Interim Clinical Considerations for Use of COVID-19 Vaccines: Latest Updates

Evelyn Twentyman, MD MPH
Advisory Committee on Immunization Practices Meeting, January 5, 2022
# Interim Clinical Considerations for Use of COVID-19 Vaccines

## Summary of Latest Updates* and Anticipated Next Updates

<table>
<thead>
<tr>
<th>Date of Update</th>
<th>Highlighted Updates to Interim Clinical Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>December 10, 2021</td>
<td>• Updated guidance for booster dose: Pfizer-BioNTech in adolescents ages 16–17 years</td>
</tr>
<tr>
<td>December 17, 2021</td>
<td>• Updated guidance on use of Janssen (J&amp;J) with preferential recommendation for mRNA vaccines</td>
</tr>
<tr>
<td>December 23, 2021</td>
<td>• Newest formulation of Pfizer-BioNTech – “gray top”</td>
</tr>
</tbody>
</table>
| **Anticipated** January 6, 2022 | • Guidance to reflect outcomes of the ACIP meeting 1/5/22  
• Third Pfizer-BioNTech primary series dose for some children ages 5–11 years with immunocompromise  
• Decrease in booster interval after Pfizer-BioNTech primary series: now 5 months |
Latest Updates to Interim Clinical Considerations: December 2021
Adolescents ages 16–17 years may receive a booster dose of Pfizer-BioNTech ≥6mos after completion of primary series

- **Safe:**
  - Vaccine safety surveillance data for adolescents ages 16–17 years included in data previously reviewed by ACIP
  - Myocarditis risk after booster less than that after 2nd dose\(^1\)

- **Effective:**
  - Relative vaccine efficacy (RVE) for booster vaccination of 95.3% among adolescents ages 16-17 years who received a booster dose in previous 2 months compared with those who had completed primary series only\(^2\)

- **Needed:**
  - 4.7 million adolescents ages 16–17 years were fully vaccinated with Pfizer-BioNTech\(^3\)

- **Recommended:**
  - Following amendment of Pfizer-BioNTech EUA, CDC recommended that people adolescents 16–17 years may receive a Pfizer-BioNTech booster dose based on their individual benefits and risks\(^4\)

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1 FDA Review Memorandum, describing Israel Ministry of Health Vaccine Safety Data, 8 December 2020
2 FDA Review Memorandum, Pfizer-BioNTech Booster for Ages 16-17, 8 December 2021
3 CDC Vaccine Surveillance Data, 8 December 2021
4 CDC Interim Clinical Considerations, 10 December 2021
**Preferential recommendation for mRNA vaccines**

- Additional case review and ongoing safety surveillance identified cases (previous and newly occurring) of TTS, including deaths
- No longer in the setting of limited mRNA COVID-19 vaccine supply in the US
- ACIP December 16 Vote: mRNA COVID-19 vaccines are **preferred** over the Janssen COVID-19 vaccine for the prevention of COVID-19 for those aged ≥18 years
### Newest formulation of Pfizer-BioNTech COVID-19 Vaccine

<table>
<thead>
<tr>
<th>Description</th>
<th>Dilute Before Use</th>
<th>Do Not Dilute</th>
<th>Dilute Before Use</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age Group</strong></td>
<td>12 years and older&lt;sup&gt;1,2&lt;/sup&gt;</td>
<td>12 years and older&lt;sup&gt;3&lt;/sup&gt;</td>
<td>6 through 11 years&lt;sup&gt;4&lt;/sup&gt; (“Age 6y to &lt;12y” on vial label)</td>
</tr>
<tr>
<td><strong>Vial Cap Color</strong></td>
<td>Purple</td>
<td>Gray</td>
<td>Orange</td>
</tr>
<tr>
<td><strong>Dose</strong></td>
<td>30 mcg</td>
<td>30 mcg</td>
<td>10 mcg</td>
</tr>
<tr>
<td><strong>Dose Volume</strong></td>
<td>0.3 mL</td>
<td>0.3 mL</td>
<td>0.2 mL</td>
</tr>
<tr>
<td><strong>Amount of Diluent Needed per Vial</strong></td>
<td>1.8 mL</td>
<td>NO DILUTION</td>
<td>1.3 mL</td>
</tr>
<tr>
<td><strong>Doses per Vial</strong></td>
<td>6 doses per vial (after dilution)</td>
<td>6 doses per vial</td>
<td>10 doses per vial (after dilution)</td>
</tr>
</tbody>
</table>

