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ORIGINAL ARTICLE

Dual impact of donor service area removal from kidney allocation system and Coronavirus Disease 2019 pandemic on access to transplantation

Srijan Tandukar[1] | **Zenith Tandukar**[2]

[1]John C. McDonald Regional Transplant Center, Willis-Knighton Medical Center, Shreveport, Louisiana, USA

[2]University of Minnesota, Saint Paul, Minnesota, USA

Correspondence
Srijan Tandukar MD, Transplant Nephrologist, John C. McDonald Regional Transplant Center, Willis-Knighton Medical Center, 2751 Albert L. Bicknell Drive, Suite 4A, Shreveport, LA 71103, USA.
Email: srijantandukar@gmail.com

Abstract

Introduction: Donor service area was removed from kidney and pancreas allocation system in the United States on March 15, 2021 in favor of a distance based policy to provide geographic equity to access to transplantation. The policy change was introduced at a time when ongoing Coronavirus Disease 2019 (COVID-19) pandemic cases were declining following the first delta wave.

Methods: In this Scientific Registry of Transplant Recipients based study, deceased donor kidney transplant recipients between March 15 and December 2 of 2019, 2020 and 2021 were compared representing pre-policy change, pre-COVID cohort; pre-policy change, early COVID cohort; and post-policy change, late COVID cohort.

Results: There were 11336, 11808, and 12914 kidney transplants in the 2019, 2020, and 2021 cohorts, respectively. Proportion of kidney transplants increased from 8798 (78%) to 9496 (80%) to 11152 (86%), and decreased from 2538 (22%) to 2312 (20%) to 1762 (14%) within and beyond 250 nautical miles in subsequent years. Median distance between donor and transplant hospital increased (73 vs. 63 vs. 119 nautical miles, $P < .001$) and mean cold ischemia time increased (18.1 vs. 17.8 vs. 19.9 h, $P < .001$). Access to transplantation did not change for various racial groups ($P = .07$), pediatric patients ($P = .29$), dialysis vintage of >5 years ($P = .21$), veterans ($P = .07$) and decreased for those with calculated PRA of 99% and 100% ($P < .001$). Rate of kidney discard (19.6% vs. 20.4% vs. 24%) remained high. Although there were numerical increases in transplants from donors with donation after circulatory death, donor acute kidney injury, kidney donor profile index >85% and donor age >60 years in successive years, rates of kidney discard also increased proportionally.

Conclusion: Improvement in the access to transplantation following the policy change was attenuated by the concurrent prevalence of the COVID-19 pandemic.

KEYWORDS
allocation circle, donor service area, kidney allocation system, kidney transplant

1 INTRODUCTION

The deceased donor kidney allocation system (KAS) was developed to provide equitable access to kidney transplantation to the candidates including ones who are harder to match due to prior sensitization, decrease organ discard rates and provide a framework for matching limited donor organs to potential recipients in order to optimize allograft and patient longevity.[1] The United States territory was divided into 57 donor service areas (DSA) and 11 regions by the United Network for Organ Sharing (UNOS) for purposes of coordinating the national algorithm of KAS which was introduced on December 4, 2014.[2] On March 15, 2021, DSA and region designations were removed from kidney and pancreas allocation system in favor of a distance-based approach following similar policy changes by the Organ Procurement and Transplantation Network (OPTN) for all other organ types.[3] Under this policy, DSA and region designations were replaced with a 250 nautical mile (nm) fixed circle around the donor hospital allowing proximity points to be added to the candidate's total allocation score.[3] This change in policy occurred while the country was in the recovery phase of the first delta wave of the Coronavirus Disease 2019 (COVID-19) pandemic (Figure 1). Many transplant programs had reduced the number of transplants, with some halting it altogether due to the pandemic-related strain on the healthcare system at the time.[4]

The goals of the policy change were to increase geographic equity in access to transplantation regardless of a candidate's place of listing, limit transportation time and thereby, cold ischemia times (CIT) and cost incurred, provide a higher priority for prior living donors and pediatric candidates, provide greater access to transplantation to ethnic minorities and vulnerable groups of patients including those meeting the 'medical urgency for kidney transplantation' criteria.[2] The impact of this policy change on kidney transplantation in the era of the COVID-19 pandemic is not currently known.

The changes to the KAS were proposed in response to the results obtained from statistical simulation modeling performed by Scientific Registry of Transplant Recipients (SRTR) known as Kidney-Pancreas Simulation Allocation Model (KPSAM).[5] Under the prior KAS policy, OPTN found that the candidates' place of residence or listing was the largest factor related to disparity in kidney allocation.[6,7] The KPSAM showed that replacing DSAs as units of allocation with a 250 nm fixed circle around the donor hospital increased rates of transplantation among pediatric, female, African American, Latino candidates, and highly sensitized (80–99% of calculated panel reactive antibodies, cPRA) candidates. Rates of kidney-pancreas (KP) transplants increased with subsequent decreases in kidney and pancreas alone transplants in the models.

We hypothesized that removal of DSA from the KAS would decrease the distance between donor and recipient hospital and consequently, CIT. We also hypothesized that access to transplantation would increase for pediatric, female, African American, Latino and highly sensitized candidates. Since the state of Alaska does not currently have any transplant centers, a 250 nm radius around any donor hospital in Alaska would mean that all donor kidneys would be allocated nationally instead of locally first, creating inefficiencies in organ placement. To address this issue, the Seattle-Tacoma International Airport (Sea-Tac) was used as a substitute for all Alaskan donor hospitals for purposes of allocation, acting as the center of the 250 nm circle.[8] We expected the rates of donor organ utilization from Alaska to increase with the new policy. We also anticipated a decrease in overall kidney discard rates following policy change. We anticipated that using distance-based allocation policy instead of DSAs would lead to each Organ Procurement Organization (OPO) placing their donor kidneys in more number of

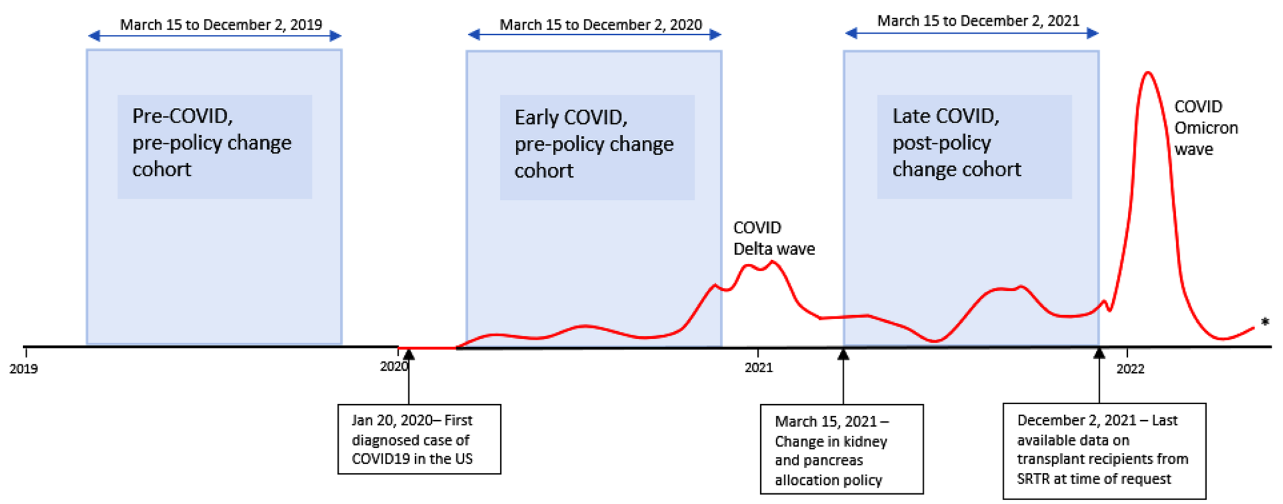

FIGURE 1 The three cohorts derived from the years 2019 to 2021 and their timing with respect to the kidney and pancreas allocation policy change and the Coronavirus Disease 2019 (COVID-19) pandemic. *Source:* *Centers for Disease Control and Prevention. COVID Data Tracker. Atlanta, GA: US Department of Health and Human Services, CDC; 2022, May 02. https://covid.cdc.gov/covid-data-tracker

transplant centers than in the past. However, we predicted that the ongoing COVID-19 pandemic would lead to some dampening of these improvements that was projected in the simulations.

