

After the Pause – What Do We Advise?

USET ECHO Presentation

May 7, 2021

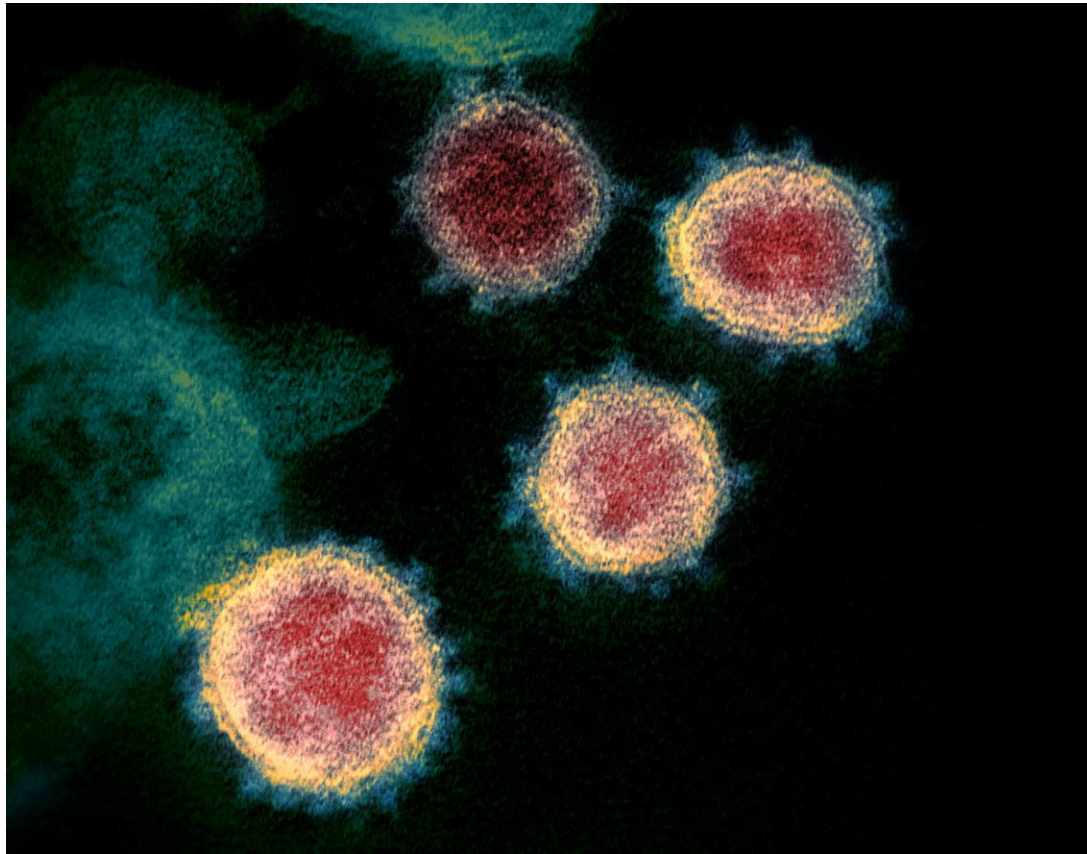
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Day 423 of the COVID-19 Pandemic: Objectives



- 1) Become familiar with the rare, but serious side effect of TTS with the Janssen (J&J) vaccine
- 2) Be able to adequately counsel patients on the risks and benefits of the Janssen (J&J) vaccine

No disclosures, conflicts of interest

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What's Good at 14 Months into This Era?

