Published in final edited form as:

J Racial Ethn Health Disparities. 2018 December ; 5(6): 1171–1179. doi:10.1007/s40615-018-0464-3.

Evolving Trends in Racial Disparities for Peri-Operative Outcomes with the New Kidney Allocation System (KAS) Implementation

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Abstract

Introduction—To improve kidney transplant allocation equitability, a new Kidney Allocation System (KAS) was implemented December 4, 2014. The purpose of this study was to determine if the impact of KAS on peri-operative outcomes differed by recipient race/ethnicity.

Methods—This was a time series analysis using data aggregated in monthly intervals from October 2012 through September 2015 using the University HealthSystem Consortium (UHC). This includes national data aggregated at the center level of all US kidney transplant centers that participate in the UHC (416 centers). Segmented regression with interaction terms was used to determine the impact of KAS on outcomes and differences by race/ethnicity.

Results—A total of 28,809 deceased donor kidney transplants were included with 25 months of pre-KAS data and 10 months of post-KAS data. After KAS implementation, the estimated transplant rate per month decreased significantly for Caucasians by 17.6 cases per month ($p = 0.0001$), and increased significantly for AAs by 37.8 ($p = 0.0001$), Hispanics by 16. ($p = 0.0001$), and other races by 8.2 cases per month ($p = 0.0001$). Delayed graft function, 7- and 14-day readmissions significantly increased after KAS, which did not differ by race. Hispanics saw a 7.7% decrease in ICU admissions after KAS, which differed as compared to other racial/ethnic cohorts ($p = 0.0026$). Costs of kidney transplantation increased significantly after KAS in all groups except Hispanics. Mortality, length of stay, in-hospital complications, and 30-day readmissions were not significantly impacted by KAS, also not differing by race/ethnicity.

Conclusion—KAS had substantial impact on transplant rates by race/ethnicity. KAS also led to increased costs, readmissions, and delayed graft function (DGF) across all racial/ethnic groups. The impact of KAS on ICU cases solely within Hispanics requires further investigation into potential etiologies.

Keywords

KAS; Racial disparities; Peri-operative outcomes; Kidney transplant

Introduction/Background

On average, 22 people die daily awaiting an organ transplant [1]. Of these, almost half are kidney transplants. Kidney transplant is the gold-standard treatment for end-stage renal disease (ESRD), with 1-year post-operative survival rates at 98 and 94% for living-donor kidneys and deceased-donor kidneys, respectively [1]. Although over 33,500 people receive organ transplants in the USA in 2016, setting a new record, there are still over 117,000 people currently on the waiting list for organ transplant and every 11 min another person is added [1]. Of the wait listed, over 95,000 are currently kidney transplant patients [1]. Because kidney donation is a life-saving procedure and there is a substantial shortage of organs available, it is important that the process of kidney allocation is as effective and equitable as possible [2, 3].

Kidney transplantation was first performed in 1954 with the first successful kidney transplant, performed between identical twins [4]. At this time, there was no true kidney allocation policy, meaning there was no organization or means for establishing equity and maximizing positive outcomes. In attempts to better structure the process and knowledge of organ transplantation, in 1968, the South-Eastern Organ Procurement Foundation (SEOPF) was formed as a membership and scientific organization for the use of transplant professionals, later implementing United Network of Organ Sharing (UNOS) [4] (Fig. 1). NOTA passed in the 1980s prohibits the sale of organs and attempts to improve rates of donation after death and establish federal guidelines for organ sharing and allocation [4]. Currently, the OPTN is in contract with UNOS to oversee allocation policy and operationalize organ allocation for the USA.

Allocation policies continue to evolve, with a number of significant changes occurring over the last 3–4 decades. Point system changes include increased points for panel-reactive antibody 80%, increased points for waiting times, pediatrics, and living organ donors who then develop end-stage renal disease [5, 6]. In the 1980s, kidney allocation was based heavily on waiting time as well as availability of organs for donation, both live and deceased. This created a gap between number of patients awaiting transplant and organs available for transplant that has since then grown progressively [7]. In 1998, medical criteria for initiating wait listing for kidney candidates were defined [5]. In 2002, expanded criteria donors (ECD) were defined in an attempt to address the growing shortage of kidneys and provide a larger donor pool for those on the waiting list. In the early 2000s, other changes ensued that changed allocation of kidneys from being heavily dictated by human leukocyte antigen (HLA) matching to it being predominately dictated by time on the list. Allocation based on HLA matching was associated with access limitations for minorities and thus eliminating its use reduced racial disparities although not eliminating them entirely [5].

