

## **OPTN Kidney Transplantation Committee**

### **Meeting Summary**

**July 19, 2021**

**Conference Call**

**Martha Pavlakis, MD, Chair**

**Jim Kim, MD, Vice Chair**

### **Introduction**

The Kidney Transplantation Committee met via teleconference on 07/19/2021 to discuss the following agenda items:

1. Committee Member Introductions
2. Multi-Organ Transplant Committee Recommendations
3. Reassess Race in estimated glomerular filtration rate (eGFR) calculation request for feedback
4. Committee Orientation

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

#### **1. Committee Member Introductions**

Committee leadership welcomed new members to the Kidney Transplantation Committee, and members introduced themselves to each other. The Committee also reviewed onboarding and continuing education requirements, a volunteer opportunity with the Fiscal Impact Group, and the upcoming in-person OPTN Kidney Committee meeting in October.

#### Summary of discussion:

There were no questions or comments.

#### **2. Multi-Organ Transplant Committee Recommendations**

The Committee reviewed the work projected for the OPTN Ad Hoc Multi-Organ Transplantation Committee, including a project to develop heart-kidney and lung-kidney medical eligibility criteria and safety net policies, as well as a potential project to review and update the simultaneous liver-kidney (SLK) policy.

#### Data summary:

The Ad Hoc Multi-Organ Committee is currently working to develop and seeking feedback on heart-kidney and lung-kidney eligibility criteria and safety net policy.

- Eligibility criteria are qualifying medical conditions for a candidate to receive a second organ
  - Ensures organs are only allocated to multi-organ candidates who meet some threshold of medical urgency
- Safety net policy gives priority to patients who receive a single organ but who could qualify for a second organ shortly after transplant
  - Protects access to transplant for patients who do not recover function in a second organ after a single-organ transplant

- Both eligibility criteria and safety net policies exist for liver-kidney allocation, also known as simultaneous liver-kidney (SLK)
- Current policy states when the kidney must be offered with heart or lung, based on severity of the heart or lung disease. There are no restrictions in policy related to severity of kidney disease
  - The overall rate of heart-kidney and lung-kidney transplants is increasing, but at a lower rate than kidney-alone transplant
- Current literature supports simultaneous heart-kidney for certain heart candidates and heart-kidney safety net policy
  - Literature shows mixed evidence on kidney graft survival with simultaneous heart-kidneys, but no indications of futility
- Current literature supports simultaneous lung-kidney transplant for certain lung candidates and lung-kidney safety net policy

#### 2019 Simultaneous Heart-Kidney (SHK) Consensus Conference Recommendations

- Eligibility criteria
  - Patients with established GFR less than 30 ml/min/1.73 m<sup>2</sup> may be considered for SHK
  - Patients with established GFR of 30–44 ml/min/1.73 m<sup>2</sup> and firm evidence of CKD such as small kidney size or persistent proteinuria greater than 0.5 g/day in the presence of stable hemodynamics may also qualify for SHK on an individual basis
- Safety Net
  - Heart candidates with established GFR of 45–59 ml/min/1.73 m<sup>2</sup> may not be appropriate for SHK - they may benefit from a proposed safety net policy
  - Heart recipients on chronic dialysis or with persistent GFR less than or equal to 20 ml/min/1.73 m<sup>2</sup> for 6 weeks during day 30 to day 365 posttransplant should be given priority for kidney transplantation (donors with KDPI greater than 20 percent)
- GFR thresholds are based on analysis of heart recipient GFR and mortality rates

The Ad Hoc Multi-Organ Committee proposes using current SLK eligibility and prior liver recipient safety net policy as a starting point for heart-kidney and lung-kidney policy, as the SLK policy is based on kidney function.

