NEW MEXICO Department of 1	Health
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#### NEW MEXICO HEALTH ALERT NETWORK (HAN) ALERT

### CDC and FDA Update Indications for Pfizer-BioNTech COVID-19 Vaccine

January 6, 2022

#### Background

On January 5, 2022, the Centers for Disease Control and Prevention (CDC) endorsed the Advisory Committee on Immunization Practices' (ACIP) recommendation to expand booster dose eligibility to children ages 12 to 15. Previously, boosters were approved only for those 16 years of age and older.

The CDC made the following additional recommendations for the Pfizer-BioNTech COVID-19 vaccine:

- 1) The booster interval was updated to *five months* for individuals 12 and older who have received a Pfizer primary series. The previous booster interval was six months.
- Children ages 5 11 who are immune compromised should receive a third primary series dose (additional dose) 28 days from the second dose. Previously, only immune compromised individuals 12+ were eligible for the "additional dose".
- Adolescents ages 12 17 *should* get a booster 5 months after completion of the primary series. Previously, CDC recommended that adolescents 12-17 years *can* receive a booster dose.

The Food and Drug Administration (FDA) amended the Pfizer-BioNTech COVID-19 vaccine emergency use authorization (EUA) on January 3, 2022. The New Mexico Medical Advisory Team (MAT) reviewed and concurred with the FDA and CDC's recommendations.

#### **Recommendations for Clinicians:**

#### Children:

- Children ages 5 11 who are immune compromised should receive a third primary series dose (additional dose) of Pfizer vaccine given 28 days from the second dose.
- Children ages 5 -- 11 who are fully vaccinated and are not immunocompromised **do not** need a third (booster) dose at this time. The FDA continues to review data for this pediatric population.

#### Adolescents:

- A Pfizer booster dose is now recommended for adolescents ages 12 -17 at least five months after completion of the primary series.
- The booster dose for people 12 years and older is the same formulation and dosage strength as the Pfizer primary series.
- At this time, only the Pfizer-BioNTech COVID-19 vaccine is authorized for adolescents aged 12-17.

Adults:

• For adults 18 years and older who had a primary Pfizer/Comirnaty series, a booster dose should now be administered at least *five months* after completion of the primary series. Previously the booster was recommended at 6 months. The booster dose can be any vaccine brand although mRNA vaccines are preferred in most situations.

### Safety Considerations:

- Potential risks of a Pfizer booster dose include the rare risks of myocarditis and pericarditis. Based on vaccine safety data, the group at highest risk for myocarditis and pericarditis is males aged 12-29 years<sup>1</sup>.
- The risk of myocarditis or pericarditis associated with SARS-CoV-2 infection is greater than the risk of myocarditis or pericarditis occurring after receipt of an mRNA COVID-19 vaccine in adolescents and adults.
- ACIP reviewed the available safety data following the administration of over 25 million vaccine doses in adolescents. The data shows there are no new safety concerns following a booster in this population. There were no new cases of myocarditis or pericarditis reported to date in these individuals.
- No new safety concerns have emerged from a population of over 4.1 million individuals 16 years of age and older in Israel who received a booster dose at least five months following completion of the primary vaccination series<sup>2</sup>.

# Access to Vaccine Boosters Doses in New Mexico

- New Mexico COVID-19 vaccine providers can immediately implement the above recommendations.
- The statewide registration app has also implemented the above recommendations for scheduling. Parents and guardians can schedule boosters at: <u>vaccinenm.org/kids</u>.
- People can also schedule primary vaccine and boosters with their medical or pharmacy provider.
- Vaccine appointments can also be found on the CDC Vaccine Finder website: <u>Vaccines.gov Find</u> <u>COVID-19 vaccine locations near you</u>.

# Additional Resources:

- 1. Updated CDC page on boosters: <u>COVID-19 Vaccine Booster Shots | CDC</u>
- 2. Pfizer EUA for 5 11: <u>https://www.fda.gov/media/153714/download</u>
- 3. Pfizer EUA for 12+: https://www.fda.gov/media/153715/download
- 4. Full clinical recommendations will be posted on the CDC website in the coming days: <u>Interim</u> <u>Clinical Considerations for Use of COVID-19 Vaccines | CDC</u>
- 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)

#### EPIDEMIOLOGY AND RESPONSE

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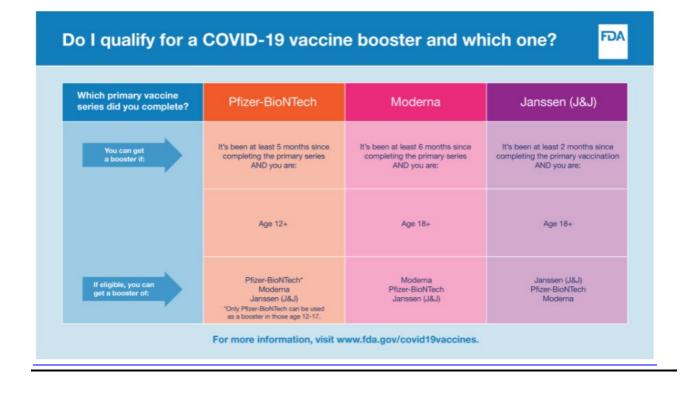
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<sup>&</sup>lt;sup>1</sup> <u>Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC</u> <sup>2</sup><u>https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine#additional</u>



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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 <u>https://nm.readyop.com/fs/4cjZ/10b2</u> Please provide all information requested to begin

receiving important health alerts and advisories.