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COVID-19 UPDATE

Pfizer Bivalent Vaccine Booster Dose for Children 6 Months to 4 Years Old

The FDA has expanded its Emergency Use Authorization (EUA) for the COVID-19 vaccine manufactured by Pfizer/BioNTech *(Comirnaty)* to permit use of the bivalent formulation (containing mRNA from the original and BA.4/5 Omicron strains of SARS-CoV-2) as a booster dose in children 6 months to 4 years old who completed the primary series with 3 doses of the monovalent formulation ≥2 months previously. The Pfizer bivalent vaccine had previously been authorized for use as a booster dose in persons ≥5 years old and as a third primary dose in children 6 months to 4 years old. Booster doses of the Moderna bivalent COVID-19 vaccine *(Spikevax)* for children 6 months to 5 years old were authorized earlier.[1,2]

CLINICAL STUDIES — Expansion of the EUA was primarily based on the results of an unpublished immunogenicity trial (summarized in the FDA fact sheet) in which 60 children 6 months to 4 years old who had received 3 primary-series doses of the Pfizer monovalent vaccine were given a booster dose of the bivalent vaccine. Geometric mean neutralizing antibody titer levels against the BA.4/5 variant increased 8- to 9-fold in the month following booster immunization.[3] Whether use of the booster dose reduces the incidence or severity of COVID-19 in children in this age group remains to be established.

ADVERSE EFFECTS — Adverse effects of the bivalent Pfizer vaccine in children 6 months to 4 years old have included injection-site reactions, fatigue, irritability, fever, chills, muscle and joint pain, headache, vomiting, decreased appetite, muscle and joint pain, and lymphadenopathy. Severe allergic reactions and myocarditis/pericarditis have been reported.

RECOMMENDATIONS — For children 6 months to 4 years old receiving the Pfizer vaccine, CDC guidelines recommend a 3-dose primary series: two 3-mcg doses of the monovalent formulation given 3-8 weeks apart, followed by a 3-mcg dose of the bivalent vaccine given ≥8 weeks after the second monovalent dose. In those who have already completed a primary series with 3 doses of the monovalent vaccine, a 3-mcg booster dose of the bivalent formulation given ≥2 months after the third primary-series dose is recommended. Booster immunization is not currently recommended for children who received the bivalent vaccine as the final dose of their primary series.[4] ■

1. COVID update: Bivalent vaccine booster doses authorized for children ≥5 years old. Med Lett Drugs Ther 2022; 64:e1.
2. COVID-19 update: Bivalent Pfizer and Moderna vaccines authorized for children ≥6 months old. Med Lett Drugs Ther 2022; 64:e209.
3. FDA. Fact sheet for health care providers administering vaccine (vaccination providers). Emergency Use Authorization (EUA) of the Pfizer-BioNTech COVID-19 vaccine and the Pfizer-BioNTech COVID-19 vaccine, bivalent (original and Omicron BA.4/BA.5) to prevent coronavirus disease 2019 (COVID-19). For 6 months through 4 years of age. March 14, 2023. Available at: https://bit.ly/3HJhcUT. Accessed March 30, 2023.
4. CDC. Interim clinical considerations for use of COVID-19 vaccines currently approved or authorized in the United States. March 16, 2023. Available at: https://bit.ly/3KgPdxl. Accessed March 30, 2023.

Additional Content Available Online: COVID-19 Tables/Charts

Please check our website for the latest information on COVID-19, including our continuously updated tables/charts on treatments and vaccines. Available at: www.medicalletter.org/drugs-for-covid-19.

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