American Journal of Transplantation 23 (2023) 1209–1220

Contents lists available at ScienceDirect

American Journal of Transplantation

journal homepage: www.amjtransplant.org

Original Article

Increased volume of organ offers and decreased efficiency of kidney placement under circle-based kidney allocation

David C. Cron [1,2], Syed A. Husain [3,4], Kristen L. King [3,4], Sumit Mohan [3,4,5], Joel T. Adler [6,*]

[1] Department of Surgery, Massachusetts General Hospital, Boston, Massachusetts, USA
[2] Center for Surgery and Public Health, Brigham and Women's Hospital, Boston, Massachusetts, USA
[3] Division of Nephrology, Department of Medicine, Vagelos College of Physicians & Surgeons, Columbia University, New York, New York, USA
[4] The Columbia University Renal Epidemiology (CURE) Group, New York, New York, USA
[5] Department of Epidemiology, Mailman School of Public Health, Columbia University, New York, New York, USA
[6] Division of Transplantation, Department of Surgery and Perioperative Care, Dell Medical School at The University of Texas at Austin, Austin, Texas, USA

ARTICLE INFO

Keywords:
kidney transplant
allocation policy
kidney allocation system
concentric circle
broader distribution organ offer
kidney offer
transplant center

ABSTRACT

The newest kidney allocation policy kidney allocation system 250 (KAS250) broadened geographic distribution while increasing allocation system complexity. We studied the volume of kidney offers received by transplant centers and the efficiency of kidney placement since KAS250. We identified deceased-donor kidney offers (N = 907,848; N = 36,226 donors) to 185 US transplant centers from January 1, 2019, to December 31, 2021 (policy implemented March 15, 2021). Each unique donor offered to a center was considered a single offer. We compared the monthly volume of offers received by centers and the number of centers offered before the first acceptance using an interrupted time series approach (pre-/post-KAS250). Post-KAS250, transplant centers received more kidney offers (level change: 32.5 offers/center/mo, $P < .001$; slope change: 3.9 offers/center/mo, $P = .003$). The median monthly offer volume post-/pre-KAS250 was 195 (interquartile range 137-253) vs. 115 (76-151). There was no significant increase in deceased-donor transplant volume at the center level after KAS250, and center-specific changes in offer volume did not correlate with changes in transplant volume (r = −0.001). Post-KAS250, the number of centers to whom a kidney was offered before acceptance increased significantly (level change: 1.7

Abbreviations: COVID-19, corona virus disease 2019; DDKT, deceased-donor kidney transplant; DSA, donation service area; IQR, interquartile range; KAS250, kidney allocation system 250; KDPI, kidney donor profile index; KDRI, kidney donor risk index; OPO, organ procurement organization; SRTR, Scientific Registry of Transplant Recipients; United States, US.

* Corresponding author. Department of Surgery and Perioperative Care, The University of Texas at Austin, Dell Medical School, 1601 Trinity St., Bldg. B, Austin, TX 78712, USA.
E-mail address: joel.adler@austin.utexas.edu (J.T. Adler).

https://doi.org/10.1016/j.ajt.2023.05.005
Received 10 February 2023; Received in revised form 19 April 2023; Accepted 7 May 2023
Available online 16 May 2023
1600-6135/

centers/donor, $P < .001$; slope change: 0.1 centers/donor/mo, $P = .014$). These findings demonstrate the logistical burden of broader organ sharing, and future allocation policy changes will need to balance equity in transplant access with the operational efficiency of the allocation system.

1. Introduction

The shortage of kidneys available for transplant remains a challenge for the 89,000 prevalent patients waitlisted for a kidney transplant in the United States (US).[1] Given the scarcity of this lifesaving resource—with 25,498 kidney transplants performed in 2022—allocation policy in the US has been intentionally designed and periodically revised to improve equity while maximizing utility in the prioritization of patients for transplant. Although allocation changes introduced in 2014 reduced racial disparities in transplant rates for waitlisted patients,[2,3] a large geographic variation in access to kidney transplant persisted.[4,5] These geographic disparities drew national and judicial attention in 2017 when Miriam Holman brought a lawsuit against the Department of Health and Human Services for being unfairly deprioritized for a lung transplant based on her place of residence.[6] Thereafter, in response to federal mandate, allocation policy was ultimately revised in March 2021 to enable broader sharing of deceased-donor kidneys in an effort to improve geographic disparities.[7,8]

Historically, donors' kidneys were first allocated "locally" to waitlisted patients within the donation service area (DSA) where the kidney was recovered (Fig. 1A). However, there was significant variation in organ availability[5] and transplant access across DSAs.[9] The newest iteration of the kidney allocation policy—"kidney allocation system 250 (KAS250)"—eliminated the geographic boundaries of the 57 DSAs from allocation prioritization, replacing them with 250 nautical mile circles centered on the donor hospital (Fig. 1B), although still allowing proximity points for transplant centers closer to the donor hospital. Yet, with this broader sharing comes greater operational complexity—in terms of workload for transplant centers[10] and logistical burden of allocation and organ distribution for organ procurement organizations (OPOs)[11]—as centers and OPOs learn to operate within new, broader networks.[12] These concerns are a threat to the utility of the organ donation system, as an inefficient allocation system is not best equipped to serve our patients and may exacerbate the current problem of nonutilization of donor organs.[13] With upcoming and potentially more disruptive allocation changes being planned,[14] there is an urgent need to evaluate KAS250's implementation to identify potential inefficiencies in the system and inform the design of future iterations of allocation policy in the US.

We used national transplant registry data to study the impact of KAS250 on the efficiency of deceased-donor kidney allocation. We quantified trends in the number of kidney donors offered to transplant centers, hypothesizing that offers increased after KAS250. We then quantified the change in deceased-donor kidney transplant (DDKT) volume across transplant centers to evaluate the relationship between changes in offer vs. transplant volume. We also measured the efficiency with which a donor's kidney is placed in an accepting center, hypothesizing that donors must be offered more widely under KAS250 and that the resulting cold ischemia time would be longer.

2. Material and methods

2.1. Data source and study population

This study used data from the Scientific Registry of Transplant Recipients (SRTR). The SRTR data system includes data on all donors, waitlisted 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, US Department of Health and Human Services, provides oversight for the activities of the OPTN and SRTR contractors. Candidate, recipient, and donor data from the standard analysis file were linked to the potential transplant recipient file, which includes all deceased-donor kidney offers to candidates, including the priority order and decision made for each offer (accept/decline). We included all deceased-donor kidney offers made between January 1, 2019, and December 31, 2021 (the most recently available data). We excluded centers receiving <10 offers in any given month and centers inactive in the pre-KAS250/post-KAS250 periods (Supplementary Fig. S1). This study was approved by the University of Texas at Austin institutional review board (#00002097).

2.2. Exposure: policy change

KAS250 was implemented on March 15, 2021. When quantifying trends over time, outcomes were analyzed from January 1, 2019, to December 31, 2021. When discretely comparing metrics in the pre-KAS250 vs. post-KAS250 periods, to ensure balanced time periods, we compared pre-KAS250 (March 15, 2020, to December 31, 2020) to post-KAS250 (March 15, 2021, to December 31, 2021).

