

A Brief Note on the FDA Pause of J&J COVID-19 Vaccine
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On Tuesday, the FDA announced a pause of the Johnson and Johnson (J&J) COVID-19 vaccine. This announcement has created a lot of uncertainty and anxiety, especially for people who have received this vaccine already. Although Butler Health System (BHS) has never administered any J&J vaccine, many people in our community have received it, especially many of Pennsylvania's educational workers. We wanted to share our perspective on what is known so far. To date, there have been no similar concerns raised about the Pfizer or Moderna vaccines that BHS has been giving, and we urge the public to continue to get vaccinated.

First, the facts that lead to the pause:

- Six (6) cases of cerebral venous sinus thrombosis (CVST) have been reported among the 6.8 million (6,800,000) people who have received the J&J vaccine in the US.
- Just as it sounds, CVST is a clotting within certain veins in the brain, although some of these cases had clots elsewhere too, like in their legs or lungs.
- All cases were in women, aged 18 and 48.
- All cases occurred between 6 and 13 days after vaccination.
- Cases also had low platelets in their blood. This is different from standard cases of CVST.
- One person has died from her CVST.

Because these rare cases have occurred in young women, the CDC has focused in on women aged 20 to 50 years old as potentially being at risk. The CDC reports 1.4 million women in this age group received the J&J vaccine. They then estimate that among women 20-50, CVST is between 3 and 15 times more likely after the J&J vaccine than in general population, although some have questioned the "background" number chosen for this calculation. The J&J may not significantly increase the risk of CVST across all ages and both genders.

For perspective, Up To Date (a popular medical reference) states the following about CVST in general public (nothing to do with vaccination):

- Each year, about 0.22 to 1.57 cases per 100,000 people. This is called the incidence.
- Females make up 3-times as many cases as males.
- Mean age for women afflicted is 34.
- Oral contraceptives, pregnancy, or recent pregnancy are all risk factors which increase of CVST.
- Not commonly associated with low platelet counts.

The CDC convened a meeting of the Advisory Committee on Immunization Practices (ACIP), a group of independent scientists and physicians who guide national vaccine policies. They continue to review the data available. For the time being, they have left the pause on J&J in place.

In Europe, the AstraZeneca (AZ) vaccine has also been reported to cause CVST and other clots, also with low platelet counts (thrombocytopenic thrombosis). The AZ and J&J vaccines have a similar mechanism, so-called adenoviral vector vaccines. This suggests that the common mechanism of these vaccines may cause a similar clotting problem. We do not have enough data to conclude that yet.



At this point, it seems like the J&J vaccine may lead to CVST, but through a different mechanism than sporadic CVST we typically encounter.

The two vaccines still available in the US (Pfizer and Moderna) are both mRNA vaccines, a different mechanism than the adenoviral vector vaccines. The CDC has found no connection of these mRNA vaccines with a similar platelet-clot problem. Nearly 98 million doses of Pfizer have been given, with no episodes of CVST. Nearly 85 million doses of Moderna have been given, with 3 reports of CVST (but the cases had normal platelet counts). There are other, ongoing studies to examine any increased risks with these vaccines.

Keep in mind that a COVID-19 infection increases the risk of CVST significantly, approximately 80-fold (compared to the 3 to 15 fold for J&J vaccine).

Before the vaccines were rolled out, we knew we would encounter stories of bad things happening around time of vaccinations. When vaccinating millions and millions of people, it is inevitable that usual health events occur in the background. But the challenge is teasing out what is a true causal relationship from what are unfortunate coincidences and bad timing, or identifying a new problem. This can be difficult. We don't know how long to expect this pause to last.

If you have received the J&J vaccine, there are no special precautions or testing to do right now if you feel well. However, if you develop any of these symptoms within 3 weeks of a J&J vaccine, notify your doctor:

- Easy bruising
- Shortness of breath
- Severe headache that is new for you
- Leg pain
- Abdominal pain

When calling your doctor about this, be sure you mention that you received the J&J vaccine; your medical records may not show that.

We urge everyone to get vaccinated with the Pfizer or Moderna vaccines. There is no evidence that these mRNA vaccines may cause the same (very rare) problems that J&J is under investigation for. In contrast, our community remains at imminent threat from COVID-19, as cases continue to rise and deaths continue to occur.

We wish we had some special insights into what direction this all will go. Please contact your primary care provider with questions or concerns.

Stay safe,
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P.S. This memo is both dated and timed because information is changing quickly. Keep this in mind when reading it.