

# SARS-CoV-2 Antibody Seroprevalence Among Maintenance Dialysis Patients in the United States



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**Rationale & Objective:** Reported coronavirus disease 2019 (COVID-19) cases underestimate the actual number of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infections. Patients receiving maintenance dialysis are at high risk for COVID-19 and higher case rates have been reported relative to the general population. To better understand infection patterns, we performed a seroprevalence study among maintenance dialysis patients at a large dialysis organization in the United States.

**Study Design:** Cross-sectional.

**Setting & Participants:** We measured immunoglobulin G antibodies in an institutional review board–approved study of remnant serum samples collected for routine laboratory screenings in a national sample of 12,932 maintenance dialysis patients (May 27 to July 1, 2020).

**Exposure:** State, sex, age, and race.

**Outcomes:** Seropositivity; ratio of seropositivity to known COVID-19 case rate.

**Analytic Approach:** Seropositivity was calculated overall and by state, sex, age, and race. The ratio of seropositivity to known COVID-19 cases was calculated overall and by state.

**Results:** 747 (5.8%) samples were seropositive. Seroprevalence varied by state and was lowest in

Kentucky (1.0%) and highest in New York (23.6%). Seroprevalence was similar among men and women. Among samples from patients younger than 70 years, 6.0% to 6.5% were seropositive; whereas 5.2% and 3.9% of samples from patients aged 70 to 79 and 80 years or older, respectively, were seropositive. Samples from Black and Hispanic patients were 7.3% and 7.7% positive, respectively, compared with 2.8% of samples from White patients. After adjustment, risk differences among racial groups were lower but not eliminated. During the study period, the known COVID-19 case rate was 3.3%. The ratio of seropositivity to known COVID-19 cases was 1.7.

**Limitations:** Imperfect assay sensitivity; results represent infections occurring before July 2020; deidentification prevented comparison of antibodies to previous COVID-19 status for individual patients; may not generalize to patients dialyzing with other providers or in other countries.

**Conclusions:** Seroprevalence was 5.8% among dialysis patients as of July 1, 2020. This indicates that the actual number of infections was 1.7 times greater than reported cases. This ratio is lower than reported in the general population, suggesting that there were fewer unknown infections among maintenance dialysis patients.

## Visual Abstract included

Complete author and article information provided before references.

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Coronavirus disease 2019 (COVID-19), caused by novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), was declared a global pandemic on March 11, 2020.<sup>1</sup> As of July 31, 2020, there were more than 17 million confirmed cases worldwide, including nearly 5 million in the United States. SARS-CoV-2 infection can result in a spectrum of clinical manifestations ranging from asymptomatic to severe symptomatology, including hypoxia, respiratory failure, and death.<sup>2</sup> Because any infected patient can transmit SARS-CoV-2,<sup>3</sup> it is vital to understand the actual burden of infection above and beyond the reported case rates of symptomatic COVID-19.

In the United States, shortages in testing supplies and infrastructural limitations have precluded large-scale surveillance efforts. Fortunately, the seropositivity of anti-SARS-CoV-2 antibodies can be used to illuminate the underlying infection rates post hoc. Not surprisingly, given challenges in testing and surveillance, data from the general population in the United States demonstrate a large

number of unreported SARS-CoV-2 infections that exceed the number of reported COVID-19 cases by many fold.<sup>4-6</sup>

Patients with end-stage kidney disease receiving maintenance dialysis represent a special case because they are enriched for several characteristics that are putative risk factors for COVID-19, including older age, high proportions of people of color, a dense urban geographic footprint, and disproportionate rates of heart failure, diabetes, and obesity.<sup>2,7</sup> Therefore, it may not be surprising that reported case rates are higher in these patients than in the general population.<sup>8</sup> However, most maintenance dialysis patients are treated with hemodialysis. Following guidance from the Centers for Disease Control and Prevention, US dialysis organizations have put into place robust entrance screening procedures whereby all patients entering a clinic are asked about symptoms, high-risk contacts, or both. Patients who screen positive then undergo testing for viral RNA.<sup>9</sup> These procedures, as well as the high rate of interaction with the health care system

**PLAIN-LANGUAGE SUMMARY**

There are likely more severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infections than reported coronavirus disease 2019 (COVID-19) cases, and case rates are reportedly higher in dialysis patients versus the general population. We measured SARS-CoV-2 antibodies in a national sample of US dialysis patients. Seroprevalence ranged from 1.0% to 23.6% for individual states and 5.8% overall. Seroprevalence was not different among men and women; the lower seroprevalence among older patients was likely due to greater infection-related mortality. Consistent with known disparities in COVID-19 incidence, seropositivity was greater among non-White versus White patients. There were 1.7 times more infections than reported COVID-19 cases, lower than that reported for the general population. Thus, despite higher case rates, the gap between known and unknown infections is smaller for dialysis patients than for the general population.

