

Use of Respiratory Syncytial Virus Vaccines in Adults Aged ≥60 Years: Updated Recommendations of the Advisory Committee on Immunization Practices — United States, 2024

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Abstract

Respiratory syncytial virus (RSV) is a major cause of respiratory illness and hospitalization in older adults during fall and winter in the United States. The 2023–2024 RSV season was the first during which RSV vaccination was recommended for U.S. adults aged ≥60 years, using shared clinical decision-making. On June 26, 2024, the Advisory Committee on Immunization Practices voted to update this recommendation as follows: a single dose of any Food and Drug Administration–approved RSV vaccine (Arevxy [GSK]; Abrysvo [Pfizer]; or mResvia [Moderna]) is now recommended for all adults aged ≥75 years and for adults aged 60–74 years who are at increased risk for severe RSV disease. Adults who have previously received RSV vaccine should not receive another dose. This report summarizes the evidence considered for these updated recommendations, including postlicensure data on vaccine effectiveness and safety, and provides clinical guidance for the use of RSV vaccines in adults aged ≥60 years. These updated recommendations are intended to maximize RSV vaccination coverage among persons most likely to benefit, by clarifying who is at highest risk and by reducing implementation barriers associated with the previous shared clinical decision-making recommendation. Continued postlicensure monitoring will guide future recommendations.

Introduction

Respiratory syncytial virus (RSV) is a major cause of respiratory illness and hospitalizations in older adults during fall and winter in the United States (1). On June 21, 2023, CDC's Advisory Committee on Immunization Practices (ACIP) issued its first adult RSV vaccination recommendation, stating that adults aged ≥60 years may receive a single dose of RSV vaccine, using shared clinical decision-making (2).

As of spring 2024, 20%–25% of U.S. adults aged ≥60 years were estimated to have received RSV vaccine,* and the first postlicensure safety and effectiveness data for GSK's Arevxy and Pfizer's Abrysvo became available.† In addition, on May 31, 2024, the Food and Drug Administration (FDA) approved a third RSV vaccine (mResvia [Moderna]) for prevention of RSV-associated lower respiratory tract disease (RSV-LRTD) in adults aged ≥60 years‡ (3,4).

To update adult RSV vaccination recommendations, ACIP considered data from previous meetings; new data from randomized, observer-blind, placebo-controlled clinical trials (RCTs) of mResvia; and postlicensure data on Arevxy and Abrysvo. This report summarizes that evidence and presents updated ACIP recommendations for RSV vaccination in adults aged ≥60 years.§

Methods

The ACIP Work Group for RSV prevention in adults met at least monthly since July 2023 to consider updates to adult RSV vaccination recommendations, using the Evidence to Recommendation Framework (EtR) to guide its deliberations.** Work Group conclusions were publicly presented to ACIP on June 26, 2024. Full details for Grading of Recommendations, Assessment, Development, and Evaluations (GRADE) are available at <https://www.cdc.gov/vaccines/acip/recs/grade/mrna-rsv-vaccine-older-adults.html> and <https://www.cdc.gov/vaccines/acip/recs/grade/protein-subunit-rsv-vaccines-older-adults.html> and for EtR are available at <https://www.cdc.gov/>

† In this report, RSV vaccine trade names are used to help differentiate between RSV vaccine products because the products have similar generic names. The use of trade names is for identification only and does not indicate endorsement of any specific RSV vaccine product.

§ mResvia is a 1-dose (0.5 mL) mRNA vaccine containing nucleoside-modified mRNA encoding RSV F protein stabilized in the prefusion conformation.

¶ This report summarizes recommendations for nonpregnant adults aged ≥60 years. Recommendations for the use of RSV vaccines in pregnant adults for prevention of RSV-LRTD in infants are available at <https://www.cdc.gov/mmwr/volumes/72/wr/mm7241e1.htm>

** Through the EtR framework, the Work Group reviewed data on the public health problem caused by RSV, as well as the benefits and harms, value to the target population, acceptability to key stakeholders, feasibility, societal resource use, and equity implications of RSV vaccination.

