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## CDC, kidney community leaders push safety of COVID-19 vaccines for staff, patients

Kidney care organizations and dialysis providers joined the CDC last week in efforts to assure dialysis clinic and transplant center staff that COVID-19 vaccinations are safe for themselves and their patients.

"We have tracked 21 cases of anaphylaxis in the United States among 1.89 million doses given," Kathleen **Dooling, MD, MPH,** a medical officer at the CDC and a panelist on the webinar "Safety and efficacy of COVID-19 vaccines in the dialysis population," which was organized by the American Society of Nephrology, said. "That is 11.1 cases of anaphylaxis per million doses."



Source: Adobe Stock

Both the Moderna and the Pfizer-BioNTech vaccines approved by the FDA have demonstrated efficacy at greater than 90% across age groups, as well as across racial and ethnic groups during trials, Dooling said.

While the vaccine safety profile of both products is acceptable, she said, dialysis providers should counsel patients before vaccination about expected local and systemic post-vaccination symptoms.

"Among clinical trial participants, 80% to 89% reported one local reaction or more that included pain or swelling at the injection site; 55% to 83% of clinical trial participants reported one or more systemic reaction, which included fever, fatigue, muscle aches, headache and chills," Dooling said. "Most are mild to moderate in severity, occur within the first 3 days of vaccination and resolve within 1 to 2 days of onset."

Vaccinations should be offered regardless of history of prior symptomatic or asymptomatic SARS-CoV-2 infection, Dooling said. People with HIV infection, other immunocompromising conditions or who take immunosuppressive medications, such as transplant patients, might be at increased risk for severe COVID-19, she said. "Data is not currently available to establish safety and efficacy of the vaccines in these groups," she said.

Health care personnel and long-term care facility residents have been prioritized by federal agencies to receive one of the two vaccines to treat COVID-19. In the kidney care community, dialysis center staff receive high priority, like other health care workers, to receive the vaccine, as do patients on dialysis who are older than 75 years.

The virus has led to 381,000 deaths in the United States in the past year.

Panelist **Talat Alp Ikizler**, **MD**, said efficacy of the two vaccines in patients on dialysis remains unclear because high-risk individuals were not included in the Moderna and Pfizer-BioNTech trials.

"The Pfizer trial only included 250 chronic kidney disease patients among the 40,000 patients receiving the vaccine," Ikizler, the director of the division of nephrology and hypertension and professor of medicine and Catherine McLaughlin Hakim chair in vascular biology at the Vanderbilt University School of Medicine in Nashville, Tennessee, said. "The Moderna trial did not include any patients with CKD.

"Fortunately, there are 236 registered vaccine trials for COVID-19 going on now around the world," Ikizler said. "That is a number we should be optimistic about."

That includes 12 vaccines being studied in phase 3 trials. Novavax Inc. plans to enroll 30,000 people at approximately 115 sites in the United States and Mexico for one of those phase 3 trials and will include patients with end-stage kidney disease and CKD, he said.

While patients on dialysis are a high priority for the vaccination, other patients in that category – phase A1c – include those with COPD and other conditions, like obesity, Ikizler said. "That means we will have to compete with one out of every two patients" to get patients on dialysis vaccinated, he said. Patients who smoke are also part of the same vaccination group. "This is an important problem that we need to take into account," he said.

While both vaccines worked effectively among all patients, "there is a trust gap ... there is a history of mistreatment in medical care" among people of color that might make patients hesitant about taking the vaccine, Dooley said.

Likewise, dialysis staff have shown some reluctance about taking the vaccine. "We have seen a 50/50 split among staff in my unit among those who are taking the vaccine and those who are not," Elizabeth Fortune, a patient on dialysis and spokesperson for the National Kidney Foundation, said during the webinar.

Recently, the CDC collaborated with the Ad Council on a <u>video encouraging health care workers</u> to get vaccinated.



With patients on dialysis selected as a high priority by the CDC for vaccinations, particularly older patients, panelist **Brigitte Schiller**, **MD**, who leads quality and medical policy strategy at Satellite Healthcare, said centers need to be proactive about delivering vaccinations. "There are over 100 million patients who fit into the phase A1c category ... we need to identify patients who are older than 75 years of age in our clinics. The U.S. Renal Data System indicates there are

162,000 patients in this age group," she said.

Clinics should start vaccine surveys among patients and address logistics for distribution to assess immediate need and to determine how to obtain the vaccine. "Continue to advocate for higher risk allocation vs. less risky conditions," Schiller said.

Patients on in-center hemodialysis should get the vaccine during their treatment; patients on home dialysis should be vaccinated during their monthly visits. Vaccine administration should take place at least 30 minutes prior to leaving the dialysis clinic.

"It is important to monitor and document any potential systemic reactions or adverse responses for 30 minutes post vaccination and perform a vital sign check after the vaccination," she said.

## **Reference:**

American Society of Nephrology. Safety and efficacy of COVID-19 vaccines in the dialysis population. Presented: Jan. 7, 2021. www.asn-online.org/covid-19/

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