(~13 clinic visits per month for dialysis treatments), may lead to a narrower gap between viral infections and reported cases among maintenance dialysis patients.

Because dialysis patients undergo routine monthly laboratory testing, leftover patient samples provide an opportunity to explore SARS-CoV-2 seropositivity. We performed this national seroprevalence survey among patients receiving dialysis from a single provider organization to understand better: (1) the prevalence of SARS-CoV-2 infection nationally and within individual states, (2) how SARS-CoV-2 seropositivity varies across subgroups of patients, and (3) the magnitude of the gap between SARS-CoV-2 seropositivity and known COVID-19 case rates.

**METHODS****Antibody Testing in Remnant Serum Samples**

The protocol for this study was reviewed by an independent institutional review board (IntegReview Institutional Review Board) and it was determined that under Title 45, part 46, of the US Department of Health and Human Services' Code of Federal Regulations, this study was exempt and informed consent was not required. This study used deidentified remnant serum samples collected for routine laboratory screening from a national sample of maintenance dialysis patients treating with DaVita in the United States.

Blood samples were collected before dialysis treatment in a 5-mL serum separation tube, clotted for 30 minutes, centrifuged, and refrigerated before shipment. All samples were processed at a centralized, accredited laboratory (DaVita Labs). During the course of 6 weeks (May 27 to July 1, 2020), a quasi-random set of tubes from those

processed on the prior day were identified using FlexLab automation software (Inpeco SA) to undergo immunoglobulin G (IgG) antibody testing. On average, 2,115 remnant samples were processed per week during the study.

Indirect chemiluminescence immunoassays for anti-SARS-CoV2 IgG antibodies (Diazyme Laboratories, Inc) were performed according to the manufacturer's protocol. The tests detect antibodies against the SARS-CoV-2 spike and nucleocapsid proteins. Per the manufacturer's recommendation, samples were scored IgG positive if the corresponding test reading was >1 arbitrary unit/mL and negative otherwise. In addition to IgG concentration, patient sex, age, race, zip code, and collection date were recorded for each sample. Because this was a remnant sample study, no attempts were made to identify patients or link findings to medical record data.

**Statistical Analysis**

Reported COVID-19 cases and deaths among patients with a COVID-19 diagnosis through July 1, 2020, were ascertained from DaVita electronic medical records overall and by US state. Beginning in March 2020, universal screening was performed on entrance to DaVita clinics. All DaVita clinics use standardized screening tools and all clinic personnel are trained to perform screening in a standardized manner. Patients screening positive for COVID-19 symptoms or indicating recent contact with individuals with COVID-19 diagnosed were subsequently tested for viral RNA with a nasal swab and a polymerase chain reaction assay. Patients with a positive polymerase chain reaction test result were assigned a COVID-19 diagnosis. Additionally, patients reporting receipt of a positive COVID-19 test result from another health care setting, such as a hospital or department of health screening center, were also assigned a COVID-19 diagnosis.

Seroprevalence was determined by calculating the proportion of samples considered IgG positive overall and stratified by sample collection date, sex, age, race, and state. CIs were estimated using an exact binomial distribution. Seroprevalence estimates by patient race were also adjusted for age, population density, median income, and geographic COVID-19 prevalence using a generalized linear model. Age was considered as the following categories: younger than 50, 50 to 59, 60 to 69, 70 to 79, and 80 years or older. Population density and median income were assigned based on the zip code of the dialysis clinic and derived from the 2010 US Census and were considered as continuous variables. Geographic COVID-19 prevalence was dichotomized at the state level into high (New York, New Jersey, Connecticut, Massachusetts, Michigan, and Louisiana) and low prevalence (all others) based on known case burden among the general population through April 30, 2020. Relative risk was estimated based on a binomial distribution and was considered as the ratio of proportions.