* <https://www.cdc.gov/vaccines/imz-managers/coverage/rsvvaxview/index.html>

vaccines/acip/recs/grade/mrna-rsv-vaccine-older-adults-etr.html and <https://www.cdc.gov/vaccines/acip/recs/grade/protein-subunit-rsv-vaccines-older-adults-etr.html>.

Vaccine Efficacy and Safety

mRNA RSV Vaccine (Moderna mResvia)

In considering recommendations for use of Moderna's mResvia, ACIP reviewed data from two RCTs. A phase 2/3 trial contributed safety and efficacy data from 36,685 immunocompetent participants aged ≥ 60 years who received a single dose of mResvia (50 μ g of mRNA encoding the prefusion RSV F protein) or saline placebo; participants were enrolled on a rolling basis during November 2021–December 2022 (Moderna, mRNA-1345 phase 2/3 clinical trial, unpublished data, 2024) (5). A phase 1 trial contributed additional safety data from 106 participants aged 65–79 years who received either the phase 2/3 trial vaccine formulation or placebo (6).

Vaccine efficacy. In Moderna's primary efficacy analysis (median per participant postvaccination follow-up time = 3.7 months; range = 0.5–12.6 months), efficacy of 1 dose was 78.7% (95% CI = 62.8%–87.9%) in preventing symptomatic, laboratory-confirmed RSV-LRTD with two or more lower respiratory symptoms and 80.9% (95% CI = 50.1%–92.7%) in preventing RSV-LRTD with three or more lower respiratory symptoms^{††} (Table 1) (7). Using all available follow-up time (median = 18.8 months per participant; range = 0.5–24 months), efficacy of mResvia was

47.4% (95% CI = 35.0%–57.4%) against RSV-LRTD with two or more symptoms and 48.4% (95% CI = 27.9%–63.1%) against RSV-LRTD with three or more symptoms (Moderna, mRNA-1345 phase 2/3 clinical trial, unpublished data, 2024) (7).

Efficacy point estimates were higher during the first 12 months after vaccination compared with the subsequent 12 months. The trial was not powered to estimate efficacy against medically attended RSV illness, including hospitalization, or RSV-associated death.

Vaccine safety. Severe reactogenicity events were more common among mResvia recipients than among placebo recipients^{§§} (pooled relative risk = 1.54 [95% CI = 1.40–1.68]); (Supplementary Table, <https://stacks.cdc.gov/view/cdc/159161>) (4). The pooled relative risk for serious adverse events comparing the intervention and control groups was 1.00 (95% CI = 0.95–1.05).^{¶¶} No cases of Guillain-Barré syndrome (GBS), other inflammatory neurologic events, myocarditis, or pericarditis were recorded within 42 days after mResvia vaccination.

Protein Subunit RSV Vaccines (GSK Arexvy and Pfizer Abrysvo)

Vaccine effectiveness. Postlicensure data were reviewed from four observational studies of vaccine effectiveness (VE) of protein subunit RSV vaccination against RSV-associated

^{§§} Relative risk is pooled risk of events across phase 2/3 and phase 1 trials. Severe reactogenicity events were defined as grade 3 or higher solicited local reactions (injection site pain, redness, swelling or induration, and ipsilateral axillary swelling or tenderness) or systemic reactions (fatigue, fever, headache, nausea or vomiting, arthralgia, myalgia, and chills) recorded during days 0–7 after vaccination.

^{¶¶} Relative risk is pooled risk of events across phase 2/3 and phase 1 trials. Serious adverse events were defined as any untoward medical occurrence during all available follow-up time that resulted in death, was life threatening, required inpatient hospitalization or prolongation of existing hospitalization, resulted in persistent disability or incapacity, or was a congenital anomaly or birth defect.

^{††} Lower respiratory symptoms included shortness of breath, cough or fever ($\geq 37.8^{\circ}\text{C}$ [100.0°F]), wheezing, rales, or rhonchi, sputum production, tachypnea, hypoxemia (new oxygen saturation $\leq 93\%$ or new or increasing use of supplemental oxygen), or pleuritic chest pain for at least 24 hours. In case of inability to fully assess other clinical parameters, radiologic evidence of pneumonia with RSV infection confirmed by reverse transcription–polymerase chain reaction (RT-PCR) could also be used to confirm RSV-LRTD.

