MDHHS
Michigan Department of Health & Human Services

Janssen (Johnson & Johnson)

COVID-19 Vaccine Update

April 22, 2021

Housekeeping

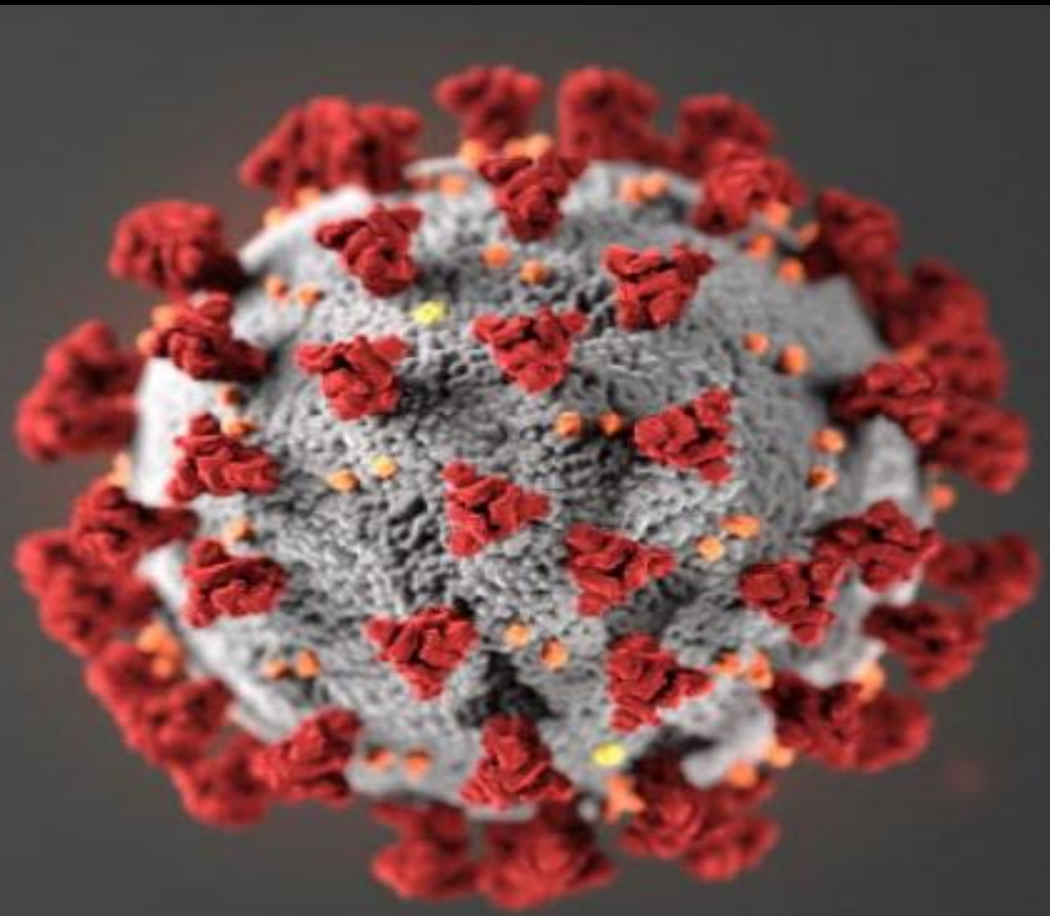
- **How to Ask Questions**
  - Click on the 

 icon found at the bottom part of your screen
  - A box will open where you can type in questions, comments, indicate sound problems, etc.
  - Use this throughout the webinar to ask questions
- **Slides & Recording**
  - This webinar is being recorded and a link as well as slides will be emailed out through our listserv as well as posted on our website at: www.michigan.gov/COVIDvaccine → Provider Guidance and Education

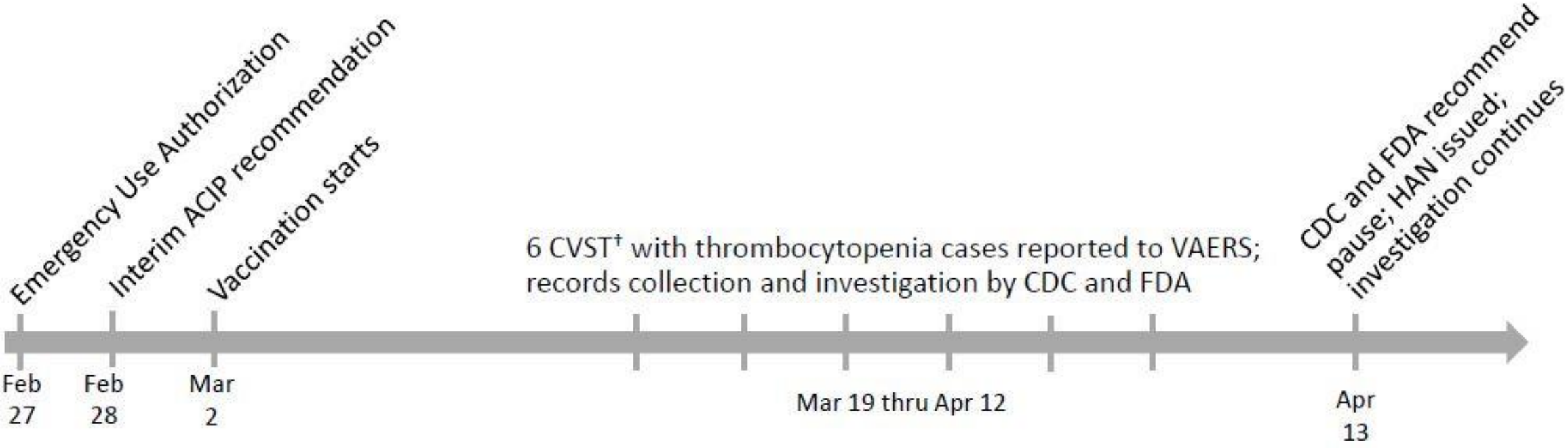
Topics Covered

- Janssen (Johnson & Johnson) COVID-19 Vaccine Timeline
- Cerebral Venous Sinus Thrombosis (CVST)
- Data Source and Case Reports
- What We Know and What We Don’t Know
- ACIP’s Response and Next Steps
- What Clinicians Should Know

