

OPTN Kidney Transplantation Committee

Meeting Summary

June 24, 2022

Conference Call

Martha Pavlakis, MD, Chair

Jim Kim, MD, Vice Chair

Introduction

The Kidney Transplantation Committee (the Committee) met via teleconference on 6/24/2022 to discuss the following agenda items:

1. *Modify Waiting Time for Candidates Affected by Race-Inclusive Calculations* Proposal
2. Eliminate Use of Donor Service Area (DSA) from Kidney Allocation One Year Post-Implementation Monitoring Report

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

1. *Modify Waiting Time for Candidates Affected by Race-Inclusive Calculations* Proposal

The Committee reviewed the *Modify Waiting Time for Candidates Affected by Race-Inclusive estimated Glomerular Filtration Rate (eGFR) Calculations* proposal, and voted to approve sending the proposal to August 2023 Public Comment.

Presentation summary:

The proposal aims to:

- Address waiting time modification for registered Black kidney candidates who have been affected by race-inclusive eGFR calculations
- Provide programs the opportunity to request eGFR waiting time modifications for already registered candidates, as not to disadvantage these individuals based upon time of registration

Summary of discussion:

One member expressed support, remarking that this proposal is a tangible step forward in reducing racial inequality. The member asked why the modification time period would be limited to one year, as opposed to leaving it open-ended. The Chair responded that, going forward, candidates will no longer be listed utilizing a race-inclusive qualifier. The Chair continued that the one year duration was chosen with consideration for how long it would take programs to apply for waiting time modifications. The Chair remarked that this is a restitution for candidates who were harmed by race-inclusive eGFR calculations, and that this should be a finite number of people in the candidate pool that the proposed policy would apply to. The Chair noted that having a limited period of time will encourage programs to apply for waiting time modifications in a timely fashion, and that the one year duration was to give programs, even those with resource challenges, sufficient time to address these modifications. Staff added that once this proposal is in place, the requirement for race-neutral eGFR calculation use will already exist, and going forward, new candidates should not be impacted by race-inclusive calculations. The member agreed.

The member provided a scenario, asking what would happen if, for some reason, a candidate was overlooked and needed to submit a waiting time modification for race-based GFR use after the 365 day period. The member noted that many institutions have thousands of patients on their waiting list, and that it's not impossible for someone to be overlooked. The Chair pointed out that such a patient might be eligible for a standard waiting time modification appeal based on programmatic missteps. The member noted that as long as such a safety net exists, then this solution should work well and will be a tangible step forward. The member added that this is a thoughtful solution, and should be well supported.

Another member agreed, noting that practically, many patients are referred late, with referring doctors that may still use race-based calculations. The member continued that it may be complicated to find when some patients reached a race-neutral eGFR of 20. The member added that they would support removing the 365 day time limit, as in many cases, a transplant program may not see a patient for over a year. The member recommended leaving the waiting time modification pathway open and then closing it when cases are significantly reduced. The Chair agreed that was something to consider, particularly if the program doesn't see the patient for several years. Staff recommended that the Committee pose this question in public comment, particularly as the 365 day limit will not be included in the policy language itself. The Committee could revisit this after public comment closes and determine whether the timeframe is still appropriate. The Chair agreed. Another member acknowledged the concern about the time limit, and remarked that programs should not wait to identify patients at follow ups or later on, but request waiting time modification for those impacted as early as possible.

One member asked why this modification wouldn't be required for affected patients, and if there would be recourse available to patients in the case their program did not address this modification. The Chair explained that, if this modification were required, there would need to be some metric for tracking which programs didn't submit modifications. The Chair noted that it would be difficult to enforce such a requirement. The Chair continued that public outreach is important, particularly with regards to patient awareness. The Chair added that the National Kidney Foundation and American Society of Nephrology have written strong public statements in support of the *Establish OPTN Requirement for Race-Neutral eGFR Calculations* proposal, going to the Board this June. The Chair noted that, currently, a patient can't address waiting time modifications, and these are always submitted by the program. The member pointed out that, while it's good to assume everyone will do things the way they should, there is always a possibility that a program wouldn't submit these modifications. The member noted that these patients shouldn't be adversely affected. The Chair remarked that could be patients that this modification wouldn't make sense for, such as someone who had normal kidney function and then an incident causing profound and rapid impact to their kidney function, resulting in an immediate low eGFR, and then was referred and listed. For that patient, there would be no race-based eGFR calculation that would have previously allowed them to be listed sooner. The Chair noted that this modification will apply to many Black patients on the waiting list, but not all of them. The Chair pointed out that this modification request pathway will be monitored, and if very few programs apply, there will be an indication that the policy is being underutilized.

VOTE: The Committee voted unanimously to approve sending the *Modify Waiting Time for Candidates Affected by Race-Inclusive eGFR Calculations Proposal* to August 2023 Public Comment.

2. Eliminate Use of Donor Service Area (DSA) from Kidney Allocation One Year Post-Implementation Monitoring Report

Staff presented the Circles-Based Kidney Allocation One Year Post-Implementation Monitoring Report.

Data summary:

There was an overall increase in the number of transplants, with 17,398 deceased donor kidney transplants in the pre-policy era, which increased to 18,910 deceased donor kidney transplants in the post policy era. This correlates to a 16 percent increase in transplant rate overall, with an increase from 31 transplants per 100 patient years pre-policy to 37 transplants per 100 patient years post-policy.