In this registry-based study from SRTR, we evaluated the changes in trends of kidney transplantation after the removal of DSAs and regions from the KAS.

2 | MATERIALS AND METHODS

2.1 | Patient population

This study used data from the SRTR. The SRTR data system includes data on all donor, wait-listed candidates, and transplant recipients in the US, submitted by the members of the Organ Procurement and Transplantation Network (OPTN). The Health Resources and Services Administration (HRSA), U.S. Department of Health and Human Services provides oversight to the activities of the OPTN and SRTR contractors. The study was exempt from review by the Institutional Review Board and informed consent was deferred as the data for the patients were de-identified.

The patient population was divided into three cohorts of deceased donor kidney transplant alone recipients depending upon the timing of policy change and the stage of the COVID-19 pandemic – (i) Pre-policy change, pre-COVID cohort (March 15 to December 2, 2019), (ii) Pre-policy change, early COVID cohort (March 15 to December 2, 2020), and (iii) Post-policy change, late COVID cohort (March 15 to December 2, 2021) (Figure 1).

2.2 | Baseline characteristics

Baseline recipient and donor characteristics included age, sex, race, history of hypertension and diabetes mellitus, body mass index (BMI), recipient's cause of end stage renal disease (ESRD), dialysis vintage, prior living donation, donor's cause of death, donor Hepatitis C serostatus, donor terminal creatinine, kidney donor profile index (KDPI), donation after circulatory death (DCD) status, CIT and number of human leukocyte antigen (HLA) mismatches.

2.3 | Distance between donor hospital and recipient transplant center and cold ischemia time

The distance between donor hospital and transplant center was computed using the latitude and longitude coordinates corresponding to their zip codes. The cohorts were divided into two subgroups – (i) Within 250 nm and (ii) More than 250 nm. One nautical mile is approximately equal to 1.1508 statute miles. The CIT for kidney transplants were also compared between the cohorts. Mean CIT and median distance between the donor hospital and transplant center were also analyzed on the basis of the volume of the transplant center categorized as <50, 50–100, 100–150 and >150 transplants per year based on the number of kidney transplants performed in 2019.

2.4 | Change in access to transplantation for vulnerable groups

Change in the access to transplantation for vulnerable groups were analyzed which included ethnic minorities, highly sensitized patients with cPRA >80%, those with >5 years of dialysis vintage, women, children, prior living donors and veterans. Trends of transplantation in the Black population was separately studied by classifying the transplant centers as those performing <50% or >50% of total transplants in Black recipients.

2.5 | Changes in kidney discard rates

The rates of donor kidneys recovered, and the proportion of transplanted versus discarded kidneys were analyzed from 2015 to 2021 cohorts. These cohorts were chosen to provide a temporal analysis of the trends of discards following the introduction of allocation policy in 2014. For purposes of comparison, all cohorts comprised of organs recovered between March 15 and December 2 of the respective year.

For donor kidneys that were discarded, detailed donor characteristics were compared between the 2019, 2020, and 2021 cohorts separately. Additionally, causes of donor kidney discards were also noted.

Subgroup analysis of discards among DCD kidneys, donors with acute kidney injury (AKI), donor with high KDPI >85% and older donors >60 years were done. Discards among non-DCD donors, without donor AKI and KDPI <60%, which are considered to be low risk for discard in general, were also compared between the cohorts. A donor was considered to have an AKI if the maximum donor serum creatinine was at least >50% higher than the initial donor serum creatinine.

Rates of donor organ recovery from Alaska resulting in successful kidney transplantation were compared. The donor hospitals in Alaska contributing to these recovered organs were also identified.

2.6 | Change in number of transplants performed by different transplant centers and organ procurement organizations

Change in the number of transplants were analyzed individually for each transplant center. Transplant centers were also subcategorized based on 0, 1–3, 4–6, 7–9 and >9 other transplant centers within a 50 nm distance. The 50 nm distance was arbitrarily chosen as to be of sufficiently low proximity to influence organ acceptance/decline patterns.

Changes in the number of donor kidneys transplanted versus discarded were compared across different OPOs and OPTN Regions in the three cohorts. Since there was an anticipated increase in the placement of donor organs to a larger number of transplant centers following policy change, this was also compared among the three cohorts.

2.7 | Statistical analysis

Descriptive statistics were used to summarize baseline characteristics in the patient cohorts with mean and standard deviation for continuous parametric data, and median and interquartile range for continuous non-parametric data. Categorical variables were summarized as proportions. Continuous parametric variables were compared between the cohorts using student's t-test or Analysis of Variance (ANOVA) for two or more than two groups, respectively. Continuous non-parametric variables were compared using the Kruskal-Wallis test. Categorical variables were compared using Chi-squared test. All statistical analysis was performed in R statistical software (R Foundation for Statistical Computing, Vienna, Austria).

3 | RESULTS

3.1 | Study population

There were a total of 11336, 11808, and 12914 deceased donor kidney transplants performed between March 15 and December 2 of 2019, 2020, and 2021, respectively.

3.2 | Baseline characteristics

The mean (SD) age of patients transplanted in the 2019, 2020, and 2021 cohorts were 52.2(15.1), 52(15.1) and 51.5(15.2) years, respectively ($P < .001$). Kidney donors in the >60 years age group comprised of the lowest proportion in each cohort [778(6.9%), 743(6.3%) and 898(7%), $P < .001$] in successive years. Among all donors, those with terminal donor creatinine >1.5 mg/dl comprised of only 2522(22.2%), 2772(23.5%) and 2973(23%) in the three consecutive cohorts, with the remainder with terminal donor creatinine <1.5 mg/dl. Interestingly, the mean recipient and donor body mass index (BMI) were approximately 28 kg/m^2 in all the cohorts. In terms of number of HLA mismatches, the largest proportion was seen in five HLA mismatches (>30%) in each of the cohorts (Table 1).

The characteristics of patients transplanted within and beyond 250 nm distance between the donor hospital and the transplant center is presented in Table S1. Proportion of donor kidneys transplanted with terminal donor serum creatinine >1.5 mg/dl was higher beyond 250 nm compared to within 250 nm distance ($P < .001$).

