

April 16, 2021

CLINICAL PEARLS

• J&J COVID-19 vaccine pause:

Dr. Scott Morrow, Health Officer Cassius Lockett, PhD, Director

- 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. In light of 6 recent cases of cerebral venous sinus thrombosis (CVST) in combination with thrombocytopenia following administration of the J&J COVID-19 vaccine, and out of an abundance of caution, the CDC and FDA are recommending a pause in the use of the J&J COVID-19 vaccine.
- All six cases occurred among women aged 18–48 years. One died. The six patients 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 CVST by intracranial imaging; two patients were also diagnosed with splanchnic and portal vein thrombosis. Unlike most patients presenting with thrombotic events, all six patients also showed evidence of thrombocytopenia, consistent with a condition known as thrombotic thrombocytopenia, with platelet nadir counts ranging from 10,000 to 127,000 during their hospitalizations. Four patients developed intraparenchymal brain hemorrhage and one subsequently died.
- These reports are similar to reports of thrombotic events with thrombocytopenia after receipt of the AstraZeneca COVID-19 vaccine in Europe. Both vaccines contain replication-incompetent adenoviral vectors (human [Ad26.COV2.S] for J&J and chimpanzee [ChAdOx1] for AstraZeneca) that encode the spike glycoprotein of SARS-CoV-2, the virus that causes COVID-19. To date, there have been no reports of CVST with thrombocytopenia among persons who received either of the two mRNA-based COVID-19 vaccines.
- 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 may be associated with platelet-activating antibodies against platelet factor 4 (PF4). Anti-PF4, also known as heparin-PF4 antibody, can induce thrombotic thrombocytopenia in a small percentage of persons exposed to heparin. However, none of the cases reported from Europe had recent heparin exposure. As with heparin-induced thrombocytopenia, the administration of the anticoagulant heparin should be avoided in patients with potential vaccine-associated immune thrombotic thrombocytopenia (VITT), unless heparin-induced thrombocytopenia (HIT) testing is negative. Non-heparin anticoagulants and high-dose intravenous immune globulin should be considered when treating patients who present with immune-mediated thrombotic events with thrombocytopenia after J&J COVID-19 vaccination. Consultation with hematology specialists is strongly recommended.
- Clinicians 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, including severe headache, backache, new neurologic symptoms, severe abdominal pain, shortness of breath, leg swelling, petechiae, or new or easy bruising. Clinicians should obtain platelet counts and screen for evidence of immune thrombotic thrombocytopenia.
- Patients presenting with a thrombotic event and thrombocytopenia after the J&J COVID-19 vaccine should be evaluated with a screening PF4 enzyme-linked





immunosorbent (ELISA) assay as would be performed for autoimmune HIT. Consultation with a hematologist is strongly recommended.

