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2024 ANNUAL CONVENTION

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Inhale, Exhale, Immunize: Navigating the Latest in Respiratory Vaccines

NCPA 2024 Annual Convention and Expo

Columbus, Ohio

Speaker

David Ha, PharmD

STANFORD UNIVERSITY SCHOOL OF MEDICINE

STANFORD HEALTH CARE

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Disclosure Statement

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Disclosure Statement

This education program is supported by Cooperative Agreement Number NH23IP922660 from the Centers for Disease Control and Prevention (CDC). Its contents are solely the responsibility of the presenters and do not necessarily represent the official views of CDC.

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Pharmacist and Technician Learning Objectives

1. Discuss changes that have been made in the respiratory vaccination schedules and recommendations based on expert consensus guidelines
2. Summarize considerations for use of newly approved respiratory agents and agents under consideration, including those that may be used for emergency preparedness and response.
3. Review unique guidance for storage and administration of respiratory vaccines.
4. Discuss best practices for documentation, reporting, and referral of respiratory vaccines.

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Question 1 of 4

Which of the following is TRUE related to COVID-19 vaccination?

a. Second doses are recommended for older adults (65+ years old)
b. 3 vaccines are available: Moderna and Pfizer (mRNA) and Novavax (protein subunit)
c. COVID-19 vaccines can be given at the same time as influenza and RSV
d. All of the above are true

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Question 2 of 4

Which of the following is FALSE related to influenza vaccination?

a. Older patients (age 65+) should preferentially receive high dose (Fluzone High-Dose), adjuvanted (Fluad) or recombinant (Flublok) vaccine
b. Solid organ transplant patients may receive high dose (Fluzone High-Dose), adjuvanted (Fluad) vaccine
c. Patients with egg allergy should never receive influenza vaccine
d. FluMist (live vaccine) should not be given to pregnant or immunocompromised patients

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Question 3 of 4

Which of the following describes an eligible candidate for RSV vaccine?

a. mRESVIA for a pregnant woman
b. mRESVIA, Arexvy, or Abrysvo for healthy 41-year-old man
c. mRESVIA, Arexvy, or Abrysvo for a 68-year-old nursing home resident
d. Nirsevimab for a 78-year-old healthy man

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Question 4 of 4

A 68-year-old patient who has already completed pneumococcal vaccination (PCV13 at 65 years + PPSV23 at 66 years) is interested in PCV21. Which of the following is true?

a. He is not eligible since he has completed pneumococcal vaccine series

b. He may receive PCV21 after you discuss the risks and benefits, and a shared decision is made to give vaccine (shared clinical decision making)

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Outline

- COVID-19
- Influenza
- RSV
- Pneumococcal

- Content Slides + Resource Slides + Hot Off the Press ACIP Updates

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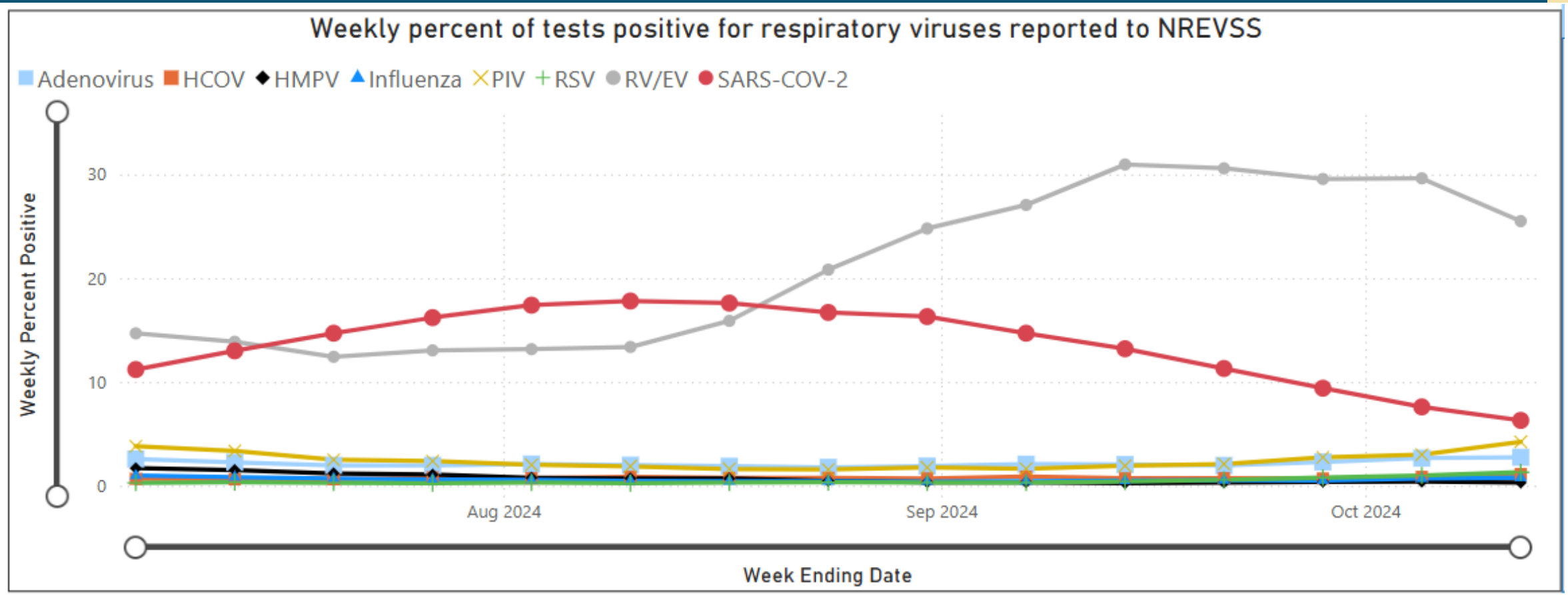
Respiratory Season in US



https://www.cdc.gov/nrevss/php/dashboard/index.html

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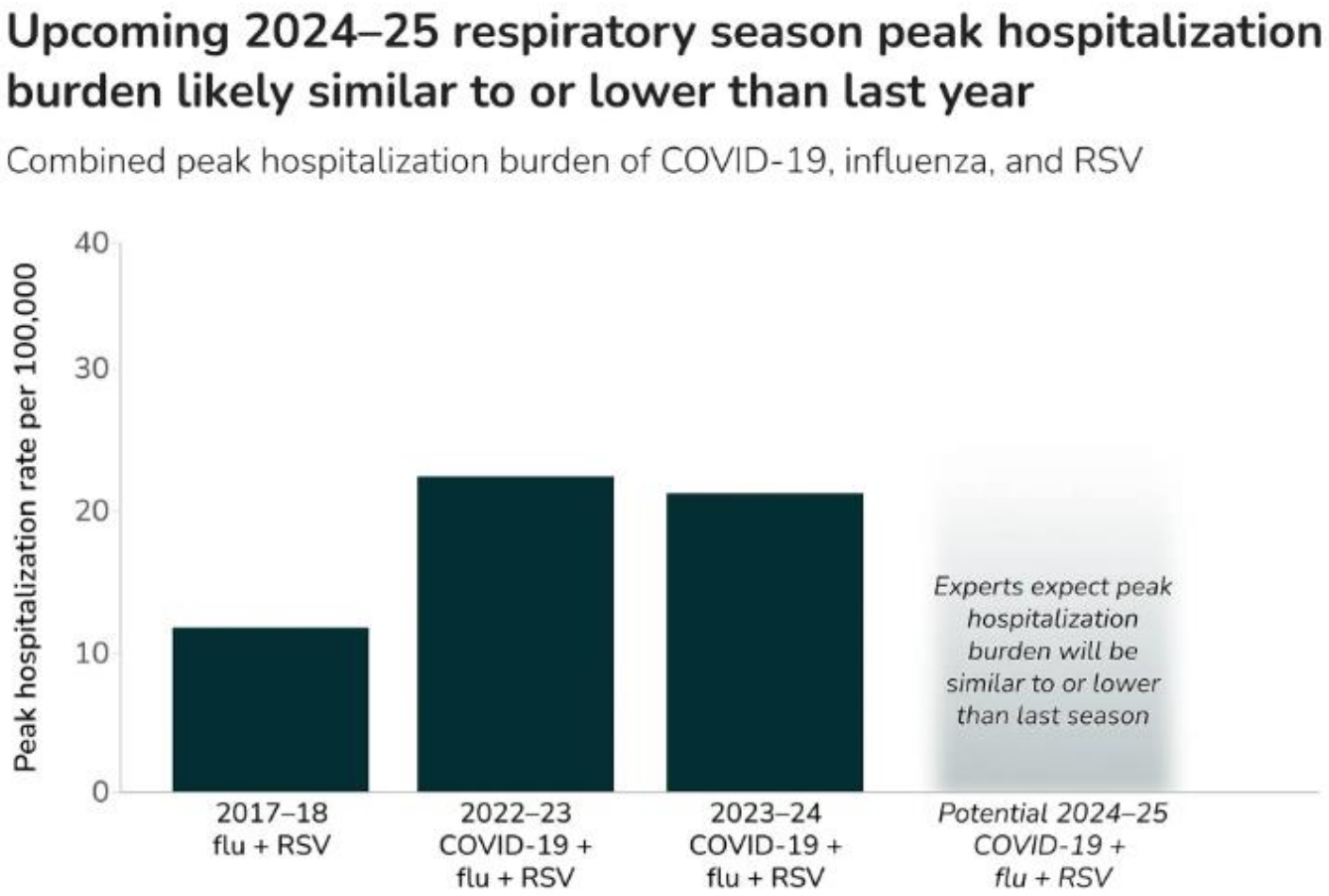
Respiratory Season Outlook



https://www.cdc.gov/cfa-qualitative-assessments/php/data-research/season-outlook24-25/index.html

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COVID-19

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US COVID-19 Activity

COVID-19 Update for the United States

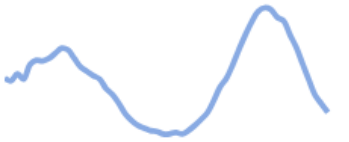
Early Indicators

Test Positivity

% Test Positivity

5.6%

Week ending October 19, 2024
Previous week 6.6%



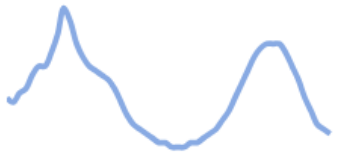
Oct 28, 2023 Oct 19, 2024

Emergency Department Visits

% Diagnosed as COVID-19

0.6%

Week ending October 19, 2024
Previous week 0.7%



Oct 28, 2023 Oct 19, 2024

These early indicators represent a portion of national COVID-19 tests and emergency department visits. Wastewater information also provides early indicators of spread.

