March 9, 2021

Health Alert Notice for District of Columbia Health Care Providers

Guidance on the Janssen Covid-19 Vaccine (Ad26.COV2. S)

SUMMARY

On February 27, 2021, the FDA issued an Emergency Use Authorization for the Janssen COVID-19 Vaccine in the United States. The District of Columbia Department of Health (DC Health) continues to implement distribution administration recommendations as outlined in the District's *COVID-19 Vaccination Plan.* The Janssen vaccine has been shown to be safe and effective as determined by the interim analysis of the international clinical trial COV3001 which involves more than 40,000 individuals worldwide drawn from diverse ethnic and socioeconomic backgrounds including those with underlying medical conditions. Current evidence demonstrates that the known and potential benefits of the vaccine outweigh the known and potential harms associated with COVID-19. This health notice provides information on safe administration, clinical considerations, reporting requirements, and highlights important resources for healthcare providers.

BACKGROUND

The Advisory Committee on Immunization Practices (ACIP) has provided interim recommendations to the Centers for Disease Control and Prevention (CDC) for administration of the Janssen COVID-19 (Ad26.COV2. S) vaccine to prevent COVID-19. This vaccine is a recombinant, replication-incompetent adenovirus serotype 26 (Ad26) vector vaccine, encoding the stabilized prefusion spike glycoprotein of SARS-CoV-2, the virus that causes COVID-19. The vaccine's authorization is based on an interim analysis of the Phase III clinical trial COV3001.

COV3001 is an ongoing international randomized controlled trial being conducted in the United States, Mexico, South America, and South Africa which started in September 2020. The trial enrolled >44,000 persons aged 18-100 (median age=52). The primary endpoints for the interim analysis were prevention of symptomatic laboratory-confirmed COVID-19 in persons without evidence of previous SARS-CoV-2 infection at baseline, assessed at day 14 and at day 28 after vaccination. Results showed effectiveness of the vaccine varied geographically, with highest efficacy in the United States. Of note, 96% of the COVID-19 cases which occurred in the US arm of the trial were wild type SARS-CoV-2 (D614G), while the South Africa arm had 94.5% prevalence of the B.1.351 variant, and the cases in Brazil had 69.4% prevalence of the P2 variant.

The vaccine had efficacy of 66% against moderate to severe COVID-19 and 85% efficacy against severe COVID-19 globally. The vaccine had a 72% efficacy against moderate to severe COVID-19 and 85.9% efficacy in prevention of severe/critical COVID-19 in the United States. There was similar vaccine efficacy and safety profile across ages, races and ethnicities, and comorbidity status. Preliminary evidence in a small group of participants suggests that the Janssen vaccine may prevent asymptomatic SARS-CoV-2 infection as well as clinical illness, but additional data are needed. Since vaccine prevention of asymptomatic infection is not yet proven, the possibility exists that vaccinated persons could still spread the virus to others. For this reason**, it is important that vaccinated individuals be instructed to continue following mitigation measures such as wearing masks and social distancing in public to protect those around them.** Detailed information on recommendations for fully vaccinated people will be published on www.coronavirus.dc.gov.

VACCINE CONTRAINDICATIONS

- The Janssen vaccines should not be administered to:
  - Individuals with a known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine.

- Individuals outside the authorized age range.

VACCINE ADMINISTRATION

- The safety and efficacy of a mixed product COVID-19 vaccination series has not been fully evaluated; however, administration may be considered under the following exceptional situation.
  - If a first dose of mRNA vaccine was received, but a person is unable to complete the mRNA vaccine series with the same or a different mRNA vaccine (e.g., contraindication), consider administering a single dose of the Janssen vaccine.
    - A minimum of 28 days must have passed since the first vaccine dose.
    - Patient would be considered fully vaccinated 14 days after the Janssen vaccine.
- COVID-19 vaccines are NOT currently recommended to be co-administered with other vaccines.
  - The safety and efficacy of administering a COVID-19 vaccine along with another vaccine has not been evaluated.
  - A minimum of 14 days is recommended before or after an individual has received any other vaccine.
- COVID-19 vaccines are NOT currently recommended for:
  - Individuals with an active COVID-19 infection. Vaccination should occur after isolation is completed. Since re-infection with COVID-19 is uncommon in the 90 days following an infection, individuals may choose to delay getting vaccinated until after 90 days have passed.
  - Individuals under quarantine for COVID-19 in the community, to avoid potentially exposing others. Vaccination should occur after quarantine is completed.
  - Persons who have received monoclonal antibodies or convalescent plasma as part of COVID-19 treatment in the previous 90 days.
  - Managing a COVID-19 outbreak or as post-exposure prophylaxis
- Vaccine Fact Sheets may be found at fda.gov/media/146304/download

CLINICAL CONSIDERATIONS

The Janssen COVID-19 vaccine may be given to persons with chronic or underlying health conditions provided they have no contraindication for administration. Similar safety and efficacy profiles were demonstrated in clinical trials in individuals with certain underlying medical conditions including those at highest risk for severe COVID-19 infection as compared to the general population.

