OPTN Kidney Transplantation Committee
Meeting Summary
April 15, 2024
Teleconference

Jim Kim, MD, Chair
Arpita Basu, MD, Vice Chair

Introduction

The Kidney Transplantation Committee (the Committee) met via teleconference on 4/15/2024 to discuss the following agenda items:

1. 1-Year Monitoring Report: *Modify Waiting Time for Candidates Affected by Race Inclusive estimated Glomerular Filtration Rate (eGFR) Calculations*
2. OPTN Membership and Performance Standards Committee (MPSC) Referral on eGFR Monitoring
3. Voting Item: Kidney Donor Profile Index (KDPI) and Expected Post-Transplant Survival (EPTS) Mapping Tables

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

1. 1-Year Monitoring Report: *Modify Waiting Time for Candidates Affected by Race Inclusive eGFR Calculations*

The Committee received an update on monitoring data on the modification of waiting times for candidates affected by race inclusive eGFR calculations.

Presentation Summary:

The purpose of this report was to provide follow-up on requirements for all kidney transplant programs to submit an attestation affirming that the program completed review of their waiting lists and request for eGFR waiting time modification for all registered Black kidney candidates impacted by race-inclusive eGFR calculations. This policy was implemented on January 5, 2023, with completion of this requirement due by January 3, 2024. Evaluation was to be completed at approximately six months and one yar post-implementation.

There was a total of 14,701 processed modifications between January 5, 2023 and January 3, 2024. 14,503 registrations had at least one processed waiting time modification and 196 registrations received more than one waiting time modification. 13,528 patients had at least one registration with a processed waiting time modification. As of January 4, 2024, there were 781 modifications marked as not processed. Reasons a modification may be marked as not processed include, but were not limited to, errors in submitted documentation such as missing dates or lab values or the candidate not being eligible due to policy requirements. The number of modifications marked as not processed changes as proper documentation is received and the Organ Center continues to accept new documentation for modifications marked as not processed. The total of 2,709 candidates with a waiting time modification received a deceased donor transplant and 158 received a living donor transplant. As of January 4, 2024, the OPTN received attestations from all 230 active kidney programs (including pediatric programs) confirming that they went through their lists, sent the required notifications, and submitted all required waiting time modifications.

The data was broken down by:

- Distribution of waiting time awarded
    - The median time awarded to registration with a processed waiting time modification was 1.7 years, with 75 percent of registrations receiving 2.9 years or less.
    - About 50 percent of the modified registrations received between 1 and 3 years of waiting time.
    - The maximum time gained was 21 years.
- Number of Processed Modifications by Date Processed
    - June 2023 was the month with the most modifications processed, followed by July 2023.
    - April, May, and June reflected a large spike in activity and this correlates with education and webinars on this topic.
- Number of Modified Registrations by Registration Year
    - The majority of registrations with a processed modification were added to the waiting list in either 2022 or 2023.
    - There were 42 individuals with modified registration who were registered prior to 2012.
- Modified Registrations by Blood Type
    - The majority of registrations with a processed modification were for blood type O candidates (53.99 percent). This distribution is similar to the distribution of all Black, non-Hispanic registrations on the waiting list from January 5, 2023, to January 3, 2024 where 53.52 percent were blood type O. This similar distribution was true across all blood types.
- Modified Registrations by Birth Sex
    - The majority of registrations with a processed modification were for male candidates (57.49 percent). The distribution of modified registrations by registrant's birth six was similar to the distribution of all Black, non-Hispanic registrations on the waiting list from January 5, 2023, to January 3, 2024 where the majority were for male candidates (59.74 percent).
- Modified Registration by Age at Listing
    - The majority of registrations with a processed modification were for candidates aged 50-64 years old at listing (48.05 percent), followed by candidates aged 35-39 at listing (26.69 percent). The distribution of modified registrations by age at listing is similar to distribution of all Black, non-Hispanic registrations on the waiting list from January 5, 2023, to January 3, 2024, where 44.13 percent were aged 50-64 at listing and 29.44 percent were age 35-49 at listing.

