COVID-19 Emerging Treatments Update



February 23, 2022

Emergency Use Instructions

CDC Issues Updated Guidance on COVID-19 mRNA Vaccine Dosing Interval

CDC Emergency Use Instructions¹⁻³:

On February 22, 2022 the CDC issued <u>Emergency Use Instructions</u> (EUI) which provide information about emergency use of the licensed COVID-19 vaccines by <u>Pfizer-BioNTech</u> (<u>Comirnaty</u>[®]) and <u>Moderna</u> (<u>Spikevax</u>[®]). The CDC-issued EUI provide instructions and information for the use of these vaccines that are beyond the FDA-approved labeling. Authority for the issuance of EUI is allowed under the <u>Pandemic and All Hazards</u> Preparedness Reauthorization Act.

Summary of Revisions to CDC Interim Clinical Considerations for Use of COVID-19 Vaccines^{1,4}:

Update of COVID-19 vaccine guidance to include addition of considerations for an 8-week interval between the first and second doses of a primary mRNA vaccine schedule **for certain persons ages 12-64 years of age**: (Note that this applies only to use of Spikevax® (Moderna) for people ages 18 years and older and Comirnaty® (Pfizer-BioNTech) for people ages 12 years and older).

Vaccine	First Dose	Second Dose	Booster Dose
Pfizer-BioNTech (ages 5-11 years)	Month 0	3 weeks after 1st dose	NA
Pfizer-BioNTech (ages 12 years and older)	Month 0	3-8 weeks after 1st dose	At least 5 months after 2nd dose
Moderna (ages 18 years and older)	Month 0	4-8 weeks after 1st dose	At least 5 months after 2nd dose
Janssen (ages 18 years and older)	Month 0	NA	At least 2 months after 1st dose

For a link to the original CDC table graphic, please click here: https://www.cdc.gov/vaccines/covid-19/images/covid-19-vac-schedule-chart-01.png? = 42169?noicon

The originally recommended interval (3 weeks for Pfizer-BioNTech; 4 weeks for Moderna) between the first and second primary doses remains the recommended interval for:

- people who are moderately to severely immunocompromised:
- adults ages 65 years and older; and
- others who need early protection due to increased concern about community transmission or risk of severe disease.

Rationale⁵:

International data on risk of myocarditis, especially among the highest risk group (males ages 12-39 years of age post dose 2) along with international data on an extended primary series interval related to the risk of myocarditis and vaccine effectiveness suggest that an extended 8-week dosing interval between the 1st and 2nd dose of an mRNA COVID-19 primary vaccine series may;

- increase duration of vaccine protection
- reduce the small risk of myocarditis & pericarditis

Updated CDC mRNA COVID-19 Vaccine EUI Fact Sheets²⁻³:

For Healthcare Providers:

- Pfizer-BioNTech COVID-19 Vaccine EUI Fact Sheet
- Moderna COVID-19 Vaccine EUI Fact Sheet

For Recipients and Caregivers:

- Pfizer-BioNTech COVID-19 Vaccine EUI Fact Sheet
- Moderna COVID-19 Vaccine EUI Fact Sheet

References:

- 1. U.S. Centers for Disease Control and Prevention, Vaccine Interim Clinical Considerations for Use of COVID-19 Vaccines. Accessed 2/23/22.
- 2. U.S. Centers for Disease Control and Prevention, <u>Emergency Use Instructions for Healthcare Providers</u>: Pfizer-BioNTech COVID-19 vaccine for Primary, Additional, and/or Booster Doses. Accessed 2/23/22.
- 3. U.S. Centers for Disease Control and Prevention, <u>Emergency Use Instructions for Healthcare Providers</u>: Moderna COVID-19 vaccine for Primary, Additional, and/or Booster Doses. Accessed 2/23/22.
- 4. U.S. Centers for Disease Control and Prevention, Questions and Answers about Emergency Use Instructions. Accessed 2/22/22.
- Advisory Committee on Immunization Practices, <u>Myocarditis and COVID-19 Vaccines Intervals</u>, International Data & Policies, Danielle Moulia, Feb 4, 2022.