**Table 1.** Patient Demographics and Characteristics of Remnant Samples

	Patient Samples (N =12,932)
Women	5,394 (41.7%)
Age category	
<50 y	2,398 (18.5%)
50-59 y	2,669 (20.6%)
60-69 y	3,568 (27.6%)
70-79 y	2,873 (22.2%)
≥80 y	1,424 (11.0%)
Race/ethnicity	
Black	4,179 (32.3%)
White	4,354 (33.7%)
Hispanic	2,579 (19.9%)
Asian	529 (4.1%)
Other/unknown/missing	1,291 (10.0%)

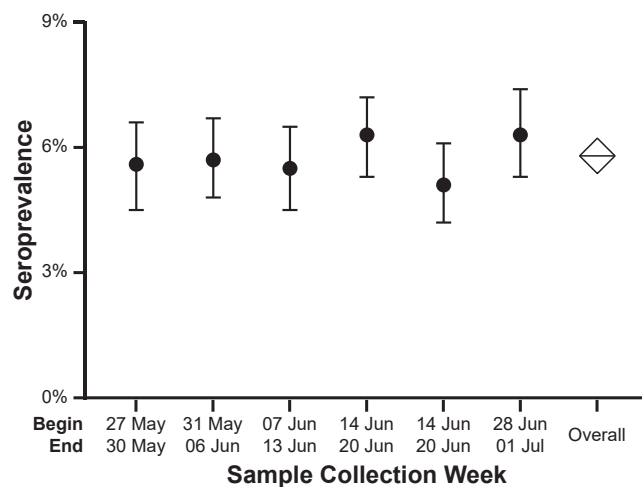
Samples were collected from all contiguous US states except for those without DaVita clinics (Vermont and Wyoming) and from Washington, DC and were used in overall analyses and analyses stratified by sex, age, and race. For state-level analyses, states from which fewer than 50 samples were available (Idaho, Maine, Montana, North Dakota, Nebraska, New Hampshire, New Mexico, Rhode Island, South Dakota, Utah, and West Virginia) are not reported because insufficient sample sizes limited precision and therefore generalizability to the general population.

Given the deidentified nature of the sample collection, correspondence between COVID-19 case status and serologic status could not be examined at the level of individual patients. Instead, we considered the ratio of aggregate known case rate to aggregate seropositivity rate, henceforth termed the infection discovery ratio. The infection discovery ratio was considered at the national level and at the level of individual states. Because patients who had died of COVID-19 before the sample collection period otherwise counted as cases but were not sampled for seroprevalence, they were not counted toward the numerator of the infection discovery ratio. The infection discovery ratio was calculated as a cross-section as of July 1, 2020.

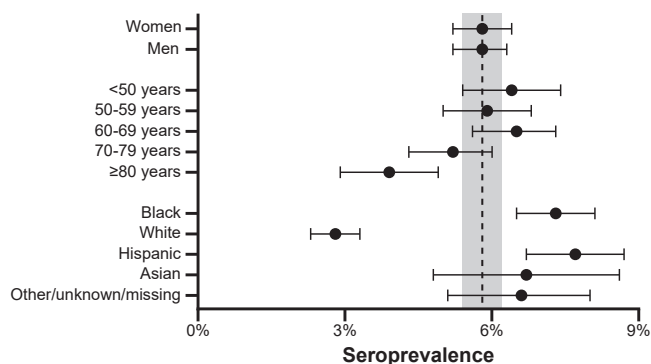
## RESULTS

We tested 12,932 remnant serum samples for IgG antibodies for SARS-CoV-2. Table 1 contains demographic characteristics of the patients from whom the samples were obtained. Overall, 747 (5.8%) samples were seropositive. There was no longitudinal trend observed in seropositivity (Fig 1).

Figure 2 shows seroprevalence by patient sex, age, and race. There was no difference in seroprevalence among samples from men and women. Seroprevalence was 6.0% to 6.5% among samples from patients younger than 70 years, 5.2% among samples from patients 70 to 79 years old, and 3.9% for samples from patients 80 years or older.



**Figure 1.** Seroprevalence of remnant samples by sample collection week. Plotted are the proportion of patient samples that were positive for immunoglobulin G and 95% confidence limits. Overall seroprevalence is depicted by the center line on the diamond, with 95% confidence limits represented by the top and bottom peaks.



**Figure 2.** Seroprevalence by patient sex, age, and race. Plotted are the proportion of patient samples that were positive for immunoglobulin G and 95% confidence limits. Overall seroprevalence (dashed lines) and 95% confidence limits (gray rectangle) shown for reference.

Seroprevalence was 7.3%, 2.8%, 7.7%, and 6.7% among samples from Black, White, Hispanic, and Asian patients, respectively. Compared with samples from White patients, this represented a crude relative risk of 2.6, 2.7, and 2.4 for samples from Black, Hispanic, and Asian patients, respectively. After adjustment for demographic, geographic, and socioeconomic factors, the relative risk was 1.6 for samples from both Black and Hispanic patients and 1.3 for samples from Asian patients.