3.3 | Distance between donor hospital and recipient transplant center and cold ischemia time

The proportion of kidney transplants occurring within 250 nm distance between the donor hospital and transplant center increased in subsequent years from 8798(78%) to 9496(80%) to 11152(86%) with a corresponding decline in transplants done beyond 250 nm distance (Table S1 and Figure 2A).

The median distance between the donor hospital and the transplant center was highest for the 2021 cohort compared to the 2020 and 2019 cohorts (119 nm vs. 63 nm vs. 73 nm, $P < .001$) (Figure 2B). When evaluated across transplant centers of different volumes, a consistent trend of a higher median distance was seen in each category for the 2021 cohort (P for all categories < .001) (Figure S1A).

The mean CIT for the 2021 cohort was longest compared to the 2020 and 2019 cohorts (19.9 vs. 17.8 vs. 18.1 h, $P < .001$) (Figure 2C). When stratified by volume of transplants performed per year, the mean CIT were consistently higher for the 2021 cohort (P for all comparisons < .001) (Figure S1B).

3.4 | Change in access to transplantation for vulnerable groups

3.4.1 | Ethnic minorities

The proportion of kidney transplants increased for all ethnic groups from 2019 to 2021 with the largest proportional gains for Pacific Islanders and Blacks ($P = .14$) (Figure S2A). There was a statistically non-significant overall increase in the number of transplants performed in transplant centers performing >50% transplants in Black recipients ($P = .23$) (Figure S2B). There were small changes in proportion of Latino recipients from 20.3% to 19.1% to 21.7% in subsequent years ($P < .001$) (Table 1).

3.4.2 | Highly sensitized population

The kidney transplants for highly sensitized group of patients were analyzed as a proportion of all kidney transplants performed in the cohort and compared with the other cohorts. The proportion of kidney transplants for recipients with cPRA 99% (2.4% vs. 1.9% vs. 1.8%) and 100% (5.5% vs. 4.2% vs. 4.2%) decreased. For other highly sensitized subgroups between cPRA 80% and 98% there was an initial dip from 2019 to 2020 cohorts with subsequent increases in the 2021 cohort ($P < .001$) (Table 1 and Figure S2C).

3.4.3 | Dialysis vintage >5 years

The proportion of kidney transplants in patients with a dialysis vintage >5 years decreased initially from 2019 to 2020 cohort from 4061(38.3%) to 3764(33.6%), but increased post-policy change in 2021 cohort to 4188(39.1%) ($p = .21$) (Table 1).

3.4.4 | Women

There was minimal change in the proportion of kidney transplants in women in successive years (39.8% vs. 39.4% vs. 39.8%, $P = .77$) (Table 1).

TABLE 1 Baseline characteristics of deceased donor kidney transplant recipients in the 2019, 2020, and 2021 cohorts representing the pre-policy change, pre-COVID cohort; pre-policy change, early COVID cohort; and post-policy change, late COVID cohort. The 2019, 2020 and 2021 cohorts indicate deceased donor kidney transplants performed between March 15 and December 2 in the respective calendar year.

	2019 cohort (Pre-policy change, pre-COVID cohort) *N* = 11336	2020 cohort (Pre-policy change, early COVID cohort) *N* = 11808	2021 cohort (Post-policy change, late COVID cohort) *N* = 12914	*P* value
Recipient characteristics				
Recipient age, years	52.2 (15.1)	52.0 (15.1)	51.5 (15.2)	<.001
Recipient gender				.77
Male	6822 (60.2%)	7155 (60.6%)	7775 (60.2%)	
Recipient race				.07
White	6384 (56.3%)	6703 (56.8%)	7080 (54.8%)	
Black	3809 (33.6%)	3907 (33.1%)	4537 (35.1%)	
Asian	869 (7.7%)	894 (7.6%)	996 (7.7%)	
Multi-racial	114 (1.0%)	130 (1.1%)	120 (.9%)	
Native American	102 (.9%)	112 (.9%)	104 (.8%)	
Pacific Islander	58 (.5%)	62 (.5%)	77 (.6%)	
Recipient ethnicity				<.001
Latino	2297 (20.3%)	2251 (19.1%)	2807 (21.7%)	
Non-Latino	9039 (79.7%)	9557 (80.9%)	10107 (78.3%)	
Recipient diabetes mellitus	4155 (36.7%)	4335 (36.7%)	4718 (36.5%)	.96
Recipient hypertension	1658 (87.2%)	954 (90.0%)	776 (89.7%)	.03
Recipient cause of ESRD				.16
Diabetes mellitus	3433 (30.3%)	3555 (30.1%)	3880 (30.0%)	
Hypertension	2724 (24.0%)	2760 (23.4%)	3161 (24.5%)	
Polycystic Kidney Disease	873 (7.7%)	906 (7.7%)	907 (7.0%)	
Others	4306 (38.0%)	4587 (38.8%)	4966 (38.5%)	
Prior living donor	30 (.3%)	32 (.3%)	51 (.4%)	.34
Recipient body mass index, kg/m^2	28.3 (5.6)	28.6 (5.6)	28.4 (5.7)	.001
Dialysis vintage				.21
Pre-emptive transplant	1239 (11.7%)	1406 (12.6%)	1288 (12%)	
<5 years	5302 (50%)	6005 (53.7%)	5223 (48.7%)	
>5 years	4061 (38.3%)	3764 (33.6%)	4188 (39.1%)	
Calculated panel reactive antibody				<.001
0%	6513 (57.5%)	7114 (60.3%)	7166 (55.5%)	
1–79%	2948 (26%)	3036 (25.7%)	3284 (25.4%)	
80–96%	794 (7%)	782 (6.6%)	1289 (10%)	
97%	81 (.7%)	74 (.6%)	160 (1.2%)	
98%	108 (1%)	76 (.6%)	241 (1.9%)	
99%	273 (2.4%)	225 (1.9%)	227 (1.8%)	
100%	619 (5.5%)	499 (4.2%)	545 (4.2%)	
Donor characteristics				
Donor age				<.001
<20 years	1380 (12.2%)	1301 (11%)	1446 (11.2%)	
20–40 years	4600 (40.6%)	5141 (43.5%)	5248 (40.6%)	
40–60 years	4578 (40.4%)	4623 (39.2%)	5322 (41.2%)	
>60 years	778 (6.9%)	743 (6.3%)	898 (7%)	

(Continues)

TABLE 1 (Continued)

