CDC/IDSA Clinician Call

September 14, 2023

Welcome & Introductions

Dana Wollins, DrPH, MGC
Senior Vice President, Strategy
Infectious Diseases Society of America

- 99th in a series of calls, initiated in 2020 as a forum for information sharing among frontline clinicians caring for patients with COVID-19.
- The views and opinions expressed here are those of the presenters and do not necessarily reflect the official policy or position of the CDC or IDSA. Involvement of CDC and IDSA should not be viewed as endorsement of any entity or individual involved.
- This webinar is being recorded and can be found online at www.idsociety.org/cliniciancalls.

COVID-19 New Booster Vaccine & Variants Update; Plus Updates on RSV, Influenza & Pneumococcal Immunizations

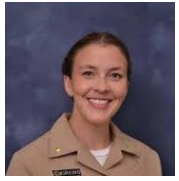
COVID-19 Real-Time Learning Network

Brought to you by CDC and IDSA

1. Preparing for the Fall Respiratory Infection Season: What to Expect

Carlos del Rio, MD, FIDSA
IDSA President
Distinguished Professor of Medicine, Division of Infectious Diseases
Emory University School of Medicine
Professor of Epidemiology & Global Health
Rollins School of Public Health of Emory University

2. COVID-19 Updates



COVID-19 Status & Variants Update

Hannah Kirking, MD
CDR United States Public Health Service
Outbreak Response and Community Team Lead, Respiratory Viruses Epidemiology Branch
Coronavirus and Other Respiratory Viruses Division
U.S. Centers for Disease Control and Prevention

COVID-19 Vaccine Update

Ruth Link-Gelles, PhD, MPH
CDR U.S. Public Health Service
Coronavirus and Other Respiratory Viruses Division
COVID-19 Vaccine Effectiveness Program Lead
U.S. Centers for Disease Control & Prevention

Keipp Talbot, MD, MPH
Professor of Medicine, Division of Infectious Diseases
And Professor of Health Policy
Vanderbilt University

3. The Latest on RSV Immunization for Adults & Children

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Vaccine Effectiveness & Policy Team
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Coronavirus & Other Respiratory Viruses Division
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IDSA Vice President
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ACIP Maternal/Pediatric RSV WG Co-Lead
Coronavirus & Other Respiratory Viruses Division
National Center for Immunization & Respiratory Diseases
U.S. Centers for Disease Control & Prevention

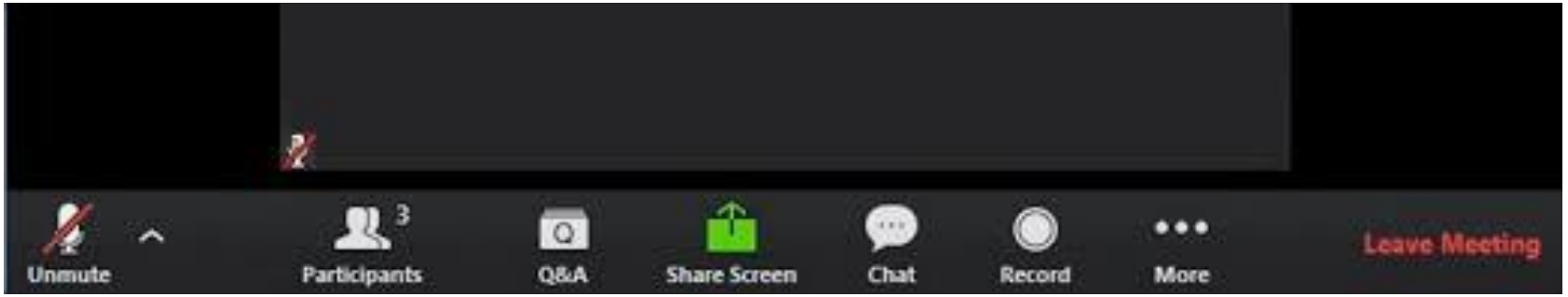
4. Pneumococcal Vaccine for Adults: Update on New Recommendations

Miwako Kobayashi, MD, MPH
Medical Epidemiologist
Respiratory Diseases Branch
National Center for Immunization & Respiratory Diseases
U.S. Centers for Disease Control & Prevention

5. Q&A/Discussion

Question?
Use the “Q&A” Button

Comment?
Use the “Chat” Button



Preparing for the Fall Respiratory Infection Season: What to Expect

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COVID-19 Updates

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Coronavirus and Other Respiratory Viruses Division
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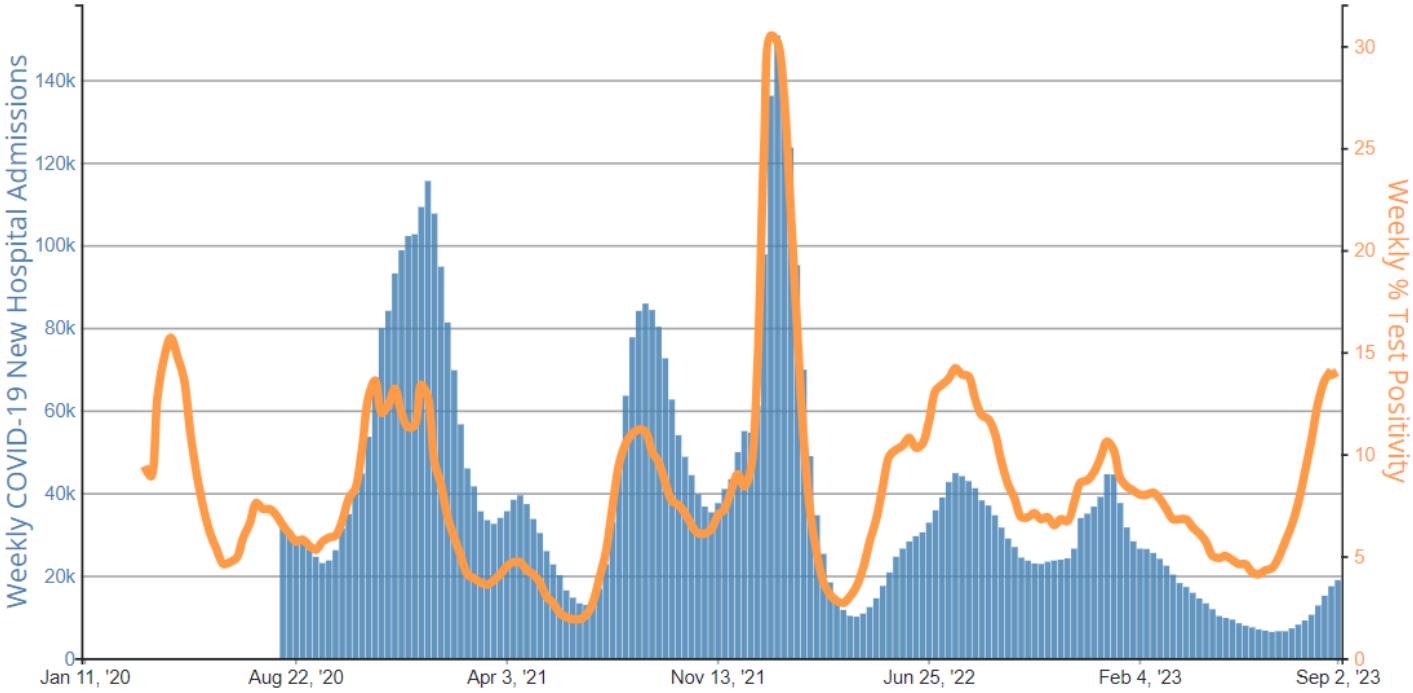
Summary of COVID-19 trends by US region

Metric	US	R1	R2	R3	R4	R5	R6	R7	R8	R9	R10
Test Positivity	→	↑	↓	↑	→	→	→	→	↓	↓	→
ED visits	→	↑	↑	↑	↓	↑	↓	↑	↑	→	↑
Hospital Admissions	↑	→	→	↑	↑	↑	↑	↑	↑	↑	↑

As of September 8, 2023

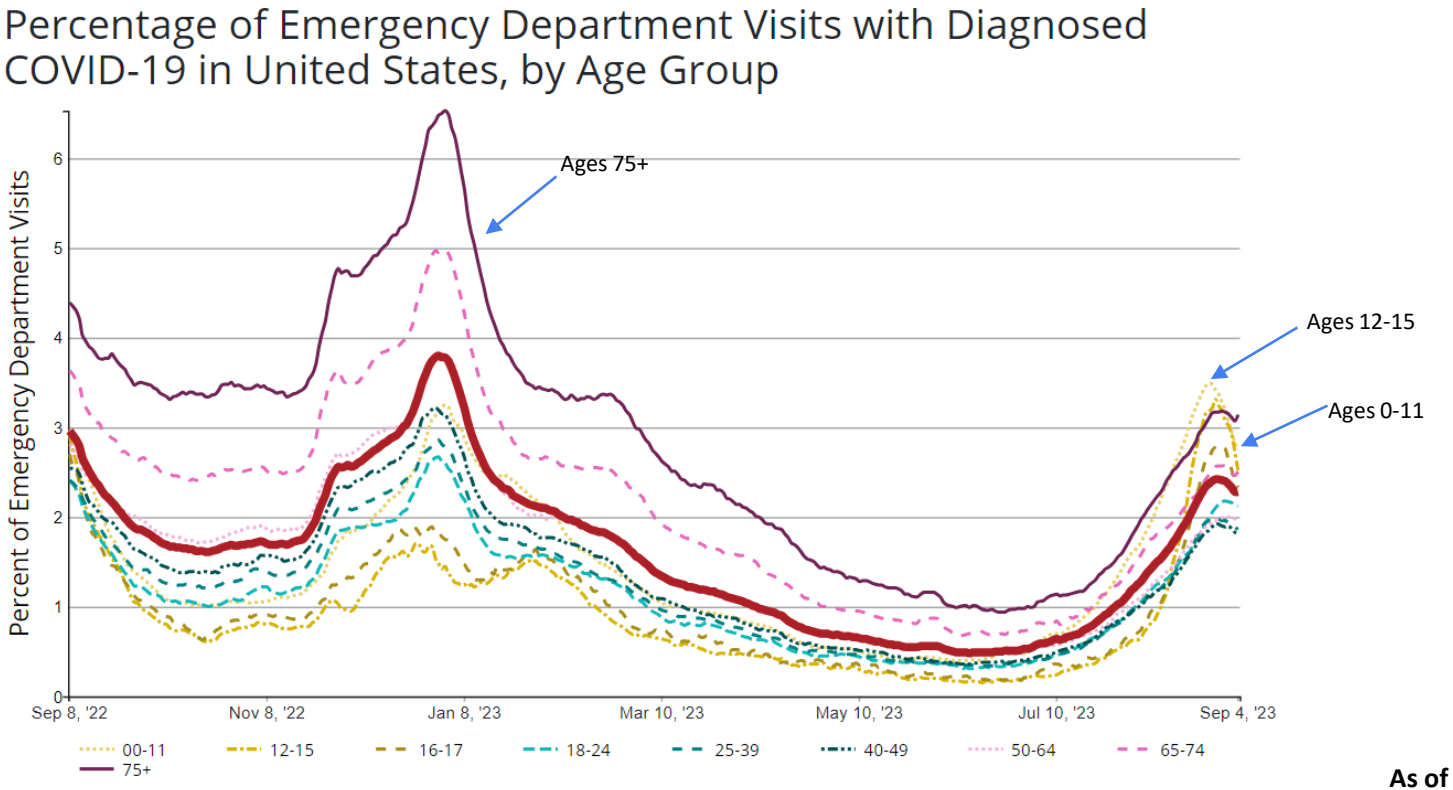
COVID-19 New Hospital Admissions and Nucleic Acid Amplification Test (NAAT) Percent Positivity, by Week



As of September 8, 2023

https://covid.cdc.gov/covid-data-tracker/#trends_weeklyhospitaladmissions_testpositivity_00

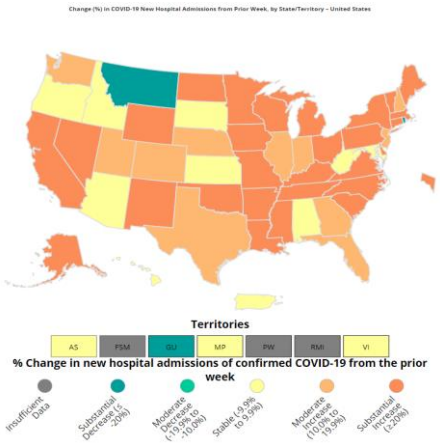
Increases in COVID-19 emergency department visits leveling off in some age groups



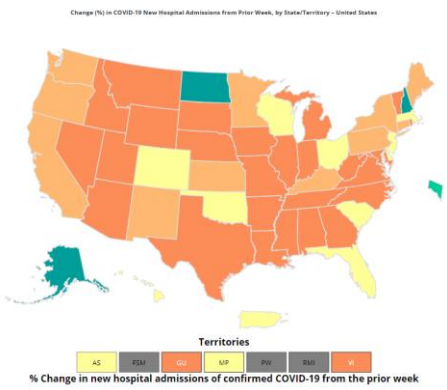
As of September 8, 2023

Change in Proportion of Hospitalizations for COVID-19

Weekly change 3 weeks ago

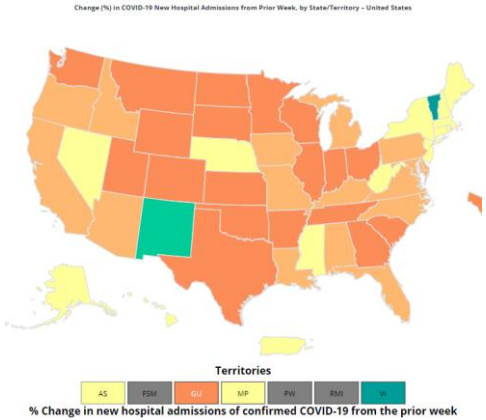


Weekly change 2 week ago



Weekly change last week

Current



Insufficient Data

Substantial Decrease (≤ -20%)

Moderate Decrease (-19.9% to -10.0%)

Stable (-9.9% to 9.9%)

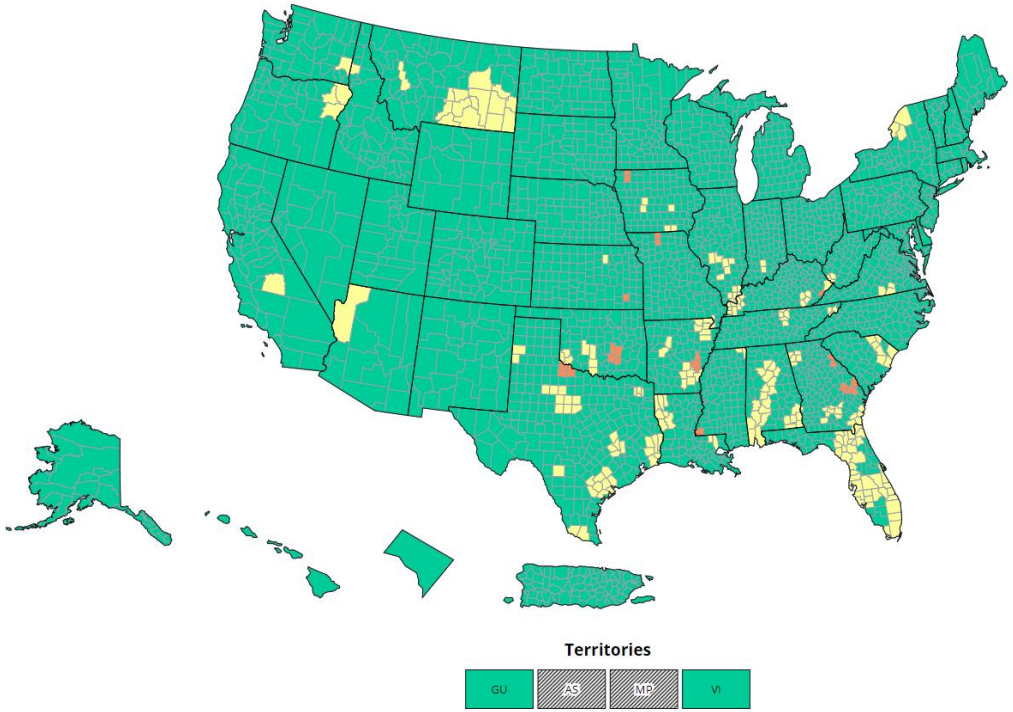
Moderate Increase (10.0% to 19.9%)

