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Technical Bulletin

Date: **November 3, 2021**
Topic: **Clinical considerations for administering Pfizer-BioNTech COVID-19 vaccine to children ages 5-11 years**
Contact: **Susan Vilardi, RN, Nevada state Immunization Program**
To: **All Health Care Providers and Facilities; Pharmacists; Local Health Authorities**

Background:

On November 2, 2021, the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) **recommend** **use of the Pfizer-BioNTech 10mcg COVID-19 vaccine in children ages 5-11 years in the United States.** This comes after the U.S. Food and Drug Administration (FDA) expanded its Emergency Use Authorization (EUA) for the Pfizer-BioNTech 10mcg COVID-19 vaccine to include this age group on Friday, October 29, 2021. Previously the Pfizer vaccine was authorized for those ages 12 years and older in a higher dosage.

Additionally, the American Academy of Pediatrics (AAP) issued a policy statement recommending COVID-19 vaccination for "all children and adolescents 5 years of age and older who do not have contraindications using a COVID-19 vaccine authorized for use for their age," including children with previous COVID infection and those with underlying health conditions. The AAP's statement, coupled with the recommendations from CDC, support administration of the Pfizer-BioNTech 10mcg two-dose series in children ages 5-11 years.

The AAP and CDC also support coadministration of routine childhood immunizations, including seasonal influenza vaccine, with the COVID-19 vaccine to help catch children up on any missed vaccinations (based on the CDC/AAP Recommended Child and Adolescent Immunization Schedule) caused by the ongoing pandemic. The Nevada State Immunization Program encourages all vaccinating providers to use patient visits as an opportunity to promote and provide all vaccines and not miss an opportunity to protect children from all vaccine-preventable diseases.

Pfizer-BioNTech COVID-19 Vaccine Availability for Children 5-11 Years

Nevada received an initial allocation of 95,100 doses of the Pfizer-BioNTech 10mcg COVID-19 vaccine which will allow approximately one-third of children ages 5-11 in the state to receive one dose. Incoming supply allocations are expected to be sufficient to ensure children can receive their second dose three weeks later and that unvaccinated children can continuously receive primary doses.

To offer COVID-19 vaccines to Nevadans, providers must be enrolled with the Nevada State Immunization Program. All interested providers are encouraged to click here to begin the enrollment process. Currently, 233 providers across Nevada are enrolled to receive COVID-19 vaccines and can vaccinate children ages 5 years and older. Additionally, many pharmacies will be receiving direct allocations from the CDC to stores across the state.

Dosing for the Pfizer-BioNTech 10mcg COVID-19 Vaccine

- **2 – 10mcg doses each (0.2mL), administered intramuscularly, 21 days apart.**

- Formulations of the adult (30mcg) and childhood (10mcg) Pfizer-BioNTech COVID-19 Vaccines are **NOT** interchangeable.

    - If a child ages 5-11 years inadvertently receives 30mcg for their first dose, then they should receive a single age-appropriate 10mcg dose for their second dose 21 days later and should be considered as having completed a primary series.

    - If a child ages 5-11 years inadvertently receives 30mcg for their second dose, then they should be considered as having completed a primary series.

- Dose should be based on the child's age on the day of vaccination, regardless of their size or weight (i.e., a child on their twelfth birthday would receive the adult dosage of the Pfizer-BioNTech COVID-19 vaccine).

    - If a child turns from age 11 to age 12 years in-between their first and second dose and receives the childhood (10mcg) formulation for their second dose, then they **do not** need to repeat the dose, and this is not considered an administration error per the FDA EUA.

- Serologic testing to assess for prior infection is not recommended for the purpose of vaccine decision-making.

- Children with known current infection should defer vaccination at least until they have recovered from acute illness (if symptomatic) AND they have met the criteria to discontinue isolation.

    - Isolation can typically be discontinued 10 days after a positive test if asymptomatic or 10 days after symptom onset, and after resolution of fever for at least 24 hours.

Expected Side Effects from the Pfizer-BioNTech 10mcg COVID-19 Vaccine

- Local reactions include pain, swelling, and erythema at the injection site.

