Vaccine Update: COVID-19 and RSV

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No conflicts of interest to disclose
Disclaimer

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COVID-19 Vaccines
Currently Available FDA-Approved COVID-19 Vaccines

• mRNA Vaccines
  - Moderna COVID-19 Vaccine (2023-2024 formula) and SPIKEVAX.
    • SPIKEVAX is the product licensed for people ages ≥ 12 years
  - Pfizer-BioNTech COVID-19 Vaccine (2023-2024 formula) and COMIRNATY.
    COMIRNATY is the product licensed for people ages ≥ 12 years

• Protein subunit vaccine
  - Novavax COVID-19 Vaccine, Adjuvanted authorized for people ages ≥ 12 years

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#table-02
Updated COVID-19 Vaccines

- Now monovalent vaccines again
- Targeted toward Omicron XBB.1.5 sublineage of SARS-CoV-2
  - The original and bivalent vaccines targets the wild-type strain and Omicron BA.4/BA.5
How well do the new COVID-19 vaccines work?

- EG.5 now the most prevalent
- Descendent of XBB strain and genetically similar so vaccine is predicted to work
- Not going to prevent all symptomatic infection
- No head-to-head studies of mRNA vs protein subunit vaccine
- Goal is to still prevent hospitalizations and deaths
- CDC estimates that with universal COVID-19 vaccine recommendation, 400,000 hospitalizations and 40,000 deaths could be prevented over the next 2 years

- Should I mix and match?

  Some data suggest that Novavax booster after primary mRNA vaccine suggest similar to superior responses to mRNA boosters
# 2023-2024 CDC ACIP COVID-19 Vaccine Recommendations

<table>
<thead>
<tr>
<th>COVID-19 vaccination history prior to updated (2023–2024 Formula) vaccine*</th>
<th>Updated (2023–2024 Formula) vaccine</th>
<th>Number of updated (2023–2024 Formula) doses indicated</th>
<th>Dosage (mL/ug)</th>
<th>Vaccine vial cap and label colors³</th>
<th>Interval between doses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unvaccinated</td>
<td>Moderna</td>
<td>1</td>
<td>0.5 mL/50 ug</td>
<td>Dark blue cap; blue label</td>
<td>—</td>
</tr>
<tr>
<td>OR</td>
<td>Novavax</td>
<td>2</td>
<td>0.5 mL/50 ug rS protein and 50 ug Matrix-M adjuvant</td>
<td>Blue cap; blue label</td>
<td>Dose 1 and Dose 2: 3–8 weeks¹</td>
</tr>
<tr>
<td>OR</td>
<td>Pfizer-BioNTech</td>
<td>1</td>
<td>0.3 mL/30 ug</td>
<td>Gray cap; gray label</td>
<td>—</td>
</tr>
<tr>
<td>1 or more doses any mRNA; 1 or more doses Novavax or Janssen, including in combination with any Original monovalent or bivalent COVID-19 vaccine doses</td>
<td>Moderna</td>
<td>1</td>
<td>0.5 mL/50 ug</td>
<td>Dark blue cap; blue label</td>
<td>At least 8 weeks after last dose</td>
</tr>
<tr>
<td>OR</td>
<td>Novavax</td>
<td>1</td>
<td>0.5 mL/50 ug rS protein and 50 ug Matrix-M adjuvant</td>
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<td>At least 8 weeks after last dose</td>
</tr>
<tr>
<td>OR</td>
<td>Pfizer-BioNTech</td>
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<td>0.3 mL/30 ug</td>
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https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#table-01
# 2023-2024 CDC ACIP COVID-19 Vaccine Recommendations for Moderate to Severely Immunocompromised Persons

