

OPTN Patient Affairs Committee

Meeting Summary

April 19, 2022

Conference Call

Garrett Erdle, MBA, Chair

Molly McCarthy, Vice Chair

Introduction

The OPTN Patient Affairs Committee (the Committee) met via Citrix GoTo Meeting teleconference on 04/19/2022 to discuss the following agenda items:

1. Establish OPTN Requirement for Race-Neutral eGFR Calculations
2. OPTN Kidney Paired Donation Workgroup Update
3. OPTN Policy Oversight Committee-reviewed projects

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

1. Establish OPTN Requirement for Race-Neutral eGFR Calculations

The Committee discussed and provided feedback regarding a possible proposal to allow waiting time modifications for candidates whose eGFR was calculated using a race-based calculation.

Summary of discussion:

A member asked how many programs use a race-based eGFR calculation. Staff responded that the number of programs using a race-based eGFR calculation is unknown because that information is not collected by the OPTN.

Another member asked whether the practice of using race-based eGFR calculation will be eliminated after the implementation of this policy change. Staff confirmed and added that there already appears to be a general movement to adopting non-race based eGFR calculations in the transplant community.

A member asked for information on how a proposal regarding waiting time modifications would be implemented. Staff responded that should there be waiting time modifications for candidate's whose eGFR was calculated using a race-based formula, it would require transplant programs to be proactive to necessitate the modifications. Since the OPTN does not collection information regarding eGFR formulas, it would be the transplant program's responsibility to retrospectively review records in order to modify waiting time.

Another member asked how many patients would be impacted by waiting time modifications. Staff said it is unknown how many candidates would be impacted should a proposal to address waiting time modifications be developed, since data on eGFR formulas is not collected.

A member asked how the OPTN would track compliance to ensure programs have switched a race-exclusive eGFR calculation. Staff responded that the proposed monitoring plan states that transplant programs who are suspected to be using a race-based eGFR calculation may be evaluated.

The Chair asked whether the best eGFR calculation should be identified as a requirement to be used by all transplant programs. Staff responded that the Minority Affairs and Kidney Transplantation Committees discussed identifying a required eGFR calculation but ultimately did not want to restrict the

transplant community due to the rapidly evolving field of nephrology. The Chair asked if variation in eGFR calculations will disadvantage patients. A member responded that this may be true of a lot of laboratory tests.

The Committee supported the development of a proposal to address waiting time modifications for transplant candidates that have been impacted by the use of race-based eGFR calculations, if it is possible. If it is not possible, the Committee requests a follow-up to understand why.

The Chair asked for an overview of the timeline for this potential proposal. Staff responded that the Minority Affairs and Kidney Transplantation Committees are seeking to develop a proposal for the upcoming Fall 2022 public comment period.

A member asked what happens to transplant programs if they violate OPTN policy. Staff responded that the OPTN Membership and Professional Standards Committee (MPSC) reviews OPTN policy violations for members of the OPTN. The actions taken by the MPSC are dependent on the OPTN policy violation.

Additionally, a member requested information on the background of kidney donor profile index (KDPI) and the use of race within that calculation. Staff will follow up.

Next steps:

The feedback will be relayed to the Minority Affairs and Kidney Transplantation Committees. The Committee will be updated on the progress of the project.

2. OPTN Kidney Paired Donation Workgroup Update

The Committee discussed and provided feedback regarding recent work of the OPTN Kidney Paired Donation (KPD) Workgroup.

Summary of discussion:

A member asked whether a paired candidate is guaranteed a kidney within a year of when their paired donor donates. Staff responded that there are various KPD programs in the United States, and the KPD Workgroup works with the OPTN KPD Pilot Program (KPDPP). The OPTN KPDPP does not guarantee a transplant within a year of a paired donor's donation. However, the OPTN KPDPP categorizes candidates in these situations as "orphan candidates", and these individuals receive a lot of priority in match runs to ensure they have as much access to transplant as possible.

Another member asked how many transplants occur within the OPTN KPDPP. Staff responded that prior to the COVID-19 pandemic there were about fifty transplants a year; currently, it has decreased to about twenty to thirty transplants a year and is appearing to increase.

The Committee was asked to provide feedback regarding informed consent for KPD living donors. The KPD Workgroup is discussing the potential to specify and emphasize specific financial risks within informed consent that may be important to KPD living donors.

A member stated that the informed consent should be broad, and inclusion of financial risk is important as many individuals may not consider that when becoming a living kidney donor. For example, living donors may want to update their life insurance policies prior to donation so that they can potentially secure a lower rate than they might receive after donation. The Committee agreed.

The Vice Chair asked about legislation regarding insurance coverage for living donors. Staff responded that the KPD Workgroup is discussing adding references to financial resources into KPD informed consent.

Another member stated that informed consent should include potential psychosocial outcomes post-donation for living donors. A member agreed and added that resources could be added to this as well.

The KPD Workgroup is discussing the potential to update the OPTN KPD policy related to bridge donors. The KPD Workgroup is seeking feedback on whether a signature should be required for a bridge donor's informed consent approval. A member responded that it is necessary to have as many signatures as needed to ensure that individuals understand and have clearly reviewed the documentation. Another member agreed and stated that signatures should be required before an individual goes to the operating room in order to have a meaningful conversation. The Chair stated that a continuous conversation regarding consent to donate is as important, if not more important, than a signature.

Next steps:

The feedback will be relayed to the KPD Workgroup as they develop a policy proposal.

3. OPTN Policy Oversight Committee-reviewed projects

The Committee reviewed projects recently approved by the OPTN Policy Oversight Committee (POC).

Summary of discussion:

A summary of recently approved OPTN committee projects by the POC:

- Apply Transplant Program Notification Requirements for Vascularized Composite Allograft (VCA) Program Inactivation, OPTN VCA Committee
- Continued Review of National Liver Review Board Policy and Guidance, OPTN Liver and Intestinal Transplantation Committee
- Improve Deceased Donor Evaluation for Endemic Diseases, OPTN Ad Hoc Disease Transmission Advisory Committee
- Require Confirmatory HLA Typing for Deceased Donors, OPTN Histocompatibility Committee

These committees do not anticipate collaborating with the Committee on these projects. There were no comments or questions.

Upcoming Meetings

- May 17, 2022 (teleconference)
- June 21, 2022 (teleconference)
- July 18, 2022 (teleconference)

Attendance

- **Committee Members**
 - Betsey Brada
 - Christopher Woody
 - Chris Yanakos
 - Darnell Waun
 - Diego Acero
 - Earl Lovell
 - Eric Tanis
 - Garrett Erdle
 - James Sharrock
 - Julie Ice
 - Julie Spear
 - Justin Wilkerson
 - Justine Van Der Pool
 - Kenny Laferriere
 - Kristen Ramsay
 - Molly McCarthy
 - Sarah Koohmaraie
 - Sejal Patel
- **HRSA Representatives**
 - Jim Bowman
- **SRTR Staff**
 - Katie Audette
- **UNOS Staff**
 - Kaitlin Swanner
 - Kayla Temple
 - Kelley Poff
 - Kim Uccellini
 - Lauren Motley
 - Meghan McDermott
 - Sara Rose Wells
- **Other Attendees**
 - Calvin Henry
 - Dana Hong
 - Laurel Avery
 - Lorrinda Gray-Davis
 - Steve Weitzen
 - Wendy Leavitt