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DATE: May 3, 2021

TO: Health Care Providers, Health Care Facilities, Pharmacies, and Local Health Departments

FROM: New York State Department of Health (NYSDOH)

Health Advisory: Recommendations to Resume Use of the Janssen/Johnson & Johnson COVID-19 Vaccine

Please distribute immediately to all personnel conducting medical screening, medical evaluation, vaccine administration, local health departments, pharmacists, specialists, and all primary care providers.

Summary

- On April 13, 2021 the CDC and the FDA recommended pausing administration of the Janssen (Johnson & Johnson) COVID-19 vaccine due to reports of cases of thrombosis with thrombocytopenia syndrome (TTS) among Janssen (Johnson & Johnson) vaccine recipients.
- A review of all available data determined that the known and potential benefits of the Janssen (Johnson & Johnson) COVID-19 vaccine outweigh the known and potential risks.
- On April 23, 2021 the Advisory Committee on Immunization Practices (ACIP) reaffirmed its interim recommendation for the use of the Janssen (Johnson & Johnson) COVID-19 vaccine in all persons aged ≥ 18 years under the U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA).
- Following discussions with New York State's Clinical Advisory Task Force, NYS Health Commissioner Dr. Howard Zucker recommended on April 24, 2021 that New York State accept the federal recommendations and resume Johnson & Johnson vaccinations effective immediately.
- TTS is a very rare syndrome that involves acute venous or arterial thrombosis with new onset thrombocytopenia in patients with no recent known exposure to heparin. Although rare, TTS has been noted after receipt of the Janssen (Johnson & Johnson) vaccine primarily in women 18-49 years of age.
- The FDA has added warnings regarding these rare clotting events to the EUA, the fact sheet for health care providers, the fact sheet for vaccine recipients, and the prescribing information.
- Women younger than 50 years can receive any COVID-19 vaccine if they do not have a contraindication. However, they should be counseled on the rare occurrence of TTS after receipt of the Janssen (Johnson & Johnson) vaccine.
- The NYSDOH, CDC, and FDA will continue to monitor the safety of all COVID-19 vaccines.

Thrombosis with thrombocytopenia syndrome (TTS)

TTS is a very rare syndrome involving acute venous or arterial thrombosis and new onset thrombocytopenia with no recent known exposure to heparin. It appears to be similar to a rare immune-mediated syndrome known as heparin-induced thrombocytopenia (HIT). Rare occurrences of TTS have occurred after receipt of the Janssen (Johnson & Johnson) COVID-19 vaccine. Blood clots have occurred in the blood vessels in the brain, abdomen and legs along with thrombocytopenia.

- Most incidents occurred 1-2 weeks after receipt of the Janssen (Johnson & Johnson) vaccine in women 18-49 years of age. TTS reporting rates to VAERS were:
 - 7.0 cases per million doses administered to women aged 18-49 years, and
 - 0.9 cases per million doses administered to women aged ≥ 50 years.
- The FDA has added warnings regarding rare occurrences of TTS after Janssen (Johnson & Johnson) vaccination to the EUA, fact sheets, and prescribing information.
- Women under 50 years of age can receive the Janssen (Johnson & Johnson) vaccine, but they should be made aware of the rare risk of TTS.

Additional information for the diagnosis and treatment of TTS are available in the April 13th Health Alert Network (HAN) announcement from the CDC (available here: <https://emergency.cdc.gov/han/2021/han00442.asp>) and in guidance from the American Society of Hematology (available here: <https://www.hematology.org/covid-19/vaccine-induced-immune-thrombotic-thrombocytopenia>).

Considerations for the use of the Janssen (Johnson & Johnson) COVID-19 vaccine in certain populations

Until more is known about the etiology of TTS, experts advise that persons with a history of an episode of an immune-mediated syndrome characterized by thrombosis and thrombocytopenia, such as heparin-induced thrombocytopenia (HIT), should be offered another FDA-authorized COVID-19 vaccine (i.e., mRNA vaccine) if they are within 6 months after resolution of their illness.

