CORONAVIRUS
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FAQs on the CDC and FDA decision to "pause" administration of the Johnson & Johnson vaccines

Updated April 27, 2021

Situation updates

For people who have already received the Johnson & Johnson vaccine or who have appointments for this vaccine

For people who have already received the Pfizer or Moderna vaccines or who have appointments for these vaccines

For healthcare providers

Situation updates

What happened with the Johnson & Johnson COVID-19 vaccine? Why were the Johnson & Johnson vaccines "paused"?
Scientists and doctors have constantly and carefully reviewed all reports of COVID-19 vaccine side effects and adverse events since use of COVID-19 vaccines began in the United States.

On April 13, 2021, the CDC and FDA recommended vaccine providers wait to give any more Johnson & Johnson vaccines after 6 cases of people who got a rare type of blood clot after getting the Johnson & Johnson COVID-19 vaccine (out of 6.85 million doses) were reported to the CDC's Vaccine Adverse Events Reporting System (VAERS).

During the pause, medical and scientific teams at the FDA and CDC examined available data to assess the risk of thrombosis involving the cerebral venous sinuses, or CVST (large blood vessels in the brain), and other sites in the body along with thrombocytopenia, or low blood platelet counts. The pause allowed the FDA and CDC to give healthcare providers instructions on how to recognize and diagnose patients who may have this rare health problem, how to treat them appropriately, and to report any cases they feel may be related to the vaccine. The pause also gave scientists and medical experts time to carefully review all available data and do a risk-benefit analysis around the use of this vaccine.

The FDA, CDC, and Advisory Committee on Immunization Practices (ACIP) carefully reviewed all of the available data before recommending use of the Johnson & Johnson vaccine again on April 23, 2021. The Utah Department of Health supports this recommendation and will begin distribution of the Johnson & Johnson vaccine right away.

The vaccine's known and potential benefits outweigh the known and potential risks. The FDA and CDC are confident the vaccine is safe and effective in preventing COVID-19. The CDC and ACIP predict that the risks of lifting the pause may result in 26-45 more cases of this rare blood clot. However, the benefits of using the Johnson & Johnson vaccine outweigh this risk - the vaccine will prevent 1,435 deaths in the United States and 2,236 ICU admissions. The risk of blood clotting is much higher for people who get COVID than it is for people who receive the Johnson & Johnson vaccine. The risk of blood clots from having COVID is 165,000 per million cases compared to 7 per million vaccinations.

For most people, getting the first available COVID vaccine is the best thing you can do to protect yourself and your family. Your odds of having a possibly life-threatening case of COVID-19 are much higher than your odds of serious side effects from the vaccine.

If these side effects are so rare, why do we need to pause administering the Johnson & Johnson vaccine?

We have had many questions about why they would pause vaccine administration. We have also been asked why they would pause vaccine administration when there are many medications— like oral contraceptives or birth control, as well as many others— that increase your risk for blood clots.

The blood clots these people got were a very rare, but severe, type of blood clot called thrombosis with thrombocytopenia syndrome (TTS). TTS is a rare but serious health problem that involves blood clots with low levels of blood platelets (thrombocytopenia). Doctors have to treat these types of blood clots differently, with different medicine, than other blood clots. This condition is treatable, but doctors must know how to recognize it, how to report it, and how to treat it. Usually, the anticoagulant drug called heparin is used to treat blood clots. In these cases, the use of heparin may be harmful, and alternative treatments need to be given.

The CDC and FDA wanted to wait before giving any more Johnson & Johnson vaccines, until we understood more about what happened and to make sure healthcare providers had all of the information they needed to be able to effectively treat someone who may get this rare side effect. This pause was the right thing to do to ensure that happened. This is a good example of how the safety systems we have in place work to flag possible safety concerns for vaccines. Pausing Johnson & Johnson vaccine administration does not mean the vaccine is not safe for most people. It also does not mean that all or most of the people who have already received the Johnson & Johnson vaccine will get blood clots. These are RARE side effects. They paused the administration of this brand of vaccine because we want everyone to have all of the information, so they can make informed health decisions.

