RSV Vaccination in Adults: Introduction

Albert Shaw, MD, PhD
Chair, Adult RSV Work Group
Advisory Committee on Immunization Practices
April 16, 2025

Adult RSV Work Group Membership

ACIP Voting Members
Albert Shaw (Chair)
Helen Chu
Mini Kamboj
Keipp Talbot

Ex Officio Members
Nicholas Geagan (FDA)
Rachel Zhang (FDA)
Michelle Juaneza (HRSA)
Uzo Chukwuma (IHS)
Sonnie Kim (NIH/NIAID)

CDC Co-Leads
Amadea Britton
Michael Melgar
Diya Surie

Liaisons
Bindy Crouch (AIM)
April Killikelly (NACI, PHAC)
Gretchen LaSalle (AAFP)
Ruth Lynfield (NFID)
Steven Pergam (IDSA)
Kenneth Schmader (AGS)
Winnie Siu (NACI, PHAC)
Elizabeth Skoy (APhA)
Vidya Sundareshan (ACP)
Katherine Williams (APTR)

Consultants
Robert Atmar (Baylor College of Medicine)
Peter Donofrio (Vanderbilt University)
Marie Griffin (Vanderbilt University)
Camille Kotton (Massachusetts General Hospital)
Cynthia Lucero (Veterans Health Administration)
Tracy Ruckwardt (NIH/NIAID)
Jonathan Temte (University of Wisconsin)

CDC Contributors

Coronavirus and Other Respiratory Viruses Division

Melissa Coughlin
Fatima Dawood
Jarrett Gartin
Monica Godfrey
Fiona Havers
Suzanne Heitfield
Michele Hlavsa
Jefferson Jones
Ruth Link-Gelles
Amber Kautz
Agustin Lopez
Josephine Mak
Meredith McMorrow
Noelle-Angelique Molinari
Danielle Moulia
Ismael Ortega-Sanchez
Lakshmi Panagiotakopoulos
Pragna Patel
Monica Patton
Amanda Payne
Mila Prill
Lauren Roper
Melisa Shah
Natalie Thornburg
Dennis Wang
Trang Wisard

Immunization Safety Office

Tarayn Fairlie
Julianne Gee
Anne Hause
Sarah Meyer
Michael McNeil
Pedro Moro
Christine Olson
David Shay
John Su
Evelyn Twentyman
Eric Weintraub

Influenza Division

Jill Ferdinands
Lisa Grohskopf

Immunization Services Division

Carla Black
Kayla Calhoun
Nicole Dowling
Jennifer Kriss
Andrew Leidner
Jamison Pike

NCIRD Office of the Director

Jessica MacNeil
Hannah Rosenblum
Melinda Wharton

June 2024 ACIP Recommendations for RSV Vaccination in Older Adults:

ACIP recommends all adults aged ≥75 years and adults aged 60–74 years who are at increased risk of severe RSV disease receive a single dose of RSV vaccine.[1,2]

1. Recommendation is for any Food and Drug Administration–approved RSV vaccine (Arexvy [GSK]; Abrysvo [Pfizer]; or mResvia [Moderna]). There is no product preference.
2. 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.

Chronic medical conditions and other risk factors associated with increased risk of severe RSV disease

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 FDA-approved RSV vaccines

- **Protein subunit (based on RSV F protein in prefusion conformation)**
  - **GSK Arexvy**[1]: monovalent RSV-A, $AS01_E$ adjuvant
  - **Pfizer Abrysvo**[2]: bivalent RSV-A/RSV-B, no adjuvant

- **Messenger RNA (mRNA, encoding RSV F protein in prefusion conformation)**
  - **Moderna mResvia**[3]: monovalent RSV-A, no adjuvant

1. https://www.fda.gov/media/167805/download
2. https://www.fda.gov/media/168889/download
3. https://www.fda.gov/media/179005/download

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Approved for prevention of lower respiratory tract disease (LRTD) caused by RSV in **adults aged ≥60 years**

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Approved for prevention of LRTD caused by RSV in **adults aged 50–59 years who are at increased risk for LRTD caused by RSV***

*There is no current ACIP recommendation for RSV vaccination in adults aged <60 years, **except** for the maternal vaccination recommendation: https://www.cdc.gov/mmwr/volumes/72/wr/mm7241e1.htm

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→ Approved for prevention of LRTD caused by RSV in **adults aged 18–59 years who are at increased risk of LRTD caused by RSV***

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Also approved and recommended for active immunization in **pregnancy*** at 32–36 weeks gestational age for the prevention of LRTD and severe LRTD caused by RSV in infants from birth through 6 months of age.

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- **mRNA**
  - **Moderna mResvia**[3]: monovalent RSV-A, no adjuvant → Moderna has submitted an application for licensure for adults aged 18–59 years who are at increased risk of LRTD caused by RSV. PDUFA date June 12th, 2025.[4]

PDUFA: Prescription Drug User Fee Act

1. https://www.fda.gov/media/167805/download
2. https://www.fda.gov/media/168889/download
3. https://www.fda.gov/media/179005/download
4. https://investors.modernatx.com/news/news-details/2025/Moderna-Reports-Fourth-Quarter-and-Fiscal-Year-2024-Financial-Results-and-Provides-Business-Updates/default.aspx