In 2003, among other changes, candidates began to accrue waiting time even in inactive status, and during the next several years, public forums were held to discuss major topics such as life-years from transplant (LYFT), kidney donor profile index (KDPI), estimated post-transplant survival score (EPTS), and possible donor/recipient age matching [8]. In 2013, the OPTN Board of Directors approved the new kidney allocation policy, and on December 4, 2014, the new Kidney Allocation System (KAS) went into effect [2, 8]. This

new allocation system has attempted to better match allograft and recipient longevity through the scoring systems of EPTS and KDPI, which assess relative longevities of recipient and allograft considering a variety of factors [9]. Very early results demonstrate that KAS has reduced longevity mismatches in deceased donor kidney transplants, and expanded access of organs to patients previously disadvantaged because of being highly sensitized to common HLA subtypes [10]. A marginal decline in pediatric transplants was also seen, but has since diminished. KAS has also increased access to transplantation for patients previously affected by delayed referral, due to back-dating, with accrual of time starting at the time of dialysis, not at the time of listing. Blood type B recipients still appear to be underrepresented, and KAS has significantly increased “sharing” of kidneys across regions [10].

On a broad scale, studies have been performed to assess outcomes of kidney transplantation using peri-operative measures to assess transplant center value and thus aiding in predicting long-term graft and patient survival [11, 12]. We recently completed a study assessing the impact of KAS on peri-operative outcomes and costs, but did not assess if these outcomes differed by race. A recent study has also found KAS to narrow disparities in transplantation rates in Blacks and Hispanics compared to whites, however did not address outcomes [13]. Thus, the aim of this national study was to use an interrupted time series analysis to assess the impact of KAS on peri-operative racial and ethnic disparities, including post-transplant length of stay (LOS), surgical complications, in-hospital mortality, readmissions, and costs.

Materials and Methods

Study Design and Patients

This was a time series analysis of national data aggregated at the center level from the University HealthSystem Consortium (UHC). Accredited US kidney transplant centers that participate in the UHC were included in this study representing approximately two thirds of US transplant centers. For the accredited US kidney transplant centers that participated, all patients in the center were included. UHC allows for affiliates to have access to peri-operative clinical information at the hospital level for download and analysis. The UHC database includes up to 416 academic medical centers and affiliates. Based on previous work using this data, the UHC transplant population is generally similar to the overall US population with a tendency to include higher-risk cases. The clinical information includes cases, length of stay, ICU cases, ICU length of stay, complications, death, costs, and readmissions. To be included in this study, patients must have received a kidney transplant at one of the affiliated UHC centers between October 2012 and September 2015. Pediatrics, non-renal transplants, and living donor recipients were excluded. As the data from this study was accessed as the hospital-level and no patient-level data was obtained or analyzed, the study was conducted by receiving IRB exempt status.

Study Objectives

The primary objective of this study was to assess the impact of KAS on racial and ethnic differences for peri-operative outcomes over a 35-month period (25 months pre-KAS and 10 months post-KAS). KAS was implemented on December 4, 2014.