Severity Indicators

Hospitalizations

Rate per 100,000 population

2.8

Week ending October 5, 2024
Previous week 3.3

Oct 14, 2023 Oct 5, 2024

Deaths

% of All Deaths in U.S. Due to COVID-19

1.4%

Week ending October 19, 2024
Previous week 1.5%

Oct 28, 2023 Oct 19, 2024

CDC | Test Positivity data through: October 19, 2024; Emergency Department Visit data through: October 19, 2024; Hospitalization data through: October 5, 2024; Death data through: October 19, 2024.
Posted: October 25, 2024 12:06 PM ET

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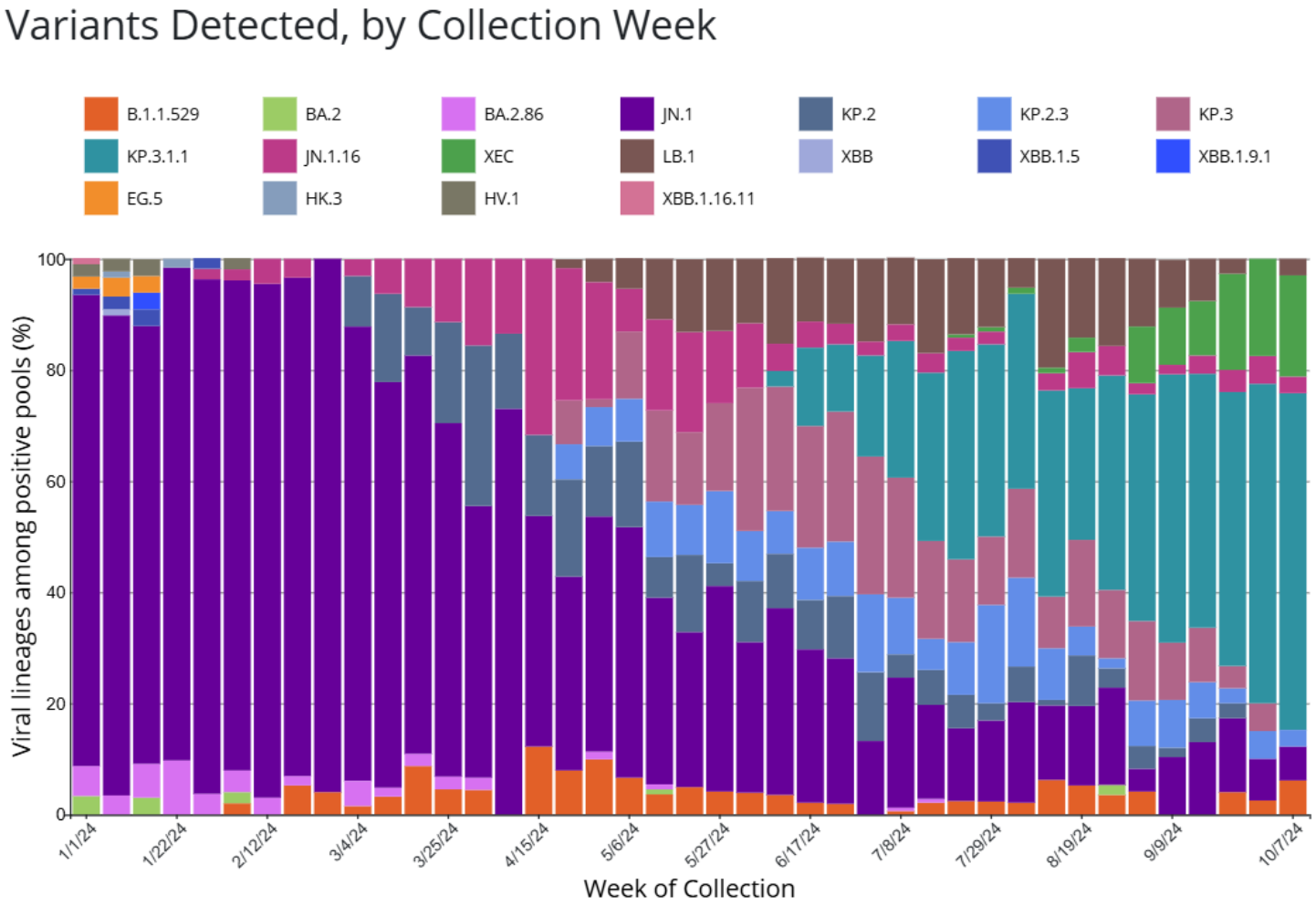
https://covid.cdc.gov/covid-data-tracker/#datatracker-home

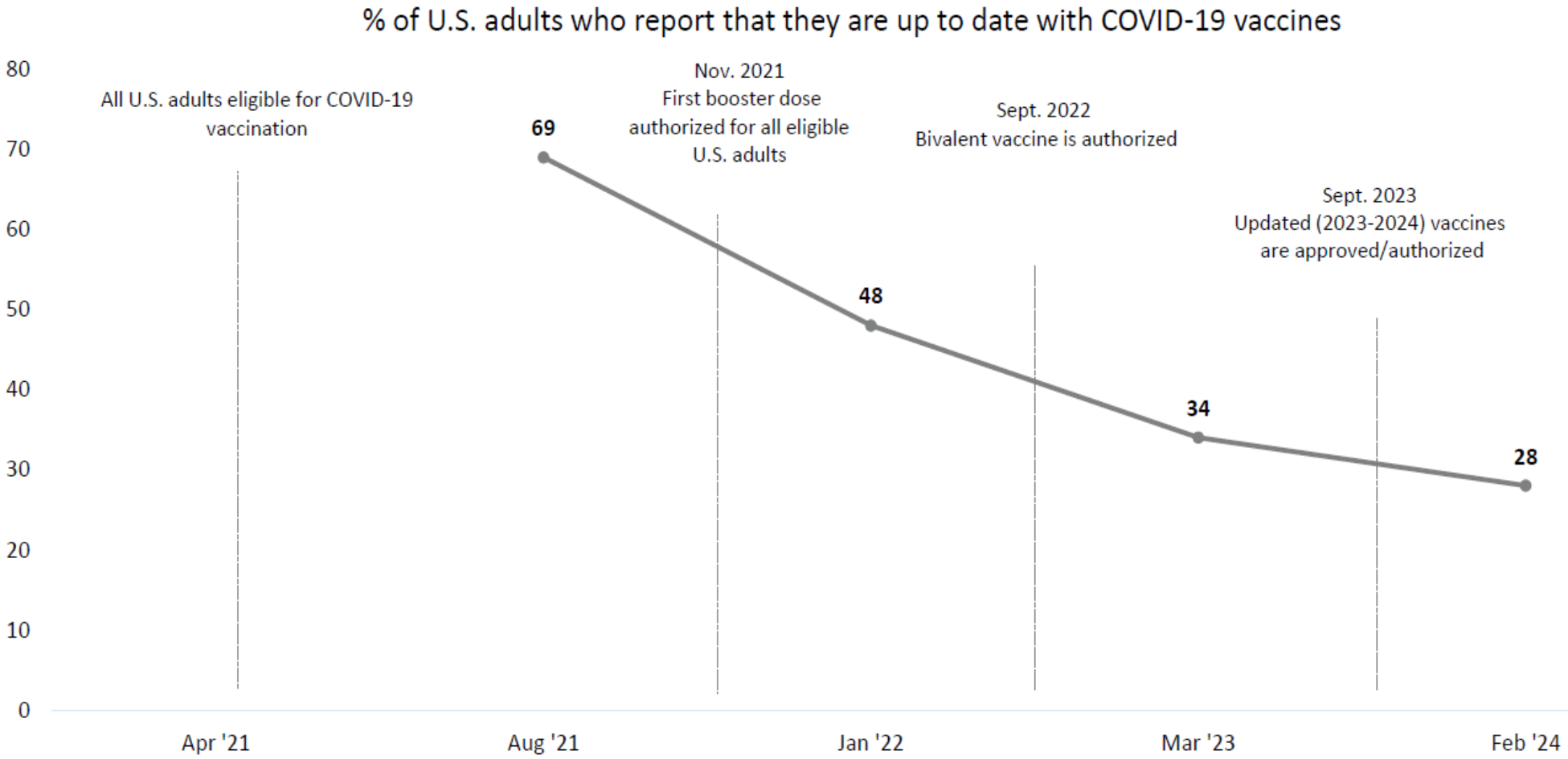
2024-2025 COVID-19 Vaccine Formulation

- Strain change
- Not new vaccine
- Monovalent Omicron JN.1-lineage of SARS-CoV, KP.2 (previously XBB)
  - mRNA vaccines (Moderna/Pfizer) authorized by FDA August 22
  - Novavax August 30



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

2023-24 Uptake



Link-Gelles R. ACIP Meeting Presentation. June 27, 2024.

2023-24 Vaccine Efficacy

- Across all age groups, 2023-24 vaccine was effective against
  - COVID-19 infection
  - ED/Urgent Care visits
  - Hospitalizations

- 2023-24 formulation vaccine efficacy persisted for at least 6 months post-vaccination
  - Waning observed 4-6 months (similar to prior years)

Link-Gelles R. ACIP Meeting Presentation. June 27, 2024.

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2023-24 Safety

- V-Safe data showed similar adverse reactions to prior seasons (any symptoms ~60% Moderna, ~50% Pfizer or Novavax)
- Vaccine Safety Datalink (VSD) safety signals:
  - Pfizer: GBS in 65+, 4.1 cases per million, unclear if associated or by chance, not found in prior seasons, not impacted by co-administration of flu vaccine
  - Pfizer and Moderna: Ischemic stroke (50-64 Pfizer, 65+ Moderna), inconsistent across age groups, found in 2022-23 Pfizer, not impacted by flu vaccine, further study planned
  - ACIP workgroup considered evidence **inadequate** for a formal safety concern
- VSD found no signal for myocarditis/pericarditis in males 12-39 years
  - May be limited by low vaccine uptake

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Soon to be Updated

ACIP Recommendations

- 2024-25 formulation (strain change, not new vaccine)
  - Monovalent Omicron JN.1-lineage of SARS-CoV, KP.2 (previously XBB)
  - mRNA vaccines (Moderna/Pfizer) authorized by FDA August 22, Novavax August 30
- *5 years and older:* 1 dose of 2024-25 mRNA vaccine or Novavax 12 years+
  - mRNA 1 dose regardless of previous vaccination, 3 doses of 2024-25 mRNA vaccines for moderate-severe immunocompromise
  - Novavax 2 doses (3+ weeks apart) if not previously vaccinated
  - At least 2 months after prior vaccine doses
- *6 months to 4 years (previous vax):* 1 dose of Moderna, 1-2 doses of Pfizer*
  - *2 doses of Pfizer if 1 prior Pfizer dose, 1 dose of Pfizer if 2+ prior Pfizer doses
- *6 months to 4 years (initial vax):* 2-3 doses of Moderna, 3 doses of Pfizer
- ~~Booster NOT currently recommended~~

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html

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ACIP October 2024 Update

Major Changes:

- 65+ years: Second dose recommended
  - Ideally 6 (minimum 2) months from initial/prior dose
- 6 months and older with moderate-severe immunocompromise: At least 2 doses
  - Second dose recommended routinely, additional doses (3rd or more) by SCDM
    - Ideally 6 (minimum 2) months interval between doses
- Interchangeability (Novavax)
  - Ideally use same manufacturer, may interchange mRNA if same not available
  - Novavax (new): Initial 2 dose series should be Novavax, but if >8 weeks since first dose, can substitute mRNA if only mRNA available

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Schechter R. ACIP Meeting Presentation. October 23, 2024.

ACIP October 2024 Update

Moderate-Severe Immunocompromise:

- Self-attestation of immunocompromise status continues to be sufficient, specific documentation not required
- Examples of moderate-severe immunocompromise
  - Transplant
  - Cancer
    - E.g., chemotherapy or blood cancers
  - Chronic kidney, hematologic disease
  - HIV
  - Primary immunodeficiency
  - Drug-induced
    - Moderate to high dose corticosteroids
    - Medications for autoimmune conditions, cancer chemotherapy

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https://www.cdc.gov/covid/vaccines/immunocompromised-people.html

ACIP October 2024 Update

Rationale:

- 65+ years 70% of hospitalizations, highest death rate, highest reliance on vaccination vs. infection-induced immunity, 4-6 month waning
  - Vaccination additionally protected against thromboembolic events in 65+ years
- 1 in 6 hospitalized patients have immunocompromising condition, vaccine efficacy is lower in immunocompromised with 4-6 month waning
- Routine vs. SCDM recommendations easier to implement
- 6-month interval chosen for simplicity, 2-month minimum chosen for individualization (risk/circumstances)

Schechter R. ACIP Meeting Presentation. October 23, 2024.

