FDA, CDC recommend “pause” in use of Johnson & Johnson’s COVID vaccine over rare but unusual blood clots

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13 April 2021

The US Centers for Disease Control and Prevention (CDC) and the US Food and Drug Administration (FDA) have recommended that the US temporarily halt vaccinations with the Johnson & Johnson (J&J) COVID-19 vaccine over concerns about “rare and severe” types of blood clots.

Reportedly, six people developed cerebral venous sinus thrombosis (CVST) shortly after inoculation with the J&J vaccine. One person died. All six were women between the ages of 18 and 43 who developed symptoms six to 13 days after receiving the vaccines. Thus far, almost 7 million doses of the J&J vaccine have been given, meaning that the negative outcome is literally one in a million.

Last week, the European Medicines Agency (EMA), the UK’s Medicines and Healthcare products Regulatory Agency (MHRA) and the World Health Organization (WHO) issued statements that there were plausible links between AstraZeneca’s COVID-19 vaccine and these very rare and unusual blood clot disorders that are accompanied by a drop in the platelet counts.

The J&J and AstraZeneca vaccines share a common mechanism for their products. A modified human adenovirus that contains a gene for making the spike protein of the SARS-CoV-2 virus is used to inoculate people who then develop antibodies against the coronavirus.

Two recent scientific studies, one from Germany and the other from Norway, have established a causal relationship between the AstraZeneca vaccine and the severe thrombotic complications, according to an account published on Monday on *Medscape*.

The report says: “These unusual severe thrombotic events that are accompanied by thrombocytopenia (low platelets) are caused by rogue antibodies directed against platelet factor 4 (PF4), which cause massive platelet aggregation and thrombosis, and result in reduced platelet count elsewhere, leading in turn to bleeding. Patients can therefore have both severe thrombosis (blood clots) and severe bleeding.”

The syndrome dubbed “vaccine-induced immune thrombotic thrombocytopenia (VITT)” is treated like a similar condition known as heparin-induced thrombocytopenia using intravenous immunoglobulins (IVIG) and blood thinners. It has yet to be determined if the immune mechanism that has been elucidated for AstraZeneca will prove to implicate the J&J COVID-19 vaccines, though the diagnoses of these patients are the same.

Dr. Carlos del Rio of Emory University School of Medicine, speaking to CNN, commented that the blood clotting may be connected to the fact that J&J’s vaccine is an adenovirus vector vaccine, the same type as AstraZeneca’s. However, these researchers still do not know why these vaccines are inducing these immune-mediated complications.

Dr. Peter Marks, director of the FDA’s Center for Biologics Evaluation and Research, and Dr. Anne Schuchat, principal deputy director of the CDC, issued a joint statement yesterday announcing that the Advisory Committee on Immunization Practices (ACIP) would meet Wednesday “to further review these cases and assess their potential significance.”

Complications with J&J’s COVID vaccine were first announced last Friday by the EMA through their Pharmacovigilance Risk Assessment Committee. They had stated they were reviewing four cases from the US of unusual blood clotting that included one fatality. One of these recipients of the vaccine had developed the blood clot during the clinical trials.

The mRNA vaccines, Pfizer and Moderna, have had their share of concerns raised with low platelets found after immunizations. A Florida physician developed a severe though unusual blood disorder called acute immune thrombocytopenia, where his platelet counts dropped rapidly. He died of bleeding in his brain 16 days after receiving his first dose of the Pfizer vaccine. In total, 20 cases have been reported with low platelets after administration of these vaccines.

In line with these recommendations, J&J issued its own statement on Tuesday stating it is “proactively” delaying the rollout of its vaccine in Europe. “We have been working closely with medical experts and health authorities, and we strongly support the open communications of this information to healthcare professionals and the public,” the company said. They also added that recipients of the J&J vaccine who develop severe headaches, abdominal pain, leg pain, or shortness of breath within three weeks of their injection should seek medical attention.

Since receiving emergency use authorization from the FDA in February, J&J’s single-dose COVID-19 vaccine has faced a series of serious setbacks, most of them involving production rather than use. The present concerns over these rare complications will certainly impede the accelerating national vaccine rollout.

Just two weeks ago, it was reported that 15 million doses of the

J&J COVID-19 vaccines, manufactured at the Baltimore, Maryland, biotech plant operated by Emergent BioSolutions, had inadvertently been contaminated with material intended for production of the AstraZeneca vaccine, which was also being produced there.