2.3. Outcomes: offer and transplant volume

Each donor goes through a "match run," in which it is offered to multiple candidates across different centers until each kidney is accepted for transplant. Organ offer decisions are made by the centers on behalf of the patients (see Supplementary Table S1 for further explanation). For our primary analysis, we measured the median number of deceased donors offered per center per month—meaning 1 donor offered to 3 candidates at a center would be counted as a single donor offer to that center. This approach prevents offer volumes from being influenced by a

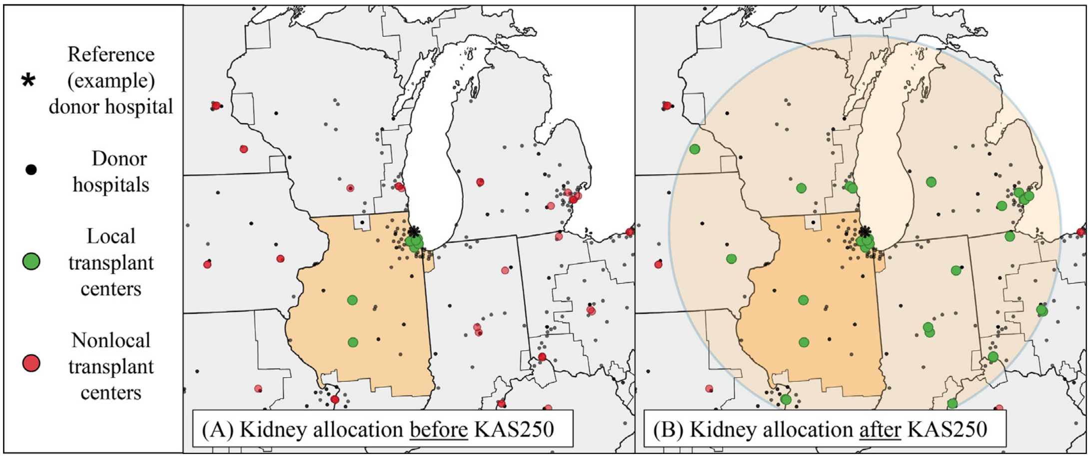

Figure 1. Geographic distribution of deceased-donor kidneys under the previous system compared with the new kidney allocation system. Kidney allocation system 250 (KAS250) refers to the newest policy change to broader sharing. The asterisk indicates a reference donor hospital for this example. Before KAS250 (A), donor kidneys originating from that hospital would be allocated "locally first" to transplant centers (green circles, N = 9) within that hospital's donor service area (yellow shaded area). Red circles indicate nonlocal transplant centers, which would typically only receive kidney offers in this instance when they had been first declined by all local centers. After KAS250 (B), kidneys from the reference donor hospital are now allocated "locally first" to any transplant centers (green circles, N = 40) within a 250-nautical mile circle around the reference donor hospital. Prioritization is given to centers closest to the donor hospital within the 250-mile circle.

center's waitlist size, more accurately capturing the true cognitive workload required for centers to determine the acceptability of donor organ quality. We limited ourselves to instances where centers responded to the offer (even when the kidney was ultimately accepted at a higher position on the match run), and we excluded offers not actually seen by centers ("bypasses").[15] This definition is reflective of the actual workload from the center/surgeon's perspective. For example, a center might receive and review an offer at sequence 4 on the match run, but it could ultimately be accepted at sequences 1 through 3 by another center. Similarly, kidneys that do not end up being accepted by any center are still reviewed by many centers. As a sensitivity analysis, we defined "offer" in multiple additional ways: (1) only transplanted kidneys; (2) excluding offers where a kidney was accepted at an earlier position on the match run; and (3) a combination of the 2, to assess if our results were robust to these various definitions.

We also measured the median number of DDKTs performed per center. To assess if changes in offer volume applied equally to lower vs. higher quality kidneys, we separately stratified by the kidney donor profile index (KDPI, a percentile score ranging from 0 [greatest longevity] to 100 [lowest longevity]; reference years 2019 and 2020).[16] We also compared donor characteristics pre-KAS250/post-KAS250 using donor age, donation after brain death vs. donation after circulatory death, KDPI, and donor terminal serum creatinine.

2.4. Outcomes: efficiency of kidney placement

Next, we quantified the efficiency of kidney placement by (1) calculating the median number of transplant centers considering a donor before their first kidney was accepted for transplant and (2) the number of patients (across all centers) to whom the organ was offered before it was accepted. These analyses excluded kidneys procured for transplant but not ultimately transplanted. An organ being declined by many centers or patients is reflective of either organ quality or, more likely, the efficiency of the allocation system.[17] We also quantified the proportion of kidneys allocated "out of sequence"—defined by the refusal codes 861 ("operational OPO"), 862 ("donor medical urgency"), or 863 ("offer not made due to expedited placement attempt")—in which OPOs exercise discretion to bypass the match run's prioritization to place a kidney in an expedited fashion.[18] Finally, we reported national trends in the following: total national DDKT volume, median cold ischemia time (hours the kidney spent ex vivo), the proportion of kidneys with delayed graft function (defined as needing dialysis within 7 days posttransplant), and proportion of recovered kidneys procured but not used (for any reason).

2.5. Statistical analysis

To estimate the effect of KAS250 on our measures of interest (donor offer volume, center-level DDKT volume, and efficiency of placement), we used an interrupted time series approach using ordinary least squares regression and Newey-West standard errors to handle autocorrelation and possible heteroskedasticity.[19] Autocorrelation was tested with a Cumby-Huizinga test.[20] This approach accounts for existing temporal trends and quantifies the level change (immediate change at KAS250's implementation) and the slope change after KAS250. Each model adjusted for the following covariates: month, median donor age and kidney donor risk index (KDRI) each month, and proportion of donations after circulatory death donors recovered each month. We then computed the median or frequency of each outcome metric and of the donor characteristics for post-KAS250 vs. pre-KAS250 periods, comparing their statistical significance using a Wilcoxon rank-sum test, Fisher exact test (independent samples), or Wilcoxon signed-rank test (paired samples).

Next, we assessed the association of center-level changes in median offer volume, offer quality, and offer acceptance rates (using SRTR's definition)[21] with changes in DDKT volume (Pearson correlation). We computed the proportional change in each of these metrics by dividing the post-KAS250 value by the pre-KAS250 value. For these correlational analyses only, we removed outlier centers >3 standard deviations above the mean (Fig. 3 footnotes).

Finally, for transplant centers experiencing proportional changes in offer volume below vs. above the median, we compared the following center characteristics: pre-KAS250 kidney transplant volume and characteristics of prevalent waitlist populations at KAS250 implementation (waitlist size and factors determining allocation priority: waiting time, the proportion of highly sensitized patients, and median estimated posttransplant survival of the waitlist cohort).[22]

3. Results

We identified 907,848 deceased-donor kidney offers for 36,226 unique donors to 185 US transplant centers from January 1, 2019, to December 31, 2021 (Supplementary Fig. S1). When divided into pre-KAS250/post-KAS250 periods for discrete comparisons, the pre-KAS250 period (March 15, 2020, to December 31, 2020) included 192,152 offers for 9,395 donors, and the post-KAS250 period (March 15, 2021, to December 31, 2021) included 363,025 offers for 10,717 donors.

