Kentucky Hospital Research & Education Foundation
Emergency Preparedness Update
for April 13, 2021

CDC and FDA Pause Johnson & Johnson COVID-19 Vaccine
Convening ACIP Wednesday to Begin a Review

(Joint Statement) As of April 12, more than 6.8 million doses of the Johnson & Johnson (Janssen) vaccine have been administered in the U.S. CDC and FDA are reviewing data involving six reported U.S. cases of a rare and severe type of blood clot in individuals after receiving the J&J 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. 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.

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, we are recommending a pause in the use of this vaccine out of an abundance of caution.*** This is important, 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.

Right now, these adverse events appear to be extremely rare. COVID-19 vaccine safety is a top priority for the federal government, and we take all reports of health problems following COVID-19 vaccination very seriously. People who have 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.

Health care providers are asked to report adverse events to the Vaccine Adverse Event Reporting System at https://vaers.hhs.gov/reportevent.html.

Listen to media briefing: https://www.youtube.com/watch?v=_ELXnGYgsJY

CDC Issues a Health Alert Advisory of
Cases of Cerebral Venous Sinus Thrombosis with Thrombocytopenia
after Receipt of the Johnson & Johnson COVID-19 Vaccine

In addition to recapping the press release above, the CDC HAN also includes RECOMMENDATIONS:

For Clinicians

1. Pause the use of the J&J COVID-19 vaccine until the ACIP is able to further review these CVST cases in the context of thrombocytopenia and assess their potential significance.
2. 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 (tiny red spots on the skin), or new or easy bruising. Obtain platelet counts and screen for evidence of immune thrombotic thrombocytopenia.
3. In patients with a thrombotic event and thrombocytopenia after the J&J COVID-19 vaccine, evaluate initially with a screening PF4 enzyme-linked immunosorbent (ELISA) assay as would be performed for autoimmune HIT. Consultation with a hematologist is strongly recommended.
4. Do not treat patients with thrombotic events and thrombocytopenia following receipt of J&J COVID-19 vaccine with heparin, unless HIT testing is negative.
5. 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.
6. Report adverse events to VAERS, including serious and life-threatening adverse events and deaths in patients following receipt of COVID-19 vaccines as required under the Emergency Use Authorizations for COVID-19 vaccines.

For Public Health

1. Pause the use of the J&J COVID-19 vaccine in public health clinics until the ACIP is able to further review these CVST cases in the context of thrombocytopenia and assess their potential significance.
2. Encourage healthcare providers and the public to report all serious and life-threatening adverse events and deaths following receipt of COVID-19 vaccines to VAERS as required under the EUAs for COVID-19 vaccines.
3. Disseminate this alert to healthcare providers in your jurisdictions.

For the Public

1. If you have received the J&J COVID-19 vaccine and develop severe headache, abdominal pain, leg pain, or shortness of breath within three weeks after vaccination, contact your healthcare provider, or seek medical care.
2. Report adverse events following receipt of any COVID-19 vaccine to VAERS.
3. If you are scheduled to receive the J&J vaccine, please contact your healthcare provider, vaccination location, or clinic to learn about additional vaccine availability.

Full HAN-00442 direct link: https://emergency.cdc.gov/han/2021/han00442.asp

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KY Governor Comments on Temporary Pause of J&J Vaccines
Updated COVID-19 data

(Press Release) Gov. Andy Beshear and Dr. Steven Stack, commissioner of the Kentucky Department for Public Health, advised all Kentucky vaccine providers to temporarily pause the use of the Johnson & Johnson (J&J) vaccine.

"Everyone should still get one of the other two COVID-19 vaccines during this pause. We cannot let this slow us down. The United States is going to get about 1.85 million more doses of Pfizer and Moderna vaccines this week. We should be able to make up any loss of appointments," Gov. Beshear said. "Stay calm – it looks like the risk here from the J&J vaccine is very, very small versus the really significant risk of being harmed by COVID."

The Governor reported 1,586,411 Kentuckians have received at least one COVID-19 vaccine dose so far. There were 799 new cases today, with 405 currently hospitalized. The positivity rate is 3.20%. There were three new deaths recorded, with 1 new audit death, for a total of 6,261.

