

## **OPTN Kidney Transplantation Committee**

### **Meeting Summary**

**January 25, 2021**

**Conference Call**

**Vincent Casingal, MD, Chair**  
**Martha Pavlakis, MD, Vice Chair**

### **Introduction**

The Kidney Transplantation Committee met via teleconference on 01/25/2021 to discuss the following agenda items:

1. Cross-Committee Updates
2. Overview of the OPTN Kidney Paired Donation (KPD) Pilot Program
3. eGFR Project Introduction
4. Committee Appointment Update

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

#### **1. Cross-Committee Updates**

Committee members in the Kidney-Pancreas Continuous Distribution Workgroup, Policy Oversight Committee, Biopsy Best Practices Workgroup, and Technology Tools Workgroup provided updates on their respective projects.

##### Data summary:

The Kidney-Pancreas Continuous Distribution Workgroup has finished identifying attributes and will begin assigning values to each attribute for the continuous distribution model.

The Policy Oversight Committee (POC) approved all proposals for the upcoming 2021 Winter Public Comment period, as well as new project proposals. All projects were approved, including the Ethics Committee white paper to revise general considerations and assessments for transplant candidacy. The POC also discussed the 2021-2024 strategic plan.

The Biopsy Best Practices Workgroup met for the first time in December to review project history and goals.

The OPO Committee's Technology Tools Workgroup has begun providing feedback to staff on a number of projects, including DonorNet Mobile. The Technology Tools Workgroup has asked for further feedback from committee members to identify what kinds of information are critical upon organ offer receipt and what kinds of capabilities could be useful.

##### Summary of discussion:

The Committee had no comments or questions.

#### **2. Overview of the OPTN Kidney Paired Donation (KPD) Pilot Program**

Staff presented an overview of the OPTN Kidney Paired Donation (KPD) pilot program and KPD Workgroup, including program history, previous projects, and potential projects and composition for the

upcoming re-establishment of the KPD Workgroup. Staff presented a call for volunteers to participate in the workgroup, with participation in the OPTN KPD Pilot Program preferred, but not required.

#### Data Summary:

The KPD Workgroup began in 2004, with NOTA amendment in 2006 allowing for the creation of an operational Kidney Paired Donation Pilot Program in 2010. The KPD program was initially governed by their own operational guidelines until 2012, when those guidelines were partially moved into policy. The KPD Workgroup still aims to finish converting the operation guidelines to policy completely. KPD operational guidelines and policy are only applicable to transplant centers participating in the OPTN KPD Pilot Program. The last KPD Workgroup project was implemented in 2019, and the KPD Workgroup has been on hold since.

The KPD policy change process is identical to the OPTN policy change process, including public comment and approval from the Board of Directors. The operation guidelines do not have a public comment process, and after development by the KPD Workgroup, are approved by a majority vote of the Kidney Transplantation Committee.

The KPD Workgroup was developing a number of projects when it was placed on hold, including:

- Repairing KPD Chains, to increase number of kidney transplants by creating better match opportunities for participating pairs and transplant hospitals
- Deceased Donor Chains, to increase number of kidney transplants by having a chain start with a deceased donor, and therefore utilizing more non-directed and bridge living donors
- Improving KPD Donor Pre-Select, to decrease the number of offer refusals and improve match success rate
- Incorporation of KPD Operational Guidelines into OPTN Policy

Upon re-establishment, the upcoming KPD Workgroup will consider a number of potential projects, including:

- Match quality and optimization projects to increase the number of kidney transplants
- Chain repairs and match enhancements
- Updating distribution of non-directed and bridge donors
- Policy and operational guideline alignment
- Prioritizing donor pre-select matches
- Deceased donor chains
- Data streamlining to improve data on eligibility and screening on pairs

The upcoming KPD Workgroup aims to be composed of representatives from.

#### Summary of discussion:

A Committee member asked if the KPD Workgroup and its projects are independent of the National Kidney Registry. Staff confirmed it is independent to the OPTN KPD program.

A HRSA representative suggested the Workgroup composition include representation from the Patient Affairs committee, or else have patient representatives. Staff agreed.

A Committee member asked about the timeline for potential projects. Staff noted that most initiatives are currently in the pipeline, and that the KPD Workgroup would first need to prioritize.

### 3. eGFR and Race Project Introduction

The Vice-Chair provided a brief overview of the history of estimated Glomerular Filtration Rate (eGFR), including several studies used to develop formulas for eGFR and their inclusion of a race covariate for black and non-black Chronic Kidney Disease (CKD) patients. The Vice-Chair further discussed the use of race in eGFR calculation and issues with equity in patient access, and presented the upcoming OPTN workgroup to evaluate the use of eGFR and Race for listing criteria, which will include collaboration with the Minority Affairs Committee and Kidney Transplantation Committee.

