OPTN Liver and Intestinal Organ Transplantation Committee
Meeting Summary
April 14, 2021
Conference Call

James Trotter, MD, Chair
James Pomposelli, MD, PhD, Vice Chair

Introduction

The OPTN Liver and Intestinal Organ Transplantation Committee (the Committee) met via Citrix GoToMeeting teleconference 04/14/2021 to discuss the following agenda items:

1. Calculate Median MELD at Transplant (MMaT) Around the Donor Hospital and Update Sorting within Liver Allocation - Voting Item
2. Update National Liver Review Board (NLRB) Guidance Documents and Policy Clarification – Voting Item
3. Committee Project Portfolio – Discussion Item
4. Data Monitoring Reports – Discussion Item
5. Data Monitoring Reports – Discussion Item
6. OPTN Executive Committee COVID-19 Emergency Action Request for Feedback – Discussion Item
7. Pediatric End-Stage Liver Disease (PELD) Project Update – Discussion Item
8. Model for End-Stage Liver Disease (MELD) Project Update – Discussion Item
9. Data Monitoring Reports – Discussion Item
10. Updating Diagnoses on the Transplant Candidate Recipient (TCR) Form - Discussion Item

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

1. Calculate Median MELD at Transplant (MMaT) Around the Donor Hospital and Update Sorting within Liver Allocation- Voting Item

The Committee reviewed public comment feedback on the *Calculate Median MELD at Transplant around the Donor Hospital and Update Sorting within Liver Allocation* proposal and voted on language to send to the OPTN Board of Directors.

Summary of discussion:

The Committee considered a post- public comment change that would sort pediatric candidates first after allocation MELD scores and blood type compatibility.

A member asked how many pediatric candidates would be impacted by this post public comment change. Another member responded that because just a fraction of the total number of pediatric liver candidates will be impacted, it should be no issue to prioritize this patient group and noted that the OPTN Pediatric Transplantation Committee supported this change.

The Committee discussed transition procedures for *Calculate Median MELD at Transplant Around the Donor Hospital and Update Sorting within Liver Allocation*. The Committee recommended that candidates who accrued time at a higher exception score prior to implementation should keep that time as part of their time at score or higher.

Committee members voted on the following: "Do you support sending the *Calculate Median MELD at Transplant around the Donor hospital and Update Sorting within Liver Allocation* proposal as presented today to the OPTN Board of Directors for consideration?"

Vote: 16- Support, 1- Abstain, 0- Oppose

Next steps:

Calculate Median MELD at Transplant Around the Donor Hospital and Update Sorting within Liver Allocation will move forward to the OPTN Board of Directors for consideration in June 2021.

2. Update National Liver Review Board (NLRB) Guidance Documents and Policy Clarification – Voting Item

The Committee reviewed public comment feedback on the *Update National Liver Review Board Guidance Documents and Policy Clarification* proposal and voted on language to send to the OPTN Board of Directors.

Summary of discussion:

The Committee reviewed the final policy and guidance language and determined that *Update National Liver Review Board Guidance Documents and Policy Clarification* would not require transition procedures as no candidates are expected to be disadvantaged as a result of the proposed changes.

Committee members voted on the following: "Do you support sending the *Update National Liver Review Board Guidance Documents and Policy Clarification* guidance as presented today to the OPTN Board of Directors for consideration?"

Vote- All voting Committee members supported

Next steps:

Update National Liver Review Board Guidance Documents and Policy Clarification guidance will move forward to the OPTN Board of Directors for consideration in June 2021.

3. Committee Project Portfolio – Discussion Item

The Committee reviewed the current project portfolio:

Pending Board Approval:

- *Calculate Median MELD at Transplant around the Donor Hospital and Update Sorting within Liver Allocation*
- *Update National Liver Review Board Guidance Documents and Policy Clarification*

Project Approval/ Evidence Gathering:

- *Ongoing Review of NLRB Guidance and Policy Diagnoses*

Evidence Gathering:

- *PELD/Status 1B*
- *Improving MELD Calculation*

Idea:

- *Updating Diagnoses on the TCR*
- *Continuous Distribution*

Summary of discussion:

A member confirmed that a proposal for the improving the MELD Calculation project was projected for public comment in January 2022 as opposed to August 2021.