Johns Hopkins: Health Security Headlines
Extracts from April 12, 2021 & April 13, 2021

Updated NIH COVID-19 Treatment Guidelines Recommend REGEN-COV for Non-hospitalized, High Risk Patients *(Homeland Preparedness News)* A mix of casirivimab and imdevimab, Regeneron Pharmaceuticals Inc.'s REGEN-COV, is now strongly recommended by the National Institutes of Health (NIH) for high risk COVID-19 patients that are non-hospitalized. The drug was given a strong rate based on randomized trials, which involved more than 4,500 outpatients. That data showed REGEN-COV significantly reduced the risk of hospitalization or death by 70 percent when compared to placebo.

Incorporating HIV Screening With COVID-19 Testing in an Urban Emergency Department During the Pandemic *(JAMA Internal Medicine)* The COVID-19 pandemic has had negative consequences on HIV care and prevention programs, including routine HIV screening in health care settings. Herein, we report the results of incorporating phlebotomy for universal HIV screening into COVID-19 testing at The University of Chicago Medicine (UCM) emergency department (ED) for the purpose of maintaining screening volumes. Most sites experienced significant reductions in HIV screens during the pandemic, and overall, the program saw a 49% reduction in testing events from January 1 to April 30, 2020. The ED at UCM, however, maintained HIV screening volumes throughout the pandemic and performed 19,111 HIV screens (14,215 in the ED) between January 1 and October 16, 2020, along with 112,242 COVID-19 polymerase chain reaction (PCR) tests (18,830 in the ED).

States Have Been Slow to Order Allotted Vaccine Doses, Spurring Calls For New Approach *(Washington Post)* States have delayed ordering hundreds of thousands of vaccine doses available to them even as coronavirus outbreaks escalate — a sign the nation is moving past its supply pinch and now faces more acute challenges related to demand, staffing and inoculation of hard-to-reach populations. The question that defined the early weeks of the vaccine rollout was why states were taking so long to administer the doses they got from

the federal government. Four months into the effort, what's most mystifying is the number of states waiting to order all the doses they've been allotted, based on their adult populations and the supplies available that week.

$100K bond set for Michigan man charged after allegedly claiming he had a car bomb at an Ohio Nuclear Power Plant

Learn more: https://www.news5cleveland.com/news/local-news/oh-lake/100k-bond-set-for-michigan-man-charged-after-allegedly-claiming-he-had-a-bomb-at-perry-nuclear-power-plant

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Brain disease transmitted by tick bites may be treatable

(Medical Xpress) Tick-borne encephalitis is a disease just as nasty as it sounds. Once bitten by an infected tick, some people develop flu-like symptoms that resolve quietly but leave behind rampant neurological disease—brain swelling, memory loss, and cognitive decline. Cases are on the rise in Central Europe and Russia with some 10,000 incidents reported each year. Vaccines can provide protection, but only for a limited time. There is no cure.

Now a new study describes antibodies capable of neutralizing the virus transmitted by tick bites. These so-called broadly neutralizing antibodies have shown promise in preventing TBE in mice and could inform the development of better vaccines for humans. Further, preliminary results suggest that the antibodies may not only prevent tick-borne encephalitis but even treat the condition, as well as the related Powassan virus emerging in the United States.

Full story: https://medicalxpress.com/news/2021-04-brain-disease-transmitted-treatable.html

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DHS S&T expands cybersecurity tech pilot

(Homeland Preparedness News) The U.S. Department of Homeland Security (DHS) Science and Technology Directorate (S&T) announced that it is expanding a pilot test of technology that improves the cybersecurity defenses for the country's emergency communications infrastructure. In a news release issued on Thursday, S&T said it would be funding Odenton, MD.-based SecuLore Solutions to do research and development of a cybersecurity defense solution based on predictive analytics and cyber data to detect and mitigate cybersecurity attacks on emergency communications systems, including Next Generation 911 and Internet Protocol-based technologies. <Read more >

The KHREF Emergency Preparedness Update is assembled several times a week. When events make it necessary, the Update may be sent out several times a day to keep our hospital and the healthcare community advised on preparedness news and information. Most of this information is compiled from open sources, and where possible reference links will be provided. There is an archive of Emergency Preparedness Updates available here. If you would like to added or deleted, or have something you would like to contribute to a future edition of the Emergency Preparedness Update, please contact Preparedness@kyha.com (include your current email address). The preparedness program for the Kentucky Hospital Association (KHA) and KHREF are supported by US DHHS ASPR HPP funds through a contract with Kentucky Public Health.