Summary of Proposed Clinical Considerations for RSV Vaccines

June 21, 2023

ACIP Older Adult RSV Vaccine Session

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Overview of clinical considerations

- Shared clinical decision-making based on risk assessment among adults aged 60–64 years
- Timing of RSV vaccination for the 2023–2024 RSV season
- Coadministration of RSV vaccines with other vaccines
- Persons with immunocompromising conditions

Clinical consideration: Shared clinical decision-making based on risk assessment among adults aged 60–64 years

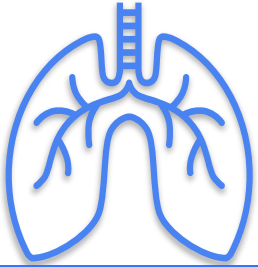
For shared clinical decision-making recommendations there is no default.

The decision about whether or not to vaccinate an individual may be informed by:

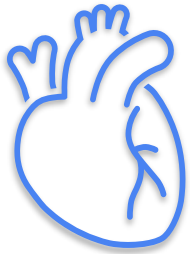
- Best available evidence of who may benefit
- An individual's characteristics, values, and preferences
- Health care provider's clinical discretion
- Characteristics of the vaccine being considered

Source: CDC. ACIP Shared Clinical Decision-Making Recommendations. Website: https://www.cdc.gov/vaccines/acip/acip-scdm-faqs.html. Last updated February 10, 2020. Accessed June 13, 2023.

If shared clinical decision-making is recommended adults who may be at higher risk of RSV disease include persons with:



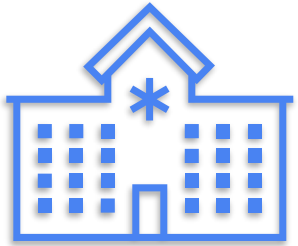
Chronic lung diseases such as COPD and asthma



Chronic cardiovascular diseases such as congestive heart failure and coronary artery disease

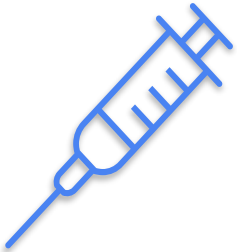
Immune compromise

Hematologic disorders

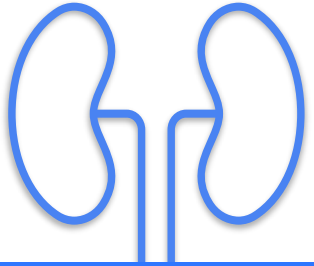


Residents of nursing homes and other long-term care facilities

Neurologic disorders



Endocrine disorders such as diabetes



Kidney and liver disorders

Other underlying conditions or factors that the provider determines might increase the risk of severe respiratory illness

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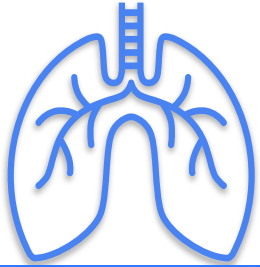

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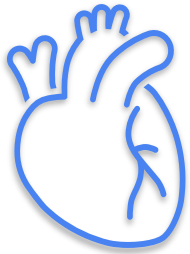

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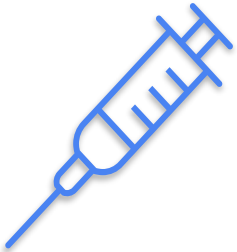

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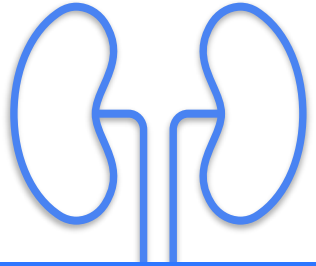

