

**INFORMATION for PEDIATRIC PROVIDERS**  
**Emergency Use Authorization of Pfizer COVID-19 Vaccine for Adolescents 12-15 yo**

- The Pfizer –BioNTech COVID-19 vaccine (“vaccine”) is authorized by the FDA for emergency use; it is NOT an FDA-approved vaccine
- The vaccine is authorized by the FDA for emergency use in individuals 12 years of age and older
- The vaccine is administered intramuscularly as a series of two doses (0.3ml each) three weeks apart (this is the same dosing and interval as the adult vaccine)
- COVID-19 vaccines were previously recommended to be administered alone, with a minimum interval of 14 days before or after administration of any other vaccines. This was out of an abundance of caution and not due to any known safety or immunogenicity concerns. Although data are not available for COVID-19 vaccines administered simultaneously with other vaccines, extensive experience with non-COVID-19 vaccines has demonstrated that immunogenicity and adverse event profiles are generally similar when vaccines are administered simultaneously as when they are administered alone. **The CDC’s Advisory Committee on Immunization Practices (ACIP) has changed the clinical guidelines to now allow COVID-19 vaccines to be given on the same day and/or within 14 days of other vaccines. The American Academy of Pediatrics supports co-administration.**
- The vaccine study included 2,260 adolescents (1,131 received the vaccine; 1,129 the placebo). Of those, 660 of those who received the vaccine have been studied for at least 2 months for the 2<sup>nd</sup> dose. The safety evaluation is ongoing.
- The efficacy of the vaccine in preventing symptomatic COVID-19 disease in the 12 to 15 year old age group is **100%** (7 days after Dose #2) for patients who both had NO evidence of prior SARS-CoV-2 infection and WITH evidence of prior SARS-CoV-2 infection
- In the 12-15 year old age group compared to the 16-25 year old age group, the vaccine is more immunogenic with evidence of higher mean titers of neutralizing titers to SARS-CoV-2 obtained 1 month after Dose 2.
- The only contraindication to receiving the vaccine is having a known history of severe allergic reaction (eg. Anaphylaxis) to any component of the Pfizer –BioNTech COVID-19 vaccine. Patients that have other allergic reactions to food (eg. peanuts, tree nuts, etc.), drugs (eg. Penicillin, etc.), etc. may still receive the vaccine.

Updated 5/13/2021

- In the study population, adverse reactions in adolescents 12 through 15 years of age included :
  - Pain at the injection site (90.5%) ← more than adults
  - Fatigue (77.5%) ← more than adults
  - Headache (75.5%) ← more than adults
  - Chills (49.2%) ← more than adults
  - Muscle Pain (42.2%) ← more than adults
  - Fever (24.3%) ← more than adults
  - Joint Pain (20.2%) ← less than adults
  - Injection Site Swelling (9.2%) ← less than adults
  - Injection Site Redness (8.6%) ← less than adults
  - Lymphadenopathy (0.8%) ← more than adults
  - Nausea (0.4%) ← less than adults
  
- Particularly in adolescents, syncope may occur with administration of injectables (not an immediate side effect of the vaccine itself). Vaccine administration locations will have procedures in place to avoid injury from fainting.
  
- Immunocompromised people, including those receiving immunosuppressant therapy, may have a diminished response to the vaccine

Please see the following document from the New York City Department of Health for plain language answers to some commonly asked questions by patients/caregivers:

[Addressing Patients' COVID-19 Vaccine Questions: A Guide for Health Care Providers](#)

The FDA information about the Pfizer –BioNTech COVID-19 vaccine for individuals 12 years of age and older can be found here:

[FACT SHEET for Healthcare Providers Administering Vaccine - Emergency Use Authorization of the Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 \(COVID-19\)](#)

AAP New article:

[AAP, CDC recommend COVID-19 for ages 12 and older](#)