3.1. National trends in transplant volume, ischemia time, delayed graft function, and nonuse

National monthly DDKT volume increased over time throughout the study period, with an immediate increase (level change: 2028. DDKT/mo, $P = .009$) followed by a downtrend after KAS250 (slope change: −48.6 DDKT/mo, $P = .002$; Supplementary Table S2, Supplementary Fig. S2). Total DDKTs performed were 13,580 pre-KAS250 and 14,751 post-KAS250 (Table 1). Compared with the pre-KAS250 period, the post-KAS250 period showed increases in median cold ischemia time (19.3 vs. 17.1 h, $P < .001$), the incidence of delayed graft function (30.8% vs. 28.3%, $P < .001$), and nonuse proportion (24.4% vs. 20.7%, $P < .001$) (Table 1).

3.2. Characteristics of deceased-donor kidney offer

Characteristics of the deceased donor's kidney offered in the pre-KAS250/post-KAS250 periods are reported in Supplementary Table S3. Post-KAS250 period donors were older (median 43 vs. 41 y, $P < .001$), more likely to donate after circulatory death (31.7% vs. 26.5%, $P < .001$), and slightly lower quality (median KDPI: 50 vs. 47, $P < .001$).

3.3. Trends in deceased-donor kidney offer and transplant volume

Figure 2A shows the median number of deceased-donor kidney offers/transplant centers/mo over time. Offer volume increased significantly after the KAS250 period (level change: 31.8 offers/center/mo, $P < .001$; slope change: 4.1 offers/center/mo, $P = .002$; Supplementary Table S2). In contrast, at the center level, there was no immediate change in the median number of DDKT/center/mo following KAS250 (level change: 1.6, $P = .058$), but there was a small downtrend (slope change: −0.3 DDKT/center/mo, $P = .003$; Supplementary Table S2). Compared with the pre-KAS250 period, median offer volume was 70% higher in the post-KAS250 period (195 vs. 115 offers/center/mo, P < .001) and median DDKT volume was similar (6 vs. 6 DDKT/center/mo, $P = 0.017$; Table 1). Similar increases in offer volume post-KAS250 vs. pre-KAS250 periods were observed across ranges of kidney quality (Table 1, interrupted time series results in Supplementary Table S2). When alternate definitions of an organ offer were used as a sensitivity analysis, the overall results were similar, with a 70% to 90% proportional increase in offer volume post-KAS250 vs. pre-KAS250 and a significant level change (increase) in offer volume post-KAS250 (Supplementary Table S4 and Supplementary Fig. S3A-D**)**.

3.4. The efficiency of kidney placement

Figure 2B shows the trend in the median number of centers to whom a donor must be offered prior to receiving the first acceptance. This number increased significantly after KAS250 (level change: 1.7 centers/donor, $P < .001$; slope change: 0.1 centers/donor/mo; $P = .010$; Supplementary Table S2). Compared with the pre-KAS250 period, kidneys were offered to twice as many centers before finding an accepting center in the post-KAS250 period (4 vs. 2, $P < .001$), and similar increases were seen across KDPI strata (Table 1). This metric varied across OPOs, as the median number of centers offered prior to first acceptance ranged from 1 to 6 pre-KAS250 and 1 to 12 post-KAS250.

The median sequence number—or the number of candidates to whom a donor was offered prior to the first kidney acceptance—also increased significantly after KAS250 (level change: 2.5 positions, $P < .001$; slope change: 0.2 positions/mo, $P = .001$; Supplementary Table S2; median 7 vs. 3, $P < .001$; Table 1). Similar increases were seen across KDPI strata (Table 1). This metric varied across OPOs, as the sequence number at first acceptance ranged from 2 to 14 pre-KAS250 and 2 to 19 post-KAS250. Nationally, out-of-sequence kidney allocations have become more common. The proportion of all donors with an out-of-sequence allocation increased from 3.3% to 5.6% after KAS250 ($P < .001$; interrupted time series analysis: level change 2.0% points, $P < .001$), and this practice has become increasingly common since KAS250 (Supplementary Fig. S4).

3.5. Relationship between changes in center offer volume and transplant volume

The proportional change in offer volume following the KAS250 period ranged from 0.7 to 8.4 across centers (median 1.7, IQR 1.4-2.0; Supplementary Fig. S5), and change in DDKT volume ranged from 0.2 to 6.0 (median 1.0, IQR 0.8-1.5). At the center level, the change in offer volume was not correlated with the change in DDKT volume (r = −0.001, $P = .988$, Fig. 3A). The