- Patients with thrombotic events and thrombocytopenia following receipt of J&J COVID-19 vaccine **should not be treated with heparin, unless HIT testing is negative.**
- If HIT testing is positive or unable to be performed in patient with thrombotic events and thrombocytopenia following receipt of J&J COVID-19 vaccine, non-heparin anticoagulants and high-dose intravenous immune globulin should be strongly considered.
- All adverse events, including serious and life-threatening adverse events and deaths in patients following receipt of COVID-19 vaccines should be immediately reported to <u>VAERS</u>.
- A syndrome similar to autoimmune heparin-induced thrombocytopenia (HIT) may occur in some persons after vaccination with AstraZeneca's Covid-19 vaccine, ChAdOx1 nCoV-19.
 - <u>A report from Germany and Austria</u> detailed 11 cases of thrombosis or thrombocytopenia following immunization with the ChAdOx1 nCov-19 vaccine among 28 patients with blood samples referred for investigation due to suspicion of vaccine-associated blood clots. Nine of the 11 patients were women, with a median age of 36 years, who presented with one or more thrombotic events 5-16 days following vaccination. Six of the patients died.
 - <u>Another report from Norway detailed 5 cases</u> in healthcare workers who presented with venous thrombosis and thrombocytopenia within 7-10 days of receiving a first dose of the vaccine. Four of the patients experienced severe cerebral venous thrombosis with intracranial hemorrhage, and three of these patients died.
 - Both cohorts showed high levels of the HIT-related antibodies platelet factor 4-polyanion complexes, despite the fact that none of the patients had received heparin prior to symptom onset. Triggers other than heparin exposure can cause pro-thrombotic disorders that strongly resemble HIT, including exposure to certain polyanionic drugs. The first study's authors suggested that the thrombotic events be named "novel entity vaccine-induced immune thrombotic thrombocytopenia (VITT) to avoid confusion with heparin-induced thrombocytopenia." They also wrote: "Given the parallels with autoimmune heparin-induced thrombocytopenia, anticoagulant options should include nonheparin anticoagulants used for the management of heparin-induced thrombocytopenia, unless a functional test has excluded heparin-dependent enhancement of platelet activation."
 - British health officials announced last week that the ChAdOx1 nCov-19 Covid-19 vaccine would no longer be given to anyone under the age of 30 due to mounting evidence that younger people, especially women, have an increased risk of developing blood clots from the vaccine. Health officials in Italy have recommended against giving the shot to people under the age of 60 and several other countries where the vaccine is approved, including Germany, France, Canada, and the Netherlands stopped using the vaccine in younger adults. The AstraZeneca vaccine is not currently approved for use in the United States.

PUBLIC HEALTH UPDATES

- Joint CDC and FDA Statement on Johnson & Johnson COVID-19 Vaccine
- <u>ACOG Statement on the Johnson & Johnson COVID-19 Vaccine</u>
- NIH trial of anti-CD14 antibody to treat COVID-19 respiratory disease begins
- FDA Recommends Transition from Use of Decontaminated Disposable Respirators Letter to Health Care Personnel and Facilities
- FDA Issues Emergency Use Authorization for the Symbiotica COVID-19 Self-Collected Antibody Test System



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GUIDANCE/GUIDELINES

- CDPH
 - o COVID-19 Public Health Recommendations for Fully Vaccinated People
 - o <u>Guidance for the Prevention of COVID-19 Transmission for Gatherings</u>
- CDPH/CalOSHA
 - o <u>COVID-19 Guidance: Outdoor Seated Live Events and Performances (effective April 1, 2021)</u>
 - o <u>COVID-19 Guidance: Indoor Seated Live Events and Performances (effective April 15, 2021)</u>
 - o <u>COVID-19 Guidance: Private Venues and Events</u> (effective April 15, 2021)
- <u>Guidance produced from the Expert Haematology Panel (EHP) focused on Covid-19 Vaccine induced</u> <u>Thrombosis and Thrombocytopenia (VITT)</u>

RESOURCES

- Joint Media Call: U.S. health officials hold briefing on Johnson & Johnson vaccine
- CDC
 - COCA Call: Johnson & Johnson/Janssen COVID-19 Vaccine and Cerebral Venous Sinus Thrombosis with Thrombocytopenia – Update for Clinicians on Early Detection and Treatment
 - o <u>Post-COVID Conditions: Information for Healthcare Providers</u>
 - o <u>Strategies for Optimizing the Supply of N95 Respirators</u>
- IDSA:
 - o Media Briefing: Vaccine Q&A
 - o Podcast: COVID-19: Lessons Learned and Future Preparedness
- CDC/IDSA COVID 19 Clinician Call:
 - o The Johnson & Johnson Vaccine: Current Situation & Anticipated Next Steps
 - o <u>COVID-19 in Pregnant Individuals; Plus Vaccine Q&A Hosted in partnership with ACOG</u>
- American Society for Microbiology: <u>Tracking COVID-19 Variants: The Role of Advanced Molecular Detection</u> <u>and Genomic Surveillance webinar</u>
- Kaiser Family Foundation
 - o KFF COVID-19 Vaccine Monitor- Rural America
 - o Mental Health Impact of the COVID-19 Pandemic: An Update
- School Reopening Tracker by <u>Los Angeles Times</u> and <u>Burbio</u>
- WHO
 - o <u>COVID-19 Virtual Press conference transcript April 12, 2021</u>
 - o <u>COVAX reaches over 100 economies, 42 days after first international delivery</u>

