U.S. Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Weekly / Vol. 74 / No. 32
August 28, 2025

# Drug Overdose Deaths Involving Stimulants — United States, January 2018–June 2024

Lauren J. Tanz, ScD[1]; Kimberly D. Miller, MPH[1]; Amanda T. Dinwiddie, MPH[1]; R. Matt Gladden, PhD[1]; Alice Asher, PhD[1]; Grant Baldwin, PhD[1]; Brandon Nesbit, MPH[1]; Julie O'Donnell, PhD[1]

## Abstract

Drug overdose deaths involving stimulants have increased in the United States since 2011. This report describes characteristics of stimulant-involved overdose deaths during January 2021–June 2024 using CDC's State Unintentional Drug Overdose Reporting System data and trends by drug and race and ethnicity during 2018–2023 using CDC's National Vital Statistics System data. Overall, 59.0% of overdose deaths involved stimulants, 43.1% co-involved stimulants and opioids, and 15.9% involved stimulants and no opioids during January 2021–June 2024. Persons who died of overdoses involving stimulants and no opioids were older (aged ≥45 years; 66.5% versus 44.2%) and more frequently had a history of cardiovascular disease (38.7% versus 21.2%) than those who died of overdoses involving stimulants and opioids. Stimulant-involved overdose death rates increased from 2018 to 2023 (cocaine: 4.5 per 100,000 population to 8.6; psychostimulants with abuse potential, primarily methamphetamine: 3.9 to 10.4). Increases were largest for psychostimulants among non-Hispanic American Indian or Alaska Native persons (11.0 in 2018 to 32.9 in 2023) and cocaine among non-Hispanic Black or African American persons (9.1 to 24.3), driven by deaths co-involving stimulants and opioids. Increases in stimulant-involved deaths suggest the need for expanded access to evidence-based stimulant use disorder treatments, evaluation of medication-based treatments for stimulant use disorder and treatments for co-occurring substance use disorders, and engagement of persons who use stimulants and who might be missed by opioid-focused prevention efforts.

## Introduction

Drug overdose deaths involving stimulants, primarily cocaine and psychostimulants with abuse potential (mostly methamphetamine), have increased substantially in the United States since 2011 (*1*). The number of overdose deaths involving cocaine increased from 4,681 in 2011 to 29,449 in 2023; those involving psychostimulants with abuse potential increased from 2,266 to 34,855 (*1*). Provisional data show declines in 2024, but deaths remained well above 2011 levels.* Increases are primarily attributed to deaths co-involving opioids, although stimulant-involved deaths without opioid co-involvement have also increased (*2*). This report analyzes characteristics of stimulant-involved overdose deaths during January 2021–June 2024 using CDC's State Unintentional Drug Overdose Reporting System (SUDORS) data and trends by drug and race and ethnicity during 2018–2023 using CDC's National Vital Statistics System (NVSS) data.

* Products - Vital Statistics Rapid Release - Provisional Drug Overdose Death Counts (Accessed May 14, 2025).

INSIDE



**Continuing Education** examination available at https://www.cdc.gov/mmwr/mmwr_continuingEducation.html

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION

## Methods

### Data Sources

SUDORS[†] funds 49 states and the District of Columbia (DC) to report data on unintentional and undetermined intent drug overdose deaths from death certificates, postmortem toxicology reports, and medical examiner or coroner reports under CDC's Overdose Data to Action in States program.[§] SUDORS defines stimulants as cocaine, methamphetamine, other amphetamines, synthetic cathinones,[¶] prescription stimulants,[**] and any other central nervous system stimulants.

NVSS[††] collects death certificate data for all deaths in the United States and can be used to assess national trends in overdose death rates. In NVSS, overdose deaths were identified through *International Classification of Diseases, Tenth Revision* (ICD-10) underlying cause-of-death codes X40–44 (unintentional) and Y10–14 (undetermined intent) and multiple cause-of-death codes for cocaine (T40.5); psychostimulants with abuse potential (T43.6 [psychostimulants]), which primarily includes methamphetamine and other amphetamines; and opioids (T40.0–T40.4 and T40.6). In NVSS, the categories of cocaine and psychostimulants with abuse potential combined are referred to as stimulants.

### Statistical Analysis

For SUDORS data, percentages of overdose deaths during January 2021–June 2024 involving[§§] any stimulant, and methamphetamine and cocaine as specific stimulants, were calculated and stratified by opioid co-involvement. Within strata, percentages by demographic characteristics and circumstances were calculated.

For NVSS data, annual age-adjusted rates (rates)[¶¶] of stimulant-involved overdose deaths during 2018–2023 were calculated overall and by race and ethnicity. Analyses were performed using SAS software (version 9.4; SAS Institute).

[†] About the State Unintentional Drug Overdose Reporting System (SUDORS) | Overdose Prevention | CDC (Accessed April 14, 2025). For SUDORS, overdose deaths were identified by funded jurisdictions both through ICD-10 underlying cause-of-death codes X40–44 (unintentional) and Y10–14 (undetermined intent) and through text searches of literal cause of death fields on death certificates that indicated acute drug toxicity.

[§] Overdose Data to Action in States | Overdose Prevention | CDC (Accessed April 14, 2025).

[¶] Synthetic cathinones are laboratory-made stimulants chemically related to substances found in the khat plant. Synthetic Cathinones ("Bath Salts") | National Institute on Drug Abuse (NIDA)

[**] Prescription stimulants include armodafinil, benzphetamine, bromantane, clenbuterol, clobenzorex, dexmethylphenidate, diethylpropion, lisdexamfetamine, mephentermine, methylphenidate, modafinil, phendimetrazine, phentermine, propylhexedrine, and ritalinic acid. This category also includes amphetamine (including 4-hydroxyamphetamine and dextroamphetamine) if methamphetamine is not detected, levoamphetamine if dextroamphetamine is not detected, and levomethamphetamine if dextromethamphetamine is not detected.

[††] NVSS - Mortality Statistics (Accessed April 14, 2025).

[§§] A drug was classified as involved or co-involved in overdose deaths if the medical examiner or coroner listed it as cause of death on the death certificate or in the medical examiner or coroner report or postmortem toxicology report.

[¶¶] Age-adjusted death rates were calculated by weighting age-specific rates per 100,000 vintage year population to the 2000 U.S. Census Bureau standard population.

The *MMWR* series of publications is published by the Office of Science, U.S. Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services, Atlanta, GA 30329-4027.

**Suggested citation:** [Author names; first three, then et al., if more than six.] [Report title]. MMWR Morb Mortal Wkly Rep 2025;74:[inclusive page numbers].

This activity was reviewed by CDC, deemed not research, and was conducted consistent with applicable federal law and CDC policy.***

## Results

### SUDORS: Stimulant-Involved Overdose Deaths During January 2021–June 2024

**Types of stimulants involved.** Among 309,274 overdose deaths during January 2021–June 2024 in 49 states and DC,††† 59.0% involved any stimulant, 31.2% involved methamphetamine, and 30.0% involved cocaine; 3.8% involved both methamphetamine and cocaine (Figure 1). Prescription stimulants (1.6%), synthetic cathinones (0.7%), and 3,4-methylenedioxymethamphetamine (MDMA)/3,4-methylenedio xyamphetamine (MDA) (0.4%) were rarely involved. Most (73.0%) stimulant-involved overdose deaths co-involved opioids, including 79.1% of cocaine-involved and 68.8% of methamphetamine-involved deaths; 14.5% of deaths involved only stimulants.

**Characteristics of stimulant-involved overdose deaths.** Overall, 182,502 (59.0%) overdose deaths involved stimulants, 133,293 (43.1%) co-involved stimulants and opioids, and 49,209 (15.9%) involved stimulants and no opioids (Table). Across stimulant and opioid groups, approximately 70% of decedents were male, and 30% were female. A higher percentage of persons who died of overdoses involving stimulants and no opioids was aged ≥45 years (66.5%) than of those who died of overdoses co-involving stimulants and opioids (44.2%).

Among 46 states and DC§§§ with sufficient circumstance data,¶¶¶ higher percentages of persons who died of overdoses involving stimulants and no opioids had a known history of cardiovascular disease (CVD) compared with those who died of overdoses co-involving stimulants and opioids (38.7% versus 21.2%) and were seen in the emergency department (ED) for the fatal overdose (33.1% versus 18.4%). Lower percentages of persons who died of overdoses involving stimulants and no opioids, compared with those co-involving stimulants and opioids, had evidence of opioid use history (11.6% versus 35.8%) and of ever receiving treatment for mental health or substance use disorders (SUDs) (14.9% versus 23.4%). For deaths specifically involving cocaine or methamphetamine, with or without opioid co-involvement, patterns were comparable to those for deaths involving any stimulant.

### NVSS: Trends in Stimulant-Involved Overdose Death Rates from 2018 to 2023

Overall, 520,525 unintentional and undetermined intent overdose deaths occurred during 2018–2023 in the U.S. Overdose death rates per 100,000 population involving cocaine and psychostimulants with abuse potential increased from 2018 to 2023 (cocaine: 4.5 to 8.6; psychostimulants: 3.9 to 10.4) (Supplementary Figure). Among non-Hispanic American Indian or Alaska Native (AI/AN) persons, the rate of overdose deaths involving psychostimulants increased from 11.0 in 2018 to 32.9 in 2023 and was higher than the cocaine-involved death rate throughout the time frame (Figure 2). Among non-Hispanic Black or African American (Black) persons, the cocaine-involved death rate increased from 9.1 in 2018 to 24.3 in 2023 and exceeded the psychostimulant-involved death rate throughout. In addition, the psychostimulant-involved death rate increased from 7.4 in 2018 to 16.3 in 2023 among non-Hispanic Native Hawaiian or Pacific Islander persons. Although stimulant-involved death rates were lower across the time frame for non-Hispanic White, non-Hispanic Asian, and Hispanic or Latino persons, the rates also increased from 2018 to 2023. Across groups, the largest increases were in deaths co-involving stimulants and opioids.

## Discussion

Although most overdose deaths involve opioids (*1*), 182,502 persons died of overdoses involving stimulants (with or without other drugs co-involved) in the United States during January 2021–June 2024, accounting for 59% of all overdose deaths. From 2018 to 2023, the largest increases were in deaths co-involving stimulants and opioids, although types of stimulants involved and corresponding increases, varied by race and ethnicity. Persons who died of overdoses involving stimulants and no opioids differed (e.g., were older and more often had a history of CVD) from those who died of overdoses co-involving stimulants and opioids.

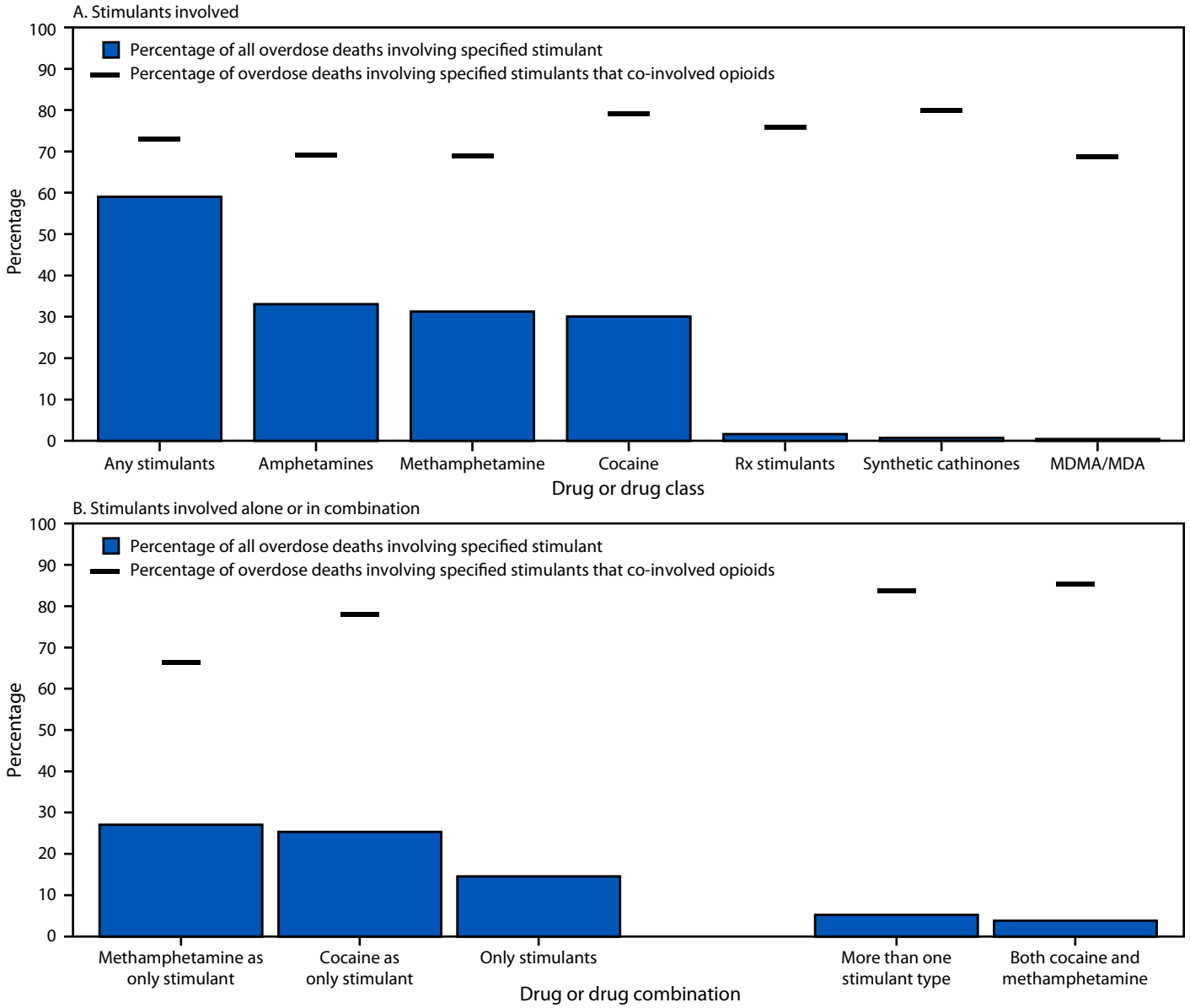
*** 45 C.F.R. part 46.102(l)(2), 21 C.F.R. part 56; 42 U.S.C. Sect. 241(d); 5 U.S.C. Sect. 552a; 44 U.S.C. Sect. 3501 et seq.

††† For inclusion, jurisdictions were required to report ≥75% of overdose deaths in their jurisdiction in at least one 6-month period during January 2021–June 2024. All jurisdictions except four (California, Texas, Wisconsin, and Wyoming) reported deaths for the full time frame. California and Wisconsin were included for a subset of the time frame. Texas and Wyoming were only funded for SUDORS starting with deaths that occurred during January–June 2024. North Dakota was not included because it is not funded for SUDORS.

§§§ Alabama, Alaska, Arizona, Arkansas, Colorado, Connecticut, Delaware, DC, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Massachusetts, Maryland, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, and Wyoming.

¶¶¶ For inclusion, jurisdictions were required to report ≥75% of overdose deaths in their jurisdiction and have circumstance data for ≥75% of overdose deaths in at least one 6-month period during January 2021–June 2024. Thirty-two jurisdictions met the requirements for the full time frame; 15 met the requirements for at least one 6-month period. Among the 47 included jurisdictions, 93.1% of deaths had data on circumstances and were included in analyses. Demographic characteristics of deaths included in this sample are similar to demographic characteristics in the sample including all deaths.

**FIGURE 1. Percentage of overdose deaths (N = 309,274), by type of stimulant*,†,§,¶,**,†† involved§§ (A) and by combinations of stimulants involved (B) — State Unintentional Drug Overdose Reporting System, United States,¶¶ January 2021–June 2024**




**Abbreviations:** MDA = 3,4-methylenedioxyamphetamine; MDMA = 3,4-methylenedioxymethamphetamine; Rx = prescription; SUDORS = State Unintentional Drug Overdose Reporting System.

* Amphetamines is an overarching category that includes all amphetamines, including methamphetamine, methylenedioxymethamphetamine, and methylenedioxyamphetamine as well as all enantiomers (e.g., dextroamphetamine) and metabolites of these substances.

† Prescription stimulants include armodafinil, benzphetamine, bromantane, clenbuterol, clobenzorex, dexmethylphenidate, diethylpropion, lisdexamfetamine, mephentermine, methylphenidate, modafinil, phendimetrazine, phentermine, propylhexedrine, and ritalinic acid. This category also includes amphetamine (including 4-hydroxyamphetamine and dextroamphetamine) if methamphetamine is not detected, levoamphetamine if dextroamphetamine is not detected, and levomethamphetamine if dextromethamphetamine is not detected.

§ Synthetic cathinones are laboratory-made stimulants chemically related to substances found in the khat plant.

¶ The methamphetamine as only stimulant and cocaine as only stimulant categories could have had other nonstimulant drugs (e.g., opioids) involved.