It is also important to point out that this recommendation to pause vaccine administration is only for the Johnson & Johnson vaccine, not the Pfizer or Moderna vaccines. There have been no reports of TTS in people who got the Pfizer or Moderna vaccine.

How many people had this type of reaction to the Johnson & Johnson vaccine?
As of April 23, only 15 of more than 8 million people in the United States who have gotten the Johnson & Johnshon vaccine have reported this type of rare side effect. The CDC and FDA are reviewing these cases of a rare and severe type of blood clot called thrombosis with thrombocytopenia syndrome (TTS). TTS is a rare but serious health problem that involves blood clots with (CVST) and were seen in combination with low levels of blood platelets (thrombocytopenia). TTS was confirmed in 15 people after receiving the Johnson & Johnson vaccine. All 15 cases happened in women between the ages of 18 and 59, and symptoms started 6 to 15 days after vaccination.

This side effect is very rare. Based on these reports, 7 cases out of 1 million vaccinations occur among women between the ages of 18 and 49. It's even more rare for women 50 and older (less than 0.91 per 1 million vaccinations) and men of all ages. Your odds of having a possibly life-threatening case of COVID-19 are much higher than your odds of serious side effects from the vaccine.

The vaccine's known and potential benefits outweigh the known and potential risks. The FDA and CDC are confident the vaccine is safe and effective in preventing COVID-19. For most people, getting the first available COVID vaccine is the best thing you can do to protect yourself and your family.

Is it normal for the FDA and CDC to pause the distribution of a vaccine?
We take vaccine safety very seriously in the United States. Whenever a possible serious adverse effect of vaccination is reported, we investigate it. Transparency is key and we want to tell people what we know, when we know it, how we got the information, and what we're doing to find out more. We have a safety measure in place to help public health, healthcare providers, and scientists understand any problems possibly related to vaccinations. It's normal to temporarily pause clinical trials or distribution of vaccines or medications if data tells us there may be something that needs further investigation. **This is done to protect people from harmful side effects and to make sure communities impacted the most by a disease - or in this case, the pandemic - do not suffer from further inequities.** If someone gets a vaccine and has an adverse event after vaccination, the healthcare provider or the person who got vaccinated can report the adverse event to the CDC's Vaccine Adverse Event Reporting System (VAERS). This means that anyone who has gotten a vaccine, not just healthcare providers, can report any side effect he or she thinks may be related to the vaccine. The VAERS system is set up like this to make sure we have as much information as possible to study, and is why public health can confidently give vaccine recommendations.

Vaccines are monitored so closely in the United States, that we know mild or moderate side effects, like a fever or sore arm, are normal after any vaccination. We also know that severe side effects from vaccination are very rare. Monitoring vaccines so closely lets us not only be confident that vaccines are safe, but also lets us give good recommendations to healthcare providers for things to watch for, as well as the best ways to treat rare, severe side effects from vaccination.

The CDC and FDA wanted to wait before giving any more Johnson & Johnson vaccines, until we understood more about what happened and to make sure healthcare providers had all of the information they needed to be able to effectively treat someone who may get this rare health problem. This condition is treatable, but doctors must know how to recognize it, how to report it, and how to treat it. Usually, the anticoagulant drug called heparin is used to treat blood clots. In these cases, the use of heparin may be harmful, and alternative treatments need to be given.

There have been no reports of TTS in people who got the Pfizer or Moderna vaccine. If you have a vaccine appointment for the Pfizer or Moderna vaccines, please keep it. COVID-19 is a very serious virus, and can cause serious long-term health effects or even be deadly to many people. More than 1.9 million people have been hospitalized for severe illness and more than 556,000 people have died from the virus, just in the United States alone. There is no way to know if you will experience severe illness from COVID-19. The benefits of getting vaccinated outweigh the risks for most people.

Where can I get more information on this situation?

