

December 9, 2020

The Honorable Richard E. Neal
Ways and Means Committee
U.S. House of Representatives
1102 Longworth House Office Building
Washington, D.C. 20515

Chairman Neal:

On behalf of the American Society of Transplant Surgeons (ASTS), I am pleased to have the opportunity to respond to your important request for information (RFI) on the issue of racial bias in clinical tools used in the field of transplantation. ASTS is a medical specialty society representing over 1,800 professionals dedicated to excellence in transplantation surgery. Our mission is to advance the art and science of transplant surgery through patient care, research, education, and advocacy.

ASTS has worked for many years to reduce racial disparities in transplantation. To further progress in this area, ASTS has recently launched a national campaign, **ASTS Boldly Against Racism**, to directly address racism and to promote permanent and positive change. Among other things, this initiative will involve dedicating funding for ASTS members to promote the scholarship of identifying and addressing structural barriers, including systemic racism, that contribute to racial disparities in transplant access and outcomes.¹

We applaud the committee for establishing its Rural and Underserved Communities Health Task Force and holding hearings on these important issues, and we welcome the opportunity to discuss ASTS' views on ways to eliminate racial bias in clinical tools and implement related policies to reduce health care disparities in our field, particularly in light of the COVID crisis.

Race and Transplantation

It is important to begin by noting some overarching clinical truisms about race and transplantation. First, race is a social construct that is used as a surrogate for specific (and increasingly identifiable) biological processes. More precise biologic markers are now available or potentially discoverable that have the potential to supplant race (e.g., APOL1 testing) in the design of clinical tools in our field and others. As progress is made in the identification of biologic markers, it is our hope that the use of racial factors per se in clinical tools will become anachronistic. We are buoyed by recent medical advances that will replace race with more precise biologic markers and believe that Congress could plan a critical role by advancing NIH funding in this area.

Second, because Black patients are disproportionately afflicted with renal disease (both incidence and prevalence), anything that reduces either access to transplantation or

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American Transplant Congress

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¹ See more detailed action items at <https://asts.org/news-and-publications/asts-news/article/2020/07/28/asts-boldly-against-racism>.

organ supply (i.e., discards of potentially transplantable organs) disproportionately impacts Black patients. Further, patients in lower socio-economic strata are more likely to be dependent on Medicare and Medicaid.² As such, federal policies designed to increase access to transplantation are critical if racial disparities in transplantation are to be reduced.

ASTS-Supported Legislation

ASTS has long been a strong champion of legislation and policy changes that we believe hold considerable potential to ensure that racial/ethnic constructs and socioeconomic status are not barriers to care.

- We strongly support H.R. 5534, the Comprehensive Immunosuppressive Drug Coverage for Kidney Transplant Patients Act of 2019, bipartisan legislation introduced by committee member Rep. Ron Kind (D-WI). We are greatly appreciative of the committee's role in passage on the House floor this week and hopeful to see final passage before the end of 2020.
- We strongly support H.R. 1224, the Living Donor Protection Act of 2019, legislation that would preclude insurance companies from discriminating against living donors and that would explicitly extend Family Medical Leave Act protections to living donors.
- Through the National Living Donor Assistance Center (NLDAC), ASTS administers the day-to-day operations in support of the HRSA grant "Removing Financial Disincentives to Living Organ Donation."
- We have also been advocating for revisions to Transplant Center metrics in order to remove disincentives to transplantation, and we look forward to working with our peers, other stakeholders, and the new Administration on these efforts.

General Comments

ASTS believes that substantial work needs to be done to face racial disparities in access to transplantation and to better understand and address racial disparities in transplant outcomes. At the same time, it is important to acknowledge that progress has been made in some areas. For example, improvements³ in national kidney allocation policy have evened out the rates at which African-American, Hispanic, and Caucasian transplant candidates receive kidneys from deceased donors, according to data from United Network for Organ Sharing (UNOS)⁴. The incorporation of dialysis time as wait-time, sequential changes to the role and scope of HLA matching in deceased donor kidney allocation, and other changes incorporated into the allocation system were designed specifically to improve access and appear to have done so. Additional changes in kidney allocation may have the potential to further improve access and equity, potentially further reducing disparities for vulnerable populations. It is clear that reducing disparities in transplant rates is not enough to conclude that minorities in the United States have equal access to transplantation. It does indicate, however, that the allocation system itself is not the problem, and that a significant component is further upstream.

In particular, minority populations deserve equal initial access to healthcare, leading to prompt diagnosis of renal disease and the appropriate early referral to Transplant Centers, preferably before beginning dialysis. Addressing this issue effectively is complex, requiring changes at multiple levels of the healthcare system. For example, the Organ Procurement and Transplantation Network (OPTN) does not have the jurisdiction to collect information about all patients referred to a Transplant Center, which necessarily includes those who turn out to be clinically unsuitable for transplantation, and the OPTN recently decided not to implement data collection efforts

² <https://ajph.aphapublications.org/doi/pdf/10.2105/AJPH.87.5.805>

³ We note that references 6, 7, 8, 9, 10 in the RFI were published before these changes in allocation policy were made

⁴ See [UNOS REPORT](#).

