Centers for Disease Control and Prevention
Office of Readiness and Response

Preparing for the Upcoming Respiratory Virus Season: Recommendations for Influenza, COVID-19, and RSV Vaccines for Older Adults

Clinician Outreach and Communication Activity (COCA) Call

Tuesday, September 19, 2023

Free Continuing Education

- Free continuing education is offered for this webinar.
- Instructions on how to earn continuing education will be provided at the end of the call.

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- In compliance with continuing education requirements, all planners and presenters must disclose all financial relationships, in any amount, with ineligible companies over the previous 24 months as well as any use of unlabeled product(s) or products under investigational use.

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- Content will not include any discussion of the unlabeled use of a product or a product under investigational use with the exception of Dr. Lisa Grohskopf's discussion of FDA-approved package inserts for egg-based influenza vaccines that indicate that their use is contraindicated for persons who have had a severe allergic reaction to any vaccine component which includes egg for egg-based vaccine. However, the ACIP and CDC recommend that persons with egg allergy of any severity should receive influenza vaccine, and that they may receive any influenza vaccine that is otherwise appropriate for age and health status (egg based or non-egg based).

- CDC did not accept financial or in-kind support from ineligible companies for this continuing education activity.

Objectives

At the conclusion of today's session, the participant will be able to accomplish the following:

1. Describe the recommendations and clinical considerations for administering influenza, COVID-19, and RSV vaccines to older adults.
2. List key points for clinicians to use when discussing influenza, COVID-19, and RSV vaccination with older adults.
3. Describe where to find online resources for clinicians about vaccination of older adults against influenza, COVID-19, and RSV.

To Ask a Question

- Using the Zoom Webinar System
  - Click on the “Q&A” button
  - Type your question in the “Q&A” box
  - Submit your question

- If you are a patient, please refer your question to your healthcare provider.

- If you are a member of the media, please direct your questions to CDC Media Relations at 404-639-3286 or email media@cdc.gov.

Today's Presenters

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Preparing for the Upcoming Respiratory Virus Season: Recommendations for Influenza, COVID-19, and RSV Vaccines for Older Adults

September 19, 2023

Key Messages for Clinicians for Fall/Winter Viral Respiratory Season

- **We have more tools than ever**: This is the first fall and winter virus season where vaccines are available for the three viruses responsible for most hospitalizations – COVID-19, RSV, and flu.
  - **Co-administration** of vaccines is an acceptable practice.
    - If vaccines are NOT administered the same day, there is no required interval between vaccines

- **The time is now**: Cases of COVID-19 and RSV are rising – and flu season is on the horizon, so talk to your patients today about how to protect themselves and their loved ones from severe respiratory illness.


YOU are patients' **most trusted** source of information on vaccines.

Key Information for Clinicians for Fall/Winter Viral Respiratory Season

Influenza	• Vaccination of all persons aged ≥6 months who do not have contraindications is recommended.
	• **Changes**: Updated U.S. influenza vaccine composition for 2023–2024
	  • Adults 65+ should get a high-dose or adjuvated flu vaccine
	  • Persons with egg allergy: Should receive influenza vaccine, no additional safety measures required

COVID-19	• Updated COVID-19 vaccines recommended for everyone aged ≥6 • The vaccines are **covered by insurance**. Uninsured and underinsured children and adults have access to vaccines through **VFC** or **Bridge Program**. • Everyone ages **5 years** and older recommended for a single 2023 – 2024 dose • No additional dose for age 65+ recommended **at this time**
RSV	• RSV can cause serious illness in older adults. Certain underlying medical conditions and advanced age are associated with increased risk of severe RSV. • Adults 60+ may receive an RSV vaccine based on shared clinical decision-making with a healthcare provider.

Influenza

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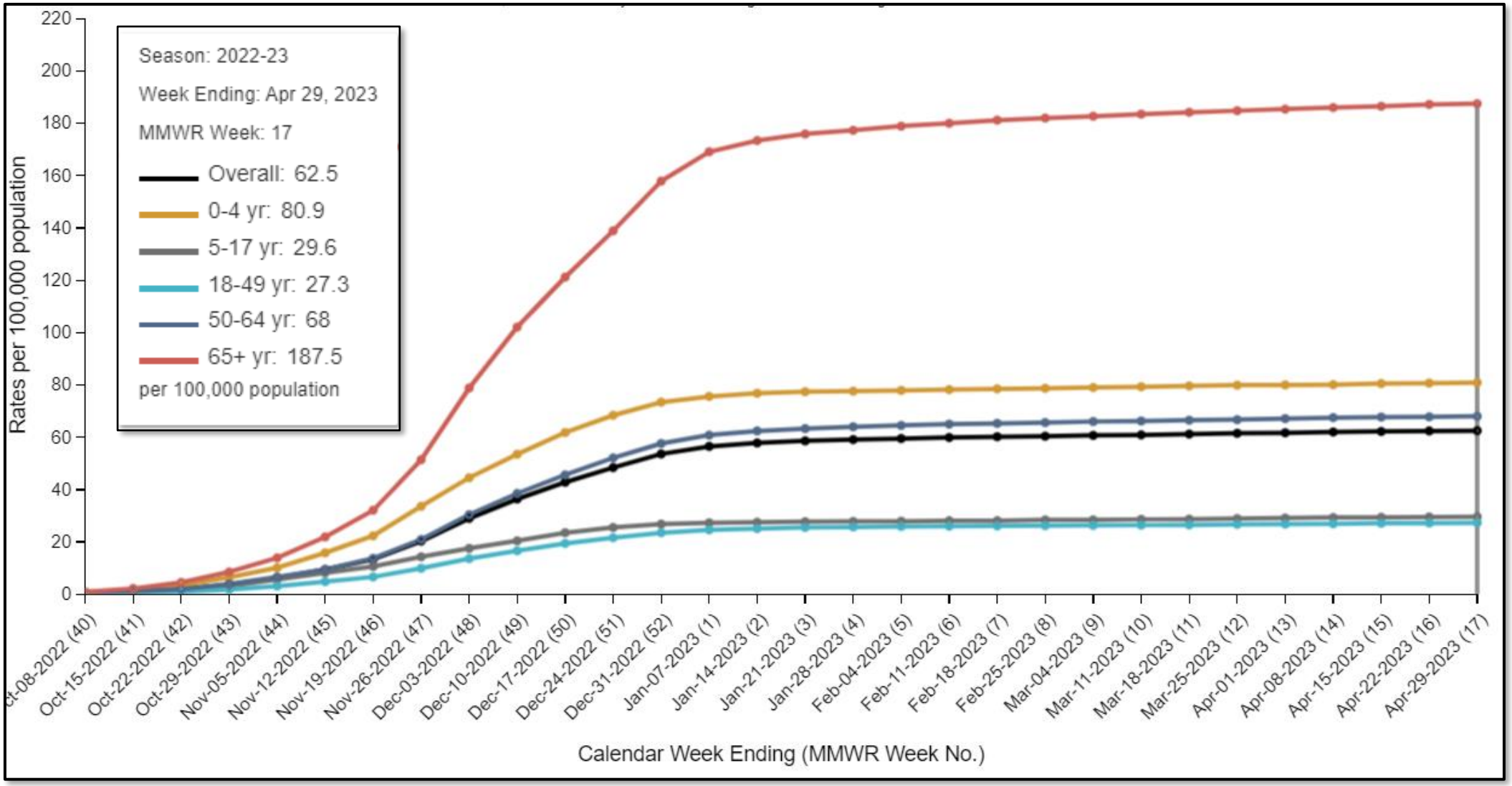
2023–2024 Influenza Vaccination Recommendations Overview

- Vaccination of all persons aged ≥6 months who do not have contraindications continues to be recommended.

- Recommendations concerning older adults are similar to those of last season.

- Changes include:
  - Updated U.S. influenza vaccine composition for 2023–2024.
  - Changes to the recommendations for vaccination for persons with egg allergy.

Cumulative Influenza Hospitalizations—FluSurv-NET, All Ages, 2022–2023 Season



Weekly U.S. Influenza Surveillance Report

FluView Interactive

Influenza Vaccines by Age Indication, United States, 2023–2024 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 Cell culture-based inactivated (ccIIV4)		Flucelvax Quadrivalent				
	Standard-dose adjuvanted inactivated (aIIV4)						Fluad Quadrivalent*
	High-dose inactivated (HD-IIV4)						Fluzone High-Dose Quadrivalent*
RIV4	Recombinant (RIV4)				Flublok Quadrivalent*		
LAIV4	Live attenuated (LAIV4)			FluMist Quadrivalent			

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*

* Preferred for those aged ≥65 years

Influenza Vaccine Effectiveness Among Older Adults

Season	Overall VE, % (all ages, viruses, and vaccine types)	≥65 yrs (all viruses and vaccine types)
2021–22	36 (21, 48)	10 (-60, 49)*
2019–20	39 (32, 44)	39 (9, 59)
2018–19	29 (21, 35)	12 (-31, 40)
2017–18	38 (31, 43)	17 (-14, 39)
2016–17	40 (32, 46)	20 (-11, 43)
2015–16	48 (41, 55)	42 (6, 64)
2014–15	19 (10, 27)	32 (3, 52)
2013–14	52 (44, 59)	50 (16, 71)
2012–13	49 (43, 55)	26 (-10, 50)
2011–12	47 (36, 56)	43 (-18, 72)

* Age ≥50 yrs

Past Seasons' Vaccine Effectiveness Estimates

- Influenza vaccines are often less effective for older adults compared with younger populations.
- Data support greater potential effectiveness of HD-IIV3, aIIV3, or RIV4 compared with standard-dose unadjuvanted IIVs.
  - Most data available for HD-IIV3.
  - Comparisons of these vaccines with one another are limited, as are data for currently available quadrivalent HD-IIV and aIIV.

Influenza Vaccination of Persons Aged ≥65 Years

- Adults aged ≥65 years should preferentially receive any one of the following higher dose or adjuvanted influenza vaccines:
  - Quadrivalent high-dose inactivated influenza vaccine (HD-IIV4),
  - Quadrivalent recombinant influenza vaccine (RIV4), or
  - Quadrivalent adjuvanted inactivated influenza vaccine (aIIV4).

- If none of these three vaccines is available at an opportunity for vaccine administration, then any other age-appropriate influenza vaccine should be used.
- Vaccination of older adults in July and August should be avoided unless later vaccination might not be possible.
  - Due to potential waning of immunity.