Timing of Vaccination

- CDC does not recommend specific timing of COVID-19 vaccination
- Protection is maximal in the first weeks-months after vaccination
  - High risk don't wait (e.g., age 75+, obesity, immunocompromised)
    - Pemgarda authorized by FDA for immunocompromised patients
  - Low risk patients may consider timing vaccination a few weeks before big events/major meetings.
    - Note: You are considered high risk if you live in close quarters with a high-risk patient
- Masking is reasonable especially prior to updated vaccination
- Co-administration with other vaccines (flu, RSV) is encouraged
  - Increases likelihood of completion, minimal impact on efficacy, possibly increases ADR
  - Exception is mpox vaccine given *theoretical* additive risk of myocarditis
- Recent COVID-19 infection – consider delay 3 months from symptoms/+test

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html

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Preparation and Storage

	Moderna (Spikevax)	Pfizer-BioNTech (Comirnaty)	Novavax
How supplied	**Pre-filled syringe** 10-pack	**Prefilled syringe (12+ years):** 10-pack **Vials (<12 years):** 3 dose multi-dose vial 10-pack (6 mos-4 years), single dose vial 10-packs (5-11 years)	**Pre-filled syringe** 10-pack
Reconsti-tution	**No reconstitution required**	**6 months – 4 years multi-dose vial formulation requires constitution** **Other formulations no reconstitution required**	**No reconstitution required**
Storage	Frozen till expiry, 30 days in fridge	Prefilled syringe (12+ years): Fridge until expiry, Never frozen Vials (<12 years): **Ultra-cold till expiry**, 10 wks Fridge, Use within 12 hours of dilution, Need to time ordering based on demand if no ultra-cold storage	Refrigerated until expiry

Access

- Free to patient (No cost-sharing) via private health insurance, Medicare, and Medicaid
  - Effective immediately
  - Eligible children may receive via Vaccines for Children (VFC) program
- Fewer and fewer PCPs carrying COVID-19 vaccine
  - Community pharmacies are critical for public access
- Bridge Access Program ended August 2024
  - Provided free vaccine for uninsured/insurance not covering COVID-19 vaccine

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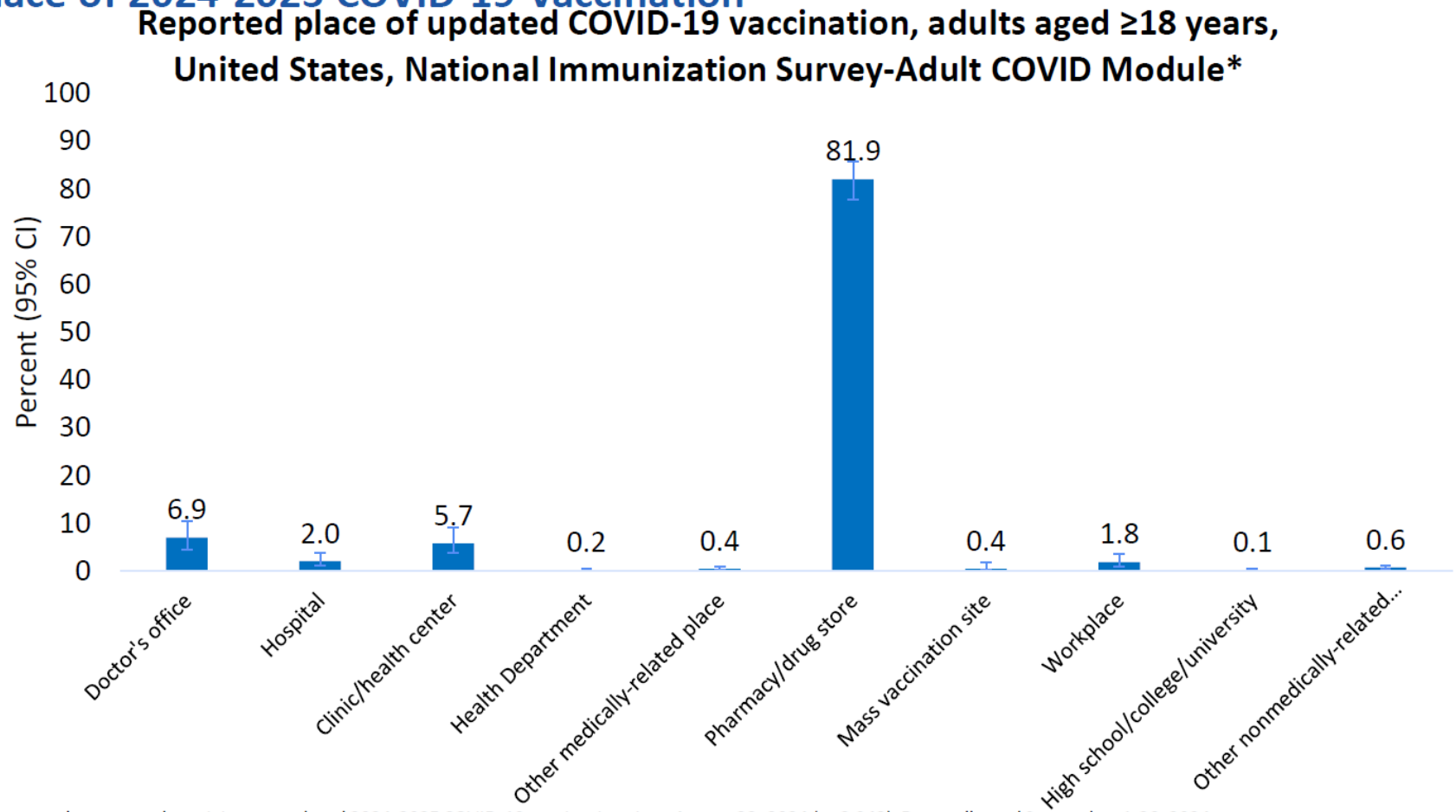
Access – My Favorite Graph

Place of 2024-2025 COVID-19 Vaccination



*Among persons who reported receiving an updated 2024-2025 COVID-19 vaccination since August 22, 2024 (n=2,943). Data collected September 1-28, 2024.

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Free COVID Tests – covidtests.gov

https://covidtests.gov/

Question 1 of 4

Which of the following is TRUE related to COVID-19 vaccination?

a. Second doses are recommended for older adults (65+ years old)
b. 3 vaccines are available: Moderna and Pfizer (mRNA) and Novavax (protein subunit)
c. COVID-19 vaccines can be given at the same time as influenza and RSV
d. All of the above are true

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Question 1 of 4

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Influenza

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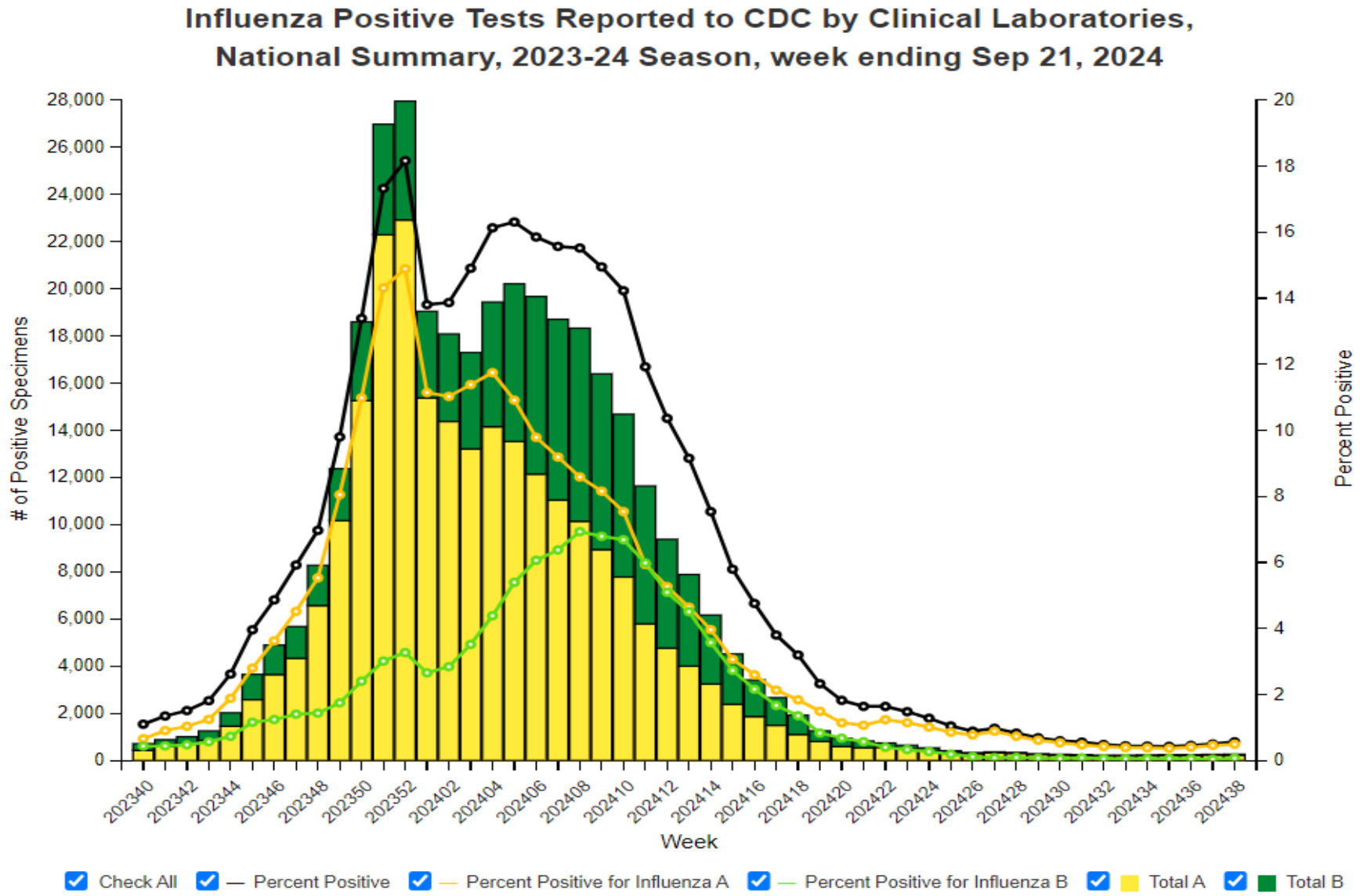
US Influenza Activity



https://www.cdc.gov/flu/weekly/index.htm

2024-25 Formulation Changes

- Quadrivalent → Trivalent
  - Influenza B/Yamagata strain removed
  - No cases of B/Yamagata detected since 2020 due to COVID-19 interventions

- 2024-25 Formulation
  - A/H1N1 (Victoria)
  - A/H3N2 (Thailand) – updated from 2023-24 season
    - H3N2 (Massachusetts) for cell and recombinant vaccines
  - B/Austria (Victoria-Like lineage)

https://www.cdc.gov/flu/professionals/acip/summary/summary-recommendations.htm

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ACIP Recommendations

- >6 months: Routine vaccination for all
  - Unchanged
- ≥65 years: Preferentially receive high dose (Fluzone High-Dose®), adjuvanted (Fluad®), or recombinant (Flublok)
  - Other formulations acceptable but less preferred. Unchanged.
- Solid organ transplant patients: May receive high dose (Fluzone High-Dose®) or adjuvanted (Fluad®)
  - No preference over other formulations. New for 2024-25 Season.