TABLE 1. Efficacy of 1 dose of Moderna mResvia vaccine against respiratory syncytial virus–associated lower respiratory tract disease among adults aged ≥ 60 years during phase 2/3 pivotal efficacy trial — multiple countries, 2021–2024

Efficacy evaluation period	Vaccine efficacy against outcome, % (95% CI)*	
	RSV-associated LRTD with ≥ 2 symptoms [†]	RSV-associated LRTD with ≥ 3 symptoms [†]
All available follow-up time [§]	47.4 (35.0 to 57.4)	48.4 (27.9 to 63.1)
14 days–4 months postvaccination [¶]	78.7 (62.8 to 87.9)	80.9 (50.1 to 92.7)
14 days–12 months postvaccination	56.1 (42.2 to 66.7)	54.9 (30.5 to 70.7)
12–24 months postvaccination	30.0 (1.1 to 50.7)	36.0 (–12.6 to 64.3)

Abbreviations: LRTD = lower respiratory tract disease; RSV = respiratory syncytial virus; RT-PCR = reverse transcription–polymerase chain reaction; VE = vaccine efficacy.

* Manufacturer-calculated efficacy based on hazard ratios. Includes events ≥ 14 days after injection in Moderna's pivotal phase 2/3 trial. For VE against RSV-LRTD with two or more symptoms through 4 months, 95.04% alpha-adjusted CI was provided; for VE against RSV-LRTD with three or more symptoms through 4 months, 95.10% alpha-adjusted CI was provided. For all other VEs reported in the table, 95% CIs were provided. Estimates are available at <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2024-06-26-28/04-RSV-Adult-Das-508.pdf> or are unpublished data provided by Moderna to ACIP Work Group for RSV in Adults, June 2024.

[†] LRTD symptoms included shortness of breath, cough or fever ($\geq 100.0^{\circ}\text{F}$ [$\geq 37.8^{\circ}\text{C}$]), wheezing or rales or rhonchi, sputum production, tachypnea, hypoxemia (new oxygen saturation $\leq 93\%$ or new or increasing use of supplemental oxygen), or pleuritic chest pain for ≥ 24 hours. In case of inability to fully assess other clinical parameters, radiologic evidence of pneumonia with RT-PCR–confirmed RSV infection could also be used to confirm RSV-associated LRTD.

[§] Median per-participant postvaccination follow-up time considering all available follow-up time through March 8, 2024 = 18.8 months.

[¶] Median per-participant postvaccination follow-up time through November 30, 2022 = 3.7 months; this represents Moderna's primary analysis.

hospitalization among adults aged ≥ 60 years during the first RSV season after vaccination^{***}; estimates from the general population or among immunocompetent adults only ranged from 75% (95% CI = 50%–87%) to 82% (95% CI = 69%–89%) (8). VE was similar across vaccine products (GSK Arexvy and Pfizer Abrysvo) and patient age groups (60–74 years and ≥ 75 years). In addition, effectiveness was demonstrated among adults aged ≥ 60 years with certain immunocompromising conditions^{†††} and those with end-stage renal disease.

Vaccine safety: Guillain-Barré syndrome. Postlicensure safety data were reviewed from an FDA self-controlled case series analysis estimating risk for GBS attributable to protein subunit RSV vaccination among Medicare beneficiaries aged ≥ 65 years (9). The analysis compared GBS incidence during a risk interval (days 1–42 postvaccination) with that during a control interval (days 43–90 postvaccination). Among beneficiaries vaccinated before October 8, 2023, the GBS adjusted incidence rate ratio in the risk interval versus the control interval was 2.30 (95% CI = 0.39–13.72) for GSK's Arexvy and 4.48 (95% CI = 0.88–22.90) for Pfizer's Abrysvo. In this analysis, GBS cases were identified using medical claims data and were not yet confirmed by review of medical records; a final analysis will incorporate medical record review for confirmation of GBS diagnoses and will include additional adults vaccinated later in the 2023–2024 RSV season. Overall, results from this initial analysis did not provide clear, conclusive evidence of an elevated risk for GBS associated with RSV vaccination in older adults, but an elevated risk of GBS could not be ruled out. GBS safety surveillance is ongoing and additional analyses are underway.

