

The Medical Letter[®]

on Drugs and Therapeutics

Volume 63

September 20, 2021

ISSUE No.

1633

IN THIS ISSUE

In Brief: Third Dose of mRNA-based COVID-19 Vaccines for Immunocompromised Persons..p 145

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 63 (Issue 1633)

September 20, 2021

Take CME Exams

IN BRIEF

Third Dose of mRNA-based COVID-19 Vaccines for Immunocompromised Persons

The FDA has expanded the Emergency Use Authorizations (EUAs) for the mRNA-based COVID-19 vaccines manufactured by Pfizer/BioNTech (*Comirnaty*) and Moderna (*Spikevax*) to include administration of a third dose in persons ≥ 12 years old (Pfizer/BioNTech) or ≥ 18 years old (Moderna) who have undergone solid organ transplantation or have a condition that compromises the immune system to a similar extent (see Table 1).¹

Immunocompromised persons are more likely than healthy individuals to have an inadequate antibody response to COVID-19 vaccination, breakthrough SARS-CoV-2 infection, and severe COVID-19 requiring hospitalization. About 2.7% of adults in the US are considered immunocompromised, but 40-44% of hospitalizations for breakthrough COVID-19 cases have occurred in such persons.² In a study in 658 solid organ transplant recipients who received 2 doses of an mRNA-based vaccine, anti-SARS-CoV-2 antibodies were detectable in only 54% of persons 28-31 days after the second dose.³

Several clinical studies have demonstrated that the immunogenicity of mRNA-based COVID-19 vaccines in immunocompromised persons is increased with

administration of a third dose. In a double-blind trial in 120 organ transplant recipients, median antibody, T-cell, and virus neutralization levels were significantly higher in persons who received 3 doses of the Moderna vaccine (at 0, 1, and 3 months) than in those who received 2 doses.⁴ In 5 cohort studies, administration of a third dose of an mRNA-based vaccine to a total of 112 organ transplant recipients or hemodialysis patients who tested negative for anti-SARS-CoV-2 antibodies following their second dose resulted in seroconversion rates ranging from 33% to 50%.² Adverse effects with a third vaccine dose in immunocompromised persons have been similar to those observed with the first two doses.⁵

Immunocompromised persons who have received two doses of the Pfizer/BioNTech or Moderna vaccine can now receive a third dose of the same vaccine at least ≥ 28 days after their second dose.^{6,7} The FDA has not authorized to date the use of additional doses of any COVID-19 vaccine in immunocompromised persons who received the Johnson & Johnson (Janssen) adenovirus-based vaccine. ■

Table 1. Some Immunocompromising Conditions¹

- ▶ Active or recent treatment for a solid tumor or hematologic malignancy
- ▶ Receipt of a solid-organ or hematopoietic stem cell transplant
- ▶ Severe primary immunodeficiency
- ▶ Advanced or untreated HIV infection
- ▶ Active immunosuppressive or immunomodulatory treatment (e.g., high-dose corticosteroids, antimetabolites, alkylating agents, tumor necrosis factor inhibitors)
- ▶ Chronic renal disease (especially requiring hemodialysis)
- ▶ Anatomical or functional asplenia

1. K Dooling. Evidence to recommendations framework: an additional dose of mRNA COVID-19 vaccine following a primary series in immunocompromised people. Advisory Committee on Immunization Practices meeting, August 13, 2021. Available at: <https://bit.ly/2Uqqy3H>. Accessed August 18, 2021.

1. FDA News Release. Coronavirus (COVID-19) update: FDA authorizes additional vaccine dose for certain immunocompromised individuals. August 12, 2021. Available at: <https://bit.ly/3AM8QHq>. Accessed August 18, 2021.
2. K Dooling. Evidence to recommendations framework: an additional dose of mRNA COVID-19 vaccine following a primary series in immunocompromised people. Advisory Committee on Immunization Practices meeting, August 13, 2021. Available at: <https://bit.ly/2Uqqy3H>. Accessed August 18, 2021.
3. BJ Boyarsky et al. Antibody response to 2-dose SARS-CoV-2 mRNA vaccine series in solid organ transplant recipients. *JAMA* 2021; 325:2204.
4. VG Hall et al. Randomized trial of a third dose of mRNA-1273 vaccine in transplant recipients. *N Engl J Med* 2021 August 11 (epub).
5. M Espi et al. Justification, safety, and efficacy of a third dose of mRNA vaccine in maintenance hemodialysis patients: a prospective observational study. *MedRxiv* 2021 July 6 (preprint). Available at: <https://bit.ly/3snU1bd>. Accessed August 18, 2021.
6. 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). August 23, 2021. Available at: <https://bit.ly/37fX1NG>. Accessed September 7, 2021.
7. 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). August 27, 2021. Available at: <https://bit.ly/3nosylA>. Accessed September 7, 2021.

PRESIDENT: Mark Abramowicz, M.D.; **VICE PRESIDENT AND EXECUTIVE EDITOR:** Gianna Zuccotti, M.D., M.P.H., F.A.C.P., Harvard Medical School
VICE PRESIDENT AND 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; Franco M. Muggia, M.D., New York University Medical Center; 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

Permissions:

To reproduce any portion of this issue,
 please e-mail your request to:
 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
 Call: 800-211-2769
 Special rates available for bulk
 subscriptions.

Get Connected:  

Copyright 2021. ISSN 1523-2859

The
 Medical
 Letter