- CDC recommends use of Johnson & Johnson's Janssen COVID-19 vaccine resume https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/JJUpdate.html
- Revised Janseen COVID-19 Vaccine Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) https://www.fda.gov/media/146304/download
- Revised Janseen COVID-19 Vaccine Fact Sheet for Recipients and Caregivers https://www.fda.gov/media/146305/download
- MMWR Updated Recommendations from the Advisory Committee on Immunization Practices for Use of the Janssen (Johnson & Johnson) COVID-19 Vaccine After Reports of Thrombosis with Thrombocytopenia Syndrome Among Vaccine Recipients — United States, April 2021 https://www.cdc.gov/mmwr/volumes/70/wr/mm7017e4.htm
- Joint statement from the CDC and FDA about the Johnson & Johnson vaccines: https://www.cdc.gov/media/releases/2021/s0413-JJ-vaccine.html
- CDC Health Alert Network: https://emergency.cdc.gov/han/2021/han00442.asp
- April 13, 2021 press conference with the FDA and CDC discussing these rare events and decision to pause administration of the Johnson & Johnson vaccines: https://www.youtube.com/watch?v=_ELXnGYgsJY
- April 23, 2021 press conference with the FDA and CDC discussing the recommendation to resume use of the Johnson & Johnson vaccines: https://www.youtube.com/watch?v=Nf_OuB1rBi0
- ACIP presentation slides from April 23, 2021 meeting https://www.cdc.gov/vaccines/acip/meetings/slides-2021-04-23.html
- ACIP presentation slides from April 14, 2021 meeting https://www.cdc.gov/vaccines/acip/meetings/slides-2021-04.html

For people who have already received the Johnson & Johnson vaccine or who have an appointment for this vaccine

What should I watch for if I received the Johnson & Johnson vaccine? When should I be worried or get medical care?
Doctors say it is normal for you to get mild to moderate flu-like symptoms, including a headache, one or two days after receiving the Johnson & Johnson vaccine. **If you received the Johnson & Johnson vaccine more than 3 weeks, the risk of having this rare but serious side effect is very low.** However, if you had a Johnson & Johnson vaccine in the last 3 weeks, you should be aware of these symptoms. If you get any of the following symptoms, call your healthcare provider, or go to the emergency room or urgent care. Let your healthcare providers know that you recently received the Johnson & Johnson vaccine.

- Severe headaches or headaches that won't go away
- Blurred vision
- Chest pain
- Severe abdominal pain that won't go away
- Shortness of breath
- Leg swelling
- Petechiae (tiny red spots on the skin)
- New or easy bruising

How do I tell the difference between normal side effects and more serious ones after vaccination that require medical care?
It's common to have mild or moderate side effects after you get any vaccination. This means your body has started to create an immune response and is learning to fight the virus. Side effects like a sore arm, fever, achy body, or a headache are normal after you get a vaccine. These reactions usually happen within the first 24-48 hours after you get a vaccine. These side effects can affect your daily activities, but go away after a few days. Severe allergic reactions after receiving a COVID-19 vaccination are rare and usually occur within minutes to hours after vaccination.

The side effects we are concerned about with the Johnson & Johnson vaccine are different and happened between 1-2 weeks after the person received the Johnson & Johnson vaccine. If you received the Johnson & Johnson vaccine more than 3 weeks ago, your risk for severe reactions is very low.

However, if you were vaccinated in the last 3 weeks with a Johnson & Johnson vaccine and get any of the following symptoms, call your healthcare provider, or go to the emergency room or urgent care. Let your healthcare providers know that you recently received the Johnson & Johnson vaccine.

- Severe headache or headaches that won't go away
- Blurred vision

- Chest pain
- Severe abdominal pain that won't go away
- Shortness of breath
- Leg swelling
- Petechiae (tiny red spots on the skin)
- New or easy bruising

Should I report any side effects after I get vaccinated for COVID-19?
We take vaccine safety very seriously in the United States. If you get a vaccine and have an adverse event after vaccination, like a health problem or symptom you didn't have before getting vaccinated, you or your healthcare provider can report the adverse event to the CDC's Vaccine Adverse Event Reporting System (VAERS). This means that anyone who has gotten a vaccine, not just healthcare providers, can report any side effect you think may be related to the vaccine. The VAERS system is set up like this to make sure we have as much information as possible to study, and is why public health can confidently give vaccine recommendations. VAERS helps scientists and medical experts quickly detect unusual or unexpected patterns of health problems (also called "adverse events") that might indicate a possible safety problem with a vaccine. It's important to remember that if a health problem is reported to VAERS, that doesn't mean that the vaccine caused the problem. It simply warns vaccine safety experts of potential problems that may need to be looked at more carefully.