#### Summary of discussion:

The Chair remarked that the purpose of safety net policy is to allow eligibility criteria policy to be overly conservative in sharing kidneys for extra-renal transplants, so a non-renal candidate in need of a kidney may still receive one with priority. The Chair expressed concern about the simultaneous heart-kidney recommendations, particularly for patients with a GFR of 30-44, as many chronic kidney disease (CKD) patients fall in that range not only don't have access to transplant, but don't really need it. The Chair continued that extra-renal multi-organ allocation policy should rely more on safety net policies than on loose eligibility criteria.

One member agreed, pointing out that estimating or measuring GFR in a dynamic setting such as exists for heart and lung patients is difficult, and to say a patient has a sustained GFR for a certain amount of time and commit them to an organ they may not need could be overkill. The member continued that heart-kidney and lung-kidney safety net should be similar to current liver safety net policy, but questioned if the time frame of 30 to 365 days for heart and lung recipients should differ from liver safety net policy, which utilizes a time frame of 60 to 365 days.

The member asked if multi-visceral organs would be included in this work, particularly for multi-visceral intestine patients who may need a kidney as well. Staff clarified that the Ad Hoc Multi-Organ Committee are currently focusing on heart-kidney and lung-kidney.

Another member expressed concern about overutilization of kidneys for multi-organ candidates. The member wondered if there was data on the recovery of native kidney function in SLK recipients, 3- or 6-months post-transplant. The Chair noted that Beth-Israel Deaconess Medical Center performed a similar study many years before the implementation of the SLK eligibility and safety net policy, and shared that about a third of those SLK recipients were found to have both native kidneys and their transplanted kidneys functioning. The Chair noted that it would not necessarily be in the purview of the OPTN to perform such a study.

The Vice Chair pointed out it could be helpful to see the change in the number of safety net kidneys and SLK transplants over the years. The Vice Chair shared that, in his experience, heart-kidneys are more likely to be approved as a result of the lack of heart-kidney safety net policy. It can be difficult to predict if a patient will need dialysis post-transplant, and choosing not to approve a heart-kidney candidate could be seriously detrimental if that patient needs a kidney post-heart-transplant. The candidate would receive no priority on the kidney list and have no waiting time, and thus be severely disadvantaged for heart graft outcomes. The Vice Chair added the thoracic community would likely be more agreeable to strict simultaneous heart-kidney and lung-kidney criteria if there is an effective safety net policy. The Chair agreed.

Staff asked the Committee if heart-kidney and lung-kidney safety net candidates would receive the same priority as liver-kidney safety net candidates. The Chair remarked that there seemed to be no reason to prioritize them differently. One member agreed, but added that literature showing significant differences in mortality would be a justification to differentiate between heart, lung, or liver safety net kidney candidates.

The Vice Chair pointed out that unbundling the safety net priority as it stands against other classifications could be difficult, but that it may be worth considering their prioritization overall. The Vice Chair continued that many safety net patients receive increased priority over kidney alone patients who have many more years of dialysis and may be more sick. The Chair agreed, noting if initial criteria are overly generous, safety net priority becomes less important and kidneys are likely being over-utilized in populations where there is less relative need.

#### Next Steps:

The Kidney Committee's feedback will be provided to the Ad Hoc Multi-Organ Transplantation Committee for further discussion.

### **3. Reassess Race in eGFR Calculation Request for Feedback**

The Committee Chair presented an overview of the Reassess Race in eGFR Calculation project and upcoming request for feedback.

#### Data summary:

The Minority Affairs and Kidney Transplantation Committee's Reassess Race in eGFR Calculation Workgroup aims to evaluate the use of the Black race coefficient in the eGFR calculation as it relates to wait time criteria in kidney allocation and use OPTN community feedback gathered in a Request for Feedback to help determine what future policy should be developed.

The eGFR is commonly used as a surrogate to measure kidney function, utilizing various formulas – some of which include race as a variable. This variable results in an otherwise identical Black patient having a higher GFR than a non-Black counterpart, essentially overestimating their kidney function.