Vaccine safety: immune thrombocytopenia. Results of rapid cycle analysis performed by the Vaccine Safety Datalink^{§§§} demonstrated a statistical signal for immune thrombocytopenia (ITP) in a risk interval (days 1–21) after GSK Arexvy vaccination, without simultaneous receipt of another vaccine, compared with a comparison interval (days 22–42)^{¶¶¶} (10). However, medical record

review revealed that onset of most ITP cases occurred before vaccination; onset after vaccination occurred in only four cases identified during the risk interval and one case during the comparison interval. Because of the small number of cases, an association cannot be confirmed between GSK Arexvy vaccination and ITP; supplementary evaluation of identified cases and monitoring for additional cases are ongoing.

Balance of benefits and risks. In a modeling study, estimated public health benefits of protein subunit RSV vaccination were compared with potential GBS risk. Benefits were estimated using observational VE, surveillance data on incidence of RSV-associated outcomes, and RCT evidence of duration of vaccine-conferred protection; risk for GBS was estimated from the FDA self-controlled case series analysis (11). Estimated RSV-associated hospitalizations, intensive care unit admissions, and deaths preventable over two consecutive RSV seasons per 1 million RSV vaccine doses administered exceeded estimated numbers of potential vaccine-attributable GBS cases but varied by age and risk group (Table 2). Study limitations included inability to evaluate all risk factors that might be associated with severe RSV disease, uncertainty in VE beyond 4 months postvaccination, and estimates of GBS risk based on few identified cases.

Recommendations for Use of RSV Vaccines for Prevention of RSV-Associated Disease in Adults Aged ≥ 60 Years

On June 26, 2024, ACIP recommended a single dose of any FDA-approved RSV vaccine for all adults aged ≥ 75 years and for adults aged 60–74 years who are at increased risk for severe RSV disease.^{****} Adults who have previously received RSV vaccine should not receive another dose. Adults aged 60–74 years who are at increased risk include persons with certain chronic medical conditions, persons with moderate or severe immune compromise, and persons living in nursing homes (Box). These recommendations replace the June 2023 shared clinical decision-making recommendation for RSV vaccination for adults aged ≥ 60 years and apply to all RSV vaccines licensed for adults aged ≥ 60 years (i.e., Arexvy [GSK], Abrysvo [Pfizer], or mResvia [Moderna]).

Qualified vaccinators, including pharmacists, nurse practitioners, and other providers (based on state and jurisdictional law) may determine patient eligibility for RSV vaccination based on clinical assessment even in the absence of medical documentation of a named risk condition. Patient attestation

*** VE estimates came from four studies: CDC's VISION Network included separate estimates for those aged ≥ 60 years with and without immune compromise; both CDC's IVY Network and the Veteran's Health Administration included estimates among the general population of adults aged ≥ 60 years, regardless of immune compromise status; Medicare estimates included adults aged ≥ 65 years with end-stage renal disease.

††† Immune compromise was broadly defined. No estimates of VE are currently available specifically among persons with solid organ or hematopoietic stem cell transplant.

§§§ <https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vsd/index.html>

¶¶¶ GSK Arexvy accounted for 87.7% of RSV vaccine doses in the Vaccine Safety Datalink. If present, an association between Pfizer Abrysvo and ITP with a similar effect size might not have been detected because fewer doses were recorded.

**** ACIP passed two unanimous motions (vote = 11–0) recommending that adults aged ≥ 75 years receive a single dose of RSV vaccine and recommending that those aged 60–74 years who are at increased risk for severe RSV disease receive a single dose of RSV vaccine.