Study Definitions and Outcomes

The number of cases per month included adult solitary kidney recipients of deceased donor transplants in the time frame, which was stratified by race/ethnicity. Racial/ethnic cohorts were defined as non-Hispanic white (NHW), non-Hispanic black (NHB), Hispanic, and other, which included all other race/ethnicities. Peri-operative complications were identified and analyzed as defined by UHC diagnostic codes (www.vizientinc.com). Complications included the following: in-hospital stroke, aspiration pneumonia (during hospitalization), GI hemorrhage prevention (GI hemorrhage prophylaxis may not have been provided or was provided inadequately resulting in a GI bleed), hospital-acquired acute myocardial infarction, adverse events due to anesthesia, post-operative infection (during same hospitalization), infection and inflammatory reaction due to internal prosthetic device, implant and graft, postoperative shock, hospital-acquired *Clostridium Difficile* enteritis, readmissions for infection due to previous care (within 30 days of discharge), readmissions for other complications of internal prosthetic device, implant or graft (readmission within 30 days of discharge, not considered infection or mechanical complication of device), readmissions for post-operative hemorrhage, hematoma, seroma, or other surgical wound complications (within 30 days of discharge). Complications were addressed as a mean percentage of in-hospital complications occurring in patients undergoing kidney transplantation. Readmissions were defined as percentages subcategorized as readmitted to the index transplant hospital within 7, 14, or 30 days post-discharge.

ICU cases included patients transferred to the ICU following kidney transplant. Costs were estimated as direct costs, using UHC standards as total costs. In brief, UHC estimates costs using cost-to-charge ratios derived from the Medicare cost Report, which are further regionally adjusted using cost of living/wage indices. Delayed graft function (DGF) was defined as the need for post-transplant dialysis during the index hospitalization. Other variables included mean length of stay, ICU length of stay, defined as mean days in the hospital and ICU after the surgical event; death was defined as in-hospital mortality following the index hospitalization.

Statistical Analysis Plan

Peri-operative outcomes were analyzed over time and stratified by race/ethnicity (AA, Hispanic, Caucasian, other). First, peri-operative outcomes were assessed for the entire followup period stratified and compared by race/ethnicity. Outcomes included length of stay, ICU cases, mean ICU length of stay, complications and mortality (in-hospital), readmissions, costs, and delayed graft function. Changes in peri-operative outcomes were then analyzed by race/ethnicity as a result of KAS implementation. Segmented regression analysis using autoregression, which accounts for correlation over time, was used to estimate intercepts and slopes for transplant rates in cases per month, complications as a percentage per month, ICU cases as a percentage per month, direct costs in dollars per case, and DGF as a percentage per month. This allowed for a visual assessment of the time series pattern before and after the intervention (KAS) and the policy changes immediate impact on each racial and ethnic group. The estimated impact of KAS on outcomes and cost was then assessed for each cohort (AA, Hispanic, other) in reference to the Caucasian cohort using interaction terms (KAS*race/ethnicity). This was used to observe significantly different

changes in peri-operative outcomes following KAS by race/ethnicity. A two-sided p value of < 0.05 was considered statistically significant, and all data were analyzed using SAS version 9.4 (SAS Institute, Cary, NC) [14].

Results

Patient Demographics

A total of 20,809 deceased donor kidney transplant recipients were included in the study. Of these, 8362 (40%) were non-Hispanic white, 6666 (32%) were non-Hispanic black, 2308 (11%) were Hispanic, and 3473 (17%) were of other races/ethnicities. Table 1 displays baseline characteristics for all four racial/ethnic groups. The mean ages were 54.2, 51.4, 50.0, and 52.6 years, respectively. A majority were males for all races and common comorbidities included deficiency anemias, diabetes, hypothyroidism, and obesity.

Peri-Operative Outcomes Across the Study Period

Table 2 presents the peri-operative outcomes for the entire follow-up period stratified by race/ethnicity. This includes all data from the specified dates in 2012 to 2015. The mean length of stay was between 6 and 7 days for all groups. ICU cases ranged between 20 and 30%. In-hospital complications ranged between 6 to 7%, and in-hospital mortality was less than 1% for all cohorts. For non-Hispanic whites, 7-day readmissions were at 5.7% and 14 days at 9.6%; for non-Hispanic blacks, 7.1 and 11.3%; and for other races, 6.1 and 9.0%. Thirty-day readmissions were slightly higher for the non-white cohorts. The mean total direct costs were \$76,662, \$73,466, \$77,548, and \$71,291 for NHW, NHB, Hispanic, and other, respectively. The delayed graft function was lowest in NHW at 26.80% and highest in Hispanics at 43.10% for the entire follow-up period.

