

FDA & CDC Recommend Pause in J&J Vaccine Distribution: Virtua to Follow Guidance

Today the Food & Drug Administration (FDA) and Centers for Disease Control (CDC) issued a statement calling for a pause in injections of the Johnson & Johnson single-dose vaccine due to recent complications seen in six individuals (out of 6.8 million) who developed severe blood clots. The condition is being referred to as “vaccine-induced prothrombotic immune thrombocytopenia” ([VIPIT](#)). In response, Virtua’s Chief Clinical Officer, Reginald Blaber, MD, and Chief of Infectious Disease, Martin Topiel, MD, have issued the following message:

Scientists from the FDA and CDC will use this pause to examine any possible relationship between the Johnson & Johnson vaccine and the rare side effect that six women have experienced. While the pause is concerning, people should find comfort in the thoroughness of our experts to revisit this particular vaccine’s safety, despite the very small number of adverse events. This is how we keep people safe.

People should continue to get vaccinated with Pfizer and Moderna and remember that the serious risks and complications of getting COVID 19 far outweigh the potential adverse reaction of getting vaccinated.

In mid-March, Virtua administered nearly 1,000 doses of the Johnson & Johnson vaccine in its medical practices. Virtua also provided 2,000 Johnson & Johnson vaccine doses at the Burlington County Mega-Site between April 7 and 10. To date, none of these patients have experienced complications and/or are outside the window when the effects would likely occur.

Clinicians should be mindful of patients who have received the J&J vaccine, and experience abdominal pain, leg pain, shortness of breath, severe headache or other unusual symptoms within three weeks after vaccination. Patients should be directed to seek immediate treatment if they experience symptoms.

Thus far, it is known that heparin is not recommended, as reported by the [New York Times](#).

In a media call earlier today, Peter Marks, MD, Ph.D., director of the FDA Center for Biologics Evaluation and Research, said: “Treatment of this specific type of blood clot is different from typical treatments for other types of blood clots, which usually involve an anticoagulant called heparin. With cerebral venous sinus thrombosis, heparin may be dangerous and alternative treatments need to be given, preferably under the guidance of physicians experienced with the treatment of blood clots.”

Virtua’s senior clinical leaders are working to develop a protocol if any patients should present.

Vaccinations with the Pfizer and Moderna vaccines continue at the mega-site. We will update you as information develops.