

**Pfizer-BioNTech COVID-19 vaccine for 5 to <12 years old children**

<b>DATE:</b>	11/05/2021
<b>TO:</b>	Health Alert Network
<b>FROM:</b>	Alison V. Beam, JD, Acting Secretary of Health
<b>SUBJECT:</b>	Pfizer-BioNTech COVID-19 vaccine for 5 to <12 years old children
<b>DISTRIBUTION:</b>	Statewide
<b>LOCATION:</b>	n/a
<b>STREET ADDRESS:</b>	n/a
<b>COUNTY:</b>	n/a
<b>MUNICIPALITY:</b>	n/a
<b>ZIP CODE:</b>	n/a

**This transmission is a “Health Advisory” and provides important information for a specific incident or situation; may not require immediate action.**

**HOSPITALS:** please share with all medical, pediatric, nursing and laboratory staff in your hospital;

**EMS COUNCILS:** please distribute as appropriate;

**FQHCs:** please distribute as appropriate;

**LOCAL HEALTH JURISDICTIONS:** please distribute as appropriate;

**PROFESSIONAL ORGANIZATIONS:** please distribute to your membership;

**LONG-TERM CARE FACILITIES:** please share with all medical, infection control, and nursing staff in your facility.

**SUMMARY**

- CDC [guidance](#) released on November 2, 2021 recommends **all children aged 5 to <12 years old** get pediatric formulation of Pfizer-BioNTech COVID-19 vaccines to help protect against COVID-19.
- [A recent vaccine study](#) showed that the Pfizer-BioNTech vaccine is [safe and effective](#) for 5 to <12 year old children with vaccine effectiveness of 90.9% in preventing symptomatic COVID.
- This is a **2-dose** (10 µg/ 0.2 ml) primary series administered at least 21 days apart.
- [Pediatric formulation](#) (10 µg/ 0.2 ml) and dosing (0.2 ml) for Pfizer-BioNTech COVID-19 vaccine is **different** from the [adult/adolescent formulation](#) (30 µg/0.3 ml) and dosing (0.3 ml). The two formulations are **NOT** interchangeable and require **different** storage conditions.
- All cases of myocarditis and pericarditis, and any adverse events following vaccination should be reported to [VAERS](#), even if it is unclear that the vaccination caused that adverse event.
- If you have any questions, please call PA DOH at 1-877-PA-HEALTH (1-877-724-3258) or your local health department.

**Background**

- As of October 2021, there were 1.9 million children 5 to <12 years old who have been infected with SARS-CoV-2. Children aged 5 to <12 years old are at risk for severe illnesses from COVID-19. These include;
  - approximately 8,300 COVID-19 hospitalizations,
  - 2,316 Multisystem Inflammatory Syndrome (MIS) cases, and
  - 94 deaths.



- [Post-COVID conditions](#) do exist in children and may occur in up to 7-8% of patients following mild to severe infections or after MIS.
- [A recent vaccine study](#) showed that the Pfizer-BioNTech vaccine is [safe and effective](#) for 5 to <12 years old children with vaccine effectiveness of 90.9% in preventing symptomatic COVID. Adverse events were more common after dose 2 and included pain at the injection sites, fatigue, and headache.
- Myocarditis and/or pericarditis have occurred **rarely** in some people following receipt of mRNA COVID-19 vaccines, typically within a few days following receipt of the second dose. The observed risk is highest in males 12-29 years of age. The risk of myocarditis and pericarditis after receipt of mRNA COVID-19 vaccine is **lower** than the risk of myocarditis associated with SARS-CoV-2 infection in adolescents and adults.

