccine and in any vaccine recipient, regardless of allergy history**
  - All vaccines should be administered in settings in which personnel and equipment needed for rapid recognition and treatment of acute hypersensitivity reactions are available

Question from NIP-INFO

We have a 55 y.o. patient and we accidentally administered FluMist to them. Should we revaccinate them with an age-appropriate inactivated influenza vaccine? If so, should we wait a certain amount of time?

COVID-19

COVID-19 Vaccines

- **mRNA Vaccines**
  - Moderna
  - Pfizer-BioNTech
- **Protein subunit vaccine**
  - Novavax

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  - Moderna
  - Pfizer-BioNTech

The 2023–2024 formulation has been updated to a monovalent vaccine based on the Omicron XBB.1.5 sublineage

Bivalent formulation should not be used

- **Protein subunit vaccine**
  - Novavax

COVID-19 Vaccines

- **mRNA Vaccines**
  - Moderna
  - Pfizer-BioNTech

The 2023–2024 formulation has been updated to a monovalent vaccine based on the Omicron XBB.1.5 sublineage

Bivalent formulation should not be used

- **Protein subunit vaccine**
  - Novavax

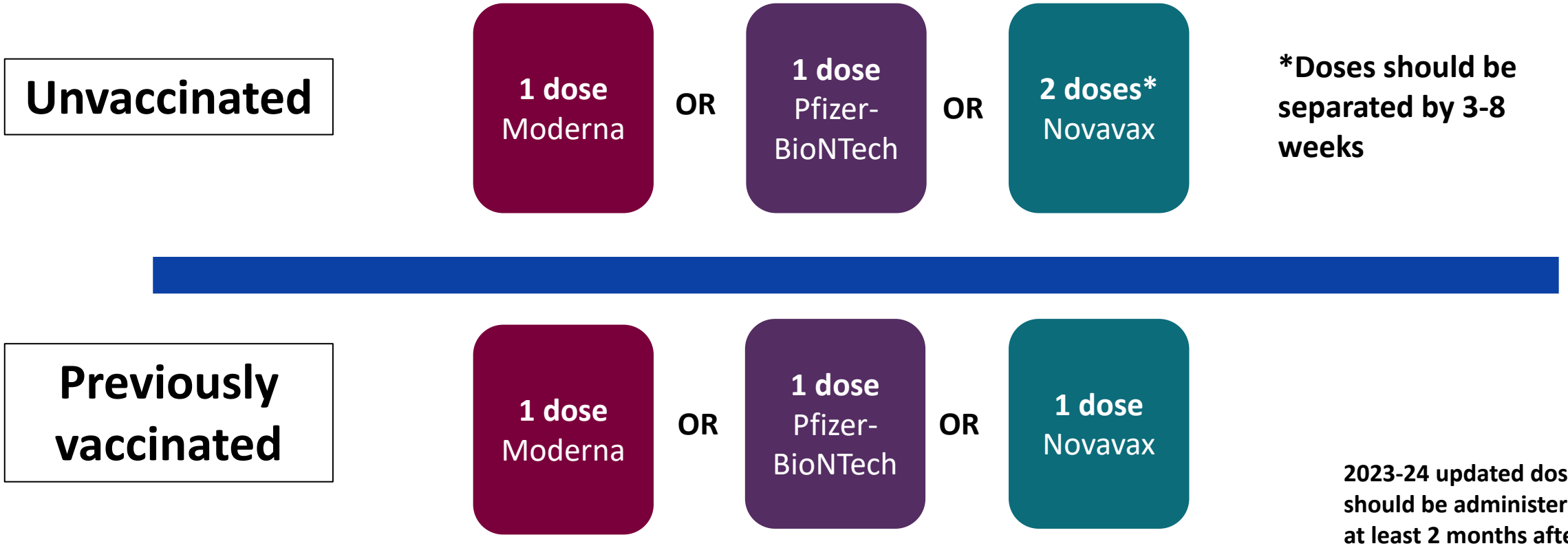
The 2023–2024 formulation has been updated to a monovalent vaccine based on the Omicron XBB.1.5 sublineage

Original monovalent formulation should not be used

No Preferential Recommendation

- **No preferential recommendation for the use of any one COVID-19 vaccine over another when more than one recommended and age-appropriate vaccine is available**

Recommendations for updated 2023-24 COVID-19 Vaccines for Adults without Immunocompromise



