



Update: Thrombosis with thrombocytopenia syndrome (TTS) following COVID-19 vaccination

**Advisory Committee on Immunization Practices (ACIP)
May 12, 2021**

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Disclaimer

- The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention (CDC) or the U.S. Food and Drug Administration (FDA)
- Mention of a product or company name is for identification purposes only and does not constitute endorsement by CDC or FDA

Topics

- Background
- Thrombosis with thrombocytopenia syndrome (TTS) following COVID-19 vaccination
- Summary

Background

Thrombosis*

- Thrombosis occurs when blood clots block blood vessels
 - Thromboses can be venous or arterial
 - Complications include heart attack, stroke, and other infarctions
- Causes and risk factors include:
 - Trauma, immobility, inherited disorders (genetic), autoimmune disease, obesity, hormone therapy or birth control pills, pregnancy, smoking, cancer, older age
- Symptoms may include:
 - Pain and swelling in an extremity, chest pain, numbness or weakness on one side of the body, sudden change in mental status
- Diagnosed mainly through imaging (e.g., CT, MRI, ultrasound) with blood tests (e.g., D-dimer)

Platelets and thrombocytopenia (low platelets)*

- Platelets (thrombocytes) are colorless blood cells that help blood clot; normal platelet count is 150,000–450,000 per microliter
- Platelets stop bleeding by clumping and forming plugs in blood vessel injuries
- Thrombocytopenia is a condition in which you have a low blood platelet count (<150,000 per microliter)
- Dangerous internal bleeding can occur when your platelet count falls below 10,000 per microliter
- Though rare, severe thrombocytopenia can cause bleeding into the brain, which can be fatal

**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 Events 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 suspicion 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 type 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

AstraZeneca's COVID-19 vaccine: EMA finds possible link to very rare cases of unusual blood clots with low blood platelets

Share

News 07/04/2021

EMA confirms overall benefit-risk remains positive Research

EMA's safety committee (PRAC) has concluded to be listed as very rare side effects of Vaxzevria (for

In reaching its conclusion, the committee took into advice from an ad hoc expert group.

JAMA | Original Investigation

US Case Reports of Cerebral Venous Sinus Thrombosis With Thrombocytopenia After Ad26.COV2.S Vaccination, March 2 to April 21, 2021

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Centers for Disease Control and Prevention
MMWR

Early Release / Vol. 70

Morbidity and Mortality Weekly Report

April 30, 2021

Safety Monitoring of the Janssen (Johnson & Johnson) COVID-19 Vaccine — United States, March–April 2021

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On February 27, 2021, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for Janssen (Ad.26.COV2.S) COVID-19 vaccine (Janssen Biotech, Inc., a Janssen Pharmaceutical company, Johnson

VAERS reports reviewed, 97% were classified as nonserious and 3% as serious,[†] including three reports among women of cases of thrombosis in large arteries or veins accompanied by thrombocytopenia during the second week after vaccination.

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

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Summary

What is already known about this topic?

On April 13, 2021, CDC and the Food and Drug Administration (FDA) recommended pausing use of the Janssen COVID-19 vaccine after reports of thrombosis with thrombocytopenia syndrome (TTS) among vaccine recipients.

What is added by this report?

On April 23, the Advisory Committee on Immunization Practices concluded that the benefits of resuming Janssen COVID-19 vaccination among persons aged ≥ 18 years outweighed the risks and reaffirmed its interim recommendation under FDA's Emergency Use Authorization, which includes a new warning for rare clotting events among women aged 18–49 years.

What are the implications for public health practice?

Resuming use of the Janssen COVID-19 vaccine will ensure flexibility, choice, and improved access. Education about TTS risk with Janssen COVID-19 vaccine is critical.

Update on TTS cases

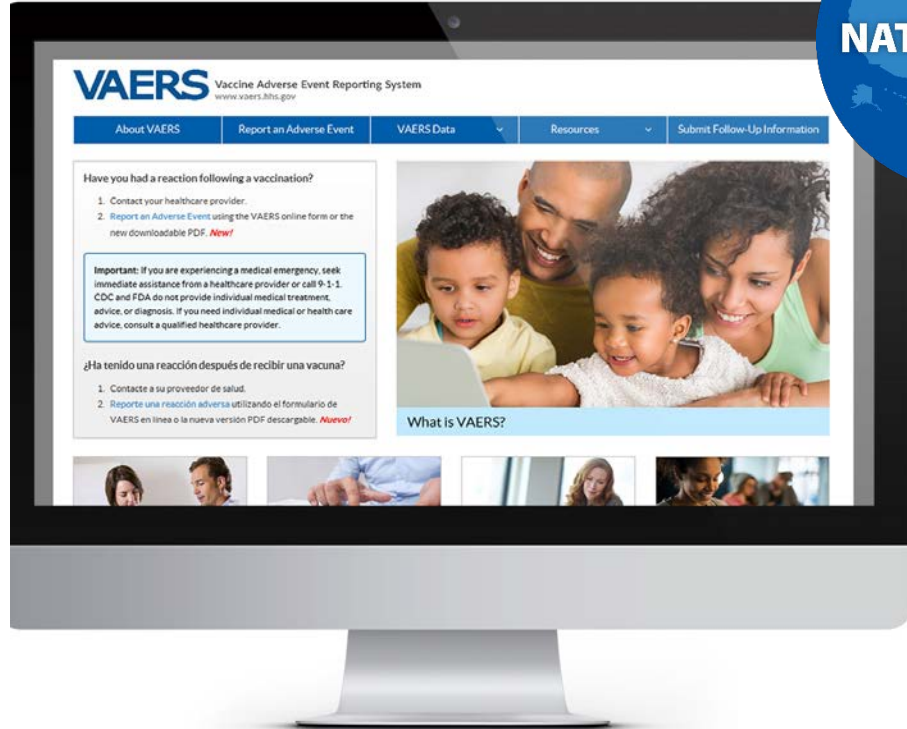
VAERS is the nation's early warning system for vaccine safety



