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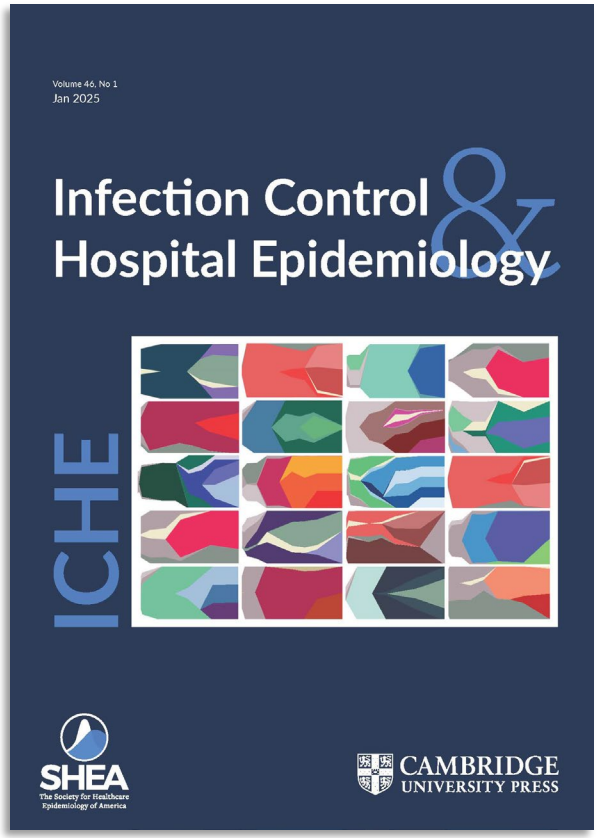

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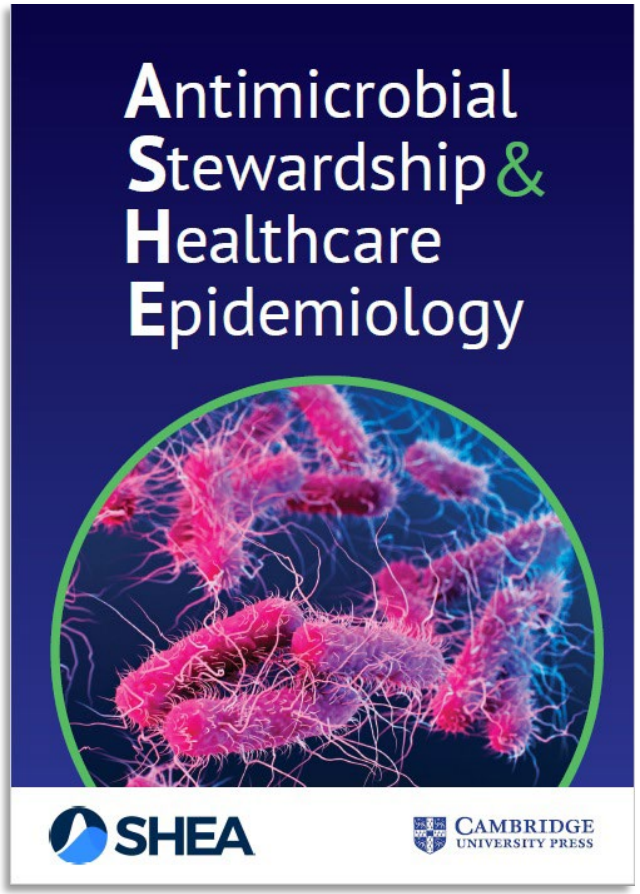

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May 22, 2025 | 2:30 – 3:30 pm ET

Infection Control Practices for Vector Mediated Gene Therapy in Healthcare Settings

June 26, 2025 | 3:30 – 4:30 pm ET

Advancing Healthcare Sustainability in Infection Prevention

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  June 6, 2025 | 1:30 - 2:30 pm ET

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May Town Hall Panelists:

Dr. Marci Drees
ChristianaCare

Dr. Matthew Linam
Emory University

Dr. Trish Perl
UT Southwestern Medical Center

Invited Panelist:

Anu Malani, MD
Medical Director, Antimicrobial Stewardship, Hospital Epidemiology, and Special Pathogens
Trinity Health Michigan

Today’s Agenda

2024-25 respiratory viral season summary (RSV, flu, COVID-19)

-Vaccine uptake

-Literature review

-ACIP recap (April 14-15 meeting)

HICPAC draft guidance for transmission-based precautions to prevent transmission via air

Discussion/Q&A

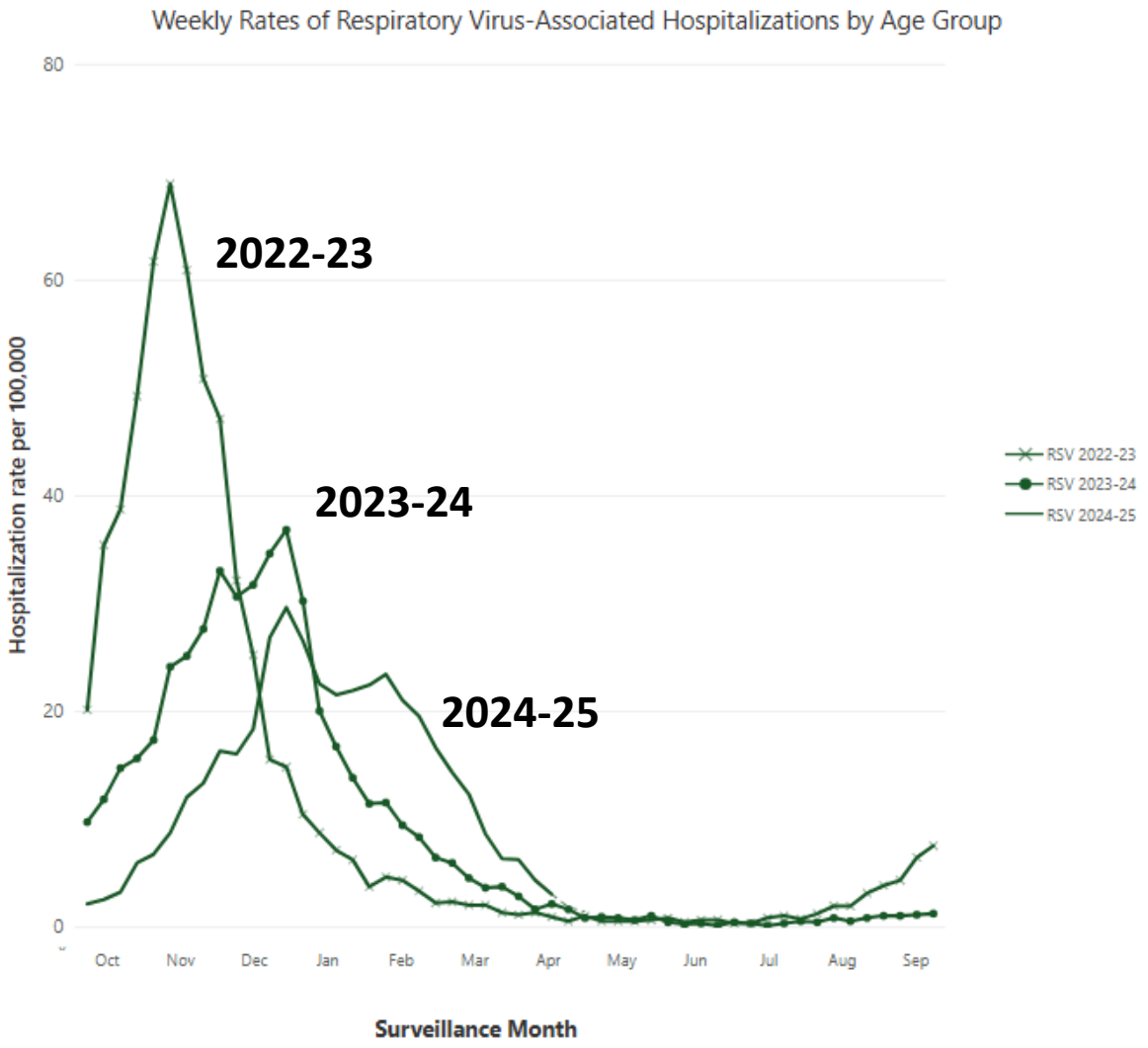
Question: As we prepare for the next respiratory virus season, which area do you think poses the most important challenge to effective prevention and response? (select one)

