### About Respiratory Syncytial Virus (RSV)

<table>
<thead>
<tr>
<th><strong>Common respiratory virus</strong></th>
<th><strong>Causes mild, cold-like symptoms</strong></th>
<th><strong>Seasonal epidemics</strong></th>
<th><strong>Spread through respiratory droplets, direct contact, fomites</strong></th>
</tr>
</thead>
</table>

**Respiratory Syncytial Virus Infection (RSV)**
Clinical Presentation in Adults

- Usually **mild or no symptoms**
- Older adults are at **increased risk** for becoming **seriously ill**
- This includes:
  - Lower respiratory tract infection
  - Exacerbation of existing conditions
Annual RSV Burden Among Adults Ages 65 Years and Older

- 900,000–1,400,000 medical encounters
- 60,000–160,000 hospitalizations
- 6,000–10,000 deaths
Chronic Underlying Medical Conditions Associated with Increased Risk of Severe RSV Disease

- Lung disease
- Cardiovascular disease
- Moderate or severe immune compromise
- Diabetes Mellitus
- Neurologic or neuromuscular conditions
- Kidney disorders
- Liver disorders
- Hematologic disorders

Other conditions that might increase the risk for severe disease
Other Factors Associated with Increased Risk of Severe RSV Disease

- Residence in a nursing home or other long-term care facility (LTCF)
- Frailty
- Advanced age
RSV Vaccines

Efficacy and safety
In June 2023, CDC’s Advisory Committee on Immunization Practices (ACIP) recommended the first two RSV vaccines for older adults.

- **RSVPreF3** *(Arexvy, GSK)* is a 1-dose adjuvanted (ASo1E) recombinant prefusion F protein (preF) vaccine.

- **RSVpreF** *(Abrysvo, Pfizer)* is a 1-dose recombinant preF vaccine.
Vaccine Efficacy (VE): GSK

- Randomized, double-blinded, placebo-controlled phase 3 clinical trial
  - 17 countries
  - 24,973 participants

- VE against RSV-associated lower respiratory tract disease (LRTD):
  - Season 1: 82.6%
  - Season 2: 56.1%
  - Combined Season 1 & 2 (Interim): 74.5%
Vaccine Efficacy (VE): Pfizer

- Randomized, double-blinded, placebo-controlled phase 3 clinical trial
  - 7 countries
  - 36,862 participants
- VE against RSV-associated lower respiratory tract disease (LRTD)*:
  - Season 1: 88.9%
  - Season 2 (Interim): 78.6%
  - Combined Season 1 & 2 (Interim): 84.4%

*Based on trial efficacy against RSV LRTI with at least three lower respiratory signs/symptoms

Use of Respiratory Syncytial Virus Vaccines in Older Adults: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023
Vaccine Efficacy (VE)

- Pfizer’s RSVpreF and GSK’s adjuvanted RSVPreF3 vaccines both have demonstrated significant efficacy against lower respiratory tract illness caused by RSV among older adults over at least two seasons
  - Trials were underpowered to show efficacy in the oldest adults and in adults who are frail
  - Trials were underpowered to show efficacy against RSV hospitalization
    - Efficacy against symptomatic illness may indicate efficacy against more severe disease
- RSV vaccination has the potential to prevent considerable morbidity from RSV disease among older adults, particularly in those with chronic medical conditions and those who are frail (e.g., long-term care facility residents)

Vaccine Safety: GSK & Pfizer

- Generally **well-tolerated** with an acceptable safety profile

- Most common side effects **are similar to those of other vaccines**

- Pain at injection site
- Fatigue
- Headache
- Muscle pain
- Joint pain
Vaccine Safety: GSK & Pfizer

- Six cases of **inflammatory neurologic events** reported in clinical trials.

- It is **unknown** at this time whether these events occurred by chance, or whether RSV vaccination increases the risk of these events.

- Imbalance in the small number of **atrial fibrillation events**; more cases among vaccine recipients, compared with placebo recipients.
Vaccine Safety

- CDC will monitor adverse events following RSV vaccination through VAERS and the Vaccine Safety Datalink.

- Per FDA requirements, both manufacturers will conduct further studies.

- Report any adverse event after RSV vaccination to the Vaccine Adverse Event Reporting System.
Recommendations and Clinical Considerations
RSV Vaccination Recommendations

- ACIP and CDC recommend that adults ages 60 years and older may receive a **single dose** of RSV vaccine using **shared clinical decision making**.
Shared clinical decision-making

- There is no default decision to vaccinate.
- Recommendations are individually based and informed by a decision process between the health care provider and patient.

