



30 E. 33rd Street
New York, NY 10016

Tel 212.889.2210
Fax 212.689.9261
www.kidney.org

Position Statement on Kidney Patient Prioritization for COVID-19 Vaccines and Therapeutics

The National Kidney Foundation (NKF), representing the more than 37 million adults in the U.S. with kidney disease, their families, and the professionals who care for them, believes 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, we urge the federal government to prioritize kidney patients and kidney care professionals, along with residents of long-term care facilities and health care workers, in receiving access to COVID-19 vaccines to reduce their increased risk of severe morbidity and mortality caused by the novel coronavirus.**

The federal government must also prioritize the development of an infrastructure to support the dissemination of the COVID-19 vaccine to kidney patients. Over 500,000 people in the U.S. 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.

COVID-19 and its Impact on Kidney Patients

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, possibly higher than 20 percent. Since the

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

onset of the COVID-19 pandemic all-cause mortality among all dialysis patients has been between 16 and 37 percent higher than during the corresponding weeks in previous years.²

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 After the onset of the COVID-19 pandemic, mortality among transplant recipients has been between 61 and 26 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 the federal government to prioritize kidney patients and their caregivers in their COVID-19 vaccine distribution plans and to work with states to ensure prompt vaccine distribution to kidney patients. 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
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

Vaccine Safety and Efficacy

NKF appreciates the efforts of the Administration, specifically the leadership of the Department of Health and Human Services (HHS), the Food and Drug Administration, the National Institutes

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>

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of Health (NIH), researchers, and vaccine manufacturers 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, vaccine manufacturers, and developers 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

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 federal, state, and local policymakers follow the recommendations of public health leaders of Color on how best to encourage vaccine uptake in these communities.

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>

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