** The only stimulants category includes deaths in which only stimulants were considered to have caused or contributed to the death; other drugs could have been detected but were not considered to have contributed to the death.

†† The more than one stimulant type category includes deaths in which stimulants in more than one of the following categories were considered to have caused or contributed to the death: methamphetamine, cocaine, prescription stimulants, cathinones, MDMA/MDA, or other stimulants (e.g., phenethylamine).

§§ A drug was classified as involved or co-involved in overdose deaths if the medical examiner or coroner listed it as cause of death on the death certificate, or in the medical examiner or coroner report or postmortem toxicology report.

¶¶ Includes 49 states and the District of Columbia. For inclusion, jurisdictions were required to report ≥75% of overdose deaths in their jurisdiction in at least one 6-month period during January 2021–June 2024. All jurisdictions except four (California, Texas, Wisconsin, and Wyoming) reported deaths for the full time frame. California and Wisconsin were included for a subset of the time frame. Texas and Wyoming were only funded for SUDORS starting with deaths that occurred during January–June 2024. North Dakota was not included because it is not funded for SUDORS.

**TABLE. Number and percentage of overdose deaths involving* stimulants and opioids, by select decedent characteristics and overdose circumstances — State Unintentional Drug Overdose Reporting System, United States, January 2021–June 2024**

| Characteristic | No. (%) | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Total stimulant-involved overdose deaths† | | | Cocaine-involved overdose deaths | | | Methamphetamine-involved overdose deaths | | |
| | Total overdose deaths | Total | Opioids co-involved | Opioids not involved | Total | Opioids co-involved | Opioids not involved | Total | Opioids co-involved | Opioids not involved |
| **Overall (49 states and DC)§,¶** | **N = 309,274** | **n = 182,502 (59.0%)** | **n = 133,293 (43.1%)** | **n = 49,209 (15.9%)** | **n = 92,697 (30.0%)** | **n = 73,292 (23.7%)** | **n = 19,405 (6.3%)** | **n = 96,614 (31.2%)** | **n = 66,475 (21.5%)** | **n = 30,139 (9.7%)** |
| **Age group, yrs**** | | | | | | | | | | |
| <15 | **836 (0.3)** | **146 (0.1)** | 70 (0.1) | 76 (0.2) | **52 (0.1)** | 36 (<0.1) | 16 (0.1) | **91 (0.1)** | 34 (0.1) | 57 (0.2) |
| 15–24 | **17,042 (5.5)** | **6,597 (3.6)** | 5,659 (4.2) | 938 (1.9) | **3,204 (3.5)** | 2,876 (3.9) | 328 (1.7) | **3,449 (3.6)** | 2,879 (4.3) | 570 (1.9) |
| 25–34 | **64,535 (20.9)** | **34,860 (19.1)** | 29,517 (22.1) | 5,343 (10.9) | **16,485 (17.8)** | 14,534 (19.8) | 1,951 (10.1) | **19,577 (20.3)** | 16,246 (24.4) | 3,331 (11.1) |
| 35–44 | **81,098 (26.2)** | **49,257 (27.0)** | 39,112 (29.3) | 10,145 (20.6) | **22,901 (24.7)** | 19,626 (26.8) | 3,275 (16.9) | **28,350 (29.4)** | 21,534 (32.4) | 6,816 (22.6) |
| 45–54 | **65,527 (21.2)** | **41,972 (23.0)** | 29,339 (22.0) | 12,633 (25.7) | **21,297 (23.0)** | 16,755 (22.9) | 4,542 (23.4) | **22,323 (23.1)** | 14,147 (21.3) | 8,176 (27.1) |
| 55–64 | **59,721 (19.3)** | **38,307 (21.0)** | 23,760 (17.8) | 14,547 (29.6) | **22,003 (23.7)** | 15,537 (21.2) | 6,466 (33.3) | **17,898 (18.5)** | 9,498 (14.3) | 8,400 (27.9) |
| ≥65 | **20,463 (6.6)** | **11,326 (6.2)** | 5,816 (4.4) | 5,510 (11.2) | **6,744 (7.3)** | 3,920 (5.3) | 2,824 (14.6) | **4,899 (5.1)** | 2,125 (3.2) | 2,774 (9.2) |
| **Sex**** | | | | | | | | | | |
| Female | **89,029 (28.8)** | **50,936 (27.9)** | 37,743 (28.3) | 13,193 (26.8) | **25,612 (27.6)** | 20,406 (27.8) | 5,206 (26.8) | **26,871 (27.8)** | 18,968 (28.5) | 7,903 (26.2) |
| Male | **220,231 (71.2)** | **131,561 (72.1)** | 95,545 (71.7) | 36,016 (73.2) | **67,082 (72.4)** | 52,883 (72.2) | 14,199 (73.2) | **69,739 (72.2)** | 47,503 (71.5) | 2,236 (73.8) |
| **Race and ethnicity**** | | | | | | | | | | |
| American Indian or Alaska Native, NH | **4,557 (1.5)** | **2,819 (1.6)** | 1,820 (1.4) | 1,071 (2.2) | **623 (0.7)** | 480 (0.7) | 143 (0.7) | **2,372 (2.5)** | 1,420 (2.2) | 952 (3.2) |
| Asian, NH | **2,429 (0.8)** | **1,483 (0.8)** | 876 (0.7) | 607 (1.2) | **706 (0.8)** | 502 (0.7) | 204 (1.1) | **784 (0.8)** | 408 (0.6) | 376 (1.3) |
| Black or African American, NH | **64,655 (21.1)** | **41,764 (23.2)** | 30,362 (23.0) | 11,402 (23.5) | **33,990 (37.1)** | 25,362 (35.0) | 8,628 (45.0) | **9,966 (10.4)** | 6,946 (10.6) | 3,020 (10.1) |
| Native Hawaiian or Pacific Islander, NH | **382 (0.1)** | **280 (0.2)** | 115 (0.1) | 165 (0.3) | **44 (<0.1)** | 33 (<0.1) | 11 (0.1) | **244 (0.3)** | 87 (0.1) | 157 (0.5) |
| White, NH | **194,730 (63.6)** | **110,822 (61.4)** | 81,629 (61.9) | 29,193 (60.1) | **43,575 (47.6)** | 35,873 (49.5) | 7,702 (40.2) | **70,896 (74.2)** | 49,414 (75.1) | 21,482 (72.2) |
| Multiple races, NH | **3,565 (1.2)** | **2,212 (1.2)** | 1,431 (1.1) | 781 (1.6) | **744 (0.8)** | 601 (0.8) | 143 (0.7) | **1,537 (1.6)** | 895 (1.4) | 642 (2.2) |
| Hispanic or Latino | **35,813 (11.7)** | **20,953 (11.6)** | 15,589 (11.8) | 5,364 (11.0) | **11,902 (13.0)** | 9,572 (13.2) | 2,330 (12.2) | **9,762 (10.2)** | 6,633 (10.1) | 3,129 (10.5) |
| **Among deaths with circumstance data (46 states and DC)¶,††,§§,¶¶** | **N = 226,698** | **n = 134,109 (59.2%)** | **n = 99,534 (43.9%)** | **n = 34,575 (15.3%)** | **n = 71,622 (31.6%)** | **n = 57,567 (25.4%)** | **n = 14,055 (6.2%)** | **n = 67,831 (29.9%)** | **n = 46,985 (20.7%)** | **n = 20,846 (9.2%)** |
| **Medical history** | | | | | | | | | | |
| Cardiovascular disease*** | **55,305 (24.4)** | **34,467 (25.7)** | 21,084 (21.2) | 13,383 (38.7) | **18,159 (25.4)** | 12,805 (22.2) | 5,354 (38.1) | **17,488 (25.8)** | 9,288 (19.8) | 8,200 (39.3) |
| Obesity | **28,099 (12.4)** | **15,485 (11.5)** | 10,842 (10.9) | 4,643 (13.4) | **8,063 (11.3)** | 6,288 (10.9) | 1,775 (12.6) | **7,835 (11.6)** | 4,942 (10.5) | 2,893 (13.9) |
| **History of drug use** | | | | | | | | | | |
| Any drugs | **176,546 (77.9)** | **106,071 (79.1)** | 80,414 (80.8) | 25,657 (74.2) | **55,692 (77.8)** | 45,304 (78.7) | 10,388 (73.9) | **54,960 (81.0)** | 39,304 (83.7) | 15,656 (75.1) |
| Stimulants††† | **59,367 (26.2)** | **46,840 (34.9)** | 31,362 (31.5) | 15,478 (44.8) | **24,394 (34.1)** | 18,209 (31.6) | 6,185 (44.0) | **24,916 (36.7)** | 15,238 (32.4) | 9,678 (46.4) |
| Cocaine | **34,972 (15.4)** | **26,638 (19.9)** | 19,630 (19.7) | 7,008 (20.3) | **23,174 (32.4)** | 17,179 (29.8) | 5,995 (42.7) | **5,472 (8.1)** | 4,105 (8.7) | 1,367 (6.6) |
| Methamphetamine | **29,257 (12.9)** | **24,033 (17.9)** | 14,515 (14.6) | 9,518 (27.5) | **3,083 (4.3)** | 2,481 (4.3) | 602 (4.3) | **22,331 (32.9)** | 13,193 (28.1) | 9,138 (43.8) |
| Opioids§§§ | **77,025 (34.0)** | **39,607 (29.5)** | 35,601 (35.8) | 4,006 (11.6) | **19,434 (27.1)** | 17,965 (31.2) | 1,469 (10.5) | **21,876 (32.3)** | 19,333 (41.1) | 2,543 (12.2) |
| **Mental health and substance use disorders** | | | | | | | | | | |
| Evidence of a mental health diagnosis | **63,046 (27.8)** | **34,629 (25.8)** | 26,299 (26.4) | 8,330 (24.1) | **17,645 (24.6)** | 14,443 (25.1) | 3,202 (22.8) | **17,963 (26.5)** | 12,882 (27.4) | 5,081 (24.4) |
| Ever treated for mental health or substance use disorders¶¶¶ | **54,978 (24.3)** | **28,452 (21.2)** | 23,300 (23.4) | 5,152 (14.9) | **15,236 (21.3)** | 13,084 (22.7) | 2,152 (15.3) | **14,208 (20.9)** | 11,253 (24.0) | 2,955 (14.2) |

See table footnotes on the next page.

**TABLE. (*Continued*) Number and percentage of overdose deaths involving stimulants and opioids,* by selected decedent characteristics and overdose circumstances — State Unintentional Drug Overdose Reporting System, United States, January 2021–June 2024**

| Characteristic | No. (%) | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Total stimulant-involved overdose deaths† | | | Cocaine-involved overdose deaths | | | Methamphetamine-involved overdose deaths | | |
| | Total overdose deaths | Total | Opioids co-involved | Opioids not involved | Total | Opioids co-involved | Opioids not involved | Total | Opioids co-involved | Opioids not involved |
| Current treatment for mental health or substance use disorders¶¶¶ | **33,301 (14.7)** | **16,111 (12.0)** | 13,152 (13.2) | 2,959 (8.6) | **8,963 (12.5)** | 7,743 (13.5) | 1,220 (8.7) | **7,404 (10.9)** | 5,743 (12.2) | 1,661 (8.0) |
| Ever treated for substance use disorders¶¶¶ | **34,807 (15.4)** | **18,270 (13.6)** | 15,824 (15.9) | 2,446 (7.1) | **9,723 (13.6)** | 8,686 (15.1) | 1,037 (7.4) | **9,487 (14.0)** | 8,078 (17.2) | 1,409 (6.8) |
| Current treatment for substance use disorders¶¶¶ | **14,856 (6.6)** | **7,084 (5.3)** | 6,243 (6.3) | 841 (2.4) | **4,064 (5.7)** | 3,693 (6.4) | 371 (2.6) | **3,303 (4.9)** | 2,834 (6.0) | 469 (2.3) |
| **Experiencing homelessness or housing instability**** | **24,113 (11.0)** | **17,639 (13.5)** | 13,517 (14.0) | 4,122 (12.2) | **6,804 (9.8)** | 5,824 (10.4) | 980 (7.2) | **11,827 (17.9)** | 8,606 (18.9) | 3,221 (15.7) |
| **Overdose circumstances** | | | | | | | | | | |
| Overdose occurred where they lived | **132,561 (60.3)** | **72,699 (55.7)** | 52,978 (54.8) | 19,721 (58.4) | **40,307 (57.4)** | 31,625 (56.0) | 8,682 (63.1) | **34,532 (52.8)** | 23,325 (51.8) | 11,207 (55.1) |
| Naloxone administered†††† | **51,539 (22.7)** | **29,559 (22.0)** | 24,156 (24.3) | 5,403 (15.6) | **14,937 (20.9)** | 12,719 (22.1) | 2,218 (15.8) | **15,964 (23.5)** | 12,719 (27.1) | 3,245 (15.6) |
| Potential bystanders present§§§§ | **98,772 (43.6)** | **57,515 (42.9)** | 43,289 (43.5) | 14,226 (41.2) | **29,957 (41.8)** | 24,425 (42.4) | 5,532 (39.4) | **29,708 (43.8)** | 20,927 (44.6) | 8,781 (42.1) |
| No pulse at first responder arrival | **142,484 (63.8)** | **85,339 (64.6)** | 64,433 (65.7) | 20,906 (61.3) | **44,812 (63.4)** | 36,529 (64.3) | 8,283 (59.6) | **44,096 (66.1)** | 31,231 (67.7) | 12,865 (62.6) |
| Seen in emergency department¶¶¶¶ | **48,254 (21.7)** | **29,205 (22.2)** | 17,939 (18.4) | 11,266 (33.1) | **15,591 (22.1)** | 10,573 (18.7) | 5,018 (36.4) | **14,233 (21.4)** | 7,989 (17.4) | 6,244 (30.3) |

**Abbreviations:** DC = District of Columbia; NH = non-Hispanic; SUDORS = State Unintentional Drug Overdose Reporting System.

* A drug was classified as involved or co-involved in overdose deaths if the medical examiner or coroner listed it as cause of death on the death certificate, or in the medical examiner or coroner report or postmortem toxicology report. Because deaths might involve both cocaine and methamphetamine, some deaths are included in both categories; categories across stimulant types are not mutually exclusive. Within stimulant types, categories with and without opioid co-involvement are mutually exclusive (e.g., among cocaine-involved overdose deaths "opioids co-involved" is mutually exclusive from "opioids not involved").

† Includes deaths involving cocaine, methamphetamine, and any other stimulants (e.g., synthetic cathinones (laboratory-made stimulants chemically related to substances found in the khat plant), prescription dextroamphetamine/amphetamine, 3,4-methylenedioxymethamphetamine) involved in overdose deaths.

§ For inclusion, jurisdictions were required to report ≥75% of overdose deaths in their jurisdiction in at least one 6-month period during January 2021–June 2024. All jurisdictions except four (California, Texas, Wisconsin, and Wyoming) reported deaths for the full time frame. California and Wisconsin were included for a subset of the time frame. Texas and Wyoming were only funded for SUDORS starting with deaths that occurred during January–June 2024. North Dakota was not included because it is not funded for SUDORS.

¶ Percentages in rows titled "overall" and "among deaths with circumstance data" are row percentages. All other percentages are column percentages.

** Missing values were excluded from calculations of percentages. Thus, the counts of each category might not sum to the total due to missing data. Percentages might not sum to 100 because of rounding. Overall, <0.1% of deaths were missing age, <0.1% were missing sex, and 1.0% were missing race and ethnicity.

†† Includes Alabama, Alaska, Arizona, Arkansas, Colorado, Connecticut, Delaware, DC, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Massachusetts, Maryland, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Utah, Vermont, Virginia, Washington, Wisconsin, West Virginia, and Wyoming.

§§ For inclusion, jurisdictions were required to report ≥75% of overdose deaths in their jurisdiction and have circumstance data for ≥75% of overdose deaths in at least one 6-month period during January 2021–June 2024. Thirty-two jurisdictions met the requirements for the full time frame; 15 met the requirements for at least one 6-month period. Among the 47 included jurisdictions, 93.1% of deaths had data on circumstances and were included in analyses. Demographic characteristics of deaths included in this sample are similar to demographic characteristics in the sample including all deaths.

¶¶ Missing values were excluded from calculations of percentages. Percentage missing for each variable is as follows: ever treated for substance use disorders, <0.1%; current treatment for substance use disorders, <0.1%; experiencing homelessness or housing instability, 2.9%; overdose occurred where they lived, 3.0%; naloxone administered, <0.1%; potential bystanders present, <0.1%; no pulse at first responder arrival, 1.5%; seen in emergency department, 2.0%. All other variables had no missing data.

*** In SUDORS, history of cardiovascular disease excludes hypertension.

††† Includes history of cocaine or methamphetamine use.

§§§ Includes history of any opioid use, such as prescription opioid misuse or use of heroin or illegally manufactured fentanyls.

¶¶¶ Treatment for substance use disorders includes medications for opioid use disorder, living in an inpatient rehabilitation facility, participating in mental health or substance use disorder outpatient treatment, or attending Narcotics Anonymous or Alcoholics Anonymous (if specified to be for drug use).

