



American Society of Transplant Surgeons®

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April 28, 2021

Marquita N. Cullom
Associate Director
Agency for Healthcare Research and Quality (AHRQ)
U.S. Health and Human Services
5600 Fishers Lane
Rockville, MD 20857

Re: [Request for Information on the Use of Clinical Algorithms That Have the Potential To Introduce Racial/Ethnic Bias Into Healthcare Delivery](#) (Document citation: 86 FR 12948)

Dear Associate Director Cullom:

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 use of clinical algorithms that have the potential to introduce racial/ethnic bias into healthcare delivery. ASTS is a medical specialty society representing approximately 1,900 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.

We welcome the opportunity to discuss ASTS' views on racial bias in clinical tools, including clinical algorithms. Our comments on this topic are limited to the use of clinical algorithms and other tools in the field of transplantation.

ASTS has worked for many years to reduce racial disparities in transplantation. The *ASTS Diversity, Equity and Inclusion Committee* (formerly the *Diversity Issues Committee*) has spearheaded several society initiatives aimed at eliminating racial and ethnic disparities in transplantation. A year ago, ASTS also launched a national campaign, *ASTS Boldly Against Racism* (accessible [here](#)) to directly address racism as a root cause of racial disparities in transplantation¹ and to promote permanent and

¹ Purnell TS, Simpson DC, Callender CO, Boulware LE. [Dismantling structural racism as a root cause of racial disparities in COVID-19 and transplantation. Am J Transplant. 2021 Feb 18;10.1111/ajt.16543.](#) doi: 10.1111/ajt.16543. Epub ahead of print. PMID: 33599027; PMCID: PMC8014768.

Crews DC, Purnell TS. COVID-19, [Racism, and Racial Disparities in Kidney Disease: Galvanizing the Kidney Community Response. J Am Soc Nephrol. 2020 Aug;31\(8\):1-3.](#) doi: 10.1681/ASN.2020060809. Epub 2020 Jul 13. PMID: 32660968; PMCID: PMC7460889.

Arriola KJ. [Race, Racism, and Access to Renal Transplantation among African Americans. J Health Care Poor Underserved. 2017;28\(1\):30-45.](#) doi: 10.1353/hpu.2017.0005. PMID: 28238984.

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positive changes in the field. This initiative resulted in the launch of the *ASTS Boldly Against Racism Task Force* and the *ASTS-Natera Socioeconomic and Racial Disparities (SERD) In Transplantation Research Grant* (accessible [here](#)), which provides dedicated 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.²

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 often used in clinical decision making and research as a surrogate for specific (and increasingly identifiable) biological processes. As noted by several NIH leaders in 2018, “imprecise use of race and ethnicity data as population descriptors in genomics research has the potential to miscommunicate the complex relationships among an individual’s social identity, ancestry, socioeconomic status, and health, while also perpetuating misguided notions that discrete genetic groups exist.”³ More precise biologic markers are now available or potentially discoverable that have the potential to more accurately reflect genetic variants (e.g., APOL1 testing) to guide the design of clinical tools in our field and others. As we continue to make progress in the identification of biologic markers, it is our expectation that the imprecise and potentially harmful⁴ use of race as a surrogate for biologic markers or genetic ancestry in clinical tools will discontinue. We are buoyed by recent medical advances that will replace race with more precise biologic markers and believe that Congress could play a critical role by advancing NIH funding in this area.

Second, because Black patients are disproportionately impacted by end-stage organ failure (e.g., the incidence and prevalence of kidney failure), the presence of structural barriers within healthcare that reduce access to either transplantation or organ supply (i.e., discards of potentially transplantable organs) have the potential to doubly harm Black patients. Further, patients in lower socio-economic strata are more likely to be dependent on Medicare and Medicaid.⁵ 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.

- Over the past decade, ASTS has strongly supported the extension of Medicare coverage of immunosuppressive drugs, and we are gratified that this legislation has been enacted. We believe that the extension of immunosuppressive drug coverage to those without other forms of

² See more detailed action items at <https://asts.org/news-and-publications/asts-news/article/2020/07/28/asts-boldly-against-racism>.

³ Bonham VL, Green ED, Pérez-Stable EJ. [Examining How Race, Ethnicity, and Ancestry Data Are Used in Biomedical Research](#). JAMA. 2018 Oct 16;320(15):1533-1534. doi: 10.1001/jama.2018.13609. PMID: 30264136; PMCID: PMC6640836.

⁴ Vyas DA, Eisenstein LG, Jones DS. [Hidden in Plain Sight - Reconsidering the Use of Race Correction in Clinical Algorithms](#). N Engl J Med. 2020 Aug 27;383(9):874-882. doi: 10.1056/NEJMms2004740. Epub 2020 Jun 17. PMID: 32853499.

⁵ <https://ajph.aphapublications.org/doi/pdf/10.2105/AJPH.87.5.805>

coverage is likely to have a disproportionate impact on communities of color and has the potential to increase both access to transplantation and organ retention.