Egg Allergy

- Affects approximately 1–3% of children by age 3 years.
- Resolves for many in later childhood/adolescence (~68% by age 16 years).
- While more common among children, some adults might be concerned about receiving influenza vaccine due to egg allergy.
  - Severe allergic reaction to any vaccine component is listed as a contraindication in package inserts for egg-based influenza vaccines.
- Previously it was recommended that all with egg allergy should receive any influenza vaccine appropriate for age and health status.
  - Those with severe egg allergy recommended to be vaccinated in a medical setting if an egg-based vaccine used.

Eggesbo M et al. Allergy 2001;56(5):403-411; Erlewyn-Lajeunesse M et al. BMJ 2009;339:b3680.; Savage JH et al. J Allergy Clin Immunol 2007;120(6):1413-7.

Egg Allergy—Update for 2023–2024

- 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.
- No recommendations for specific vaccines or vaccination setting.
- 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

Influenza Antiviral Medications

- Treatment is recommended ***as soon as possible*** for any patient with suspected or confirmed influenza who:
  - Is hospitalized;
  - Has severe, complicated, or progressive illness; or
  - Is at higher risk for influenza complications (including those ≥65 years).
- Should not wait for laboratory confirmation of influenza.
- Oral oseltamivir, oral baloxavir, inhaled zanamivir, and intravenous peramivir can be used for older adults.
  - Zanamivir not recommended for people with underlying respiratory disease (e.g., asthma, chronic obstructive pulmonary disease).
- Additional information on use of antivirals for treatment and chemoprophylaxis is available at:
  - Influenza Antiviral Medications: Summary for Clinicians

Self-knowledge Check

Which influenza vaccines are appropriate for people with egg allergy?

A. Egg-free cell-based inactivated influenza vaccine (ccIIV4) only.
B. Egg-free recombinant influenza vaccine (RIV4) only.
C. Any influenza vaccine, egg based or non-egg based.
D. A and B (egg-free vaccines only).
E. None—egg allergic people should not receive influenza vaccine.

Self-knowledge Check

The correct answer is: C.

People with egg allergy can receive any influenza vaccine (egg based or non-egg based) that is appropriate for their age and health status.

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.

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

Megan Wallace, DrPH, MPH
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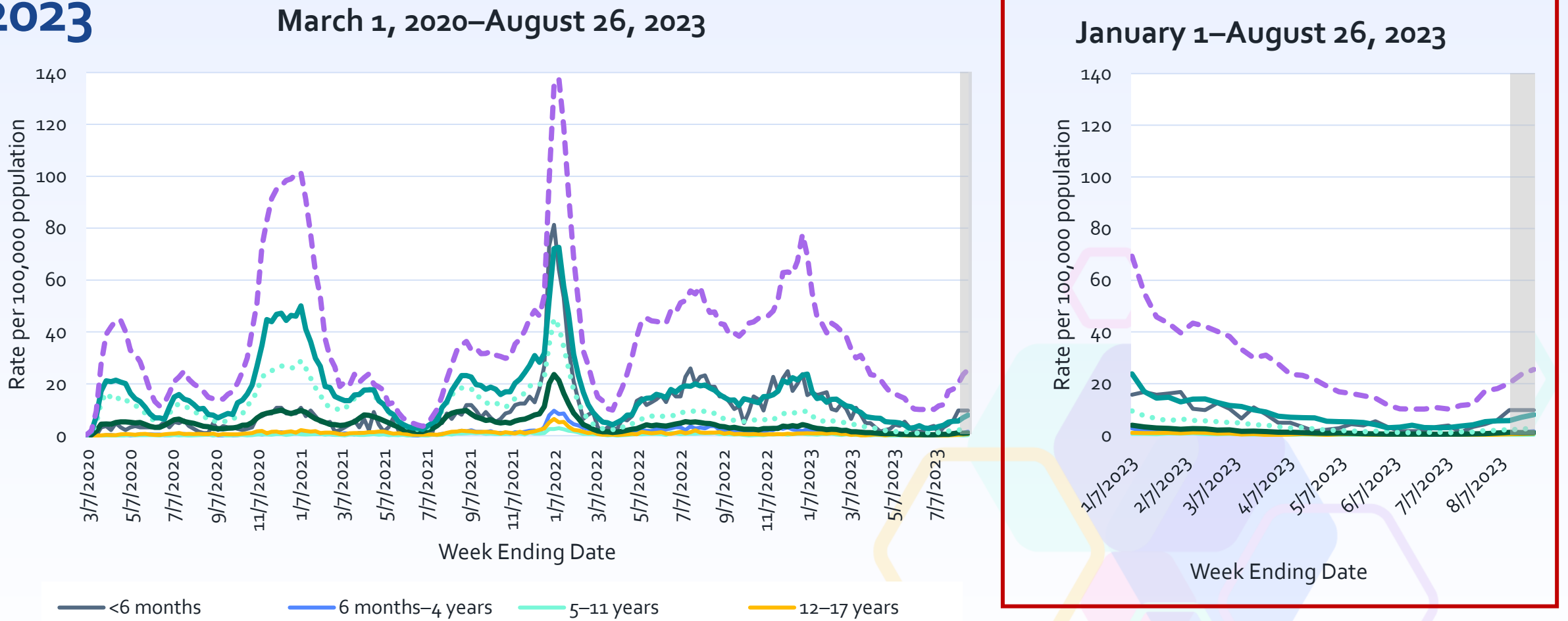
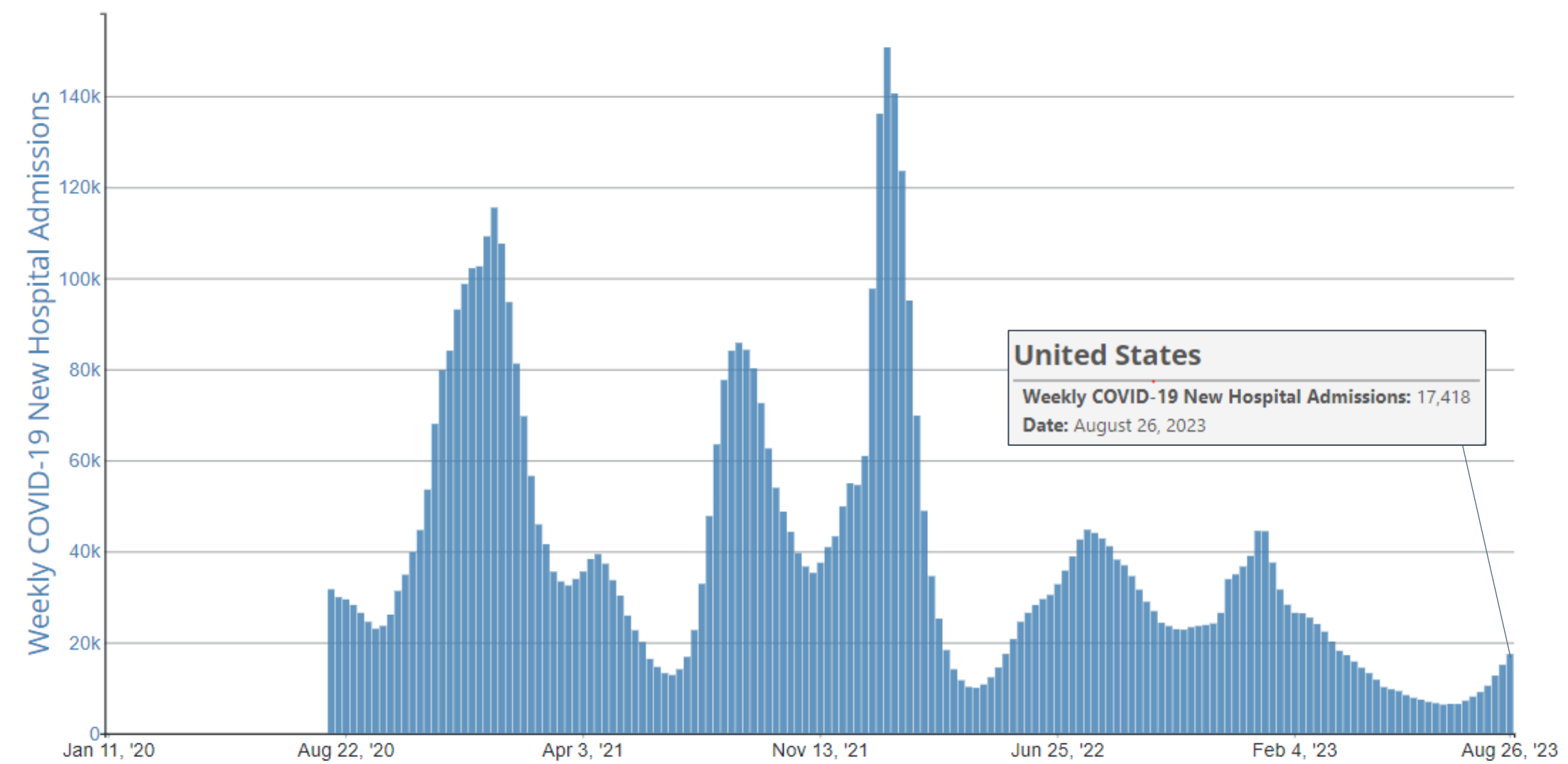
Weekly Population-Based Rates of COVID-19-Associated Hospitalizations — COVID-NET, March 2020–August 26, 2023



Rates highest in ≥75 years, followed by infants <6 months and adults 65–74 years

Gray boxes indicate potential reporting delays. Interpretation of trends should be excluded from these weeks.

COVID-19 new hospital admissions, by week, in the United States National Healthcare Safety Network (NHSN), August 2020 – August 2023



Source: COVID-19–associated hospitalization data reported to CDC's National Healthcare Safety Network (NHSN).

