ACIP Adult RSV Work Group Clinical Considerations

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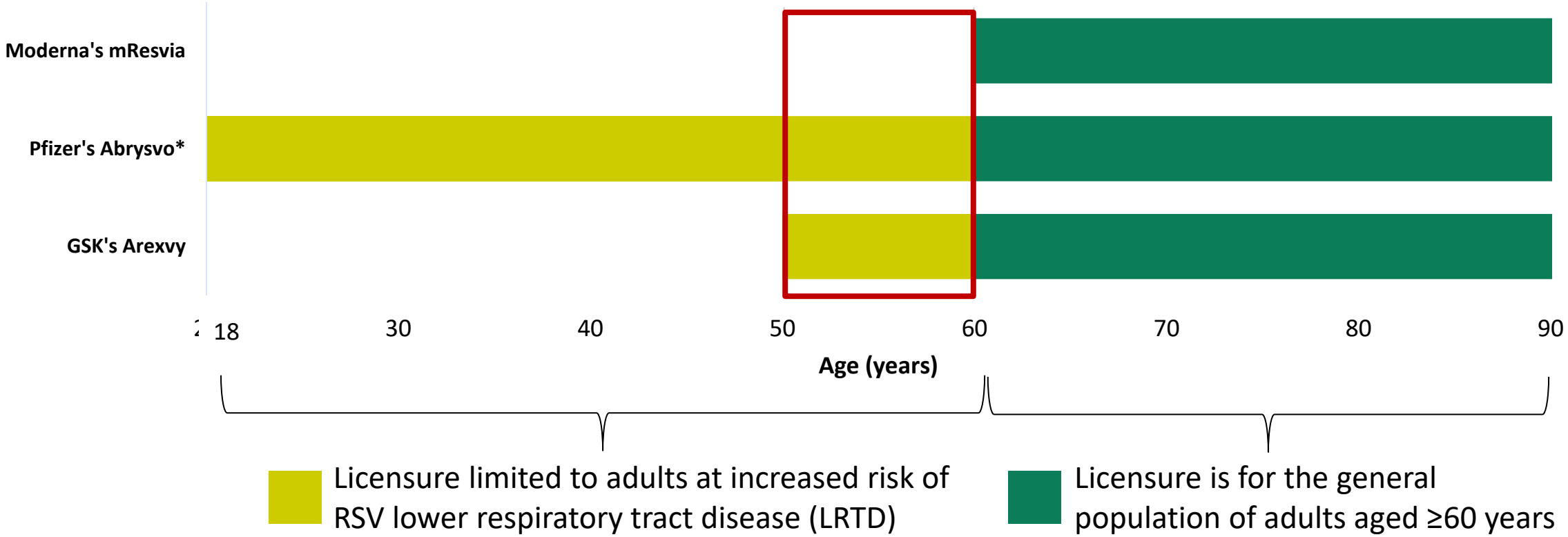
Overview

- Licensed products for use in adults aged 50–59 years at increased risk of severe RSV disease
- Adults aged 50–59 years at increased risk of severe RSV disease
- Timing of RSV vaccination for the 2025–2026 RSV season
- Coadministration of RSV vaccines with other vaccines

RSV vaccine FDA licensure for RSV prevention in adults, as of April 16, 2025



***Pfizer's Abrysvo is also licensed and recommended for use in pregnancy to prevent RSV LRTD in infants after birth. No other RSV vaccine should be administered in pregnancy.**