Substantial Increase (≥20%)

https://covid.cdc.gov/covid-data-tracker/#maps_percent-inpatient-beds-change-state

As of September 8, 2023

Reported COVID-19 New Hospital Admissions Rate per 100,000 population in the past week



COVID-19 hospital admissions levels in U.S. by county

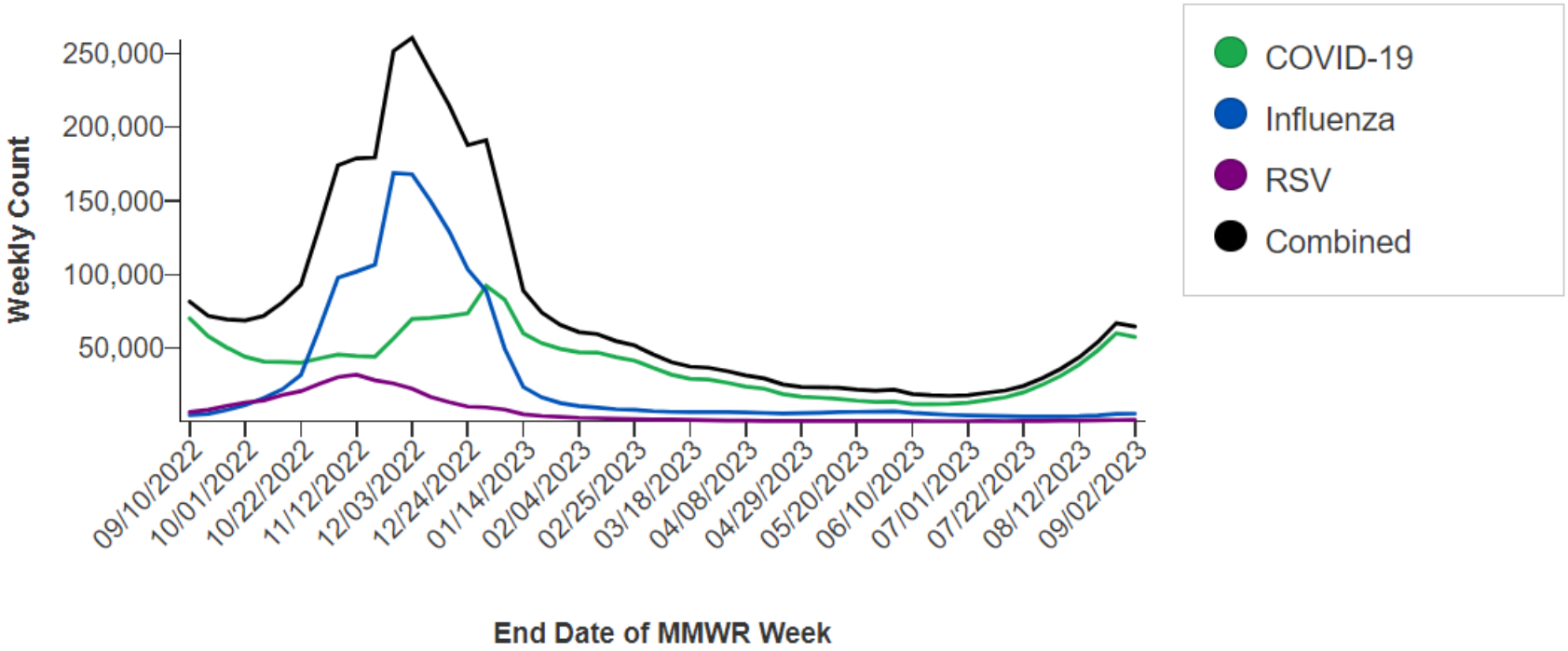
Based on new COVID-19 hospital admissions per 100,000 population

	Total	Percent	% Change
≥ 20.0	22	0.68%	0.22%
10.0 - 19.9	230	7.14%	0.4%
<10.0	2970	92.18%	-0.56%

https://covid.cdc.gov/covid-data-tracker/#maps_new-admissions-rate-county

As of September 8, 2023

CDC Integrated Respiratory Virus Activity Dashboard



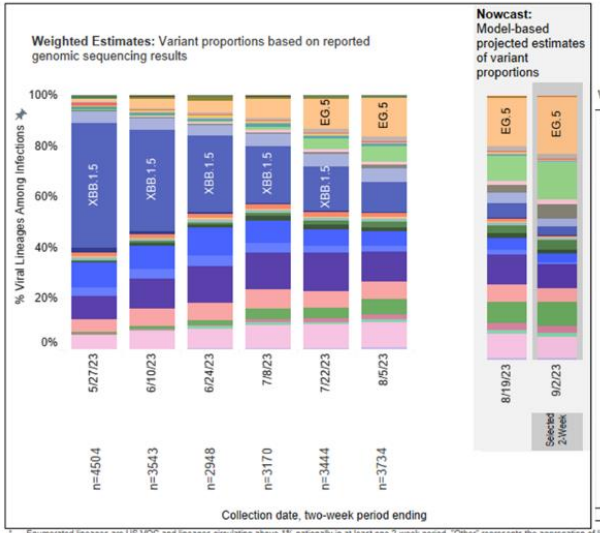
https://www.cdc.gov/respiratory-viruses/index.html

As of September 8, 2023

SARS-CoV-2 Variants – Nowcast Estimates

- EG.5, which is a sublineage of XBB.1.9.2, continues to increase in proportion.
  - Projected to comprise the largest proportion (21.5%) of circulating SARS-CoV-2 strains in the United States
- Nowcast estimates that HV.1 will be the fastest-growing lineage, representing 5.1% of viruses nationally

Weighted and Nowcast Estimates in United States for 2-Week Periods in 5/14/2023 – 9/2/2023



Nowcast Estimates in United States for 8/20/2023 – 9/2/2023

USA

WHO label	Lineage #	%Total	95%PI
Omicron	EG.5	21.5%	19.0-24.3%
	FL.1.5.1	14.5%	10.5-19.6%
	XBB.1.16.6	9.2%	7.6-11.0%
	XBB.1.16	8.9%	7.8-10.3%
	XBB.2.3	8.1%	7.0-9.2%
	HV.1	5.1%	3.3-7.9%
	XBB.1.16.1	5.0%	4.2-6.0%
	XBB.1.5.70	3.5%	2.6-4.7%
	XBB	3.3%	2.7-4.1%
	XBB.1.5	3.1%	2.6-3.7%
	XBB.1.9.1	3.0%	2.5-3.5%
	XBB.1.16.11	2.8%	1.8-4.5%
	EG.6.1	1.8%	1.2-2.7%
	GE.1	1.6%	1.1-2.4%
	XBB.1.5.72	1.6%	1.2-2.1%
	XBB.1.42.2	1.3%	0.7-2.3%
	XBB.1.9.2	1.1%	0.9-1.3%
	XBB.1.5.10	0.9%	0.7-1.2%
	XBB.1.5.68	0.8%	0.5-1.1%
	XBB.2.3.8	0.7%	0.4-1.2%
	FD.1.1	0.6%	0.4-0.8%
	FE.1.1	0.5%	0.3-0.8%
	XBB.1.5.59	0.4%	0.3-0.6%
	CH.1.1	0.4%	0.3-0.6%
	EU.1.1	0.1%	0.1-0.2%
	XBB.1.5.1	0.0%	0.0-0.1%
	BA.2.12.1	0.0%	0.0-0.1%
	BA.5	0.0%	0.0-0.0%
	BQ.1	0.0%	0.0-0.0%
	FD.2	0.0%	0.0-0.0%
	B.1.1.529	0.0%	0.0-0.1%
Other	Other*	0.0%	0.0-0.1%

* Enumerated lineages are US VOC and lineages circulating above 1% nationally in at least one 2-week period. "Other" represents the aggregation of lineages which are circulating <1% nationally during all 2-week periods displayed.
# BA.1, BA.3 and their sublineages (except BA.1.1 and its sublineages) are aggregated with B.1.1.529. Except BA.2.12.1, BA.2.75, XBB and their sublineages. BA.2 sublineages are aggregated with BA.2. Except BA.2.75.2, CH.1.1 and BN.1, BA.2.75 sublineages are aggregated with BA.2.75. Except BA.4.6, sublineages of BA.4 are aggregated to BA.4. Except BF.7, BF.11, BA.5.2.6, BQ.1 and BQ.1.1, sublineages of BA.5 are aggregated to BA.5. Except the lineages shown and their sublineages, sublineages of XBB are aggregated to XBB. Except XBB.1.5.1,XBB.1.5.10,FD.2,EU.1.1,XBB.1.5.68 and XBB.1.5.70 sublineages of XBB.1.5 are aggregated to XBB.1.5. Except FL.1.5.1, sublineages of XBB.1.9.1 are aggregated to XBB.1.9.1. Except XBB.1.16.1,XBB.1.16.11 sublineages of XBB.1.16 are aggregated to XBB.1.16, sublineages of XBB.1.42.2 are aggregated to XBB. Except FE.1.1, sublineages of XBB.1.18.1 are aggregated to XBB. For all the other lineages listed, their sublineages are aggregated to the listed parental lineages respectively. Previously, FL.1.5.1, GE.1, EG.6.1 and HV.1, FD.1.1, XBB.2.3.8 was aggregated to XBB.1.9.1, XBB.2.3.10, XBB.1.9.2, XBB.1.5.15 and XBB.2.3 respectively. Lineages BA.2.75.2, XBB, XBB.1.5, XBB.1.5.1, XBB.1.5.10, FD.2, XBB.1.9.1, XBB.1.9.2, XBB.1.16, XBB.1.16.1, XBB.2.3, BN.1, BA.4.6, BF.7, BF.11, BA.5.2.6 ,BQ.1.1, EU.1.1, XBB.1.5.68, FE.1.1, EG.5, XBB.1.5.72 , FL.1.5.1, GE.1, EG.6.1,XBB.1.16.11, FD.1.1, XBB.1.5.70, XBB.2.3.8, HV.1 and XBB.1.42.2 contain the spike substitution R346T.

https://covid.cdc.gov/covid-data-tracker/#variant-proportions

As of September 8, 2023

What is BA.2.86?

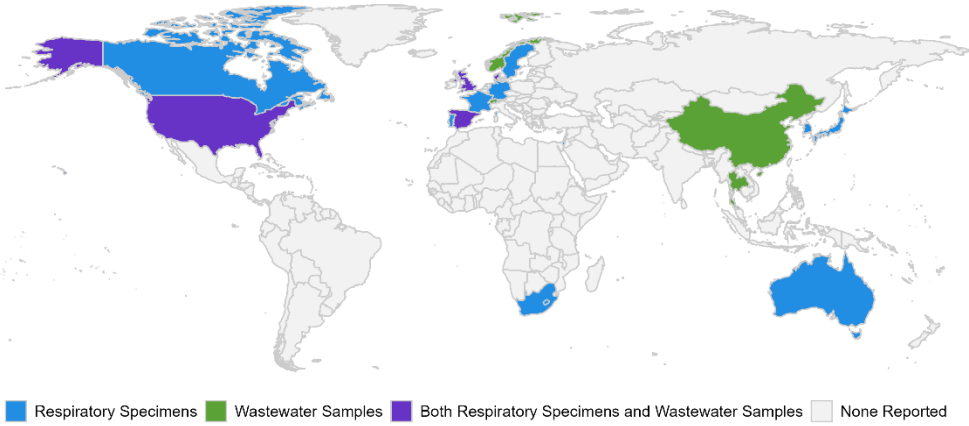
- New variant of SARS-CoV-2 initially detected in samples from people in Denmark and Israel
  - First reported August 13 with specimens collected July 31
- Contains >35 spike mutations with respect to XBB.1.5
  - Concern for greater escape from existing immunity
- US SARS-CoV-2 Interagency Group monitors risks associated with variants
  - BA.2.86 currently categorized as a Variant Being Monitored (VBM)

https://www.cdc.gov/respiratory-viruses/whats-new/covid-19-variant.html
https://www.cdc.gov/coronavirus/2019-ncov/variants/variant-classifications.html

BA.2.86 Detections

- **15 countries reporting this sequence**
- **Nine respiratory specimens** sequenced in the US from **eight states**
  - **Two states with wastewater detections**
- On COVID Data Tracker, BA.2.86 still remains aggregated within BA.2 until it comprises 1% of sequences for a 2-week period
- CDC monitoring internal and public sequencing data daily

Global BA.2.86 Detection Map:
Respiratory Specimens and Wastewater Surveillance



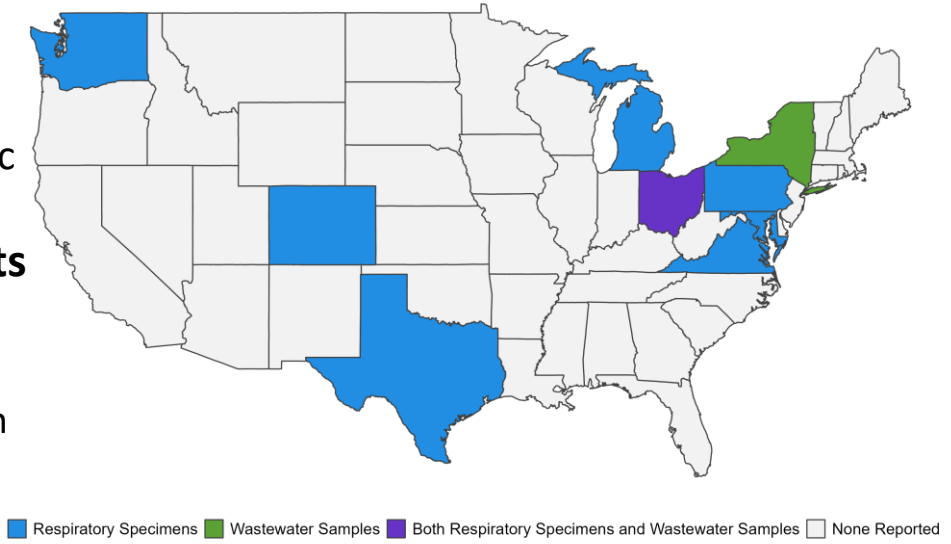
BA.2.86 data reported through 17:00 9/13/23

https://www.cdc.gov/respiratory-viruses/whats-new/covid-19-variant-update-2023-09-08.html

BA.2.86 Assessment

- **Likely low levels of community transmission of BA.2.86** in several countries, including parts of the United States.
  - Multiple individuals without epidemiologic links or travel history
- **Transmissibility relative to other variants remains unknown.**
  - Recent UK BA.2.86 outbreak in a long-term care facility illustrates that transmission is possible in congregate settings
- At this point, there is no evidence that this variant is causing more severe illness.