If you aren't sure if you should report a side effect or have questions, call a healthcare provider. You may also call the Utah Poison Control Center at 1-800-222-1222. They have poison specialists available 24 hours a day 7 days a week to help answer questions about whether you need to report a side effect to VAERS or potentially seek medical care.

You can also use the CDC v-safe tool to report any side effects after you receive a COVID-19 vaccine. V-safe is a smartphone-based tool that uses text messaging and web surveys to quickly tell CDC if you have any side effects after getting a COVID-19 vaccine. Depending on your answers to the web surveys, someone from the CDC may call to check on you and get more information.

Vaccines are monitored so closely in the United States, that we know mild or moderate side effects, like a fever or sore arm, are normal after any vaccination. We also know that severe side effects from vaccination are very rare. Monitoring vaccines so closely lets us not only be confident that vaccines are safe, but also lets us give good recommendations to healthcare providers for things to watch for, as well as the best ways to treat rare, severe side effects after vaccination.

Whenever a possible serious adverse effect of vaccination is reported, it's investigated. Transparency is key and we want to tell people what we know, when we know it, how we got the information and what we're doing to find out more. We have a safety measure in place to help public health, healthcare providers, and scientists understand any problems possibly related to vaccinations.

Who can get the Johnson & Johnson vaccine?
The Johnson & Johnson vaccine is authorized for use by anyone in the United States who is 18 years of age and older.

For most people, getting the first available COVID vaccine is the best thing you can do to protect yourself and your family. However, people, especially women younger than 50, should be aware of a rare but serious blood clotting issue that can happen 1-2 weeks after getting the Johnson & Johnson vaccine. If you are worried or have questions, talk to a doctor. You may also choose to get the Pfizer or Moderna vaccine for which this rare side effect has not been seen.

Where can I get a Pfizer or Moderna vaccine instead?
You can find a vaccine location near you at https://coronavirus.utah.gov/vaccine-distribution/ or at vaccinefinder.org.

For people who have received the Pfizer or Moderna vaccines or who have appointments for these vaccines

Are the Pfizer and Moderna vaccines paused too? Has this side effect been reported in people who got the Pfizer or Moderna vaccines?
No. The recommendation to pause vaccine administration was only for the Johnson & Johnson vaccine, not the Pfizer or Moderna vaccines. There have been no reports of TTS in people who got the Pfizer or Moderna vaccine. If you have a vaccine appointment for the Pfizer or Moderna vaccines, please keep it. COVID-19 is a very serious virus, and can cause serious long-term health effects or even be deadly to many people. More than 1.9 million people have been hospitalized for severe illness and more than 556,000 people have died from the virus, just in the United States alone. There is no way to know if you will experience severe illness from COVID-19. The benefits of getting vaccinated outweigh the risks for most people.

Are the Pfizer and Moderna vaccines the same kind of vaccine that Johnson & Johnson is?
No. The Pfizer and Moderna vaccines are mRNA vaccines. You can learn more about mRNA vaccines here: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/mRNA.html.

The Johnson & Johnson vaccine is a type of adenoviral vector or viral vector vaccine. You can learn more about a viral vector vaccine here: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/viralvector.html.

Should I keep my appointment if I am supposed to get the Pfizer or Moderna vaccine?
Yes. There have been no reports of TTS in people who got the Pfizer or Moderna vaccine. If you have a vaccine appointment for the Pfizer or Moderna vaccines, please keep it. COVID-19 is a very serious virus, and can cause serious long-term health effects or even be deadly to

many people. More than 1.9 million people have been hospitalized for severe illness and more than 556,000 people have died from the virus, just in the United States alone. There is no way to know if you will experience severe illness from COVID-19. The benefits of getting vaccinated outweigh the risks for most people.

