

OPTN Patient Affairs Committee

Meeting Summary

August 24, 2021

Conference Call

Garrett Erdle, M.B.A., Chair

Molly McCarthy, Vice Chair

Introduction

The Patient Affairs Committee met via Citrix GoToMeeting teleconference on 08/24/2021 to discuss the following agenda items:

1. Opening Remarks and Welcome
2. **Public Comment Presentation:** OPTN Executive Committee – Update on OPTN Regional Review Project
3. **Public Comment Presentation:** OPTN Membership and Professional Standards Committee (MPSC) – Enhance Transplant Program Performance Monitoring System
4. **Public Comment Presentation:** OPTN Lung Transplantation Committee – Continuous Distribution of Lungs
5. Day 2 Debrief and Closing Remarks

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

1. Opening Remarks and Welcome

The Chair provided an overview of the agenda and what to expect for today's meeting. Committee members who were unable to attend Monday's meeting provided a brief introduction.

2. Public Comment Presentation: OPTN Executive Committee - Update on OPTN Regional Review Project

Brian Shepard, the Chief Executive Officer of UNOS, presented the OPTN Executive Committee's public comment item Update on OPTN Regional Review Project.

Summary of discussion:

A member suggested utilizing the census regions since it is a system that the U.S. government is already using. Alternatively, a member suggested developing a matrix or grid structure. The presenter was in favor of using maps with more transplant specific data for public comment consideration than the existing census regions. The presenter noted that maps might not be the solution to the entire situation. Some type of map would be needed to identify representatives to the Board of Directors and Committees, but not necessary to facilitate conversations for different groups. Additionally, maps should equalize patients for voting processes but not for other purposes.

Multiple members voiced the need for increased patient representation in the OPTN and the importance of providing a pathway for patients to become more knowledgeable of the organ transplant system as they progress in the Committee and Board service. A member suggested utilizing social engineering technological tools to engage patients with the OPTN. Another member identified a gap where the OPTN falls short of engaging with patient communities online and serving as a resource to them.

Another member suggested utilizing time during the Regional Meetings to recruit volunteers for the patient centric committees, such as Living Donor and Minority Affairs Committees. While recognizing the importance of increasing and amplifying the patient voice, the presenter noted the importance for professionals to reside on the Living Donor Committee to navigate the safety-related work done by the Committee. A member expressed the need to recruit professionals whose expertise is organization efficiency and IT. A member inquired about the budgeting process for the OPTN. A member responded that the Board of Directors focuses primarily on policy and allocation while the Board of Directors Finance Committee oversees the management of the budget.

A member expressed concerns about how access to health care and social determinants of health could factor in to develop regions that are more equitable and representative of the issues faced by the transplant community.

Next steps:

UNOS staff will compile the feedback from today's conversation to develop the official public comment for the committee. If members have any additional questions or comments on the proposal, please reach out to UNOS staff.

3. Public Comment Presentation: OPTN Membership and Professional Standards Committee (MPSC) - Enhance Transplant Program Performance Monitoring System

Dr. Richard Formica, the Region 1 Councillor and Chair of the MPSC Performance Monitoring Subcommittee, presented the public comment proposal Enhance Transplant Program Performance Monitoring System.

Summary of discussion:

Member expressed desire to have more data readily available for patient access, especially as this proposal directly or indirectly affects all patients. Members requested clarification on how this proposal would interact with the data collected by the Scientific Registry of Transplant Recipients (SRTR). The presenter noted that while the process is available to the public, the results of this process are not released for public consumption. By utilizing a peer-reviewed process instead, it allows the clinicians to discuss openly and candidly for improvement. The SRTR data does not interact with this proposal and will remain publicly accessible.

Overall, it was felt that this proposal lacked readability and clarity to the public. A member suggested including a list of metrics in the 'specific questions for feedback' section of the Executive Summary.

Members expressed concern over the proposals potential to unintentional disincentives transplantation while the patient population would rather incentivize more risky transplants. The presenter responded that these decisions are in the hands of the physicians who are doing what is most medically appropriate for their patient. A member countered that there should be flexibility for centers to make those riskier decisions when it is medically appropriate for the patient.

