

## **OPTN Kidney Transplantation Committee**

### **Meeting Summary**

**March 21, 2022**

**Conference Call**

**Martha Pavlakis, MD, Chair**

**Jim Kim, MD, Vice Chair**

### **Introduction**

The Kidney Transplantation Committee (the Committee) met via teleconference on 3/21/2022 to discuss the following agenda items:

1. Follow-up: Establish Eligibility Criteria and Safety Net for Heart-Kidney and Lung-Kidney Allocation
2. Social Determinants of Health
3. Preview of April Committee Meetings

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

### **1. Follow up: *Establish Eligibility Criteria and Safety Net for Heart-Kidney and Lung-Kidney Allocation***

The Committee continued discussions on the Ad Hoc Multi-Organ Committee's proposal *Establish Eligibility Criteria and Safety Net for Heart-Kidney and Lung-Kidney Allocation*.

#### Presentation Summary:

The Host OPO is required to offer both organs for simultaneous transplant if the candidate meets the following criteria:

The candidate must meet either of the below primary organ criteria:

- Heart: adult status 1, 2, or 3 or any active pediatric status, within 500 nautical miles (NM) of the donor hospital
- Lung: composite allocation score (CAS) of 28 or greater or any pediatric candidate

And one of the below kidney criteria

- Chronic kidney disease: on dialysis or have a creatinine clearance or estimated glomerular filtration rate (eGFR) of less than or equal to 30 mL/min
- Sustained acute kidney injury: one of the following at least once every 7 days, for 6 weeks:
  - On dialysis
  - Creatinine clearance or GFR of less than or equal to 25 mL/min

Lung and Heart recipients who meet safety net criteria will receive some additional priority in kidney allocation, similar to the priority received by liver recipient safety net candidates. To qualify for the safety net classification, the heart or lung recipient must be on dialysis or have a creatinine clearance or eGFR of less than or equal to 20 mL/min between 60 and 365 days after transplant.

Looking at eGFR at time of transplant, the simultaneous liver kidney (SLK) eligibility criteria has done a good job of keeping SLK transplants at lower eGFR thresholds. Right now, lung-kidney and heart-kidney patients are being transplanted at higher eGFR thresholds.

The Heart Committee did recommend including heart status 4 patients. In 2021, there are at least 42 heart kidney status 4 and 12 of them were on dialysis. Also, you can see some of these recipients in status 1, 2, and 3 did not meet the qualifying criteria.

The prior liver recipient safety net classification provides good kidney offers, with 29.35 percent of candidates in this classification receiving 21-34 percent KDPI kidneys, and 69.98 percent receiving KDPI 35-85 percent. The median days between kidney registration and transplant is 109 days.

Summary of discussion:

One member remarked that there doesn't seem to be a reason to not include Heart Status 4 and 5 candidates within the eligibility criteria. The Vice Chair noted that giving a kidney to a dialyzed patient makes sense, but that patient would still need to meet the heart criteria to allocate them a simultaneous heart-kidney. Staff confirmed that the heart-kidney candidate would need to meet both the heart and the kidney criteria, and asked if it makes sense to expand the heart criteria to status 4 and 5 heart candidates on dialysis to ensure they had access to simultaneous heart-kidney offers.

The Chair recommended making the kidney criteria different for status 4 and 5 heart candidates as opposed to the status 1, 2, 3, or pediatric heart candidates. Another member commented that there should not be a restriction for heart status 4 or 5 candidates, as status 4 includes candidates who are stable on LVADs and are at higher risk of developing complications. The member added that proportionally, the number of status 4 heart candidates on dialysis is relatively large. The member supported a heart candidate at any status meeting the proposed kidney criteria being eligible for the simultaneous heart-kidneys. Another member agreed, adding that there isn't really MELD criteria for simultaneous liver-kidney (SLK) allocation.

The Chair asked if heart policy currently allocates out to a 500 NM circle, noting that this is a different allocation circle for kidneys alone. Staff confirmed that the first four classifications for heart status 1 and 2 patients goes out to 500 NM.

The Chair expressed concern that setting 500 NM could end up becoming a standard. The Chair explained that, with the implementation of the new SLK policy, the number of SLK transplants leveled off and stopped increasing at the rate it had been before. Over time, however, the rate of SLKs is beginning to increase again towards the same rate of increase it had been before the SLK eligibility criteria policy. The Chair continued that this could be due to the growth in chronic kidney disease (CKD) criteria, which doesn't require a certain GFR measurement. If the GFR is measured on creatinine, the liver candidate may not qualify; if the GFR is measured by cystatin-C, which accounts for the patient's loss of muscle mass, the candidate can qualify for CKD criteria with a reasonable and healthy creatinine. The Chair added that the kidney community is already concerned about too many kidneys going to multi-organ transplant.

Staff asked if there was support for not restricting heart status, so that as long as the heart candidate met the kidney criteria, they could be a required share for the simultaneous heart-kidney offers within 500 NM.

