

# Johnson & Johnson/Janssen COVID-19 Vaccine and VITTS Update

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# Brief Recap of Events from April 2021

- 14 April: ACIP (vaccine advisory team) recommended a pause on the use of J&J single dose COVID vaccine due to safety concerns of a rare auto-immune clotting syndrome
  - Thrombosis with Thrombocytopenia Syndrome (TTS)
  - At the time 6 cases had been identified in the US
  - A similar safety concern in Europe occurred with a different vaccine that has same mechanism of action (adenovirus vector and DNA)
- After the pause, additional cases of this autoimmune clotting syndrome with low platelets were identified.
- As of 15 April, 15 cases confirmed out of 7.98 million vaccine doses given
- 23 April: ACIP voted to lift the pause and restart administration of J&J vaccine

## Reporting rates of TTS after Janssen COVID-19 vaccine in women

- 3.99 million vaccine doses administered to women\* with 15 confirmed TTS cases<sup>†</sup> as of April 21, 2021
  - Some age-specific doses administered data were imputed

	Females		
Age group	TTS cases	Doses admin	Reporting rate <sup>‡</sup>
18-29 years old	3	579,709	5.2 per million
30-39 years old	7	594,215	11.8 per million
40-49 years old	3	692,370	4.3 per million
50-64 years old	2	1,367,529	1.5 per million
65+ years old	0	757,710	0 per million

\* Source of doses administered: <https://covid.cdc.gov/covid-data-tracker/#vaccinations>; <sup>†</sup> One case was excluded from the final analysis: a female aged <50 years who had concurrent diagnosis of COVID-19 and TTS following receipt of Janssen vaccine; <sup>‡</sup> Reporting rate = TTS cases per 1 million Janssen COVID-19 vaccine doses administered

# Characteristics of patients with TTS after Janssen COVID-19 vaccine, N=15

- Median age 37 years (range 18–59)
- Median time to symptom onset 8 days (range 6–15 days)
- All cases occurred in females
- 12 cases were cerebral venous sinus thrombosis (CVST)
- Pregnant or post-partum\* (n=0)
- COVID-19 disease (n=2); both by history, no documentation of serology testing
- Risk factors for thrombosis<sup>†</sup>
  - Oral contraceptive use (n=2)
  - Obesity (n=7)
  - Hypothyroidism (n=2)
  - Hypertension (n=2)
  - Diabetes (n=0)
  - Coagulation disorders (n=0)

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

# Important Take Home Points

- FDA has added a warning to the J&J vaccine EUA and fact sheet regarding rare clotting event.
- TTS is rare, but appears to be very similar to another rare condition that happens in some patients who get heparin (blood thinner)
  - Heparin-Induced Thrombocytopenia (HIT)
  - Patients who have had this issue should already have it documented as a heparin allergy in their medical records
  - Highest risk seen in women <50 YO, and they should be made aware of the risk
- Experts advise patients with history of HIT should be offered a different COVID vaccine (mRNA vaccine, Pfizer or Moderna), especially if HIT happened within 90-180 days