A member emphasized the fact that this proposal is for a peer review process, but was hesitant that the data being used to be up to date and reflective of the current practices of the center. The presenter noted that by the time this issue was identified by the MPSC it is likely that the transplant center has already resolved the issue. The presenter also shared that since the transplant centers are compared to themselves, if their observed performance is in line with their expected performance it is possible to have no transplant centers that need improvement. There was some feedback that retroactive data should be used when this policy is implemented, but the presenter expanded that the MPSC did not want to hold members accountable for something that was not yet in policy.

Next steps:

UNOS staff will compile the feedback from today's conversation to develop the official public comment for the committee. If members have any additional questions or comments on the proposal, please reach out to UNOS staff.

4. Public Comment Presentation: OPTN Lung Transplantation Committee - Continuous Distribution of Lungs

Dr. Erika Lease, the Chair of the OPTN Lung Transplantation Committee, presented the public comment proposal Continuous Distribution of Lungs.

Summary of discussion:

A member inquired how post-transplant monitoring will occur if the recipients moves transplant center within the first year of transplant, specifically who is responsible for reporting and which center gets credit for the post-transplant outcome? The presenter responded that the transplant center that completes the transplant is responsible for completing the follow up documentation on the patient but if the patient switches center then they will send that documentation to the new center for them to complete. However, the credit for the transplant will go to the center that completed the transplant surgery not the center that completed the follow up in this case.

A member asked how to increase the acceptance rate ratio for centers so more transplant occur? The presenter noted that this is outside the purview of the continuous distribution model, but also noted that many of the factors used to determine if lungs are suitable for transplant are not hard data points.

A member requested clarification on how post-transplant points are determined in the Composite Allocation Score (CAS). Currently, post-transplant outcomes are calculated in the Lung Allocation Score (LAS) and that formula will be transitioned into the CAS.

A member inquired how the Committee plans to educate patients on what their scores mean and what their implications are. The presenter responded that the patient will be able to know what their CAS is, but without the points for placement efficiency because that will not be known until a match run is completed. The presenter also noted that the implications for a patient's LAS or CAS are all relative because they are placed in the context of other patients which is unknown.

A member thanked the presenter for utilizing the AHP exercise, specifically in its ability to amplify the patient voice and making determinations based on those results. Multiple members shared their support for this policy framework and its ability appropriately match organs with patients.

A member asked the presenter to provide her insight on what types of things the PAC should focus on as the other organ specific committees develop their continuous distribution frameworks. The presenter encouraged the members to think outside of the box and consider factors that are not currently in practice. Additionally, the presenter noted the necessity of doing multiple modeling requests and taking the extra time to ensure that the correct changes were made.

A member inquired if there is a trial process for this policy roll out. The presenter informed the group that the policy would roll out nationwide at once with a very in depth post-evaluation monitoring plan.

Next steps:

UNOS staff will compile the feedback from today's conversation to develop the official public comment for the committee. If members have any additional questions or comments on the proposal, please reach out to UNOS staff.

5. Day 2 Debrief and Closing Remarks

Members shared their feedback following the two-day meeting series. Members discussed how they felt about public comment and the policy development process in general.

Upcoming Meetings

- September 21, 2021
- October 19, 2021
- November 16, 2021
- December 21, 2021

Attendance

- **Committee Members**
 - Anita Patel
 - Betsey Brada
 - Chris Yanakos
 - Darnell Waun
 - Diego Acero
 - Earl Lovell
 - Eric Tanis
 - Garrett Erdle
 - James Sharrock
 - Julie Ice
 - Julie Spear
 - Justine van der Pool
 - Kenny Laferriere
 - Marvin Lim
 - Molly McCarthy
 - Sarah Koochmaraie
 - Sejal Patel
 - Christopher Woody
- **HRSA Representatives**
 - Jim Bowman
- **SRTR Staff**
 - Katie Audette
- **UNOS Staff**
 - Brian Shepard
 - Elizabeth Miller
 - Kaitlin Swanner
 - Krissy Laurie
 - Laura Schmitt
 - Lindsay Larkin
 - Sally Aungier
 - Sara Rose Wells
 - Sharon Shepherd
 - Susan Tlusty
- **Other Attendees**
 - Erika Lease
 - Richard Formica