Peri-Operative Outcomes of KAS

Seven- and 14-day readmissions increased significantly by 2.52% ($p = 0.0037$) and 2.04% ($p = 0.0039$), following implementation of KAS. Thirty-day readmissions increased by 1.83%. These rates did not differ by race or ethnicity prior to or after KAS implementation. Delayed graft function increased by 3.5% following KAS. The number of cases increased by 8 per month following KAS, and length of stay by 20.83%. The number of complications increased by 1.27% with marginal significance, and the number of ICU cases decreased significantly by 3.0% ($p = 0.0251$). The ICU length of stay also increased by 1.2% and death by 4.4%. Direct costs increased overall by \$2217 per case with marginal significance after implementation of KAS.

Clinical Impact of Race/Ethnicity on Peri-Operative Outcomes

Figures 2, 3, 4, 5, and 6 display estimated regression lines for transplant rates, complications, ICU cases, costs, and DGF stratified by race/ethnicity with a single vertical line indicating the implementation of KAS. The transplant rate decreased by 17.6 cases per month in NHW, which differed significantly when compared to the other race/ethnicities. The transplant rate increased by 37.8 cases per month in NHB, 16.3 in Hispanics, and 8.2 in all other races. The number of in-hospital complications decreased by 0.8% in NHW, 0.2% in Hispanics, and 0.3% in all other races, but increased by 0.2% in NHB. The number of ICU

cases decreased by 1.1, 0.1, 7.7, and 2.0% for NHW, NHB, Hispanics, and others, respectively, with a significant difference seen only in the Hispanic cohort ($p = 0.0026$). The estimated costs per case increased for all cohorts except for Hispanics whose increase was significantly less than Caucasians. The increase in costs for Hispanics was \$1037.17 ($p = 0.0477$) compared to the increase of \$4169.17 for Caucasians. Delayed graft function increased for NHW, NHB, Hispanics, and other races by 2.1, 5.1, 5.6, and 2.0%, respectively. ICU length of stay also increased by 26% ($p = 0.0243$) for NHB, which was found to be significantly different by race/ethnicity. Table 3 represents the estimated impact of KAS on outcomes and cost by race/ethnicity and highlights the outcomes that demonstrated significant variability by race/ethnicity.

Discussion

Through using deceased donor kidney transplant data collected on a national level from accredited US kidney transplantation centers, this study allowed us to determine if the impact of KAS on peri-operative outcomes significantly differed by race/ethnicity. Results demonstrate that kidney allocation is becoming more equitable in the USA as a result of KAS by increasing the number of transplants in historically disadvantaged minorities such as African Americans and Hispanics. The gap in number of transplant cases per month is decreasing between Caucasians and these historically disadvantaged minorities. These results have great implications as one of KAS's main goals is to make kidney allocation more equitable. In order to equalize the gap, Caucasian transplants must decrease while transplant rates in minorities increase. As expected, the increases in transplant cases per month for all minority groups varied significantly from Caucasians as a result of race/ethnicity. Results also demonstrated that costs, DGF, and readmissions for each cohort all increased as a result of KAS. The decrease in ICU cases and increased estimated cost per case differed significantly for the Hispanic cohort by race/ethnicity. There is currently no strong rationale for why these changes occurred specifically within Hispanics other than noting this was a small sample of the total population and thus could have been prone to programmatic changes within one or two transplant centers.

This study showed, in concordance with previous studies, an increase in transplants among African Americans and Hispanics and a decrease in transplants in the Caucasian cohort. Previous studies observed no significant change for Asians while this study did not assess that cohort, specifically. Previous studies also observed an increase in DGF but did not assess this as a result of race/ethnicity [10, 15]. ICU cases also significantly varied by race/ethnicity in the Hispanic cohort with a decrease of about 6.6% more than the decrease in ICU cases for Caucasians. This may be related to the fact that transplants in Hispanics tend to be more clustered at a few large centers; thus, changes in protocols in these centers can have more dramatic implications on outcomes at a national level.