https://www.cdc.gov/flu/professionals/acip/summary/summary-recommendations.htm

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Timing of Vaccination

- Older adults
  - Ideally September and October
- Pregnancy in 3rd trimester
  - May receive earlier (July/August) to reduce risk of influenza infection during first months after birth (when newborn too young for vaccination)
- Children 6 months to 8 years who require 2 doses (first series):
  - First dose ASAP (including July/Aug if available), to allow second dose 1+ months after to be given ideally by end of October
    - Second dose 4+ weeks after first dose
- Children 8 and older req only 1 dose: July/August may be considered
  - Ahead of back-to-school

https://www.cdc.gov/flu/professionals/acip/summary/summary-recommendations.htm

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Other Reminders

- Egg allergy is not a contraindication to flu vaccine
  - Regardless of formulation (egg- vs. non-egg-based)
  - No additional safety measures needed
- Coadministration acceptable with other vaccines (COVID-19, RSV)
  - Exception: LAIV3 with other live vaccines
- Avoid LAIV3 (Flumist) in pregnant, immunocompromised
- If recently receives(ed) influenza antiviral (e.g., oseltamivir)
  - Reduced effectiveness of LAIV3 (Flumist) 2 days before to 2 weeks after oseltamivir (different intervals for peramivir or baloxavir)
  - Revaccinate with non-live vaccine if within interval above

https://www.cdc.gov/flu/professionals/acip/summary/summary-recommendations.htm

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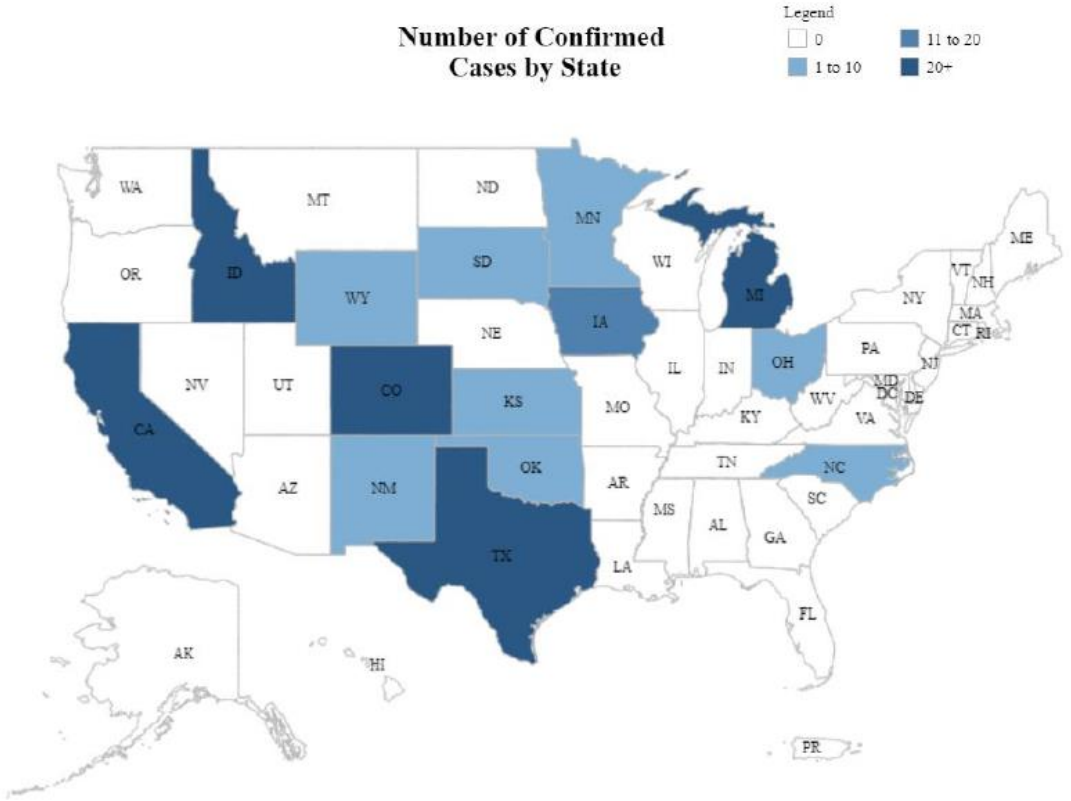
Highly Pathogenic Avian Influenza A (H5N1)

- 324 farms in 14 states
- 31 human cases as of October 18, 2024
  - All had contact with animals, mild disease
  - Missouri case ruled out human transmission
- No human-to-human transmission
- No markers of antiviral resistance
- CDC monitoring cases and wastewater in collaboration with USDA
- **Current risk to public: LOW**



https://www.cdc.gov/bird-flu/index.html
https://www.aphis.usda.gov/livestock-poultry-disease/avian/avian-influenza/hpai-detections/livestock

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FluMist™ At Home

- Approved September 20, 2024 by FDA
- Self/Caregiver-Administered
- Recipients:
  - Ages 2-49
    - Caregiver Ages 2-17
    - Self-Administer Ages 18-49
  - Must be non-pregnant & immunocompetent
- Anticipated availability for 2025-26 season via home delivery

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Question 2 of 4

Which of the following is FALSE related to influenza vaccination?

a. Older patients (age 65+) should preferentially receive high dose (Fluzone High-Dose), adjuvanted (Fluad) or recombinant (Flublok) vaccine
b. Solid organ transplant patients may receive high dose (Fluzone High-Dose), adjuvanted (Fluad) vaccine
c. Patients with egg allergy should never receive influenza vaccine
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RSV
Older Adults

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RSV… What's the Big Deal?

RSV vaccination is at least as important as Influenza and COVID-19

Let's Make It Standard

- 6,000-10,000 **deaths**/year
- 60,000-160,000 **hospitalizations**/year
- 0.9-1.4 million **medical encounters (like ED/Urgent Care Visits)**/year
- **Older, long term care residence, cardiopulmonary conditions** are particularly high risk for severe RSV
- RSV can cause **more severe disease than Influenza *and* COVID-19**

Havers et al. MMWR Morb Mortal Wkly Rep 2023;72:1075–1082.
Surie et al. JAMA Netw Open. 2024;7(4):e244954.
https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2023-02/slides-02-23/RSV-Adults-04-Melgar-508.pdf

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CDC and FDA RSV Milestones

2023

- *May 2023: Arexvy (GSK) FDA approval for ages 60+*
- *May 2023: Abrysvo (Pfizer) FDA approval for ages 60+*
- *June 2023: ACIP recommends RSV vaccine for 60+ years using SCDM*
  - *2 products : Arexvy, Abrysvo*
- *July 2023: Nirsevimab (Sanofi/AZ) FDA approved for <24 months*
- *August 2023: Abrysvo (Pfizer) FDA approval for pregnant 32-36 weeks*
- *August 2023: ACIP recommends Nirsevimab for 8-19 months*
- *October 2023: ACIP recommends Abrysvo for pregnant women (32-36 wks)*

2024

- May 2024: mRESVIA (Moderna) FDA approved
- June 2024: Arexvy (GSK) FDA approval for ages 50-59
- August 2024: ACIP recommends RSV vaccine for 75+ years and 60-74 at high risk for severe disease
  - 3 products: Arexvy, Abrysvo, mRESVIA

https://www.cdc.gov/flu/professionals/acip/summary/summary-recommendations.htm

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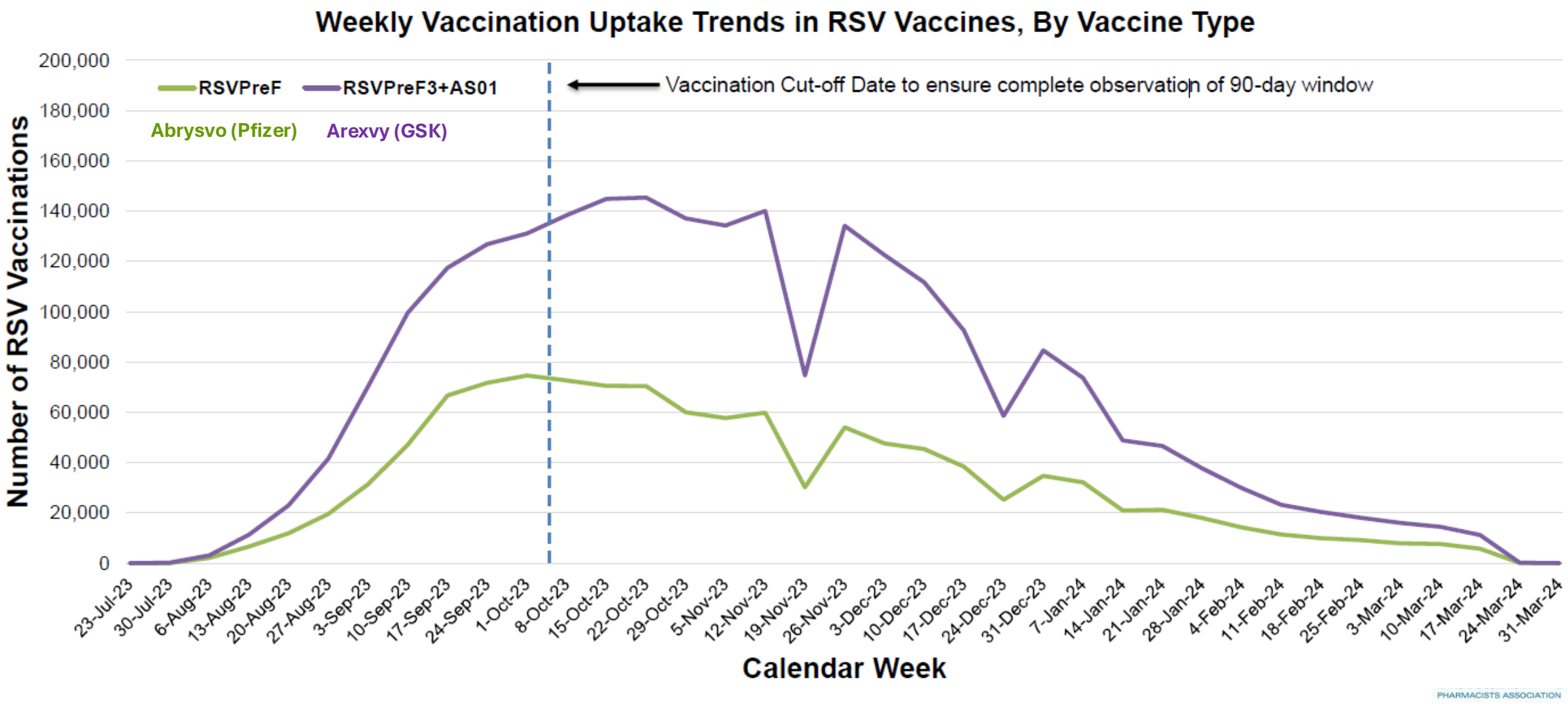
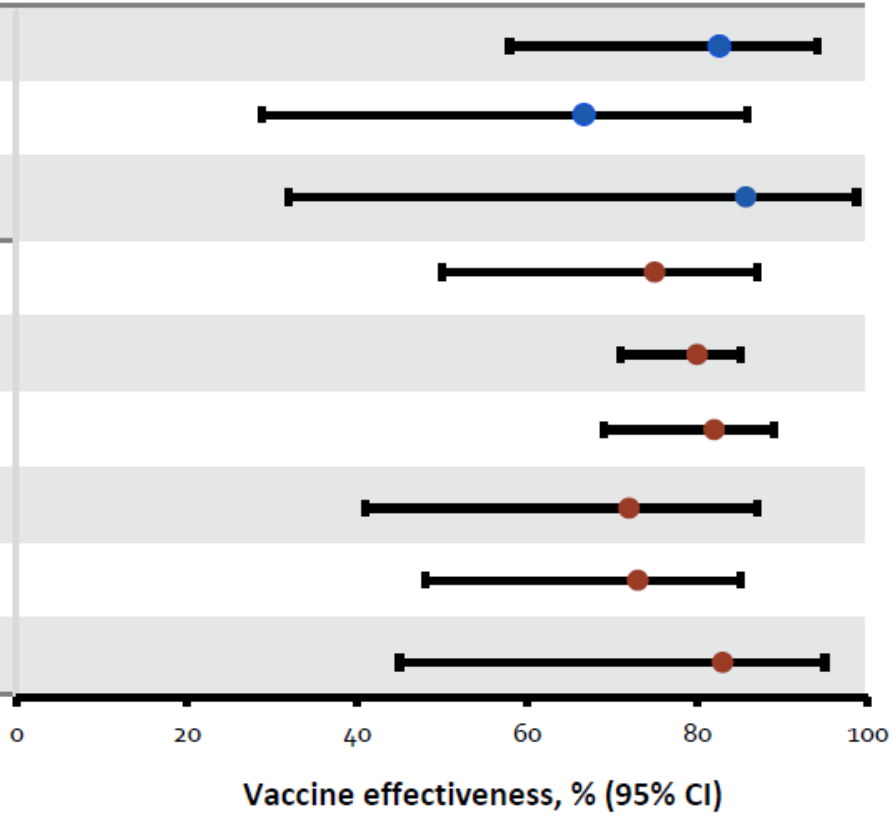
RSV Vaccination Uptake Trends 2023-24



https://www.cdc.gov/rsv/php/surveillance/rsv-net.html

Real World Efficacy Similar to Clinical Trials

Outcome	Analysis	Vaccine efficacy/effectiveness, % (95% CI)
Symptomatic, RSV-associated lower respiratory tract disease (LRTD)	GSK trial (≥2 or 3 sx LRTD, primary endpoint)†	83 (58–94)
	Pfizer trial (≥2 sx LRTI, co-primary endpoint)*	67 (29–86)
	Pfizer trial (≥3 sx LRTI, co-primary endpoint)*	86 (32–99)
RSV-associated hospitalization	IVY Network, adults ≥60 years§	75 (50–87)
	VISION, adults ≥60 years, immunocompetent	80 (71–85)
	VHA, adults ≥60 years§	82 (69–89)
	Medicare ESRD, otherwise immunocompetent, ≥65y	72 (41-87)
	VISION, immunocompromised	73 (48–85)
	Medicare ESRD, additional immunocompromise, ≥65y	83 (45-95)

