

OPTN Executive Committee

Meeting Summary

September 22, 2021

Conference Call

Matthew Cooper, Chair

Introduction

The Executive Committee met via telconference on 09/22/2021 to discuss the following agenda items:

1. Closed Session
2. New Projects
 - a. Establish Eligibility Criteria and Safety Net for Heart-Kidney and Lung-Kidney Transplantation (Multi-Organ)
 - b. VCA Graft Failure Definition (VCA)
3. Updated SARS-CoV-2 Summary of Evidence
4. COVID 19 Policy Data Review
5. OPTN Charter Revision Project
6. Update on OPTN Regional Review Project

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

1. Closed Session

The Executive Committee met briefly in a closed session to conduct routine confidential business.

2. New Projects

Dr. Matthew Cooper, Chair of the Executive Committee, introduced Dr. Nicole Turgeon, Chair of the Policy Oversight Committee (POC) to present two new projects:

- VCA Graft Failure Definition (VCA): This project seeks to modify a policy definition of and data collection on graft failure for VCA to more accurately determine rates of graft failure for VCA, based on type of VCA. The POC supports this project.
- Establish Eligibility Criteria and Safety Net for Heart-Kidney and Lung-Kidney Transplantation (Multi-Organ Transplantation): This project is part of the strategic policy priority of improved equity for multi-organ and single-organ candidates. The POC supports this project. Dr. Turgeon provided an overview of the Multi-Organ Transplantation (MOT) Committee project map. A question was raised about the prioritization between kidney multi-organ and single-organ. Dr. Turgeon explained that the prioritization project looks at whether heart-kidney should go above liver-kidney in multi-organ prioritization. The MOT Committee will also consider questions on whether highly sensitized candidates or pediatric candidates should go above a multi-organ candidate. A member of the Executive Committee asked if multi-organ prioritization projects need to be completed before implementation of continuous distribution. Dr. Turgeon explained that the MOT Committee was developed to answer some of these multi-organ questions during the transition to continuous distribution. The MOT Committee has decided to develop eligibility criteria and safety net first, and then consider how to fit this in with continuous distribution. Dr. Cooper noted that under continuous distribution, it will be easier and quicker to make changes to multi-organ allocation, if necessary. A member of the Committee noted that it will be

essential to include the Pediatric Committee is this project and other multi-organ projects. A Committee member asked about patients who comes up as sequence 1 many times, but do not get an organ because it is allocated to a multi-organ recipient. Dr. Turgeon explained that the Pediatric Committee is well represented in these discussions, and that this project focuses only on heart-kidney eligibility. The safety net is below pediatric candidates. Additional feedback will be solicited during public comment. Dr. Turgeon reviewed the project resources and implementation hours by Board cycle. A motion was made and seconded to approve the new projects.

By a vote of 100% yes, 0 no, and 0 abstentions, the new projects were approved.

3. Updated SARS-COV-2 Summary of Evidence

Dr. Cooper introduced Dr. Ricardo La Hoz, Chair of the OPTN Ad Hoc Disease Transmission Advisory Committee (DTAC). Dr. La Hoz explained that in December of 2020 the DTAC was tasked with developing a summary of evidence on SARS-COV-2. The goal of the document is to review information on COVID-19 relevant to minimizing the risk of donor-derived transmission while maximizing donor utilization. DTAC reviews the document quarterly and updates it with new evidence when available. The new edition of the document contains information on the delta variant and new data from the lung donor lower respiratory testing policy. The document was developed in collaboration with AST, ASTS, and APOPO. The updated document was approved unanimously by the DTAC.

Summary of discussion:

A question was raised about follow-up on non-lung organs from SARS-COV-2 positive donors. Dr. La Hoz explained that there are multiple different scenarios that could involve a positive donor. The DTAC, in collaboration with the CDC, has investigated around 40 potential donor derived transmission events. Other small studies have been done. The results of these studies are encouraging, but each transplant center needs to evaluate potential risks when accepting organs from these donors. The DTAC has summarized the available evidence, but does not make a specific recommendation. There was a question about the discussion with the CDC regarding storage of donor information for a 10-year period. The sentiment of the DTAC is that having this time frame for storing samples provides a level of safety to the system that allows maintenance of trust in the community. The Committee plans to revisit this topic during a later meeting.

By a vote of 100% yes, 0 no, and 0 abstentions, the updated summary of evidence was approved (Exhibit A).

4. COVID 19 Policy Data Review

Dr. Cooper introduced Laura Cartwright and Sarah Booker from the UNOS Research Department to provide an update on the COVID-19 policies. They explained that this is the final update on Policy 3 (Modify Wait Time Initiation for Non-Dialysis Kidney Candidates), because it was repealed effective September 1, 2021. Use of this policy has remained consistent at roughly one third of wait time modification requests. There is very high compliance with the lower respiratory testing policy, and 98.3% of lung donors have LRT results reported on or before the day of transplant. The data from the 2-month report is consistent with the data from the 1-month report. The policy will be assessed again at 3 months post-implementation. There were no questions or comments from members of the Committee

5. OPTN Charter Revision Project

Dr. Cooper introduced Liz Robbins Callahan, UNOS Associate General Counsel. Ms. Robbins Callahan reminded the Committee that the OPTN Charter revision project is part of OPTN contract task 3.2.2. She

walked the Committee through the document and explained that the potential edits will eliminate inconsistencies with the OPTN Bylaws and redundancies with the Final Rule. There are specific edits to the Membership categories that the Committee is encouraged to review. The Committee is also encouraged to review feedback from HRSA in the document. The proposed revisions will be distributed to the Committee before their October meeting and they will be asked to provide feedback. Mr. Chris McLaughlin, Contracting Officer's Representative (HRSA), requested that the Committee specifically review the Membership categories.

6. Update on OPTN Regional Review Project

Dr. Cooper introduced Mr. James Alcorn to provide an update on the Regional Review Project. During public comment, there has been strong support for multidisciplinary forums. Feedback shows that people like having meetings based around geographical neighbors or relationships, but they are open to the idea of reevaluating how regions are defined. There is support for different groupings for different purposes.

Mr. Alcorn was asked about next steps, and explained that feedback will be accepted through public comment until the end of September. In October, EY will give a report to the Executive Committee reviewing public comments. The feedback will be turned into a defined concept paper in spring 2022. If there is support for redrawing the boundaries for specific purposes, some of those modifications may require bylaw changes. Some operational changes have been suggested that will not require any policy or bylaw changes, if implemented. Any policy or bylaw changes that are necessary will go out in the fall of 2022. If the Executive Committee identifies any operation changes, some of those changes can be made in the meantime.

Dr. Cooper thanked the Committee and ended the meeting.

Upcoming Meeting

- October 26, 2021

Attendance

- **Committee Members**
 - Matthew Cooper
 - David Mulligan
 - Jerry McCauley
 - Lisa Stocks
 - Mindy Dison
 - Patrick Healey
 - Richard Formica
 - Stacey Lerret
 - Valinda Jones
 - William Hildebrand
 - Bradley Kornfeld
- **HRSA Representatives**
 - Chris McLaughlin
- **Other Attendees**
 - Nicole Turgeon
 - Ricardo La Hoz
- **UNOS Staff**
 - Laura Cartwright
 - Liz Robins Callahan
 - James Alcorn
 - Susie Sprinson