- **Immunocompromised individuals** with no contraindications may receive the vaccine with the following in mind:
  - Persons with stable HIV infection were included in the vaccine trials, but there is currently limited data to establish vaccine safety and efficacy in individuals with HIV infection or other immunocompromising conditions.
  - Individuals should be counseled about the unknown safety and efficacy profiles in the immunocompromised, the potential for decreased immune response to the vaccination, and the need to continue the same everyday prevention measures utilized prior to receiving the vaccine.
  - Re-vaccination is not currently recommended once immune competence is regained such as during chemotherapy or after discontinuation of immunosuppressive drugs.
- **Pregnant individuals** or those trying to become pregnant may receive the vaccine with the following in mind:
  - Clinical trials to include pregnant women are currently underway, however, potential risks of the Janssen vaccine to the pregnant individual and the developing fetus are unknown due to lack of completed clinical trials in this population.
  - Experts believe that vaccine is unlikely to pose a risk to pregnant individuals or fetuses because the vaccine is not a live vaccine.

- Pregnant individuals are encouraged to speak with their health care provider to prior to vaccination to discuss the individual's level of risk, the efficacy and side effects of the vaccine, and the lack of data during pregnancy.

VACCINE SAFETY

Before vaccination, providers should counsel vaccine recipients about possible post-vaccination symptoms, local (e.g., pain, swelling, erythema at the injection site, localized axillary lymphadenopathy on the same side as the vaccinated arm) and systemic (e.g., fever, fatigue, headache, chills, myalgia, arthralgia).

- 50% of vaccinated individuals experience at least one local symptom and 55% experience at least one systemic symptom.
- Post-vaccination symptoms can occur within 7-8 days. Symptoms are usually mild to moderate in severity, most commonly occurring within the first 2 days after vaccination and resolving within 1–2 days of onset.
- Antipyretics (e.g., acetaminophen, non-steroidal anti-inflammatory drugs) may be taken for the treatment of post-vaccination local or systemic symptoms, if medically appropriate. However, routine prophylactic administration is not currently recommended, as information on the impact the adenovirus vector vaccine-induced antibody response is unknown.
- Encourage patients to utilize V-Safe.
  - V-Safe is a new, voluntary, smartphone-based tool developed by the CDC that uses text messaging and web surveys to provide patients with near real-time health check-ins after they receive a COVID-19 vaccination.
  - CDC/v-safe call center representatives will follow up on reports of medically significant health impacts to collect additional information to enter into the Vaccine Adverse Event Reporting System (VAERS). More information on VAERS can be found in the reporting section of this document.

ANAPHYLAXIS

While rare, there have been reports of anaphylactic reactions following administrations of other COVID-19 vaccines.

- A history of any immediate allergic reaction to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies not related to a component of Janssen COVID-19 vaccine or polysorbate) is considered a precaution but not a contraindication.
  - Risk of exposure, and risk of severe disease or death due to COVID-19 should be considered.
  - Recommend vaccination at a site where appropriate medical care for anaphylaxis is immediately available.
- **ALL** individuals should be observed after receiving the vaccine.
  - 30 minutes for individuals with a history of an immediate allergic reaction of any severity to a vaccine or injectable therapy and/or a history of anaphylaxis due to any other cause
  - 15 minutes for all other individuals
- Symptoms often occur within 15-30 minutes of vaccination, though it can sometimes take several hours for symptoms to appear.
  - Inform patients on what to look for and what to do after leaving the vaccine clinic.
- Sites providing vaccination must have healthcare personnel trained and available to recognize the signs and symptoms of anaphylaxis and provide initial treatment.

REPORTING

Vaccine Administration Reporting

- Vaccine administration must be reported to the District of Columbia Immunization Information System, (DOCIIS) **within 24 hours of administration.**
- DOCIIS is the Immunization Program's key tool for tracking individual- and population- level immunization data in DC. Health care providers use DOCIIS to check immunization history to ensure their patients receive recommended vaccines as prescribed, and schools and LCDCs use DOCIIS to track compliance with immunization laws and regulations (e.g. DC Law 3-20). For more information on DOCIIS please visit dchealth.dc.gov/dociis.
- ALL vaccine administration errors should be reported to the Vaccine Adverse Event Reporting System (VAERS) as described below.

