

## Pfizer COVID-19 Vaccine – Expanded use in children 12 – 15 years old

- On May 10, 2021, the FDA approved an expansion to the Emergency Use Authorization (EUA) for the coronavirus disease 2019 (COVID-19) vaccine produced by Pfizer/BioNTech to include adolescents age 12 – 15 years.
- To date, 139.8 million doses of the Pfizer/BioNTech vaccine have been administered.
- Updated Fact Sheet for Healthcare Providers Authorized Use Statement: The Pfizer-BioNTech COVID-19 Vaccine is authorized for use under an EUA for active immunization to prevent COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 12 years of age and older.
- The EUA is supported by a trial involving 2,260 participants ages 12 through 15 years old; of these, 1,131 received the vaccine.
  - Safety: The most commonly reported side effects in the adolescent clinical trial, which typically lasted 1-3 days, were pain at the injection site, tiredness, headache, chills, muscle pain, fever and joint pain. Reactions were more common after the second dose. This is consistent with the side effect profile observed in individuals 16 years and older.
  - Efficacy: Among participants without evidence of prior infection with SARS-CoV-2, no cases of COVID-19 occurred among 1,005 vaccine recipients and 16 cases of COVID-19 occurred among 978 placebo recipients; the vaccine was 100% effective in preventing COVID-19.
- Pfizer continues to study the vaccine and has ongoing trials in pregnant women, children 6 months to 11 years old, and is also studying boosters to address new variants of COVID-19. Results of these trials are expected in the second half of 2021.
- The CDC's Advisory Committee on Immunization Practices (ACIP) has scheduled an emergency meeting for Wednesday, May 12, 2021 to discuss the new indication expansion for the Pfizer/BioNTech vaccine. The ACIP will then provide updated recommendations for use at that meeting.