

TO: Vermont Health Care Providers and Health Care Facilities
FROM: Jennifer S. Read, MD, FIDSA; Medical Epidemiologist

Interim Recommendation for Use of Pfizer-BioNTech COVID-19 in Adolescents Aged 12-15 Years

Background:

The [updated Health Advisory](#) regarding the use of the COVID-19 vaccine developed by Pfizer-BioNTech in persons 16 years of age and older was issued on December 24, 2020. On May 10, 2021, the U.S. Food and Drug Administration (FDA) issued an [Emergency Use Authorization](#) (EUA) for the use of this vaccine in adolescents aged 12-15 years. On May 14, 2021, the [interim recommendation](#) of the CDC's Advisory Committee on Immunization Practices (ACIP) regarding the use of the Pfizer-BioNTech COVID-19 vaccine in adolescents aged 12-15 years was issued.

Efficacy

Most of the data regarding the use of the Pfizer-BioNTech COVID-19 vaccine comes from one randomized, double-blind, placebo-controlled Phase II/III clinical trial that eventually enrolled approximately 2,200 participants aged 12–15 years. The participants were randomized 1:1 to receive vaccine or placebo. The interim results of this trial included data from participants with a median of two months of follow-up.

The estimated efficacy of the vaccine was supported by: 1) clinical efficacy; and 2) immunobridging:

- **Clinical efficacy:** Efficacy was 100% (95% confidence interval [CI] = 75.3%–100%) in preventing symptomatic, laboratory-confirmed COVID-19 without evidence of previous SARS-CoV-2 infection.
- **Immunobridging:** Results from adolescents aged 12-15 years was compared to those from recipients aged 16–25 years. The immune response to two doses of the vaccine in persons aged 12-15 years was at least as high as the response observed in persons aged 16–25 years; the geometric mean ratio for 50% neutralizing antibody titer was 1.76 (95% CI = 1.47–2.10), demonstrating statistical noninferiority.

Safety

Reactogenicity symptoms (solicited local injection site or systemic reactions during the 7 days after vaccination) occurred in almost all vaccine recipients (90.9% reported any local reaction; 90.7% reported any systemic reaction). However, these symptoms were usually mild to moderate. Systemic adverse reactions were more commonly reported after the second dose (than after the first dose), began 1-4 days (median) after vaccine receipt, and resolved in 1–2 days (median). Severe local and systemic adverse reactions (grade ≥ 3 , defined as interfering with daily activity) occurred more commonly in vaccine recipients (than in placebo recipients): 10.7% of vaccine recipients reported any reaction of grade ≥ 3 . The most common symptoms

were: fatigue (3.5%), fever (3.0%), headache (2.7%), chills (2.1%), and injection-site pain (1.5%). As with systemic adverse reactions overall, reactions of grade ≥ 3 were more commonly reported after the second dose than after the first dose. Five serious adverse events (0.4%) were reported among vaccine recipients and two (0.2%) among placebo recipients (no statistically significant difference). None were considered to be related to vaccination. In summary, no specific safety concerns were identified.

FDA requires that vaccination providers report vaccination administration errors, serious adverse events, cases of multisystem inflammatory syndrome, and cases of COVID-19 that result in hospitalization or death after administration of COVID-19 vaccine under an EUA. Adverse events that occur after receipt of any COVID-19 vaccine should be reported to the **Vaccine Adverse Events Reporting System (VAERS)**. Information on how to submit a report to VAERS is available at <https://vaers.hhs.gov/index.html> or 1-800-822-7967.

In addition, CDC has developed **v-safe**, a new, voluntary smartphone-based online tool that uses text messaging and online surveys to provide near real time health check-ins after receipt of a COVID-19 vaccine. Parents or guardians can register their adolescent children in v-safe and complete the health surveys on their behalf. CDC's v-safe call center follows up on reports to v-safe that include possible medically significant health events to collect additional information for completion of a VAERS report. Information on v-safe is available at <https://www.cdc.gov/vsafe>.

REQUESTED ACTION

1. Understand the efficacy and safety data related to the use of the Pfizer-BioNTech COVID-19 vaccine in adolescents aged 12 to 15 years.
2. Ensure you are providing patients with the [EUA factsheet](#) for the Pfizer-BioNTech COVID-19 vaccine.
3. Report adverse events following immunization to VAERS. Encourage enrollment in v-safe.

If you have any questions, please contact the HAN Coordinator at 802-859-5900 or vthan@vermont.gov.

HAN Message Type Definitions

Health Alert: Conveys the highest level of importance; warrants immediate action or attention.

Health Advisory: Provides important information for a specific incident or situation may not require immediate action.

Health Update: Provides updated information regarding an incident or situation; unlikely to require immediate action.

Info Service Message: Provides general correspondence from VDH, which is not necessarily considered to be of an emergent nature.