

OPTN Liver and Intestinal Organ Transplantation Committee

Meeting Summary

September 8, 2023

Conference Call

Scott Biggins, MD, Chair

Shimul Shah, MD, MHCM, Vice Chair

Introduction

The OPTN Liver and Intestinal Organ Transplantation Committee (the Committee) met via Citrix GoToMeeting teleconference on 09/08/2023 to discuss the following agenda items:

1. Public Comment Presentation: Organ Procurement Organization (OPO) Committee (Modify Organ Offer Acceptance Limit)
2. Continuous Distribution: Placement Efficiency Attributes

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

1. Public Comment Presentation: OPO Committee (Modify Organ Offer Acceptance Limit)

The Committee heard a presentation on the OPTN OPO Committee's public comment proposal, *Modify Organ Offer Acceptance Limit*.

Summary of discussion:

Decision: The Committee expressed their concerns with the *Modify Organ Offer Acceptance Limit* proposal and made suggestions on how to improve it.

A member asked about unintended consequences for pediatric candidates. Another member asked about regional variability, as they are concerned that this proposal will negatively impact some regions more than others. The Chair believes this proposal lacks important details, such as data for pediatric candidates, as well as region-specific data. The Chair also expressed concern for small-statured candidates.

A member asked if the OPTN OPO committee reviewed the quality of organs that have multiple acceptances and are allocated out of sequence compared to others. They asked if multiple acceptances are driven by OPOs or if it is driven by the liver transplant community. The Chair of the OPTN OPO Committee said that multiple acceptances cause chaos among OPOS, donor families, recipient families, and other accepting transplant centers. A member agreed that it is important to look at data regarding the quality of the organs. They said data shows that livers are often turned down about an hour and a half prior to cross-clamp compared to six hours for lung. They explained this data shows that lung transplant teams have more information about the graft, whereas liver grafts depend upon the OPO doing the pre-transplant workup. They recommended standardizing how OPOs work-up liver grafts, which will help provide more information about the graft and could potentially reduce late declines. A member said that another barrier is that procurement does not happen until several hours after the donor has passed and, in that time, a lot can happen, such as a transplant center accepting a more suitable graft.

The Chair said the thoracic organs will often dictate the timing of the procurement and that may be why liver is the outlier. A member said that the proposal should not disincentivize reviewing medically complex graft offers because they must pick between organs. The member suggested modeling how many medically complex offers will be overlooked if this proposal were to go into policy. They echoed a previous member's sentiments, saying that many OPOs do not have a standardized way of working up a liver, which contributes to late turn downs to livers.

The Vice Chair requested additional data about the quality of livers, as well as clarification on the specific operational outcomes of this proposal, as they believe it is currently too vague as it is. They asked the Committee if they need to have two acceptances in for a candidate with a Model for End-Stage Liver Disease (MELD) score less than 35, as the data suggests that those who have a MELD 35 or higher or is a Status 1A or 1B represents 68% of these donors. They suggested that the policy be modified to allow for two acceptances for those with a MELD 35 or higher or a Status 1A or 1B, as these are the most medically urgent candidates. The Vice Chair also feels that the process of procurement needs to be more standardized, including clearer language. Another member stated that there are many variables that could have detrimental effects on high MELD candidates, and eliminating the time component of this proposal is important. They said the timeframe in this proposal needs to be defined and needs to be limited to one that will truly result in late turndown, otherwise this can severely disadvantage very sick candidates. They said they recommend an exception in this policy for Status 1A and 1B candidates and candidates with a MELD score of 40.

A member said they do not think this proposal will be effective unless there is a clear definition of primary acceptance that is uniform across all OPOs. A member said that the OPOs must be willing to work with transplant centers to change things from acceptances to provisional yeses as transplant centers navigate this acceptance rule.

A member said that the foundational issue with multiple acceptances comes down to communication problems and transparency with OPOs as well as other transplant centers. They said that if the software allowed for transplant centers to see that there are two provisional acceptances, it would allow for OPOs to have a strong back-up. They said if software could be updated to do this, it would solve a lot of the issues, otherwise it will be difficult to move towards one acceptance for medically urgent candidates.

