Nevada Department of Health and Human Services DIVISION OF PUBLIC AND BEHAVIORAL HEALTH

Technical Bulletin



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Topic: Implementation Considerations for the Janssen (Johnson & Johnson) COVID-19 Vaccine

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To: All Health Care Providers and Facilities, Local Health Authorities, and Pharmacists

Implementation Considerations for the Janssen COVID-19 Vaccine

Current Status

On February 27, 2021, the Food and Drug Administration issued an Emergency Use Authorization for the Janssen COVID-19 vaccine. On February 28, 2021, after a transparent evidence-based review of all available data, the Advisory Committee on Immunization Practices (ACIP) issued an <u>interim recommendation</u> for the use of the Janssen COVID-19 vaccine in persons aged 18 years and older for the prevention of COVID-19.ⁱ The ACIP states no preference for any of the three (3) authorized vaccines (Modera, Pfizer-BioNTech, and Janssen).

Details about the Janssen COVID-19 vaccine can be found here: https://www.cdc.gov/vaccines/covid-19/info-by-product/janssen/.

Vaccine Efficacy

It is not recommended to compare the efficacy of the three (3) available COVID-19 vaccines. This is primarily because the Janssen Phase III trials occurred during a different calendar time and in different places than the trials for the mRNA vaccines (i.e., the Pfizer and Moderna vaccines).

Janssen COVID-19 vaccine efficacy:

- 85% vaccine efficacy against severe COVID-19 disease globally, including in the United States
 - Complete protection against COVID-19 related hospitalizations and deaths 28 days or more after vaccination
- 72% vaccine efficacy against moderate to severe/critical COVID-19 disease in the United States
- 66% vaccine efficacy against moderate to severe/critical COVID-19 disease across all studied countries
 - o Protection as of 2 weeks after vaccination
- Similar vaccine efficacy demonstrated by age, comorbidities status, sex, race, and ethnicity

Versatility in Different Clinical Implementation Situations

The Janssen COVID-19 vaccine creates new opportunities for versatility and ease of use in reaching more Nevadans.

Potential Advantages of the Janssen Vaccine

- 1) A single-dose schedule that can more easily reach persons who:
 - a. Do not want to or cannot easily return for a second dose
 - b. Cannot be recalled or reminded to return for the second dose using phone or email
 - c. Are being transferred or discharged from a hospital
 - d. Have limited or no transportation availability
 - e. Are homebound
 - f. Are anxious about the potential for a stronger reaction following a second dose and so may not return

- 2) Stable storage in a refrigerator for up to three (3) months allows for easy storage and transport to:
 - a. Mobile/pop-up clinics
 - b. Newly established vaccine administration sites
 - c. Sites that do not have any freezer capacity (e.g., adult primary care offices that usually only stock flu vaccines)

Supporting Equity

The Janssen COVID-19 vaccine can play a critical role in expanding vaccine access to Nevadans who have been disproportionately impacted by the COVID-19 pandemic. The addition of a third vaccine will help Nevada counties expand access to and reach community members who may have access challenges due to transportation, a transient living situation, or lack of consistent and reliable communication making follow-up for a second dose difficult and leaving the person without full protection from vaccination.

This vaccine will help Nevada apply the <u>ethical principles of the COVID-19 vaccine response</u> as set by the ACIP in November 2020.

Specifically, the Janssen product will allow Nevada to focus on the following ethical principles:

- Promoting Justice
 - All eligible persons should have equal opportunity to be vaccinated
 - Commitment to removing unfair, unjust, and avoidable barriers to vaccination that disproportionately affect groups that have been economically or socially marginalized
 - Commitment to a fair and consistent implementation process
- Mitigate Health Inequities
 - Every person should be given the opportunity to receive the vaccine and not be disadvantaged from receiving the vaccine because of social position or other socially determined circumstances
 - Vaccine allocation strategies should aim to reduce existing health disparities and not create new disparities
 - Commitment to identifying and removing obstacles and barriers to receiving a COVID-19 vaccine, including limited access to health care or residence in rural, hard-to-reach areas

Storage and Handling Considerations:

The Janssen COVID-19 vaccine is much easier to store and handle compared to the other COVID-19 vaccines.

- Shipped from McKesson in a normal Styrofoam shipping container at refrigerator temperatures
- Can be refrigerated for 3 months (2 to 8°C)
- No diluent or mixing required
- 100 dose minimum order
- 2 small packages with 50 doses in each package
- 5 doses per vial, possible 6th but not recommended at this time by the CDC
- Ancillary kit for 100 doses provided with the vaccine

Safety

- Demonstrated acceptable safety and reactogenicity profile in clinical trial; most adverse events were mild or moderate
- The benefits of vaccine administration outweigh the risks
- Vaccine recipients should be encouraged to enroll in V-Safe after vaccination; healthcare providers and vaccinating sites will provide the QR code to vaccine recipients after vaccination
- Providers are required to report unexpected or severe adverse events to the Vaccine Adverse Events Reporting System (VAERS)
- Janssen vaccine should not be used to complete a vaccination series initiated with another COVID vaccine
- There is a remote chance the Janssen COVID-19 vaccine could cause a severe allergic reaction

Questions:

For updated guidance, please review the DPBH Technical Bulletin <u>website</u> and Nevada's COVID-19 response <u>website</u> regularly.

If you have questions about your county's specific vaccine rollout plan, please email COVIDVaxHelp@immunizenevada.org.

A statewide call center is also available to help answer your questions and guide you to a vaccination provider if you are eligible to receive the vaccine based on your county's plans.

Please call 1-800-401-0946 for assistance with any COVID-19 vaccination or testing questions.

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i https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7009e4-H.pdf

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