Health Advisory

Janssen (Johnson & Johnson) COVID-19 Vaccine: Information for Clinicians and Vaccine Providers

March 9, 2021

The following information is issued on behalf of the SF COVID Command Center

Situational Update: Janssen Vaccine

- Janssen Biotech is a subsidiary of Johnson & Johnson. FDA and CDC are referring to the newly approved vaccine as the "Janssen" vaccine.
- The Vaccines and Related Biological Products Advisory Committee (VRBPAC) of the FDA voted to recommend approval of the Janssen COVID-19 vaccine (2/26/2021).
- The FDA issued an Emergency Use Authorization (EUA) for Janssen Vaccine (2/27/2021), complete with the required Fact Sheets for Healthcare Providers and for Patients.
- The CDC's Advisory Committee on Vaccination Practices (ACIP) confirmed the safety and efficacy of the vaccine and has issued an interim recommendation for use of Janssen vaccine in persons aged ≥18 years for the prevention of COVID-19 (3/2/2021).
- Initial quantities of Janssen COVID-19 vaccine are expected to reach San Francisco this week; regular flow of this vaccine into SF is not expected to begin until the latter part of the month.

San Francisco Allocation Priorities for Janssen Vaccine

San Francisco COVID Command is following national, state, and local prioritization frameworks for COVID-19 vaccination, independent of the vaccine product used. Janssen vaccine doses will be made available, as supply allows, for allocation:

- To vaccination providers and sites that, due to any of the operational considerations noted below, request the Janssen product
- With a view toward making Janssen doses available broadly among a range of vaccination settings, populations, and geographic locations within San Francisco

Operational Considerations for Use of Janssen Vaccine

The Janssen vaccine series consists of a single, one-time dose, as currently authorized, and the vaccine is stored and transported at refrigerator temperatures (36–46°F or 2–8°C).

As vaccine supply allows, these characteristics of the Janssen vaccine have the potential to increase availability and feasibility of COVID-19 vaccinations:

- In settings where the requirement for frozen or ultra-frozen storage of the mRNA vaccines is a barrier, such as some community, primary and specialty care clinics, and mobile vaccination operations

- In settings where vaccinees might have difficulty returning for a second dose, such as vaccination of hospitalized patients just prior to discharge, or settings where patients express a preference for a single-dose vaccine or a vaccine with a lower rate of side effects.

Consumers may appreciate being informed which vaccine product(s) are available at any given site, however vaccination providers are not required or expected to offer vaccinees a choice among vaccine products.

Clinical Considerations for Use of Janssen Vaccine

There are now three COVID-19 vaccine products authorized for emergency use during the pandemic. While they have different composition (Pfizer-BioNTech and Moderna products are mRNA vaccines while the Janssen product is a viral vector vaccine), all three products have exceeded pre-specified FDA standards for efficacy and have exhibited excellent safety profiles.

Providers can play a critical role in educating patients and providing reliable information about the currently available COVID-19 vaccines.

Efficacy and safety data from Janssen's phase III vaccine trial are now publicly available; see the FDA briefing document, Janssen's presentation to ACIP, and ACIP's synthesis of the evidence. Study participants reflected the diversity of the overall U.S. population and the vaccine performed well across all clinical and demographic groups analyzed; no sub-populations within the trial were definitively shown to derive greater or lesser benefit from the vaccine.

The Janssen vaccine showed 72-74% efficacy in preventing moderate-or-severe COVID-19 in the U.S., with protection starting at day 14 post-vaccination. Efficacy was even higher in preventing severe disease (77-85%) and hospitalization (93-100%), with protection starting at day 7 post-vaccination. No COVID-19-related deaths occurred in trial participants receiving the Janssen vaccine. Notably, results were similar in the South African arm of the trial where a highly transmissible COVID-

19 variant strain predominated, indicating that the Janssen vaccine can protect against variant strains.

ACIP notes that Janssen vaccine efficacy is not directly comparable with mRNA vaccine efficacy as the studies were performed at different calendar times, with different circulating variants and different background incidence of disease.

In addition, ACIP did not identify any clinical or demographic groups for which any of the three authorized vaccines should be preferentially offered. As is often the case when multiple vaccines are available for the same indication, **ACIP stated no product preference** among them, instead concluding that persons aged ≥18 years (≥16 years for Pfizer-BioNTech vaccine) may receive any of these vaccines and should be **encouraged to receive the earliest vaccine available to them.**

Clinical Guidance on COVID-19 Vaccination

CDC has updated its interim clinical considerations for use of COVID-19 vaccines to incorporate guidance on the use of all three currently authorized vaccines.

Bookmark this FDA page to easily find updated FDA COVID-19 Vaccine Fact Sheets for Providers and Patients/Caregivers.

Sample COVID-19 vaccine protocols (including a new sample protocol for administration of Janssen vaccine), clinical FAQ for providers administering COVID-19 vaccines, and other SFDPH-developed documents are regularly updated and available at www.sfcdcp.org/covidvax-administer.

Additional Information from SF COVID Command

COVID-19 vaccination information for the general public: https://SF.gov/covidvax

Please contact covidvax@sfdph.org with questions.