



NEW YORK CITY DEPARTMENT OF

HEALTH AND MENTAL HYGIENE

Dave A. Chokshi, MD, MSc

*Commissioner*

March 22, 2021

Dear Colleague:

The Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the [Johnson & Johnson/Janssen](#) (Johnson & Johnson) adenovirus vector vaccine against COVID-19 on February 27, 2021, and the Advisory Committee on Immunization Practices (ACIP) voted to approve use of this vaccine on February 28, 2021. The phase 3 clinical trial included over 40,000 participants from eight countries.<sup>1</sup> The study included diverse enrollment across race, ethnicity, and age groups above 18 years. Participants were 62% White; 17% Black/African American; 8% American Indian/Alaska Native; 4% Asian; and 0.3% Native Hawaiian/Pacific Islander. Forty-five percent of participants were Hispanic. The median age was 52 years (range, 18 to 100 years) and 20% of participants were age 65 years or older. Forty percent of participants had at least one medical comorbidity.

Vaccine efficacy against symptomatic COVID-19 illness of any severity was 66% at 28 or more days after vaccination. Efficacy against severe/critical COVID-19 was estimated at 85% and efficacy against COVID-19-associated hospitalization was 100% at 28 or more days after vaccination. No COVID-19-associated deaths occurred among vaccine recipients during the study observation period. Vaccine efficacy was comparable across age, sex, and race/ethnicity, and in participants with and without comorbidities. Preliminary data suggest that the vaccine might also provide protection against asymptomatic SARS-CoV-2 infection.<sup>2</sup>

Efficacy of the Johnson & Johnson COVID-19 vaccine should not be directly compared to that of the authorized mRNA COVID-19 vaccines because the trials were conducted at different times and in different geographic settings. The Johnson & Johnson trial took place during a time of higher background COVID-19 incidence and circulation of known variants of concern.

The adenovirus vector used in the Johnson & Johnson COVID-19 vaccine is grown in media containing no animal-derived proteins. The vaccine contains no adjuvants, antibiotics, preservatives, eggs, gelatin, latex, fetal tissue or human cells. The vector used in the Johnson & Johnson COVID-19 vaccine cannot replicate in humans or cause disease. The genetic material delivered by the viral vector cannot integrate into or change a person's DNA.

There are limited data on the use of the Johnson & Johnson COVID-19 vaccine in pregnant people. However, the adenovirus vector has been used for other Johnson & Johnson vaccine

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<sup>1</sup> Vaccines and Related Biological Products Advisory Committee Meeting. February 26, 2021. [FDA Briefing Document: Janssen Ad26.COV2.S Vaccine for the Prevention of COVID-19](#).

<sup>2</sup> Oliver SE, Gargano JW, Scobie H, et al. The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Janssen COVID-19 Vaccine — United States, February 2021. *MMWR Morb Mortal Wkly Rep.* 2021;70(9):329-332. DOI: <http://dx.doi.org/10.15585/mmwr.mm7009e4>.

development programs that have included pregnant people. Based on current knowledge, experts believe that the vaccine is unlikely to pose a risk to the pregnant person or the fetus.

Common side effects of the Johnson & Johnson COVID-19 vaccine during the clinical trial included headache, chills, fatigue, myalgias, and injection site pain lasting a median of one to two days. Symptoms were less frequent in older adults compared to younger adults. Serious allergic reactions were rare. No significant safety concerns were identified.

ACIP states no preference for any of the three currently authorized COVID-19 vaccines and encourages people to receive the vaccine that becomes available to them first. The New York City Department of Health and Hygiene (NYC Health Department) strongly encourages people to receive the first vaccine available to them once they are eligible.

### **Recommendation for use of Johnson & Johnson adenovirus vector COVID-19 vaccine**

The Johnson & Johnson COVID-19 vaccine is authorized for people ages 18 years and older in the EUA. The vaccine is administered intramuscularly as a single dose (0.5 mL). Before vaccination, an [EUA Fact Sheet](#) should be provided to recipients and caregivers. Store unpunctured multi-dose vials of the Johnson & Johnson COVID-19 vaccine at 2 degrees Celsius (C) to 8 degrees C (36 degrees Fahrenheit [F] to 46 degrees F) and protect from light until use, expiration date or up to three months (whichever comes first). Do not store frozen. After the first dose has been withdrawn, maintain the vial temperature between 2 to 8 degrees C (36 to 46 degrees F) for up to 6 hours or at room temperature (maximally 25 degrees C/77 degrees F) for up to two hours. Discard the vial if vaccine is not used within these times. Before withdrawing each dose of vaccine, carefully mix the contents of the multi-dose vial by swirling gently in an upright position for 10 seconds. **Do not shake.** Each vial contains five doses.

