

**OPTN Minority Affairs Committee (MAC) and Kidney Transplantation Committee
Reassess Race in Estimated Glomerular Filtration Rate (eGFR) Calculation Workgroup
Meeting Summary
November 1, 2021
Conference Call**

**Paulo Martins, MD, PhD, Chair
Martha Pavlakis, MD, Chair**

Introduction

The Reassess Race in eGFR Calculation Workgroup (the Workgroup) met via Citrix GoToMeeting teleconference on 10/01/2021 to discuss the following agenda items:

1. Transition Plan
2. Monitoring Plan
3. Education and Communication Plan
4. Member Compliance Plan
5. Update: *Removal of the Black Race Coefficient From the eGFR Equation Improves Transplant Eligibility for Black Patients at a Single Center Study*

The following is a summary of the Workgroup's discussions.

1. Transition Plan

The Workgroup discussed potential impact to specific patient populations and the benefits of a policy change solution.

Data summary:

Final Rule – 42 CFR 121.8(d)(1): Transition Patient Protections

- (1) General. When the OPTN revises organ allocation policies under the section, it shall consider whether to adopt transition procedures that would treat people on the waiting list and awaiting transplantation prior to the adoption or effective date of the revised policies no less favorably than they would have been treated under the previous policies. The transition procedures shall be transmitted to the Secretary for review together with the revised allocation policies.

Summary of discussion:

A member pointed out that any time a limited resource's allocation is shifted, some populations will have greater access at the expense of other populations having less access. The number of organs available will not change with this policy, though a certain population will have increased access than before. The member continued that this was just the match, but that this policy will be correcting a disadvantage to Black patients.

One member remarked that the use of "less favorably" isn't the best language, and establishes a hypocritical framework. Improving equitably doesn't necessarily mean that others are being treated less favorably. The member added that the performance of the equations recommended by the National Kidney Foundation (NKF) and American Society of Nephrology (ASN) task force show that non-Black populations are minimally impacted compared to the Black population. Another member agreed, noting

that these equations have improved and acceptable accuracy for all demographic groups. A member noted that major renal societies have endorsed these formulas, and that this policy reflects their guidance.

One member remarked that, in a purely mathematical sense, some populations will be treated “less favorably” than before because this regards a finite resource. However, this policy will correct a present disadvantage. One Chair disagreed, remarking that non-Black patients will not necessarily be disadvantaged, as increased waiting time resulting from improved equity is not necessarily disadvantaging that population.

One Chair noted that an enlarged transplant pool isn’t necessarily a disparity or unfavorable treatment, as it could be argued that the transplant candidate pool is currently being unfairly held down. A member agreed, pointing out that there is a need to be transparent about the results of this policy and commenting that use of the terms “less favorably” isn’t a great description of potential impact. Several members agreed, including a Scientific Registry of Transplant Recipients (SRTR) representative, who remarked that this policy is eliminating an unfair advantage.

One member pointed out that, taking exact value, the answer would be no populations will be treated less favorably. This policy will result in different distributions, not unfavorable distributions. The Workgroup agreed.

Next Steps:

The Workgroup determined no transition procedures are necessary.

2. Monitoring Plan

The Workgroup discussed monitoring plans for the policy proposal, including potential analyses and metrics to measure whether the proposal has achieved its stated goals post-implementation.

Data summary:

Analyses to include:

- Pre/Post-implementation comparison of
 - Count of transplants to African American candidates
 - eGFR at listing for African American candidates qualifying through eGFR
- Longer term comparisons – it may take several years to appropriately evaluate effects
 - Waitlist mortality for African American candidates
 - Time waiting to transplant for African American candidates

Summary of discussion:

A member noted that monitoring of this policy could be difficult in the context of other factors affecting Black patients’ access to transplant. The member suggested gathering feedback from institutions and periodically reviewing center practices to learn what formulas are used to calculate the eGFR. Staff clarified that member compliance plans cover center adherence and review.

One member remarked that these analyses are worthwhile, including wait time. The member commented that utilizing length of time on the waitlist, with the eGFR referral as time zero, could allow analysis of systematic changes in waitlist time or time to waitlist after the change in policy. The member also recommended collecting this data for all of the racial groups over time as well.

A member suggested that, to continue this work, the narrative of this policy proposal should involve the implementation of race-neutral eGFR as one step in a system-wide process of reducing disparities. A Chair of the Workgroup agreed.

Several members of the Workgroup agreed that the timeline was sufficient.

Next steps:

This monitoring plan will be reflected in the *Establish OPTN Requirement for Race- Neutral eGFR Calculations* public comment proposal.

3. Education and Communication Plan

The Workgroup discussed potential education and communication plans for the policy proposal post-implementation.

Data summary:

Education – develop educational resources for OPTN members, include race-neutral eGFR transition resources for transplant programs

Communications – inform members of changes to OPTN policy, including OPTN member memos of implementation date and changes, patient resources, and UNOS website content

Summary of discussion:

A member recommended producing a frequently asked questions (FAQ) resource for transplant centers to provide to patients.