TABLE 2. Estimated respiratory syncytial virus–associated outcomes preventable over two consecutive respiratory syncytial virus seasons and potential vaccine-attributable cases of Guillain-Barré syndrome per 1 million protein subunit respiratory syncytial virus vaccine doses administered among adults aged ≥60 years* — United States, 2024

Vaccine product/Recipient age and risk groups	No. of estimated RSV-associated outcomes preventable per 1 million protein subunit RSV vaccine doses administered (range) ^{†,§}			No. of estimated vaccine-attributable GBS cases (range) [¶]
	Hospitalizations	ICU admissions	Deaths	
GSK Arexvy				
≥75 yrs	4,283 (2,235–6,957)	630 (329–1,023)	605 (202–1,263)	3 (0–10) ^{††}
60–74 yrs; ≥1 chronic medical condition**	2,839 (1,478–4,699)	647 (337–1,071)	246 (83–436)	
60–74 yrs; no chronic medical conditions**	456 (247–731)	72 (39–115)	39 (16–71)	
Pfizer Abrysvo				
≥75 years	3,817 (1,927–6,288)	561 (283–924)	539 (190–1,106)	16 (3–29)
60–74 yrs; ≥1 chronic medical condition**	2,530 (1,363–4,224)	577 (311–963)	219 (74–399)	
60–74 yrs; no chronic medical conditions**	406 (219–679)	64 (34–107)	35 (14–63)	

Abbreviations: ACIP = Advisory Committee on Immunization Practices; GBS = Guillain-Barré syndrome; ICU = intensive care unit; RSV = respiratory syncytial virus.

* <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2024-06-26-28/09-RSV-Adult-Hutton-508.pdf>

[†] Preventable outcomes over two RSV seasons were estimated using data from observational studies and clinical trials. Age- and risk-stratified annual incidence of RSV-associated outcomes was from analyses using the RSV Hospitalization Surveillance Network (RSV-NET) and the Behavioral Risk Factor Surveillance System (<https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2024-02-28-29/03-RSV-Adults-Woodruff-508.pdf>). Vaccine effectiveness in preventing outcomes was from CDC's VISION Network during October 1, 2023–March 31, 2024 (<https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2024-06-26-28/07-RSV-Adult-Surie-508.pdf>). Waning of vaccine effectiveness over two seasons was from waning of clinical trial efficacy against RSV-associated lower respiratory tract disease.

[§] Ranges in estimated preventable disease incorporated uncertainty in incidence of RSV-associated outcomes and in vaccine effectiveness, using Monte Carlo simulation.

[¶] Product-specific risk of vaccine-attributable GBS was based on initial results of a Food and Drug Administration self-controlled case series analysis among Medicare beneficiaries aged ≥65 years who received RSV vaccine before October 8, 2023. The analysis compared GBS incidence during a risk interval (days 1–42 postvaccination) with that in a control interval (days 43–90 postvaccination). <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2024-06-26-28/06-RSV-Adult-Lloyd-508.pdf>

** Chronic medical conditions considered in the model included chronic obstructive pulmonary disease, asthma, coronary artery disease, diabetes mellitus, chronic kidney disease, and severe obesity (body mass index ≥40 kg/m²). No chronic medical conditions was defined as absence of at least one of these conditions.

^{††} Self-controlled case series analysis estimated vaccine-attributable risk of three (95% CI = –3 to 10) GBS cases. However, the range was truncated at zero for benefit-risk analyses.

is sufficient evidence of the presence of a risk factor; vaccinators should not deny RSV vaccination to a person because of lack of documentation. These factors should be considered to optimize patient access, including in administrative procedures, such as reimbursement policies for RSV vaccination.