Spacing Considerations

- **The updated 2023-24 dose should be administered at least 8 weeks after receipt of the last covid vaccine dose**

- **Additional updated 2023-24 doses for immunocompromised people, administered at the discretion of the health care provider, should be spaced by at least 8 weeks from the previous dose**

- **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**
  - A low risk of reinfection has been observed in the weeks to months following infection

People 65 Years and Older

- **People ages 65 years and older should only receive the recommended number of dose(s) of updated (2023–2024 Formula) mRNA or Novavax vaccine doses**
  - No option for additional dose(s)

Fall COVID-19 Vaccine Transition

- **Monovalent XBB.1.5 vaccines are the first COVID-19 vaccines to be available directly from the manufacturers as part of the commercial market**
  - In other words, not available through the United States Government (USG)
- **Providers no longer required to report inventory to Vaccines.gov**
  - Voluntary reporting is encouraged
  - Reporting the minimum age (in months and years) for whom a location can administer vaccine is also encouraged
- **CDC will continue efforts to ensure all people have access to COVID-19 medical countermeasures**

CDC. HHS Commercialization Transition Guide: Sunsetting the US Government COVID-19 Vaccine Distribution Program. https://www.cdc.gov/vaccines/covid-19/downloads/HHS-Commercialization-Transition-Guide-508.pdf Accessed August 4, 2023

CDC’s Bridge Access Program

- **CDC’s Bridge Access Program provides no-cost COVID-19 vaccines to uninsured or underinsured adults**
  - All CDC-recommended COVID-19 vaccinations are included in the Bridge Access Program.
  - No-cost COVID-19 vaccines through this program will be available through December 31, 2024.

Where Can Someone Get No-Cost COVID-19 Vaccines Through the Bridge Access Program?

- Local Healthcare Providers
- HRSA-Supported Centers
- Retail Pharmacies:
  Walgreens, CVS, eTrueNorth

→ Community events or pop-up sites with these groups

Visit Vaccines.gov to find a provider that offers no-cost COVID-19 vaccines through the Bridge Access Program!

Question from NIP-INFO

We still have bivalent mRNA COVID-19 vaccine at our clinic and we don't want to waste it. Is it OK for us to administer this to patients?

Polio

Poliovirus

- **There are three distinct serotypes of poliovirus: 1, 2, and 3**
  - Immunity to one serotype does not provide much protection from other serotypes
  - A history of having recovered from polio disease is not to be considered evidence of immunity to polio

2 Types of Polio Vaccines

- **Oral polio vaccine (OPV)**
  - Trivalent OPV (tOPV): Protects against all 3 serotypes
  - Bivalent OPV (bOPV): Protects against serotypes 1 & 3
  - Monovalent OPV (mOPV): Protects against only 1 serotype
- **Inactivated polio vaccine (IPV)**
  - Protects against all 3 serotypes

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- **Inactivated polio vaccine (IPV)**
  - Protects against all 3 serotypes

Not available in U.S.

Oral Polio Vaccine (OPV)

- **Among the 3 wild poliovirus types, type 2 was declared eradicated in 2015**
  - In 2016, the World Health Organization directed all OPV-using countries to switch from tOPV to bOPV vaccine
  - OPV administered before April 2016 generally was tOPV

Trivalent Oral Polio Vaccine (tOPV)

- **Although tOPV was used for routine poliovirus vaccination in all OPV-using countries before April 2016, mOPV or bOPV were often used in vaccination campaigns**

- **Only tOPV constitutes proof of vaccination according to U.S. polio vaccination recommendations**

Oral Polio Vaccine (OPV)

- **Records noting "OPV" can generally be assumed to be tOPV if:**
  - Administered before April 1, 2016

    and

  - Not noted as being administered during a vaccination campaign

Fractional IPV

- **Used in some countries as an alternative to the intramuscular injection of a full dose of IPV**
  - Fractional doses (1/5 of the full IPV dose) administered via the intradermal route
  - Dose-sparing strategy in the context of an IPV shortage
- **Does NOT count as a valid dose according to the U.S. schedule**

Recommendations: Adults

- **Adults who are known or suspected to be unvaccinated or incompletely vaccinated against polio should complete a primary vaccination series with inactivated polio vaccine (IPV)**
  - In general, unless there are specific reasons to believe they were not vaccinated, most adults who were born and raised in the United States can assume they were vaccinated against polio as children