One member suggested partnering with the National Kidney Foundation (NKF) and American Society of Nephrology (ASN), who are developing several initiatives to improve education and referral for transplant. Staff asked what kind of resources have been developed, and the member shared that a toolkit for lab implementation of race-neutral eGFR equations has been released. Another member agreed that partnering with the NKF and ASN is a great idea. One member remarked that other societies have a strong message, and partnerships with them could allow for more efficient education and communication.

A member offered that this kind of education could extend beyond this project and encompass early referral, to encourage use of the correct formula to refer early.

Next steps:

The Workgroup will continue discussing the education and communication plan during a future meeting.

4. Member Compliance Plan

The Workgroup discussed a potential member compliance plan.

Data Summary:

Implementation will involve education and communication to inform members of changes to policy and educating transplant programs on new expectations.

Compliance plans involve investigation by the OPTN into any potential non-compliances reported through the patient safety portal.

Summary of discussion:

One member remarked that this plan sounds reasonable.

The Workgroup had no other questions or comments.

Next Steps:

This member compliance plan will be reflected in the *Establish OPTN Requirement for Race- Neutral eGFR Calculations* public comment proposal.

5. Update: Removal of the Black Race Coefficient From the eGFR Equation Improves Transplant Eligibility for Black Patients at a Single Center Study

A Workgroup Chair presented an overview of a recently published study, “Removal of the Black race coefficient from the eGFR equation improves transplant eligibility for Black patients at a single center,” co-authored by Melanie P. Hoenig and Alison Mann.¹

Data summary:

Beth Israel Deaconess Medical Center removed the race coefficient from eGFR calculations in 2017, and followed pre-dialysis African American patients who were subsequently referred for transplant.

Previous arguments against the removal of the Black race coefficient included statements that removing the Black race coefficient would have no impact on cumulative wait time. The analyses looked the pre-dialysis referrals to Beth Israel before and after the change to race neutral eGFR to see if there was any difference over time in the number or percent of Black patients added to the list. Results showed a steady increase in the percent of pre-dialysis black patients who qualified for listing. Up to roughly 60 percent of pre-dialysis referrals were listed that wouldn't have been listed otherwise, roughly equivalent to the rate at which white patients were listed pre-dialysis. Disparities in listing were reduced.

There were several changes over this cohort, including the implementation of the Kidney Allocation System (KAS) in 2014. At this time, many doctors had the mentality of teaching options, performing access surgery, initiating dialysis and then referring for transplant. Over time, efforts were made to encourage providers to refer for transplant well before dialysis access placement in order to list patients as early as possible.

This study tracked the nine Black pre-dialysis patients who were listed with a GFR of less than 20 without the race variable who would not have qualified if the race coefficient were included in the eGFR calculation. Creatinine was tracked in these patients to see how long it would have taken for them to qualify using the old eGFR calculation. On average, 1.3 years of wait time was gained for these individuals. This finding negates arguments that changing the eGFR equation wouldn't yield any meaningful improvement in wait time accumulated for Black patients. So far, none of these nine patients have initiated dialysis, and for now, none have been transplanted, negating arguments that removal of the race coefficient would result in early dialysis initiation and early transplant.

Summary of discussion:

One of the Workgroup Chairs remarked that this study will have a huge impact, and could pose an example for how data from individual centers should be mapped together to produce a larger pool. Another member agreed that research combating the narratives that removing race coefficients from the eGFR calculation is very impactful. The more research that shows benefits outweigh any perceived potential consequences the better.

¹ Hoenig et al, Removal of the Black race coefficient from the estimated glomerular filtration equation improves transplant eligibility for Black patients at a single center; *Clinical Transplant* 2021; <https://pubmed.ncbi.nlm.nih.gov/34605076/>

The presenting Workgroup Chair remarked that there is discussion about a similar study on a multi-center scale. The Chair continued that direct encouragement for centers and labs to make this change is also impactful and effective.

Upcoming Meeting

- TBD

Attendance

- **Workgroup Members**
 - Paulo Martins
 - Martha Pavlakis
 - Alejandro Diez
 - Amaka Eneanya
 - Bea Concepcion
 - Jerry McCauley
 - Jim Kim
 - Oscar Serrano
 - Oyedolamu Olaitan
 - Precious McCowan
 - Peter Reese
- **HRSA Representatives**
 - Adriana Martinez
 - Jim Bowman
 - Marilyn Levi
 - Vanessa Arriola
- **SRTR Staff**
 - Bryn Thompson
 - Christian Folen
 - Grace Lyden
 - Jon Miller
 - Monica Colvin
 - Peter Stock
- **UNOS Staff**
 - Kelley Poff
 - Lindsay Larkin
 - Joann White
 - Anne McPherson
 - Kayla Temple
 - Kelsi Lindblad
 - Ross Walton
 - Sara Moriarty
 - Tina Rhoades