Janssen (Johnson & Johnson) COVID-19 Vaccine Timeline

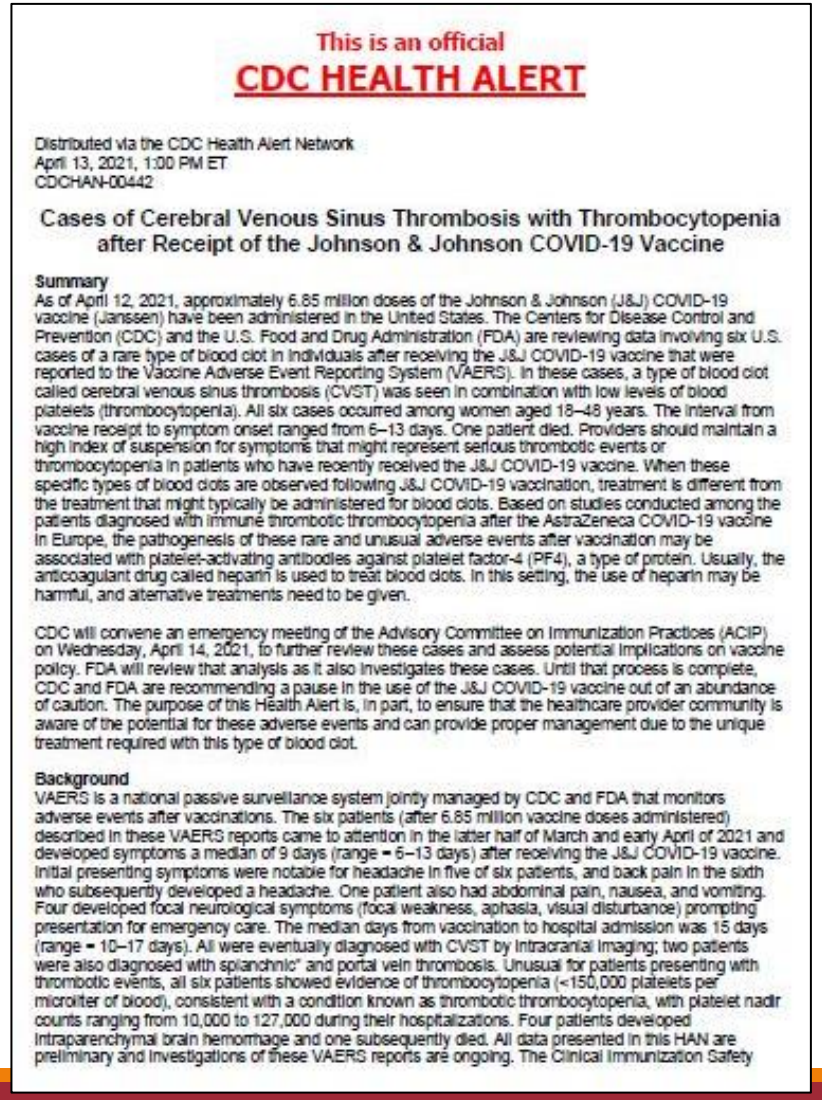


Janssen COVID-19 vaccine timeline* (2021)



* For illustrative purposes, not drawn to scale, † cerebral venous sinus thrombosis

April 13th CDC & FDA Statement Release



This is an official

CDC HEALTH ALERT

Distributed via the CDC Health Alert Network
April 13, 2021, 1:00 PM ET
CDCHAN-00442

Cases of Cerebral Venous Sinus Thrombosis with Thrombocytopenia after Receipt of the Johnson & Johnson COVID-19 Vaccine

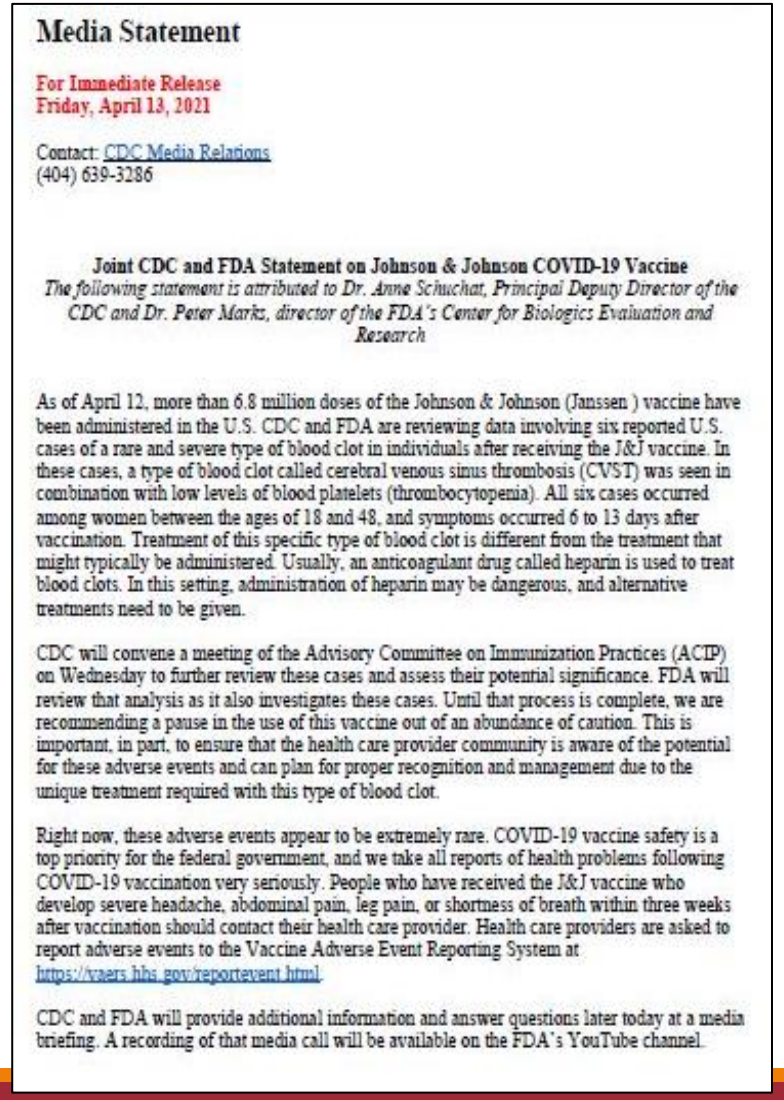
Summary

As of April 12, 2021, approximately 6.85 million doses of the Johnson & Johnson (J&J) COVID-19 vaccine (Janssen) have been administered in the United States. The Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA) are reviewing data involving six U.S. cases of a rare type of blood clot in individuals after receiving the J&J COVID-19 vaccine that were reported to the Vaccine Adverse Event Reporting System (VAERS). 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 aged 18–48 years. The interval from vaccine receipt to symptom onset ranged from 6–13 days. One patient died. Providers should maintain a high index of suspension for symptoms that might represent serious thrombotic events or thrombocytopenia in patients who have recently received the J&J COVID-19 vaccine. When these specific types of blood clots are observed following J&J COVID-19 vaccination, treatment is different from the treatment that might typically be administered for blood clots. Based on studies conducted among the patients diagnosed with immune thrombotic thrombocytopenia after the AstraZeneca COVID-19 vaccine in Europe, the pathogenesis of 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.

CDC will convene an emergency meeting of the Advisory Committee on Immunization Practices (ACIP) on Wednesday, April 14, 2021, to further review these cases and assess potential implications on vaccine policy. FDA will review that analysis as it also investigates these cases. Until that process is complete, CDC and FDA are recommending a pause in the use of the J&J COVID-19 vaccine out of an abundance of caution. The purpose of this Health Alert is, in part, to ensure that the healthcare provider community is aware of the potential for these adverse events and can provide proper management due to the unique treatment required with this type of blood clot.

Background

VAERS is a national passive surveillance system jointly managed by CDC and FDA that monitors adverse events after vaccinations. The six patients (after 6.85 million vaccine doses administered) described in these VAERS reports came to attention in the latter half of March and early April of 2021 and developed symptoms a median of 9 days (range = 6–13 days) after receiving the J&J COVID-19 vaccine. Initial presenting symptoms were notable for headache in five of six patients, and back pain in the sixth who subsequently developed a headache. One patient also had abdominal pain, nausea, and vomiting. Four developed focal neurological symptoms (focal weakness, aphasia, visual disturbance) prompting presentation for emergency care. The median days from vaccination to hospital admission was 15 days (range = 10–17 days). All were eventually diagnosed with CVST by intracranial imaging; two patients were also diagnosed with splanchnic and portal vein thrombosis. Unusual for patients presenting with thrombotic events, all six patients showed evidence of thrombocytopenia (<150,000 platelets per microliter of blood), consistent with a condition known as thrombotic thrombocytopenia, with platelet nadir counts ranging from 10,000 to 127,000 during their hospitalizations. Four patients developed intraparenchymal brain hemorrhage and one subsequently died. All data presented in this HAN are preliminary and investigations of these VAERS reports are ongoing. The Clinical Immunization Safety



Media Statement

For Immediate Release
Friday, April 13, 2021

Contact: CDC Media Relations
(404) 639-3286

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

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.