	2019 cohort (Pre-policy change, pre-COVID cohort) *N* = 11336	2020 cohort (Pre-policy change, early COVID cohort) *N* = 11808	2021 cohort (Post-policy change, late COVID cohort) *N* = 12914	*P* value
Donor gender				.002
Male	7033 (62.0%)	7544 (63.9%)	8271 (64.0%)	
Donor race				<.001
White	9410 (83.0%)	9597 (81.3%)	10641 (82.4%)	
Black	1465 (12.9%)	1731 (14.7%)	1750 (13.6%)	
Asian	280 (2.5%)	310 (2.6%)	322 (2.5%)	
Multi-racial	85 (.7%)	36 (.3%)	58 (.4%)	
Native American	68 (.6%)	105 (.9%)	104 (.8%)	
Pacific Islander	28 (.2%)	29 (.2%)	39 (.3%)	
Donor diabetes mellitus	839 (7.5%)	988 (8.5%)	1047 (8.2%)	.01
Donor hypertension	3185 (28.4%)	3355 (28.8%)	3715 (29.2%)	.36
Donor terminal creatinine				.08
Donor Creatinine <= 1.5 mg/dl	8814 (77.8%)	9036 (76.5%)	9941 (77.0%)	
Donor Creatinine >1.5 mg/dl	2522 (22.2%)	2772 (23.5%)	2973 (23.0%)	
Donor hepatitis C serology				.22
Hepatitis C seropositive	1133 (10.0%)	1245 (10.5%)	1281 (9.9%)	
Kidney Donor Profile Index (KDPI)				<.001
<20%	2156 (19%)	2508 (21.2%)	2774 (21.5%)	
20–35%	1947 (17.2%)	2133 (18.1%)	2189 (17%)	
35–85%	6150 (54.3%)	6280 (53.2%)	6973 (54%)	
>85%	1081 (9.5%)	887 (7.5%)	978 (7.6%)	
Donor body mass index, kg/m^2	28.3 (7.3)	28.6 (7.4)	28.8 (7.5)	<.001
Transplant characteristics				
Donation after circulatory death	2970 (26.2%)	3214 (27.2%)	4166 (32.3%)	<.001
Number of HLA mismatches				.01
0	574 (5.1%)	517 (4.4%)	639 (4.9%)	
1	159 (1.4%)	154 (1.3%)	135 (1.0%)	
2	559 (4.9%)	574 (4.9%)	639 (4.9%)	
3	1578 (13.9%)	1700 (14.4%)	1884 (14.6%)	
4	3167 (27.9%)	3208 (27.2%)	3667 (28.4%)	
5	3636 (32.1%)	3825 (32.4%)	4113 (31.8%)	
6	1663 (14.7%)	1830 (15.5%)	1837 (14.2%)	
Donor cause of death				<.001
Anoxia	5162 (45.5%)	5696 (48.2%)	6271 (48.6%)	
Cerebrovascular/Stroke	2566 (22.6%)	2383 (20.2%)	2577 (20.0%)	
Head trauma	3242 (28.6%)	3363 (28.5%)	3605 (27.9%)	
Others	366 (3.2%)	366 (3.1%)	461 (3.6%)	
Cold ischemia time, hours	18.1 (8.5)	17.9 (8.3)	19.9 (7.8)	<.001

Data are presented as *N*(%) or mean(SD), unless specified otherwise.

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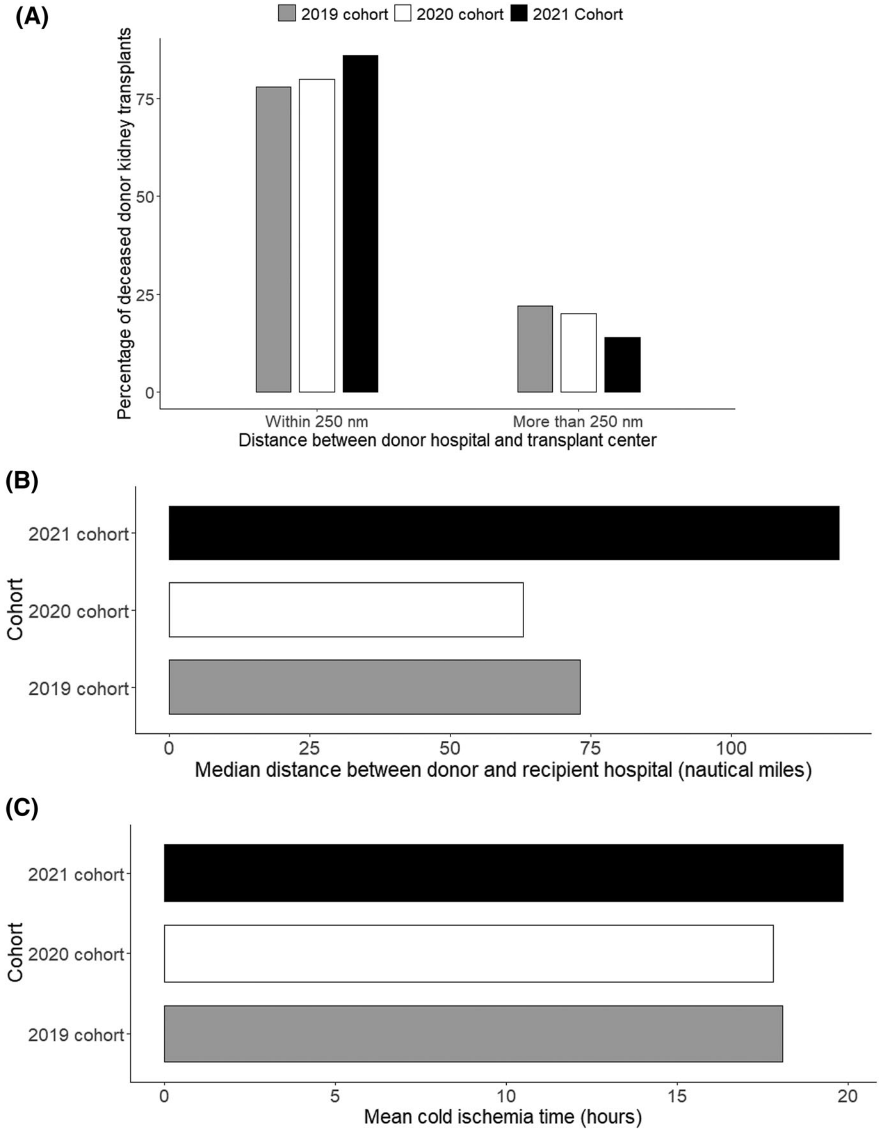

FIGURE 2 Change in proportion of deceased donor kidney transplants within and beyond 250 nautical miles, median distance between donor hospital and transplant center, mean cold ischemia times in the 2019, 2020 and 2021 cohorts. The cohorts represent pre-policy change, pre-COVID cohort; pre-policy change, early COVID cohort; and post-policy change, late COVID cohort. The cohorts indicate deceased donor kidney transplants between March 15 and December 2 in the respective calendar year. (A) Change in proportion of deceased donor kidney transplants done within and beyond 250 nautical mile distance (*P* < .001). (B) Comparison of the median distance between the donor hospital and the transplant center (*P* < .001). (C) Comparison of the mean cold ischemia times (*P* < .001).

3.4.5 | Pediatric population

There was no significant change in the proportion of pediatric kidney transplant recipients (3.2% vs. 2.9% vs. 3.2%, *P* = .29) (Figure S2D).

3.4.6 | Prior living donors

The proportion of kidney transplants in prior living donors changed from 30(.3%) to 32(.3%) to 51(.4%) in the subsequent years (*P* = .34) (Table 1).

3.4.7 | Veterans

The proportion of kidney transplants in the Veterans Affairs (VA) hospitals decreased from 116(1.02%) to 112(.95%) to 97(.75%), respectively in subsequent years (*P* = .07) (Figure S2E). It must be noted that some veterans do receive their kidney transplants in non-VA hospitals as well.