ACADEMIC/RESEARCH PAPERS

- New England Journal of Medicine
 - o <u>Thrombotic Thrombocytopenia after ChAdOx1 nCov-19 Vaccination</u>
 - o <u>Thrombosis and Thrombocytopenia after ChAdOx1 nCoV-19 Vaccination</u>
- medRxiv
 - Evidence for increased breakthrough rates of SARS-CoV-2 variants of concern in BNT162b2 mRNA vaccinated individuals
 - Inhaled budesonide for COVID-19 in people at higher risk of adverse outcomes in the community: interim analyses from the PRINCIPLE trial



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- <u>The vaccine-elicited immunoglobulin profile in milk after COVID-19</u> <u>mRNA-based vaccination is IgG-dominant and lacks secretory antibodies</u>
- Pediatrics
 - o Neonatal SARS-CoV-2 Infections in Breastfeeding Mothers
 - o Safety of Breastfeeding by Mothers With COVID-19: New Evidence From Israel
- Canadian Medical Association Journal
 - o Infectivity of severe acute respiratory syndrome coronavirus 2 in children compared with adults
- JAMA
 - o <u>Characteristics and Disease Severity of US Children and Adolescents Diagnosed With COVID-19</u>
 - o SARS-CoV-2-Specific Antibodies in Breast Milk After COVID-19 Vaccination of Breastfeeding Women
 - Incorporating HIV Screening With COVID-19 Testing in an Urban Emergency Department During the Pandemic
- Annals of Internal Medicine
 - <u>A Deferred-Vaccination Design to Assess Durability of COVID-19 Vaccine Effect After the Placebo</u> <u>Group Is Vaccinated</u>
- Cell
 - <u>Complete map of SARS-CoV-2 RBD mutations that escape the monoclonal antibody LY-CoV555 and</u> <u>its cocktail with LY-CoV016</u>
- Lancet
 - <u>Genomic characteristics and clinical effect of the emergent SARS-CoV-2 B.1.1.7 lineage in London,</u> UK: a whole-genome sequencing and hospital-based cohort study
 - Suicide trends in the early months of the COVID-19 pandemic: an interrupted time-series analysis of preliminary data from 21 countries
- Nature
 - o Endothelial dysfunction and immunothrombosis as key pathogenic mechanisms in COVID-19
- Trials
 - <u>Multi-arm Trial of Inflammatory Signal Inhibitors (MATIS) for hospitalised patients with mild or</u> <u>moderate COVID-19 pneumonia: a structured summary of a study protocol for a randomised</u> <u>controlled trial</u>
- BMJ Journal
 - <u>Physical inactivity is associated with a higher risk for severe COVID-19 outcomes: a study in 48 440</u> <u>adult patients</u>
- Annals of Surgery
 - <u>Analysis of COVID-19 Patients with Acute Respiratory Distress Syndrome Managed</u> with Extracorporeal Membrane Oxygenation at us Academic Centers
- Blood
 - <u>Post-Discharge Thromboembolic Outcomes and Mortality of Hospitalized COVID-19 Patients: The</u> <u>CORE-19 Registry</u>
- Annals of Emergency Medicine
 - Symptoms of Anxiety, Burnout, and PTSD and the Mitigation Effect of Serologic Testing in Emergency Department Personnel During the COVID-19 Pandemic
- Journal of the American Society of Nephrology
 - o Initial Effects of COVID-19 on Patients with ESKD
- National Kidney Foundation
 - o SARS-CoV-2 Vaccine Acceptability in Patients on Dialysis: A Nationwide Survey