A member said a main concern is the timeframe in which transplant surgeons change their minds in terms of donors. They suggested looking at what the role of timing is in acceptance and how it impacts the OPOs ability to secure an acceptance for a second potential transplant recipient should there be a turndown.

The Chair of the OPTN Pediatric Transplantation Committee recommended that if there were to be a threshold of multiple acceptances, they encourage a lower threshold for pediatric candidates in comparison to adults.

The Chair said they feel that the proposal is vague in how it would be implemented and there is concern about unintended consequences and data may help alleviate some of the concerns. The Committee has concerns about candidates with a MELD score of 35 or higher and Status 1 candidates, as well small-statured candidates, including the pediatric group. The Chair questioned why the quality of donor grafts has not been considered in this proposal, which can cause less than ideal outcomes.

Next steps:

Feedback will be summarized, and the Committee will post an official comment on the *Modify Organ Offer Acceptance Limit* proposal on the OPTN public comment website.

2. Continuous Distribution: Placement Efficiency Attributes

The Committee discussed the attributes related to placement efficiency- travel efficiency and proximity efficiency.

Summary of discussion:

Decision: The Committee decided to use driving versus flying as the input to the travel efficiency attribute in the liver continuous distribution framework.

Attribute: Travel Efficiency

A member expressed concern about using travel efficiency as it relates to cost, as they believe that it is not their role and find it to be ethically troubling. The Chair said the Committee does not have to use cost and said that they may need to develop a different justification for distance. They said they think it is responsible to include some sort of logistics component, which to them, driving versus flying is intuitive and has been translated into cost. They continued, saying that the logistics of flying versus driving are relevant.

A member said that it is important to note that a flying versus driving threshold for a liver is not the same as a flying versus driving divide for a lung, as the cold ischemic times are different for each organ and liver does not fly as often as lung.

The Committee determined that they will be using the driving versus flying inputs for travel efficiency attribute. A member confirmed that the Committee will reassess the driving time for livers. The Chair said they do not think driving is a good metric because it changes based on traffic congestion.

Attribute: Proximity Efficiency

The Chair said they feel that using proximity efficiency is not an ideal name for the attribute, as they feel this attribute is trying to expedite placement for organs that are at-risk for non-use.

Next steps:

The Committee will proceed using driving versus flying as an input for the travel efficiency attribute. The Committee will continue discussing other attributes within the placement efficiency goal that will be used in the liver continuous distribution framework.

Upcoming Meetings

- September 15, 2023 @ 2:00 PM ET (teleconference)
- October 6, 2023 @ 2:00 PM ET (teleconference)

Attendance

- **Committee Members**
 - Aaron Ahearn
 - Allison Kwong
 - Cal Matsumoto
 - Christine Radolovic
 - Colleen Reed
 - Erin Maynard
 - Jennifer Lau
 - Joseph DiNorcia
 - Kathy Campbell
 - Kym Watt
 - Lloyd Brown
 - Neil Shah
 - Scott Biggins
 - Shimul Shah
 - Sophoclis Alexopoulos
 - Tovah Dorsey-Pollard
 - Vanessa Cowan
 - Vanessa Pucciarelli
- **HRSA Representatives**
 - Jim Bowman
 - Marilyn Levi
- **SRTR Staff**
 - Jack Lake
 - Katie Audette
 - Nicholas Wood
 - Tim Weaver
- **UNOS Staff**
 - Betsy Gans
 - Erin Schnellinger
 - James Alcorn
 - Jessica Higgins
 - Joel Newman
 - Katrina Gauntt
 - Kayla Balfour
 - Matt Cafarella
 - Meghan McDermott
 - Niyati Upadhyay
 - Robert Hunter
 - Susan Tlusty
- **Other**
 - Emily Perito
 - Lori Markham
 - PJ Geraghty
 - Samantha DeLair
 - Samantha Taylor

- Tomoaki Kato