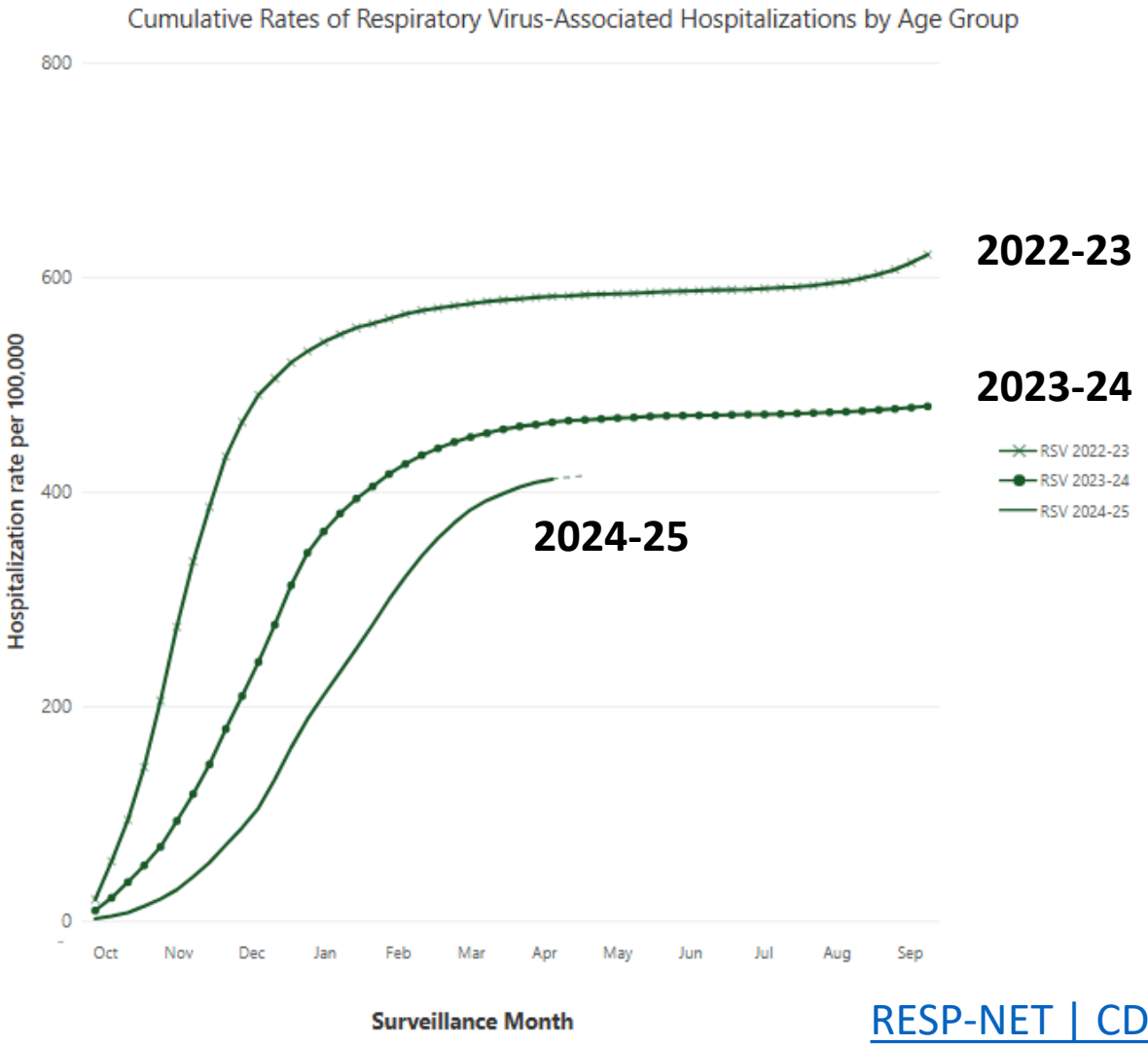
Answer choices:

- Low vaccine uptake among patients
- Inconsistent staff immunization rates
- Gaps in surveillance and early detection
- Isolation protocols and return-to-work policies
- Communication and coordination across care settings (e.g., hospitals and LTCFs)

RESP-NET
Respiratory Virus Hospitalization Surveillance Network

RSV Hospitalizations – Pediatrics (0-4 y)

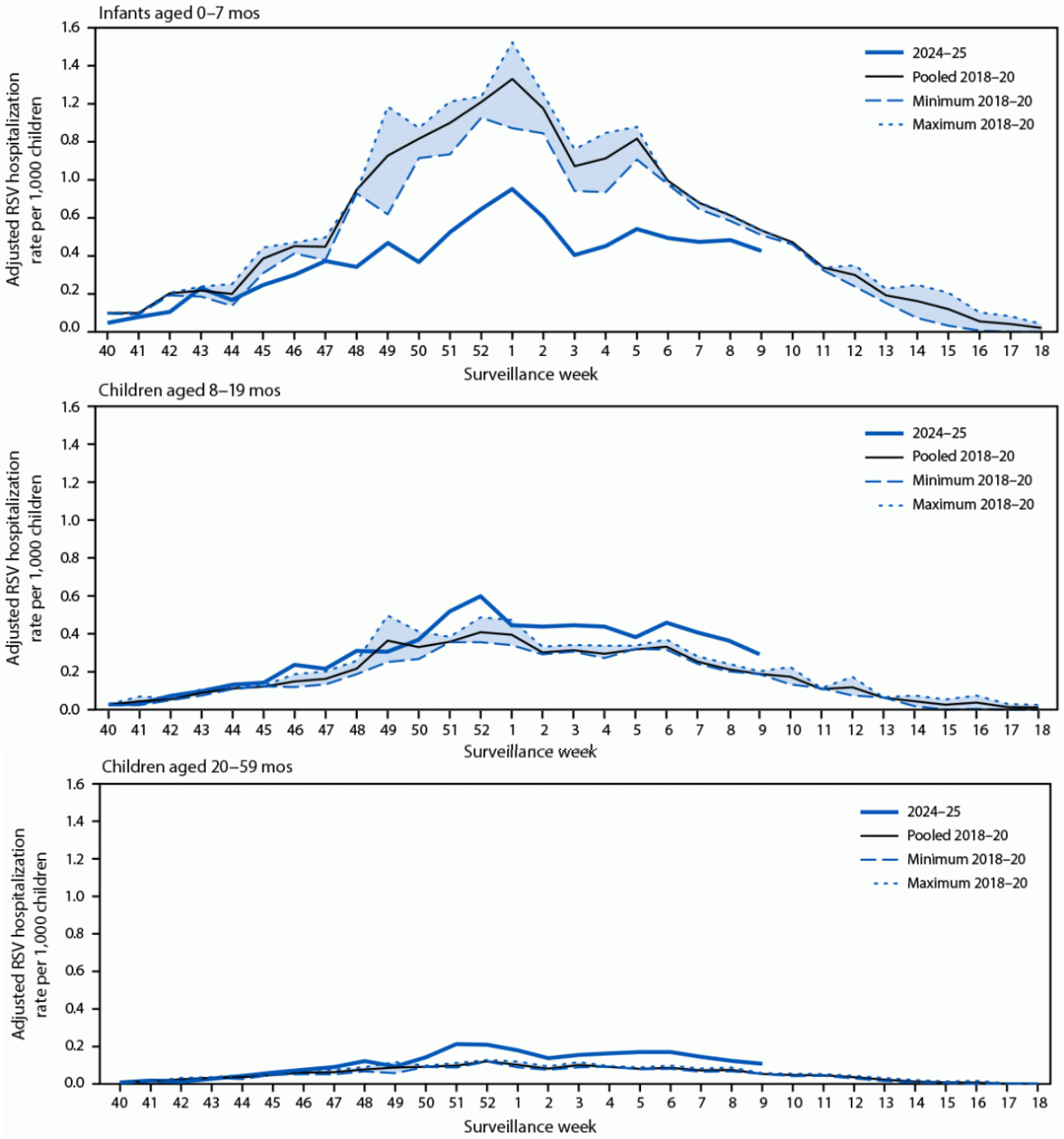




RESP-NET | CDC

2024-25 RSV Season

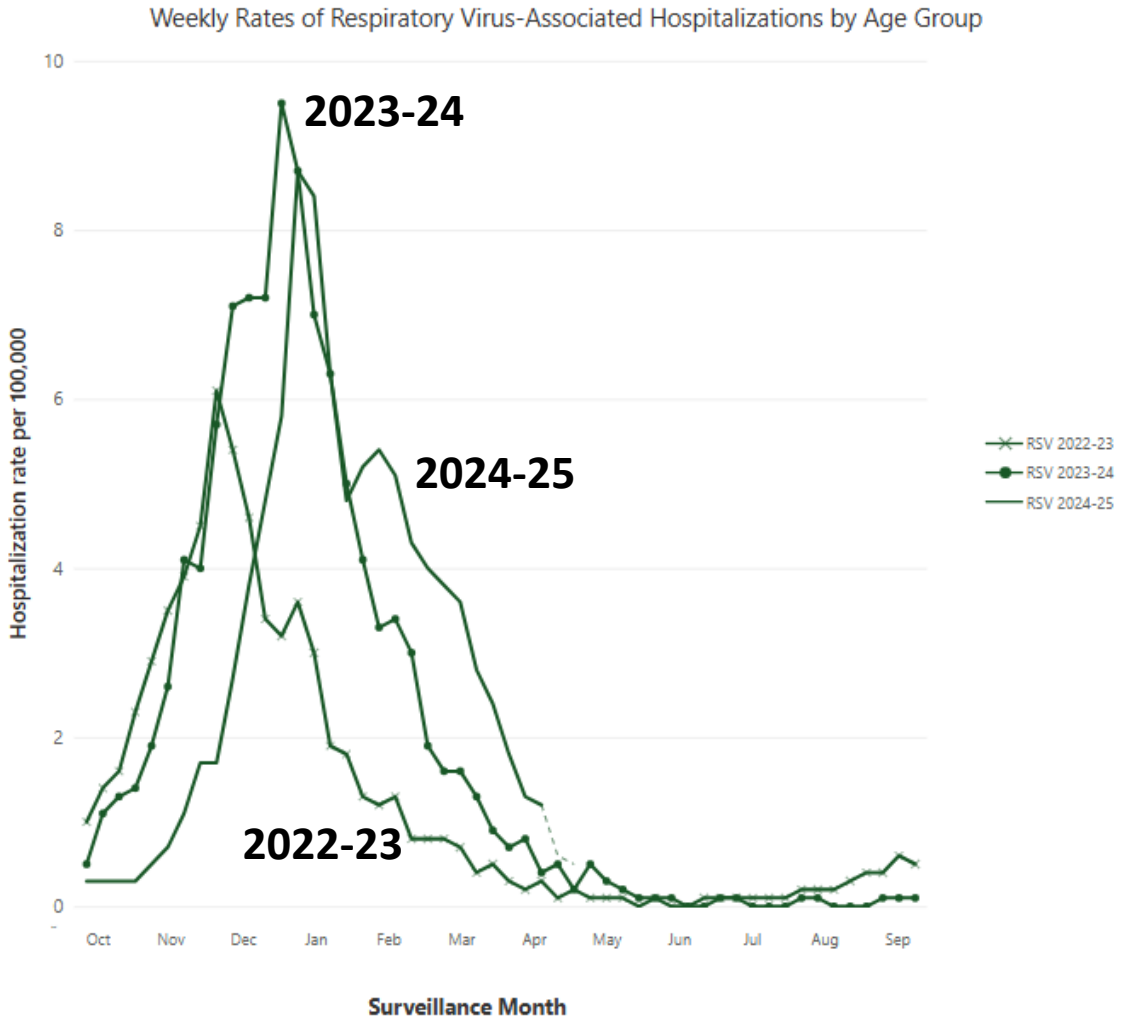
- Ecologic analysis comparing RSV hospitalization rates during 2024-25 to pooled 2018-20 seasons using RSV-NET & NVSN data
- Among children 0-7 months, RSV-associated hospitalization rates were 43% & 28% lower
- Among children 0-2 months, 52% & 45% reduction
- 66% of infants 0-7 months estimated to protected by either maternal vaccination or nirsevimab (as of Feb 2025)

