

# The Medical Letter<sup>®</sup>

## on Drugs and Therapeutics

Volume 64

July 11, 2022

ISSUE No.

1654

### IN THIS ISSUE

COVID-19 Update.....p 110

## Important Copyright Message

### FORWARDING OR COPYING IS A VIOLATION OF U.S. AND INTERNATIONAL COPYRIGHT LAWS

The Medical Letter, Inc. publications are protected by U.S. and international copyright laws. Forwarding, copying or any distribution of this material is prohibited.

Sharing a password with a non-subscriber or otherwise making the contents of this site available to third parties is strictly prohibited.

By accessing and reading the attached content I agree to comply with U.S. and international copyright laws and these terms and conditions of The Medical Letter, Inc.

For further information click: [Subscriptions](#), [Site Licenses](#), [Reprints](#)  
or call customer service at: 800-211-2769

# The Medical Letter®

## on Drugs and Therapeutics

Volume 64 (Issue 1654)

July 11, 2022

[Take CME Exams](#)

### 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.<sup>1</sup>

**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.<sup>2,3</sup>

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.<sup>4-6</sup>

**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 <sup>1</sup>	Primary Dose 1	Primary Dose 2	Primary Dose 3	Booster Dose <sup>2</sup>
<b>Pfizer/BioNTech Vaccine (Comirnaty)<sup>3</sup></b>					
6 mos-4 yrs <sup>4</sup>	All	3 mcg at wk 0	3 mcg at wk 3 <sup>5</sup>	3 mcg ≥8 wks after PD2	Not authorized
5-11 yrs	Normal	10 mcg at wk 0	10 mcg at wk 3 <sup>5</sup>	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 <sup>5</sup>	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
<b>Moderna Vaccine (Spikevax)<sup>6</sup></b>					
6 mos-5 yrs	Normal	25 mcg at mo 0	25 mcg at mo 1 <sup>5</sup>	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 <sup>5</sup>	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 <sup>5</sup>	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

- 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.
- Use of heterologous ("mix-and-match") booster doses in children <18 years old is not currently authorized by the FDA.
- FDA. Comirnaty and Pfizer-BioNTech COVID-19 vaccine. June 17, 2022. Available at: <https://bit.ly/3zOwPZm>. Accessed June 23, 2022.
- 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.
- 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>).
- 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 <sup>1</sup>
<b>Pfizer/BioNTech vaccine (Comirnaty)</b>				
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
<b>Moderna vaccine (Spikevax)</b>				
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 <sup>2</sup>

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.<sup>2,3</sup>

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.<sup>4-10</sup>

**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  $\geq 8$  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.<sup>2</sup>

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.<sup>11</sup> Booster doses of the Moderna vaccine are not currently authorized for use in children <18 years old.<sup>4-6</sup> ■

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.
4. FDA. Fact sheet for healthcare providers administering vaccine (vaccination providers). Emergency Use Authorization (EUA) of the Moderna COVID-19 vaccine to prevent coronavirus disease 2019 (COVID-19). Primary series presentation. 6 months through 5 years of age. June 17, 2022. Available at: <https://bit.ly/3xJAAMR>. Accessed June 23, 2022.
5. FDA. Fact sheet for healthcare providers administering vaccine (vaccination providers). Emergency Use Authorization (EUA) of the Moderna COVID-19 vaccine to prevent coronavirus disease 2019 (COVID-19). Primary series. 6 years through 11 years of age. June 17, 2022. Available at: <https://bit.ly/3tP63vU>. Accessed June 23, 2022.
6. Fact sheet for healthcare providers administering vaccine (vaccination providers). Emergency Use Authorization (EUA) of the Moderna COVID-19 vaccine to prevent coronavirus disease 2019 (COVID-19). Primary series and booster dose presentation. Primary series doses for 12 years and older. Booster doses for 18 years and older. June 17, 2022. Available at: <https://bit.ly/3tP65Uy>. Accessed June 23, 2022.
7. CB Creech et al. Evaluation of mRNA-1273 Covid-19 vaccine in children 6 to 11 years of age. *N Engl J Med* 2021; 386:2011.
8. K Ali et al. Evaluation of mRNA-1273 SARS-CoV-2 vaccine in adolescents. *N Engl J Med* 2021; 385:2241.
9. R Wisch. FDA review of effectiveness and safety of Moderna COVID-19 vaccine in children 6 months through 5 years of age. Emergency use authorization amendment. Vaccines and Related Biological Products Advisory Committee Meeting. June 15, 2022. Available at: <https://bit.ly/39DnUiE>. Accessed June 23, 2022.
10. R Zhang. FDA review of effectiveness and safety of Moderna COVID-19 vaccine in children 6 through 17 years of age. Emergency use authorization amendment. Vaccines and Related Biological Products Advisory Committee Meeting. June 15, 2022. Available at: <https://bit.ly/3tSxIMO>. Accessed June 23, 2022.
11. CDC. COVID-19 vaccines for people who are moderately or severely immunocompromised. June 19, 2022. Available at: <https://bit.ly/3iREJYo>. Accessed June 23, 2022.