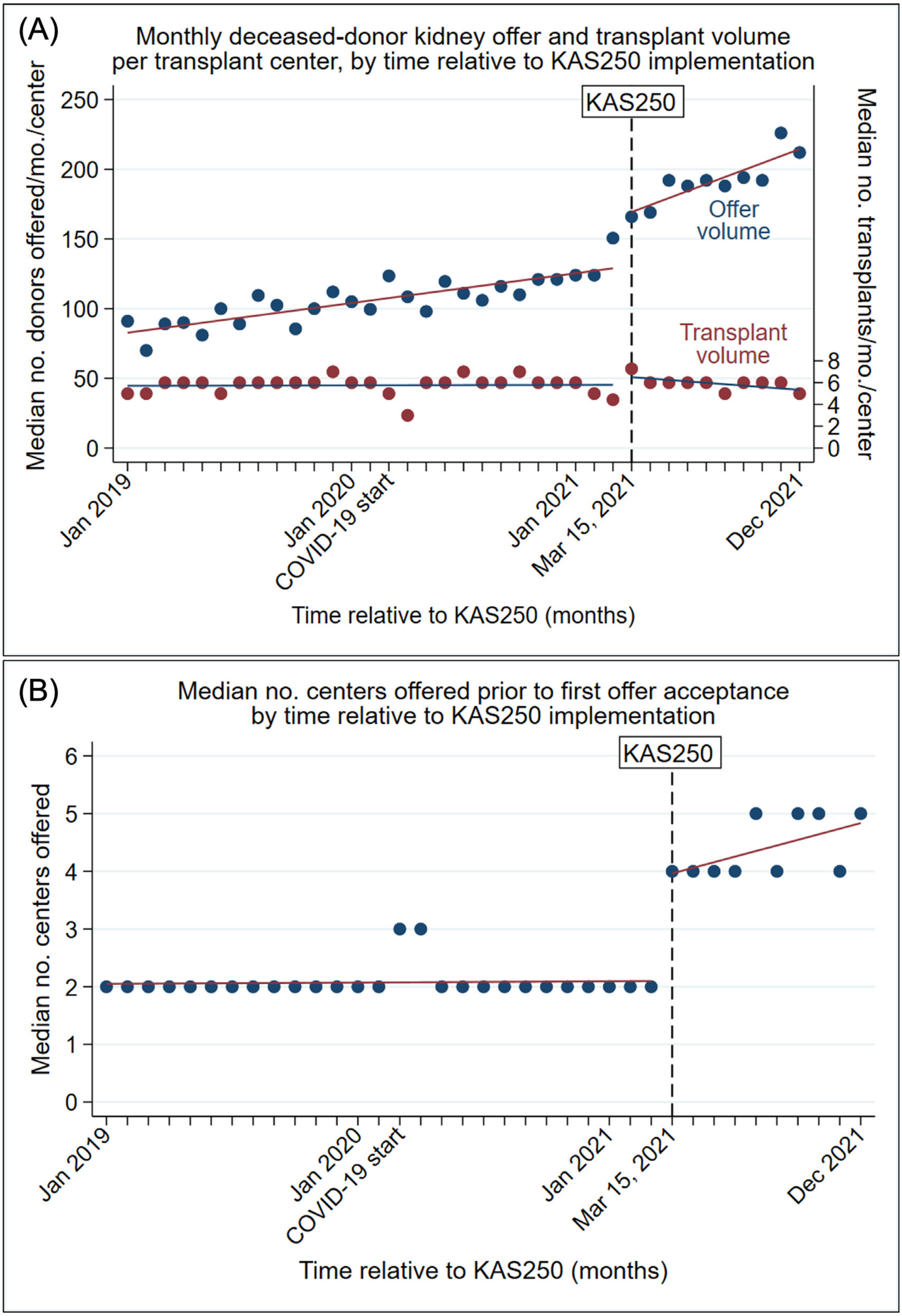

Figure 2. Trends in transplant center-specific deceased-donor kidney offer and transplant volume, and efficiency of kidney placement, relative to the implementation of the kidney allocation policy change. Kidney allocation system 250 (KAS250) refers to he newest policy change to broader sharing. (A) shows the trend over time in the median number of deceased-donor kidney offers received (blue dots and red trend line) and deceased-donor kidney transplants performed (red dots and blue trend line) per transplant center per month. The dashed vertical line indicates the implementation date of KAS250 (March 15, 2021). (B) shows the trend over time in the median number of transplant centers to which a deceased donor is offered before their first kidney is accepted.

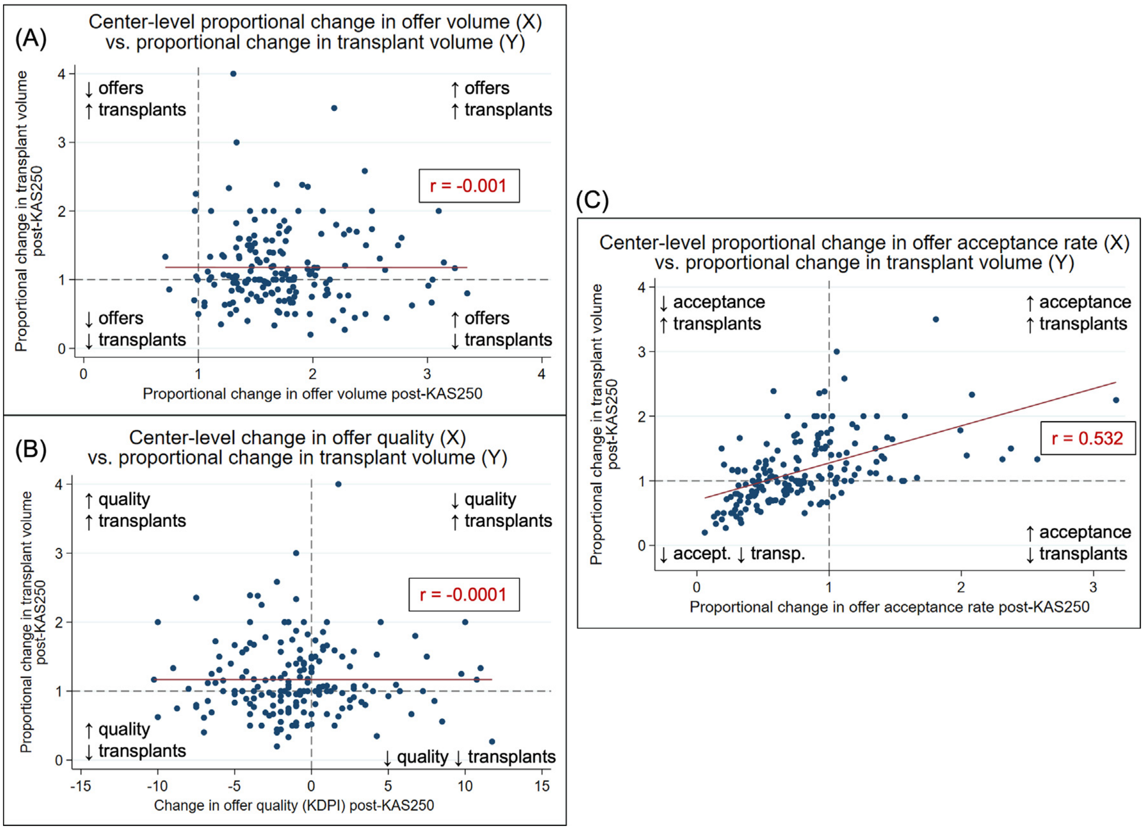

Figure 3. Association between center-level changes in deceased-donor kidney transplant volume and kidney offer volume (A), quality of kidneys offered (B), and kidney offer acceptance (C). Kidney allocation system 250 (KAS250) refers to the newest policy change to broader sharing. Each dot indicates 1 of the 185 transplant centers. The Y-axis for each plot represents the transplant center-level proportional change in deceased-donor kidney transplant volume in the 9 months after KAS250 compared with the equivalent 9-month period before KAS250. The X-axes represent the center-level proportional change in deceased-donor kidney offer volume (A), the absolute change in the quality (kidney donor profile index, KDPI, with higher numbers indicating lower expected graft longevity) of kidney offers received (B), and the proportional change in offer acceptance rate (C) after KAS250. Outliers were removed from these plots when they were >3 standard deviations from the mean (number of centers removed: 2 from A, 3 from B, and 4 from C).

change in the quality of organs offered to a center was also not correlated with the change in DDKT volume ($r = -0.0001$, $P = .999$, Fig. 3B). Centers who received more offers after the KAS250 period had an associated *decrease* in their offer acceptance rate ($r = -0.366$, $P < .001$), but centers who *increased* their acceptance rate had an associated increase in DDKT volume post-KAS250 period ($r = .532$, $P < .001$, Fig. 3C). Nationally, there was no statistically significant change in the covariate-adjusted offer acceptance rate over time or following the KAS250 period (Supplementary Fig. S6).

3.6. Characteristics of centers with smaller vs. larger changes in offer volume

Centers with the largest proportional increases in offer volume after KAS250 were predominantly located in areas densely populated with donor hospitals and transplant centers—namely the Northeast and Midwest (Fig. 4A), whereas centers with large increases in DDKT volume were more geographically dispersed (Fig. 4B). The median proportional change in offer volume observed by transplant centers varied 4.6-fold across DSAs (0.7-3.3). Table 2 compares the characteristics of transplant centers based on the degree to which their offer volume changed after KAS250. Centers that showed greater increases in offer volume after KAS250, compared with centers that showed lesser increases in offer volume, were lower DDKT volume centers at baseline (median pre-KAS250 DDKT volume 49 vs. 73 annual DDKT per center, $P = .026$), but were otherwise similar with respect to their waitlist population's characteristics (Table 2).

