ACIP Recommendations for Pfizer-BioNTech COVID-19 Vaccine Use (including Special Populations)

- CDC/MMWR

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Following the FDA issuance of an Emergency Use Authorization for the Pfizer-BioNTech COVID-19 vaccine, the Advisory Committee on Immunization Practices (ACIP) issued interim recommendations for the prevention of COVID-19 in persons aged ≥16 years.

The PfizerCOVID-19 vaccine (BNT162b2) is a lipid nanoparticle-formulated, nucleoside-modified mRNA vaccine encoding the prefusion spike glycoprotein of SARS-CoV-2, the virus that causes COVID-19. Vaccination consists of 2 intramuscular doses (30 μg, 0.3 mL each) given 3 weeks apart.

The ACIP employed the Evidence to Recommendation (EtR) Framework, using the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach to develop further guidance based on one large, randomized, double-blind, placebo-controlled Phase II/III clinical trial that enrolled >43,000 participants (median age = 52 years, range = 16–91 years).

Interim findings from this clinical trial (with a median of 2 months of follow-up) indicates that this COVID-19 vaccine was 95.0% effective in preventing symptomatic laboratory-confirmed COVID-19 in persons without evidence of previous SARS-CoV-2 infection.

Consistent high efficacy (≥92%) was observed regardless of age, sex, race, ethnicity and among underlying medical conditions. These studies also showed a reduced risk of hospitalization, death and severe outcomes among vaccinated persons compared to placebo recipients.

Reactogenicity symptoms, defined as solicited local injection site or systemic reactions during the 7 days after vaccination, were frequent and mostly mild to moderate and were more commonly reported after the second dose than after the first dose. Reactogenicity was generally more frequent and severe in persons aged 18–55 years than in those aged >55 years.

Systemic adverse reactions had a median onset of 1–2 days after vaccine receipt and resolved in a median of 1 day. Severe local and systemic adverse reactions (grade ≥3, defined as interfering with daily activity) occurred more commonly in vaccine recipients than in placebo recipients. Among vaccine recipients, 8.8% reported any grade ≥3 reaction; the most common symptoms were fatigue (4.2%), headache (2.4%), muscle pain (1.8%), chills (1.7%), and injection site pain (1.4%). The potential benefits are:

- High certainty evidence that the Pfizer-BioNTech COVID-19 vaccine can prevent symptomatic COVID-19.
- Low certainty evidence for the prevention of COVID-19–associated hospitalization
- Very low certainty evidence for the prevention of death.

Data supports the use of the Pfizer-BioNTech COVID-19 vaccine, with the ACIP noting that COVID-19 is a major public health problem and that use of the Pfizer-BioNTech COVID-19 vaccine is a reasonable and efficient allocation of resources.

Whereas there might be uncertainty in how all populations value the vaccine, it was determined that for most populations, the desirable effects outweigh the undesirable effects.

- Before vaccination, the EUA (vaccine) Fact Sheet should be provided to recipients and caregivers.
- Providers should counsel COVID-19 vaccine recipients about expected systemic and local reactogenicity.

Vaccination in Special Populations

- Persons with underlying medical conditions: the vaccine may be administered to persons with underlying medical conditions who have no contraindications to vaccination. Phase 2/3 clinical trials demonstrated similar safety and efficacy profiles in persons with some underlying medical conditions, including those that place them at increased risk for severe COVID-19, compared to persons without comorbidities.
- Immunocompromised persons: Persons with HIV infection, other immunocompromising conditions, or who take immunosuppressive medications or therapies might be at

increased risk for severe COVID-19. *Data are not currently available to establish vaccine safety and efficacy in these groups*. Persons with stable HIV infection were included in phase 2/3 clinical trials, though data specific to this group are not yet available. **Immunocompromised individuals may still receive COVID-19 vaccination if they have no contraindications to vaccination. However, they should be counseled about the unknown vaccine safety profile and effectiveness in immunocompromised populations, as well as the potential for reduced immune responses and the need to continue to follow all current guidance to protect themselves against COVID-19.**

- Pregnancy: Observational data demonstrate that while the absolute risk is low, pregnant people with COVID-19 have an increased risk of severe illness, including illness resulting in ICU admission, mechanical ventilation, or death. Additionally, they might be at an increased risk of adverse pregnancy outcomes, such as preterm birth. There are currently no available data on the safety of COVID-19 vaccines, in pregnant people. However, animal developmental and reproductive toxicity (DART) studies are ongoing and results are expected to be available soon; studies in pregnant people are planned. In addition, the manufacturer is following outcomes on people in the clinical trials who became pregnant. mRNA vaccines are not live vaccines. The mRNA in the vaccine is degraded quickly by normal cellular processes and does not enter the nucleus of the cell. Based on current knowledge, experts believe that mRNA vaccines are unlikely to pose a risk for people who are pregnant. If pregnant people are part of a group that is recommended to receive a COVID-19 vaccine (e.g., healthcare personnel), they may choose to be vaccinated. A conversation between the patient and their clinical team may assist with decisions regarding the use of vaccines approved under EUA for the prevention of COVID-19. While a conversation with a healthcare provider may be helpful, it is not required prior to vaccination.
    - When making a decision, pregnant people and their healthcare providers should consider the level of COVID-19 community transmission, the patient's personal risk of contracting COVID-19, the risks of COVID-19 to the patient and potential risks to the fetus, the efficacy of the vaccine, the side effects of the vaccine and the lack of data about the vaccine during pregnancy. Pregnant people who experience fever following vaccination may be counseled to take acetaminophen as fever has been associated with adverse pregnancy outcomes. Acetaminophen may be offered as an option for pregnant people experiencing other post-vaccination symptoms as well.There is no recommendation for routine testing before receipt of a COVID-19 vaccine. Those who are trying to become pregnant do not need to avoid pregnancy after Pfizer-BioNTech COVID-19 vaccination.
- Lactating people: There are no data on the safety of COVID-19 vaccines in lactating people or the effects of mRNA vaccines on the breastfed infant or milk production/excretion. mRNA vaccines are not thought to be a risk to the breastfeeding infant. A lactating person who is part of a group recommended to receive a COVID-19 vaccine (e.g., healthcare personnel) may choose to be vaccinated.
- Adolescents: Adolescents aged 16–17 years are included among persons eligible to receive the Pfizer-BioNTech COVID-19 vaccine under the EUA. The interim analysis of the Phase 2/3 clinical trial included 153 participants aged 16–17 years, with no safety concerns identified. While vaccine safety and efficacy data in this age group are limited, there are no biologically plausible reasons for safety and efficacy profiles to be different

than those observed in persons 18 years of age and older. Adolescents aged 16–17 years who are part of a group recommended to receive a COVID-19 vaccine may be vaccinated, with appropriate assent.

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[The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine — United States, December 2020]