Past and Present Policy Efforts in Achieving Racial Equity in Kidney Transplantation

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Abstract
Purpose of Review Inequities in transplant access for underrepresented minorities and people of low socioeconomic status persist. The central principle to organ allocation, the “Final Rule” is grounded on “equitable allocation of cadaveric organs,” regardless of background, including race/ethnicity, gender, and socioeconomic status, and there have been ongoing previous and current efforts in achieving the goal of equity in access to transplantation.
Recent Findings Some of these disparities are caused by impeded access to the transplant waiting list (i.e., lack of referral to transplantation, socioeconomic constraints) and are somewhat beyond the purview of Organ Procurement and Transplantation Network/United Network for Organ Sharing (OPTN/UNOS) policy. This paper examines past and present OPTN/UNOS policy efforts that strive to make access to kidney transplantation more racially equitable.
Summary Past and current policy efforts have brought the transplant community closer to the goal of achieving equity in access to transplantation. More comprehensive data collection may aid in further understanding existing challenges.

Keywords Kidney transplant · Equity · Access to organ transplantation · Race · OPTN/UNOS

Introduction
Balancing the principles of justice and utility, the central governing “Final Rule”, issued by the U.S. Department of Health and Human Services and implemented in March of 2000, mandates the “equitable allocation of cadaveric organs in accordance with §121.8 policies for the equitable allocation of cadaveric organs” (https://optn.transplant.hrsa.gov/governance/about-the-optn/final-rule/). Part of the strategic plan of the United Network for Organ Sharing (UNOS), which administers the Organ Procurement and Transplantation Network (OPTN), dedicates resource allocation to five major initiatives, one of which includes equity in access to transplantation. This prioritization directive for OPTN/UNOS policy development seeks to improve equity in access to transplantation and analyze data on vulnerable populations, including underrepresented minorities.

In addition, within the organizational committee structure of OPTN, the Minority Affairs Committee (MAC) is charged with creating policy that upholds equitable organ allocation across racial/ethnic groups and vulnerable populations. MAC was created in 1992 as an ad hoc committee to study the difference in waiting times and transplant rates in minority populations. In 1993, it was determined that the issues involved in reviewing trends in access in allocation in minority populations were significant enough to warrant establishing a permanent standing committee (personal communication, UNOS archives). Since its inception, the MAC has sponsored policy changes that address inequities in the
organ allocation and vets existing and new policy proposals that potentially hinder access to transplantation by race and ethnicity. Despite several efforts to create policies that promote fairness and equity, there remain racial and socioeconomic inequities in access to transplantation [1].

Some racial inequities exist due to barriers in referral to transplantation and are beyond the scope of what OPTN policy can directly address. Currently, OPTN/UNOS does not capture data on patients before their addition to the waitlist, and therefore, research on access to the transplant waiting list has largely relied on independent surveys or examination of patient data registries to collect information. For patients suffering from kidney failure, Black patients disproportionately make up a larger percentage of patients on dialysis and also have reduced access to the transplant waiting list [2•]. Furthermore, Black individuals and other underrepresented minorities are less likely to be referred for transplant and also complete transplant evaluation [3–5]. Multiple studies have shown that Black patients and patients of lower socioeconomic status are less likely to be referred for preemptive kidney transplantation [6, 7, 8•, 9].

This paper looks at both past and current examples to address racial inequities in the allocation system—with a particular focus on kidney allocation and lessons learned in policy creation.

Historic Creation of Policy That Sought to Achieve Racial Equity

Kidney Allocation System (KAS) and Re-calculation of Dialysis Waiting Time

Historically, patients began kidney transplant waitlist time at the point of kidney transplant listing, which was dependent on the timing of patient referral for transplantation. Multiple studies demonstrated racial disparities in access to the waiting list due to delayed referral and inequities in preemptive transplant waitlisting, specifically for Black and Hispanic patients, women, and patients with lower socioeconomic status [2•, 3–5]. The revised Kidney Allocation System (KAS), implemented in December 2014, sought to address these inequities in access to the transplant waiting list, allowing patients to accrue waiting time at the start of documented kidney failure (i.e., dialysis initiation), rather than at the point of waitlisting. In addition, the revised KAS sought greater prioritization among patients who are highly sensitized, another cohort that is disproportionately comprised of underrepresented racial minority individuals [10].

Initial findings since the implementation of KAS suggest that these policies have achieved partial success in reducing racial disparities in kidney transplant waitlisting. In a 1-year analysis post-KAS, Zhang et al. found partial improvement in waitlisting rates between Black and White patients. Pre-KAS, Black patients held a 19% lower waitlisting rate compared to White patients, and post-KAS, the disparity declined to 12% [2•]. Part of this decrease was attributed to a decline in inactive waitlisting among all individuals, which correspondingly led to a higher proportion of active waitlisting among Black patients. Although KAS has appeared to lessen the racial disparity in kidney transplantation, the disparity still exists.

