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COVID-19 UPDATE

Pfizer/BioNTech and Moderna Vaccines Authorized for Children ≥6 Months Old

The FDA has expanded its Emergency Use Authorizations (EUAs) for the mRNA COVID-19 vaccines manufactured by Pfizer/BioNTech *(Comirnaty)* and Moderna *(Spikevax)* to allow for their use in children as young as 6 months old. The Pfizer vaccine was previously authorized for use in persons ≥5 years old, and the Moderna vaccine was authorized for use in adults ≥18 years old.[1]

CLINICAL STUDIES — Expansion of the EUAs of both vaccines was based primarily on immunogenicity data; data on the efficacy of the vaccines in preventing infection and severe disease in younger populations were generally limited by short follow-up times and low infection and hospitalization rates.

A study compared the immunogenicity of three 3-mcg doses of the **Pfizer vaccine** in 82 children 6-23 months old and 143 children 2-4 years old with that of two 30-mcg doses in 170 persons 16-25 years old. Geometric mean titer levels of anti-SARS-CoV-2 neutralizing antibodies 1 month after the final dose were higher in children 6-23 months old (1406.5) and 2-4 years old (1535.2) than in persons 16-25 years old (1180.0). All children 6 months to 4 years old experienced a seroresponse.[2,3]

Studies compared the immunogenicity of two doses of the **Moderna vaccine** in 230 children 6-23 months old (25 mcg), 264 children 2-5 years old (25 mcg), 320 children 6-11 years old (50 mcg), and 340 adolescents 12-17 years old (100 mcg) with that of two 100-mcg doses of the vaccine in cohorts of ~300 adults 18-25 years old. Geometric mean titer levels of anti-SARS-CoV-2 neutralizing antibodies 28 days after the second dose were at least as high in each pediatric cohort as they were in the comparator adult cohorts (1780.7 in children 6-23 months old, 1410.0 in children 2-5 years old, 1610.2 in children 6-11 years old, and 1401.7 in adolescents 12-17 years old vs 1299.9-1390.8 in adults 18-25 years old), and 99-100% of pediatric vaccine recipients experienced a seroresponse.[4-6]

ADVERSE EFFECTS — In a randomized, observer-blind trial, the most common adverse effects of the **Pfizer vaccine** in children 6-23 months old were irritability,

Table 1. FDA-Authorized COVID-19 Vaccine Schedules for Children

Age	Immune Status[1]	Primary Dose 1	Primary Dose 2	Primary Dose 3	Booster Dose[2]
Pfizer/BioNTech Vaccine *(Comirnaty)*[3]					
6 mos-4 yrs[4]	All	3 mcg at wk 0	3 mcg at wk 3[5]	3 mcg ≥8 wks after PD2	Not authorized
5-11 yrs	Normal	10 mcg at wk 0	10 mcg at wk 3[5]	Not authorized	10 mcg ≥5 mos after PS
	Compromised	10 mcg at wk 0	10 mcg at wk 3	10 mcg ≥28 days after PD2	10 mcg ≥5 mos after PS
12-17 yrs	Normal	30 mcg at wk 0	30 mcg at wk 3[5]	Not authorized	30 mcg ≥5 mos after PS
	Compromised	30 mcg at wk 0	30 mcg at wk 3	30 mcg ≥28 days after PD2	30 mcg ≥5 mos after PS
Moderna Vaccine *(Spikevax)*[6]					
6 mos-5 yrs	Normal	25 mcg at mo 0	25 mcg at mo 1[5]	Not authorized	Not authorized
	Compromised	25 mcg at mo 0	25 mcg at mo 1	25 mcg ≥1 mo after PD2	Not authorized
6-11 yrs	Normal	50 mcg at mo 0	50 mcg at mo 1[5]	Not authorized	Not authorized
	Compromised	50 mcg at mo 0	50 mcg at mo 1	50 mcg ≥1 mo after PD2	Not authorized
12-17 yrs	Normal	100 mcg at mo 0	100 mcg at mo 1[5]	Not authorized	Not authorized
	Compromised	100 mcg at mo 0	100 mcg at mo 1	100 mcg ≥1 mo after PD2	Not authorized

PD2 = primary dose 2; PS = completion of primary series

1. Vaccine recipients are considered immunocompromised if they are solid organ transplant recipients or have a condition that compromises the immune system to a similar extent.
2. Use of heterologous ("mix-and-match") booster doses in children <18 years old is not currently authorized by the FDA.
3. FDA. Comirnaty and Pfizer-BioNTech COVID-19 vaccine. June 17, 2022. Available at: https://bit.ly/3zOwPZm. Accessed June 23, 2022.
4. Children who will turn 5 years old during their primary series may instead be given a 10-mcg dose of the vaccine as their second and/or third primary-series doses, or they may receive two 10-mcg primary-series doses given 3 weeks apart, as is indicated for children 5-11 years old.
5. According to the CDC, an 8-week interval between the first and second primary doses may be optimal for some immunocompetent children, especially males 12-17 years old (https://bit.ly/3uXZTLI).
6. FDA. Spikevax and Moderna COVID-19 vaccine. June 17, 2022. Available at: https://bit.ly/3n54fLD. Accessed June 23, 2022.

