OPTN Minority Affairs Committee
Meeting Summary
September 30, 2024
Detroit, Michigan

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

Introduction

The OPTN Minority Affairs Committee (the Committee) met in Detroit, Michigan on 09/30/3034 to discuss the following agenda items:

1. Current Project: *Monitor Ongoing eGFR Modification Policy Requirements*
2. Implementation Update: *Refit Kidney Donor Profile Index without Race and Hepatitis C Virus*
3. Update: Expeditious Task Force
4. Update: Continuous Distribution

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

1. Current Project: *Monitor Ongoing eGFR Modification Policy Requirements*

Contractor staff reviewed the timeline of the project with an anticipated date of January 2025 for public comment. Staff reminded the Committee this project was referred by the OPTN Members and Professional Standards Committee (MPSC).

Contractor staff reviewed feedback on the project from other stakeholder OPTN Committees, and then remaining questions the Committee needs to address before the project can move forward. These questions include:

- Could confirmation of candidate race also include internal audit for any discrepancies in the Electronic Medical Record (EMR) vs intake and registration documents, face to face confirmation, email, or other processes?
- What are effective practices for documenting compliance with eGFR monitoring policy?
- Should there be a requirement for transplant programs to notify candidates of their eligibility?
- Should fulfillment of the notification requirements be documented by transplant programs in each candidate's EMR?
- Should candidates registered from January 4, 2024, onward be required to receive an outcome notification from the transplant program?

Summary of discussion:

Decision #1: The Committee reached a consensus that all candidates should be notified regarding their eGFR modification outcome, including those candidates registered from January 4, 2024, onward.

Decision #2: The Committee reached a consensus that centers should have a document review and notification process for site survey and auditing purposes. The Committee agreed that it should be up

to the individual centers to develop their own process, but the process must be written and documented.

Members emphasized the importance of having a documented process for confirming candidate race to ensure accurate representation in transplant program documentation and the OPTN waiting list. The Committee and guests from the OPTN Transplant Coordinators Committee (TAC) use various approaches (differing by centers), including two-coordinator verification systems, patient self-identification forms, and verbal confirmations. Members agreed that documentation could take multiple forms, such as electronic medial records (EMR) notes, printed verification forms with date and initials similar to ABO verification, or internal audits comparing EMR data with OPTN listing information. The Committee addressed concerns about mixed-race candidates and those who might discover African American ancestry through genetic testing, noting that race is self-identified and can be updated if new information emerges. Some Members described using letters to inform candidates of their listed race and providing opportunities to correct any misidentification. Regarding notification requirements, the Committee discussed updating the terminology from "eligibility" to "outcome" notification to prevent misinterpretation and ensure candidates receive complete information about their modification status. Members agreed that all candidates should be informed of the policy upon registration, and that notifications about the policy and outcomes could be delivered either separately or together, depending on candidate eligibility. Multiple members of the Committee emphasized the importance of clear and specific communication with candidates about their eligibility and outcomes, recommending education at a fifth-grade comprehension level to ensure understanding.

Members emphasized the importance of informing all candidates about the policy, not just those identifying as Black or African American, since some patients may not initially disclose their race or may be multiracial. The discussion highlighted that education should occur at multiple points throughout the evaluation process, including initial evaluation and listing, with programs having flexibility in their education methods (PowerPoint presentations, videos, written materials, or one-on-one conversations).

Committee members discussed the challenges of patient education, noting that many patients, particularly those with heart failure, may need multiple conversations to fully understand the information due to their medical conditions. They emphasized the importance of being specific when explaining why patients do or do not meet criteria. The Committee clarified that this process involves two steps: first, educating patients about the policy and their potential eligibility, and second, notifying them of the outcome of any waiting time modifications. They agreed that education should be documented, though programs should have flexibility in how they document. For example, through EMR notes, checklists, or other methods that could be center specific.

Committee members noted that different programs handle education differently, with some conducting group sessions and others providing individual education. The Committee discussed various points where education could occur, such as during evaluation appointments or activation training. Members emphasized that while the specific format of education could vary by program, the key requirement is that programs must be able to demonstrate to site survey personnel that they provided both education about the policy and notification of eligibility/outcomes.