### Storage Conditions

<table>
<thead>
<tr>
<th>Storage Conditions</th>
<th>Dilute Before Use</th>
<th>Do Not Dilute</th>
<th>Dilute Before Use</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ultra-Low-Temperature (ULT) Freezer</strong></td>
<td>9 months&lt;sup&gt;1&lt;/sup&gt;</td>
<td>6 months&lt;sup&gt;1&lt;/sup&gt;</td>
<td>8 months&lt;sup&gt;1&lt;/sup&gt;</td>
</tr>
<tr>
<td><strong>Freezer</strong></td>
<td>2 weeks</td>
<td>DO NOT STORE</td>
<td>DO NOT STORE</td>
</tr>
<tr>
<td><strong>Refrigerator</strong></td>
<td>1 month</td>
<td>10 weeks</td>
<td>10 weeks</td>
</tr>
<tr>
<td><strong>Room Temperature</strong></td>
<td>2 hours prior to dilution (including any thaw time)</td>
<td>12 hours prior to first puncture (including any thaw time)</td>
<td>12 hours prior to dilution (including any thaw time)</td>
</tr>
<tr>
<td><strong>After First Puncture</strong></td>
<td>Discard after 6 hours</td>
<td>Discard after 12 hours</td>
<td>Discard after 12 hours</td>
</tr>
</tbody>
</table>

Image Credit: Pfizer-BioNTech, Vaccine Formulation Presentation Guide
Anticipated Updates to Interim Clinical Considerations: January 6, 2022
Some children ages 5–11 years with immunocompromise should receive an additional Pfizer-BioNTech primary series dose

- Vaccine effectiveness is lower among patients with immunocompromise\(^1\)
- CDC recommends an additional primary series mRNA vaccine dose in people with immunocompromise aged ≥12 years\(^2\)
- Approximately 1.4 million children ages 5-17 have an immunocompromising condition\(^3\)
- Safety findings from VAERS and v-safe during administration of >8 million doses of Pfizer-BioNTech: rare reporting of any serious side effects\(^4\)

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1 Embi et al MMWR 5 Nov 2021; 2 CDC Interim Clinical Considerations; 3 Patel et al EID 2021; 4 Hause et al MMWR 31 Dec 2021
Moderately and severe immunocompromise

- Active treatment for solid tumor and hematologic malignancies
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Receipt of CAR-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
- Moderate or severe primary immunodeficiency (e.g., DiGeorge, Wiskott-Aldrich syndromes)
- Advanced or untreated HIV infection
- Active treatment with high-dose corticosteroids (i.e., ≥20mg prednisone or equivalent per day), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, TNF blockers, and other biologic agents that are immunosuppressive or immunomodulatory

Pfizer-BioNTech booster 5 months after completion of a primary series of COVID-19 vaccination for those eligible

- People who have completed a primary series and booster may be better protected against symptomatic infection with Omicron than those without booster\(^1,2\)
- Two studies from Israel document the effectiveness of Pfizer-BioNTech booster dose 5 months after primary series against severe illness\(^3\) and death\(^4\) secondary to COVID-19
- 188 million (73%) of U.S. adults aged ≥18 years are fully vaccinated; 38% of those have received a booster\(^5\)
- 4.74 million (57%) of U.S. adolescents* ages 16-17 are fully vaccinated with Pfizer-BioNTech COVID-19 vaccine; 6% have received a booster\(^6\)
- Rare occurrences of myocarditis in people aged ≥16 years following a booster dose at 5 months occurred at less than half the rate observed following 2\(^{nd}\) dose\(^7\)


* Vaccination data is not available for Idaho
# COVID-19 Vaccine Booster Dose by Primary Series, with Interval

<table>
<thead>
<tr>
<th>Primary series COVID-19 vaccine product*</th>
<th>Age for vaccine booster (years)</th>
<th>Interval between final primary dose and booster dose</th>
<th>COVID-19 vaccine products that may be given as booster dose*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer-BioNTech</td>
<td>≥16 (may change to ≥12)</td>
<td>≥5 months</td>
<td>Pfizer-BioNTech, Moderna, Janssen/J&amp;J</td>
</tr>
<tr>
<td>Moderna</td>
<td>≥18</td>
<td>≥6 months</td>
<td>Pfizer-BioNTech, Moderna, Janssen/J&amp;J</td>
</tr>
<tr>
<td>Janssen/J&amp;J</td>
<td>≥18</td>
<td>≥2 months</td>
<td>Pfizer-BioNTech, Moderna, Janssen/J&amp;J</td>
</tr>
</tbody>
</table>

*Only Pfizer-BioNTech is authorized as primary series or booster dose for people aged <18 years. For the prevention of COVID-19 in those aged ≥18 years, mRNA vaccines (Pfizer-BioNTech; Moderna) are preferred over the Janssen/J&J COVID-19 Vaccine for both primary series and booster doses.
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- DAV Vaccine Team
- Vaccine Safety Team
- Epidemiology and Surveillance Task Force
- Vaccine Task Force
Thank you

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.