COLORADO
Department of Public Health & Environment

HEALTH ALERT NETWORK BROADCAST
MESSAGE ID: 04302021 15:00
FROM: CO-CDPHE
SUBJECT: HAN Update – Johnson & Johnson (Janssen COVID-19) Vaccine Update
RECIPIENTS: Local Public Health Agencies / IPs / Clinical Labs / EDs / ID Physicians / Coroners
RECIPIENT INSTRUCTIONS: Local Public Health Agencies –please forward to healthcare providers

HEALTH UPDATE | Johnson & Johnson (Janssen) COVID-19 Vaccine Update | April 30, 2021

Health care providers: Please distribute widely in your office

This information is for the public health and health care community. Do not post this document on a public web or social media site.

Key points

On April 23, CDC and FDA lifted their recommended pause on the use of Johnson & Johnson (Janssen) COVID-19 vaccine after completing a review of rare reports of thrombosis with thrombocytopenia syndrome (TTS), particularly among women under the age of 50.

- Providers may now administer the Janssen COVID-19 vaccine to all adults 18 years of age or older. FDA has added a warning to the Janssen COVID-19 vaccine EUA and fact sheets regarding rare clotting events that have been reported among vaccine recipients. Updated patient education and communication materials reflecting this warning are critical in ensuring that women aged <50 years are aware of the increased risk for TTS and that other COVID-19 vaccines are available (i.e., mRNA vaccines).

- The EUA fact sheet should be provided to all vaccine recipients and their caregivers (as relevant) for careful review before vaccination with any authorized COVID-19 vaccine (https://www.fda.gov/media/146305/download).

- Before resuming Janssen COVID-19 vaccine administration, providers should review the updated FDA Fact Sheet for Vaccination Providers (https://www.fda.gov/media/146304/download). The FDA letter granting Janssen's Emergency Use Authorization (EUA) amendments can be found here: https://www.fda.gov/media/147865/download.

- CDC has updated its interim clinical considerations for COVID-19 vaccines, including the section on the use of the Janssen COVID-19 vaccine in certain populations: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html

- CDC recommends that clinicians consult the CDC Health Alert Network (HAN) notification published on April 13 (https://emergency.cdc.gov/han/2021/han00442.asp) and guidance from the American Society of Hematology (https://www.hematology.org/covid-19/vaccine-induced-immune-thrombotic-thrombocytopenia) for information on the diagnosis and treatment of suspected cases of TTS.

- Clinical recommendations for vaccination of individuals with a history of an episode of an immune-mediated syndrome characterized by thrombosis and thrombocytopenia, such as heparin-induced thrombocytopenia (HIT) can be found at: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#janssen-vaccine-certain-populations
- Providers should encourage vaccine recipients to enroll in CDC's V-Safe (https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html), a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after they receive a COVID-19 vaccine.
- Health care providers are required to report TTS and all other adverse events following COVID-19 vaccination to the CDC Vaccine Adverse Event Reporting System (VAERS) at https://vaers.hhs.gov/reportevent.html.
- In addition to reporting to VAERS, CDPHE also requires that health care providers report blood clot events following COVID-19 vaccination directly to the state using this secure, HIPAA-compliant REDCap form: https://redcap.link/9ytrvg22. Health care providers can contact CDPHE at 303-692-2700 with questions.

Background information

The FDA authorized the Johnson & Johnson (Janssen) COVID-19 vaccine, a single-dose adenovirus-vector based DNA vaccine for use in adults in February 2021. Following FDA's authorization, CDC's Advisory Committee on Immunization Practices (ACIP) issued an interim recommendation for use of the Janssen COVID-19 vaccine in persons aged ≥18 years for the prevention of COVID-19. Based on six reports of vaccine recipients experiencing blood clots and low platelets (or thrombosis with thrombocytopenia syndrome [TTS]) in the following weeks, the FDA and CDC recommended pausing use of the Janssen COVID-19 vaccine on April 13 in order to further investigate these adverse events.

Out of nearly 8 million doses given in the United States, a total of 15 confirmed cases of TTS have been identified as of April 21 (all in women, 13 cases in women under the age of 50 years, 3 of which have been fatal).

On April 23, ACIP concluded that the benefits of resuming Janssen COVID-19 vaccination among persons aged ≥18 years outweighed the risks and reaffirmed its interim recommendation under FDA's Emergency Use Authorization, which includes a new warning for rare clotting events among women aged 18–49 years. This warning is not a contraindication against use of the Janssen COVID-19 vaccine in this group.

Recommendations / guidance

- Providers may now administer the Janssen COVID-19 vaccine to all adults 18 years of age or older. Women aged <50 years can receive any FDA-authorized COVID-19 vaccine. However, they should be aware of the rare risk of TTS after receipt of the Janssen COVID-19 vaccine as well as the availability of other FDA-authorized COVID-19 vaccines (i.e., mRNA vaccines). The highest rates of TTS per vaccine doses administered were identified in women <50 years of age. TTS reporting rates to VAERS were 7.0 cases per million Janssen COVID-19 vaccine doses administered to women aged 18–49 years and 0.9 per million to women aged ≥50 years.

