Article

A Donor Utilization Index to Assess the Utilization and Discard of Deceased Donor Kidneys Perceived as High Risk

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Abstract

Background and objectives An increasing number of patients on the waitlist for a kidney transplant indicates a need to effectively utilize as many deceased donor kidneys as possible while ensuring acceptable outcomes. Assessing regional and center-level organ utilization with regards to discard can reveal regional variation in suboptimal deceased donor kidney acceptance patterns stemming from perceptions of risk.

Design, setting, participants, & measurements We created a weighted donor utilization index from a logistic regression model using high-risk donor characteristics and discard rates from 113,640 deceased donor kidneys procured for transplant from 2010 to 2016, and used it to examine deceased donor kidney utilization in 182 adult transplant centers with >15 annual deceased donor kidney transplants. Linear regression and correlation were used to analyze differences in donor utilization indexes.

Results The donor utilization index was found to significantly vary by Organ Procurement and Transplantation Network region ($P<0.001$), revealing geographic trends in kidney utilization. When investigating reasons for this disparity, there was no significant correlation between center volume and donor utilization index, but the percentage of deceased donor kidneys imported from other regions was significantly associated with donor utilization for all centers (rho=0.39; $P<0.001$). This correlation was found to be particularly strong for region 4 (rho=0.83; $P=0.001$) and region 9 (rho=0.82; $P=0.001$). Additionally, 25th percentile time to transplant was weakly associated with the donor utilization index ($R^2=0.15$; $P=0.03$).

Conclusions There is marked center-level variation in the use of deceased donor kidneys with less desirable characteristics both within and between regions. Broader utilization was significantly associated with shorter time to transplantation.

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Introduction

Despite an increasing number of kidney transplants performed in the United States annually, the number of waitlisted patients continues to grow (1). Currently, about 5000 waitlisted patients die each year while waiting for a deceased donor kidney transplant. Despite the lower risk of death associated with transplantation, organs from donors with suboptimal clinical characteristics are often overlooked by transplant centers as an option for their patients, thus contributing to a high discard rate and many patients being passed over before an organ is accepted (2−5). Transplant centers frequently attribute long wait times to the paucity of organs available for transplantation, while at the same time declining organ offers for individual patients, presumably with the expectation of a better subsequent organ offer. There appears to be considerable variation in clinical practice with regard to the types of organs that a center will accept, much of which has been presumed to be driven by variations in the local candidate waiting time and organ quality, with some literature suggesting regulatory pressure as a major factor (5–8). Given the lower risk of death associated with transplantation using any quality organ compared with dialysis, transplant centers' willingness to use organs with less desirable characteristics results in advantages for their waitlisted candidates *via* shorter wait times and higher probability of being transplanted (9). Identification of transplant centers that are more willing to accept less than ideal organs would be important for patients to make informed choices about where to receive care given their primary concern being how quickly they will get a transplant (10). An improved understanding of transplant center practices can also potentially improve the efficiency of the allocation system and help organ procurement organizations limit the rising rate of organ discard (11,12). Previous literature from Garonzik-Wang, *et al.* (11) has suggested that an aggressive transplant center phenotype exists, with recent research positing that such aggressiveness may be driven down in part due to perceived risk and loss aversion (6). Through this study we sought to create an objective measurement of center high-risk kidney utilization from the perspective of their willingness to accept organs with characteristics that are strongly associated with discard, and to use this willingness as a measure of the variation in organ acceptance practices both within and between regions. Such a measure could serve to help provide feedback to centers about their organ utilization patterns, help patients make more informed choices, and potentially broaden the criteria used in regions that are more conservative.

Materials and Methods

Study Design and Population

This study used data from the Scientific Registry of Transplant Recipients (SRTR). The SRTR data system includes data on all donor, waitlisted candidates, and transplant recipients in the United States, submitted by the members of the Organ Procurement and Transplantation Network (OPTN). The Health Resources and Services Administration (HRSA), US Department of Health and Human Services (DHHS), provides oversight to the activities of the OPTN and SRTR contractors. We used the SRTR standard analytical file (2017 Quarter 2) to identify the proportion of kidneys from donors with unfavorable attributes that were accepted at adult kidney transplant centers across the United States, and further used these proportions along with the odds of kidney discard for each attribute to create a donor utilization index. To ensure appropriate sample size, 182 adult kidney transplant centers were identified that transplanted >15 deceased donor kidneys per year during 2010–2016 from a total of 265 transplant centers nationwide. These 182 centers performed 78,812 deceased donor kidney transplants during this time period. All procedures performed were approved by and conducted in accordance with the ethical standards of Columbia University Irving Medical Center's Institutional Review Board. The clinical and research activities being reported are consistent with the Principles of the Declaration of Istanbul as outlined in the "Declaration of Istanbul on Organ Trafficking and Transplant Tourism."