Rationale for Recommendations

The 2023 shared clinical decision-making RSV vaccination recommendation was made in the setting of uncertainty in some portions of the evidence profile. RCTs of both protein subunit vaccines (GSK Arexvy and Pfizer Abrysvo) were underpowered to demonstrate protection against RSV-associated hospitalization or death, and enrolled few participants who were frail or aged ≥75 years. Although both vaccines were well-tolerated and exhibited an acceptable safety profile, a small number of inflammatory neurologic events, including GBS, were observed after RSV vaccination in clinical trials. Because of the small number of GBS cases in the trials, it was unclear whether they represented an association between RSV vaccination and GBS or occurred because of chance alone. Acknowledging these uncertainties, in June 2023 ACIP recommended shared clinical decision-making to encourage providers and patients to consider individual risk of RSV disease (2); however, shared clinical decision-making has drawbacks. Providers find it confusing and time-consuming to implement

(12,13). After one season of RSV vaccine availability, vaccination coverage among adults with chronic medical conditions has been only modestly higher than that among adults without conditions (14). The challenges of shared clinical decision-making, along with the updated evidence on balance of benefits and risks, led ACIP in June 2024 to make an age-based recommendation for adults aged ≥75 years and a risk-based recommendation for those aged 60–74 years. These updated recommendations are intended to maximize RSV vaccination coverage among persons most likely to benefit, by clarifying who is at highest risk and by reducing implementation barriers associated with the previous shared clinical decision-making recommendation (15).

ACIP recognized that a risk-based recommendation for adults aged 60–74 years might result in lower RSV vaccination coverage among persons at increased risk compared with an age-based recommendation for this group (16). However, ACIP judged that postlicensure safety surveillance suggests a potential increased risk for GBS after protein subunit RSV vaccination (GSK Arexvy and Pfizer Abrysvo), and although no GBS signal was observed after Moderna mResvia vaccination in RCTs, postlicensure safety surveillance has yet to occur. Based on currently available evidence, ACIP concluded that the benefits of RSV vaccination did not clearly outweigh the potential harms in adults aged 60–74 years without risk

BOX. Risk factors for severe respiratory syncytial virus disease among adults aged 60–74 years*

- Chronic cardiovascular disease (e.g., heart failure, coronary artery disease, or congenital heart disease [excluding isolated hypertension])
- Chronic lung or respiratory disease (e.g., chronic obstructive pulmonary disease, emphysema, asthma, interstitial lung disease, or cystic fibrosis)
- End-stage renal disease or dependence on hemodialysis or other renal replacement therapy
- Diabetes mellitus complicated by chronic kidney disease, neuropathy, retinopathy, or other end-organ damage, or requiring treatment with insulin or sodium-glucose cotransporter-2 (SGLT2) inhibitor
- Neurologic or neuromuscular conditions causing impaired airway clearance or respiratory muscle weakness (e.g., poststroke dysphagia, amyotrophic lateral sclerosis, or muscular dystrophy [excluding history of stroke without impaired airway clearance])
- Chronic liver disease (e.g., cirrhosis)
- Chronic hematologic conditions (e.g., sickle cell disease or thalassemia)
- Severe obesity (body mass index ≥ 40 kg/m²)
- Moderate or severe immune compromise[†]
- Residence in a nursing home
- Other chronic medical conditions or risk factors that a health care provider determines would increase the risk for severe disease due to viral respiratory infection (e.g., frailty,[§] situations in which health care providers have concern for presence of undiagnosed chronic medical conditions, or residence in a remote or rural community where transportation of patients with severe RSV disease for escalation of medical care is challenging[¶])

Abbreviation: RSV = respiratory syncytial virus.

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

[†] A list of moderately or severely immunocompromising conditions can be found in the COVID-19 vaccination interim clinical considerations. <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#immunocompromised>

[§] Frailty is a multidimensional geriatric syndrome that reflects a state of increased vulnerability to adverse health outcomes. Although no consensus definition exists, one frequently used tool for determination is the Fried frailty phenotype assessment (<https://pubmed.ncbi.nlm.nih.gov/11253156/>) in which frailty is defined as a clinical syndrome with three or more of the following symptoms present: unintentional weight loss (10 lbs [4.5 kg] in the past year), self-reported exhaustion, weakness (grip strength), slow walking speed, or low physical activity.

