OPTN Patient Affairs Committee
Meeting Summary
April 16, 2024
Conference Call

Garrett W. Erdle, Chair
Molly J. McCarthy, Vice Chair

Introduction

The Patient Affairs Committee met via WebEx teleconference on April 16, 2024 to discuss the following agenda items:

1. Welcome and Announcements
2. 1-Year Monitoring Report: Modify Waiting Time for Candidates Affected by Race-Inclusive eGFR Calculations
3. Inactive Status Efforts: Next Steps
4. Public Forum
5. Adjourn

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

1. Welcome and Announcements

Committee members received a brief follow-up to address ongoing questions related to Directors & Officer (D&O) insurance protections.

Summary of discussion:

No decisions were made by the Committee.

OPTN Contractor staff offered confirmation that D&O protections remained the same as they had in previous contracts. A Committee member noted that they remain interested in exploring this coverage and shared that his conversation is ongoing with OPTN Contractor staff.

Next steps:

Any additional updates related to D&O coverage will be shared with the Committee.

2. 1-Year Monitoring Report: Modify Waiting Time for Candidates Affected by Race-Inclusive eGFR Calculations

The Committee received an update on one-year monitoring data on modifications to 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-year post-implementation. The data was presented to the Kidney and Minority Affairs Committees on 4/15/2024.

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. 13,528 patients had at least one registration with a processed waiting time modification. There were 196 registrations that received more than one waiting time modification. This may be the result of submitting a modification and then finding additional data with an earlier date for a patient. This additional time would be added to the first 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 are not limited to, errors in submitted documentation such as missing dates or lab values, or the candidate not being eligible per the policy requirements. The number of modifications marked as not processed continues to change as proper documentation is received and the Organ Center continues to accept new documentation for modifications marked as not processed. A 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% of registrations receiving 2.9 years or less.
    - About 50% 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%). 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% were blood type O.
- Modified Registrations by Birth Sex
    - The majority of registrations with a processed modification were for male candidates (57.49%). 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%).
- 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%), followed by candidates aged 35-39 at listing (26.69%). 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% were aged 50-64 at listing and 29.44% were age 35-49 at listing.

Summary of discussion:

No action or voting items. This was a follow-up report to the Committee.

After receiving the data presentation, a Committee member questioned whether the data had been reviewed by region or geographical grouping to determine if any areas were more highly impacted by the policy change. The OPTN Contractor staff noted that the data were not sorted in that manner for this report as it was focused on getting information out on total numbers. It was noted that some centers moved to a race neutral calculation prior to this policy change, so their areas would reflect few, if any, modifications during this review period. The member followed up, questioning the geographical locations or groupings of the 781 modifications marked as not processed.

Similarly, another Committee member asked about centers that were not cooperative or have no modifications, and whether there is any report of distribution of centers that have low numbers or no forms submitted. The OPTN Contractor staff shared that the Membership and Professional Standards Committee (MPSC) followed up with centers with lower numbers of modifications yet a high proportion of Black candidates on their waiting list to ensure they reviewed records submitted waiting time modifications as required per policy.

A member was concerned that there were only 14,000 processed modifications for such a lengthy time period. She would expect a larger number, even recognizing that those no longer on the waiting list from this time period were not included. She opined that the number seems small considering the thousands of people both active and inactive on the current waiting list, and asked if there is a number that reflects who was not contacted or did not receive modifications. OPTN Contractor staff noted that because the type of calculation used at evaluation is not captured on the data forms, it is challenging to estimate how many candidates should have received modifications. The total number of Black, African American, and biracial or multi-racial (dependent on the categories checked on the registration form) candidates on the waiting list is estimated at 30,000. This would indicate that nearly half of these individuals received wait time modifications. OPTN Contractor staff shared that ongoing follow-up is being done with certain programs. The data indicated that another 781 modifications remained unprocessed at the time the report was generated. Reasons for this include, but were not limited to, errors in submitted documentation such as missing dates or lab values, or the candidate not being eligible per the policy requirements.

