Updates to Interim Clinical Considerations for Use of COVID-19 Vaccines

Elisha Hall, PhD
Advisory Committee on Immunization Practices Meeting
February 4, 2022
Anticipated Updates

- Clarification and updates on guidance for people who are moderately or severely immunocompromised
- Updates to recommendations on passive antibody products
- Reduction and reorganization for ease of use
Updated guidance for people who are moderately or severely immunocompromised
People Who Are Moderately or Severely Immunocompromised

- People with immunocompromising conditions or people who take immunosuppressive medications or therapies:
  - Are at increased risk for severe COVID-19
  - May **not mount a protective immune response** after initial vaccination
  - Have **waning protection** over time
## CURRENT COVID-19 Vaccination Schedule for People Who Are Moderately or Severely Immunocompromised

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Vaccination Schedule</th>
<th>Booster dose*</th>
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</thead>
<tbody>
<tr>
<td><strong>Pfizer-BioNTech</strong></td>
<td></td>
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<tr>
<td>(ages 5 years and older)</td>
<td>1&lt;sup&gt;st&lt;/sup&gt; dose</td>
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<td>3&lt;sup&gt;rd&lt;/sup&gt; dose (at least 28 days after 2&lt;sup&gt;nd&lt;/sup&gt; dose)</td>
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<tr>
<td><strong>Moderna</strong></td>
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<td>Booster dose* (at least 2 months after 1&lt;sup&gt;st&lt;/sup&gt; dose)</td>
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*Any COVID-19 vaccine can be used for the booster dose in people ages 18 years and older, though mRNA vaccines are preferred. For people ages 12–17 years, only Pfizer-BioNTech can be used. People ages 5–11 years should not receive a booster dose at this time.
People who are moderately or severely immunocompromised should receive:
- 3-dose primary series
- 1 booster dose
Emergency Use Instructions (EUI)

- Allowed under the Pandemic and All-Hazards Preparedness Reauthorization Act
- Provides information about emergency use of FDA-approved medical products that may not be included or differ from the information provided in the FDA-approved labeling package insert.
- Applies only to the use of:
  - Spikevax (Moderna) for people ages 18 years and older
  - Comirnaty (Pfizer-BioNTech) for people ages 12 years and older

https://www.cdc.gov/vaccines/covid-19/eui/index.html
Emergency Use Instructions (EUI)

COVID-19 Vaccine Emergency Use Instructions (EUI) Resources

On November 17, 2021, CDC issued Emergency Use Instructions (EUI) to provide information about use of the formulation of the COVID-19 vaccine by Pfizer-BioNTech which is approved (licensed) by the Food and Drug Administration (FDA) for the prevention of COVID-19 in individuals 16 years of age and older. EUI provide information about emergency use of FDA-approved medical products that may not be included in or differ in some way from the information provided in the FDA-approved labeling (package insert). See below the CDC-issued Pfizer-BioNTech COVID-19 vaccine EUI fact sheets for healthcare providers and recipients/caregivers regarding Pfizer-BioNTech COVID-19 vaccine, and FAQs.

EUI Fact Sheet for Healthcare Providers:
Pfizer-BioNTech COVID-19 vaccine for Additional Primary and Booster Doses in Certain Persons Who Completed Primary Vaccination with Vaccines Not Approved/Authorized in the United States

EUI Fact Sheet for Recipients and Caregivers:
Pfizer-BioNTech COVID-19 vaccine for Additional Primary and Booster Doses in Certain Persons Who Completed Primary Vaccination with Vaccines Not Approved/Authorized in the United States

EUI FAQs
Find answers to your questions about the Pfizer-BioNTech COVID-19 vaccine EUI

https://www.cdc.gov/vaccines/covid-19/eui/index.html
Updates for People Who Are Moderately or Severely Immunocompromised

- Shorter booster interval after an mRNA COVID-19 vaccine primary series
- An additional dose after a Janssen COVID-19 Vaccine primary series
- Case-by-case clinical decision making
Revised Guidance for a 3-Month Booster Interval After an mRNA COVID-19 Vaccine Primary Series

Current guidance

People who are moderately or severely immunocompromised should receive a booster dose at least 5 months after the last (third) dose of an mRNA COVID-19 vaccine.

Revised guidance

People who are moderately or severely immunocompromised should receive a booster dose at least 3 months after the last (third) dose of an mRNA COVID-19 vaccine.

Rationale for 3-Month Booster Interval After an mRNA COVID-19 Vaccine Primary Series

- Concern about initial immune response and **loss of protection** over time, particularly during period of **high community transmission**.
- Small studies in people with immune compromise demonstrate **immunogenicity** of a 4th dose when administered ~1-3 months after the 3rd dose.
- Multiple studies in the general population demonstrate **immunogenicity** of a booster as early as **3 months** following a 2-dose primary series.
- Multiple countries have **implemented booster doses as early as 3 months** in the general population following a 2-dose primary series.

Schedule for People Who Received a Janssen COVID-19 Vaccine Primary Series

Current guidance

Primary dose

Dose 1

At least 2 months

Dose 2

Booster dose
Schedule for People Who Received a Janssen COVID-19 Vaccine Primary Series

Current guidance:
- Primary dose
  - Dose 1
  - At least 2 months
  - Dose 2
  - Booster dose

Revised guidance:
- Primary dose
  - Dose 1
  - At least 28 days
- Additional dose
- Booster dose
  - At least 2 months
  - Dose 3
Case-by-Case Decision Making Based on Clinical Judgement

- On a case-by-case basis, providers who care for moderately or severely immunocompromised patients may administer mRNA COVID-19 vaccines outside of the FDA and CDC dosing intervals based on clinical judgement when the benefits of a different vaccination schedule or dosage are deemed to outweigh the potential and unknown risks.
## REVISED COVID-19 Vaccination Schedule for People Who Are Moderately or Severely Immunocompromised

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People ages 5–11 years should not receive a booster dose.

†Only Pfizer-BioNTech or Moderna COVID-19 Vaccine should be used.
Passive antibody products
Passive Antibody Products

Current guidance

Defer COVID-19 vaccination for:
• 30 days if product used for post exposure prophylaxis
• 90 days if product used for treatment
• No guidance for pre-exposure prophylaxis

Revised guidance

• No recommended deferral period
• However, tixagevimab/cilgavimab (EVUSHELD™) should be deferred for at least two weeks after vaccination

Passive Antibody Products

- Study among nursing home residents and staff demonstrated that recipients of bamlanivimab mounted a robust immune response to mRNA vaccination, regardless of age, risk category, or vaccine type.

- Although antibody response was numerically lower in people who received monoclonal antibodies, they were still considered to be high and the clinical significance of the reduction is unknown.

- There was no correlation between interval to COVID-19 vaccination and neutralizing titers in recent monoclonal antibody recipients.

- Programmatically, there are challenges to current intervals between receipt of monoclonal antibodies and COVID-19 vaccination.

- Getting vaccinated is a priority.

Interim Clinical Considerations

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#CoV-19-vaccination
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.