Summary of discussion:

A participant asked how many centers had no waiting time modifications when submitting their attestation. This information was not included in this report. OPTN Contract staff shared that centers with no modification requests were submitted to the MPSC for follow-up. Additional information from the MPSC perspective was to be shared later in the meeting.

A Committee member asked if there was a graph that superimposes the number of transplants versus how much time was awarded. There was interest in better understanding where the transplant occurred according to the adjust median waiting time. OPTN Contractor staff noted that this was not looked at for this report. The Committee member recognized that this would be interesting data, but perhaps a lot of work to obtain. The member questioned whether those with the most waiting time added were transplanted quickly.

The Chair noted that this is ongoing, and programs still have the opportunity to request modifications as they evaluate and list new patients. The Chair agreed that it will be important to understand how this new policy impacted the end result, which is hopefully transplanting these individuals.

There was a request to understand how these numbers aligned with the projections for waiting time modifications. Without anyone on the call directly involved in these projections, the OPTN Contractor staff noted that she believes the actual data fell between the two projections (with one being on the high end and the second reflecting the lower end.[1]

A Committee member shared anecdotal data that his center saw a patient two patients transplanted within days of a week of their waiting time adjustment.

Next steps:

OPTN Contractor staff shared that the Contractor is conducting a survey to gather information on how committee members use monitoring reports and what improvements they would like to see in the future. The survey focuses on three topics: content, delivery, and structure. The survey link will be circulated after the meeting. She requested that Committee members take some time to provide feedback through this survey.

2. MPSC Referral on eGFR Monitoring

The Committee received an update from the OPTN Contractor staff regarding a referral from the MPSC.

Presentation Summary:

As background regarding this request, the OPTN Contractor staff shared that the MPSC may recommend a policy change when it finds a policy is:

- No longer applicable or lacking necessary elements based on changes in practice;
- Confusing to members;
- Difficult to monitor;
- Difficult to enforce; or
- Can be improved to address known safety or efficiency issues.

The MPSC's process for identifying these opportunities for improvement and seeking resolution was shared with the Committee:

1. First, the MPSC case reviews identify trends or opportunities for improvement
2. The MPSC then discusses the issue and determines if it should be referred to a policy committee
3. Staff summarize the issue and MPSC project recommendations
4. Policy Committees and the Policy Oversight Committee Leadership receive the MPSC referral
5. Policy Committees review suggestions and provide response to the POC/MPSC within 2 months
6. Recommendations that result in a project enter the policy development lifecycle

Information included in referrals from the MPSC includes (1) a description of the problem and any relevant MPSC suggestions; and (2) the urgency and priority of each issue referred for review. Committees receiving such referrals are asked to review and decide if they agree to proceed with the

[1] Pavlakis, Martha. A Restorative Justice Project in Kidney Allocation—The Wait Time Modification for Black and African American Candidates Affected by the Race-Based eGFR Equation. Journal of the American Society of Nephrology 34(10):p 1618-1620, October 2023. | DOI: 10.1681/ASN.0000000000000198

project, documenting their decision. If a committee agrees, they must identify a timeline to start project work. If the committee does not agree, it must provide a plan for follow-up (including need for additional information, a data request, level of urgency, additional collaborators, or other elements relevant to an issue). The committee must also establish if it considers the project to be urgent and identify whether other OPTN committees should co-sponsor or collaborate on the project.