Table 2 shows seroprevalence among patient samples and reported COVID-19 case rates for US states with 50 or more tested patient serum samples. Seroprevalence ranged from 1.0% to 23.6%. Seroprevalence was highest in New York, with 82 (23.6%) seropositive samples, and lowest in

**Table 2.** Comparison of Seroprevalence and Reported COVID-19 Case Rates Overall and by State

State	No. of Serum Samples	No. of Seropositive Samples	Seroprevalence (95% CI)	Reported Case Rate	Infection Discovery Ratio
Overall	12,932	747	5.8% (5.4%-6.2%)	3.3%	1.7
Alabama	179	4	2.2% (0.1%-4.4%)	3.0%	0.8
Arizona	291	16	5.5% (2.9%-8.1%)	4.4%	1.3
Arkansas	141	2	1.4% (0.0%-3.4%)	1.7%	0.8
California	2,255	115	5.1% (4.2%-6.0%)	2.4%	2.1
Colorado	127	7	5.5% (1.5%-9.5%)	2.7%	2.0
Connecticut	112	17	15.2% (8.5%-21.8%)	9.0%	1.7
Florida	2,170	75	3.4% (2.6%-4.1%)	1.8%	1.9
Georgia	487	38	7.8% (5.4%-10.2%)	3.2%	2.4
Illinois	439	38	8.7% (6.0%-11.3%)	4.7%	1.8
Indiana	152	8	5.3% (1.7%-8.8%)	3.0%	1.8
Iowa	80	2	2.5% (0.0%-5.9%)	2.7%	0.9
Kansas	84	2	2.4% (0.0%-5.6%)	1.5%	1.6
Kentucky	97	1	1.0% (0.0%-3.0%)	1.9%	0.5
Louisiana	91	15	16.5% (8.9%-24.1%)	5.5%	3.0
Maryland	360	26	7.2% (4.6%-9.9%)	3.9%	1.9
Massachusetts	112	13	11.6% (5.7%-17.5%)	8.4%	1.4
Michigan	371	31	8.4% (5.5%-11.2%)	4.3%	1.9
Minnesota	167	7	4.2% (1.2%-7.2%)	3.4%	1.2
Mississippi	59	1	1.7% (0.0%-5.0%)	3.4%	0.5
Missouri	141	7	5.0% (1.4%-8.6%)	2.6%	1.9
Nevada	145	6	4.1% (0.9%-7.4%)	2.2%	1.9
New Jersey	389	55	14.1% (10.7%-17.6%)	9.3%	1.5
New York	348	82	23.6% (19.1%-28.0%)	9.4%	2.5
North Carolina	443	16	3.6% (1.9%-5.4%)	1.5%	2.3
Ohio	337	10	3.0% (1.2%-4.8%)	1.7%	1.8
Oklahoma	125	2	1.6% (0.0%-3.8%)	1.0%	1.5
Oregon	153	6	3.9% (0.9%-7.0%)	0.9%	4.5
Pennsylvania	440	27	6.1% (3.9%-8.4%)	3.9%	1.6
South Carolina	140	8	5.7% (1.9%-9.6%)	2.4%	2.4
Tennessee	263	8	3.0% (1.0%-5.1%)	1.7%	1.8
Texas	1,300	38	2.9% (2.0%-3.8%)	2.6%	1.1
Virginia	354	26	7.3% (4.6%-10.1%)	3.2%	2.3
Washington	195	10	5.1% (2.0%-8.2%)	2.3%	2.2
Wisconsin	140	7	5.0% (1.4%-8.6%)	2.4%	2.1

Abbreviation: COVID-19, coronavirus disease 2019.

Kentucky, for which 1 (1.0%) sample was seropositive. Overall, the reported COVID-19 case rate was 3.3% of all patients. The reported COVID-19 case rate ranged from 1.9% to 9.4% of patients by state. The highest reported COVID-19 case rates were in New York (9.4%) and the lowest were in Oregon (1.9%). Overall, the infection discovery ratio was 1.7 but ranged from 0.5 to 4.5 for individual states.

## DISCUSSION

In this study, we found that seroprevalence of antibodies to SARS-CoV-2 among maintenance dialysis patients in the United States varied by geography, age, race, and ethnicity. Moreover, our data indicate that there were more infections than known COVID-19 cases among the maintenance dialysis patient population as of July 1, 2020.

