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NEW MEXICO HEALTH ALERT NETWORK (HAN) ALERT

CDC and FDA Recommend Updated (2023-2024) COVID19 Vaccines

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Background:

On September 11, 2023, the FDA approved the 2023-2024 formulation of both the Moderna COVID-19 and the Pfizer-BioNTech COVID-19 vaccines for everyone 6 months of age and older. The Advisory Committee on Immunization Practices (ACIP) voted on September 12, 2023, to recommend the updated vaccines and the CDC endorsed the ACIP recommendations the same day.

The 2023-2024 formulation, also referred to as the “updated COVID-19 vaccine” is a monovalent vaccine directed against the XBB.1.5 variant. Studies have shown that the updated vaccines will bolster immunity and produce neutralizing antibodies to current circulating variants.

As of 9/11/23, the FDA removed authorization for the bivalent COVID-19 mRNA vaccines. All bivalent COVID-19 mRNA vaccine doses should be removed from storage units, reported as wastage and disposed of as medical waste.

Eligibility for the Updated (2023-2024) COVID Vaccines:

- Individuals 5 years of age and older are eligible for a single dose of either the Moderna or Pfizer COVID-19 Vaccine (2023-2024 formulations) if it has been at least two months since the most recent COVID-19 vaccine. This recommendation is regardless of previous vaccination history.
- Children ages 6 months–4 years should complete a multi-dose initial series (2 doses of Moderna or 3 doses of Pfizer-BioNTech mRNA COVID-19 vaccine) with at least one dose of the 2023–2024 COVID-19 vaccine. Children who have completed an initial series should receive one dose of the updated (2023-2024) vaccine at least 2 months after the most recent dose.
- People who are moderately or severely immunocompromised should complete a 3- dose initial series with at least one dose of the 2023–2024 COVID-19 vaccine and may receive 1 or more additional 2023–2024 COVID-19 vaccine doses.

Efficacy:

The manufacturers presented data showing that their XBB.1.5 vaccine provides antibody response and consistent neutralization against all variants, including XBB subvariants and other emerging variants.

Safety Considerations:

- Safety of the XBB.1.5 vaccine is consistent with previous vaccine formulations. The XBB.1.5 vaccine is the same platform as previous formulations, only the strain has changed.

- Safety and immunogenicity were studied with XBB.1.5, but clinical data are not available in children, immunocompromised or other specific populations. The safety and efficacy in those populations is based on studies with previous formulations. This is consistent with flu vaccine where separate clinical trials are not conducted for specific populations when there is a strain update.
- Post marketing data with authorized or approved mRNA COVID-19 vaccines demonstrate increased risks of myocarditis and pericarditis, particularly within the first week following vaccination. For Moderna COVID-19 Vaccine, the observed risk is highest in males 18 years through 24 years of age. For the Pfizer-BioNTech COVID-19 Vaccine, the observed risk is highest in males 12 through 17 years of age. Although some cases required intensive care support, available data from short-term follow-up suggest that most individuals have had resolution of symptoms with conservative management. Information is not yet available about potential long-term sequelae.
- The side effect profile of the updated vaccines (2023-2024) appears to be similar to that of the monovalent vaccines. Among the study participants who received the updated vaccine, the most reported side effects included pain, redness and swelling at the injection site, fatigue, headache, muscle pain, joint pain, chills, swelling of the lymph nodes in the same arm of the injection, nausea/vomiting, and fever.

Additional Considerations:

1. **Up to date status:** CDC currently defines “up to date” with COVID-19 vaccine as having completed a 2023-2024 COVID-19 vaccine for those ages 5 years and older. Children 6 months – 4 years are up to date if they have completed a 2 dose Moderna series or 3 dose Pfizer series which includes at least one updated (2023-2024) vaccine.
2. **Co-administration of Vaccine:**
 - COVID-19 vaccines may be administered without regard to timing of other vaccines.
 - Flu vaccine can be administered at the same time as COVID-19 vaccines.
3. The **updated Novavax COVID-19 vaccine** for individuals 12 and older is still pending FDA approval. The current Novavax COVID-19 vaccine formulation may still be administered to eligible individuals.

Access to the updated (2023-2024) COVID-19 vaccines:

- Most Americans can still get a COVID-19 vaccine for free. Most health insurance plans (including Medicaid and Medicare Part B) will cover COVID-19 vaccine at no cost.
- Uninsured individuals can receive the COVID-19 vaccine free of charge through a network of health centers, public health offices, and participating pharmacies in the CDC's [Bridge Access Program](#), ensuring universal vaccine access.
- Children eligible for the [Vaccines for Children](#) program also may receive the vaccine from a provider enrolled in that program.
- Once vaccines are available, vaccine appointments can be found both on the NMDOH COVID vaccine finder website: vaccinesNM.org and on the CDC Vaccine Finder website: Vaccines.gov - Find COVID-19 vaccine locations near you.

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Additional Resources:

1. Clinical recommendations from CDC will be updated here: [Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC](#)
2. COVID-19 Vaccine fact sheets for vaccines under EUA and product inserts for vaccines that have been FDA approved (Moderna Spikevax and Pfizer Comirnaty) are available and are accessible here: [Coronavirus Disease 2019 \(COVID-19\) | FDA](#)
3. Vaccine Information Sheets (VIS) will be available in the coming weeks for the FDA approved vaccines (Moderna Spikevax and Pfizer Comirnaty): [Vaccine Information Statement | Current VISs | CDC](#)
4. Clinicians with questions about COVID-19 vaccine administration can contact the NM DOH Immunization Team at covid.vaccines@state.nm.us or find more information at: [Immunization Education & Tools for Healthcare Providers \(nmhealth.org\)](#)

New Mexico Health Alert Network: *To register for the NM Health Alert Network, please visit the following site <https://nm.readyop.com/fs/4cjZ/10b2> Please fill out the registration form completely and click Submit at the bottom of the page, to begin receiving Important health alerts, advisories, and updates.*

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