Racial disparities related to high-sensitization status did not appear to improve after KAS implementation. One study showed that for patients with lower degrees of HLA-sensitization, 0 to 79% cPRA, there was no statistical difference at 1-year post-KAS in transplant probability among racial/ethnic minority individuals. However, at higher sensitization statuses of cPRA of 80% or greater, White patients were observed to have a higher transplant probability than Black patients. Similarly, for patients with a cPRA of 90% or greater, Hispanic patients appeared to have an advantage over Black patients in receiving a transplant [11]. Another study examining active vs. inactive waitlist candidates and PRA found that White patients were more likely to be moved from inactive to active status, compared to Hispanic or Black patients, raising concerns around access to transplantation even after listing [12].

Lastly, the introduction of KAS has not been shown to have a significant impact on preemptive transplantation rates for underrepresented minorities [8•]. The change in crediting wait time from the point of dialysis initiation could theoretically decrease the sense of urgency of kidney transplant referral and therefore decrease overall preemptive transplantation. However, several studies have shown an increase in the overall proportion of preemptive kidney transplants post-KAS. However, there is a continued disparity in preemptive kidney transplant among underrepresented minority individuals [8•, 9].

Non-A/B Deceased Donor Kidney Transplant Variance

One of the factors impacting access to transplantation is recipient blood type; it is well-established that patients with blood group O and B have longer waiting times [13–16]. Blood types AB, A, O, and B have mean deceased donor kidney transplant wait times of 2, 3, 5, and 6 years, respectively [13]. In 2015, blood group B candidates comprised 16% of candidates waiting on the kidney transplant waitlist, but they received only 13% of the total transplants [13]. The national blood group B waitlist in 2015 was composed of 61.6% minority racial/ethnic candidates, defined as Black, Asian, Hispanic, American Indian/Alaska Native, Native Hawaiian/other Pacific Island, and multiracial minority racial/ethnic candidates [13].
In order to provide better equity among blood types and possibly racial groups disadvantaged on the transplant waiting list due to their blood type, MAC sponsored a variance in 2002, which was later adopted into the non-A1/non-A1B → B component of KAS. This variance was based on multiple studies demonstrating the safe and effective transplantation of blood group B kidney transplant recipients with donors having the less immunogenic, non-A1 subtype [13–15]. The variance also directed blood group B deceased donor kidneys away from AB plant recipients with donors having the less immunogenic, non-A1 subtype [13–15]. The variance also directed blood group B deceased donor kidneys away from AB plant recipients with donors having the less immunogenic, non-A1 subtype [13–15]. The variance also directed blood group B deceased donor kidneys away from AB plant recipients with donors having the less immunogenic, non-A1 subtype [13–15]. The variance also directed blood group B deceased donor kidneys away from AB plant recipients with donors having the less immunogenic, non-A1 subtype [13–15]. The variance also directed blood group B deceased donor kidneys away from AB plant recipients with donors having the less immunogenic, non-A1 subtype [13–15]. The variance also directed blood group B deceased donor kidneys away from AB plant recipients with donors having the less immunogenic, non-A1 subtype [13–15]. The variance also directed blood group B deceased donor kidneys away from AB plant recipients with donors having the less immunogenic, non-A1 subtype [13–15]. The variance also directed blood group B deceased donor kidneys away from AB plant recipients with donors having the less immunogenic, non-A1 subtype [13–15]. The variance also directed blood group B deceased donor kidneys away from AB plant recipients with donors having the less immunogenic, non-A1 subtype [13–15].

According to an 18-month kidney allocation system (KAS) post-implementation analysis, an increase in non-A1/non-A1B → B transplants was observed. Compared to the 19 (0.2%) non-A1/non-A1B → B transplants performed 1-year pre-KAS, there were 179 (1.0%) performed in the 18-months post-KAS—a 5-fold increase. Despite this success, only 5.5% of active blood type B patients were registered in the UNOS electronic platform UNet as eligible for these transplants either at the current time or time of removal for all kidney candidates ever waiting in 2015.

Participation in the variance remains low across transplantation centers. Despite an increase in participation from 11 centers 1-year pre-KAS to 46 centers 18-months post-KAS, an overwhelming majority of transplant centers still do not participate [16]. MAC tried to gauge the reasons for the lack of participation and entry of blood type B patients in the non-A1/non-A1B → B variance by sending out a survey to transplant centers. In unpublished data, 54% of respondent centers stated that they currently do not perform A2/A2B → B kidney transplants, and the overwhelming majority (92%) of these centers is not currently consenting blood type B patients for the A2/A2B → B transplantation. Non-participant centers listed a myriad of reasons that prevented center participation. Interestingly, nearly a quarter (29%) of non-participant centers harbored concerns for poor patient outcomes with A2/A2B → B utilization. Centers also expressed difficulty developing protocol titer thresholds (32%), an informed consent policy (21%), and determining (18%) and maintaining (11%) candidate eligibility. Twenty-nine percent of non-participating centers also stated that the expense of testing posed a barrier to policy implementation.

Because this policy change was developed as a variance, rather than a policy mandate, the methods are experimental. However, the data can be used for the development and testing of interventions to improve allocation. More information is needed to understand programmatic participation in this variance and what can be done to encourage greater participation in the non-A1/non-A1B → B variance [16, 17].