Index Development

A list of donor characteristics that are typically seen as unfavorable and increase the risk of organ discard were identified for inclusion in the donor utilization index using a systematic literature review and expert clinical opinion from transplant surgeons and transplant nephrologists (13–24) (Supplemental Table 1). The following 15 dichotomous risk (of discard) characteristics of donors were identified: age >49 years, diagnosis of hypertension, diagnosis of diabetes, classification as Public Health Service increased risk, black race, terminal serum creatinine >2 mg/dl, diagnosis of hepatitis C, history of stroke, body mass index >35 kg/m^2, donation after cardiac death, history of drug abuse (nonintravenous), history of smoking >20 pack-years of tobacco, history of cancer, cold ischemia time >24 hours, six HLA mismatches, and Kidney Donor Profile Index >85%. Given temporal changes in how clinical characteristics of donors are viewed, we attempted to limit our analysis to a relatively recent cohort of donors. The relative prevalence of these risks was estimated using the 78,812 donor kidneys transplanted at the 182 included transplant centers from 2010 to 2016.

To convert these risks into an aggregate index, a multivariable logistic regression model was implemented examining the effect of each high-risk characteristic on odds of discard of kidneys after procurement. The use of a model for weighting was intended to minimize potential bias that might arise through an unweighted scoring system. This model included 113,640 kidneys procured for transplant from 2010 to 2016. HLA mismatches and cold ischemia time could not be included in this model, as they are only available for kidneys that were transplanted. The parameter estimates yielded for each high-risk characteristic from the logistic regression were subsequently multiplied by the proportion of donor kidneys at each center with each characteristic and aggregated to create the weighted donor utilization index.

To further assess the validity of the donor utilization index in light of previously observed changes in organ utilization after Kidney Allocation System (KAS) implementation in 2014, a sensitivity analysis was also performed. A pre-KAS cohort from 2010 to 2013 that included 40,944 kidneys from 178 transplant centers was compared against a post-KAS cohort from 2016 to March 2018 of 31,480 kidneys from the same set of transplant centers to examine the potential effect of the new allocation system on the donor utilization index (Supplemental Figure 2). The 2014–2015 period was excluded to avoid any transient phenomena that resulted from the initial bolus of patients with high dialysis vintage immediately after the implementation of KAS.

Statistical Analyses

Study data were screened to detect erroneous data entries, missing data, and outliers to test normality. The disparity of donor utilization index across OPTN regions was examined using linear regression (Supplemental Table 2). Spearman correlations were performed where applicable to examine key relationships between variables such as donor utilization index scores and proportion of deceased donor kidneys imported, count of annual deceased donor transplants at each center, and Kidney Donor Risk Index (KDRI). Analyses were performed using SAS 9.4 (SAS Institute Inc., Cary, NC). Statistical significance was identified by a P value <0.05.

Results

Overall, 78,812 deceased donor kidneys were transplanted at centers throughout our study period. The proportion of deceased donor kidneys with each unfavorable donor characteristic showed fairly large variation across centers, with most interquartile ranges (IQRs) falling around 10%, confirming major differences present across centers and their acceptance of organ offers (Figure 1). Although the median center-level prevalence of the majority of high-risk donor characteristics examined was between 6% and 20%, several characteristics were more common among kidneys transplanted at some of the included centers, such as nonintravenous drug use and death due to stroke, having median proportions of 44% and 29%, respectively. Other high-risk donor variables were not as prevalent, including

