

The Medical Letter[®]

on Drugs and Therapeutics

Volume 63

Published online May 3, 2021

Online
Only
Article

IN THIS ISSUE

Johnson & Johnson COVID-19 Vaccine Suspended

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

Published online May 3, 2021

Online
Only
Article

IN THIS ISSUE

Johnson & Johnson COVID-19 Vaccine Suspended

IN BRIEF

Johnson & Johnson COVID-19 Vaccine Suspended

Update 4/28/21: See next page for article on suspension being lifted.

On April 13, 2021, the FDA and CDC advised suspending use of the Johnson & Johnson adenovirus-based COVID-19 vaccine while the agencies investigate 6 cases of cerebral venous sinus thrombosis (CVST) and thrombocytopenia that occurred following administration of the vaccine.^{1,2} In an April 14 emergency meeting, the Advisory Committee on Immunization Practices (ACIP) recommended continuing the suspension until more data become available. About 7 million people in the US have received the Johnson & Johnson vaccine.¹⁻³

All 6 cases occurred in women 18-48 years old. Symptom onset occurred 6-13 days after administration of the single-dose vaccine. In addition to CVST, three of the women had extracranial thromboses. Four women developed intraparenchymal brain hemorrhage, and one died. Comorbid conditions included obesity (n=3), hypertension (n=1), hypothyroidism (n=1), and asthma (n=1); one woman was taking estrogen/progesterone.¹⁻³

CVST with thrombocytopenia has also been reported with the Oxford/AstraZeneca adenovirus-based COVID-19 vaccine (not authorized for use in the US). With both adenovirus-based vaccines, incidence of CVST with thrombocytopenia has been associated

with high serum levels of antibodies against platelet factor 4 (PF4)-polyanion complexes similar to those that occur in heparin-induced thrombocytopenia (HIT). No cases of CVST with thrombocytopenia have been associated with the ~180 million Pfizer and Moderna mRNA-based COVID-19 vaccine doses administered in the US.³⁻⁵

The CDC recommends that persons who experience a thrombotic event and thrombocytopenia after administration of the Johnson & Johnson vaccine be screened with a PF4 HIT enzyme-linked immunosorbent assay (ELISA) and referred to a hematologist. If the assay is positive or cannot be completed, heparin should not be used for thrombosis management; other anticoagulants and intravenous immune globulin should be considered instead.² ■

1. FDA Statement. Joint CDC and FDA statement on Johnson & Johnson COVID-19 vaccine. April 13, 2021. Available at: <https://bit.ly/3aaa704>. Accessed April 16, 2021.
2. CDC Health Alert Network. Cases of cerebral venous sinus thrombosis with thrombocytopenia after receipt of the Johnson & Johnson COVID-19 vaccine. April 13, 2021. Available at: <https://bit.ly/3sjDO4X>. Accessed April 16, 2021.
3. T Shimabukuro. Update on thromboembolic events, COVID-19 vaccines safety surveillance. ACIP Presentation Slides: April 14, 2021 Meeting. Available at: <https://bit.ly/3gcWf9l>. Accessed April 16, 2021.
4. A Greinacher et al. Thrombotic thrombocytopenia after ChAdOx1 nCov-19 vaccination. *N Engl J Med* 2021 April 9 (epub).
5. NH Schultz et al. Thrombosis and thrombocytopenia after ChAdOx1 nCoV-19 vaccination. *N Engl J Med* 2021 April 9 (epub).

The Medical Letter[®]

on Drugs and Therapeutics

Volume 63

Published online April 28, 2021

Online
Only
Article

IN THIS ISSUE

Suspension of Johnson & Johnson COVID-19 Vaccine Lifted

IN BRIEF

Suspension of Johnson & Johnson COVID-19 Vaccine Lifted

On April 23, 2021, on advice from the Advisory Committee on Immunization Practices (ACIP), the FDA and CDC recommended that use of the Johnson & Johnson adenovirus-based COVID-19 vaccine resume despite its association with development of thrombosis with thrombocytopenia syndrome (TTS). Administration of the vaccine had been paused on April 13 because of 6 reports of TTS, but after completing a data review that identified a further 9 cases associated with the formulation, the agencies concluded that the benefits of the vaccine outweighed its risks. About 7.98 million doses of the single-dose vaccine had been administered in the US at the time of the review.¹⁻⁴

All 15 cases of TTS associated with the Johnson & Johnson vaccine occurred in women, 13 of whom were 18-49 years old. Symptom onset occurred 6-15 days after vaccine administration (median 8 days). Cerebral venous sinus thromboses were present in 12 of the women. Platelet factor 4 heparin-induced thrombocytopenia enzyme-linked immunosorbent assay (PF4 HIT ELISA) testing was positive in all 11 women with available results. Three of the women who developed TTS died.⁴

The fact sheet for the Johnson & Johnson vaccine now includes a warning about the risk of TTS, but use of the formulation has not been restricted based on age or sex.⁵ No cases of TTS have been associated with the >200 million Pfizer and Moderna mRNA-based COVID-19 vaccine doses administered in the US.⁴

The American Society of Hematology recommends that patients who present with thrombosis or thrombocytopenia 4-30 days after administration of the Johnson & Johnson vaccine be evaluated promptly for TTS. Patients with confirmed or suspected TTS should not be treated with heparin; intravenous immune globulin and non-heparin anticoagulants should be used instead.⁶ ■

1. In brief: Johnson & Johnson COVID-19 vaccine suspended. *Med Lett Drugs Ther* 2021 May 3 (epub).
2. FDA News Release. FDA and CDC lift recommended pause on Johnson & Johnson (Janssen) COVID-19 vaccine use following thorough safety review. April 23, 2021. Available at: <https://bit.ly/3aHuO3C>. Accessed April 28, 2021.
3. CDC. CDC recommends use of Johnson & Johnson's Janssen COVID-19 vaccine resume. April 25, 2021. Available at: <https://bit.ly/3xqch5M>. Accessed April 28, 2021.
4. T Shimabukuro. Thrombosis with thrombocytopenia syndrome (TTS) following Janssen COVID-19 vaccine. ACIP presentation slides: April 23, 2021 meeting. Available at: <https://bit.ly/3ez3m9r>. Accessed April 28, 2021.
5. FDA. Fact sheet for healthcare providers administering vaccine (vaccination providers). Emergency Use Authorization (EUA) of the Janssen COVID-19 vaccine to prevent coronavirus disease 2019 (COVID-19). April 23, 2021. Available at: <https://bit.ly/3e6KEaD>. Accessed April 28, 2021.
6. American Society of Hematology. Thrombosis with thrombocytopenia syndrome (also termed vaccine-induced thrombotic thrombocytopenia). April 25, 2021. Available at: <https://bit.ly/2R7fqXl>. Accessed April 28, 2021.

Online Tables: COVID-19 Treatments and Vaccines

Please check our website for the latest information on COVID-19, including our continuously updated tables: Treatments Considered for COVID-19 and COVID-19 Vaccine Comparison Chart. Available at: www.medicalletter.org/drugs-for-covid-19.

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

FULLFILLMENT 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 0025-732X

The
 Medical
 Letter