

OPTN Data Advisory Committee

Meeting Summary

September 12, 2022

Conference Call

Sumit Mohan, MD, MPH, Chair

Jesse Schold, PhD, M.Stat., M.Ed., Vice-Chair

Introduction

The Data Advisory Committee (the Committee) met via Citrix GoToMeeting teleconference on 09/12/2022 to discuss the following agenda items:

1. Public Comment Presentations

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

1. Public Comment Presentations

The Committee reviewed three proposals out for public comment that had requested the Committee's review.

Data summary:

The Committee reviewed the following proposals:

- **Modify Waiting Time for Candidates Affected by Race-Inclusive Estimated Glomerular Filtration Rate (Kidney, Minority Affairs Committees)**
 - This proposal will address waiting time modifications for registered Black kidney candidates affected by race-inclusive eGFR calculations. It will provide a pathway for affected candidates to regain lost time.
- **Transparency in Program Selection (Ethics)**
 - This white paper will increase transparency, facilitate patient autonomy, and allow for greater shared decision-making through the transplant process.
- **Modify Heart Policy to Address Patient Safety Following Device Recall (Heart)**
 - This proposal was implemented on 7/14/2022 due to the emergent need for it after a mechanical circulatory support device (MCSD) recall by the Food and Drug Administration (FDA). It will allow for programs to list candidates impacted by the device recall at a higher status.

Summary of discussion:

Modify Waiting Time for Candidates Affected by Race-Inclusive Estimated Glomerular Filtration Rate

The Committee was in favor of this proposal, but had the following suggestions: 1) The updated formula that does not use a black race coefficient should be identified on the modification form, as this may reveal center-level bias and variation; 2) If a program has a black candidate and the center indicates that they are using an eGFR calculation that includes a black race coefficient, the modification should automatically be performed; 3) The number of candidates impacted by this proposal whose programs submitted wait time modification forms should be tracked over time by the OPTN, allowing then for the OPTN to contact programs before the conclusion of the policy who have not voluntarily submitted

modification forms. Members felt that the policy needs to collect information on which programs are changing candidates' eGFR values, as well as the formula used, such that programs level variation in practice can be reduced. A member also requested that patients be informed of their program's actions surrounding this policy to ensure they understand why their eGFR score is or is not impacted; a second member emphasized that this data is incredibly meaningful to patients as this impacts their opportunity to receive an organ. It was suggested that an option could be for the OPTN to collect the component parts of eGFR calculations and perform a second calculation to confirm that a race-neutral eGFR was used; another member added that the OPTN could perform the calculation in order to standardize practice.

Transparency in Program Selection

The Committee was supportive of this paper overall, noting that many patients' knowledge of the variation in practice between programs is currently opaque. A member requested that this paper be distributed to pre-waitlist clinicians performing evaluations in order to educate the subset of patients who were not referred for transplant following evaluation. A second member wondered if there would be a way to validate what a program's actual listing criteria are in comparison to what they say they are. It was also suggested that the Ethics Committee determine what data is already being gathered by the Scientific Registry of Transplant Recipients on donor characteristics being transplanted at the program level. The Committee agreed that the starting point for creating equity amongst program selection was collecting candidate listing and transplant data.

Modify Heart Policy to Address Patient Safety Following Device Recall

The Chair noted this was retrospective public comment as the proposal had already been implemented through the emergency pathway. Staff stated the intent of the proposal was to transplant candidates with the implanted device in order to prevent device failure from occurring while the candidate was waiting. Members were supportive of this proposal, noting that it seemed well-designed and was clear about which devices would be impacted due to the recall.

Next steps:

Committee feedback will be formalized and published as the Committee's public comment.

Upcoming Meeting

- October 3, 2022

Attendance

- **Committee Members**
 - Sumit Mohan
 - Jesse Schold
 - Jamie Bucio
 - Earnest Davis
 - Lauren Kearns
 - Paul MacLennan
 - Krishnaraj Mahendraraj
 - Bilal Mahmood
 - Michael Marvin
 - Meghan Muldoon
 - Daniel Stanton
- **HRSA Representatives**
 - Adrianna Martinez
- **SRTR Staff**
 - Bert Kasiske
 - Jon Snyder
- **UNOS Staff**
 - Matt Belton
 - Brooke Chenault
 - Amber Fritz
 - Isaac Hager
 - Nadine Hoffman
 - Courtney Jett
 - Lindsay Larkin
 - Krissy Laurie
 - Eric Messick
 - Joel Newman
 - Janis Rosenberg
 - Laura Schmitt
 - Serena Straub
 - Susan Tlusty
 - Scott Verbeke