United States BA.2.86 Detection Map:
Respiratory Specimens and Wastewater Surveillance



BA.2.86 data reported through 17:00 9/13/23

BA.2.86 Assessment

- During the ACIP meeting on September 12, major manufacturers of the 2023-2024 COVID-19 vaccine presented laboratory evidence demonstrating that their vaccines can provide protection against the virus that causes COVID-19, including the BA.2.86 variant.
- Preliminary *laboratory-based* research findings from the US and other countries indicate some potential impact on immunity against the new variant, BA.2.86
- **We know from real-world experience with past variants that people with prior immunity (from vaccines, infection, or both) still have protection against severe COVID-19.**

Cao et al., https://www.biorxiv.org/content/10.1101/2023.08.30.555211v1
Murrell et al., https://www.biorxiv.org/content/10.1101/2023.08.30.555211v1
Barouch et al., prelim data posted on X (formerly Twitter)
Sato et al., https://www.biorxiv.org/content/10.1101/2023.09.07.556636v1
Sigal et al., https://www.medrxiv.org/content/10.1101/2023.09.08.23295250v1

For more information, contact CDC Emergency Operations Center
770-488-7100
www.cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

COVID-19 Vaccine Update

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CDR U.S. Public Health Service
Coronavirus and Other Respiratory Viruses Division
COVID-19 Vaccine Effectiveness Program Lead
U.S. Centers for Disease Control & Prevention

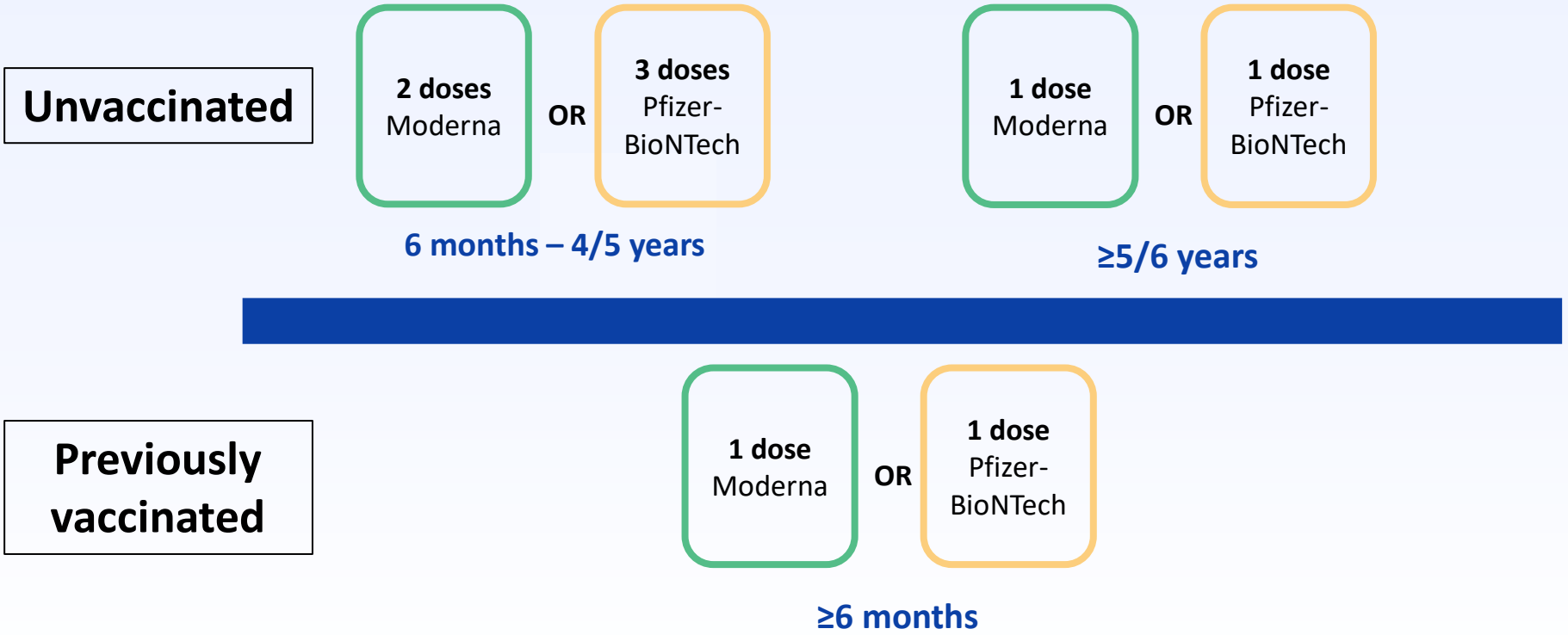
Centers for Disease Control and Prevention
National Center for Immunization and Respiratory Diseases

Updates to COVID-19 Vaccine Policy

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

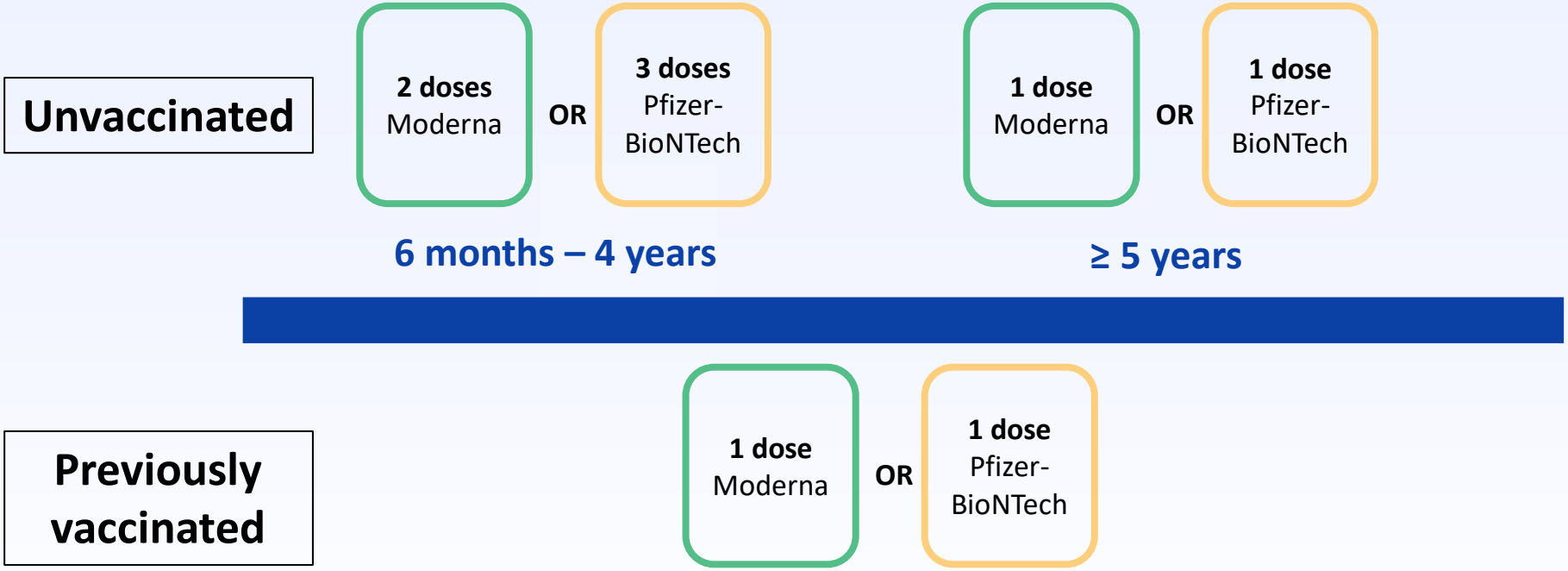
Ruth Link-Gelles, PhD, MPH
Coronavirus and Other Respiratory Viruses Division
Centers for Disease Control and Prevention
September 14, 2023

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

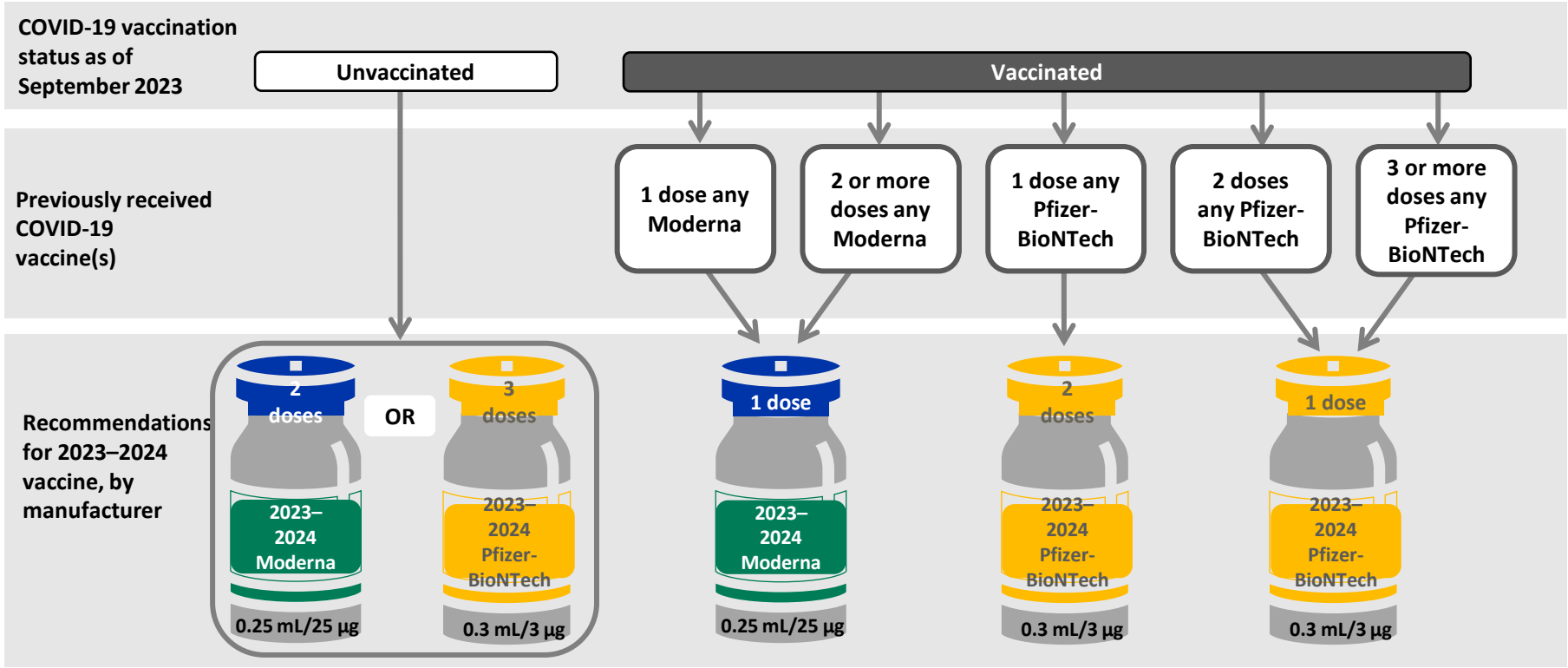
Recommendations for children aged 6 months – 4 years without immunocompromise

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

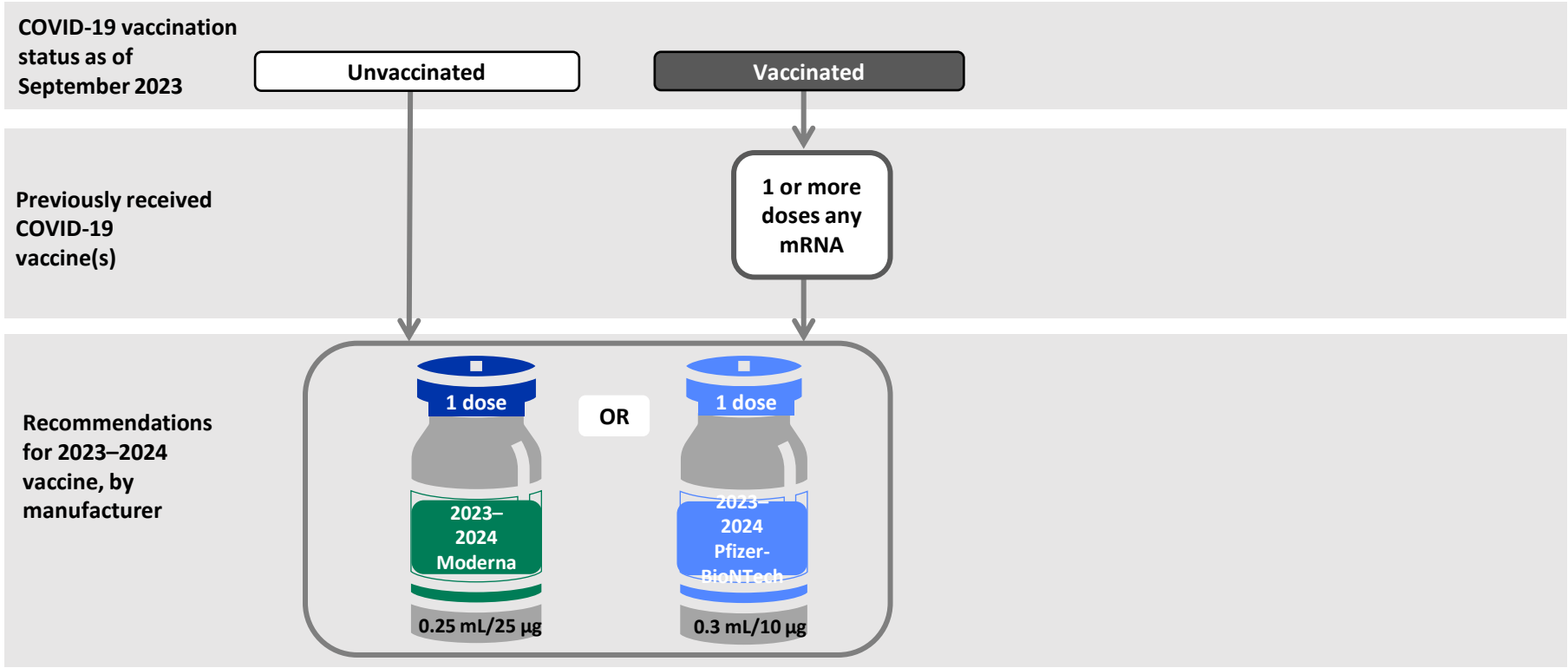
Recommendations for people aged 5 years and older without immunocompromise

Doses recommended:

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

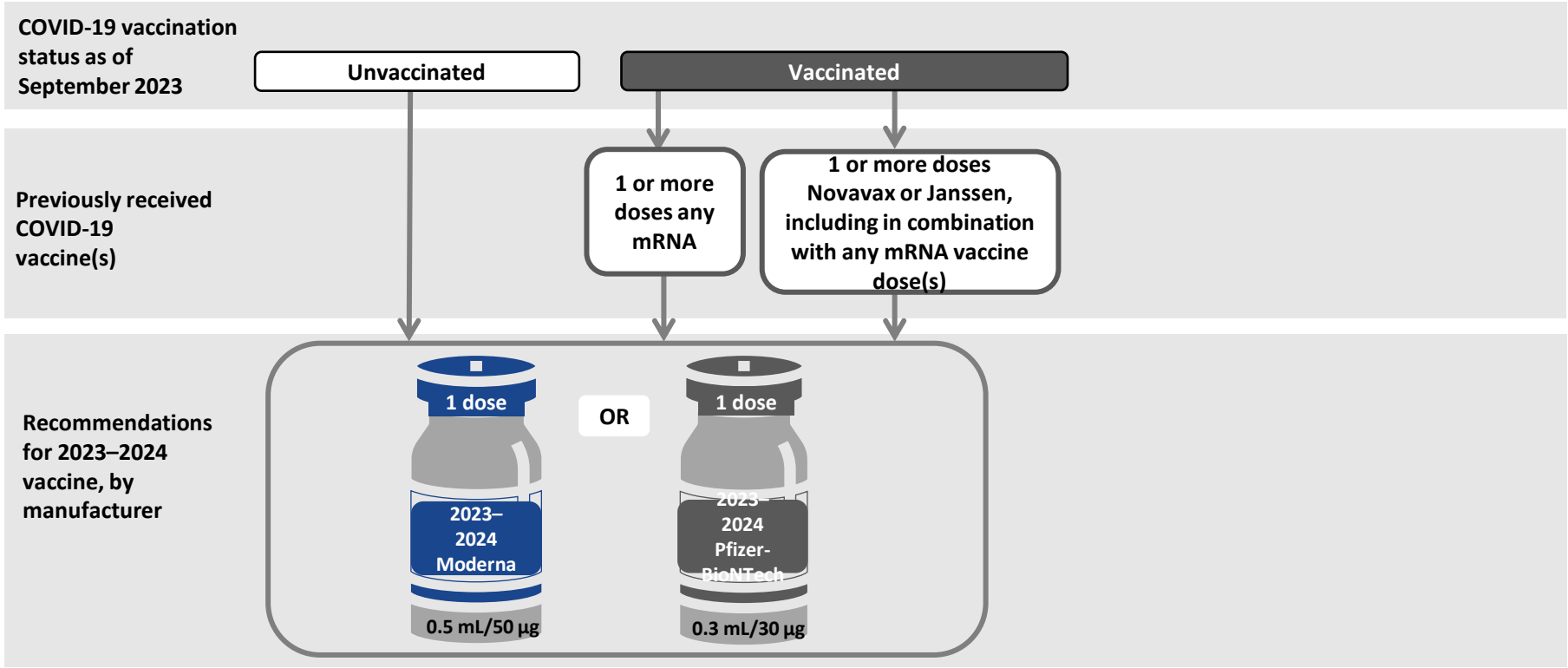
- New harmonized age cutoff for recommendations for young children for Moderna and Pfizer-BioNTech COVID-19 vaccines
- Resulting in simplified recommendations for 5-year-olds
- All Moderna doses in ages 6 months – 11 years are now 25 µcg
- 2023–2024 COVID-19 vaccine dose is recommended at least 2 months 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