- Systemic reactions include fever, fatigue, headache, chills, muscle aches, joint stiffness, and lymphadenopathy.

- Routine fever reducers, such as Ibuprofen, can be provided to a child post-vaccination to treat local or systemic symptoms, if medically appropriate.

- In general, Aspirin is **not recommended** for use in children or adolescents ages 18 years and younger following receipt of the COVID-19 vaccine for at least two or more days following vaccination.

Packaging and Storage and Handling for the Pfizer-BioNTech 10mcg COVID-19 Vaccine

- The Pediatric (10mcg) formulation of the Pfizer-BioNTech COVID-19 vaccine contains 10 doses per vial, has an **orange vial cap**, **orange banding** on the vial, and **orange outer packaging.**
  - The Pediatric vaccine formulation is available in a minimum order size of 100 doses.
  - The childhood formulation does NOT have an expiration date printed on the vial.
  - Instead, each vial has the lot number and **date of manufacture** printed on the label.
  - The QR code on the Pfizer Pediatric Vaccine carton links to the EUA for ages 5-11 years but **does not provide information on expiration dates.**

- The Adult/Adolescent (30mcg) formulation of the Pfizer-BioNTech COVID-19 vaccine contains 6 doses per vial, has a **purple vial cap, purple banding** on the vial, and **purple outer packaging**.

Storage of the Pediatric Formulation

- Ultra-low temperature freezer for up to 6 months
- Refrigerator for up to 10 weeks
- Do NOT store in a standard freezer

Expiration of the Pediatric Formulation

- Pfizer does not have an expiration date look-up tool. The QR code on the label links to the EUA Fact Sheet.
- The Pediatric formulation has a 6-month expiration if held frozen at ultra-low temperatures:
  - Manufacturing date + 6 months (inclusive of month of manufacture) = expiration date
  - Ex: An 08/2021 manufacture date has a vial expiration date of 01/2022.

Coadministration of COVID-19 Vaccines in Children 5-11 Years

COVID-19 vaccines may be administered without regard to timing of other age-appropriate recommended vaccines; this includes simultaneous administration of a COVID-19 vaccine dose and other recommended vaccine(s) on the same day. If multiple vaccines are administered at a single visit, then administer each vaccination in a different injection site, according to recommendations by age:

- Separate injection sites by at least 1 inch
- For children ages 11 years and older, the deltoid muscle can be used
- For children ages 5 through 10 years, if more than two vaccines are being injected in a single limb, the vastus lateralis muscle of the anterolateral thigh is the preferred site due to greater muscle mass.

COVID-19 Vaccination of Children with History of Multi-Inflammatory System-Children (MIS-C)

The benefits of COVID-19 vaccination for children and adolescents with a history of MIS-C are likely to outweigh the theoretical risk of a MIS-like illness or the known risks of COVID-19 disease for children who meet the following criteria:

- Clinical recovery has occurred, including return to normal cardiac function.
- It has been 90 days or more since the patient's diagnosis of MIS-C.
- The patient lives in an area of high or substantial community transmission, or otherwise has an increased risk for exposure and transmission of COVID-19 disease.
- The onset of MIS-C occurred before any COVID-19 vaccine dose.

Additional Resources

- Clinical (COCA) Call – Thursday, November 4th from 11a-12p PT/2-3pm ET (Pediatric COVID-19 Vaccines: CDC's Recommendations for COVID-19 Vaccine Primary Series in Children 5–11 years old)
- Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States – site will be updated by CDC in the coming days
- COVID-19 Vaccines for Children and Teens
- Pediatric Healthcare Professionals COVID-19 Vaccination Toolkit: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/toolkits/pediatrician.html
- FAQs for Providers (who are implementing COVID vaccination in-practice): https://www.cdc.gov/vaccines/covid-19/vaccine-providers-faq.html
- Pfizer-BioNTech Fact Sheets (English) and FAQs

Questions:

For updated guidance, please review the DPBH Technical Bulletin website and the Nevada Health Response website regularly. If you have other questions regarding the expansion of COVID-19 vaccines to children ages 5-11 years, please email dpbhcovid19vax@health.nv.gov.

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