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Helene Gayle, M.D., M.P.H.
Committee Co-Chair
President and Chief Executive Officer
The Chicago Community Trust

Re: Discussion Draft of the Preliminary Framework for Equitable Allocation of COVID-19 Vaccine

Dear Drs. Foege and Gayle,

The National Kidney Foundation (NKF) appreciates the opportunity to offer our comments on the Discussion Draft of the Preliminary Framework for Equitable Allocation of COVID-19 vaccine. We are further grateful for the efforts of the experts and staff of the Committee on Equitable Allocation of Vaccine for the Novel Coronavirus to produce a preliminary framework for the allocation of a vaccine against *Coronavirus SARS-CoV-2* on such a rapid timeline. The need for a framework to guide allocation decisions has taken on increasing importance as the United States federal government, through Operation Warp Speed, has already selected three candidate vaccines for which to fund Phase 3 studies.

NKF 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 are in agreement that a principle of the framework is that it "seeks to reduce the risks of severe morbidity and mortality causes by transmission due to the novel coronavirus for those most at risk of infection and serious outcomes."¹

Per the Centers for Disease Control and Prevention (CDC), patients affected by kidney disease, including patients with chronic kidney disease (CKD), end-stage kidney disease (ESKD), and those who have received kidney transplants, are some of the highest risk populations for severe illness from COVID-19.² Preliminary Fee-For-Service (FFS) claims-based data from the Centers for Medicare and Medicaid Services (CMS) also demonstrate that End Stage Renal Disease (ESRD) beneficiaries have the highest rate of COVID-19 infections and COVID-19 hospitalizations among Medicare beneficiaries, including both FFS and Medicare Advantage (MA). Low income ESRD beneficiaries, known as "dual

¹ <https://www.nap.edu/read/25914/chapter/1>

² <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html#chronic-kidney-disease>

eligibles,” have the highest rates of COVID-19 infection and hospitalizations among all ESRD beneficiaries.³

Though we do agree that, in principle, a COVID-19 vaccine should be allocated as efficiently as possible to those who are at highest risk of poor outcomes if COVID-19 is contracted, we believe the following considerations have special relevance for the patients and professionals that NKF serves.

Lack of Evidence of Vaccine Efficacy in High-Risk Populations

According to Draft Table 2: *Applying the Allocation Criteria to Specific Population Groups*, people with significant comorbid conditions will be in allocation phase 1b. We believe this may represent a discordance between the need to make a vaccine available to those at highest risk from COVID-19 and the lack of data we expect to have from vaccine trials. The majority of COVID-19 vaccine studies registered with clinicaltrials.gov exclude at least one group of patients affected by kidney disease, including patients with CKD and ESKD (estimated glomerular filtration rate (eGFR) <60 mL/min/1.73m²), patients with common CKD comorbidities such as diabetes mellitus and chronic cardiovascular disease, and patients on immunosuppressive treatment, which would include those with solid organ, e.g. kidney, transplants. To the extent patients affected by kidney disease are included in clinical studies, we believe few if any ongoing trials are appropriately powered for evaluations of safety and efficacy in these subpopulations. Studies that evaluate vaccine effectiveness in populations at risk of severe illness and mortality will be critically important and must be conducted as swiftly as possible. At this time, however, the U.S. Food and Drug Administration (FDA) has not offered guidance to trial sponsors on the subject.

Account for the Patient Perspective

It is important to understand that there is no single viewpoint on priority access to vaccination among patients. We note that, in this context, priority access to vaccination is different from the decision to be vaccinated at all. Patients have different views on being the first to receive a vaccine for which there is little evidence of safety and efficacy for their specific circumstances. For example, kidney transplant recipients may weigh the tradeoffs between benefits and risks of vaccination differently given that transplant recipients are not usually able to take live vaccines, as well as that the tolerance of the vaccine might not be fully understood until later stages of vaccine development.

Shared decision-making between the patient and her/his care team on when to be vaccinated and in the context of what amount of evidence is an essential element of ethical vaccine allocation. Some patients affected by kidney disease may want to receive priority access to a vaccine, while others may prefer to continue to self-isolate. A common theme is that patients wish to make these decisions in collaboration with the professionals who care for them.

Ensure that Physicians, Professionals, and Family Members Caring for High-Risk Patients are Allocated Vaccine

³ <https://www.cms.gov/files/document/medicare-covid-19-data-snapshot-fact-sheet.pdf>



We acknowledge that the committee has already recognized the importance of prioritizing frontline workers for a COVID-19 vaccine. We offer the following comments that are aligned with the general principle, but that are from the specific perspective of kidney patients and professionals.

Because many of the most vulnerable patients to severe COVID-19 infection may not be able to or may not wish to take a vaccine when it is first made available, the physicians, professionals, and family members who care for and/or live with CKD patients, ESKD patients, and transplant recipients must be vaccinated as soon as possible, presuming they are healthy adults. Nursing home staff, dialysis facility staff, transplant center staff, hospital staff, physicians, and other healthcare professionals should receive priority access to a COVID-19 vaccine. Despite the wide availability of telehealth services, telehealth is not the best option for every patient. Many patients affected by kidney disease are elderly and uncomfortable using technology, live in areas without broadband access, or are not sufficiently stable to be seen virtually.

Dialysis facilities and nursing homes are still sites of significant COVID-19 transmission. Even when dialysis facilities implement robust precautions and screening measures, the potential for pre-symptomatic and asymptomatic transmission is significant because patients come to dialysis from other settings. Patients who rely on in-center dialysis must travel to and from the dialysis facility three times per week, where they are in close proximity to other patients, some of whom travel from nursing homes in shared rides. It is imperative that dialysis facility staff and nursing home staff receive a COVID-19 vaccine as soon as possible. While this will not entirely stem the transmission of COVID-19 in these settings and while vaccination of the staff will not entirely insulate these patients from infection, we do believe that providing priority access to a COVID-19 vaccine to dialysis and nursing home staff will help mitigate the astonishingly high rates of COVID-19 infections and hospitalizations among in-center dialysis patients.

The National Kidney Foundation (NKF) again offers our thanks to the National Academy of Medicine and the Committee on Equitable Allocation of Vaccine for the Novel Coronavirus for the opportunity to offer our perspective on allocation of a COVID-19 vaccine. NKF would welcome the opportunity to elaborate on these comments. Please contact Miriam Godwin at miriam.godwin@kidney.org.

Sincerely,

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

Kevin Longino
CEO and transplant patient

A handwritten signature in black ink, appearing to read "Holly Mattix Kramer".

Holly Mattix Kramer, MD, MPH
President