May 21, 2021

Dear Colleague,

We are writing to update you on important guidance issued by the Centers for Disease Control and Prevention (CDC) regarding administration of the Johnson & Johnson/Janssen COVID-19 vaccine and vaccination recommendations for individuals who have been partially or fully vaccinated with a COVID-19 vaccine that has not been authorized by the U.S. Food and Drug Administration (FDA).

Updated Recommendations for Use of the Johnson & Johnson/Janssen COVID-19 Vaccine

On April 27, 2021, the Advisory Committee on Immunization Practices (ACIP) reaffirmed its interim recommendation for use of the Johnson & Johnson/Janssen COVID-19 vaccine for all people ages 18 years and older in accordance with the Emergency Use Authorization (EUA), which now contains a warning about thrombosis with thrombocytopenia syndrome (TTS). Updated ACIP recommendations were issued to address the risk of TTS among recipients.

As of May 7, 2021, 28 cases of TTS have been reported among recipients of the Johnson & Johnson/Janssen COVID-19 vaccine. These cases were predominantly among females (female, 22; male, 6) with a median age of 40 years (range, 18-59 years).

The ACIP based these recommendations on a careful analysis that concluded that the benefits of the Johnson & Johnson/Janssen COVID-19 vaccine, including its efficacy in preventing serious illness, hospitalization, and death due to COVID-19, outweigh the rare but potential risk of TTS. It is critical that all potential vaccine recipients, especially women aged less than 50 years, be educated about the risk for TTS from the Johnson & Johnson/Janssen COVID-19 vaccine and the availability of alternative COVID-19 vaccines (i.e., mRNA vaccines) to enable informed vaccine decision-making and early recognition of TTS. The updated Johnson & Johnson/Janssen patient fact sheet must be provided to all vaccine recipients before vaccination.

The CDC also issued revised clinical considerations for use of COVID-19 vaccines on April 27, 2021. In addition to affirming the importance of educating potential Johnson & Johnson/Janssen COVID-19 vaccine recipients about the risk for TTS, key updates include the following:

- People with a history 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 it has been ≤90 days since their illness resolved. After 90 days, patients may be vaccinated with any FDA-authorized COVID-19 vaccine.
- Based on current evidence, experts believe that people with risk factors for or a personal history of venous thromboembolism or another type of thrombosis, including central venous sinus
thrombosis, that is not associated with thrombocytopenia are unlikely to be at an increased risk for TTS after receipt of the Johnson & Johnson/Janssen COVID-19 vaccine. This includes people who are pregnant, post-partum, or using hormonal contraceptives. These people can receive any authorized COVID-19 vaccine.

- It is not recommended that people take aspirin or an anticoagulant before vaccination with the Johnson & Johnson/Janssen COVID-19 vaccine or any other FDA-authorized COVID-19 vaccine (i.e., mRNA vaccine), unless they take these medications as part of their routine medications.

- Although TTS after receipt of this vaccine is rare, providers should educate patients to watch for possible symptoms of TTS within 3 weeks after receiving this vaccine and to seek medical care immediately if they develop any of the following symptoms:
  - Shortness of breath
  - Chest pain
  - Leg swelling
  - Persistent abdominal pain
  - Severe or persistent headache or blurred vision
  - Easy bruising or petechiae beyond the site of the injection

Patients with suspected TTS after Johnson & Johnson/Janssen COVID-19 vaccination should not be treated with heparin unless a platelet factor 4-ELISA (“HIT” ELISA) assay is negative. Additional information about the diagnosis and treatment of TTS is available from the American Society of Hematology.

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

Although there is a risk of TTS after receipt of the Johnson & Johnson/Janssen vaccine, available data suggest this risk is very low. Many patients may continue to prefer this vaccine over other COVID-19 vaccines. Rates of COVID-19 in New York City (NYC) remain high in all boroughs, and we encourage you to talk about COVID-19 vaccines with your patients at every opportunity. Patients consistently say their provider’s recommendation is the most important factor when deciding whether to get vaccinated.

COVID-19 vaccine communication resources include:

- Provider resources
  - CDC: Discussing Johnson & Johnson/Janssen Vaccine with Patients
  - NYC Health Department:
    - Addressing Patients’ COVID-19 Vaccine Questions
    - COVID-19 Vaccine Communication Resources for Providers
Non-FDA-authorized COVID-19 Vaccines

The CDC issued guidance for people who received a COVID-19 vaccine not currently authorized in the United States.

- For COVID-19 vaccines not authorized by the FDA but authorized for emergency use by the World Health Organization (WHO):
  - People who completed a COVID-19 vaccination series with such a vaccine (currently, the Oxford-AstraZeneca and Sinopharm vaccines) do not need any additional doses with an FDA-authorized COVID-19 vaccine.
  - People who are partially vaccinated with such a vaccine should start and complete a new vaccine series with an FDA-authorized COVID-19 vaccine (either two doses of the Pfizer-BioNTech or Moderna vaccine or one dose of the Johnson & Johnson/Janssen vaccine).

- For COVID-19 vaccines not authorized by the FDA or WHO:
  - People who completed a full or partial COVID-19 vaccine series with a vaccine not authorized by either FDA or WHO should start and complete a new vaccine series with an FDA-authorized COVID-19 vaccine (either two doses of the Pfizer-BioNTech or Moderna vaccine or one dose of the Johnson & Johnson/Janssen vaccine).

The minimum interval between the last dose of a non-FDA authorized COVID-19 vaccine and an FDA-authorized COVID-19 vaccine is 28 days.

Where to Get a COVID-19 Vaccine in New York City

The Johnson & Johnson/Janssen, Pfizer-BioNTech, and Moderna COVID-19 vaccines are available at numerous sites throughout NYC. See here for a list of NYC sites that accept walk-ins. Patients can check vaccinefinder.nyc.gov, or call 877-VAX-4NYC (877-829-4692) for assistance making an appointment at a City-run site. They can also find out which vaccine is available at each site and which sites have walk-in services.

Providers and staff can now access a dedicated provider line to help patients make vaccine appointments by calling 877-VAX-4NYC (877-829-4692) and pressing 2 at the second prompt.
Thank you for your continued partnership in the NYC COVID-19 vaccination campaign.

Sincerely,
Celia Quinn, MD, MPH
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Bureau of Healthcare and Community Readiness
Office of Emergency Preparedness and Response

NYC Health Department Resources
- For information for providers on COVID-19 vaccines, go to nyc.gov/health/covidvaccineprovider
- For information for providers on communicating with patients about COVID-19 vaccines, go to nyc.gov/VaccineTalks
- To receive Health Alerts, go to https://a816-healthpsi.nyc.gov/NYCMED/Account/HANSsubscribe
- To subscribe to receive Dear Colleague Letters, sign up for a City Health Information subscription at nyc.gov/health/register
- For general provider information and to register to attend the NYC Health Department’s COVID-19 Provider Webinars, go to https://www1.nyc.gov/site/doh/covid/covid-19-providers.page

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