4. Discussion

KAS250 has resulted in large increases in the number of kidney donor offers received by transplant centers. Although the total number of transplants performed nationally continues to increase over time—a welcome finding resulting from national efforts to procure more organs and increase transplantation—at the transplant center level, receiving more offers was not associated with an increase in DDKTs. Increased offer volume increases the workload for transplant centers and staff[10] (thus distracting from other patient care activities), and an inelastic response between offers and transplants reflects the greater logistical burden of allocation for centers and OPOs. However,

Table 1

Deceased-donor kidney offer and transplant volume, the efficiency of placement, and characteristics of donors, before and after implementation of the newest kidney allocation policy. Kidney allocation system 250 (KAS250), the newest allocation policy change which eliminated donor service areas and implemented 250 nautical mile circles to broaden the distribution of donor's kidneys.

Metrics	Pre-KAS250 (3/15/2020-12/31/2020)	Post-KAS250 (3/15/2021-12/31/2021)	Proportional increase (Post-KAS250 vs. pre-KAS250)	*P*-value[d]
Total counts				
Total no. donors	9,395	10,717	1.14	–
Total no. offers	192,152	363,025	1.89	–
National trends				
Total national deceased-donor kidney transplant volume	13,580	14,751	1.09	–
Median cold ischemia time (h)	17.1 (11.5-22.7)	19.3 (14.4-24.1)	1.13	<.001
Proportion with delayed graft function	3,844 (28.3%)	4,539 (30.8%)	1.09	<.001
Proportion of kidneys recovered but not used	3,792 (20.7%)[a]	5,119 (24.4%)[a]	1.18	<.001
Trends per center per mo				
Deceased-donor kidney transplant volume	6 (3-10)	6 (3-12)	1.00	.017
No. donors offered, overall (median, interquartile range [IQR])	115 (76-151)	195 (137-253)	1.70	<.001
High longevity (kidney donor profile index [KDPI][b] < 20)	10 (8-12)	17 (13-22)	1.70	<.001
Good longevity (KDPI 21-34)	10 (7-13)	18 (13-23)	1.80	<.001
Moderate longevity (KDPI 35-85)	64 (46-90)	112 (75-145)	1.75	<.001
Poor longevity (KDPI > 85)	26 (14-40)	45 (25-69)	1.73	<.001
Efficiency of kidney placement				
No. of centers offered prior to first acceptance, overall (median, IQR)	2 (2-2)	4 (4-4)	2.00	<.001
High longevity (KDPI < 20)	2 (2-2)	3 (3-3)	1.50	<.001
Good longevity (KDPI 21-34)	2 (2-2)	4 (4-4)	2.00	<.001
Moderate longevity (KDPI 35-85)	3 (2-3)	5 (5-5)	1.67	<.001
Poor longevity (KDPI > 85)	5 (4-7)	10 (10-12)	2.00	<.001
No. of patients offered[c] **prior to first acceptance**, overall (median, IQR)	3 (3-4)	7 (6-7)	2.33	<.001
High longevity (KDPI < 20)	2 (2-2)	5 (4-5)	2.50	<.001
Good longevity (KDPI 21-34)	3 (2-3)	6 (5-7)	2.00	<.001
Moderate longevity (KDPI 35-85)	4 (4-5)	8 (7-9)	2.00	<.001
Poor longevity (KDPI > 85)	22 (16-38)	50 (39-64)	2.27	<.001

[a] Total number of recovered kidneys: 18,346 (pre-KAS250) and 20,976 (post-KAS250).

[b] KDPI is a percentile score ranging from 0 (highest expected graft longevity) to 100 (lowest expected graft longevity). Calculated using each year's corresponding mapping table.

[c] This is the "sequence number" of the match run (how far down the list the kidney was placed).

[d] *P*-value obtained from Wilcoxon rank-sum or Fisher exact test (independent samples), or Wilcoxon signed-rank test (dependent samples, ie, center-specific comparisons).

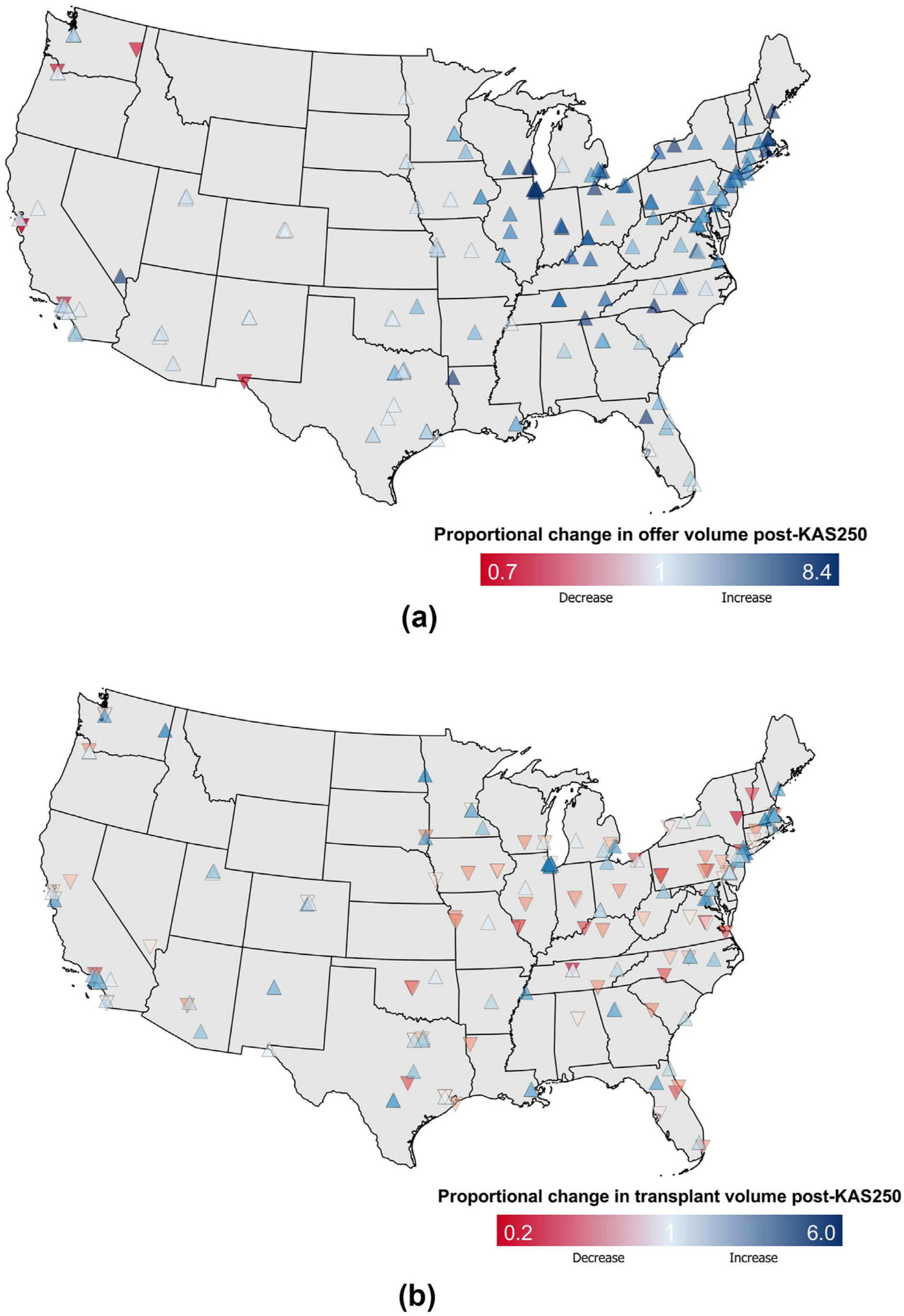

Figure 4. Location of US kidney transplant centers and their proportional change in deceased-donor kidney offer (A) and transplant (B) volume after kidney allocation system 250 (KAS250). Alaska, Puerto Rico, and Hawaii are not depicted here; allocation rules are different in these areas. Each arrow represents a transplant center. Upward-facing arrows indicate an increase in volume after KAS250, with darker blue indicating a greater increase. Downward-facing arrows indicate a decrease in volume after KAS250, with darker red indicating a greater decrease.

