

OPTN Executive Committee

Meeting Summary

May 11, 2023

Webex

Jerry McCauley, MD, MPH, FACP, Chair

Introduction

The OPTN Executive Committee met via Cisco Webex Meetings teleconference on 05/11/2023 to discuss the following agenda items:

1. Welcome & Announcements
2. New Projects from the Policy Oversight Committee
3. Notable Project Update: Kidney-Pancreas Continuous Distribution Timeline
4. Closed Session
5. Closed Session

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

1. Welcome and Announcements

Dr. Jerry McCauley, OPTN Board President, welcomed the Executive Committee to the meeting and shared the agenda for the meeting.

2. New Projects from the Policy Oversight Committee (POC)

Dr. Nicole Turgeon, Chair of the Policy Oversight Committee (POC), presented a new project to Amend Adult Heart Status 2 Mechanical Device Requirements from the Heart Committee. The presentation highlighted a modification to the current adult heart allocation policy that would require proof of inotrope failure within 7 days prior to the use of an Intra-Aortic Balloon Pump (IABP) to gain Status 2. This change is a result of potential inappropriate use of IABPs to gain Status 2. The new project aligns with the strategic plan to improve waitlisted patient, living donor, and transplant recipient outcomes.

Dr. Turgeon also presented a new project from the Histocompatibility Committee on HLA Tables Update 2023. The project would perform updates to the OPTN Policy HLA equivalency tables in order to remain current with increasing HLA typing capabilities. The new project aligns with the strategic plan, as it will work to increase the number of transplants.

Dr. Scott Lindberg, Vice Chair of the Membership and Professional Standards Committee (MPSC) presented a project proposal from the committee to Require Reporting of Patient Safety Events. The project was originally presented to the Executive Committee on April 28; however, additional questions were raised during an e-mail vote so the MPSC brought the proposal back to present additional information to the Executive Committee. As it currently stands, the OPTN contract requires that the OPTN notify MPSC leadership and HRSA of certain types of safety events within a specific timeframe. OPTN policy does not specifically require the reporting of some patient safety events, including near misses. The change is intended to clarify specific safety events that staff must report to key stakeholders so that they may, in a timely fashion, fully investigate the event, and submit it for MPSC review. The project aligns with the strategic goal to promote living donor and transplant recipient safety.

Summary of discussion:

When discussing the project from the Heart Committee, a committee member asked if the POC had spoken with the experts in this area to determine who needs an IABP and who does not. Dr. Turgeon explained that based on research and information gathering, the Heart Committee felt very strongly about the policy and advocated for it. Dr. Turgeon confirmed that the proposal was adequate, as excess use of this technology was potentially being used to game the system.

A committee member stated that the presentation focused on required patient safety reporting was helpful, as it narrowly defined what a near miss would be. The committee member voiced their support and noted that it would be a new way for the MPSC to collect and process data, which wouldn't necessarily prove to be burdensome for individual programs. Another committee member agreed that the presentation provided clarification and suggested that providing examples of near misses would be helpful.

A committee member asked what would be done with the data the MPSC collected, who would be analyzing it, and what the consequence of sharing the data would be. In addition, they added that there may be some redundancy of systems. If a mistake is caught at the last moment due to the multiple checks and verifications, then that would mean that the system put in place is working. Dr. Lindberg responded and agreed that the near miss reports would indicate that the system worked, however, despite the near misses, there were still instances in which failures occurred. Regarding the comments about the data, it was explained that such data would remain within the MPSC. The trends and problems identified within it, however, would be used to provide and communicate guidance to the community. Overall, the data and project are meant help the system improve.

A committee member noted that the membership requirement revisions project from the MPSC is currently being worked on and urged the MPSC to complete the project. A second committee member agreed and expressed that there has been an unfair application and review process for the HLA Director position. A committee member asked if additional OPO performance metrics were still being considered. Dr. Lindberg acknowledged that there have been discussions on the matter, however, it has not yet made it on the worklist.

Vote:

The Executive Committee approved amendments to Heart Status 2 Mechanic Device Requirements from the Heart Transplantation Committee, HLA Tables Update 2023 from the Histocompatibility Committee, and Changes to Requirements for Reporting Patient Safety Events from the Membership and Professional Standards Committee (MPSC).

3. Notable Project Update: Kidney-Pancreas Continuous Distribution Timeline

Dr. Jim Kim, Vice Chair of the Kidney Transplantation Committee, provided an update on the kidney-pancreas continuous distribution timeline. The committee has successfully submitted their second modeling request that is expected to be returned by July 11. Considering the operational components of continuous distribution, the committee will submit a request for feedback regarding efficiency issues for the Summer 2023 public comment cycle. The committee has also created additional workgroups to collaborate across committees and share their expertise. The committees will be reviewing the workgroup's recommendations and will finalize decisions on review board and operational considerations, and updates to policy language. The Committees plan to release an update and request for feedback for the Summer 2023 public comment cycle that will focus on operational components of continuous distribution.

Summary of discussion:

A committee member asked if the Kidney Committee would be prepared to submit a proposal for the Winter 2024 public comment cycle. Dr. Kim explained that after the committee receives the second round of modeling, they should be able to move forward. A committee member asked whether they would be looking at operational components from a transplant center level or only from the OPTN perspective. Dr. Kim responded that they would be looking at the components from the OPTN level but would also be sensitive to the changes on the transplant center level as well.

A committee member asked what the logistical implications of the proposal would be prior to submitting it for public comment. They commented that knowing the logistical aspects, such as proximity factors, can be key to the success of continuous distribution. These implications may be identified through analyses of three-month data that look where donors were, where the organs were procured, and where they organs were transplanted. Dr. Kim stated that proximity efficiency has been a huge consideration and challenge to balance with longevity matching. Since kidneys can be shared more broadly and handle more ischemic time, considerations regarding how to handle low KDPI kidneys versus marginal donors must also be considered. In addition, the second round of modeling should provide a better picture of the practical implications of the operational considerations.

4. Closed Session

The Executive Committee held a closed session.

5. Closed Session

The Executive Committee held a closed session.

Attendance

- **Committee Members**
 - Annette Jackson
 - Dianne LaPointe Rudow
 - Gail Stendahl
 - Irene Kim
 - Jeffrey Orłowski
 - Jerry McCauley
 - Jim Sharrock
 - Linda Cendales
 - Lloyd Ratner
 - Matthew Cooper
 - Valinda Jones
- **HRSA Representatives**
 - Adrienne Goodrich-Doctor
 - Chris McLaughlin
 - Frank Holloman
 - Shannon Taitt
- **UNOS Staff**
 - Anna Messmer
 - Cole Fox
 - Dale Smith
 - David Klassen
 - Isaac Hager
 - Jacqui O'Keefe
 - Jason Livingston
 - Joann White
 - Kayla Temple
 - Kieran McMahan
 - Kimberly Uccellini
 - Krissy Laurie
 - Lindsay Larkin
 - Liz Robbins Callahan
 - Maureen McBride
 - Morgan Jupe
 - Rebecca Brookman
 - Roger Brown
 - Susan Tlusty
 - Susie Sprinson
 - Tiwan Nicholson
 - Tynisha Smith
- **Other Attendees**
 - Jim Kim
 - Nicole Turgeon
 - Scott Lindberg