

Issue Brief

Pfizer-BioNTech COVID-19 Vaccine Emergency Use Authorization Vaccination Implementation Resources

May 18, 2021

The FDA issuance of an Emergency Use Authorization (EUA) of the Pfizer-BioNTech vaccine to prevent COVID-19 illness marks a major milestone toward fighting the pandemic. This document provides a summary of key information and resources to assist state and territorial health departments with implementation of the first phase of COVID-19 vaccination. A timeline of events leading to the FDA EUA and the Advisory Committee on Immunization Practices (ACIP) use recommendations and list of key resources are below:

Timeline

- **Dec. 1, 2020:** ACIP voted 13 to 1 to prioritize the first doses of COVID-19 vaccine for healthcare workers and long-term care facilities. Additional details on the ACIP recommendation can be found in [MMWR: ACIP Allocation of Initial Supplies of COVID-19 Vaccine \(Dec. 11\)](#).
- **Dec. 10, 2020 :** The [Vaccines and Related Biological Products Advisory Committee](#) recommended, in a 17 to 4 vote, with one abstention, to endorse the Pfizer-BioNTech COVID-19 vaccine for people 16 and older based on a favorable benefit-risk profile. The committee received a [briefing document](#) to support [discussions](#) related to the vaccine, including concerns about vaccinating 16-to-17-year-old children, pregnant and/or lactating women, and those with severe allergies.
- **Dec. 11, 2020:** FDA [authorized](#) the Pfizer-BioNTech COVID-19 vaccine for use among persons 16 years and older. The decision culminated through a [documented](#) review process.
- **Dec. 12, 2020:** ACIP voted 11 to 0, with three recusals due to conflicts, to issue an interim recommendation for use of the Pfizer-BioNTech COVID-19 vaccine in persons older than 16 years under the FDA emergency authorization. Robert Redfield, director of CDC, approved the recommendations and CDC published [MMWR: ACIP Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine \(Dec. 13\)](#). The MMWR includes specific research, including a detailed summary of [safety data](#), a [GRADE](#) review of the evidence for benefits and harms, and information on administration and use in [special populations](#).
- **(NEW) May 10, 2021:** FDA [expanded](#) the EUA for the Pfizer-BioNTech COVID-19 vaccine to include adolescents 12-15 years of age. Additional details are available through a recorded [press briefing](#).
- **(NEW) May 12, 2021:** ACIP voted 14 to 0 to [recommend](#) the use of Pfizer COVID-19 vaccine for adolescents aged 12-15 years old. COVID-19 vaccines and other vaccines can be [administered](#) without regard to timing. This includes administration of COVID-19 vaccines and other vaccines on the same day or within two weeks of vaccination. The CDC director released a [statement](#) announcing the adoption of ACIP's recommendations for Pfizer-BioNTech COVID-19 vaccine in individuals aged 12 and older. CDC also released an [MMWR](#) summarizing ACIP's interim recommendations for the use of Pfizer-BioNTech COVID-19 vaccine in adolescents aged 12-15. The American Academy of Pediatrics released a [policy statement](#) supporting the coadministration of childhood immunizations with COVID-19 vaccines.

CDC Materials to Support Implementation

A variety of materials have been released to train and assist healthcare providers with vaccine administration.

- **(UPDATED)** [Interim Clinical Considerations for Use of Pfizer-BioNTech COVID-19 Vaccine](#) (Includes Information on Coadministration of Vaccines)
- [Interim Considerations for COVID-19 Vaccination of Healthcare Personnel and Long-Term Care Facility Residents](#) (Last updated Dec. 3, 2020)
- [Adverse Events and Reactions](#) (Clinical Trial Results from Pfizer-BioNTech Vaccine)
- [CDC's COVID-19 Vaccination Communication Toolkit for Medical Centers, Clinics, and Clinicians](#)
- [COVID-19 Vaccine](#) (Storage and Handling, ACIP Recommendations, and EUA)
- [Pfizer-BioNTech Vaccine](#) (Specific Information for Pfizer-BioNTech Vaccine)
- [Training and Education Materials](#) and [Quick Link](#) (Healthcare Provider Training Modules)
- [V-Safe Information](#) (New CDC Text/Web-Based Adverse Event System)
- [Pfizer-BioNTech COVID-19 Vaccine Questions](#) (FAQs about Vaccine Supply, Distribution, and Administration)

(UPDATED) Pfizer-BioNTech COVID-19 Vaccine Emergency Use Authorization Factsheets

Factsheets were developed by Pfizer-BioNTech to hand out to healthcare providers administering the vaccine, as well as to their patients.

- [Factsheet for Healthcare Providers](#)
- [Factsheet for Patients](#)

Cold Chain, Storage, and Dry Ice Operations

The Cybersecurity & Infrastructure Security Agency has developed [critical questions and considerations](#) that may inform and assist in further reducing risk to these life-saving efforts.

Additional Information

- CDC is offering direct technical assistance and support through these mechanisms:
 - CDC's Vaccine Coordination Center launched a 24/7 Jurisdictional Watch Desk to provide COVID-19 vaccine technical assistance to the 64 jurisdictions funded by the Immunization Services Division. The Jurisdictional Watch Desk began operations at 8 a.m. ET Friday, Dec. 11, and will operate 24 hours a day, seven days a week. (Local health departments will be directed to their state or territorial health department.)
 - The CDC Clinician On-Call Center launched a 24-hour hotline with trained CDC clinicians standing by to answer COVID-19 questions from healthcare personnel on a wide range of topics, such as diagnostic challenges, clinical management, and infection prevention and control. To reach this service, call 800-CDC-INFO (800-232-4636) and ask for the Clinician On-Call Center.
 - CDC field staff are being assigned to immunization and preparedness programs and will be visiting a sample of sites to observe and document receipt of vaccine shipment and integrity. These visits will be communicated with jurisdictions beforehand and support process improvements as needed. The field staff will complete the brief online survey on behalf of the sites they are observing and send photos to CDC documenting any concerning aspects of the shipment.