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COVID-19 Digest Issue 51

- PNAS
 - o Learning loss due to school closures during the COVID-19 pandemic
- Psychiatry Research
 - Changes in body dysmorphic disorder, eating disorder, and exercise addiction symptomology during the COVID-19 pandemic: A longitudinal study of 319 health club users
- American Society for Radiation Oncology (ASTRO)
 - <u>COVID-19 and Radiation Oncology Results of a national physician survey by the American Society for</u> <u>Radiation Oncology (ASTRO)</u>
- Journal of Virology
 - Transmission and protection against re-infection in the ferret model with the SARS-CoV-2 USA-WA1/2020 reference isolate
- Global Fund
 - THE IMPACT OF COVID-19 ON HIV, TB AND MALARIA SERVICES AND SYSTEMS FOR HEALTH: A SNAPSHOT FROM 502 HEALTH FACILITIES ACROSS AFRICA AND ASIA
- 73rd American Academy of Neurology Annual Meeting Abstract
 - <u>Neurologic and radiographic findings associated with Pediatric Inflammatory Multisystem Syndrome</u> <u>Temporally associated with SARS-CoV-2 (PIMS-TS) in Children</u>

MMWR

- <u>COVID-19 Incidence and Mortality Among American Indian/Alaska Native and White Persons Montana,</u> <u>March 13–November 30, 2020</u>
- Trends in Racial and Ethnic Disparities in COVID-19 Hospitalizations, by Region United States, March— December 2020
- <u>Emergency Department Visits for COVID-19 by Race and Ethnicity 13 States, October–December 2020</u>
- <u>Update: COVID-19 Pandemic–Associated Changes in Emergency Department Visits United States,</u> <u>December 2020–January 2021</u>
- <u>Laboratory Modeling of SARS-CoV-2 Exposure Reduction Through Physically Distanced Seating in Aircraft</u> <u>Cabins Using Bacteriophage Aerosol — November 2020</u>

HOT OFF THE (LAY) PRESS

- New York Times
 - o <u>C.D.C. Panel Keeps Pause on Use of J&J Vaccine, Citing Need to Assess Potential Risks</u>
 - o Johnson & Johnson Vaccinations Paused After Rare Clotting Cases Emerge
 - o Pause in Vaccinations Leads to Canceled Appointments Across States
 - o <u>The U.S. is nearing universal Covid-19 vaccine eligibility for adults.</u>
 - o <u>Pfizer and BioNTech requested the F.D.A.'s authorization to use their vaccine in 12- to 15-year-olds</u>
 - o Johnson & Johnson vaccine deliveries are about to take a big dip in the U.S
 - o Blood Clots Linked to AstraZeneca Vaccine Stem From Rare Antibody Reaction
 - o <u>Western Warnings Tarnish Vaccines the World Badly Needs</u>
 - o <u>What Women Need to Know About the Covid Vaccine</u>
 - o How New Mexico Became the State With the Highest Rate of Full Vaccinations
 - o <u>The struggle against vaccine hesitancy comes to Mississippi.</u>
 - o <u>'Vaccine passports' have kicked off a heated debate. Here's what we know.</u>
 - o The N.F.L. will restrict unvaccinated coaches and staff from working with players.
 - o Kati Kariko Helped Shield the World From the Coronavirus