These results overall support KAS's goals of making kidney allocation more effective and equitable. Because of the variations in baseline demographics, KAS was expected to impact peri-operative outcomes by race/ethnicity. However, it will be important to follow these outcomes in the future and observe whether the changes in equity are sustained or simply the result of a "bolus" effect. The bolus effect is essentially the impact of the backlog

of patients based on years of dialysis and high PRA. It is assumed that over time, these patients would be cleared off of the list and an equilibrium would be reached, where patients with long dialysis time and high PRA would be added to the list at the same rate that they are removed [12].

It is also important to acknowledge that along with racial disparities, regional wait listing disparities across the USA exist, which could ultimately affect allocation by race and outcomes depending on the make-up of a geographic region. As of 2015, in no UNOS region do whites face a lower likelihood of being wait listed when compared to the US average (an unintended difference between cohorts) [16]. However, one study demonstrated that 39% of African Americans reside in regions with large racial disparities in wait listing, thus having a decreased likelihood of being wait listed compared to Caucasians, although they make up a large proportion of the ESRD population in the same regions [3, 16]. KAS has opted to prioritize highly sensitized patients in hopes of allowing these patients equitable access to organs. However, in this particular category, a point of concern could be that antibodies to HLA-DP and HLA-DQ antigens are not incorporated into the current algorithm. These particular antibodies were found in 63% of highly sensitized wait list patients in a study done including 593 candidates with the aforementioned descriptors. It is difficult to know how the omission of this testing could lead to different post-operative outcomes, but important to acknowledge for future research [17–19].

KAS also prioritizes younger patients and serves to better age-matched organs. In acknowledgment of this, one can consider the impact of increased deceased donor kidney transplantation in younger patients on rates of live donor kidney transplants. Also, this shift may cause an increased dependence on live donors, which are less available, for older recipients, thus appearing as age discrimination [3]. Simultaneously, it is predicted that KAS will ultimately increase overall life-years of patient survival, likely due to transplantation in younger patients (shift toward younger patients is intentional) [20].

Our study has several limitations that require discussion. The analysis accounts for only 10 months of post-KAS data; thus, the time frame is not clearly indicative of which changes might be temporary versus sustained. Pediatric patients were excluded, thus prohibiting the assessment of this category of recipients and how KAS has and will continue to affect their peri-operative outcomes. Readmission data were not available for the Hispanic cohort, since we were not able to categorize readmissions by ethnicity (only race). Other limitations include the retrospective nature of the study and the center- level analysis. It is also important to consider that many factors can or may affect peri-operative outcomes. It will be necessary to allow for more time and data collection for significant analysis of outcomes.

In summary, the implementation of KAS had a substantial impact on transplant rates by race and ethnicity, increasing rates in Hispanics and NHBs, while decreasing rates in NHWs. KAS also led to increased costs, readmissions, and DGF, which was consistent across all racial and ethnic groups. Finally, after the implementation of KAS, the rates of ICU cases decreased significantly only in Hispanics. The reasons for this require further investigation.

Acknowledgements

Medical University of South Carolina Department of Surgery and Medical University of South Carolina College of Medicine Alumni Association were acknowledged. This research was supported through grants from the National Institute of Diabetes and Digestive and Kidney Diseases under Award Numbers K23DK099440 and T35DK007431.

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Fig. 1. Timeline of major kidney transplant and kidney allocation milestones

Fig. 2.

Number of kidney transplant cases nationally over a 35-month period, October 1, 2012 through September 30, 2015. The data analyzed includes 25 months of pre-KAS data and 10 months of post-KAS data, demonstrating a significant increase in transplant rates for AAs, Hispanics, and other. A significant decrease in transplant rates was seen in Caucasians

Fig. 3. Percentage of complications nationally over a 35-month period, October 1, 2012 through September 30, 2015. The data analyzed includes 25 months of pre-KAS data and 10 months of post-KAS data, demonstrating a decrease in all but AAs

Fig. 4.

Percentage of ICU cases nationally over a 35-month period, October 1, 2012 through September 30, 2015. The data analyzed includes 25 months of pre-KAS data and 10 months of post-KAS data, demonstrating a decrease in all groups

Fig. 5.

Direct costs of deceased donor kidney transplants nationally over a 35-month period, October 1, 2012 through September 30, 2015. The data analyzed includes 25 months of pre-KAS data and 10 months of post-KAS data, demonstrating increases in Caucasians, AAs, and other. A significant increase was observed in Hispanics

Fig. 6.