- We strongly support 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 also strongly support revisions to Transplant Center metrics to remove disincentives to transplantation, and we look forward to working with our peers, other stakeholders, and the new Administration on these efforts.

ASTS Recommendations

ASTS believes that substantial work needs to be done to eliminate racial disparities in access to transplantation and to better understand and address racism as a fundamental driver of racial disparities in transplant access and outcomes. At the same time, it is important to acknowledge that policy changes are often required to make real progress to advance equity. For example, targeted initiatives⁶ to change the national kidney allocation policy have resulted in comparable rates at which Black/African American, Hispanic, and White transplant patients who make it to the waiting list receive kidney transplants from deceased donors.⁷ 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 targeted changes incorporated into the allocation system were designed specifically to address structural barriers that disproportionately impact Black and Hispanic patients. Additional targeted efforts, such as the removal of structural barriers to transplant referral and placement on the waiting list are needed to further reduce transplant disparities for vulnerable populations.

More upstream, Black, Hispanic, and other medically underserved patients deserve timely access to high-quality primary healthcare, leading to prompt diagnosis of kidney disease and the appropriate early referral to nephrologists and transplant centers. As with all forms of healthcare disparities, addressing this issue effectively is complex, requiring changes at multiple levels of the healthcare system. One of the most pressing changes that should be made with respect to the use of racially biased algorithms in transplantation relates to the use of a race correction in the estimated glomerular filtration rate (eGFR) calculation, which is used to measure a patient’s level of kidney function and determine the patient’s stage of kidney disease. There is strong clinical evidence that the use of race correction in the eGFR calculation adversely impacts access to transplantation for Black patients with kidney disease.⁸

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

⁷ See [UNOS REPORT](#).

⁸ Vyas DA, Eisenstein LG, Jones DS. [Hidden in Plain Sight - Reconsidering the Use of Race Correction in Clinical Algorithms](#). N Engl J Med. 2020 Aug 27;383(9):874-882. doi: 10.1056/NEJMms2004740. Epub 2020 Jun 17. PMID: 32853499.

Eneanya ND, Yang W, Reese PP. [Reconsidering the Consequences of Using Race to Estimate Kidney Function](#). JAMA. 2019 Jul 9;322(2):113-114. doi: 10.1001/jama.2019.5774. PMID: 31169890.

Boulware LE, Purnell TS, Mohottige D. [Systemic Kidney Transplant Inequities for Black Individuals: Examining the Contribution of Racialized Kidney Function Estimating Equations](#). JAMA Netw Open. 2021 Jan 4;4(1):e2034630. doi: 10.1001/jamanetworkopen.2020.34630. PMID: 33443577.

The ASTS joins other professional societies, including the National Kidney Foundation (NKF⁹) and the American Society of Nephrology (ASN¹⁰) in recommending “that race modifiers should not be included in kidney function estimating equations, and that a suitable approach be put in its place that is accurate; representative for all regardless of race, ethnicity, age, or sex; not differentially produce bias, inaccuracy, or inequalities; and be standardized across the United States.” As a society of transplant professionals, we are happy to work closely with our nephrology colleagues, patient, and community advocacy organizations (e.g., National Minority Organ Tissue Transplant Education Program, American Association of Kidney Patients), and our own society members who are experts in the scholarship of race and health equity to develop a multi-pronged strategy to advance the field.

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 further identifying and eliminating racial bias in the algorithms and other clinical tools used in the field of transplantation. Please contact ASTS Executive Director Maggie Kebler-Bullock at Maggie.Kebler@asts.org or on (703) 414-7870 if you have any questions or comments.

Sincerely,



Marwan Abouljoud, MD, FACS, CPE, MMM
President
American Society of Transplant Surgeons

Norris KC, Eneanya ND, Boulware LE. [Removal of Race From Estimates of Kidney Function: First, Do No Harm.](#) JAMA. 2021 Jan 12;325(2):135-137. doi: 10.1001/jama.2020.23373. PMID: 33263722.

⁹ Delgado C, Baweja M, Burrows NR, Crews DC, Eneanya ND, Gadegbeku CA, Inker LA, Mendu ML, Miller WG, Moxey-Mims MM, Roberts GV, St Peter WL, Warfield C, Powe NR. [Reassessing the Inclusion of Race in Diagnosing Kidney Diseases: An Interim Report from the NKF-ASN Task Force.](#) Am J Kidney Dis. 2021 Apr 8:S0272-6386(21)00506-0. doi: 10.1053/j.ajkd.2021.03.008. Epub ahead of print. PMID: 33845065.

¹⁰ Delgado C, Baweja M, Burrows NR, Crews DC, Eneanya ND, Gadegbeku CA, Inker LA, Mendu ML, Miller WG, Moxey-Mims MM, Roberts GV, St Peter WL, Warfield C, Powe NR. [Reassessing the Inclusion of Race in Diagnosing Kidney Diseases: An Interim Report from the NKF-ASN Task Force.](#) J Am Soc Nephrol. 2021 Apr 9:ASN.2021010039. doi: 10.1681/ASN.2021010039. Epub ahead of print. PMID: 33837122.