Globally, there is evidence that reported COVID-19 case rates underestimate the true burden of SARS-CoV-2 infection. Maintenance dialysis patients have many characteristics that put them at high risk for COVID-19, and it has been reported that case rates are higher than in the general population. We measured antibodies to SARS-CoV-2 using remnant serum samples in a large national sample of US dialysis patients. We sought to understand the prevalence of SARS-CoV-2 infection nationally and within individual states, the variability of seropositivity among patient subgroups, and the magnitude of the gap between SARS-CoV-2 seropositivity and known COVID-19 case rates among maintenance dialysis patients.

We estimated the national seroprevalence of SARS-CoV-2 among US maintenance dialysis patients to be 5.8% as of July 1, 2020. Unfortunately, there have been no published national seroprevalence studies among the US general

population to compare with our estimates in dialysis patients. Moreover, there are salient differences between the US general population and the dialysis patient population in terms of characteristics, health status, and the ability to shelter in place; therefore, we did not attempt to standardize our estimates to extrapolate seroprevalence to the US general population.

At the state level, seropositivity rates in our sample were directionally similar to reported case rates. For example, New York and New Jersey, states with high reported case burdens, had among the highest seropositivity rates in our sample, and Kentucky and Arkansas, states with low reported case burdens, had among the lowest seropositivity rates in our sample. Direct comparison of seropositivity rates in our sample to the general population of states must be interpreted cautiously for 2 important reasons: (1) our seroprevalence data were from a later period and are subject to be higher as the epidemic progressed and (2) the high-risk nature of maintenance dialysis patients. However, for states for which general population data have been reported, seroprevalence in the dialysis population was approximately 2 to 3 times that in the general population: Louisiana (16.5% vs 5.8%), Connecticut (15.2% vs 4.9%), Missouri (5.0% vs 2.7%), and New York (23.6% vs 12.5%).<sup>4,5</sup> Notwithstanding these limitations (which would tend to bias in a direction that exaggerates risk in the dialysis population), this difference in seroprevalence is substantively lower than the 5-fold difference in reported case rates between maintenance dialysis patients and the general population.<sup>8</sup>

Next, we sought to understand how seropositivity differs by patient demographics. Similar to other seroprevalence studies, we did not observe a difference between samples from men and women.<sup>4,10-12</sup> Samples from patients older than 70 years were less likely to be seropositive. Mortality is higher among older patients with COVID-19 diagnosed<sup>2</sup>; therefore, it is possible that there were fewer samples available from older patients who were infected by SARS-CoV-2. The relative risk for infection was greater among samples from non-White patients compared with samples from White patients, a fact that should be neither underestimated nor overlooked. There is evidence of racial and ethnic disparities in COVID-19 incidence and outcomes within the general population, reflecting well-known health inequities within the United States.<sup>7,13-17</sup> Some of the factors associated with health inequities are greater poverty and a higher probability of residing in densely populated urban areas among minorities.<sup>18</sup> DaVita has many clinics in urban areas and has a large presence in specific geographies that were severely affected early in the pandemic, such as the Bronx.

After adjustment for demographic, geographic, and socioeconomic factors, the relative risk for infection was comparatively lower; however, the residual inequities in infections are troubling. Our observations are supported by an ecological analysis examining the correlation between COVID-19 positivity per capita with

sociodemographic characteristics and the number of dialysis stations for zip codes in Cook County, Illinois. The authors observed that positive tests per capita were positively correlated with the number of dialysis stations, percentage of households living in poverty, and percentage of residents of Black race and Hispanic ethnicity.<sup>19</sup>

Finally, we compared seroprevalence estimates to known COVID-19 cases to quantify the gap between recognized and unrecognized infections in the maintenance dialysis patient population. Comparison of the known COVID-19 cases (3.3%) to SARS-CoV-2 seroprevalence (5.8%) indicates that there were 1.7 times more infections than known cases as of July 1, 2020. Similar estimates were reported for hemodialysis patients in China and the United Kingdom.<sup>20,21</sup> However, our estimate is lower than that reported for the general population, which ranged from 6 to 43 times more than the number of known cases in US states for which data have been reported and 10 to 16 times in European locales.<sup>4-6,10,11,22</sup> The lower number of unrecognized infections among dialysis patients is likely related to higher testing rates relative to the general population. Most DaVita patients visit a clinic 3 times per week for hemodialysis treatments, are screened upon clinic entry, and are referred for testing if symptoms are present. Therefore, it is highly probable that infections among dialysis patients are recognized at a greater rate than in the general population.