- <u>Study bolsters the case that Regeneron's antibody drugs can protect</u> <u>against Covid-19</u>
- o Beyond Pandemic's Upheaval, a Racial Wealth Gap Endures
- o Parents, Stop Talking About the 'Lost Year'
- o Out of the Pandemic, Chances for Another Future
- Scientific American
 - o How Could a COVID Vaccine Cause Blood Clots?
- Bloomberg
 - o J&J Covid Vaccine Reviewed by EU Regulator After Blood Clots
- Guardian
 - o <u>How UK doctor linked rare blood-clotting to AstraZeneca Covid jab</u>
- The Hill
 - o <u>Pfizer pushes to speed up its vaccine delivery after J&J pause</u>
 - o Biden eyes bigger US role in global vaccination efforts
 - o <u>40 percent of Marines have declined the coronavirus vaccine</u>
- NPR
 - o <u>CDC Studies 'Breakthrough' COVID Cases Among People Already Vaccinated</u>
 - o <u>CDC Director Declares Racism A 'Serious Public Health Threat'</u>
 - o <u>COVID Hotspots Spark Debate On How Best To Allocate Vaccine Doses</u>
 - o More Colleges Say They'll Require Students To Have COVID-19 Vaccines For Fall
 - o <u>Supreme Court Rules For Worshippers And Against California COVID Restrictions</u>
 - o U.K. Coronavirus Strain Does Not Lead To More Severe Illness And Death, Study Finds
- The Washington Post
 - o Why Biden health officials decided to pause J&J's coronavirus vaccine
 - o <u>CDC ramps up scrutiny of rare post-vaccination 'breakthrough infections'</u>
 - <u>A quarter of the country won't get the coronavirus vaccine. Half of them trust Trump's medical</u> <u>advice</u>
 - o For immigrants, IDs prove to be a barrier to a dose of protection
 - o Trump officials celebrated efforts to change CDC reports on coronavirus, emails show
 - o More than 562,000 people have died from coronavirus in the U.S.
 - o CDC director says Michigan should 'shut things down' amid rise in cases, not bet on vaccines
- Reuters
 - o White House says it is prepared to send more COVID-19 therapeutics to Michigan
 - o <u>UK trial on switching COVID-19 vaccines adds Moderna and Novavax shots</u>
 - o In world first, Denmark ditches AstraZeneca's COVID-19 shot
 - o France extends gap between mRNA vaccine shots to ramp-up rollout
 - o Ontario closes in-person schools due to rising COVID-19 cases
 - o <u>'I'm so excited' England reopens with pints pulled, shopping sprees and hair cuts</u>
 - o EU countries move towards COVID passes to reopen summer travel
- AP News
 - o <u>'Zoom in a Room'? California's schools lag in reopening push</u>
 - o Governor pushes school reopening as many districts resist
 - o Italy prosecutors: WHO exec lied about spiked virus report
 - o Top Chinese official admits vaccines have low effectiveness



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- Global Times
 - <u>China's first mRNA vaccine expected to enter Phase III trials in LatAm,</u> paves way for mixed jabs against variants
- VOA News
 - o Most New COVID Cases, Hospitalizations in US Are Among Younger Adults
- USA Today News
 - o <u>Thousands of meatpacking workers have been vaccinated, but the industry's crisis continues</u>
- Insider
 - <u>Gov. Greg Abbott's claim that Texas is 'very close' to herd immunity is not 'even close' to being true,</u> says expert
- Politico
 - o The big hole in America's plan to fight Covid-19 variants
- National Geographic
 - o How this more contagious virus variant became dominant in the U.S.
 - o <u>A 'double mutant' is reported in the U.S., as cases continue to rise</u>
 - o Does everyone need to wear a mask outside? Experts weigh in.
 - o <u>Why we need booster shots against variants to help end the pandemic</u>
 - o <u>Can a new app predict the next pandemic?</u>
- STAT News
 - o Biden pushes Congress to boost public health, pandemic preparedness funding
 - o <u>Scientists work toward an elusive dream: a simple pill to treat Covid-19</u>
 - o Signs Of Economic Boom Emerge As Retail Sales Surge, Jobless Claims Hit Pandemic Low
- World Economic Forum
 - o <u>When will life return to 'pre-COVID normal'?</u>
- Kaiser Health News
 - o <u>12 Months of Trauma: More Than 3,600 US Health Workers Died in Covid's First Year</u>
 - o The Gender Vaccine Gap: More Women Than Men Are Getting Covid Shots
 - o <u>What Covid Means for the Athlete's Heart</u>
- CBS
 - o <u>Hospitals open pediatric long-haul COVID units as children grapple with lingering virus effects</u>
- Medpage Today
 - o New-Onset Neuro Symptoms Common in Kids With MIS-C
- EurekAlert!
 - o Half of kids with inflammatory syndrome after COVID-19 have neurologic symptoms
- JAMA Medical News and Perspectives
 - o Pandemic Boosts an Old Idea—Bringing Acute Care to the Patient
 - o Experts Discuss COVID-19—Variants and Vaccine Efficacy, Immunosuppressed Patients, and More
- Global Fund
 - <u>New Global Fund Report Shows Massive Disruption to Health Care Caused by COVID-19 in Africa and</u> <u>Asia</u>
- Regeneron News
 - PHASE 3 PREVENTION TRIAL SHOWED 81% REDUCED RISK OF SYMPTOMATIC SARS-COV-2 INFECTIONS WITH SUBCUTANEOUS ADMINISTRATION OF REGEN-COV™ (CASIRIVIMAB WITH IMDEVIMAB)