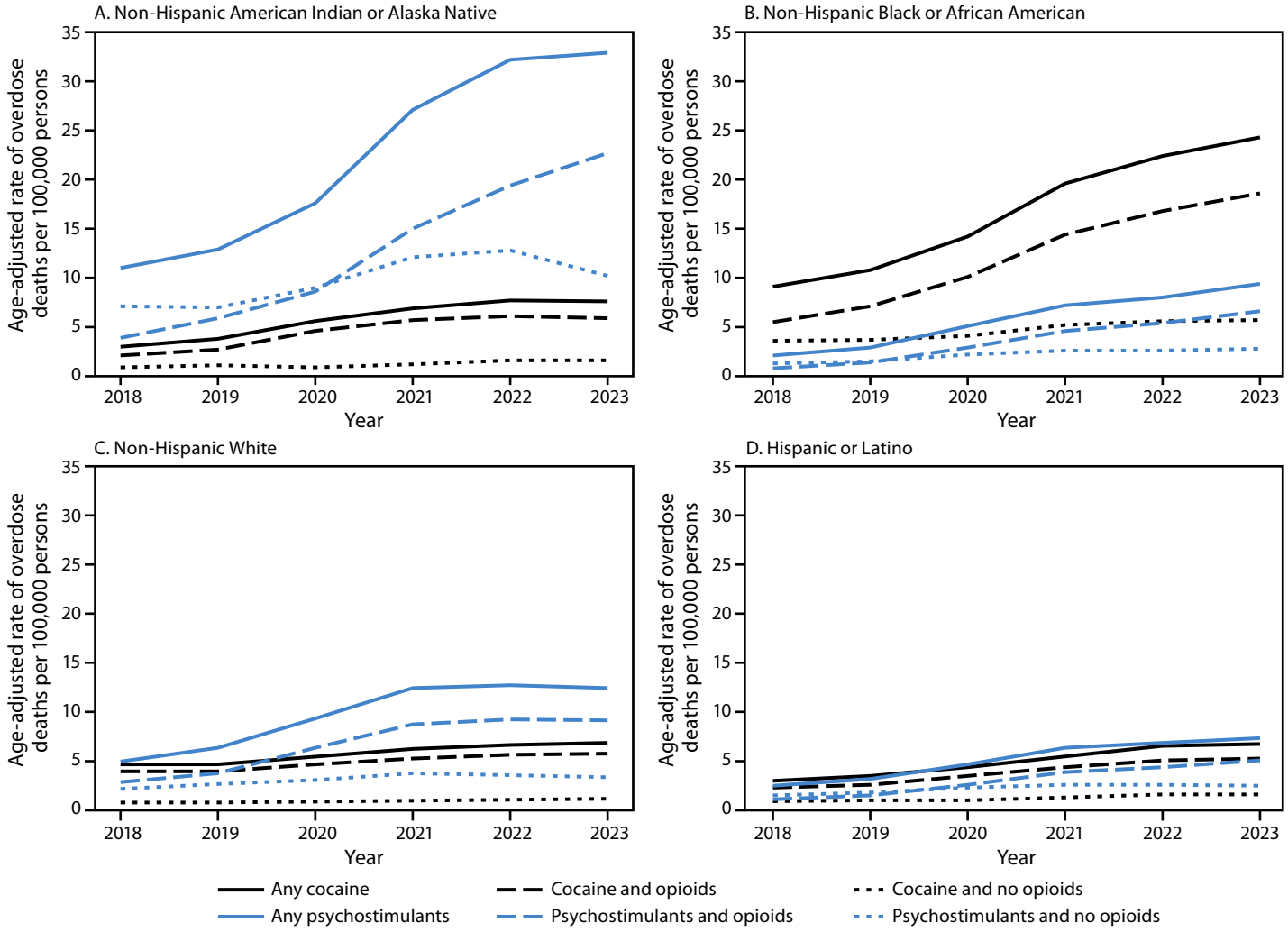
**** Persons experiencing homelessness were those who lived in places not designed for or ordinarily used as regular sleeping accommodations or in a supervised shelter or drop-in center designated to provide temporary living arrangements, congregate shelters, or temporary accommodations provided by a homeless shelter. Persons experiencing housing instability were not experiencing homelessness but lacked the resources or support networks to obtain or retain permanent housing, including interrelated challenges such as trouble paying rent, overcrowding, moving frequently, or staying with relatives.

†††† Naloxone is a life-saving medication that can reverse an overdose from opioids, including heroin, fentanyl, and prescription opioids. Because SUDORS only includes people who died of a drug overdose, evidence of naloxone administration reflects failed administration (i.e., it did not reverse the overdose). This could be because naloxone was not administered soon enough or in sufficient dosages to reverse the overdose, it was not effective (i.e., overdose did not involve opioids), or its effectiveness was affected by polydrug use.

§§§§ A potential bystander is defined as a person aged ≥11 years who was physically nearby during or shortly preceding an overdose and potentially had an opportunity to intervene or respond. This includes persons in the same structure (e.g., same room or same building, but different room) as the decedent during that time. This does not include persons in different self-contained parts of buildings (e.g., persons in a different apartment in the same apartment building would not be a potential bystander).

¶¶¶¶ Denotes whether the person was seen in an emergency department for the fatal overdose regardless of whether they were dead or alive on arrival and regardless of whether or not they received treatment.

**FIGURE 2. Age-adjusted rates* of overdose deaths† involving stimulants and co-involving opioids,§,¶ by race and ethnicity** and year of death — National Vital Statistics System, United States, 2018–2023**




**Abbreviation:** ICD-10 = *International Classification of Diseases, Tenth Revision*.

* Age-adjusted death rates were calculated by weighting age-specific rates per 100,000 vintage year population to the 2000 U.S. Census Bureau standard population.

† Overdose deaths were identified through ICD-10 underlying cause-of-death codes X40–44 (unintentional) and Y10–14 (undetermined intent).

§ Drug categories were defined using multiple cause-of-death ICD-10 codes: cocaine (T40.5), psychostimulants with abuse potential (T43.6), and opioids (T40.0–T40.4 and T40.6).

¶ Because deaths might involve both cocaine and psychostimulants, some deaths are included in both categories.

** Overall data and data for non-Hispanic Asian and non-Hispanic Native Hawaiian or Pacific Islander persons are shown in the Supplementary Figure.

Stimulant overdoses often present as cardiovascular complications (e.g., stroke), disrupt thermoregulation, and cause mental health symptoms (*3*,*4*); long-term stimulant use is associated with CVD, increasing stimulant overdose risk (*4*). Correspondingly, 38.7% of persons who died of overdoses involving stimulants and no opioids, and 21.2% of those who died of overdoses involving both stimulants and opioids, had a known history of CVD (versus approximately 10% among all U.S. adults) (*5*). Assessing stimulant use during health care visits might identify persons at increased risk for stimulant-induced cardiovascular events (*4*).

Teaching persons who use drugs and their family and friends, as well as medical professionals, how to identify symptoms of stimulant overdoses (e.g., CVD events or psychosis) might improve response timeliness and save lives. Unlike opioids, no stimulant overdose reversal agents or approved medication-based treatments for stimulant use disorder exist (*3*). Contingency management, a behavioral intervention that positively reinforces recovery-related behaviors (e.g., abstinence), is the most effective treatment for stimulant use disorder but remains underused**** (*4*). Low-barrier care

**** Contingency Management for the Treatment of Substance Use Disorders: Enhancing Access, Quality, and Program Integrity for an Evidence-Based Intervention (Accessed April 14, 2025).

models and improved linkage to care (e.g., during ED visits for nonfatal overdoses involving stimulants) might increase treatment uptake and retention.[††††]

Seventy three percent of stimulant-involved overdose deaths co-involved opioids, representing almost 45% of all overdose deaths. Drug-checking programs rarely detected opioids in recent stimulant products, suggesting that persons who died of overdoses involving both stimulants and opioids intentionally co-used separate stimulant and opioid products (*6*,*7*). Reasons persons have reported for co-using opioids and stimulants include reducing opioid withdrawal symptoms and balancing the sedating effects of opioids; despite perceived benefits, co-use can increase overdose risk (*3*). In the event of an overdose, opioid reversal agents do not reverse stimulant effects; therefore, additional treatment of stimulant effects (e.g., treatment for agitation or seizures and implementation of cooling strategies) might be needed when opioids and stimulants are used together (*3*). In addition, stimulant use complicates opioid use disorder (OUD) treatment, and guidance is limited for treating co-occurring stimulant use disorder and OUD (*4*). Coordinated, evidence-based treatments for co-occurring use disorders are urgently needed. Provisional data indicating declines in overdose deaths in 2024 primarily reflect decreases in deaths involving synthetic opioids such as illegally manufactured fentanyls (IMFs) (*8*); challenges treating co-occurring stimulant use disorder and OUD might attenuate declines.

Approximately 50,000 (15%) overdose deaths during 3.5 years involved stimulants and no opioids. Nearly 40% had a CVD history, possibly representing long-term stimulant use (*4*). Persons who use stimulants but not opioids have limited tailored interventions and treatments available to prevent death and support recovery and might be missed by existing opioid-focused prevention efforts. Including stimulant-specific guidance in risk reduction strategies and improving access to and retention in treatment for stimulant use disorder might reduce overdose deaths. In addition, persons who died of overdoses involving stimulants and no opioids were older and less often had an opioid use history than those who died of overdoses co-involving stimulants and opioids; overdose prevention and response efforts might therefore require different outreach strategies to reach this population.

From 2018 to 2023, AI/AN persons experienced the largest increases in psychostimulant-involved overdose death rates, and Black persons experienced the largest increases in cocaine-involved death rates. During this time, the prevalence of methamphetamine use among AI/AN persons, cocaine use among Black persons, and opioid use and misuse in both groups remained relatively stable.[§§§§] This suggests increased drug potency or differential access to health care and treatments for SUDs among these groups (*9*). Compared with eastern U.S. drug markets, IMFs proliferated later in southern markets where Black persons disproportionately live, and in western markets where AI/AN persons disproportionately live (*10*); recent increases in deaths co-involving stimulants and opioids among these groups might reflect these market changes. Prevention messaging addressing specific stimulants commonly involved in different populations and improved engagement and retention in care might decrease deaths.

**Summary**

What is already known about this topic?

Stimulant-involved overdose deaths have increased in the United States since 2011.

What is added by this report?

During January 2021–June 2024, 59.0% of overdose deaths involved stimulants, 43.1% co-involved stimulants and opioids, and 15.9% involved stimulants and no opioids. Persons who died of overdoses involving stimulants and no opioids were older and more frequently had a history of cardiovascular disease than those who died of overdoses involving stimulants and opioids. Increases in stimulant-involved deaths from 2018 to 2023 were largest among non-Hispanic American Indian or Alaska Native and non-Hispanic Black or African American persons and driven by deaths co-involving stimulants and opioids.

What are the implications for public health practice?

Expanded access to evidence-based treatments for stimulant use disorder, evaluation of medication-based treatments, and engagement of persons using stimulants who might be missed by opioid-focused efforts might reduce deaths.

## Limitations

The findings in this report are subject to at least five limitations. First, given cardiovascular outcomes, some stimulant-involved overdose deaths might be certified such that they do not receive overdose-specific ICD-10 codes (e.g., cause of death listed as acute cerebrovascular event in setting of methamphetamine toxicity) and thus be missed. Second, postmortem toxicology testing varies within and across jurisdictions, and testing for emerging stimulants is not routine. Together, these factors likely contribute to an underestimation of stimulant-involved overdose deaths. Third, circumstance information depends on availability in investigative reports; percentages are likely underestimated. Fourth, race and ethnicity might be

[††††] Advisory: Low Barrier Models of Care for Substance Use Disorders; Public Safety-Led Post-Overdose Outreach (Accessed April 23, 2025).

[§§§§] 2018 NSDUH Detailed Tables | CBHSQ Data; 2019 NSDUH Detailed Tables | CBHSQ Data; 2020 NSDUH Detailed Tables | CBHSQ Data; 2021 NSDUH Detailed Tables | CBHSQ Data; 2022 NSDUH Detailed Tables | CBHSQ Data; 2023 NSDUH Detailed Tables | CBHSQ Data (Accessed April 14, 2025).

misclassified, potentially affecting race- and ethnicity-specific death rates. Finally, although analyses included nearly all states, some large states were excluded from SUDORS circumstance analyses, reducing generalizability.

### Implications for Public Health Practice

Nearly 60% of overdose deaths during January 2021–June 2024 involved stimulants, highlighting the need for expanded access to evidence-based behavioral treatments (e.g., contingency management) for stimulant use disorder, additional evaluation of medication-based treatments for stimulant use disorder and treatments for co-occurring use disorders, and increased retention in care. In addition, because the signs and symptoms of stimulant overdoses differ from those of opioid overdoses, teaching persons who use drugs and their family and friends how to recognize and respond to stimulant overdoses might save lives. Persons who died from overdoses involving stimulants and no opioids were different (e.g., were older and more often had a history of CVD) from those who died from overdoses co-involving stimulants and opioids and might be missed by opioid-focused prevention efforts. Expanding prevention efforts focused on stimulant overdoses might reduce deaths.

## Acknowledgments

Jurisdictions participating in CDC's Overdose Data to Action (OD2A) program and providing data to the State Unintentional Drug Overdose Reporting System, including state and jurisdictional health departments, vital registrar offices, and medical examiner and coroner offices; CDC OD2A-State team, Division of Overdose Prevention, National Center for Injury Prevention and Control, CDC.

Corresponding author: Lauren J. Tanz, ltanz@cdc.gov.

[1]Division of Overdose Prevention, National Center for Injury Prevention and Control, CDC.

All authors have completed and submitted the International Committee of Medical Journal Editors form for disclosure of potential conflicts of interest. No potential conflicts of interest were disclosed.

## References

1. Garnett MF, Miniño AM. Drug overdose deaths in the United States, 2003–2023. NCHS Data Brief, no 522. Hyattsville, MD: National Center for Health Statistics; 2024. https://dx.doi.org/10.15620/cdc/170565
2. Spencer MR, Miniño AM, Garnett MF. Co-involvement of opioids in drug overdose deaths involving cocaine and psychostimulants, 2011–2021. NCHS Data Brief, no 474. Hyattsville, MD: National Center for Health Statistics; 2023. https://dx.doi.org/10.15620/cdc:129733
3. CDC. Division of overdose prevention stimulant guide: answers to emerging questions about stimulants in the context of the overdose epidemic in the United States. Atlanta, GA: National Center for Injury Prevention and Control; US Department of Health and Human Services, CDC; 2022. https://www.cdc.gov/overdose-prevention/media/pdfs/2024/03/CDC-Stimulant-Guide.pdf
4. Substance Abuse and Mental Health Services Administration. Treatment for stimulant use disorders: treatment improvement protocol (TIP) series 33. SAMHSA Publication No. PEP21–02–01–004. Rockville, MD: Substance Abuse and Mental Health Services Administration; 2021. https://www.ncbi.nlm.nih.gov/books/NBK576541/
5. Tsao CW, Aday AW, Almarzooq ZI, et al.; American Heart Association Council on Epidemiology and Prevention Statistics Committee and Stroke Statistics Subcommittee. Heart disease and stroke statistics-2023 update: a report from the American Heart Association. Circulation 2023;147:e93–621. PMID:36695182 https://doi.org/10.1161/cir.0000000000001123
6. Wagner KD, Fiuty P, Page K, et al. Prevalence of fentanyl in methamphetamine and cocaine samples collected by community-based drug checking services. Drug Alcohol Depend 2023;252:110985 Published online October 5, 2023. PMID:37826988 https://doi.org/10.1016/j.drugalcdep.2023.110985
7. Wallace B, Shkolnikov I, Kielty C, et al. Is fentanyl in everything? examining the unexpected occurrence of illicit opioids in British Columbia's drug supply. Harm Reduct J 2025;22:28. PMID:40065423 https://doi.org/10.1186/s12954-025-01189-w
8. Ahmad FB, Cisewski JA, Garnett M, Warner M. Provisional drug overdose death counts by specific drugs. Hyattsville, MD: National Center for Health Statistics, US Department of Health and Human Services, CDC; 2025. https://www.cdc.gov/nchs/nvss/vsrr/prov-drug-involved-mortality.htm
9. Acevedo A, Panas L, Garnick D, et al. Disparities in the treatment of substance use disorders: does where you live matter? J Behav Health Serv Res 2018;45:533–49. Erratum in: J Behav Health Serv Res 2019;46:187. PMID:29435862 https://doi.org/10.1007/s11414-018-9586-y
10. O'Donnell J, Tanz LJ, Gladden RM, Davis NL, Bitting J. Trends in and characteristics of drug overdose deaths involving illicitly manufactured fentanyls—United States, 2019–2020. MMWR Morb Mortal Wkly Rep 2021;70:1740–6. PMID:34914673 https://doi.org/10.15585/mmwr.mm7050e3

# Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices — United States, 2025–26 Influenza Season

Lisa A. Grohskopf, MD[1]; Lenee H. Blanton, MPH[1]; Jill M. Ferdinands, PhD[1]; Carrie Reed, DSc[1]; Vivien G. Dugan, PhD[1]; Demetre C. Daskalakis, MD[2]

## Abstract

This report updates the 2024–25 recommendations of the Advisory Committee on Immunization Practices (ACIP) concerning the use of seasonal influenza vaccines in the United States. Routine annual influenza vaccination is recommended for all persons aged ≥6 months who do not have a contraindication to vaccination. Multiple formulations of the trivalent inactivated influenza vaccines (IIV3s), trivalent recombinant influenza vaccine (RIV3), and trivalent live attenuated influenza vaccine (LAIV3) are expected to be available for the 2025–26 influenza season. Updates for the 2025–26 season include 1) antigenic composition of 2025–26 U.S. seasonal influenza vaccines, 2) Food and Drug Administration (FDA) approval of FluMist (LAIV3) for self-administration or caregiver administration, 3) FDA approval of a change in age indication for Flublok (RIV3) from ≥18 years to ≥9 years, and 4) a new ACIP recommendation that children aged ≤18 years, pregnant women, and all adults receive seasonal influenza vaccines only in single-dose formulations that are free of thimerosal as a preservative. A comprehensive summary of recommendations, including those discussed in this report, as well as previous recommendations concerning topics not addressed in this report and that remain unchanged for the 2025–26 season, is available at Influenza | ACIP Recommendations for Vaccination. Additional background information also is available at Prevention and Control of Seasonal Influenza with Vaccines.

