



NATIONAL KIDNEY
FOUNDATION®

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January 24, 2021

José R. Romero MD, FAAP
Chair, Advisory Committee on Immunization Practices
Secretary, Arkansas Department of Health
4815 West Markham
Little Rock, AR 72205

Amanda Cohn, MD
Executive Secretary, Advisory Committee on Immunization Practices
Centers for Disease Control and Prevention
1600 Clifton Road
Roybal Campus, Building 24, Room 8124
Atlanta, GA 30329

Stephanie Thomas
ACIP Committee Management Specialist
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National Center for Immunization and Respiratory Diseases
1600 Clifton Road NE, MS-H24-8
Atlanta, GA 30329-4027

Re: Docket No. CDC-2021-0002, c/o Attn: January 27, 2021 ACIP Meeting

Dear Dr. Romero,

The National Kidney Foundation (NKF) wishes to express our gratitude to the Centers for Disease Control and Prevention and specifically the members of the Advisory Committee on Immunization Practices for your service to the nation during these unprecedented times of the COVID-19 pandemic. In advance of the January 27, 2021 ACIP meeting, the following letter highlights the special vulnerability of kidney patients to COVID-19.

The National Kidney Foundation (NKF) represents the more than 37 million adults in the U.S. with kidney disease, their families, and the professionals who care for them. We believe that a key principle of ethical vaccine allocation must be that the vaccine is made available to patients at the highest risk of severe outcomes from COVID-19 infection. *Accordingly, as ACIP continues to provide guidance on vaccine prioritization to federal, state, and local jurisdictions, we request that the committee take steps to prioritize kidney patients and kidney care professionals in order to reduce their increased risk of severe morbidity and mortality caused by the novel coronavirus.*



Patients on dialysis are at particularly high risk from COVID-19, due to the increased age of the population, numerous underlying comorbidities, community exposure, and the inability of dialysis patients to social distance in the dialysis facility, where patients spend 11 to 12 hours a week in close contact with others.

As identified by Medicare’s COVID-19 Data Snapshot, Medicare beneficiaries with ESRD are nearly four times as likely to have contracted COVID-19 as aged or disabled beneficiaries and more than seven times more likely to be hospitalized.¹ Dialysis patients who contract COVID-19 are at extremely high risk of short-term mortality, likely higher than 20 percent. During the peak of the first wave of the COVID-19 pandemic, all-cause mortality among all dialysis patients in the United States was 37 percent higher than during the corresponding weeks in previous years.² **Between the end of March and the end of June 2020, the total number of patients with ESRD actually declined, an unprecedented development that underscores the profound impact of COVID-19 on kidney patients.**

Kidney disease patients who have not reached kidney failure are at similarly high risk. Patients with more serious forms of kidney disease are also at high risk of death, higher even than patients with more commonly cited risk factors for poor COVID-19 outcomes such as hypertension, chronic heart disease, chronic lung disease, or obesity.

Individuals who have received a kidney transplant are also at unique risk of COVID-19 infection, given their lifelong reliance on immunosuppressive drug therapy. Transplant recipients appear to have clinically worse outcomes from SARS-CoV-2 infection compared to non-transplant recipients due to comorbidities or immunosuppression.³ During the peak of the first wave of the COVID-19 pandemic, mortality among transplant recipients was 61 percent higher than during the corresponding weeks of each of the three prior years.⁴

Given the relative risk of kidney patients to severe COVID-19 infection and outcomes, NKF calls on ACIP to prioritize kidney patients and their caregivers in their COVID-19 vaccine prioritization strategy. Among kidney patients, we recommend prioritization based on relative risk for poor COVID-19 outcomes, using the following approach:

1. In-center dialysis patients and staff
2. Home dialysis patients
3. Transplant patients

¹ <https://www.cms.gov/files/document/medicare-covid-19-data-snapshot-fact-sheet.pdf>

² <https://adr.usrds.org/2020/covid-19-supplement/1-covid-19-supplement>

³ Caillard S, Chavarot N, Francois H, Matignon M, Greze C, Kamar N, et al. Is COVID-19 infection more severe in kidney transplant recipients? *Am J Transplant*. 2020.

