NACo FAQ: Johnson and Johnson Vaccine Distribution Pause

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SUMMARY/OVERVIEW

On April 13, The Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) recommended pausing the use of Johnson and Johnson's Janssen vaccine out of an abundance of caution after reports of blood clotting in 6 individuals who recently received the vaccine.

While NACo is closely monitoring this announcement in an effort to put forth timely and relevant information for members, please see below for answers from federal officials to commonly asked questions regarding the announcement.

1. *Why was the paused announced?*

The FDA & CDC has recommended a pause (not a stop) of J&J vaccinations based solely on the below:

1. Due to the rare nature of the clotting condition, it is important that doctors and healthcare professionals know what signs and symptoms to look out for. This particular clotting condition cannot be treated with the standard procedures for blood clotting, and requires special medical procedures to treat or otherwise it can be fatal. The pause gives the FDA and CDC time to aggressively provide outreach to healthcare providers on how they can diagnose, treat, and report this rare condition.

2. The pause gives the scientific and medical community more time to assess correlation of the clotting condition to the Johnson and Johnson vaccine or predisposing conditions of those impacted. *So in other words, is this a direct result of the vaccination or do these individuals have other illnesses and conditions that contribute to their likelihood of developing blood clots?*

3. The pause will allow a panel of CDC advisors to make new or modified recommendations on who should get the vaccine, if necessary based on further investigation.

2. *What should messaging be for those individuals who have already received the Johnson and Johnson vaccine?*

The occurrence of these blood clots following the J&J vaccination are extremely rare, impacting only 6 individuals out of approximately 7 million people who have received the vaccine thus far. As the below press release indicates, all 6 of these cases occurred in women between the ages of 18-48, with symptoms occurring 6-13 days after vaccination.

FDA officials are encouraging people who received J&J in last couple weeks to monitor symptoms of blood clotting, which include severe headaches, abdominal pain, leg pain, and/or shortness of breath. These symptoms differ from typical symptoms people generally have after being vaccinated, which include (but are not limited to) pain the arm where the shot was administered, fatigue, and fever.

Officials from both CDC and FDA emphasized that people who have received a vaccine from either Pfizer or Moderna , or have received a Johnson and Johnson vaccine more than three weeks ago should not be concerned. No clotting incidences have been identified in the nearly 185 million people combined that have received the Pfizer Moderna vaccines. Those individuals who are experiencing symptoms of blood clotting after being vaccinated by the Johnson and Johnson vaccine should contact their medical provider and disclose that they were recently vaccinated.

3. *What impact will this have on vaccination appointments & vaccine supply?*

Local officials should work to reschedule appointments with patients who had appointments to receive the Johnson and Johnson vaccines and redirect them to Pfizer or Moderna vaccine appointments, until federal authorities indicate that Johnson and Johnson vaccinations are safe to continue.

On April 13, the White House released a statement indicating that the announcement regarding the Johnson and Johnson vaccine will not impact the supply vaccine doses to local authorities. The federal government intends to make 28 million doses of Pfizer and Moderna available to states beginning the week of April 12 to account for the potential impact, a 3 million dose increase from the previous week.

4. *How long will the pause last?*

CDC and FDA experts are projecting that the pause should only last for a matter of days, though there was no specific timeline given. The CDC's Advisory Committee on Immunization Practices (ACIP) held an emergency meeting on at 1:30 p.m. on April 14 to review these cases, assess their significance, and determine next steps. Following this event, the FDA and CDC will examine the committee's findings and communicate their results with healthcare providers.

5. *What is the federal government advising local distribution sites to do with Johnson and Johnson vaccine doses at this time, especially given that the timeline for the pause remains uncertain?*

The CDC recommends continuing to store the J&J vaccine in a refrigerator between 36°F and 46°F, which some counties are already doing because of the pause. Additionally, the CDC recommends determining if the expiration date has been extended by scanning the QR code before disposing of the vaccine.

6. *What some of the key messages county officials can deliver to their constituents to ensure that vaccine hesitancy does not spread in light of the announcement about the Johnson and Johnson vaccine?*

   The CDC has emphasized the vaccines continue to undergo the most intensive safety monitoring in U.S. history. The CDC has also reiterated there have been no reported cases of blood clotting related to the Pfizer and Moderna vaccines, and the risk of developing a blood clot as a result of the J&J vaccine is very low.

7. *What insights are there from the advisory committee meeting that took place on April 14 regarding the timeline for resuming Johnson and Johnson vaccinations?*

   A CDC panel of experts will likely reconvene within 7-10 days to asses how to proceed with the vaccine. The group, which did not rule on the J&J vaccine in its meeting yesterday due to a lack of data, will likely decide by Friday on when it will reconvene.