[¶] Health care providers caring for adults aged 60–74 years residing in these communities may use clinical judgement, knowledge of local RSV epidemiology, and community incidence of RSV-associated hospitalization to recommend vaccination for a broader population in this age group.

factors for severe RSV disease. However, ACIP also stressed that research regarding RSV risk factors is ongoing, so providers should continue to have flexibility in offering RSV vaccine to patients they assess to be at increased risk for severe disease even if they do not fall into an explicitly named risk category. As with all vaccines, patients should be informed of the benefits and risks of RSV vaccination (17); for protein subunit RSV vaccines, this information includes potential risk for GBS.

Clinical Guidance

Administration of RSV vaccine with other adult vaccines during the same visit is acceptable. Additional information regarding coadministration and regarding contraindications and precautions is available at <https://www.cdc.gov/vaccines/vpd/rsv/hcp/older-adults.html>.

Timing of RSV Vaccination

Eligible adults are currently recommended to receive a single dose of RSV vaccine; adults who have already received RSV

vaccination should not receive another dose. A single dose provides protection for at least two RSV seasons. The need for additional RSV vaccine doses will be evaluated by ACIP in the future; ACIP will update recommendations as needed.

Eligible adults who have not previously received RSV vaccination may be vaccinated at any time of year, but vaccination will have the most benefit if administered in late summer or early fall, just before the RSV season. In most of the continental United States, this corresponds to vaccination during August–October.

Reporting of Vaccine Adverse Events

Adverse events after vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS). Reporting of any clinically significant adverse event is encouraged, even if it is uncertain whether the vaccine caused the event. Information on how to submit a report to VAERS is available at <https://vaers.hhs.gov/index.html> or by telephone at 1-800-822-7967.

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

On June 21, 2023, the Advisory Committee on Immunization Practices (ACIP) recommended that adults aged ≥ 60 years may receive a single dose of respiratory syncytial virus (RSV) vaccine, using shared clinical decision-making.

What is added by this report?

On June 26, 2024, ACIP voted to update these recommendations as follows: all adults aged ≥ 75 years and adults aged 60–74 years who are at increased risk for severe RSV disease should receive a single dose of RSV vaccine.

What are the implications for public health practice?

These updated recommendations are intended to maximize RSV vaccination coverage among persons most likely to benefit. Continued postlicensure monitoring will guide future recommendations.

Future RSV Vaccine Policy for Adults

On June 7, 2024, FDA approved use of GSK's Arexvy in adults aged 50–59 years who are at increased risk for RSV-LRTD (18). As of June 2024, ACIP judged that insufficient evidence was available to inform a vote on RSV vaccination policy in adults aged 50–59 years who are at increased risk for RSV disease. Before voting on a recommendation in this age group, ACIP expressed that the following items are needed: updated RSV vaccine safety analyses among adults aged ≥ 60 years, including results from the full 2023–2024 RSV season in the FDA analysis incorporating chart confirmation of GBS diagnoses; additional data on duration of protection from RSV vaccination and immune response after revaccination; and immunogenicity data in adults with immunocompromise. ACIP will review evidence and vote on RSV vaccination policy in this age group when additional data are available.

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References

- McLaughlin JM, Khan F, Begier E, Swerdlow DL, Jodar L, Falsey AR. Rates of medically attended RSV among US adults: a systematic review and meta-analysis. *Open Forum Infect Dis* 2022;9:ofac300. PMID:35873302 <https://doi.org/10.1093/ofid/ofac300>
- Melgar M, Britton A, Roper LE, et al. Use of respiratory syncytial virus vaccines in older adults: recommendations of the Advisory Committee on Immunization Practices—United States, 2023. *MMWR Morb Mortal Wkly Rep* 2023;72:793–801. PMID:37471262 <https://doi.org/10.15585/mmwr.mm7229a4>
- Food and Drug Administration. MRESVIA [Approval letter]. Silver Spring, MD: US Department of Health and Human Services, Food and Drug Administration; 2024. <https://www.fda.gov/media/179015/download?attachment>
- Food and Drug Administration. MRESVIA [Package insert]. Silver Spring, MD: US Department of Health and Human Services; 2024. <https://www.fda.gov/media/179005/download>
- Wilson E, Goswami J, Baqui AH, et al.; ConquerRSV Study Group. Efficacy and safety of an mRNA-based RSV PreF vaccine in older adults. *N Engl J Med* 2023;389:2233–44. PMID:38091530 <https://doi.org/10.1056/NEJMoa2307079>
- Shaw CA, Essink B, Harper C, et al. Safety and immunogenicity of an mRNA-based RSV vaccine including a 12-month booster in a phase I clinical trial in healthy older adults. *J Infect Dis* 2024;jiae081. PMID:38385566 <https://doi.org/10.1093/infdis/jiae081>
- Das R. Update on Moderna's RSV vaccine, mRESVIA (mRNA-1345), in adults ≥ 60 years of age [Presentation slides]. Presented at the Advisory Committee on Immunization Practices meeting, Atlanta, GA; June 26, 2024. <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2024-06-26-28/04-RSV-Adult-Das-508.pdf>