## Introduction

The Advisory Committee on Immunization Practices (ACIP) provides annual recommendations for the use of influenza vaccines for the prevention and control of seasonal influenza in the United States. This report summarizes updates to the 2024–25 recommendations for use of seasonal influenza vaccines in the United States for the 2025–26 influenza season. As in previous seasons, routine annual influenza vaccination is recommended for all persons aged ≥6 months who do not have a contraindication to vaccination. Various formulations of influenza vaccines are available. Contraindications to and precautions for the use of influenza vaccines are summarized. Updated recommendations discussed in this report reflect discussions held during public ACIP meetings on April 15 and June 26, 2025.

This report describes new and updated recommendations for the 2025–26 season, as well as several topics for which recommendations remain unchanged from the 2024–25 season, including populations for whom influenza vaccination is recommended, timing of vaccination, selection of vaccines, and contraindications and precautions. Previous recommendations concerning topics and specific populations not discussed in this report remain unchanged from the 2024–25 season. Additional information on topics not addressed in this report are available the 2024–25 ACIP seasonal influenza vaccination recommendations (*1*). Recommendations and updates included in this report supersede previous recommendations. In addition, a comprehensive summary of the recommendations for the 2025–26 influenza season, including topics covered and not covered in this report, is available at Influenza | ACIP Recommendations for Vaccination.

## Methods

### Influenza Work Group Activities

The ACIP Influenza Work Group meets by teleconference regularly throughout the year to review topics before they are discussed at ACIP meetings. Systematic review and evidence assessment are not performed for changes in the viral antigen composition of seasonal influenza vaccines recommended by the Food and Drug Administration (FDA) and changes that reflect use that is consistent with FDA-approved indications and prescribing information. Systematic review and evaluation of evidence using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach (*2*) are typically performed for new recommendations or substantial changes in current recommendations. Evidence is reviewed by the ACIP Influenza Work Group, and work group considerations are included within the ACIP Evidence to Recommendations (EtR) framework to guide the development of recommendations proposed for a vote by ACIP (*2*,*3*). Because the reaffirmed recommendations for seasonal influenza vaccination had no new recommendations or substantial changes, this recommendation did not require performance of GRADE or EtR. However, GRADE and the EtR framework were used in the development of the previous recommendations mentioned in this report for influenza vaccination of adults aged ≥65 years (*4*,*5*) (June 2022), persons

with a history of egg allergy (*6*,*7*) (June 2023), and solid organ transplant recipients aged 18 through 64 years (*8*,*9*) (June 2024). GRADE and EtR were not used to develop the recommendation to avoid seasonal influenza vaccines containing thimerosal as a preservative, and this topic, recommendation, and recommendation language were not discussed by the Influenza Work Group.

### Updates to the Influenza Vaccination Recommendations

Four updates to the 2024–25 recommendations are presented in this report. These include three FDA-approved labeling changes and a new recommendation approved through discussion at the June 2025 ACIP meeting.

1. In March 2025, FDA issued recommendations for the antigenic composition of 2025–26 U.S.-approved influenza vaccines (*10*).
2. In September 2024, FDA approved FluMist (LAIV3) for self-administration (for recipients aged 18 through 49 years) or administration by a caregiver aged ≥18 years (for children and adolescents aged 2 through 17 years). FluMist for self-administration or caregiver administration is anticipated to become available during the 2025–26 season (*11*).
3. In March 2025, FDA expanded approval of Flublok (RIV3), previously approved for persons aged ≥18 years, to children and adolescents aged 9 through 17 years. Flublok is now approved for persons aged ≥9 years (*12*).
4. On June 26, 2025, ACIP made a new recommendation that children aged ≤18 years, pregnant women, and all adults receive seasonal influenza vaccines only in single-dose formulations that are free of thimerosal as a preservative.

## Vaccine Composition for the 2025–26 Influenza Season

Based on review of U.S. and global influenza surveillance data (*10*), all influenza vaccines available in the United States during the 2025–26 season will be trivalent vaccines containing hemagglutinin derived from 1) an influenza A/Victoria/4897/2022 (H1N1)pdm09-like virus (for egg-based vaccines) or an influenza A/Wisconsin/67/2022 (H1N1) pdm09-like virus (for cell culture–based and recombinant vaccines); 2) an influenza A/Croatia/10136RV/2023 (H3N2)-like virus (for egg-based vaccines) or an influenza A/District of Columbia/27/2023 (H3N2)-like virus (for cell culture–based and recombinant vaccines); and 3) an influenza B/Austria/1359417/2021 (Victoria lineage)-like virus. This composition reflects an update in the influenza A(H3N2) component compared with that contained in the vaccines during the 2024–25 influenza season (*10*).

## Recommendations for Influenza Vaccination for the 2025–26 Season

Routine annual influenza vaccination of all persons aged ≥6 months who do not have a contraindication to vaccination continues to be recommended. Information on timing, selection, administration, and contraindications and precautions follows.

### Timing of Vaccination

For most persons who require only 1 dose of influenza vaccine for the season, vaccination should ideally be offered during September or October. However, vaccination should continue after October and throughout the influenza season as long as influenza viruses are circulating and unexpired vaccine is available.

Vaccination during July and August is not recommended for most groups because of potential waning of vaccine-induced immunity during the influenza season (*13*–*33*), particularly among older adults (*13*,*14*,*16*,*23*,*26*,*32*). However, vaccination during July or August may be considered for any recipient if there is concern that later vaccination might not be possible. Considerations for timing of vaccination follow.

- **Most adults (particularly those aged ≥65 years) and pregnant women in the first or second trimester.** Vaccination during July and August should be avoided unless there is concern that vaccination later in the season might not be possible.
- **Children who require 2 influenza vaccine doses.** Children aged 6 months through 8 years who did not receive ≥2 trivalent or quadrivalent influenza vaccine doses before July 1, 2025, or whose influenza vaccination history is unknown, require 2 doses of influenza vaccine for the season (Supplementary Figure). These children should receive their first dose as early as possible (including during July and August, if vaccine is available) to permit receipt of the second dose (which must be administered ≥4 weeks later), ideally by the end of October.
- **Children who require only 1 influenza vaccine dose.** Vaccination during July and August can be considered for children of any age who need only 1 dose of influenza vaccine for the season. Although waning of immunity after vaccination during the season has been observed among all age groups (*13*–*33*), fewer studies report this specifically among children (*13*,*22*,*24*,*25*,*29*,*31*,*32*). Moreover, children in this group might visit health care providers during the late summer months for a medical examination before the start of school, which represents a vaccination opportunity.

- **Pregnant women in the third trimester.** Vaccination during July and August can be considered for women who are in the third trimester of pregnancy during these months because vaccination has been associated in multiple studies with reduced risk for influenza illness in their infants during the first months after birth, when they are too young to receive influenza vaccine (*34*–*38*). For pregnant women in the first or second trimester during July and August, waiting until September or October to vaccinate is preferable, unless there is concern that later vaccination might not be possible.

### Selection of Vaccine

As in past years, various influenza vaccines will be available for the 2025–26 influenza season (Table 1). In addition to contraindications and precautions (Table 2) (Table 3), considerations for vaccine selection include the following recommendations from ACIP:

- Children aged ≤18 years, pregnant women, and all adults should receive seasonal influenza vaccines only in single-dose formulations that are free of thimerosal as a preservative.
- All persons should receive an age-appropriate influenza vaccine (i.e., one that is approved for their age), with the exception that solid organ transplant recipients aged 18 through 64 years who are receiving immunosuppressive medication regimens may receive either trivalent high-dose inactivated influenza vaccine (HD-IIV3) or trivalent adjuvanted inactivated influenza vaccine (aIIV3) as acceptable options (without a preference over other age-appropriate IIV3s or trivalent recombinant influenza vaccine [RIV3]) (*8*,*9*).
- Except for vaccination for adults aged ≥65 years, ACIP makes no preferential recommendation for a specific vaccine when more than one licensed and recommended vaccine is available. Among adults aged ≥65 years any one of the following higher dose or adjuvanted influenza vaccines is preferentially recommended: HD-IIV3, RIV3, or aIIV3. If none of these three vaccines is available at an opportunity for vaccine administration, any other available age-appropriate influenza vaccine should be used (*4*,*5*).
- LAIV3 is not recommended during pregnancy, for immunocompromised persons, for persons with certain medical conditions, or for persons who are receiving, have recently received, or are about to receive influenza antiviral medications (Table 2). LAIV3 should not be administered to persons aged <2 or >49 years.

### Number of Doses, Route of Administration, and Dose Volumes

Children aged 6 months through 8 years who have received ≥2 previous doses of trivalent or quadrivalent influenza vaccine ≥4 weeks apart before July 1, 2025, should receive 1 dose of 2025–26 influenza vaccine. The previous 2 doses are not required to have been received during the same or consecutive influenza seasons. Children aged 6 months through 8 years who have not received ≥2 doses of trivalent or quadrivalent influenza vaccine administered ≥4 weeks apart before July 1, 2025, or whose influenza vaccination history is unknown, should receive 2 doses of 2025–26 influenza vaccine ≥4 weeks apart (Supplementary Figure). For children aged 8 years who require 2 doses of vaccine, both doses should be administered even if the child reaches age 9 years between receipt of dose 1 and receipt of dose 2. All persons aged ≥9 years need only 1 dose of a 2025–26 influenza vaccine.

Injectable influenza vaccines (i.e., inactivated and recombinant influenza vaccines) are administered intramuscularly. FDA-approved dose volumes are 0.5 mL for all age groups, with two exceptions (Table 1). The approved dose volume for Afluria (IIV3) is 0.25 mL per dose for children aged 6 through 35 months. The dose volume for children aged ≥3 years and adults is 0.5 mL per dose (*39*). The Afluria 0.5-mL prefilled syringes should not be administered to children aged <3 years, and 0.25-mL prefilled syringes are not available. Because use of multidose seasonal influenza vaccine formulations containing thimerosal as a preservative is no longer recommended, there is currently no ACIP-recommended formulation of Afluria for children aged 6 through 35 months.

The approved dose volume for Fluzone (IIV3) is either 0.25 mL or 0.5 mL per dose for children aged 6 through 35 months. Children aged ≥3 years and adults should receive 0.5 mL per dose (*40*). Although 0.25-mL prefilled syringes are not available, the Fluzone 0.5-mL prefilled syringes can be used for all persons aged ≥6 months. Use of multidose seasonal influenza vaccine formulations containing thimerosal as a preservative is no longer recommended.

### Contraindications and Precautions

Each influenza vaccine has a labeled contraindication for persons with a history of a severe allergic reaction (e.g., anaphylaxis) to any component of that vaccine (Table 2) (Table 3) (*11*,*12*,*39*–*45*). Vaccine components are listed in product package inserts. A history of severe allergic reaction (e.g., anaphylaxis) to egg is a labeled contraindication to the use of egg-based IIV3s and LAIV3, which might contain residual egg protein (*11*,*39*–*41*,*43*–*45*). However, ACIP recommends that all persons aged ≥6 months with egg allergy should receive influenza vaccine and that any influenza vaccine (egg based or

**TABLE 1. Influenza vaccines — United States, 2025–26 influenza season***

| Vaccine type and trade name (manufacturer) | Presentation | Age indication | μg HA (IIV3s and RIV3) or virus count (LAIV3) for each vaccine virus (per dose) | Route | Contains thimerosal as preservative |
|---|---|---|---|---|---|
| **IIV3s (standard-dose, egg-based vaccines†)** | | | | | |
| Afluria (Seqirus) | 0.5-mL PFS§ | ≥3 yrs§ | 15 μg/0.5 mL | IM¶ | No |
| | 5.0-mL MDV** | ≥6 mos§ (needle and syringe) | 7.5 μg/0.25 mL | IM¶ | Yes |
| | | 18 through 64 yrs (jet injector)¶ | 15 μg/0.5 mL | | 24.5 μg Hg/0.5 mL** |
| Fluarix (GlaxoSmithKline) | 0.5-mL PFS | ≥6 mos | 15 μg/0.5 mL | IM¶ | No |
| FluLaval (GlaxoSmithKline) | 0.5-mL PFS | ≥6 mos | 15 μg/0.5 mL | IM¶ | No |
| Fluzone (Sanofi Pasteur) | 0.5-mL PFS†† | ≥6 mos†† | 15 μg/0.5 mL | IM¶ | No |
| | 5.0-mL MDV** | ≥6 mos†† | 7.5 μg/0.25 mL | IM¶ | Yes |
| | | | 15 μg/0.5 mL | | 25 μg Hg/0.5 mL** |
| **ccIIV3 (standard-dose, cell culture–based vaccine)** | | | | | |
| Flucelvax (Seqirus) | 0.5-mL PFS | ≥6 mos | 15 μg/0.5 mL | IM¶ | No |
| | 5.0-mL MDV** | ≥6 mos** | 15 μg/0.5 mL | IM¶ | Yes |
| | | | | | 25 μg Hg/0.5 mL** |
| **HD-IIV3 (high-dose, egg-based vaccine†)** | | | | | |
| Fluzone High-Dose (Sanofi Pasteur) | 0.5-mL PFS | ≥65 yrs | 60 μg/0.5 mL | IM¶ | No |
| **aIIV3 (standard-dose, egg-based vaccine† with MF59 adjuvant)** | | | | | |
| Fluad (Seqirus) | 0.5-mL PFS | ≥65 yrs | 15 μg/0.5 mL | IM¶ | No |
| **RIV3 (recombinant HA vaccine)** | | | | | |
| Flublok (Sanofi Pasteur) | 0.5-mL PFS | ≥9 yrs | 45 μg/0.5 mL | IM¶ | No |
| **LAIV3 (egg-based vaccine†)** | | | | | |
| FluMist (AstraZeneca) | 0.2-mL prefilled single-use intranasal sprayer | 2 through 49 yrs | $10^{6.5–7.5}$ FFU/0.2 mL | Intranasal | No |

**Abbreviations:** ACIP = Advisory Committee on Immunization Practices; aIIV3 = adjuvanted inactivated influenza vaccine, trivalent; ccIIV3 = cell culture–based inactivated influenza vaccine, trivalent; FDA = Food and Drug Administration; FFU = fluorescent focus units; HA = hemagglutinin; HD-IIV3 = high-dose inactivated influenza vaccine, trivalent; Hg = mercury; IIV3 = inactivated influenza vaccine, trivalent; IM = intramuscular; LAIV3 = live attenuated influenza vaccine, trivalent; MDV = multidose vial; PFS = prefilled syringe; RIV3 = recombinant influenza vaccine, trivalent.

* Manufacturer package inserts and updated CDC and ACIP guidance should be consulted for additional information including, but not limited to, indications, contraindications, warnings, precautions. Package inserts for U.S.-licensed vaccines are available from FDA at Vaccines Licensed for Use in the United States. Availability and characteristics of specific products and presentations might change or differ from what is described in this table and in the text of this report.

† Although a history of severe allergic reaction (e.g., anaphylaxis) to egg is a labeled contraindication to the use of egg-based IIV3s and LAIV3, ACIP recommends that all persons aged ≥6 months with egg allergy should receive influenza vaccine and that any influenza vaccine (egg based or non–egg based) that is otherwise appropriate for the recipient's age and health status can be used (see Persons with a History of Egg Allergy in Prevention and Control of Seasonal Influenza with Vaccines).