The Johnson & Johnson COVID-19 vaccine is not interchangeable with other COVID-19 vaccines. Individuals who have received one dose of an mRNA COVID-19 vaccine should receive a second dose of the same vaccine to complete the series. However, if a patient is unable to complete the series with the same or different mRNA COVID-19 vaccine, such as in the case of contraindications to the mRNA vaccines, consideration can be given as to whether the patient can receive a single dose of the Johnson & Johnson COVID-19 vaccine at a minimum interval of 28 days after the mRNA dose. Note that persons with a contraindication to mRNA COVID-19 vaccines have a precaution to the Johnson & Johnson COVID-19 vaccine. Consider consultation with an allergist-immunologist or contacting the Centers for Disease Control and Prevention (CDC) [Clinical Immunization Safety Assessment COVIDvax](#) project before administering the Johnson & Johnson COVID-19 vaccine to someone with a contraindication to the mRNA COVID-19 vaccines.

## ACIP Recommendations for Clinical Use

ACIP has aligned [guidance for the Johnson & Johnson COVID-19 vaccine](#) with guidance for use of the authorized mRNA COVID-19 vaccines, including:

- Not to co-administer with other vaccines
- Observation period after vaccination
- Vaccination of pregnant people and people with underlying medical conditions, prior and past COVID-19 infection, and past receipt of monoclonal antibodies or convalescent plasma

## Contraindications and Precautions

COVID-19 vaccines are contraindicated in individuals with a history of severe or immediate allergic reaction to any of the [vaccine components](#). Immediate allergic reaction is defined as any hypersensitivity-related signs or symptoms consistent with urticaria, angioedema, respiratory distress (e.g., wheezing, stridor) or anaphylaxis that occur within four hours following administration.

A history of immediate allergic reaction to any vaccine or injectable therapy (intramuscular, intravenous or subcutaneous) is a precaution to vaccination but is not a contraindication. This includes people who experienced an allergic reaction to either of the mRNA COVID-19 vaccines. For patients with a precaution to vaccination, a risk assessment should be conducted to determine the type of reaction and certainty of information, and the individual should receive counseling about the unknown risks of developing a severe allergic reaction, balancing these risks against the benefits of vaccination. Vaccination should be undertaken in an appropriate setting under the supervision of a health care provider experienced in the management of severe allergic reactions. Administration of antihistamines to COVID-19 vaccine recipients before vaccination to prevent allergic reactions is not recommended. Antihistamines do not prevent anaphylaxis and their use might mask cutaneous symptoms, which could lead to a delay in the diagnosis and management of anaphylaxis.

As with the mRNA vaccines, vaccine providers should observe patients after vaccination to monitor for the occurrence of immediate adverse reactions. Individuals with a history of an immediate allergic reaction of any severity to a vaccine or injectable therapy, with a contraindication to a different type of COVID-19 vaccine, or with a history of anaphylaxis due to any cause should be observed for 30 minutes; all other people should be observed for 15 minutes. Providers should ensure that appropriate medical treatment used to manage immediate allergic reactions is immediately available in the event an acute anaphylactic reaction occurs. See CDC's [Interim Considerations: Preparing for the Potential Management of Anaphylaxis at COVID-19 Vaccination Sites](#).

## Reporting to the Citywide Immunization Registry (CIR)

Reporting of all administered COVID-19 vaccine doses to the [CIR](#) is required within 24 hours of administration. See the "Prepare to Report COVID-19 Vaccinations to the CIR" section in our [vaccine enrollment letter](#). Record patient [self-reported demographics](#), including race and

ethnicity in reports to the CIR. New York State [Executive Order 202.82](#) removes the requirement that adults must consent to have their immunization information reported to the CIR.

#### **COVID-19 Vaccine Communication Resources**

- NYC Health Department:
  - [COVID-19 Vaccine Information for Providers](#)
  - Dear Colleague: [Building Confidence in COVID-19 Vaccines and Vaccination](#)
  - Presentation: [Building Vaccine Confidence Among Health Care Providers, Support Staff and Patients](#)
- CDC:
  - [Engaging in Effective COVID-19 Vaccine Conversations](#)
  - [Toolkit for Medical Centers, Pharmacies, and Clinicians](#)

The NYC Health Department will continue to share information as it becomes available to help providers plan for allocation, distribution and administration of COVID-19 vaccines.

Sincerely,

Jane R. Zucker, MD, MSc  
Assistant Commissioner  
Bureau of Immunizations