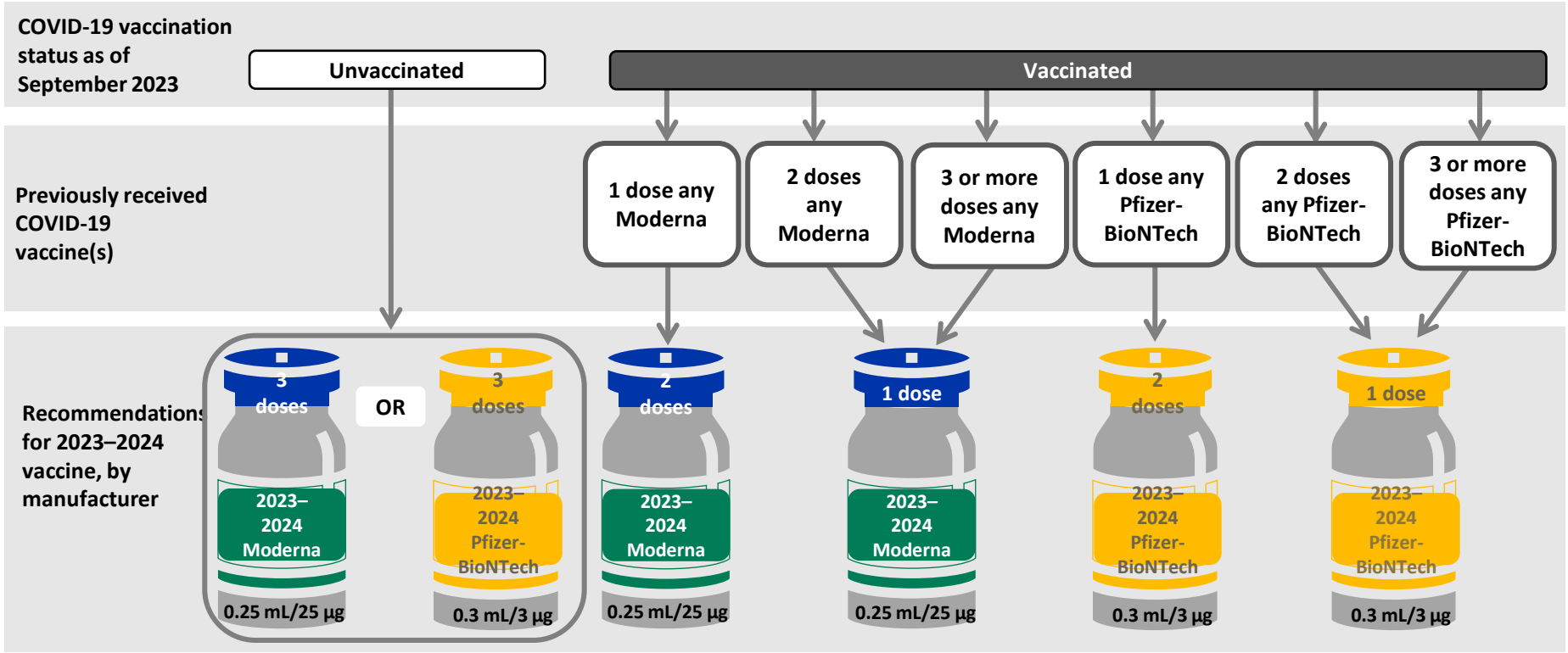
Doses recommended:

- 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).

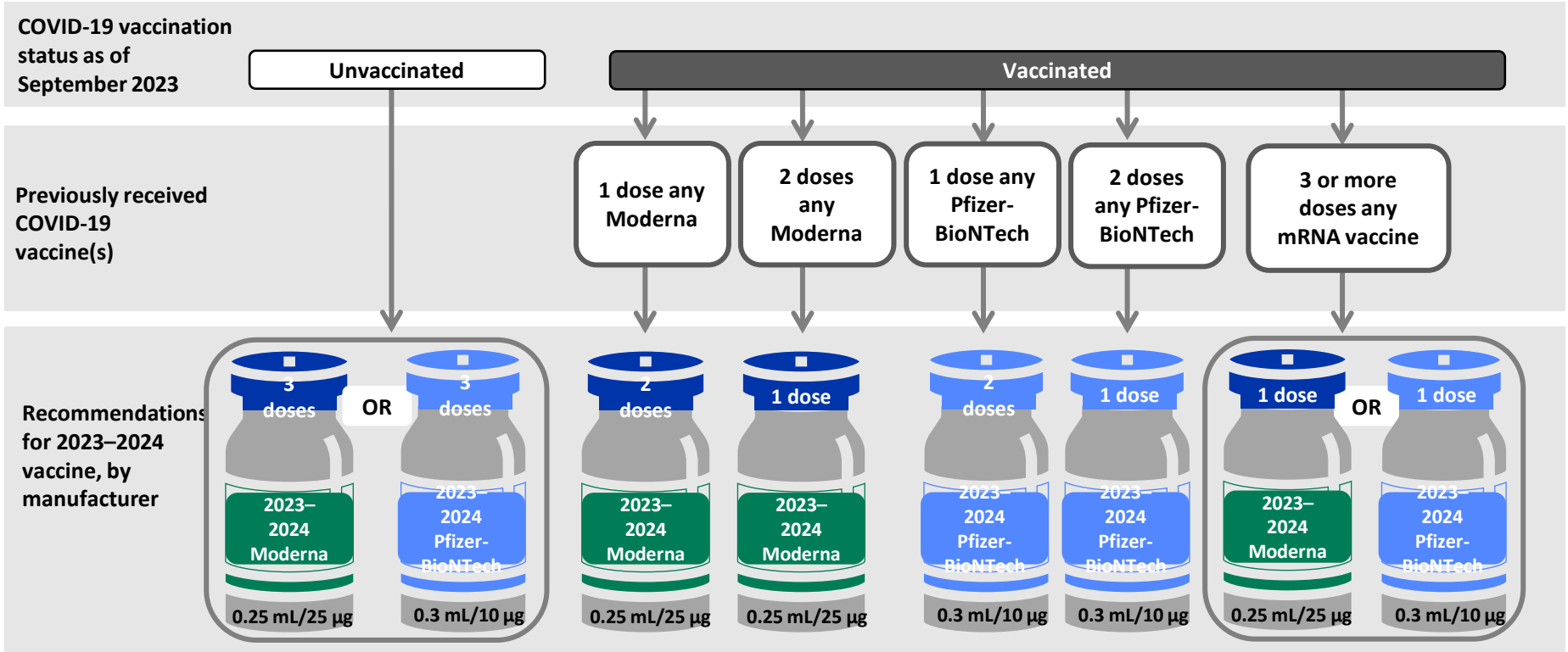
**Further additional dose(s) may be administered, informed by the clinical judgement of a healthcare provider and personal preference and circumstances. Further additional doses should be administered at least 2 months after the last 2023-2024 COVID-19 vaccine dose.

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



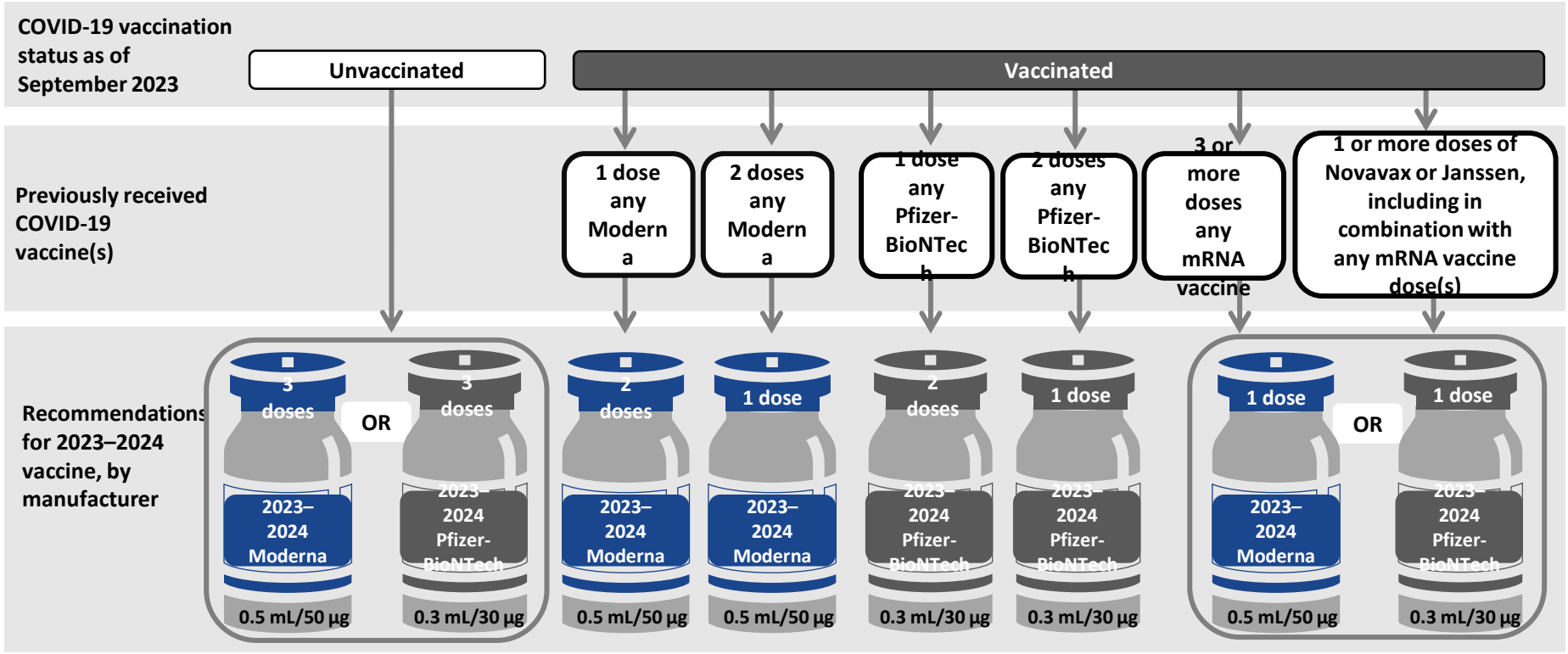
*For information about administration intervals, people who transition from age 4 years to age 5 years during an mRNA vaccination series, and administration of additional dose(s), see Table 2 in Interim Clinical Considerations for Use of COVID-19 Vaccines.

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

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

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)

Immunization Services Division, internal planning documents

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

Immunization Services Division, internal planning documents

Available data from COVID-19 vaccine manufacturers

- **Moderna**
  - Clinical trial data
    - Randomized 101 patients to monovalent XBB.1.5 containing dose or bivalent BA.4/5 + XBB.1.5 containing dose
    - Patients that received the monovalent XBB.1.5 containing dose demonstrated an increase in neutralizing antibodies, with similar levels of neutralization across several XBB sub-variants
    - Reported reactogenicity was similar to or lower than that reported from previous doses
- **Novavax**
  - Preclinical data
    - Macaques boosted with XBB.1.5 demonstrated increased neutralizing response across several XBB pseudoviruses
- **Pfizer-BioNTech**
  - Preclinical data
    - Mice boosted with XBB.1.5 demonstrated increased neutralizing response across several XBB pseudoviruses

Calculating Risk: Myocarditis and COVID-19 vaccines

- Limited data to inform myocarditis risk after bivalent COVID-19 vaccine booster dose
  - Myocarditis rates following **booster doses** in adolescent and young adult males are **lower** than rates following **primary series**, but estimates are limited by fewer numbers of doses for both the bivalent boosters and the previous monovalent boosters administered in VSD[1]
- Myocarditis risk **lower** with **longer time between doses**
  - Rates of myocarditis **lower** with **extended interval** between dose 1 and dose 2 for primary series[2]
  - Longer interval between updated doses may also impact myocarditis rates
- Most individuals with myocarditis/pericarditis have **fully recovered** at follow-up[3]
- The risk of adverse cardiac outcomes were **1.8 – 5.6 times higher** after SARS-CoV-2 infection than after mRNA COVID-19 vaccination among males ages 12-17 years[4]

[1] https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2023-02/slides-02-24/COVID-02-Shimabukuro-508.pdf
[2] https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-02-04/11-COVID-Moulia-508.pdf
[3] https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-02-04/04-COVID-Kracalic-508.pdf
[4] https://www.cdc.gov/mmwr/volumes/71/wr/mm7114e1.htm?s_cid=mm7114e1_w

Summary

Public Health Problem

- COVID-19 burden is **currently lower** than at previous points in the pandemic, however the **absolute number** of hospitalizations and deaths is still **high**
- Although hospitalization rates are currently low in some age groups, we have seen rates increase in recent weeks and **anticipate further increases** as we enter respiratory virus season
- Infants and older adults have the **highest** COVID-19-associated hospitalization rates
- Children and adults with **no underlying medical conditions** still experience severe illness due to COVID-19
- Post-COVID Conditions are **common** following SARS-CoV-2 infection, decrease with time since infection, and have decreased since the start of the pandemic
- People of racial and ethnic minority groups continue to be **disproportionately impacted** by COVID-19
- High proportions of underlying conditions may put certain groups at **increased risk** for severe outcomes due to COVID-19

Summary and Work Group Interpretation: Public Health Burden

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

Summary and Work Group Interpretation: Benefits and Risks

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

Summary and Work Group Interpretation: Considerations Regarding a Universal vs. Non-universal Policy

- Work Group considered non-universal policy options, with considerable discussion around the magnitude of benefits in the young, healthy population
- As part of these deliberations, Work Group requested additional data on severe illness due to COVID-19 in those with and without underlying conditions
  - No group that clearly had no risk of severe illness
  - The vast majority of the US population has an underlying condition that would qualify under a risk based recommendation
    - Prevalence of overweight and obesity alone is >70% of adults[1]
  - Risk based recommendation would not allow access to COVID-19 vaccines for all that wanted them
- Shared clinical decision making could create barriers to vaccination and may not effectively target those at highest risk
- COVID-19 epidemiology remains uncertain and non-universal recommendations would need to be quickly revisited if there was an increase in burden
- Still substantial COVID-19 disease burden and simple, stable recommendations may increase vaccine coverage over time
- Work Group emphasized that COVID-19 recommendations should be reviewed on an ongoing basis as more is learned about COVID-19 seasonality and disease burden in the future

[1]National Health Statistics Reports; https://stacks.cdc.gov/view/cdc/106273

Summary and Work Group Interpretation: COVID-19 vaccine recommendations for children

- Burden of severe illness due to COVID-19 is **lowest** among children ages 5 – 17 years
- Despite lower burden relative to other age groups, **hundreds** of deaths due to COVID-19 occurred in this age group in 2021 and 2022
  - **Half** of pediatric COVID-19 deaths were in individuals with **no underlying conditions**
- Number of COVID-19 hospitalizations and deaths in this age group are **comparable** to the burden seen in other vaccine preventable diseases for which there are universal recommendations
- **Potential additional benefits of vaccination**, such as prevention of post-COVID conditions and potential for reduced school absenteeism
- Risk of myocarditis appears **lower** than the risk observed following primary series doses
  - Potentially lower due to increased interval between doses
  - Certainty is limited by relatively lower sample size of booster recipients in VSD
- Future COVID-19 epidemiology remains **uncertain** and the low disease burden we are currently seeing may not last
- After a robust discussion, Work Group was supportive of a universal recommendation **at this time**

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

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

COVID-19 and COVID-19 Vaccines: Clinical Considerations

Keipp Talbot, MD, MPH
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We still have a lot to learn

i.e., recommendations will likely continue to change overtime.

When is COVID-19 season?