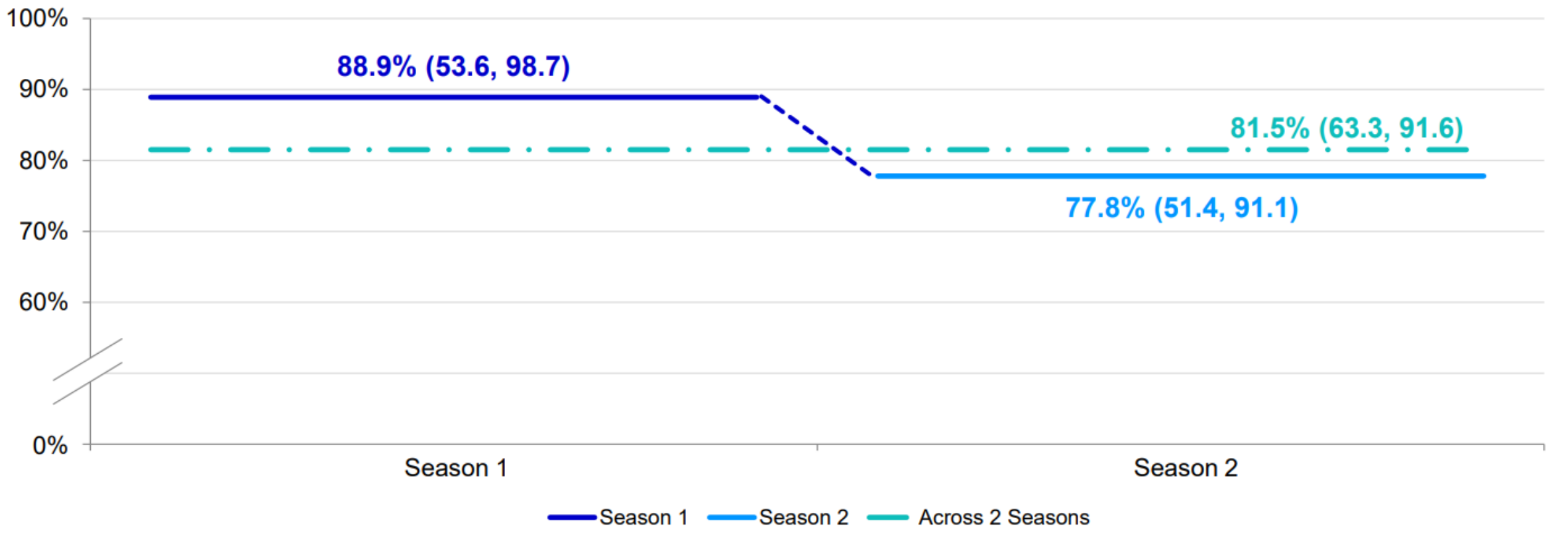


Abbreviations: LRTI = lower respiratory tract infection; LRTD = lower respiratory tract disease; sx = symptoms or signs; y = years

† Papi A, et. al. Respiratory Syncytial Virus Prefusion F Protein Vaccine in Older Adults. *N Engl J Med*. 2023;388:595–608. See slide 43 for detailed definitions.
* Walsh E, et. al. Efficacy and Safety of a Bivalent RSV Prefusion F Vaccine in Older Adults. *N Engl J Med*. 2023;388:1465–77. See slide 43 for detailed definitions.
§ Includes patients with immunocompromising conditions in the displayed VE estimate.

RSV Vaccine Efficacy Persists At Least 2 Seasons

VE Against RSV-associated LRTD in Subjects with ≥3 New or Worsened Lower Respiratory Symptoms (95% CI)[1,2]

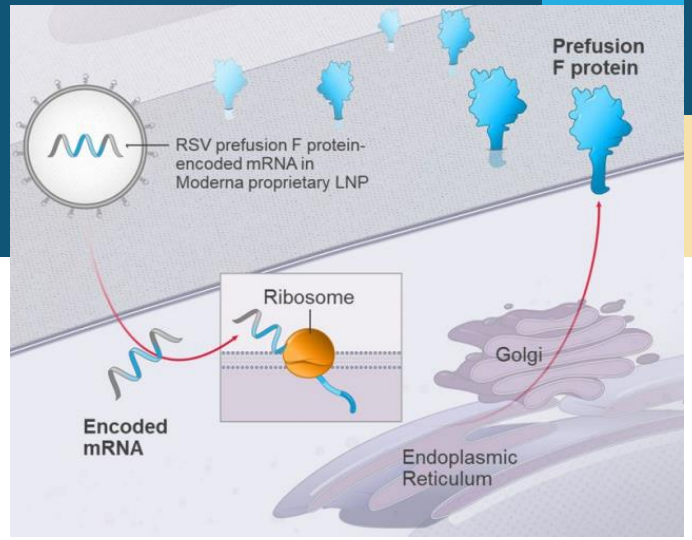


LRTD = lower respiratory tract disease

1. Eiras D. 2024 (May 17-22). ATS 2. Walsh EE, et al. *N. Engl J Med*. 2023:338:1465-1477.

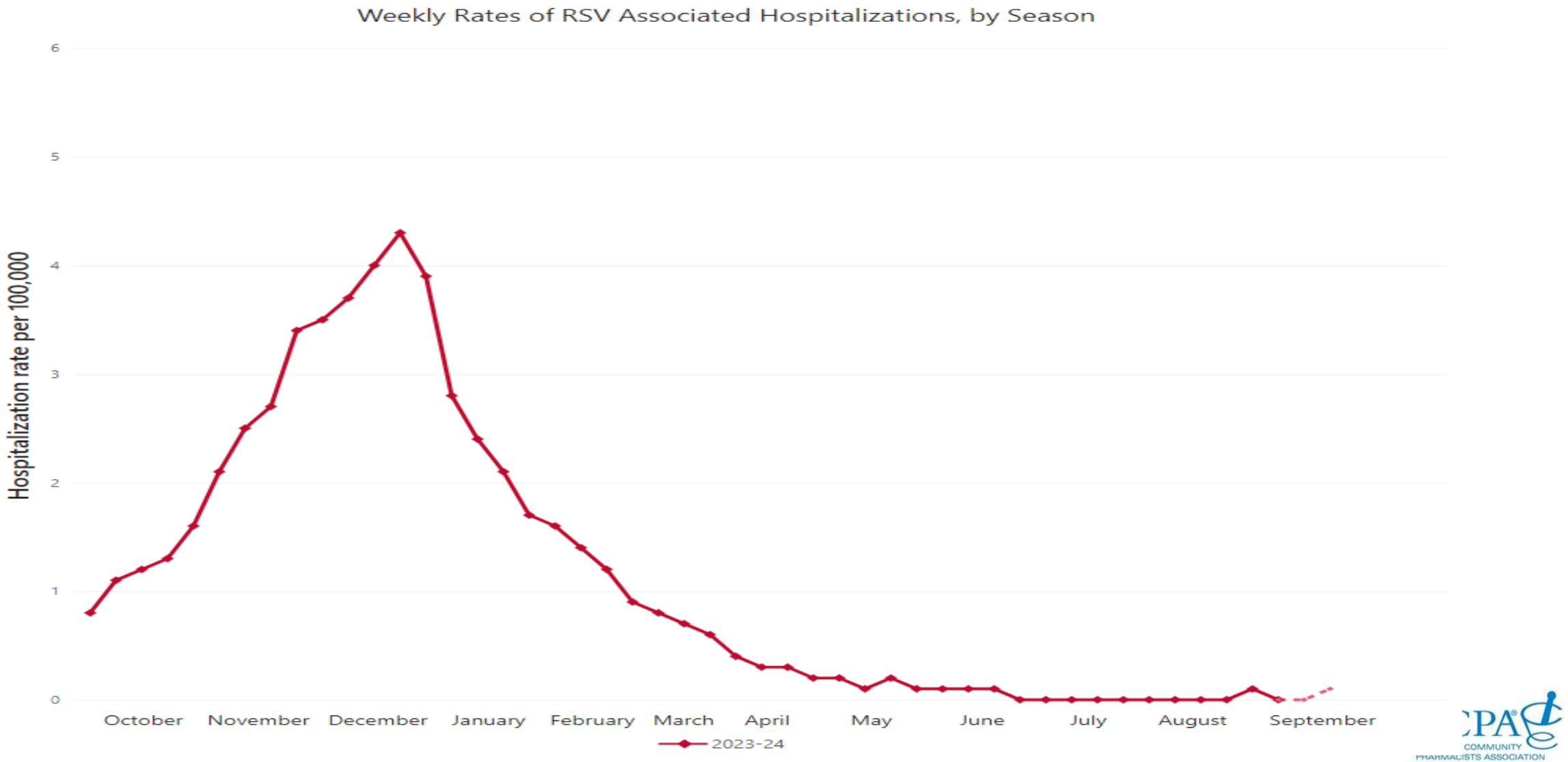
mRESVIA™ (mRNA-1345, Moderna)

- mRNA-based vaccine
  - Encodes RSV fusion (F) protein illiciting immune response, cross reacts RSV A and B
- FDA approved May 2024 for 60+ Years
- Single dose, Prefilled Syringe, Frozen
- Efficacy demonstrated through 19 months