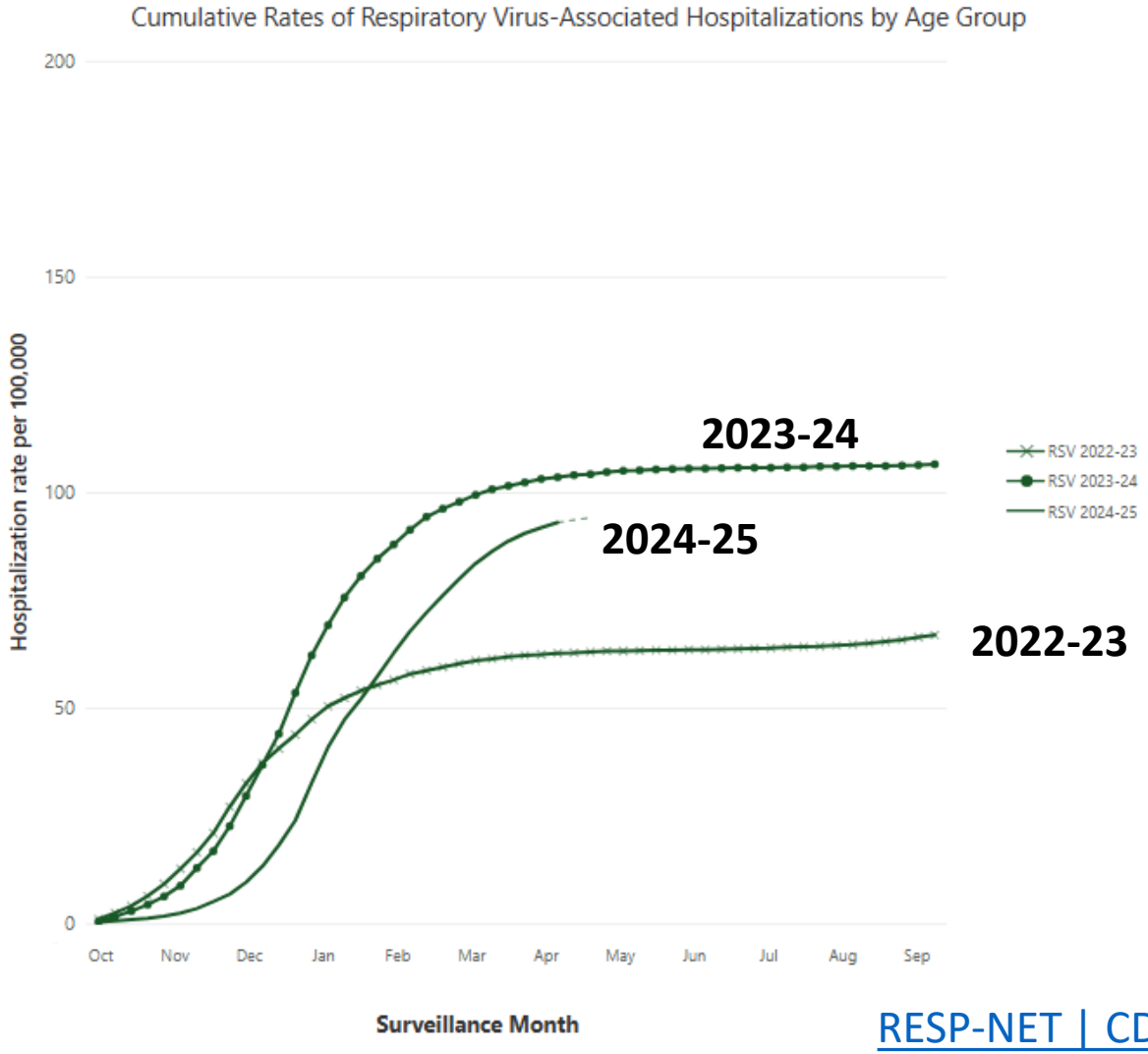


[Patton ME et al. | MMWR May 8 2025]

RESP-NET
Respiratory Virus Hospitalization Surveillance Network

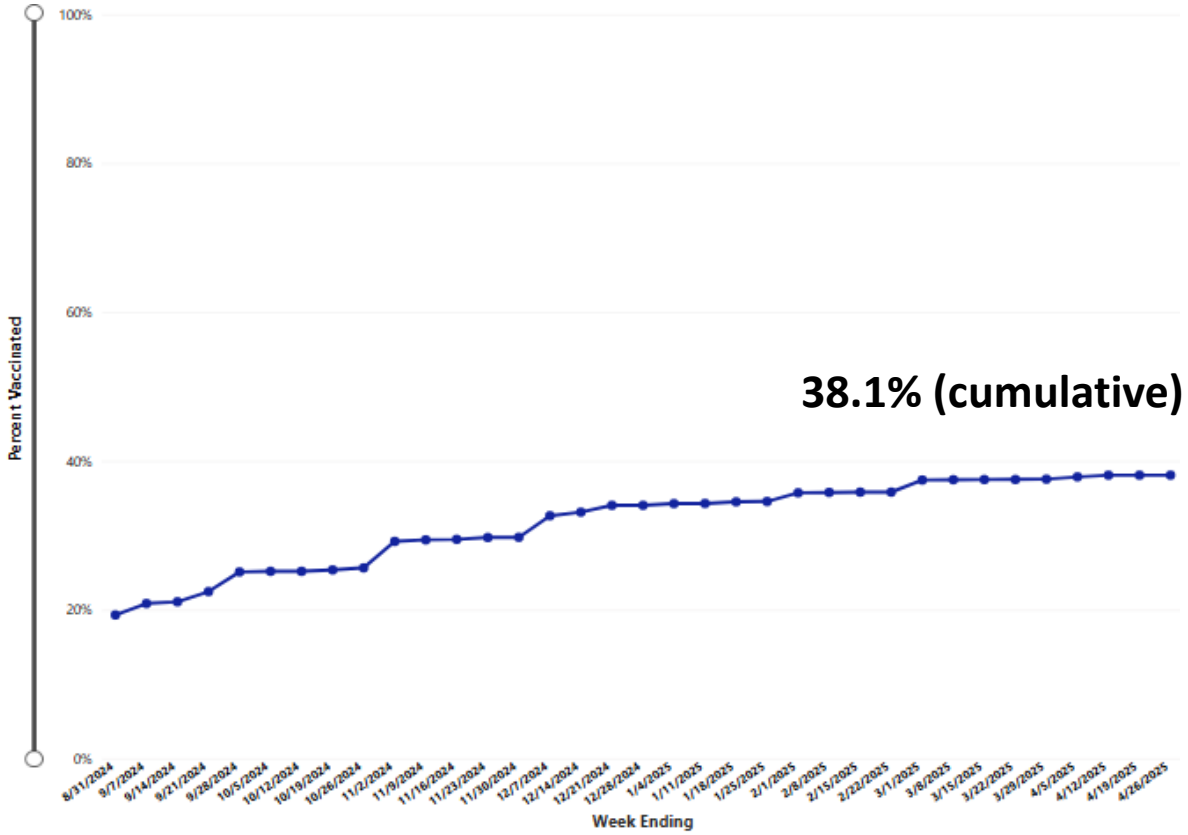
RSV Hospitalizations – Adults ≥ 65 years



