



TOHONO O'ODHAM NATION HEALTH CARE

COVID-19 VACCINATIONS UPDATE-Please Distribute Widely

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Hospital & Health Centers

TON Public Health Information
officer
Donna Hobbs
(520) 383-7256 or
(520) 383-7263

TON Sells Hospital
P.O. Box 548
Highway 86 & Topawa Rd
Sells, AZ 85634
(520) 383-7200

TON San Xavier
Health Center
7900 S. J Stock Road
Tucson, AZ 85746
(520) 295-2550

TON Santa Rosa
Health Center
HC01 Box 8700
Federal Route 15
Milepost 12
Sells, AZ 85634
(520) 383-5570

TON San Simon
Health Center
HC01 Box 8150
Highway 86, Milepost 74
Sells, AZ 85634
(520) 362-7007

Janssen COVID-19 Vaccine Use Paused by CDC and FDA

Today, the CDC and FDA have released a joint statement (see below) regarding the Johnson & Johnson/Janssen vaccine. Out of an abundance of caution, the CDC and FDA are recommending a pause to Johnson & Johnson/Janssen vaccinations. The CDC and FDA are reviewing data involving six reported U.S. cases of a rare and severe type of blood clot in individuals after receiving the Johnson & Johnson vaccine. Proper recognition and management of blood clots is important and should be considered urgent. The CDC's Advisory Committee on Immunization Practices (ACIP) will meet 4/13/21 to further review these cases.

At this time, TONHC

- will pause use of Johnson & Johnson/ Janssen vaccine
- will continue to offer Moderna to persons seeking COVID-19 vaccination
- will share information as it becomes available.

Please contact a health care provider immediately if you received a Johnson & Johnson (Janssen) COVID-19 vaccine and experience any of the following within 3 weeks of vaccination:

- severe headache
- abdominal pain
- leg pain or swelling
- shortness of breath

If you received the Johnson & Johnson (Janssen) COVID-19 vaccine and have questions, please contact your provider.

Media Statement

Joint CDC and FDA Statement on Johnson & Johnson COVID-19 Vaccine

The following statement is attributed to Dr. Anne Schuchat, Principal Deputy Director of the CDC and Dr. Peter Marks, director of the FDA's Center for Biologics Evaluation and Research
For Immediate Release

Tuesday, April 13, 2021

As of April 12, more than 6.8 million doses of the Johnson & Johnson (Janssen) vaccine have been administered in the U.S. CDC and FDA are reviewing data involving six reported U.S.

cases of a rare and severe type of blood clot in individuals after receiving the J&J vaccine. In these cases, a type of blood clot called cerebral venous sinus thrombosis (CVST) was seen in combination with low levels of blood platelets (thrombocytopenia). All six cases occurred among women between the ages of 18 and 48, and symptoms occurred 6 to 13 days after vaccination. Treatment of this specific type of blood clot is different from the treatment that might typically be administered. Usually, an anticoagulant drug called heparin is used to treat blood clots. In this setting, administration of heparin may be dangerous, and alternative treatments need to be given.

CDC will convene a meeting of the Advisory Committee on Immunization Practices (ACIP) on Wednesday to further review these cases and assess their potential significance. FDA will review that analysis as it also investigates these cases. Until that process is complete, we are recommending a pause in the use of this vaccine out of an abundance of caution. This is important, in part, to ensure that the health care provider community is aware of the potential for these adverse events and can plan for proper recognition and management due to the unique treatment required with this type of blood clot.

Right now, these adverse events appear to be extremely rare. COVID-19 vaccine safety is a top priority for the federal government, and we take all reports of health problems following COVID-19 vaccination very seriously. People who have received the J&J vaccine who develop severe headache, abdominal pain, leg pain, or shortness of breath within three weeks after vaccination should contact their health care provider. Health care providers are asked to report adverse events to the Vaccine Adverse Event Reporting System at

<https://vaers.hhs.gov/reportevent.html>.

CDC and FDA will provide additional information and answer questions later today at a media briefing. A recording of that media call will be available on the FDA's YouTube channel.