During its January 19, 2024 meeting, the MPSC asserted that OPTN Policy 3.7.D (Waiting Time Modifications for Kidney Candidates Affected by Race-Inclusive eGFR Calculations)[2] does not provide direction to programs on how they should meet the requirements or document their processes to address review and request for waiting time modifications. This has led to compliance monitoring challenges. OPTN Contractor staff noted that some centers had no wait time modifications or very low rates of wait time modifications for their population. The OPTN Board of Directors asked that inquiries be sent to these centers. Some of the reasons why these numbers were so low or even zero were that some programs had implemented a race-neutral calculation years in advance of it becoming a requirement. Review of some centers with other reasons are still underway and not available for discussion. During these discussions, it was recognized that the policy, as written, does not provide direction to programs on how to meet the requirements or document their processes. This leads to compliance monitoring challenges. In this case, an OPTN Board directive drove the follow up, but regular monitoring will not be possible without these requirements being specifically outlined in policy.

As a result, the MPSC recommends that every transplant hospital maintain a written protocol that can be reviewed during site surveys. This would be for patients listed going forward and would not necessarily include further attestations. This issue was referred to the Minority Affairs Committee for previous eGFR policy experience and this Committee for subject matter expertise. The urgency for this request was noted as high, with a response due to MPSC and POC leadership by June 1, 2024.

OPTN Contractor staff noted that the Minority Affairs Committee heard the referral on April 4, 2024, and is eager to take on the work, with input from the Kidney Committee. Any questions or feedback were sought to determine interest from the Committee in providing input to Minority Affairs on this project.

Summary of discussion:

The Committee was supportive of the Minority Affairs Committee leading the MPSC referral request effort and providing subject matter expertise as needed.

Volunteers interested in working with the Minority Affairs Committee to consider and address the MPSC referral were asked to let OPTN Contractor staff know.

OPTN Contractor staff noted that this MPSC request had been discussed with Committee leadership upon receipt. Additionally, the full Minority Affairs Committee heard the referral at their in-person meeting in early April. They are eager to take on this work with input from this Committee.

A Committee member asked if the MPSC had recognized any discrepancies in waiting time for patients who are listed at multiple centers, as this might be dependent on which transplant program provided the data for review. The Committee member explained that the candidate may have received different waiting time modifications at different programs, depending on the lab values available to and used by the programs they are listed at. The member asked if there has been any effort to see if there are such

[2] OPTN Policy. https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf (Accessed on 4/19/2024)

discrepancies for multi-listed patients. OPTN Contractor staff noted that this was not part of the MPSC inquiries sent earlier this year.

A Committee member asked if there were other reasons outside of using the race neutral equations as to why centers did not have any or had very few waiting time modifications. OPTN Contractor staff explained that one of the reasons where centers had less than 20% modifications was based on population demographics. Other inquiries from MPSC were based on the desire to make sure that every avenue available to seek this data and make modifications had been exhausted and that information had not been included in the inquiry response. Many of the follow ups were completed to get more details in terms of continued inquires to alleviate any and all concerns and make sure that every possible avenue had been explored. The Committee member noted that this data may be critically informative. OPTN Contractor staff noted this request can be explored with OPTN Contractor research. If an official data request is needed, this could be pursued as part of this referral effort.

The Chair recognized the importance of these questions being explored as part of this referral process. It will be important that, though the Minority Affairs Committee will take the primary lead on this referral, there is Committee representation engaged in the effort. It was acknowledged that the Minority Affairs Committee's focus may be slightly different from this Committee, so there is value in collaboration to recommend a stronger monitoring process and serve the public.

The Chair asked if Committee members were comfortable with the Minority Affairs Committee taking the lead on this referral and requested that Committee members interested in participating in this effort let OPTN Contractor staff know.

A Committee member commented that monitoring multi-listed candidates will be a good metric to consider, determining if they were able to secure the same amount of qualifying time across centers.

A Committee member questioned whether the process that each transplant program may be asked to develop is meant to capture patients who may have been impacted by a calculation in the past or for moving forward as far as standard workflow. OPTN Contractor staff noted that the MPSC recommendation is that a workflow is established that allows for continuous monitoring as patients are listed so that hospitals are all meeting the same set criteria that satisfies concerns that all patients are being properly compensated with waiting time for any disadvantage.

A Committee member noted that discrepancies between multi-listed patients is something that should be proactively looked into. OPTN Contractor staff noted that a formal data request could be developed to look into multi-listed patients, and that this could be considered by the Minority Affairs Committee in taking this project on.