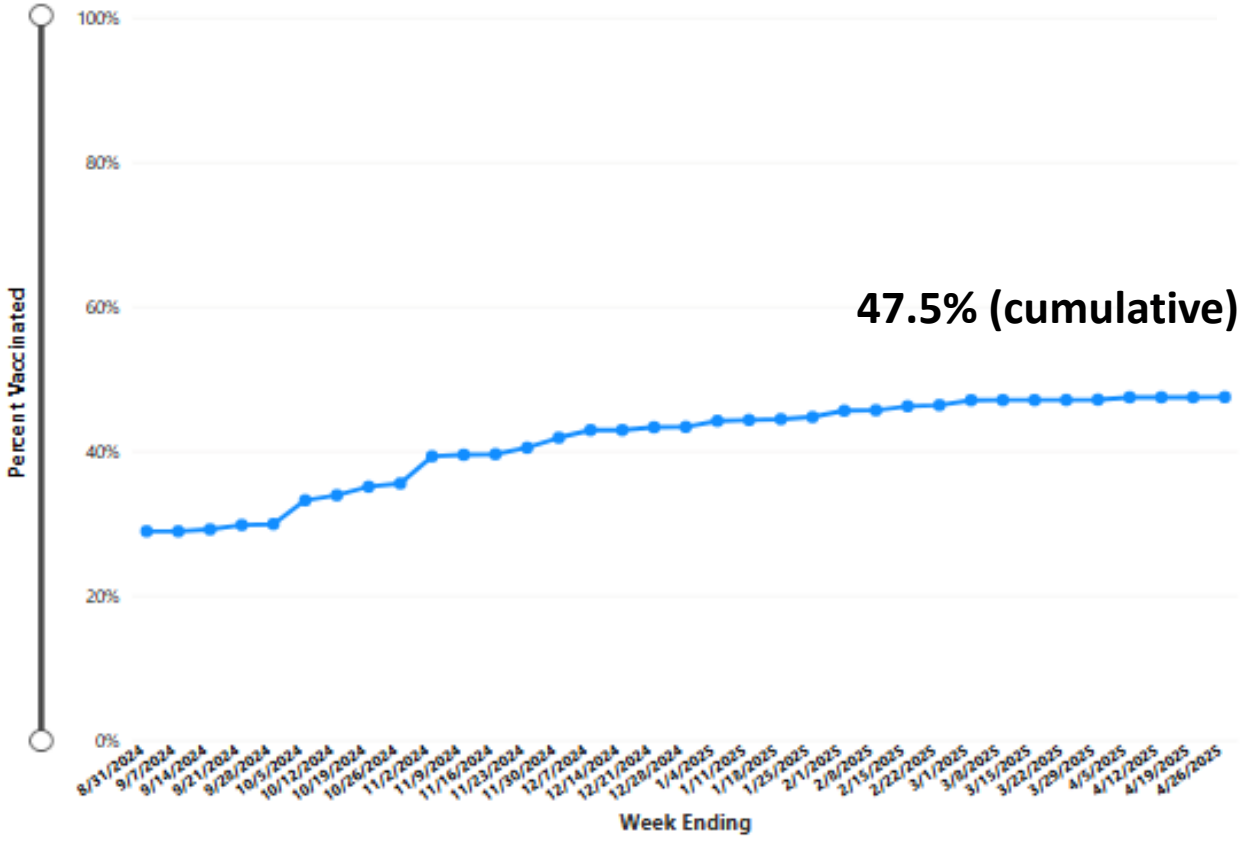


RESP-NET | CDC

RSV Vaccine Uptake, Adults, 2024-25



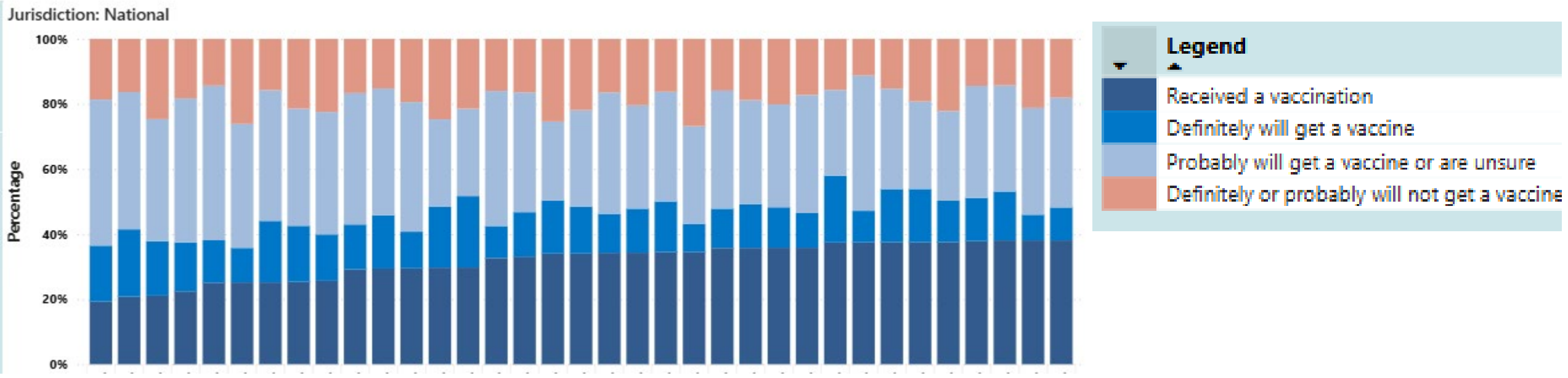
60-74 years (high-risk)



75+ years

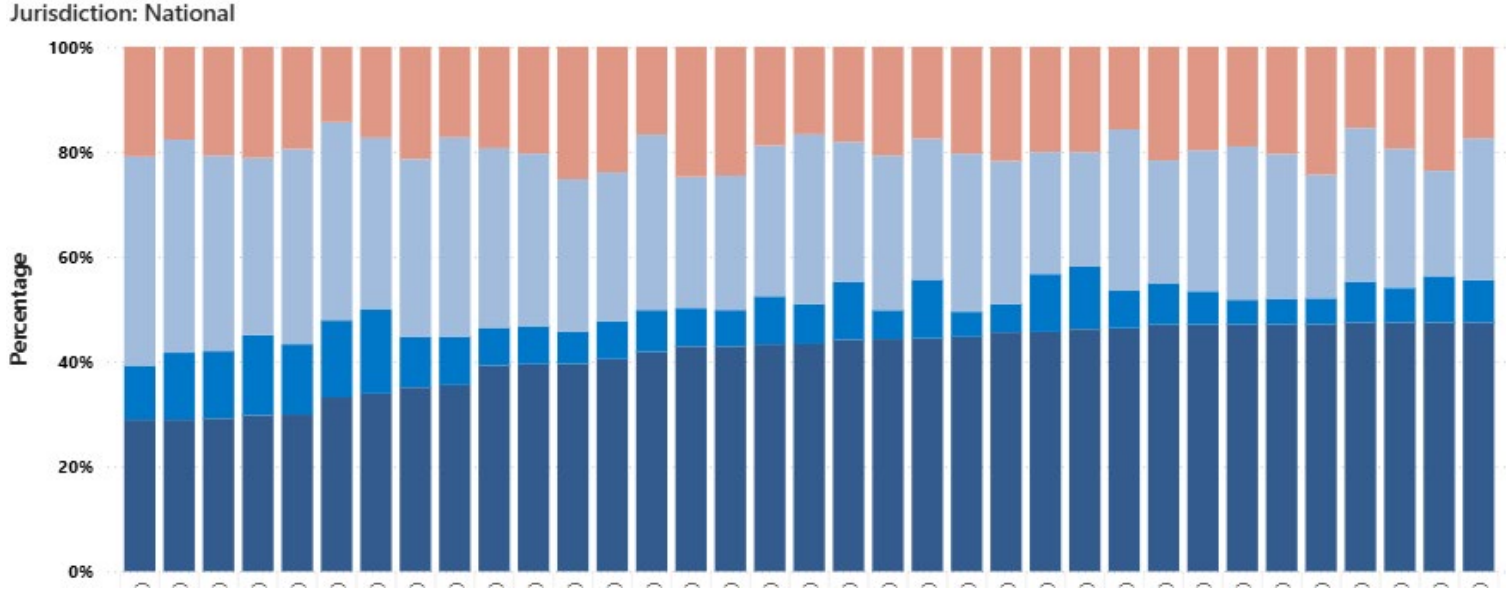
RSVVaxView | CDC

RSV Vaccination Intent, Adults



Age 60-74 years

Age 75 years and above



[RSVVaxView | CDC]

Literature Review: RSV

Pediatrics:

- Garcia-Garcia ML, et al. Impact of Nirsevimab on RSV and Non-RSV Severe Respiratory Infections in Hospitalized Infants. *Influenza Other Resp Viruses* 2025; 19(5). May 2025.
- Amarin JZ et al. Respiratory Syncytial Virus Co-Detection With Other Respiratory Viruses Is Not Significantly Associated With Worse Clinical Outcomes Among Children Aged <2 Years: New Vaccine Surveillance Network, 2016–2020. *Clin Infect Dis* 2025; published online 5/9/25.

Adults:

- Mensah AA, et al. Early impact of RSV vaccination in older adults in England. *Lancet* 2025; 405(10485)
- Fry SE, et al. Effectiveness and Safety of Respiratory Syncytial Virus Vaccine for US Adults Aged 60 Years or Older. *JAMA Network Open* 2025; 8(5):e258322
- Surie D, et al. Patient- and Community-Level Characteristics Associated With Respiratory Syncytial Virus Vaccination. *JAMA Network Open* 2025; 8(4):e252841
- Begier E et al. Detection of RSV using nasopharyngeal swabs alone underestimates RSV-related hospitalization incidence in adults: the Multispecimen study's Final Analysis. *J Infect Dis* 2025 Apr 18; (accepted manuscript)

ACIP Recap: RSV (Adults)

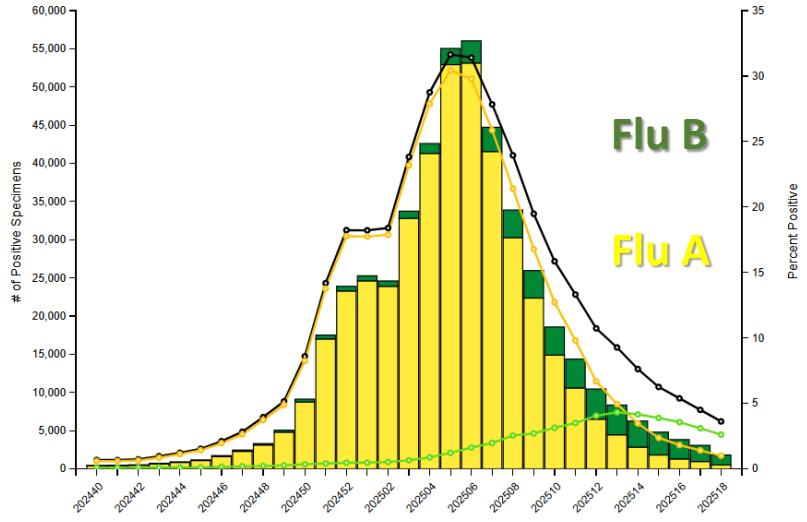
- Current FDA-approved RSV vaccines have various ages for use (all approved for 60+ years):
  - GSK Arexvy: 50-59 years who are at increased risk of RSV LRTD
  - Pfizer Abrysvo: 18-59 years who are at increased risk (+ separate pregnancy indication)
  - Moderna mResvia: application submitted for 18-59 years who are at increased risk (PDUFA date 6/12/25)
- Moderna & GSK presented revaccination data
  - Immune responses non-inferior to original vaccination (ie, could be boosted)
  - No safety/tolerabilty concerns
- Cost-effectiveness of vaccinating 50-59 year olds with at least 1 high risk condition (U of Michigan team)
  - Protein subunit vaccines: $43K/QALY (Q3 year)
  - mRNA vaccine: $152K/QALY (Q2 year) or $95K/QALY (Q3 year)
  - Vaccinating those with certain conditions (CKD, COPD, severe obesity, transplant) may be cost-saving
- ACIP ultimately voted to approve single dose of RSV vaccine for adults 50-59 years at increased risk of severe RSV disease
  - Younger populations to be discussed at future meetings