(supported by ASTS) that would have augmented our understanding of the composition of Transplant Center waitlists. For this reason, UNOS (outside its role as the OPTN contractor) has just launched a study pairing OPTN transplant data with other data sources to try to answer some of the questions necessary to analyze waitlist referrals and composition, and this effort is supported by ASTS.

Responses to Request for Information

The RFI asks four specific questions, each of which is addressed below.

1. *What strategies has ASTS undertaken to reevaluate the scientific basis for the use of Black race in KDRI calculation?*
 - a. *How will ASTS work to support, encourage, and coordinate with other specialty organizations that are also conducting a reevaluation of the misuse of race in clinical algorithms?*

From a clinical lens, it is important not to conflate eGFR estimation with KDRI. KDRI is a predictor of post-transplant renal allograft survival. KDRI was validated based on approximately 69,440 kidney transplant recipients of deceased donor organs⁵, and, because KDRI has been validated as a robust and evidence-based tool, it serves as a means to advance the care of all transplant candidates, including those from historically disadvantaged or underserved communities. For this reason, modifications of the KDRI should not be undertaken without considerable research and validation.

Experience suggests that organs retrieved from donors who self-identify as African American are associated with decreased long-term organ survival post-transplant, and for this reason, KDRI does take race into account. Some have suggested that it may be possible in the future to test the donors for APOL1 gene presence rather than taking race into account explicitly in determining the KDRI of donor organs, but the technology is not currently available on a routine basis, and it may take some time to develop.

At this point, however, it is important to note that KDRI is used for deceased donor kidney evaluation and does not impact access to transplantation which is, in our view, the most critical issue. KDRI is a predictor of post-transplant renal allograft survival, and, as such, does not affect any group's access to organs.

2. *What has ASTS done and what does it plan to do to inform clinicians of the connection between race correction in eGFR calculation and the KDRI and racial health inequities in CKD, ESRD, and kidney transplantation?*
 - a. *While ending the use of Black race in the KDRI could take some time to implement, what guidance can ASTS issue quickly to redirect clinical practices and communicate the problem of misuse of race in the KDRI to patients?*

ASTS agrees that it is very important to eliminate race correction in the eGFR calculation. The National Kidney Foundation (NKF) and UNOS, with whom we are closely allied, as well as our Diversity Issues Committee will be working on this issue. While regulatory agencies could specifically address the need to eliminate race correction, as a practical matter it also will be necessary to conduct extensive outreach to community nephrologists who refer patients for transplant evaluation and who frequently wait for the magic "20" number before they refer. We strongly suggest a multi-pronged strategy that includes not only the transplant community, but also the American Society of Nephrology, the NKF, American Association of Kidney Patients, and other provider and patient advocacy organizations to spread the word.

⁵ Rao PS, Schaubel DE, Guidinger MK, et al. A comprehensive risk quantification score for deceased donor kidneys: The kidney donor risk index. *Transplantation*. 2009;88(2):231-236.

We note that lack of insurance coverage is also a factor contributing to the disparities in pre-emptive transplantation. Patients <65 years currently qualify for Medicare only AFTER they start dialysis (with rare exceptions). We encourage Congress to expand Medicare eligibility to people aged <65 years of age if they have CKD with an eGFR <20, which will allow more pre-emptive transplants, especially among indigent patients.

3. *What interventions could ASTS develop to ensure improved access to transplant for patients who have not received it because of use of Black race in the KDRI?*
 - a. *What role could the federal government play in support of this kind of initiative, if any?*
 - b. *What specific racial health equity metrics and outcomes will ASTS track and work to improve. Please provide details, including timeframe.*

As indicated above, KDRI does not affect any potential recipient's access to a deceased donor organ.

a. The Federal Government could support research in development of a rapid test that is universally available at a reasonable price, so all appropriate deceased and living donors can be tested in real time for APOL1 in place of race in the KDRI calculation, which would be more accurate.

b. ASTS believes that the first step in changing transplant metrics is to eliminate the use of one-year patient and graft survival as the primary metric for Transplant Center evaluation by the OPTN and to eliminate the current five star methodology to evaluate Transplant Center outcomes. This focus on Transplant Center outcomes disincentivizes the use of higher risk organs and the transplantation of higher risk recipients, which disproportionately impacts racial and ethnic minorities because of the incidence and prevalence of renal disease in that population. We also support the development of metrics that would encourage earlier referral of patients for transplant evaluation.

4. *Black, Indigenous, and Latinx scholars have a leading and vital perspective on these issues and the proposed solutions, despite being underrepresented in medicine. How is ASTS ensuring racial diversity in the discussion and strategy development relating to health equity?*

ASTS has committed to take a number of actions to increase our institutional access to Black Indigenous and Latinx perspectives on these issues, as detailed in the **ASTS Boldly Against Racism** initiative described above and accessible [HERE](#).

In conclusion, our Society thanks you for your interest and efforts to remove racial health inequities impacting access to transplantation. We look forward to working with you on advancing current legislation, developing new clinical tools through targeted research, disseminating education around issues relating to health equity in transplantation, and enhancing the diversity of our workforce. We would be happy to meet with you at your convenience.

Sincerely,



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President
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Submitted via electronic mail to Amy Hall at Amy.Hall@mail.house.gov and Melanie Egorin at Melanie.Egorin@mail.house.gov, Committee on Ways and Means, Majority Staff.