Polio Vaccine Schedule: Adults

DOSE 1

1-2 months

DOSE 2

6-12 months

DOSE 3

Accelerated Polio Vaccination Schedule: Adults

Protection needed in:			
Dose	≥8 weeks	≥4 but <8 weeks	<4 weeks
Dose 1	0	0	0
Dose 2	4 weeks	4 weeks	
Dose 3	8 weeks		

- If the accelerated schedule cannot be completed before the risk situation, the remaining doses should be given as soon as possible (e.g., in the visited country, or upon returning home) to complete the primary series at the recommended intervals, such that the third dose should be given at least 6–12 months after the second dose

Recommendations: Booster Dose for Adults

- **Adults who have received a primary series of trivalent oral polio vaccine (tOPV) or IPV in any combination and who are at increased risk of poliovirus exposure may receive another dose of IPV**

  - Available data do not indicate the need for more than a single lifetime booster dose with IPV for adults

Adults at Increased Risk for Polio

- Travelers who are going to countries where polio is epidemic or endemic
- Laboratory and healthcare workers who handle specimens that might contain polioviruses
- Health care workers or other caregivers who have close contact with a person who could be infected with poliovirus

Updates

Priorix

- **Since 1978, MMR II has been the only measles, mumps, and rubella (MMR) vaccine used in the United States**

- **In June 2022, FDA licensed an additional MMR vaccine: Priorix**
  - ACIP recommends Priorix as an additional option to prevent MMR according to existing vaccine recommendations and off-label use

- **Priorix and MMR II are fully interchangeable**
  - Either vaccine may be administered in any situation in which an MMR virus–containing vaccine is indicated

Routes of Administration for MMR Vaccines

	Licensed for SQ administration?	Licensed for IM administration?	Dose counts as valid if administered IM?
MMR-II	Yes	Yes	Yes
Priorix	Yes	No	Yes

PreHevbrio

	Engerix-B	Recombivax HB	Heplisav-B	PreHevbrio
Composition	Recombinant HBsAg	Recombinant HBsAg	Novel Adjuvanted Recombinant HBsAg	3 Antigen Recombinant HBsAg
Schedule	3 doses 0,1,6 mo	3 doses 0,1,6 mo	2 doses 0,1 mo	3 doses 0,1,6 mo
Route	IM	IM	IM	IM
Age Indications	Birth-adult	Birth-adult	18 and older	18 and older

New HBV Screening Recommendations

- **Universal screening of all adults for HBV infection**
  - HBsAg
  - Anti-HBs
  - Anti-HBc

- **Anti-HBs wanes over time following vaccination, yet initial responders remain protected for decades (as long as they are immunocompetent)**

- **Anti-HBs at a time distant from vaccination does not distinguish non-responders from persons with waning antibody**

Co-Administration

Simultaneous Administration

- **Simultaneous administration = administering more than one vaccine on the same clinic day, or "coadministration"**
- **In accordance with General Best Practice Guidelines for Immunization, age-appropriate doses of vaccines can be administered simultaneously (if there are no contraindications)**
  - For children, adolescents, and adults
  - Some exceptions
- **Administer each vaccine in a different injection site**
  - Separate injection sites by 1 inch or more, if possible, so that any local reactions can be differentiated
- **Administer vaccines associated with enhanced local reactions in separate limbs, if possible**

Influenza, COVID-19, and RSV Vaccines

- **May be administered at the same clinic visit**

Live, Attenuated Influenza Vaccine

- **LAIV4 may be administered simultaneously with other live or inactivated vaccines**
  - If not given simultaneously, then at least 4 weeks should pass between administration of LAIV4 and another live vaccine

Nirsevimab

- **May be administered at the same clinic visit as other routinely recommended immunizations**

COVID-19 and Orthopoxvirus Vaccines

- **No required minimum interval between receiving a dose of any COVID-19 vaccine and an orthopoxvirus vaccine**
  - Either JYNNEOS or ACAM2000

- **Use of JYNNEOS vaccine should be prioritized over ACAM2000 when co-administering a COVID-19 vaccine and an orthopoxvirus vaccine**

- **People, particularly adolescent or young adult males, who are recommended to receive both vaccines might consider waiting 4 weeks between vaccines**
  - Risk for myocarditis and pericarditis

Thank You!

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

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