

Meeting Summary

OPTN Liver and Intestinal Organ Transplantation Committee National Liver Review Board (NLRB) Subcommittee Meeting Summary November 15, 2022 Conference Call

James Trotter, MD, Chair

Introduction

The OPTN National Liver Review Board Subcommittee (the Subcommittee) met via Citrix GoToMeeting teleconference on 11/15/2022 to discuss the following agenda items:

1. Challenges in the Multivisceral Transplant Allocation System

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

1. Challenges in the Multivisceral Transplant Allocation System

The Subcommittee continued discussing the challenges with the multivisceral transplant allocation system.¹

Summary of discussion:

The Chair noted that the cumulative incidence of death for liver-alone candidates decreased slightly after the implementation of acuity circles (AC) policy, while the cumulative incidence of death for multivisceral candidates increased after the implementation of AC policy. The Chair noted that while the death rates for multivisceral candidates are high, the absolute numbers are small.

The Subcommittee reviewed *OPTN Policy 8.10.D: Allocation of Liver Intestines.* The Chair asked for more information on whether it is the organ procurement organization's (OPO) discretion to determine whether the multivisceral candidates are prioritized for liver-intestine offers.

The Chair noted that data shows that the majority of multivisceral candidates are listed with MELD scores under 15. The Chair added that the about half of multivisceral candidates are transplanted with MELD scores over 28. The Chair stated that the number of exception cases for multivisceral candidates have dropped since the implementation of AC policy. The Chair stated that data shows that multivisceral recipients have a higher rate of graft loss than live-alone candidates.

A member reviewed the proposed drafted guidance for multivisceral candidates with the Subcommittee. The member stated that multivisceral candidates receive a ten percent waitlist mortality increase in MELD scores but noted it is not enough. The member stated that multivisceral candidates have a variety of clinical backgrounds. The member stated that multivisceral transplant is a risky surgery and all multivisceral candidates should be eligible for a MELD exception.

The member proposed that median MELD at transplant (MMaT) minus six as an initial exception score with the opportunity to receive an additional three points every three months. The member explained

¹ Tommy Ivanics et al. "Impact of the Acuity Circle Model for Liver Allocation on Multivisceral Transplant Candidates," *American Journal of Transplantation* 22, no. 2 (2021): pp. 464-473, https://doi.org/10.1111/ajt.16803.

that multivisceral candidates are often listed with lower MELD scores, which does not lend to access to higher quality organs. The member noted this is the reason that multivisceral candidates need higher MELD to access transplant.

The Chair asked if there is data to support that multivisceral candidates need access to for high quality donor organs for transplant. The member responded that data shows that multivisceral recipients are transplanted with organs from donors less than 40 years of age. The member explained that data shows that multivisceral experts are not willing to use older aged deceased donor organs but noted there is no specific research to support the concept. The member stated the general practice is to not accept organs from deceased donor organs over the age of 40. The member explained that the risk is that the intestine is very susceptible to ischemia change and a younger donor is able to tolerate more change. The member stated there are a lot of factors that are needed to accept a multivisceral organ offer, such as age less than 50, body mass index (BMI) less than 30, no diabetes, no pancreatitis, and the factors all need to be perfect.

Another member of the community noted there is data on age, BMI, and other factors on pancreas transplant survival. The member of the community stated it is technical and fact driven as it is a very risky surgery. Another member of the community noted that multivisceral transplant is a risky operation and organ quality should be controlled in order to improve outcomes. The member of the community that marginal grafts are not acceptable in order to sustain this field.

The Chair noted that there is some concern that this guidance may create unfettered access to high quality organs. The Chair explained that guardrails would be helpful. A member stated that common conditions for multivisceral candidates could be listed. The member stated that multivisceral transplant would not be performed just to increase transplant rates. A member of the community agreed that multivisceral transplants are very risky and have worse outcomes, therefore it should not be an option considered unless absolutely necessary. The member of the community stated that liver-intestine transplants represent a small portion of liver transplants. The member of the community estimated that liver-intestine transplant have been historically in the 50-60 per year. The Chair agreed that the numbers are small when considering the larger context of liver transplant.

Another member asked how MMaT plus six was proposed. A member responded that MMaT plus three does not help increase access, but MMaT plus six would increase multivisceral candidates' MELD scores enough to improve access. The member stated there is still concern the liver would be shared locally so additional points each month is reasonable to increase access. Another member asked if there is a scientific way to determine how many MELD points are acceptable for multivisceral candidate exceptions, such as reviewing cumulative incidence curves. The Chair stated that the 10 percentage point increase does not increase a MELD score enough to improve access to high quality organs for transplant.

