OPTN Liver and Intestinal Organ Transplantation Committee
Meeting Summary
April 4, 2022
Chicago, Illinois

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

Introduction

The OPTN Liver and Intestinal Organ Transplantation Committee (the Committee) met in Chicago, Illinois on 04/04/2022 to discuss the following agenda items:

1. Improving Liver Allocation: MELD, PELD, Status 1A, Status 1B: Public Comment Review and Vote
2. Ongoing Review of National Liver Review Board (NLRB) Diagnoses: Public Comment Review and Vote
3. Median MELD at Transplant (MMaT) Around the Donor Hospital: HI/PR Cohort Policy Clarification
4. Policy Oversight Committee (POC) Update
5. NLRB Subcommittee Update
6. Region 8 Split Liver Variance: 2 Year Evaluation Report
7. Region 8 Split Liver Variance Discussion
8. Continuous Distribution (CD)

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

1. *Improving Liver Allocation: MELD, PELD, Status 1A, Status 1B*: Public Comment Review and Vote

The Committee reviewed public comment feedback and voted on final language to send to the Board of Directors (BOD).

Summary of discussion:

The Committee reviewed all public comment feedback submitted on the proposal titled, *Improving Liver Allocation: MELD, PELD, Status 1A, and Status 1B*. The Committee specifically discussed concerns raised throughout public comment related to the inclusion of albumin in MELD 3.0. The American Society of Transplantation (AST) noted particular concern with the inclusion of albumin in the MELD score due to the potential for healthcare providers to withhold albumin infusion when clinically indicated in order to receive a higher MELD score.

A member explained that the inclusion of albumin improves the statistical power of MELD 3.0 and that the interaction term between albumin and creatinine is incorporated such that as creatinine increases, the impact of albumin diminishes. The inclusion of albumin should not be of concern, as it will not impact high creatinine candidates. The effect of albumin will be more pronounced at low creatinine levels, where albumin is typically not given. The Committee further noted that albumin has little relative weight at higher MELD scores and will only be used to differentiate between candidates with lower MELD scores. The Committee agreed to continue to pursue an albumin inclusive MELD calculation, but to also connect with AST to discuss their concerns.

A member pointed out the opportunity to educate the liver community about albumin as MELD 3.0 is implemented. Another member suggested monitoring the impact of albumin upon implementation. A member noted that the liver simulated allocation model (LSAM) results predicted continued high waitlist mortality for petite women. This member continued that developing MELD 3.0 is a great step forward, but would like to see more done to reduce waitlist mortality for this population. Another member agreed and expressed that size matching between donors and recipients is an issue of access to transplant that could be accounted for in CD. The Committee decided to not make any significant post-public comment changes and move forward with the proposal as written.

A vote was taken regarding: Does the Committee support sending the *Improving Liver Allocation: MELD, PELD, Status 1A, Status 1B* proposal as presented today to the BOD for consideration?

Results were as follows: 21 (100%) Support; 0 (0%) Abstain; 0 (0%) Oppose

Next steps:

The proposal will move forward for consideration by the BOD in June 2022.

2. *Ongoing Review of National Liver Review Board (NLRB) Diagnoses* Public Comment Review and Vote

The Committee reviewed public comment feedback and voted on final language to send to the BOD.

Summary of discussion:

The Committee reviewed all public comment feedback submitted on the proposal titled, *Ongoing Review of NLRB Diagnoses*. The Committee reviewed the proposed changes to guidance for candidates with polycystic liver disease (PLD). A member clarified that a candidate could qualify for an exception if they meet any of the included criteria and that candidates are not required to meet all of the criteria.

A vote was taken regarding: Does the Committee support sending the *Ongoing Review of NLRB Diagnoses* proposal as presented today to the BOD for consideration?

Results were as follows: 21 (100%) Support; 0 (0%) Abstain; 0 (0%) Oppose

Next steps:

The proposal will move forward for consideration by the BOD in June 2022.

3. Median MELD at Transplant (MMaT) around the Donor Hospital: HI/PR Cohort Policy Clarification

The Committee reviewed updated policy for the MMaT cohort for donor hospitals in Hawaii and Puerto Rico.

Summary of discussion:

A vote was taken regarding: Does the Committee support sending the *HI/PR Clarification* as presented today to the BOD for consideration?