The Committee discussed flexibility for centers in implementing these requirements while maintaining clear documentation of their process. Members agreed that integrating this education into existing patient education processes could be effective. A member emphasized the importance of giving special attention to this topic given its historical impact on disadvantaged patients. They noted that some disagreement still exists in the nephrology community regarding eGFR calculations, underlining the importance of clear communication with patients about this policy.

The Committee then discussed notification requirements for candidates registered from January 2024 onward. While there was initially no requirement for a second outcome notification due to concerns about program burden, members ultimately agreed that patients should be notified of the outcome of their eGFR modification review, whether or not they received additional waiting time. This decision was driven by patient feedback and the importance of transparency, while acknowledging the additional workload for transplant centers. The Committee discussed how to operationalize these notifications, suggesting that centers should document their notification process while maintaining flexibility in their specific approach. Members emphasized that while the method of notification could vary by center, documentation should be in writing to protect both centers and patients. They also clarified that transplant candidates that were transplanted and are therefore considered recipients would not require notification as they would no longer fall under this policy. Regarding documentation protocols, the Committee discussed the importance of centers having a consistent, documented process for reviewing supporting documentation, with programs specifying their minimum sources for review. Members agreed that while the specific sources might vary between centers using different systems, having a documented protocol would help standardize the process within centers and make it auditable, while also serving as a guide for new coordinator training.

Next steps:

The Committee will continue to discuss this project during their October and November 2024 meetings.

2. Implementation Update: Refit Kidney Donor Profile Index without Race and Hepatitis C Virus

The Committee reviewed data and addressed implementation questions regarding the Refit Kidney Donor Profile Index (KDPI) without race and Hepatitis C Virus (HCV) project.

Contractor staff presented the Kidney Donor Risk Index (KDRI) to KDPI mapping table. The mapping table was updated in April 2024, to be based on kidney donors from 2023. The KDPI mapping table will change again as a result of the removal of race and HCV from KDPI. When tracking raw KDRI distribution over time, the values for the 50th percentile, 75th percentile, and 95th percentile slightly decreased this year compared to previous years.

Summary of discussion:

No decisions were made by the Committee.

The Committee discussed changes to KDPI calculation with the removal of race and HCV variables. The data showed that without these variables, the risk of graft failure decreases for kidneys with KDPI of 95 and 75, while showing a modest increase in lower KDPI kidneys, demonstrating the "zero sum game" nature of the changes. A committee member mentioned that the OPTN Pediatric Committee raised concerns about pediatric candidates potentially receiving HCV-positive organs, noting that pediatric treatments for HCV are not approved. Additional concerns were raised about the smaller pool of kidneys in the 0-20 KDPI range, as some kidneys would shift into higher KDPI categories due to the remaining variables carrying more weight.

The Committee examined implementation planning and potential community questions, including how the policy change affects the KDPI scale, deceased donor kidney offers, equity, and impact on non-black donors and candidates. The discussion focused on the potential for increased appetite for higher KDPI organs, as the data suggested these organs may perform better than previously measured. Members noted that the historical discard rate for black donor kidneys was higher than for white or Hispanic donors, partly due to KDPI calculations. A member of the Committee acknowledged that while a

complete revamp of the KDPI system might be beneficial ("KDPI 2.0"), the current changes focusing on race and HCV were chosen as more immediate solutions to address clear inequities.

Some members of the Committee raised concerns about the potential stigma of high KDPI kidneys and whether the changes might lead to more non-utilization of organs. However, one member noted that the data suggested KDPI 85-90 kidneys might not be "as bad as we thought," and the changes could actually increase the appetite for transplanting these organs. A contract staff member clarified that while the proportion of organs above 85% KDPI would remain constant due to the percentile-based system, the specific organs falling into that category would change, with fewer black donor organs in the higher KDPI ranges.

3. Update: Expeditious Task Force

A member of the OPTN Expeditious Task Force (the Task Force) presented an update to the Committee on the ongoing work of the Task Force.

The presenter updated the Committee on the three ongoing non-use initiatives, reviewed the rescue pathways protocol that will be launching soon, and updated the committee on the Transplant Growth Collaboration events that are taking place which are intended to increase c-suite level support for transplant growth.

Summary of discussion:

No decisions were made by the Committee.