- We have 3 effective vaccines in the US for COVID-19
- Cases are going down overall in the US
- The US has administered 250 million doses of vaccine
- 32% of the total population is now **fully** vaccinated
- 41% of the adult population (18+) is **fully** vaccinated
- 70% of the 65+ population is **fully** vaccinated
- There will soon be a vaccine (or 2) for the 12 – 17 year old age group

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Ad26.COV2.S – (Janssen/J&J Vaccine)

- Non-replicating viral-vectored vaccine (adenovirus 26)
- 66% efficacy at preventing symptomatic infection
- 85% effective at preventing severe disease
- Highly effective at preventing hospitalization and death (almost 100%)
- Single dose!
- Refrigerator storage

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The Pause – Janssen Vaccine Timeline

- 2/27/21 – EUA issued by FDA for individuals 18 and older
- 4/13/21 – CDC and FDA recommended a pause in administration after 6 cases of cerebral venous sinus thrombosis with thrombocytopenia were reported
- 2 emergency meetings of ACIP (Advisory Committee on Immunization Practices) were held to review safety concerns
- 4/23/21 – ACIP re-affirmed its recommendation for use of the vaccine in all age groups, along with a warning that rare clotting events could occur within 3 weeks after vaccination, esp in women 18 - 49

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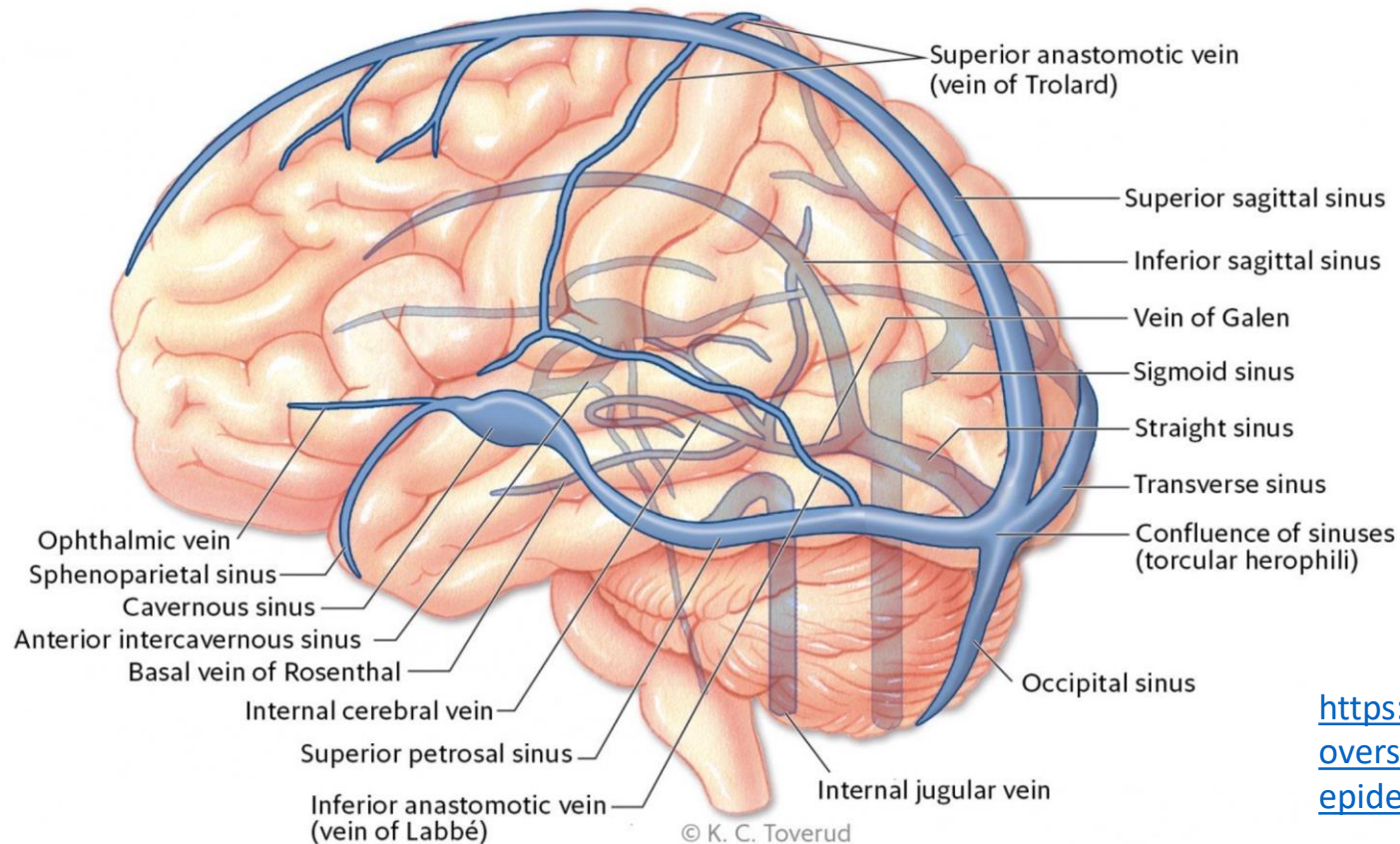
What Was the Serious Side-Effect that Led to the Pause?

