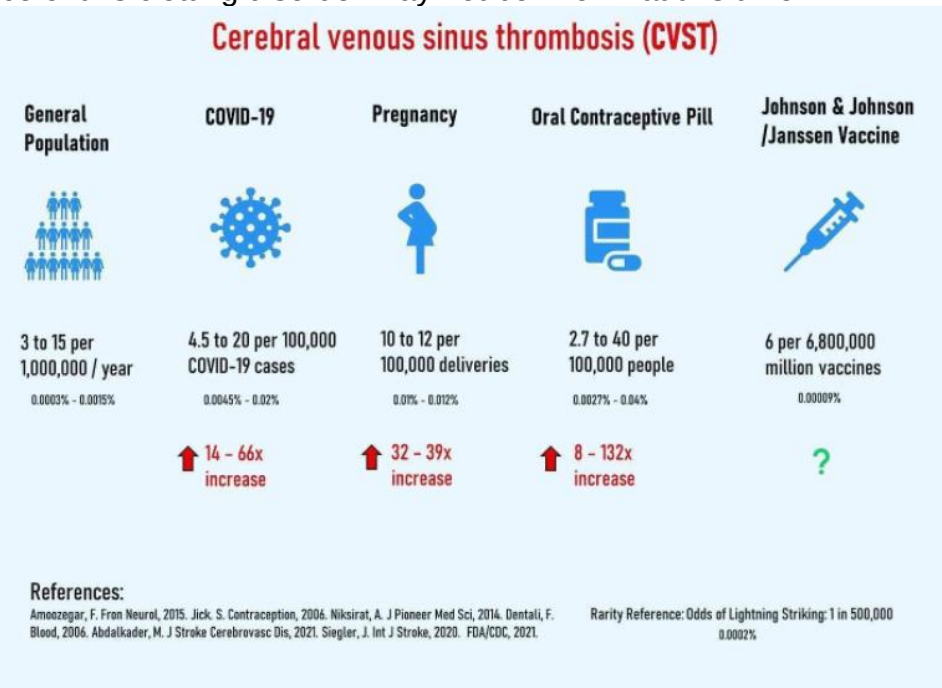
FIRST WATCH
Helping the Helpers

FDA/CDC Recommend Pause in Johnson & Johnson (J&J) Vaccinations

THE FDA & CDC have recommended a pause in administering J&J (Janssen) COVID vaccinations after the VAERS (Vaccine Adverse Event Reporting System) had reports of six (6) women, between the ages of 18 and 48, developing a rare type of blood clot between 6 & 13 days after receiving the J&J vaccine. **This type of clot is called a cerebral venous sinus thrombosis (CVST), which is rare enough on its own, but in these cases, is seen also in combination with thrombocytopenia (low platelet levels). The CDC has issued its highest level of message, a Health Alert, at: https://emergency.cdc.gov/han/2021/han00442.asp .**

It is important to note that this is **only a recommendation**, and will pause all J&J vaccinations at federal sites. The CDC/FDA have specifically said private physicians and states will not be kept from administering the vaccine, although most seem to be following the recommendation. **One of the main reasons for the HAN Alert is so that physicians & other healthcare providers are made aware of the possibility of these adverse events, know they are medical emergencies, & require atypical treatment**.

There are a few important pieces of info that should be considered while waiting for the experts' decision on what the plan going forward. 1) If you had the J&J vaccine in the last 3-4 weeks, particularly in the 18-50 age range, you may want to discuss with your personal healthcare provider what symptoms you should be looking for & what to do if any appear. Your personal PCP is aware of your history, medications, etc., and can help you determine a risk profile. 2) The risk of blood clots is significantly greater with COVID disease than with the J&J vaccine. 3) The case reports of CVST/Thrombocytopenia may not be the only cases of clotting for those vaccinated with the J&J vaccine. Milder symptoms may not be noticed or brought to the attention of medical personnel, so the true incidence of this clotting disorder may not be known at this time.



Excerpted from a 4/13/21 Tweet from **Ali H. Mokdad** @AliHMokdad Prof. of Health Metric Sciences, Uni. of Wash.

There is no absolute proof that the vaccine & the rare clot/platelet events are related, but those reviewing the VAERS data are concerned that there could be, and want to investigate further, without the potential for ongoing harm. There is a special team, made up of infectious disease & hematology (blood) experts who have been reviewing the data. And, the Advisory Committee on Immunization Practice (ACIP), met Wednesday, 4/14 and have now asked for a few days to do a deeper dive into the cases before making a recommendation. Many experts, not associated with the teams, have suggested that there might be exceptions for gender and/or age developed for the J&J vaccine, much like the approach in Europe with the Astra Zeneca vaccine, exclusion if there is a known/suspected risk for blood clots, or that a clotting panel (blood work) should be done to look for underlying clotting disorders. Astra Zeneca is the other adenovirus-vector COVID vaccine that has also had reports of a similar pattern of CVST & thrombocytopenia, primarily in Europe, with 11 known cases; 9 females & 2 males; 6 deaths. There have also been rumors that the Russian COVID vaccine has also had clotting disorders reported, although nothing confirmed by their government.