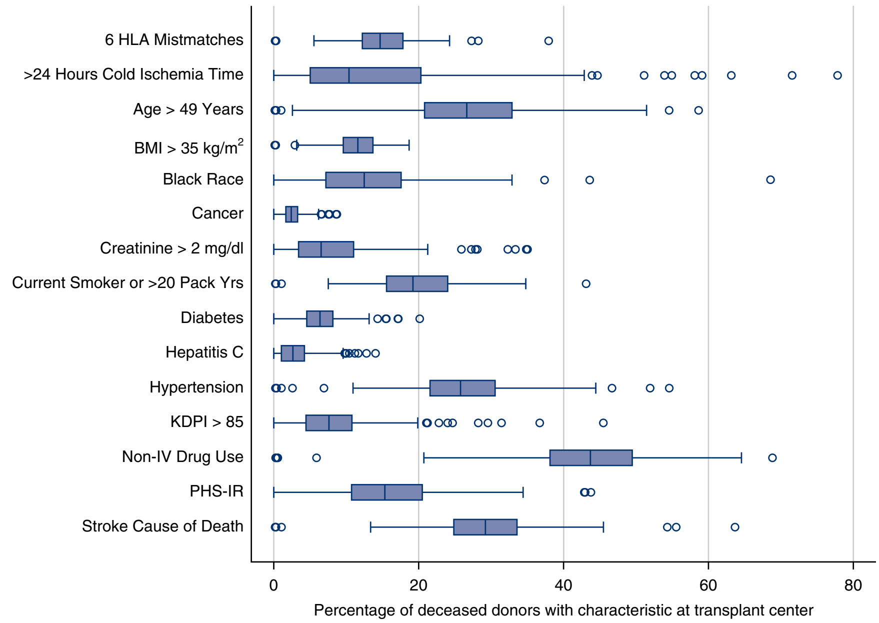

Figure 1. | Distribution of high-risk donor variables for transplanted deceased donor kidneys across transplant centers (*n*=182) in the United States, 2010–2016. BMI, body mass index; KDPI, kidney donor profile index; IV, intravenous; PHS-IR, Public Health Service Increased Risk.

history of cancer (median center 2%) and hepatitis C (median center 2%).

Using the 113,640 deceased donor kidneys procured for transplant from 2010 to 2016, a weighted donor utilization index was created from the coefficients obtained from a multivariable logistic regression with the high-risk donor characteristics estimating the odds of kidney discard (Table 1). The high-risk covariates included in the model were found to be significantly associated with odds of discard. Presence of hepatitis C represented the greatest increase in odds of discard (odds ratio [OR], 8.82; 95% confidence interval [95% CI], 8.16 to 9.54; $P<0.001$), followed by terminal creatinine >2 mg/dl (OR, 5.21; 95% CI, 4.95 to 5.47; $P<0.001$) and Kidney Donor Profile Index >85% (OR, 3.77; 95% CI, 3.57 to 3.98; $P<0.001$). Notably, donors who were black (OR, 0.81; 95% CI, 0.76 to 0.85; $P<0.001$) or had a history of nonintravenous drug use (OR, 0.79; 95% CI, 0.76 to 0.82; $P<0.001$) were found have reduced odds of kidney discard. Donor body mass index >35 kg/m^2 was the least impactful covariate associated with discard (OR, 1.10; 95% CI, 1.04 to 1.15; $P=0.007$).

On the basis of the results of the logistic regression, the parameter values were used to weight high-risk proportions and create a donor utilization index. The median donor utilization index among centers was found to be 88.7 (IQR, 69.8–109.8). Center donor utilization index scores were then visualized against center volume (Figure 2A). There was no significant correlation between centers' donor utilization index and number of annual kidney transplants performed. After visualizing the relationship between donor utilization index and mean annual kidneys transplants by region (Figure 2B), a significant linear trend was found only in region 2 (rho=0.46; $P=0.02$). All OPTN regions with the exception of regions 3, 4, and 8 were found to have significantly higher donor utilization index scores when compared with region 6. In particular, regions 1 (47.0±12.2) and 9 (61.8±12.1) had noticeably higher donor utilization index scores (Table 2).

The correlation between KDRI and donor utilization index was examined to check validity (Supplemental Figure 1). Consistent with our expectations, donor utilization index (rho=0.90; $P<0.001$) was strongly correlated with mean center-level KDRI.

