

Meeting Summary

OPTN Minority Affairs Committee Meeting Summary April 4, 2024 Conference Call

Alejandro Diez, MD, Chair Oscar Serrano, MD, Vice Chair

Introduction

The OPTN Minority Affairs Committee (the Committee) met via Webex teleconference on 04/04/2024 to discuss the following agenda items:

- 1. Refit Kidney Donor Profile Index (KDPI) without Race and Hepatitis C (HCV)
- 2. Modify Waiting Time for Candidates Affected by Race-Inclusive estimated Glomerular Filtration Rate (eGFR) Calculations
- 3. Project Prioritization Discussion
- 4. New Project Next Steps

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

1. Refit Kidney Donor Profile index (KDPI) without Race and Hepatitis C (HCV)

The Committee reviewed public comment feedback as it relates to their *Refit KDPI without Race and Hepatitis C* public comment proposal.¹

Presentation summary:

Public Comment Analysis:

- Generally, public comment sentiment has been supportive of this proposal
 - Sentiment scores by member type range from 4.1 to 4.9.
 - The total sentiment score of 4.3 was indicated by member type and regional meeting feedback
 - Sentiment scores by region ranged from 3.4 to 4.7, with most regions supporting or strongly supporting the proposal
 - Opposition was observed in 9 regions, particularly prominent in region 6
 - Concerns in region 6 were primarily related to the removal from the calculation and its impact on the pediatric population
 - Overall, support outweighed opposition

Public Comment Themes:

- Support for the removal of race & HCV from KDPI
- Discussion on SRTR modeling
- Potential impact on pediatric population

¹ "Refit KDPI without Race and Hepatitis C," OPTN, Public Comment Proposal, available https://optn.transplant.hrsa.gov/media/ekkfxy4t/mac_kdpiracehcv_pcjan24.pdf.

• Apolipoprotein L1 gene (APOL1) Testing

SRTR staff presented the data related to the addendum request from public comment related to discrimination and calibration of the new model. The SRTR reported that none of the coefficients showed concern or large change. Plot graphs revealed no increase in risk from the new model. Overall, removing donor race and HCV status from the model estimating KDRI does not have a substantial impact on model fit statistics.

Summary of discussion:

Vote: Do you support sending *Refit Kidney Donor Profile Index without Race or Hepatitis C* as presented today to the OPTN Board of Directors for consideration?

Support (12), Abstain (0), Oppose (0)

One member pointed out potential data skewing due to the significantly larger number of respondents from transplant hospitals compared to other member types, such as Organ Procurement Organizations (OPOs). With 210 respondents from transplant hospitals versus 56 from OPOs, he asked the Committee to consider the broader context of the data to avoid drawing conclusions solely based on the larger group. In discussing the potential impact of the policy change on the pediatric patient population, the Committee Chair emphasized the principle of maximizing benefits for the greatest number of patients. He noted that the percentage of deceased donors utilized for pediatric candidates is relatively small.

Vote: Do you support sending *Refit Kidney Donor Profile Index without Race or Hepatitis C* as presented today to the OPTN Board of Directors for consideration?

Support (12), Abstain (0), Oppose (0)

Next steps:

This proposal will move forward to the OPTN Board of Directors in June 2024.

2. Modify Waiting Time for Candidates Affected by Race-Inclusive eGFR Calculations

OPTN Membership and professional Standard Committee (MPSC) Staff presented an eGFR monitoring policy referral project that would require every transplant hospital to maintain a written protocol that can be reviewed by site survey.

Presentation summary:

MPSC Project Referral:

- Jan 19 MPSC meeting- The OPTN policy (3.7.D) as written does not provide direction to programs on how they should meet the requirements or document their processes
 - Leads to compliance monitoring challenges
- MPSC Recommendation: Require every transplant hospital to maintain a written protocol that can be reviewed by site survey
- Referred to:
 - MAC for previous eGFR policy experience
 - Kidney for subject matter expertise
- Urgency- High
 - Response to MPSC and POC leadership by June 1, 2024

Summary of discussion:

The Committee did not make any decisions.

When discussing the potential development of a template, a committee member suggested it may be helpful for standardization, although staff indicated that a guidance document or educational course might be more suitable within policy constraints. The Chair and other members agreed that a guidance document or simple statement could be effective. Staff clarified that the MPSC did not provide specific criteria for the referral, emphasizing that the Committee would primarily determine the criteria.