https://www.cdc.gov/rsv/php/surveillance/rsv-net.html

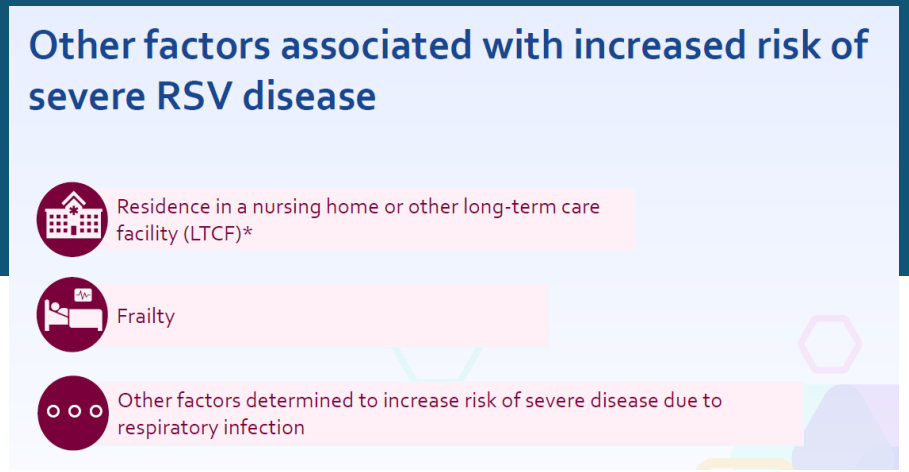
Recent US RSV Activity

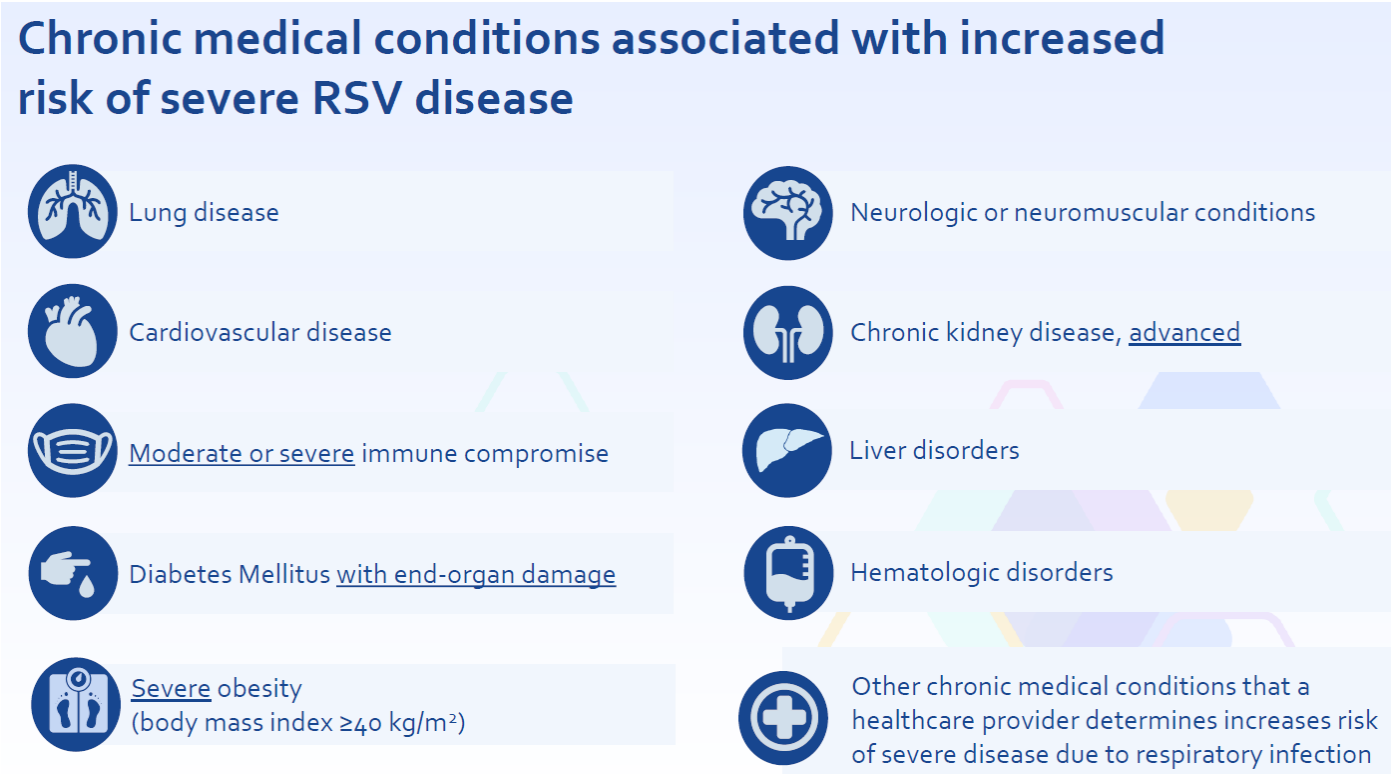


https://www.cdc.gov/rsv/php/surveillance/rsv-net.html

ACIP Recommendations

- *75+ years, Unvaccinated:* Routine vaccination
- *60-74 years, Unvaccinated:* Routine vaccination if high risk for severe disease
  - Chronic medical conditions
  - Nursing home residence or Frailty
- *Previously vaccinated:* No repeat vaccine indicated
  - Considered still protected





https://www.cdc.gov/vaccines/vpd/rsv/hcp/older-adults.html

Chronic medical conditions and risk factors for a risk-based recommendation for RSV vaccination in adults aged 60–74 years

- **Chronic cardiovascular disease** (e.g., heart failure, coronary artery disease, congenital heart disease; *excluding isolated hypertension*)
- **Chronic lung disease** (e.g., chronic obstructive pulmonary disease [COPD], emphysema, asthma, interstitial lung disease, cystic fibrosis)
- **Chronic kidney disease, advanced** (e.g., stages 4–5, dependence on hemodialysis or other renal replacement therapy)
- **Diabetes mellitus with end-organ damage** (e.g., diabetic nephropathy, neuropathy, retinopathy, or cardiovascular disease)
- **Severe obesity** (body mass index **≥40** kg/m²)
- **Decreased immune function** from disease or drugs (i.e., **immunocompromising conditions***)
- **Neurologic or neuromuscular conditions** (e.g., neuromuscular conditions causing impaired airway clearance or respiratory muscle weakness; *excluding history of stroke without impaired airway clearance*)
- **Liver disorders** (e.g., cirrhosis)
- **Hematologic conditions** (e.g., sickle cell disease, thalassemia)
- **Frailty**
- **Residence in a nursing home or other long-term care facility**
- **Other chronic medical conditions or risk factors that a health care provider determines would increase the risk of severe disease due to respiratory infection**

*List of immunocompromising conditions would match the existing list from the COVID-19 vaccination Interim Clinical Considerations: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#immunocompromised

Patient attestation is sufficient evidence of the presence of a risk factor; vaccinators should not deny RSV vaccination to a person because of lack of documentation.

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https://www.cdc.gov/mmwr/volumes/73/wr/mm7332e1.htm

Timing and Co-Administration

- No formal recommendation for timing
  - Suggested to administer in **August to October** for maximal benefit
  - However, if outside this window, eligible patients may still be vaccinated if opportunity arises

- Co-administration with other vaccines is acceptable
  - Influenza, COVID-19
  - Pneumococcal, Td/Tdap, Zoster
  - Studies ongoing (additional supportive data from ACIP October 2024)

https://www.cdc.gov/flu/professionals/acip/summary/summary-recommendations.htm

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Common Questions

- Healthy 60–74-year-olds who want vaccination
  - Unfortunately, this is no longer within CDC recommendations
- Abrysvo vs. Nirsevimab
  - Abrysvo is generally preferable given access, cost, and provides both mother and infant with active and passive immunity, respectively
  - If mother refuses Abrysvo, administer Nirsevimab to infant
- Pregnant woman receives non-Abrysvo vaccine
  - Do not give any further RSV vaccines, administer Nirsevimab to infant
- Duration of Nirsevimab passive immunity in infants
  - Nirsevimab persists in bloodstream for at least 5 months

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ACIP October 2024 Update

- No formal votes for changes
- GBS signal developing, higher than influenza and zoster, benefit of vaccination continues to exceed risk – no recommendation change
- Additional data for acceptable immunogenicity/tolerability with coadministration with SD/HD influenza vaccine
  - Occasional signal of lower immunogenicity but unclear clinical significance
- New data for benefit in transplant patients 18+ years
  - Second dose of Arexvy but not Abrysvo associated with better immunogenicity
- Continued evaluation of benefit in high risk <60-year-olds

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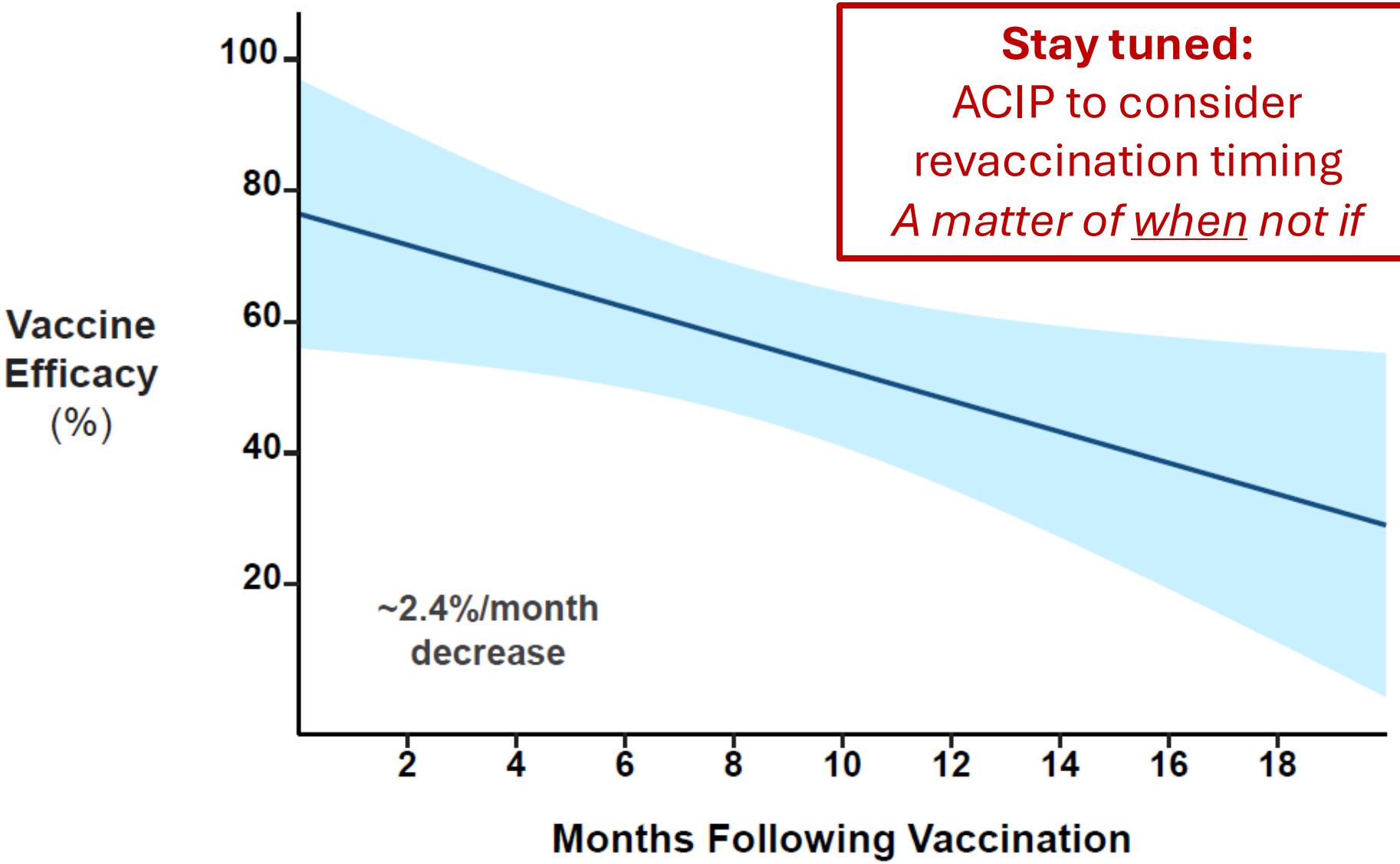
Future Considerations… RSV Revaccination Timing



Stay tuned:
ACIP to consider revaccination timing
A matter of <u>when</u> not if

https://www.cdc.gov/rsv/php/surveillance/rsv-net.html

RSV

Pregnant Women and Infants/Children

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2023-24 Season

- 17.8% pregnant women 18-49 years overall
  - 10.3% among Black pregnant women
- 51.2% infants protected either via Nirsevimab or maternal RSV vax
- Challenges
  - Licensure/Launch at beginning of RSV season
  - Complexity of recommendations (timing + gestational age + Nirsevimab)
  - Shortages of Nirsevimab/Need for prioritization
  - Access issues (e.g., insurance denials, prescription requirements)
  - Lack of co-administration data

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Abrysvo Safety Updates

- Data from VAERS, V-Safe, Vaccine Safety Datalink (VSD)
- Pre-term birth – *more encouraging data!*
  - More pre-term births in vaccine arm in clinical trials
    - Results were NOT statistically significant
  - Incidence of pre-term birth in vaccine recipients was within expected range
    - 4.1% incidence (3.1-6.1% predicted background rate)
  - Corroborated in additional data from October 2024 ACIP meeting
- Local/systemic reactions
  - Similar rates to clinical trials, no concerning signals
  - Ex: Fatigue, headache, muscle pain

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ACIP Recommendations

- *Pregnant women 32-36 weeks*: 1 dose Abrysvo if not previously given
  - Seasonal administration (September-January in most US states)
  - No revaccination, Only 1 lifetime dose (for now)
  - Only Abrysvo should be given, neither ~~Arexvy~~ nor ~~mRESVIA~~ are approved

[2] In jurisdictions with RSV seasonality that differs from most of the continental United States, including Alaska, southern Florida, Guam, Hawaii, Puerto Rico, U.S.-affiliated Pacific Islands, and U.S. Virgin Islands, providers should follow state, local, or territorial guidance. However, nirsevimab may be administered outside of routine seasonal administration (ie., October through March) based on local RSV activity and other special circumstances. For infants born during October through March, nirsevimab should be administered in the first week of life—ideally during the birth hospitalization.

Abrysvo image courtesy of Keri Hurley-Kim, PharmD, MPH, BCACP, APh | Chu H. ACIP Meeting Presentation, October 23, 2024.

