

OPTN Pancreas Transplantation Committee

Meeting Summary

January 31, 2024

Conference Call

Oyedolamu Olaitan, MD, Chair

Ty Dunn, MD, MS, FACS, Vice Chair

Introduction

The OPTN Pancreas Transplantation Committee (the Committee) met via Cisco WebEx teleconference on 01/31/2024 to discuss the following agenda items:

1. Special Public Comment Presentation: Expedited Placement Variance

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

1. Special Public Comment Presentation: Expedited Placement Variance

The Committee received a presentation on the OPTN Executive Committee's *Expedited Placement Variance* proposal.

Summary of discussion:

The Committee's feedback will be synthesized into a formal statement that will be submitted for public comment.

The Committee voiced support for the proposal and provided some questions and feedback for consideration.

The Committee suggested that there be various ways to monitor the variances received as well as the evaluation of the variances once implemented. As variances are being received, it should be determined what variances are similar and could be combined. Acknowledging that regions vary, if variances submitted are similar to specific regions, those variances should be available for those respective regions to work on together. Additionally, monitoring should also include identifying variances that may not be working for some programs. Data on allocations out of sequence and non-utilization should be evaluated to determine the causes of these instances. There should be acknowledgement that the timeline in monitoring changes/impacts of these variances can vary by organ type. For example, variances related to kidney may accumulate more data in a faster timeframe than a variance related to pancreas due to the sample size evaluated.

A member asked if this proposal would apply to all organs or if it was organ specific. Staff clarified that this proposal was written to include all organ types, although some feedback has been limited to kidney. Staff added that these variances would be monitored and that if programs are submitting protocols, the OPTN Executive Committee could combine and develop one variance for programs to opt in on.

Another member asked how this proposal differs to out of sequence allocation practices that are currently happening. Staff replied that the variances would be evaluated to determine which protocols work and could potentially become policy to avoid deviation from policy.

A member asked how many policies the variances may result in. Staff stated that there was no limit, and that the proposal is not limited to just organ procurement organizations (OPOs) submitting protocols. The member then asked for clarity on the review process for the protocols would be and what would the timeline be for reviewing these protocols. Staff stated that the Executive Committee would be reviewing the variances that come in and that the timeline for this review is to be determined.

Another member advised there should be some monitoring to identify if a variance is not working for a program. Additionally, evaluation of these variances should include data/information on out of sequence allocation by OPOs that result in non-use of organs.

A member cautioned that monitoring of these variances should be dependent on what organ type the variance is focused on. For example, a variance related to pancreas would require more time to monitor changes than kidney due to the population being smaller.

Another member inquired about facilitated pancreas and what the process may be in creating a variance around this. Staff replied that the expectation for the variances is to not make programming changes, however, it is possible that the Committee could take some aspects to the current policy to develop a variance.

The Committee suggested consultation with organ specific Committees to review and have the opportunity to provide their expertise/input early on in the process. This would also give Committees an idea of what protocols could be utilized in the future.

The Committee acknowledged the merits of the variances by providing a structured approach in studying how these systems could work and making efforts to avoid unintended consequences.

Next steps:

The Committee's feedback will be synthesized into a formal statement that will be submitted for public comment.

Upcoming Meetings

- February 5, 2024
- February 26, 2024
- March 8, 2024 (in-person)

Attendance

- **Committee Members**
 - Oyedolamu Olaitan
 - Asif Sharfuddin
 - Colleen Jay
 - Dean Kim
 - Diane Cibrik
 - Mallory Boomsma
 - Neeraj Singh
 - Rupi Sodhi
 - Todd Pesavento
 - Muhammad Yaqub
- **HRSA Representatives**
 - Jim Bowman
 - Marilyn Levi
- **SRTR Staff**
 - Jon Miller
 - Bryn Thompson
 - Raja Kandaswamy
- **UNOS Staff**
 - Joann White
 - Kaitlin Swanner
 - Lauren Motley
 - Cole Fox