The Chair noted that there are no restrictions on the MELD for SLK, but expressed concern that this could result in heart recipients with three functioning kidneys. A member asked if there was any real difference between heart status 4 and 5 candidates versus heart status 1, 2, and 3 candidates, outside of increasing the number of multi-organ kidneys. The member added that from an eligibility criteria standpoint, these patients should all be treated equally.

The Chair agreed that it is hard to justify separating these candidates, and asked how these statuses were separated for eligibility criteria initially. Staff explained that the OPTN Organ Procurement

Organization (OPO) Committee's previous proposal to clarify multi-organ policy was based on multi-organ transplant data. Staff added that the addition of kidney eligibility criteria changes the considerations. The Chair asked if these were separated for efficiency reasons, and a Scientific Registry of Transplant Recipients (SRTR) representative explained that this was based on the fact that the majority of heart-kidney transplants were in statuses 1, 2, and 3. Another member agreed, recalling that these numbers were reviewed. Staff added that there was some concern that including other statuses would require too many heart-kidney transplants.

The member remarked that it is difficult to exclude the status 4 and 5 heart-kidney candidates if they clearly met kidney criteria, regardless of the nuances of GFR measurement. The Vice Chair agreed, adding that the safety net criteria is an important aspect of this policy to remember, and allows a lot more flexibility. The Chair added that transplant programs know there is a safety net, and so are more comfortable accepting a liver or thoracic organ without a kidney. The Chair agreed that the safety net is beneficial, and has been resulting in patients receiving expedited kidney transplants who have proved they can survive the liver transplant and still need the kidney transplant. The Chair also agreed that it would be out of scope for the Kidney Committee to dictate heart criteria.

The Chair referenced the presented data, noting that there are heart-kidney candidates simultaneously transplanted at very high GFRs for which nephrologists would never transplant a kidney-alone patient. The Chair continued, pointing out that a GFR of 50 is very high at a level often seen in post-transplant kidney recipients, and heart surgeons are doing heart-kidney transplants at that pre-transplant GFR. The Chair expressed concern that heart programs will not make judicious use of the safety net, and that caution is necessary in assuming that the safety net policy will be used appropriately. Another member agreed with the Chair, adding that the prior liver recipient safety net is doing well. The member supported the overall policy, adding that this policy is a move in the right direction. The Chair remarked that there are simultaneous lung-kidney transplants performed for candidates with pre-transplant GFRs of 60, and added that the Kidney Committee needs to be stewards of these kidneys.

## **2. Social Determinants of Health Research Update**

The Committee received an update on OPTN Social Determinants of Health research projects.

### Presentation Summary:

The objective of this update is to inform the OPTN Committees of the OPTN Contractor's progress on two ongoing social determinants of health (SDoH) studies.

Social Determinants of Health (SDoH) are conditions in the environments of where people live, work, and age that affect a wide range of quality-of-life and health outcomes. Domains and elements can differ across SDoH Frameworks. SDoH can include:

- Economic Stability – poverty, employment, food insecurity, housing instability
- Education – high school graduation, enrollment in higher education, language and literacy, early childhood development and education
- Health and Health Care – access to health care, access to primary care, health literacy, insurance status
- Neighborhoods and Built Environment – access to healthy food, quality of housing, crime and violence, environmental conditions
- Social and Community Context – social cohesion, civic participation, discrimination, incarceration

Fiscal Year 2021 SDoH Project:

- Partnered with a third party vendor to link approximately 112k OPTN records of adult kidney candidates ever waiting in 2020 to current address records and patient and geographic-level SDoH measures. There was a match rate of 99 percent.
- Analyzed linked data to determine whether the study team felt it could be used to further study of SDoH factors in transplantation

#### Fiscal Year 2022 SDoH Project

- Funded by HRSA
- Study 1: Population based analysis of SDoH and the US Kidney Waitlist
- Study 2: SDoH and Kidney Waitlist Outcomes

#### Population Study

- What is the relationship between candidate level SDoH and the SDoH of their places of residence?
  - Outcomes: educational attainment, primary payer, household income, and household poverty status of all adult kidney candidates ever waiting in 2020
- Do counties with higher prevalence of chronic kidney disease/end stage kidney disease have proportionally higher numbers of waitlisted candidates?
  - Outcomes: number of adult kidney candidates ever waiting in 2020 per 100,00 persons in each county in the US

#### Waitlist Outcomes Study

- Objective is to characterize the relationship between SDoH and waitlist outcomes
- Specific research questions:
  - Which SDoH are associated with waitlist outcomes?
  - To what extent do SDoH affect waitlist outcomes
  - Are some waitlist outcomes more affected by SDoH compared to others?
- Primary outcomes variables:
  - Receipt of deceased donor kidney transplant
  - Receipt of living donor kidney transplant
  - Waitlist mortality (death/delisting for too sick)
  - Removal from waitlist for other reason

#### Summary of discussion

The Chair expressed support for these projects, and noted that the OPTN Minority Affairs Committees (MAC) had previously proposed collecting more financial and SDoH data, such as household income and number of dependents in the household. The Chair also noted these variables seem to be getting at the chronic burden and influence of racism in the healthcare system or community, and asked if there are other variables that could be considered.

