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

Adult Respiratory Syncytial Virus (RSV) Session

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Chair, Adult RSV Work Group

Advisory Committee on Immunization Practices (ACIP)

February 29, 2024

In June 2023, ACIP made the first-ever recommendation for the use of RSV vaccine in older adults.

- As a reminder, ACIP recommended that adults aged ≥60 years may receive RSV vaccination, **using shared clinical decision-making.**
- **There are currently two licensed and recommended products for adults aged ≥60 years:**
  - GSK RSV vaccine (Arexvy): a 1-dose adjuvanted ($AS01_E$) recombinant prefusion F protein (preF) vaccine.
  - Pfizer RSV vaccine (Abysvo): a 1-dose recombinant preF vaccine.

https://www.cdc.gov/mmwr/volumes/72/wr/mm7229a4.htm

In October 2023, GSK presented data to ACIP demonstrating that the humoral immune response to a single dose of GSK RSV vaccine in adults 50–59 years is non-inferior to that in adults ages 60 years and older.

- The ACIP Adult RSV Work Group shared their early interpretations of these data and the potential role of RSV vaccination in adults younger than 60 years, including subpopulations that would benefit most from vaccination and equity implications.
- **At that time ACIP members expressed the importance of reviewing safety surveillance data to inform future preferred policy recommendations**.

At today's meeting CDC and FDA will be sharing preliminary data from multiple safety surveillance platforms.

- The Work Group is committed to incorporating what we are learning from post-licensure data in a transparent way that ensures safety for the public and clarity for providers.
- The preliminary data shared today are the first in what will be a series of rigorous analyses across multiple different platforms.
- CDC and the Work Group will be engaged in ongoing re-assessment and future policy will be responsive to what is learned over the coming months.

The Work Group has simultaneously been reviewing additional data to prepare for upcoming potential policy decisions.

- Risk of severe RSV disease in adults ages 50-59 years, especially those with chronic medical conditions
- RSV vaccine uptake among different demographic groups
- Potential policy options that would transition away from shared clinical decision-making

The Work Group has also begun reviewing data from Moderna on their investigational RSV vaccine (mRNA-1345) in adults aged ≥60 years.

- We will open today's session with a presentation from Moderna, who will be sharing safety and efficacy data with ACIP for the first time from their primary Phase 2-3 trial evaluating mRNA-1345.

Agenda: February 29, 2024

Manufacturer presentation: Overview of Moderna's Investigational RSV Vaccine (mRNA-1345) in Adults ≥60 Years of Age	Dr. Rituparna Das (Moderna)
Risk-stratified rates of RSV-associated hospitalization among adults	Dr. Rebecca Woodruff (CDC)
Implementation update: older adult RSV vaccination	Dr. Carla Black (CDC)
Post-marketing safety surveillance of older adult RSV vaccination	Dr. Tom Shimabukuro (CDC)
Preliminary Analysis of Guillain-Barré Syndrome (GBS) following RSV Vaccination among adults 65 years and older	Dr. Patricia Lloyd (FDA)
Older adult RSV vaccination: benefits and risks discussion	Dr. Michael Melgar (CDC)
Work Group interpretations and discussion	Dr. Amadea Britton (CDC)

Adult RSV Work Group Membership

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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.