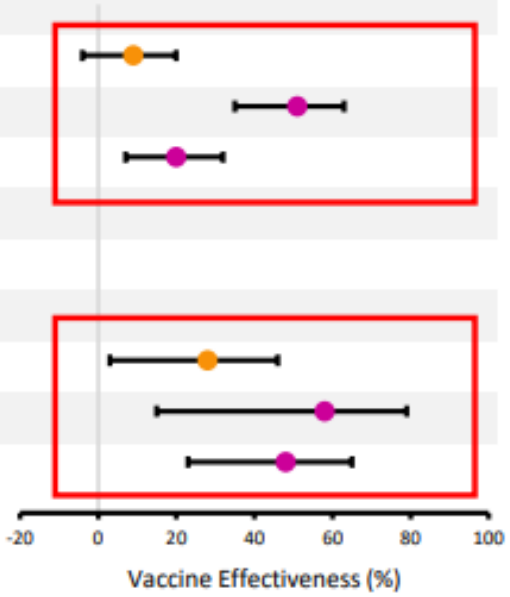
Updated COVID-19 Vaccines for Use in the United States Beginning in Fall 2023

- XBB sub-lineages accounted for more than 95% of the circulating virus variants in the U.S. as of early June 2023
- Evidence influencing strain selection included
  - Virus surveillance and genomic analyses
  - Antigenic characterization of viruses
  - Human serology studies from current vaccines
  - Pre-clinical immunogenicity studies evaluating immune responses generated by candidate vaccines.
  - Manufacturing timelines.
- Moving to an XBB.1.5 composition for vaccine would improve protection against currently circulating Omicron XBB strains

VISION: *Absolute* VE of *monovalent* and *bivalent* booster doses against *hospitalization* and *critical illness* among immuno*competent* adults aged ≥18 years, during *XBB* predominance – January – May 2023

mRNA Dosage Pattern	Total tests	SARS-CoV-2-test-positive, N (%)	Median interval since last dose, days (IQR)	Adjusted VE (95% CI)
Hospitalization				
Unvaccinated (ref)	4,979	409 (8)	--	Ref
Monovalent doses only	11,279	980 (9)	469 (375-605)	9 (-4 to 20)
Bivalent booster, 7-89 days earlier	1,045	60 (6)	65 (43-79)	**51 (35 to 63)**
Bivalent booster, 90-179 days earlier	4,654	419 (9)	139 (119-157)	**20 (7 to 32)**
Critical illness				
Unvaccinated (ref)	4,652	82 (2)	--	Ref
Monovalent doses only	10,439	140 (1)	469 (375-602)	**28 (3 to 46)**
Bivalent booster, 7-89 days earlier	994	9 (1)	65 (43-78)	**58 (15 to 79)***
Bivalent booster, 90-179 days earlier	4282	47 (1)	139 (119-157)	**48 (23 to 65)**



CDC unpublished data. VE estimates adjusted for age, sex, race and ethnicity, geographic region, and calendar time.

* These interim estimates are imprecise, which might be because of a relatively small number of persons in each level of vaccination or case status. This imprecision indicates the actual VE may be substantially different from the point estimate shown, and estimates should therefore be interpreted with caution. Additional data accrual should increase precision and allow appropriate interpretation.

Variant predominance based on regional circulation: https://covid.cdc.gov/covid-data-tracker/#variant-proportions

45

Policy Considerations for Fall 2023-2024 COVID-19 Vaccine Composition Change

Policy on COVID-19 vaccine composition change will be coordinated with FDA for regulatory action and CDC for recommendations for use

Next Steps

- **Continue to recommend bivalent mRNA COVID-19 vaccines**
  - Bivalent mRNA COVID-19 vaccines protect against severe COVID-19 from currently circulating XBB lineage variants.
  - People who receive a bivalent mRNA vaccine now will most likely be eligible for the Fall 2023 composition (with appropriate interval between doses).

- No changes to FDA or CDC guidance have been made at this time
  - Expect Fall CDC ACIP meeting for clinical guidance recommendations


New *MMWR* on ACIP's **respiratory syncytial virus (RSV) vaccine recommendations**
Stay up to date on recommendations for adults 60 years and older
bit.ly/mm7229a4
JULY 14, 2023
CDC

Older Adult RSV Vaccine Recommendations

- Full recommendations published in *Morbidity and Mortality Weekly Report* (MMWR) on 7/20/23.

- For the 2023–24 season, clinicians should offer RSV vaccination to adults aged ≥60 years using shared clinical decision-making as early as vaccine supply becomes available and should continue to offer vaccination to eligible adults who remain unvaccinated.

- Coadministration of RSV vaccines with other adult vaccines during the same visit is acceptable.

- Recommendation for RSV vaccines for older adults based on efficacy in preventing symptomatic RSV-associated lower respiratory tract infections. Trials were not powered to demonstrate efficacy against hospitalization and death.

CDC RSV Media Statement June 29, 2023

MMWR: Use of Respiratory Syncytial Virus Vaccines in Older Adults: ACIP Recommendations

Shared Clinical Decision-Making Guidance

- For RSV vaccination, the decision to vaccinate a patient should be based on a discussion between the health care provider and the patient, which might be guided by the patient's risk for disease and their characteristics, values, and preferences; the provider's clinical discretion; and the characteristics of the vaccine.

- As part of this discussion, providers and patients should consider the patient's risk for severe RSV-associated disease.
  - Persons with chronic medical conditions
  - Those who are frail or who are of advanced age*
  - Residents of nursing homes and long-term care facilities*

- *However, only limited enrollment of these populations in clinical trials

MMWR: Use of Respiratory Syncytial Virus Vaccines in Older Adults: ACIP Recommendations

ACIP Shared Clinical Decision-Making Recommendations: Frequently Asked Questions

FDA Approval For Nirsevimab in Infants & Toddlers

- FDA approval on July 17th, 2023 for Beyfortus (Nirsevimab) – single IM injection for the prevention of:
  - RSV lower respiratory tract infection (LRTI) in neonates/infants in 1st RSV season
  - RSV LRTI in children up to 24 months who remain vulnerable going into their 2nd RSV season
- Safety & efficacy supported by 3 clinical trials
  - 2 trials were randomized, double-blind, placebo-controlled, multicenter clinical trials
- Possible side effects: rash, injection site reaction

FDA Approves New Drug to Prevent RSV in Babies and Toddlers

Upcoming Meeting

CDC Advisory Committee on Immunization Practices (ACIP)

Topic: Respiratory Syncytial Virus Vaccines - Maternal/Pediatric, Nirsevimab & VFC Vote

Date & Time: August 3rd, 2023, 8am

Meeting Materials

Draft Agenda