Another recently published study measured the seroprevalence of SARS-CoV-2 antibodies in serum samples from 28,503 patients treating at various independent dialysis providers throughout the United States.<sup>12</sup> In general, we observed similar patterns of infection among patient types and geographies as they reported. However, their overall seroprevalence estimate was higher than in our study (8.3% vs 5.8%). This difference is most likely because their samples were collected in July 2020, when national case rates were quickly increasing, whereas most of our samples were collected in June, when case rates were relatively steady. Another key difference is that our study was performed among patients dialyzing with a single provider, which treats approximately one-third of all maintenance dialysis patients in the United States and therefore our results may be more representative of the patient population in the United States.

There are limitations to our study. The sensitivity of the antibody assay is imperfect; therefore, it is likely that the seroprevalence and number of undetected infections estimated here are low. Samples were collected May 27 to July 1, 2020, when the daily new case rate in the United States was at a steady state after the initial peak in April. There was a national resurgence in cases beginning in late June, which is not reflected in antibodies measured here, possibly due to insufficient time for seroconversion before study end. Because dialysis patients have impaired antibody responses, it is possible that some infected patients did not develop or lost IgG to SARS-CoV-2 and therefore were misclassified as never infected. The remnant samples

were deidentified and we could not match samples to previously known COVID-19 cases; therefore, we could not determine the proportion of cases that were truly asymptomatic or the relationship between symptom onset and antibody levels for those who were considered COVID-19 positive. Finally, this study was limited to patients at a single dialysis organization in the United States and may not generalize to maintenance dialysis patients treating with other providers or in other countries.

In conclusion, we analyzed antibodies to SARS-CoV-2 in blood samples from more than 12,000 dialysis patients in the United States and observed a seroprevalence of 5.8% as of July 1, 2020. We observed similar patterns of infection among specific demographic groups and US geographies, as reported for the US general population. Our results indicate that there are 1.7 times as many SARS-CoV-2 infections as known COVID-19 cases among dialysis patients. However, due to tight surveillance, the number of unknown infections among dialysis patients appears to be substantially lower than reported among the general population.

## ARTICLE INFORMATION

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**Authors' Contributions:** Research area and study design: AY, CW, NM, SMB; data acquisition: CW, NM, GM; statistical analysis: SS, AGW; data analysis and interpretation: AGW, SS, SZF, SMB; supervision and mentorship: AY, SZF, SMB. Each author contributed important intellectual content during manuscript drafting or revision and accepts accountability for the overall work by ensuring that questions pertaining to the accuracy or integrity of any portion of the work are appropriately investigated and resolved.

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# What is the seroprevalence of SARS-CoV-2 antibody among maintenance dialysis patients compared to general population in the United States ?



## Cross sectional Study

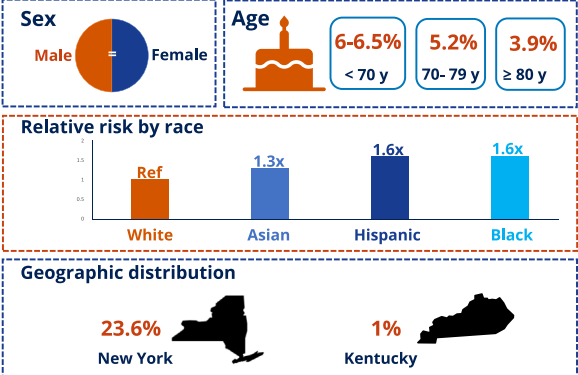
-  USA (DaVita)
-  Remnant Serum Samples
-  Anti SARS-CoV-2 IgG antibodies
-  N = 12932
-  27 May- 1 Jul 2020
-  Dialysis

## Limitations

-  Imperfect Assay sensitivity
-  Cannot be generalized
-  De-identified [Cannot link diagnosis at patient level]
-  Infections before Jul '20

## Results Seropositive (total): 5.8% (N = 747)

Ratio of seropositivity to known COVID cases is 1.7



**Conclusion:** Seroprevalence was 5.8% among dialysis patients, a prevalence 1.7-times greater than reported cases (3.3%). This ratio is lower than reported in the general population, suggesting fewer unknown infections in the dialysis population.

**Reference:** Walker AG, Sibbel S, Wade C et al. SARS-CoV-2 antibody seroprevalence among maintenance dialysis patients in the United States. *Kidney Medicine*, 2021.

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