DATE
November 5, 2021

SUBJECT
CDC recommends Pfizer-BioNTech COVID-19 Pediatric Formulation to Children Aged 5-11 Years

INSTRUCTIONS

DISTRIBUTE to your local HAN contacts. This HAN is intended for general sharing of information.
• Time for Forwarding: As Soon As Possible
• Please forward to DPHHS at hhshan@mt.gov
• Remove this cover sheet before redistributing and replace it with your own

 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.
Information Service: passes along low level priority messages that do not fit other HAN categories and are for informational purposes only.

Please update your HAN contact information on the Montana Public Health Directory
DATE
November 5, 2021

SUBJECT
CDC recommends Pfizer-BioNTech COVID-19 pediatric formulation to children aged 5-11 years.

Background
Yesterday, the CDC’s independent Advisory Committee on Immunization Practices (ACIP) recommended that children between the ages of 5 and 11 receive the Pfizer-BioNTech COVID-19 Vaccine. CDC Director Dr. Rochelle Walensky accepted those recommendations.

COVID-19 vaccines have undergone and will continue to undergo intensive safety monitoring. Vaccinating children will help protect them from getting COVID-19 and therefore reduce their risk of severe disease, hospitalization, or the development of long-term COVID-19 complications. Getting your children vaccinated can help protect them against COVID-19, reduce disruptions to in-person learning and other activities, and help curb community transmission.

DOSING AND ADMINISTRATION
• The Pfizer-BioNTech COVID-19 vaccine for children aged 5-11 years is supplied in a different vial and a different formulation than that authorized for individuals aged 12 years and older.
• The vial for children aged 5-11 years is supplied in a multiple dose vial with an orange cap and a label with an orange border.
• The vial requires dilution with 1.3 mL sterile 0.9% sodium chloride injection prior to use.
• Each vial contains 10 doses.
• Children aged 5-11 years should receive two doses consisting of 10 mcg (0.2 mL) per dose.
• Doses should be separated by three weeks (21 days).
• The 10 mcg dose is one-third of the dose authorized for individuals aged 12 years and older and was selected based on safety, tolerability, and immunogenicity data.
• The Pfizer vaccine authorized for individuals aged 12 and older (adolescent and adult vaccine) cannot be used interchangeably with the vaccine authorized for individuals aged 5-11 (pediatric vaccine), nor can pediatric vaccine be used for adults.

STORAGE and HANDLING
• The Pediatric Pfizer-BioNTech vaccine can be stored in:
  o Ultracold storage (-90ºC to -60ºC) for up to six months
  o Refrigeration temperatures (2 ºC to 8 ºC) for up to 10 weeks from the time they are thawed
DO NOT store this vaccine at standard freezer temperatures.

RECOMMENDATIONS
Healthcare Providers:
All providers should continue to recommend COVID-19 vaccination for all individuals 5+ who are eligible for vaccine to reduce the risk of infection, serious illness, or death, as well reduce transmission to others, many of whom may be
at increased risk. Providers are reminded that patients under 18 years of age will most likely need a parent or legal guardian’s consent for COVID-19 vaccination.

Review the Pfizer-BioNTech COVID-19 Vaccine EUA Fact Sheet for Healthcare Providers

Provide all patients (or parents or legal guardians) the Pfizer-BioNTech COVID-19 Vaccine EUA Fact Sheet for Recipients and Caregivers prior to administration.

**Local Health Jurisdictions**

Continue to work with vaccine providers in the community to monitor vaccine supplies and local efforts to continue to vaccinate anyone who is eligible. To increase COVID-19 vaccination rates in your community, continue the following activities:

- Offering special hours of COVID-19 vaccination for walk-ins at your clinic. This may help reduce wastage from the larger multi-dose vials.
- Providing educational materials and/or trainings to other local partners on the importance of COVID-19 vaccination in the community.
- Encouraging other vaccine providers, including primary care and pediatric clinics, to enroll as COVID-19 vaccination providers.
- Work with other community partners to reduce barriers by simplifying processes or assisting with scheduling, transportation, etc. as possible.

**Additional Resources:**

- Updated webpage – COVID-19 Vaccines for Children and Teens [cdc.gov]
- Updated interim clinical considerations [cdc.gov]

**Referenced Links**

1. EUA Fact Sheet for Healthcare Providers: https://www.fda.gov/media/153714/download
2. EUA Fact Sheet for Recipients and Caregivers: https://www.fda.gov/media/153717/download