

OPTN Policy Oversight Committee

Meeting Summary

January 9, 2023

Conference Call

Nicole Turgeon, MD, FACS, Chair

Jennifer Prinz, RN, BSN, MPH, CPTC, Vice Chair

Introduction

The Policy Oversight Committee (“Committee”) met via Citrix GoToMeeting teleconference on 01/09/2023 to discuss the following agenda items:

1. Updates
2. Public Comment Review

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

1. Updates

Staff provided three updates on the in-person Committee meeting in Chicago, meeting attendance requirements, and subcommittee work report-outs to OPTN committees.

Summary of discussion:

In-Person Meeting

Staff requested that, if members had not responded to the poll regarding availability, they do so.

Meeting Attendance Requirements

Staff reminded members that an expectation of the vice-chair role was to attend 80% of all required meetings. However, because the work of the Committee is crucial and frequently intersects with many other OPTN committees, if any member is unable to attend, it is requested that they have a member from their committee attend in their place.

Subcommittee Work Report-Outs

Staff noted that during the February 2023 – April 2023 timeline, each committee should receive an update from their vice chair about the work the Committee has been doing on reviewing benefit scoring and post-implementation monitoring.

2. Public Comment Review

The Committee reviewed the proposals being submitted for approval for the winter 2023 public comment cycle and voted whether to approve each.

Data Summary:

- **Continuous Distribution of Kidneys and Pancreata Committee Update** (OPTN Kidney/Pancreas Committees)
 - This paper contains recent discussions and decisions regarding attributes, their associated rating scales, results of the Committee's first modeling request, and

considerations for utilization and the development of kidney and pancreas specific review boards

- **Continuous Distribution of Livers and Intestines** (OPTN Liver and Intestines Committee)
 - The purpose of this request for feedback is to supplement the values prioritization exercise that is currently available for members of the transplant community to complete. The values prioritization exercise asks community members to compare the relative importance of the different factors that will be included in the new allocation system.
- **Align OPTN Kidney Paired Donation Blood Type Matching Policy and Establish Donor Re-Evaluation Requirements** (OPTN Kidney Paired Donation Committee)
 - The OPTN Kidney Transplant Committee proposes the alignment of OPTN KPDPP blood type A, non-A1 and AB, non-A1B matching policy and establishing a new requirement for annual donor re-evaluation. The proposed changes will improve the efficiency of the OPTN KPDPP system, which may increase the OPTN KPDPP match success rate and may ultimately increase the number of transplants. The Kidney Transplantation Committee is also proposing a new requirement for annual donor re-evaluation which will include psychosocial, medical, and informed consent re-evaluation requirements
- **Expand Required Simultaneous Liver-Kidney Allocation** (OPTN Ad Hoc Multi-Organ Transplant Committee)
 - The Ad Hoc Multi-Organ Transplantation Committee proposes expanding the distance threshold for required liver-kidney allocation. This change is expected to improve equity in access to simultaneous liver-kidney transplantation across the nation.
- **Require Human Leukocyte Antigen (HLA) Confirmatory Typing for Deceased Donors** (OPTN Histocompatibility Committee)
 - The OPTN Histocompatibility Committee, the Committee, proposes to create additional safety protocols for other causes of HLA discrepancies by requiring two HLA typings be performed on all deceased donors with samples drawn at two separate times.
- **Modify Heart Policy for Intended Incompatible Blood Type (ABOi) Offers to Pediatric Candidates** (OPTN Heart Committee)
 - The OPTN Heart Transplantation Committee proposes an incremental step to improve waitlist mortality rates by allowing candidates registered prior to turning 18 years old to receive offers of intended incompatible blood type (ABOi) donor hearts, lungs, and heart-lungs. In addition, eligibility for ABOi donor organs will be extended to pediatric status 2 heart candidates, as well as all pediatric lung candidates under the proposal, essentially removing status as an eligibility consideration.
- **National Liver Review Board (NLRB) Guidance for Multivisceral Transplant Candidates** (OPTN Liver and Intestines Committee)
 - This proposal seeks to improve the NLRB guidance document for adult MELD exceptions by creating a section specific to multivisceral transplant (MVT) candidates who have experienced reduced access to transplant and increased waitlist mortality in the post-acuity circles period. 2 MVT candidates are those candidates listed for any of the following organ combinations:
 - Liver-intestine
 - Liver-intestine-pancreas