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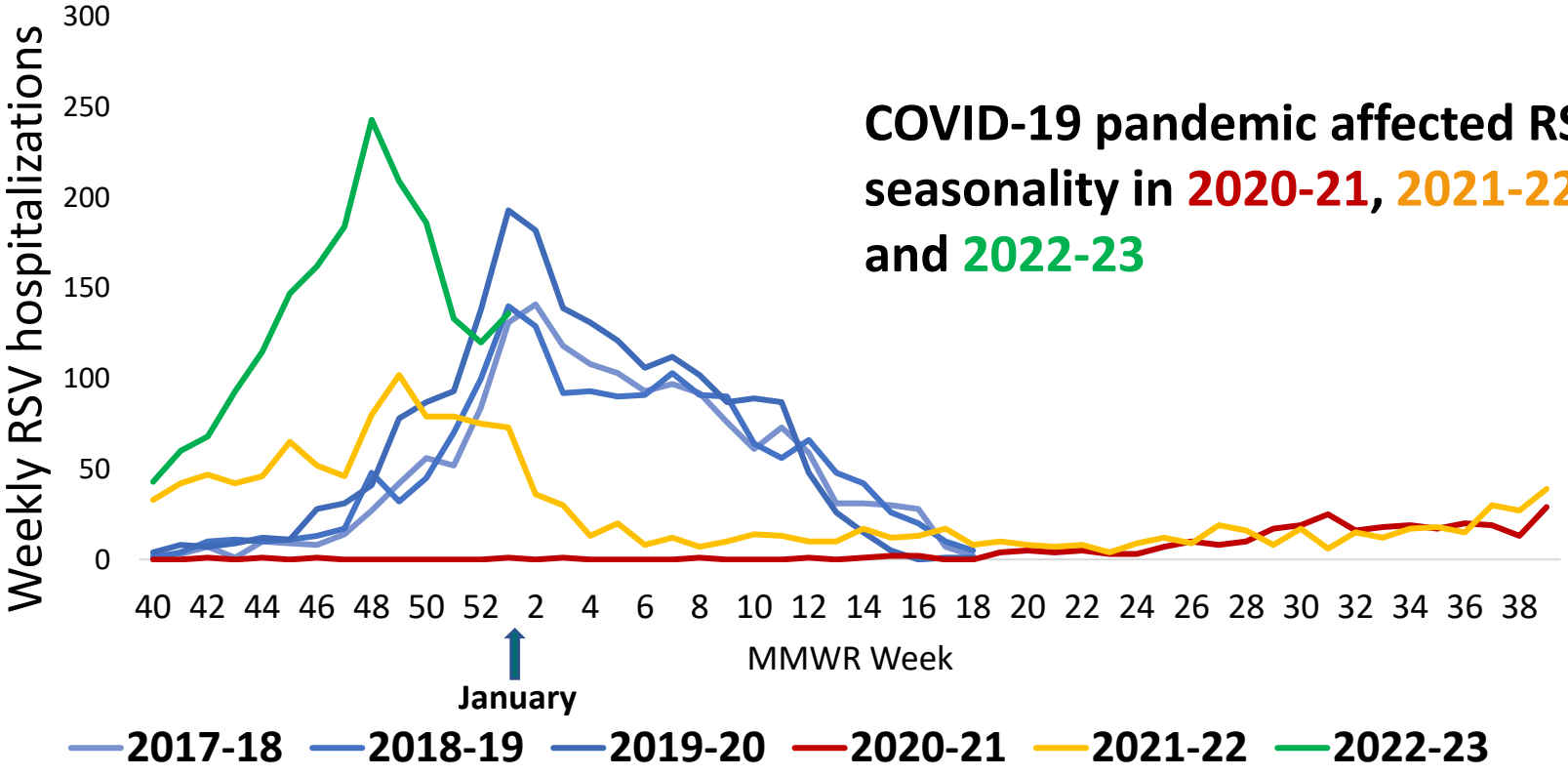
Clinical consideration: Timing of RSV vaccination for the 2023–2024 RSV season

RSV vaccination is currently approved and recommended as a single dose.

Optimally, vaccination of eligible adults should occur **before the onset of increased RSV activity** in the community.

The timing of the onset, peak, and decline of RSV activity varies each year, and RSV seasonality during the COVID-19 pandemic deviated from prior seasons.

RSV Hospitalizations in adults aged ≥65 years by season: RSV-NET 2017–2023



RSV-NET: unpublished data. Surveillance for 2017-18 through 2019-20 seasons were conducted from October – April; for 2020-21 and 2021-22 surveillance was conducted continuously from October – September. Data shown for 2022-23 season is from October – December 2022.

Clinical consideration: Timing of RSV vaccination for the 2023–2024 RSV season

Given this variability the ideal time to start vaccinating cannot be predicted in advance of the 2023-2024 RSV season.

Providers **should therefore offer RSV vaccination as soon as vaccine supply becomes available.**

Providers should continue to offer RSV vaccination throughout the RSV season to eligible adults who remain unvaccinated.

There are insufficient data at this time to determine the need for revaccination.

Clinical consideration: Coadministration of RSV vaccines with other vaccines

In accordance with General Best Practice Guidelines for Immunization, coadministration of RSV vaccines with other adult vaccines is acceptable.*

This includes giving RSV vaccines simultaneously with seasonal influenza vaccines, COVID-19 vaccines, pneumococcal vaccines, Td/Tdap, and recombinant zoster vaccine (Shingrix).

*ACIP Timing and Spacing Guidelines for Immunization | CDC

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.
- 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.

Reactogenicity and safety of coadministration of RSV vaccines with other vaccines

- Coadministration of multiple vaccines at the same visit may increase reactogenicity.
- Only coadministration of RSV and influenza vaccines have clinical trial data available. Evidence is mixed on whether there may be increased reactogenicity with coadministration of RSV and influenza vaccines.
- Data are lacking on coadministration of other vaccines that might be recommended for people in this age group, such as COVID-19 vaccines, pneumococcal vaccines, Td/Tdap, and the recombinant zoster vaccine (Shingrix by GSK) which contains the same adjuvant as RSVPreF3 vaccine (Arexvy by GSK).
- Post-licensure safety monitoring of coadministration of RSV vaccines with other vaccines will further inform coadministration guidance.

Clinical consideration: RSV vaccines and persons with immunocompromising conditions

Adults with immunocompromising conditions are at risk of severe RSV-associated disease and death.

They may benefit from RSV vaccination but were not included in the clinical trials so efficacy in this population is unknown.

These individuals, including those receiving immunosuppressive therapy, may have a diminished immune response to RSV vaccination.

Persons with immunocompromising conditions are recommended to receive the RSV vaccine under shared clinical decision-making given the potential for significant benefit.

Acknowledgements:
Michael Melgar
Lauren Roper
Hannah Rosenblum
Melinda Wharton
Tara Anderson
Lisa Grohskopf
David Shay
Tom Shimabukuro
Karen Broder
Mila Prill
Anne Hause
Fiona Havers
Meredith McMorrow
Jefferson Jones
Katherine Fleming-Dutra
Andrew Kroger
Manisha Patel
Sarah Meyer
Neil Murthy
Patricia Wodi
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