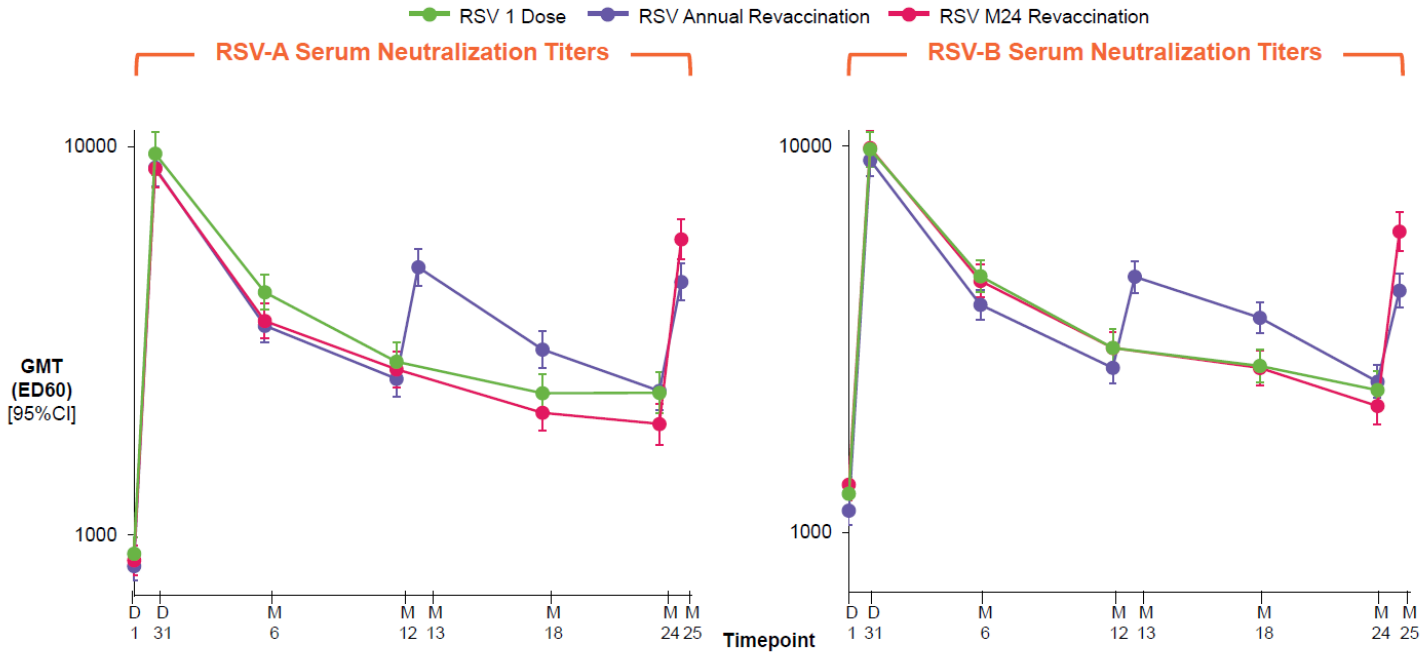
Revaccination

- Not currently recommended
  - Lower antibody titers with revaccination within 12 months
  - ?Pre-term birth signal
  - Nirsevimab available
- <u>But… If vaccinated in 23-24 and gives birth in 24-25 season: Infant should receive Nirsevimab</u>

AReSVi-004

CO-6

Higher RSV-A and RSV-B Neutralizing Antibody Titers Observed After 24 Month Vaccination Interval



RSV Annual revaccination (N=250-341): Participants receiving first dose (Dose 1) of AREXVY at Day 1, followed by revaccination dose at 12 months post Dose 1 and at 24 months post Dose 1;
RSV M24 revaccination (N= 223-319): Participants receiving first dose (Dose 1) of AREXVY at Day 1 followed by revaccination dose at 24 months post Dose 1;
RSV 1 dose (N=281-318): Participants receiving single dose (Dose 1) of AREXVY at Day 1; ED60: estimated dilution 60; GMT: geometric mean titer

Presentation by GSK at ACIP June 26, 2024

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Vaccine Supply 2024-25 Season

- No anticipated supply issues with Abrysvo
  - Already widely available and stocked

- Nirsevimab should be broadly available by October
  - Production ramping up September

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Preparation and Storage

	GSK AREXVY	Pfizer ABRYSVO	Moderna mRESVIA
How supplied	10-pack of **single-dose kits**	Single dose, or as a 5- pack of **single-dose kits**	Single dose **pre-filled syringe** or 10-pack
Reconsti-tution	**Reconstitution required:** single dose vial of lyophilized powder (antigen component) + single dose vial of liquid (adjuvant component)	**Reconstitution required:** single dose vial of lyophilized powder (antigen component) + single dose vial OR prefilled syringe with sterile water diluent	No reconstitution required
Storage	Both components should be **refrigerated** (2 to 8°C) in original container, protected from light	Product should be **refrigerated** (2 to 8°C) in original container, protected from light	Store **frozen** (-40 to -15°C), may be stored refrigerated (2 to 8°C) for up to 30 days prior to use, protected from light
	After reconstitution, the product should be administered within **4 hours**, otherwise discarded	After reconstitution, the product should be administered within **4 hours**, otherwise discarded	The pre-filled syringes may be stored at room temperature (8 to 25°C) for a total of **24 hours** after removal from refrigerated conditions, otherwise discard

Vaccinating Pregnant Patients

- Provide access
  - OB/GYN access limited and in decline in many parts of US
  - Strategies to target underserved minorities and communities
- Motivational Interviewing
  - Provide a strong consistent recommendation
  - Emphasize benefit to baby and benefit to pregnant person
  - Engage patient in decision-making
  - Acknowledge risks and limitations of data
- No difference in injection technique pregnant vs. non-pregnant

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Vaccinating Adolescents and Pregnant Women

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Question 3 of 4

Which of the following describes an eligible candidate for RSV vaccine?

a. mRESVIA for a pregnant woman
b. mRESVIA, Arexvy, or Abrysvo for healthy 41-year-old man
c. mRESVIA, Arexvy, or Abrysvo for a 68-year-old nursing home resident
d. Nirsevimab for a 78-year-old healthy man

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Question 3 of 4

Which of the following describes an eligible candidate for RSV vaccine?

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c. mRESVIA, Arexvy, or Abrysvo for a 68-year-old nursing home resident

d. Nirsevimab for a 78-year-old healthy man

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ACIP October 2024 Update

- No formal votes for changes
- Additional safety data from VSD corroborated no detectable risk of pre-term birth or SGA at birth
  - Further study ongoing for other outcomes
- Clesrovimab data presented
  - Monoclonal antibody for passive RSV immunity in infants (similar to Nirsevimab)
  - Phase 2b/3 studies concluded high (>90%) efficacy through 6 months and well tolerated
  - Pursuing FDA approval, Goal availability for 2025-26 season

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Schechter R. ACIP Meeting Presentation. October 23, 2024.

Pneumococcal

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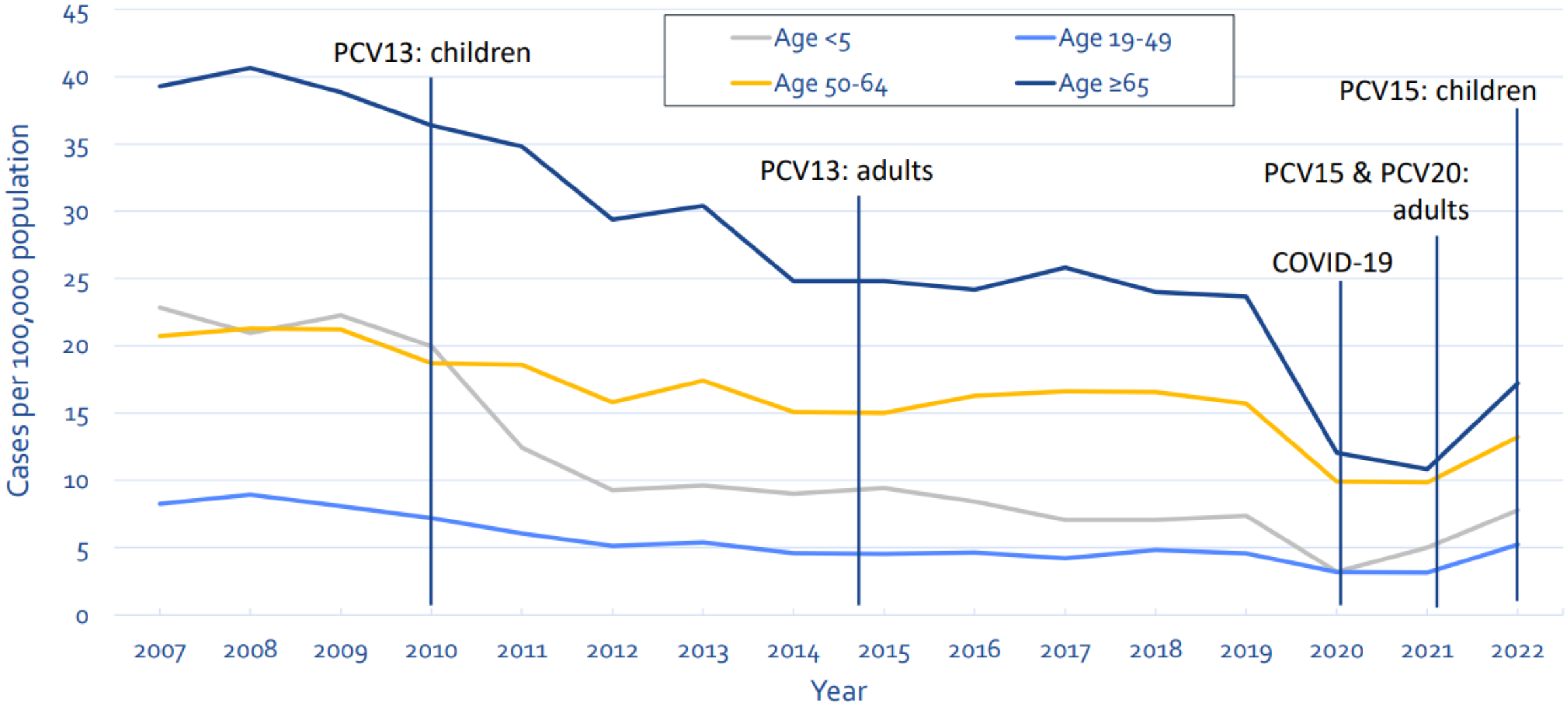
Invasive Pneumococcal Disease, US, 2007-2023



https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2024-02-28-29/02-Pneumococcal-Gierke-508.pdf

Pneumococcal Vaccination Coverage

- 66% of 65+ year olds have received *any* pneumococcal vaccination
- 12% PCV15/20 coverage among 65+ years Medicare A/B beneficiaries
- 22% of 19-64 years with risk-based indications have received *any* pneumococcal vaccination

https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2024-02-28-29/02-Pneumococcal-Gierke-508.pdf