A Committee member shared the challenges in accessing this data, as there is no uniformity in how to gather it. When candidates have moved to your center or are not really cognizant of their medical history, finding this information is very difficult. This could be the result of variances in multi-listed patients. The idea of the OPTN warehousing this data was suggested to reduce these center challenges by seeing what other centers have found to help assure that patients get the waiting time modifications evenly across all centers.

The MPSC recommendation is for programs to codify their process into a written policy and outline any particular criteria that the committees feel are important here. Recognizing the administrative burden that was introduced to this system, a Committee member asked how this will ensure compliance. The OPTN Contract staff noted that this policy is not currently being monitored outside of the attestations. This additional policy will enable continuous monitoring to determine whether programs are following the policy that they outline. Current *Policy 3.7.D* does not require documentation. It requires submission

of the actual wait time modification, but not the process used to seek the information driving the modification. A participant questioned whether the process for seeking this information would vary between programs. It was noted that this may be part of the discussion on addressing the referral.

A Committee member asked if the current policy allowing for qualifying wait time modifications is ongoing, or if it has an end date. There is no sunset date for this policy at this time, but this may be something discussed in the future as this referral and future monitoring is considered by Minority Affairs and this Committee.

Next Steps:

Committee members were asked to share their interest in working with the Minority Affairs Committee on this MPSC referral with OPTN Contractor staff.

3. Voting Item: KDPI and EPTS Mapping Tables

The Committee reviewed the annual remapping tables for KDPI and EPTS, and voted to approve KDPI and EPTS remapping.

Presentation Summary:

OPTN Contract staff shared that, each year, the Committee must review KDRI and EPTS mapping tables. Each donor's Kidney Donor Risk Index (KDRI) is converted to a Kidney Donor Profile Index (KDPI) percentage using a KDRO to KDPI mapping table. This table is based on all deceased donor kidneys recovered in the previous calendar year. The current table is based on 2022 donors. Ther reference population used to determine this mapping is reviewed annually by the Committee and updated by the OPTN Contractor on or before June 1 of each calendar year.

EPTS works similarly. The EPTS mapping table is used to convert a candidate's raw EPTS score into an EPTS score, with all scores rounded to the nearest integer. Similarly, the reference population used to determine the top 20% EPTS threshold is reviewed annually by the Committee and updated by the contractor on or before June 1 of each calendar year.

KDPI updates recommended this year:

- Reference population will be updated to 2023 (from 2022)
- Subtle changes year-over-year related to Kidney Donor Risk Index (KDRI) distribution over time. There is a slight increase.
- In tracking the KDRI distribution over time, there were increases in the 25th, 50th, 75th, and 95th percentiles, while the 5th percentile remained the same.
- Donor age did increase over the last year, with the average moving from 43 to 45 years old.
- Donor race/ethnicity has fluctuated slightly from year to year, with a 2 percent decrease for 2023. This characteristic is currently involved in a proposed policy project by the Minority Affairs Committee that would remove it from KDPI. For now, it remains in the calculation.
- No changes in creatinine from 2022 to 2023.
- More donors have history of hypertension as compared to 2022 (3 percent increase)
- More donors have history of diabetes as compared to 2022 (again, around a 3 percent increase)
- Donor cause of death has remained relatively the same over the past few years. This shows whether a donor's cause of death was identified as cerebrovascular accident (stroke), which did decrease slightly from 2022 to 2023, but was noted as a very small decrease.
- No changes in height or weight distribution were reported.
- Donation after Circulatory Death (DCD) has increased by approximately 4 percent, and more DCD donors are being recovered overall.

- Hepatitis C Virus (HCV) status has remained about the same, with a slight decrease (around 0.5 percent). This is another element under consideration by the Minority Affairs Committee that will no longer be included in the calculation if approved. It remains for the 2023 update. (A positive HCV status does increase KDRI, but the increase is not wholly reflective of why the KDRI is shifting upwards overall).