<table>
<thead>
<tr>
<th>COVID-19 vaccination history prior to updated (2023–2024 Formula) vaccine(^*)</th>
<th>Updated (2023–2024 Formula) vaccine</th>
<th>Number of updated (2023–2024 Formula) doses indicated(^*)</th>
<th>Dosage (mL/ug)</th>
<th>Vaccine vial cap and label colors(^*)</th>
<th>Interval between doses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unvaccinated</td>
<td>Moderna</td>
<td>3</td>
<td>0.5 mL/50 ug</td>
<td>Dark blue cap; blue label</td>
<td>Dose 1 and Dose 2: 4 weeks Dose 2 and Dose 3: At least 4 weeks</td>
</tr>
<tr>
<td></td>
<td>NOVAVAX</td>
<td>2</td>
<td>0.5 mL/5 ug rS protein and 50 ug Matrix-M adjuvant</td>
<td>Blue cap; blue label</td>
<td>Dose 1 and Dose 2: 3 weeks</td>
</tr>
<tr>
<td></td>
<td>Pfizer-BioNTech</td>
<td>3</td>
<td>0.3 mL/30 ug</td>
<td>Gray cap; gray label</td>
<td>Dose 1 and Dose 2: 3 weeks Dose 2 and Dose 3: At least 4 weeks</td>
</tr>
</tbody>
</table>

[https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#table-02](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#table-02)
RSV Vaccines
Respiratory Syncytial Virus (RSV)

• One of the most common causes of illness
• Most common cause of hospitalization in infants
• Adults typically have mild or no symptoms but people 60+ at higher risk for lower respiratory disease
• RSV season starts in the fall and peaks in the winter typically
RSV: Risk Factors for Severe Disease

Chronic underlying medical conditions associated with increased risk

- Lung disease (such as chronic obstructive pulmonary disease and asthma)
- Cardiovascular diseases (such as congestive heart failure and coronary artery disease)
- Moderate or severe immune compromise
- Diabetes mellitus
- Neurologic or neuromuscular conditions
- Kidney disorders
- Liver disorders
- Hematologic disorders
- Other underlying conditions that a health care provider determines might increase the risk for severe respiratory disease

Other factors associated with increased risk

- Frailty
- Advanced age
- Residence in a nursing home or other long-term care facility
- Other underlying factors that a health care provider determines might increase the risk for severe respiratory disease
RSV Vaccines

Morbidity and Mortality Weekly Report (MMWR)

Use of Respiratory Syncytial Virus Vaccines in Older Adults: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023

Weekly / July 21, 2023 / 72(29);793–801

- 2 FDA approved vaccines
  - RSVPreF3 (Arexvy, GSK)
  - RSVPreF (Abrysvo, Pfizer)
TABLE 1. Efficacy of 1 dose of GSK respiratory syncytial virus RSVpreF3 vaccine against respiratory syncytial virus-associated disease among adults aged ≥60 years — multiple countries, 2021–2023

<table>
<thead>
<tr>
<th>Efficacy evaluation period</th>
<th>Vaccine efficacy against outcome*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>RSV-associated LRTD*</td>
</tr>
<tr>
<td>Season 1§</td>
<td>82.6 (57.9–94.1)**</td>
</tr>
<tr>
<td>Season 2§§</td>
<td>56.1 (28.2–74.4)**</td>
</tr>
<tr>
<td>Combined seasons 1 and 2 (interim)***</td>
<td>74.5 (60.0–84.5)**⊥⊥</td>
</tr>
</tbody>
</table>

TABLE 3. Efficacy of 1 dose of Pfizer respiratory syncytial virus RSVpreF vaccine against respiratory syncytial virus-associated disease among adults aged ≥60 years — multiple countries, 2021–2023

<table>
<thead>
<tr>
<th>Efficacy evaluation period</th>
<th>Vaccine efficacy against outcome, % (95% CI)*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>RSV-associated LRTD†</td>
</tr>
<tr>
<td>Season 1§</td>
<td>88.9 (53.6–98.7)</td>
</tr>
<tr>
<td>Season 2 (interim)**</td>
<td>78.6 (23.2–96.1)</td>
</tr>
<tr>
<td>Combined seasons 1 and 2 (interim)§§</td>
<td>84.4 (59.6–95.2)</td>
</tr>
</tbody>
</table>
### TABLE 2. Safety* of 1 dose of GSK respiratory syncytial virus RSVPreF3 vaccine in adults aged ≥60 years — multiple countries, 2021–2023