When considering the urgency of the referral project, the Chair emphasized the need to prioritize it alongside other projects. A member suggested proceeding with the project but acknowledged that while urgent, it may not require immediate attention.

Next steps:

The MAC will discuss the prioritization of this project.

3. Project Prioritization Discussion

The Committee discussed projects for consideration and how they should be prioritized.

Presentation summary:

Projects to Prioritize:

- Incarcerated Populations Project
- MPSC Referral on eGFR Monitoring

Incarcerated Population Project:

- Need: Equity in access to transplantation for incarcerated individuals
- Impact: Guidance document that recommends best practices
- Not aligned with 2024-2027 strategic plan goals
- Feasibility: There is not a great amount of data available, but there is potential to use the OPTN survey process

Summary of discussion:

Decision: The Committee will prioritize the MPSC referral project first, then will consider the incarcerated population project.

The Chair highlighted the organic origin of the incarceration population project within the Committee, emphasizing its perceived importance and the recognized need for its development. The Chair acknowledged the potential for the MPSC referral project to receive streamlined approval due to MPSC appetite and noted the MAC's previous ownership of eGFR projects. One member expressed that addressing the incarcerated population project might be challenging given the significant amount of work required. They proposed prioritizing the MPSC referral project, as the Committee has already worked on the policies related to it. Another member agreed, advocating for prioritizing the MPSC referral to prevent it from being delayed behind the potentially lengthier incarcerated populations project. They suggested that collecting necessary data for the incarcerated population project could be pursued simultaneously but should be a secondary effort to the eGFR monitoring policy project.

Next steps:

The Committee will discuss next steps for the eGFR monitoring policy project

4. New Project Next Steps

OPTN contractor staff provided an overview of the Committees next steps as they proceed with the MPSC Referral on eGFR Monitoring.

Presentation summary:

MPSC Referral on eGFR Monitoring:

- Purpose: Enable compliance monitoring to ensure that all candidates are being properly evaluated for eligibility for a Waiting Time Modification for Kidney Candidates affected by Race-Inclusive eGFR Calculations
- Proposal: Require every transplant program to maintain a written protocol that outlines the process for completing eGFR calculations and checking if new additions to the OPTN Waiting List qualify for waiting time modifications
- Monitoring: OPTN staff can monitor these policies by reviewing the written protocols for compliance with OPTN criteria, conducting staff interviews to ensure practice is in alignment, and requesting eGFR documentation for patients in survey samples

Other Considerations by MPSC:

- eGFR calculator built into the OPTN Computer System
 - Decided against this since formulas are constantly being worked on and updated, this would require the OPTN to select one calculator, and because there are no validated formulas for a patient with just one kidney
- Additional member burden:
 - Policies 1.2 and 3.7.D currently do not have a sunset date identified
 - Concluded that this policy improvement would still benefit patients who are referred for transplant past recipients a qualifying eGFR score

Summary of discussion:

The Committee did not make any decisions.

The Chair agreed with the decision not to incorporate a built-in calculator into the OPTN Computer System. He noted that various methods exist to assess renal function, making it impractical to prescribe a specific formula. The Chair suggested inviting a representative from the transplant administrator community to provide insight into the internal workings of transplant programs, as their early involvement would benefit the Committee and the project.

Upcoming Meeting

• April 15, 2024

Attendance

• Committee Members

- o Alejandro Diez
- o Oscar Serrano
- o Steven Averhart
- o John Bayton
- o Donna Dennis
- o Sandy Edwards
- o Amaka Eneanya
- o Christiana Gjelaj
- o Adrian Lawrence
- o Jason Narverud
- o Anthony Panos
- Catherine Vascik
- HRSA Representatives
 - o Shelley Tims Grant
 - o Mesmin Germain
- SRTR Representatives
 - o Bryn Thompson
 - o Jon Miller
- UNOS Staff
 - o Kelley Poff
 - Alex Carmack
 - Carol Covington
 - o Jessie Howell
 - Houlder Hudgins
 - o Kaitlin Swanner
 - o Jamie Panko

• Other Attendees

o Christy Baune