Adverse Event Reporting

Adverse events that occur in a recipient following COVID-19 vaccination should be reported to VAERS. Vaccination providers are required by the Food and Drug Administration to report the following that occur after COVID-19 vaccination under Emergency Use Authorization:

- Vaccine administration errors
- Serious adverse events
- Cases of Multisystem Inflammatory Syndrome
- Cases of COVID-19 that result in hospitalization or death
- Cases of COVID-19 infection in fully vaccinated individuals (14 days after completion of a COVID-19 vaccination series)

Reporting is encouraged for any other clinically significant adverse event even if it is uncertain whether the vaccine caused the event. Information on how to submit a report to VAERS is available at vaers.hhs.gov or by calling 1-800-822-7967.

ADDITIONAL RESOURCES

- **District of Columbia's COVID-19 Vaccine website** coronavirus.dc.gov/vaccine
- **District of Columbia's *COVID-19 Vaccination Plan***: coronavirus.dc.gov/sites/default/files/dc/sites
- **FDA's Fact Sheet for Vaccine Recipients and Caregivers: fda.gov/media/146305/download**
- **CDC's COVID-19 Vaccine Website:** www.cdc.gov/vaccines/covid-19/index.html
- Emergency Use Authorizations of the Janssen vaccine on the FDA website: fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-third-covid-19-vaccine
- **Full ACIP interim recommendations** for use of the vaccines: cdc.gov/mmwr/volumes/70/wr/mm7009e4.htm
- **ACIP Presentation Slides: February 28 - March 1, 2021 Meeting on the Janssen vaccine**: cdc.gov/vaccines/acip/meetings/slides-2021-02-28-03-01.html
- **More information on clinical considerations for vaccine administration:** cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html.

The guidelines above will continue to be updated as the outbreak evolves. Please visit coronavirus.dc.gov/vaccine for the most current information.

Please contact DC Health regarding COVID-19 at:
Phone: 202-576-1117 Fax: 202-442-8060 | Email: coronavirus@dc.gov

Triage of people presenting for COVID-19 vaccination

CONTRAINDICATION TO VACCINATION	PRECAUTION TO VACCINATION	MAY PROCEED WITH VACCINATION
History of the following: • Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to component of the vaccine† • Immediate allergic reaction* of any severity after a previous dose or known (diagnosed) allergy to a component of the vaccine†	**Among people without a contraindication, a history of:** • Any immediate allergic reaction* to other vaccines or injectable therapies‡ Note: people with a contraindication to mRNA COVID-19 vaccines have a precaution to Janssen COVID-19 vaccine, and vice versa. See footnote for additional information on additional measures to take in these people.#	**Among people without a contraindication or precaution, a history of:** • Allergy to oral medications (including the oral equivalent of an injectable medication) • History of food, pet, insect, venom, environmental, latex, etc., allergies • Family history of allergies
Actions: • Do not vaccinate. • Consider referral to allergist-immunologist. • Consider other vaccine alternative.†	**Actions:** • Risk assessment • Consider referral to allergist-immunologist • 30-minute observation period if vaccinated	**Actions:** • 30-minute observation period: people with history of anaphylaxis (due to any cause) • 15-minute observation period: all other people

† See Appendix C for a list of ingredients. People with a contraindication to one of the mRNA COVID-19 vaccines should not receive doses of either of the mRNA vaccines (Pfizer or Moderna).

* Immediate allergic reaction to a vaccine or medication 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.

‡Includes people with a reaction to a vaccine or injectable therapy that contains multiple components, one of which is a vaccine component, but in whom it is unknown which component elicited the immediate allergic reaction.

#Polyethylene glycol (PEG) is an ingredient in both mRNA COVID-19 vaccines, and polysorbate 80 is an ingredient in Janssen COVID-19 vaccine. PEG and polysorbate are structurally related, and cross-reactive hypersensitivity between these compounds may occur. People with a contraindication to mRNA COVID-19 vaccines (including due to a known allergy to PEG) have a precaution to Janssen COVID-19 vaccine. Among people who received one mRNA COVID-19 dose but for whom the second dose is contraindicated, consideration may be given to vaccination with Janssen COVID-19 vaccine (administered at least 28 days after the mRNA COVID-19 dose). People with a contraindication to Janssen COVID-19 vaccine (including due to a known allergy to polysorbate) have a precaution to mRNA COVID-19 vaccines. For people with these precautions, referral to an allergist-immunologist should be considered. Healthcare providers and health departments may also request a consultation from the Clinical Immunization Safety Assessment COVIDvax project. In patients with these precautions, vaccination should only be undertaken in an appropriate setting under the supervision of a health care provider experienced in the management of severe allergic reactions. Table above can be found at cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Appendix-B