

Making the Case for Change:

Including People with Kidney Diseases in COVID-19 Trials

Clinical trials often exclude people with kidney diseases. This means that 37 million people in the United States are rarely represented in the kind of research that advances change in treatment and care. The challenges that result from such exclusion are highlighted by the current COVID-19 crisis.

Preliminary [studies](#) indicate that people with kidney diseases demonstrate an increased risk (two- to sixteen-fold) for developing severe COVID-19 symptoms. These data support US statistics that show acute kidney injury occurs in up to 5% of hospitalized COVID-19 patients and 50-90% of patients in the intensive care unit. ([reference](#)) Responding effectively to the COVID-19 pandemic should include people with kidney diseases.

The development of effective therapies for COVID-19 positive patients who have underlying kidney diseases may also support efforts to minimize the burden to healthcare systems by preventing and reducing the need for hospitalizations and mechanical ventilator support in this high-risk population.

The US Food and Drug Administration (FDA) encourages enrollment practices that lead to clinical trials better reflecting the population most likely to use and benefit from the therapy being studied. This can be achieved through novel trial designs or broadening eligibility criteria, when appropriate, to increase enrollment of underrepresented populations. FDA has long encouraged adaptive trial designs, novel enrichment strategies, and adopting enrollment and retention practices that enhance inclusiveness for populations like those with kidney diseases. ([reference](#))

The Kidney Health Initiative, a public-private partnership with the American Society of Nephrology, FDA, and over 100 companies and organizations, urges all investigators to include people with kidney diseases when developing vaccines, preventative therapies or treatments related to COVID-19. This population demonstrates increased risk of exposure, infection, and severe morbidity, and inclusion of people with kidney diseases in trials would benefit all aspects of health care.

For more information or to learn more, please visit www.kidneyhealthinitiative.org.

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