Table 2. COVID-19 Vaccine Formulations for Children

Age	Vial Label Color	Requires Dilution?	Dose	Doses per Vial[1]
Pfizer/BioNTech vaccine *(Comirnaty)*				
6 mos-4 yrs	Maroon	Yes	3 mcg/0.2 mL	10
5-11 yrs	Orange	Yes	10 mcg/0.2 mL	10
12-17 yrs	Purple	Yes	30 mcg/0.3 mL	6
	Gray	No	30 mcg/0.3 mL	6
Moderna vaccine *(Spikevax)*				
6 mos-5 yrs	Magenta	No	25 mcg/0.25 mL	10
6-11 yrs	Teal or purple	No	50 mcg/0.5 mL	5
12-17 yrs	Light blue	No	100 mcg/0.5 mL	10-11 or 13-15[2]

1. A low dead-weight syringe or needle may be required to extract the labeled number of doses from the vial.
2. Available in 5.5-mL vials (10-11 doses) and 7.5-mL vials (13-15 doses).

decreased appetite, fever, and injection-site tenderness, redness, and swelling. Adverse effects in children 2-4 years old included fatigue, fever, headache, chills, muscle pain, and injection-site pain, redness, and swelling. Lymphadenopathy occurred rarely (<0.5%) in both age cohorts. Most adverse effects were mild to moderate in severity. Myocarditis and anaphylaxis due to the vaccine were not reported.[2,3]

In randomized, observer-blind trials, the most common adverse effects of the **Moderna vaccine** in children 6-36 months old were irritability, sleepiness, loss of appetite, fever, axillary or groin swelling or tenderness, and injection-site pain, erythema, and swelling. Adverse effects in older children included fatigue, headache, myalgia, arthralgia, fever, chills, nausea/vomiting, axillary or groin swelling or tenderness, and injection-site pain, erythema, and swelling. Most adverse effects were mild to moderate in severity and occurred at a higher frequency after the second dose. Myocarditis and anaphylaxis due to the vaccine were not reported.[4-10]

DOSAGE AND ADMINISTRATION — Children receiving the **Pfizer vaccine** should be given three 3-mcg primary-series doses intramuscularly; the second dose should be given 3 weeks after the first, and the third dose ≥8 weeks after the second. Alternative dosing schedules are authorized for children who will turn 5 years old during their primary series (see Table 1, footnote 4). Booster doses of the Pfizer vaccine are not currently authorized for use in children <5 years old.[2]

Children receiving the **Moderna vaccine** should be given two age-appropriate primary-series doses (25 mcg for ages 6 months-5 years, 50 mcg for ages 6-11 years, and 100 mcg for ages 12-17 years) intramuscularly 1 month apart. A third primary-series dose, equal in strength to the first two, should be administered at least 1 month after the second dose to children who have undergone solid organ transplantation or have a condition that compromises the immune system to a similar extent.[11] Booster doses of the Moderna vaccine are not currently authorized for use in children <18 years old.[4-6] ■

1. FDA News Release. Coronavirus (COVID-19) update: FDA authorizes Moderna and Pfizer-BioNTech COVID-19 vaccines for children down to 6 months of age. June 17, 2022. Available at: https://bit.ly/3xObgFQ. Accessed June 23, 2022.
2. FDA. Fact sheet for health care providers administering vaccine (vaccination providers). Emergency Use Authorization (EUA) of the Pfizer-BioNTech COVID-19 vaccine to prevent coronavirus disease 2019 (COVID-19). For 6 months through 4 years of age. June 17, 2022. Available at: https://bit.ly/3HJhcUT. Accessed June 23, 2022.
3. S Wollersheim. FDA review of the effectiveness and safety of Pfizer-BioNTech COVID-19 Vaccine in children 6 months through 4 years of age. Emergency use authorization amendment. Vaccines and Related Biological Products Advisory Committee Meeting. June 15, 2022. Available at: https://bit.ly/3bfM2bs. Accessed June 23, 2022.
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