- Recommended a pause in the use of the Janssen COVID-19 Vaccine
- Rare and severe type of blood clot had been reported after receiving the vaccine

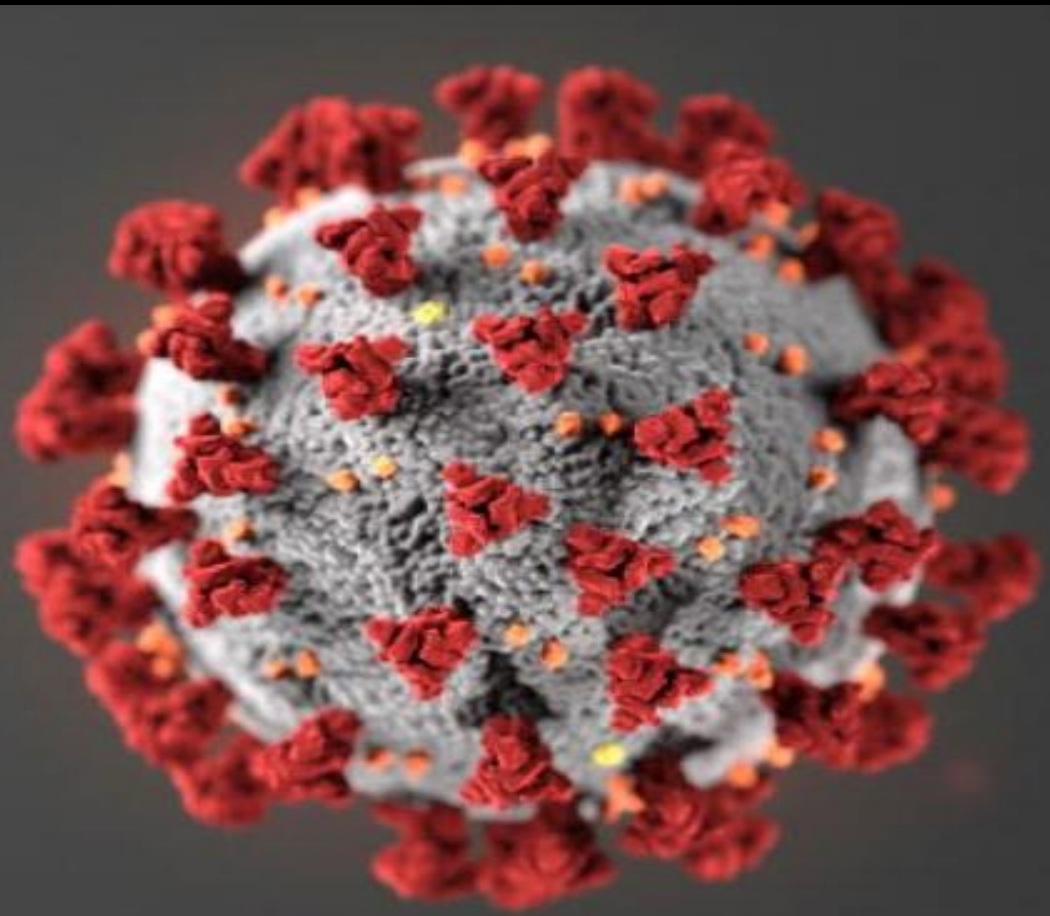
Summary of CDC & FDA's Statement

- As of April 12, more than 6.8 million doses of the Janssen vaccine have been administered in the U.S.
- CDC and FDA are reviewing data involving 6 cases of CVST (Cerebral Venus Sinus Thrombosis) in combination with low platelets
- "CDC will convene a meeting of the Advisory Committee on Immunization Practices on Wednesday to further review these cases and assess their potential significance"
- "Until that process is complete, we are recommending a pause in the use of this vaccine out of an abundance of caution"

What Does a Pause Mean?

- Although the Janssen COVID-19 vaccine is still authorized for use, CDC and FDA recommend this vaccine not be given to anyone until we know more
- This gives scientists a chance to review the data and decide if recommendations on who should get the vaccine need to change
- CDC and FDA will share more information as soon as possible with healthcare providers, people who got the vaccine, and the public

Cerebral Venous Sinus Thrombosis (CVST)



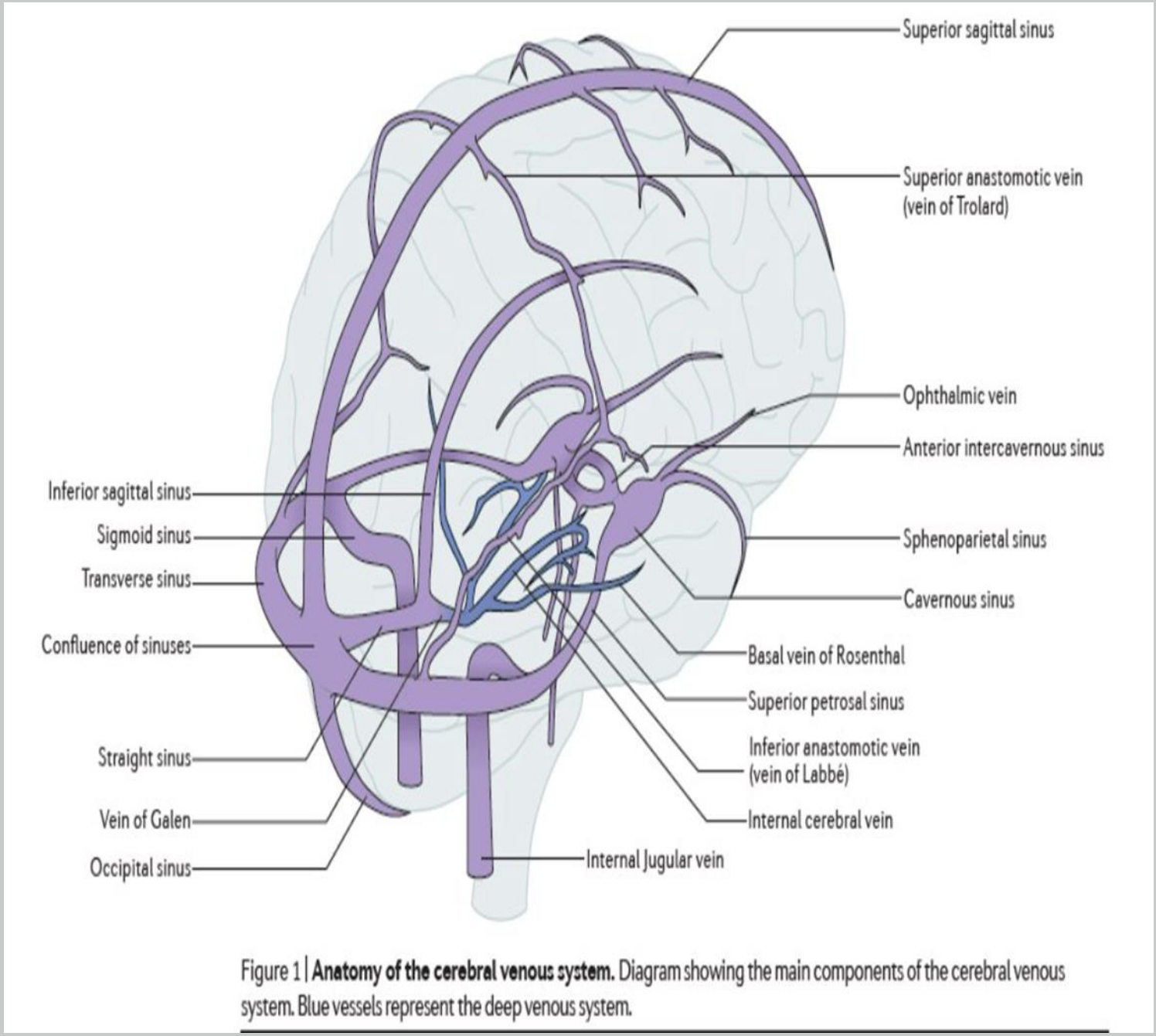


Figure 1 | **Anatomy of the cerebral venous system.** Diagram showing the main components of the cerebral venous system. Blue vessels represent the deep venous system.

