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Technical Bulletin

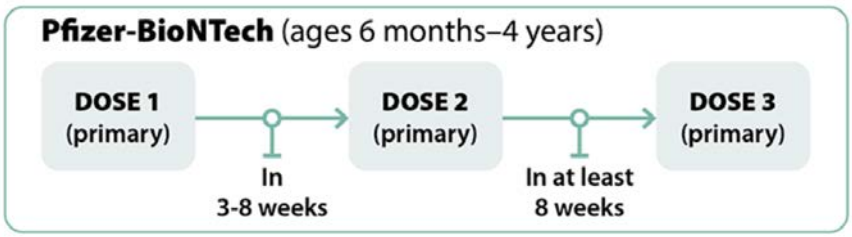
Date: June 22, 2022
Topic: Pediatric COVID-19 Vaccines Recommended for Children Aged 6 months – 5 years
Contact: Jessica Lamb, RN, Nevada State Immunization Program
To: All Health Care Providers and Facilities; Pharmacists; Local Health Authorities

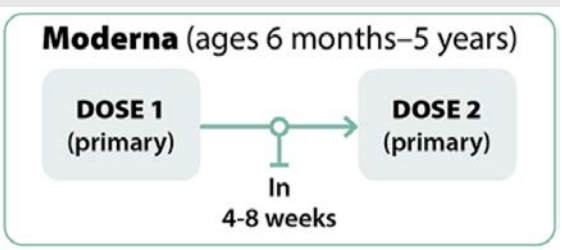
Background:

On June 15, 2022, the Vaccines and Related Biological Products Advisory Committee (VRBPAC) unanimously voted to recommend the authorization of both the Moderna COVID-19 vaccine two-dose primary series for children 6 months to 5 years of age and the Pfizer three-dose series for children 6 months to 4 years of age under Emergency Use Authorization (EUA). On June 17, 2022, the U.S. Food and Drug Administration (FDA) authorized the emergency use of the Moderna COVID-19 vaccine and the Pfizer-BioNTech COVID-19 vaccine for the prevention of COVID-19 to include use in children under 5 years of age.

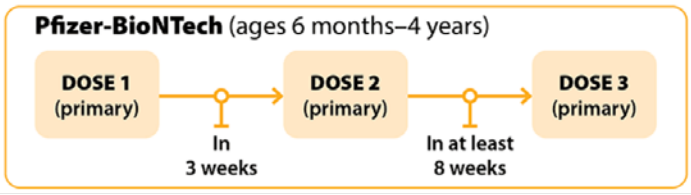
According to disease burden data presented on day one of the two-day Advisory Committee on Immunization Practices (ACIP) meeting, children ages 6 months through 4 years are at risk of severe COVID -19 infection and more than 2 million cases of the illness have been identified among this population. COVID-19-associated hospitalizations among children ages 6 months through 4 years have similar severity compared to older children and adolescents and more than half of the hospitalized children ages 6 months through 4 years had no underlying conditions. The burden of COVID-19associated death among this population is similar to or exceeds that of other pediatric vaccine-preventable diseases. On June 18, 2022, ACIP unanimously voted to recommend the use of the Moderna COVID-19 vaccine two-dose primary series for children ages 6 months to 5 years and the Pfizer three-dose series for children ages 6 months to 4 years.

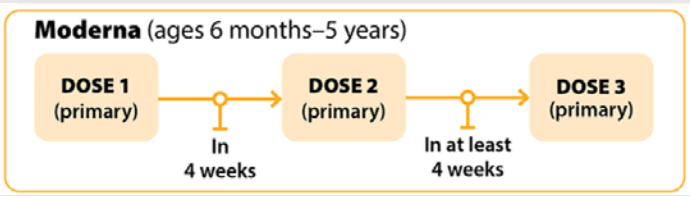
Recommendations for **Non-Immunocompromised Children**





Recommendations for **Moderately to Severely Immunocompromised Children**





In general, the same mRNA vaccine product should be used for all doses in the primary series. COVID-19 vaccines may be co-administered with other routine age-appropriate vaccines at the same visit. Prior infection may not provide broad

protection against newer SARS-CoV-2 variants and vaccination should still be recommended post infection. For children who have been infected with COVID-19, their next dose can be delayed three months from when symptoms started or, if they did not have symptoms, when they received a positive test. For additional information regarding the definition of what is included with moderate to severe immunocompromising conditions, timing and interchangeability of COVID-19 vaccines, refer to the interim clinical considerations found here.

