COVID-19 Vaccine Frequently Asked Questions & Answers
April 16, 2021

<u>What we heard this week</u>:

What happened with the J&J vaccine?

- CDC and FDA recommended all states temporarily pause the use of the J&J vaccine while they reviewing data involving six reported cases in the U.S., of a rare and severe type of blood clot in individuals who had received the vaccine.
- In these cases, a type of blood clot called cerebral venous sinus thrombosis (CVST) was seen in combination with low levels of blood platelets (thrombocytopenia). All six cases occurred among women between the ages of 18 and 48, and symptoms occurred 6 to 13 days after vaccination.
- None of these cases occurred in Delaware.
- CDC will convene a meeting of the Advisory Committee on Immunization Practices (ACIP) on Wednesday to further review these cases and assess their potential significance. FDA will review that analysis as it also investigates these cases.
- Until that process is complete, DPH will not schedule any vaccine appointments using J&J vaccine, and has asked all vaccinating partners (pharmacies, hospitals, etc.) not to use J&J until we receive further federal guidance. **These cases are extremely rare.** This is out of an abundance of caution, and in part, to ensure that the health care provider community is aware of the potential for these adverse events and can plan for proper recognition and management due to the unique treatment required with this type of blood clot.
- Treatment of this specific type of blood clot is different from the treatment that might typically be administered. Usually, an anticoagulant drug called heparin is used to treat blood clots. In this setting, administration of heparin may be dangerous, and alternative treatments need to be given.
- As of April 12, more than 6.8 million doses of the Johnson & Johnson (Janssen) vaccine have been administered in the U.S. The occurrence of these cases equals 1 in 1 million doses administered.
- The CDC has indicated that they are not seeing the same types of issues with Moderna and Pfizer, so if you have an appointment for one of these two vaccines, you should keep it.

What is DE going to do about the people such as myself that received the J&J vaccine within the last week?

- DPH shares the FDA's and CDC's concerns regarding the six cases of blood clots nationwide, among those who received the Johnson & Johnson vaccine.
- Though we are unaware of any issues of blood clots in Delaware that may be related to this vaccine, out of an abundance of caution, we have asked our Delaware vaccine partners hold off on using the J&J vaccine until the situation has been further assessed. The state will not use J&J at its vaccination sites until we receive further federal guidance.
- Anyone scheduled for Johnson & Johnson vaccinations in Delaware for the rest of this week should expect to hear from the pharmacy or provider that scheduled their J&J vaccine about next steps.

- DPH shared information and its official statement with community partners, health care providers and pharmacies, and placed that information on its website here: https://coronavirus.delaware.gov/vaccine/vaccine-safety-and-monitoring/ and on social media.
- DPH is sharing information from the CDC such as: The risk to anyone who was vaccinated with J&J four weeks or more ago is extremely low. Those who were vaccinated more recently should look for symptoms such as severe headache, abdominal pain, leg pain, or shortness of breath within 3 weeks after vaccination. If you experience those symptoms, contact your health care provider.

How many of the "infected" doses did we [DE] receive?

- None of the doses were infected.
- Delaware has so far received 45,000 doses of the J&J vaccine. 20,923 people have received J&J vaccine with no serious issues.
- They've mostly been distributed at state-run mass vaccination events, including one over the weekend that served about 5,500 people.
- We are unaware of any issues of blood clots in Delaware that may be related to this vaccine.

What symptoms should I look for that indicate blood clots have developed?

- The risk to anyone who received the vaccine four or more weeks ago is very low.
- You should watch out for severe headache, abdominal pain, leg pain, or shortness of breath within three weeks after vaccination. In the 6 identified cases reactions typically began 6 days or more after being vaccinated. If you experience these symptoms contact your health care provider.
- These symptoms are different than the typical flu-like symptoms people experience (minor headache, fever, nausea, redness or pain at the injection site) within 1-3 days after being vaccinated. These symptoms are expected.

Should I call my doctor and get checked out immediately just in case?

- People who received the J&J vaccine who develop severe headache, abdominal pain, leg pain, or shortness of breath within three weeks after vaccination should contact their health care provider.

Why was the vaccine made so quickly?

- The vaccine was developed in a much shorter period of time due to the obvious need to address the public health threat the pandemic posed to the nation.
- The shorter development time is the result of technology advances to map the virus's DNA and using vaccine platforms developed for other diseases. The clinical trial process was accelerated by enrolling more people in trials to enhance rapid data collection and earlier analysis of safety data for demographically diverse populations.
- This also sped up the FDA review process as they have been monitoring the data all along. Delivery/distribution time was shortened by allowing manufacturing to occur at the same time as instead of after, vaccine approval.
- A shorter review time does not mean the vaccine is unsafe.
- Experts and scientists from the FDA and the Advisory Committee on Immunization Practices reviewed the vaccine development data. Extensive post-monitoring efforts will be implemented to safeguard those immunized.

Why don't the makers have liability? What is an EUA?

- An Emergency Use Authorization (EUA) is a mechanism to facilitate the availability and use of medical countermeasures, including vaccines, during public health emergencies, such as the current COVID-19 pandemic.
- Under an EUA, FDA may allow the use of unapproved medical products, or unapproved uses of approved medical products in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when certain statutory criteria have been met, including that there are no adequate, approved, and available alternatives.
- Taking into consideration input from the FDA, manufacturers decide whether and when to submit an EUA request to FDA.

What are the long-term effects of the vaccine?

- At this time the FDA, manufacturers and researchers are still gathering data to determine if there are any long-term side effects of the vaccine. The early phases of some clinical trials began as early as last May so it still hasn't been quite a year that the vaccine has been in use. However, the manufacturers, FDA and CDC continue to follow those in clinical trials to identify any potential issues.

What are the impacts on fertility?

- Pregnant individuals are at an increased risk for severe illness for COVID-19 when compared to non-pregnant people.
- There has been no evidence that COVID-19 vaccination causes pregnancy or fertility problems.
- Pregnant women may choose to be vaccinated when it is offered and may want to consider speaking to their physician if they have concerns.
- According to the CDC, the vaccinated mother will transfer protection to the child by transplacental transfer of IgG antibody to the infant, also through breastfeeding.

When can individuals 12-15 be vaccinated?

- Trials are currently underway for this age group (Pfizer and Moderna).
- Pfizer has submitted its trial data to the FDA and requested that its EUA be amended to include eligibility for 12 -- 15 year olds. The FDA has promised an expedited review but has not shared any specific timeline.

Why would a healthy person get the vaccine?

- Vaccines are the best defense we have against infectious diseases.
- There are many reasons to get the vaccine when it becomes available. The most compelling one is that it could protect you and those around you from this life-threatening virus.
- It's also safe. The FDA will only approve vaccines for release under these emergency conditions that have data proving its safety and that meet or exceed minimum efficacy thresholds.
- It is effective. Like with the flu vaccine, it's the most effective way to prevent getting COVID-19, and experts believe it may help you from getting seriously ill even if (much like the flu) you do get the virus.
- Large-scale clinical trials have shown that two of the vaccines currently approved have more than a 90 percent effectiveness rate. **All three are equally effective (100%) at preventing death and hospitalization**, and are similarly effective at preventing severe disease from COVID.

- COVID-19 does not discriminate. We have seen completely healthy young people become extremely ill and some even continue to experience effects such as compromised immune systems for as long as a year after. You cannot guarantee that you would only experience a mild case of the disease. By getting vaccinated you are giving yourself the best chance at preventing serious illness, hospitalization and death.