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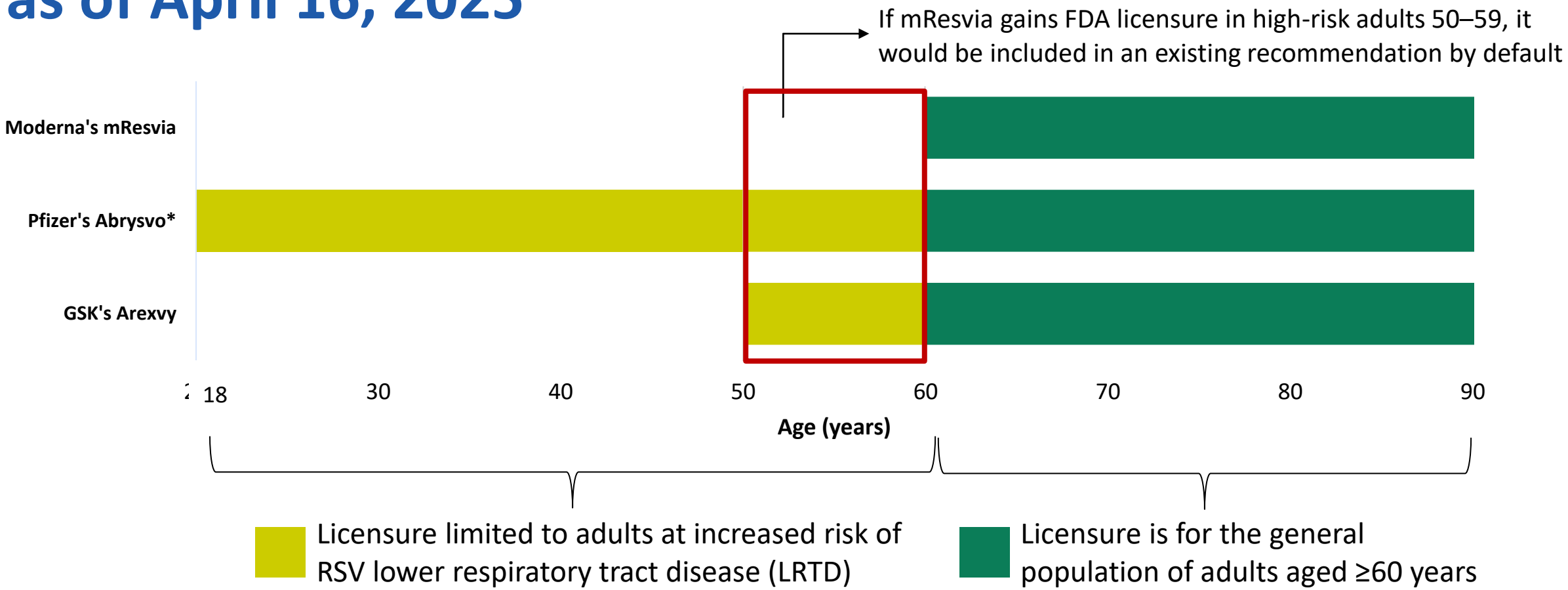

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Adults aged 50–59 years at increased risk of severe RSV disease

Proposed list of risk factors for the 50–59 recommendation is the same as that currently used for the 60–74 recommendation

Chronic cardiovascular disease

Chronic lung or respiratory disease

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

Severe obesity
(body mass index ≥40 kg/m^2)

End stage renal disease/dialysis dependence

Chronic hematologic conditions

Chronic liver disease

Neurological or neuromuscular conditions
causing impaired airway clearance or respiratory muscle weakness

Residence in a nursing home

Moderate or severe immunocompromise

Other chronic medical conditions or risk factors that a provider determines would increase risk of severe disease due to viral respiratory infection (e.g., frailty)

Britton A, Roper LE, Kotton CN, et al. Use of Respiratory Syncytial Virus Vaccines in Adults Aged ≥60 Years: Updated Recommendations of the Advisory Committee on Immunization Practices — United States, 2024. MMWR Morb Mortal Wkly Rep 2024;73:696-702. DOI: http://dx.doi.org/10.15585/mmwr.mm7332e1.