Pfizer-BioNTech's vaccine information fact sheets for recipients and/or caregivers and healthcare providers have also been updated by the FDA for reference, in addition to a Letter to Healthcare Providers and a comprehensive wall chart (also see screen shot below).

Pfizer-BioNTech COVID-19 Vaccine Presentations

Age Group	6 months through 4 years	5 through 11 years	12 years and older	12 years and older
Vial Cap Color and Label Border Color	MAROON 	ORANGE 	PURPLE** 	GRAY** 
Is Dilution Needed?	Dilute Before Use	Dilute Before Use	Dilute Before Use	Do Not Dilute
Amount of Diluent* Needed per Vial	2.2 mL	1.3 mL	1.8 mL	NO DILUTION
Dose Volume	0.2 mL	0.2 mL	0.3 mL	0.3 mL
For storage and expiry information, see FDA-authorized Fact Sheet or scan QR code.	www.cvdvaccine-us.com	www.cvdvaccine-us.com	www.cvdvaccine-us.com	www.cvdvaccine-us.com

*Diluent: sterile 0.9% Sodium Chloride Injection, USP. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent.

** The FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the EUA-authorized Pfizer-BioNTech COVID-19 Vaccine for individuals 12 years of age and older, when prepared according to their respective instructions for use, can be used interchangeably.

Moderna's vaccine information fact sheets for recipients and/or caregivers and healthcare providers have also been updated by the FDA for reference, in addition to a comprehensive wall chart (see screen shot below).

MODERNA COVID-19 VACCINE PRESENTATIONS

Age Group	6 months through 5 years (*Primary Series*)	6 years through 11 years (*Primary Series*) *Currently unavailable (Use the vial with dark blue cap and a label with a purple border)*	6 years through 11 years (*Primary Series*) 18 years and older (*Booster Dose*)	12 years and older (*Primary Series*) 18 years and older (*Booster Dose*)
Vial Cap Color	Dark Blue	Dark Blue	Dark Blue	Red
Vial Label Border Color	MAGENTA	TEAL	PURPLE	LIGHT BLUE
Vial Image				
Primary Dose Volume	0.25 mL	0.5 mL	0.5 mL	0.5 mL
Booster Dose Volume	None	None	0.5 mL	0.25 mL
For storage and expiry information, see FDA-authorized Fact Sheet or scan QR code.	www.modernatx.com/covid19vaccine-eua	www.modernatx.com/covid19vaccine-eua	www.modernatx.com/covid19vaccine-eua	www.modernatx.com/covid19vaccine-eua

After careful review of the data presented to the U.S. FDA VRBPAC meeting on June 14-15, 2022, and to the ACIP meeting held on June 17-18, 2022, and each committee's recommendations concerning the Moderna COVID-19 vaccine for infants and children 6 months through 5 years of age (two vaccine doses) and the Pfizer BioNTech COVID-19 vaccine for infants and children 6 months through 4 years of age (three vaccine doses), the Western States Scientific Safety Review Workgroup concluded that the benefits of completing the COVID-19 vaccine series substantially outweigh the known or likely risks. "The Workgroup strongly encourages our states to strengthen existing efforts to ensure widespread, equitable access to age-appropriate COVID-19 vaccines among all vaccine-eligible individuals who have not yet been vaccinated or boosted, regardless of geographic location, socio-economic status, race and ethnicity, and immigration status. We must assure that all our states' diverse communities are aware that now everyone over 6 months of age is recommended to receive COVID-19 vaccines." The Workgroup also encourages, "All healthcare providers and vaccine recipients to report any suspected adverse events following receipt of a COVID-19 vaccine to the Vaccine Adverse Events Reporting System (VAERS) and vaccine recipients to participate in the V-safe system because the various U.S. systems for monitoring the safety of vaccinations, including COVID-19 vaccines are important to sustaining confidence in immunization and guiding vaccination policy."

The Nevada Department of Health and Human Services is encouraging families to speak with a health care provider about vaccination and COVID-19 vaccines. Families may be referred to NVCOVIDFighter.org or 800-401-0946 for more information on vaccine access and other COVID-19 resources.

It is important to note the primary goal of the COVID-19 vaccine response should continue to be COVID-19 vaccine administration to the unvaccinated.

Questions:

For updated guidance, review the DPBH Technical Bulletin web page and the Nevada Health Response website regularly. Email questions to dpbhcovid19vax@health.nv.gov.

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