COVID Data Tracker

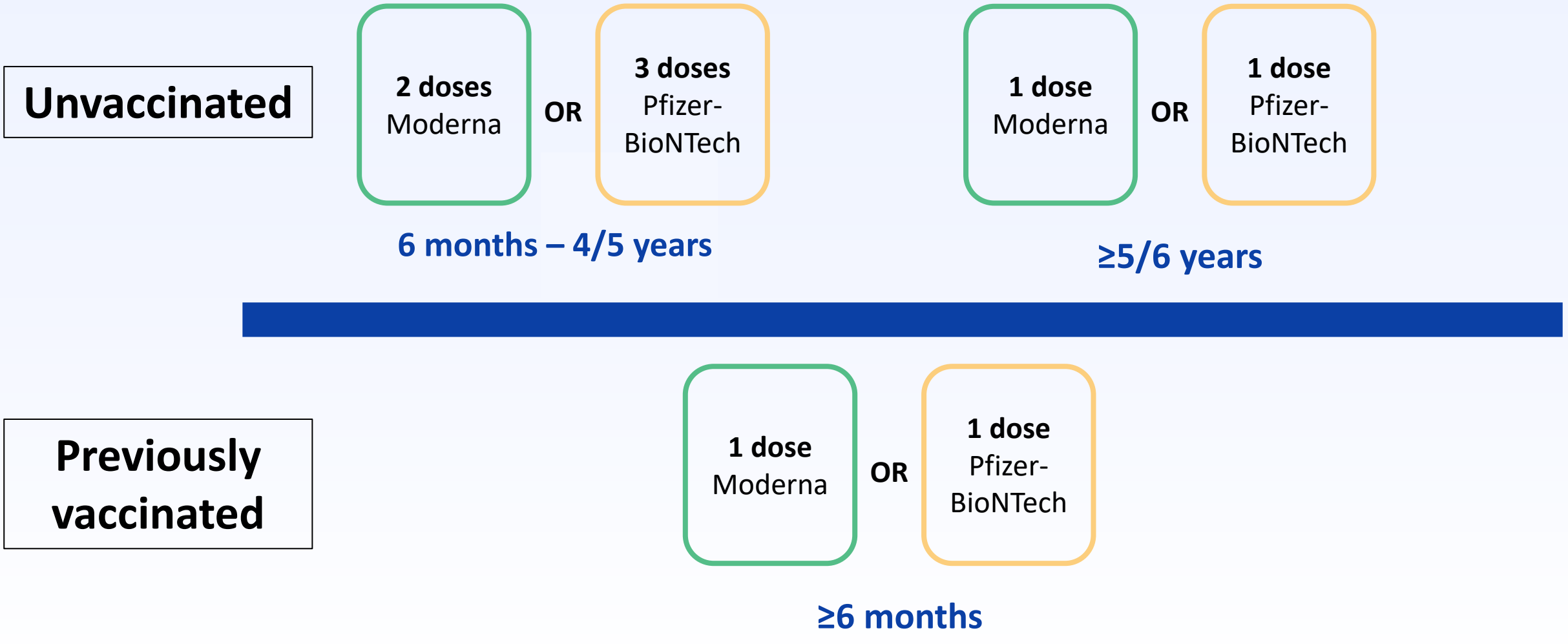
Summary and Work Group Interpretation: Public Health Burden

- 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

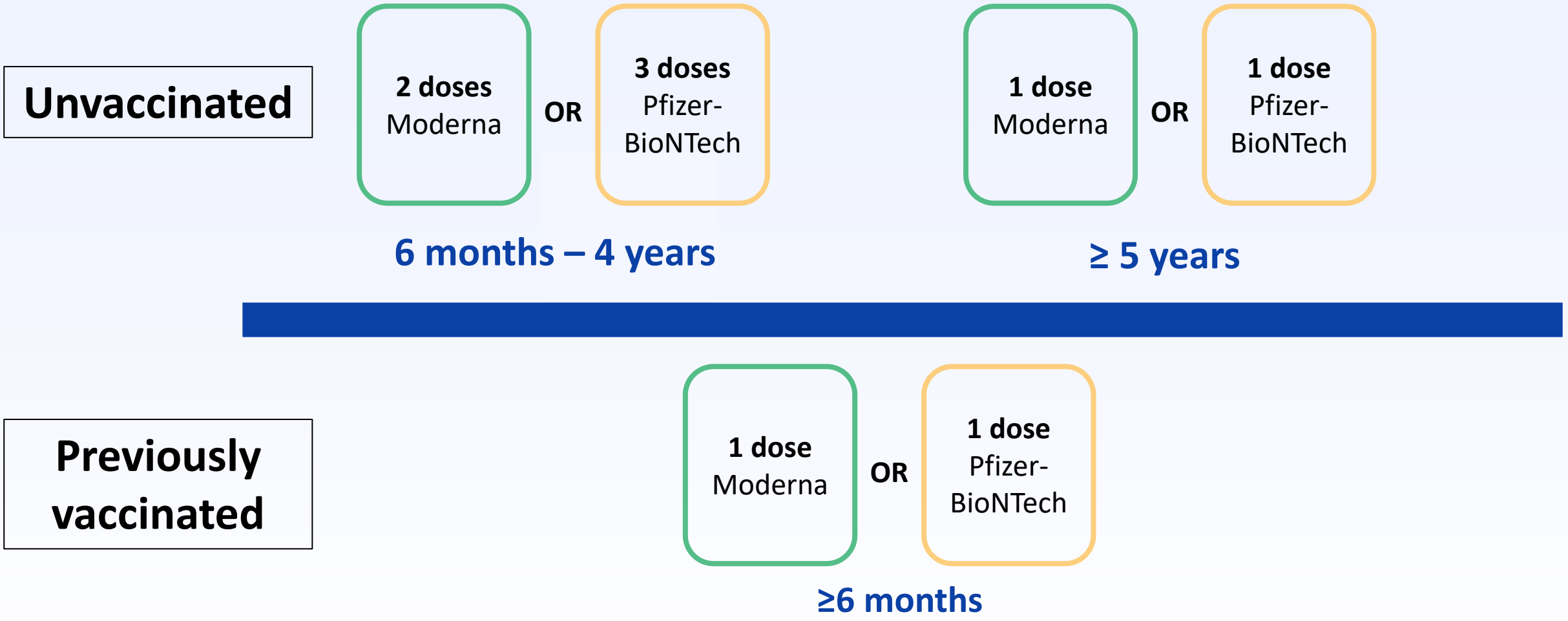
- Monovalent XBB containing COVID-19 vaccines **increase the immune response** against the currently circulating variants
- Last year's vaccine was **effective** at preventing medically attended COVID-19, hospitalization due to COVID-19, and death due to COVID-19
- COVID-19 vaccines have a **high degree** 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

Bivalent COVID-19 vaccine recommendations for mRNA COVID-19 vaccines



Note: Those ages 6 months – 4 years who have previously received a single dose of Pfizer-BioNTech would need 2 additional doses. Additional doses are recommended for persons with immunocompromising conditions.

2023 – 2024 COVID-19 vaccine recommendations for mRNA COVID-19 vaccines



Note: Those ages 6 months – 4 years who have previously received a single dose of Pfizer-BioNTech would need 2 additional doses. Additional doses are recommended for persons with immunocompromising conditions.

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 2nd 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 who are not moderately or severely immunocompromised

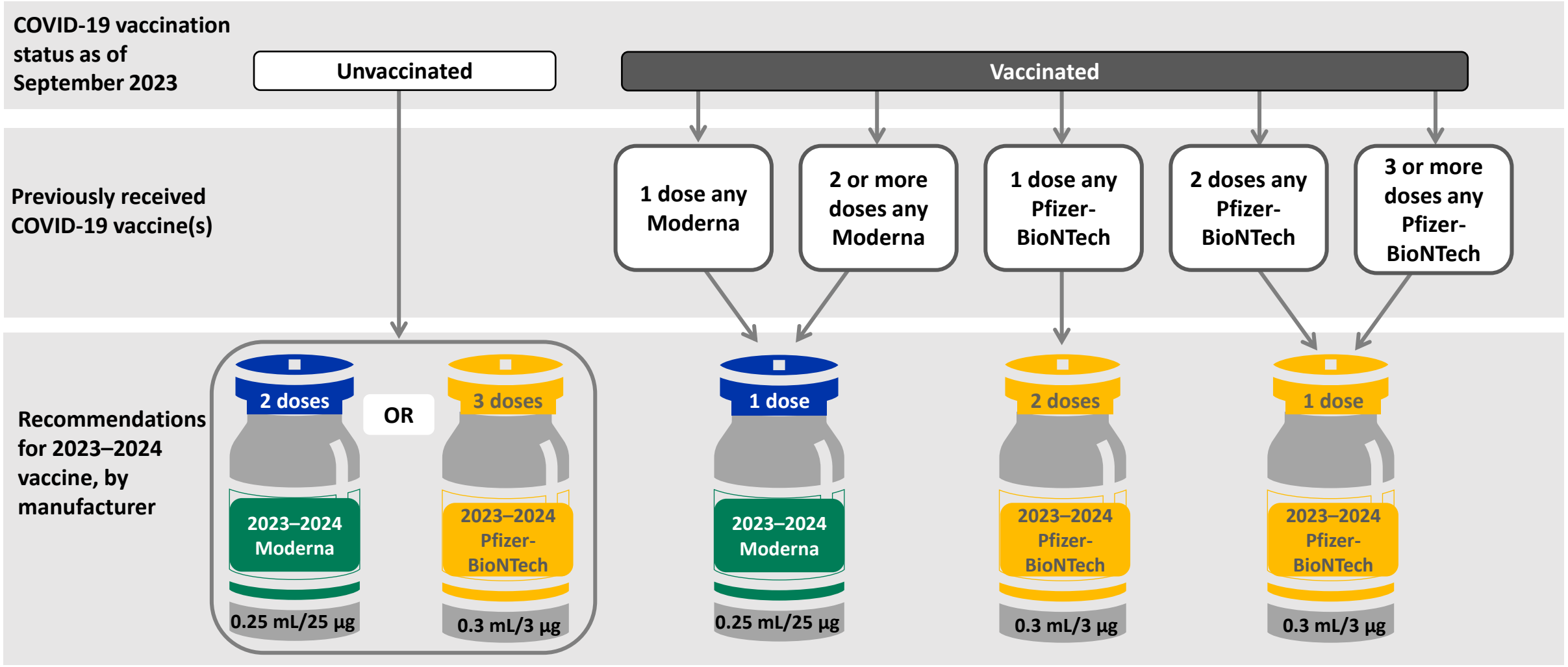
Recommendations for children aged 6 months – 4 years without immunocompromise

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 people who transition from age 4 years to age 5 years during an mRNA vaccination series, see Table 1 in the Interim Clinical Considerations for Use of COVID-19 vaccines.