<table>
<thead>
<tr>
<th>Safety event</th>
<th>Risk for event</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>RSVPreF3 recipients no./No. (%)</td>
<td>Placebo recipients no./No. (%)</td>
<td>Relative risk (95% CI)</td>
<td></td>
</tr>
<tr>
<td>Serious AE**</td>
<td>549/12,570 (4.4)</td>
<td>540/12,604 (4.3)</td>
<td>1.02 (0.91–1.15)</td>
<td></td>
</tr>
<tr>
<td>Severe reactogenicity events††</td>
<td>37/979 (3.8)</td>
<td>9/976 (0.9)</td>
<td>4.10 (1.99–8.45)</td>
<td></td>
</tr>
<tr>
<td>Inflammatory neurologic events‡‡</td>
<td>3 events in trials without placebo recipients</td>
<td>—</td>
<td>—</td>
<td></td>
</tr>
</tbody>
</table>

### TABLE 4. Safety* of 1 dose of Pfizer respiratory syncytial virus RSVpreF vaccine in adults aged ≥60 years — multiple countries, 2021–2023

<table>
<thead>
<tr>
<th>Safety event</th>
<th>Risk for event</th>
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<tbody>
<tr>
<td></td>
<td>RSVpreF recipients no./No. (%)</td>
<td>Placebo recipients no./No. (%)</td>
<td>Relative risk (95% CI)</td>
</tr>
<tr>
<td>Serious AE**</td>
<td>792/18619 (4.3%)</td>
<td>749/18334 (4.1%)</td>
<td>1.04 (0.94–1.15)</td>
</tr>
<tr>
<td>Severe reactogenicity events††</td>
<td>36/3673 (1.0%)</td>
<td>24/3491 (0.7%)</td>
<td>1.43 (0.85–2.39)</td>
</tr>
<tr>
<td>Inflammatory neurologic events‡‡</td>
<td>3/18622 (—)</td>
<td>0/18335 (—)</td>
<td>—</td>
</tr>
</tbody>
</table>
RSV Vaccines Summary

• Two new RSV vaccines from GSK (Arexvy) Pfizer (Abrysvo) were FDA approved in May 2023 for adults ≥60
• Both vaccines were generally safe and well-tolerated in phase 3 clinical trials, and demonstrated >80% efficacy against symptomatic
• Both are protein-based (not live) vaccines
• Immunocompromised patients were not included in the trials; efficacy in this group is unknown, and further studies are needed to assess for any specific safety concerns
CDC ACIP RSV Vaccine Recommendations 2023-2024

• Adults age ≥ 60 years **MAY** receive a single dose of RSV vaccine using **shared decision-making**

• Abrysvo (Pfizer) is also FDA approved for pregnant individuals between 32 and 36 weeks of gestational age to confer RSV protection to young infants

• If given, vaccinate before onset of RSV season ideally

• Ok to give with other vaccines (no data however)

• Infants: New monoclonal antibody (Nirsevimab)
  - Recommended for all infants younger than 8 months born during RSV season or entering their first RSV season (except if born ≥ 14 days after maternal RSV vaccination)
  - Some children 8-19 months at increased risk for severe RSV and entering their second RSV season

- Premature with chronic lung disease
- Severe immunocompromise
- Cystic fibrosis
- American Indian and Alaska Native
Summary

• Don’t forget flu shots

• Recommendations for COVID-19 vaccine 2023-2024 booster for people with HIV not different from general population except:
  - CD4 count < 200 or uncontrolled HIV – then follow immunocompromised vaccine schedule guidance

• RSV vaccine is a “consider” recommendations for people 60+ through shared decision making, except for pregnant individuals for whom there is a stronger recommendation

• On a different note – mpox is back! Don’t forget to immunize those at risk who didn’t receive or complete their vaccination series before!
Acknowledgment

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