

OPTN Minority Affairs Committee

Meeting Summary

July 15, 2024

Conference Call

Alejandro Diez, MD, Chair

Oscar Serrano, Credentials, Vice Chair

Introduction

The OPTN Minority Affairs Committee (the Committee) met via Webex teleconference on 07/15/24 to discuss the following agenda items:

1. June 24th meeting recap
2. Policy language vs. evaluation plan
3. Protocol steps and documentation

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

1. June 24th meeting recap

The Committee heard a summary of the progress from their last meeting.

- Reviewed OPTN policies with protocol requirements
 - 5.7 Organ Check-In
 - 5.8 Pre-Transplant Verification
- Discussed applicable site survey monitoring options
 - *Review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that...*
 - *Review the transplant program's internal policies, procedures, and protocols to verify that it has a written protocol(s) that includes...*
 - *Interview transplant hospital staff to verify that hospital staff practices align with OPTN policy and with the hospital's policies and procedures*
- Began discussion on steps for ongoing compliance with *OPTN Policy 3.7.D: Waiting Time Modifications for Kidney Candidates Affected by Race Inclusive eGFR Calculations*
 - Supported the inclusion of: *Review the program's internal policies, procedures, and protocols to verify that it has a written protocol(s) that includes... in the eGFR monitoring policy*
 - Supported the development of an eGFR monitoring checklist to define the requirements during site survey
 - Discussed that the policy will "self-sunset" as race inclusive eGFR calculations become obsolete.
 - Discussed inclusion of verification that candidates have been notified per policy 3.7.D in eGFR monitoring policy
 - Discussed challenges with establishing
 - Max number of years programs should look back
 - Threshold of expected modifications for programs

Summary of discussion:

No decisions were made.

There was no discussion.

2. Policy language vs. evaluation plan

The Committee was presented with information on the difference between policy language and evaluation plan language.

- While it is important to understand the site survey monitoring possibilities, the Committee has been charged with modification of the policy language
- The policy language is a committee product, while the Evaluation Plan (EP) is an OPTN contract deliverable
- The Committee will focus its efforts on proposed new language and Member Quality will work alongside us to develop an EP to match
 - The EP is built from the proposed policy language

Summary of discussion:

No decisions were made.

There was no discussion.

3. Protocol steps and documentation

The Committee reviewed the parts of ongoing eGFR policy requirements.

1. Continue to send a notification to all newly registered kidney candidates to make them aware of the policy
2. Assess newly registered kidney candidates to determine eligibility
3. Submit completed waiting time modification requests to the OPTN for every candidate who should have qualified to accrue waiting time sooner

For each part of the ongoing requirements, the Committee considered the following questions:

- Should any changes be proposed to current ongoing policy requirements?
 - Clarity/overall improvements
- Should ongoing policy requirements be included in protocol?
 - Should details or sub-steps be included?
- Should ongoing requirements be verified with documentation?
 - Should the program be required to provide documentation supporting this portion of the protocol?

Summary of discussion:

- Supported the inclusion of the following protocol steps for *3.7.D.i Notification Requirement*
 - Process for confirmation of candidate race
 - Process for notifying candidates twice to 1) Inform candidates of the policy before or upon candidate registration and 2) to inform candidates of their eligibility
 - Process for notifying/asking for supporting documentation from dialysis units (when applicable)

- Supported the inclusion of the following protocol steps for *3.7.D.ii Determination of Eligible Candidates*
 - Listing of available internal and external sources for seeking supporting documentation
 - Process for recording if documentation was or was not found for each candidate

The Committee considered the above key questions for *3.7.D.i Notification Requirement*, which currently requires kidney transplant programs to send a notification to all newly registered kidney candidates to make them aware of the policy. A member suggested that more than one notification and more than one mode of notification (letter, phone call, etc.) should be required for each candidate. An attendee noted that the policy requirements in place from Jan. 5, 2023, through Jan. 3, 2024, required two notifications, including notifying candidates of their eligibility for an eGFR waiting time modification. This attendee continued that requiring multiple methods of notification for each candidate in transplant programs' protocols could be too prescriptive but agreed that the protocol should speak to the methods of notification programs use. A member added that the inclusion of methods for notification in the protocol will help programs understand what documentation site survey may request. An attendee described their program's thorough process for keeping candidates informed of policy 3.7.D and its potential impact on their waiting time:

- Prior to evaluation: Educate on policy
- Included in candidate education class
- Before registering to waiting list: Verbally confirm race, let candidate know if they may/may not be eligible based on information program has at that time
- Listing letters: Include explanation of policy
- After modification request was approved/not approved: Inform verbally

This attendee continued that the Black/African American population is small at their program, so this process does not create substantial burden. A member asked for more details about the confirmation of race process at this attendee's program. The attendee explained that prior to registration, coordinators at their program call candidates to confirm important information, including candidate race. Once the candidate's race is confirmed verbally, coordinators document this in the Electronic Medical Record (EMR). Other members agreed that the confirmation of candidate race should be added to the eGFR monitoring protocol. Members also agreed that program's protocols should include two notifications, one to inform candidates of the policy and another to inform candidates of their eligibility.

A member mentioned that dialysis units had been helpful in supplying eGFR supporting documentation and put forth the idea that programs should include the notification of dialysis units (when applicable) in their eGFR monitoring protocol. Other attendees expressed that dialysis units were not as helpful to their programs in obtaining eGFR supporting documentation, but the addition of this notification would not be burdensome. These attendees explained that candidates are being assessed for eGFR modifications upon registration and at a lower volume than during the Jan. 5, 2023, through Jan. 3, 2024, time period.

The Committee then began their discussion on *3.7.D.ii Determination of Eligible Candidates*. A candidate is eligible for a waiting time modification if the candidate is registered as Black or African American in the OPTN Computer System and has documentation establishing that the candidate had an eGFR that was over 20 mL/min and would have been 20 mL/min or less if a race-neutral calculation had been used. Currently, this part of the policy does not include evaluation-specific processes. An attendee suggested that each program's eGFR monitoring protocol could include a list of available internal (example- EMR) and external (example- labs) sources for seeking documentation. Attendees agreed that not only would listing these sources map programs' source seeking processes but would also help site survey

understand the number of resources each program has, as this can vary from program to program. The protocol would require the program to record if documentation was or was not found for each candidate but would not include the date each piece of supporting documentation was requested or obtained, as this would substantially increase burden on transplant coordinators.

Next steps:

The Committee will continue discussion during their next meeting.

Upcoming Meeting

- August 19, 3-4pm ET (teleconference)

Attendance

- **Committee Members**
 - Alejandro Diez
 - Oscar Serrano
 - Adrian Lawrence
 - April Stempien-Otero
 - Christy Baune
 - Donna Dennis
 - Hilda Elena Fernandez
 - John Bayton
 - Niviann Blondet
 - Steven Averhart
 - Obi Davies Ekwenna
- **HRSA Representatives**
 - Adriana Martinez
- **SRTR Staff**
 - Bryn Thompson
 - Monica Colvin
- **UNOS Staff**
 - Kelley Poff
 - Alex Carmack
 - Jesse Howell
 - Meng Li
- **Other Attendees**
 - Ashley Cardenas
 - Karl Neumann
 - Kristin Smith