Venous thromboembolism (VTE) as deep vein thrombosis, pulmonary embolism or both are common. The underlying biological mechanism of VTE differs from HIT and TTS. Based on the current knowledge of TTS, experts believe that persons with risk factors for VTE (or arterial thrombi) without thrombocytopenia are unlikely to be at increased risk for TTS.

Women under 50 years of age can receive any FDA authorized COVID-19 vaccine. However, they should be made aware of the rare occurrences of TTS in persons who have received the Janssen (Johnson & Johnson) vaccine.

Pregnant women can receive any FDA authorized COVID-19 vaccine for which they do not have a contraindication. They should be counseled on the limited data available on COVID-19 vaccine administration during pregnancy, but early data from three U.S. vaccine safety surveillance systems did not identify any safety concerns for pregnant people who were vaccinated or for their babies. People who are pregnant or postpartum do not appear to have higher rates of TTS after the Janssen (Johnson & Johnson) vaccine than people who are not pregnant. Pregnant women may receive any FDA-authorized COVID-19 vaccine. They may

choose to receive mRNA vaccines if they do not wish to receive the Janssen (Johnson & Johnson) vaccine.

People who take aspirin or anticoagulants as part of routine medical treatment do not need to stop these medications prior to vaccination with the Janssen (Johnson & Johnson) COVID-19 vaccine. The American Society of Hematology recommends avoiding aspirin for treatment or prophylaxis for TTS as aspirin is not effective at preventing HIT antibodies from activating platelets and could increase bleeding risk in TTS.

Persons who receive the Janssen (Johnson & Johnson) vaccine should be made aware of these rare occurrences of TTS and to seek medical attention right away if they have any of the following symptoms:

- Shortness of breath
- Chest pain
- Leg swelling
- Persistent abdominal pain
- Severe or persistent headaches or blurred vision
- Easy bruising or tiny blood spots under the skin beyond the site of the injection

All adverse events after receipt of any vaccine, including COVID-19 vaccines, should be reported to VAERS even if it is not known that the vaccine caused the adverse event. Information on reporting to VAERS is available at: <https://vaers.hhs.gov/reportevent.html>.

The CDC has also developed a patient education fact sheet with information regarding the Janssen (Johnson & Johnson) COVID-19 vaccine. The fact sheet is available here: <https://www.cdc.gov/coronavirus/2019-ncov/downloads/talking-patients-jj-vaccine-html.pdf>.

Resources:

For questions, call the NYSDOH COVID-19 hotline 1-888-364-3065 or email the NYS Department of Health at immunize@health.ny.gov or the NYC DOHMH at nycimmunize@health.nyc.gov.

- CDC: Morbidity and Mortality Weekly Report (MMWR): Updated Recommendations from the Advisory Committee on Immunization Practices for Use of the Janssen (Johnson & Johnson) COVID-19 Vaccine After Reports of Thrombosis with Thrombocytopenia Syndrome Among Vaccine Recipients – United State, April 2021: https://www.cdc.gov/mmwr/volumes/70/wr/mm7017e4.htm?s_cid=mm7017e4_w
- CDC Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States: <https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>
- Reporting an adverse event to VAERS: <https://vaers.hhs.gov/reportevent.html>
- NYS COVID-19 Vaccine web page: <https://covid19vaccine.health.ny.gov/>
- FDA Janssen COVID-19 Vaccine Frequently Asked Questions: <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/janssen-covid-19-vaccine-frequently-asked-questions>
- Janssen COVID-19 Vaccine Fact Sheet for Health Care Providers: <https://www.fda.gov/media/146304/download>

- Janssen COVID-19 Vaccine Fact Sheet for Vaccine Recipients: <https://www.fda.gov/media/146305/download>
- American College of Obstetricians and Gynecologists (ACOG): Vaccinating Pregnant and Lactating Patients Against COVID-19: <https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2020/12/vaccinating-pregnant-and-lactating-patients-against-covid-19>