- Still awaiting to see what the season will be –
  - Year-round
  - Bimodal – summer and winter
  - Winter

- Until then the decision has been to give the COVID-19 vaccine around the time of the influenza and RSV vaccines

Bye-Bye Booster

- No longer giving “boosters”
- Currently giving the 2023-2024 Vaccine

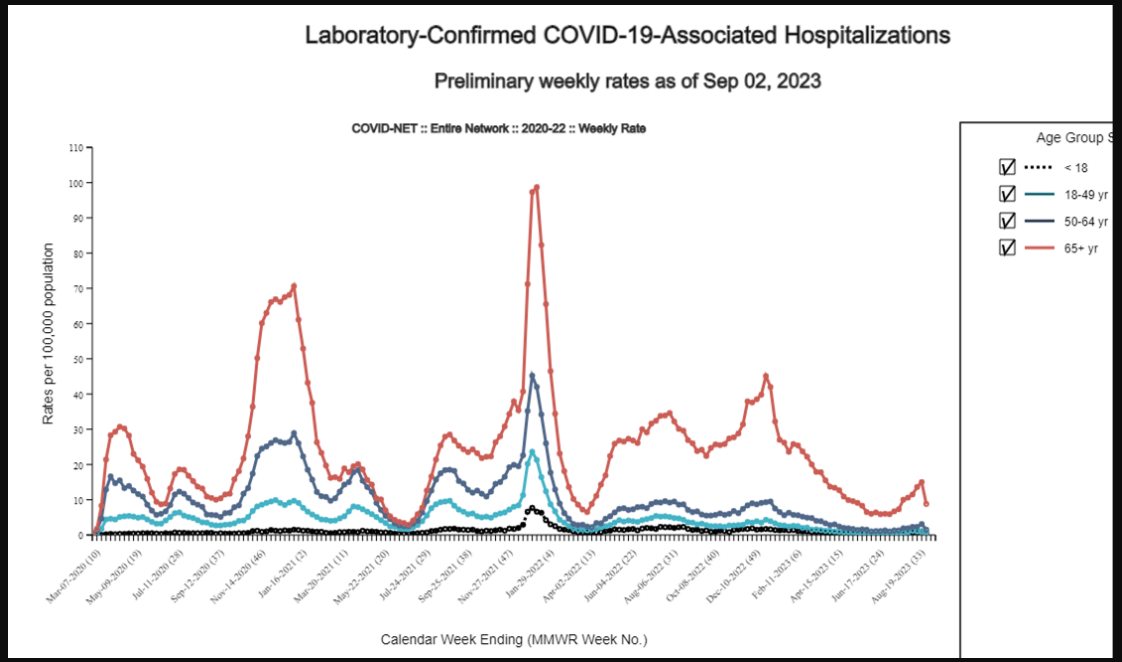
vaers.hhs.gov

Novovax COVID-19 Vaccine

- SARS-CoV-2 spike protein + Matrix-M adjuvant.
  - Matrix M-adjuvant contains saponin extracts from the bark of the Soapbark tree.

- New XBB variant vaccine has not yet been FDA approved

COVID-NET


Laboratory-Confirmed COVID-19-Associated Hospitalizations
Preliminary weekly rates as of Sep 02, 2023
COVID-NET :: Entire Network :: 2020-22 :: Weekly Rate
Rates per 100,000 population
Calendar Week Ending (MMWR Week No.)
Age Group
< 18
18-49 yr
50-64 yr
65+ yr

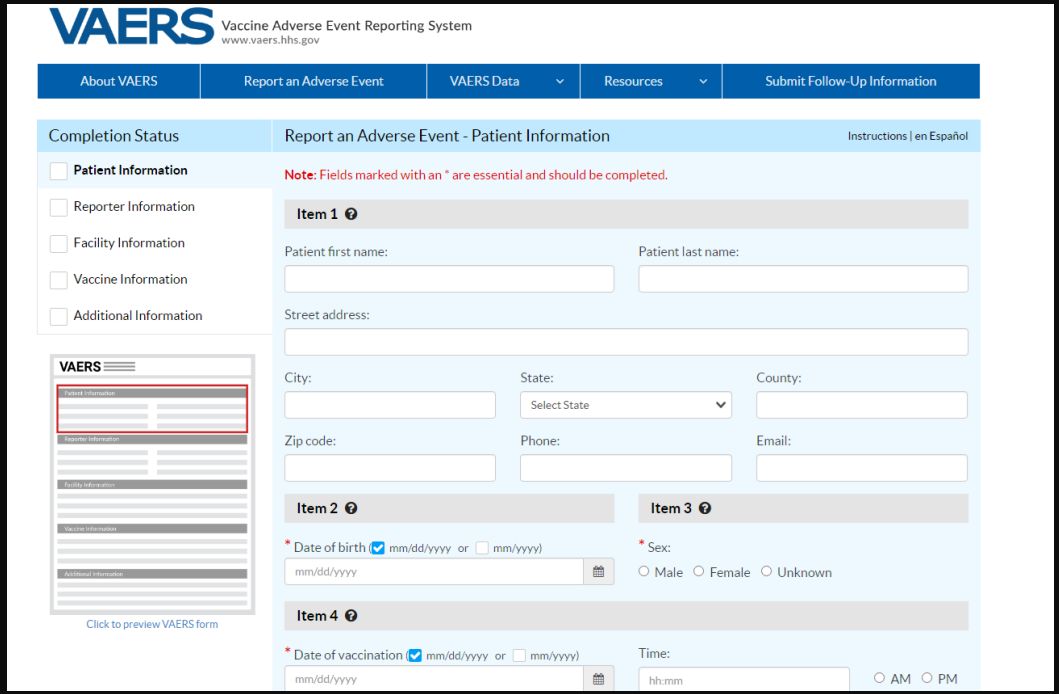
Special Timing of Vaccination

- Recently received the bivalent booster:
  - wait 2 month before receiving the new updated vaccine.
- Pregnancy
  - No need to wait for a specific trimester
  - Immunize with the 2023-2024 COVID-19 vaccine now

What if immunocompromised?

- Okay to give a dose followed by a second dose later.
- Not clear if this will be needed every year

VAERS


VAERS
Vaccine Adverse Event Reporting System
www.vaers.hhs.gov
About VAERS
Report an Adverse Event
VAERS Data
Resources
Submit Follow-Up Information
Completion Status
Patient Information
Reporter Information
Facility Information
Vaccine Information
Additional Information
Click to preview VAERS form
Report an Adverse Event - Patient Information
Instructions | en Español
Note: Fields marked with an * are essential and should be completed.
Item 1
Patient first name:
Patient last name:
Street address:
City:
State:
Select State
County:
Zip code:
Phone:
Email:
Item 2
Item 3
* Date of birth (mm/dd/yyyy or mm/yyyy)
mm/dd/yyyy
* Sex:
Male
Female
Unknown
Item 4
* Date of vaccination (mm/dd/yyyy or mm/yyyy)
mm/dd/yyyy
Time:
hh:mm
AM
PM

The Latest on RSV Immunization for Adults & Children

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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

CDC/IDSA Clinician Call

September 14, 2023

Amadea Britton, MD, SM

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

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

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.

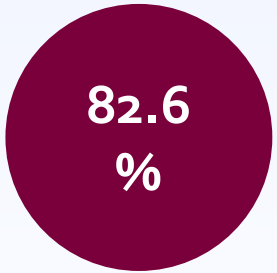
- RSVPreF3 (**Arexvy, GSK**) is a 1-dose adjuvanted ($AS01_E$) recombinant prefusion F protein (preF) vaccine.

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

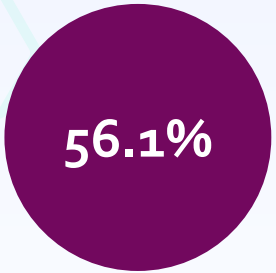
https://www.cdc.gov/mmwr/volumes/72/wr/mm7229a4.htm

Vaccine Efficacy (VE): GSK

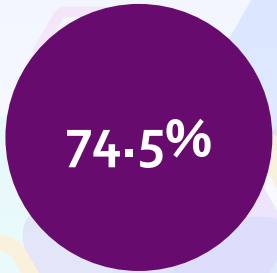
- Randomized, double-blinded, placebo-controlled phase 3 clinical trial
  - 17 countries
  - 24,973 participants
- VE against RSV-associated lower respiratory tract disease (LRTD):



Season 1



Season 2

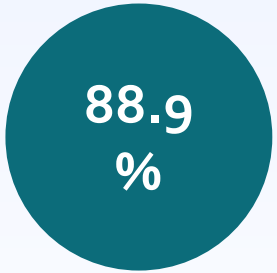


Combined Season 1 & 2 (Interim)

https://www.cdc.gov/mmwr/volumes/72/wr/mm7229a4.htm

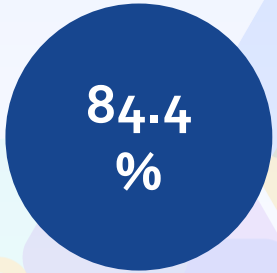
Vaccine Efficacy (VE): Pfizer

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



Season 1

Season 2
(Interim)



Combined
Season 1 & 2
(Interim)

*Based on trial efficacy against RSV LRTI with at least **three** lower respiratory **signs/symptoms**
https://www.cdc.gov/mmwr/volumes/72/wr/mm7229a4.htm

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.

https://www.cdc.gov/mmwr/volumes/72/wr/mm7229a4.htm

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**.

https://www.cdc.gov/mmwr/volumes/72/wr/mm7229a4.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

https://www.cdc.gov/mmwr/volumes/72/wr/mm7229a4.htm

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

https://www.cdc.gov/mmwr/volumes/72/wr/mm7229a4.htm

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

https://www.cdc.gov/mmwr/volumes/72/wr/mm7229a4.htm

Data on immunogenicity of coadministration of RSV vaccines with other vaccines

- **Coadministration with all other adult vaccines is acceptable.**
- 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 RSVPreF3 vaccine (Arexvy by GSK) and adjuvanted quadrivalent inactivated influenza vaccine.

https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2023-06-21-23/07-RSV-Adults-Britton-508.pdf

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.

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Pediatric RSV Disease and Vaccines

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- **Advisor/Consultant:**
  - **Merck, Sanofi Pasteur, GSK, Pfizer, IliAD, Moderna, Novavax**

- **Research Funding:**
  - **GSK, AstraZeneca**

RSV Epidemiology

- **RSV is one of the most common causes of acute respiratory tract infection in people of all ages.**
- **RSV typically circulates in Fall, Winter, and Spring – usually October to end of March in US.**
- **Each year in the United States, RSV leads to approximately:**

  - 2.1 million outpatient (non-hospitalization) visits among children younger than 5 years of age - vast majority of cases occur in full-term, healthy infants under 6 months of age

  - 58,000-80,000 hospitalizations among children younger than 5 years of age

  - 60,000-120,000 hospitalizations among adults 65 years and older

  - 6,000-10,000 deaths among adults 65 years and older

  - 100–300 deaths in children younger than 5 years of age

Hall CB, etl. NEJM 2009;360(6):588-598; Rha B et al. Pediatrics 2020;146(1):e20193611; McLaughlin JM et al. JID 2022;225(6):1100-1111; McLaughlin MJM et al. OFID 2022;9(7):ofac300; Hansen CL et al. JAMA Network Open 2022 Feb 1;5(2):e220527

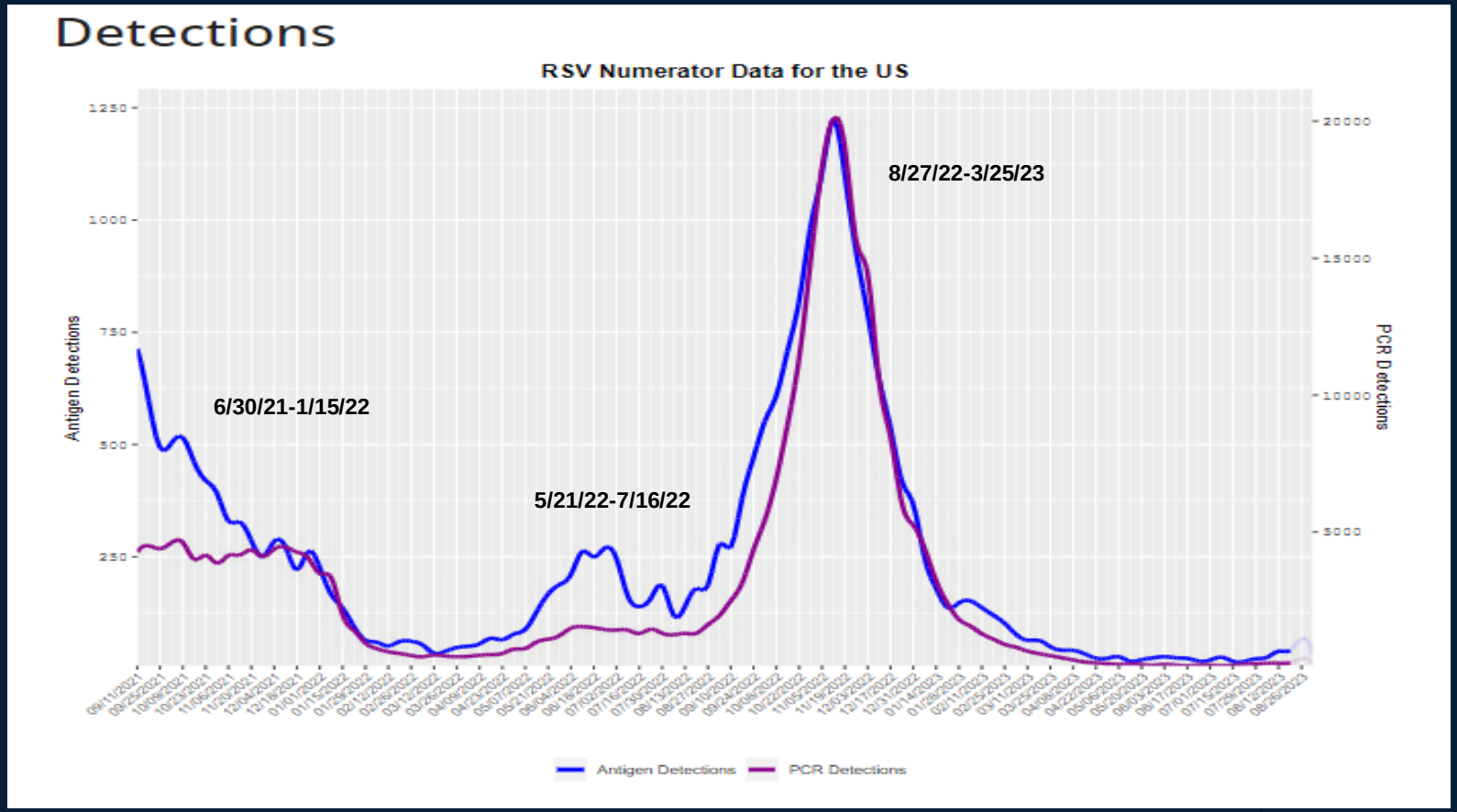
RSV in Infants and Children
Risk Factors for Severe Illness

- Premature birth
- Very young infants, especially those ≤6 months of age
- ≤ 2 years with chronic lung disease or congenital heart disease
- Weakened immune system
- Neuromuscular disorders, including those who have difficulty swallowing or clearing mucus secretions

Most infants with RSV infection are otherwise healthy term infants in the first 2-3 months of life

