VERMONT
DEPARTMENT OF HEALTH

Health Update
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TO: Vermont Health Care Providers and Health Care Facilities
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Use of Pfizer-BioNTech COVID-19 Vaccine in Children Aged 5-11 Years

Background

According to the Advisory Committee on Immunization Practices (ACIP), COVID-19 in children is a major public health problem.

- Approximately 1.9 million COVID-19 cases and 8,300 hospitalizations among U.S. children aged 5–11 years had been reported to CDC as of October 10, 2021.
- As of October 4, 2021, CDC had received reports of 5,217 cases of multisystem inflammatory syndrome in children (MIS-C), a severe hyperinflammatory syndrome occurring several weeks after acute SARS-CoV-2 infection; 44% of MIS-C cases have occurred in children aged 5–11 years. No cases of MIS-C have been reported in Vermont to date.
- Children aged 5–11 years represent a growing proportion of new COVID-19 cases reported to CDC (10.6% of infections for the week of October 10, 2021, although children aged 5–11 years represent 8.7% of the population). During the week October 31 through November 6, the overall population case rate in Vermont was 33.1 per 10,000 while the rate among children ages 6-11 years was 68.1 per 10,000.
- Children can contribute to transmission of SARS-CoV-2 in households and communities.

The U.S Food and Drug Administration (FDA) approved a Biologics License Application (BLA) for use of the Pfizer-BioNTech COVID-19 (Pfizer) vaccine in August 2021 for persons aged ≥16 years. This vaccine is also recommended for adolescents aged 12–15 years under an Emergency Use Authorization (EUA) from the FDA. All persons aged ≥12 years are recommended to receive two doses (30 micrograms, 0.3 mL each), administered 3 weeks apart. In October 2021, the FDA issued an EUA amendment for a new formulation of Pfizer vaccine for use in children aged 5–11 years, administered as 2 doses (10 micrograms, 0.2 mL each), 3 weeks apart. On November 2, 2021, the ACIP issued an interim recommendation for use of the Pfizer vaccine in children aged 5–11 years for the prevention of COVID-19.

Immunogenicity, Efficacy, and Safety

Most data regarding the immunogenicity, efficacy, and safety of the Pfizer vaccine among children aged 5–11 years came from one randomized, double-blind, placebo-controlled phase II/III clinical trial. This trial initially enrolled 2268 children randomized 2:1 to receive vaccine or saline placebo. Interim findings from this clinical trial were based on data from participants with a median follow-up of 3.3 months.

Vaccine efficacy was supported by two types of evidence:

- Direct efficacy against symptomatic infection
    - Vaccine efficacy was 90.9% (95% CI = 68.3%–98.3%) in preventing symptomatic, laboratory-confirmed COVID-19 in children aged 5–11 years with or without evidence of previous SARS-CoV-2 infection.
- Immunobridging data (neutralizing antibody titers from vaccine recipients aged 5–11 years who received two doses of 10 micrograms each compared with those from vaccine recipients aged 16–25 years who received two doses of 30 micrograms each)
    - Immune response to two doses of the Pfizer-BioNTech COVID-19 vaccine in children aged 5–11 years without evidence of previous SARS-CoV-2 infection was at least as high as the response observed in persons aged 16–25 years.

No data were available to assess the other potential benefits of the vaccine, i.e., prevention of hospitalization for COVID-19, prevention of MIS-C, nor were data available regarding prevention of asymptomatic SARS-CoV-2 infection.

Safety

- Reactogenicity symptoms (solicited local injection site or systemic reactions during the seven days after vaccination) were frequent (86.2% with any local reaction; 66.6% reported any systemic reaction). Most reactions were mild to moderate. Generally, reactogenicity symptoms occurred less frequently in this age group than in persons aged 16–25 years.
- Systemic adverse reactions were more commonly reported after the second dose than after the first dose, had a median onset of 1–2 days after vaccination, and resolved in a median of 1–2 days.
- Severe local and systemic adverse reactions (grade ≥3, defined as interfering with daily activity) occurred in 2.7% of vaccine recipients and 1.1% of placebo recipients. Among vaccine recipients who reported any reaction of grade ≥3, the most common symptoms were fatigue (0.9%), headache (0.3%), fever (0.8%) and injection site pain (0.6%).
- Overall, reactions of grade ≥3 were also more commonly reported after the second dose than after the first dose.
- The prevalence of related adverse events was lower in children who were seropositive at baseline (two of 133; 1.5%) compared with the prevalence in those who were seronegative at baseline (44 of 1,385; 3.2%); in addition, individual local and systemic reactions were less common in seropositive children.
- Serious adverse events were uncommon and occurred with similar frequency among vaccine (0.07%) and placebo (0.10%) recipients.
- An expanded safety cohort of 2,379 children (including 1,591 vaccine recipients) was added (median follow-up of 2.4 weeks after receipt of the second dose). No serious adverse events related to the vaccination were identified in either group.

Summary: ACIP reviewed the balance of benefits and risks of vaccination of children aged 5–11 years, considering evidence around both known and potential benefits and risks. ACIP determined that the benefits of COVID-19 vaccination outweigh the known and potential risks.

Before vaccination, all healthcare personnel should review the **EUA Fact Sheet for Healthcare Providers**, and the **EUA Fact Sheet for Recipients** should be provided to parents or guardians.

Reporting Vaccine Adverse Events

FDA requires that vaccination providers report vaccination administration errors, serious adverse events, cases of multisystem inflammatory syndrome, and cases of COVID-19 that result in hospitalization or death after administration of COVID-19 vaccine under an EUA.

- VAERS: Adverse events that occur after receipt of any COVID-19 vaccine should be reported to the Vaccine Adverse Event Reporting System (VAERS). Information on how to submit a report to VAERS is available at https://vaers.hhs.gov/index.htmlexternal icon or 1-800-822-7967. Any person who administers or receives a COVID-19 vaccine (or their parent or guardian) is encouraged to report any clinically significant adverse event, whether or not it is clear that a vaccine caused the adverse event.
- V-safe online tool: CDC has developed a new, voluntary smartphone-based online tool (v-safe) that uses text messaging and online surveys to provide near real-time health check-ins after receipt of a COVID-19 vaccine. Parents or guardians can register their children in v-safe and complete the health surveys on their behalf. CDC's v-safe call center follows up on reports that include possible medically significant health events to collect additional information for completion of a VAERS report. Information on v-safe is available at https://www.cdc.gov/vsafe.

REQUESTED ACTIONS

1. Recognize that COVID-19 in children is a major public health problem.
2. Be familiar with the efficacy and safety data regarding the Pfizer COVID-19 vaccine in children.
3. Review the EUA Fact Sheet for Healthcare Providers.
4. Provide the EUA Fact Sheet for Recipients to parents or guardians before vaccination.
5. Be aware of requirements for reporting of vaccine adverse events (VAERs and v-safe).

If you have any questions, please contact the HAN Coordinator at 802-859-5900 or vthan@vermont.gov.

HAN Message Type Definitions
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.
Info Service Message: Provides general correspondence from VDH, which is not necessarily considered to be of an emergent nature