- Cerebral Venous Sinus Thrombosis (CVST) is a type of rare blood clot that forms in the venous sinuses in your brain

- This is a system of veins found between the layers of the dura mater -- the tough outer layer of your brain that lies directly under your skull

Cerebral venous sinus thrombosis (CVST)

Background epidemiology[1-3]

- Rare, 0.22–1.57 per 100,000, ~0.5-1% of all strokes
- Median age 37 years
- 8% of patients >65 years
- Female:male ratio of 3:1

Risk factors[4]

- Prothrombotic conditions (genetic or acquired)
- Oral contraceptives
- Pregnancy and the post-partum period
- Malignancy
- Infection
- Mechanical precipitants (lumbar puncture)

[1] Cerebral vein and dural sinus thrombosis in Portugal: 1980-1998. Ferro JM, Correia M, Pontes C, Baptista MV, Pita F, Cerebral Venous Thrombosis Portuguese Collaborative Study Group (Venoport) Cerebrovasc Dis. 2001;11(3):177.
[2] The incidence of cerebral venous thrombosis: a cross-sectional study. Coutinho JM, Zuurbier SM, Aramideh M, Stam J. Stroke. 2012 Dec;43(12):3375-7.
[3] Cerebral Venous Sinus Thrombosis Incidence Is Higher Than Previously Thought: A Retrospective Population-Based Study. Devasagayam S, Wyatt B, Leyden J, Kleinig T. Stroke. 2016 Sep;47(9):2180-2.
[4] Diagnosis and management of cerebral venous thrombosis: a statement for healthcare professionals from the American Heart Association/American Stroke Association. Saposnik G, et al. 2011;42(4):1158.

CVST Signs and Symptoms

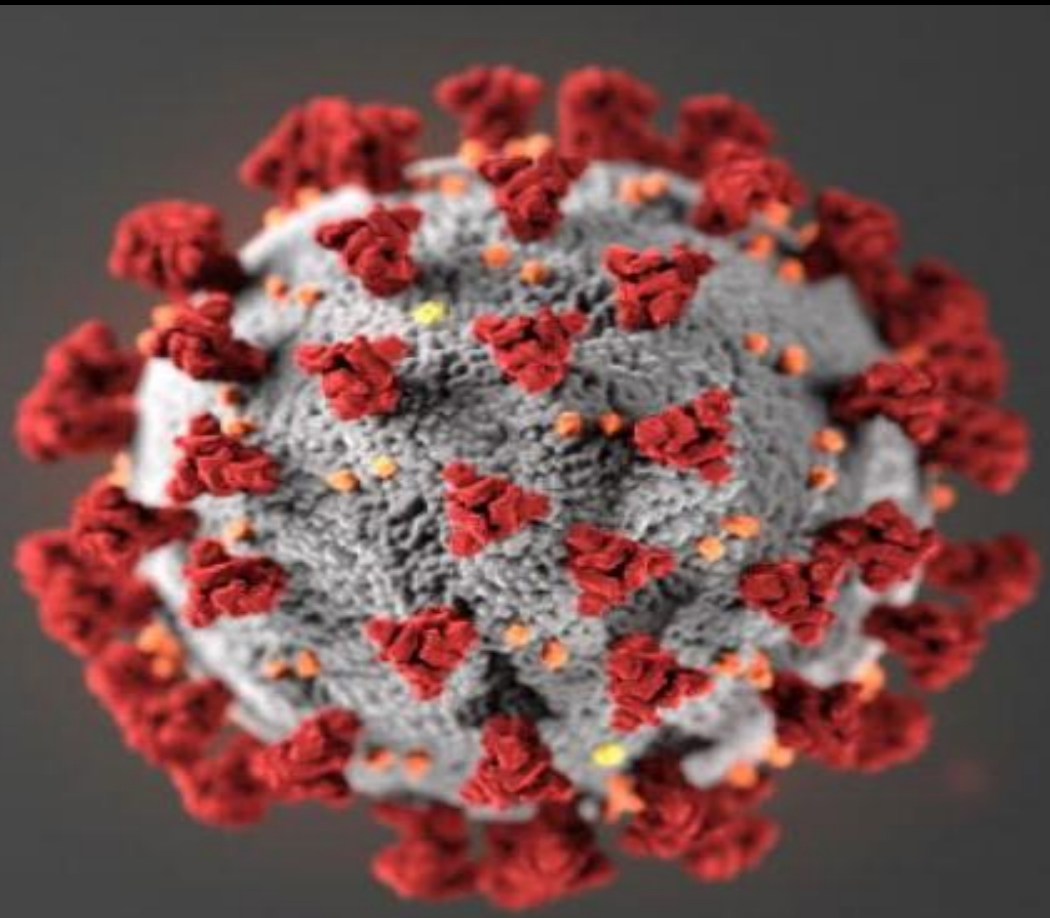
More common presentations

- Isolated intracranial hypertension syndrome (headache with or without vomiting, papilledema, and visual problems)
- Focal syndrome (focal deficits, seizures, or both)
- Encephalopathy (multifocal signs, mental status changes, stupor, or coma)

Rare presentations

- Cavernous sinus syndrome
- Subarachnoid hemorrhage
- Cranial nerve palsies

Data Source & Case Reports



VAERS is the nation's early warning system for vaccine safety

CDC + FDA

VAERS

Vaccine Adverse Event Reporting System

http://vaers.hhs.gov

Reports of CVST to VAERS as of 4-12-21

Janssen COVID-19 Vaccine

- 6 reports of CVST with thrombocytopenia (platelet counts <150K/mm3) following 6.86 million doses administered
  - Reporting rate of 0.87 cases per million doses administered

Pfizer-BioNTech COVID-19 Vaccine

- 0 reports following 97.9 million doses administered

Moderna COVID-19 Vaccine

- 3 reports following 84.7 million doses administered
- All 3 with normal platelet counts; onset 2, 6, and 12 days after vaccination

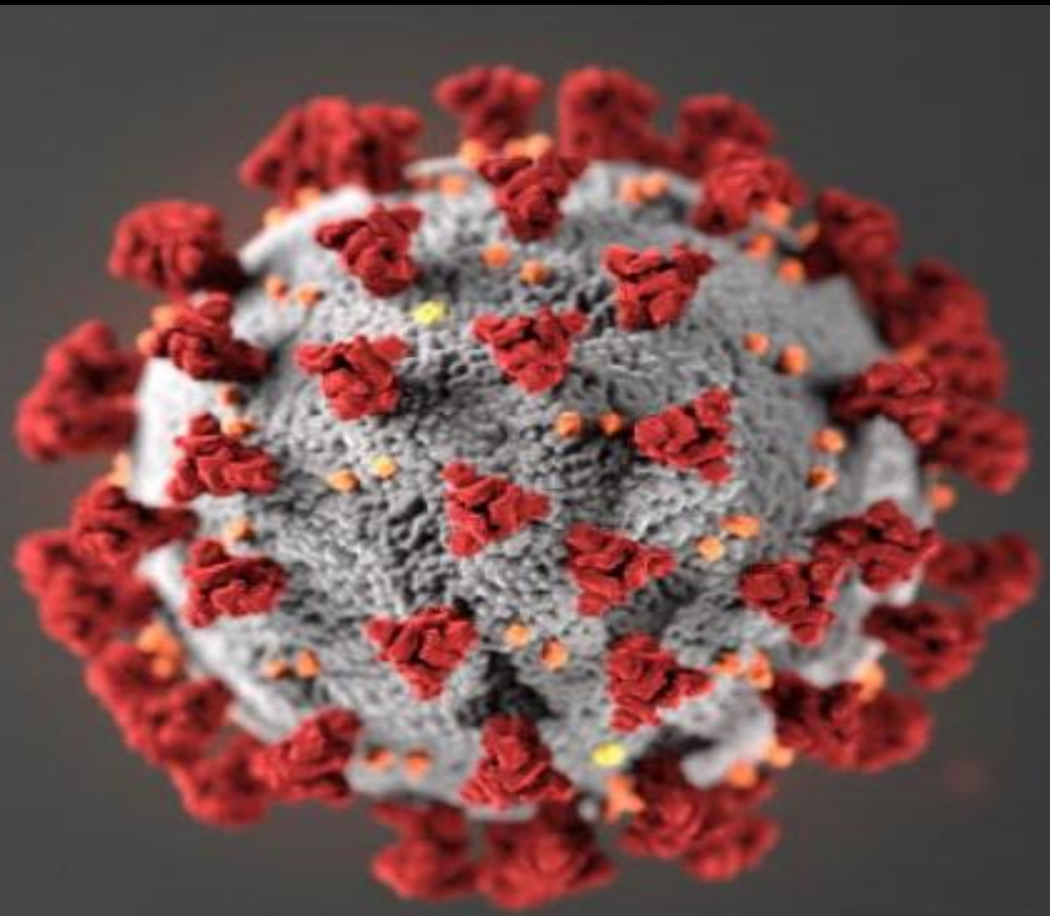
Source of doses administered: https://covid.cdc.gov/covid-data-tracker/#vaccinations