ACIP Recap: RSV (Peds)

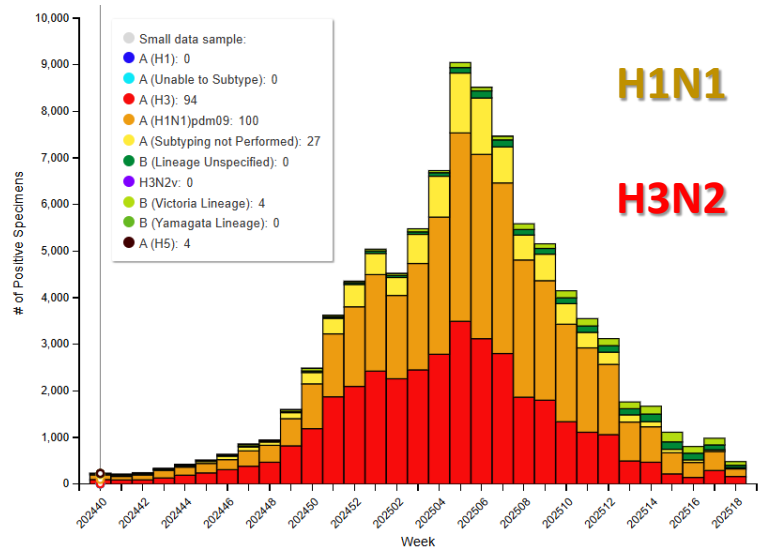
- Evidence to Recommendation (EtR): Clesrovimab
  - First discussed Oct 2024 ACIP meeting
  - FDA PDUFA date: June 10, 2025
  - Planned vote at June 2025 ACIP meeting (pending FDA action)
- Clesrovimab:
  - Effectiveness:
    - ~60% vs. RSV-associated medically attended LRTI
    - ~90% vs. RSV-associated LRTI with hospitalization
    - 100% vs. RSV LRTI with ICU admission
  - Similar side effect profile as placebo
  - Shorter half-life than nirsevimab (42 vs. 71 days) but efficacy appears sustained through 150 days
  - Additional benefits of having 2 approved long-acting monoclonal Ab for RSV prevention in infants (resistance, supply issues, cost)
  - Implementation expected to be similar to nirsevimab, except:
    - Same dose regardless of weight
    - Only expected to be approved for 1st RSV season (infants < 8 months)

Seasonal Influenza – Week 18 (ending 5/3/25)

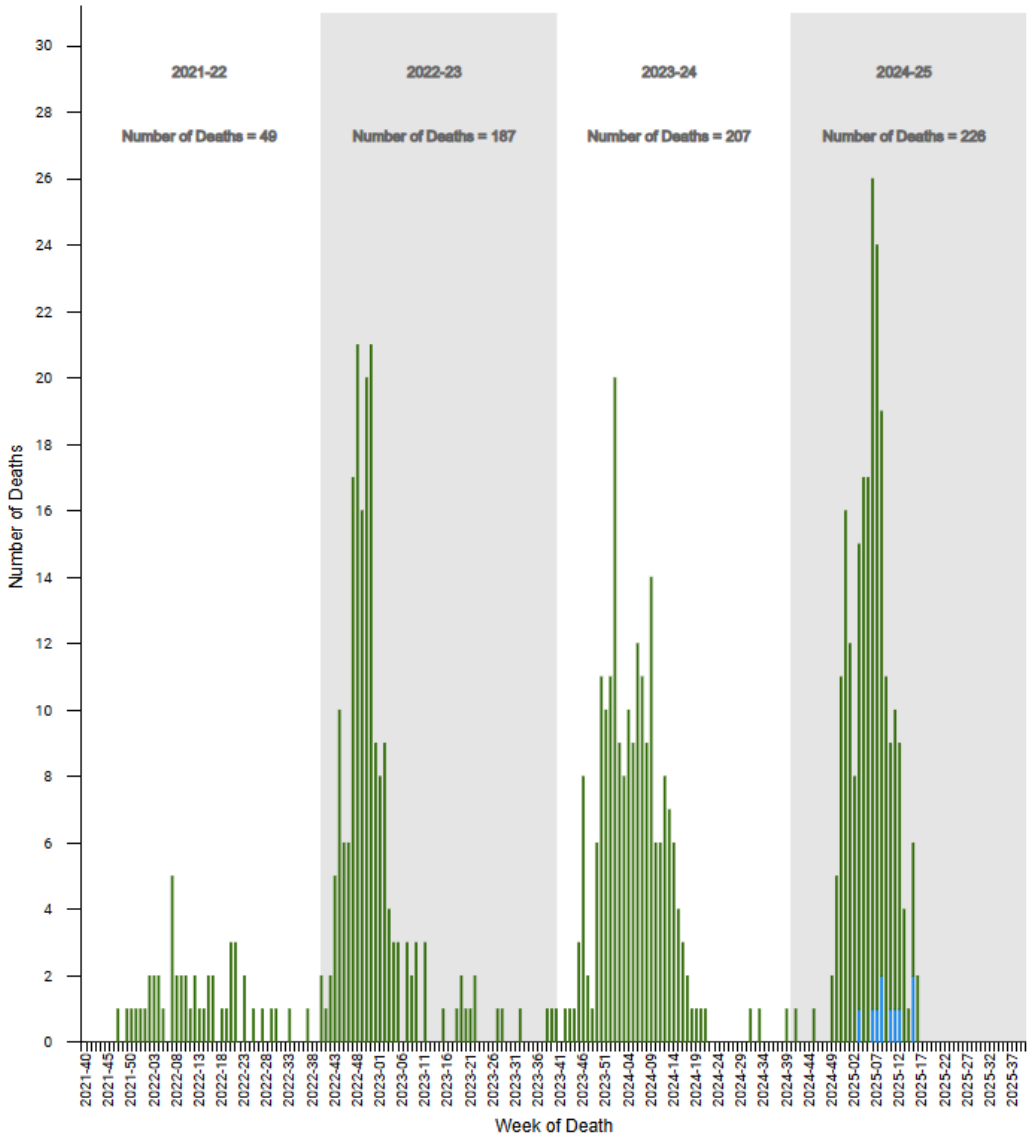
Commercial labs



Public Health labs



Pediatric deaths (n = 226)