Recommendations for people aged 5 years and older who are not moderately or severely immunocompromised

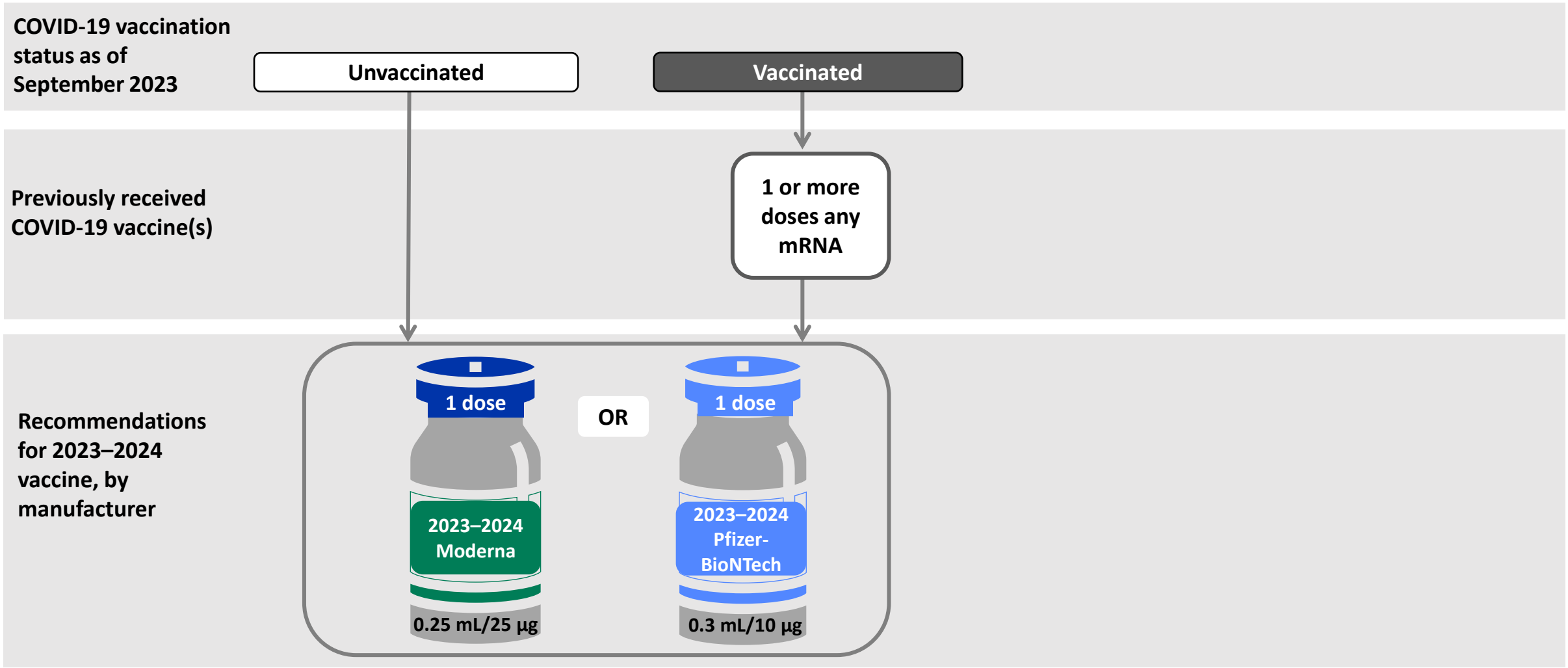
Recommendations for people aged 5 years and older without immunocompromise

Doses recommended:

- **1 dose of 2023–2024 COVID-19 vaccine**, regardless of prior vaccination history

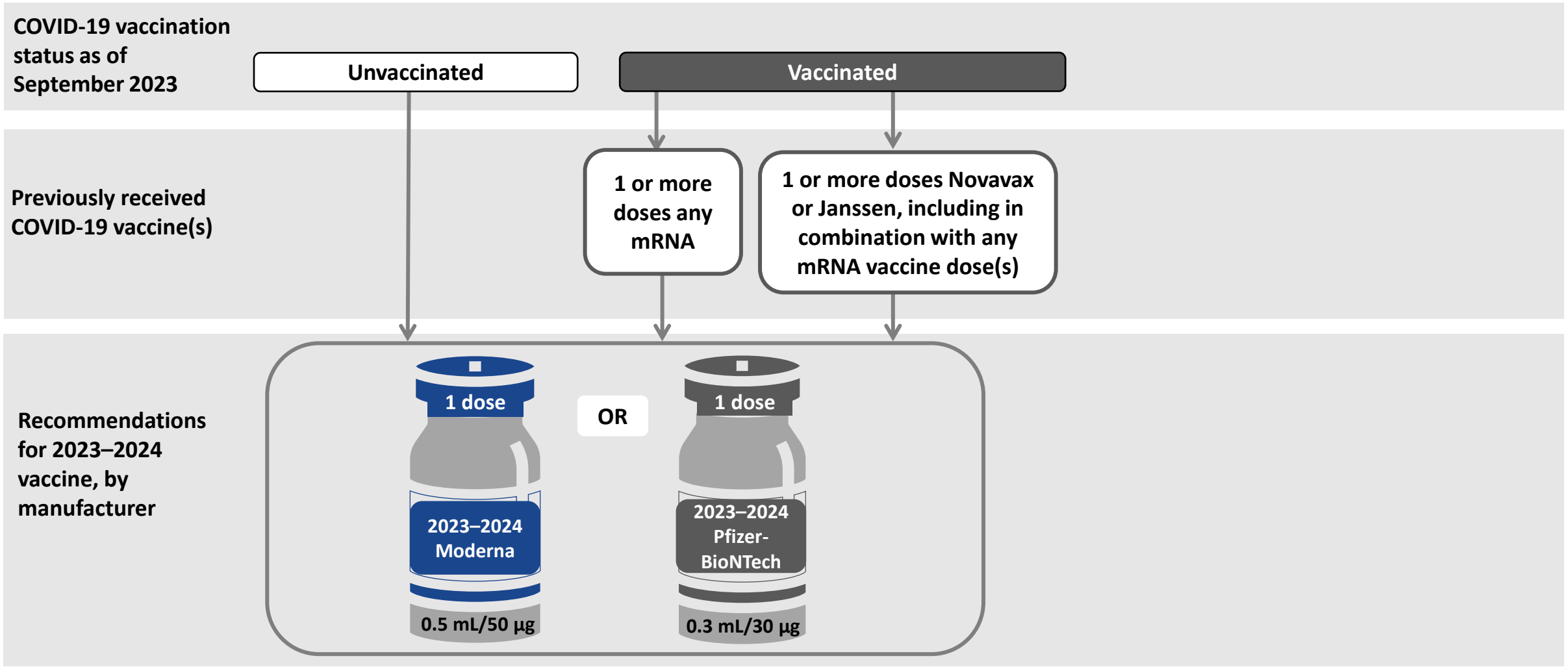
- New harmonized age cutoff for recommendations for young children for Moderna and Pfizer-BioNTech COVID-19 vaccines
- Resulting in simplified recommendations for 5-year-olds
- All Moderna doses in ages 6 months – 11 years are now 25 µcg
- 2023–2024 COVID-19 vaccine dose is recommended at least 2 months 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 people who transition from age 4 years to age 5 years during an mRNA vaccination series, see Table 1 in the Interim Clinical Considerations for Use of COVID-19 vaccines.

Recommended 2023–2024 COVID-19 mRNA vaccines for people who are NOT immunocompromised, aged ≥12 years*



*For information about administration intervals, see Table 1 in the Interim Clinical Considerations for Use of COVID-19 vaccines.

Recommendations for people who are moderately or severely immunocompromised

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

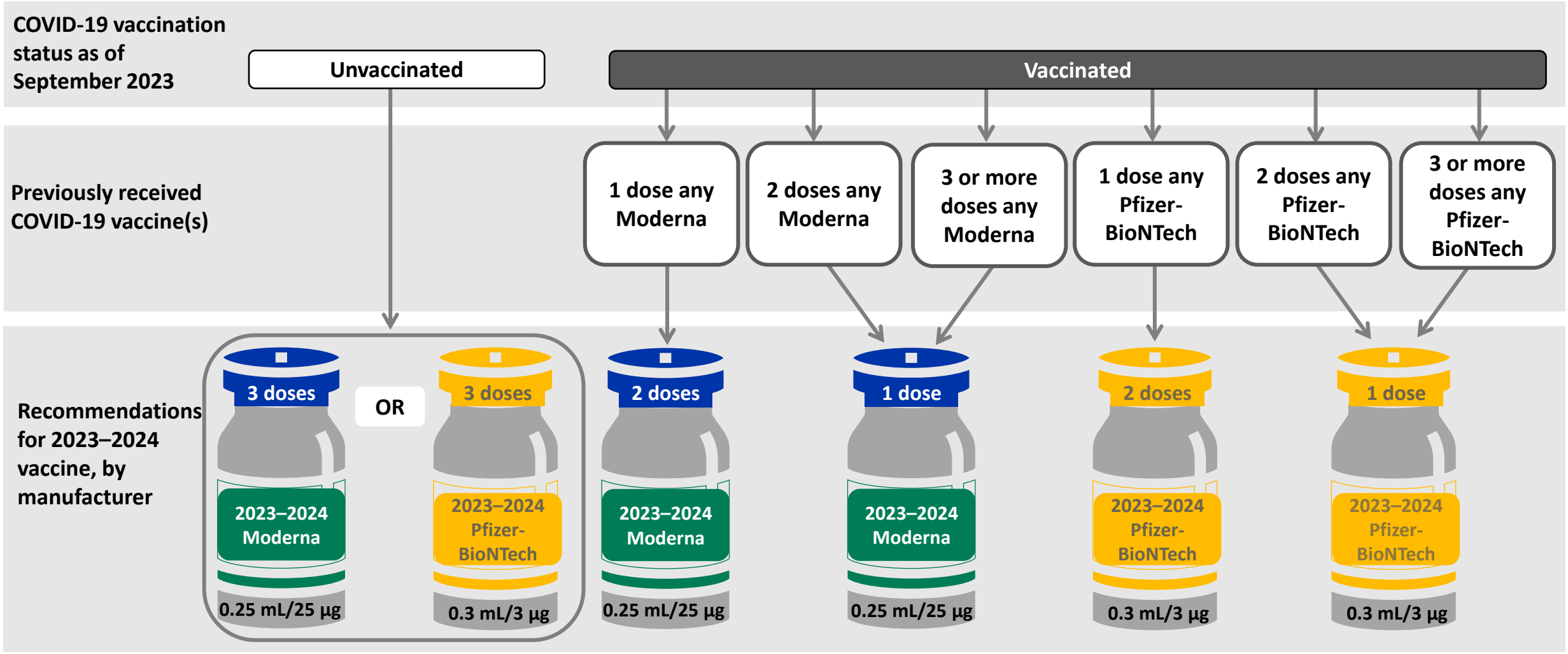
Doses recommended:

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

*Series of 3 homologous mRNA 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).