Recent research suggests that use of the Black race coefficient disadvantages Black patients being treated for chronic kidney disease (CKD). Studies have shown the use of the Black race coefficient results in:

- Increases in Black patients' eGFR by as much as 16 percent, despite having all other variables in the formula remain equal
- Delayed referral for transplant
- Delayed initiation for qualified waiting time for non-dialysis patients
- Impeded timely CKD management and contribute to worst outcomes
- Exacerbated existing disparities in transplantation

Furthermore, race is a social construct and an unreliable proxy for genetic difference. Race-inclusive GFR calculators use a binary Black/non-Black coefficient, which accounts for neither existing genetic diversity within the Black population nor multi-racial individuals.

Recent studies suggest removing the Black race coefficient could result in:

- 16 percent increase in the total number of Black patients classified as having CKD
- 3.1 percent or 64 Black participants reclassified to an eGFR equal or less than 20mL/min
- 35 percent higher occurrence of having GFR eligible for transplant referral
- Black patients reaching the transplant referral threshold 1.9 years earlier

The Reassess Race in eGFR Calculation Workgroup is currently discussing an OPTN policy regarding the use of race neutral formulas for the initiation of waiting time accrual for non-dialysis candidates and the impact of such a policy change on members.

#### Summary of Discussion:

The Vice Chair thanked the Chair for bringing this project to the forefront, noting that earlier discussions lead to increasing initiatives to change GFR calculation practices on an individual transplant center level. The Vice Chair added that while OPTN policy does not dictate which GFR formula should be used, this is something transplant centers should consider.

Another member agreed, remarking on the rising attention on this topic and the general support for change removing the race covariate. The member continued that time will be a critical element in education to bring everyone up to the current standard.

One member shared that they had informally introduced this project among end-stage renal disease (ESRD) peers, particularly African American patients challenged with access to listing, and there was significant support and excitement for change as a result of this project.

A member remarked that the 1.9 year disadvantage for black patients in waitlist access presents a difficult logistical question, and asked if time could retroactively be given to patients who should have qualified to be listed and can't get that time back. The Chair agreed that will be difficult logistically, adding that the first steps are to gather feedback and develop a proposal before tackling that issue. The Chair continued that it will be difficult for patients who were never referred to a center, but that time could possibly be more easily given back to a patient who was referred for transplant and sent away due to their GFR. Current policy does not provide for retroactive time for non-dialysis, GFR qualifying patients.

#### **4. Committee Orientation**

Staff oriented new Committee members to OPTN governance structures, Committee meetings and involvement, Kidney Committee-sponsored projects, Committee support structures, and member expectations.

##### Summary of discussion:

One member asked if there were specific expectations for an at-large committee member. Staff clarified that all committee members are expected to participate in all committee meetings and relevant subcommittee or workgroup meetings, review materials prior to meetings, and engage in discussions.

There were no additional questions or comments.

##### **Upcoming Meetings**

- August 16, 2021 – Teleconference

## Attendance

- **Committee Members**
  - Martha Pavlakis
  - Jim Kim
  - Arpita Basu
  - Amy Evenson
  - Asif Sharfuddin
  - Bea Concepcion
  - Cathi Murphey
  - Deirdre Sawinski
  - Caroline C. Jadlowiec
  - Julianne Kemink
  - Marilee Clites
  - Nidyanandh Vadivel
  - Peter Lalli
  - Precious McCowan
  - Sanjeev Akkina
  - Erica Simonich
  - Jodi Smith
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Ajay Israni
  - Bryn Thompson
  - Jon Miller
  - Nick Salkowski
- **UNOS Staff**
  - Lindsay Larkin
  - Tina Rhoades
  - Amanda Robinson
  - Kayla Temple
  - Ben Wolford
  - Chelsea Haynes
  - James Alcorn
  - Jennifer Musick
  - Joel Newman
  - Kaitlin Swanner
  - Laura Schmitt
  - Lauren Motley
  - Leah Slife
  - Matt Prentice
  - Melissa Lane
  - Olga Kosachevsky
  - Ross Walton
  - Sara Moriarty
  - Nicole Benjamin

- **Additional Attendees**
  - David Weimer