- Best available evidence
- Patients’ risk for disease, characteristics, values, preferences
- Clinical discretion
- Characteristics of the vaccine
Chronic Underlying Medical Conditions Associated with Increased Risk of Severe RSV Disease

<table>
<thead>
<tr>
<th>Lung disease</th>
<th>Neurologic or neuromuscular conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiovascular disease</td>
<td>Kidney disorders</td>
</tr>
<tr>
<td>Moderate or severe immune compromise</td>
<td>Liver disorders</td>
</tr>
<tr>
<td>Diabetes Mellitus</td>
<td>Hematologic disorders</td>
</tr>
</tbody>
</table>

Other conditions that might increase the risk for severe disease

Use of Respiratory Syncytial Virus Vaccines in Older Adults: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023
Other Factors Associated with Increased Risk of Severe RSV Disease

- Residence in a nursing home or other long-term care facility (LTCF)
- Frailty
- Advanced age
Other Factors Associated with Increased Risk of Severe RSV Disease

- Advanced age
- Residence in a nursing home or other long-term care facility (LTCF)
- Frailty

RSV incidence increases with advancing age.
**Vaccination Timing: 2023-2024 Season**

**Summer:**
Offer RSV vaccination as early as vaccine is available

[https://www.cdc.gov/mmwr/volumes/72/wr/mm7229a4.htm](https://www.cdc.gov/mmwr/volumes/72/wr/mm7229a4.htm)
Vaccination Timing: 2023-2024 Season

**Summer:**
Offer RSV vaccination as early as vaccine is available

Continue to offer vaccination throughout the RSV season to eligible adults who remain unvaccinated

[https://www.cdc.gov/mmwr/volumes/72/wr/mm7229a4.htm](https://www.cdc.gov/mmwr/volumes/72/wr/mm7229a4.htm)
Coadministration

- Coadministration with all other adult vaccines is acceptable.

- If vaccines are NOT administered the same day, there is no required interval between vaccines.
Data on immunogenicity of coadministration of RSV vaccines with other vaccines

- There are currently limited data available on immunogenicity of coadministration of RSV vaccines and other vaccines.
- In general, coadministration of RSV and seasonal influenza vaccines met non-inferiority criteria for immunogenicity.*
- However, RSV and influenza antibody titers were generally somewhat lower with coadministration; the clinical significance of this is unknown.
- Additional studies on immunogenicity of coadministration of RSV with other adult vaccines are in process.

* Pre-specified non-inferiority criteria for immune responses were met across trials, with the exception of the FluA/Darwin H3N2 strain after simultaneous administration of RSVPreF3 vaccine (Arexvy by GSK) and adjuvanted quadrivalent inactivated influenza vaccine.
Considerations for Coadministration

- Whether the patient is **up to date** with currently recommended vaccines
- Likelihood of **returning**
- Risk for acquiring **vaccine-preventable disease**
- Vaccine **reactogenicity** profiles
- Patient **preferences**

https://www.cdc.gov/mmwr/volumes/72/wr/mm7229a4.htm
RSV can cause serious illness in older adults.

Underlying medical conditions and other factors are associated with increased risk of severe RSV.

Two RSV vaccines are licensed.

Adults ages 60 years and older may receive a single dose of RSV vaccine, using shared clinical decision-making.

Coadministration with RSV and other adult vaccines is acceptable.
Older adult RSV vaccine resources

- RSV Vaccination: What Older Adults 60 Years of Age and Over Should Know
- Frequently Asked Questions About RSV Vaccine for Adults
- Healthcare Providers: RSV Vaccination for Adults 60 Years of Age and Over
- RSV Vaccine Fact Sheet for Healthcare Providers
- ACIP Shared Clinical Decision-Making Recommendations
Acknowledgements

Amadea Britton
Lauren Roper
Hannah Rosenblum
Melinda Wharton
Tara Anderson
Lisa Grohskopf
David Shay
Tom Shimabukuro
Karen Broder
Mila Prill
Anne Hause
Fiona Havers
Diya Surie
Jennifer DeCuir
Meredith McMorrow
Jefferson Jones
Katherine Fleming-Dutra
Ruth Link-Gelles
Andrew Kroger
Elisha Hall
Manisha Patel
Sarah Meyer
Neil Murthy
Patricia Wodi
Sara Oliver
Kara Jacobs Slifka
Nimalie Stone
Theresa Rowe
Jeneita Bell
Melissa Schaefer

For more information, contact CDC
1-800-CDC-INFO (232-4636)

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

Photographs and images included in this presentation are licensed solely for CDC/NCIRD online and presentation use. No rights are implied or extended for use in printing or any use by other CDC CIOs or any external audiences.