centers that responded by increasing their offer acceptance rate after KAS250 did experience an associated increase in DDKT volume. As further evidence of inefficiency while the allocation system adapts to this new policy, deceased-donor kidneys are now offered to twice as many transplant centers before an accepting center is found. In turn, cold ischemia time, the proportion of transplanted kidneys with delayed graft function, and the proportion of kidneys recovered but not used have all increased since KAS250. These consequences of the recent kidney allocation change demonstrate the logistical burden of broader organ sharing and should be considered when designing the next round of changes planned under continuous organ distribution.

The increased complexity accompanying broader sharing was identified as a potential concern given the dramatic increase in the number of centers now considered "local"—ie, given distance-based allocation priority in the first round of the matching algorithm.[12] Single-center reports describe a near doubling of offer volumes[10]—which we show is a shared experience nationally, and the time spent by transplant teams evaluating these offers has nearly doubled.[10] Even using conservative estimates of 9 minutes per offer, at 1 institution, this increase resulted in 25 hours per month

 American Journal of Transplantation 23 (2023) 1209–1220

Table 2

Characteristics of transplant centers by a proportional change indeceased-donor kidney offer volume, relative to the median center, before and after kidney allocation system 250 (KAS250) implementation. KAS250, the newest allocation policy change eliminated donor service areas and implemented KAS250 nautical mile circles to broaden the distribution of donor kidneys. The 2 comparison groups are centers below vs. above the median proportional change in offer volume postpolicy change (proportional change $\leq$ 1.70 vs. $>$ 1.70). Numbers represent the median (interquartile range). Waiting time, sensitization, and estimated posttransplant survival all contribute to a patient's priority on the waitlist.

Transplant center characteristic	Decrease or smaller increase in offer volume post-KAS250	Larger increase in offer volume post-KAS250	*P*-value
Total no. transplant centers	93	92	–
Proportional change in offer volume post-KAS250 (range)	0.7-1.7	1.7-8.4	–
Pre-KAS250 deceased-donor kidney transplant volume[a]	73 (34-109)	49 (24-89)	.026
Post-KAS250 deceased-donor kidney transplant volume[b]	70 (38-125)	48 (26-107)	.043
Pre-KAS250 living donor kidney transplant volume[a]	14 (4-27)	13 (6-25)	.963
Post-AS250 living donor kidney transplant volume[b]	19 (6-36)	16 (8-35)	.848
Kidney transplant waitlist population[c]			
Total no. patients	54,656	42,184	
Waitlist size (per center)	370 (217-801)	373 (186-591)	.201
Waiting time (y)[d]	2.8 (2.3-3.5)	2.7 (2.3-3.1)	.155
Proportion of highly sensitized patients (panel reactive antibody titer > 98%)	3.3% (2.3% to 4.5%)	3.1% (2.2% to 4.2%)	.155
Proportion with high estimated posttransplant survival (score < 20)[e]	23.8% (20.1% to 27.5%)	23.7% (21.7% to 27.0%)	.802

[a] Total volume from March 15, 2020, to December 31, 2020.
[b] Total volume from March 15, 2021, to December 31, 2021.
[c] Prevalent waitlist population on March 15, 2021.
[d] Time since dialysis start or waitlist date (whichever is earlier).
[e] Estimated posttransplant survival is a percentile score ranging from 0 (highest estimated survival) to 100 (lowest estimated survival). This is calculated using the 2021 reference.

spent by physicians on this singular aspect of the allocation system (evaluating offers) and 91 hours spent by transplant coordinators on related tasks.[10] For the centers facing this increased offer-related workload, when it is not coupled with an increase in transplants, it instead can distract from other patient care activities and divert effort that could be directed elsewhere to improve access to transplantation. Others have raised concerns over the efficiency of allocation under KAS250 and the impact on kidney utilization and outcomes.[11,13] Our study has identified the contribution of offer volume as a driver of inefficiency in this system, and we have quantified the extent of this problem nationally, which affects nearly all transplant centers.

The rate of nonuse of deceased-donor kidneys has reached an all-time high despite calls to action from a White House Executive Order,[23] a report from the National Academies of Sciences, Engineering, and Medicine,[24] and a Center for Medicare and Medicaid Services collaborative.[25] Similar political imperatives[26] have stimulated OPOs to procure more donors—as reflected in the annually increasing national DDKT volumes—and coupled with the pursuit of more marginal quality donors, this likely explains the increasing trend in offer volume before KAS250. Yet, with longer cold ischemia times,[27] and with centers and OPOs overwhelmed by offer volumes, kidney utilization is worsening.[13] Beyond the allocation changes, OPOs and transplant centers also share a role and may not have been adequately prepared to respond to these changes. OPOs vary in their efficiency of organ placement, which may reflect differences in organ quality or network size or differences in OPO practices around organ offers and placement. OPOs are increasingly resorting to out-of-sequence allocation to get kidneys placed in the face of the longer match runs, greater distances, and longer cold ischemia times. Transplant centers, too, have differed in their preparedness for the allocation changes. Preparation for a sudden increase in offer volume would include optimizing waitlist management (to ensure patients are ready for the transplant), increasing staffing when possible, instituting offer filters, and possibly reconsidering one's acceptance criteria. Offer filters—which are underutilized across centers—can prevent centers from being notified about kidneys they are unwilling to use. Offer acceptance rates of transplant centers are scrutinized and are now a performance metric. On the national scale, offer acceptance rates have not changed since KAS250; however, some centers did increase their offer acceptance over this time, and these centers tended to increase their DDKT volume as well. In other words, centers that changed their behavior in response to the KAS250 tended to do more transplants during this time as well. Thus, we suggest that policies affecting the distribution of kidneys must be coupled with changes in behavior and performance at the center and OPO levels to improve kidney utilization.

The impetus for KAS250 was a need to improve geographic equity, which we have not measured with the present study. More kidney offers for transplant candidates is a positive aspect of allocation policy change when this translates to an increased likelihood of transplant for the patients most in need without overburdening the system or compromising kidney utilization. We show that simply receiving more kidney offers is not sufficient to increase the number of transplants at the center level. However, increasing transplant volume does not equate to increasing equity, and once sufficient post-KAS250 follow-up time has accrued, it will be critical to study the effect of a broader distribution on geographic disparities in access to kidney transplants. Early results from the OPTN's one-year monitoring report[28] showed a 16% increase in the overall transplant rate following KAS250, with greater increases in certain marginalized subpopulations, but geographic disparities have not yet been assessed. These results are encouraging, and time will tell if the beneficial aspects of broader distribution outweigh the downsides highlighted in this manuscript. Ultimately, organ allocation seeks to balance equity in patient access to lifesaving donor organs with utility in maximizing their benefit (while also attempting to minimize nonutilization). Inefficiency and workforce strain in the transplant system can impede progress toward both goals; a focus on efficiency and practicality of allocation and organ distribution is necessary to align these goals and to better serve our patients.

