ACIP COVID-19 Vaccines Work Group

Dr. Matthew F. Daley, Work Group Chair

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cdc.gov/coronavirus
Trends in COVID-19 cases in the United States

January 23, 2020 – November 16, 2021

47,244,379 total cases

COVID-19 Work Group activities – November 2021

- Reviewing updated data for booster doses of COVID-19 vaccines
  - Pfizer-BioNTech clinical trial for booster doses
  - Safety updates for booster doses
  - GRADEing of evidence
  - Updates to Evidence to Recommendations Framework
  - Discussion of booster dose policy options
FDA expands Emergency Use Authorization (EUA) of the Pfizer-BioNTech and Moderna COVID-19 vaccines

• Use of a single booster dose in individuals 18 years of age and older at least 6 months after completion of primary vaccination with any FDA-authorized or approved COVID-19 vaccine

• EUA allows for the use of each available COVID-19 vaccine as heterologous (or “mix and match” booster dose in eligible individuals following completion of primary vaccination with a different COVID-19 vaccine
  • The dosing interval for the heterologous booster dose is the same as that authorized for a booster dose of the vaccine used for primary vaccination.
COVID-19 vaccines among children 5–11 years of age

- **1,970,760** first doses have been administered to children ages 5–11 through November 17
- **6.2%** of children 5–11 years of age have received a first dose of Pfizer-BioNTech COVID-19 vaccine
- Ongoing review of safety data
May be underreported due to data lags

Notes: CDC received reports of children who either are or through recoding appear to be <12-years-old and have received COVID-19 vaccination prior to the Emergency Use Authorization for pediatric vaccination. These reports included 203,019 first doses and 127,737 dose completions. These reports could be the result of any of the following: (1) data reporting errors (2) participation in a clinical trial (3) 12-years-old children miscategorized as 11-years-old due to recoding of incomplete birth dates submitted (e.g., year of birth only). Of those children receiving at least the first dose and of those completing the series, 94% and 97% respectively of those coded as being <12-years-old are coded as being 11-years-old. The most recent five days of reporting may be underreported due to delays in reporting. All reported numbers might change over time as historical data are reported to CDC.

Source: Immunization Data Lake. Data as of November 17, 2021, 0600AM.
Emergency Use Instructions: COVID-19 vaccine by Pfizer-BioNTech

- On November 17, 2021, CDC issued Emergency Use Instructions (EUI) about use of the COVID-19 vaccine by Pfizer-BioNTech approved by the Food and Drug Administration (FDA)

- approved by the Food and Drug Administration (FDA) to prevent COVID-19 in people aged ≥16 years

- The EUI authority* allows CDC to create and issue EUI to permit emergency use of FDA-approved medical products
  - EUI are provided as fact sheets for healthcare providers and recipients
  - Include information about such products’ approved, licensed, or cleared conditions of use

*2013 Pandemic and All-Hazards Preparedness Reauthorization Act
Allowed uses of the Pfizer-BioNTech COVID-19 vaccine under EUI

- EUI cover use in people who completed primary vaccination with a non-FDA authorized or -approved COVID-19 vaccine:
  - Certain people vaccinated outside the United States with a COVID-19 vaccine listed for emergency use by the World Health Organization
  - Certain participants in COVID-19 vaccine clinical trials within or outside the United States

- EUI provide information about use as:
  - An additional primary dose in certain moderately or severely immunocompromised persons* aged ≥12 years
  - A single booster dose in certain adults* aged ≥18 years

*Refer to CDC’s Interim Clinical Considerations for additional information on moderately or severely immunocompromised persons recommended for an additional primary dose and populations recommended for a booster dose [https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccinesus.html](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccinesus.html)
Emergency Use Instructions (EUI) Fact Sheets for Healthcare Providers and for Recipients and Caregivers

Emergency Use Instructions 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

The Centers for Disease Control and Prevention (CDC) is issuing Emergency Use Instructions (EUI) to provide information about the 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. These EUI provide information about the use of the COVID-19 vaccine by Pfizer-BioNTech as an additional primary dose in certain immunocompromised persons aged ≥12 years and as a booster dose in certain adults aged ≥18 years after completion of primary vaccination with an FDA-authorized or approved COVID-19 vaccine.

These EUI for healthcare providers contain key information regarding the EUI specific to this use. For additional information about the COVID-19 vaccine to the Comirnaty package insert or the Full Emergency Use Authorization to CDC’s Interim Clinical Considerations for detailed recommendations relevant information is contained under the headings “People who received COVID-19 vaccine in the United States” and “People who received COVID-19 vaccine as part of a clinical trial.”

Emergency Use Instructions (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

You may be eligible for COVID-19 vaccine by Pfizer-BioNTech as an additional primary dose (if aged ≥12 years) or a single booster dose (if aged ≥18 years) after completing a primary series vaccination with a certain COVID-19 vaccine not authorized or approved by the Food and Drug Administration (FDA). For example, people who were vaccinated outside the United States or from clinical trial participation (such as the AstraZeneca COVID-19 vaccine, the Novavax COVID-19 vaccine, or the Sinopharm COVID-19 vaccine) may be eligible to receive an additional primary dose and/or a booster dose.

The additional primary and booster doses of COVID-19 vaccine by Pfizer-BioNTech are described in these Emergency Use Instructions (EUI), which are issued by the Centers for Disease Control and Prevention (CDC) and are further explained in this Fact Sheet.
Agenda: Tuesday November 19 2021

- Efficacy and safety of BNT162b2 booster dose
  Dr. Perez (Pfizer)
- Update from Moderna
  Dr. Das (Moderna)

Break

PUBLIC COMMENT
- COVID-19 vaccine booster dose safety
  Dr. Shimabukuro (CDC)
- VaST summary
  Dr. Talbot (VaST Chair)
- Updates to the EtR Framework:
  Pfizer-BioNTech and Moderna COVID-19 vaccine booster doses
  Dr. Oliver (CDC)

VOTE
Work group members

ACIP members
- Matthew Daley (chair)
- Beth Bell
- Grace Lee
- Keipp Talbot
- Oliver Brooks

Ex-officio/government members
- FDA: Doran Fink, Rachel Zhang
- NIH: Chris Roberts
- IHS: Thomas Weiser, Uzo Chukwuma
- DOD: Bryan Schumacher
- CMS: Jeff Kelman
- BARDA: Christine Oshansky
- HHS: David Kim

CDC Leads
- Sara Oliver

Liaisons
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- ACP: Jason Goldman
- AGS: Ken Schmader
- AIM: Rob Shechter (primary), Jane Zucker (alternate)
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- APhA: Michael Hogue
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- IDSA: Jeff Duchin (primary), Carol Baker (alternate)

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- SHEA: Marci Drees

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For more information, contact CDC
1-800-CDC-INFO (232-4636)

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.