The ensuing investigation had revealed that Emergent has been facing severe quality control issues at its plant for some time. Internal documents had shown that several batches of its AstraZeneca's vaccine had to be discarded in October and December, which would have accounted for 2 to 3 million doses.

Additional concerns unearthed by recent audits include lack of strict adherence to protocols and inadequate controls of the movement of staff and materials, with risks of microbiological contamination, all because the company was under pressure to expedite production. Federal regulators had known about these issues, but little has been done to address these growing concerns.

According to an exposé published by the *New York Times* on April 6, "An examination … of manufacturing practices at the Baltimore facility found serious problems, including a corporate culture that often ignored or deflected missteps and a government sponsor, the Biomedical Advanced Research and Development Authority (BARDA), that acted more as a partner than a policeman. Previously undisclosed internal documents and interviews with current and former federal officials and former company employees depict a factory operation that was ill-equipped to take on such a mammoth manufacturing task, despite Emergent's having received a $163 million federal contract to improve the facility and prepare it for high-volume production."

Through the Department of Health and Human Services, the Biden administration intervened soon after news of the contamination of the vaccines was made public by placing J&J in charge of the Baltimore biotech firm, including its employees, and discontinued the production of AstraZeneca COVID-19 vaccines at the Baltimore facility. This was an unprecedented move to transfer leadership responsibility to J&J for overseeing all production and manufacturing at the Emergent plant. White House officials were concerned the debacle would seriously impact public confidence in the product and needed to act quickly to shore up their public relations.

Prior to the present pause in using the J&J vaccine, the CDC had estimated that it would be allocating 86 percent fewer doses of the J&J vaccine across the country than previously promised. The ongoing investigation found that the error had been made some time in February but had gone undiscovered for several days until J&J's quality control check picked it up before readying the vaccines for distribution.

Though the factory has made roughly 150 million doses of COVID vaccines, government regulators have yet to certify the factory to allow the vaccines to be distributed to the public. Currently, all J&J vaccines being distributed in the US have been produced at J&J's plant in the Netherlands.

Federal officials had attempted to downplay concerns raised by state governments that the loss in supplies from J&J would impact their vaccination drives, by claiming that Pfizer's and Moderna's mRNA vaccines could make up the shortfall. However, California has reported it expects to see a 15 percent drop (400,000 fewer doses) in all vaccines next week. Similarly, states like Texas, Virginia and Florida will see drastic reductions in their vaccine allotments.

New York Governor Andrew Cuomo said in a statement last week, "We will not be able to get as many shots into New Yorkers' arms as we would like. As has been the case since the beginning of our vaccination effort, the X factor is supply, supply, supply." Maryland Governor Larry Hogan told the press, "The last thing we wanted to hear about was we're getting less vaccines." Michigan Governor Gretchen Whitmer has begged President Biden "to surge vaccines" into her state, where the outbreak is leading to another growing health care crisis. However, none of these state governors has opted to use mitigation strategies to curb the tide of infections.

Additionally, it has been reported that several vaccination sites administering the J&J vaccines—one in Colorado, three in North Carolina, one in Georgia and still another in Iowa—all temporarily suspended operations after several reports of adverse reactions raised concerns over the vaccine's safety. Approximately 45 people, a number higher than expected, had experienced nausea, dizziness, fainting or lightheadedness.

The current issues emerging with rare but serious complications from COVID-19 vaccines are on par with historical experience. It is important that scientists and specialists have the necessary time to investigate these drawbacks. However, the fundamental problem with the US vaccine campaign is attempting to entirely supplement what is most necessary—a comprehensive public health effort to stem the rising tide of infections.

A vaccination campaign must be conducted in a coherent and well-regulated manner to ensure the utmost safety and thorough documentation of all adverse reactions. More so, a system of reporting post-vaccination infections and health outcomes needs to be in place to assure recipients that their concerns and safety are a priority.

Critical is also the establishment of manufacturing and production centers that have been thoroughly vetted by inspectors providing the highest quality assurance. Redundant safety measures must be in place to ensure these life-saving treatments are produced according to the highest standards. It is precisely under a policy of herd immunity that the frenzy to produce and distribute the vaccine has led to the current debacles that continue to erode the public's trust, further exacerbating the efforts to bring the pandemic to an end.