To examine the relationship between center donor utilization index and the net flux of shared organs into or out of a region, we explored the correlation between percentage of kidneys imported and donor utilization index within a given region (Table 3). When examining the overall

Table 1. Multivariable logistic regression examining the association between high-risk characteristics and the probability of discard for kidneys procured for transplant in 2010–2016

Covariates	Odds Ratio	95% CI
Age >49 yr	2.39	2.28 to 2.51
Hypertension	1.80	1.72 to 1.88
Diabetes	1.88	1.79 to 1.99
Public Health Service Increased Risk	1.23	1.16 to 1.30
Creatinine >2 mg/dl	5.21	4.95 to 5.47
Hepatitis C	8.82	8.16 to 9.54
Stroke cause of death	1.32	1.26 to 1.37
BMI>35 kg/m^2	1.10	1.04 to 1.15
Donation after cardiac death	1.88	1.79 to 1.98
Black race	0.81	0.76 to 0.85
Drug use (nonintravenous)	0.79	0.76 to 0.82
Current smoker or >20 pack-yr	1.43	1.37 to 1.49
Cancer	1.57	1.44 to 1.72
KDPI>85%	3.77	3.57 to 3.98

n=113,640. 95% CI, 95% confidence interval; BMI, body mass index; KDPI, Kidney Donor Profile Index.