§ The approved dose volume for Afluria is 0.25 mL for children aged 6 through 35 months and 0.5 mL for persons aged ≥3 years. However, 0.25-mL PFSs are no longer available, and ACIP recommends that children aged ≤18 years, pregnant women, and all adults receive seasonal influenza vaccines only in single-dose formulations that are free of thimerosal as a preservative. The Afluria 0.5-mL PFS presentation should be used only for persons aged ≥3 years.

¶ IM-administered influenza vaccines should be administered by needle and syringe. Although the MDV presentation of Afluria is approved by FDA for administration via the PharmaJet Stratis jet injector for adults aged 18 through 64 years, ACIP recommends that children aged ≤18 years, pregnant women, and all adults receive seasonal influenza vaccines only in single-dose formulations that are free of thimerosal as a preservative. For older children and adults, the recommended site for IM influenza vaccination is the deltoid muscle. The preferred site for infants and young children is the anterolateral aspect of the thigh. Additional specific guidance regarding site selection and needle length for IM administration is available in the CDC General Best Practices for Immunization.

** An MDV formulation containing thimerosal might be available for the 2025–26 season. However, ACIP recommends that children aged ≤18 years, pregnant women, and all adults receive seasonal influenza vaccines only in single-dose formulations that are free of thimerosal as a preservative.

†† Fluzone is approved for children aged 6 through 35 months at either 0.25 mL or 0.5 mL per dose. However, 0.25-mL PFSs are no longer available, and ACIP recommends that children aged ≤18 years, pregnant women, and all adults receive seasonal influenza vaccines only in single-dose formulations that are free of thimerosal as a preservative. The Fluzone 0.5-mL PFS may be used for persons aged ≥6 months.

non–egg based) that is otherwise appropriate for the recipient's age and health status may be used (*6*,*7*). This recommendation was based on a review of evidence from 20 studies (16 of IIVs, one of virosomal influenza vaccine, and three of LAIV) that examined reactions after administration of seasonal influenza vaccines to egg-allergic persons via either full single-dose or split-dose administration protocols (13 of which reported inclusion of persons with a history of severe reaction or anaphylaxis to egg). No instances of anaphylaxis were reported (GRADE certainty level: very low) (*6*). Egg allergy alone necessitates no additional safety measures for influenza vaccination beyond those recommended for any recipient of any vaccine, regardless of severity of previous reaction to egg.

For persons who have had a severe allergic reaction (e.g., anaphylaxis) to a specific influenza vaccine, further receipt of that vaccine is contraindicated. Per package inserts, all egg-based IIV3s and LAIV3 are contraindicated for persons who have had a severe allergic reaction (e.g., anaphylaxis) to any influenza vaccine. Recommendations concerning consideration of non–egg-based influenza vaccines for such persons depends on the type of influenza vaccine associated with the previous severe allergic reaction (Table 2) (Table 3). Providers also might consider consulting with an allergist to help identify the vaccine component responsible for the reaction. Clinical settings in which vaccines are administered should be equipped to recognize and manage acute allergic reactions (*46*).

**TABLE 2. Contraindications and precautions for the use of influenza vaccines — United States, 2025–26 influenza season***

| Vaccine type | Contraindications | Precautions |
|---|---|---|
| Egg-based IIV3s | • History of severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine† or to a previous dose of any influenza vaccine (i.e., any egg-based IIV, ccIIV, RIV, or LAIV)§ | • Moderate or severe acute illness with or without fever<br>• History of Guillain-Barré syndrome within 6 wks of receipt of influenza vaccine |
| ccIIV3 | • History of severe allergic reaction (e.g., anaphylaxis) to a previous dose of any ccIIV or any component of ccIIV3§ | • Moderate or severe acute illness with or without fever<br>• History of Guillain-Barré syndrome within 6 wks of receipt of influenza vaccine<br>• History of severe allergic reaction to a previous dose of any other influenza vaccine (i.e., any egg-based IIV, RIV, or LAIV)¶ |
| RIV3 | • History of severe allergic reaction (e.g., anaphylaxis) to a previous dose of any RIV or any component of RIV3§ | • Moderate or severe acute illness with or without fever<br>• History of Guillain-Barré syndrome within 6 wks of receipt of influenza vaccine<br>• History of severe allergic reaction to a previous dose of any other influenza vaccine (i.e., any egg-based IIV, ccIIV, or LAIV)¶ |
| LAIV3 | • History of severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine† or to a previous dose of any influenza vaccine (i.e., any egg-based IIV, ccIIV, RIV, or LAIV)§<br>• Concomitant aspirin- or salicylate-containing therapy in children and adolescents§<br>• Children aged 2 through 4 yrs who have received a diagnosis of asthma or whose parents or caregivers report that a health care provider has told them during the preceding 12 mos that their child had wheezing or asthma or whose medical record indicates a wheezing episode has occurred during the preceding 12 mos<br>• Children and adults who are immunocompromised due to any cause, including but not limited to immunosuppression caused by medications, congenital or acquired immunodeficiency states, HIV infection, anatomic asplenia, or functional asplenia (e.g., due to sickle cell anemia)<br>• Close contacts and caregivers of severely immunosuppressed persons who require a protected environment<br>• Pregnancy<br>• Persons with active communication between the CSF and the oropharynx, nasopharynx, nose, or ear, or any other cranial CSF leak<br>• Persons with cochlear implants**<br>• Receipt of the influenza antiviral medications oseltamivir or zanamivir within the previous 48 hours; receipt of peramivir within the previous 5 days; or receipt of baloxavir within the previous 17 days†† | • Moderate or severe acute illness with or without fever<br>• History of Guillain-Barré syndrome within 6 wks of receipt of influenza vaccine<br>• Asthma in persons aged ≥5 yrs<br>• Other underlying medical conditions that might predispose to complications after wild-type influenza infection (e.g., chronic pulmonary, cardiovascular [except isolated hypertension], renal, hepatic, neurologic, hematologic, or metabolic disorders [including diabetes mellitus]) |

**Abbreviations:** ACIP = Advisory Committee on Immunization Practices; ccIIV = cell culture–based inactivated influenza vaccine (any valency); ccIIV3 = cell culture–based inactivated influenza vaccine, trivalent; CSF = cerebrospinal fluid; IIV = inactivated influenza vaccine (any valency); IIV3 = inactivated influenza vaccine, trivalent; LAIV = live attenuated influenza vaccine (any valency); LAIV3 = live attenuated influenza vaccine, trivalent; RIV = recombinant influenza vaccine (any valency); RIV3 = recombinant influenza vaccine, trivalent.

* Manufacturer package inserts and updated CDC and ACIP guidance should be consulted for additional information including, but not limited to, indications, contraindications, warnings, and precautions. When a contraindication is present, a vaccine should not be administered. When a precaution is present, vaccination should generally be deferred but might be indicated if the benefit of protection from the vaccine outweighs the risk for an adverse reaction (General Best Practices for Immunization | CDC). Package inserts for U.S.-licensed vaccines are available from FDA at Vaccines Licensed for Use in the United States.

† Although a history of severe allergic reaction (e.g., anaphylaxis) to egg is a labeled contraindication to the use of egg-based IIV3s and LAIV3, ACIP recommends that all persons aged ≥6 months with egg allergy should receive influenza vaccine and that any influenza vaccine (egg based or non–egg based) that is otherwise appropriate for the recipient's age and health status can be used (see Persons with a History of Egg Allergy in Prevention and Control of Seasonal Influenza with Vaccines).

§ Labeled contraindication noted in package insert.

¶ If administered, vaccination should occur in a medical setting and should be supervised by a health care provider who can recognize and manage severe allergic reactions. Providers can consider consulting with an allergist in such cases to assist in identification of the component responsible for the allergic reaction.

** Injectable vaccines are recommended for persons with cochlear implant because of the potential for CSF leak, which might exist for a period after implantation. Providers might consider consultation with a specialist concerning risk for persistent CSF leak if an inactivated or recombinant vaccine cannot be used.

†† Use of LAIV3 in the context of influenza antivirals has not been studied; however, interference with activity of LAIV3 is biologically plausible, a possibility that is noted in the package insert for LAIV3. In the absence of data supporting an adequate minimum interval between influenza antiviral use and LAIV3 administration, the intervals provided are based on the half-life of each antiviral. The interval between influenza antiviral receipt and LAIV3 for which interference might occur might be further prolonged in the presence of medical conditions that delay medication clearance (e.g., renal insufficiency). Influenza antivirals might also interfere with LAIV3 if initiated within 2 weeks after vaccination. Persons who receive antivirals during the period starting with the specified time before receipt of LAIV3 through 2 weeks after receipt of LAIV3 should be revaccinated with an age-appropriate IIV3 or RIV3.

Moderate or severe acute illness with or without fever is a general precaution for vaccination (*46*). A history of Guillain-Barré syndrome within 6 weeks after receipt of a previous dose of influenza vaccine is considered a precaution for the use of all influenza vaccines (Table 2).

In addition to labeled contraindications for LAIV3 that are listed in the package insert, ACIP also considers several other conditions to be contraindications or precautions to the use of LAIV3 (Table 2). In addition, LAIV3 is not approved for and should not be given to persons aged <2 or >49 years.

**TABLE 3. Influenza vaccine contraindications and precautions for persons with a history of severe allergic reaction to a previous dose of an influenza vaccine* — United States, 2025–26 influenza season**

| Vaccine (of any valency) associated with previous severe allergic reaction (e.g., anaphylaxis) | Available 2025–26 influenza vaccine | | |
|---|---|---|---|
| | Egg-based IIV3s and LAIV3 | ccIIV3 | RIV3 |
| Any egg-based IIV or LAIV | Contraindication† | Precaution§ | Precaution§ |
| Any ccIIV | Contraindication† | Contraindication† | Precaution§ |
| Any RIV | Contraindication† | Precaution§ | Contraindication† |
| Unknown influenza vaccine | Allergist consultation recommended | Allergist consultation recommended | Allergist consultation recommended |

**Abbreviations:** ACIP = Advisory Committee on Immunization Practices; ccIIV = cell culture–based inactivated influenza vaccine (any valency); ccIIV3 = cell culture–based inactivated influenza vaccine, trivalent; IIV = inactivated influenza vaccine (any valency); IIV3 = inactivated influenza vaccine, trivalent; LAIV = live attenuated influenza vaccine (any valency); LAIV3 = live attenuated influenza vaccine, trivalent; RIV = recombinant influenza vaccine (any valency); RIV3 = recombinant influenza vaccine, trivalent.

* Manufacturer package inserts and updated CDC and ACIP guidance should be consulted for additional information including, but not limited to, indications, contraindications, warnings, and precautions. Package inserts for U.S.-licensed vaccines are available from FDA at Vaccines Licensed for Use in the United States.

† When a contraindication is present, a vaccine should not be administered, consistent with CDC's General Best Practices for Immunization. In addition to the contraindications based on history of severe allergic reaction to influenza vaccines that are noted in the table, each individual influenza vaccine is contraindicated for persons who have had a severe allergic reaction (e.g., anaphylaxis) to any component of that vaccine. Vaccine components can be found in package inserts. Although a history of severe allergic reaction (e.g., anaphylaxis) to egg is a labeled contraindication to the use of egg-based IIV3s and LAIV3, ACIP recommends that all persons aged ≥6 months with egg allergy should receive influenza vaccine and that any influenza vaccine (egg based or non–egg based) that is otherwise appropriate for the recipient's age and health status can be used (see Persons with a History of Egg Allergy in Prevention and Control of Seasonal Influenza with Vaccines).

§ When a precaution is present, vaccination should generally be deferred but might be indicated if the benefit of protection from the vaccine outweighs the risk for an adverse reaction, consistent with CDC's General Best Practices for Immunization. Providers can consider using the following vaccines in these instances; however, vaccination should occur in an inpatient or outpatient medical setting with supervision by a health care provider who is able to recognize and manage severe allergic reactions: 1) for persons with a history of severe allergic reaction (e.g., anaphylaxis) to any egg-based IIV or LAIV of any valency, the provider can consider administering ccIIV3 or RIV3; 2) for persons with a history of severe allergic reaction (e.g., anaphylaxis) to any ccIIV of any valency, the provider can consider administering RIV3; and 3) for persons with a history of severe allergic reaction (e.g., anaphylaxis) to any RIV of any valency, the provider can consider administering ccIIV3. Providers can also consider consulting with an allergist to help determine which vaccine component is responsible for the allergic reaction.


**Summary**

**What is already known about this topic?**

Influenza vaccination protects against influenza and its potential complications. The Advisory Committee on Immunization Practices makes influenza vaccination recommendations for each influenza season.

**What is added by this report?**

Information for the 2025–26 influenza season includes the updated vaccine composition, approval of FluMist (nasal spray live attenuated influenza vaccine) for self-administration or caregiver administration, expansion of the approved age threshold for Flublok (recombinant influenza vaccine) from ≥18 years to ≥9 years, and a recommendation that only single-dose seasonal influenza vaccines not containing thimerosal as a preservative be used.

**What are the implications for public health practice?**

Routine annual influenza vaccination is recommended for all persons aged ≥6 months without a contraindication to vaccination to protect against influenza and its complications.


## Recent Influenza Vaccine Labeling Changes

**FluMist (LAIV3).** In September 2024, FDA approved the nasal spray live attenuated influenza vaccine FluMist (LAIV3) for self-administration (for recipients aged 18 through 49 years) or administration by a caregiver aged ≥18 years (for children and adolescents aged 2 through 17 years) (*11*). FluMist for self-administration or caregiver administration is anticipated to become available during the 2025–26 season via the FluMist Home program, through which consumers provide information to determine their eligibility to order the vaccine (*47*). For persons who meet eligibility criteria to receive FluMist, vaccine will be shipped under temperature-controlled conditions to the address provided by the person placing the order. ACIP recommendations, contraindications, and precautions for use of FluMist for self-administration or caregiver administration are the same as those for health care provider administration (Table 2) (Table 3). FluMist will continue to be available for ordering and administration by health care providers.

**Flublok (RIV3).** In March 2025, FDA expanded approval of Flublok (RIV3), previously approved only for persons aged ≥18 years, to children and adolescents aged 9 through 17 years. The new labeled age indication for Flublok is ≥9 years (*12*). Approval was based on a nonrandomized open-label study comparing immunogenicity and safety of Flublok Quadrivalent (RIV4) among children and adolescents aged 9 through 17 years with immunogenicity and safety in adults aged 18 through 49 years (*12,48*). Flublok Quadrivalent met prespecified criteria for noninferiority of immunogenicity (lower limit of the two-sided 95% CI of the geometric mean titer ratios between age groups of >0.667 and lower limit of the two-sided 95% CI of the difference in seroconversion rates of >–10% at day 29 postvaccination for all four viral components). Among children and adolescents aged 9 through 17 years, the most common adverse reactions (occurring in ≥10% of participants) were injection site pain (34.4%), myalgia (19.3%), headache (18.5%), and malaise (16.1%) (*12*). Flublok is not approved or recommended for children aged <9 years.

Corresponding author: Lisa A. Grohskopf, Lgrohskopf@cdc.gov.

[1]Influenza Division, National Center for Immunization and Respiratory Diseases, CDC; [2]National Center for Immunization and Respiratory Diseases, CDC.

## Disclosure of Relationship and Unlabeled Use

All authors have completed and submitted the International Committee of Medical Journal Editors form for the disclosure of potential conflicts of interest. No potential conflicts of interest were disclosed.

This report includes discussion of the unlabeled use of influenza vaccines in the recommendations for persons with a history of egg allergy and for solid organ transplant recipients aged 18 through 64 years. With regard to persons with a history of egg allergy, history of severe allergic reaction (e.g., anaphylaxis) to the vaccine or any of its components (which include egg for certain vaccines) is a labeled contraindication to receipt of most trivalent inactivated influenza vaccines (IIV3s) and trivalent live attenuated influenza vaccine (LAIV3). However, ACIP recommends that all persons aged ≥6 months with egg allergy receive influenza vaccine. Any influenza vaccine (egg based or non–egg based) that is otherwise appropriate for the recipient's age and health status can be used. With regard to solid organ transplant recipients aged 18 through 64 years, the trivalent high-dose inactivated influenza vaccine (HD-IIV3) and trivalent adjuvanted inactivated influenza vaccine (aIIV3) are approved for persons aged ≥65 years. However, ACIP recommends that solid organ transplant recipients aged 18 through 64 years who are receiving immunosuppressive medication regimens may receive either HD-IIV3 or aIIV3 as acceptable options, without a preference over other age-appropriate IIV3s or trivalent recombinant influenza vaccine (RIV3).

