J&J FDA/CDC Pause
Call Center FAQ

4/13/2021

How does the report of pausing J&J vaccine affect me?

Caroline County will pause the administration of all J&J vaccines until additional guidance is received from the federal government and Maryland Department of Health. Any scheduled J&J clinics will be changed to Moderna clinics.

The adverse events reported that led to the pause in J&J vaccine administration reflect an extremely rare event. The federal government takes vaccine safety as a top priority. Pausing the administration of the J&J vaccine will allow time for the reported events to be reviewed and assessed for significance.

If you were scheduled to receive the J&J vaccine through Caroline County Health Department, you will be notified that you have been transitioned to the Moderna vaccine, keeping your original date and time of your appointment.

I received the J&J vaccine, what additional side effects should I be aware of at this time?

- If you develop a severe headache, abdominal pain, leg pain, or shortness of breath within three weeks after vaccination you should contact your healthcare provider right away. If you received the J&J vaccine over a month ago, the risk of these side effects is very low.
- If you experience a life-threatening situation, call 9-1-1 or go to the nearest hospital.

What are the normal side effects of the J&J vaccine?

- Normal side effects that have been reported with J&J vaccine include:
    - Injection site reactions: pain, redness of the skin and swelling.
    - General side effects: headache, feeling very tired, muscle aches, nausea, and fever.

  There is a remote chance that the Janssen COVID-19 Vaccine could cause a severe allergic reaction (anaphylaxis) . A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the Janssen COVID-19 Vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:
    - Difficulty breathing,
    - Swelling of your face and throat,
    - A fast heartbeat,
    - A bad rash all over your body,
    - Dizziness and weakness.

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How should I report side effects if I've received the J&J vaccine?

- If you experience a severe allergic reaction or life-threatening situation, call 9-1-1, or go to the nearest hospital.
- Call the vaccination provider or your healthcare provider if you have any side effects that bother you or do not go away.
- Healthcare providers, as well as, patients and parents, can report side effects to the Vaccine Adverse Event Reporting System (VAERS)
- Report vaccine side effects to FDA/CDC Vaccine Adverse Event Reporting System (VAERS). The VAERS toll-free number is 1-800-822-7967 or report online to https://vaers.hhs.gov/reportevent.html. Please include "Janssen COVID-19 Vaccine EUA" in the first line of box #18 of the report form.
- In addition, you can report side effects to Janssen Biotech, Inc. at the contact information provided below.

e-mail	Fax number	Telephone numbers
JNJvaccineAE@its.jnj.com	215-293-9955	US Toll Free: 1-800-565-4008 US Toll: (908) 455-9922

VSAFE

It is preferred that individuals receiving COVID-19 vaccine enroll in V-SAFE.
V-safe is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. V-safe asks questions that help CDC monitor the safety of COVID-19 vaccines. V-safe also provides live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information on how to sign up, visit: www.cdc.gov/vsafe.

Why is the Johnson & Johnson COVID-19 vaccine administration being paused or temporarily halted in the US?

- In an April 13, 2021 FDA statement, it is reported that there are six cases of a rare and severe type of blood clot in individuals after receiving the J&J vaccine. The cases appear to be extremely rare. COVID-19 vaccine safety is a top priority for the federal government and they are taking this precaution to allow time to review the cases and assess the significance. As of April 13, 2021, there have been approximately 6.8 million doses of J&J administered in the United States.
- While the adverse events reported that led to the pause in the use of the J&J vaccine are extremely rare, it is very important that healthcare providers are aware of the situation in order to administer the proper treatment needed in these very rare circumstances. The pause in the use of J&J vaccine will allow for healthcare providers to receive the guidance needed to screen and treat individuals presenting with cerebral venous sinus thrombosis and thrombocytopenia. The pause will provide time for ACIP to review the cases and assess the significance.

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How long will the pause on the usage of J&J be in effect?

- We don't know how long the pause will be at this point. COVID-19 vaccine safety is a top priority for the federal government and they are taking this precaution to allow time to review the cases and assess the significance. The Advisory Committee on Immunization Practices (ACIP) will convene on Wednesday, April 14, 2021 to review the cases and assess the significance.

How many doses of J&J vaccine have been administered by Caroline County Health Department and the FEMA mobile vaccine unit?

As of April 13, 2021, a total of 2,227 doses of J&J vaccine have been administered by Caroline County Health Department and the FEMA mobile vaccine unit.

Are there any reports of cerebral venous sinus thrombosis after J&J vaccine in Caroline County?

To our knowledge there have been no reports of cerebral venous sinus thrombosis by Caroline residents or anyone receiving J&J through the Caroline County Health Department

What are the details of the adverse events reported that has led to the pause of the J&J vaccine administration?

- Six reported cases of a rare and severe type of blood clot in individuals after receiving the J&J vaccine.
- Cases reported a type of blood clot called cerebral venous sinus thrombosis (CVST) in combination with low levels of blood platelets (thrombocytopenia).
- All cases were among women between 18-48, 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.
  (FDA. 4/13/2021. Joint CDC and FDA Statement on Johnson & Johnson COVID-19 Vaccine. https://www.fda.gov/news-events/press-announcements/joint-cdc-and-fda-statement-johnson-johnson-covid-19-vaccine)

Are there similar adverse events reported for the Moderna or Pfizer COVID-19 vaccine?

At this time there are no reports of cerebral venous sinus thrombosis and thrombocytopenia with the Moderna or Pfizer COVID-19 vaccine.

Where can I get additional information?

https://www.fda.gov/news-events/press-announcements/joint-cdc-and-fda-statement-johnson-johnson-covid-19-vaccine.