- Although the etiology of TTS associated with the Janssen COVID-19 vaccine is unclear, it appears to be similar to another rare immune-mediated syndrome, heparin-induced thrombocytopenia (HIT). Clinical recommendations for vaccination in individuals with a history of an episode of an immune-mediated syndrome characterized by thrombosis and thrombocytopenia, such as heparin-induced thrombocytopenia (HIT) can be found at: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#janssen-vaccine-certain-populations
- Venous thromboembolism (VTE), defined as deep vein thrombosis, pulmonary embolism, or both, is common. The biologic mechanisms for VTE (as well as arterial thrombi) differ from the underlying immune-mediated mechanism for HIT. Based on current knowledge, experts believe that people with risk factors for VTE (e.g., inherited or acquired thrombophilia including Factor V Leiden, prothrombin gene 20210A mutation, antiphospholipid syndrome, protein C, protein S or antithrombin deficiency), or a prior history of other types of thromboses (including cerebral venous sinus thrombosis [CVST]) not associated with thrombocytopenia are unlikely to be at increased risk for TTS. Likewise, although the risk of thrombosis is increased during pregnancy and the postpartum period, and with certain hormonal contraceptives (e.g., combined oral contraceptives, patch, and ring), experts believe that these factors do not make people more susceptible to TTS after receipt of the Janssen COVID-19 vaccine. These people can receive any FDA-authorized vaccine, including the Janssen COVID-19 vaccine.
- People who take aspirin or anticoagulants as part of their routine medications do not need to stop these medications prior to receipt of the Janssen COVID-19 vaccine. It is not recommended that people who do not otherwise take these medicines start to take aspirin or an anticoagulant before vaccination with the Janssen COVID-19 vaccine or any other FDA-authorized COVID-19 vaccine (i.e., mRNA vaccine).
- Before resuming Janssen COVID-19 vaccine administration, providers should review the updated FDA Fact Sheet for Vaccination Providers (https://www.fda.gov/media/146304/download) as well as the updated Fact Sheet for Recipients and Caregivers (https://www.fda.gov/media/146305/download). The FDA letter granting Janssen's EUA amendments can be found here: https://www.fda.gov/media/147865/download. The updated FDA Fact Sheet for Recipients and Caregivers should be provided to all potential Janssen COVID-19 vaccine recipients and their caregivers (as relevant) for careful review before vaccination.
- Per the CDC (https://emergency.cdc.gov/han/2021/han00442.asp), providers should maintain a high index of suspicion for symptoms that might represent serious thrombotic events or thrombocytopenia in patients who have recently received Janssen COVID-19 vaccine including severe headache, backache, new neurologic symptoms, severe abdominal pain, shortness of breath, leg swelling, petechiae, or new or easy bruising. Obtain platelet counts and screen for evidence of immune thrombotic thrombocytopenia in any patients with these symptoms who have recently (for example, within 30 days) received Janssen COVID-19 vaccine.
- In patients with a thrombotic event and/or thrombocytopenia after receiving Janssen COVID-19 vaccine, evaluate initially with a screening platelet factor-4 (PF4) enzyme-linked immunosorbent (ELISA) assay as would be performed for autoimmune heparin induced thrombocytopenia (HIT). Consultation with a hematologist is strongly recommended.
- Do not treat patients with thrombotic events and thrombocytopenia following receipt of Janssen COVID-19 vaccine with heparin unless HIT testing is negative.

- If HIT testing is positive or unable to be performed in patients with thrombotic events and thrombocytopenia following receipt of Janssen COVID-19 vaccine, non-heparin anticoagulants and high-dose intravenous immune globulin should be strongly considered. Again, consultation with a hematologist is strongly recommended.
- The American Society of Hematology has also provided TTS diagnostic and treatment recommendations that can be found here: https://www.hematology.org/covid-19/vaccine-induced-immune-thrombotic-thrombocytopenia

Reporting

- Health care providers are required to report TTS and all other adverse events following COVID-19 vaccination to the CDC Vaccine Adverse Event Reporting System (VAERS) at https://vaers.hhs.gov/reportevent.html.
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More information

Add links to relevant websites, apps and CDPHE contact information.

- https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html
  https://www.cdc.gov/mmwr/volumes/70/wr/mm7017e4.htm
- https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/JJUpdate.html
- https://emergency.cdc.gov/han/2021/han00442.asp
- https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html
- https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/janssen-covid-19-vaccine-frequently-asked-questions
- https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/janssen-covid-19-vaccine
- https://www.hematology.org/covid-19/vaccine-induced-immune-thrombotic-thrombocytopenia

CDPHE Disease Reporting Line: 303-692-2700 or 303-370-9395 (after hours)