Present Policy Efforts

Reassessing Race in the eGFR Equation for Kidney Transplant Waitlisting

Several methods exist in quantifying kidney function, but the most widely used approach utilizes an estimating glomerular filtration rate (eGFR) equation based on serum creatinine measurement. Many of these calculations use a race-based rate coefficient that assigns a higher eGFR specifically to Black patients [18–20]. It has been recognized that the race-based coefficient offers only modest improvement in accuracy for Black patients, and recently, several medical societies including the National Kidney Foundation (NKF) and the American Society of Nephrology (ASN) have called for the removal of the Black race coefficient in eGFR calculations [20, 21].

The implications of the removal of this race adjustment are multifold. First, removing the Black race coefficient would increase the prevalence of chronic kidney disease (CKD) for Black adults from 14.9 to 18.4% [22], and more Black patients with existing CKD may be reclassified as having greater severity of disease [23]. Second, the clinical impact of these changes has far-reaching implications in transplantation, including the timing of kidney transplant waitlisting for Black patients, determination of living donor suitability, and simultaneous liver/kidney listing, to name a few [24]. For example, a recent study showed that changing policy to allow for earlier registration on the waiting list of eGFR of 24–25 ml/min per 1.73 m² for Black patients might improve racial equity in accruable wait time before ESKD onset [25].

Current OPTN policy states that transplant programs are not required to use any particular eGFR equation (including those with the Black race coefficient), when listing a patient for a kidney transplant. It is currently not known what percentage of transplant centers use the Black race coefficient when registering from the kidney waiting list. Research and the formation of a policy workgroup with members of the UNOS Minority Affairs (MAC) and Kidney Committees are currently exploring the creation of policy versus guidelines for the elimination of the Black race coefficient for kidney transplant listing. A policy would help reduce racial variation in the patient listing experience and would allow for earlier kidney transplant listing for Black patients with CKD—particularly for those who were previously deemed “not sick enough” for listing with the application of the Black race coefficient in eGFR equations.

Concurrently, the medical community also strives to find a better equation that is both easily accessible for clinicians and more accurate to assess kidney function, regardless of race. Until such an equation is developed and validated, the removal of the race coefficient serves to eliminate
Data Collection to Assess Socioeconomic Status and Access to Transplantation

While research has shown substantial variation in access to transplant referral and evaluation across both U.S. dialysis facilities and transplant centers, there is no national surveillance data collection by UNOS/OPTN or any other federal or private entity on steps prior to waitlisting [28, 29]. UNOS/OPTN currently does not collect data on the socioeconomic status (SES) of patients and several recent papers have demonstrated poorer access to transplantation among patients of lower SES [4, 30–33]. The current assessment of SES within OPTN/UNOS relies on data proxies, such as patient zip code or level of education for the analysis of SES disparities. In 2019, the MAC sponsored an OPTN policy proposal to obtain SES data on transplant candidates at the time of listing for transplantation. The current markers used by the OPTN as indicators of SES have included the highest level of education, primary source of payment for transplant, and employment status. This policy proposal, which called for the collection of income ranges and household size data, would have made it possible to calculate the approximated poverty index, a SES variable that is well validated and used by the US government to decide on the eligibility of assistance programs [34]. However, the policy proposal went to public comment in the fall of 2019 and was met with criticism related to additional data collection burden by transplant centers, data use and data protection concerns, and intrusiveness of the question on sensitive SES variable collection. Due to these concerns, the policy proposal did not pass after initial public comment and reconsideration by the UNOS Board of Directors.

Conclusions

Our healthcare system is reckoning with the prominent racial inequities that exist, exacerbated by the disparate impact of COVID-19 on communities of color [35]. Despite longstanding efforts from the transplant community to reduce racial inequities in organ transplantation, only modest progress has been made in achieving equity. The responsibility for us all to use data to better understand patient access to transplant so we can develop solutions to address inequities is critical. The OPTN should do its part within the area it can impact: addressing inequities in access to transplantation—a core responsibility under the Final Rule (https://optn.transplant.hrsa.gov/governance/about-the-optn/final-rule/).

Without understanding and working to reduce structural barriers to transplantation, the disparity gap will persist and patients from underrepresented minorities or with low SES may continue to be disadvantaged. Some barriers may be outside of the OPTN’s immediate policy reach but nonetheless necessary for the delivery of transplantation care (e.g., psycho-social support, medication compliance, public policies for immunosuppression coverage) and important to understand if the system is dedicated to addressing health inequities. These inequities are multifactorial and are observed in every step of the organ transplant process, from time of diagnosis to post-transplant outcomes. The creation of new policies has helped alleviate some of these inequities, but more needs to be done to understand and ultimately eliminate the barriers to successful transplantation. Additional data collection of new socioeconomic variables and pre-transplant data will help address the relevant factors along with the transplant evaluation and post-surgical pathways that may help guide future policy creation.

The creation of a new policy has helped alleviate some of these inequities, but more needs to be done in understanding the barriers to transplantation. Additional opportunities in data collection of socioeconomic and pre-transplant factors may help guide future policy creation.

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