3.5 | Change in donor kidney discards

Proportion of recovered donor kidneys that were discarded had remained steady from 2015 to 2019 around 18–19% but increased to 20.4% and 24% in 2020 and 2021 cohorts, respectively (Figure 3A). Donor characteristics of these discarded donor kidneys are presented in Table S2. The donor age group of 40–60 years comprised of the largest number of discarded donor kidneys (>50% in each cohort) (*P* < .001). Interestingly, kidneys with terminal donor creatinine <1.5 mg/dl were discarded more often than those with levels >1.5 mg/dl (*P* < .001). The proportion of donor kidneys discarded with positive Hepatitis C serostatus was >10% (13.8% vs. 12.4% vs. 11.2%, *P* = .004). The most common reasons given for discarding Hepatitis C seropositive kidneys were no recipient located – list exhausted

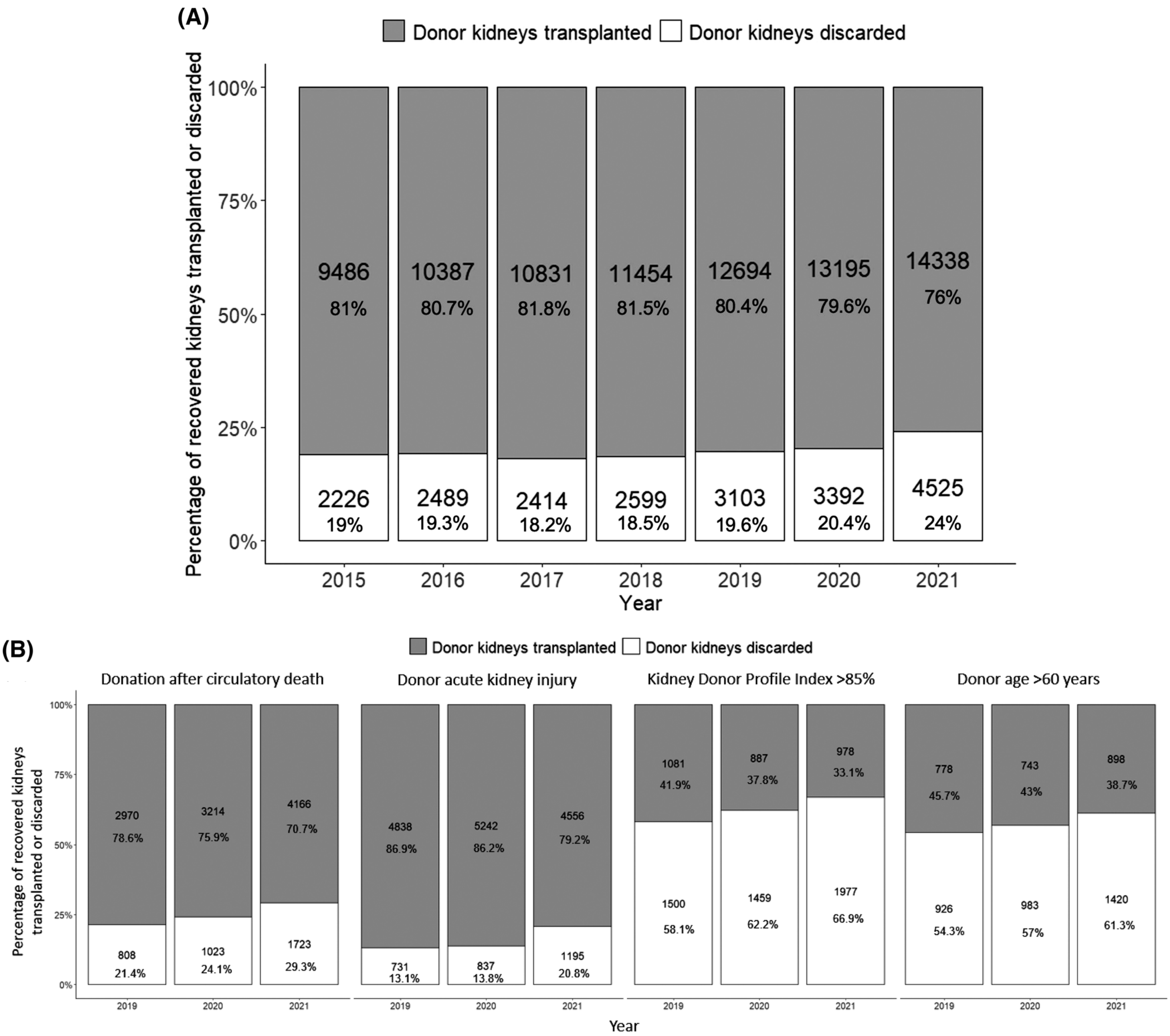

FIGURE 3 Change in kidney and pancreas transplants and discards since kidney and pancreas allocation system implementation on Dec 4, 2014. Since donor service area was removed from KAS on March 15, 2021, the cohort in each year extend from March 15 to December 2 of the respective year for purposes of comparison. (A) Percentage bar chart showing number and percentage of recovered donor kidneys transplanted and discarded. (B) Percentage bar chart showing number and percentage of donor kidneys transplanted and discarded among all donation after circulatory death, donor acute kidney injury, kidney donor profile index >85% and donor age >60 years donor kidneys that were recovered in the 2019, 2020, and 2021 cohorts.

($N = 750$), biopsy findings ($N = 272$), other ($N = 96$), poor organ function ($N = 68$) and anatomical abnormalities ($N = 27$). The O blood group donor kidneys were discarded most often ($P = .02$). More than 85% of donor kidneys that were discarded were biopsied ($P < .001$).

In subgroup analyses, discard rates increased for DCD donor kidneys (21.4% vs. 24.1% vs. 29.3%), donor AKI kidneys (13.1% vs. 13.8% vs. 20.8%), KDPI >85% kidneys (58.1% vs. 62.2% vs. 68.9%) and donor age >60 years (54.3% vs. 57% vs. 61.3%) in the subsequent years (Figure 3B). There was an increase in the absolute numbers of these donor subgroups that were transplanted in successive years despite rising discard rates, owing to higher overall numbers of these donors being procured by the OPOs.

When evaluating specifically for non-DCD donors without AKI and KDPI <60%, discard rates were 288(9.3%), 370(10.9%) and 385(8.6%) in successive years ($P = .003$) (Table S2).

We also looked at reasons given for kidney discards and found that the most common reasons were no recipient located – list exhausted (5609), others (1158), biopsy findings (2140), poor organ function (530), anatomical abnormalities (371), diseased organ (193), too old on ice (90), vascular damage (86) and donor medical history (86) (Table S3).

The number of deceased donor kidneys recovered from Alaska decreased progressively from 53 to 39 to 33 in subsequent cohorts. There were two donor hospitals where kidneys were recovered from in 2019 cohort (Central Peninsula Hospital and Mat-Su Regional Medical Center) that did not contribute to any donor kidneys in the 2021 cohort (Table S4).

3.6 | Change in number of transplants performed by different transplant centers and organ procurement organizations

The change in the number of transplants performed by individual transplant centers along with number of other transplant centers in a 50 nm distance from the index transplant center is presented in Table S5. Two interactive US maps have been provided to illustrate the change in number of transplants performed by individual transplant centers in the supplementary materials.

The changes in the donor kidneys transplanted versus discarded by the different OPOs is presented in Table 2. The range of donor kidney discards ranged from 6.7% to 48.8% in 2019, 10.1% to 36.5% in 2020 and 9.9% to 42% in 2021 cohorts across the different OPOs. With the onset of pandemic in 2020, there was a decline in the number of transplant centers where donor kidneys were placed by individual OPOs as compared to the pre-pandemic 2019 cohort for 39 out of 57 OPOs. Among these 39 OPOs, after the policy change in 2021 and the increased control of COVID-19 pandemic, the number of transplant centers where the donor kidneys were placed increased for 35 OPOs and continued to decrease for four remaining OPOs.