For healthcare providers

What should I do if I have a patient with these symptoms who received the Johnson & Johnson vaccine?
You should monitor patients who have recently received the Johnson & Johnson COVID-19 vaccine closely for symptoms that could be signs of serious thrombotic events or thrombocytopenia.

- Severe headache or headaches that won't go away
- Blurred vision
- Chest pain
- Severe abdominal pain that won't go away
- Shortness of breath
- Leg swelling
- Petechiae (tiny red spots on the skin)
- New or easy bruising

It is important to be aware that treatment for a patient who gets these specific types of blood clots following Johnson & Johnson COVID-19 vaccination is different from how you might typically treat blood clots. Usually, the anticoagulant drug called heparin is used to treat blood clots. In these cases, the use of heparin may be harmful, and alternative treatments need to be given. Providers should get platelet counts and screen patients for signs of immune thrombotic thrombocytopenia.

It is strongly recommended you follow screening guidelines from the HAN message and consult with a hematologist for patients with a thrombotic event and thrombocytopenia after the Johnson & Johnson COVID-19 vaccine.

These reports following the Johnson & Johnson COVID-19 vaccine are similar to reports of thrombotic events with thrombocytopenia after receipt of the AstraZeneca COVID-19 vaccine in Europe. Studies of patients in Europe who were diagnosed with immune thrombotic thrombocytopenia after having the AstraZeneca COVID-19 vaccine, indicate these rare and unusual adverse events after vaccination may be associated with platelet-activating antibodies against platelet factor-4 (PF4), a type of protein. Usually, the anticoagulant drug called heparin is used to treat blood clots. In this setting, the use of heparin may be harmful, and alternative treatments need to be given.

Where can I report any side effects my patients have after getting a COVID-19 vaccine?
We take vaccine safety very seriously in the United States. Healthcare providers should report any adverse events their patients have after getting a vaccination to the CDC's Vaccine Adverse Event Reporting System (VAERS). Patients may also report their side effects to VAERS. This means that anyone who has gotten a vaccine, not just healthcare providers, can report any side effect you think may be related to the vaccine. The VAERS system is set up like this to make sure we have as much information as possible to study, and is why public health can confidently give vaccine recommendations. VAERS helps scientists and medical experts quickly detect unusual or unexpected patterns of health problems (also called "adverse events") that might indicate a possible safety problem with a vaccine. It's important to remember that if a health problem is reported to VAERS, that doesn't mean that the vaccine caused the problem. It simply warns vaccine safety experts of potential problems that may need to be looked at more carefully.

If you aren't sure if you should report a patient's side effect or have questions, you may call the Utah Poison Control Center at 1-800-222-1222. They have poison specialists available 24 hours a day 7 days a week to help answer questions.

Encourage your patients to use the CDC v-safe tool to report any side effects after they receive a COVID-19 vaccine. V-safe is a smartphone-based tool that uses text messaging and web surveys to quickly tell CDC if you have any side effects after getting a COVID-19 vaccine. Depending on your answers to the web surveys, someone from the CDC may call to check on you and get more information.

Where can I get more information on this situation?

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- Joint statement from the CDC and FDA about pausing the Johnson & Johnson vaccines: https://www.cdc.gov/media/releases/2021/s0413-JJ-vaccine.html
- CDC Health Alert Network notice, Cases of Cerebral Venous Sinus Thrombosis with Thrombocytopenia after Receipt of the Johnson & Johnson COVID-19 Vaccine: https://emergency.cdc.gov/han/2021/han00442.asp
- April 13, 2021 press conference with the FDA and CDC discussing these rare events and decision to pause administration of the Johnson & Johnson vaccines: https://www.youtube.com/watch?v=_ELXnGYgsJY

- April 23, 2021 press conference with the FDA and CDC discussing the recommendation to resume use of the Johnson & Johnson vaccines: https://www.youtube.com/watch?v=Nf_OuB1rBi0
- ACIP presentation slides from April 23, 2021 meeting https://www.cdc.gov/vaccines/acip/meetings/slides-2021-04-23.html
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