- Liver-intestine-pancreas-kidney
 - Liver-intestine-kidney
- **Establish Member System Access, Security Requirements, Incident Management, and Reporting Requirements (OPTN Network Operations Oversight Committee)**
 - The OPTN Network Operations Oversight Committee (NOOC) aims to establish member system access and security framework requirements to enhance the security of the OPTN Computer System. These requirements will address the following:
 - Security framework and controls for all members with access to the OPTN Computer System
 - Self-attestation from members on the security framework in place
 - Auditing and compliance monitoring for security requirements
 - Security requests for information
 - Development of an incident response plan, required actions for a security incident
 - Establishment of an information security contact role
 - Security training for all member organization staff
- **Identify Priority Shares in Kidney Multi-Organ Allocation (OPTN Ad Hoc Multi-Organ Transplant Committee)**
 - The Ad Hoc Multi-Organ Transplantation Committee’s concept paper aims to establish an updated framework for kidney multi-organ allocation to improve equity in access to transplant between single organ and multi-organ candidates, and to improve efficiency in allocating multiple organ types from one donor.
- **Ethical Evaluation of Multiple Listings (OPTN Ethics Committee)**
 - This white paper answers the question “What are the ethical implications of permitting patients to be listed at multiple transplant programs?” The Committee considers this question with a focus on access to multiple listing and how it impacts the transplant system as a whole, as opposed to the individual.
- **Improve Deceased Donor Evaluation for Endemic Disease (OPTN Ad Hoc Disease Transmission Advisory Committee)**
 - This revision of OPTN policy aims to maintain transplant recipient safety through infectious disease testing by minimizing disease transmission through organ transplantation.

Summary of discussion:

- **Continuous Distribution of Kidneys and Pancreata Committee Update (OPTN Kidney/Pancreas Committees)**

The review group supported the proposed timeline and areas of engagement, but requested more information on how multi-organ allocation would be considered.

With no further comments, the POC approved this releasing this proposal for public comment (12 yes, 0 no, 0 abstain).

- **Continuous Distribution of Livers and Intestines** (OPTN Liver and Intestines Committee)

The review group had three questions: first, whether there would be any post-transplant outcomes points awarded to liver candidates; second, how many points prior living donors would receive; and third, whether social determinants of health would have any impact on scores.

Staff replied that there was not enough data or modeling done on social determinants of health to include them in the initial framework, but it was certainly something the Liver committee was considering. Similarly, the Liver committee was not confident in the ability of post-transplant outcome models for liver to accurately predict mortality, and did not want to ascribe points to them yet. However, as the data continues to evolve, they will be reinvestigating how those elements should be incorporated. Staff encouraged public comment feedback to present ideas on how these suggestions should be considered.

With no further comments, the POC approved this releasing this proposal for public comment (12 yes, 0 no, 0 abstain).

- **Align OPTN Kidney Paired Donation Blood Type Matching Policy and Establish Donor Re-Evaluation Requirements** (OPTN Kidney Paired Donation Committee)

The review group supported the proposal, and wondered how often the donor re-evaluation would have to take place. They felt that the proposal accurately captured the sentiment that, if a donor does not donate within a set time period, there should be required re-evaluation.

The sponsoring committee's vice-Chair contributed that, in the current system, there is not a requirement for re-evaluation; this would provide a required one year annual evaluation.

- **Expand Required Simultaneous Liver-Kidney Allocation** (OPTN Ad Hoc Multi-Organ Transplant Committee)

Review group members supported the proposal's evaluation of the problem, as well as its presentation that the proposal would have an impact on a small number of multivisceral candidates, but not kidney or pancreas candidates.

With no further comments, the POC approved this releasing this proposal for public comment (14 yes, 0 no, 0 abstain).

- **Require Human Leukocyte Antigen (HLA) Confirmatory Typing for Deceased Donors** (OPTN Histocompatibility Committee)

The review group noted that they aptly provided an explanation for their proposal. They expressed concern about the increased time and cost to OPOs when compared to the benefit in patient safety.

With no further comments, the POC approved this releasing this proposal for public comment (14 yes, 0 no, 0 abstain).

- **Modify Heart Policy for Intended Incompatible Blood Type (ABOi) Offers to Pediatric Candidates** (OPTN Heart Committee)

Review group members endorsed this proposal, noting that it addressed the problem of high mortality rates for extremely young pediatric heart candidates. Additionally, they appreciated that it took care to align heart and lung policy. However, they expressed concern over the lack of evidence and data about the safety of incompatible transplants in older children. They felt that much of the guidance in the proposal was based off of clinical experience and data, rather than data; they did acknowledge, though, that it would be difficult to gather this data without performing the ABO incompatible transplants that this proposal would allow.

The vice-Chair of the Heart committee replied that some of the policy would rely on transplant programs to gauge where the edge of feasibility is for patients that are too ill for transplant. Therefore, there would be a natural limiter on how much programs can use this policy.

With no further comments, the POC approved this releasing this proposal for public comment (14 yes, 0 no, 1 abstain).

- **National Liver Review Board (NLRB) Guidance for Multivisceral Transplant Candidates** (OPTN Liver and Intestines Committee)

The review group appreciate the amount of careful detail that went into the proposal, especially in the area of pediatrics. They requested that the median time till transplant prior to the implementation of acuity circles be included in the paper. Furthermore, they expressed concern that this guidance could encourage programs to become more conservative as patients will gain points with every other status exception extension (totaling 180 days).

Staff replied that the donor pool required for these candidates is very selective, and therefore require high prioritization for the donors they can use. The concern from the liver community was that these candidates were being prioritized too quickly, and were not concerned about the candidates reaching the peak MELD score of 40 within 6-12 months.