A member of the community stated that the MELD score was not designed for multivisceral transplant. The member of the community stated that the MELD score does not accurately account for the mortality causes for multivisceral candidates. The member of the community suggested the Subcommittee determine an MMaT exception score by considering where multivisceral candidates should appear on a match run, rather than fit them in a MELD model for liver allocation.

A member suggested that the OPTN Liver & Intestinal Organ Transplantation Committee consider creating a classification outside of MELD for multivisceral candidates. The Chair stated that developing a priority score is difficult due to the small numbers and wide variety of clinical indications. Another member agreed. The member noted that exceptions may increase access to transplant for multivisceral candidates and which may result in less of a need to develop a separate priority score. Another member

of the community noted that a status system could be developed. The member of community noted there would need to be a large multivisceral representation to ensure proper status indication.

A member of the community stated that they did not agree with the concern about unfettered use of high quality organs. The member of the community stated that the current allocation could be viewed as unfettered use of high quality organs since multivisceral candidates are not receiving appropriate access to specific organs of need.

Another member asked if the guidance is applicable to liver-pancreas candidates. A member of the community responded that multivisceral candidates include liver-intestine-pancreas. Another member of the community that there is not a good pathway for liver-pancreas, but noted that is a different issue which is outside the scope of this guidance.

A member suggested removing the first paragraph of the drafted guidance for multivisceral candidates because it may not be helpful as a historical reference.

Another member asked if each condition needs to be described in detail for the drafted guidance. Staff noted that the Subcommittee has worked to ensure that NLRB guidance for specific diagnoses is concise and specific to the candidates the need exceptions.

Another member asked about the increase of MMaT plus three every three months for multivisceral candidates. The member stated that an automatic increase of MMaT plus three every three months would mean that some multivisceral candidates have a MELD score of 40 within six months. The member explained that this may incentivize transplant programs to list multivisceral candidates early and in order to ensure they receive a MELD score of 40. The Chair clarified that the MMaT increase helps slow down the exception process compared to having every multivisceral candidates have an automatic exception for a MELD score of 40. The Chair stated multivisceral candidates currently do not have enough access to organ offers, therefore the Subcommittee needs to consider whether the exception should allow immediate access to high MELD score or a slower increase of a MELD score.

A member of the community noted that a slower increase of MELD score allows transplant programs the opportunity to accept organs for multivisceral candidates at lower MELD scores. The member of the community noted that some multivisceral candidates may receive quality offers at a MELD score 33 or 35 and might not need MELD of 40 to have appropriate access. The Chair noted that the data appeared to show that multivisceral candidates were receiving a transplant with MELD scores of 29. A member shared their experience is that transplant programs will decline the organ offers due to concern of diseases such as hepatitis C virus, which then allows multivisceral candidates with lower MELDs access to organ offers.

A member asked if the Subcommittee should establish an upper limit on the exception scores for multivisceral candidates. The member suggested an upper limit of a MELD score of 38 or 39. Another member responded that a multivisceral candidate could wait compared to a candidate with hepatic artery thrombosis (HAT) with MELD of 40. Another member of the community stated that cap of MELD 39 is reasonable. A member agreed. Staff noted the system only allows exceptions relative to MMaT or MELD 40.

The Chair stated that multivisceral expertise is needed on the NLRB to ensure that those who are best informed are providing input on these cases. Another member stated that transplant programs would need to volunteer NLRB reviewers with multivisceral expertise.

The Chair stated that MMaT plus six is a high exception request score, especially for places like California. A member agreed and asked if the guidance should state "an additional increase could be considered". Another member asked what percentage of transplants happen above MMaT above six.

A member stated that due to the geographical differences in MMaT, the exception request should be MMaT plus six with a three point increase every three months. A member responded that the geographic differences in MMaT are to account for the MELD scores needed to access transplant. The member did not agree with the logic that MMaT plus six is needed for every multivisceral candidate across the nation.

Next steps:

The OPTN Liver & Intestinal Organ Transplantation Committee will review the drafted guidance and score recommendation during the November 18, 2022 meeting.

Upcoming Meeting

• December 8, 2022 @ 2:30 PM ET (teleconference)

Attendance

• Subcommittee Members

- o Allison Kwong
- o Greg McKenna
- o James Eason
- o Jim Trotter
- o Joseph DiNorcia
- o Kym Watt
- o Neil Shah
- o Shunji Nagai
- o Sophonclis Alexopolous

• HRSA Representatives

o Jim Bowman

• SRTR Representatives

Jack Lake

UNOS Staff

- o Erin Schnellinger
- o Katrina Gauntt
- o Matt Cafarella
- o Meghan McDermott
- Niyati Upadhyay

Other Attendees

- o Chandrashekhar Kubal
- o Jonathan Fridell