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NEW MEXICO HEALTH ALERT NETWORK (HAN) ALERT

CDC and FDA Authorize a Pfizer Booster Dose for Children Ages 5 - 11

May 20, 2022

Background:

The FDA expanded the Pfizer-BioNTech EUA to include a single booster dose for children ages 5 – 11 on May 17, 2022. The Advisory Committee on Immunization Practices (ACIP) voted on May 19, 2022, to recommend a **COVID-19 booster doses for everyone 5 years and older.** The CDC endorsed the ACIP recommendation for children 5-11 years of age shortly after the meeting and strengthened the CDC's recommendation for *second booster* doses for previously designated groups.¹

Booster Dose Recommendations for Children ages 5-11:

- Children ages 5 11 should receive a booster dose of the Pfizer-BioNTech COVID-19 vaccine at least 5
 months after completing a primary vaccine series. The Pfizer-BioNTech vaccine is the only vaccine
 currently approved for this age group.
- Children ages 5 11 who are moderately or severely immune compromised should receive a booster dose at least *3 months* after completion of a 3-dose primary series. The *3 dose primary series* is as follows: a first dose followed 3 weeks later by a second dose and then four weeks later by a third dose.
- The Pfizer booster dose is the same as that for the primary series which is 0.2ml (10 μ g). The pediatric formulation is in the vial with the orange cap.

CDC's Strengthened Booster Dose Recommendations:

- A second booster dose of mRNA vaccine should be given to individuals 50 and older; for those 12 and older who are immunocompromised; and for those who have received 2 doses of the Janssen vaccine.
- The second booster should be given 4 months after the first booster.

Safety Considerations:

- The FDA noted no new safety concerns in a study of 400 children who received a booster dose at least 5 months after completing a two-dose primary series.
- The most reported side effects were pain, redness and swelling at the injection site, as well as fatigue, headache, muscle or joint pain and chills and fever.
- The vaccine safety data reviewed by ACIP show that the risk of cardiac complications (including myocarditis) is higher from COVID disease than it is from mRNA vaccination. Twenty cases of myocarditis have been reported in VAERS for the 5 11 age group after a primary series dose.
 Myocarditis in the 5-11 population is more common in males and following the second dose.

¹ Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC

• Since authorization, 18.1 million doses of Pfizer-BioNTech vaccine have been administered to children ages 5–11 years in the United States.

Additional Considerations:

- 1) Data reviewed by the FDA showed that children 5 11 had a robust immune response to a booster dose.
- 2) People who have had SARS-CoV-2 infection and recovered should still get all recommended doses of COVID-19 vaccine and boosters. People who recently had COVID-19 may consider delaying their first or second COVID-19 vaccine booster dose by 3 months from symptom onset or positive test (for asymptomatic infection). Studies have shown that increasing the time between infection and vaccination may result in an improved immune response to vaccination. Also, a low risk of reinfection has been observed in the weeks to months following infection, although Individual risk factors should be considered to determine optimal timing of vaccine. Patients should complete their isolation period before getting vaccinated.

Access to Vaccine Booster Doses in New Mexico:

- New Mexico COVID-19 vaccine providers can immediately implement the above recommendations.
- The statewide registration app has been updated to allow booster scheduling for children 5 11. People can schedule at: Get Vaccinated New Mexico | NMDOH (vaccinenm.org)
- New Mexicans can also schedule boosters with their medical and pharmacy providers.
- Vaccine appointments can also be found on the CDC Vaccine Finder website: <u>Vaccines.gov Find COVID-19 vaccine locations near you</u>.
- All providers are encouraged to provide office-based COVID-19 vaccines.

Additional Resources:

- 1. Pfizer EUA for Providers: <u>Pfizer Fact Sheet for Healthcare Providers for 5-11 years of age, orange cap (must dilute) (fda.gov)</u>
- 2. Pfizer EUA for Vaccine Recipients: Recipients and Caregivers 5-11 years of age (fda.gov)
- 3. Clinical recommendations from CDC will be updated here: Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC
- For clinicians wishing to administer COVID-19 vaccine, please contact the NM DOH Immunization Team at covid.vaccines@state.nm.us or register online at TakeCareNM.com: For Providers | NMDOH (rtscustomer.com)

New Mexico Health Alert Network: To register for the New Mexico Health Alert Network, click the following link to go directly to the HAN registration page https://nm.readyop.com/fs/4cjZ/10b2 Please provide all information requested to begin receiving important health alerts and advisories.

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