8. Surie D. Effectiveness of adult respiratory syncytial virus (RSV) vaccines, 2023–2024 [Presentation slides]. Presented at the Advisory Committee on Immunization Practices meeting, Atlanta, GA; June 26, 2024. <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2024-06-26-28/07-RSV-Adult-Surie-508.pdf>
9. Lloyd P. Evaluation of Guillain-Barre syndrome (GBS) following RSV vaccination among adults 65 years and older [Presentation slides]. Presented at the Advisory Committee on Immunization Practices meeting, Atlanta, GA; June 26, 2024. <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2024-06-26-28/06-RSV-Adult-Lloyd-508.pdf>
10. Donahue J. Update: rapid cycle analysis of RSV vaccines in older adults [Presentation slides]. Presented at the Advisory Committee on Immunization Practices meeting, Atlanta, GA; June 26, 2024. <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2024-06-26-28/05-RSV-Adult-Donahue-508.pdf>
11. Hutton D. Risk-benefit analysis of RSV vaccination in older adults [Presentation slides]. Presented at the Advisory Committee on Immunization Practices meeting, Atlanta, GA; June 26, 2024. <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2024-06-26-28/09-RSV-Adult-Hutton-508.pdf>
12. Kempe A, Lindley MC, O’Leary ST, et al. Shared clinical decision-making recommendations for adult immunization: what do physicians think? *J Gen Intern Med* 2021;36:2283–91. PMID:33528783 <https://doi.org/10.1007/s11606-020-06456-z>
13. Black C. RSV vaccination implementation update [Presentation slides]. Presented at the Advisory Committee on Immunization Practices meeting, Atlanta, GA; February 29, 2024. <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2024-02-28-29/04-RSV-Adults-Black-508.pdf>
14. Black CL, Kriss JL, Razzaghi H, et al. Influenza, updated COVID-19, and respiratory syncytial virus vaccination coverage among adults—United States, fall 2023. *MMWR Morb Mortal Wkly Rep* 2023;72:1377–82. PMID:38127675 <https://doi.org/10.15585/mmwr.mm7251a4>
15. Melgar M, Britton A, Roper LE. Evidence to recommendations framework (EtR): RSV vaccination in adults aged 50–59 years, 60–74 years, and 75 years and older [Presentation slides]. Presented at the Advisory Committee on Immunization Practices meeting, Atlanta, GA; June 26, 2024. <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2024-06-26-28/11-RSV-Adult-Melgar-Roper-Britton-508.pdf>
16. Weng MK, Doshani M, Khan MA, et al. Universal hepatitis B vaccination in adults aged 19–59 years: updated recommendations of the Advisory Committee on Immunization Practices—United States, 2022. *MMWR Morb Mortal Wkly Rep* 2022;71:477–83. PMID:35358162 <https://doi.org/10.15585/mmwr.mm7113a1>
17. Kroger A, Bahta L, Long S, Sanchez P. General best practice guidelines for immunization. 2023; <https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html>
18. Food and Drug Administration. AREVY [Package insert]. Silver Spring, MD: U.S. Department of Health and Human Services, Food and Drug Administration; 2024. <https://www.fda.gov/media/167805/download>