#### Data Summary:

The Glomerular Filtration Rate (GFR) can be measured, estimated, and calculated, and is used as a benchmark for kidney function. The first study to develop a formula to estimate GFR was the Modification of Diet in Renal Disease Study Group (MDRD), which calculated GFR as clearance of iothalamate and identified variables to predict eGFR through stepwise multiple regressions. Though only 12 percent of their 1600+ study population were black, the study found that black race was independently associated with a slightly higher GFR at the same creatinine level. The MDRD study group utilized a few prior, small studies that found black patients had differences in body composition among the pediatric population, total body potassium, and serum creatinine kinase to justify their finding. Creatinine differences can be related to a variety of mechanisms outside of those indicated by the MDRD study.

Subsequent modifications and studies utilized larger black cohorts, and found smaller black race coefficients. The CKD-EPI model found a coefficient of 1.159, and the CKD-EPI Cystatin-C with Creatinine found a coefficient of 1.08. The CKD Epi Cystatin-C modification found no black race coefficient.

If all other factors are held the same, a non-black patient would have a waitlist qualifying eGFR of 19.2, while a black patient could have a non-qualifying eGFR of 23.3. Mixed race patients also pose a problem for race-based eGFR formulas, and asking patients how they self-identify racially is not a sufficient method of evaluating race for the purposes of kidney candidacy evaluation.

#### Summary of discussion:

The Vice-Chair stated access to wait time accumulation is highly valuable in access to transplant, and dividing patients into black and non-black categories makes little scientific sense and supports ongoing racial disparity in access to transplant for black candidates.

The Vice-Chair further commented while there is legitimate and important debate regarding the impact of removing black and non-black from eGFR in other applications of the formula, and there are other barriers to transplant access, dropping the race covariate for the purposes of transplant listing will have immediate and important impacts for black-identifying transplant candidates eligible for listing pre-dialysis.

One member noted that some hospitals have already removed the race covariate in their eGFR calculations, and that others are in the process of doing so. The member continued that their program is currently discussing removal of the race covariate for eGFR in context of all creatinine measures for all patients in the hospital system, and the impact on CKD stage evaluation and medication dosing. The member remarked that their program has switched from the MDRD formula to the CKD Epi formula, with current discussion working towards the use of Cystatin-C or otherwise removal of race coefficient entirely. The Vice-Chair shared that her hospital stopped utilizing race in reporting, and now calculates an eGFR range accounting for a number of variables, not including race. The Vice-Chair continued that the lowest end of the eGFR range is used to list kidney candidates for transplant.

The Chair explained that the upcoming eGFR Workgroup will collaborate to decide how to address this problem and at what level, including whether policy change or education is needed.

A member asked if there was anything in OPTN Policy or the Evaluation Plan that would prevent a hospital from making their own policy to remove the race coefficient, and proposed releasing a statement or guidance notifying the transplant centers that they can make this decision on their own. The Chair confirmed that nothing in OPTN policy dictates how eGFR must be calculated, and that potential responses could include a statement or form of education. The Vice Chair confirmed that it seemed unlikely that a transplant center would be cited for not using the race covariate when policy did not dictate which eGFR formula should be used.

#### **4. Committee Appointment Update**

Staff presented an overview of the committee appointment timeline, and notified the Committee that official appointments for regional appointees and the Vice-Chair were being finalized. The Committee reviewed expected committee demographics as of July 1, 2021 to identify potential gaps in relevant expertise, medical and non-medical committee balance, surgeon and physician balance, and racial and gender diversity.

##### Summary of discussion:

The Committee had no questions or comments.

#### **Upcoming Meetings**

- February 22, 2021

## Attendance

- **Committee Members**
  - Martha Pavlakis
  - Vincent Casingal
  - Amy Evenson
  - Andrew Weiss
  - Cathi Murphey
  - Jim Kim
  - Julianne Kemink
  - Marilee Clites
  - Precious McCowan
  - Asif Sharfuddin
  - Erica Simonich
- **HRSA Representatives**
  - Jim Bowman
  - Raelene Skerda
- **SRTR Staff**
  - Bryn Thompson
  - Nick Salkowski
  - Peter Stock
  
- **UNOS Staff**
  - Amanda Robinson
  - Ben Wolford
  - Chelsea Haynes
  - James Alcorn
  - Roger Brown
  - Joel Newman
  - Jennifer Musick
  - Kayla Temple
  - Kelley Poff
  - Lauren Motley
  - Lindsay Larkin
  - Matt Prentice
  - Megan Oley
  - Meghan McDermott
  - Melissa Lane
  - Ruthanne Leishman
  - Sarah Moriarty
  - Sarah Booker
  - Tina Rhoades