**PRESIDENT:** Mark Abramowicz, M.D.; **VICE PRESIDENT, EDITOR IN CHIEF:** Jean-Marie Pflomm, Pharm.D.; **ASSOCIATE EDITORS:** Susan M. Daron, Pharm.D., Amy Faucard, MLS, Corinne Z. Morrison, Pharm.D., Michael P. Viscusi, Pharm.D. **CONSULTING EDITORS:** Joanna Esterow, PA-C, Mordechai Sacks, DMSc, PA-C, Brinda M. Shah, Pharm.D., F. Peter Swanson, M.D.

**CONTRIBUTING EDITORS:** Carl W. Bazil, M.D., Ph.D., Columbia University College of Physicians and Surgeons; Ericka L. Crouse, Pharm.D., B.C.P.P., C.G.P., F.A.S.H.P., F.A.S.C.P., Virginia Commonwealth University; Vanessa K. Dalton, M.D., M.P.H., University of Michigan Medical School; Eric J. Epstein, M.D., Albert Einstein College of Medicine; David N. Juurlink, BPhM, M.D., Ph.D., Sunnybrook Health Sciences Centre; Richard B. Kim, M.D., University of Western Ontario; Sandip K. Mukherjee, M.D., F.A.C.C., Yale School of Medicine; Dan M. Roden, M.D., Vanderbilt University School of Medicine; Esperance A.K. Schaefer, M.D., M.P.H., Harvard Medical School; Neal H. Steigbigel, M.D., New York University School of Medicine; Arthur M. F. Yee, M.D., Ph.D., F.A.C.R., Weill Medical College of Cornell University

**MANAGING EDITOR AND DIRECTOR OF CONTENT OPERATIONS:** Susie Wong; **EDITORIAL ASSISTANT:** Karrie Ferrara

**FULFILLMENT AND SYSTEMS MANAGER:** Cristine Romatowski; **EXECUTIVE DIRECTOR OF SALES:** Elaine Reaney-Tomaselli

**EXECUTIVE DIRECTOR OF MARKETING AND COMMUNICATIONS:** Joanne F. Valentino; **INTERIM PUBLISHER:** Jean-Marie Pflomm, Pharm.D.

Founded in 1959 by Arthur Kallet and Harold Aaron, M.D.

**Copyright and Disclaimer:** The Medical Letter, Inc. is an independent nonprofit organization that provides healthcare professionals with unbiased drug prescribing recommendations. The editorial process used for its publications relies on a review of published and unpublished literature, with an emphasis on controlled clinical trials, and on the opinions of its consultants. The Medical Letter, Inc. does not sell advertising or receive any commercial support. No part of the material may be reproduced or transmitted by any process in whole or in part without prior permission in writing. The editors do not warrant that all the material in this publication is accurate and complete in every respect. The editors shall not be held responsible for any damage resulting from any error, inaccuracy, or omission.

#### Subscription Services

#### Address:

The Medical Letter, Inc.  
145 Huguenot St. Ste. 312  
New Rochelle, NY 10801-7537  
www.medicalletter.org

#### Customer Service:

Call: 800-211-2769 or 914-235-0500  
Fax: 914-632-1733  
E-mail: [custserv@medicalletter.org](mailto:custserv@medicalletter.org)

#### Permissions:

To reproduce any portion of this issue,  
please e-mail your request to:  
[permissions@medicalletter.org](mailto:permissions@medicalletter.org)

#### Subscriptions (US):

1 year - \$159; 2 years - \$298;  
3 years - \$398. \$65 per year  
for students, interns, residents,  
and fellows in the US and Canada.  
Reprints - \$45 per issue or article

#### Site License Inquiries:

E-mail: [SubQuote@medicalletter.org](mailto:SubQuote@medicalletter.org)  
Call: 800-211-2769  
Special rates available for bulk  
subscriptions.

Get Connected:    

Copyright 2022. ISSN 0025-2859

The  
Medical  
Letter