## References

1. Grohskopf LA, Ferdinands JM, Blanton LH, Broder KR, Loehr J. Prevention and control of seasonal influenza with vaccines: recommendations of the Advisory Committee on Immunization Practices—United States, 2024-25 influenza season. MMWR Recomm Rep 2024;73(No. RR-5):1–25. PMID:39197095 https://doi.org/10.15585/mmwr.rr7305a1
2. CDC. Advisory Committee on Immunization Practices grading of recommendations assessment, development, and evaluation handbook for developing evidence-based recommendations. Atlanta, GA: US Department of Health and Human Services, CDC; 2024. https://www.cdc.gov/acip-grade-handbook/hcp/table-of-contents/index.html
3. CDC. ACIP evidence to recommendation user's guide. Atlanta, GA: US Department of Health and Human Services, CDC; 2020. https://www.cdc.gov/acip/media/pdfs/2024/09/ACIP-EtR-Users-Guide_October-1-2020.pdf
4. CDC. Advisory Committee on Immunization Practices: GRADE: higher dose and adjuvanted influenza vaccines for persons aged ≥65 years. Atlanta, GA: US Department of Health and Human Services, CDC; 2023. https://www.cdc.gov/acip/grade/influenza-older-adults.html
5. CDC. Advisory Committee on Immunization Practices: evidence to recommendations (EtR) framework: higher dose and adjuvanted influenza vaccines for persons aged ≥65 years. Atlanta, GA: US Department of Health and Human Services, CDC; 2024. https://www.cdc.gov/acip/evidence-to-recommendations/influenza-older-adults-etr.html
6. CDC. Advisory Committee on Immunization Practices: grading of recommendations, assessment, development, and evaluation (GRADE): safety of influenza vaccines for persons with egg allergy. Atlanta, GA: US Department of Health and Human Services, CDC; 2024. https://www.cdc.gov/acip/grade/influenza-egg-allergy.html
7. CDC. Advisory Committee on Immunization Practices: evidence to recommendations (EtR) framework: safety of influenza vaccines for persons with egg allergy. Atlanta, GA: US Department of Health and Human Services, CDC; 2023. https://www.cdc.gov/acip/evidence-to-recommendations/influenza-egg-allergy-etr.html
8. CDC. Advisory Committee on Immunization Practices: grading of recommendations, assessment, development, and evaluation (GRADE): higher-dose and adjuvanted influenza vaccines for solid organ transplant recipients. Atlanta, GA: US Department of Health and Human Services, CDC; 2024. https://www.cdc.gov/acip/grade/influenza-solid-organ-transplant.html
9. CDC. Advisory Committee on Immunization Practices: evidence to recommendations (EtR) framework: high-dose and adjuvanted influenza vaccines for solid organ transplant recipients. Atlanta, GA: US Department of Health and Human Services, CDC; 2024. https://www.cdc.gov/acip/evidence-to-recommendations/influenza-solid-organ-transplant-etr.html
10. Food and Drug Administration. Influenza vaccine composition for the 2025–2026 U.S. influenza season. Silver Spring, MD: US Department of Health and Human Services, Food and Drug Administration; 2025. https://www.fda.gov/vaccines-blood-biologics/influenza-vaccine-composition-2025-2026-us-influenza-season
11. FluMist [Package insert]. Gaithersburg, MD: MedImmune; 2025. https://www.fda.gov/vaccines-blood-biologics/vaccines/flumist
12. Flublok [Package insert]. Pearl River, NY: Protein Sciences; 2025. https://www.fda.gov/vaccines-blood-biologics/vaccines/flublok
13. Belongia EA, Sundaram ME, McClure DL, Meece JK, Ferdinands J, VanWormer JJ. Waning vaccine protection against influenza A (H3N2) illness in children and older adults during a single season. Vaccine 2015;33:246–51. PMID:24962752 https://doi.org/10.1016/j.vaccine.2014.06.052
14. Castilla J, Martínez-Baz I, Martínez-Artola V, et al.; Primary Health Care Sentinel Network; Network for Influenza Surveillance in Hospitals of Navarre. Decline in influenza vaccine effectiveness with time after vaccination, Navarre, Spain, season 2011/12. Euro Surveill 2013;18:20388. PMID:23399423 https://doi.org/10.2807/ese.18.05.20388-en
15. Ferdinands JM, Fry AM, Reynolds S, et al. Intraseason waning of influenza vaccine protection: evidence from the US Influenza Vaccine Effectiveness Network, 2011–12 through 2014–15. Clin Infect Dis 2017;64:544–50. PMID:28039340 https://doi.org/10.1093/cid/ciw816
16. Ferdinands JM, Gaglani M, Martin ET, et al. Waning vaccine effectiveness against influenza-associated hospitalizations among adults, 2015–2016 to 2018–2019, United States Hospitalized Adult Influenza Vaccine Effectiveness Network. Clin Infect Dis 2021;73:726–9. PMID:33462610 https://doi.org/10.1093/cid/ciab045
17. Kissling E, Nunes B, Robertson C, et al.; I-MOVE case–control study team. I-MOVE multicentre case-control study 2010/11 to 2014/15: is there within-season waning of influenza type/subtype vaccine effectiveness with increasing time since vaccination? Euro Surveill 2016;21. PMID:27124420 https://doi.org/10.2807/1560-7917.ES.2016.21.16.30201
18. Kissling E, Valenciano M, Larrauri A, et al. Low and decreasing vaccine effectiveness against influenza A(H3) in 2011/12 among vaccination target groups in Europe: results from the I-MOVE multicentre case-control study. Euro Surveill 2013;18:20390. PMID:23399425 https://doi.org/10.2807/ese.18.05.20390-en

19. Mira-Iglesias A, López-Labrador FX, García-Rubio J, et al. Influenza vaccine effectiveness and waning effect in hospitalized older adults. Valencia Region, Spain, 2018/2019 season. Int J Environ Res Public Health 2021;18:1129. PMID:33514058 https://doi.org/10.3390/ijerph18031129
20. Ng Y, Nandar K, Chua LAV, et al. Evaluating the effectiveness of the influenza vaccine during respiratory outbreaks in Singapore's long term care facilities, 2017. Vaccine 2019;37:3925–31. PMID:31160102 https://doi.org/10.1016/j.vaccine.2019.03.054
21. Pebody RG, Andrews N, McMenamin J, et al. Vaccine effectiveness of 2011/12 trivalent seasonal influenza vaccine in preventing laboratory-confirmed influenza in primary care in the United Kingdom: evidence of waning intra-seasonal protection. Euro Surveill 2013;18:20389. PMID:23399424 https://doi.org/10.2807/ese.18.05.20389-en
22. Powell LN, Bégué RE. Influenza vaccine effectiveness among children for the 2017–2018 season. J Pediatric Infect Dis Soc 2020;9:468–73. PMID:31774120 https://doi.org/10.1093/jpids/piz077
23. Puig-Barberà J, Mira-Iglesias A, Tortajada-Girbés M, et al.; Valencia Hospital Network for the Study of Influenza and other Respiratory Viruses (VAHNSI, Spain). Waning protection of influenza vaccination during four influenza seasons, 2011/2012 to 2014/2015. Vaccine 2017;35:5799–807. PMID:28941618 https://doi.org/10.1016/j.vaccine.2017.09.035
24. Radin JM, Hawksworth AW, Myers CA, Ricketts MN, Hansen EA, Brice GT. Influenza vaccine effectiveness: maintained protection throughout the duration of influenza seasons 2010–2011 through 2013–2014. Vaccine 2016;34:3907–12. PMID:27265447 https://doi.org/10.1016/j.vaccine.2016.05.034
25. Ray GT, Lewis N, Klein NP, et al. Intraseason waning of influenza vaccine effectiveness. Clin Infect Dis 2019;68:1623–30. PMID:30204855 https://doi.org/10.1093/cid/ciy770
26. Young BE, Mak TM, Ang LW, et al. Influenza vaccine failure in the tropics: a retrospective cohort study of waning effectiveness. Epidemiol Infect 2020;148:e299. PMID:33261680 https://doi.org/10.1017/S0950268820002952
27. Hu W, Sjoberg PA, Fries AC, DeMarcus LS, Robbins AS. Waning vaccine protection against influenza among Department of Defense adult beneficiaries in the United States, 2016–2017 through 2019–2020 influenza seasons. Vaccines (Basel) 2022;10:888. PMID:35746496 https://doi.org/10.3390/vaccines10060888
28. Regan AK, Fielding JE, Chilver MB, et al. Intraseason decline in influenza vaccine effectiveness during the 2016 southern hemisphere influenza season: a test-negative design study and phylogenetic assessment. Vaccine 2019;37:2634–41. PMID:30952499 https://doi.org/10.1016/j.vaccine.2019.02.027
29. Sahni LC, Naioti EA, Olson SM, et al. Sustained within-season vaccine effectiveness against influenza-associated hospitalization in children: evidence from the New Vaccine Surveillance Network, 2015–2016 through 2019–2020. Clin Infect Dis 2023;76:e1031–9. PMID:35867698 https://doi.org/10.1093/cid/ciac577
30. Uemura K, Ono S, Michihata N, Yamana H, Yasunaga H. Duration of influenza vaccine effectiveness in the elderly in Japan: a retrospective cohort study using large-scale population-based registry data. Vaccine 2023;41:3092–8. PMID:37045684 https://doi.org/10.1016/j.vaccine.2023.03.066
31. Chung H, Campitelli MA, Buchan SA, et al.; Canadian Immunization Research Network (CIRN) Provincial Collaborative Network (PCN) Investigators. Measuring waning protection from seasonal influenza vaccination during nine influenza seasons, Ontario, Canada, 2010/11 to 2018/19. Euro Surveill 2024;29:2300239. PMID:38390652 https://doi.org/10.2807/1560-7917.ES.2024.29.8.2300239
32. Domnich A, Orsi A, Signori A, et al. Waning intra-season vaccine effectiveness against influenza A(H3N2) underlines the need for more durable protection. Expert Rev Vaccines 2024;23:380–8. PMID:38494919 https://doi.org/10.1080/14760584.2024.2331073
33. Young B, Sadarangani S, Jiang L, Wilder-Smith A, Chen MI-C. Duration of influenza vaccine effectiveness: a systematic review, meta-analysis, and meta-regression of test-negative design case-control studies. J Infect Dis 2018;217:731–41. PMID:29220496 https://doi.org/10.1093/infdis/jix632
34. Madhi SA, Nunes MC, Cutland CL. Influenza vaccination of pregnant women and protection of their infants. N Engl J Med 2014;371:2340. PMID:25494283 https://doi.org/10.1056/NEJMoa1401480
35. Steinhoff MC, Katz J, Englund JA, et al. Year-round influenza immunisation during pregnancy in Nepal: a phase 4, randomised, placebo-controlled trial. Lancet Infect Dis 2017;17:981–9. PMID:28522338 https://doi.org/10.1016/S1473-3099(17)30252-9
36. Tapia MD, Sow SO, Tamboura B, et al. Maternal immunisation with trivalent inactivated influenza vaccine for prevention of influenza in infants in Mali: a prospective, active-controlled, observer-blind, randomised phase 4 trial. Lancet Infect Dis 2016;16:1026–35. PMID:27261067 https://doi.org/10.1016/S1473-3099(16)30054-8
37. Zaman K, Roy E, Arifeen SE, et al. Effectiveness of maternal influenza immunization in mothers and infants. N Engl J Med 2008;359:1555–64. PMID:18799552 https://doi.org/10.1056/NEJMoa0708630
38. Eick AA, Uyeki TM, Klimov A, et al. Maternal influenza vaccination and effect on influenza virus infection in young infants. Arch Pediatr Adolesc Med 2011;165:104–11. PMID:20921345 https://doi.org/10.1001/archpediatrics.2010.192
39. Afluria [Package insert]. Parkville, Victoria, Australia: Seqirus; 2025. https://www.fda.gov/vaccines-blood-biologics/vaccines/afluria-afluria-southern-hemisphere
40. Fluzone [Package insert]. Swiftwater, PA: Sanofi Pasteur; 2025. https://www.fda.gov/vaccines-blood-biologics/vaccines/fluzone-and-fluzone-high-dose
41. Fluarix [Package insert]. Dresden, Germany: GSK Biologicals; 2025. https://www.fda.gov/vaccines-blood-biologics/vaccines/fluarix
42. Flucelvax [Package insert]. Holly Springs, NC: Seqirus; 2025. https://www.fda.gov/vaccines-blood-biologics/vaccines/flucelvax
43. FluLaval [Package insert]. Quebec City, QC, Canada: ID Biomedical Corporation of Quebec; 2025. https://www.fda.gov/vaccines-blood-biologics/vaccines/flulaval
44. Fluzone High-Dose [Package insert]. Swiftwater, PA: Sanofi Pasteur; 2025. https://www.fda.gov/vaccines-blood-biologics/vaccines/fluzone-and-fluzone-high-dose
45. Fluad [Package insert]. Holly Springs, NC: Seqirus; 2025. https://www.fda.gov/vaccines-blood-biologics/vaccines/fluad
46. CDC. Vaccines & immunizations: general best practices for immunization. Atlanta, GA: US Department of Health and Human Services, CDC; 2025 https://www.cdc.gov/vaccines/hcp/imz-best-practices/
47. Bandell A. FluMist self/caregiver administration [Presentation slides]. Presented at the Advisory Committee on Immunization Practices meeting, Atlanta, GA; April 15, 2025. https://www.cdc.gov/acip/downloads/slides-2025-04-15-16/04-bandell-influenza-508.pdf
48. Folegatti P. Immunogenicity and safety of quadrivalent recombinant influenza vaccine (RIV4) in children and adolescents aged 9 to 17 years and adults aged 18 to 49 years [Presentation slides]. Presented at the Advisory Committee on Immunization Practices meeting, Atlanta, GA; June 26, 2025. https://www.cdc.gov/acip/downloads/slides-2025-06-25-26/02-folegatti-influenza-508.pdf

# Use of Clesrovimab for Prevention of Severe Respiratory Syncytial Virus–Associated Lower Respiratory Tract Infections in Infants: Recommendations of the Advisory Committee on Immunization Practices — United States, 2025

Danielle L. Moulia, MPH[1]; Ruth Link-Gelles, PhD[1]; Helen Y. Chu, MD[2]; Denise Jamieson, MD[3]; Oliver Brooks, MD[4]; Sarah Meyer, MD[5]; Eric S. Weintraub, PhD[5]; David K. Shay, MD[5]; Mila M. Prill, MSPH[1]; Ebony S. Thomas, MPH[6]; David Hutton, PhD[7]; Ismael R. Ortega-Sanchez, PhD[1]; Adam MacNeil, PhD[1]; Meredith L. McMorrow, MD[1]; Jefferson M. Jones, MD[1]

## Abstract

Before the introduction of universal respiratory syncytial virus (RSV) immunization recommendations for infants, RSV was the leading cause of hospitalization among infants in the United States. Since 2023, CDC's Advisory Committee on Immunization Practices (ACIP) has recommended that all infants be protected against RSV-associated lower respiratory tract infection (LRTI) through either 1) maternal RSV vaccination during pregnancy (Abrysvo, Pfizer) or 2) administration of nirsevimab (Beyfortus, Sanofi and AstraZeneca), a long-acting RSV monoclonal antibody, to the infant. In June 2025, the Food and Drug Administration licensed clesrovimab (Enflonsia, Merck), a second long-acting RSV monoclonal antibody, for prevention of RSV-associated LRTI in infants. Since September 2024, the ACIP Maternal/Pediatric RSV Work Group has reviewed evidence regarding the safety and efficacy of clesrovimab use in infants. On June 26, 2025, ACIP recommended clesrovimab as a second long-acting monoclonal antibody product that could be used as an alternative to nirsevimab for prevention of RSV-associated LRTI among infants aged <8 months who are born during or entering their first RSV season and who are not protected through maternal RSV vaccination. All infants should be protected against RSV-associated LRTI through use of one of these three products (i.e., maternal RSV vaccination or administration of nirsevimab or clesrovimab to the infant). No one product is preferred; the choice should be guided by parent preference, product availability, and timing of the infant's birth relative to the RSV season.

## Introduction

Before the introduction of universal respiratory syncytial virus (RSV) immunization recommendations for infants in 2023, RSV was the leading cause of hospitalization among U.S. infants (aged <12 months) (*1*): an estimated 2%–3% of infants aged <3 months were hospitalized for RSV each year (*2*). RSV led to an estimated 58,000–80,000 RSV-associated hospitalizations and 100–300 RSV-associated deaths annually among U.S. infants and children aged <5 years (*3*–*5*). The rate of RSV-associated hospitalization is highest during the first 6 months of life, peaking at age 1 month and decreasing with increasing age (*6*). Most infants hospitalized with RSV have no known risk factors for severe RSV. Thus, all infants are at risk for severe RSV disease (*7*).

Nirsevimab (Beyfortus, Sanofi, in collaboration with AstraZeneca), a long-acting* monoclonal antibody for prevention of RSV-associated lower respiratory tract infection (LRTI), was recommended by the Advisory Committee on Immunization Practices (ACIP) in August 2023; administration of RSV vaccine (Abrysvo, Pfizer) to pregnant women at 32–36 weeks' gestation was recommended by ACIP in September 2023 (*8*). ACIP recommended that all infants be protected against RSV-associated LRTI through either 1) maternal RSV vaccination during pregnancy or 2) administration of a long-acting RSV monoclonal antibody (nirsevimab) to the infant. Use of both products was not recommended for most infants.