4 | DISCUSSION

We found that removal of DSA and region from the KAS in favor of a distance-based allocation policy led to an increase in the proportion of kidney transplants performed within 250 nm distance and a decrease beyond 250 nm distance between the donor hospital and the transplant center. These changes were sustained both before and after the onset of the COVID-19 pandemic. However, contrary to our expectations, the median distance and the mean CIT were higher after the policy change compared to before. We also found that these results held up when evaluated across different subgroups of transplant centers stratified by volume of transplants performed per year. There were numerical increases in the number of transplants in the vulnerable groups, but the proportions were mostly similar across the three cohorts. Although the access to transplantation increased for those with high sensitization with cPRA of 80%–98%, the rates of transplantation were lower for the most highly sensitized patients with cPRA of 99% and 100%. We saw a predictable increase in the number of kidney transplant alone after policy change that followed the trends we have seen since the introduction of KAS with increasing number of donors over time. Number of donor kidneys recovered from Alaska decreased post policy change, but this downward trend started with the onset of COVID-19 pandemic pre-policy change. The lack of improvement in some of these areas could also be from the effects of COVID-19 pandemic as these trends were evident even before the policy change, attenuating its overall positive impact.

The new policy removes DSA and region from kidney and pancreas allocation and replaces them with a 250 nm fixed circle around the donor hospital allowing for proximity points to be added to the candidate's total allocation score[3] (Table S6). This policy change was executed to align with the OPTN Final Rule which stipulates that the policies "shall not be based on the candidate's place of residence or place of listing, except to the extent required".[1,9] Candidates located within the circle closest to the donor hospital can receive a maximum of two proximity points. Candidates located outside the circle can receive a maximum of four proximity points, depending upon the proximity of their center of listing to the donor hospital. The proximity points decrease linearly both within and outside the 250 nm circle. Candidates listed at a hospital outside the 250 nm circle do not receive proximity priority until all the candidates inside the circle have been considered for the organ offer.[3,10] The aspects of KAS that did not change were the prioritization of transplant candidates based on estimated post-transplant survival (EPTS) and initial categorization of kidneys based on kidney donor profile index (KDPI) for subsequent allocation.[11,12]

As expected from simulation studies, we saw an increase in number of transplants performed within the 250 nm distance and a decrease in transplants beyond. However, this did not translate into a lower median distance for all transplants performed and in fact, increased the mean CIT for the transplants. Some factors that could have led to the longer CIT post policy change could be a systematic delay in processing the organ offers due to the disruption in the usual transplant workflow, an increase in the number of organ offers for individual transplant centers, transportation delays, logistical issues relating to the pandemic such as need for donor and recipient COVID testing and the inability of the transplant center to re-allocate the organ if the primary intended recipient is not able to be transplanted.[2] Under the new policy, if the donor kidney is not utilized for the initial intended recipient, the transplant hospital is not allowed to choose an alternate recipient at their hospital and has to release the kidney back to the host OPO for re-allocation. The importing OPO is no longer allowed to re-allocate these organs. What this means for an individual transplant center is that instead of interacting mostly with one OPO like they did under the old system, they are now interacting with multiple different OPOs, adding to the complexity of the organ allocation.[2]

The number of deceased donor kidney transplants have gone up every year following the introduction of KAS in 2014 including the year of 2020 when the hospitals across the country were reeling from overwhelming COVID-19 related admissions with temporary halting of kidney transplants in many centers.[13] The COVID-19 pandemic has had a protracted and sustained strain on the healthcare system.[4] Surveys among nursing staff have revealed increased incidences of burnout, dissatisfaction with career choice, early retirement, reduction in number of hours worked, and the pursuit of a non-clinical career path within and outside nursing.[14] The resulting acute shortage in the nursing workforce due to these myriad factors along with COVID-19

TABLE 2 Changes in donor kidneys transplanted and discarded categorized by Organ Procurement Transplantation Network (OPTN) regions and corresponding Organ Procurement Organizations (OPO). Number of transplant centers where the donor kidneys were placed is also shown.

			2019 cohort (Pre-COVID, Pre-policy change cohort)			2020 cohort (Early COVID, Pre-policy change cohort)			2021 cohort (Late COVID, Post-policy change cohort)		
OPTN region[a]	States included	Organ Procurement organization	Donor kidneys transplanted (N = 11336)	Donor kidneys discarded (N = 3103)	Number of transplant centers where kidneys were placed	Donor kidneys transplanted (N = 11808)	Donor kidneys discarded (N = 3392)	Number of transplant centers where kidneys were placed	Donor kidneys transplanted (N = 12914)	Donor kidneys discarded (N = 4525)	Number of transplant centers where kidneys were placed
1	CT, Eastern VT, ME, MA, NH, RI	CTOP	89 (87.3%)	13 (12.7%)	22	81 (78.6%)	22 (21.4%)	14	–	–	–
		MAOB	353 (82.1%)	77 (17.9%)	44	284 (77.8%)	81 (22.2%)	38	473 (81.6%)	107 (18.4%)	78
2	DE, DC, MD, NJ, PA, WV	MDPC	134 (65.7%)	70 (34.3%)	23	121 (69.5%)	53 (30.5%)	13	127 (65.8%)	66 (34.2%)	42
		NJTO	215 (78.2%)	60 (21.8%)	33	199 (79%)	53 (21%)	33	205 (69.3%)	91 (30.7%)	56
		PADV	628 (75.7%)	202 (24.3%)	69	563 (71.9%)	220 (28.1%)	60	674 (73.3%)	245 (26.7%)	89
		PATF	276 (80.5%)	67 (19.5%)	42	280 (72.5%)	106 (27.5%)	37	259 (63.6%)	148 (36.4%)	59
3	AL, AR, FL, GA, LA, MS, PR	ALOB	177 (75.3%)	58 (24.7%)	34	173 (76.9%)	52 (23.1%)	32	217 (64.4%)	120 (35.6%)	42
		AROR	72 (82.8%)	15 (17.2%)	11	71 (89.9%)	8 (10.1%)	21	126 (85.1%)	22 (14.9%)	27
		FLUF	149 (74.1%)	52 (25.9%)	36	168 (67.5%)	81 (32.5%)	23	219 (77.9%)	62 (22.1%)	30
		FLFH	217 (84.4%)	40 (15.6%)	38	230 (84.6%)	42 (15.4%)	34	236 (81.7%)	53 (18.3%)	30
		FLMP	157 (84.4%)	29 (15.6%)	27	155 (75.6%)	50 (24.4%)	17	161 (73.9%)	57 (26.1%)	22
		FLWC	237 (80.1%)	59 (19.9%)	41	294 (85.7%)	49 (14.3%)	36	317 (76.9%)	95 (23.1%)	31
		GALL	287 (74.7%)	97 (25.3%)	44	342 (84%)	65 (16%)	43	334 (66.5%)	168 (33.5%)	45
		LAOP	210 (76.4%)	65 (23.6%)	45	191 (79.9%)	48 (20.1%)	29	246 (81.5%)	56 (18.5%)	42
		MSOP	69 (75.8%)	22 (24.2%)	17	99 (82.5%)	21 (17.5%)	21	100 (90.1%)	11 (9.9%)	19
		PRLL	53 (69.7%)	23 (30.3%)	10	59 (68.6%)	27 (31.4%)	13	63 (73.3%)	23 (26.7%)	19
4	OK, TX	OKOP	195 (73%)	72 (27%)	39	224 (75.9%)	71 (24.1%)	31	231 (77.8%)	66 (22.2%)	36
		TXSB	361 (69.7%)	157 (30.3%)	53	363 (75.9%)	115 (24.1%)	38	402 (72.2%)	155 (27.8%)	69
		TXGC	414 (78.6%)	113 (21.4%)	59	353 (73.1%)	130 (26.9%)	52	413 (75.5%)	134 (24.5%)	53
		TXSA	223 (77.7%)	64 (22.3%)	32	205 (85.1%)	36 (14.9%)	32	265 (74.9%)	89 (25.1%)	40
5	AZ, CA, NV, NM, UT	AZOB	298 (80.8%)	71 (19.2%)	40	288 (77.2%)	85 (22.8%)	40	297 (73.2%)	109 (26.8%)	44
		CAOP	476 (67.6%)	228 (32.4%)	49	499 (74%)	175 (26%)	47	551 (75.5%)	179 (24.5%)	48
		CASD	138 (79.8%)	35 (20.2%)	31	125 (72.3%)	48 (27.7%)	25	136 (70.5%)	57 (29.5%)	26
		CADN	400 (81.5%)	91 (18.5%)	60	390 (77.7%)	112 (22.3%)	42	380 (80.7%)	91 (19.3%)	40
		CAGS	78 (87.6%)	11 (12.4%)	19	169 (87.1%)	25 (12.9%)	22	153 (75.7%)	49 (24.3%)	20
		NVLV	136 (78.6%)	37 (21.4%)	26	141 (69.5%)	62 (30.5%)	30	131 (58%)	95 (42%)	21
		NMOP	67 (80.7%)	16 (19.3%)	17	70 (81.4%)	16 (18.6%)	19	85 (73.9%)	30 (26.1%)	20
		UTOP	139 (88%)	19 (12%)	30	145 (85.8%)	24 (14.2%)	21	192 (76.5%)	59 (23.5%)	28