There is no question that the CDC & FDA got the attention of many people in the US and others from around the world who are watching our vaccine rollout. Depending on who you talk to, recommending that there be a pause in J&J (Janssen) vaccinations was either the best or worse thing to do. Here's what the pause & investigations do:

1. **It gives the medical community time to look at the information available, educate themselves & others, including the lay public, to make sure that any symptoms of these adverse events are caught, quickly evaluated by the appropriate medical personnel, and managed appropriately. It also gives notice, so that everyone is paying attention and will actively look for the signs & symptoms associated with the clots and decreased platelet levels and think about recent (within 3 weeks) vaccine history.**

2. **Suggests that the system to monitor for vaccine safety is in place and works**. These cases were from late March and early April, were already identified, are in the process of being investigated and a plan, taking into account risk/benefit, will be identified in the short term. This article doesn't contain all the details, although there is a page of Resources & Links, posted as a sub-document, that will contain much of the known material, which provides a lot of proof that those involved want true transparency and or everyone to aware the risks & benefits of this vaccine.

3. **The vaccine is still under Emergency Use Authorization (EUA) because of a public health emergency**. It's still proving itself as more & more data is collected with each shot given. Basically, it's still in an "advanced testing phase" and potential problems MUST be explored. Vaccine trials are relatively small, with volunteers in the tens of thousands rather than the millions that have been vaccinated with this adenovirus-vector type vaccine. So, rare adverse reactions, like one in a million, or even one in ½ million, won't be seen in during the trials because not enough people received the vaccine to find it.

4. When a **potential** significant problem has been identified with any vaccine, drug, device, etc., particularly one that has serious harm or death as a result, as this one has, there must be an investigation to look to see if the vaccine (or whatever item) is responsible or contributing to the problem. It's not OK to just continue to potentially let more adverse reactions occur until the cause is known.

Totally unrelated to CVST, but worth noting, is that there were vaccination sites in a few states, namely Colorado, Georgia, Iowa, & North Carolina, that have temporarily halted vaccinations when multiple persons who received a J&J vaccination immediately (on site) developed adverse reactions such as fainting, nausea, dizziness, lightheadedness, and/or rapid breathing. Most were treated on scene; several were taken to the hospital for follow-up care. Plans going forward include identifying those that have a history of fainting or having symptoms around needles, as well as supplying snacks and drinks, and not moving them to another area for their observation time. Two links to these reports are found at the end of the Resources & Links page posted with this article.

What First Responders Can Do

1. **Know the signs/symptoms of someone who MAY have CVST**, although they are pretty non-specific, depend on the actual location of the clot, how big it is, and may need to be coupled with a COVID vaccination in the past 3 weeks.

CVST: (Most typical in these cases)	***Headaches, often severe (most common symptom; 70-90%)** **Abdominal Pain** **Chest Pain** **Leg Pain** **Shortness of Breath** **Swollen areas such as a leg**
(Other S/S that may be seen)	Blurred Vision or other Visual Disturbances Confusion or other AMS Trouble Speaking Numbness and/or Weakness in Arms and/or Legs Loss of Control over Movement in a Part of the Body Fainting Nausea/Vomiting Seizures May also involve any of the cranial nerves including facial weakness, hearing deficits, difficulty speaking

2. **Although the 6 known cases in the US, after J&J vaccination, have been female, 2 of the 11 patients with CVST/thrombocytopenia after Astra Zeneca vaccination in Europe, were male**. So, anyone with these symptoms should seek medical attention urgently. Ask about COVID vaccination within the past 3 weeks, as well as any medications/supplements being taken, and medical history, including previous blood

clots. If there is correlation between J&J vaccine in the previous 3-4 weeks and the presence of any of these symptoms, transport per your policy & protocol, including calling a Stroke Alert **IF** signs/symptoms meet the criteria to do so. Consult with Medical Oversight with any questions or concerns.

3. **In your communication with the Receiving Hospital and with anyone on the health care team upon arrival at the hospital and in the transfer of care, make sure you repeat the information that there is a recent history of J&J vaccination**. **There is a definitive plan of care for this type of CVST and avoiding Heparin as an anticoagulant (a usual starting anticoagulant) is essential.**

4. As always, document your assessment, including medical history, medications and supplements, recent vaccine history, and treatment. **If this is a vaccine-related event, all medical reporting will likely become part of the VAERS case**.

5. As the investigation and resulting recommendation evolves, stay abreast of the latest developments and apply them to your practice.

6. Share the information about this issue with your family and friends to make sure they are aware.