CDC. https://www.cdc.gov/rsv/high-risk/infants-young-children.html

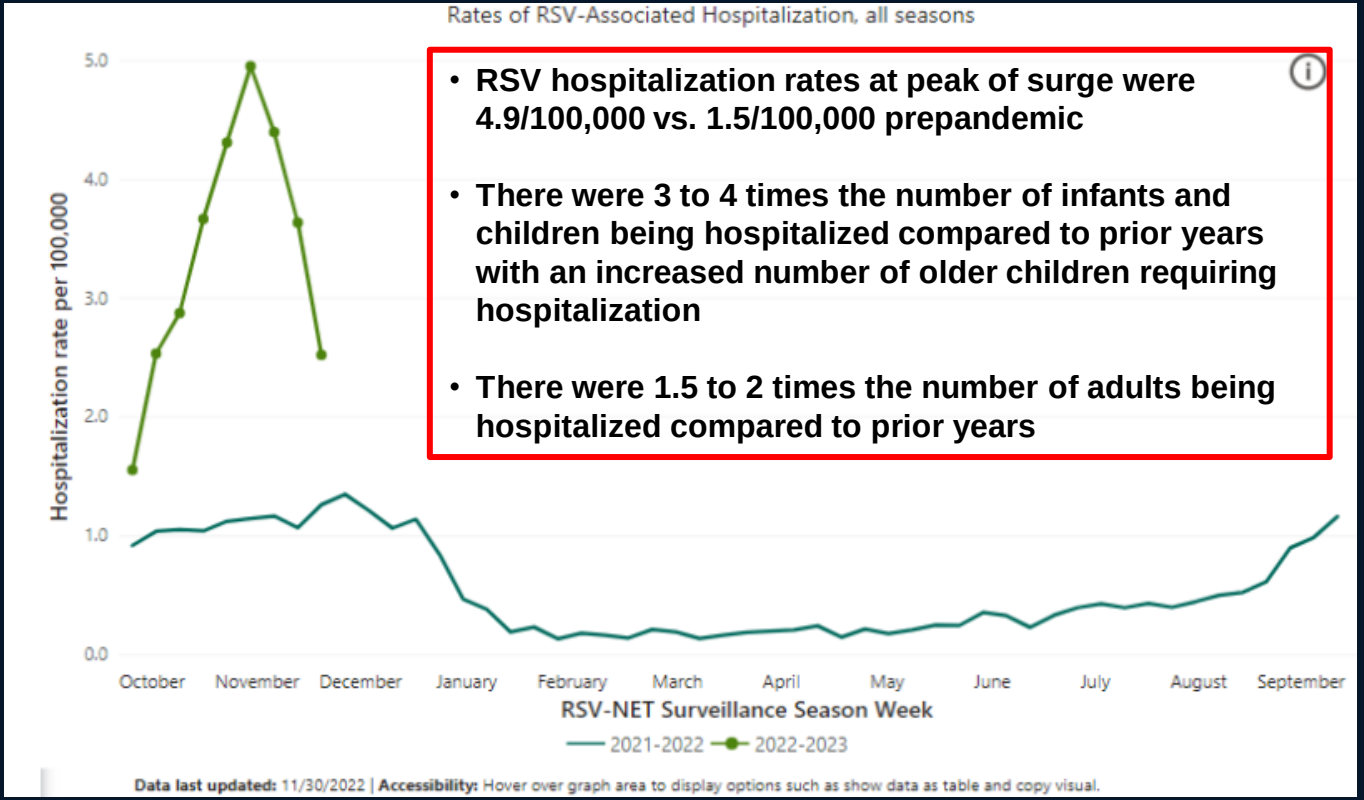
RSV Cases in US 9/11/21-9/26/23



cdc.gov

https://www.cdc.gov/surveillance/nrevss/rsv/natl-trend.html

RSV Hospitalizations



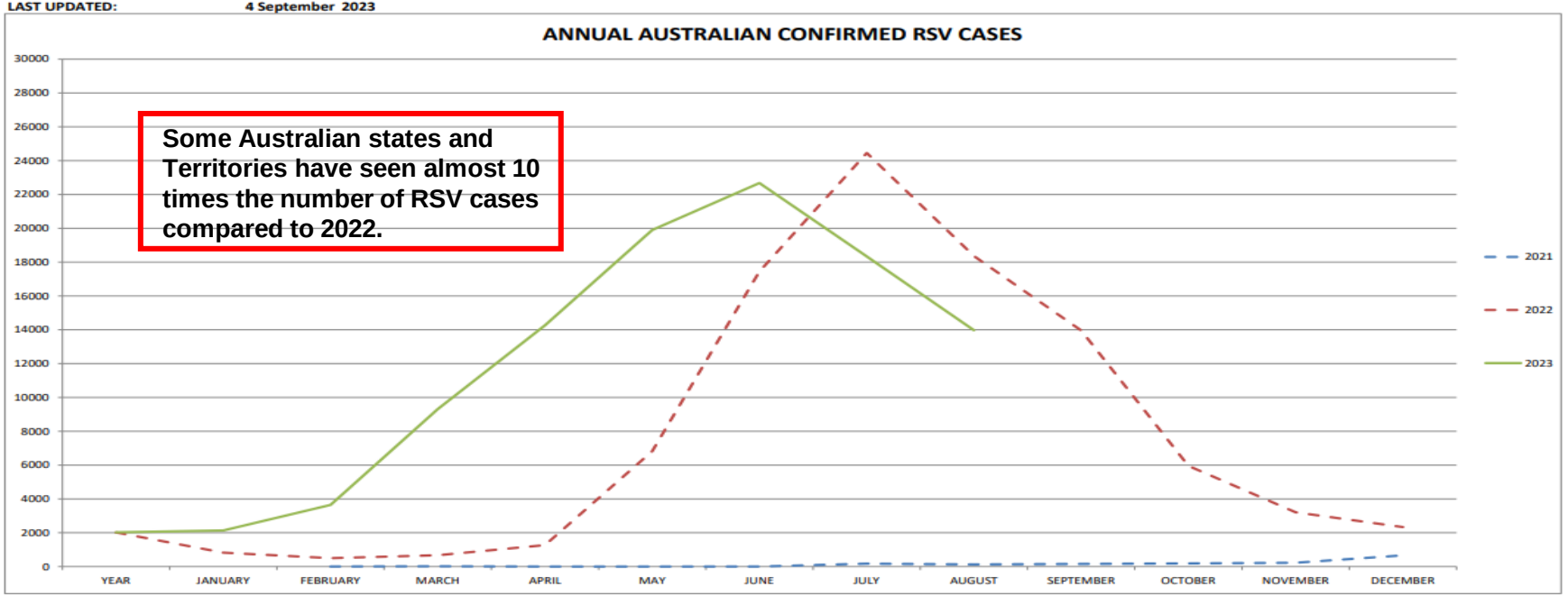
- **RSV hospitalization rates at peak of surge were 4.9/100,000 vs. 1.5/100,000 prepandemic**
- **There were 3 to 4 times the number of infants and children being hospitalized compared to prior years with an increased number of older children requiring hospitalization**
- **There were 1.5 to 2 times the number of adults being hospitalized compared to prior years**

Outlook for RSV 2023-2024

ANNUAL AUSTRALIAN RESPIRATORY SYNCYTIAL VIRUS (RSV) STATISTICS

YEAR	JANUARY	FEBRUARY	MARCH	APRIL	MAY	JUNE	JULY	AUGUST	SEPTEMBER	OCTOBER	NOVEMBER	DECEMBER	TOTALS
2021		6	15			1	172	127	159	185	228	660	**1,553**
2022	822	496	670	1,268	6,819	17,448	24,452	18,356	13,953	5,954	3,208	2,332	**95,778**
2023	2,134	3,641	9,311	14,260	19,901	22,677	18,337	13,972	350				**104,583**

LAST UPDATED: **4 September 2023**



Some Australian states and Territories have seen almost 10 times the number of RSV cases compared to 2022.

Reference: These statistics are taken from the Aust Government Department of Health, National Notifiable Diseases Surveillance System

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

Recommendations and Clinical Guidance for Use of Nirsevimab in Infants and Young Children

CDC/IDSA Clinical Call
September 14, 2023

CDR Jefferson Jones MD MPH FAAP, USPHS
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Coronavirus and Other Respiratory Viruses Division
National Center for Immunization and Respiratory Diseases

Nirsevimab efficacy estimates from clinical trials

Outcome	Efficacy estimate*
Benefits	
Medically attended RSV LRTI	79.0% (95% CI: 68.5%–86.1%)
RSV LRTI with hospitalization	80.6% (95% CI: 62.3%–90.1%)
RSV LRTI with ICU admission	90.0% (95% CI: 16.4%–98.8%)
Death due to RSV respiratory illness	None recorded
All-cause medically attended-LRTI	34.8% (95% CI: 23.0–44.7%)
All-cause LRTI-associated hospitalization	44.9% (95% CI:24.9%–59.6%)

*Pooled phase 2b (excluding underdosed) and phase 3 trial estimate comparing nirsevimab arm to placebo arm

Muller WJ, Madhi SA, Seoane Nunez B, et al. Nirsevimab for Prevention of RSV in Term and Late-Preterm Infants. N Engl J Med. Apr 20 2023;388(16):1533-1534. Griffin MP, Yuan Y, Takas T, Domachowske JB, Madhi SA, Manzoni P, et al. Single-Dose Nirsevimab for Prevention of RSV in Preterm Infants. New England Journal of Medicine. 2020. 383(5): 415-425.

ACIP Recommendations

- Infants aged <8 months born during or entering their first RSV season are recommended to receive one dose of nirsevimab (50 mg for infants <5 kg and 100 mg for infants ≥5 kg)

- Children aged 8–19 months who are at increased risk of severe RSV disease and entering their second RSV season are recommended to receive one dose of nirsevimab (200 mg)

Timing of nirsevimab

- Providers should target administration[1]:
  - In the first week of life for infants born shortly before and during the season
  - Shortly before the start of the RSV season for infants aged <8 months
  - Shortly before the start of the RSV season for children aged 8–19 months who are at increased risk of severe RSV disease
- Based on pre-pandemic patterns, this means nirsevimab could be administered in most of the continental United States from October through the end of March
- Because timing of the onset, peak, and decline of RSV activity may vary, providers can adjust administration schedules based on local epidemiology
- Providers in tropical climates and Alaska should consult state, local, or territorial guidance on timing of nirsevimab administration

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

Coadministration with routine childhood vaccines

- In accordance with CDC's general best practices for immunizations, simultaneous administration of nirsevimab with age-appropriate vaccines is recommended
- In clinical trials, when nirsevimab was given concomitantly with routine childhood vaccines, the safety and reactogenicity profile of the coadministered regimen was similar to the childhood vaccines given alone[1]
- When coadministered, nirsevimab is not expected to interfere with the immune response to vaccines[2]

[1]FDA label for nirsevimab ; [2]Espocito Front Immunol. 2021 Aug 11;12:708939.

Children aged 8–19 months recommended to receive nirsevimab when entering their second RSV season because of increased risk of severe disease

- Children with chronic lung disease of prematurity who required medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) 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 (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest imaging that persist when stable) or weight-for-length <10th percentile
- American Indian and Alaska Native children

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

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

Pneumococcal Vaccine for Adults: Update on New Recommendations

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U.S. Centers for Disease Control & Prevention

Disclosures

None

Pneumococcal Disease in U.S. Adults

- Before the COVID-19 pandemic, each year pneumococcus caused approximately[1]:
  - 100,000 pneumonia hospitalizations
  - 30,000 invasive pneumococcal disease (IPD) cases
    - 3,000 deaths from IPD
- In late 2022 when resurgence of non-SARS-CoV-2 respiratory virus infections was reported in the United States, IPD incidence exceeded pre-COVID-19 baseline incidence in children and young adults[3]

IPD=invasive pneumococcal disease defined as pneumococcal infection in a normally sterile site

1. Kobayashi October 2021 ACIP meeting presentation
2. Centers for Disease Control and Prevention Unpublished Data

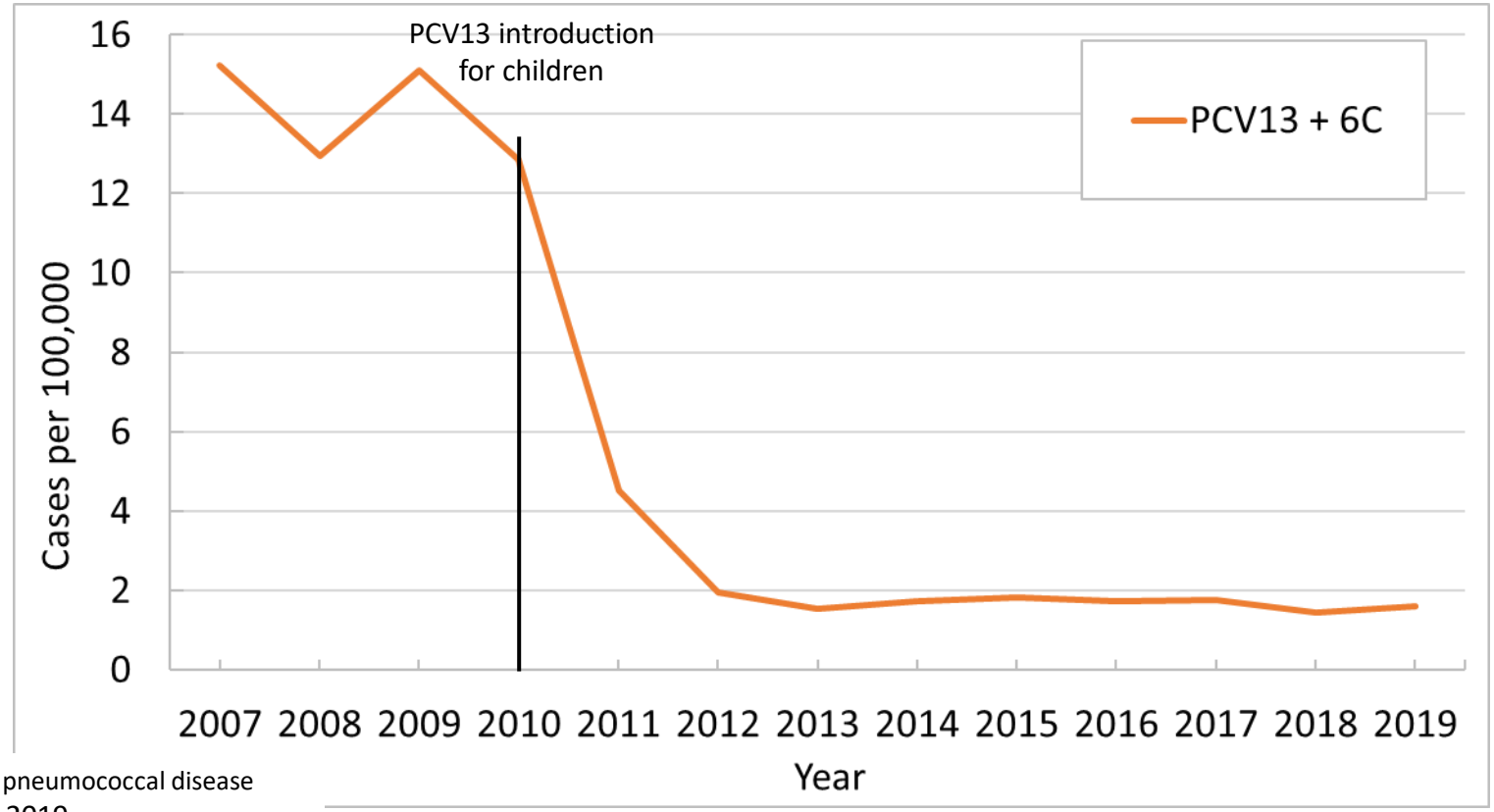
Two pneumococcal vaccines were available for use in the United States before 2021

	1	3	4	5	6A	6B	7 F	9V	14	18 C	19 A	19 F	23 F	22 F	33 F	8	10 A	11 A	12 F	15 B	2	9N	17 F	20
PCV13	■	■	■	■	■	■	■	■	■	■	■	■	■											

PPSV23	■	■	■	■		■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■

23-valent pneumococcal polysaccharide vaccine (PPSV23)	Pneumovax23®
13-valent pneumococcal conjugate vaccine (PCV13)	Prevnar13®

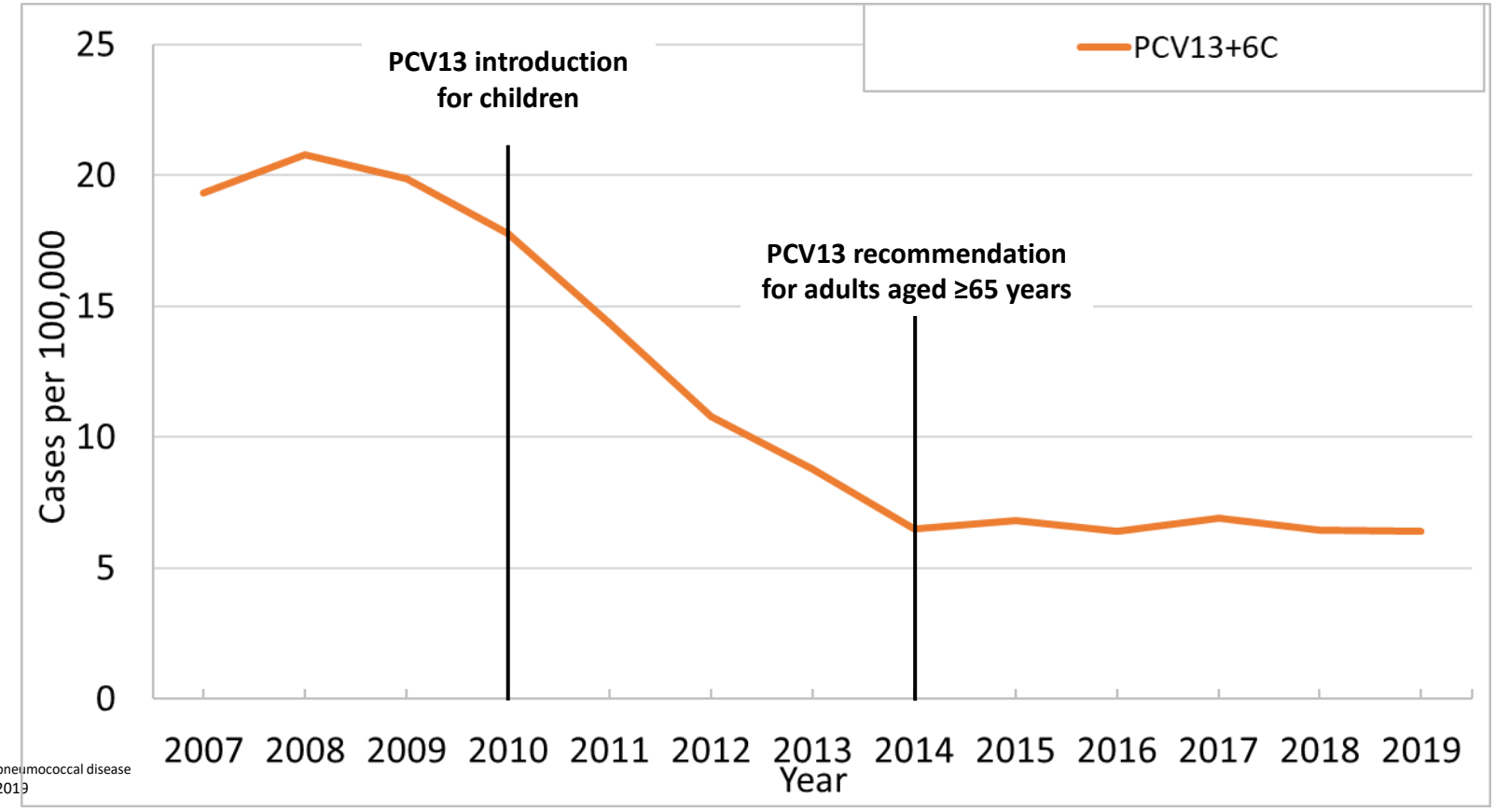
PCV13 use in children not only reduced vaccine-type IPD incidence in children who received the vaccine….