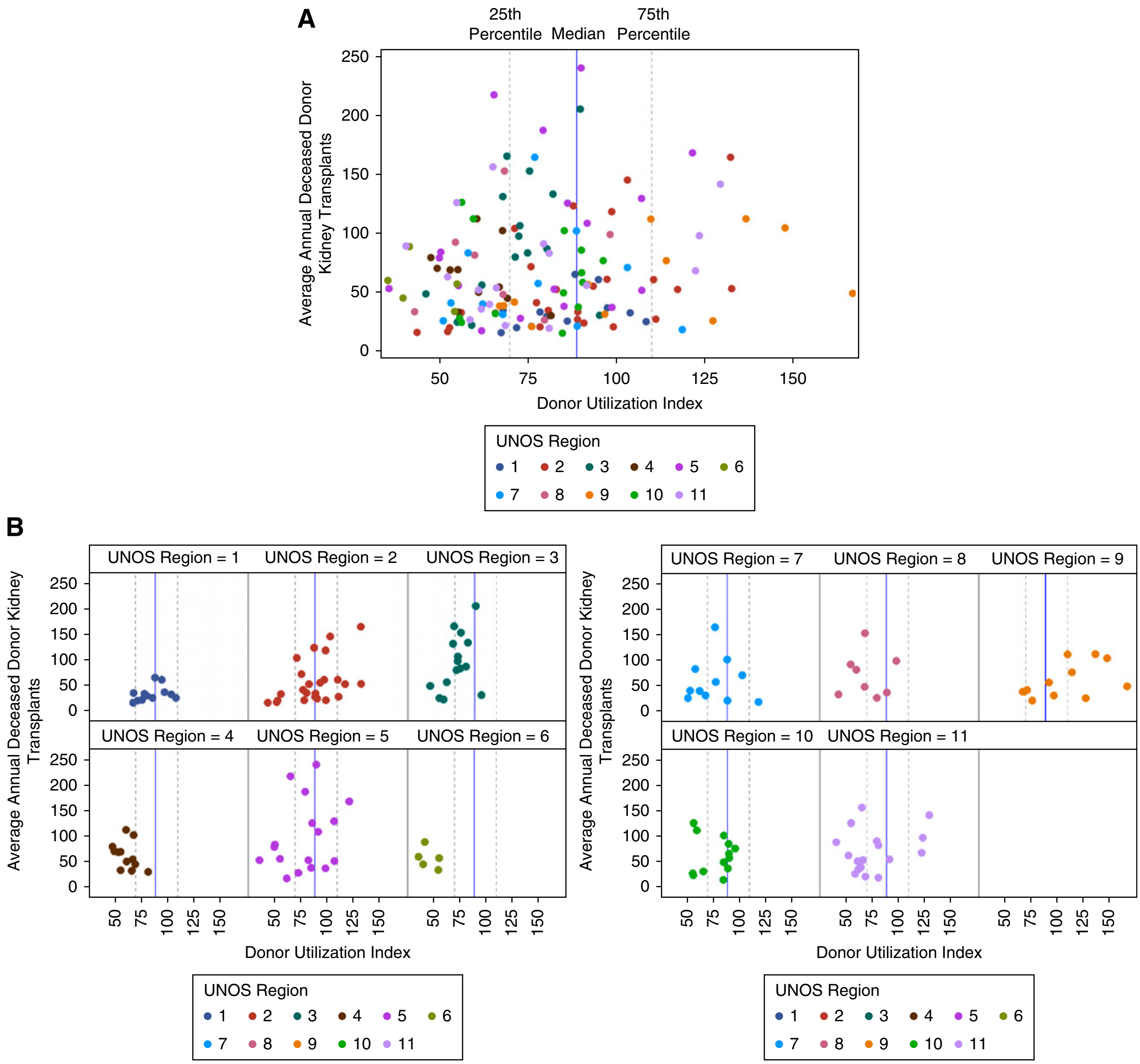

Figure 2. | Center level donor utilization index by mean center deceased donor annual kidney transplant volume stratified by OPTN region. *n*=182, overall: rho=0.12; *P*=0.16. UNOS, United Network for Organ Sharing.

correlation, we found a moderate overall association for donor utilization index with the percentage of imported kidneys transplanted at a center (rho=0.53; $P<0.001$). This relationship was particularly more pronounced in region 4 (rho=0.83; $P<0.001$) and region 9 (rho=0.82; $P<0.001$). Overall, five out of 11 regions were found to have a significant correlation between percentage of kidneys imported at a center and center donor utilization index (regions 2, 4, 5, 9, and 11).

Finally, we assessed the relationship between center donor utilization index and transplant rate using linear regression within each region. Given the limited number of centers with a reported median time to transplant, we chose to assess the association between the 25th percentile time to transplant and the donor utilization index. This association (R^2=0.15; P=0.03) suggested that a ten-point higher donor utilization index results in a mean of a 1-month shorter wait time ($t=-2.27$; P=0.03). Given that the IQR for donor utilization index scores among centers was about 40 points, varying levels of utilization could be influencing wait times by several months. Conversely, wait time could be serving to increase center donor utilization. However, although there was a significant association between donor utilization index and transplant rate (t=2.19; P=0.03), the overall model using this outcome was not significant (F=1.16; P=0.33).

In our sensitivity analysis, we compared the change in mean donor utilization index score pre- and post-KAS for 178 centers both overall (Supplemental Figure 2A), and by OPTN regions (Supplemental Figure 2B). No significant changes in donor utilization index were observed by era at the OPTN region level (Supplemental Table 3). Additionally, the overall distribution for donor utilization index

Table 2. Linear regression examining the association between Organ Procurement and Transplantation Network region and mean region donor utilization index (R^2=0.266) using region 6 as reference

Covariate	Donor Utilization Index		
	B^a	SEM	*P* Value
Constant	65.0	9.734	<0.001[b]
Region 1	47.0	12.248	<0.001[b]
Region 2	38.2	10.966	<0.001[b]
Region 3	12.9	11.472	0.26
Region 4	7.5	11.240	0.51
Region 5	28.7	11.117	0.01[b]
Region 6 (reference)	—	—	—
Region 7	29.0	11.788	0.02[b]
Region 8	21.5	11.922	0.07
Region 9	61.8	12.073	<0.001[b]
Region 10	26.7	11.671	0.02[b]
Region 11	24.9	11.566	0.03[b]

n=182. —, not applicable.
[a]Donor utilization index for each region is the constant term plus the β value for the region.
[b]$P\leq0.05$.

Table 3. Correlations comparing percentage of imported kidneys with donor utilization index at center level, stratified by Organ Procurement and Transplantation Network region

Region	% Imported Kidneys	Donor Utilization Index	
		Rho	*P* Value[a]
All Centers	21.7	0.39	<0.001[b]
Region 1	13.3	−0.05	0.88
Region 2	21.1	0.42	0.04[b]
Region 3	22.7	0.24	0.40
Region 4	16.2	0.83	0.001[b]
Region 5	24.3	0.57	0.02[b]
Region 6	12.3	−0.30	0.62
Region 7	20.4	−0.38	0.25
Region 8	21.4	0.38	<0.001[b]
Region 9	38.2	0.82	0.001[b]
Region 10	17.0	0.24	0.44
Region 11	27.2	0.58	0.02[b]

n=182.
[a]Testing difference from 0.
[b]$P\leq0.05$.

changed slightly pre- and post-KAS, but this difference was not significant (Supplemental Figure 3). Individual center donor utilization index changed a median of two index points (IQR, −16 to 20), and 62 centers had a decrease in donor utilization score by at least 10%, whereas 70 had an increase in their donor utilization score by at least 10%.

