

***Including People with Kidney Diseases in COVID-19 Trials:  
Opportunity for Participation in Vaccine Trials***

***KHI Position Statement***

***September 14, 2020***

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Founded in 2012, the Kidney Health Initiative (KHI) is a public-private partnership between the American Society of Nephrology (ASN), the US Food and Drug Administration (FDA), and more than 100 member organizations committed to catalyzing innovation and the development of safe and effective patient-centered therapies for people with kidney diseases. ASN is the largest kidney society in the world, serving over 21,000 professionals who lead the fight to prevent, treat, and cure kidney diseases throughout the world by educating health professionals and scientists, advancing research and innovation, communicating new knowledge, and advocating for the highest quality care for patients..

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Including people with kidney disease in COVID-19 vaccine trials will ensure that the effects of any vaccine candidate will be better understood in people with kidney disease as well as the general population. This inclusion is particularly important for both those with undiagnosed reduced kidney function and those clinically diagnosed with kidney diseases and kidney failure.

In May 2020, the Kidney Health Initiative (KHI) released a statement (1) urging the inclusion of people with kidney diseases in COVID-19 trials and has now identified several opportunities to increase enrollment of these populations.

Epidemiologic data indicates that populations with preexisting kidney disease, estimated at 37 million people in the United States (2) and 700 million around the world (3), have increased risk for developing severe complications from infection by SARS-CoV-2, the virus responsible for COVID-19. Vaccines are an important public health strategy for safeguarding high-risk populations by mitigating the risk of contracting and spreading COVID-19.

KHI calls upon all sponsors and investigators involved in current or planned COVID-19 vaccine trials to include people with kidney diseases and kidney failure, especially in phase 3 trials. KHI urges nephrologists to work with their clinical trial colleagues in other fields of medicine to identify and encourage appropriate patients to participate. KHI further encourages patient organizations to continue their ongoing COVID-19 campaigns to inform and educate their members to participate in vaccine trials for COVID-19, in consultation with their nephrologist and care team. Participation will maximize our knowledge and ultimately benefits any public health vaccination campaign for people with kidney disease. In addition, KHI strongly urges vaccine developers to actively promote safe inclusion of this important at-risk population in the design of upcoming or future phase 3 trials.

Given the large number of people with kidney disease, this population must be represented in clinical trials of COVID-19 vaccines intended for the general public (4). Of the 15% of the US population with kidney disease, minority populations are over-represented, further contributing to the disparities observed with the distribution of COVID-19 infection rates. In addition, individuals with severe chronic kidney disease (CKD) or kidney failure have an increased risk of exposure to the virus as they are disproportionately hospitalized or are in long-term care facilities. People living with kidney diseases are at higher risk of COVID-19 and should receive special consideration in any vaccination campaign.

FDA guidance documents for COVID-19 vaccine development encourages the inclusion of populations of racial and ethnic minorities most at risk for infection, inclusion of elderly patients and those with medical comorbidities (5). All of these criteria encompass people with kidney diseases. Effective immunity may be more difficult to achieve in this population, with a rich literature concerning the relative efficacy and safety of other vaccines in people with CKD, kidney failure and solid organ transplant (6). In the United States, two of the phase 3 trials currently enrolling participants do not exclude people with CKD or kidney failure. However, solid organ transplant recipients are excluded because of the possible negative effect of anti-rejection therapy on mounting an immune response to a vaccine (7, 8).

KHI recognizes this exclusion of solid transplant recipients in the two current vaccine trials and acknowledges that both the kidney community and industry must do more to address the special safety and efficacy considerations in vaccinating patients receiving immunosuppressive therapy.

Ultimately, including those with kidney diseases in all vaccine trials for COVID-19 will increase kidney patient trust in the science and development process for the vaccine among kidney patients. The successful dissemination of a vaccine will reduce the risk of infection in this population and help to make everyone safer from COVID-19.

For more information or to learn more, please visit [www.kidneyhealthinitiative.org](http://www.kidneyhealthinitiative.org).

#### **DISCLAIMER**

The views and opinions expressed in this statement are those of the authors and do not necessarily reflect the official policies of any KHI member organization, the U.S. Department of Veterans Affairs, or the U.S. Department of Health and Human Services, nor does any mention of trade names, commercial practices, or organization imply endorsement by the United States Government. Representatives from the National Institutes of Health's National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) did not review or contribute any material for this position paper.

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