



NEW MEXICO HEALTH ALERT NETWORK (HAN) ALERT

CDC and FDA Update COVID-19 Vaccine Schedule

April 20, 2023

Summary:

The CDC and FDA have streamlined COVID-19 vaccine recommendations, authorizing the use of bivalent COVID-19 vaccines for all recommended doses. In addition, previously unvaccinated individuals ages 6 and older are now recommended to receive one dose of a bivalent COVID-19 vaccine, and people ages 65 and older and those with immune compromise can receive a second bivalent vaccine. The monovalent Moderna and Pfizer-BioNTech COVID-19 vaccines are no longer authorized for use in the United States.

Background:

On April 18, 2023, the FDA amended the emergency use authorizations (EUAs) of the Moderna and Pfizer-BioNTech COVID-19 Bivalent vaccines to authorize the current bivalent vaccines to be used for all doses administered to individuals 6 months of age and older. With the amended EUAs, individuals 65 and older and those with immune compromise may receive an additional bivalent booster. Previously unvaccinated individuals aged 6 years and older may now get a single bivalent vaccine dose. The recommendations for children aged 5 years and under depend on age, vaccination history, and vaccine brand. Concurrently, the FDA removed authorization for the original (monovalent) COVID19 mRNA vaccines. The Advisory Committee on Immunization Practices (ACIP) endorsed these changes at their meeting on April 19, 2023. The current bivalent vaccines contain original and omicron BA.4/BA.5 strains and are unchanged from the bivalent vaccines previously authorized. These new recommendations replace all previous recommendations for the "primary series" and "booster doses".

Eligibility for the Bivalent Vaccines:

- Previously unvaccinated individuals aged 6 years and older are recommended to receive a single dose of a bivalent vaccine.
- Individuals 6 years and older previously vaccinated with one or more doses of any monovalent product (Pfizer, Moderna, Novavax, Janssen) who have not yet received a bivalent vaccine may receive a single bivalent dose at least 2 months after their last monovalent dose.
- Individuals 65 years of age and older who have received a single dose of a bivalent vaccine may receive one additional bivalent dose at least four months following their initial bivalent dose. Multiple studies show that immunity wanes in this population over time and is restored by an additional dose.
- Individuals aged 6 years and older with certain kinds of immunocompromise who have received
 a bivalent COVID-19 vaccine may receive one additional dose of a bivalent COVID-19 vaccine at
 least 2 months following a dose of a bivalent COVID-19 vaccine. The FDA authorized additional
 bivalent doses administered at the discretion of, and at intervals determined by, their
 healthcare provider. However, for immunocompromised individuals 6 months through 4 years
 of age, eligibility for additional doses will depend on the vaccine previously received.

- Children 6 months through 5 years of age who are unvaccinated may receive a two-dose series
 of the Moderna bivalent vaccine (6 months through 5 years of age) OR a three-dose series of the
 Pfizer-BioNTech bivalent vaccine (6 months through 4 years of age). Children who are 5 years of
 age may receive two doses of the Moderna bivalent vaccine or a single dose of the PfizerBioNTech bivalent vaccine.
- Children 6 months through 5 years of age who have received one, two or three doses of a
 monovalent COVID-19 vaccine may receive a bivalent vaccine, but the number of doses that
 they receive will depend on the vaccine and their vaccination history.

Clinical vaccine recommendations from CDC will be updated in the coming days: <u>Interim Clinical</u> <u>Considerations for Use of COVID-19 Vaccines | CDC.</u>

Basis for the Decision:

- Available data show that most of the U.S. population 5 years of age and older now have antibodies against SARS-CoV-2 as a result of either vaccination or infection and that serves as a foundation for the protection provided by the bivalent vaccines.
- The use of bivalent COVID-19 vaccines for all doses administered to individuals 6 months of age and older is supported by the data from numerous studies, including real-world data, with the monovalent and bivalent mRNA COVID-19 vaccines, which have been administered to millions of people, including young children.
- The evidence supporting each bivalent COVID-19 vaccine includes extensive safety and effectiveness data for each of the monovalent mRNA COVID-19 vaccines, safety and immunogenicity data obtained from a clinical study of a bivalent COVID-19 vaccine that contained mRNA from omicron variant BA.1, and nonclinical data obtained using a bivalent COVID-19 vaccine that contained mRNA of the original strain and mRNA in common between the BA.4 and BA.5 lineages of the omicron variant.

Additional Considerations:

- The immunization fact sheets have been consolidated so that Pfizer and Moderna each have a single fact sheet for recipients and one for providers. Fact sheets: Coronavirus Disease 2019 (COVID-19) | FDA
- The FDA Advisory committee (VRBPAC) will meet in June to make recommendations on fall strain composition and future COVID-19 vaccination schedules.
- New Mexico COVID-19 vaccine providers can immediately implement the above recommendations.
- The statewide registration app has been updated and can be accessed at: <u>vaccinenm.org</u>. People can also schedule directly with their medical and pharmacy providers.
- Vaccine appointments can also be found on the CDC Vaccine Finder website: <u>Vaccines.gov Find COVID-19</u> vaccine locations near you.
- For clinicians wishing to administer COVID-19 vaccine, please contact the NM DOH Immunization Team at covid.vaccines@state.nm.us.

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.