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

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





cdc.gov/coronavirus

## **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

# **<u>CURRENT</u> COVID-19 Vaccination Schedule for People Who</u> Are Moderately or Severely Immunocompromised**

Vaccine	Vaccination Schedule								
Pfizer-	1 <sup>st</sup> dose	2'	nd		3 <sup>rd</sup>			Booster	
BioNTech		do	ose		dose			dose*	
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Moderna	1 <sup>st</sup> dose		2 <sup>nd</sup>		3	rd		Boo	oster
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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.

## **Clarification of Existing Recommendation for mRNA COVID-19 Vaccine Primary Series**

- 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

# **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.



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### 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 <u>at least 5 months</u> 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 <u>at least 3 months</u> after the last (third) dose of an mRNA COVID-19 vaccine.

- 1. Kamar, N., Abravanel, F., Martion, O. (2021). Assessment of 4 Doses of SARS-CoV-2 Messenger RNA–Based Vaccine in Recipients of a Solid Organ Transplant. Infectious Diseases, 4(11), e2136030.
- 2. Benotmane, I., Bruel, T., Planas, D., et al. (2021). A fourth dose of the mRNA-1273 SARS-CoV-2 vaccine improves serum neutralization against the delta variant in kidney transplant recipients. *medRxiv*. Preprint. doi.org/10.1101/2021.11.25.21266704
- 3. Alejo, J.L., Mitchell, J., Chiang, T., et al. (2021). Antibody Response to a Fourth Dose of a SARS-CoV-2 Vaccine in Solid Organ Transplant Recipients: A Case Series. Transplantation, 105(12), e280-281.
- 4. Munro, A., Janani, L., Cornelius, V. (2021). Safety and immunogenicity of seven COVID-19 vaccines as a third dose (booster) following two doses of ChAdOx1 nCov-19 or BNT162b2 in the UK (COV-BOOST): a blinded, multicentre, randomised, controlled, phase 2 trial. *Lancet*, 398, 2258-76.
- 5. Atmar, R.L., Lyke, K.E., Deming, M.E. (2021). Heterologous SARS-CoV-2 booster vaccinations-preliminary report. medRxiv. Preprint. doi: 10.1101/2021.10.10.21264827

### 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 4<sup>th</sup> dose when administered ~1-3 months after the 3<sup>rd</sup> 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.

<sup>1.</sup> Kamar, N., Abravanel, F., Martion, O. (2021). Assessment of 4 Doses of SARS-CoV-2 Messenger RNA–Based Vaccine in Recipients of a Solid Organ Transplant. *Infectious Diseases, 4*(11), e2136030.

<sup>2.</sup> Benotmane, I., Bruel, T., Planas, D., et al. (2021). A fourth dose of the mRNA-1273 SARS-CoV-2 vaccine improves serum neutralization against the delta variant in kidney transplant recipients. *medRxiv*. Preprint. doi.org/10.1101/2021.11.25.21266704

<sup>3.</sup> Alejo, J.L., Mitchell, J., Chiang, T., et al. (2021). Antibody Response to a Fourth Dose of a SARS-CoV-2 Vaccine in Solid Organ Transplant Recipients: A Case Series. Transplantation, 105(12), e280-281.

<sup>4.</sup> Munro, A., Janani, L., Cornelius, V. (2021). Safety and immunogenicity of seven COVID-19 vaccines as a third dose (booster) following two doses of ChAdOx1 nCov-19 or BNT162b2 in the UK (COV-BOOST): a blinded, multicentre, randomised, controlled, phase 2 trial. *Lancet*, 398, 2258-76.

<sup>5.</sup> Atmar, R.L., Lyke, K.E., Deming, M.E. (2021). Heterologous SARS-CoV-2 booster vaccinations-preliminary report. medRxiv. Preprint. doi: 10.1101/2021.10.10.21264827

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



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



### **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

Vaccination Schedule									
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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.

<sup>†</sup>Only Pfizer-BioNTech or Moderna COVID-19 Vaccine should be used

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# Passive antibody products



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# **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 preexposure 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**

### Vaccines & Immunizations

### CDC > COVID-19 Vaccination

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↑ COVID-19 Vaccination Product Info by U.S. Vaccine **United States** Interim Clinical Considerations Managing Anaphylaxis Myocarditis and Pericarditis Considerations Lab Tests After Severe Allergic Reactions Clinical Care Provider Requirements and Support Training and Education Vaccine Recipient Education Health Departments Planning & Partnerships Vaccine Effectiveness Research COVID-19 Vaccine Data Systems Content Syndication Vaccinate with Confidence

Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States

Reference Materials	Y Get Email Updates							
Summary Document for Interim Clinical Considerations 📙	To receive email updates about this page, enter your email address: Email Address							
COVID-19 Vaccine Administration Error Revaccination Guidance 📕								
COVID-19 Vaccine Administration Error Revaccination Guidance – Poster 📘								
	What's this? Submit							
<ul> <li>Summary of recent changes (last updated January 6, 2022):</li> <li>Updated guidance for use of Pfizer-BioNTech COVID-19 Vaccine as a booster in people ages 12–17 years</li> <li>Updated guidance for administration of a COVID-19 vaccine booster dose at least 5 months after completion of an mRNA vaccine (Pfizer-BioNTech or Moderna) primary series</li> </ul>								
<ul> <li>Updated guidance for use of an additional primary dose for moderately or severely immunocompromised people ages 5–11 years who received a Pfizer-BioNTech vaccine primary series</li> </ul>								
Updated recommendations for people who received COVID-19 vaccines outside the United States that are not FDA- authorized or approved								
Key points								
• COVID-19 vaccines currently approved or authorized by FDA <u>are effective</u> in preventing serious outcomes of COVID- 19, including severe disease, hospitalization, and death.								
<ul> <li>COVID-19 primary series vaccination is recommended for everyone ages 5 years and older in the United States for the prevention of coronavirus disease 2019 (COVID-19).</li> </ul>								

 In most situations, Pfizer-BioNTech or Moderna COVID-19 vaccines are preferred over the Janssen COVID-19 Vaccine for primary and booster vaccination.

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



For more information, contact CDC 1-800-CDC-INFO (232-4636) TTY: 1-888-232-6348 www.cdc.gov

# 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.