Current RSV vaccine flyer for healthcare providers will be updated with any new recommendation

Includes information on risk of Guillain-Barré syndrome **for the two subunit vaccines** (GSK's Arexvy, Pfizer's Abrysvo)

https://www.cdc.gov/rsv/media/pdfs/2025/01/355818-A_RSV_VaccineForOlderAdultsFlyer-01072025-V9-WEB.pdf

RSV Vaccines for Older Adults

CDC recommends RSV vaccination for:

- All adults ages 75 years and older
- Adults ages 60–74 who are at increased risk for severe RSV (see list below)

Adults who have already received one RSV vaccine dose (including last year) **should not receive** another dose at this time. RSV vaccine is not currently an annual vaccine.

Factors associated with increased risk* for severe RSV disease include:

- **Chronic lung disease**
- **Chronic cardiovascular disease**
- **End-stage renal disease or dependence on dialysis**
- **Diabetes mellitus with end-organ damage or requiring insulin or SGLT2 inhibitor**
- **Moderate or severe immunocompromise**
- **Chronic or progressive neurological or neuromuscular conditions**

Other factors include:

- **Chronic liver disease**
- **Chronic hematologic conditions**
- **Severe obesity (BMI ≥40 kg/m²)**
- **Residence in a nursing home**
- **Other conditions or factors that put your patient at increased RSV disease risk**

*Self-attestation is sufficient evidence of a risk factor.

What else to know about RSV vaccines for older adults:

Benefits: Vaccination reduces a person's risk of RSV hospitalization by 75%.

Risks: Side effects are usually mild and resolve quickly. GSK and Pfizer RSV vaccines have been linked to a higher risk of Guillain-Barré Syndrome (GBS), but GBS after RSV vaccine is still rare, with about 10 extra cases per 1 million older adults vaccinated.

Benefits of RSV vaccine outweigh risks. For every 1 million people vaccinated, CDC estimates:

- 4,000-6,000 RSV hospitalizations are prevented
- 300-800 RSV deaths are prevented

For additional Information, scan here:

CDC

CS 355818-A 12/20/2024

Guidance on the timing of RSV vaccination is unchanged

RSV vaccination will have the most benefit if given in late summer or early fall.

- This means from **August to October in most of the United States.**
- Note this is not a formal seasonal recommendation for RSV vaccination. Eligible adults may continue to receive RSV vaccination year-round.

Adults who have already received a dose of RSV vaccine should NOT receive another dose at this time.

- RSV vaccination should be given ONLY to adults who have not yet received a dose of RSV vaccine.
- It is anticipated that adults may need additional doses of RSV vaccine in the future, but ideal revaccination timing is not yet known.

Co-administration of RSV vaccines with other adult vaccines

ACIP previously reviewed results from studies on co-administration of RSV vaccine with influenza and mRNA COVID-19 vaccines

- With two exceptions,[1,2] pre-specified non-inferiority criteria were met for simultaneous vaccination, compared with separate administration.
- The Work Group notes our limited understanding of clinical significance of decreased antibody titers with RSV vaccine co-administration.

1. Simultaneous administration of GSK's Arexvy with adjuvanted influenza vaccine resulted in lower H3N2 hemagglutination inhibition (HAI) titers, compared with sequential administration. Humoral immune response against influenza A/Darwin H3N2 was also assessed post-hoc via microneutralization, which resulted in a geometric mean titer (GMT) ratio similar to the HAI GMT ratio, with a slightly narrower confidence interval. Non-inferiority criteria were not specified for post-hoc analyses. Reference: Clark R, et al. Safety and Immunogenicity of Respiratory Syncytial Virus Prefusion F Protein Vaccine when Co-administered with Adjuvanted Seasonal Quadrivalent Influenza Vaccine in Older Adults: A Phase 3 Randomized Trial. Clin Infect Dis. 2024 Oct 15;79(4):1088-1098. https://pubmed.ncbi.nlm.nih.gov/39099085/
2. Simultaneous administration of Moderna's mResvia with high-dose influenza vaccine resulted in lower RSV-A and RSV-B neutralizing antibody titers, compared with RSV vaccination alone. Reference: https://www.cdc.gov/acip/downloads/slides-2024-10-23-24/02-RSV-Adult-Das-508.pdf

GSK provided results of a co-administration study with Arexvy and recombinant zoster vaccine (Shingrix)

- Both vaccines include the same adjuvant system (AS01); adjuvant dose in Shingrix is twice the dose in Arexvy.