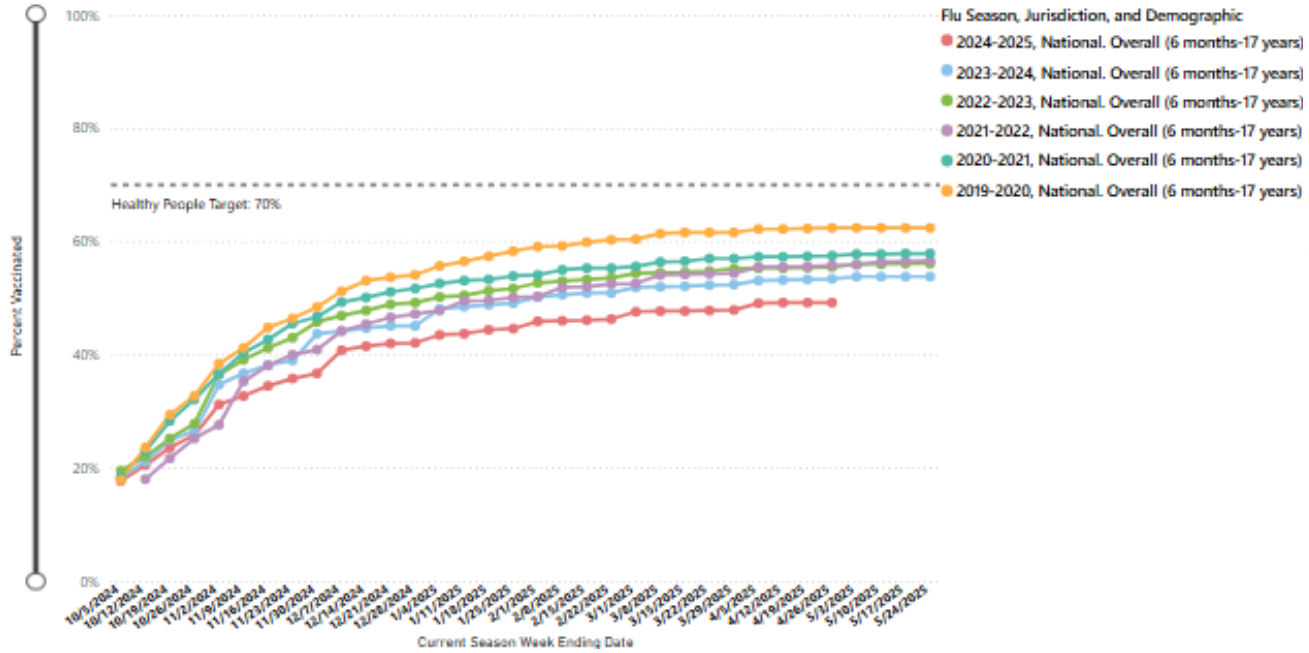


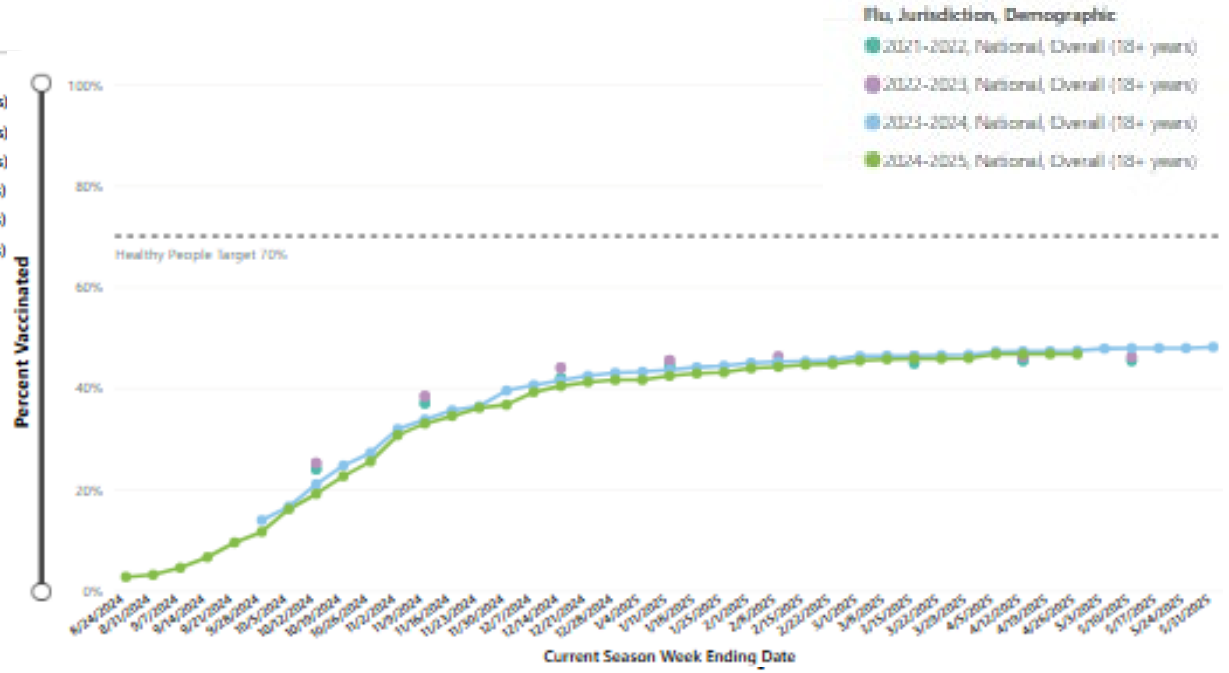
2024-25 estimates:

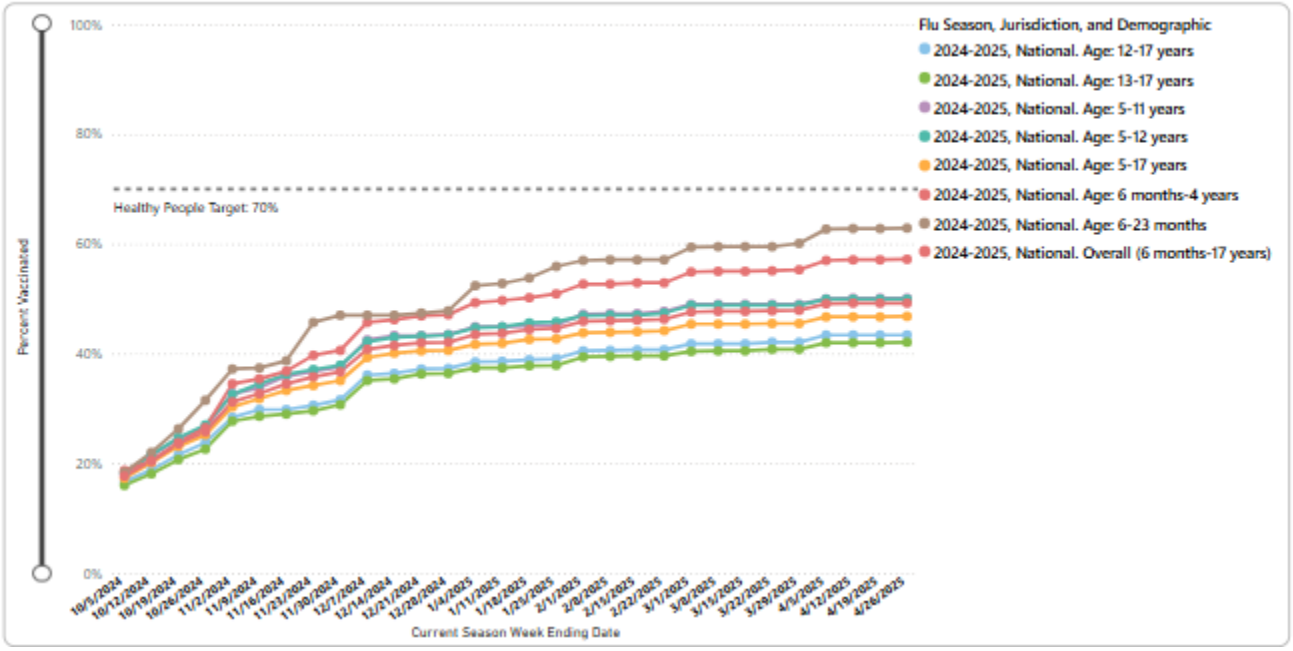
- 47 million illnesses
- 610K hospitalizations
- 27K deaths

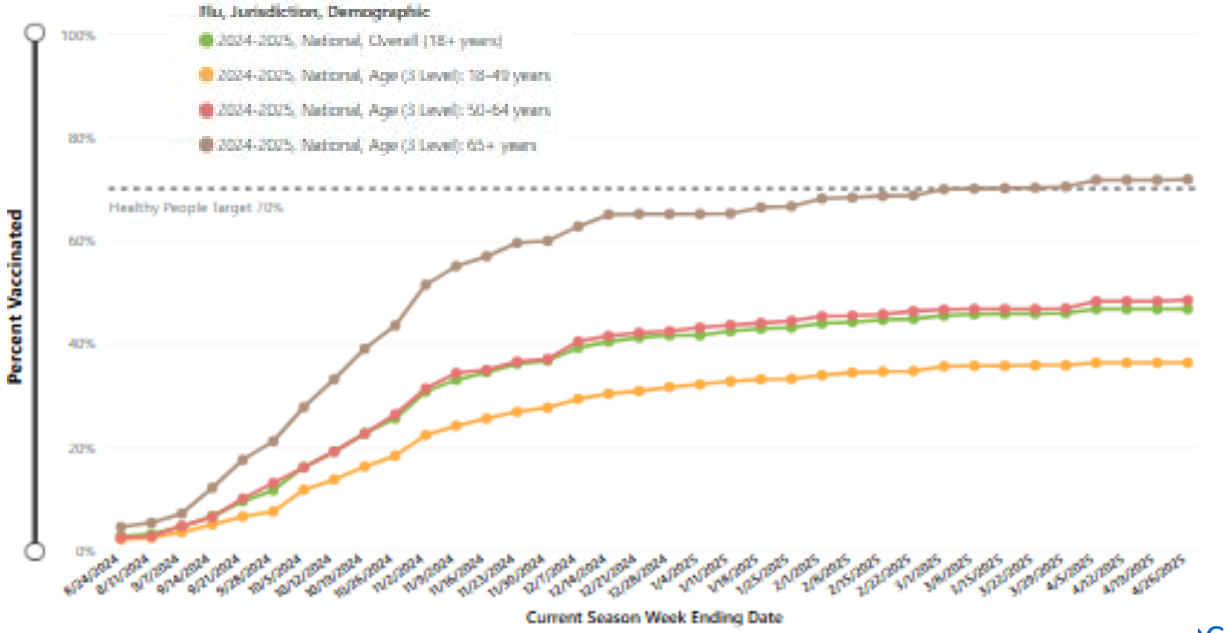
FluView | FluView | CDC

Flu Vaccine Coverage









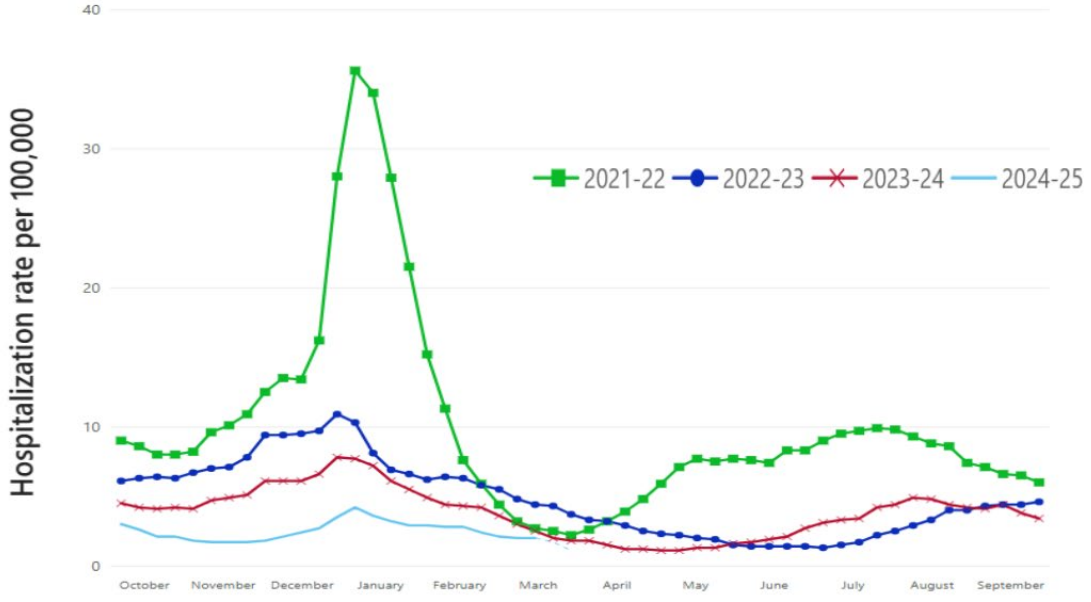
Literature Review: Influenza

- Gao Y, et al. Antiviral Medications for Treatment of Nonsevere Influenza: A Systematic Review and Network Meta-Analysis. *JAMA Internal Med* 2025; 85(3):293-301
- Monto AS, et al. Efficacy of Baloxavir Treatment in Preventing Transmission of Influenza. *NEJM* 2025;392(16):1582-93.
- Rudman Spergel AK, et al. Immunogenicity and Safety of Influenza and COVID-19 Multicomponent Vaccine in Adults ≥50 Years: A Randomized Clinical Trial. *JAMA* 2025; published online 5/7/25.