(Continues)

TABLE 2 (Continued)

OPTN region[a]	States included	Organ Procurement organization	2019 cohort (Pre-COVID, Pre-policy change cohort) Donor kidneys transplanted (N = 11336)	2019 Donor kidneys discarded (N = 3103)	2019 Number of transplant centers where kidneys were placed	2020 cohort (Early COVID, Pre-policy change cohort) Donor kidneys transplanted (N = 11808)	2020 Donor kidneys discarded (N = 3392)	2020 Number of transplant centers where kidneys were placed	2021 cohort (Late COVID, Post-policy change cohort) Donor kidneys transplanted (N = 12914)	2021 Donor kidneys discarded (N = 4525)	2021 Number of transplant centers where kidneys were placed
6	AK, HI, ID, MT, OR, WA	HIOP	37 (86%)	6 (14%)	14	50 (72.5%)	19 (27.5%)	15	48 (65.8%)	25 (34.2%)	11
		ORUO	144 (81.8%)	32 (18.2%)	28	174 (79.8%)	44 (20.2%)	31	217 (77%)	65 (23%)	42
		WALC	334 (81.1%)	78 (18.9%)	48	330 (85.7%)	55 (14.3%)	49	335 (75.6%)	108 (24.4%)	56
7	IL, MN, ND, SD, WI	ILIP	382 (78.1%)	107 (21.9%)	60	424 (77.2%)	125 (22.8%)	54	453 (74%)	159 (26%)	67
		MNOP	210 (84%)	40 (16%)	41	167 (86.1%)	27 (13.9%)	26	208 (73.2%)	76 (26.8%)	43
		WIUW	148 (78.3%)	41 (21.7%)	32	164 (85.4%)	28 (14.6%)	23	154 (74.8%)	52 (25.2%)	29
		WIDN	102 (76.7%)	31 (23.3%)	37	95 (81.2%)	22 (18.8%)	29	106 (77.9%)	30 (22.1%)	28
8	CO, IA, KS, MO, NE, WY	CORS	219 (86.9%)	33 (13.1%)	39	245 (84.5%)	45 (15.5%)	36	224 (74.2%)	78 (25.8%)	53
		IAOP	115 (90.6%)	12 (9.4%)	35	109 (79.6%)	28 (20.4%)	18	132 (67%)	65 (33%)	29
		MWOB	255 (80.7%)	61 (19.3%)	47	303 (78.5%)	83 (21.5%)	37	351 (76.8%)	106 (23.2%)	51
		MOMA	281 (83.6%)	55 (16.4%)	44	278 (79.7%)	71 (20.3%)	33	228 (71%)	93 (29%)	43
		NEOR	62 (68.9%)	28 (31.1%)	9	64 (79%)	17 (21%)	15	91 (82.7%)	19 (17.3%)	24
9	NY, Western VT	NYAP	69 (73.4%)	25 (26.6%)	19	65 (74.7%)	22 (25.3%)	16	75 (76.5%)	23 (23.5%)	36
		NYRT	271 (73.6%)	97 (26.4%)	41	262 (71.6%)	104 (28.4%)	40	336 (74.3%)	116 (25.7%)	59
		NYFL	61 (83.6%)	12 (16.4%)	11	46 (85.2%)	8 (14.8%)	11	94 (83.9%)	18 (16.1%)	35
		NYWN	21 (51.2%)	20 (48.8%)	7	33 (63.5%)	19 (36.5%)	6	48 (78.7%)	13 (21.3%)	22
10	IN, MI, OH	INOP	196 (77.2%)	58 (22.8%)	40	249 (78.8%)	67 (21.2%)	40	292 (80%)	73 (20%)	66
		MIOP	317 (79.3%)	83 (20.8%)	61	314 (69.2%)	140 (30.8%)	52	363 (65.3%)	193 (34.7%)	64
		OHOV	85 (85%)	15 (15%)	16	74 (81.3%)	17 (18.7%)	15	98 (79.7%)	25 (20.3%)	32
		OHLB	142 (76.3%)	44 (23.7%)	26	184 (80%)	46 (20%)	28	165 (72.4%)	63 (27.6%)	41
		OHLP	157 (83.1%)	32 (16.9%)	26	172 (84.7%)	31 (15.3%)	16	154 (68.8%)	70 (31.3%)	46
		OHLC	98 (93.3%)	7 (6.7%)	24	123 (71.5%)	49 (28.5%)	22	153 (70.8%)	63 (29.2%)	37
11	KY, NC, SC, TN, VA	KYDA	140 (85.4%)	24 (14.6%)	34	178 (82.8%)	37 (17.2%)	35	188 (76.7%)	57 (23.3%)	41
		NCCM	133 (91.1%)	13 (8.9%)	19	158 (84.5%)	29 (15.5%)	38	160 (75.8%)	51 (24.2%)	36
		NCNC	249 (84.1%)	47 (15.9%)	38	287 (83.9%)	55 (16.1%)	32	281 (77%)	84 (23%)	39
		SCOP	169 (74.4%)	58 (25.6%)	26	191 (67.5%)	92 (32.5%)	29	178 (64.3%)	99 (35.7%)	29
		TNMS	42 (75%)	14 (25%)	11	57 (77%)	17 (23%)	9	56 (73.7%)	20 (26.3%)	20
		TNDS	312 (76.8%)	94 (23.2%)	54	380 (77.6%)	110 (22.4%)	45	387 (76%)	122 (24%)	64
		DCTC	149 (85.6%)	25 (14.4%)	24	128 (83.7%)	25 (16.3%)	23	141 (78.8%)	38 (21.2%)	44
		VATB	188 (79.7%)	48 (20.3%)	27	222 (72.8%)	83 (27.2%)	26	205 (70.9%)	84 (29.1%)	47