Results were as follows: 21 (100%) Support; 0 (0%) Abstain; 0 (0%) Oppose

Next steps:

The updated policy will move forward for consideration by the BOD in June 2022.

4. Policy Oversight Committee (POC) Update

The Committee received an update from the POC.

Summary of discussion:

A member mentioned the current simultaneous liver kidney (SLK) policy requires organ procurement organizations (OPOs) to allocated a kidney with a liver if the SLK candidate has a MELD or PELD 15 or higher and is registered at a transplant program within 150 nautical miles of if the SLK candidate has a MELD or PELD of at least 29 (including Status 1A/1B) and is registered at a transplant program within 250 NM of the donor hospital. The member noted that the 250 NM circle may provide adequate access to SLK transplant in some parts of the country but it is not large enough in areas that are less densely populated. The member further commented that a recent proposal for simultaneous lung-kidney and heart-kidney allocation included 500 NM circle sizes for required shares and suggested that SLK policy should be aligned with these policies. Committee members agreed and asked if this concern could be discussed with the POC.

Another member noted concern with the impact of the Acuity Circles (AC) policy on access to transplant for liver-intestine candidates. The member stated that it has become more difficult for liver-intestine candidates to be transplanted and requested that this concern also be discussed with the POC.

Next steps:

The Committee will work towards bringing these project ideas to the POC for approval.

5. NLRB Subcommittee Update

The Committee reviewed progress from the NLRB Subcommittee and voted to send the next round of NLRB diagnosis review to the POC for project approval.

Summary of discussion:

Multiple Hepatic Adenomas (HA):

The Committee discussed if a few hypothetical candidates scenarios would qualify for an HA exception under current guidance. Members recommended small changes to the structure of the language. The Committee will continue to discuss HA guidance during a future meeting.

Budd Chiari:

The Committee agreed that there is not a significant amount of new literature on Budd Chiari. A member suggested the addition of "failed surgical management" to the guidance. A member asked if these candidates should receive exceptions, suggesting a categorization of acute vs. chronic to differentiate level of severity.

Hepatopulmonary Syndrome (HPS):

The Committee plans to review a data request during a future meeting to determine if these candidates should receive a higher exception score. A member mentioned an increasing number of small groups of patients for whom a higher MELD score has been recommended and that over time, this could contribute to MELD exception creep.

Familial Amyloid Polyneuropathy (FAP):

A member commented that their center is seeing fewer cases of FAP and that this could be due to additional options for therapy. The Committee agreed with the proposed changes to this policy.

Cystic Fibrosis (CF):

A member noted that pediatric candidates with CF are generally not as urgent as adult candidates and that this might suggest early intervention as the best treatment. This member explained that malnutrition and weight loss should be considered as indications for pediatric CF exceptions. Another

member asked if it was necessary to continue to include forced expiratory volume at one second (FEV1). The Committee will continue to discuss CF policy requirements at a future meeting.

A vote was taken regarding: Does the Committee support sending this project to the POC and Executive Committee for project approval?

Results were as follows: 21 (100%) Support; 0 (0%) Abstain; 0 (0%) Oppose

Next steps:

The project will move forward for POC and Executive Committee approval.

6. Region 8 Split Liver Variance: 2 Year Evaluation Report

The Committee reviewed current split liver policies and the 2-year monitoring report on the Region 8 split liver variance.

Summary of discussion:

The Committee discussed the appropriate place to split a liver, as current policy is not clear on who has the authority to decide if the split should occur at the donor hospital or at the accepting program. A member noted that when the accepting program takes the liver to their program to split, the other lobe endures serval hours of cold time, making it less usable by another center. This member favored splitting livers at the donor hospital. Another member mentioned that not all donor hospitals have the necessary equipment for splitting a liver. A member asked the Committee their thought on pediatric priority for split livers. Another member suggested that all livers that meet criteria for splitting should be identified. They continued that the first segment could go to a pediatric patient and there could be some sort of prioritization for an adult candidate to accept the second segment. Members mentioned that one way to incentivize accepting a split liver would be to increase that candidate's MELD score.

The 2-year monitoring report on the Region 8 split liver variance was presented. Multiple members agreed that the chances of successfully allocating the second segment decreases when the whole liver is taken back to the primary accepting program to split. A member suggested that in order to assess the number of discarded livers, the Committee may need to investigate how many of the partial/cut down livers were transplantable vs. non-transplantable. A member suggested in order to increase second segment utilization, adult programs should partner with multiple pediatric centers that split livers.