The presentation then moved to EPTS updates from the 2023 data. A candidate's EPTS score indicates the percentage of adult kidney candidates on the waiting list with a higher estimated post-transplant longevity. It was noted that there is a common misconception that the percentage is based on the candidate's position relative to others on the waiting list at a given moment. This is not the case. Rather, the score reflects the candidate's position relative to a recent, historical snapshot of the kidney waiting list. The current snapshot (reference population) is all adult kidney candidates on the waiting list on December 31, 2022. Approval of today's request would update this table using the date of December 31, 2023.

In tracking the EPTS distribution over time, the score has not changed much over the years. There is a slight shift towards a lower score from 2022 to 2023 when looking at the 20 percent cutoff. This indicates a higher estimated longevity in general. In considering what is driving this score:

- Candidate age has not changed, with the median age of 57 remaining from 2022 holding steady for 2023.
- Candidate diabetes status increased very slightly (0.5 percent). Overall, candidates are slightly more likely to have diabetes.
- There is a slight decrease in candidates receiving a prior transplant from 2022 to 2023 (0.5 percent).
- Candidates were more likely to have lower time on dialysis as compared to 2022.

OPTN Contractor staff shared the implications of adopting new EPTS reference population:

- Upon implementation, it is possible that slightly less candidates would qualify for Top 20 percent priority due to this recalibration.
- The raw EPTS score needed to be in the Top 20% would decrease from 1.535102 to 1.526432, a difference of 0.008670.
- Any candidate with a raw EPTS greater than 1.526432 and less than 1.535102 would have their EPTS increase from 20 percent to 21 percent.

The proposed new EPTS table was shared with the Committee for consideration.

Summary of discussion:

Decision #1: The Committee voted unanimously to approve the annual update to the KDRI mapping table.

Decision #2: The Committee voted unanimously to approve the annual update to the EPTS mapping table.

The new KDRI mapping presentation was shared with the Committee for consideration and a vote. After this presentation, Committee members were asked to consider approval for the inclusion of 2023 changes to the table.

Motion to approve the new KDPI mapping table. The Committee unanimously approved the new KDPI mapping table.

The new EPTS mapping presentation was shared with the Committee for consideration and a vote. A participant requested what the impact of the proposed EPTS score would be on candidates. OPTN Contractor staff shared that if currently implemented on Friday, there were 4 candidates noted as falling in the EPTS range that would trigger and increase from 20% to 21%. However, if someone falls into that range at this moment and is on dialysis, an extra day of dialysis and a day older in age would not leave them in this category for long with the daily update. Overall, this 1% does not pose risk.

After this presentation, Committee members were asked to consider approval for the inclusion of 2023 changes to the table.

> **Motion to approve the new EPTS mapping table. The Committee unanimously approved the new KDPI mapping table.**

Upcoming Meetings

- May 20, 2024 conference call
- June 17, 2024 conference call

Attendance

- **Committee Members**
  - Jim Kim
  - Arpita Basu
  - Kristin Adams
  - Stephen Almond
  - Leigh Ann Burgess
  - Jesse Cox
  - Patrick Gee
  - Caroline Jadlowiec
  - John Lunz
  - Jason Rolls
  - Reza Saidi
  - Eloise Salmon
  - Chandrasekar Santhanakrishnan
  - Curtis Warfield
  - George Surratt
- **HRSA Representatives**
  - Marilyn Levi
- **SRTR Staff**
  - Avery Cook
  - Grace Lyden
  - Jonathan Miller
  - Jodi Smith
- **UNOS Staff**
  - Kayla Temple
  - Shandie Covington
  - Kaitlin Swanner
  - Kimberly Uccellini
  - Jesse Howell
  - Houlder Hudgins
  - Keighly Bradbrook
  - Thomas Dolan
  - Ben Wolford
  - Marty Crenlon
- **Other**
  - Christine Hwang