Today's meeting

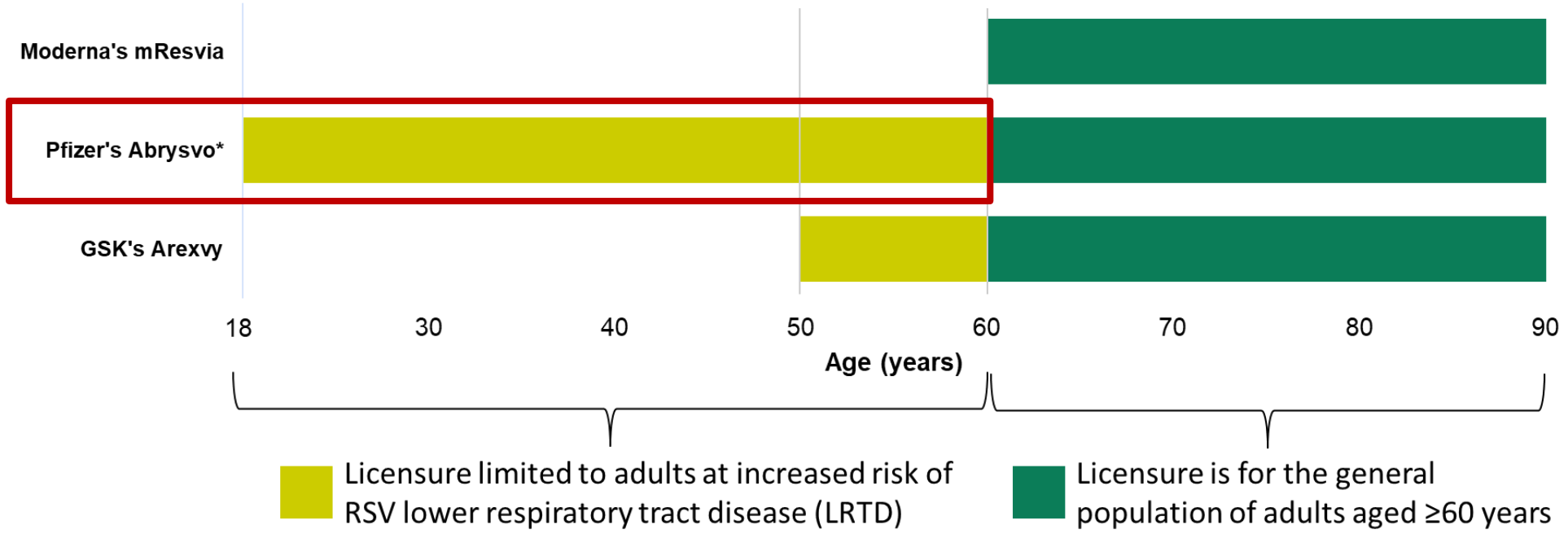
- Adult RSV Work Group will propose a policy recommendation for age expansion of the use of RSV vaccines to include adults aged 50-59 years at increased risk of severe RSV disease.

- Immunobridging and safety data in adults aged 50-59 years at increased risk of severe RSV disease were previously presented to ACIP by GSK and Pfizer; today Moderna will present immunobridging and safety data in adults aged 18-59 years at increased risk.

- ACIP will also see presentations from manufacturers on immunogenicity and safety of re-vaccination and economic analyses of RSV vaccination in adults aged 50-59 years at increased risk.

- Then we will share the complete Evidence to Recommendation framework and propose a policy recommendation for an ACIP vote.

Acknowledging there is also one FDA-approved vaccine for RSV prevention in adults aged <50 years, the Work Group continues to evaluate recommendations for RSV vaccination in this age group



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

Policy for the use of RSV vaccines in adults aged <50 years will be revisited at the June 2025 meeting.

- The Work Group recognizes that certain adults aged <50 years may benefit from RSV vaccination
- However, the Work Group has indicated there are likely **important differences in considering a recommendation for adults aged <50 years compared to adults aged ≥50 years, including:**
  - Absolute risk of RSV-associated disease and which medical conditions increase risk the most
  - Risk-benefit balance
  - Cost-effectiveness
  - Importance of ability to restore protection with revaccination
- As of today's meeting, information on the absolute risk of RSV-associated disease among adults with risk conditions is still being analyzed and estimates of risk-benefit balance and cost-effectiveness of vaccination in younger adults are not yet available.

Policy for the use of RSV vaccines in adults aged <50 years will be revisited at the June 2025 meeting.

- The Work Group is also reviewing or anticipates reviewing the following data deemed critical for a recommendation in adults aged <50 years:
  - The projected balance of public health benefits and risks considering uncertainty in vaccine-associated Guillain-Barré syndrome risk in a younger population
  - Evidence of RSV vaccine immunogenicity or effectiveness in adults with the most severely immunocompromising conditions
  - The duration of protection over time in adults aged ≥60 years who were vaccinated in 2023
  - Available data on immunogenicity of revaccination with different vaccine platforms and revaccination intervals
- **The Work Group has indicated it needs to review these data and needs additional time to consider the best policy option in adults aged <50 years.**
- The Work Group welcomes ACIP's thoughts about adults aged <50 years during discussion at the end of today's session.

Agenda: Wednesday April 16, 2025

• Manufacturer Presentation: mRNA-1345 (Moderna) Immunogenicity in Adults Aged 18-59 Years at Increased Risk; 24-Month Re-Vaccination	• Dr. Frances Priddy (Moderna)
• Manufacturer Presentation: Arexvy (GSK) 36-Month Re-Vaccination	• Dr. Susan Gerber (GSK)
• Economic Analysis of Adult RSV Vaccination, including benefits and risk discussion	• Dr. Ismael Ortega-Sanchez (CDC) on behalf of Dr. David Hutton (University of Michigan)
• Comparison of Economic Analyses of Adult RSV Vaccination	• Dr. Ismael Ortega-Sanchez (CDC)
• Evidence to Recommendations	• Dr. Michael Melgar, Dr. Diya Surie (CDC)
• Clinical Considerations	• Dr. Michael Melgar (CDC)
• ACIP discussion and vote	

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