Challenges were noted in tracking down the required lab results that may have been completed outside of the listing center. Results may be unavailable or insufficient and some labs may no longer exist over the course of the time period. There was an over 20/under 20 rule in place, meaning that the candidate's eGFR prior to modification had to be over 20, and under 20 after the modification for Black candidates. Some candidates did not meet this qualification or lab documentation was not sufficient. Additional outreach is ongoing to make sure that programs are doing everything they can for these patients. It was also shared that some centers were already using race neutral calculations so not all of the estimated 30,000 individuals were impacted as some did not require any wait time modifications. The member asked if programs are receiving follow-up regarding insufficiency in finding and collecting

the necessary information, questioning whether centers included information on specific challenges as part of their attestations. The OPTN Contractor staff noted that she was not familiar with the specifics of this follow-up as MPSC is managing the review.

The OPTN does not collect the type of calculation used, but the introduction of the 2021 CKD-EPI equation and anecdotal sharing indicate that some centers moved to race neutral equations earlier than the policy requirement. A Committee member asked how the OPTN knows that race-based calculations will no longer be used. The policy developed by the Minority Affairs Committee that was implemented in July 2022 now requires that any equation used must be race neutral. The Minority Affairs Committee is continuing its focus on this area and is taking on a new project to explore additional policy language to allow for further monitoring of this in the evaluation of potential new candidates. The Minority Affairs Committee is also exploring whether other organs have similar policies with references to equations that may incorporate race-based factors.

The Chair noted that, while some members of the Committee thought this wait time modification period should be managed within 90 days, the project was completed within the year allotted for it. Recognizing the aggressive work from centers within a 6-month period in the data presented, the Chair suggested that this indicates things can be done faster. The OPTN Contractor staff acknowledged conversations between the Minority Affairs and Kidney Transplantation committees regarding the data burden. Programs with a large number of Black candidates had a lot of work to do in tracking down labs and working to determine which patients qualified. Some needed more time than others to work through their full list.

A follow-up clarification was requested related to the slide reflecting modified registrations by a candidate's age at listing. The Chair asked if this generally mimics the waitlist age distribution across all organs. The OPTN Contractor staff clarified that this slide is specific to the kidney list. The majority of registrations with a processed modification were for candidates aged 50-64 years old at listing. The distribution of modified registrations by age at listing is similar to distribution of all Black, non-Hispanic registrations on the waiting list during this time period.

3. Inactive Status Efforts: Next Steps

The Committee considered an overview of work to date related to inactive status efforts and determined next steps for taking a potential project idea to the Policy Oversight Committee.

Presentation summary:

OPTN Contractor Staff presented a timeline of efforts to date on this project. The Committee has sought to answer the question of whether patients are aware of their waitlist status- active or inactive, and what process/processes are the major contributors to inactive status and candidates being unaware of that. The Committee has reviewed descriptive data on the proportion of candidates that are inactive on the wait list, variations by organ (perhaps driven by how waiting time accrues and how this influences allocation), potential trends in inactive status. However, there is no current OPTN or CMS requirement for patient notification of inactive status, and no related data to confirm or disprove these conversations.

Inferential analyses have been considered to learn more about inactive status. The Committee still sees value into looking into patient characteristics associated with a higher probability of inactive status or lower probability of converting from inactive status to active status. Committee members expressed an interest in developing a formal data request for the SRTR Contractor at its next meeting.

Inactive codes were briefly shared and had been emailed to the group for consideration previously. An example of how inactive status is often used as part of kidney listing was shared with the Committee, indicating that waiting time can be accrued while evaluation testing is completed.

As part of this presentation, the Committee's problem statement was identified. Neither OPTN policy nor CMS Conditions of Participation require patient notification when inactive status is used. While both require notification of removal from the wait list, inactive status is not removal but rather a suspension of organ offers. Proposed solutions were offered, including: (1) updating Policy 3.5 *Patient Notification* to add requirements for temporary patient inactive status, (2) updating inactive codes to capture more detailed data regarding their use, and (3) patient education on this topic. The Transplant Coordinators and Data Advisor Committees may be potential collaborators or provide subject matter expertise if these options are pursued.