Characteristics of patients with CVST and thrombocytopenia* after the Janssen COVID-19 Vaccine (n=6)

- Median age 33 years (range 18–48)
- Median time to symptom onset 8 days (range 6–13 days)
- All cases occurred in white females
- Current estrogen/progesterone use (n=1)
- Pregnant or post-partum (n=0)
- Pre-existing conditions
  - Obesity (n=3)
  - Hypothyroidism (n=1)
  - Hypertension (n=1)
  - Asthma (n=1)
  - Coagulation disorders (none known)

Note: Thrombosis usually does not occur in the presence of low platelets; these case presentations are atypical and consistent with cases observed after AstraZeneca COVID-19 vaccine

What we know &
What we don’t know!



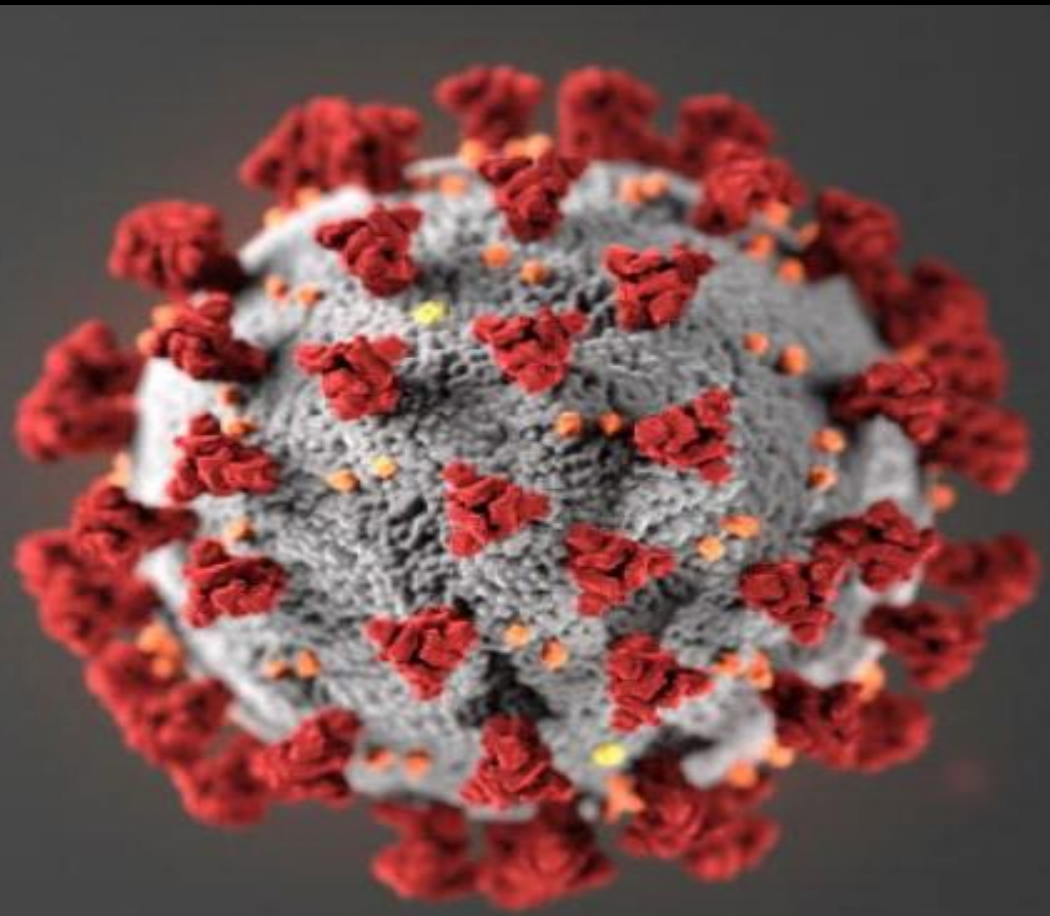
What is Known So Far

- Thrombocytopenic thrombotic events after the AstraZeneca vaccine have occurred
- In the US, 6 cases of CVST reported after receipt of the Janssen COVID-19 vaccine
- No cases of CVST with thrombocytopenia reported after receipt of either Pfizer and Moderna COVID-19 vaccines
- CVST cases have occurred primarily in younger adults, females
- CVST can be clinically devastating or fatal
- In the US, alternative COVID-19 vaccines (mRNA vaccines) are available
  - Based on current projections, supply of both mRNA vaccines stable for near future

What we do NOT Know

- True background incidence of CVST with thrombocytopenia
- Specific risk factors for thrombocytopenic thrombotic events
- Incidence of other thrombotic (non-CVST) cases with thrombocytopenia after Janssen vaccine
- Ability to compare or generalize thrombotic cases after the AstraZeneca vaccine to Janssen vaccine
- True incidence of thrombocytopenic thrombotic events/CVST after a Janssen COVID-19 vaccine
  - More cases may be identified in the coming days/weeks

ACIP's Response & Next Steps



Janssen/J&J COVID-19 vaccine:

ACIP Response

- Monday 4/12: Vaccine Safety Technical Group (VaST) meeting
- Tuesday 4/13: ACIP COVID-19 vaccines Work Group meeting
- Wednesday 4/14: Emergency ACIP meeting

Purpose of Emergency ACIP meeting

- Consider implications of reported cases of thrombosis and thrombocytopenia after Janssen/J&J vaccine on vaccination policy

Policy Options for Janssen Policy Recommendations

Do **not** recommend use of Janssen vaccine

Recommend use of Janssen/J&J COVID-19 vaccine in **some** populations

Recommend use of Janssen/J&J COVID-19 vaccine in **all adults** ≥18 years of age

Age or **gender** specific populations?

- Adults **50 years of age** and older only
- **Males** only

Next Steps

- Continue enhanced monitoring in VAERS and other vaccine safety systems (e.g., Vaccine Safety Datalink [VSD])
- Investigate potential cases through detailed clinical reviews/chart reviews
- Refine analyses to better quantify risk

ACIP Emergency Meeting Friday 4-23-21

Webcast

A virtual emergency meeting will be held to discuss Janssen (Johnson & Johnson) COVID-19 vaccine on April 23, 2021, 11:00 a.m. to 5:00 p.m. ET

May 5, 2021 meeting is a virtual meeting.

No registration is required for either meeting.