Data from real-world effectiveness studies estimate that nirsevimab and maternal RSV vaccination offer protection against approximately 70%–80% of RSV-associated hospitalizations among infants (*9*). During the 2024–2025 RSV season, the first full season when the two RSV prevention products were widely available, data from two national surveillance networks (the Respiratory Syncytial Virus Hospitalization Surveillance Network and the New Vaccine Surveillance Network) estimated that RSV-associated hospitalization rates among infants aged 0–7 months were 43% and 28% lower, respectively, compared with rates during pre–COVID-19 pandemic RSV seasons (*10*).

On June 9, 2025, the Food and Drug Administration (FDA) approved clesrovimab (Enflonsia, Merck), a second long-acting RSV monoclonal antibody, for prevention of RSV-associated LRTI among infants (*11*). Clesrovimab is administered as a single intramuscular injection before or during an infant's first RSV season. On June 26, 2025, ACIP recommended clesrovimab as one of two long-acting monoclonal antibody options (i.e., clesrovimab or nirsevimab) for the prevention of RSV-associated LRTI in infants aged <8 months born during or entering their first RSV season who are not protected

* Long-acting monoclonal antibodies for RSV require only 1 dose for protection during an RSV season. This differs from palivizumab, a monoclonal antibody that requires regular dosing throughout the season.

through maternal RSV vaccination. This report summarizes the evidence for clesrovimab and presents updated clinical guidance for protection against RSV-associated LRTI in infants.

## Methods

During September 2024–June 2025, the ACIP Maternal/Pediatric RSV Work Group met monthly to review evidence regarding the safety and efficacy of clesrovimab and determined the quality of this evidence using the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach (*12*). The Evidence to Recommendations (EtR) framework was used to guide the work group's deliberations and develop RSV prevention product recommendations for infants and children (*13*); the work group provided input on voting language. The work group conclusions regarding evidence for the use of clesrovimab in infants were presented to ACIP at public meetings on October 16, 2024; April 24, 2025; and June 25, 2025 (*14*–*16*).

## Rationale and Evidence

### Efficacy and Safety

The ACIP Maternal/Pediatric RSV Work Group evaluated the safety and efficacy of clesrovimab using data from a single phase 2b/3 randomized, double-blind, placebo-controlled trial among infants born during or entering their first RSV season† (*15, 17*,*18*). A total of 3,614 healthy preterm and term infants born at ≥29 weeks' gestation were randomized and dosed in a 2:1 ratio to receive clesrovimab (2,411) or placebo§ (1,203), with follow-up for efficacy in preventing RSV-associated medically attended LRTI and associated hospitalization through 150 days¶ after injection and for safety through 365 days after injection. The GRADE evidence profile and supporting EtR framework for the work group's assessment of clesrovimab are available at GRADE | CDC and EtR Framework | CDC.

**Efficacy.** Efficacy** of clesrovimab in preventing RSV-associated medically attended LRTI†† through 150 days was 60.4% (95% CI = 44.1%–71.9%), with the outcome occurring in 60 (2.5%) of 2,398 participants in the clesrovimab group and 74 (6.2%) of 1,201 participants in the placebo group. Efficacy against RSV-associated LRTI hospitalization§§ was 90.9% (95% CI = 76.2%–96.5%), with the outcome occurring in five participants (0.2%) in the clesrovimab group and 27 (2.2%) participants in the placebo group (*17*,*18*).

**Safety.** The incidence of all-cause serious adverse events¶¶ through 1 year after injection was similar among infants who received clesrovimab (11.5%) compared with those who received placebo (12.4%) (relative risk = 0.93; 95% CI = 0.77–1.12). Most solicited adverse events were mild or moderate, with irritability and somnolence being the most common, and the frequencies of fever and injection-site reactions were similar between trial groups.

### Economic Analysis

The ACIP Maternal/Pediatric RSV Work Group also considered whether the use of clesrovimab for infants is a reasonable and efficient allocation of resources. University of Michigan and CDC staff members updated an economic analysis performed for nirsevimab (*19*), using the same model and inputs, except that the price of clesrovimab was based on a manufacturer-generated report, and clesrovimab efficacy inputs were based on clesrovimab clinical trial data (*15*). The cost-effectiveness model compared the use of clesrovimab in eligible infants with use of palivizumab (a monoclonal antibody that was previously recommended by the American Academy of

† Clesrovimab was also evaluated in a phase 3 trial in infants and children with increased risk for severe RSV disease who were randomized to receive either clesrovimab or palivizumab. This trial was not placebo-controlled and was therefore excluded from the ACIP Maternal/Pediatric RSV Work Group's review of evidence for GRADE. This trial has not yet been completed as of the publication of this report. Preliminary data presented to ACIP on October 23, 2024, indicated that adverse events were generally comparable in the palivizumab and clesrovimab groups (Clesrovimab (MK-1654): Pediatric Clinical Program). The incidence of RSV-associated medically attended LRTI and hospitalization were similar between the palivizumab and clesrovimab groups through 6 months after injection. The concentration of clesrovimab as measured by an area under the curve through 150 days after injection were similar in the clesrovimab groups of infants and children with increased risk for severe RSV disease in this phase 3 trial and the healthy infants and children in the phase 2b/3 trial. A 105-mg dose of clesrovimab was given in both trials, and the pharmacokinetic bridging data suggest that clesrovimab would similarly protect infants and children with and without increased risk for severe RSV disease using the same dose.

§ Placebo was 0.9% sodium chloride.

¶ The phase 2b/3 trial's primary outcome was RSV-associated medically attended LRTI through 150 days. RSV-associated medically attended LRTI associated with hospitalization was a tertiary outcome. Additional outcomes included RSV-associated medically attended LRTI and associated hospitalization through 180 days.

** Efficacy was defined as (1 − relative risk) × 100, and the relative risk was estimated comparing the incidence of the outcome in the clesrovimab trial group divided by the incidence in the placebo group, using a modified Poisson regression approach with robust variance estimation.

†† RSV-associated medically attended LRTI was defined by the presence of the following in an infant seen in an outpatient or inpatient clinical setting: cough or difficulty breathing and one or more indicators of LRTI or severity (wheezing, chest wall in-drawing or retractions, rales or crackles, hypoxemia, tachypnea, and dehydration associated with respiratory signs or symptoms), and a nasopharyngeal sample that tested positive for RSV by reverse transcription–polymerase chain reaction (RT-PCR).

§§ RSV-associated LRTI hospitalization was defined as the presence of the following in an infant seen in an inpatient clinical setting: cough or difficulty breathing and one or more indicators of LRTI (wheezing, rhonchi, rales, or crackles), one or more indicators of severity (chest wall indrawing or retractions, hypoxemia, tachypnea, and dehydration associated with respiratory signs or symptoms), and a nasopharyngeal sample that tested positive for RSV by RT-PCR.

¶¶ Serious adverse events are defined as any medical occurrence that results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, or results in persistent disability or incapacity.

Pediatrics for children with certain underlying medical conditions and requires monthly dosing)*** in eligible infants and no immunization in all other infants. This model found an incremental cost-effectiveness ratio of $105,000 per quality-adjusted life-year (QALY) gained from a societal perspective, with a range from cost-saving to approximately $213,000 per QALY gained in sensitivity analyses (*15*). The base case cost per dose was $457, and influential inputs included inpatient costs, clesrovimab cost per dose, and RSV-related QALYs lost (*15*).

## Recommendations for Use of Clesrovimab

On June 25, 2025, ACIP recommended clesrovimab as one of two long-acting monoclonal antibody options (i.e., as an alternative to nirsevimab), for the protection of infants aged <8 months born during or entering their first RSV season††† who are not protected through maternal RSV vaccination. ACIP recommends that all infants be protected against RSV-associated LRTI through one of three product options: 1) maternal RSV vaccination during pregnancy; 2) infant receipt of the long-acting RSV monoclonal antibody, nirsevimab; or 3) infant receipt of the long-acting RSV monoclonal antibody, clesrovimab (Table). Health care providers should select which product to use based on parent preference, product availability, and timing relative to the RSV season, with an understanding of relative advantages and disadvantages (Box 1). Recommendations for nirsevimab and maternal vaccination have been previously published, and up-to-date clinical guidance for all three products have also been published (RSV Immunization Guidance for Infants and Young Children | CDC; RSV Vaccine Guidance for Pregnant Women | CDC).

### Routine Administration of RSV Monoclonal Antibodies

For infants aged <8 months born during or entering their first RSV season, the recommendations for nirsevimab and clesrovimab are the same, with the exception that the dose of clesrovimab (105 mg) is the same for all infants, whereas the

**TABLE. Products* to prevent respiratory syncytial virus–associated severe disease among infants aged <8 months born during or entering their first respiratory syncytial virus season — United States, 2025**

| Product | Population recommended to receive the product | Months when the product should be administered | Dosing information (by single IM injection) |
|---|---|---|---|
| RSV monoclonal antibody, clesrovimab (Enflonsia)† | Infants aged <8 mos | October–March§,¶ | 105 mg (0.7 mL) for all infants regardless of weight |
| RSV monoclonal antibody, nirsevimab (Beyfortus)† | Infants aged <8 mos | October–March§,¶ | 50 mg (0.5 mL) for infants weighing <11 lb (<5 kg)<br>100 mg (1 mL) for infants weighing ≥11 lb (≥5 kg) |
| Maternal RSV vaccine, RSVpreF (Abrysvo) | Pregnant women at 32–36 wks' gestation | September–January** | 0.5 mL |

**Abbreviations:** ACIP = Advisory Committee on Immunization Practices; IM = intramuscular; RSV = respiratory syncytial virus.

* ACIP recommends that all infants be protected against RSV-associated lower respiratory tract infection through one of the three listed products.

† A single dose of RSV monoclonal antibody is recommended for infants aged <8 months who are born during or entering their first RSV season (typically fall through spring in most of the continental United States) if 1) the mother did not receive RSV vaccine during pregnancy or 2) the mother's RSV vaccination status is unknown, or 3) the infant was born ≤14 days after maternal RSV vaccination. Except in rare circumstances, administration of RSV monoclonal antibody is not indicated for most infants who are born ≥14 days after their mother received RSV vaccine.

§ Eligible infants born during the seasonal administration window for RSV monoclonal antibody products (October 1–March 31 in most of the continental United States) should receive RSV antibody within 1 week after birth, ideally during the birth hospitalization. Any eligible infant or young child born outside the seasonal administration window (April–September) who has not yet received a recommended dose should receive RSV antibody at the earliest opportunity beginning in October to optimize protection during the peak RSV season. For infants eligible for RSV antibody with prolonged hospitalizations shortly before or during the RSV season, providers may consider administering RSV antibody during the birth hospitalization to prevent health care–associated RSV disease. This decision should be based on clinical judgment considering the potential risks and benefits.

¶ RSV monoclonal antibody should be administered during October through the end of March in most of the continental United States. However, ACIP recommendations on the timing of RSV antibody administration are intentionally flexible to optimize patient access, including reimbursement. For example, In Alaska RSV circulation patterns are less predictable, and the duration of the RSV season is often longer than the national average. Tropical climates might also have RSV circulation patterns that differ from most of the continental United States or that are unpredictable. In addition, because the timing of RSV activity varies geographically in other regions of the United States, public health authorities may elect to provide revised guidance regarding the timing of RSV antibody administration based on local surveillance data and feasibility of implementation (i.e., extending or shortening the recommended administration period of October–March). Public health authorities should consider the advantages and disadvantages of modifying the timing of administration. Providers, including regional medical centers and health systems, should consult with state or territorial health departments before systematically modifying the recommended months for RSV antibody administration for their eligible patient populations.

** In areas where the timing of the RSV season is less predictable, providers should follow state or territorial guidance on timing of maternal RSV vaccination. In addition, state and territorial health departments can consider modifying the timing of administration based on historical seasonality data and should consider the potential advantages and disadvantages of any modifications. Providers, including regional medical centers and health systems, should consult with state or territorial health departments before systematically modifying the recommended months for maternal vaccination for their eligible patient populations.

*** Before licensure of nirsevimab, the only FDA-approved product to prevent severe RSV disease among infants and young children was palivizumab, another monoclonal antibody. Before the licensure and recommendation of nirsevimab, the American Academy of Pediatrics (AAP) recommended palivizumab for infants and children with certain underlying medical conditions (accounting for <5% of all infants and children); its use is further limited by high cost and the requirement for monthly dosing. AAP no longer routinely recommends palivizumab, and palivizumab will no longer be available in the United States as of December 31, 2025. Respiratory Syncytial Virus | Red Book: 2024–2027 Report of the Committee on Infectious Diseases | Red Book Online | American Academy of Pediatrics; SYNAGIS (palivizumab) | Parent & Caregiver Website

††† Nirsevimab is the only product recommended by CDC for infants and children aged 8–19 months at high risk for RSV-associated LRTI entering their second RSV season.

nirsevimab dose differs depending on the infant's weight.[§§§] In the following recommendations, RSV antibody refers to either nirsevimab or clesrovimab. A dose of RSV antibody is recommended for all eligible infants (i.e., those aged <8 months[¶¶¶] born during or entering their first RSV season, typically fall through spring in the continental United States) if 1) the mother did not receive RSV vaccine during pregnancy, 2) the mother's RSV vaccination status is unknown, or 3) the infant was born ≤14 days after maternal RSV vaccination. Except in rare circumstances, RSV antibody is not indicated for most infants who are born ≥14 days after their mother received RSV vaccine.[****] RSV antibodies and routine childhood vaccines may be administered during the same visit.

### Timing of RSV Monoclonal Antibody Administration

**Administration to general infant population.** Eligible infants born during the seasonal administration window for RSV antibody (October 1–March 31 in most of the continental United States) should receive the RSV antibody dose within 1 week after birth, ideally during the birth hospitalization. Eligible infants born outside the seasonal administration window (i.e., during April–September) who have not yet received a recommended dose should receive RSV antibody at the earliest opportunity beginning in October to optimize protection during the peak of the RSV season.

ACIP recommendations on the timing of RSV antibody administration are intentionally flexible to improve patient access, including reimbursement. For example, in Alaska, RSV circulation patterns are less predictable, and the duration of the RSV season is often longer than the national average. Tropical climates[††††] might also have RSV circulation patterns that differ from those in most of the continental United States or that are unpredictable.

[§§§] The dose of nirsevimab is 50 mg for infants weighing <11 lb (<5 kg) and 100 mg for infants weighing ≥11 lb (≥5 kg).

[¶¶¶] The infant or child's age on the day of administration should be used to determine whether they are eligible for immunization.

[****] If an infant is born <14 days after maternal vaccination the infant should receive RSV monoclonal antibody. RSV monoclonal antibody may also be considered for infants born to vaccinated mothers in rare circumstances when, based on the clinical judgment of the health care provider, the potential incremental benefit of administration is warranted. These situations include but are not limited to infants born to mothers who might not mount an adequate immune response to vaccination (e.g., mothers with immunocompromising conditions); infants born to mothers who have conditions associated with reduced transplacental antibody transfer (e.g., mothers living with HIV infection); infants who undergo procedures leading to loss of maternal antibodies (e.g., cardiopulmonary bypass, extracorporeal membrane oxygenation, or exchange transfusion); and infants at substantially increased risk for severe RSV disease (e.g., hemodynamically significant congenital heart disease or intensive care unit admission with oxygen requirement at discharge).

[††††] Locations with tropical climates include but are not limited to southern Florida, Guam, Hawaii, Puerto Rico, U.S.-affiliated Pacific Islands, and the U.S. Virgin Islands.

**BOX 1. Advantages and disadvantages of respiratory syncytial virus maternal vaccination and respiratory syncytial virus long-acting monoclonal antibodies (clesrovimab or nirsevimab) for protection against respiratory syncytial virus–associated severe disease among infants aged <8 months born during or entering their first respiratory syncytial virus season — United States, 2025**

**Maternal RSV Vaccine (RSVpreF)**

**Advantages**

- Provides protection immediately after birth
- Might be more resistant to potential RSV mutation*

**Disadvantages**

- Protection potentially reduced if fewer antibodies are produced or are transferred from mother to infant (e.g., mother is immunocompromised, infant is born soon after vaccination, or infant has prematurity)
- Potential risk for hypertensive disorders of pregnancy†

**RSV Monoclonal Antibodies**

**Advantages**

- Protection might last longer
- Ensures infant receives antibodies directly rather than relying on transplacental transfer
- No risk for adverse pregnancy outcomes

**Disadvantages**

- Requires infant to receive an injection
- Product might not be available§

**Abbreviations**: RSV = respiratory syncytial virus; RSVpreF = maternal RSV vaccine.

* RSVpreF vaccination results in a polyclonal antibody response, which is expected to be more resistant to potential mutations in the RSV F protein than is a monoclonal RSV antibody.

† In a 2025 Vaccine Safety Datalink matched cohort study of vaccinated and unvaccinated pregnant women (13,474 matched pairs), an association between RSVpreF vaccination and hypertensive disorder of pregnancy (adjusted odds ratio = 1.09 [95% CI = 1.03–1.15]) was observed. RSVpreF Vaccine Safety 2023–24 Respiratory Season | Health Partners Institute

§ RSV monoclonal antibody products might not be available in all birthing hospitals and outpatient clinics.