IPD=invasive pneumococcal disease

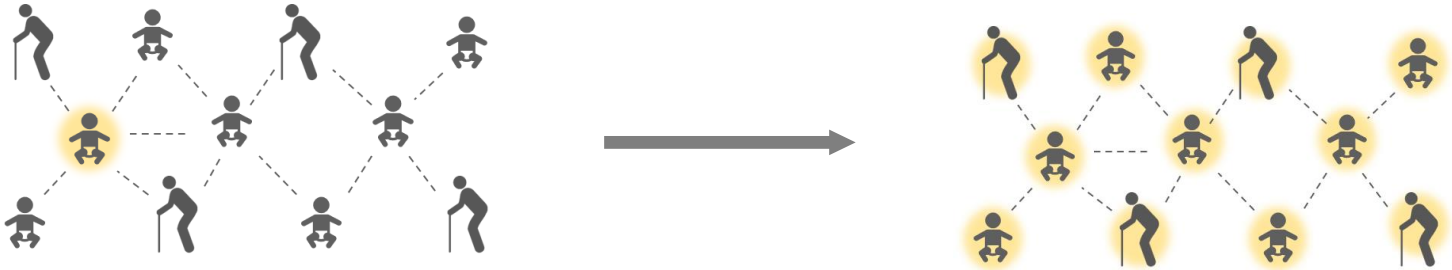
ABCs 2007–2019

But also in adults, including adults aged ≥65 years, likely due to indirect effects

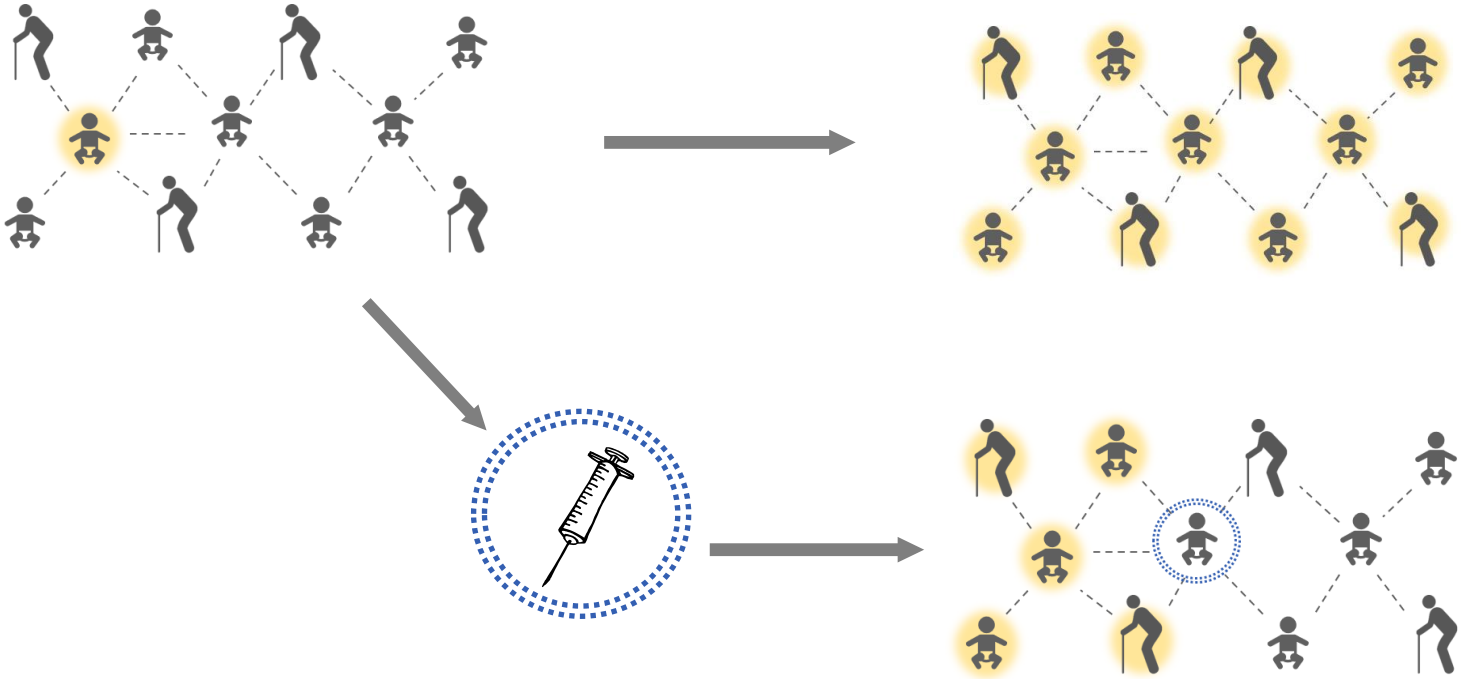


IPD=invasive pneumococcal disease
ABCs 2007–2019

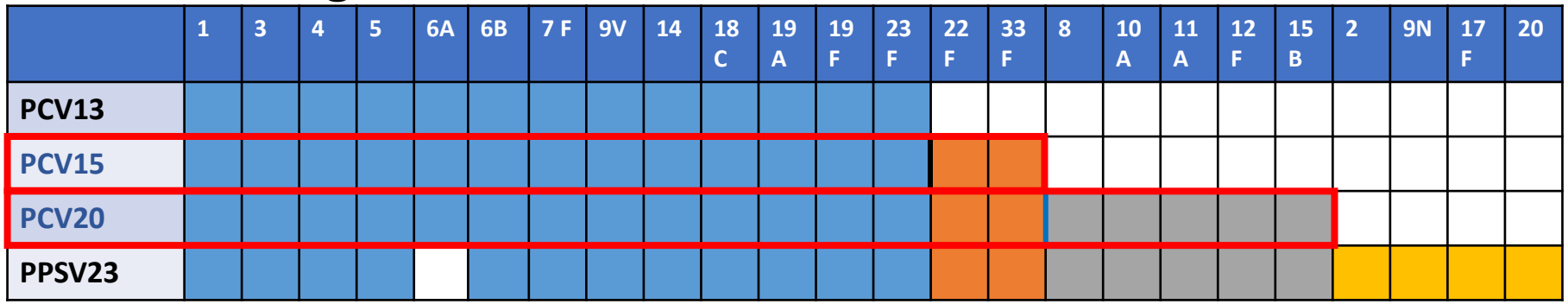
Pneumococcal conjugate vaccines (PCVs) provide direct and indirect protection



Pneumococcal conjugate vaccines (PCVs) provide direct and indirect protection

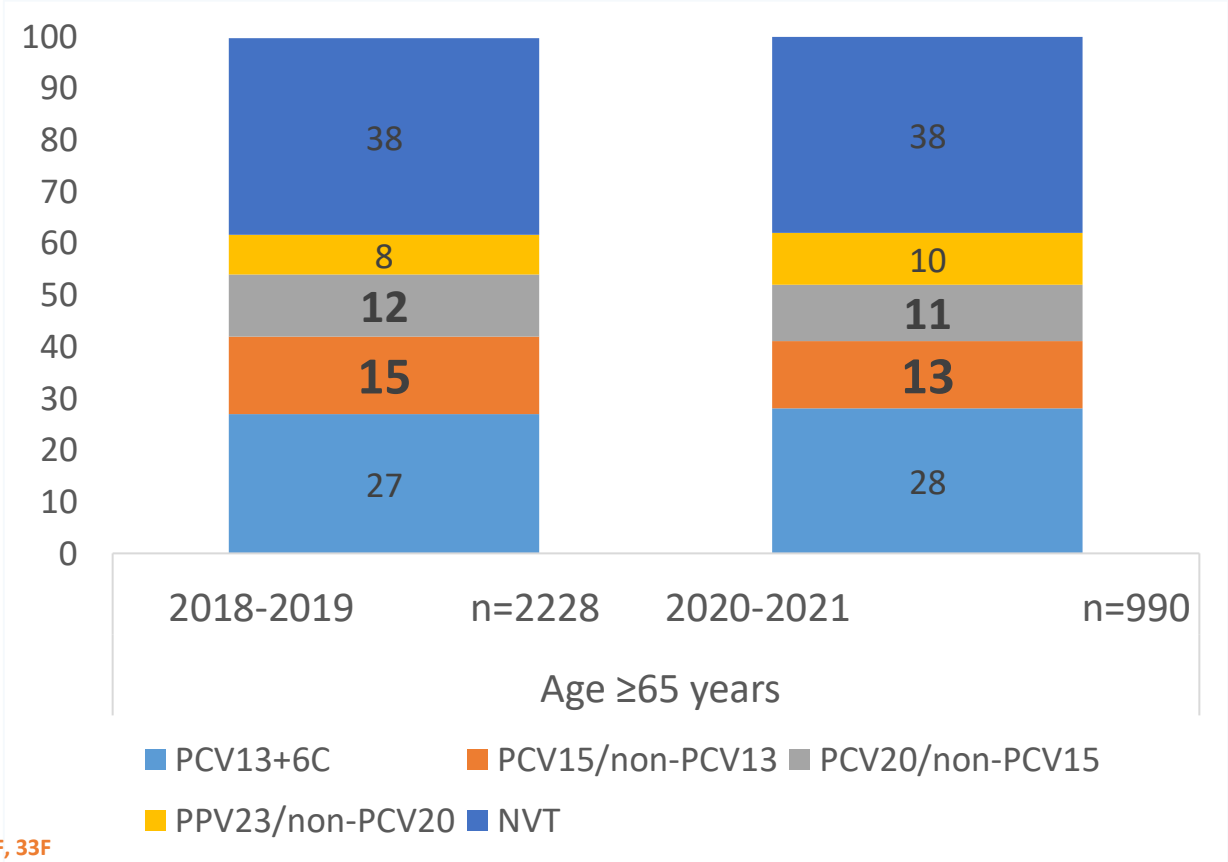


In 2021, 2 new pneumococcal conjugate vaccines were licensed for use among U.S. adults.



23-valent pneumococcal polysaccharide vaccine (PPSV23)	Pneumovax23®
13-valent pneumococcal conjugate vaccine (PCV13)	Prevnar13®
15-valent pneumococcal conjugate vaccine (PCV15)	**Vaxneuvance™**
20-valent pneumococcal conjugate vaccine (PCV20)	**Prevnar20®**

Additional serotypes contained in PCV15 and PCV20 caused about 15% and 27% of IPD cases in adults, respectively.



PCV15 non-PCV13 serotypes: 22F, 33F

PCV20 non-PCV15 serotypes: 8, 10A, 11A, 12F, 15B

PPSV23 non-PCV20 serotype: 2, 9N, 17F ,20

CDC Active Bacterial Core surveillance

Timeline of ACIP votes on new pneumococcal vaccine use for adults

ACIP meeting	Recommendation
October 2021	PCV15/PCV20 use for adults **who have not previously received PCV** or whose previous pneumococcal vaccination history is unknown
October 2022	PCV20 use for adults who have **previously received PCV13**

October 2021 ACIP recommendations simplified the previous recommendations for adults aged ≥65 years

	Previous Recommendation	New Recommendation
None of the conditions listed below	PCV13* based on shared clinical decision-making, PPSV23 for all	**PCV20 OR PCV15 and PPSV23**
Chronic medical conditions† (CMC)		
Cochlear implant, CSF leak	Both PCV13* and PPSV23	
Immunocompromising conditions		

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

*If not previously given; †Examples include alcoholism, chronic heart/liver/lung disease, diabetes, cigarette smoking
https://www.cdc.gov/vaccines/vpd/pneumo/downloads/pneumo-vaccine-timing.pdf

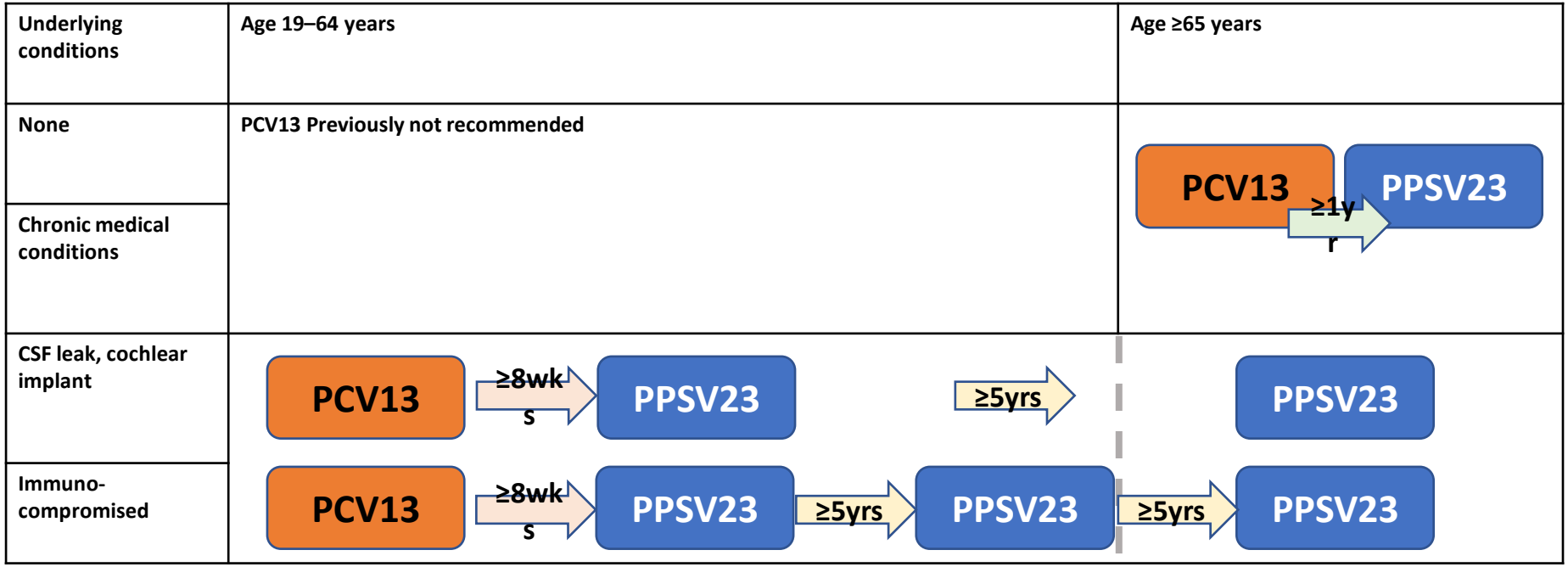
October 2021 ACIP recommendations simplified the previous recommendations for adults aged 19–64 years with risk conditions