## **Recommendations**

- The CDC [recommends](#) all children ages 5 to <12 years old get the pediatric formulation of Pfizer-BioNTech COVID-19 vaccine regardless of a history of symptomatic or asymptomatic SARS-CoV-2 infection or seropositivity.
- The vaccine series includes 2 doses of 0.2 ml (10 µg) at least 21 days apart for all children ages 5 to < 12 years old. The vaccine dosage and formulation are based on the age on the day of vaccination with each dose. Clarifications are as follow:
  - If a child aged 5-11 years inadvertently receives a 30 µg dose for their first dose, they should receive a single, age-appropriate 10 µg dose for their second dose 21 days later and should be considered as having a completed primary series.
  - If a child aged 5-11 years inadvertently receives a 30 µg dose for their second dose, they should be considered as having a completed primary series.
  - Children who will turn from 11 years to 12 years of age between their first and second doses in the primary series should receive the age-appropriate 10 µg dose for the first dose and 30 µg dose for the second dose to complete their series. However, as per [FDA Authorization](#) these children may receive, for either dose, either: (1) the Pfizer-BioNTech COVID-19 vaccine pediatric formulation (10 µg/ 0.2 ml); or (2) the Pfizer-BioNTech COVID-19 adult/adolescent formulation (30 µg/ 0.3 ml). If such dosing occurred, the series is still considered a completed primary series.
  - If a child aged >12 years inadvertently receives a 10 µg dose, the dose does not need to be repeated. However, based on clinical judgement (e.g., the adolescent received 2 doses of the incorrect formulation), a repeat dose of 30 µg may be administered at an interval of 21 days after the dose given in error. If the dose given in error is the first dose, administer the second dose (30 µg) 21 days later to complete the primary series.
- Pfizer-BioNTech COVID-19 vaccines may be [administered](#) without regard to timing of other vaccines. This includes simultaneous administration of COVID-19 vaccine and other vaccines on the same day.
- [Pediatric formulation](#) (10 µg/0.2 ml) and dosing (0.2 ml) for Pfizer-BioNTech COVID-19 vaccine is **different** from the [prior formulation](#) (30 µg/0.3 ml) and dosing (0.3 ml) for adolescents and adults. The two formulations are NOT interchangeable. Storage conditions are also different. **See Table 1.**
- Children are considered [fully vaccinated](#) 2 weeks after their second dose of this 2-dose series.
- [Contraindications](#) for the Pfizer-BioNTech COVID-19 vaccine are as follows:
  - Severe allergic reaction (anaphylaxis) after a previous dose or to a component of the Pfizer-BioNTech COVID-19 vaccine
  - Immediate allergic reaction of any severity to a previous dose or known allergy to a component of the Pfizer-BioNTech COVID-19 vaccine
  - Myocarditis after a dose of an mRNA vaccine is **NOT** an absolute contraindication; however, the second dose should be deferred until myocarditis has completely resolved and approved of by medical providers.

- All patients should be registered by their parents for [V-safe](#) and any adverse events should be reported into the [VAERS](#). If you have any questions, please call PA DOH at 1-877-PA-HEALTH (1-877-724-3258) or your local health department.

**Table 1. Formulation and dosing for Pfizer-BioNTech COVID-19 vaccines**

Description	Adult/Adolescent Formulation (30 µg/0.3 ml)	Pediatric Formulation (10 µg/0.2 ml)
Recommended age	12 years and older	5 to <12 years
Vial cap color		
Dose	30 µg	10 µg
Injection volume	0.3 ml	0.2 ml
Fill volume (before dilution)	0.45 ml	1.3 ml
Amount of diluent* needed per vial	1.8 ml	1.3 ml
Doses per vial	6 (after dilution)	10 (after dilution)
<b>Storage condition</b>		
Ultralow temperature freezer (-90°C to -60°C)	9 months	6 months
Freezer (-25 °C to -15 °C)	2 weeks	N/A
Refrigerator (2 °C to 8 °C)	1 month	10 weeks
<b>Usage</b>		
Number of doses for primary series	2	2
Interval	3 weeks (21 days)	3 weeks (21 days)
Additional dose for primary series	For moderately and severely immunocompromised patients	Not recommended
Booster dose	Not recommended for 12 – 17 years Recommended for certain groups ≥ 18 years <sup>#</sup>	Not recommended

\*Diluent: 0.9% sterile Sodium Chloride Injection, USP (non-bacteriostatic; DO NOT USE OTHER DILUENTS). Modified from <https://www.cdc.gov/vaccines/covid-19/downloads/Pfizer-Pediatric-Reference-Planning.pdf>

<sup>#</sup>Individuals 65 years and older or individuals ages 18 years and older who live in long-term care settings, have underlying medical conditions, or who work or live in high risk settings. Mbaeyi S, Oliver SE, Collins JP, et al. The Advisory Committee on Immunization Practices' Interim Recommendations for Additional Primary and Booster Doses of COVID-19 Vaccines — United States, 2021. [MMWR Morb Mortal Wkly Rep. ePub: 29 October 2021](#)

Categories of Health Alert messages:

**Health Alert:** conveys the highest level of importance; warrants immediate action or attention.

**Health Advisory:** provides important information for a specific incident or situation; may not require immediate action.

**Health Update:** provides updated information regarding an incident or situation; unlikely to require immediate action.

**This information is current as of November 5, 2021 but may be modified in the future.**