



Friday, March 24, 2023

Carole Johnson Administrator Health Resources and Services Administration 5600 Fishers Lane Rockville, MD 20857

RE: Expanding Organ Supply and Transplant Access by Removing Race from KDRI/KDPI

Dear Administrator Johnson,

The National Kidney Foundation (NKF) and the American Society of Nephrology (ASN) are committed to maximizing the gift and opportunity of deceased kidney donation and improving health equity in kidney transplantation. Therefore, it is imperative to eliminate race from the Kidney Donor Risk Index (KDRI), and the subsequently derived Kidney Donor Profile Index (KDPI) used to assess kidney suitability for organ donation. This action would mean kidneys from Black donors would no longer be inappropriately misclassified and may expand the availability of kidneys for transplantation and potentially increase utilization rates.

NKF and ASN are deeply concerned that the use of race in KDRI is inconsistent with the National Organ Transplant Act (NOTA) Final Rule as it impairs the "equitable allocation of cadaveric organs," is not based on "sound medical judgment," "does not achieve the best use of donated organs," and fails to "avoid wasting organs or promote patient access to transplantation."¹ Supporting the Health Resources and Services Administration's (HRSA's) mission to increase equitable access to healthcare services, we are dedicated to providing transplant access to the 30 million people in historically underserved communities, and the more than 1,500 rural counties and municipalities across the United States noted by HRSA. The race coefficient in the KDRI algorithm limits organ supply and decreases transplant opportunities, which contradicts the NOTA Final Rule and HRSA's goals for equitable access to healthcare.

In a study by Kelly Chong, PhD, et al., including race in KDRI creates a biased risk estimate and is unwarranted because removal does not change patient or graft survival, and eliminating it would be an essential step towards reducing the number of wasted kidneys.² In a clinical analysis by John Gill, MD, et al., race increases KDPI scores, and an estimated 60% of recovered kidneys with KDPI in the 85th percentile and higher go untransplanted.³ According to data from the Organ Procurement and Transplantation Network (OPTN), nearly 90,000 individuals are on the national transplant list waiting for a kidney transplant. HRSA and OPTN must prioritize erasing race from KDRI to ensure kidneys from all donors are

¹ 42 CFR § 121.8

 ² Chong, K, Litvinovich, I, Chen, S, Zhu, Y, Argyropoulos, C, Ng, Y. Reconsidering Donor Race in Predicting Allograft and Patient Survival Among Kidney Transplant Recipients. Kidney360. Published online November 2021. doi: 10.34067/KID.0002932021
³ Gill JS, Kelly B, Tonelli M. Time to Abolish Metrics That Sustain Systemic Racism in Kidney Allocation. *JAMA*. Published online February 27, 2023. doi:10.1001/jama.2023.1076





appropriately classified, a crucial step in increasing the supply of organs available for transplantation.

Since the publication of the final report <u>NKF-ASN Task Force on Reassessing the Inclusion of Race in</u> <u>Diagnosing Kidney Disease</u> in September 2021, OPTN has made progress in advancing equity in kidney transplantation by removing race from eGFR equations and mandating kidney transplant centers use raceneutral algorithms to assess kidney function and restore wait times to Black patients affected by the racebased formulas. HRSA and OPTN must continue this momentum by expeditiously eliminating race from KDRI/KDPI. We all agree that race has no place in clinical algorithms, and its continued use in KDRI/KDPI leads to unacceptable life-threatening consequences. NKF and ASN are looking to HRSA to expedite this initiative to end the devaluation of kidneys from Black organ donors.

We understand that the OPTN Minority Affairs Committee is currently assessing the impact of race used in the KDRI/KDPI equations, while the OPTN Kidney Committee is examining the implication of HCV in these algorithms. Removing these particular elements could avail more kidneys for transplantation and ensure all kidneys are appropriately classified, which we know is critically needed for kidney patients hoping to receive this life-saving treatment. NKF and ASN recognize that OPTN has a policy approval process, but we firmly believe that removing race, which is not a biological construct, should be an urgent initiative for OPTN, given that we are approaching the third anniversary of the call by congress to eliminate race from clinical algorithms.

From firsthand experience, NKF and ASN understand that it takes resources to conduct a thorough analysis. However, we need HRSA to ensure this matter receives the attention and action it deserves on behalf of the countless number of patients—both waitlisted and those who should be—waiting for a life-saving kidney transplant. ASN and NKF also believe that with the proper resources, OPTN could deliver a scientifically valid outcome more quickly than currently envisioned—in this calendar year, ideally sooner. OPTN could also draw on precedent and take emergent action to remove race from KDRI now, a step that could be followed by a more traditionally-paced OPTN policymaking process (which could also include, for example, consideration of removing Hepatitis C from the equation). NKF and ASN unequivocally denounce the use of race in the clinical assessment of organ suitability. The continued usage of race in these equations is an issue of utility and equity that we believe should be resolved as soon as possible.

Kidney failure patients on the waitlist have limited time; their lives are at stake, and they need the agency's rapid action. NKF and ASN are prepared to lend our expertise, guidance, and lessons learned from a similar process to support and further this initiative. We will gladly schedule a call with you have any questions or if it would be helpful to further discuss our recommendations. Please contact Morgan Reid, NKF's Director of Transplant Policy and Strategy, at Morgan.Reid@kidney.org and Rachel Meyer, ASN's Strategic Policy Advisor, at <u>rmeyer@asn-online.org</u>, with any questions.





Sincerely,

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Cc:

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