

## OPTN Kidney Transplantation Committee

### Meeting Summary

October 18, 2021

Conference Call

**Martha Pavlakis, MD, Chair**

**Jim Kim, MD, Vice Chair**

### Introduction

The Kidney Transplantation Committee (the Committee) met via teleconference on 10/18/2021 to discuss the following agenda items:

1. Review Ad Hoc Multi-Organ Committee Recommendations
2. Reassess Race in estimated Glomerular Filtration Rate (eGFR) Proposal Policy Language

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

### 1. Review Ad Hoc Multi-Organ Committee Recommendations

The Kidney Committee representative to the OPTN Ad Hoc Multi-Organ Transplant (MOT) Committee presented the Multi-Organ Committee's recommendations for incorporating Heart-Kidney and Lung-Kidney eligibility criteria and safety net policies.

#### Data Summary:

Option for incorporating eligibility criteria:

- If the Organ Procurement Organization (OPO) is offering the Heart, and a potential transplant recipient (PTR) is also registered for a Kidney, then the OPO must offer the kidney if the PTR is registered at a transplant hospital at or within 500 nautical miles (NM) of the donor hospital and meets the following criteria:
  - Heart Adult Status 1, 2, 3 and meet eligibility in *Table 5-5: Medical Eligibility Criteria for Heart Kidney Allocation*, or any active pediatric status
- If the OPO is offering the Lung and a PTR is also registered for a Kidney, then the OPO must offer a kidney if the PTR is registered at a transplant hospital at or within 500 NM of the donor hospital and meets the following criteria:
  - Lung allocation score of greater than or equal to 35 and meet eligibility in *Table 5-6: Medical Eligibility Criteria for Lung Kidney Allocation*, or candidates less than 12 years old

Eligibility Criteria, Heart-Kidney and Lung Kidney:

- If the PTR has a diagnosis of Chronic Kidney Disease (CKD) with a measured or calculated glomerular filtration rate less than or equal to 60 mL/min for greater than 90 consecutive days, then the transplant program must report to the OPTN and document in the candidate's medical record at least one of the following:
  - That the candidate has begun regularly administered dialysis as an end-stage renal disease (ESRD) patient in a hospital based, independent non-hospital based, or home setting

- At the time of registration on the kidney waiting list, that the candidate's most recent measured or calculated creatinine clearance (CrCl) or Glomerular Filtration Rate (GFR) is less than or equal to 30 mL/min
- On a date after registration on the kidney waiting list, that the candidate's measured or calculated CrCl or GFR is less than or equal to 30 mL/min
- If the PTR has a diagnosis of sustained Acute Kidney Injury (AKI), then the transplant program must report to the OPTN and document in the candidate's medical record at least one of the following, or a combination of both of the following, for the last 6 weeks:
  - That the candidate has been on dialysis at least once every 7 days
  - That the candidate has a measured or calculated CrCl or GFR less than or equal to 25 mL/min once every 7 days
- For candidates with a diagnosis of sustained AKI, if the candidate's eligibility is not confirmed at least once every seven days for the last 6 weeks, the candidate is not eligible to receive a heart or lung and a kidney from the same donor

Summary of discussion:

The Chair asked why 500 nautical miles (NM) was used instead of 250NM, and the presenting member clarified that the criteria are modelled after the heart and lungs, and that the MOT Committee didn't feel that a heart and a kidney should be separated for a patient at 300NM. The MOT Committee feels it makes more sense to keep the kidney with the heart-kidney patient at that point.

The Vice Chair asked if the MOT Committee has discussed prioritization between multi-organ combinations. The presenting member responded that while it has not been discussed yet, there are plans to begin work on that project later on. The Vice Chair commented that there is a lot of interest in the topic, particularly as it impacts both OPOs and transplant centers. The member agreed, sharing that many OPOs want guidance.

The Chair remarked that chronicity language should include duration of low GFR, such as 90 days of a GFR less than 60 that is used in simultaneous liver-kidney (SLK) policy.

The Chair also pointed out that waitlist mortality of people with kidney injury or CKD on the heart list is not the appropriate metric, and that reversibility of kidney function post-heart transplant is the important and appropriate metric, utilizing the pre-heart transplant kidney function. The Chair agreed that chronic dialysis patients who need a heart should get a heart-kidney, and that the AKI definition is sufficient.

A member asked if heart-kidney and lung-kidney should be treated differently than liver-kidney, and if there should be a similar or different definition. The member remarked that there is discussion as to whether heart-kidney patients are different than liver patients with HRS who don't have a significant amount of renal recovery.

The Chair expressed that current SLK criteria could be resulting in too many SLK transplants, and in that case, writing similar policy could be detrimental. The Chair also noted that while they are familiar with hepato-renal and cardio-renal syndromes, they were not aware of pulmonary-renal syndromes. The Chair suggested updating the SLK criteria to a GFR threshold of less than or equal to 25, instead of 30. The presenting member clarified that the MOT Committee is not rethinking SLK, just focusing on establishing heart and lung eligibility criteria and safety net for kidneys.

A member agreed that pulmonary criteria may need more consideration, and recommended reviewing data on outcomes for patients at certain GFRs without a kidney transplant. The member asked if the timelines for safety net for lung-kidney patients should be that same as for heart-kidney and liver-

kidney. The presenting member agreed, noting that the general discussion around pulmonary renal amongst the MOT Committee is that lung recipients who receive kidneys do better, and the lower the GFR of the lung patient, the more helpful a kidney will be. The member continued that calcineurin toxicity is a leading cause of renal failure in the lung population. The member pointed out that the intention of the lung-kidney safety net is to ensure those lung patients who were not appropriately classified as needing a kidney have access to a kidney post-lung transplant. The member noted that those lung recipients who should have received a kidney typically have indications of poor renal function within six months or a year. Patients who develop renal failure after a year should be considered a kidney candidate like any other. The Chair agreed, sharing that the incidence of having a GFR below 20 post-lung transplant on calcineurin inhibitors (CNIs) increases steadily. The Chair agreed that the goal would be to prevent a lung recipient from joining the kidney list within a year, but added that the idea that recipients have better outcomes without a kidney is not enough justification for a patient to receive a preemptive transplant ahead of kidney candidates.

