Health Advisory

Resuming Use of Janssen (Johnson & Johnson) COVID-19 Vaccine

April 30, 2021

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

Situation

The FDA has lifted its pause on the use of the Janssen vaccine, after a review by the CDC's Advisory Committee on Immunization Practices (ACIP) concluded that the benefits of the Janssen COVID-19 vaccine outweigh its known and potential risks in adults. ACIP considered several options but decided to reaffirm its recommendation of the vaccine for adults age 18 years without limitation, recognizing that limiting use of the vaccine could challenge public health implementation, limit personal choice, and disproportionately affect populations with barriers to vaccine access or who have difficulty returning for a second dose.

FDA updated its Emergency Use Authorization (EUA) Fact Sheets for Vaccination Providers and for Recipients to include a warning about the risk of Thrombotic Thrombocytopenia Syndrome (TTS), which as of April 21, 2021 has been confirmed by CDC in 15 persons who have received the Janssen vaccine, primarily women age 18 to 49 years, out of a total of nearly 8 million doses administered in the United States. Symptom onset occurred between 6 and 15 days after vaccination.

Risk of TTS was not found to be elevated with either of the currently authorized mRNA vaccines.

The Western States Scientific Review Workgroup conducted its own safety review, agreed with ACIP and FDA that vaccination with Janssen COVID-19 vaccine should resume, and recommended that culturally and linguistically appropriate vaccine information fact sheets should be made available in multiple languages and at an accessible reading level, to inform conversations between healthcare providers and vaccine recipients about the risk of TTS. The California Department of Public Health (CDPH) has posted this Fact Sheet for patients about the Janssen vaccine (translations pending).

Updated ACIP recommendations for use of the Janssen COVID-19 vaccine have been published, noting that education about TTS risk is critical. In its risk-benefit analysis, ACIP estimated that for every 1 million doses of the vaccine administered to women age 18 to 49 years, 297 hospitalizations, 56 ICU admissions, and 6 deaths related to COVID-19 could be prevented, compared with 7 expected TTS cases. For men age 18 years and older, and for women age 50 years and older, ACIP estimated even greater benefits of vaccination, with considerably lower risk of TTS.

CDC has also updated its main COVID-19 vaccination guidance page to include new recommendations regarding the clinical use of Janssen COVID-19 vaccine:

- Women age 18-49 years can receive any FDA-authorized COVID-19 vaccine but should be aware of the rare risk of TTS after Janssen vaccine, and of the availability of other FDA-authorized COVID-19 vaccines (i.e. mRNA vaccines).

- Persons with a history of an episode of an immune-mediated syndrome characterized by thrombosis and thrombocytopenia, such as heparin-induced thrombocytopenia (HIT), should be offered a different FDA-authorized COVID-19 vaccine (i.e. mRNA vaccine) if they are within 6 months after resolution of their illness.

- Persons with a prior history of other thromboses, or with risk factors for venous thromboembolism including but not limited to pregnancy or use of oral contraceptives, are unlikely to be at increased risk for TTS and can receive any FDA-authorized vaccine including the Janssen COVID-19 vaccine.

- Persons taking aspirin or anticoagulants do not need to stop these medications prior to receipt of the Janssen COVID-19 vaccine.

Actions Requested of SF Healthcare Providers

- Vaccination providers may resume use of Janssen COVID-19 vaccine, provided they follow recommendations above to:

    - provide appropriate fact sheet(s) and/or counseling to inform patients (especially women age 18 to 49 years) of the risk of TTS, the timing of onset and signs and symptoms of TTS, and the need for prompt medical attention should those signs and symptoms occur;

    - inform patients at risk of TTS of the availability of alternate vaccine(s); and

    - avoid administering Janssen COVID-19 vaccine to patients with recent history of a HIT-like syndrome characterized by thrombosis and thrombocytopenia.

- Vaccination providers are requested to make patients aware of the vaccine(s) offered at each site, so that patients with a vaccine preference can identify an appropriate site to visit. There is no obligation to offer more than one vaccine at a time, although providers may choose to offer multiple vaccines per event to enhance convenience and minimize missed vaccination opportunities.

- Healthcare providers should be aware that although the chance is remote, thrombosis with thrombocytopenia syndrome (TTS) may occur within 3-4 weeks after receiving Janssen COVID-19 vaccine. Providers should maintain a high index of suspicion for TTS in case of symptoms that might represent serious thrombotic events or thrombocytopenia post-vaccination. These symptoms include severe headache, visual changes, abdominal pain, nausea and vomiting, back pain, shortness of breath, leg pain or swelling, and petechiae, easy bruising, or bleeding. TTS is a rare syndrome that involves acute venous or arterial thrombosis and new onset thrombocytopenia in patients with no recent known exposure to heparin. The pathogenesis of these rare adverse events appears to be associated with platelet-activating antibodies against platelet factor-4 (PF4).

- Heparin should not be used to treat patients with suspected TTS; non-heparin anticoagulants are indicated and consultation with a hematologist is advised. For more information on diagnosis and treatment of TTS, consult the CDC Health Alert Network notification of 4/13/2021 and refer to guidance from the American Society of Hematology.

- Promptly report suspected cases of TTS to the Vaccine Adverse Event Reporting System (VAERS) and also promptly notify SFDPH Communicable Disease Control at (415) 554-2648 or by email to cdcontrol@sfdph.org

Additional Information

www.sfcdcp.org/covidvax-administer

https://sf.gov/covid-19-vaccine-san-francisco

These sites offer (or will soon offer) updated information and materials related to Janssen vaccine.

- https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/JJUpdate.html
- https://www.cdc.gov/vaccines/covid-19/info-by-product/janssen/index.html