- CVST – Cerebral Venous Sinus Thrombosis
- Thrombocytopenia – low platelet count
- TTS – Thrombosis with Thrombocytopenia Syndrome
- VITT – Vaccine-Induced Immune Thrombosis with Thrombocytopenia
- VAERS – Vaccine Adverse Event Reporting System
- By 4/13, 6 cases of CVST with thrombocytopenia reported to VAERS

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Cerebral Venous Sinus Thrombosis - Anatomy



<https://tidsskriftet.no/en/2018/08/klinisk-oversikt/cerebral-venous-thrombosis-epidemiology-diagnosis-and-treatment>

Overview of cerebral venous system

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TTS and Janssen (J&J) Vaccine

- 2 cases of CVST in Phase 3 trial (1 in placebo group, 1 in vaccine group)
- 3/2 to 4/21, 7.98 million doses administered; 15 cases of TTS reported
- 13 of 15 cases in women 18 to 49 (oldest reported was 59)
- 12 of 15 had CVST with thrombocytopenia (3 had clots elsewhere)
- 3 of 15 died
- Highest rate in 30-39 yr old age group (11.8 cases/million)

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TTS and Janssen (J&J) Vaccine

- Symptom onset was 6 – 15 days after vaccination
- None were pregnant or within 12 weeks of delivery
- Several had risk factors for clots:
 - Obesity 7
 - Oral contraceptives 2
 - Hypothyroidism 2
 - High blood pressure 2

[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 | MMWR \(cdc.gov\)](#)

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CDC Risk-Benefit Analysis

If vaccination resumed in 18+, vaccination would prevent (in 6 months):

- 3926 – 9395 COVID hospitalizations
- 928 – 2236 ICU admissions
- 586 – 1435 **deaths** from COVID

There would be 26 cases of TTP *expected*

If vaccination only resumed in 50+:

- 54 – 257 **deaths** prevented
- 2 cases of TTP expected

[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 | MMWR \(cdc.gov\)](#)



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TTS after vaccination: Clinical Features

- Blood clots, esp cerebral veins, abdominal veins
- Symptoms – headache, back pain, abdominal pain, nausea, vomiting, new neurological symptoms (focal weakness, aphasia, visual disturbance, seizures); also leg pain, shortness of breath
- Thrombocytopenia
- Similar to problems seen with AstraZeneca vaccine
- Platelet-activating antibody against Platelet Factor 4 (PF-4)
- Similar to Heparin Induced Thrombocytopenia (HIT)

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Summary (What's the Bottom Line?)

- A rare but serious side-effect can occur in people receiving Janssen (J&J) Covid vaccine
- Overall risk ~2 per million, but higher (12 per M?) in younger women
- Patients should be counseled before vaccination; no cases of TTS associated with mRNA vaccines (Moderna, Pfizer/BioNTech)
- Patients and healthcare personnel should be aware of symptoms of TTS
- If patients present with symptoms, check platelet count and PF-4 ELISA, consult hematologist if positive

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References

[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 | MMWR \(cdc.gov\)](#)

For fact sheets for Providers and Patients:

[Janssen COVID-19 Vaccine Official HCP Website \(janssencovid19vaccine.com\)](#)

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Thank You for Your Time and Attention!

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