VAERS

Vaccine Adverse Event Reporting System

<http://vaers.hhs.gov>

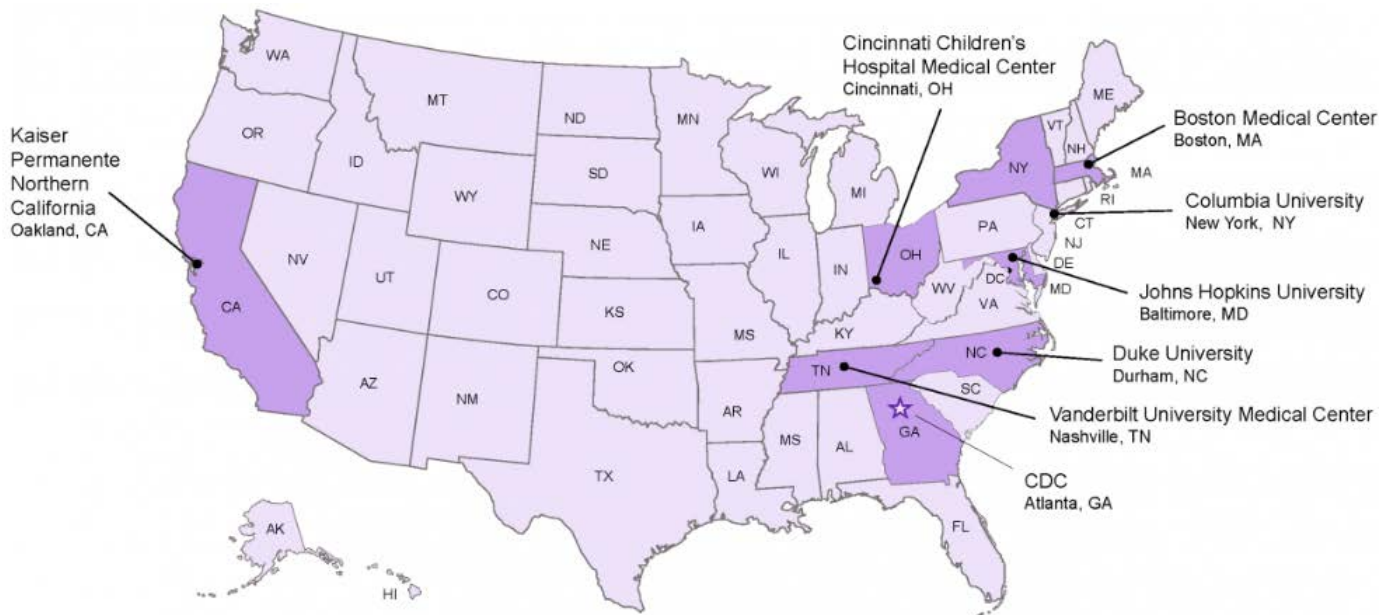




CISA

Clinical Immunization Safety Assessment (CISA) Project

7 participating medical research centers with vaccine safety experts



- clinical consult services*
- clinical research

*More information about clinical consults available at <http://www.cdc.gov/vaccinesafety/Activities/CISA.html>

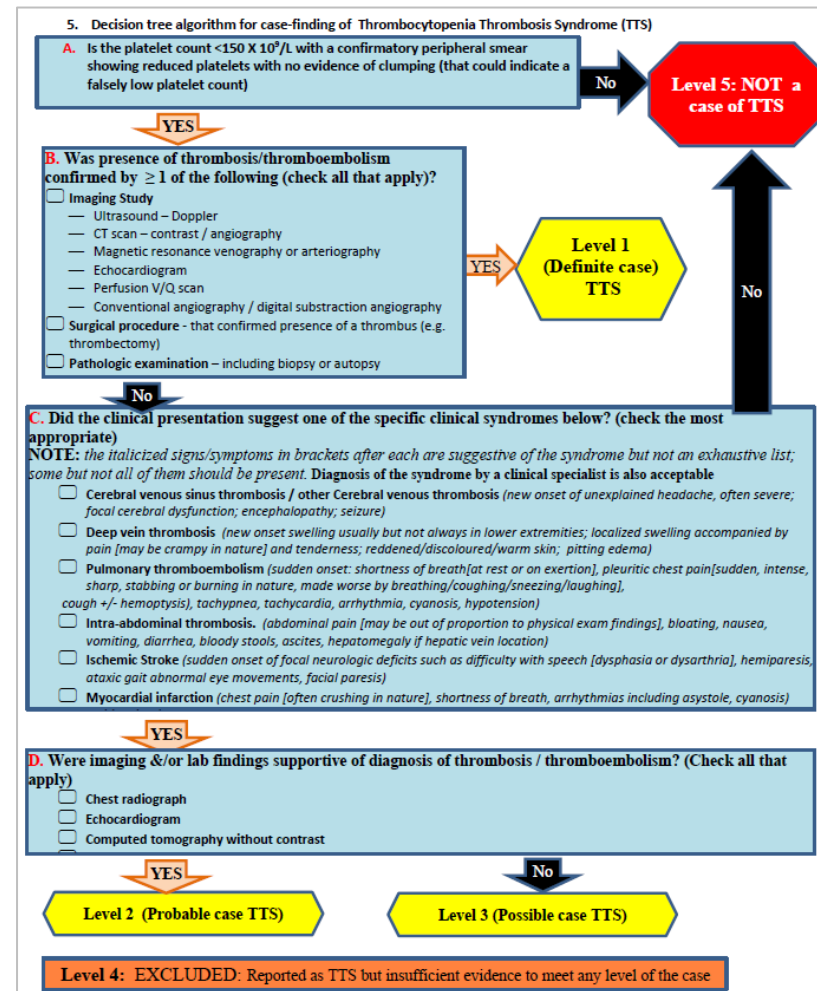
Case finding for TTS following COVID-19 vaccines*

- Healthcare providers directly contact CDC about potential TTS cases
- FDA physicians screen incoming VAERS reports daily to identify potential TTS cases (i.e., screening of pre-processed reports)
- CDC searches the VAERS database of processed reports daily for possible TTS cases
- Medical records requested for all potential TTS case reports to confirm thrombosis with laboratory evidence of thrombocytopenia, using working case definition
- CDC and FDA medical officers review TTS case reports and available medical records; CISA experts including hematologists consulted

Interim Brighton Collaboration case definition for TTS

- New onset thrombocytopenia: platelet count $<150,000$ per microliter*
- No known recent exposure to heparin
- Presence of venous or arterial thrombosis
 - In addition to rare thromboses (e.g., cerebral venous thrombosis), currently includes more common thromboses (e.g., as deep vein thrombosis, pulmonary thromboembolism, ischemic stroke, and myocardial infarction)

* A blood smear should be evaluated to rule out platelet clumping that could indicate a falsely low platelet count



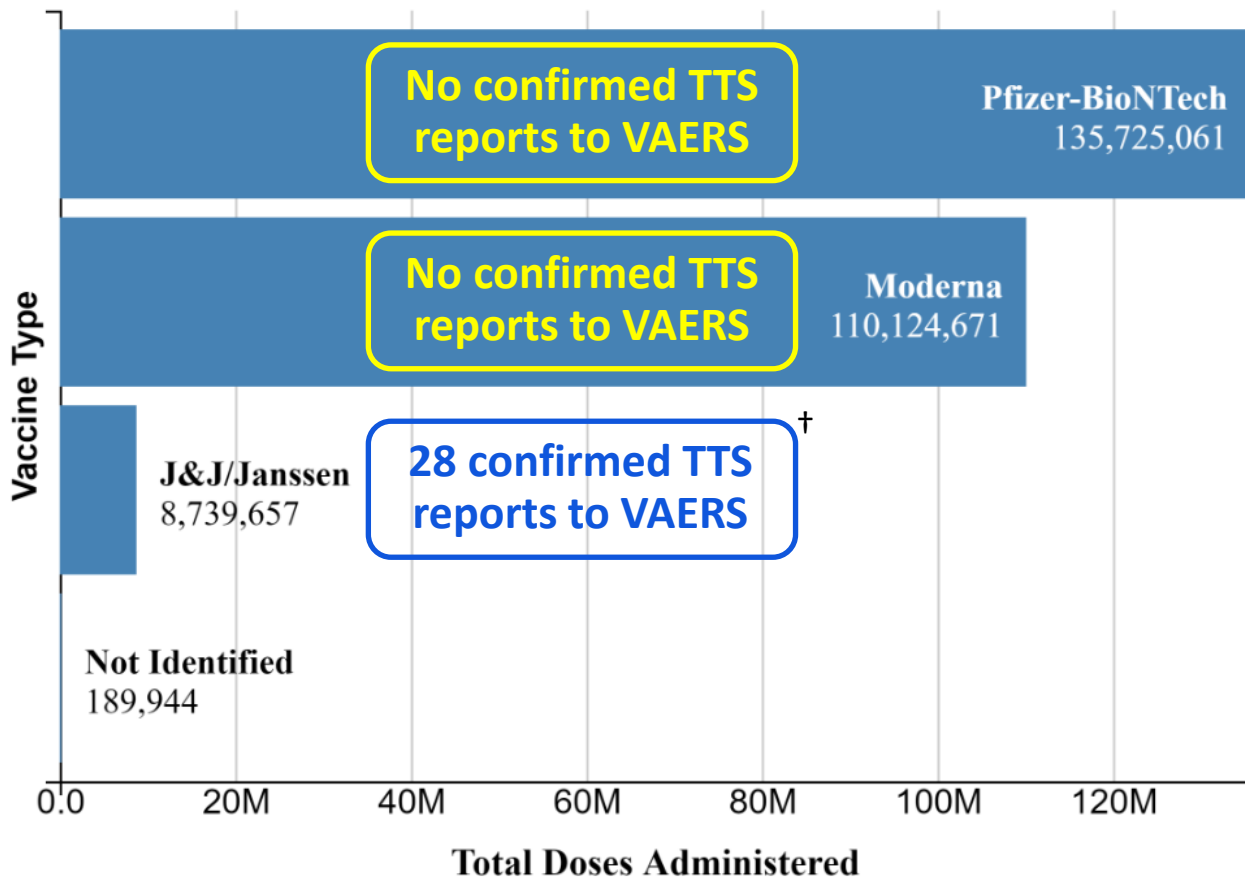
CDC working case definition for TTS following COVID-19 vaccination

- Tier 1 TTS case
 - Thrombosis in an unusual location, including cerebral venous sinuses, portal vein, splenic vein, and other rare venous and arterial thromboses
 - May also concurrently have thrombosis in more common locations (e.g., venous thromboembolism, axillary vein thrombosis, deep vein thrombosis, pulmonary embolism)
 - Platelet count <150,000 per microliter
 - Positive (+) heparin-PF4 ELISA HIT antibody* result is supportive, but not required
- Tier 2 TTS case
 - Thrombosis in a common location only (e.g., venous thromboembolism, axillary vein thrombosis, deep vein thrombosis, pulmonary embolism, etc.)
 - Excludes isolated acute myocardial infarction or ischemic stroke
 - Platelet count <150,000 per microliter
 - Positive (+) heparin-PF4 ELISA HIT antibody* result is required

* Heparin platelet factor 4 enzyme-linked immunosorbent assay heparin-induced thrombocytopenia antibody test

U.S. COVID-19 vaccine administration by product type and TTS reports to VAERS

(as of May 7, 2021)*



* Data source: <https://covid.cdc.gov/covid-data-tracker/#vaccinations>

† One CVST with thrombocytopenia case was observed in Janssen COVID-19 vaccine pre-authorization clinical trials in a 25-year-old male; this case is not included in the VAERS post-authorization confirmed case count

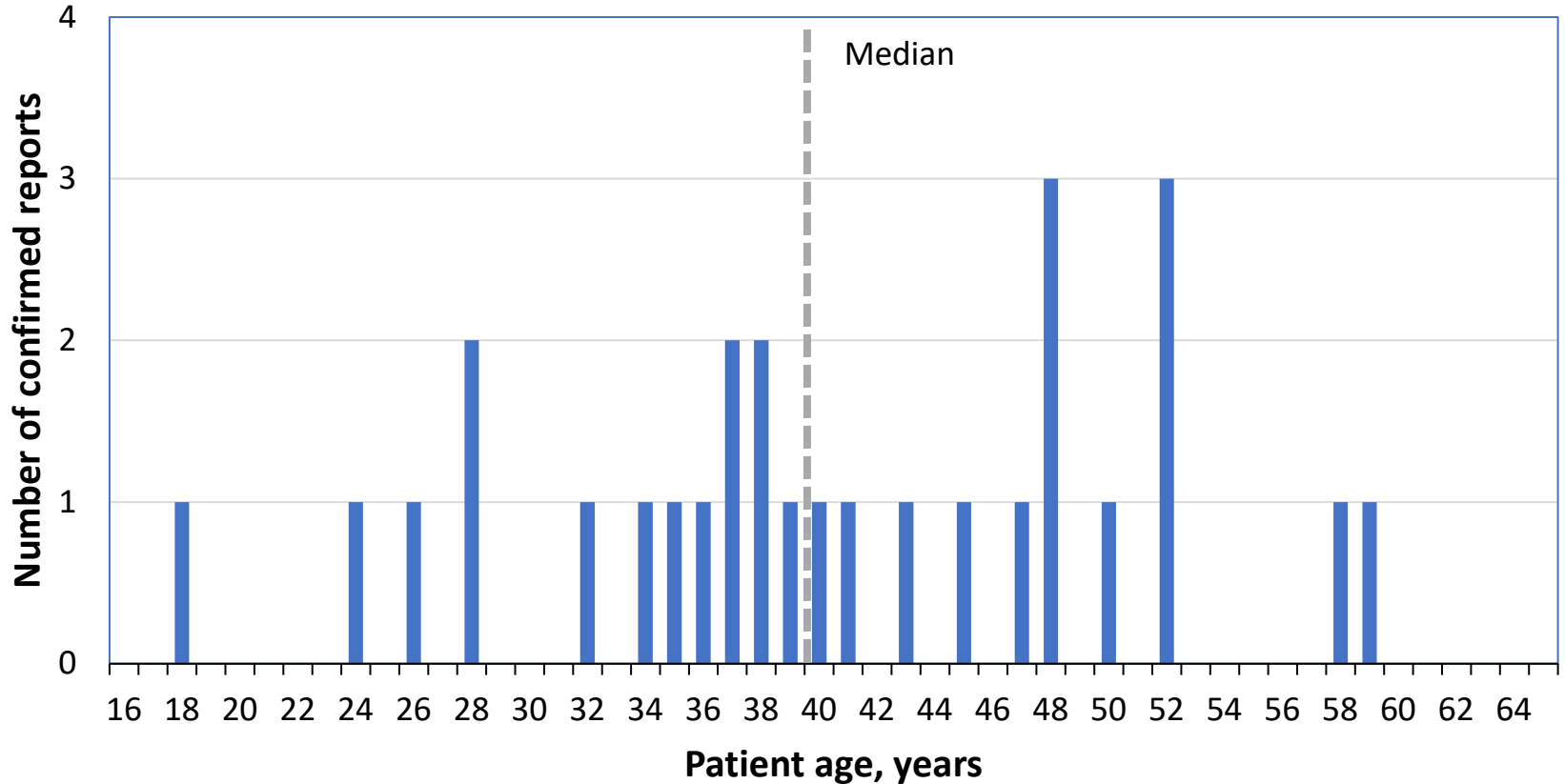
Characteristics of U.S. TTS cases after Janssen COVID-19 vaccination, N=28 (Tier 1=25, Tier 2=3, as of May 7, 2021)

- Median age: 40 years (range 18–59 years)
- Median time from vaccination to symptom onset: 9 days (range 3–15 days)
- All received the Janssen COVID-19 Vaccine before the pause on April 13, 2021
- Female (n=22), male (n=6)
- 19 of the 28 TTS cases has a cerebral venous sinus thrombosis (CVST)
- Pregnant or postpartum* (n=0)
- Past SARS-CoV-2 infection (n=5); 3 by history, 2 by nucleocapsid serology testing only
- Risk factors for thrombosis[†]
 - Systemic estrogen[‡] (n=3)
 - Obesity (n=12)
 - Hypertension (n= 7)
 - Hypothyroidism (n=3)
 - Diabetes (n=3)
 - Current cigarette smoking (n=2)
 - Malignancy (n=1)
 - Fertility treatment (n=1)
 - Coagulation disorders (n=0)

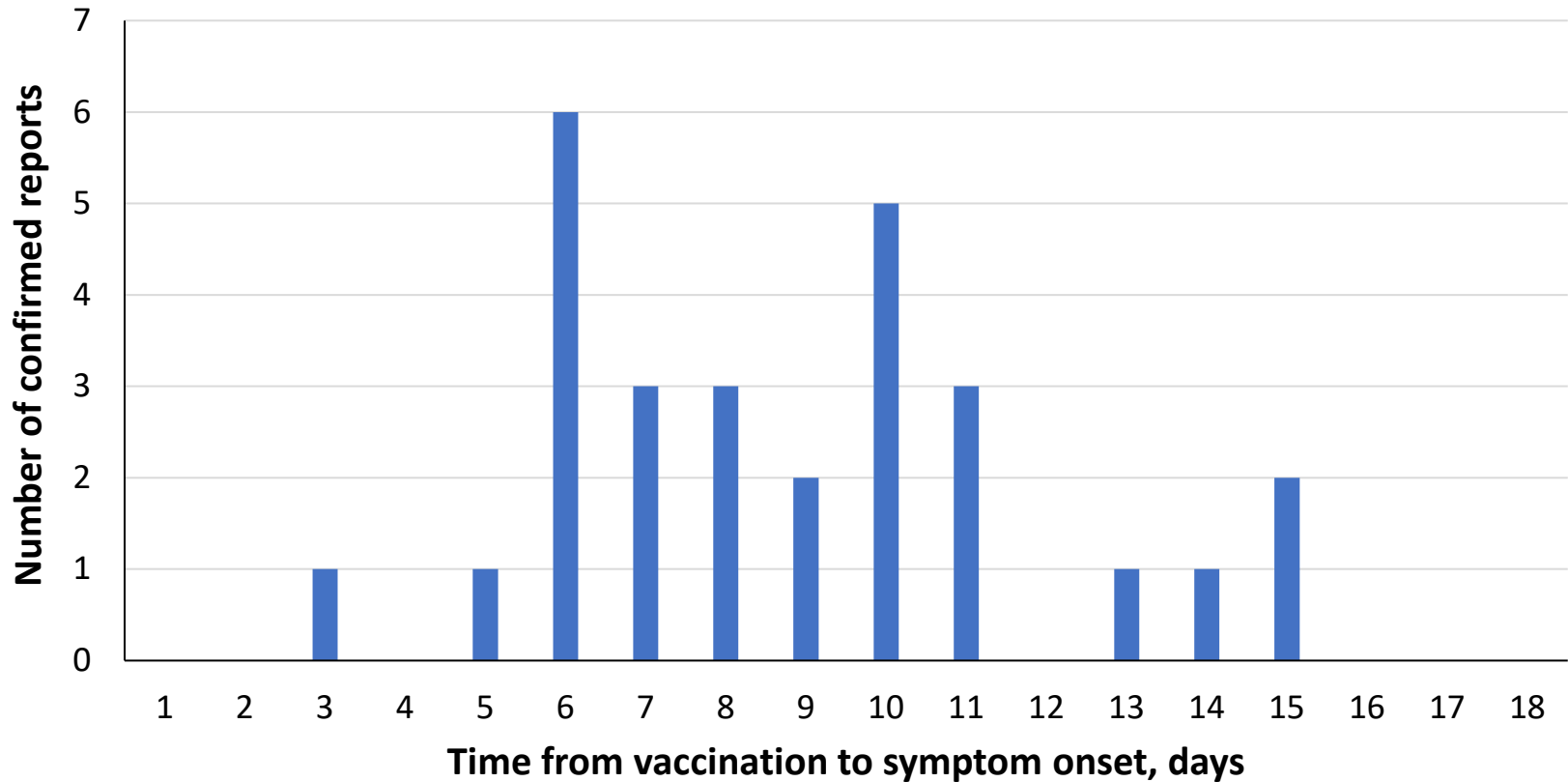
* Within 12 weeks of delivery; † Reference source: <https://www.hopkinsmedicine.org/health/conditions-and-diseases/thrombosis>;

‡ 2 patients were taking combined oral contraceptives (COCs), 1 patient was on hormone therapy (HT) estradiol patch

Confirmed U.S. case reports of TTS following Janssen COVID-19 vaccination by patient age as of May 7, 2021 (N=28)



Confirmed U.S. case reports of TTS following Janssen COVID-19 vaccination by time to symptom onset as of May 7, 2021 (N=28)



U.S. reporting rates of TTS after Janssen COVID-19 vaccination (as of May 7, 2021)

- 8.73 million total Janssen COVID-19 Vaccine doses administered*

Age group	Females			Males		
	TTS cases	Doses admin	Reporting rate [†] (per million)	TTS cases	Doses admin	Reporting rate [†] (per million)
18-29 yrs old	3	641,510	4.7	2	714,458	2.8
30-39 yrs old	8	642,745	12.4	1	728,699	1.4
40-49 yrs old	7	743,256	9.4	1	775,390	1.3
50-64 yrs old	4	1,463,416	2.7	2	1,505,505	1.3
65+ yrs old	0	814,947	0	0	697,925	0

* Source of doses administered: <https://covid.cdc.gov/covid-data-tracker/#vaccinations>; † Reporting rate = TTS cases per 1 million Janssen COVID-19 vaccine doses administered

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Locations of thromboses in U.S. TTS cases following Janssen COVID-19 vaccination, N=28 (as of May 7, 2021; not mutually exclusive)

- Cerebral venous sinuses*
- Anterior cerebral artery
- Internal carotid artery
- Femoral vein and artery
- Hepatic vein
- Iliac artery
- Internal jugular vein
- Lower extremity veins
- Portal vein
- Pulmonary artery
- Superior mesenteric vein and artery
- Splenic vein
- Upper extremity veins

*10 of 19 patients with cerebral venous sinus thrombosis experienced an intracerebral hemorrhage: temporo-parietal junction, temporal lobe, frontal lobe, occipital lobe, cerebellum, intraventricular, subarachnoid

Selected laboratory findings in U.S. TTS cases following Janssen COVID-19 vaccination, N=28 (as of May 7, 2021)

- **Platelet nadir levels (normal levels: 150,000–450,000 per microliter)***
 - <50,000..... (n=18)
 - 50–<100,000..... (n=6)
 - 100,000–149,000... (n=4)

- **Heparin-PF4 ELISA HIT antibody results**
 - Positive (+)..... (n=24)†
 - Negative (-)..... (n=2)
 - Not available..... (n=2)

* Platelet nadir range: 9,000-127,000 per microliter

† Tier 2 TTS required a positive (+) heparin-PF4 ELISA antibody test as part of definition

SARS-CoV-2 testing results in U.S. TTS cases following Janssen COVID-19 vaccination, N=28 (as of May 7, 2021)

■ **SARS-CoV-2 nucleic acid or antigen viral assay**

- Negative (n=25)
- Positive (n=0)
- Not available (n=3)

■ **SARS-CoV-2 serology by nucleocapsid antibody**

- Negative (n=4)
- Positive (n=2)*
- Not available/not specified (n=22)[†]

* Neither of these patients reported a history of COVID-19.