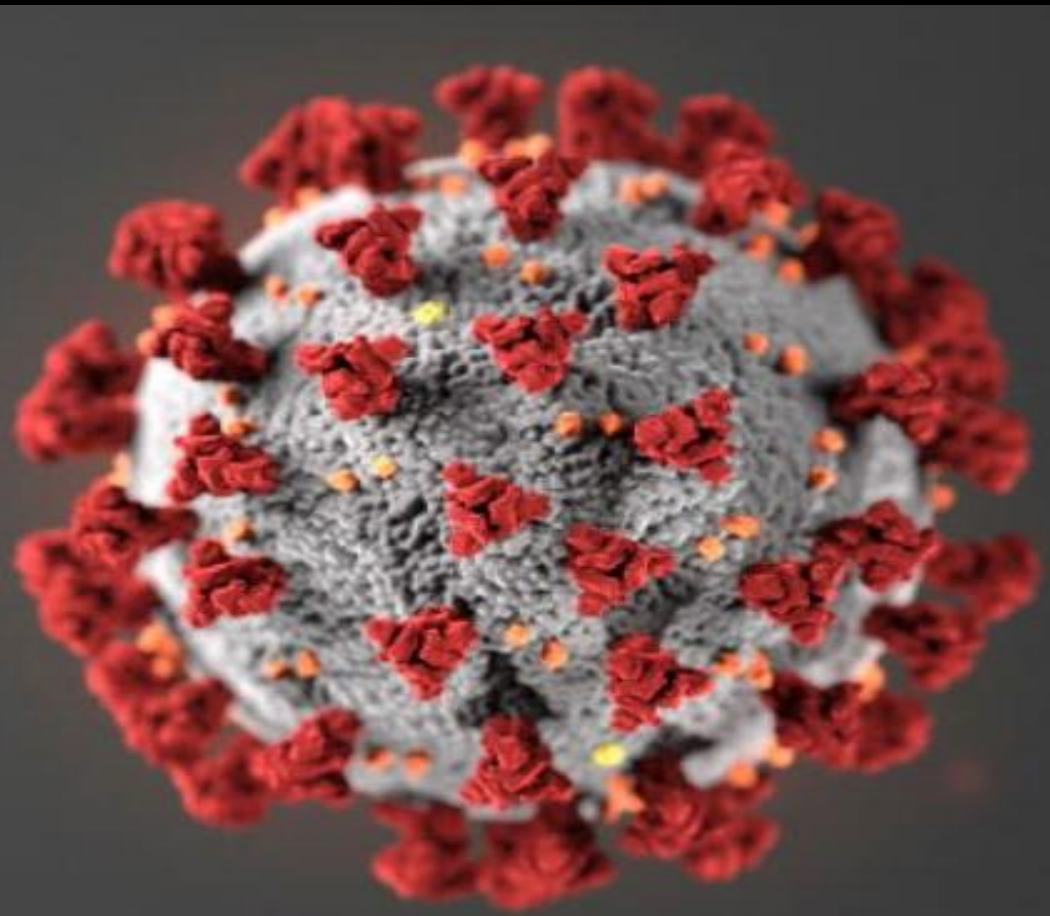
Draft Agenda – May 5, 2021

Webcast Link

To discuss next steps for the use of the Janssen COVID-19 vaccine

https://www.cdc.gov/vaccines/acip/index.html

What Clinicians Should Know



Clinicians Should…

- Maintain a high index of suspicion for symptoms that might represent serious thrombotic events or thrombocytopenia in patients who have recently received the Janssen COVID-19 vaccine, including severe headache, backache, new neurologic symptoms, severe abdominal pain, shortness of breath, leg swelling, petechiae (tiny red spots on the skin), or new or easy bruising. Obtain platelet counts and screen for evidence of immune thrombotic thrombocytopenia
- In patients with a thrombotic event and thrombocytopenia after the Janssen COVID-19 vaccine, evaluate initially with a screening PF4 enzyme-linked immunosorbent (ELISA) assay as would be performed for autoimmune HIT. Consultation with a hematologist is strongly recommended

Clinicians Should…

- **Do not treat patients with thrombotic events and thrombocytopenia following receipt of Janssen COVID-19 vaccine with heparin, unless HIT testing is negative**
- If HIT testing is positive or unable to be performed in patient with thrombotic events and thrombocytopenia following receipt of Janssen COVID-19 vaccine, non-heparin anticoagulants and high-dose intravenous immune globulin should be strongly considered
- Report adverse events to VAERS, including serious and life-threatening adverse events and deaths in patients following receipt of COVID-19 vaccines as required under the Emergency Use Authorizations for COVID-19 vaccines https://emergency.cdc.gov/han/2021/han00442.asp

How to report an adverse event to VAERS

- Go to vaers.hhs.gov
- Submit a report online
- For help:

  Call 1-800-822-7967

  Email info@VAERS.org

  video instructions
  https://youtu.be/sbCWhcQADFE

- Please send records to VAERS ASAP if contacted and asked
  - HIPAA permits reporting of protected health information to public health authorities including CDC and FDA

AMERICAN SOCIETY OF HEMATOLOGY / COVID-19 RESOURCES / VACCINE-INDUCED IMMUNE THROMBOTIC THROMBOCYTOPENIA

Vaccine-induced Immune Thrombotic Thrombocytopenia: Frequently Asked Questions

Rare cases of thrombosis with thrombocytopenia have been reported following vaccination with the Johnson & Johnson/Janssen COVID-19 vaccine. A recent one-hour seminar reviewed the background, diagnosis, and clinical management of this emerging disorder with experts from Centers for Disease Control (CDC) and the American Society of Hematology. The seminar also covered how to report cases through CDC's Vaccine Adverse Events Reporting System (VAERS).

VIEW THE WEBINAR

The presentation slide set is also available for download.

https://www.hematology.org/covid-19/vaccine-induced-immune-thrombotic-thrombocytopenia

Information for the Public

- If you have received the Janssen COVID-19 vaccine and develop severe headache, abdominal pain, leg pain, or shortness of breath within three weeks after vaccination, contact your healthcare provider, or seek medical care
- Report adverse events following receipt of any COVID-19 vaccine to VAERS
- If you are scheduled to receive the Janssen vaccine, please contact your healthcare provider, vaccination location, or clinic to learn about additional vaccine availability

Communicating with the Worried Well

- Be factual and honest
- Take time to listen to concerns and answer questions (this could build confidence)
- Acknowledge fears and explain the scientific findings to what is known at this time
- Go over the recommendations for them if they received the vaccine
- Stress that this safety signal was not detected with the other 2 vaccines under EUA (Pfizer-BioNTech and Moderna)
  - Even during the pause of the Janssen vaccine we still have 2 very effective vaccines that can be received, and we recommend that you be vaccinated
- Talk about the importance of receiving vaccine as COVID-19 is still in our communities and the best protection we have is to get vaccinated

NATIONAL FORUM ON
COVID-19 VACCINE

Communicating About COVID-19 Vaccine Safety and Risk

Most people in the United States are planning to get a COVID-19 vaccine. However, some may want more information, including information about the safety and effectiveness of COVID-19 vaccines. Take the time to listen to people's concerns and answer their questions. This can help them become confident in their decision to get vaccinated. Strong confidence in the vaccines within communities leads to more vaccinations, which in turn lead to fewer COVID-19 illnesses, hospitalizations, and deaths.

Remember: If a person has concerns or questions, this doesn't necessarily mean they won't accept a COVID-19 vaccine. Sometimes people simply want your answers to their questions.

Consider principles from Crisis and Emergency Risk Communication when communicating about COVID-19 vaccine safety.

- **Be first.** Share information and what is known, what is not known, and what is being done to fill in the gaps as quickly as possible.
- **Be right.** Ensure the information that you share is accurate in order to establish credibility.
- **Be credible.** Communicate honest, timely, and scientific evidence so the public can trust your information and guidance.
- **Express empathy.** Acknowledge what people are feeling and consider their perspectives when providing recommendations.
- **Promote action.** Keep action messages simple, short, and easy to remember.
- **Show respect.** Actively listen to the issues and solutions brought up by local communities and leaders.