One member remarked that heart candidates at status 2 and 3 are less urgent, and asked if this criteria indicates that candidates in a non-critical heart status still meet eligibility criteria. Staff clarified that the Heart Committee believes status 2 and 3 to have sufficient medical urgency to receive a kidney, and that status 4 candidates were also discussed at length in the development of the *Clarify MOT Allocation Policy Proposal* that was approved by the Board of Directors in June of 2021.

A member asked if there was data showing the outcomes or function of native (non-transplanted) kidneys based on heart status. The presenting member shared that the data report recently reviewed by the MOT Committee looks at the outcomes and function of transplanted kidneys, with patients doing better with a transplanted kidney at a higher GFR three or six months post-transplant. The member remarked that this information could be valuable.

## **2. Reassess Race in eGFR Proposal Policy Language**

The Committee reviewed policy language recommended by the Reassess Race in eGFR Workgroup (the Workgroup) for a proposal to eliminate the use of race in eGFR equations in OPTN policy.

### Data summary:

The Workgroup released the *Reassess Race in eGFR Calculations Request for Feedback* (RFF) during the August 2021 public comment period. The RFF received comments from 11 OPTN Regions, four OPTN Committees, six stakeholder societies, and 16 individuals. Overall, there was very strong support for the removal of race as a factor for calculating eGFR.

On September 23, 2021, the National Kidney Foundation and American Society of Nephrology Task Force on Reassessing the Inclusion of Race in Diagnosing Kidney Disease released their final report, which outlines a race-free approach to diagnosing kidney disease. This report recommends the adoption of eGFR 2021 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation that estimates kidney function without a race variable.

The Workgroup developed a proposal to eliminate race from eGFR equations in OPTN Policy by establishing a definition of GFR in OPTN Policy to be applied to each instance of GFR throughout policy. The proposed definition is as follows:

**Glomerular Filtration Rate (GFR):** A measure of filtering capacity of the kidneys.<sup>1</sup> GFR can be measured directly or estimated (eGFR) using various formulae. Formulae used to calculate an eGFR must not use a race-based variable.

GFR appears in the following sections of OPTN Policy:

- 1.2: Definitions
- 3.6.B.i: Non-function of a Transplanted Kidney
- 8.4.A: Waiting Time for Candidates Registered at Age 18 Years or Older
- 8.5.G: Prioritization for Liver Recipients on the Kidney Waiting List
- 9.5.H: Requirements for Primary Hyperoxaluria Model for End-Stage Liver Disease (MELD) or Pediatric End Stage Liver Disease (PELD) Score Exceptions
- 9.9.B: Liver-Kidney Candidate Eligibility for Candidates 18 Years or Older
- 13.7.G: OPTN Kidney Paired Donation (KPD) Waiting Time Reinstatement

#### Summary of discussion:

The Chair shared that the Workgroup had discussed specifying certain eGFR formulas, but decided against requiring specific formulas in consideration of upcoming formulas that will change over time. Updating policy language to ensure a race neutral formula is used as opposed to specifying formulas will ensure appropriate flexibility.

One member asked when this proposal will go out for public comment, and Staff shared that public comment for the Spring 2022 cycle opens on January 27.

The Chair expressed that continued messaging that race neutral eGFR formula use doesn't need to wait until approval of the policy is important. The Chair also remarked that the timing of the request for feedback and policy proposal allowed for effective feedback collection and to utilize the recommendations and publications from the National Kidney Foundation and American Society of Nephrology Task Force.

#### Vote:

Does the Kidney Committee support Establish OPTN Requirement for Race-Neutral eGFR Calculations going to Winter 2022 OPTN Public Comment?

The Committee voted unanimously in support of proposing updated policy language to mandate the use of race neutral eGFR formulas for the Spring 2022 public comment cycle.

#### **Upcoming Meetings**

- November 15 – Teleconference

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<sup>1</sup> KDOQI Clinical Practice Guidelines for Chronic Kidney Disease: Evaluation, Classification, and Stratification American Journal of Kidney Disease, Vol 39, No 2, Suppl 1 (February) 2002: pp S76-S110

## Attendance

- **Committee Members**
  - Martha Pavlakis
  - Jim Kim
  - Vincent Casingal
  - Amy Evenson
  - Arpita Basu
  - Asif Sharfuddin
  - Bea Concepcion
  - Caroline Jadlowiec
  - Julie Kemink
  - Peter Kennealey
  - Marion Charlton
  - Peter Lalli
  - Precious McCowan
  - Sanjeev Akkina
  - Stephen Almond
- **HRSA Representatives**
  - Adriana Martinez
  - Jim Bowman
  - Raelene Skerda
- **SRTR Staff**
  - Bryn Thompson
  - Peter Stock
  - Grace Lyden
- **UNOS Staff**
  - Lindsay Larkin
  - Ross Walton
  - Kayla Temple
  - Eric Messick
  - Amanda Robinson
  - Chelsea Haynes
  - Darren Stewart
  - Joel Newman
  - Kelley Poff
  - Laura Cartwright
  - Laura Schmitt
  - Lauren Motley
  - Leah Slife
  - Matt Prentice
  - Melissa Lane
  - Sara Moriarty
  - Tina Rhoades
- **Additional Attendees**
  - Alejandro Diez
  - Dave Weimer