Centers for Disease Control and Prevention National Center for Immunization and Respiratory Diseases



Adult Respiratory Syncytial Virus (RSV) Session

Camille Kotton, MD Chair, Adult RSV Work Group

Advisory Committee on Immunization Practices (ACIP)

June 26, 2024

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Adult RSV Work Group Membership

ACIP Voting Members

Camille Kotton (Chair) Keipp Talbot Sarah Long Albert Shaw

Ex Officio Members

Rachel Zhang (FDA) Nicholas Geagan (FDA) Nadine Peart Akindele (FDA) Sonnie Kim (NIH/NIAID) Michelle Juaneza (HRSA) Uzo Chukwuma (IHS) <u>CDC Co-Leads</u> Michael Melgar Amadea Britton

<u>Liaisons</u>

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Consultants

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Transition in Work Group Chair

Dr. Albert Shaw will be the incoming work group chair for the adult RSV work group starting in July 2024.



CDC Contributors

Coronavirus and Other Respiratory Viruses Division

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CDC and ACIP currently recommend that adults aged 60 years and older may receive a single dose of RSV vaccination, using shared clinical decision-making.

- ACIP voted on this recommendation at the June 2023 meeting
- Recommendation is not product-specific; administer whichever vaccine is available



Recap of Adult RSV session, February 2024

- Moderna presented safety and efficacy data from the first 9 months of follow up in their phase 3 trial in adults aged ≥60 years
- CDC presented risk-stratified rates of RSV-associated hospitalization in U.S. adults aged 50 years and older
- CDC gave an update on uptake and implementation of RSV vaccine in U.S. adults aged 60 years and older during the first season following the recommendation
- CDC and FDA presented on post-marketing safety of the protein subunit RSV vaccines (GSK's AREXVY and Pfizer's ABRYSVO) in adults aged 60 years and older
- CDC presented an analysis comparing the estimated magnitude of public health benefit and potential risk of Guillain-Barre syndrome (GBS) associated with protein subunit RSV vaccination in adults aged 60 years and older
- For adults aged 60 years and older who remain unvaccinated, ACIP agreed with encouraging timing of RSV vaccination in the late summer and early fall to optimize public health benefits

Recent work group discussion

- Moderna mRESVIA for use in adults aged 60 years and older (received FDA approval May 31, 2024)
- GSK AREXVY for use in adults aged 50-59 years at increased risk of severe RSV disease (received FDA approval June 7, 2024)
- Continued discussion of safety, including risk of GBS, following RSV vaccination
- Shift from a shared clinical decision-making recommendation to:
 - Potential universal recommendation in adults 75 and older
 - Potential risk-based recommendation in adults 60–74
 - Potential risk-based recommendation in adults 50–59

Re-evaluating Shared Clinical Decision-Making (SCDM) recommendation

- In June 2023, ACIP recommended RSV vaccination in adults 60 and older using shared clinical decision-making
 - In addition to benefits of vaccination, the shared clinical decision-making discussion, as intended by ACIP, is also meant to include discussion of the potential risk of vaccine-associated adverse events associated with RSV vaccine, specifically Guillain Barre Syndrome.
- In the first year following this recommendation, we have learned:
 - Feedback from healthcare providers that having SCDM conversations is not simple in practice.
 - Unlike a universal recommendation where there's a clear call to action to vaccinate, with SCDM the call to action is to discuss with a healthcare provider, a less clear message.
- A risk-based recommendation for adults 60–74 and a universal recommendation for adults ≥75 years would potentially highlight more clearly for providers and other public health officials which adults are likely to benefit from an RSV vaccine and provide a clearer recommendation for patients.

Agenda: Wednesday June 26, 2024

- Manufacturer presentation: ABRYSVO (Pfizer) safety and immunogenicity in non-pregnant adults aged 18-59 years
- Manufacturer presentation: AREXVY (GSK) immunogenicity with a 24-month revaccination interval
- Manufacturer presentation: mRESVIA (Moderna) season 2 safety and efficacy update
- Postmarketing safety updates: Vaccine Safety Datalink
- Evaluation of Guillain-Barre Syndrome (GBS) following RSV vaccination among adults 65 years and older
- Observational RSV vaccine effectiveness
- Economic analysis of adult RSV vaccination
- Update to benefits and risks discussion
- Comparison of economic analyses of adult RSV vaccination
- Evidence to Recommendations
- Clinical Considerations

- Dr. Iona Munjal (Pfizer)
- Dr. Susan Gerber (GSK)
- Dr. Rituparna Das (Moderna)
- Dr. James Donahue (Marshfield Clinic Research Institute)
- Dr. Patricia Lloyd (FDA)
- Dr. Diya Surie (CDC, NCIRD)
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