KAS250 is the first iteration of a broader geographic allocation, and there is room to refine this policy moving forward. Homogenous distribution circles ignore population size, disease burden, and organ availability; thus, a one-size-fits-all approach to distribution may be inadequate.[29] When we examined the characteristics of the centers most affected by increased offer volume, these centers did not have differences in waitlist size or allocation priority of their candidates. Rather, geography was a major driver of the variation in the extent of increased offer volume, and the largest increases in offer volume were seen in areas densely populated with donor hospitals and transplant centers. Further, the centers with greater increases in offer volume were smaller transplant centers that may not have the resources to adapt to these changes in offer volume, thus raising the potential for perpetuating or creating disparities in transplant access by favoring consolidation at the larger, more well-resourced centers.[30] Many have concerns that kidneys are being distributed away from areas of high need,[31] including rural centers where patients already have reduced access to transplants.[32,33]

KAS250 is an intermediate policy change en route to broader allocation changes termed "continuous distribution,"[8,14] which builds on KAS250 by completely eliminating geographic boundaries and other fixed strata (like age group or allosensitization status) for a continuous scoring system. Continuous distribution is a more complex policy and will still share the broader distribution component of KAS250, but proximity score as a component of the scoring system will allow for titration of this parameter and thus the potential to respond to distance-based inefficiencies in the system. Nonetheless, important lessons can be learned from KAS250's implementation to inform future iterations of allocation policy.

This study has several limitations. The timeframe of available data post-KAS250 was somewhat short; nevertheless, immediate and clear changes in the study outcomes and their trends were observed and quantified. Whether the system will eventually adapt and see offer volumes decline or efficiency improve upon reaching more of an equilibrium[34] is unknown, and ongoing surveillance is needed. Second, the confounding impact of the coronavirus disease 2019 (COVID-19) pandemic cannot be discounted. The pre-KAS250 era coincided with the onset of the COVID-19 pandemic, and pre-KAS250/post-KAS250 comparisons must be interpreted accordingly. The initial effect of the pandemic was a shutdown of transplant activity at many centers during the early months of the pandemic. Despite this, the graphical display of pre-KAS250 trends revealed a minimal effect on the national scale of COVID-19 onset on the study metrics. However, the downstream effects of the pandemic on workforce shortages, for example, may still be contributing to inefficiencies in the transplant system. Third, additional confounders may limit our ability to attribute causality to the KAS250 policy. The donor pool is expanding as OPOs face new performance metrics and more marginal quality donor organs are procured and offered. Our time series models account for pre-KAS250 trends, and we adjusted for donor pool characteristics in our models; however, these other contemporaneous changes in organ procurement and transplantation may confound our results. Lastly, there are many ways to define an "offer" with these data, and we opted for a more inclusive definition to capture all offers a transplant center would have received and spent time reviewing. However, our definition may include some offers that may have been screened by a coordinator without the center spending time to review them. As such, our estimates of the number of offers reviewed per center per month may be biased higher than the actual offer volume, but the takeaway findings are robust to the various possible definitions, as shown in our sensitivity analysis.

In this study of US transplant centers, since the implementation of KAS250—the most recent kidney allocation change to a broader geographic distribution of kidneys—the volume of kidney offers received by transplant centers increased significantly, and the allocation system became less efficient. There was an increase in kidney cold ischemia time and the kidney nonuse rate during this same time period. The effect of KAS250 on geographic equity in access to transplants was not the focus of our study but is a key question yet to be answered. Kidney allocation seeks to balance equity and utility, and an inefficient system is a threat to utility. As allocation policy continues to evolve, and with more substantial allocation changes planned ahead, these potential consequences should be recognized, and future policy iterations should balance the efficiency of the system with equity in transplant access.

Funding

The research reported in this publication was supported by the Agency for Healthcare Quality and Research under award number K08HS028476 (Adler) and National Institute of Diabetes and Digestive and Kidney Diseases of the National Institutes of Health under award numbers F32DK128981 (Cron) and K23DK133729 (Husain).

Disclosure

The data reported here have been supplied by the Hennepin Healthcare Research Institute (HHRI) as the contractor for the Scientific Registry of Transplant Recipients (SRTR). The interpretation and reporting of these data are the responsibility of the author(s) and in no way should be seen as an official policy of or interpretation by the SRTR or the US Government. The authors of this manuscript have conflicts of interest to disclose, as described by the American Journal of Transplantation. S. Mohan reports consultancy for Angion Biomedica, eGenesis, and HSAG; an advisory or leadership role for ASN Quality Committee (member), ETCLC (National Faculty Chair), Kidney International Reports (ISN; deputy editor), SRTR Review Committee (member), and UNOS data advisory committee (vicechair); and research funding from NIH (NIDDK, NIHMD, and NIBIB) and the Kidney Transplant Collaborative. The remaining authors have no conflicts of interest to disclose, as described by the American Journal of Transplantation.

Data availability

The data that support the findings of this study are available upon reasonable request from the corresponding author and pursuant to the data use agreement from the SRTR.

Declaration of Competing Interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

Dr. Adler reports personal fees from Tegus and grants from AHRQ. Dr. Mohan reports personal fees for eGenesis and Kidney International Reports, grants from the NIH and Kidney Transplant Collaborative, serving as chair of the UNOS data advisory committee and as faculty cochair for the ESRD Treatment Choices Learning Collaborative outside of the submitted work. Dr. Husain reported receiving grants personal fees from Fresenius and grants from NIH outside of the submitted work.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ajt.2023.05.005.

ORCiD

David C. Cron https://orcid.org/0000-0002-9488-6847
Syed A. Husain https://orcid.org/0000-0002-1823-0117
Kristen L. King https://orcid.org/0000-0002-7920-7615
Sumit Mohan https://orcid.org/0000-0002-5305-9685
Joel T. Adler https://orcid.org/0000-0001-8190-3444