ACIP Recap: Influenza

- FDA recommendations for 2025-26 flu vaccines (March 15, 2025):
  - For both egg-based vaccines and cell culture/recombinant vaccines, new H3N2 strains
- 2024-25 interim flu vaccine effectiveness:
  - CDC presented data from IVY, VISION, US FLU VE & New Vaccine Surveillance Network (NVSN) networks
    - Pediatric VE ranged from 32-60% against any outpatient flu, 63-78% for inpatient
    - Adult VE ranged from 36-54% against any outpatient flu, 41-55% for inpatient
    - Adult >65 y ranged from 18-51% against any outpatient flu, 38-57% for inpatient
  - California DoPH presented state VE data
    - Overall 44.7% VE (lower than 2023-24)
    - Pediatric VE 50.2% against any influenza
    - Adult >65 y VE 39.3%
    - Much better for type B vs. type A, slightly better for H1N1 vs H3N2
    - Among 2-17 yo, LAIV performed better (61% VE) than non-LAIV (48%)
- AstraZeneca presented on LAIV self-administration for 2025-26 season
  - Mail-order pharmacy; to be billed via health insurance with small shipping fee (no OOP)

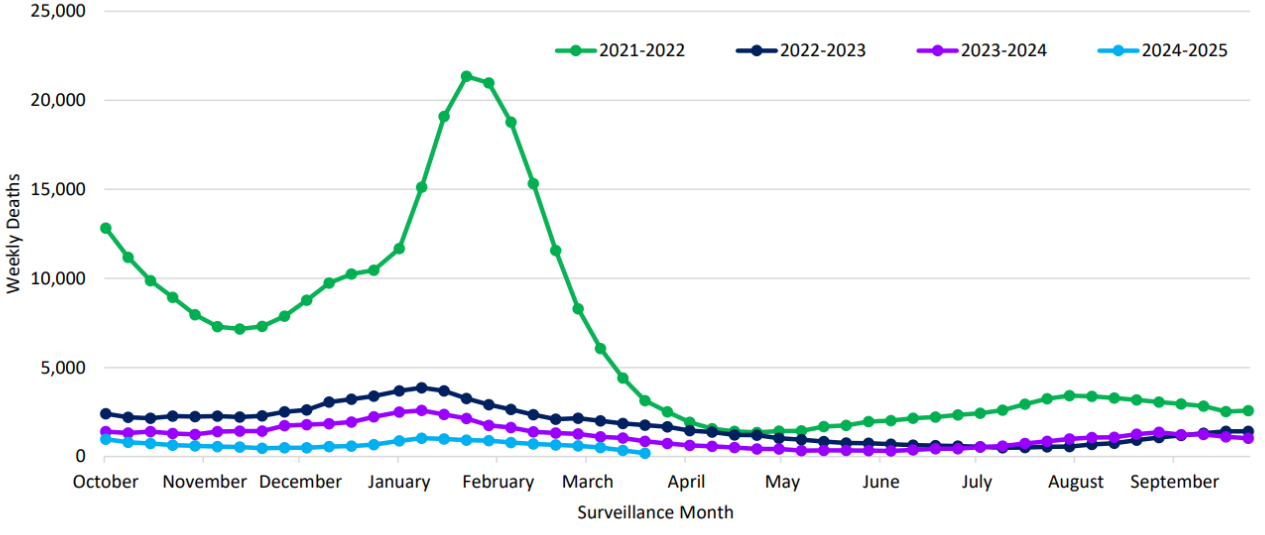
Weekly rates of COVID-19 associated hospitalizations by season – COVID-NET



Preliminary Estimates of Disease Burden, October 1, 2024 through March 22, 2025

Disease	Illnesses	Outpatient Visits	Hospitalizations	Deaths
COVID-19[1]	7.7 – 13.5 Million	1.9 – 3.2 Million	220,000 – 370,000	26,000 – 43,000
Influenza[2]	44 – 76 Million	20 – 34 Million	580,000 – 1.2 Million	25,000 – 120,000

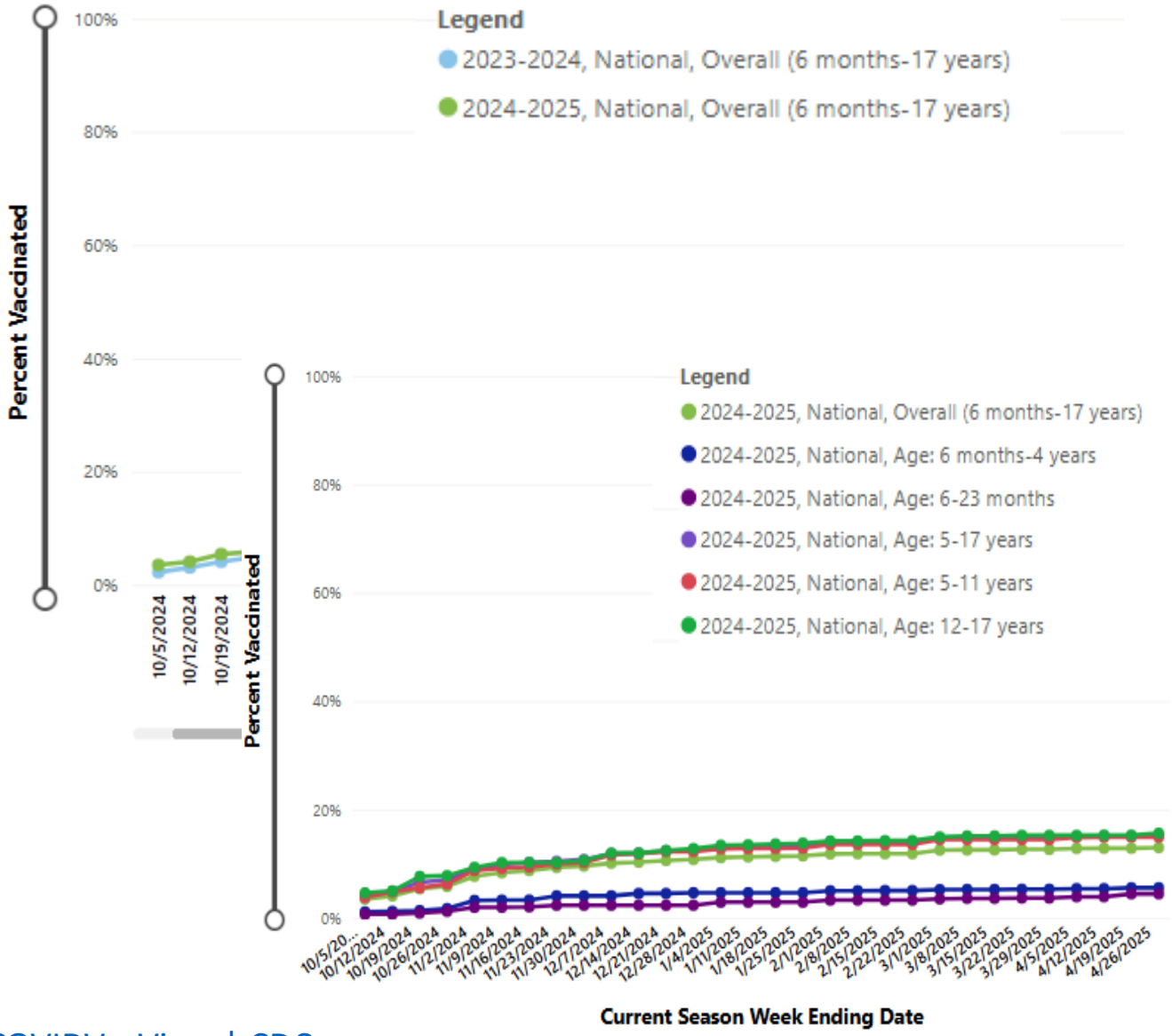
Provisional Weekly COVID-19 Deaths in the United States Reported to CDC, by Week October 2021–March 2025