- 530 immunocompetent participants aged ≥50 years were randomized 1:1 to receive either sequential (control group) or simultaneous (intervention group) vaccination with Arexvy and dose one of Shingrix, followed by completion of the Shingrix two-dose series.

Reference: Dennis P, et al. Co-administration of the adjuvanted respiratory syncytial virus (RSV) prefusion F protein vaccine (RSVPreF3 OA) with the adjuvanted recombinant zoster vaccine (RZV) in adults ≥50 years of age. 20th EuGMS Congress. 2024 Sep 18-20; Valencia, Spain.

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- Immunogenicity non-inferiority criteria were met (upper limit of 2-sided 95% CI ≤1.5 for GMT [RSV-A or RSV-B neutralization] or GMC [anti-gE] ratio; ratio calculated as separate administration/simultaneous administration)
  - One month after Arexvy administration, GMT ratio:
    - RSV-A neutralizing antibodies: 1.14 (95% CI: 0.97, 1.35)
    - RSV-B neutralizing antibodies: 0.98 (95% CI: 0.84, 1.15)
  - One month after dose two of Shingrix, GMC ratio:
    - Anti-gE antibodies: 1.24 (95% CI: 1.08, 1.42)

CI: confidence interval, GMT: geometric mean titer, GMC: geometric mean concentration

Reference: Dennis P, et al. Co-administration of the adjuvanted respiratory syncytial virus (RSV) prefusion F protein vaccine (RSVPreF3 OA) with the adjuvanted recombinant zoster vaccine (RZV) in adults ≥50 years of age. Presented at 20th EuGMS Congress. 2024 Sep 18-20; Valencia, Spain.

GSK provided results of a co-administration study with Arexvy and recombinant zoster vaccine (Shingrix)

- No specific safety concerns identified
- Reactogenicity of simultaneous administration overall greater than that of Arexvy given alone, but more similar to that of Shingrix given alone
- Serious adverse events: 4.9% in simultaneous administration group vs. 2.3% in the sequential administration group, but no clustered imbalance in any specific organ system or type of adverse event
- No cases of Guillain-Barré syndrome (GBS) or acute disseminated encephalomyelitis (ADEM)*

*With total enrollment of 530 participants, this trial was underpowered to detect rare adverse events.

Reference: Dennis P, et al. Co-administration of the adjuvanted respiratory syncytial virus (RSV) prefusion F protein vaccine (RSVPreF3 OA) with the adjuvanted recombinant zoster vaccine (RZV) in adults ≥50 years of age. 20th EuGMS Congress. 2024 Sep 18-20; Valencia, Spain.

Work Group interpretations of co-administration data

- Co-administration of RSV vaccines and other recommended adult vaccines is common.
- Given the considerable benefits of co-administration and the evidence of safety of co-administration, the Work Group continues to feel co-administration is **acceptable**.[1]
- In addition, the Work Group looks forward to learning more about an analysis by Moderna on immunologic correlates of protection for RSV when peer-reviewed publication is available.

1. This language is different from CDC's General Best Practices Guidelines for Immunization, which states that with limited exception, routine administration of all age-appropriate doses of vaccines simultaneously is recommended for persons for whom no specific contraindications exist at the time of the visit.

Kroger A, Bahta L, Long S, Sanchez P. General Best Practice Guidelines for Immunization. Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP). https://www.cdc.gov/vaccines/hcp/imz-best-practices/. Updated July 22, 2024; accessed October 22, 2024

When deciding whether to co-administer other vaccines with an RSV vaccine, providers may consider:

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

Acknowledgements

- Adult RSV Vaccine Work Group
- CDC Coronavirus and Other Respiratory Viruses Division
- CDC Immunization Services Division

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov