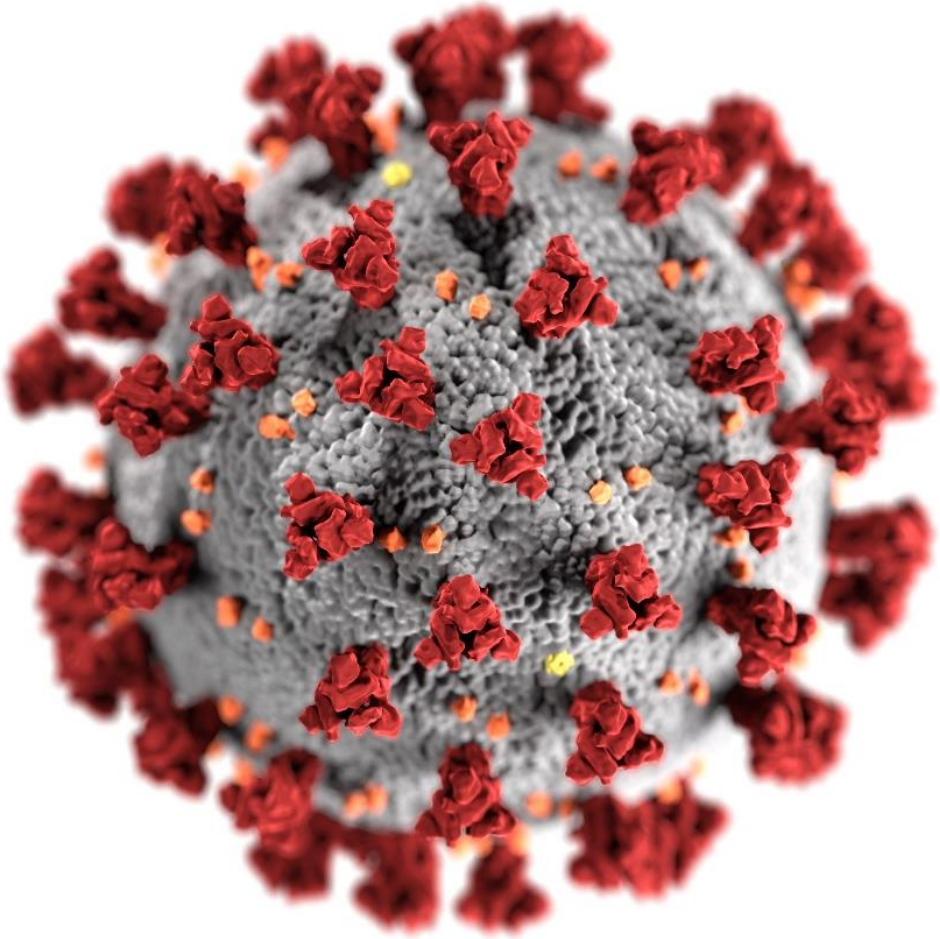
Diagnosis and Management of Suspected Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT) Following Johnson & Johnson (Janssen) COVID-19 Vaccination

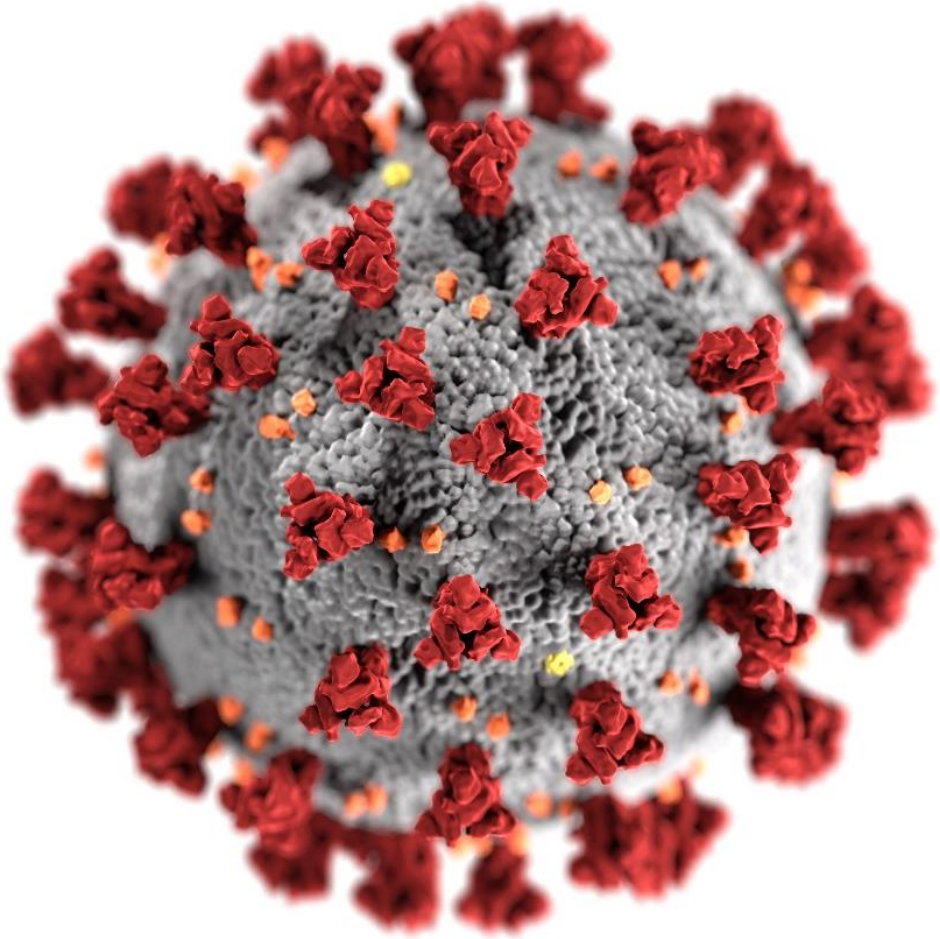


April 20th, 2021

cdc.gov/coronavirus

Disclaimer

- The findings and conclusions in this report are those of the presenters and do not necessarily represent the official position of the Centers for Disease Control and Prevention (CDC) or the American Society of Hematology (ASH)
- Mention of a product or company name is for identification purposes only and does not constitute endorsement by CDC or ASH.



cdc.gov/coronavirus

Diagnosis and Management of Suspected Vaccine-induced Immune Thrombotic Thrombocytopenia Following Johnson & Johnson (Janssen) COVID-19

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Diagnosis and Management of Suspected Vaccine-induced Immune Thrombotic Thrombocytopenia Following Johnson & Johnson (Janssen) COVID-19

Outline

- Introduction
- Background
- Diagnosis
- Management
- Adverse Event Reporting (VAERS)
- Discussion

Thrombosis with Thrombocytopenia Syndrome (TTS) after Johnson & Johnson (Janssen) COVID-19 vaccine: Background

April 20, 2021

John Su, MD, PhD, MPH

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

News 07/04/2021

EMA confirms overall benefit-risk remains positive

EMA's safety committee (PRAC) has concluded today that unusual blood clots with low blood platelets should be listed as very rare side effects of Vaxzevria (formerly COVID-19 Vaccine AstraZeneca).

In reaching its conclusion, the committee took into consideration all currently available evidence, including the advice from an ad hoc expert group.

EMA is reminding healthcare professionals and people receiving the vaccine to remain aware of the possibility of very rare cases of blood clots combined with low levels of blood platelets occurring within 2 weeks of vaccination. So far, most of the cases reported have occurred in women under 60 years of age within 2 weeks of vaccination. Based on the currently available evidence, specific risk factors have not been confirmed.

People who have received the vaccine should seek medical assistance immediately if they develop symptoms of this combination of blood clots and low blood platelets (see below).

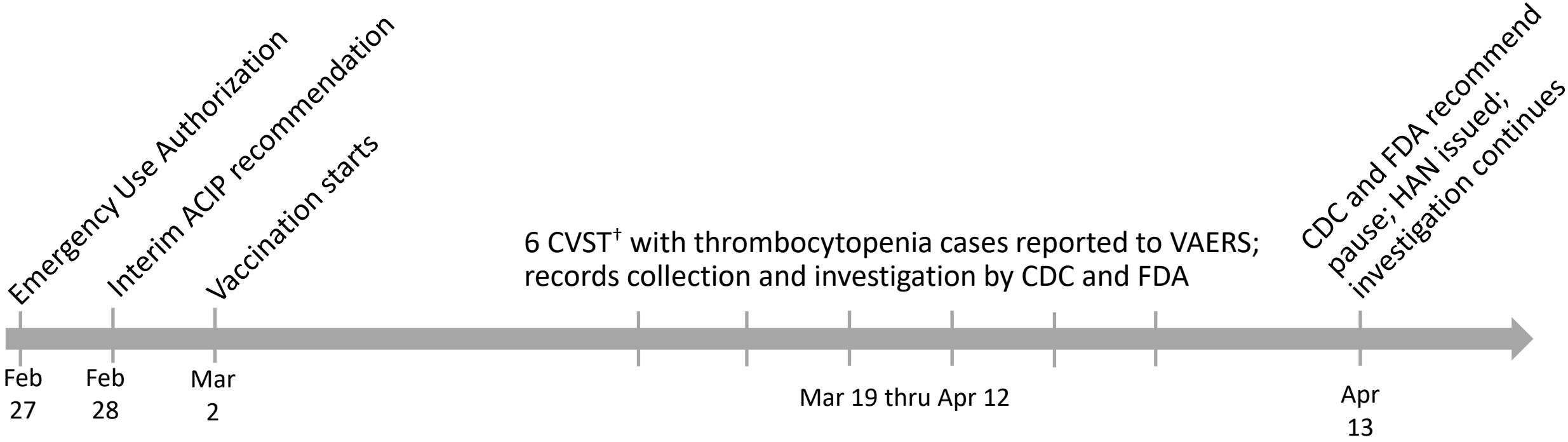
The PRAC noted that the blood clots occurred in veins in the brain (cerebral venous sinus thrombosis, CVST) and the abdomen (splanchnic vein thrombosis) and in arteries, together with low levels of blood platelets and sometimes bleeding.

The Committee carried out an in-depth review of 62 cases of cerebral venous sinus thrombosis and 24 cases of splanchnic vein thrombosis reported in the EU drug safety database (EudraVigilance) as of 22 March 2021, 18 of which were fatal.[1] The cases came mainly from spontaneous reporting systems of the EEA and the UK, where around 25 million people had received the vaccine.

COVID-19 is associated with a risk of hospitalisation and death. The reported combination of blood clots and low blood platelets is very rare, and the overall benefits of the vaccine in preventing COVID-19 outweigh the risks of side effects.

https://www.ema.europa.eu/en/news/astrazenecas-covid-19-vaccine-ema-finds-possible-link-very-rare-cases-unusual-blood-clots-low-blood

Janssen COVID-19 Vaccine Timeline* (2021)



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

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Thrombotic Thrombocytopenia after ChAdOx1 nCov-19 Vaccination

Andreas Greinacher, M.D., Thomas Thiele, M.D., Theodore E. Warkentin, M.D., Karin Weisser, Ph.D., Paul A. Kyrle, M.D., and Sabine Eichinger, M.D.

CONCLUSIONS

Vaccination with ChAdOx1 nCov-19 can result in the rare development of immune thrombotic thrombocytopenia mediated by platelet-activating antibodies against PF4, which clinically mimics autoimmune heparin-induced thrombocytopenia. (Funded by the German Research Foundation.)

https://www.nejm.org/doi/full/10.1056/NEJMoa2104840
(April 9, 2021)

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 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 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.

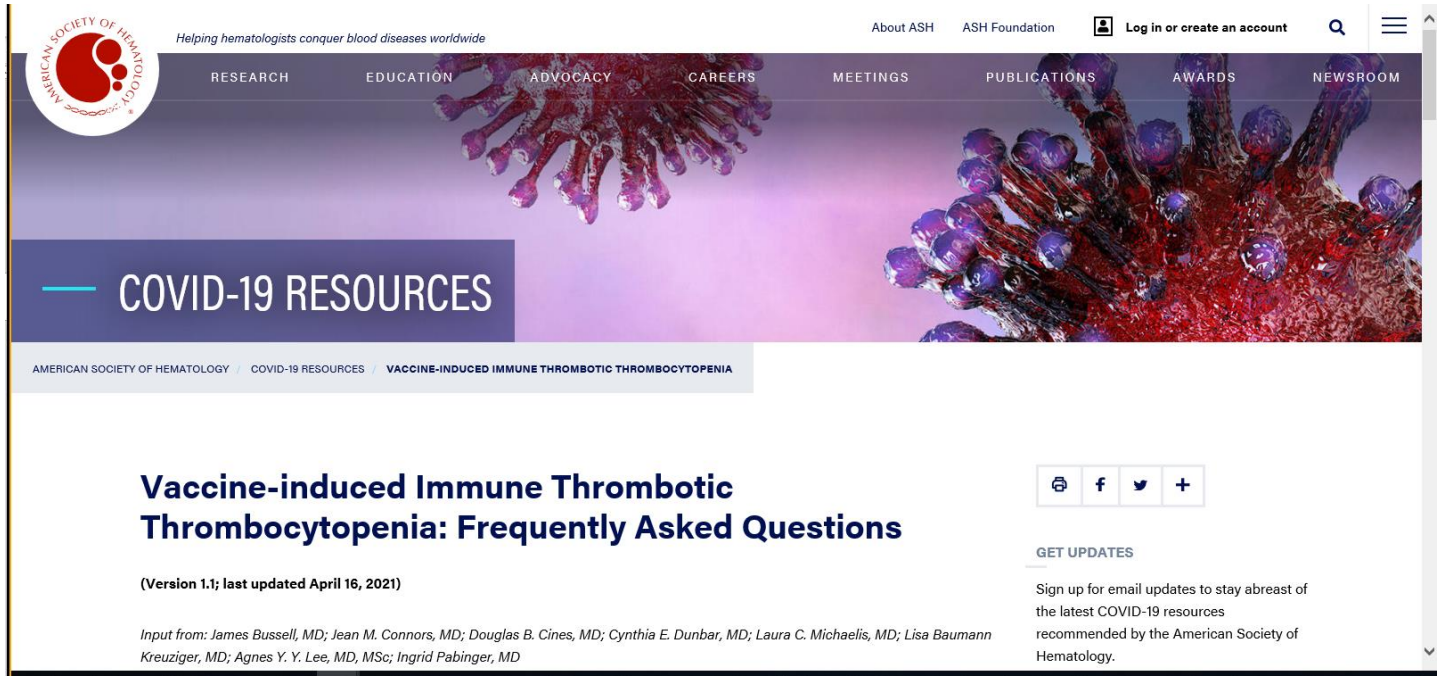
CDC will convene an emergency meeting of the Advisory Committee on Immunization Practices (ACIP) on Wednesday, April 14, 2021, to further review these cases and assess potential implications on vaccine policy. FDA will review that analysis as it also investigates these cases. Until that process is complete, 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

https://emergency.cdc.gov/han/2021/han00442.asp

U.S. National Response

- Health Alert Network Health Alert
  - Second in CDC history (first was after September 11, 2001)
- American Society for Hematology
  - Developed and released FAQ (https://www.hematology.org/covid-19/vaccine-induced-immune-thrombotic-thrombocytopenia)



U.S. Reports of TTS, as of April 16, 2021 (N = 6)

- 6 reports of CVST with thrombocytopenia (platelet counts <150K/mm3) following 6.86 million doses of Johnson & Johnson (Janssen) nCoV-19 vaccine administered
  - Crude reporting rate of 0.87 cases per million doses administered
- All reports of TTS were of CVST, which is rare, but clinically serious, and can result in substantial morbidity and mortality
  - **CVST is not usually associated with thrombocytopenia**
  - All 6 reports were in women age range 18–48 years, all with thrombocytopenia
  - No obvious patterns of risk factors detected

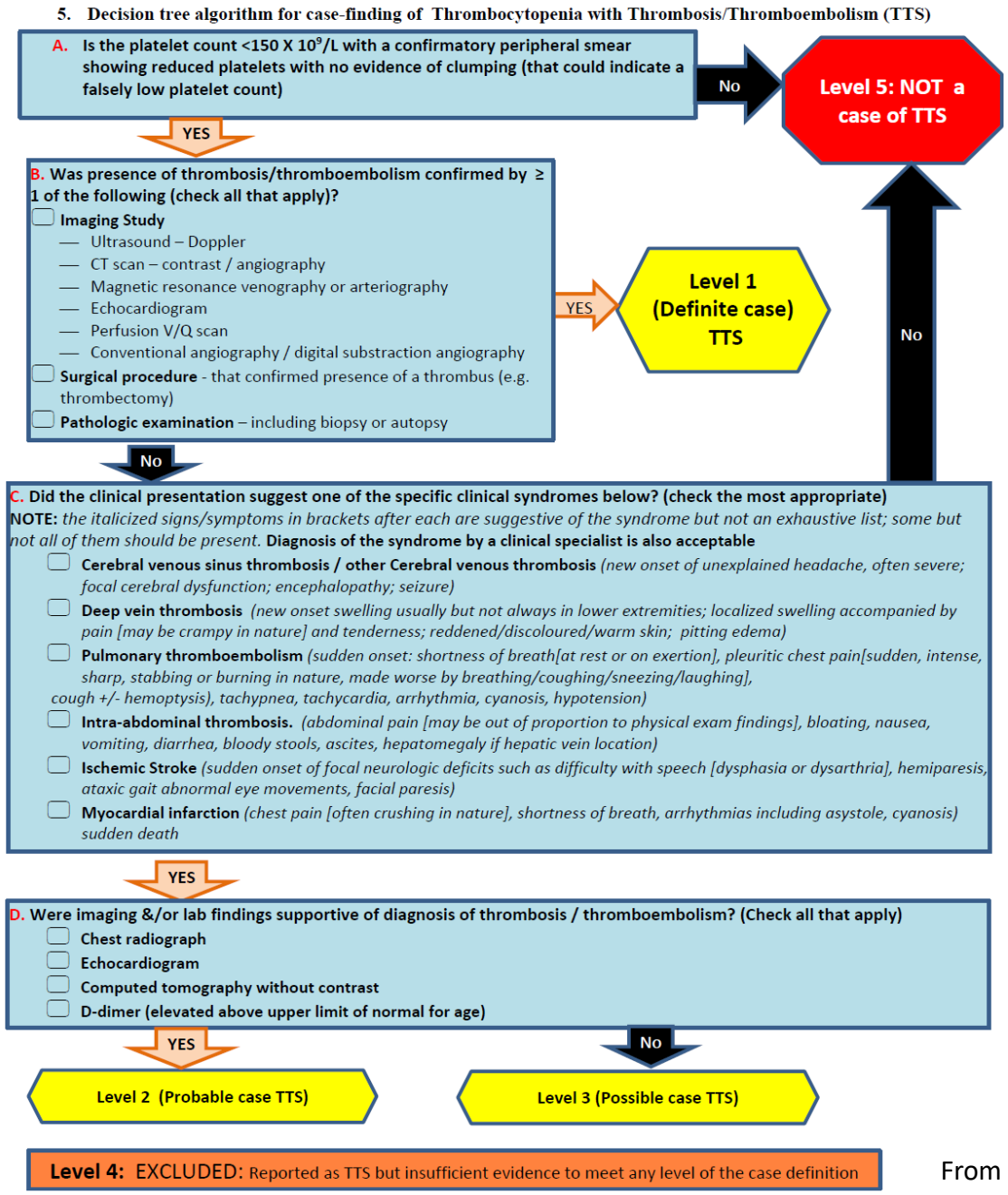
U.S. Reports of TTS, as of April 16, 2021 (N = 6)

- CVST with thrombocytopenia has not been observed after administration of the two authorized mRNA vaccines
  - 182 million mRNA COVID-19 doses administered with no reported cases to date
- Clinical features of Janssen cases are like those observed following the AstraZeneca COVID-19 vaccine in Europe
- Both Janssen and AstraZeneca vaccines contain replication-incompetent adenoviral vectors
  - human (Ad26.COV2.S) for Janssen
  - chimpanzee (ChAdOx1) for AstraZeneca

Potential Signs and Symptoms of TTS*

- Severe headache
- Backache
- New neurologic symptoms
- Severe abdominal pain
- Shortness of breath
- Leg swelling
- Tiny red spots on the skin (petechiae)
- New or easy bruising

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



Thrombocytopenia (<150,000 per mm^3)

AND either

Confirmation of thrombosis/embolus by imaging, surgery, or pathology

OR

Symptoms consistent with CVST, DVT, PE, intra-abdominal thrombosis, ischemic stroke, or MI

From https://brightoncollaboration.us/thrombosis-with-thrombocytopenia-syndrome-case-finding-definition/

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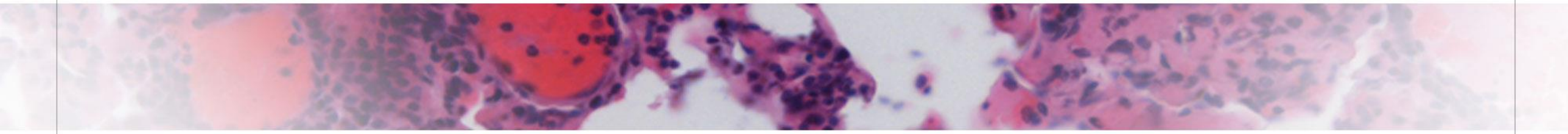

Vaccine-induced immune thrombotic thrombocytopenia: Diagnosis

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Brigham and Women's Hospital/Dana Farber Cancer Institute
Associate Professor of Medicine, Harvard Medical School

Conflict of Interest

- Scientific Advisory Boards and Consulting: Abbott, Bristol-Myers Squibb, Pfizer, Takeda
- Research Funding to Institution: CSL Behring

VITT – Vaccine Induced Immune Thrombotic Thrombocytopenia

ORIGINAL ARTICLE

April 9, 2021

(AZ)

Thrombotic Thrombocytopenia
after ChAdOx1 nCov-19 Vaccination

BRIEF REPORT

April 9, 2021

Thrombosis and Thrombocytopenia
after ChAdOx1 nCoV-19 Vaccination

(AZ)

CORRESPONDENCE

(J&J)

April 14, 2021

Thrombotic Thrombocytopenia after Ad26.COV2.S Vaccination

ORIGINAL ARTICLE

April 16, 2021

Pathologic Antibodies to Platelet Factor 4
after ChAdOx1 nCoV-19 Vaccination

Greinacher NEJM, 2021; Schultz NEJM, 2021; Muir NEJM, 2021; Scully NEJM, 2021.

Baseline characteristics reported in European VITT patients, All Astra-Zeneca ChAdOx1 nCOV-19 vaccine

	Austria/Germany	Norway	UK
Number of patients	11	5	23
Onset post vaccine, days	5-16	7-10	6-24
Age, years	22-49	32-54	21-77
Sex: male	2	1	9
female	9	4	14
Platelets x 10^9/L	13-37	10-70	7-113
PF4 assay positive	all	all	22/23

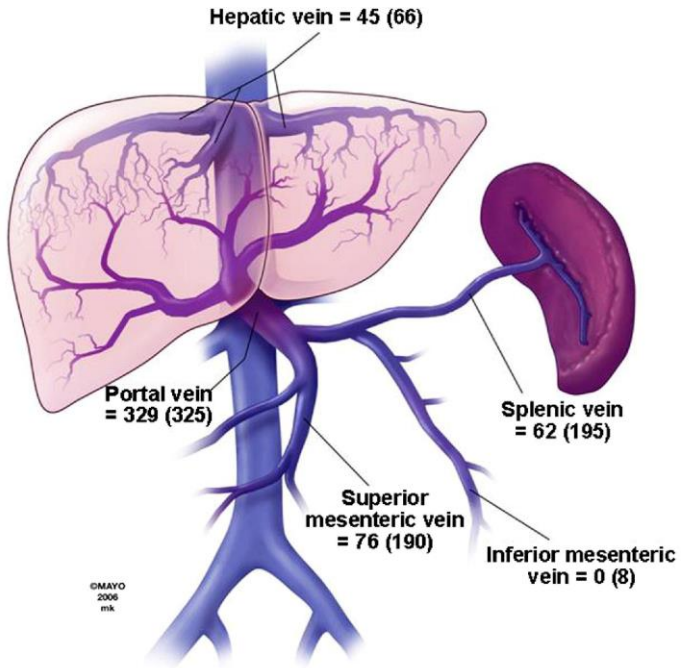
Norway: ChAdOx1 nCoV-19 vaccine administered to health care professionals <65 years of age not working with Covid-19 patients

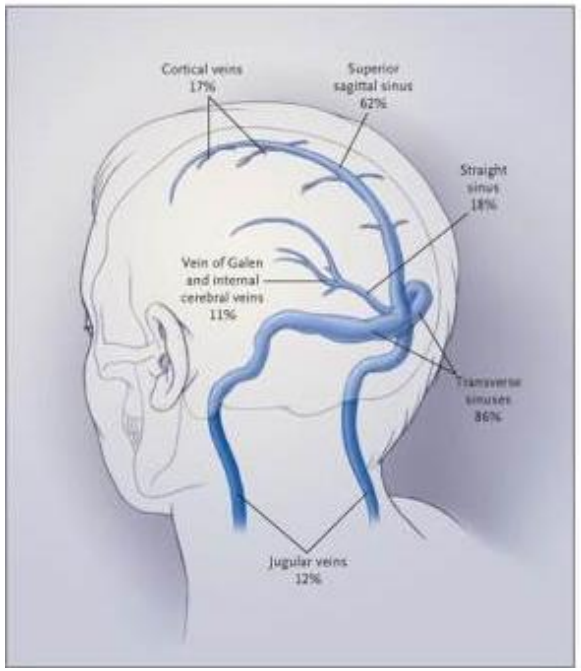
Greinacher NEJM, 2021; Schultz NEJM, 2021; Scully NEJM, 2021.

Clinical Signs and Symptoms

Reported findings

- Thrombosis in unusual locations
  - “typical” VTE sites also reported
- Thrombocytopenia
- Low fibrinogen
- Elevated D-dimer





Thrombosis in unusual locations: symptoms

- Cerebral venous sinus thrombosis (CVST)
  - Headache, vision changes, N/V, other neurologic symptoms
- Splanchnic vein thrombosis
  - Abdominal pain, back pain, N/V
- Portal, hepatic, splenic, mesenteric veins

Diagnostic tests

CBC with platelet count
- Platelets may be minimally decreased in early stages

Symptom directed imaging
- Must use IV contrast for head and abdominal imaging
- DVT, PE, multiple vascular beds and arterial thrombosis also reported

Heparin induced thrombocytopenia (HIT) assay
- Will discuss PF4 ELISA and functional platelet assays

Fibrinogen
- May be normal or low normal early in presentation
- Very low in severe cases

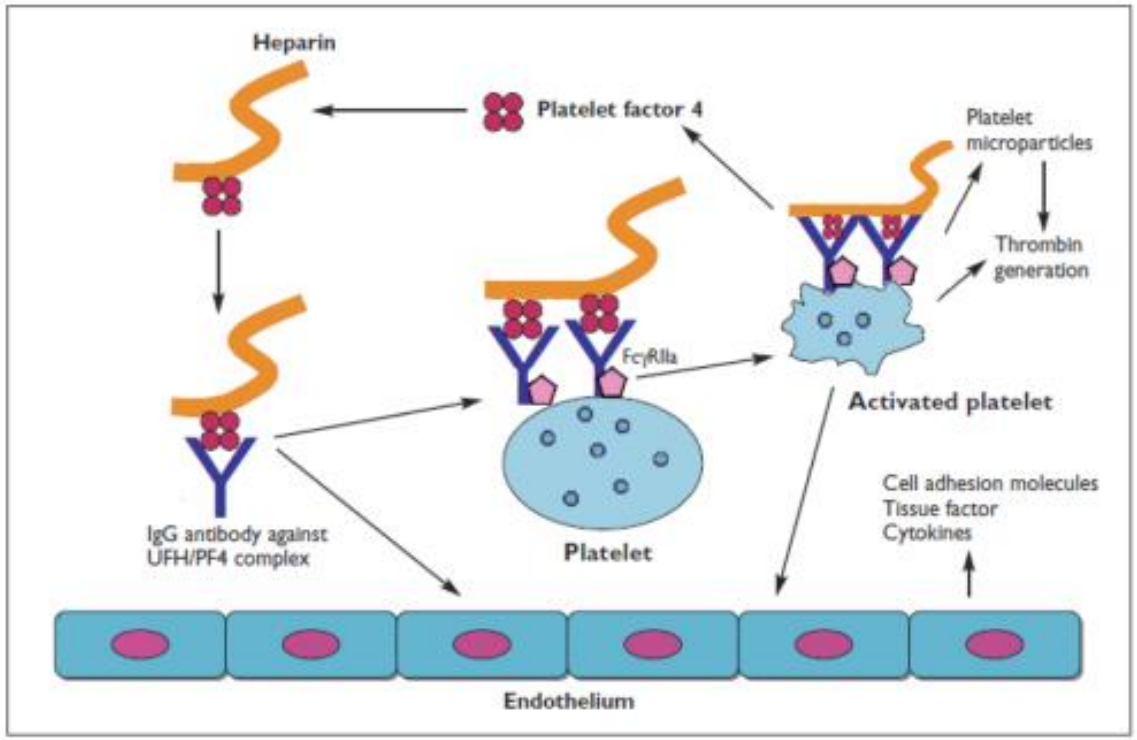
D-dimer
- Will be elevated in setting of thrombosis

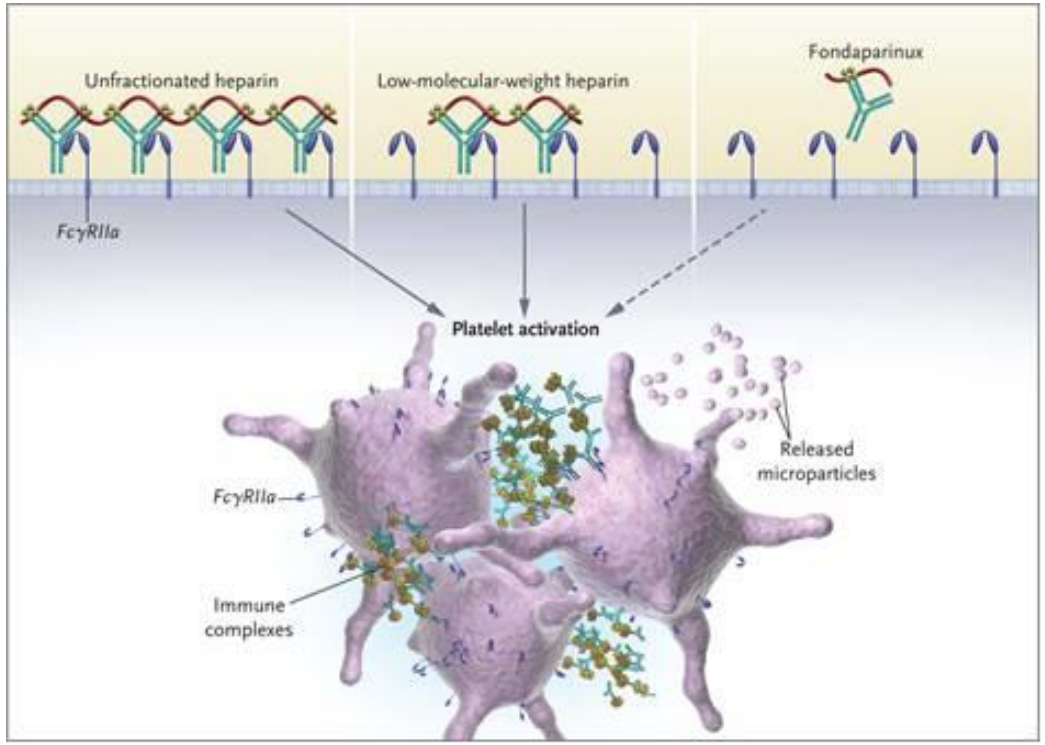
Journal of Thrombosis and Haemostasis, **15**: 2099–2114 DOI: 10.1111/jth.13813

REVIEW ARTICLE

Autoimmune heparin-induced thrombocytopenia

A. GREINACHER,* K. SELLENG* and T. E. WARKENTIN†
*Institut für Immunologie und Transfusionsmedizin, Universitätsmedizin Greifswald, Greifswald, Germany; and †Department of Pathology and Molecular Medicine, Department of Medicine, and McMaster Centre for Transfusion Research, Michael G. DeGroote School of Medicine, McMaster University, Hamilton, Ontario, Canada





Auto-immune HIT: endogenous polyanion substitutes for heparin

Lefkowitz, An Algorithmic Approach to Hemostasis Testing, 2008; Greinacher, NEJM 2015.

HIT assays

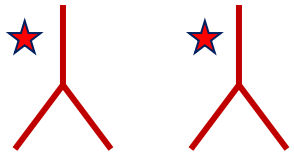
Heparin-PF4 Antibody detection

- Heparin-PF4 enzyme-linked immunosorbent assay (ELISA)
  - Standard ELISA technology
  - IgG detection has best specificity
- Rapid immunoassays (RI)
  - Have not been tested/validated in VITT
  - Magnetic beads coated with PF4 and heparin substitute
  - Particle gel immunoassay (PaGIA)

Functional platelet activation assays

- Serotonin release assay (SRA) “gold standard for HIT
- Other sophisticated assays using normal platelets to check for platelet activation by the patient’s serum containing antibodies are not available at many institutions but may be available on a send-out basis for confirmation in some settings.

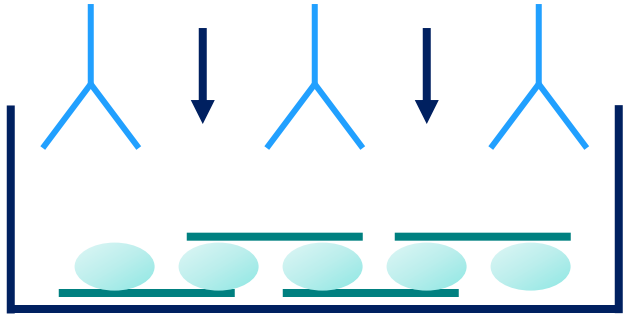
Heparin/PF4 ELISA



Anti-IgG

Patient Plasma

HIT: Anti-heparin/PF4



Patient Plasma

VITT: anti-? polyanion/PF4

PF4 and heparin or heparin-like molecules

Color indicator with read out of optical density or OD

HIT assays: what we know with VITT

- For HIT diagnosis, PF4 ELISA has excellent NPP but mediocre PPV
  - Low levels of antibodies are common in some clinical settings, e.g. cardiovascular surgery

- **VITT cases to date**:
  - Marked positive PF4 IgG ELISA with high OD
  - Addition of high dose heparin inhibits OD
  - Platelet activation by patient serum
    - Does not require heparin
    - Inhibited by high dose heparin
    - Inhibited by antibody IV.3 which blocks FcRγIIA
    - May be augmented by adding PF4
  - Rapid immunoassays shown not to be as reliable as standard PF4 IgG ELISA
    - Magnetic beads (HemosIL AcuStar HIT IgG) negative but ELISA positive in the UK cases

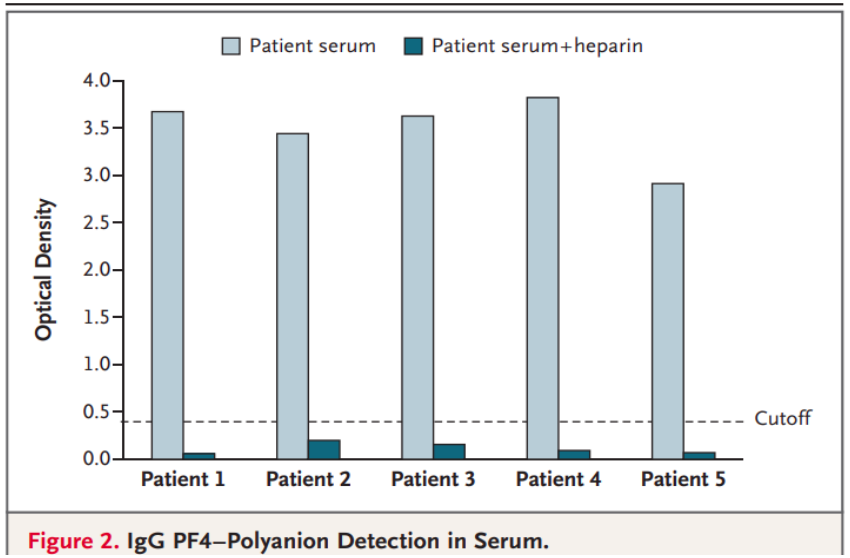


Figure 2. IgG PF4–Polyanion Detection in Serum.

Schultz, NEJM 2021

Diagnostic steps

- **High index of suspicion in recently vaccinated patients**
  - **Time** from vaccination is key
    - 5 to 24 days reported, outside this window by a few days may still be VITT
  - Thrombosis in unusual locations but typical VTE have been reported
- **Order tests**
  - CBC and platelet count
  - Heparin/PF4 IgG ELISA
  - Fibrinogen
  - D-dimer
- **Initiate treatment**
  - If thrombocytopenia and thrombosis in unusual location, **don’t wait** for PF4 ELISA results to initiate treatment

If within window post vaccine with DVT or PE but no thrombocytopenia avoid heparin anticoagulants and follow for more severe sequelae

Final comments

- Knowledge is evolving in real time
- Mechanism of development of prothrombotic state and relationship to vaccine unknown
- Patient specific factors not clear, easy to speculate based on reported data but better understanding of pathophysiology and contributing risks is needed

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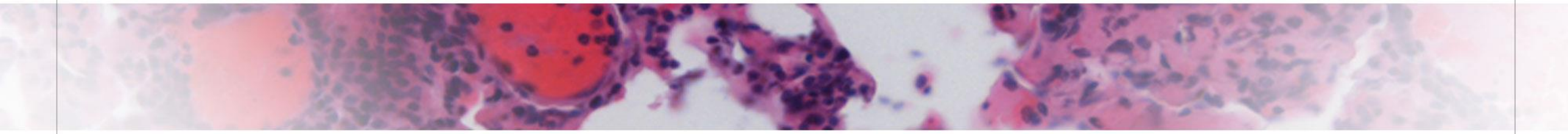


Management of VITT

Lisa Baumann Kreuziger, MD, MS

Associate Investigator, Blood Research Institute, Versiti

Associate Professor, Hematology & Oncology, Medical College of Wisconsin

Conflict of Interest

- Consulting: CSL Behring, Quercegen Pharmaceuticals, HHS Vaccine Injury Compensation Program
- Intellectual Conflict of Interest: ASH FAQ contributor, NIH COVID-19 Guideline Panel

Management of VITT

Similar to autoimmune HIT

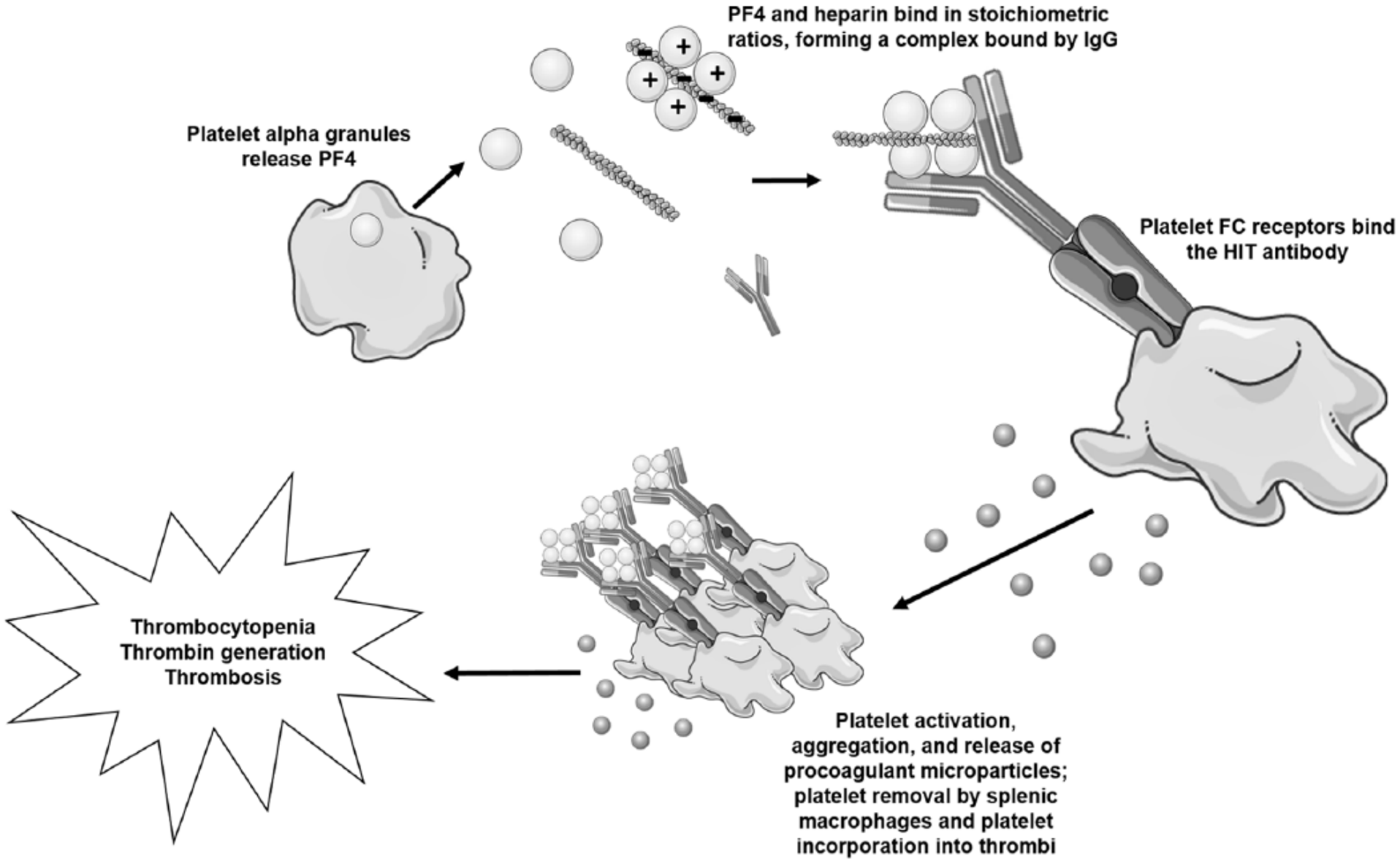
Avoid heparin & use non-heparin anticoagulant

IV Immunoglobulin (IVIG)

Avoid platelet transfusion*

Consider referral to tertiary care center for expertise in hemostasis

Pathophysiology of HIT



Hogan & Berger. Vascular Medicine 2020, Vol. 25(2) 160–173

Anticoagulation

Non-Heparin anticoagulant

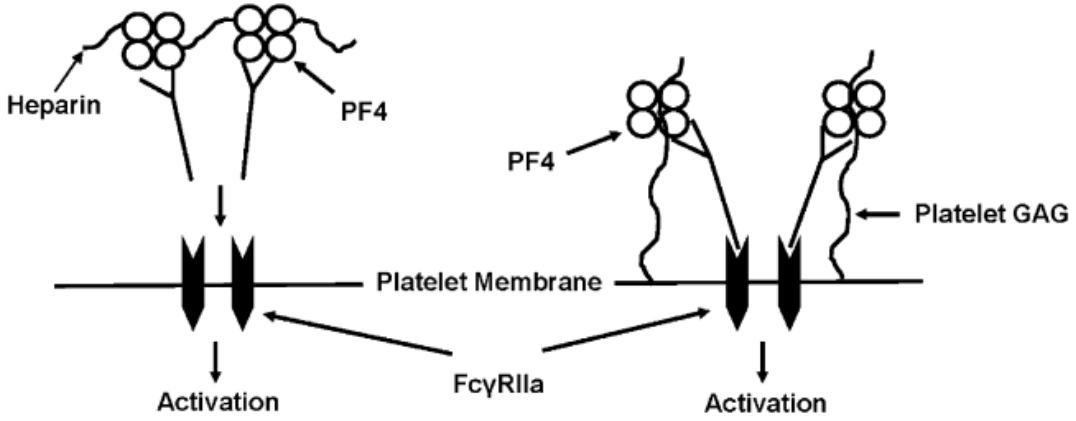
- IV direct thrombin inhibitor (bivalirudin, argatroban)
- Fondaparinux
- Apixaban or rivaroxaban

Treat for 3 months for provoked thrombosis

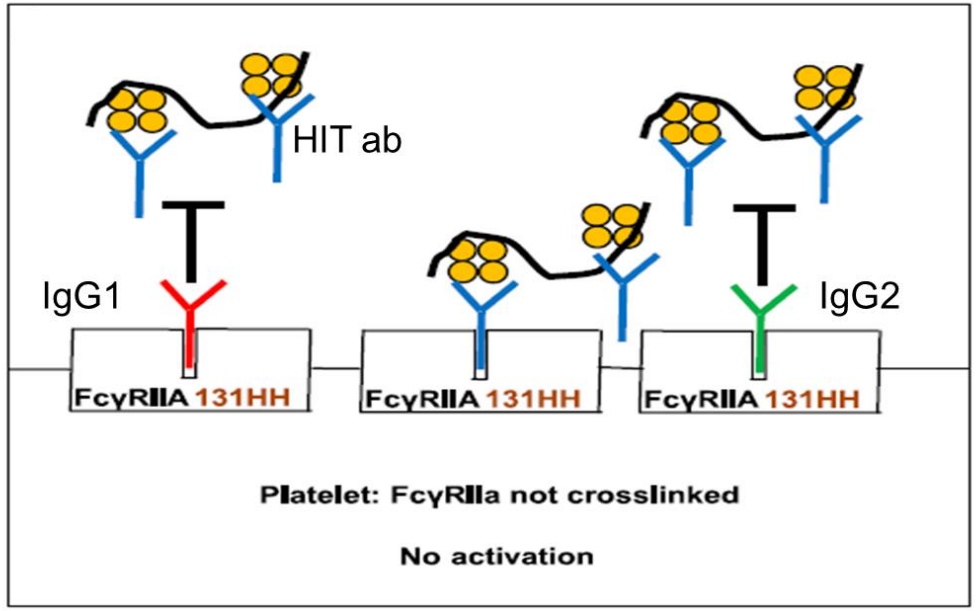
IVIG

- Decrease platelet activation
- 1-2 grams/kg IV in divided doses
- Give early if recognized
- Used in ITP also
  - Consider while awaiting PF4 ELISA

HIT

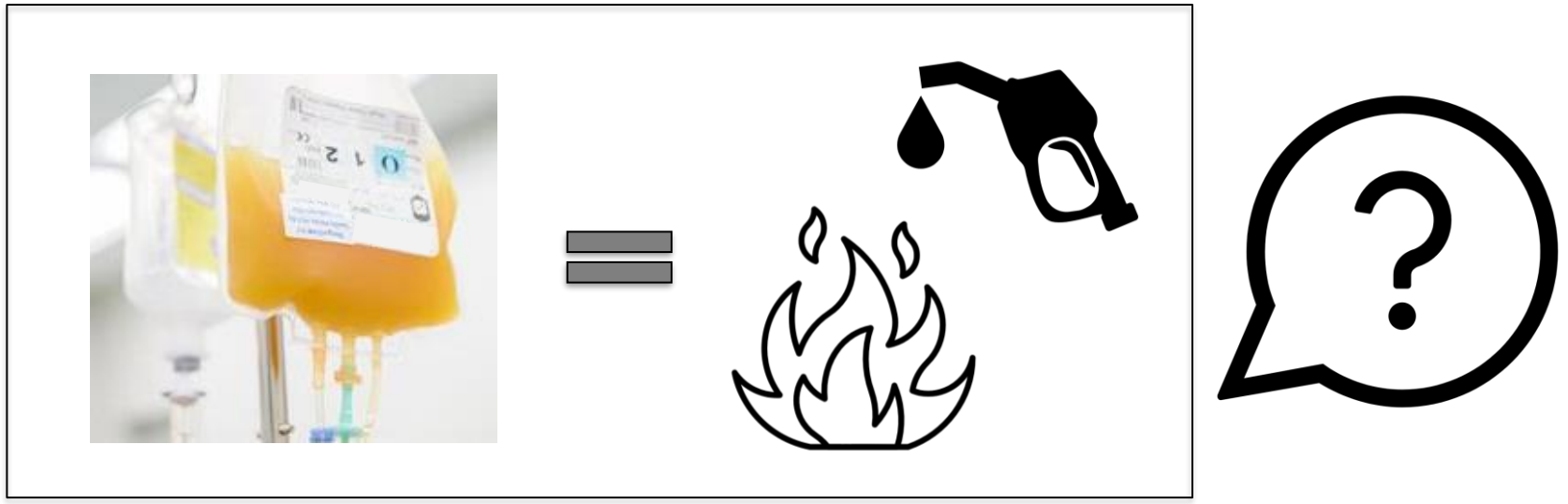


IVIG



https://b-s-h.org.uk/about-us/news/guidance-produced-by-the-expert-haematology-panel-ehp-focussed-on-vaccine-induced-thrombosis-and-thrombocytopenia-vitt/
Hamostaseologie 2021 Apr 1.doi: 10.1055/a-1469-7481. Padmanabhan et al, Blood 2015.

Platelet transfusions



- Worse mortality in HIT with platelet transfusions→ Avoid platelet transfusions
- Cerebral vein thrombosis can have intracranial hemorrhage
  - Not a contraindication to anticoagulation
  - Present in 4 of 6 patients reported after J&J/Janssen vaccination
  - Occurred in 3 of 13 patients with CVT after AZ vaccination
    - Additional thrombotic events after receiving platelet transfusion or heparin
- Determine risk benefit ratio after IVIG if severe hemorrhage or emergent surgery

Blood. 2015 Feb 26; 125(9): 1470–1476. https://bit.ly/3sigzZd
Scully M. et al. NEJM DOI: 10.1056/NEJMoa2105385

Overlap with Disseminated Intravascular Coagulation?

- High D-dimer levels and low fibrinogen reported in cases of VITT

N	Vaccine	Low Fibrinogen	Elevated D-dimer	Reference
5	AZ	3/5 (60%)	5/5 (100%)	Schultz (DOI: 10.1056/NEJMoa2104882)
11	AZ	3/6 (50%)	7/7 (100%)	Greinacher (DOI: 10.1056/NEJMoa2104840)
1	J&J/Janssen	1 (100%)	1 (100%)	Muir (DOI: 10.1056/NEJMc2105869)
23	AZ	13/23 (57%)	21/21 (100%)	Scully (DOI: 10.1056/NEJMoa2105385)

- Consider correction of fibrinogen to >150 mg/dl
- Incidence may change as recognized earlier in disease course

https://b-s-h.org.uk/about-us/news/guidance-produced-by-the-expert-haematology-panel-ehp-focussed-on-vaccine-induced-thrombosis-and-thrombocytopenia-vitt/
Hamostaseologie 2021 Apr 1.doi: 10.1055/a-1469-7481.

What if….?

- Situations will arise as more people tested & early recognition of VITT
- Other reasons for thrombocytopenia & thrombosis (e.g., cancer-associated thrombosis)→ PF4 ELISA
- DVT or PE after vaccination without thrombocytopenia
  - Avoid heparin (consider DOAC)
  - Await PF4 ELISA results
  - Follow platelet count
- Thrombocytopenia & positive PF4 ELISA without thrombosis
  - Consider IVIG
  - Consider non-heparin anticoagulant

Should aspirin be given to patients after J&J vaccination?

NO

- Blocking thromboxane does not block platelet activation in HIT
- Aspirin is associated with risk of bleeding (RR 1.3)
- Incidence of VITT is RARE

Polgar, et al. Blood 1998; 91 (2): 549-54. NEJM 1989 Jul 20;321(3):129-35.

Management of VITT

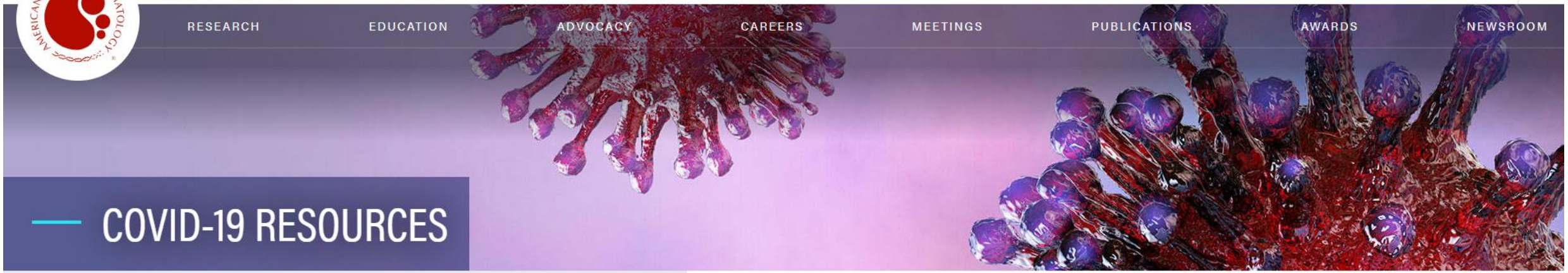
Similar to autoimmune HIT

Avoid heparin & use non-heparin anticoagulant

IV Immunoglobulin (IVIG)

Avoid platelet transfusion*

Consider referral to tertiary care center for expertise in hemostasis



COVID-19 RESOURCES

Vaccine-induced Immune Thrombotic Thrombocytopenia: Frequently Asked Questions

(Version 1.1; last updated April 16, 2021)

Input from: James Bussell, MD; Jean M. Connors, MD; Douglas B. Cines, MD; Cynthia E. Dunbar, MD; Laura C. Michaelis, MD; Lisa Baumann Kreuziger, MD; Agnes Y. Y. Lee, MD, MSc; Ingrid Pabinger, MD

HTTPS://WWW.HEMATOLOGY.ORG/COVID-19/VACCINE-INDUCED-IMMUNE-THROMBOTIC-THROMBOCYTOPENIA

Thrombosis with Thrombocytopenia Syndrome (TTS) after Johnson & Johnson (Janssen) COVID-19 vaccine: Reporting Adverse Events

April 20, 2021

John Su, MD, PhD, MPH

How to Report an Adverse Event to VAERS

- Managed by CDC and FDA
- Go to vaers.hhs.gov
- Submit a report online
- For help:

  Call 1-800-822-7967

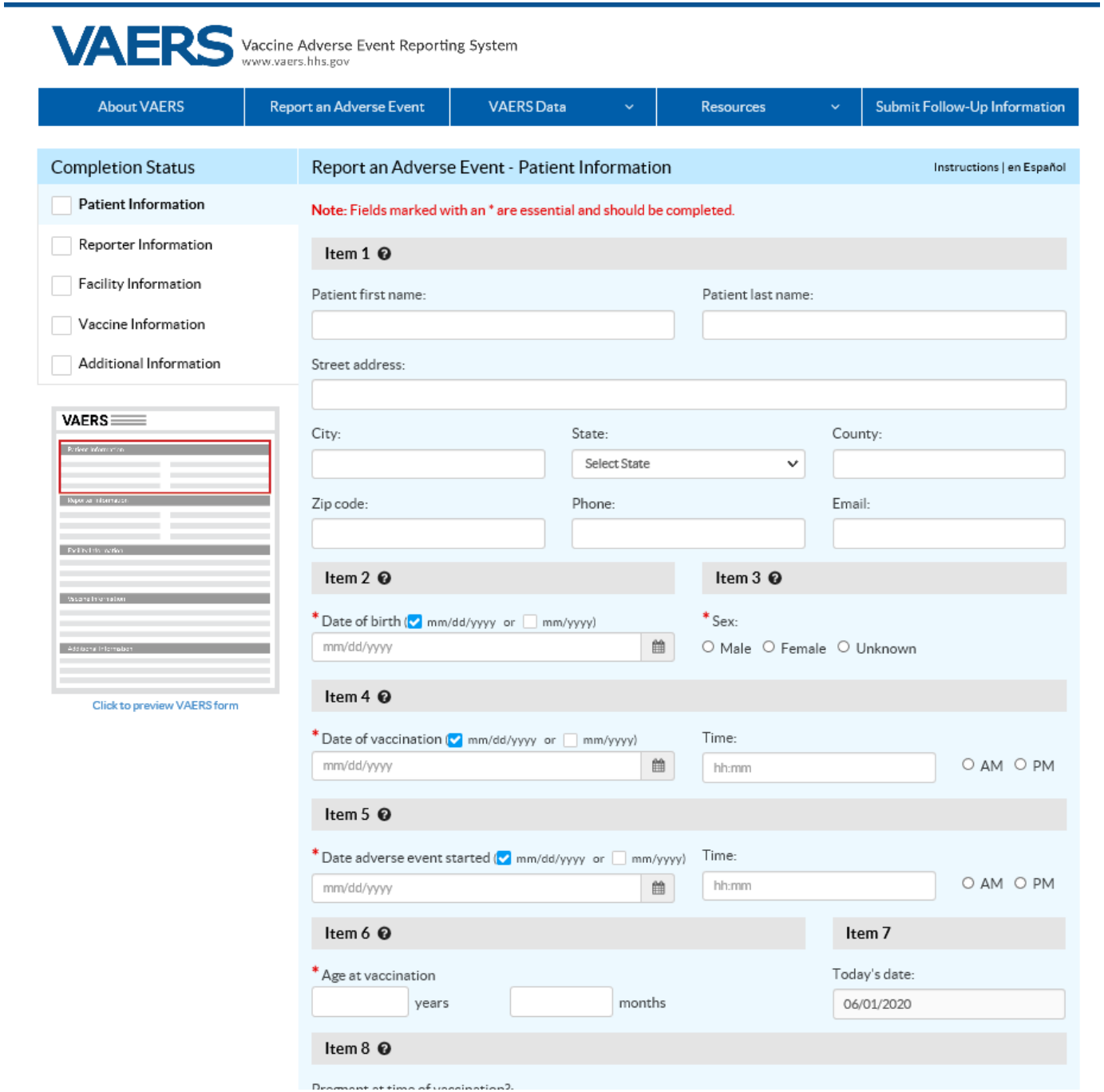
  Email info@VAERS.org

  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

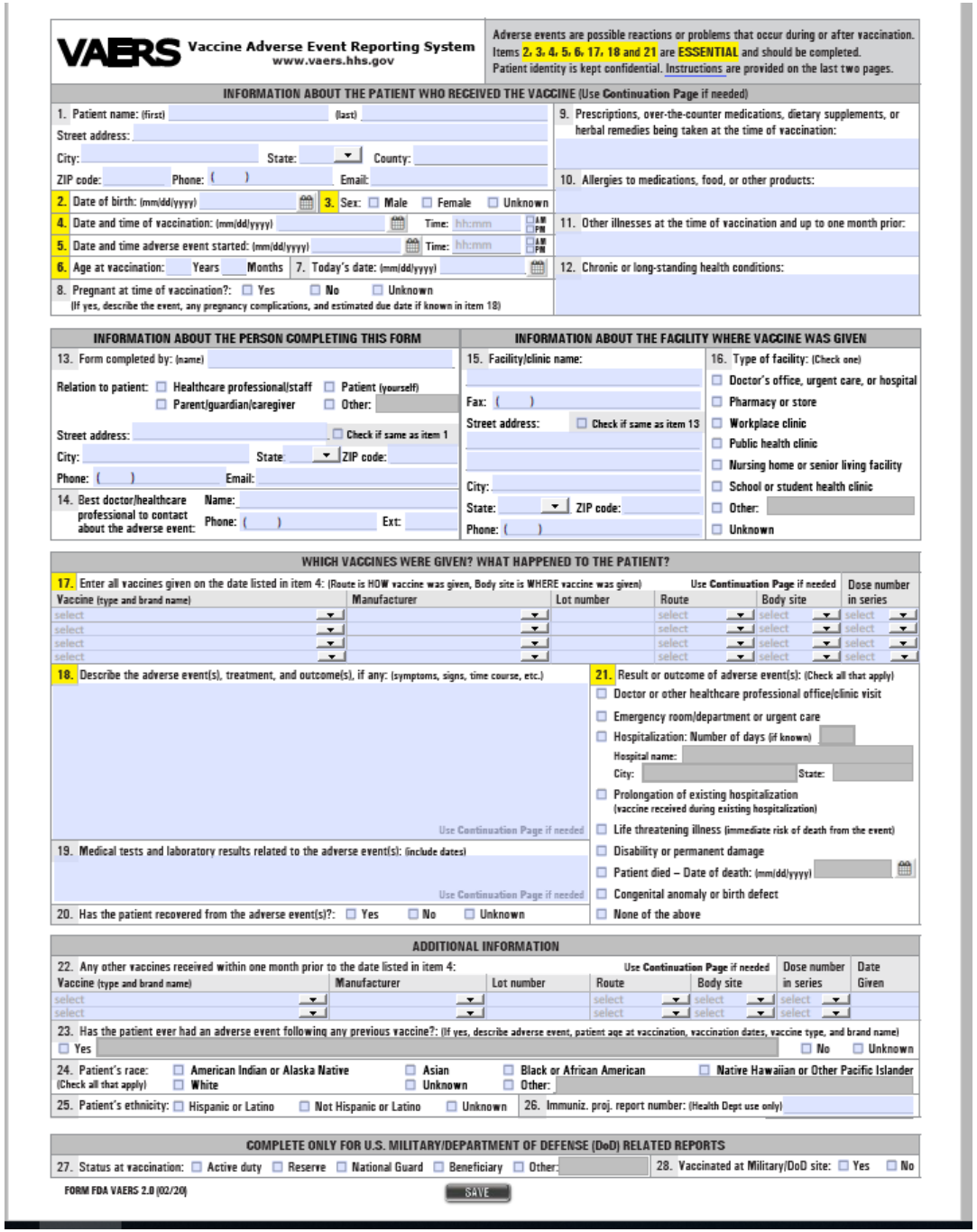
Reporting to VAERS – by website

- https://vaers.hhs.gov/esub/index.jsp
- Times out after **20 MINUTES** of inactivity
  - Warning at 15 minutes



Reporting to VAERS – by electronic form

- https://vaers.hhs.gov/uploadFile/index.jsp
- Can fill and upload **at your convenience**



VAERS Vaccine Adverse Event Reporting System
www.vaers.hhs.gov

Adverse events are possible reactions or problems that occur during or after vaccination. Items 2, 3, 4, 5, 6, 17, 18 and 21 are ESSENTIAL and should be completed. Patient identity is kept confidential. Instructions are provided on the last two pages.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE (Use Continuation Page if needed)

1. Patient name: (first) (last)
Street address:
City: State: County:
ZIP code: Phone: ( ) Email:
2. Date of birth: (mm/dd/yyyy) 3. Sex: Male Female Unknown
4. Date and time of vaccination: (mm/dd/yyyy) Time: hh:mm AM PM
5. Date and time adverse event started: (mm/dd/yyyy) Time: hh:mm AM PM
6. Age at vaccination: Years Months 7. Today's date: (mm/dd/yyyy)
8. Pregnant at time of vaccination?: Yes No Unknown
(If yes, describe the event, any pregnancy complications, and estimated due date if known in item 18)
9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:
10. Allergies to medications, food, or other products:
11. Other illnesses at the time of vaccination and up to one month prior:
12. Chronic or long-standing health conditions:

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

13. Form completed by: (name)
Relation to patient: Healthcare professional/staff Patient (yourself) Parent/guardian/caregiver Other:
Street address: Check if same as item 1
City: State: ZIP code:
Phone: ( ) Email:
14. Best doctor/healthcare professional to contact about the adverse event: Name:
Phone: ( ) Ext:

INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN

15. Facility/clinic name:
Fax: ( )
Street address: Check if same as item 13
City:
State: ZIP code:
Phone: ( )
16. Type of facility: (Check one)
Doctor's office, urgent care, or hospital
Pharmacy or store
Workplace clinic
Public health clinic
Nursing home or senior living facility
School or student health clinic
Other:
Unknown

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given) Use Continuation Page if needed

Vaccine (type and brand name)	Manufacturer	Lot number	Route	Body site	Dose number in series
select			select	select	select
select			select	select	select
select			select	select	select
select			select	select	select

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)
Use Continuation Page if needed
19. Medical tests and laboratory results related to the adverse event(s): (include dates)
Use Continuation Page if needed
20. Has the patient recovered from the adverse event(s)?: Yes No Unknown
21. Result or outcome of adverse event(s): (Check all that apply)
Doctor or other healthcare professional office/clinic visit
Emergency room/department or urgent care
Hospitalization: Number of days (if known)
Hospital name:
City: State:
Prolongation of existing hospitalization (vaccine received during existing hospitalization)
Life threatening illness (immediate risk of death from the event)
Disability or permanent damage
Patient died – Date of death: (mm/dd/yyyy)
Congenital anomaly or birth defect
None of the above

ADDITIONAL INFORMATION

22. Any other vaccines received within one month prior to the date listed in item 4: Use Continuation Page if needed

Vaccine (type and brand name)	Manufacturer	Lot number	Route	Body site	Dose number in series	Date Given
select			select	select	select	
select			select	select	select	

23. Has the patient ever had an adverse event following any previous vaccine?: (If yes, describe adverse event, patient age at vaccination, vaccination dates, vaccine type, and brand name)
Yes No Unknown
24. Patient's race: (Check all that apply) American Indian or Alaska Native Asian Black or African American Native Hawaiian or Other Pacific Islander White Unknown Other:
25. Patient's ethnicity: Hispanic or Latino Not Hispanic or Latino Unknown
26. Immuniz. proj. report number: (Health Dept use only)

COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

27. Status at vaccination: Active duty Reserve National Guard Beneficiary Other:
28. Vaccinated at Military/DoD site: Yes No

FORM FDA VAERS 2.0 (02/20)
SAVE

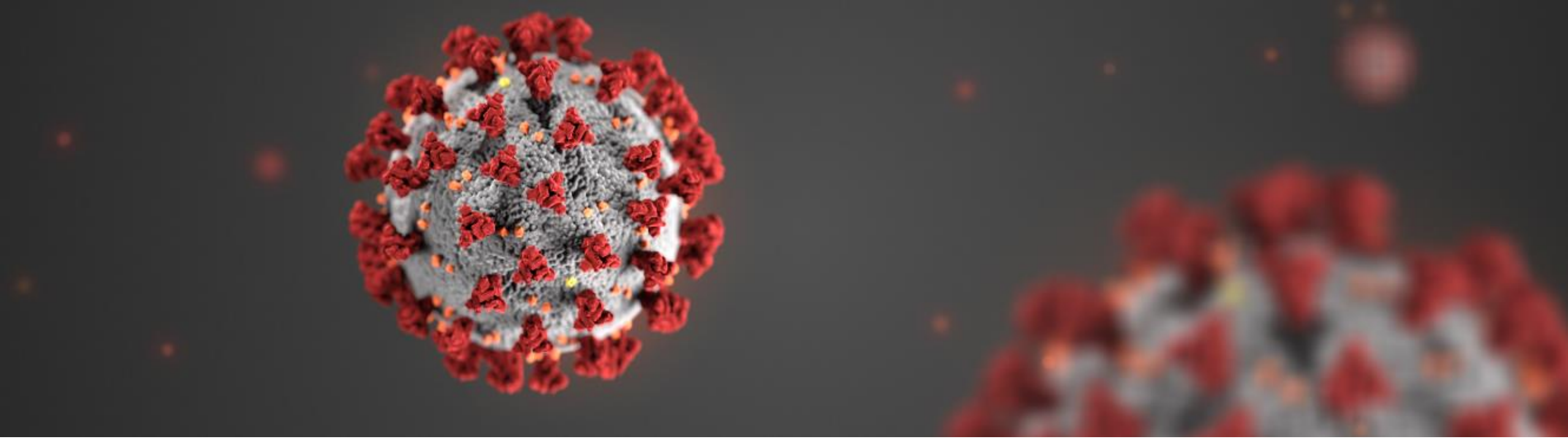
Diagnosis and Management of Suspected Vaccine-induced Immune Thrombotic Thrombocytopenia Following Johnson & Johnson (Janssen) COVID-19

Discussion

Diagnosis and Management of Suspected Vaccine-induced Immune Thrombotic Thrombocytopenia Following Johnson & Johnson (Janssen) COVID-19

Thank You

cdc.gov/coronavirus



For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

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.