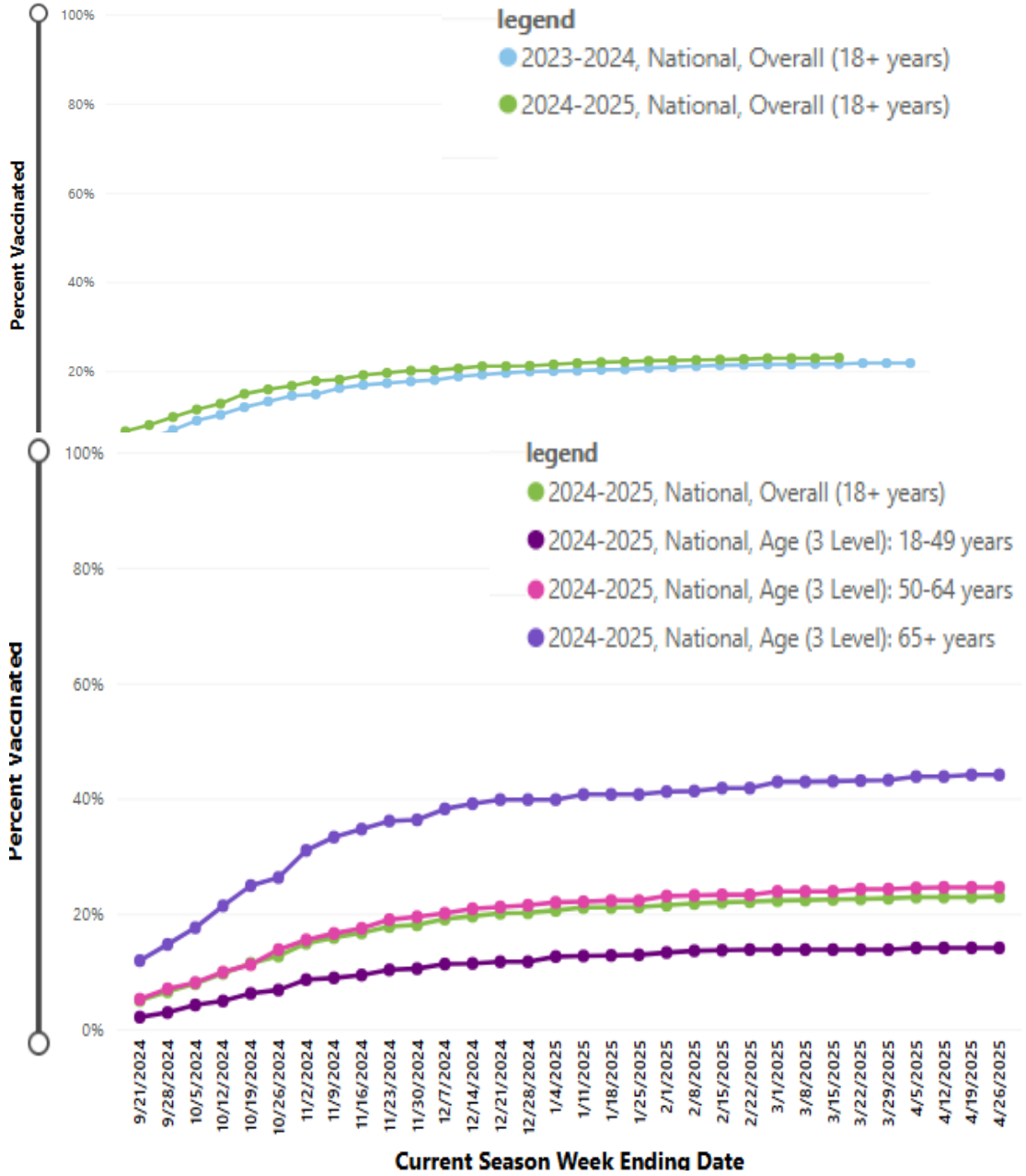


https://covid.cdc.gov/covid-data-tracker/#trends_weeklydeaths_select_00

Schechter R, ACIP Meeting, April 15, 2025

COVID-19 Vaccination Coverage





[COVIDVaxView | CDC]

ACIP Recap: COVID-19

- CDC reviewed 2024-25 COVID-19 vaccine effectiveness
  - UC/ED visits: relative VE ~30-35% across all age groups
  - Hospitalization: ~45% relative VE (~40% for immune-compromised)
  - Should be interpreted as *additional* benefit in setting of high levels of infection- and vaccine-induced immunity in population
- CDC presented COVID-19 vaccine work group considerations for 2025-26 recommendations
  - Universal recommendation (current) vs. risk- and/or age-based recommendations
  - Most other countries do not have universal recommendation (see next slide)
  - Estimated that ~3/4 of adults have ≥1 risk factors for severe COVID-19
  - Most WG members in favor of more limited recommendation for next year; ACIP voting members appeared somewhat uncomfortable with that approach
  - SHEA has endorsed including HCP in any risk-based recommendations that may ensue
- Timeline (proposed):
  - FDA's VRBPAC scheduled to meet on May 22 to discuss 2025-26 COVID-19 vaccine composition (WHO's Technical Advisory Group on COVID-19 Vaccine Composition also meeting in May)
  - ACIP to vote on use at its June meeting

Summary of international COVID-19 booster* recommendations

	UK[1]	Canada[2]	Australia[3]	WHO	US
Older adults	**≥65 years:** 12 months **≥75 years and long-term care facility residents:** 6 months	**≥80 years and long-term care facility residents:** 6 months **65-79 years:** 12 months; *may receive every 6 months*	**≥75 years:** 6 months **≥65 years:** 12 months, *may receive every 6 months*	**Country dependent, often ≥75 or ≥80 years:** 6–12-month interval **Country dependent, often 50 or 60 years**: 12-month interval	**≥65 years:** 6 months
Adults (routine)	Not recommended	*May receive every 12 months*	*May receive every 12 months*	Not routinely recommended **Pregnant adults and adolescents:** dose in each pregnancy***	12 months
High-risk adults**	12 months	12 months	*May receive every 12 months*	12 months	12 months
Immunocompromised adults	6 months	6 months	12 months, *may receive every 6 months*	6-12 months	6 months, *plus may receive additional doses at 2-month intervals*
Children (routine)	Not recommended	*May receive every 12 months*	Not recommended	Not routinely recommended	12 months
High-risk children**	12 months	12 months	Not recommended	Not routinely recommended	12 months
Immunocompromised children	6 months	6 months	**Under 5 years:** not recommended ***5-17 years:*** *May receive every 12 months*	6-12 months	6 months, *plus may receive additional doses at 2-month intervals*

Panagiotakopoulos L, ACIP Meeting, April 15, 2025

HICPAC 2024 Draft Guidance (Nov 2023)

. Transmission-Based Precautions to Prevent Transmission by Air

Category	Mask or Respiratory Protection	Eye Protection	AIIR[a]
Routine Air Precautions	Mask	Per Standard Precautions	Not routinely recommended
Special Air Precautions	NIOSH-approved® N95 (or higher-level) respirator	Yes	Not routinely recommended
Extended Air Precautions	NIOSH-approved® N95 (or higher-level) respirator	Per Standard Precautions	Yes

a. AIIR = Airborne Infection Isolation Room for containment of air in a designated space

Common, often endemic, respiratory pathogens that spread primarily over short distances

Pathogens, typically new or emerging not observed or anticipated to spread efficiently over long distances, but confers substantial risk for severe illness

Pathogens observed to spread efficiently across long distances & over extended times

***NOTE: gowns not recommended for any of above**

[DRAFT 2024 Guideline to Prevent Transmission of Pathogens in Healthcare Settings]

Questions from CDC to HICPAC (Jan 2024)

1. Should there be a category of Transmission-based Precautions that includes masks (instead of NIOSH Approved® N95® [or higher-level] respirators) for pathogens that spread by the air? Should N95 respirators be recommended for all pathogens that spread by the air?
2. Can the workgroup clarify the criteria that would be used to determine which transmission by air category applies for a pathogen? For the category of Special Air Precautions, can you clarify if this category includes only new or emerging pathogens or if this category might also include other pathogens that are more established? Can you also clarify what constitutes a severe illness?
3. Is the current guideline language sufficient to allow for voluntary use of a NIOSH Approved N95 (or higher-level) respirator? Should the document include a recommendation about healthcare organizations allowing voluntary use?
4. Should there be a recommendation for use of source control in healthcare settings that is broader than current draft recommendations? Should source control be recommended at all times in healthcare facilities?

A CDC Update on the Part One Draft update to the Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings | Blogs | CDC

Further HICPAC Discussion (Nov 2024)

Alternate Narrative A	Alternate Narrative B
Retains category framework of 2023 draft guideline: • Routine Air Precautions (mask) • Special Air Precautions (N95 + eye protection) • Extended Air Precautions (N95 + engineering controls)	Proposes a different framework from the 2023 draft guideline: • Standard of Practice Air Precautions (N95) • Limited Air Precautions (mask) • Engineering Air Precautions (N95 + engineering controls)
Pathogen-specific recommendations are based on assessment of risk of infection and associated outcomes. Important considerations: (1) Transmissibility, (2) burden of morbidity and mortality, and (3) ability of pathogen to spread over long distances (e.g., through ventilation systems).	Pathogen-specific recommendations are based on assessment of risk of infection and associated outcomes. Important considerations: (1) Transmissibility, (2) Adverse outcomes, which includes morbidity/mortality, lost workdays, onward transmission of infection.
Multiple categories (including a category for mask as PPE) are considered for pathogen-specific recommendations.	N95 (or higher level) respirators are used initially for all known pathogens with potential to transmit through the air, with subsequent exposure and risk assessment to determine whether the pathogen and/or clinical situation should warrant a higher (engineering controls) or lower risk (possible mask) category. Engineering Air Precautions are used for new/emerging pathogens.

References

- Garcia-Garcia ML, et al. *Influenza Other Resp Viruses 2025*; 19(5). May 2025.
- Amarin JZ et al. *Clin Infect Dis* 2025; published online 5/9/25.
- Mensah AA, et al. *Lancet* 2025; 405(10485)
- Fry SE, et al. *JAMA Network Open* 2025; 8(5):e258322
- Surie D, et al. *JAMA Network Open* 2025; 8(4):e252841
- Begier E et al. *J Infect Dis* 2025 Apr 18
- Interim Estimates of 2024–2025 Seasonal Influenza Vaccine Effectiveness — Four Vaccine Effectiveness Networks, United States, October 2024–February 2025 | MMWR
- Gao Y, et al. *JAMA Internal Med* 2025; 85(3):293-301
- Monto AS, et al. *NEJM* 2025;392(16):1582-93.
- Rudman Spergel AK, et al. *JAMA* 2025; published online 5/7/25.
- ACIP Presentation Slides: April 15-16, 2025 Meeting | ACIP | CDC
- DRAFT 2024 Guideline to Prevent Transmission of Pathogens in Healthcare Settings