When communicating about COVID-19 vaccine safety and risks, be sure to emphasize:

- **COVID-19 vaccines are safe and effective.**
  - » Millions of people in the United States have received COVID-19 vaccines, and these vaccines have undergone the most intensive safety monitoring in U.S. history.
- **COVID-19 vaccines meet all safety standards.**
  - » The Food and Drug Administration (FDA) carefully reviews all safety data from clinical trials and authorizes emergency vaccine use only when the expected benefits outweigh potential risks.
  - » The Advisory Committee on Immunization Practices (ACIP), a group of immunization and public health experts, reviews all safety data before recommending any COVID-19 vaccine for use in the United States.
- **COVID-19 vaccines will be continually monitored for safety.** FDA and CDC will continue to monitor the safety of COVID-19 vaccines to make sure even very rare side effects are identified.
- **After COVID-19 vaccination, many people will have mild side effects.**
  - » Pain or swelling at the injection site, fever, chills, tiredness, or a headache are common and can be a sign that the vaccine is working.
  - » A small number of people have had a severe allergic reaction (called "anaphylaxis") after COVID-19 vaccination, but this is **extremely** rare. When it does happen, vaccination providers have medicines available that they can use to effectively and immediately treat the reaction.
- **The known risks associated with getting sick with COVID-19 far outweigh any potential risks of getting a COVID-19 vaccine, especially for people at increased risk of severe COVID-19 illness.**

Additional CDC Resources and References

Education for Patients

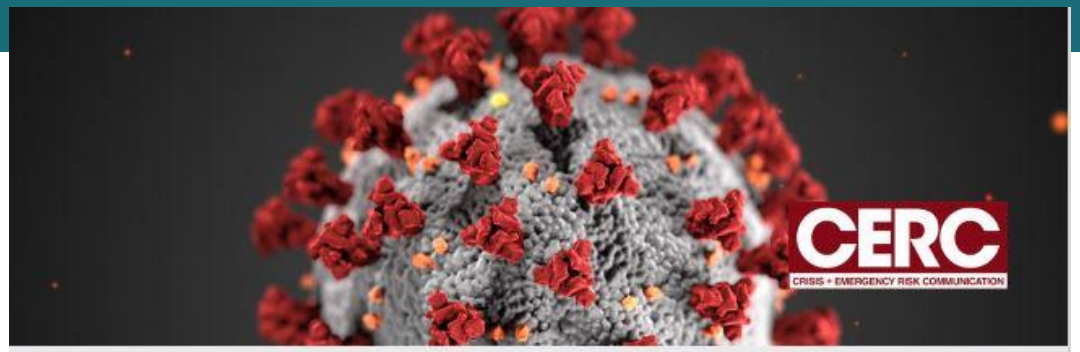
COVID-19 vaccines
People at Increased Risk
What to Expect after Getting a COVID-19 Vaccine
Ensuring the Safety of COVID-19 Vaccines in the U.S.

Tips for Providers

COVID-19 Vaccination Communication Toolkit
Vaccinate with Confidence
Answering Your Questions About the COVID-19 Vaccines
Quick Answers for Healthcare Professionals to Common Questions People May Ask about COVID-19 Vaccines
Making a Strong Recommendation for COVID-19 Vaccination
Answering Patients' Questions

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

www.cdc.gov/CovidVaccineForum

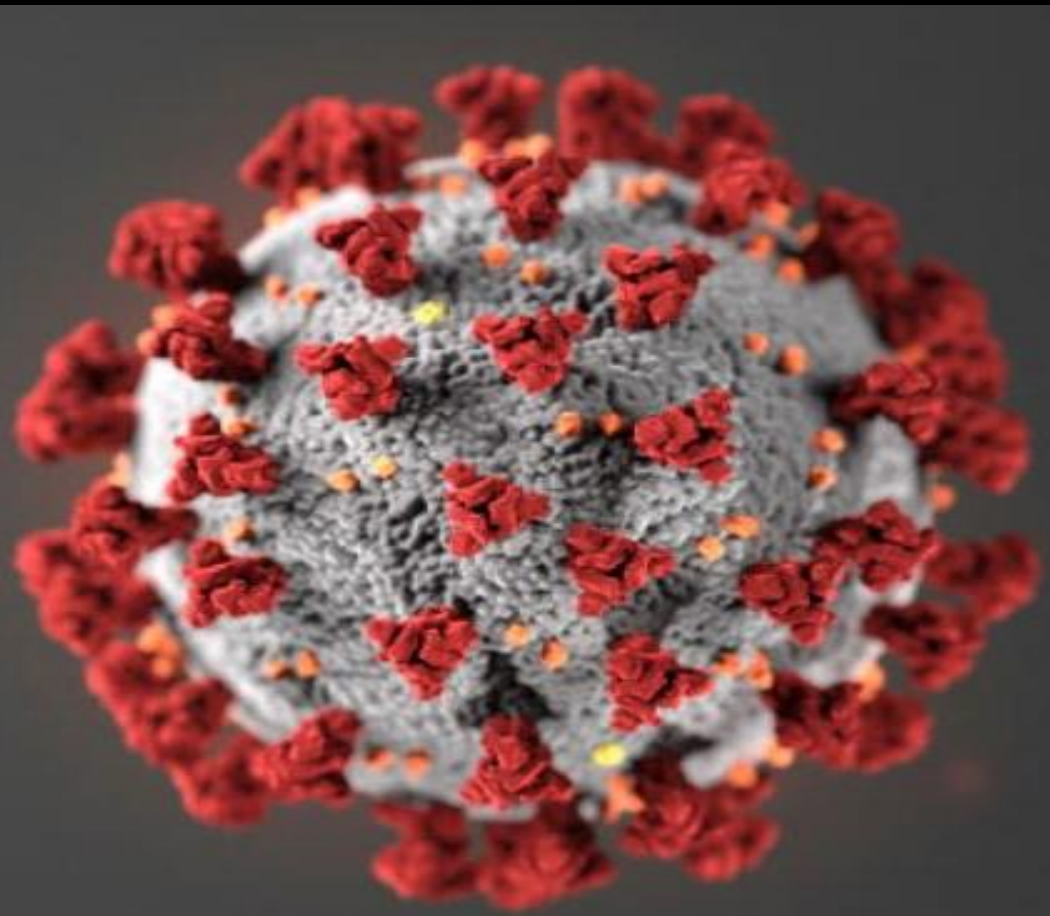


CERC in an Infectious Disease Outbreak

1. **Be First:** Quickly sharing information about a disease outbreak can help stop the spread of disease, and prevent and reduce illness and even death. People often remember the first information they hear in an emergency, so the first information they receive should come from health experts.
   - Even if the cause of the outbreak or specific disease is unknown, share facts that are available. This can help you stay ahead of possible rumors.
   - Share information about the signs and symptoms of disease, who is at risk, treatment and care options, and when to seek medical care.
2. **Be Right:** Accuracy establishes credibility. Information should include what is known, what is not known, and what is being done to fill in the information gaps.
   - Public health messages and medical guidance must complement each other. For example, public health officials should not widely encourage people to go to the doctors if doctors are turning people away and running out of medicine for critically ill people.
   - Always fact check with subject-matter experts. One incorrect message can cause harmful behaviors and may result in people losing trust in future messages.
3. **Be Credible:** Honesty, timeliness, and scientific evidence encourage the public to trust your information and guidance. Acknowledge when you do not have enough information to answer a question and then work with the appropriate experts to get an answer.
   - Do not make promises about anything that is not yet certain, such as distribution of vaccines or medications without confirmed availability.
   - Clinicians should be present at press or community events to answer medical questions.
4. **Express Empathy:** Disease outbreaks can cause fear and disrupt daily lives. Lesser-known or emerging diseases cause more uncertainty and anxiety. Acknowledging what people are feeling and their challenges shows that you are considering their perspectives when you give recommendations.
   - For example, during a telebriefing for the coronavirus disease 2019 response: *"Being quarantined can be disruptive, frustrating, and feel scary. Especially when the reason for quarantine is exposure to a new disease for which there may be limited information."*
5. **Promote Action:** In an infectious disease outbreak, public understanding of and action on disease prevention is key to stopping the spread.
   - Keep action messages simple, short, and easy to remember, like "cover your cough."
   - Promote action messages in different ways to make sure they reach those with disabilities, limited English proficiency, and varying access to information.
6. **Show Respect:** Respectful communication is particularly important when people feel vulnerable. Respectful communication promotes cooperation and rapport. Actively listen to the issues and solutions brought up by local communities and local leadership.
   - Acknowledge different cultural beliefs and practices about diseases, and work with communities to adapt behaviors and promote understanding.
   - Do not dismiss fears or concerns. Give people a chance to talk and ask questions.