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- Moderna Press Releases
 - Moderna Provides Clinical and Supply Updates on COVID-19 Vaccine Program Ahead of 2nd Annual Vaccines Day
- AstraZeneca Press Releases
 - o Update on the DARE-19 Phase III trial for Farxiga in COVID-19
- KQED
 - o San Francisco Announces Plan to Allow Indoor Concerts, Performances Starting April 15
 - o <u>Kaiser Says Vaccine Appointments Will Be Harder to Book for the Next Few Weeks</u>
 - o Advocates Work to Combat Vaccine Distrust in ICE Detention Facilities
- Los Angeles Times
 - Amid a new push to vaccinate Homeland Security employees, the wife of a hospitalized Border Patrol agent urges others not to delay COVID-19 shots.
- The Mercury News
 - o <u>Want a COVID shot now? You may have to leave the Bay Area</u>
 - o <u>How the decline in COVID-19 testing could blind California to new problems</u>
 - o <u>California surpasses 60,000 people dead from the coronavirus</u>
- San Francisco Chronicle
 - o California on track to reopen June 15 despite J&J pause, Newsom says
 - o Here's why Santa Clara County is getting a vaccine windfall this week
 - o <u>No yellow tier yet for Bay Area counties, as case counts creep up</u>
 - o 'Breakthrough' cases of vaccinated people who get COVID may be key to unlocking immunity
 - o <u>What can California expect when vaccination open season starts April 15? Ask Contra Costa County</u>
 - o Stanford enrolls children as young as 2 in Pfizer vaccine trials
 - o Facebook offers Menlo Park HQ as vaccination site for underserved communities
 - o <u>Salesforce to reopen S.F. headquarters in May, starting with vaccinated workers</u>
 - o <u>How churches, community-based organizations have stepped up to vaccinate communities of color</u>
- ABC7 News
 - o <u>Peninsula nurses launch pilot program to get COVID-19 vaccine to homebound seniors</u>

EPIDEMIOLOGY UPDATES

- CDC COVID Data Tracker
 - o <u>United States COVID-19 Cases and Deaths by State</u>
 - o CDC COVID Data Tracker: Vaccinations
 - o NEW CDC US COVID-19 Cases Caused by Variants
- US Leads the World in Confirmed COVID-19 Cases per Johns Hopkins University Center for Systems Science and Engineering Dashboard Website
- Johns Hopkins COVID-19 in the USA daily summary of key data on COVID-19 in the U.S.
- California COVID-19 by the numbers are available on the <u>CDPH Website</u> and the <u>NYT Map and</u> <u>Table</u> (includes data by county)
 - California COVID-19 Statewide Update as of April 16, 2021
- San Mateo County COVID-19 Dashboard
- <u>Santa Clara County COVID-19 Dashboard</u>





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ADDITIONAL COVID-19 RESOURCES

- San Mateo County COVID-19 Guidance and Resources for Clinicians and Facilities <u>– COVID-19 Digests</u>
- Palo Alto Online tracking the coronavirus in San Mateo and Santa Clara counties
- California COVID-19 Data and Tools
- <u>CDPH COVID-19 Assessment and Modeling Tool</u>
- California Department of Corrections and Rehabilitations Population COVID-19 Tracking Dashboards
- <u>CDC Interactive Serology Dashboard for Commercial Laboratory Surveys</u>
- <u>Children and COVID-19: State-Level Data Report</u>
- HHS Coronavirus Data Hub
- <u>COVID-19 Nursing Home Data</u>