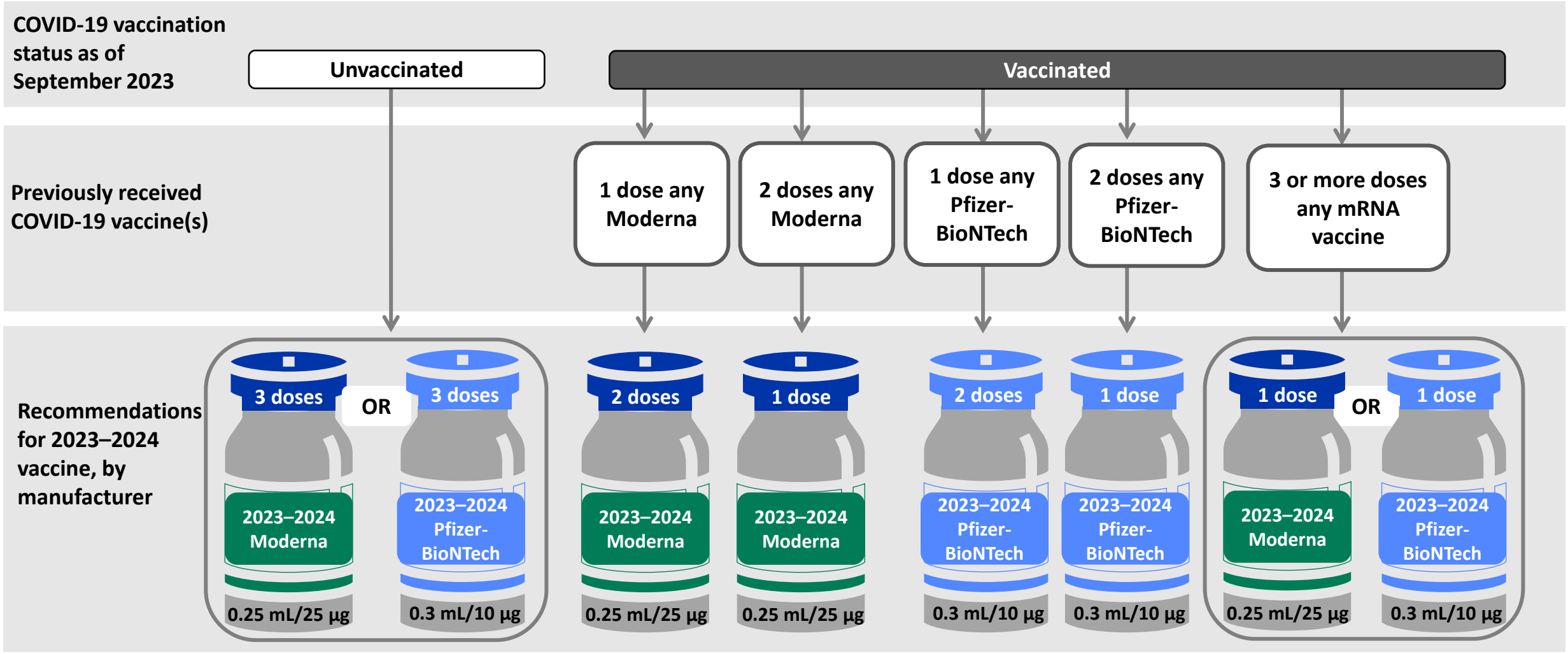
**Further additional dose(s) may be administered, informed by the clinical judgement of a healthcare provider and personal preference and circumstances. Further additional doses should be administered at least 2 months after the last 2023-2024 COVID-19 vaccine dose.

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



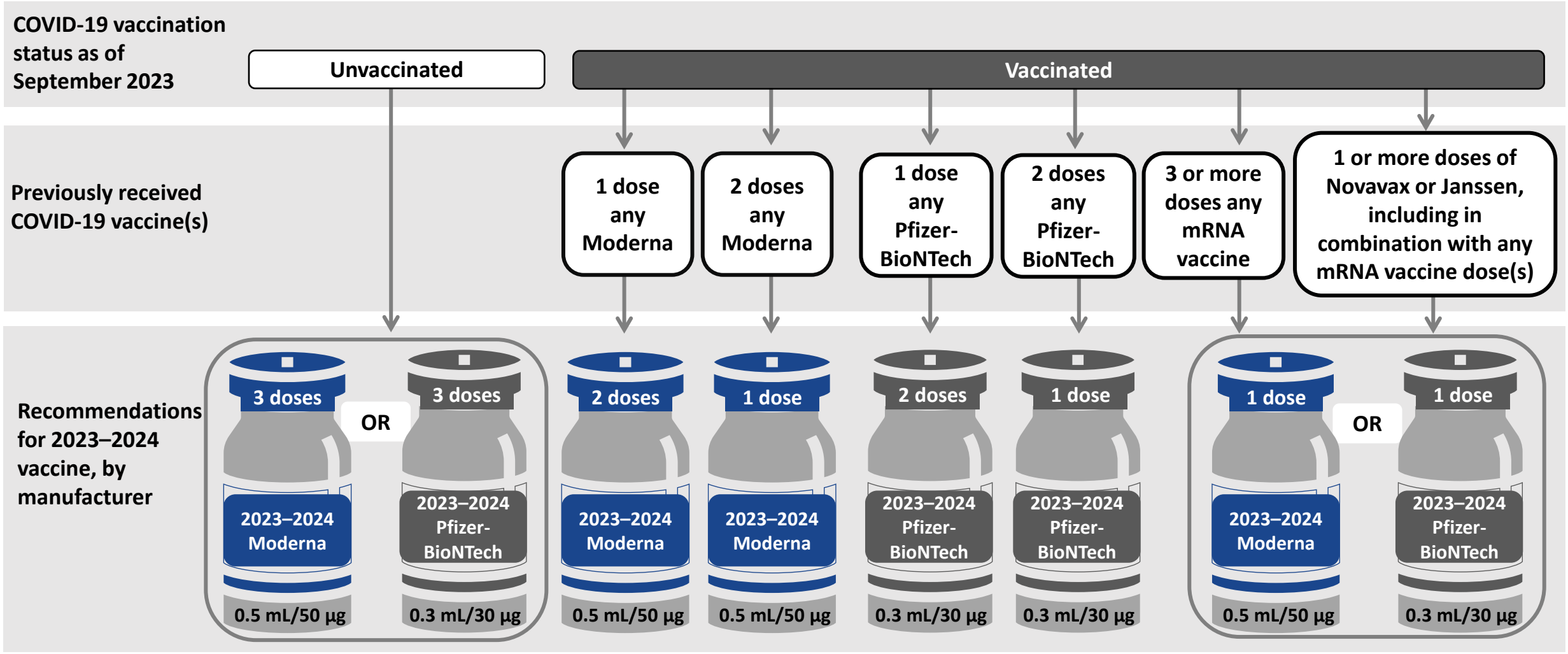
*For information about administration intervals, people who transition from age 4 years to age 5 years during an mRNA vaccination series, and administration of additional dose(s), see Table 2 in Interim Clinical Considerations for Use of COVID-19 Vaccines.

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



*For information about administration intervals, people 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 Interim Clinical Considerations for Use of COVID-19 Vaccines.

Recommended 2023–2024 COVID-19 vaccines for people who ARE moderately or severely immunocompromised, aged ≥12 years*



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

Simultaneous administration of COVID-19 and other vaccines

- In accordance with General Best Practice Guidelines for Immunization, routine administration of all age-appropriate doses of vaccines simultaneously (i.e., administering more than one vaccine on the same clinic day or "coadministration") is recommended for children, adolescents, and adults if there are no contraindications at the time of the healthcare visit.
  - 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

Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC
Use of Nirsevimab for the Prevention of Respiratory Syncytial Virus Disease Among Infants and Young Children: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023 | MMWR (cdc.gov)
Healthcare Providers: RSV Vaccination for Adults 60 Years of Age and Over | CDC
Interim Clinical Considerations for Use of JYNNEOS and ACAM2000 Vaccines during the 2022 U.S. Mpox Outbreak | Mpox | Poxvirus | CDC

Fall COVID-19 vaccine transition

- Vaccines with a monovalent XBB.1.5 composition will be the first COVID-19 vaccines to be available directly from the manufacturers as part of the commercial market, rather than through the United States Government (USG)
- The public will continue to be directed to Vaccines.gov to find providers offering COVID-19 vaccine
- While providers will no longer be required to report inventory to Vaccines.gov after vaccines transition to being available on the commercial market, they will continue to be encouraged to report voluntarily
  - Providers are also strongly encouraged to report the minimum age (in months and years) for whom a location can administer vaccine
- CDC will continue its efforts to make sure that all people have access to COVID-19 medical countermeasures and know where to find product now and in the future

HHS Commercialization Transition Guide: Sunsetting the US Government COVID-19 Vaccine Distribution Program

Feasibility of vaccine implementation

- Inclusion of COVID-19 vaccines in Vaccines for Children (VFC) will likely result in more pediatricians stocking the vaccine
- There will be single dose vial presentations and smaller minimum order quantities
  - Directly addresses concerns from health care providers (HCPs), likely to reduce wastage, eases logistics and helps with storage capacity limitations
    - Moderna, 12+ years: single dose vial (10-pack) and manufacturer-prefilled syringes (10-pack)
    - Moderna, 6 months – 11 years: single dose vial (10-pack)
    - Novavax, 12+ years: 5-dose multi-dose vial (2 vials per carton)
    - Pfizer, 12+ years: single dose vial (10-pack), limited quantity of manufacturer-prefilled syringes (10-pack)
    - Pfizer, 5 – 11 years: single dose vial (10-pack)
    - Pfizer, 6 months – 4 years: 3-dose multi-dose vial (10-pack)
- Preparation is the same or simpler than it was before
  - Moderna preparation is the same (no dilution)
  - Novavax preparation is the same (no dilution)
  - Pfizer preparation is simplified (currently 2 presentations require dilution; for 2023 – 2024 COVID-19 vaccine, ONLY little peds formulation require dilution)

Feasibility of vaccine implementation, cont'd

- Storage and handling will be the SAME as it is now
  - Moderna: Frozen until expiration; 30 days at refrigerator storage
  - Novavax: Stable at 2-8°C (refrigerator storage); 9-month shelf life; use within 12 hours of first puncture
  - Pfizer: Ultra-cold storage until expiration; 10 weeks at refrigerator storage
    - Ultra-cold storage continues to be a challenge; most provider offices do not have a unit
- Dose volume for Pfizer is simplified (all doses are 0.3mL)
- Moderna now only has two presentations, reducing the chance for errors

NIH | COVID-19 Treatment Guidelines

Does Not Require Hospitalization or Supplemental Oxygen

All patients should be offered symptomatic management **(AIII)**.