References

1. U.S. Renal Data System. *2020 USRDS annual data report: Epidemiology of kidney disease in the United States*. Bethesda, MD: National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases; 2020.
2. Melanson TA, Hockenberry JM, Plantinga L, et al. New kidney allocation system associated with increased rates of transplants among black and Hispanic patients. *Health Aff (Millwood)*. 2017;36(6):1078–1085. https://doi.org/10.1377/hlthaff.2016.1625.
3. Zhang X, Melanson TA, Plantinga LC, et al. Racial/ethnic disparities in waitlisting for deceased donor kidney transplantation 1 year after implementation of the new national kidney allocation system. *Am J Transplant*. 2018;18(8):1936–1946. https://doi.org/10.1111/ajt.14748.
4. Zhou S, Massie AB, Luo X, et al. Geographic disparity in kidney transplantation under KAS. *Am J Transplant*. 2018;18(6):1415–1423. https://doi.org/10.1111/ajt.14622.
5. King KL, Husain SA, Mohan S. Geographic variation in the availability of deceased donor kidneys per wait-listed candidate in the United States. *Kidney Int Rep*. 2019;4(11):1630–1633. https://doi.org/10.1016/j.ekir.2019.08.018.
6. Glazier AK. The lung lawsuit: a case study in organ allocation policy and administrative law. *J Health Biomed L*. 2018;14:139.
7. Israni A, Wey A, Thompson B, et al. New kidney and pancreas allocation policy: moving to a circle as the first unit of allocation. *J Am Soc Nephrol*. 2021;32(7):1546–1550. https://doi.org/10.1681/ASN.2020121679.
8. Notice of implementation: removal of DSA and region from kidney and pancreas allocation. UNOS. Accessed September 27, 2022. https://unos.org/news/implementation-notice-dsa-region-removal-kidney-pancreas-allocation.
9. Stewart DE, Wilk AR, Toll AE, et al. Measuring and monitoring equity in access to deceased donor kidney transplantation. *Am J Transplant*. 2018;18(8):1924–1935. https://doi.org/10.1111/ajt.14922.
10. Reddy V, da Graca B, Martinez E, et al. Single-center analysis of organ offers and workload for liver and kidney allocation. *Am J Transplant*. 2022;22(11):2661–2667. https://doi.org/10.1111/ajt.17144.
11. Wood NL, VanDerwerken DN, Segev DL, Gentry SE. Increased logistical burden in circle-based kidney allocation. *Transplantation*. 2022;106(10):1885–1887. https://doi.org/10.1097/TP.0000000000004127.
12. Adler JT, Husain SA, King KL, Mohan S. Greater complexity and monitoring of the new Kidney Allocation System: implications and unintended consequences of concentric circle kidney allocation on network complexity. *Am J Transplant*. 2021;21(6):2007–2013. https://doi.org/10.1111/ajt.16441.
13. Puttarajappa CM, Hariharan S, Zhang X, et al. Early effect of the circular model of kidney allocation in the United States. *J Am Soc Nephrol*. 2023;34(1):26–39. https://doi.org/10.1681/ASN.2022040471.
14. Continuous distribution: creating a more fair and patient-focused system for organ allocation. OPTN. Accessed September 27, 2022. https://optn.transplant.hrsa.gov/policies-bylaws/a-closer-look/continuous-distribution.
15. King KL, Husain SA, Cohen DJ, Schold JD, Mohan S. The role of bypass filters in deceased donor kidney allocation in the United States. *Am J Transplant*. 2022;22(6):1593–1602. https://doi.org/10.1111/ajt.16967.
16. Kidney donor profile index calculator. OPTN. Accessed October 29, 2022. https://optn.transplant.hrsa.gov/data/allocation-calculators/kdpi-calculator.
17. King KL, Chaudhry SG, Ratner LE, Cohen DJ, Husain SA, Mohan S. Declined offers for deceased donor kidneys are not an independent reflection of organ quality. *Kidney360*. 2021;2(11):1807–1818. https://doi.org/10.34067/KID.0004052021.
18. King KL, Husain SA, Perotte A, Adler JT, Schold JD, Mohan S. Deceased donor kidneys allocated out of sequence by organ procurement organizations. *Am J Transplant*. 2022;22(5):1372–1381. https://doi.org/10.1111/ajt.16951.
19. Linden A. Conducting interrupted time-series analysis for single-and multiple-group comparisons. *The Stata Journal*. 2015;15(2):480–500. https://doi.org/10.1177/1536867X1501500208.

20. Cumby RE, Huizinga J. *Testing the Autocorrelation Structure of Disturbances in Ordinary Least Squares and Instrumental Variables Regressions*. National Bureau of Economic Research; 1990.
21. Technical methods for the program-specific reports. Scientific Registry of Transplant Recipients. Accessed November 17, 2022. https://www.srtr.org/about-the-data/technical-methods-for-the-program-specific-reports#tableb11.
22. Estimate post-transplant survival calculator. OPTN. Accessed October 29, 2022. https://optn.transplant.hrsa.gov/data/allocation-calculators/epts-calculator.
23. Advancing American kidney health. Executive Office of the President. Accessed October 24, 2022. https://www.federalregister.gov/documents/2019/07/15/2019-15159/advancing-american-kidney-health.
24. National Academies of Sciences. Engineering, and Medicine. A fairer and more equitable, cost-effective, and transparent system of donor organ procurement, allocation, and distribution. In: Hackmann M, English RA, Kizer KW, eds. *Realizing the Promise of Equity in the Organ Transplantation System*. National Academies Press; 2022.
25. ESRD treatment choices (ETC) model. Centers for Medicare and Medicaid Services. Accessed November 21, 2022. https://innovation.cms.gov/innovation-models/esrd-treatment-choices-model.
26. Lynch RJ, Doby BL, Goldberg DS, Lee KJ, Cimeno A, Karp SJ. Procurement characteristics of high-and low-performing OPOs as seen in OPTN/SRTR data. *Am J Transplant*. 2022;22(2):455–463. https://doi.org/10.1111/ajt.16832.
27. Barah M, Kilambi V, Friedewald JJ, Mehrotra S. Implications of accumulated cold time for US kidney transplantation offer acceptance. *Clin J Am Soc Nephrol*. 2022;17(9):1353–1362. https://doi.org/10.2215/CJN.01600222.
28. Eliminate Use of DSA and Region from Kidney Allocation One Year Post-Implementation Monitoring Report. Organ Procurement and Transplantation Network, Kidney Transplantation Committee. Accessed April 18, 2023. https://optn.transplant.hrsa.gov/media/p2oc3ada/data_report_kidney_full_20220624_1.pdf.
29. Karami F, Kernodle AB, Ishaque T, Segev DL, Gentry SE. Allocating kidneys in optimized heterogeneous circles. *Am J Transplant*. 2021;21(3):1179–1185. https://doi.org/10.1111/ajt.16274.
30. Adler JT, Husain SA. More is better … until it is worse: can organ placement processes scale to an increasingly complex system? *Am J Transplant*. 2022;22(11):2499–2501. https://doi.org/10.1111/ajt.17168.
31. DuBay DA, Morinelli TA, Su Z, et al. Association of high burden of end-stage kidney disease with decreased kidney transplant rates with the updated US kidney allocation policy. *JAMA Surg*. 2021;156(7):639–645. https://doi.org/10.1001/jamasurg.2021.1489.
32. McPherson LJ, Barry V, Yackley J, et al. Distance to kidney transplant center and access to early steps in the kidney transplantation process in the Southeastern United States. *Clin J Am Soc Nephrol*. 2020;15(4):539–549. https://doi.org/10.2215/CJN.08530719.
33. Whelan AM, Johansen KL, McCulloch CE, et al. Longer distance from dialysis facility to transplant center is associated with lower access to kidney transplantation. *Transplant Direct*. 2020;6(10), e602. https://doi.org/10.1097/TXD.0000000000001048.
34. Formica Jr RN, Schold JD. The unintended consequences of changes to the organ allocation policy. *J Am Soc Nephrol*. 2023;34(1):14–16. https://doi.org/10.1681/ASN.0000000000000009.