With no further comments, the POC approved this releasing this proposal for public comment (15 yes, 0 no, 0 abstain).

- **Establish Member System Access, Security Requirements, Incident Management, and Reporting Requirements** (OPTN Network Operations Oversight Committee)

Review group members felt that there was a definite need for addressing the security of the OPTN systems. However, they felt that the proposal did not make clear the number of stakeholders that were involved in its creation, especially given that two OPTN committee's provided feedback on it prior to public comment.

With no further comments, the POC approved this releasing this proposal for public comment (15 yes, 0 no, 0 abstain).

- **Identify Priority Shares in Kidney Multi-Organ Allocation** (OPTN Ad Hoc Multi-Organ Transplant Committee)

Review group members appreciated that the proposal addressed the issue of priority kidney shares from multiple perspectives. A member noted that the implementation estimate for this concept paper seemed remarkably large. They added that the confounding factor in this analysis was the move to continuous distribution, and how that would affect candidate scores.

The Chair of the Committee replied that one benefit of the concept paper in the context of continuous distribution was providing a background on where community sentiment is to inform policymaking. In addition, the implementation estimate for a concept paper is zero; the graphic shows the total implementation cost of the future proposal.

With no further comments, the POC approved this releasing this proposal for public comment (15 yes, 0 no, 0 abstain).

- **Ethical Evaluation of Multiple Listings** (OPTN Ethics Committee)

Review group members supported the approach the Ethics committee took to endorse multiple listing only in the cases that a candidate is difficult to match. However, they felt it would be difficult to provide a working definition for "difficult to match" candidates and create criteria for it.

With no further comments, the POC approved this releasing this proposal for public comment (14 yes, 0 no, 0 abstain).

- **Improve Deceased Donor Evaluation for Endemic Disease** (OPTN Ad Hoc Disease Transmission Advisory Committee)

Review group members supported the proposal, but asked if the incidence rate supported the need for mandatory reporting and the cost thereof. They also wondered whether "country of origin" was specific enough to determine whether endemic disease evaluation was needed.

Finally, they inquired if the Heart committee had been involved due to the proposed changes most significantly impacting heart transplant recipients.

The sponsoring committee's vice-Chair responded that there has been an increase in positive serologic reports since 2012 for Strongyloides, which is why the committee is pursuing mandatory reporting. Furthermore, because of recipient-side treatment, the number of proven and probable cases reported to the DTAC has dropped; this leads to inadequate data collection on the incidence rate of infection. With regards to Chagas, the majority of cases have occurred in donors who were born in an endemic area, which is why the DTAC is using "country of origin" as their evaluation question.

With no further comments, the POC approved this releasing this proposal for public comment (15 yes, 0 no, 0 abstain).

- **Optimizing Usage of Kidney Offer Filters**

The review group supported this proposal, and wondered if more explanation could be given for the evidence threshold's language of "up to and including final acceptance offers". A second member asked if there would be candidate-level filters included in this proposal.

The vice-Chair clarified that this meant the model would only consider offers that were rejected by a transplant program but, at a later sequence, were accepted by a separate program. They added that this proposal would only be describing program-level filters, not candidate-level filters.

With no further comments, the POC approved this releasing this proposal for public comment (14 yes, 0 no, 0 abstain).

Upcoming Meeting

- February 13, 2022

Attendance

- **Committee Members**
 - Nicole Turgeon
 - Jennifer Prinz
 - Andy Flescher
 - Dolamu Olaitan
 - Gerald Morris
 - Jason Huff
 - Jesse Schold
 - Jim Kim
 - Jondavid Menteer
 - Kimberly Koontz
 - Lisa Stocks
 - Matthew Hartwig
 - Natalie Blackwell
 - PJ Geraghty
 - Scott Lindberg
 - Stephanie Pouch
 - Stevan Gonzalez
 - Vijay Gorantla
- **HRSA Representatives**
 - Adrienne Goodrich-Doctor
 - Marilyn Levi
 - Vanessa Arriola
- **SRTR Staff**
 - Jon Snyder
- **UNOS Staff**
 - Alex Carmack
 - Amber Fritz
 - Anna Wall
 - Cole Fox
 - Courtney Jett
 - Erick Messick
 - Isaac Hager
 - Joann White
 - Kaitlin Swanner
 - Kayla Temple
 - Kelley Poff
 - Kim Uccellini
 - Kristina Hogan
 - Kristine Althaus
 - Laura Schmitt
 - Lauren Mauk
 - Lindsay Larkin
 - Liz Robbins Callahan
 - Matt Cafarella
 - Meghan McDermott

- Morgan Jupe
- Rebecca Murdock
- Roger Brown
- Sally Aungier
- Sara Rose Wells
- Sharon Shepherd
- Stryker-Ann Vosteen
- Susan Tlusty
- Tamika Qualls
- Taylor Livelli
- Terri Helfrich
- Tina Rhoades