For patients who are at high risk of progressing to severe COVID-19,[a] use 1 of the following treatment options:

Preferred Therapies

Listed in order of preference:

- **Ritonavir-boosted nirmatrelvir (Paxlovid)[b,c] (AIIa)**
- **Remdesivir[c,d] (BIIa)**

Alternative Therapies

For use ONLY when neither of the preferred therapies are available, feasible to use, or clinically appropriate. Listed in alphabetical order:

- **Molnupiravir[c,f] (CIIa)**

The Panel **recommends against** the use of **dexamethasone[g]** or **other systemic corticosteroids** in the absence of another indication **(AIII)**.

https://www.covid19treatmentguidelines.nih.gov/management/clinical-management/clinical-management-summary/

[a] CDC webpage for criteria of high risk; [b] Caution about drug-drug interactions; [c] If hospitalized, treatment course can be completed; [d] Remdesivir is 3 consecutive day infusion; [f] Molnupiravir has lower efficacy than preferred options; [g] There is currently a lack of safety and efficacy data using glucocorticoids in non-hospitalized patients

Resources

- Interim Clinical Considerations for COVID-19 Treatment in Outpatients
- Underlying Medical Conditions Associated with Higher Risk for Severe COVID-19: Information for Healthcare Professionals
- People Who Are Immunocompromised
- NIH COVID-19 Treatment Guidelines
- IDSA Guidelines on the Treatment and Management of Patients with COVID-19
- FDA Paxlovid Patient Eligibility Screening Checklist for Providers
- HHS Therapeutics Homepage
- Test to Treat Initiative webpage and Fact Sheet
- Test to Treat Site Locator and Digital Tool Kit
- General Therapeutics Locator
- HHS Clinical Implementation Guide
- Side-by-Side Overview of Outpatient Therapeutics
- Paxlovid Potential Drug-Drug Interactions Resource (Pfizer)
- ASPR Regional Emergency Coordinators
- CMS reimbursement information for mAbs
- CMS reimbursement information for oral antivirals
- COVID-19/Therapeutics Updates

Self-knowledge Check

What are the current COVID-19 vaccine recommendations for people aged 5 years and older without immunocompromise?

A. No recommendation
B. 1 dose of 2023–2024 COVID-19 vaccine, under shared clinical decision making
C. 1 dose of 2023–2024 COVID-19 vaccine, regardless of prior vaccination history
D. Multiple doses of 2023–2024 COVID-19 vaccine

Self-knowledge Check

The correct answer is: C.

People aged 5 years and older are recommended for 1 dose of 2023–2024 COVID-19 vaccine, regardless of prior vaccination history

Self-knowledge Check

People aged ≥6 months who are moderately or severely immunocompromised may receive 1 or more additional 2023-2024 mRNA COVID-19 vaccine doses

A. True
B. False

Self-knowledge Check

The correct answer is: A.

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

Thank you

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

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

New Respiratory Syncytial Virus (RSV) Vaccines for Older Adults: General Information and Clinical Guidance

Preparing for the Upcoming Respiratory Virus Season: Recommendations for Influenza, COVID-19, and RSV Vaccines for Older Adults

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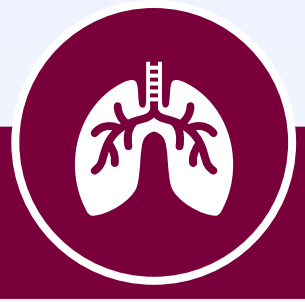
Respiratory Syncytial Virus (RSV) in Adults

About Respiratory Syncytial Virus (RSV)



Common respiratory virus

Causes mild, cold-like symptoms

Seasonal epidemics

Spread through respiratory droplets, direct contact, fomites

Respiratory Syncytial Virus Infection (RSV)

About Respiratory Syncytial Virus (RSV)

Common respiratory virus

Causes mild, cold-like symptoms

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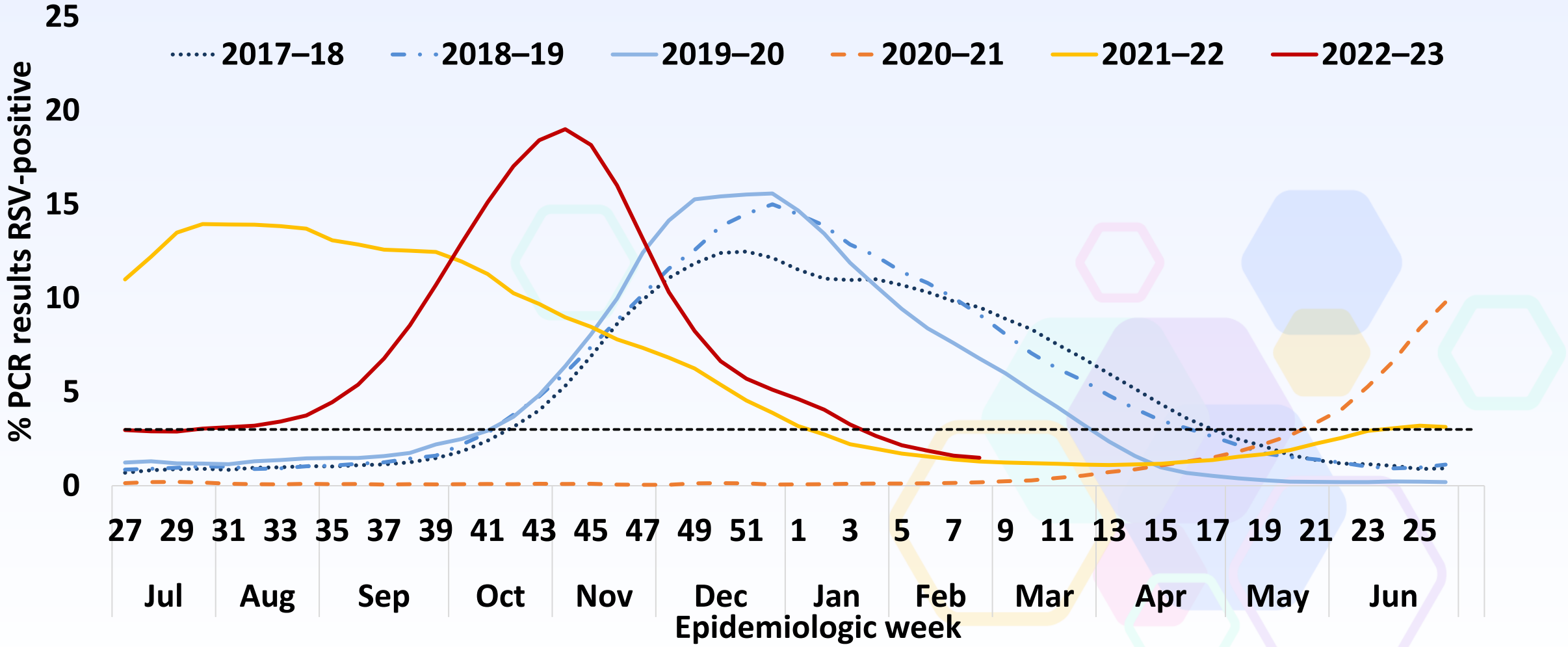
[Respiratory Syncytial Virus Infection (RSV)]

Changes in seasonality of RSV transmission following SARS-CoV2 introduction— NREVSS[1], 2017–2023



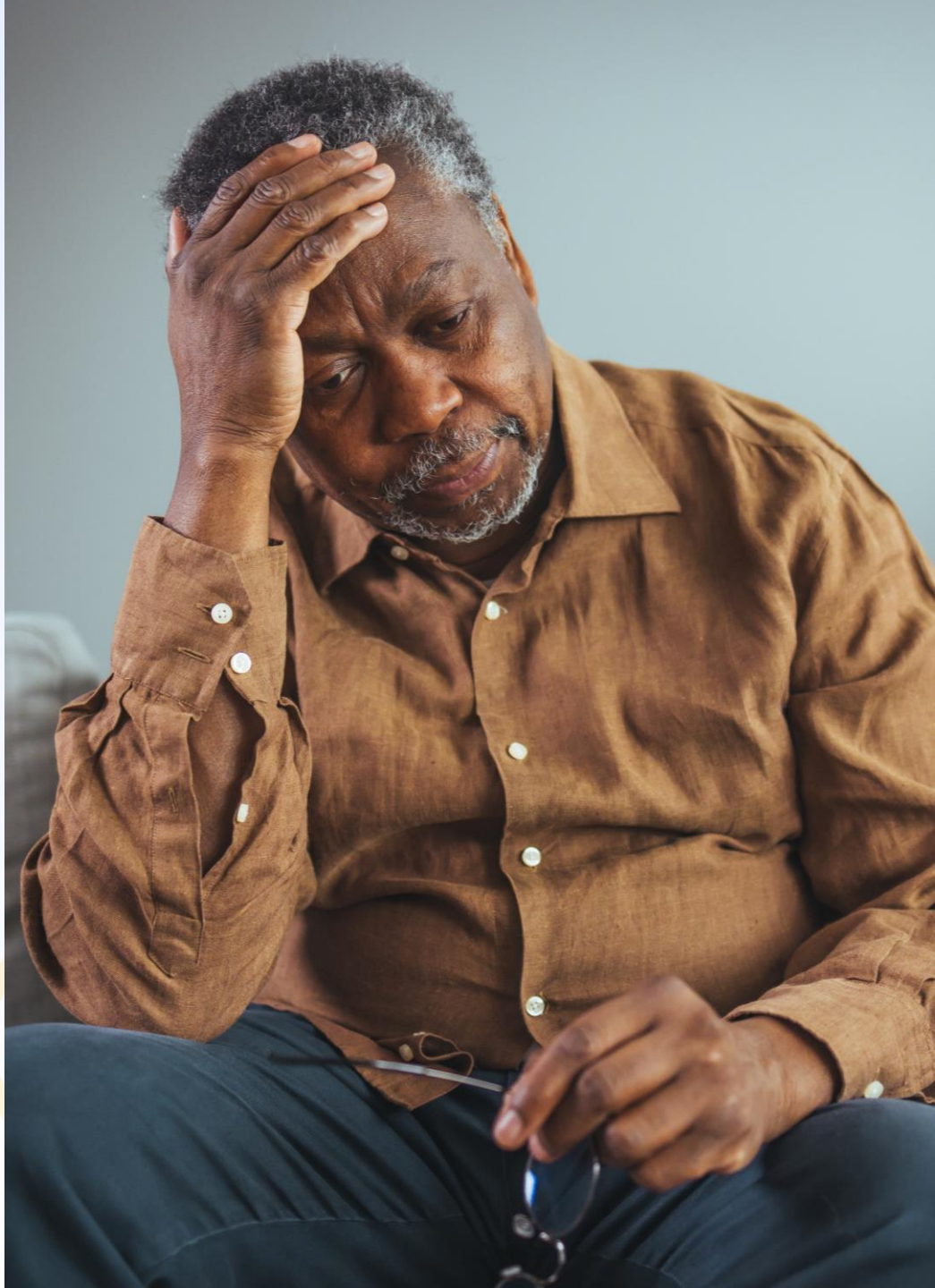
Abbreviation: PCR = polymerase chain reaction; RSV = respiratory syncytial virus.