Nest steps:

The Committee continued this conversation in the following agenda item.

7. Region 8 Split Liver Variance Discussion

The Committee discussed how to handle the Region 8 variance, which is set to expire in December 2022.

Summary of discussion:

A member reminded the Committee that because pediatric candidates make up just a small portion of the liver waiting list, the Committee could consider a solution that would increase pediatric priority without significantly harming the adult candidate population.

A member suggested recommending a solution in the short-term that fits into the Region 8 expiration timeline, but taking more time to develop a larger, more comprehensive solution to increase split liver transplant. A member agreed and suggested extending the Region 8 variance while the Committee develops a solution that increases the number of split livers, further prioritizes pediatric candidates, and potentially decreases the number of pediatric exceptions. Members agreed that in such a solution,

pediatric programs would need to understand that the second segment of a split liver is intended for allocation to reduce the amount of cut-downs.

The Committee discussed the possibility of expanding the region 8 variance nationally, but felt there is not enough data to support expanding the variance, especially given the fact that the implementation of the Region 8 variance coincided with the implementation of the AC policy and the beginning of the COVID-19 pandemic. The Committee came the consensus that they would recommend extending the Region 8 variance, while a more comprehensive change within the context of CD.

A vote was taken regarding: Does the Committee support sending this project to the POC and Executive Committee for project approval?

Results were as follows: 21 (100%) Support; 0 (0%) Abstain; 0 (0%) Oppose

Next steps:

The project will move forward for POC and Executive Committee approval.

8. Continuous Distribution (CD)

The Committee continued to discuss CD, focusing on exception diagnoses and incorporating new attributes into CD policy.

Summary of discussion:

A member asked how candidate height could be incorporated into CD. Members discussed a variety of methods for the inclusion of height including awarding points for candidate height, donor-recipient size matching and/or body surface area.

A member suggested that population density/donor availability fall into both patient access and placement efficiency categories. A member asked if the definition of patient access would be access to a transplant center or access to donors. Another member suggested this would be access donors. A member asked for more context surrounding donor factors, such as donation after circulatory death (DCD) status or age. Staff noted that the Committee will need to have much more conversation on donor factors but the system could be constructed such that different attributes are assigned different weights or rating scales based on different donor factors.

A member suggested the addition of frailty and sarcopenia to the candidate biology goal. A member mentioned that surgical complexity could be part of the candidate biology goal. Members also categorized willingness to accept a split and willingness to accept a DCD under patient access.

The Committee discussed how the rating scales and weights for individual attributes will change based upon certain donor characteristics. Members noted the opportunity to take factors other than medical urgency into account when considering the development of CD. Members discussed how post-transplant survival, utility, and medical urgency might interact as variables in the future.

A member suggested it would be difficult to include frailty, as it is hard to measure. This member suggested that variables such as frailty and sarcopenia can be used as indications for transplant, but are hard to operationalize in allocation.

The Committee determined they would examine and discuss each potential attribute closely to determine if it should be consider for further incorporation into the first iteration of CD.

Next steps:

The Committee will continue their discussion on CD during future meetings.

Upcoming Meeting

- May 6, 2022 @ 3pm ET

Attendance

- **Committee Members**
  - Ray Lynch
  - Peter Abt
  - Sophoclis Alexopoulos
  - Sumeet Asrani
  - Scott Biggins
  - James Trotter
  - Diane Alonso
  - Kim Brown
  - James Eason
  - Alan Gunderson
  - Shekhar Kubal
  - Allison Kwong
  - Jim Markmann
  - Bailey Heiting
  - Derek DuBay
  - Jen Kerney
  - Greg McKenna
  - Mark Orloff
  - James Pomposelli
  - Jorge Reyes
  - Kymberly Watt
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - David Schladt
  - Katherine Audette
  - Nick Wood
  - Tim Weaver
  - John Lake
  - Ryo Hirose
- **UNOS Staff**
  - Matt Cafarella
  - Betsy Gans
  - Kelley Poff
  - Rebecca Murdock
  - Joel Newman
  - Julia Foutz
  - Kaitlin Swanner
  - Liz Robbins Callahan
  - Matt Belton
  - Niyati Upadhyay
  - Delaney Niles
  - Tamika Qualls
  - Tina Rhoades