[†] Three had a negative serology, the report did not specify whether nucleocapsid or spike protein antibody

Treatment and outcomes among U.S. TTS cases following Janssen COVID-19 vaccination, N=28 (as of May 7, 2021)

■ Treatment

- Heparin (n=12)
 - 9/11 (82%) admitted before HAN*
 - 3/17 (18%) admitted after HAN*
- Non-heparin anticoagulants (n=26)
- Platelet transfusion (n=7)
- Intravenous immunoglobulin (n=18)

■ Outcomes[†]

- Death (n=3)[§]
- Remain hospitalized (n=4)
 - Intensive care unit (n=1)
- Discharged to post-acute care facility (n=2)
- Discharged home (n=19)

* CDC Health Alert Network (HAN) notification released on April 13, 2021

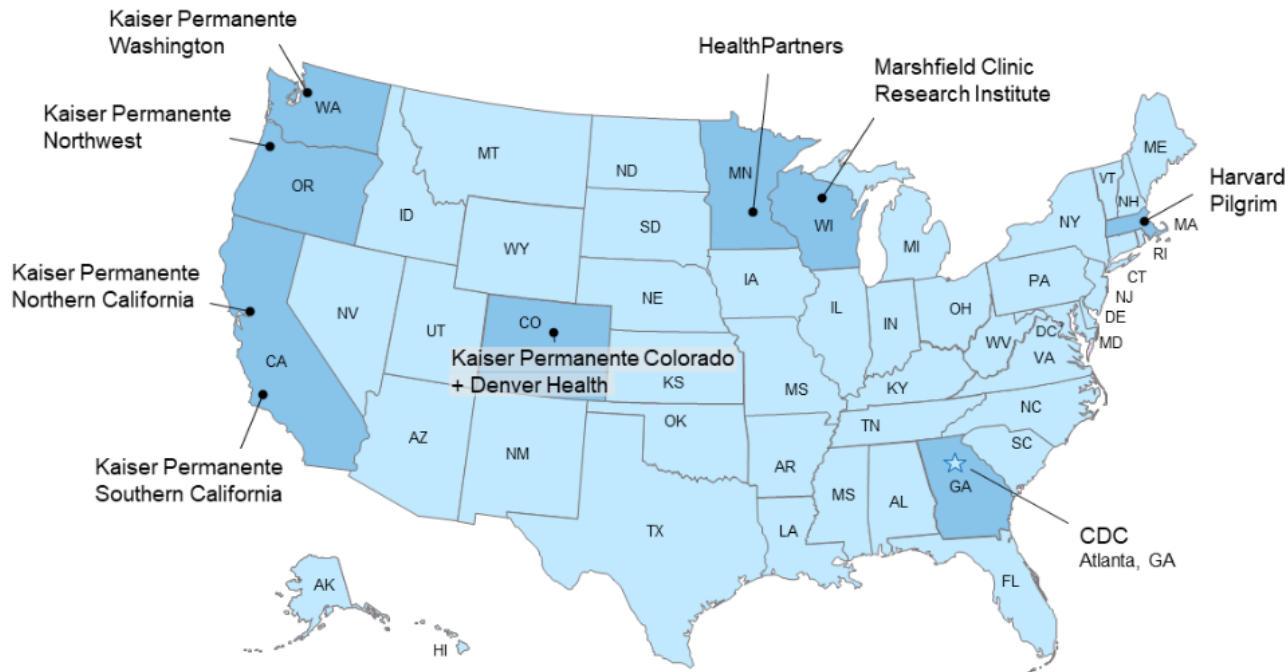
[†] As of May 7, 2021

[§] None of the patients who died received heparin; all had signs of severe CVST (hemorrhage + mass effect) on initial imaging and died within 2 days of presentation



VSD

Vaccine Safety Datalink



- **9** participating integrated healthcare organizations
- Data on over **12 million** persons per year

VSD: Cerebral venous sinus thrombosis (CVST) after mRNA COVID-19 vaccination

- 3.3 million doses of Pfizer-BioNTech and 3.0 million doses of Moderna COVID-19 vaccinations administered in VSD as of April 24, 2021
 - 11 total ICD-10 coded CVST diagnoses identified following mRNA vaccines (3 after Pfizer-BioNTech and 8 after Moderna vaccination)
 - 5 ruled out for incident cases (historical n=2, history of head injury n=2, chronic cavernous sinus syndrome n=1)
 - 6 potential CVST incident cases, but all without thrombocytopenia
- No confirmed cases of incident CVST with thrombocytopenia after 6.3 million doses of mRNA COVID-19 vaccines administered in VSD

VSD: Thrombosis events after Janssen COVID-19 vaccination

- 159,885 Janssen COVID-19 Vaccine doses administered in VSD through April 24, 2021
 - No statistical signals detected for any prespecified Rapid Cycle Analysis outcomes
 - No CVST cases identified
- 32 VTE/PE cases identified in the 1–42 days following vaccination (including 3 cases diagnosed with both VTE and PE)

- 29 of the cases have been quick reviewed to date (3 in progress)

- 29 {
- 6 were ruled out as not VTE/PE
 - 23 were confirmed VTE/PE cases

- 23 {
- 4 were determined to have symptom onset prior to vaccination
 - 1 had an indeterminate symptom onset
 - 18 are potential VTE/PE cases with incidence following vaccination

- 18 {
- » 10 female (5 PE, 5 VTE), 8 males (4 PE, 4 VTE)
 - » Ages ranged from 30–79
 - » None with history of COVID-19 infection
 - » **None with thrombocytopenia noted at time of VTE/PE**