Staff confirmed that the OPTN MAC had previously proposed this data collection, but that the proposal was not successful in public comment and so did not move on to the Board of Directors. Staff explained that the data was obtained from the vendor and linked to OPTN data. Staff continued, explaining that there is an indicator of household size that is being tested as a poverty measure, which is based on reports and guidance made available by the vendor and United States (US) Census Bureau. Staff added that there are other variables, such as estimated income, that can be compared with individual reports and household income. Staff concluded that there are a lot of variables, and an important aspect of this work is figuring out where to include them and which will be the most meaningful.

Staff shared that there are studies that directly measure perceptions of racism in healthcare, which are typically done by surveying or querying patients about their direct experiences with racism in broader social contexts and interactions with health care providers. This data is considered the gold standard, as it is a direct measure, but it's sensitive to collect. Staff added that there are other measures that were rolled into the county-level study, including racial segregation and disparities in life expectancy within the measure. Proxy measures exist, but the burden of racism is difficult to get out unless patients themselves are surveyed. Staff added that variables are selected both from a statistical perspective and by thinking through the mechanisms to figure out which variables, based on known relationships, are going to be able to capture or be associated with racism.

One member commented that voter registration is not typically included, and asked why this was a significant measure to examine. Staff explained that voter registration is a measure of social cohesion, and gives a sense of civic participation, how engaged people are in the community and how much they feel their voice matters. Staff added that this speaks to social and community context.

One member asked how changes in determinants over a particular period of time are accounted for and accurately captured. Staff explained that these are snap shot studies, and that neither trajectory over time not retrospective, inclusive cohorts have been utilized. Staff added that most SDoH studies are limited by the same constraint, and rely on point-in-time public data that are published on some routine cadence. The member noted that many patients have significant changes in their medication after two years, particularly from an insurance stand point. These patients are evaluated in a different way pre-transplant, but their outcomes are different due to the SDoH that have changed over time. Staff noted that the vendor is a credit bureau, and does follow patients over time. While this is a snapshot in time for now, there are variables that can address stability over time, such as changes in housing between renting and owning or living in a more expensive home. Staff added that this is not the same as a prospective study, but these variables can give an idea of an individual's trajectory over time.

A member commented that waitlist outcomes are important, and asked if there is interest in post-transplant outcomes. Staff explained that while there is interest, the studies are limited based on the use of the ever-waiting 2020 cohort which is linked to the most recent snapshot of people in the vendor data base. For kidney candidates, it could take a long time for even half of the ever waiting cohort in 2020 to be transplanted. Staff noted that more follow up time is required to get sufficient information on post-transplant outcomes. Staff added that this could potentially be feasible if the point of origin was time of transplant, but the study would need to be designed differently with linkage specifically for patients who have been transplanted.

Staff recommended that Committee members share any additional feedback, and suggested that members who feel strongly about collecting addresses and linking OPTN data with public SDoH data to continue talking about that data in terms of OPTN policy.

### **3. Preview of Upcoming April Meetings**

Staff provided an overview of upcoming Kidney Committee and Workgroup meetings, including post-public comment considerations and several Kidney-Pancreas Continuous Distribution Workgroup meetings ahead of modeling request submission.

#### Summary of discussion:

There were no questions or comments.

#### **Upcoming Meetings**

- April 1, 2022 – Virtual “In Person” Teleconference

- April 18, 2022 – Teleconference

## Attendance

- **Committee Members**
  - Martha Pavlakis
  - Jim Kim
  - Amy Evenson
  - Arpita Basu
  - Asif Sharfuddin
  - Bea Concepcion
  - Deirdre Sawinski
  - Elliot Grodstein
  - Erica Simonich
  - Peter Kennealey
  - Marian Charlton
  - Marilee Clites
  - Precious McCowan
  - Sanjeev Akkina
  - Stephen Almond
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
  - Raelene Skerda
- **SRTR Staff**
  - Ajay Israni
  - Grace Lyden
  - Jonathan Miller
  - Peter Stock
- **UNOS Staff**
  - Lindsay Larkin
  - Ross Walton
  - Kayla Temple
  - Amanda Robinson
  - Alex Garza
  - Andrew Placona
  - Anne Zehner
  - Benjamin Wolford
  - Bob Carrico
  - Caitlyn Nystedt
  - Darren Stewart
  - James Alcorn
  - Jennifer Musick
  - Joel Newman
  - Kaitlin Swanner
  - Kim Uccellini
  - Laura Schmitt
  - Lauren Motley
  - Melissa Lane
  - Rebecca Marino

- Tatenda Mupfudze
- Trencece Wilson
- Wida Cherikh
- Beth Coe
- Nicole Benjamin
- Sara Moriarty