1. https://www.cdc.gov/mmwr/volumes/72/wr/mm7214a1.htm

* 3-week centered moving averages of percentage of RSV-positive PCR results nationwide. The black dotted line represents the threshold for a seasonal epidemic (3% RSV-positive laboratory PCR results).

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



RSV: For Healthcare Providers

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

Evidence to Recommendations Framework

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

Use of Respiratory Syncytial Virus Vaccines in Older Adults: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023

Other Factors Associated with Increased Risk of Severe RSV Disease

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

[Use of Respiratory Syncytial Virus Vaccines in Older Adults: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023]

Self-knowledge Check

Which of the following statements about RSV clinical symptoms in older adults is FALSE?

A. RSV only causes upper respiratory symptoms like runny nose and sore throat
B. RSV can cause lower respiratory tract infection (e.g., pneumonia)
C. RSV infection can cause exacerbation (flare) of existing chronic conditions
D. Clinical symptoms are non-specific and overlap with symptoms of other respiratory infections

Self-knowledge Check

The correct answer is: A.

Although RSV infection in most adults typically causes mild upper respiratory symptoms, older adults are at increased risk of serious illness, compared with younger adults. Serious illness from RSV can include lower respiratory tract infection, like pneumonia, or an exacerbation of existing chronic conditions, like congestive heart failure or chronic obstructive pulmonary disease (COPD).

RSV Vaccines

Efficacy and safety

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 ($AS01_E$) recombinant prefusion F protein (preF) vaccine.

- RSVpreF (**Abrysvo, Pfizer**) is a 1-dose recombinant preF vaccine.

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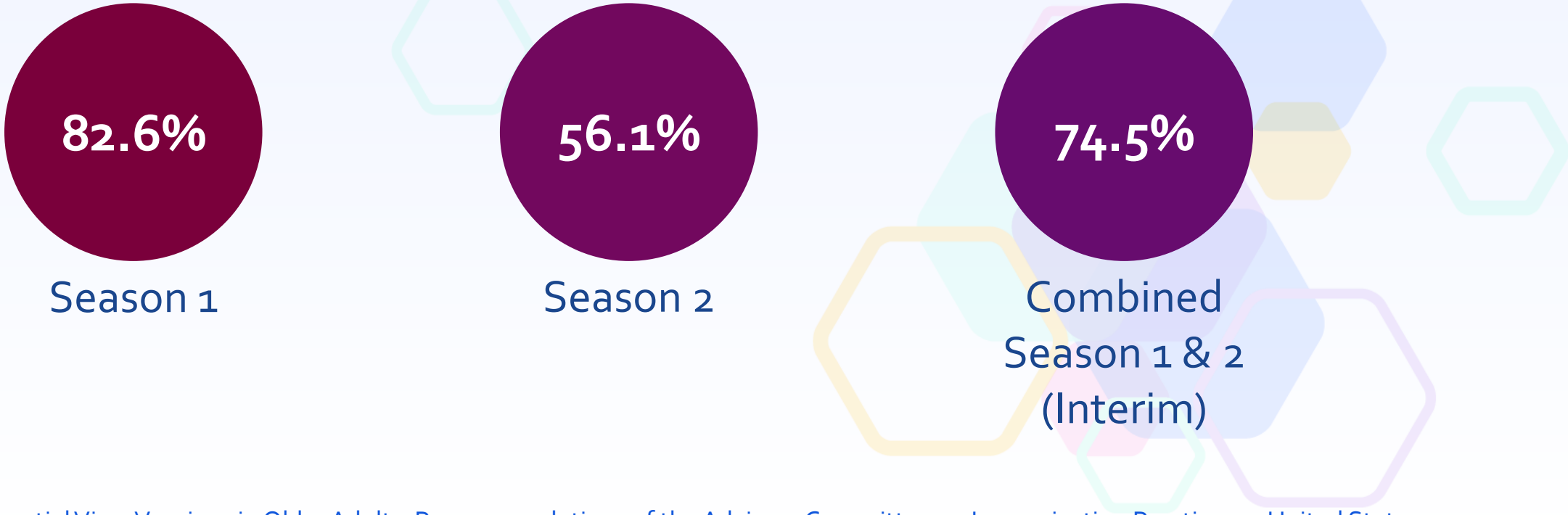
Vaccine Efficacy (VE): GSK

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



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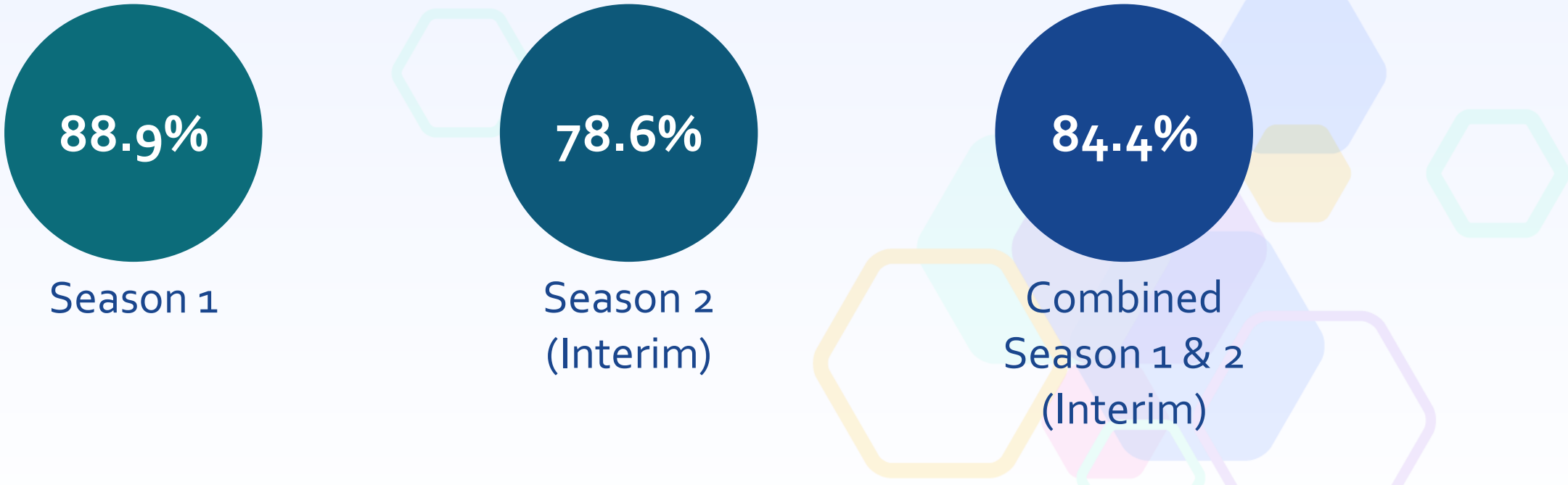
Vaccine Efficacy (VE): Pfizer

- 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 trial efficacy against RSV LRTI with at least **three** lower respiratory **signs/symptoms**

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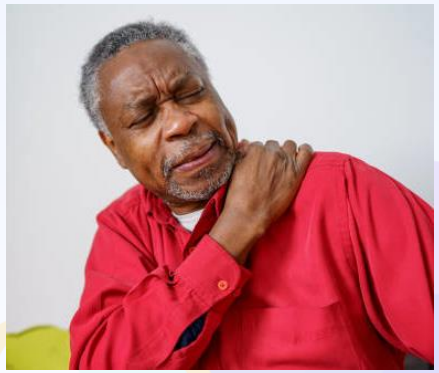
Vaccine Safety: GSK & Pfizer

- Generally **well-tolerated** with an acceptable safety profile
- Most common side effects **are similar to those of other vaccines**

Pain at injection site

Fatigue

Headache



Muscle pain

Joint pain

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Vaccine Safety: GSK & Pfizer

- 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.

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Vaccine Safety

- CDC will **monitor adverse events** following RSV vaccination through VAERS and the Vaccine Safety Datalink.
- Per FDA requirements, both manufacturers will **conduct further studies**.
- Report any adverse event after RSV vaccination to the **Vaccine Adverse Event Reporting System**.