The Committee discussed several key aspects of organ reallocation and efficiency. A member asked about the breakdown of specific organ types within the 48% reallocation rate mentioned. The presenter acknowledged they didn't have the detailed breakdown but emphasized the importance of being granular and descriptive, noting that different solutions may be needed for each organ type as the reasons for non-use may vary.

A member raised a question about reviewing previous initiatives, specifically referencing their involvement with the COIN initiative that focused on high KDPI kidneys and inter-center collaboration. They mentioned their center's continued use of a kidney shortlist for quick recipients of rescue pathway kidneys, questioning whether this was still common practice. The presenter agreed on the importance of not "reinventing the wheel" and expressed interest in identifying and sharing effective practices across the broader community.

The discussion addressed geographical challenges, with a member highlighting the significant differences between OPOs in areas like Minnesota versus smaller OPOs with multiple airports. The member noted how factors like location and flight availability impact cold time, particularly for kidneys from rural areas. The presenter agreed, acknowledging that different solutions might be needed for different areas while maintaining some standardized best practices.

A member raised a question about the current punitive system where centers face consequences for graft loss, suggesting consideration of a reward program for larger centers able to take higher-risk kidneys. The presenter acknowledged the need to align metrics and incentives with desired outcomes, noting that current evaluation methods might create barriers. They mentioned feedback from the OPTN Region Ten meeting regarding potential "hold harmless" mechanisms for centers using high KDPI organs.

4. Update: Continuous Distribution

Contractor staff presented an up to the Committee on the OPTN's work to change from a classification-based system to a points-based system with Continuous Distribution.

Continuous Distribution shifts organ allocation from a classification-based system to a points-based system, eliminating rigid categorization in favor of a more fluid scoring approach based on multiple factors. Lung allocation was the first to implement this system, showing promising results including a 29% decrease in waitlist mortality, though it has led to increased travel distances for organs. The framework demonstrated flexibility when addressing an unexpected decline in blood type O lung transplants, allowing for rapid policy adjustment. Other organs are at various stages of implementation, with kidney and pancreas committees particularly focused on organ utilization and efficiency. Recent improvements include the addition of offer filters for lung, heart, and liver allocation to help manage increased offer volumes, as well as enhancements for handling single versus double lung offers and considerations for geographically isolated areas.

Summary of discussion:

No decisions were made by the Committee.

During the presentation, a member noted interesting findings about distance distribution patterns, particularly in the non-DCD cohort, where the distribution showed a smoother decline in organ allocation over distance compared to the previous DSA system. The discussion then focused on placement efficiency points and distance considerations in organ allocation. Contractor staff explained that the committee had reviewed an Scientific Registry of Transplant Recipients (SRTR) analysis to determine typical transition points from driving to flying, with inflection points around 45 and 90 miles. The staff member elaborated that the rating scale allocates 10 points for placement efficiency, with candidates within 1000 nautical miles of the donor receiving at least 7 points, a decision based on modeling that showed increasing efficiency beyond this level could increase waitlist deaths. A member raised questions about considering actual travel time versus straight-line distance, noting the differences between urban and rural transportation challenges. Contractor staff acknowledged that while travel time has not been specifically studied, geographical differences between regions were considered in developing the rating scales. A member asked about post-transplant survival outcomes, with contractor staff indicating that initial data would be available in an upcoming 18-month report once sufficient data had been collected.

Upcoming Meetings

- October 16, 2024, 3-4pm ET
- November 18, 2024, 3- 4pm ET

Attendance

- **Committee Members**
  - Alejandro Diez
  - Oscar Serrano
  - Adrian Lawrence
  - Tony Panos
  - Christina Baune
  - Steve Averhart
  - John Bayton
  - Donna Dennis
  - Sandy Edwards
  - Obi Ekwenna
  - Hilda Fernandez
  - Ruben Quiros Tejeira
  - Catherine Vascik
- **HRSA Representatives**
  - Adriana Alvarez
  - Shelley Tims Grant
- **SRTR Staff**
  - Kait Siegert
- **UNOS Staff**
  - Kelley Poff
  - Alex Carmack
  - Kaitlin Swanner
  - Houlder Hudgins
  - Kimberly Uccellini
  - Meng Li
  - Dave Roberts
  - Susan Tlusty
- **Other Attendees**
  - Darla Granger
  - Karl Neumann
  - Kristin Smith
  - Martha Pavlakis
  - Silas Norman