

OPTN Liver and Intestinal Organ Transplantation Committee Meeting Summary March 9, 2023 Conference Call

James Pomposelli, MD, PhD, Chair Scott Biggins, MD, Vice Chair

Introduction

The OPTN Liver and Intestinal Organ Transplantation Committee (the Committee) met via Citrix GoToMeeting teleconference on 03/09/2023 to discuss the following agenda items:

- 1. Public Comment Update
- 2. Alcohol-Associated Hepatitis Project Update and Next Steps
- 3. Continuous Distribution Attribute: Waiting Time
- 4. Continuous Distribution Attribute: Other Methods of Hepatic Support

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

1. Public Comment Update

The Committee reviewed feedback to date on their two public comment items.

Summary of discussion:

National Liver Review Board (NLRB) Guidance for Multivisceral Transplant Candidates

This public comment proposal has been generally support thus far during the winter 2023 public comment period. While there is support for increased priority for multivisceral transplant candidates, regional meeting feedback has questioned whether the score recommendation of median model for end stage liver disease (MELD) at transplant (MMaT) plus six with a three point every 90 days increase is too high. During the Committee's previous deliberations, it was agreed that MMaT plus six with a three point increase every 90 days is an appropriate score recommendation in order to increase access for multivisceral candidates while balancing the needs of high MELD liver-alone candidates.

Additional feedback questioned a section of guidance that states "a candidate should not be considered for a MELD exception if the reason he or she requires a liver transplant is solely for immunological reasons". Feedback cited it is difficult to identify these candidates.

There has been some opposition to the recommended point escalation but the Committee proposed the three point increase to account for multivisceral candidates that require increased access to transplant.

Further feedback requests the Committee to monitor the impact of the proposal and adjust based on post-implementation outcomes.

A member noted that during their regional meeting it was suggested for the Committee to consider post-transplant outcomes of multivisceral recipients.

Update on Continuous Distribution of Livers and Intestines

Some feedback received from regional meetings thus far requested the Committee to consider allocation efficiency and cost to transplant programs in the new framework. There has been an increase in feedback recommending the Committee reconsider post-transplant survival as an attribute.

A member stated that a basis for model for MELD is that the sickest candidates are to receive the greatest benefit of transplant. The member explained that incorporating post-transplant survival may cause this to shift from lifesaving benefit to years of life saved.

Another member suggested reviewing lessons learned from international communities, such as the United Kingdom.

A member noted concern for the lack of models which the Committee could utilize that would predict post-transplant survival with reasonable accuracy. The member stated that there is agreement that post-transplant survival is important, the concern is due to incorporating it without an appropriate model.

Another member suggested the Committee determine whether they seek to address short-term outcomes or long-term outcomes when discussing post-transplant survival.

The Chair noted that patients are particularly interested in post-transplant survival as an attribute in continuous distribution.

Next steps:

The Committee will continue to review public comment feedback on their two proposals and incorporate post-public comment changes as needed.

2. Alcohol-Associated Hepatitis Project Update and Next Steps

The Committee discussed their potential project idea on the topic of alcohol-associated hepatitis.

Summary of discussion:

A member stated that this topic may be better addressed by a stakeholder organization. The member explained that since the Committee is not proposing any mandates related to transplant for alcohol-associated hepatitis, then it may be better addressed by a different organization.

The Chair noted that continuous distribution is a priority for the Committee, and creating a guidance document may not be the best use of time. Another member agreed. The member added, however, that the Committee will likely have to address this topic eventually. A member agreed and stated the Committee should explore whether there are unnecessary transplants occurring for alcohol-associated hepatitis. The member stated if that is an issue, then a guidance document is not the right approach.

Another member suggested the Committee could consider creating a checklist for transplant programs to ensure success, such as securing addiction resources. A member agreed and added that a document that highlights that the six-month period of abstinence is not an evidence-based best practive may be help in securing insurance coverage.

There was not strong consensus to continue forward with a project related to alcohol-associated hepatitis.

Next steps:

The Committee will revisit this topic in the future.

3. Continuous Distribution Attribute: Waiting Time

The Committee discussed waiting time as an attribute in the continuous distribution of livers. The Committee reviewed how current liver allocation policy incorporates waiting time, and how other organ-specific committees intend to utilize waiting time in continuous distribution. Additionally, initial public comment feedback cited that waiting time should be weighted very low, if included at all.

Summary of discussion:

The Chair stated that waiting time should not be included as an attribute in continuous distribution of livers. The Chair stated that waiting time could function as a tie breaker.

A member asked how granular waiting time is captured. Staff responded that waiting time is captured to the second.

The Chair requested the Committee consider whether waiting time is important to liver allocation. Members agreed that waiting time is not an important factor in liver allocation. Members supported using waiting time as a tie breaker in liver allocation for situations where two liver candidates have the exact same composite allocation score.

Next steps:

The Committee will move forward with utilizing waiting time as a tie breaker in continuous distribution.

4. Continuous Distribution Attribute: Other Methods of Hepatic Support

The Committee discussed other methods of hepatic support in the context of continuous distribution. Other hepatic support refers to hepatocyte transplant. After being offered for transplantation, livers are then offered for other methods of hepatic support. Between March 1, 2020 and May 31, 2022, one liver has been placed with the classification of other method of hepatic support, and 158 (2.7%) of candidates ever waiting in that time indicated they were willing to accept a liver for other methods of hepatic support.

Summary of discussion:

The Chair stated that national offers should be sufficient. The Chair explained that if a candidate was on a hepatocyte machine or charcoal filter machine, then they should also receive the national offers. The Chair stated that use of other hepatic support in liver allocation is redundant.

Members agreed that other methods of hepatic support can be removed in the context of continuous distribution of livers.

Next:

The Committee will remove other methods of hepatic support in continuous distribution.

Upcoming Meeting

- March 17, 2023 @ 2:30 PM ET (teleconference)
- April 3, 2023 @ 9:00 PM CT (Houston, TX & teleconference)

Attendance

• Committee Members

- Alan Gunderson
- Allison Kwong
- Christopher Sonnenday
- o Colleen Reed
- Greg McKenna
- o James Eason
- o James Markmann
- o Jim Pomposelli
- o James Trotter
- o Joseph DiNorcia
- o Neil Shah
- Kym Watt
- o Pete Abt
- Sumeet Asrani
- Vanessa Pucciarelli
- HRSA Representatives
 - o Jim Bowman
- SRTR Staff
 - o Katie Audette
 - o Nick Wood

• UNOS Staff

- Austin Chapple
- Erin Schnellinger
- o James Alcorn
- o Jennifer Musick
- o Joel Newman
- o Katrina Gauntt
- o Laura Schmitt
- o Matt Cafarella
- o Niyati Upadhyay
- Susan Tlusty