[a]OPTN Region designations were removed from the kidney allocation policy on March 15, 2021.

related mortality of healthcare workers has led to logistical challenges with maintaining and growing the volumes of transplants performed. There has been reluctance to accept donors with COVID-19 and many transplant candidates with a recent or current history of COVID-19 were turned away from transplantation due to fears that impaired immunity from induction immunosuppression may lead to more severe COVID-19 disease and mortality.[15] Our study demonstrates a transition from being very conservative in the early part of the pandemic to being more aggressive in the later part (increase of 4.2% from 2019 to 2020 cohorts, and 9.4% from 2020 to 2021 cohorts in the number of kidney transplants), with improved understanding of the consequences of COVID-19 infection, and the availability of vaccination and effective management strategies. Our study describes the changes in trends in transplantation by taking into account cohorts before and after the policy change during the COVID-19 pandemic but also allows for comparison with a pre-pandemic cohort.

Approximately one-fourth of all recovered donor kidneys are discarded every year.[16] The Centers for Medicare & Medicaid Services (CMS) regularly updates its regulations for the OPOs establishing guidelines to enhance OPO performance holding OPOs to greater oversight, transparency, and accountability.[17] The push for pursuing DCD donors, donors with AKI, KDPI >85% donors and older donors by the CMS have led to numerical increases in the number of these organs being procured and transplanted, but discard rates have also gone up proportionately. Similarly, there have been numerical increases in Hepatitis C seropositive donor kidneys being transplanted with more aggressive procurements of these organs by the OPOs, with the most common reasons for discards being related to inability to find a recipient or poor organ quality.

The OPTN recently published a report on the impact of policy change in their post-implementation monitoring report. This report compared the post-policy change cohort (March 15, 2021 to June 30, 2021) with the pre-policy change cohort (December 1, 2020 to March 14, 2021), with each cohort comprising of 3.5 months and both after the onset of COVID-19 pandemic.[18] Our study had a longer duration of comparison in each cohort (March 15 to December 2 of 2019, 2020, and 2021), with each cohort comprising of 8.5 months. We divided our cohorts into pre-policy change, pre-COVID cohort; pre-policy change, early COVID cohort; and post-policy change, late COVID cohort for comparison. The OPTN analysis is flawed due to the exclusion of a pre-pandemic cohort in their analysis. We also found a discrepancy in the rates of kidney discard between our analysis and the OPTN report. While the OPTN reports a decrease in kidney discard rate from 24% to 22% post-policy change, we found a change in discard rate from 19.6% (2019) to 20.4% (2020) to 24% (2021). This difference is likely from a longer duration of observation in our study compared to the OPTN report.

Our study has a number of strengths. It is the first reported study other than the OPTN report on the impact of KAS policy change on the access to kidney transplantation. Several findings in our study deviate from the results of the simulation studies that were performed prior to the policy change. The increase in median distance between the donor and recipient hospital and the mean CIT is concerning as these directly have an impact on transplant economics and allograft outcomes. Our study also demonstrates the attenuation of anticipated improvements in KAS due to the impact of the ongoing COVID-19 pandemic as the three cohorts over last three years occurred at different stages of the COVID-19 pandemic, and pre- and post-KAS policy change. Our study also analyzes the trends in kidney discards along with the donor characteristics of discarded organs, including subgroup analyses in DCD donors, donors with AKI, KDPI >85% donors and older donors. We have also explored the most commonly cited reasons for discards to allow for a better understanding for higher discard rates in the US compared to Europe.[19] We were able to show the trends of kidneys transplanted versus discarded among the different OPOs and the differential impact on the OPOs from the COVID-19 pandemic and the allocation policy change. We were also able to demonstrate the increase in the number of transplant centers where the donor kidneys were placed for the majority of OPOs following the policy change.

We acknowledge that our study has limitations. It provides a snapshot of the way KAS policy change has impacted access to kidney transplantation within a short period of time, but more time is likely needed to know for certain as to what has worked and what hasn't with the policy change. As such, this study should be taken as a "first look" at the policy change with the caveat that these changes may eventually reach a stage of equilibrium where some of these early findings may no longer stay valid. However, due to the protracted and evolving nature of the COVID-19 pandemic, we anticipate the time duration to achieve this equilibrium to be longer. We were able to show that mean CIT were longer for the patients post policy change, but we were not able to demonstrate a difference in delayed graft function as an endpoint. We decided against including this data as all cases of delayed graft function was likely not reported for the 2021 cohort when we obtained this data (data updated as of December 2, 2021), especially for the ones that were transplanted in the latter period of the cohort. This would falsely minimize the risk of delayed graft function in the 2021 cohort. Under the new policy, kidney transplant programs are required to enter medical urgency data for their waitlisted candidates and prioritization is provided for medically urgent kidney patients. However, we were unable to obtain the data on this variable for the study from SRTR. Although we were able to demonstrate trends of kidney transplantation and discards for the different OPOs, institutional variations in protocols for organ/candidate acceptance for transplantation in cases relating to COVID-19 could have impacted these rates which we could not account for in our study. We were also not able to ascertain the specific step in the algorithm where the donor organ was placed and thus, were unable to study how often the donor kidneys were released back to the host OPO for re-allocation after being shipped to a transplant center and deemed unacceptable for transplant due to recipient-related factors.

In summary, it remains to be seen if the results from the simulation studies that led to the current change in KAS policy will lead to long term changes in the access to kidney transplantation as the COVID-19 pandemic evolves with an increase in effective vaccinations and therapeutics. In this early study of the dual impact of KAS policy change and COVID-19 pandemic on access to kidney transplantation, we saw a promising increase in rates of transplantation for some vulnerable groups, but distance between donor hospital and recipient transplant center and CIT have increased, and approximately one-fourth of all recovered donor kidneys continue to be discarded. With steadily rising number of deceased donors annually, some of the potential detrimental effects of COVID-19 or policy changes may be offset by the increasing availability of donor organs available for transplant.[16] Given these early findings, subsequent studies on the impact of KAS policy change with larger number of patients over a longer period of time will be important as the COVID-19 pandemic comes under better control to justify the latest policy change and inform changes to future iterations of KAS.

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CONFLICT OF INTEREST

The authors of this manuscript have no conflicts of interest or funding sources to disclose.

DATA AVAILABILITY STATEMENT

The data supporting the findings of this study can be requested from SRTR at https://www.srtr.org/requesting-srtr-data/data-requests/.

ORCID

Srijan Tandukar https://orcid.org/0000-0003-3745-7533
Zenith Tandukar https://orcid.org/0000-0002-5248-8066

TWITTER

Srijan Tandukar https://twitter.com/@Tandukar702
Zenith Tandukar https://twitter.com/@Zeniticist

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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