



NEW YORK CITY DEPARTMENT OF
HEALTH AND MENTAL HYGIENE
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Commissioner

2021 Health Advisory #8

Administration of Johnson & Johnson/Janssen COVID-19 Vaccine Can Resume in New York City

- **On April 23, 2021, the U.S. Centers for Disease Control and Prevention and Food and Drug Administration lifted the pause in use of the Johnson & Johnson/Janssen COVID-19 vaccine. This followed the Advisory Committee on Immunization Practices recommendation to resume use of the vaccine for people aged 18 years or older.**
- **On April 24, 2021, New York City providers were notified by the Health Department that they could resume use of the Johnson & Johnson/Janssen COVID-19 vaccine immediately.**
- **Currently available data suggest the risk of thrombosis with thrombocytopenia syndrome after receipt of the Johnson & Johnson/Janssen COVID-19 vaccine is very low and that the benefits of vaccination outweigh this risk.**
- **Providers should become familiar with the risks and benefits of the Johnson & Johnson/Janssen COVID-19 vaccine so they can counsel patients accordingly.**

April 26, 2021

Dear Colleagues,

On April 23, 2021, the U.S. Centers for Disease Control (CDC) and Food and Drug Administration (FDA) lifted the pause in use of the Johnson & Johnson/Janssen COVID-19 vaccine. This followed a vote by the [Advisory Committee on Immunization Practices](#) (ACIP) to recommend resumption in use of the vaccine for all people ages 18 years or older in accordance with the Emergency Use Authorization (EUA). New York State and the [NYC Health Department](#) have notified vaccine providers that they may resume use of the Johnson & Johnson/Janssen COVID-19 vaccine.

On April 13, 2021, the CDC and FDA recommended pausing use of the Johnson & Johnson/Janssen COVID-19 vaccine to investigate reports of 6 cases of cerebral venous thrombosis (CVST) with thrombocytopenia among recipients of the vaccine. This recommendation was immediately communicated to NYC providers of the Johnson & Johnson/Janssen COVID-19 vaccine, and all NYC providers were [urged to remain vigilant](#) for potential thrombotic events among recipients of the vaccine.

During the pause, the CDC and FDA conducted a thorough review to identify additional cases of serious thrombotic events with thrombocytopenia, referred to as thrombosis with thrombocytopenia syndrome (TTS), among Johnson & Johnson/Janssen COVID-19 vaccine recipients. A total of 15 cases of TTS, including the 6 previously reported cases of CVST with thrombocytopenia, were identified among approximately 8 million people who received

the vaccine. The median age of the 15 patients with TTS was 37 years (range, 18 to 59 years), and all were female. The median onset of symptoms was 8 days (range, 6 to 15 days) after vaccination. Three died. No obvious pattern in comorbid conditions was identified. This description does not include one case of CVST with thrombocytopenia identified in a male Johnson & Johnson/Janssen COVID-19 vaccine clinical trial participant 8 days after vaccination. Additional information is available from a [CDC presentation](#) presented at the April 23, 2021 ACIP meeting.

After careful review of the hematologic and clinical characteristics of TTS following receipt of the Johnson & Johnson/Janssen vaccine, the risk and rates of hospitalization and death from COVID-19, and a comprehensive risk benefit analysis for continued use of the vaccine, ACIP voted to recommend resumption in use of the vaccine among all people ages 18 years or older. Vaccine safety monitoring will continue and ACIP will consider any new information about TTS and its potential impact on the risk benefit analysis of this vaccine.

The FDA has granted an amendment to the [Johnson & Johnson/Janssen COVID-19 vaccine EUA](#), updating fact sheets to inform patients and providers that most cases of TTS reported following the Johnson & Johnson/Janssen COVID-19 vaccine have occurred in females ages 18 through 49 years, though specific risk factors for TTS and the level of potential excess risk due to vaccination are under investigation. Based on currently available evidence a causal relationship between TTS and the Johnson & Johnson/Janssen COVID-19 vaccine is plausible. A warning has also been added to the [Janssen COVID-19 Vaccine Fact Sheet for Healthcare Providers Administering Vaccine \(Vaccination Providers\)](#) and additional information about the risks and symptoms of blood clots have been added to the [Fact Sheet for Recipients and Caregivers](#).

Vaccinating providers were notified by the Health Department on April 24, 2021 that they could immediately resume vaccination. Providers should review the [updated provider fact sheet](#) and must provide the [updated patient fact sheet](#) to all vaccine recipients prior to vaccination, pursuant to the terms of the EUA. Patients offered the Johnson & Johnson/Janssen COVID-19 vaccine should be counseled about the benefits and risks of vaccination, including the risk of TTS, and when to seek medical care after vaccination. CDC is developing guidance on counseling patients and expects to make this available within the next few days.

For patients who prefer not to receive the Johnson & Johnson/Janssen COVID-19 vaccine, we strongly encourage you to recommend the Pfizer-BioNTech and Moderna vaccines, available at numerous sites throughout NYC. Patients can check vaccinefinder.nyc.gov, or call 877-VAX-4NYC (877-829-4692) for assistance making an appointment at a City-run site. Many NYC sites also accept walk-ins (see [here](#) for a list). To date, no cases of TTS have been observed after receipt of the Pfizer-BioNTech or Moderna COVID-19 vaccines, over 200 million doses of which have been administered in the U.S.

Patients with symptoms suggestive of TTS (including severe headache, visual changes, new-onset shortness of breath, petechiae, or easy bruising) or other thrombotic events should be asked about COVID-19 vaccine history. Those who received the Johnson & Johnson/Janssen

COVID-19 vaccine within the preceding three weeks should be evaluated promptly and treated in accordance with [current recommendations](#), which include additional information about symptoms that should trigger evaluation. Patients with suspected TTS after Johnson & Johnson/Janssen COVID-19 vaccination should be tested for platelet factor 4 (heparin-induced thrombocytopenia, [HIT]) antibodies and should **not** be treated with heparin unless HIT testing is negative.

Providers must report thrombotic events, along with [other serious adverse events](#) that occur following vaccination, to the [Vaccine Adverse Event Reporting System \(VAERS\)](#). You are strongly encouraged to report all clinically significant adverse events following vaccination, even if it is not clear that vaccination caused the event. Prompt reporting to VAERS is critical to tracking adverse events.

CDC is expected to release final recommendations via the Morbidity and Mortality Weekly Report (MMWR) and updated [clinical considerations](#) for use of the Johnson & Johnson/Janssen COVID-19 vaccine on April 27, 2021. CDC will also offer a Clinical Outreach and Community Activity (COCA) webinar, Johnson & Johnson/Janssen COVID-19 Vaccine and Thrombosis with Thrombocytopenia Syndrome (TTS): Update for Clinicians, on Tuesday, on April 27, 2021 at 2 p.m. Click [here](#) for more information.

The NYC Health Department will provide an update on the Johnson & Johnson/Janssen COVID-19 vaccine and guidance on building confidence in COVID-19 vaccines during a webinar on Friday, April 30, 2021 at 1 p.m. Sign up on the COVID-19 Information for Providers [webpage](#) or use this registration link:

<https://nycdohmh.webex.com/nycdohmh/onstage/g.php?MTID=ee651430b17ea768aec5d4a208f7d4088>

We will provide additional information and guidance as it becomes available. Thank you for your ongoing efforts to care for New Yorkers and participate in the momentous COVID-19 vaccination campaign.

Sincerely,



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The NYC Health Department may change recommendations as the situation evolves.