VAERS Vaccine Adverse Event Reporting System
www.vaers.hhs.gov

Use of Respiratory Syncytial Virus Vaccines in Older Adults: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023
VAERS

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

RSV Vaccination Recommendations

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

[Use of Respiratory Syncytial Virus Vaccines in Older Adults: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023]

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

ACIP Shared Clinical Decision-Making Recommendations

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

- Lung disease
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- Diabetes Mellitus
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Other Factors Associated with Increased Risk of Severe RSV Disease

- Residence in a nursing home or other long-term care facility (LTCF)
- Frailty
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Use of Respiratory Syncytial Virus Vaccines in Older Adults: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023

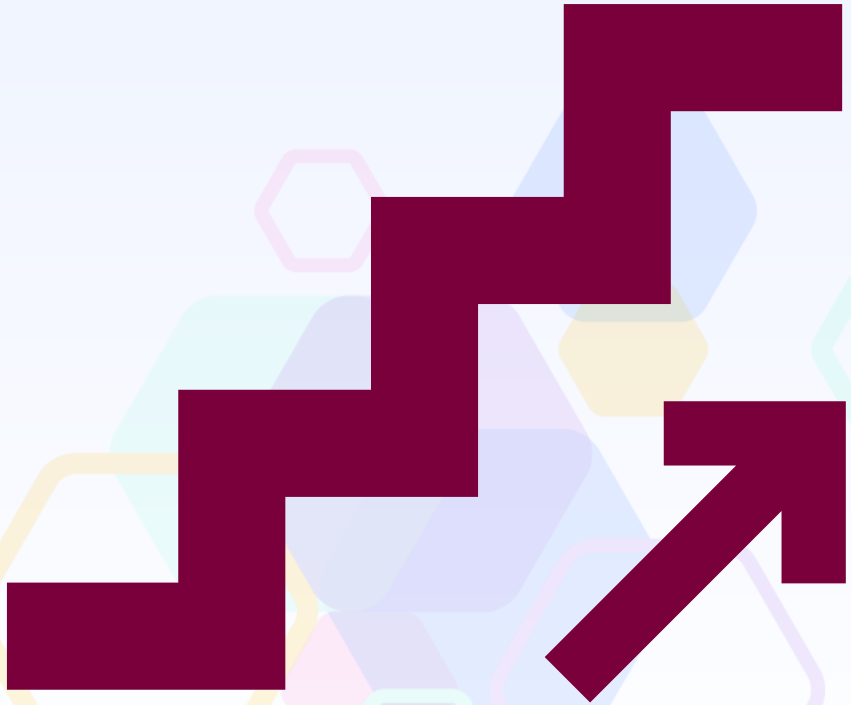
Other Factors Associated with Increased Risk of Severe RSV Disease

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

Frailty

Advanced age

RSV incidence increases with **advancing age.**



[Use of Respiratory Syncytial Virus Vaccines in Older Adults: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023]
[Evidence to Recommendations Framework]

Vaccination Timing: 2023-2024 Season

Summer: Offer RSV vaccination as early as vaccine is available

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

Use of Respiratory Syncytial Virus Vaccines in Older Adults: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023

Coadministration

- Coadministration with **all** other adult vaccines is **acceptable**.

- If vaccines are NOT administered the same day, **there is no required interval between vaccines**.

Use of Respiratory Syncytial Virus Vaccines in Older Adults: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023

Data on immunogenicity of coadministration of RSV vaccines with other vaccines

- There are currently limited data available on immunogenicity of coadministration of RSV vaccines and other vaccines.
- **In general, coadministration of RSV and seasonal influenza vaccines met non-inferiority criteria for immunogenicity.***
- However, RSV and influenza antibody titers were generally somewhat lower with coadministration; the clinical significance of this is unknown.
- Additional studies on immunogenicity of coadministration of RSV with other adult vaccines are in process.

* Pre-specified non-inferiority criteria for immune responses were met across trials, with the exception of the FluA/Darwin H_3N_2 strain after simultaneous administration of $RSVPreF_3$ vaccine (Arexvy by GSK) and adjuvanted quadrivalent inactivated influenza vaccine.

Summary of Proposed Clinical Considerations for RSV Vaccines

Summary

Summary of Key Points

- RSV can cause serious illness in older adults.
- Underlying medical conditions and other factors are associated with increased risk of severe RSV.
- Two RSV vaccines are licensed.
- Adults ages 60 years and older may receive a single dose of RSV vaccine, using shared clinical decision-making.
- Coadministration with RSV and other adult vaccines is acceptable.

RSV vaccine resources

- RSV Vaccination: What Older Adults 60 Years of Age and Over Should Know
- Frequently Asked Questions About RSV Vaccine for Adults
- Healthcare Providers: RSV Vaccination for Adults 60 Years of Age and Over
- ACIP Shared Clinical Decision-Making Recommendations

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For more information, contact CDC
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Talking to Patients about Vaccines

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National Center for Immunization and Respiratory Diseases

Vaccine Conversations

- Answering questions can be challenging
  - Staff is not always prepared for questions
  - Inconsistent messages from staff
  - Real-life time constraints
  - Frustrating! Correcting misconceptions can successfully reduce misperceptions, but does not always result in vaccination

2007 National Survey of Children's Health. Factors associated with human papillomavirus vaccine-series initiation and health care provider recommendation in U.S. adolescent females. *Vaccine* 2012;30(20):3112–3118

Knowledge

≠

Behavior

Communication Tools

1. Presumptive approach
2. Motivational interviewing

Presumptive Approach with a Strong Recommendation

- CDC recommends giving a **strong recommendation** for vaccination using the **presumptive approach**.
- The presumptive approach assumes a patient will **choose to vaccinate**.
- Your strong vaccine recommendation is the **most important part** of the vaccine conversation.

Immunization Strategies for Healthcare Practices and Providers (Pink Book)
Talking with Patients about COVID-19 Vaccination

Motivational Interviewing

Motivational Interviewing (MI)

- **Evidence-based** and **culturally sensitive** way to speak with unvaccinated patients about getting vaccinated
- The goal is to help people **manage mixed feelings** and move toward healthy behavior change consistent with their values and needs
- Ideal for situations for **concerned patients** or **patients with questions**
- Studies using MI with vaccination decisions demonstrate **increased intent to vaccinate** and **improved vaccination rates**

The use of motivational interviewing to overcome COVID-19 vaccine hesitancy in primary care settings
Using Best Practices to Address COVID-19 Vaccine Hesitancy: The Case for the Motivational Interviewing Approach
Best shot: A motivational interviewing approach to address vaccine hesitancy in pediatric outpatient settings
Motivational interviewing: A powerful tool to address vaccine hesitancy

Motivational Interviewing Quickly Builds Trust and Partnership

- Four steps to applying rapidly (1-5 minutes)

1. Be empathetic
2. Ask permission
3. Apply interviewing techniques
4. Respond to questions

Talking with Patients about COVID-19 Vaccination

Step 1: Be an Empathetic Partner

- Be compassionate and **show empathy**.
- Be **sensitive** to culture, family dynamics, and circumstances that may influence how patients view vaccines.
- Do **not** argue or debate.

Talking with Patients about COVID-19 Vaccination

Step 2: Ask Permission to Share More Information About Vaccines

- Start by **asking permission** to discuss vaccines.

- Example: "*If it is okay with you, I would like to spend a few minutes talking about COVID-19 vaccines and your family*."

Step 2: Ask Permission to Share More Information About Vaccines

- If the patient indicates they do **NOT** want to talk about vaccines:
  - Probe **about why** they don't want to talk about vaccines
    - "Can you tell me more about the reasons you don't want to discuss vaccination today?"
  - **Respect** the patient's decision
    - "You're not ready to talk about vaccines today, and that's okay."
  - Ask if they would be willing to talk about vaccines **at their next visit**
    - "Because I care about your overall health, maybe we could talk about the vaccine at your next visit?"

Step 3: Apply Interviewing Techniques

- **O**pen the conversation
  - Use open-ended starters to explore
  - Avoid yes/no questions, which stop the conversation
- **A**ffirm positive behaviors
  - *"That's great that you've gotten your flu vaccine. Now lets discuss some other vaccines."*
- **R**eflect what you hear
  - *"It sounds like you have questions."*
- **S**ummarize the conversation
  - *"Let me see if I understand what you've said so far [summarize in your own words]."*

Step 3: Apply Interviewing Techniques

- Example: Ask the patient a scaled question.
  - *"On a scale of 1 to 10, how likely are you to get a COVID-19 vaccine?"*
- Keep exploring and reflectively listen.
  - *"Why did you choose this number?"*
  - *"Why wasn't it lower?" "Why wasn't it higher?"*
  - *"What would take to get to a higher number?"*
- The goal is to help the patient become more open to moving toward high numbers (i.e., getting vaccinated).

Step 4: Respond to Questions

- If a patient **asks a question** about vaccine safety, vaccine risks, or their health or mental health, respond within the boundaries of your competence, ethics, and scope of practice.
- Most data on safety and risk is **population based**. Practice reframing safety as **individual risk**.
  - "Based on your health, you are at an increased risk of getting very sick, and in the group the vaccine will most benefit.
- If you do not know the answer to a question, discuss **how to find a good source** of information.

Talking with Patients about COVID-19 Vaccination

Self-knowledge Check

Who is the patient's most trusted source for information on vaccines?

A. Healthcare Staff
B. Dr. Google
C. Neighbors
D. Family & Friends

Self-knowledge Check

The correct answer is: A.

Multiple studies have demonstrated that healthcare providers and their staff are the patient's most trusted source for healthcare information, including information about vaccines.

To Ask a Question

- Using the Zoom Webinar System
  - Click on the “Q&A” button
  - Type your question in the “Q&A” box
  - Submit your question

- If you are a patient, please refer your question to your healthcare provider.

- If you are a member of the media, please direct your questions to CDC Media Relations at 404-639-3286 or email media@cdc.gov

Continuing Education

- All continuing education for COCA Calls is issued online through the CDC Training & Continuing Education Online system at https://tceols.cdc.gov/.

- Those who participate in today's COCA Call and wish to receive continuing education please complete the online evaluation by **Monday, October 23, 2023,** with the course code **WC4520-091923**. The access code is **COCA091923.**

- Those who will participate in the on-demand activity and wish to receive continuing education should complete the online evaluation between **October 24, 2023,** and **October 24, 2025,** and use course code **WD4520-091923.** The access code is **COCA091923.**

- Continuing education certificates can be printed immediately upon completion of your online evaluation. A cumulative transcript of all CDC/ATSDR CEs obtained through the CDC Training & Continuing Education Online System will be maintained for each user.

Today's COCA Call Will Be Available to View On-Demand

- **When:** A few hours after the live call ends*
- **What:** Video recording
- **Where:** On the COCA Call webpage https://emergency.cdc.gov/coca/calls/2023/callinfo_091923.asp

**A transcript and closed-captioned video will be available shortly after the original video recording posts on the COCA Call webpage.*

Upcoming COCA Calls & Additional Resources

- Next COCA Call: Thursday, September 21, 2023, 2 PM ET
  - Topic: Algorithms for Diagnosing the Endemic Mycoses Blastomycosis, Coccidioidomycosis, and Histoplasmosis
  - https://emergency.cdc.gov/coca/calls/2023/callinfo_092123.asp

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