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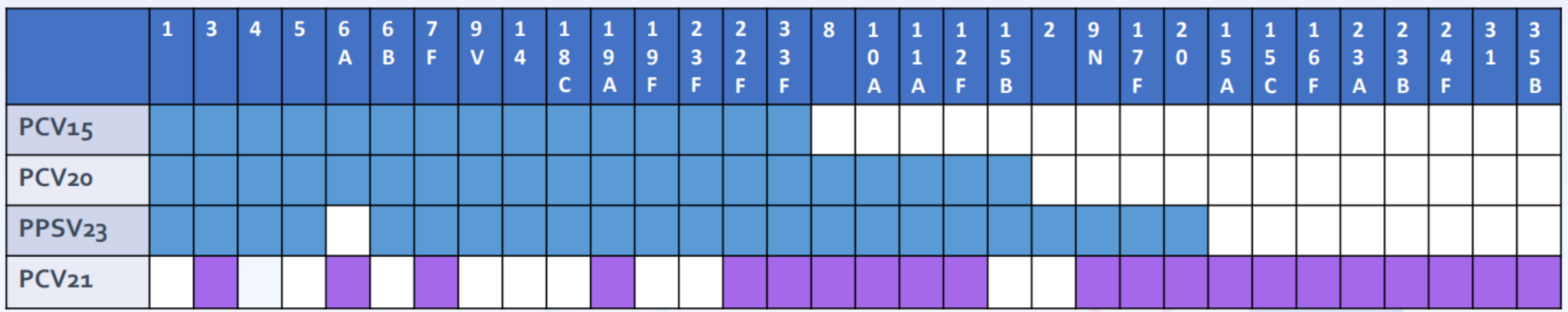
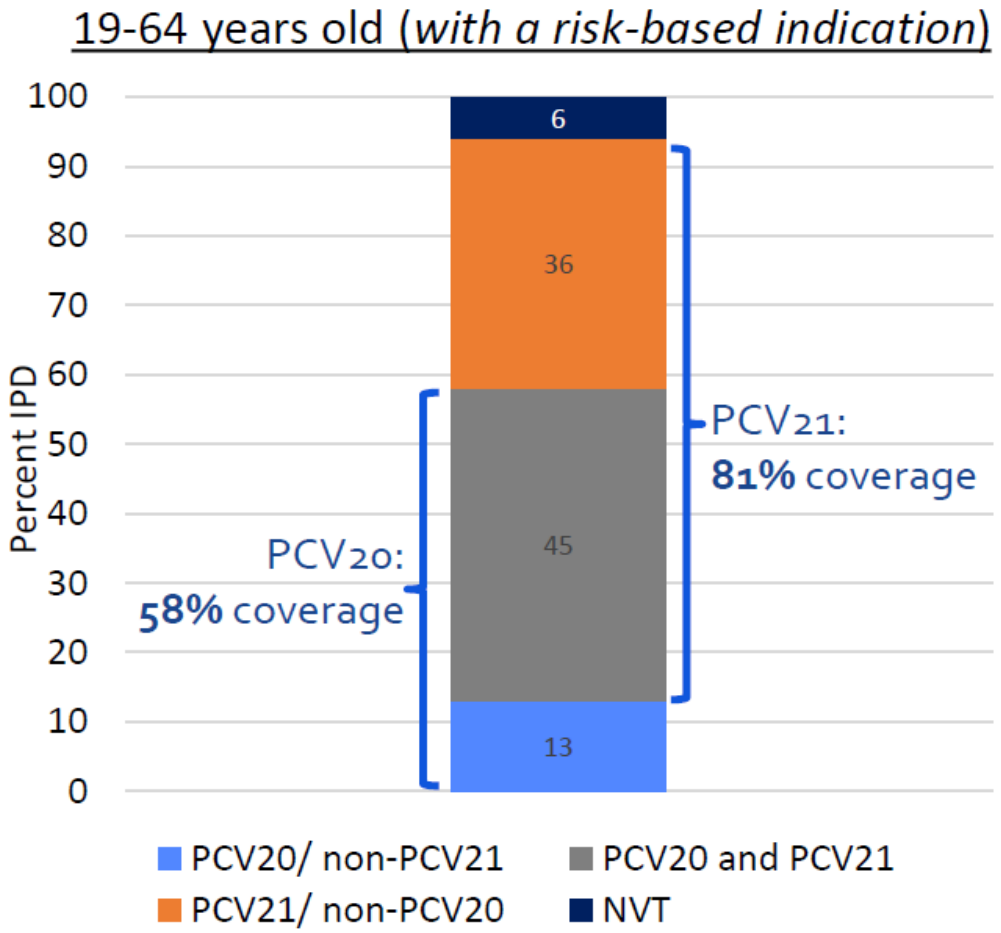
PCV21 (CAPVAXIVE, Merck)

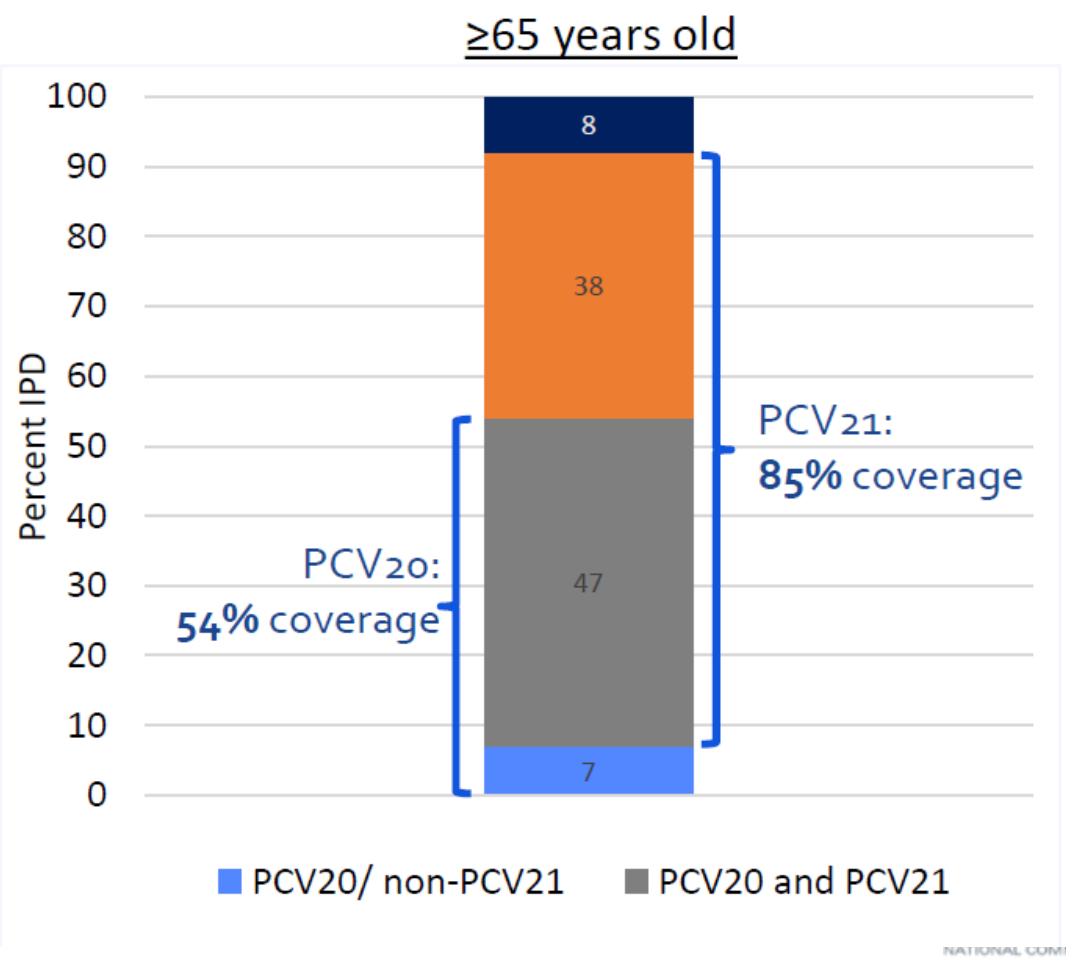
- FDA approved June 17, 2024 for 18+ years
- A ***different*** vaccine: Improved coverage of serotypes causing IPD
  - PCV21 81-84% vs. PCV20 54-58%… *Not PCV20 + 1!*
- Does not cover serogroup 4
  - Increased in adults experiencing homelessness, Alaska residents/Alaska Natives



https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2024-02-28-29/02-Pneumococcal-Gierke-508.pdf

PCV21 vs PCV20





https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2024-02-28-29/02-Pneumococcal-Gierke-508.pdf

Soon to be Updated

ACIP Recommendations

- Routine Vaccination
  - 65+ years and never received a PCV
  - 19-64 years with chronic medical conditions and never received a PCV
  - 19+ years who received PCV13 (or PCV7) but not PPSV23 (incomplete series)
  - 2-18 years with chronic medical conditions
  - Infants/Children
  - Immunocompromised
  - CSF leak, Cochlear implant
- Shared Clinical Decision-Making (SCDM)
  - 65+ years who received specifically PCV13 (any age) + PPSV23 (at 65+ years)

https://www.cdc.gov/pneumococcal/hcp/vaccine-recommendations

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SCDM 65+ Years Complete Series

- For 65+ years who received PCV13 (at any age) + PPSV (at 65+ years) PCV20 or PCV21 may be considered via SCDM
  - Does not apply if received PCV15
- Population risk is insufficient for a broad revaccination recommendation so risk assessment should be individualized
- Consider vaccinating the following…
  - Nursing home/Long term care residents
  - Areas with poor pediatric PCV uptake
  - Immunocompromised, CSF leak, Cochlear implant
  - Chronic medical conditions: heart, liver, lung disease, smoker, DM, alcoholism

https://www.cdc.gov/pneumococcal/hcp/vaccine-recommendations

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ACIP October 2024 Update

- Major Changes:
  - Reduce routine vaccination age from 65+ to 50+
  - For 19-49 who received PCV13 but not PPSV23 (incomplete series), prefer PCV20 or 21 instead of finishing with PPSV23

- Rationale
  - IPD mortality rate in 65+ year-olds is now similar to 50-64-year-olds
  - ~32-54% of 50-64-year-olds have 1+ risk factors for IPD
  - Lower vaccine coverage (37.3%) in 50-64 years with risk factors vs. 69.7% in 65+ years
  - Disparities in pneumococcal vaccine coverage and IPD incidence in 50-64
  - Age-based recommendations easier to implement vs. risk-based

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Kobayashi M. ACIP Meeting Presentation. October 23, 2024.

ACIP October 2024 Update

Likely new recommendation verbiage (subject to change)…

- 50+ years, no prior PCV: Single dose PCV
- 19-49 years, no prior PCV: Single dose PCV if risk factors
  - Likely no change to risk factors (i.e., heart, lung, liver, kidney dz, smoker, diabetes, immunodeficiency, etc.)
- 65+ years, prior PCV13+PPSV23 (complete): SCDM for PCV20 or 21
- 19+ years, prior PCV13 but not PPSV23 (incomplete): Prefer PCV20 or 21
- No preference for PCV15 vs. 20 vs. 21 but…if PCV15 given, follow up with PPSV23 1+ year later
  - Or 8 weeks+ for immunocompromised, cochlear implant, CSF leak
  - *My unofficial take: Favor PCV21 (or PCV20), if possible*

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Kobayashi M. ACIP Meeting Presentation. October 23, 2024.

PneumoRecs VaxAdvisor

CDC Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

Pneumococcal Vaccine Recommendations

PneumoRecs
VaxAdvisor

Tool to help determine which pneumococcal vaccines children and adults need.

App Store Preview

Open the Mac App Store to buy and download apps.

PneumoRecs VaxAdvisor 17+
Centers For Disease Control and Prevention
Designed for iPad
3.5 • 49 Ratings
Free

https://www.cdc.gov/pneumococcal/hcp/vaccine-recommendations/app.html

Complexity Reflects Advancement

- Pneumococcal vaccines continue to advance based on changing disease epidemiology (i.e., clinically significant serotypes and susceptible populations)
- Complex/changing recommendations part of the “growing pains”
- More changes are coming…

New Adult Pneumococcal Vaccines in Advanced Stages of Development

	1	3	4	5	6A	6B	7F	9V	14	18C	19A	19F	23F	22F	33F	8	10A	11A	12F	15B	2	9N	17F	20	15A	15C	16F	23A	23B	24F	31	35B	16F	7C
PCV15																																		
PCV20																																		
PPSV23																																		
PCV21																																		
Pn-MAPS24v																																		
VAX-24																																		
VAX-31																																		

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Question 4 of 4

A 68-year-old patient who has already completed pneumococcal vaccination (PCV13 at 65 years + PPSV23 at 66 years) is interested in PCV21. Which of the following is true?

a. He is not eligible since he has completed pneumococcal vaccine series

b. He may receive PCV21 after you discuss the risks and benefits, and a shared decision is made to give vaccine (shared clinical decision making)

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Question 4 of 4

A 68-year-old patient who has already completed pneumococcal vaccination (PCV13 at 65 years + PPSV23 at 66 years) is interested in PCV21. Which of the following is true?

a. He is not eligible since he has completed pneumococcal vaccine series

b. **He may receive PCV21 after you discuss the risks and benefits, and a shared decision is made to give vaccine (shared clinical decision making)**

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Questions?

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