

Blood Clots with Low Platelets Very Rare After COVID-19 Vaccination

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We reviewed 13,321,570 vaccine administrations across 8,081,360 patients to see whether different vaccination types were associated with four criteria typically associated with Thrombosis with Thrombocytopenia Syndrome (TTS).¹⁻³ We evaluated COVID-19 vaccinated patients admitted with a venous or arterial thrombosis (clot) within 30 days after vaccination, that had a platelet count less than 110,000/ μ L and had an abnormal PF4 antibody.

Three of 8,081,360 patients fit all four criteria, but two of them were administered heparin which could have caused their low platelet counts. The one patient meeting all these criteria and not associated with heparin was admitted 11 days after the J&J vaccine, had a platelet count of 78,000/ μ L on admission, and was not on birth control. Figure 1 shows the number of patients with the cumulative factors from left to right, meaning 406 out of 4,840,616 patients (0.008%) with a Pfizer vaccine had an admission within 30 days, a thrombosis diagnoses, and a platelet count less than 110,000/ μ L.

Patients Meeting TTS-Related Criteria After Vaccination

	Patients Vaccinated	Admission within 30 days	Thrombosis Diagnosis	Low Platelets (<110/nL)	Abnormal PF4 Result	Not Associated with Heparin
Pfizer	4,840,616	0.75% 36,112	0.13% 6,305	0.008% 406	0.00004% 2	0.00% 0
Moderna	2,982,261	1.00% 30,152	0.18% 5,286	0.01% 315	0.00% 0	0.00% 0
Janssen (J&J)	271,849	0.60% 1,625	0.09% 252	0.006% 16	0.0004% 1	0.0004% 1

"Patients Meeting TTS Criteria After COVID-19 Vaccination," 2021. Epic Health Research Network (EHRN.org)

Figure 1: Patients who received at least one dose of the COVID-19 vaccine and were subsequently admitted within 30 days, with a progression of additive factors for TTS. A platelet count less than 110,000/ μ L (<110/nL) was chosen based on other studies.³

Our analysis shows one potential Thrombotic Thrombocytopenic Syndrome (TTS) case out of 13,321,570 vaccine administrations and 8,081,360 patients.

Data are pooled from 122 organizations, representing 618 hospitals that span 50 states, with 27 million patients seen since the first emergency use authorization (EUA) for a SARS-CoV-2 vaccine. The data is from Cosmos, a HIPAA-limited data set of patient information contributed by Epic customers. Vaccination data from outside locations might not appear in our data unless the patient has an interaction with the health system. In order to include the greatest number of vaccinations, we included recent vaccinations that did not have a full 30-day elapse during our study period. This means that vaccines that have been available for longer (Moderna and Pfizer) will be comparatively more likely to have potential cases in our data than the J&J vaccine.

Term	Definition
Birth Control	<p>A prescription of a medication with a pharmaceutical class including the term “estrogen” or with a medication name including the term “estradiol”; which includes a prescribed route of “oral.”</p> <p>Start date: the date the prescription was scheduled to start. Only prescriptions scheduled to start in the 30 days prior to the relevant admission are considered.</p>
Heparin	<p>An administration of a medication with a pharmaceutical subclass of Heparins or Low Molecular Weight Heparin.</p> <p>Administration date: the date on which the medication was administered.</p> <p>Administrations occurring between 14 days prior to the relevant admission and 2 days post-admission are considered.</p>
PF4 lab result	<p>A positive/abnormal lab result for one of the following LOINC codes: 34701-3, 45155-9, 57761-9, 73816-1, 73818-7, 73819-5.</p> <p>Result date: the date on which the lab was drawn (and, if not specified, the date on which the lab was resultted).</p>
Platelet lab result	<p>A lab result for one of the following LOINC codes: 777-3, 26515-7, 49497-1</p> <p>Labs with a numeric value less than 110,000 µL or flagged as “Low Off-Scale” or “Low Panic,” or having a result referencing a low “out of range” value are considered for this study.</p> <p>Result date: the date on which the lab was drawn (and, if not specified, the date on which the lab was resultted). Only labs performed on the date of admission or the next calendar day are considered.</p>
Relevant Admission	<p>A hospital admission, with the admission date occurring between 3- and 30-days post-vaccination. Day 0 is the day of vaccination. Day 3 was included since patients admitted on Day 3 may not have their thrombosis diagnosis documented until Day 4 (within 24 hours of admission).</p>
Thrombosis diagnosis	<p>A diagnosis with one of the following ICD-10-CM codes:</p> <p>G08*, G95.1*, H34*, I21*, I22*, I23*, I24*, I26*, I63.0*, I63.1*, I63.2*, I63.3*, I63.4*, I63.5*, I63.6*, I65.0*, I65.1*, I65.2*, I65.9*, I66*, I67.6*, I74*, I75*, I76*, I81*, I82*, K55.0*, N28.0*</p> <p>Diagnosis Date: The encounter start date for the admission on which the diagnosis was documented.</p> <p>Diagnosis Context: Encounter Diagnosis or Billing Diagnosis</p>
Vaccination Date	<p>The date that the vaccine was administered (or documented as having been administered)</p> <p>Vaccines had to be administered on or after the EUA (Emergency Use Authorization) for that vaccine:</p> <ul style="list-style-type: none"> • Pfizer: December 11, 2020 • Moderna: December 18, 2020 • Janssen: February 27, 2021

References

1. Joint CDC and FDA Statement on Johnson& Johnson COVID-19 Vaccine. April 13, 2021. Accessed May 7, 2021. <https://www.cdc.gov/media/releases/2021/s0413-JJ-vaccine.html>
2. Bussel B, et. al. Thrombosis with Thrombocytopenia Syndrome (also termed Vaccine-induced Thrombotic Thrombocytopenia). American Society of Hematology. Version 1.4. April 29, 2021. Accessed May 7, 2021. <https://www.hematology.org/covid-19/vaccine-induced-immune-thrombotic-thrombocytopenia>
3. D Cines, J Bussel. SARS-CoV-2 Vaccine-Induced Immune Thrombotic Thrombocytopenia. NEJM. April 16, 2021. Accessed May 10, 2021. https://www.nejm.org/doi/full/10.1056/NEJMe2106315?query=recirc_curatedRelated_article