https://emergency.cdc.gov/cerc/resources/pdf/315829-A_FS_CERC_Infectious_Disease.pdf

Resources



COVID-19

Your Health | Vaccines | Cases & Data | Work & School | Healthcare Workers | Health Depts | Science | More

Vaccines

- Key Things to Know +
- Benefits of Getting Vaccinated
- Information for Different Groups +
- Find a Vaccine

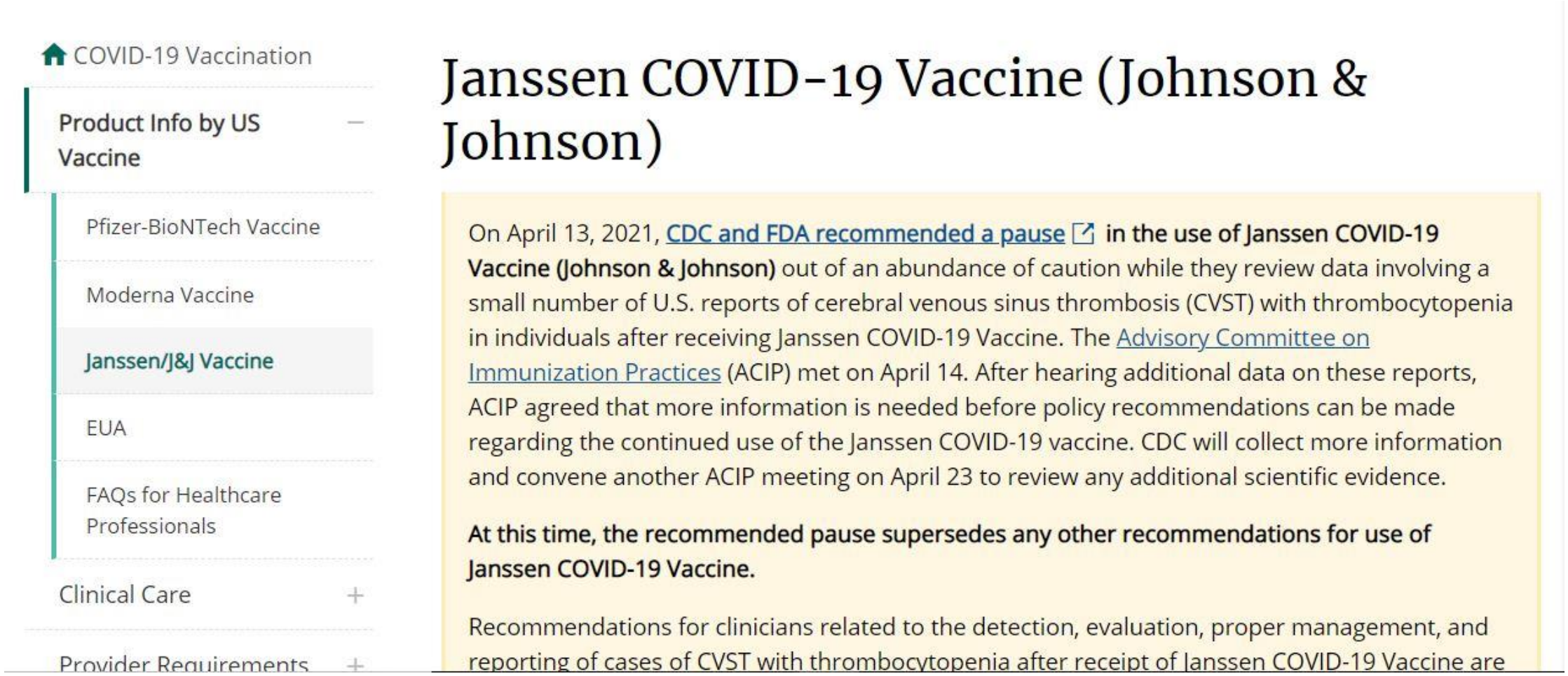
Recommendation to Pause Use of Johnson & Johnson's Janssen COVID-19 Vaccine

Updated Apr. 20, 2021 Languages Print

What you need to know:

- The use of Johnson & Johnson's Janssen (J&J/Janssen) COVID-19 Vaccine is paused for now. This is because the safety systems that make sure vaccines are safe received a small number of reports of people who got this vaccine experiencing a rare and severe type of blood clot with low platelets.

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/JJUpdate.html

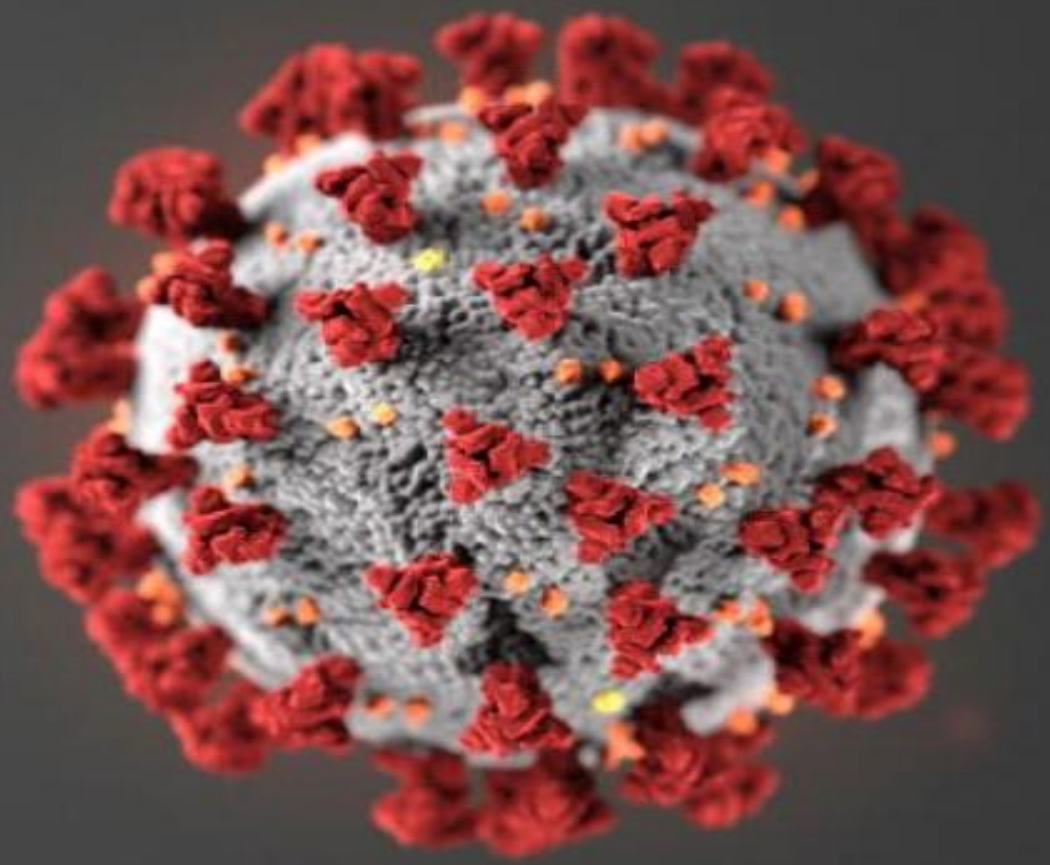


https://www.cdc.gov/vaccines/covid-19/info-by-product/janssen/index.html

Thank You!

Next “Noontime Knowledge” Update: May 6, 2021 at 12:00p.m. Topic: TBD

Please watch your email for an updated link and topic!



www.michigan.gov/COVIDvaccine →Provider Guidance and Education