Delayed graft function in deceased donor kidney transplants nationally over a 35- month period, October 1, 2012 through September 30, 2015. The data analyzed includes 25 months of pre-KAS data and 10 months of post-KAS data, demonstrating increases in all groups

Table 1

Baseline characteristics stratified by race/ethnicity

Baseline characteristic	NHW, 40.2% (N = 8362)	NHB, 32.0% (n = 6666)	Hispanic, 11.1% (N = 2308)	Other, 16.7% (N = 3473)
Mean age in years ($\pm$ SD)	54.2 $\pm$ 13.4	51.4 $\pm$ 12.6	50.0 $\pm$ 13.8	52.6 $\pm$ 13.4
Gender				
Female	39.7%	39.4%	39.8%	39.4%
Male	60.3%	60.6%	60.2%	60.6%
Comorbidities				
Congestive heart failure	6.0%	8.9%	5.3%	6.6%
Deficiency anemia	54.3%	51.9%	46.5%	57.2%
Depression	11.5%	5.1%	6.8%	7.1%
Diabetes	30.2%	27.1%	33.7%	37.3%
Diabetes with complications	22.6%	19.6%	26.7%	29.9%
Diabetes without complications	7.6%	7.5%	7.0%	7.3%
Hypothyroidism	15.6%	4.9%	9.2%	10.5%
Obesity	17.5%	17.4%	10.4%	13.2%
Peripheral vascular disease	7.8%	6.3%	6.1%	7.0%

Percentages represent cohort proportion of total population

SD standard deviation, O/E observed/expected, ICU intensive care unit, NHW non-Hispanic white, NHB non-Hispanic black

Table 2

Outcomes for the entire follow-up period stratified and compared by race/ethnicity

Outcomes	NHW, 40.2% (N = 8362)	NHB, 32.0% (n = 6666)	Hispanic, 11.1% (N = 2308)	Other, 16.7% (N = 3473)
Mean length of stay in days ($\pm$ SD)	6.9 $\pm$ 3.1	7.0 $\pm$ 2.8	7.0 $\pm$ 2.2	6.8 $\pm$ 1.9
Length of stay index (O/E)	1.11	1.14	1.15	1.11
ICU cases	27.5%	27.8%	28.7%	25.4%
Mean ICU length of stay in days ($\pm$ SD)	1.50	1.50	1.00	1.10
In-hospital complications	6.6%	7.3%	6.1%	6.4%
In-hospital mortality	0.4%	0.6%	0.3%	0.5%
Readmissions				
7 days	5.7%	7.1%	N/A	6.1%
14 days	9.6%	11.3%	N/A	9.0%
30 days	13.4%	16.2%	N/A	12.7%
Mean total direct costs ($\pm$ SD)	\$76,662	\$73,466	\$77,548	\$71,291
Direct cost index (O/E)	1.06	1.07	1.13	1.04
Delayed graft function	26.80%	39.40%	43.10%	29.60%

Percentages represent cohort proportion of total population

SD standard deviation, O/E observed/expected, ICU intensive care unit, NHW non-Hispanic white, NHB non-Hispanic black

Table 3

Estimated impact of KAS on outcomes and cost across different racial/ethnic groups

Outcome	NHW, 40.2% (N = 8362)	NHB, 32.0% (n = 6666)	Hispanic, 11.1% (N =2308)	Other, 16.7% (N =3473)
Transplant rate per month	– 17.6 *	37.8 *	16.3 *	8.2 *
In-hospital complications	– 0.8%	0.2%	– 0.2%	–0.3%
ICU cases	-1.1%	– 0.1%	– 7.7% *	– 2.0%
Estimated costs per case	\$4169.17	\$2776.17	\$1037.17 *	\$1468.17
Delayed graft function	2.1%	5.1%	5.6%	2.0%

Percentages represent cohort proportion of total population

SD standard deviation, ICU intensive care unit, NHW non-Hispanic white, NHB non-Hispanic black

* Statistically significant value ($p < 0.05$)