	Previous Recommendations	New Recommendations
None of the conditions listed below	No recommendation	No recommendation
Chronic medical conditions† (CMC)	PPSV23	**PCV20 OR PCV15 and PPSV23**
Cochlear implant, CSF leak	Both PCV13* and PPSV23	
Immunocompromising conditions	Both PCV13* and PPSV23, repeat PPSV23 after 5 years	

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

*If not previously given; †Examples include alcoholism, chronic heart/liver/lung disease, diabetes, cigarette smoking
https://www.cdc.gov/vaccines/vpd/pneumo/downloads/pneumo-vaccine-timing.pdf

Adults who started the series with PCV13 were recommended to complete with PPSV23



Use of 15-Valent Pneumococcal Conjugate Vaccine and 20-Valent Pneumococcal Conjugate Vaccine Among U.S. Adults: Updated Recommendations of the Advisory Committee on Immunization Practices — United States, 2022 | MMWR (cdc.gov)

Pneumococcal Vaccines: PCVs vs. PPSV23

	1	3	4	5	6A	6B	7 F	9V	14	18 C	19 A	19 F	23 F	22 F	33 F	8	10 A	11 A	12 F	15 B	2	9N	17 F	20
PCV13																								
PCV15																								
PCV20																								
PPSV23																								

Characteristic	**PCV**	**PPSV23**
Basic Vaccine Composition	Capsular polysaccharides conjugated to **CRM_{197} Carrier Protein**	Capsular polysaccharide antigens
Mechanism of action	T-cell **dependent**	T-cell **independent**
Memory B cell production	**Yes**	**No**

PCV: pneumococcal conjugate vaccine, PPSV23: 23-valent pneumococcal polysaccharide vaccine

Pneumococcal Vaccines: PCVs vs. PPSV23

Characteristic	PCV	PPSV23
Duration of protection	**No decline for 5 yrs**[1]	Variable findings, waning reported as early as **2 years** since vaccination[2]
Vaccine Effectiveness vs. Vaccine-type IPD	Supported by clinical efficacy/effectiveness data	Supported by clinical efficacy/effectiveness data; limited effectiveness reported in immunocompromised adults[3]
Vaccine Effectiveness vs. Vaccine-type non-invasive/non-bacteremic pneumonia	Supported by clinical efficacy data • **Moderate** protection (45%: 95% CI 14 to 63)[4]	**Variable** clinical effectiveness data • Modest protection (18%: 95% CI -4 to 35%) from a meta-analysis[5]

1. Patterson et al. Trials in Vaccinology 2016.
2. World Health Organization. Strategic Advisory Group of Experts on Immunization 5-7 October 2020. https://terrance.who.int/mediacentre/data/sage/SAGE_eYB_October_2020.pdf?ua=1
3. French et al. NEJM 2000; Andrews et al. Vaccine 2012; Rudnick et al. Vaccine 2013; Djennad et al. EClinicalMedicine 2018
4. Bonten et al. NEJM 2015
5. Farrar et al. https://www.medrxiv.org/content/10.1101/2022.10.06.22280772v1.full

New ACIP Recommendations

- For adults who have started their pneumococcal vaccine series with **PCV13** but **have not received all recommended PPSV23 doses**, administer either:
  - a single dose of **PCV20**, or
  - ≥1 dose of **PPSV23**

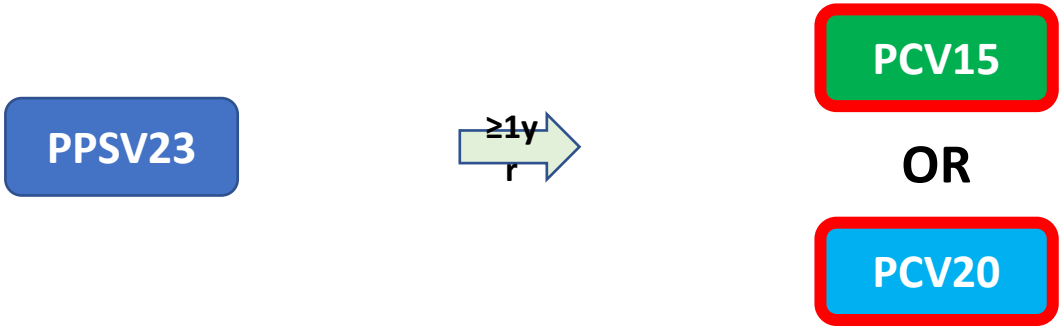
- For adults aged ≥65 years who have **completed** their recommended vaccine series with **both PCV13 and PPSV23**,
  - **shared clinical decision-making** is recommended regarding use of a **supplemental PCV20** dose

Pneumococcal Vaccine for Adults Aged ≥19 Years: Recommendations of the Advisory Committee on Immunization Practices, United States, 2023 | MMWR (cdc.gov)

Updated CDC Guidance for Implementation

- **Adults aged ≥19 years who have received PPSV23 only**

Recommended to receive a dose of either PCV20 or PCV15 at an interval ≥1 year after receipt of the last PPSV23 dose.



Pneumococcal Vaccine for Adults Aged ≥19 Years: Recommendations of the Advisory Committee on Immunization Practices, United States, 2023 | MMWR (cdc.gov)

New CDC Guidance for Implementation

- **Adults who have received PCV7 only**

Follow the recommendations for adults who have not received a pneumococcal vaccine or whose vaccination history is unknown.

- **Adults aged ≥19 years who are hematopoietic stem cell transplant (HSCT) recipients**

Recommended to receive 4 doses of PCV20, starting 3–6 months after HSCT.

- Administer 3 doses of PCV20, 4 weeks apart starting 3–6 months after HSCT. Administer a fourth PCV20 dose ≥6 months after the third dose of PCV20 or ≥12 months after HSCT, whichever is later.
- If PCV20 is not available, 3 doses of PCV15 4 weeks apart, followed by a single dose of PPSV23 ≥1 year after HSCT, can be administered. For patients with chronic graft versus host disease (GVHD) who are receiving PCV15, a fourth dose of PCV15 can be administered in place of PPSV23 because these adults are less likely to respond to PPSV23.
- A patient's clinical team is best informed to determine the appropriate timing of vaccination.

Pneumococcal Vaccine for Adults Aged ≥19 Years: Recommendations of the Advisory Committee on Immunization Practices, United States, 2023 | MMWR (cdc.gov)

A Summary of Current Adult Pneumococcal Vaccine Recommendations Published Last Week

Pneumococcal Vaccine for Adults Aged ≥19 Years: Recommendations of the Advisory Committee on Immunization Practices, United States, 2023 | MMWR (cdc.gov)

PneumoRecs VaxAdvisor Mobile App for Vaccine Providers

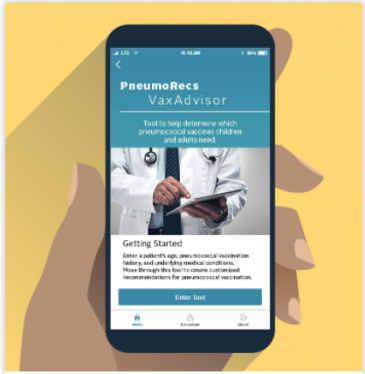
The PneumoRecs VaxAdvisor Mobile App was updated on February 9, 2022, to reflect CDC's new adult pneumococcal vaccination recommendations.

The ***PneumoRecs VaxAdvisor*** mobile app helps vaccination providers quickly and easily determine which pneumococcal vaccines a patient needs and when. The app incorporates recommendations for all ages so internists, family physicians, pediatricians, and pharmacists alike will find the tool beneficial.

Users simply:

- Enter a patient's age.
- Note if the patient has specific underlying medical conditions.
- Answer questions about the patient's pneumococcal vaccination history.

Then the app provides patient-specific guidance consistent with the immunization schedule recommended by the U.S. Advisory Committee on Immunization Practices (ACIP).



PneumoRecs VaxAdvisor is available for download on iOS and Android mobile devices.

Download the App Today

Download PneumoRecs VaxAdvisor for free:

Pneumococcal Vaccine Timing for Adults

Make sure your patients are up to date with pneumococcal vaccination.

Adults ≥65 years old
Complete pneumococcal vaccine schedules

Prior vaccines	Option A	Option B
None*	**PCV20**	**PCV15** → ≥1 year† → **PPSV23**
PPSV23 only at any age	≥1 year → **PCV20**	≥1 year → **PCV15**
PCV13 only at any age	≥1 year → **PCV20**	≥1 year† → **PPSV23**
PCV13 at any age & **PPSV23** at <65 yrs	≥5 years → **PCV20**	≥5 years§ → **PPSV23**

[PneumoRecs VaxAdvisor: Vaccine Provider App | CDC]
[Pneumococcal Vaccination: Who and When to Vaccinate | CDC]
[Pneumococcal Vaccine Timing for Adults greater than or equal to 65 years (cdc.gov)]
[Shared Clinical Decision-Making: PCV20 Vaccination for Adults 65 Years or Older-February 2, 2023 (cdc.gov)]

Conclusion and Future Directions

- New, higher-valency PCVs (PCV15, PCV20), were recommended for adults in 2021
- A recent MMWR *Recommendations and Reports* article provides updated recommendations and guidance for adult pneumococcal vaccination
- ACIP recommended use of PCV15 (2022) and PCV20 (2023) use in children
  - Indirect effects may decrease incremental benefits of PCV15/PCV20 use in adults
- New pneumococcal vaccines (e.g., 21- and 24-valency) are in advanced stages of development

Acknowledgements

- **ACIP and the Pneumococcal Vaccines Work Group**
- **CDC contributors and consultants: Ryan Gierke, Jennifer Farrar, Kristin Andrejko, Lindsay Zielinski, Emma Accorsi, Namrata Prasad, Shriya Bhatnagar, Jacquline Risalvato, Adam L. Cohen, Alison Albert, Angela Jiles, Noele Nelson, Andrew Leidner, Pedro Moro, Elizabeth Velazquez, Marc Fischer, Rebecca Morgan, Doug Campos-Outcalt**

Q&A/ Discussion

Selected Resources

Program Links:

- This webinar is being recorded and can be found with the slides online at https://www.idsociety.org/cliniciancalls
- COVID-19 Real-Time Learning Network: https://www.idsociety.org/covid-19-real-time-learning-network/
- Vaccine FAQ: https://www.idsociety.org/covid-19-real-time-learning-network/vaccines/vaccines-information--faq/

Dr. Kirking

- https://covid.cdc.gov/covid-data-tracker/#trends_weeklyhospitaladmissions_testpositivity_00
- **https://covid.cdc.gov/covid-data-tracker/#maps_percent-inpatient-beds-change-state**
- **https://covid.cdc.gov/covid-data-tracker/#maps_new-admissions-rate-county**
- **https://www.cdc.gov/respiratory-viruses/index.html**
- **https://covid.cdc.gov/covid-data-tracker/#variant-proportions**
- **https://www.cdc.gov/respiratory-viruses/whats-new/covid-19-variant.html**
- **https://www.cdc.gov/coronavirus/2019-ncov/variants/variant-classifications.html**
- **https://www.cdc.gov/respiratory-viruses/whats-new/covid-19-variant-update-2023-09-08.html**
- https://www.biorxiv.org/content/10.1101/2023.08.30.555211v1
- https://www.biorxiv.org/content/10.1101/2023.08.30.555211v1
- https://www.biorxiv.org/content/10.1101/2023.09.07.556636v1
- https://www.medrxiv.org/content/10.1101/2023.09.08.23295250v1

Selected Resources

Dr. Link-Gelles

- https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html
- https://emergency.cdc.gov/han/2023/han00498.asp
- https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html
- https://www.cdc.gov/mmwr/volumes/72/wr/mm7234a4.htm
- https://www.cdc.gov/poxvirus/mpox/clinicians/vaccines/vaccine-considerations.html
- https://www.vaccines.gov/
- https://www.cdc.gov/vaccines/covid-19/downloads/HHS-Commercialization-Transition-Guide-508.pdf

Dr. Talbot

- vaers.hhs.gov

Dr. Britton

- https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2023-02/slides-02-23/RSV-Adults-04-Melgar-508.pdf
- https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2023-02/slides-02-23/RSV-Adults-04-Melgar-508.pdf
- https://www.cdc.gov/mmwr/volumes/72/wr/mm7229a4.htm
- https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2023-06-21-23/07-RSV-Adults-Britton-508.pdf

Dr. Jones

- https://www.accessdata.fda.gov/spl/data/2f08fa60-f674-432d-801b-1f9514bd9b39/2f08fa60-f674-432d-801b-1f9514bd9b39.xml

Selected Resources

Dr. Kobayashi

- https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-10-20-21/02-Pneumococcal-Kobayashi-508.pdf
- https://www.cdc.gov/vaccines/vpd/pneumo/downloads/pneumo-vaccine-timing.pdf
- https://www.cdc.gov/mmwr/volumes/71/wr/mm7104a1.htm
- https://terrance.who.int/mediacentre/data/sage/SAGE_eYB_October_2020.pdf?ua=1
- https://www.medrxiv.org/content/10.1101/2022.10.06.22280772v1.full
- https://www.cdc.gov/mmwr/volumes/72/rr/rr7203a1.htm
- https://www.cdc.gov/vaccines/vpd/pneumo/hcp/pneumoapp.html
- https://www.cdc.gov/vaccines/vpd/pneumo/hcp/who-when-to-vaccinate.html
- https://www.cdc.gov/vaccines/vpd/pneumo/downloads/pneumo-vaccine-timing.pdf
- https://www.cdc.gov/vaccines/hcp/admin/downloads/job-aid-SCDM-PCV20-508.pdf

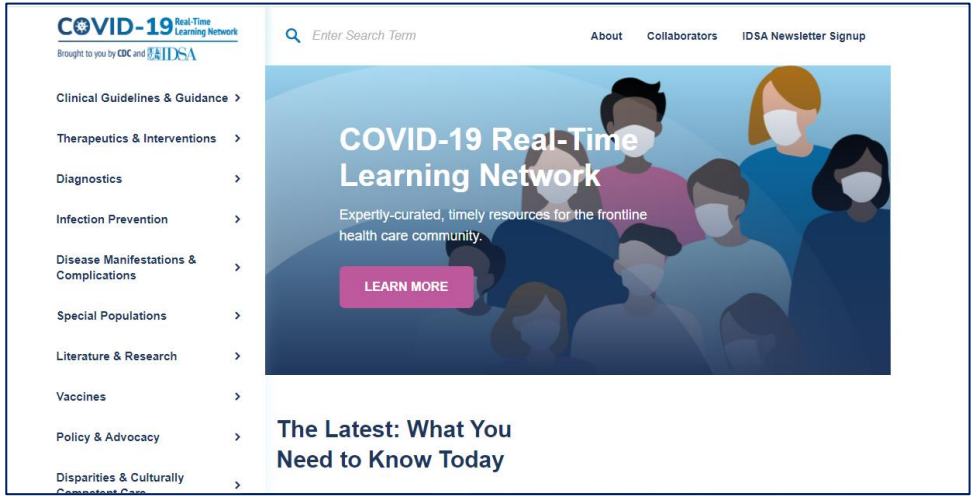
Other Resources:

Bridge Program: https://www.cdc.gov/vaccines/programs/bridge/index.html
Vaccine for Children Program: https://www.cdc.gov/vaccines/programs/vfc/index.html
Respiratory Virus Updates: https://www.cdc.gov/respiratory-viruses/whats-new/index.html

COVID-19 Real-Time Learning Network

Brought to you by CDC and IDSA

An online community bringing together information and opportunities for discussion on latest research, guidelines, tools and resources from a variety of medical subspecialties around the world.



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American Academy of Pediatrics
American College of Emergency Physicians
American College of Physicians
American Geriatrics Society
American Thoracic Society
Pediatric Infectious Diseases Society
Society for Critical Care Medicine
Society for Healthcare Epidemiology of America
Society of Hospital Medicine
Society of Infectious Diseases Pharmacists

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Please complete the post-call survey.

A recording of this call, slides and the answered Q&A will be posted at
www.idsociety.org/cliniciancalls

-- library of all past calls available --

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