Equity in access:

- Pediatric transplant rate increased substantially, from 134 transplants per 100 patient years to 219 transplants per 100 patients
- Transplant rates increased notably for Black, Hispanic/Latino, and Asian candidates:
 - Transplant rates increased from 31 transplants per 100 patient years to 38 transplants per 100 patient years for Black patients
 - Transplant rates increased from 26 to 34 transplants per 100 patient years for Hispanic patients
 - Transplant rates increased from 25 to 29 transplants per 100 patient years
- There was a notable increase in transplant rates for candidates with a calculated panel reactive antibody (cPRA) of 80-97 percent, going from 36 transplants per 100 patient years pre-policy to 65 transplants per 100 patient years post-policy
- Candidates with three or more years of dialysis at time of listing saw an increase in transplant rates as well, from 66 transplants per 100 patient years to 100 transplants per 100 patient years

Efficient allocation and utilization:

- There was an increase in median distance from donor hospital, from 68 nautical miles (NM) pre-policy to 121 NM post-policy
 - There was a peak of transplants just under 50 NM from the donor hospital
- Increase in percent of transplants occurring within 250 NM of the donor hospital, from about 80 percent pre-policy to about 85 percent post-policy
 - On average, kidneys are travelling further but are being transplanted within 250 NM of the donor more often
- Decrease in the percent of transplants performed at a transplant center in the same donor service area (DSA) as the donor hospital, from 70 percent pre-policy to 40 percent post-policy
 - Regional and national transplant rates increased to about 30 percent of all transplants
- Median cold ischemic time increased from 17 hours pre-policy to 19 hours post-policy
- Increase in discard rate for deceased donor kidneys overall, across all KDPI groups, with discard rate increasing from 21 percent pre-policy to 25 percent post-policy.

Post-transplant outcomes:

- Increase in delayed graft function (DGF) post-policy, from 28 percent in the pre-policy era to 31 percent in the post-policy era
- Six month post-transplant graft and patient survival saw no significant change

Overall, there was an increase in the number of donors recovered for transplant, from 11,883 in the pre-policy era to 13,406 in the post-policy era. There was an increase in the proportion of kidneys and donors recovered with a high KDPI, or a KDPI 35 or greater.

Summary of discussion:

One member asked if the data could be analyzed for high KDPI and expanded criteria donor (ECD) kidneys and the length of time between cross clamp and the recipient center's receipt of the organ. The

member shared that previously, their program was the most aggressive in the DSA, with the most high KDPI transplants. Now with more of the high KDPI organs being offered from further away, their center has to decline those kidneys due to extended travel time and concerns for cold time. The member suggested differentiating those aggressive centers, so that OPOs can make offers immediately rather than having those centers wait 10 hours for the 20 less aggressive centers ahead of them to decline. Staff agreed that looking at cold time broken out by KDPI could potentially help explain some of the non-utilization. Staff also noted the OPTN definition of cold time is from cross clamp to anastomosis, with no cold time recorded for kidneys that are not transplanted. The member shared that their program doesn't look at biopsy criteria when considering a kidney, but will accept a kidney if it can be transplanted within 20 hours without a pump. The member noted that their program has more and more received these offers at 14 or 15 hours cold, from further away. In these cases, their program is too distant from a major airport to accept these kidneys within their acceptance criteria. The Chair remarked that the member's comments get to the concept of some of the down side of cold ischemic time. Traditionally, conversations about cold time consider delayed graft function, but it plays into the discard rate as well. The Chair noted that there has been progress with the offer filters project to make allocation more efficient.

A Scientific Registry of Transplant Recipients (SRTR) representative noted that the OPTN also has improved data collection in terms of discard. The SRTR representative recommended looking at reason for discard stratified by KDPI, to determine if this issue with cold ischemic time is occurring there, or if there are other major reasons the high and low KDPI kidneys are not utilized. The Chair agreed that it would be important to consider the low KDPI kidneys always, noting that it's difficult to think of why low KDPI kidneys would be discarded other than cold time.

One member congratulated the Committee on these results, highlighting the increase in transplants. The member added that delayed graft function and utilization rates can be addressed, and noted that these rates are likely related to issues with high KDPI kidneys. The member noted that the increases in ischemic time and delayed graft function weren't too significant, and wondered if some of the increase in delayed graft function was related to increase in transplant rates for highly sensitized, which can contribute to delayed graft function as well. The member also recommended any data request to determine causes for delayed graft function considered sensitization as well. Staff agreed, noting that dialysis time can also impact the likelihood of delayed graft function, and that changes in patient demographics will influence other aspects of the data.

Another SRTR representative agreed that this data is exciting, and commented that it bodes well for continuous distribution to see great increases in transplant rates.

Upcoming Meetings

- July 18, 2022 - Teleconference

Attendance

- **Committee Members**
 - Martha Pavlakis
 - Jim Kim
 - Arpita Basu
 - Asif Sharfuddin
 - Bea Concepcion
 - Caroline Jadlowiec
 - Deirdre Sawinski
 - Elliot Grodstein
 - Kristen Adams
 - Marian Charlton
 - Marilee Clites
 - Nidyanandh Vadivel
 - Peter Kennealey
 - Precious McCowan
 - Sanjeev Akkina
 - Erica Simonich
- **HRSA Representatives**
 - Jim Bowman
 - Marilyn Levi
 - Raelene Skerda
 - Vincent Casingal
- **SRTR Staff**
 - Ajay Israni
 - Bryn Thompson
 - Grace Lyden
 - Jon Miller
 - Peter Stock
- **UNOS Staff**
 - Lindsay Larkin
 - Kayla Temple
 - Amanda Robinson
 - Anne Paschke
 - Ben Welford
 - Chelsea Haynes
 - Joel Newman
 - Kaitlin Swanner
 - Katrina Gauntt
 - Keighly Bradbrook
 - Kelley Poff
 - Krissy Laurie
 - Rebecca Fitz Marino
 - Ross Walton
 - Sara Moriarty
 - Stryker-Ann Vosteen