It was noted that there are questions to be considered if the policy modification project is pursued, including:

- How long is appropriate for a patient to be set to inactive status before notification is made (as there are legitimate uses for this code)
- What should be communicated?
    - Most recent date they became inactive?
    - Why are they set to inactive status?
    - Clear explanation that organ offers cannot be received while candidate is set to inactive status.
    - Phone/email to contact transplant program for any questions and/or information on how to return to active status.
- How should this alert to inactive status be conveyed?
    - Hospital's patient portal/EMR may be a real time tool to share this information (similar to receiving lab results, appointment reminders, etc.)
    - Requiring alerts in writing may be too burdensome for all notifications (this is where the Transplant Coordinator Committee's 2014 proposal failed), but may still be important for some populations without access to or comfortability within navigating EMR or patient portal.

Summary of discussion:

The Committee voted unanimously to work on project proposal development for consideration at a future Policy Oversight Committee Meeting.

The Committee supported exploring inferential data to better understand characteristics associated with a higher or lower probability of inactive status.

The 2014 Transplant Coordinators Committee proposal was recognized, noting that this is not a new problem. However, technology updates will allow for notifications beyond letters from the transplant coordinators.

A Committee member recalled being told not to travel far from her transplant center, as candidates don't know when offers might be received. Candidate travel may be limited when they are on the waitlist, and it would not be fair to oblige a candidate to follow these restrictions if they are inactive and not receiving offers. Additionally, a member reiterated the potential correlations of race and the likelihood of being inactive for months if not longer. Committee members agreed that real time visibility of their status and a path to rectify this if it is seen as an error is critical. From a technical perspective, a

member said that the hospitals have no issue reaching out in real time if money is owed and suggested that notification of waitlist status should not be any different. If additional staff are needed, this should be dealt with to make these notifications happen in real time.

A Committee member questioned how age may play into this, for example, whether older people being listed and then moved to inactive status just to make them feel better rather than having the conversation that those individuals may not be suitable transplant recipients.

Suggesting that the current system is far too complex, a member noted that the whole system needs remodeling and the policy language needs to be redefined. Committee members stated that it has taken far too long to understand this issue.

Committee members next delved into discussion regarding what programming of this notification might look like, with waitlisted individuals being able to see their status as green for active or another color to denote inactive status or an issue. It was also suggested that one's status or proximity to the "top" of the list might be displayed. This information would need to be very simplistic and easy to understand. With its availability, a member suggested that this type of information might even decrease transplant coordinator workload, as automation typically reduces workload.

OPTN Contractor staff noted that a simple policy notification to require that all patients be notified of inactive status would be a direct starting point to address these concerns. This project proposal would need to go to the Policy Oversight Committee for approval and would require public comment. Interest in exploring and editing the inactive codes themselves could be considered as a separate project.

The Committed voted to send the project forward to the Policy Oversight Committee to require patient notification when patients are moved to inactive status on the wait list (14 in favor, 0 opposed, 0 abstentions).

The Committee Chair noted that he had been in contact with the Transplant Coordinator Committee Chair, who shared their program's handling of inactive status notifications and how they manage their waitlist. He suggested that she be invited to come to the Committee's next meeting and share their best practices.

The Chair also suggested that members committed to this effort create a subcommittee rather than filling full committee meeting time with this project.

A Committee member recognized the interest in continuing to explore available data on this topic, noting the interest in inferential data from the SRTR. This will be discussed during the May meeting in tandem to formalizing a project proposal.

Next steps:

1. Work on project proposal form for Policy Oversight Committee
2. Invite Transplant Coordinator Committee Chair to present to Committee in May
3. Seek Committee member interest in participating in Inactive Status Work Group

4. Public Forum

No public forum items were offered for discussion.

Upcoming Meetings

- May 21, 2024 conference call
- June 18, 2024 conference call (tentative)

Attendance

- **Committee Members**
  - Garrett Erdle
  - Molly McCarthy
  - Densie Abbey
  - Cheri Coleman
  - Tonya Gomez
  - Lorrinda Gray-Davis
  - Calvin Henry
  - Wendy Leavitt
  - Andreas Price
  - Cathy Ramage
  - Julie Spear
  - Jenny Templeton
  - Steven Weitzen
  - Justin Wilkerson
- **HRSA Representatives**
  - Mesmin Germain
- **SRTR Staff**
  - Katie Audette
- **UNOS Staff**
  - Shandie Covington
  - Jesse Howell
  - Houlder Hudgins
  - Laura Schmitt
  - Kelley Poff
  - Kaitlin Swanner
  - Desiree Tenenbaum
  - Kimberly Uccellini