VTE = venous thromboembolism
PE = pulmonary embolism

Summary and next steps

Summary

- TTS is a rare, clinically serious and potentially life-threatening condition; current evidence suggests a plausible causal association with the Janssen COVID-19 Vaccine
- Symptom onset appears to occur from several days after vaccination to up to 2 weeks, with most cases having symptom onset around 1–2 weeks after vaccination
- Most cases are in women, with most aged 18-49 years old
- The clinical features of TTS following Janssen COVID-19 vaccination appear similar to what is being observed following AstraZeneca COVID-19 vaccination in Europe
- It is important to recognize TTS early and initiate appropriate treatment
 - Do not treat cases of thrombosis with thrombocytopenia with heparin unless heparin-PF4 ELISA HIT antibody testing is negative
- TTS does not appear to be associated with mRNA COVID-19 vaccines
- The U.S. vaccine safety monitoring system is able to rapidly detect rare adverse events following vaccination and quickly assess safety signals
- CDC is committed to open and transparent communication of vaccine safety information

Next steps

- Continue enhanced monitoring in VAERS and conduct surveillance in other vaccine safety systems (e.g., VSD, Centers for Medicare & Medicaid Services data, Veterans Affairs electronic health record data)
- Update ACIP and the public as additional information becomes available

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



Adolescent vaccination and v-safe enrollment

Smartphone-based active safety monitoring



<http://cdc.gov/vsafe>



Use of v-safe for adolescent COVID-19 vaccination

- CDC encourages parents and guardians to enroll their vaccinated adolescents into v-safe
- Parents and guardians can complete health surveys on behalf of their adolescents, describing symptoms and health events after vaccination
 - CDC encourages completing health surveys even if vaccinated persons are feeling well and have no side effects
- Participation in **v-safe** will help CDC continue to monitor the safety of COVID-19 vaccines as use is expanded into younger populations
- Promote **v-safe** participation at vaccination locations
 - Take advantage of the post-vaccination observation period to encourage v-safe participation

Acknowledgments

We wish to acknowledge the contributions of investigators from the following organizations:

Centers for Disease Control and Prevention

COVID-19 Vaccine Task Force

Vaccine Safety Team

Immunization Safety Office

Division of Healthcare Quality Promotion

Clinical Immunization Safety Assessment Project

Vaccine Safety Datalink

Food and Drug Administration

Center for Biologics Evaluation and Research

Vaccine safety in the United States

- Authorized COVID-19 vaccines are being administered under **the most intensive vaccine safety monitoring effort in U.S. history**
- Strong, complementary systems are in place—both new and established

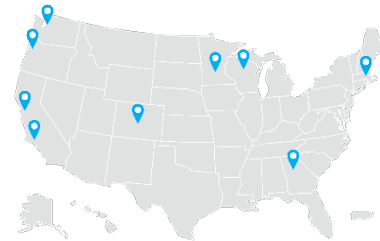
v-safe



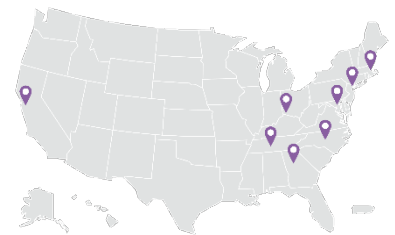
VAERS



VSD



CISA Project



Full list of U.S. COVID-19 vaccine safety monitoring systems

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

Back-up Slides

Proposed VAERS MedDRA PT and text string search terms for TTS

- **MedDRA PTs for large vessel thrombosis and embolism in unusual locations**

- Aortic embolus, aortic thrombosis, aseptic cavernous sinus thrombosis, brain stem embolism, brain stem thrombosis, carotid arterial embolus, carotid artery thrombosis, cavernous sinus thrombosis, cerebral artery thrombosis, cerebral venous sinus thrombosis, cerebral venous thrombosis, superior sagittal sinus thrombosis, transverse sinus thrombosis, mesenteric artery embolism, mesenteric artery thrombosis, mesenteric vein thrombosis, splenic artery thrombosis, splenic embolism, splenic thrombosis, thrombosis mesenteric vessel, visceral venous thrombosis, hepatic artery embolism, hepatic artery thrombosis, hepatic vein embolism, hepatic vein thrombosis, portal vein embolism, portal vein thrombosis, portosplenomesenteric venous thrombosis, splenic vein thrombosis, spontaneous heparin-induced thrombocytopenia syndrome, femoral artery embolism, iliac artery embolism, jugular vein embolism, jugular vein thrombosis, subclavian artery embolism, subclavian vein thrombosis, obstetrical pulmonary embolism, pulmonary artery thrombosis, pulmonary thrombosis, pulmonary venous thrombosis, renal artery thrombosis, renal embolism, renal vein embolism, renal vein thrombosis, brachiocephalic vein thrombosis, vena cava embolism, vena cava thrombosis, truncus coeliacus thrombosis

- **MedDRA PTs for more common thrombotic events**

- Axillary vein thrombosis, deep vein thrombosis, pulmonary embolism

- **MedDRA PTs for thrombocytopenia**

- Autoimmune heparin-induced thrombocytopenia, Heparin-induced thrombocytopenia, Immune thrombocytopenia, Non-immune heparin associated thrombocytopenia, Spontaneous heparin-induced thrombocytopenia syndrome, Thrombocytopenia, Thrombocytopenic purpura

- **Text string for**

- “thrombocytopenia” or “low platelets” in symptom text