Discussion

Currently, there are >95,000 individuals waiting for a kidney in the United States, yet >3500 kidneys (20% of all kidneys procured for transplant) are discarded annually according to OPTN data as of January 31, 2019 (1,2,25,26). There is increasing recognition that transplant center level practice patterns, coupled with the geographic variations in the need for organs and in access to organs for transplant centers, influence organ acceptance patterns and thus access to transplantation (9,27−30). Centers with high donor utilization indexes are those that use donor organs that have previously been turned down at most other centers and are at high risk for discard. Yet these centers benefit their patients by improving their access to transplantation as well as decreasing the time spent waiting for a deceased donor transplant. In the current environment of widespread risk-averse behavior that runs contrary to stated patient preferences, measurement of variations in clinical practice is an essential first step to eliminating any unwanted variation in the acceptance of less than ideal deceased donor kidneys and optimizing efficiency in organ allocation and disposition (8,12). Not surprisingly, patients express a preference for centers that will result in shorter waiting times given that the single biggest factor determining long-term survival for waitlisted patients is whether they will be transplanted (12).

In this study, we aimed to create a measure to capture transplant center utilization of perceived high-risk kidneys in the context of organ discard, and attempt to understand how this is influenced by regional variations in organ supply and demand. We found that donor characteristics associated with increased likelihood of organ discard are not rare among deceased donor kidneys that are transplanted, indicating that many centers commonly utilize at least some deceased donor kidneys with such risks. The low IQR spread among some characteristics suggests that they are generally considered undesirable by centers (cancer) or relatively infrequent among donors (hepatitis C). Similarly, some characteristics had very wide spreads between the 25th and 75th percentile, such as cold ischemia time, nonintravenous drug use, and donor age >49 years. These variations underscore the current heterogeneity in clinical practice across centers in the willingness to use these organs for the benefit of their patients.

Previous research has demonstrated that aggressive centers tend to be those with large waitlists and high wait times for optimal grafts (11). However, although we initially hypothesized that more liberal utilization would play a large role in dictating transplant center volume, we found no clear relationship between these variables. This finding suggests that transplant centers with relatively high organ availability may not feel the need to be more aggressive in their organ offer acceptance despite the size of their waitlists.

Certain OPTN regions, such as regions 1 and 9, have particularly high mean donor utilization indicies, whereas others, such as regions 4 and 6, have lower indexes overall. Geographic differences in organ availability, either actual or perceived, compared with waitlist size potentially explain this variation (30). However, regional trends in aggressiveness are not totally explained by organ availability or ESKD incidence. Further, despite shorter mean wait times in certain regions, minimizing dialysis vintage through the use of earlier transplantation with less than ideal donor kidneys would still provide a lower risk of death for most subgroups of candidates (31−33).

It seems clear that different regions have access to differing qualities of kidneys. General population densities, difference in ESKD prevalence, and demographic breakdowns of each region might explain some of this difference, with certain regions not having a proportionate number of donors to their transplant needs. Organ procurement organizations play a major role in organ procurement and allocation, and as such also meaningfully contribute to these regional differences (34). Volatile numbers of available deceased donors can greatly influence availability of organs in a given year for each organ procurement organization (35). If a center simply does not have enough access to kidneys within their donation service area or region, they often resort to importing from other regions to fill their need.

Although the disparities in utilization that exist between regions may be easier to understand, the underlying geographic variations in organ allocation are concerning (9). Within-region heterogeneity is a center level phenomenon and not directly related to the allocation system, yet potentially results in differential access to deceased donor transplants for patients as well as creating inefficiencies in the allocation system. It is likely that regulatory factors that prioritize short-term post-transplant outcomes rather than waitlist outcomes play a role in influencing organ acceptance behavior, and center flagging by Centers for Medicare and Medicaid Services (CMS) and the SRTR has been linked to changes in practice (34,36,37). Shifting incentives to those that encourage acceptance by rewarding aggressiveness are going to be essential to improving organ utilization. For instance, routine feedback reports to centers that detail their organ utilization patterns compared with other centers in their region may help reduce organ discards. Recent efforts by the SRTR to increase the emphasis on waitlist outcomes and time to transplant are an important first step in this regard. Additionally, proposed changes by CMS to reduce regulatory burdens and direct focus toward quality improvement efforts could also serve to encourage broader donor kidney utilization (38).