⁴ <https://adr.usrds.org/2020/covid-19-supplement/1-covid-19-supplement>

4. Immunosuppressed chronic kidney disease (CKD) patients (e.g., patients with glomerular disease, auto-immune disorders, etc.)
5. Other CKD patients
6. Individuals living in the same household as kidney patients.

Though out of scope for ACIP specifically, we note the importance for all policymakers of the need for an infrastructure to support the dissemination of the COVID-19 vaccine. Over 500,000 patients nationally rely on life-saving dialysis to replace kidney function. Almost 90 percent of these patients dialyze in facilities, where dialysis is performed three times a week for 4 hours at a time. While dialysis facilities are a practical site for vulnerable kidney patients to be vaccinated, facilities may not have the supplies to safely store the vaccine. It is vital that dialysis facilities, among other sites where kidney patients receive care, have the support and supplies needed to expeditiously implement priority vaccinate practices.

Vaccine Safety and Efficacy

NKF appreciates national efforts to ensure that vaccine candidates meet rigorous standards for safety and efficacy. As several vaccine candidates were developed from research conducted on previous coronaviruses, evidence about safety and efficacy is promising.

It is worth noting, however, that few of the vaccine candidates were widely tested in individuals with kidney disease. The Pfizer-BioNTech COVID-19 vaccine briefing document submitted to the U.S. Food and Drug Administration Vaccines and Related Biological Products Advisory Committee noted that patients with kidney disease could be enrolled in phase 2/3 at the investigator's judgement, however that the most common comorbidities represented in both treatment groups were diabetes and pulmonary disease with only 0.7% of enrolled patients having kidney disease.^{5,6} People on immunosuppressive therapy were excluded from the Pfizer-BioNTech phase 2/3, Moderna phase 3, and Astra-Zeneca/Oxford studies.^{7,8} Thus, it is our impression that none of the first-to-market COVID-19 vaccinations will have been tested in solid organ recipients.

NKF calls on policymakers and vaccine manufacturers to carefully monitor and collect data on vaccine safety and efficacy among kidney patients to ensure patient safety and to inform future vaccine development.

Vaccine Hesitancy

⁵ <https://www.fda.gov/media/144246/download>

⁶ <https://www.nejm.org/doi/full/10.1056/NEJMoa2034577>

⁷ <https://www.nejm.org/doi/full/10.1056/NEJMoa2034577>

⁸ <https://clinicaltrials.gov/ct2/show/NCT04470427>



The burdens of kidney disease and COVID-19 disproportionately on Black and Hispanic communities. Recent survey data from the COVID Collaborative, Langer Research, UnidosUS and the NAACP identify low levels of trust in a COVID-19 vaccine among both Black and Hispanic people, though particularly among Black adults only 14 percent of whom “completely or mostly trust that a vaccine will be safe.”⁹ NKF recommends that state and local policymakers follow the recommendations of public health leaders of Color on how best to encourage vaccine uptake in these communities.

Once again, we thank ACIP for its guidance in providing COVID-19 recommendations to state and local policymakers and for its service to public health. NKF would welcome the opportunity to comment further on the needs of people affected by kidney disease as the COVID-19 pandemic continues. Please contact Miriam Godwin, Director of Health Policy, at miriam.godwin@kidney.org,

Sincerely,

A handwritten signature in black ink, appearing to be "K. Longino".

Kevin Longino
CEO and transplant patient

A handwritten signature in black ink, appearing to be "P. Palevsky".

Paul Palevsky, MD
President

⁹ <https://www.covidcollaborative.us/content/vaccine-treatments/coronavirus-vaccine-hesitancy-in-black-and-latinx-communities>