In addition, because the timing of RSV activity varies geographically in other regions of the United States (*20*), public health authorities may provide revised guidance regarding the timing of RSV antibody administration based on local surveillance data and feasibility of implementation (i.e., extending or shortening the recommended administration period of October–March).[§§§§] Public health authorities should consider the potential advantages and disadvantages of modifying the timing of administration (Box 2). Providers, including regional medical centers and health systems, should consult with state

[§§§§] In areas with clear increases in RSV transmission before October, administration before October can be considered. In areas with high RSV transmission through the end of March, administering to newborns beyond the end of March can be considered. Beginning administration after October or ending administration before March can also be considered.

**BOX 2. Potential advantages and disadvantages of modifying timing of administration of maternal respiratory syncytial virus vaccine and respiratory syncytial virus long-acting monoclonal antibodies (clesrovimab or nirsevimab) — United States, 2025**

### Starting Administration of Maternal Vaccine Before September or RSV Monoclonal Antibodies Before October

**Advantages**

- **RSVpreF maternal vaccine:** Can provide protection to infants born before October and for infants who might experience a delay in receipt of RSV antibody
- **RSV monoclonal antibody**: Can provide more time for infants to receive RSV antibody before start of the RSV season
- Potentially useful for jurisdictions with early RSV seasonality

**Disadvantage**

- Maximum protection is expected shortly after administration (for infant RSV monoclonal antibody) or birth (for RSVpreF maternal vaccine). Protection wanes over time, although the rate of decrease is unknown. Therefore, infants who receive RSV monoclonal antibody in September or who are born to a mother who was vaccinated in August, might be less protected during the peak of the RSV season and toward the end of the RSV season.

### Extending Duration of Administration of Maternal RSV Vaccine Past January or RSV Monoclonal Antibodies Past March

**Advantage**

- Either product type could protect infants during their first months of life when they are at highest risk for severe disease.

**Disadvantages**

- The risk for RSV exposure and infection toward the end of the RSV season might be low.
- **RSVpreF maternal vaccine:** A woman vaccinated at 32–36 weeks' gestation during February or March could give birth to the infant in April or May, and that infant would generally not be recommended to receive an RSV monoclonal antibody* dose in October because most infants born to vaccinated mothers are not recommended to receive RSV monoclonal antibody. Administering a dose in October instead of vaccinating the mother could provide protection for an entire RSV season.
- **RSV monoclonal antibody**: Most infants born to unvaccinated mothers are recommended to receive only 1 dose of an RSV monoclonal antibody. Therefore, most infants who receive RSV antibody in April would not be recommended to receive a dose in October. Administering the dose in October instead of April could provide protection for an entire RSV season.

**Abbreviations:** RSV = respiratory syncytial virus; RSVpreF = maternal RSV vaccine.

* Infants born <14 days after maternal vaccination should receive RSV monoclonal antibody. RSV monoclonal antibody may also be considered for infants born to vaccinated mothers in rare circumstances when, based on the clinical judgment of the health care provider, the potential incremental benefit of administration is warranted. These situations include but are not limited to 1) infants born to mothers who might not mount an adequate immune response to vaccination (e.g., mothers with immunocompromising conditions); 2) infants born to mothers who have conditions associated with reduced transplacental antibody transfer (e.g., mothers living with HIV infection); 3) infants who undergo procedures leading to loss of maternal antibodies (e.g., cardiopulmonary bypass, extracorporeal membrane oxygenation, or exchange transfusion); and 4) infants at substantially increased risk for severe RSV disease (e.g., hemodynamically significant congenital heart disease or intensive care unit admission with oxygen requirement at discharge).

or territorial health departments¶¶¶¶ before systematically modifying the recommended months for RSV antibody administration for their eligible patient populations.*****

¶¶¶¶ Consultation with health departments will ensure that RSV monoclonal antibody will be available for use when the months of administration are modified. Consultation with health departments by health care systems will also ensure that health care providers within the system are receiving consistent recommendations on the timing of RSV antibody administration.

***** Health care providers may use clinical judgement in determining when to give RSV antibody outside the months of October–March. Special circumstances might also need to be considered, such as travel to areas with increased RSV activity or concerns that the infant or child might not return for a visit when nirsevimab should ideally be administered. When health care providers are using clinical judgment to adjust the timing of RSV antibody for individual patients, consultation with state or territorial health care providers is not needed.

**Administration to hospitalized infants.** Health care–associated RSV disease occurs; however, the incidence is unknown (*21*,*22*). Standard and contact infection control practices are indicated to decrease health care–associated RSV disease (*23*). Safety data for use of RSV antibody in infants with a postmenstrual age (gestational age at birth plus chronologic age) of <32 weeks or who weigh <3.5 lb (<1.6 kg) are limited (Summary of Product Characteristics | Beyfortus | INN-nirsevimab) (*24*). To prevent health care–associated RSV disease, providers may consider administering RSV antibody to eligible hospitalized infants during their hospitalization. This decision should be based on clinical judgment, considering the potential risks and benefits, as well as local RSV activity.

**Summary**

What is already known about this topic?

To prevent respiratory syncytial virus (RSV)–associated lower respiratory tract infection (LRTI) in infants, since 2023, the Advisory Committee on Immunization Practices (ACIP) has recommended either 1) maternal RSV vaccination during pregnancy or 2) administration of nirsevimab, a long-acting RSV monoclonal antibody, to the infant.

What is added by this report?

On June 26, 2025, ACIP recommended clesrovimab, a newly licensed long-acting RSV monoclonal antibody, as an alternative to nirsevimab for infants aged <8 months born during or entering their first RSV season who did not receive protection through maternal RSV vaccination.

What are the implications for public health practice?

All infants should be protected against RSV LRTI through either maternal RSV vaccination or receipt of a long-acting RSV monoclonal antibody (clesrovimab or nirsevimab).

### Precautions and Contraindications

Clesrovimab is contraindicated for and should not be administered to persons with a history of severe allergic reaction, such as anaphylaxis, to any product component. Components can be found in the package inserts for clesrovimab: Clesrovimab Label | FDA.

### Reporting of Adverse Events

Adverse events might occur after administration of an RSV antibody. Reporting of any clinically significant adverse event is encouraged, regardless of whether a causal relationship with the product is certain.

Adverse events after administration of an RSV antibody alone should be reported to FDA's MedWatch system online (The FDA Safety Information and Adverse Event Reporting Program | Medwatch), by fax, by mail, or by calling 800-332-1088.[†††††]

Adverse events after coadministration of an RSV antibody with a vaccine should be reported to the Vaccine Adverse Event Reporting System (VAERS) online at Vaccine Adverse Event Reporting System (VAERS), by fax, by mail, or by calling 800-822-7967. The report should specify that the patient received nirsevimab or clesrovimab.[§§§§§] If an adverse event occurs after coadministration of an RSV antibody with a vaccine and is reported to VAERS, a duplicate report to MedWatch is not necessary.

[†††††] Adverse events can be reported to MedWatch because FDA has classified clesrovimab and nirsevimab as drugs.

[§§§§§] Information about any prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being take at the time of vaccination is solicited in section 9 of the VAERS report.

Corresponding author: Danielle L. Moulia, media@cdc.gov.

[1]Coronavirus and Other Respiratory Viruses Division, National Center for Immunization and Respiratory Diseases, CDC; [2]University of Washington, Seattle, Washington; [3]University of Iowa, Iowa City, Iowa; [4]Watts Healthcare Corporation, Los Angeles, California; [5]Division of Healthcare Quality Promotion, National Center for Emerging and Zoonotic Diseases, CDC; [6]Immunization Services Division, National Center for Immunization and Respiratory Diseases, CDC; [7]University of Michigan, Ann Arbor, Michigan.

All authors have completed and submitted the International Committee of Medical Journal Editors form for disclosure of potential conflicts of interest. Helen Y. Chu reports receipt of grants or contracts from the National Institutes of Health; payment or honoraria from Merck for a 1-day meeting in January 2023 on molnupiravir use as RSV antiviral treatment (an activity that was reviewed by the ACIP secretariat and was determined not to constitute a conflict of interest at the time of the disclosure, which was more than 6 months before work group review of clesrovimab or any Merck products), Medscape (speaker bureau), Clinical Care Options (speaker bureau), Catalyst Medical Education (speaker bureau), Vir Biotechnology (advisory board), U.S. Department of Defense (advisory board), the American Heart Association (lecture honoraria), the University of Minnesota (lecture honoraria), Roche (advisory board), Catholic University, Seoul, South Korea (lecture honoraria), Washington University in St. Louis (lecture honoraria), and the American Academy of Allergy, Asthma & Immunology (AAAAI) meeting (lecture honoraria); and travel or meeting support from Medscape (respiratory syncytial virus continuing medical education [RSV CME]), Prime (RSV CME), Infectious Diseases Society of America (annual meeting), International Symposium on Antimicrobial Agents and Resistance, Washington University Virology Symposium, Pediatric Academic Society, and AAAAI meeting; and service on CDC's Advisory Committee on Immunization Practices. No other potential conflicts of interest were disclosed.

## References

1. Suh M, Movva N, Jiang X, et al. Respiratory syncytial virus is the leading cause of United States infant hospitalizations, 2009–2019: a study of the national (nationwide) inpatient sample. J Infect Dis 2022;226(Suppl 2):S154–63. PMID:35968878 https://doi.org/10.1093/infdis/jiac120
2. McMorrow ML, Moline HL, Toepfer AP, et al. Respiratory syncytial virus–associated hospitalizations in children <5 years: 2016–2022. Pediatrics 2024;154:e2023065623. PMID:38841769 https://doi.org/10.1542/peds.2023-065623
3. Hall CB, Weinberg GA, Iwane MK, et al. The burden of respiratory syncytial virus infection in young children. N Engl J Med 2009;360:588–98. PMID:19196675 https://doi.org/10.1056/NEJMoa0804877
4. McLaughlin JM, Khan F, Schmitt HJ, et al. Respiratory syncytial virus–associated hospitalization rates among US infants: a systematic review and meta-analysis. J Infect Dis 2022;225:1100–11. PMID:33346360 https://doi.org/10.1093/infdis/jiaa752
5. Hansen CL, Chaves SS, Demont C, Viboud C. Mortality associated with influenza and respiratory syncytial virus in the US, 1999–2018. JAMA Netw Open 2022;5:e220527. PMID:35226079 https://doi.org/10.1001/jamanetworkopen.2022.0527

6. Curns AT, Rha B, Lively JY, et al. Respiratory syncytial virus–associated hospitalizations among children <5 years old: 2016 to 2020. Pediatrics 2024;153:e2023062574. PMID:38298053 https://doi.org/10.1542/peds.2023-062574
7. Hall CB, Weinberg GA, Blumkin AK, et al. Respiratory syncytial virus–associated hospitalizations among children less than 24 months of age. Pediatrics 2013;132:e341–8. PMID:23878043 https://doi.org/10.1542/peds.2013-0303
8. Fleming-Dutra KE, Jones JM, Roper LE, et al. Use of the Pfizer respiratory syncytial virus vaccine during pregnancy for the prevention of respiratory syncytial virus–associated lower respiratory tract disease in infants: recommendations of the Advisory Committee on Immunization Practices—United States, 2023. MMWR Morb Mortal Wkly Rep 2023;72:1115–22. PMID:37824423 https://doi.org/10.15585/mmwr.mm7241e1
9. MacNeil A. CDC. Effectiveness and impact of RSV prevention products in infants during the 2024–2025 RSV season. [Presentation slides]. Presented at the Advisory Committee on Immunization Practices meeting, Atlanta, GA; June 26, 2025. https://www.cdc.gov/acip/downloads/slides-2025-06-25-26/03-MacNeil-Mat-Peds-RSV-508.pdf
10. Patton ME, Moline HL, Whitaker M, et al. Interim evaluation of respiratory syncytial virus hospitalization rates among infants and young children after introduction of respiratory syncytial virus prevention products—United States, October 2024–February 2025. MMWR Morb Mortal Wkly Rep 2025;74:273–81. PMID:40338822 https://doi.org/10.15585/mmwr.mm7416a1
11. Food and Drug Administration. Enflonsia (clesrovimab-cfof) [Package insert]. Silver Spring, MD: US Department of Health and Human Services, Food and Drug Administration; 2025. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/761432s000lbl.pdf
12. CDC. Grading of recommendations, assessment, development, and evaluation (GRADE): clesrovimab. Atlanta, GA: US Department of Health and Human Services, CDC; 2023. https://www.cdc.gov/acip/grade/clesrovimab-infants.html
13. CDC. ACIP evidence to recommendations for use of clesrovimab in infants born during RSV season and entering their first RSV season. Atlanta, GA: US Department of Health and Human Services, CDC; 2023. https://www.cdc.gov/acip/evidence-to-recommendations/clesrovimab-infants.html
14. Moulia DL; CDC. Maternal and pediatric RSV work group interpretations and next steps. [Presentation slides]. Presented at the Advisory Committee on Immunization Practices meeting, Atlanta, GA; October 23, 2024. https://www.cdc.gov/acip/downloads/slides-2024-10-23-24/04-RSV-Mat-Peds-Moulia-508.pdf
15. Moulia DL; CDC. Evidence to recommendations framework: clesrovimab. [Presentation slides]. Presented at the Advisory Committee on Immunization Practices meeting, Atlanta, GA; April 16, 2025. https://www.cdc.gov/acip/downloads/slides-2025-04-15-16/02-Moulia-maternal-peds-RSV-508.pdf
16. MacNeil A; CDC. Updates on evidence to recommendations framework: clesrovimab. [Presentation slides]. Presented at the Advisory Committee on Immunization Practices meeting, Atlanta, GA; June 26, 2025. https://www.cdc.gov/acip/downloads/slides-2025-06-25-26/05-MacNeil-Mat-Peds-RSV-508.pdf
17. Sinha A. Merck. Clesrovimab (MK-1654): Pediatric clinical program. [Presentation slides]. Presented at the Advisory Committee on Immunization Practices meeting, Atlanta, GA; October 23, 2024. https://www.cdc.gov/acip/downloads/slides-2024-10-23-24/02-RSV-Mat-Peds-Sinha-508.pdf
18. Food and Drug Administration, Center for Drug Evaluation and Research. Integrated review of clesrovimab application. Silver Spring, MD: US Department of Health and Human Services, Food and Drug Administration; 2025. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/761432Orig1s000IntegratedR.pdf
19. Hutton DW, Prosser LA, Rose AM, et al. Cost-effectiveness of nirsevimab for respiratory syncytial virus in infants and young children. Pediatrics 2024;154:e2024066461. PMID:39582316 https://doi.org/10.1542/peds.2024-066461
20. Hamid S, Winn A, Parikh R, et al. Seasonality of respiratory syncytial virus—United States, 2017–2023. MMWR Morb Mortal Wkly Rep 2023;72:355–61. PMID:37022977 https://doi.org/10.15585/mmwr.mm7214a1
21. Gettler EB, Talbot HK, Zhu Y, et al. Respiratory syncytial virus: an under-recognized healthcare-associated infection. Infect Control Hosp Epidemiol 2025;46:1–5; Epub May 16, 2025. PMID:40376828 https://doi.org/10.1017/ice.2025.88
22. Langley JM, LeBlanc JC, Wang EE, et al. Nosocomial respiratory syncytial virus infection in Canadian pediatric hospitals: a Pediatric Investigators Collaborative Network on Infections in Canada Study. Pediatrics 1997;100:943–6. PMID:9374561 https://doi.org/10.1542/peds.100.6.943
23. Kimberlin DW, Banerjee R, Barnett ED, eds. Respiratory Syncytial Virus [Section 3]. In: Red Book: 2024–2027 Report of the Committee on Infectious Diseases, 32nd ed.; 2024. https://publications.aap.org/redbook/book/755/Red-Book-2024-2027-Report-of-the-Committee-on?autologincheck=redirected
24. MacNeil A. Work group considerations and clinical considerations for clesrovimab. [Presentation slides]. Presented at the Advisory Committee on Immunization Practices meeting, Atlanta, GA; June 26, 2025. https://www.cdc.gov/acip/downloads/slides2025-06-25-26/06-MacNeil-Mat-Peds-RSV-508.pdf

The *Morbidity and Mortality Weekly Report (MMWR)* Series is prepared by the U.S. Centers for Disease Control and Prevention (CDC) and is available free of charge in electronic format. To receive an electronic copy each week, visit *MMWR* at *https://www.cdc.gov/mmwr/index.html*.

Readers who have difficulty accessing this PDF file may access the HTML file at https://www.cdc.gov/mmwr/index2025.html. Address all inquiries about the *MMWR* Series to Editor-in-Chief, *MMWR* Series, Mailstop V25-5, CDC, 1600 Clifton Rd., N.E., Atlanta, GA 30329-4027 or to mmwrq@cdc.gov.



ISSN: 0149-2195 (Print)