The correlations between donor utilization index and percentage of imported deceased donor kidneys help to explain some of these between-region differences. Certain regions, such as regions 8 and 9, have a particularly strong relationship between kidneys imported and donor utilization index, underscoring the notion that net importing regions are willing to use the organs that other regions have declined in an attempt to improve their candidates' probability of transplantation and better outcomes. In contrast, regions 1 and 6 have much lower mean numbers of imported kidneys, and correspondingly displayed no correlation between kidneys imported and donor utilization index. Despite the links to importation, shifts in allocation due to KAS did not appear to drive any significant changes in donor utilization index between the pre- and post-KAS eras.

Our data demonstrates that aggressiveness in utilization has some effect the mean wait-time for a deceased donor kidney, with an increasing donor utilization index corresponding with a lower 25th percentile wait time for a kidney. Given that centers and regions with more liberal utilization are achieving acceptable short-term outcomes for transplanted patients using suboptimal organs, perhaps less aggressive centers and regions should be encouraged to emulate such utilization and transplant more patients on their waitlists.

Including a measure of aggressiveness in publicly available center reports may help potential transplant candidates choose centers whose values align with their own. Additionally, incorporation of a mechanism to "fast track" organs at very high risk of discard to the centers that are likely to use them by center utilization may also address the rising discard rate. One potential solution would be to default the UNOS UNet^{sm} bypass criteria to reflect the practice patterns of the individual transplant center in the preceding year while allowing centers to retain the ability to adjust these criteria if they desire to do so. This would allow allocation to be more consistent with clinical practice and potentially improve the efficiency of the allocation system.

Our donor utilization index has unique strengths and limitations. We believe that index weighting on the basis of pretransplant perceived risk of the donor characteristic as measured by odds of discard is a true reflection of center perception of risk. Discard was chosen because conservative procurement decreases the availability of donor kidneys perceived as suboptimal, despite good outcomes for kidneys with characteristics considered high risk (3). The donor utilization index being described here is focused primarily on donor organs and does not consider center behavior relative to recipients. Certain centers may be willing to waitlist recipients with more risks than others, and this aggressiveness could be defined in a similar manner as the donor utilization index. Thus, ideally utilization and aggressiveness should be considered as a combination of these two factors. Additionally, our utilization index does not account for the potential changes in behavior that have been previously been shown to occur at centers following periods that are flagged by CMS as low performing (39).

In conclusion, we successfully developed a novel quantitative assessment of deceased donor kidney utilization, and demonstrated variations in utilization underscoring large undesirable heterogeneity in the clinical practice around organ acceptance. Additionally, broader utilization was significantly associated with shorter time to transplantation consistent with patient preferences. Better characterization of aggressiveness is needed in order to help align center incentives to promote improved organ utilization and move toward patient-centered care.

Acknowledgments

This study used data from SRTR. The SRTR data system includes data on all donors, waitlisted candidates, and transplant recipients in the United States, submitted by members of OPTN. HRSA, DHHS, provides oversight to the activities of the OPTN and SRTR contractors.

The funders did not have any role in the study design, collection, analysis, and interpretation of data, writing the report, or the decision to submit the report for publication. The data reported here have been supplied by the Hennepin Healthcare Research Institute HHRI as the contractor for the 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 content is the responsibility of the authors alone and does not necessarily reflect the views or policies of DHHS, nor does mention of trade names,

commercial products, or organizations imply endorsement by the US Government.

Disclosures

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Supplemental Material

This article contains the following supplemental material online at http://cjasn.asnjournals.org/lookup/suppl/doi:10.2215/CJN.02770319/-/DCSupplemental.

Supplemental Table 1. Donor characteristics utilized in the donor utilization index along with their reason of inclusion and references.

Supplemental Table 2. States, territories, and districts comprising each OPTN region.

Supplemental Table 3. Mean donor utilization index and percent import by region for pre-KAS (2010–2013) and post-KAS (2016–2018) for 178 centers.

Supplemental Figure 1. Scatter plot examining correlation between KDRI and donor utilization index (rho=0.90; $P<0.001$) (n=182) by UNOS region.

Supplemental Figure 2. Donor utilization index scores pre-KAS and post-KAS (a) by region mean (R^2=0.81; $P<0.001$) and (b) by centers within each region (n=178).

Supplemental Figure 3. Box plot of donor utilization indexes for the pre-KAS and post-KAS cohort (n=178), and full cohort (n=181).

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