A member proposed revisiting the idea of broadening the scope of the liver committee's charge. Other members voiced support for updating the charge so that the Committee could consider all patients with end-stage liver disease. Members noted that expanding the committee charge would not address the many reasons for which patients with end-stage liver disease are not able to access liver transplant such as transportation and center-specific behavior. The Committee took a straw poll to determine if there was interest in discussing the committee change during an upcoming meeting. It was determined that that the Committee would discuss their charge at an upcoming meeting.

Next steps:

The Committee determined that they will discuss their charge in greater detail during their next meeting.

4. Data Monitoring Reports – Discussion Item

The Committee reviewed three data monitoring reports:

Increased Access for Highly Urgent Candidates in HI and PR Variance

- The first year of data suggest that the variance is allowing Status 1A/1B and MELD/PELD 37+ candidates in Hawaii (HI) and Puerto Rico (PR) to receive liver offers and transplants from outside of their respective organ procurement organizations (OPOs).

Split Liver Variance

- The first year of data do not suggest an increase in split liver transplants or significant shifts in recipient or donor characteristics for these recipients, though more time and data are needed to assess the true impact of the variance.

National Liver Review Board

- Increased approval rates of extension request forms.
- Review Board- Adult HCC had the highest approval rates of initial and extension request forms.
- Pediatric candidates saw the largest decreases in registrations with exception scores at the end of each month after the implementation of the NLRB.
- Pediatric transplants (12-17) saw the highest increase in recipients transplanted without an exception from RRB to NLRB.
- Adult other diagnosis review board had the shortest total time to process an exception form.

Summary of discussion:

The Committee discussed the *Increased Access for Highly Urgent Candidates in HI and PR* variance. A member commented that although transplant numbers are low, the variance seems to be serving its purpose. Another member commented on difficulties Hawaii has reported since implementation of the variance, notably that all high acuity recipients were transplanted with donors from Hawaii and that three other candidates were removed from the waitlist while waiting for a transplant. This member continued that the Organ Procurement Organizations are likely struggling with the logistics of getting organs to Hawaii and suggested that more regional cooperation is necessary. A member responded that there are plans to meet with a representative from Hawaii and discuss this data.

The Committee discussed the Region 8 Split Liver Variance. A member suggested that this policy should be nationalized as it would give small women and children more access to livers. A member noted that

livers suitable to be split are going to high MELD candidates and their center is not comfortable splitting more marginal livers. A member recommended incentivizing splitting livers in order to encourage the behavior.

The Committee discussed the National Liver Review Board monitoring report. A member asked how the liver transplant rate and death/removed from the waitlist both increased. UNOS research explained that both of these increases can happen at the same time as they are not mutually exclusive. A member noted that waiting list mortality for exception candidates with hepatocellular carcinoma (HCC) did not change even though the number and rate for those transplant patients is lower.

Next steps:

The Committee will continue to monitor these projects on an ongoing basis.

5. Data Monitoring Reports – Discussion Item

The Committee reviewed acuity circles one-year post-implementation and considered the following:

- Transplant rates significantly increased for liver-alone candidates with MELD or PELD scores 29+/Status 1A/1B.
- Waiting list dropout rates significantly increased for liver–alone candidates with MELD or PELD scores 29-36.
- Increased offer rates for all MELD or PELD score/status groups
- No significant changes in six-month assumed alive post-transplant patient survival rates
- Utilization rate and rate of livers recorded and not transplanted decreased nationally.

Summary of discussion:

A member suggested that these data should be reported in a manuscript to share with the liver transplant community. A member noted that it would be interesting to examine the donor populations in each region with special attention on which regions have increased their number of DCD transplants. A member commented that his or her program's time from electronic offer to cross-clamp has increased substantially, while the presented data suggests a small increase.

Next steps:

The Committee will continue to monitor this project on an ongoing basis.

6. OPTN Executive Committee COVID-19 Emergency Action Request for Feedback – Discussion Item

The Committee provided feedback on the repeal of the OPTN Executive Committee's emergency action as a result of the COVID-19 pandemic.

The Committee considered the following feedback questions:

- Are there still logistical barriers to obtaining regular candidate lab updates due to the COVID- 19 pandemic?
- Do you recommend the executive committee repeal this policy action?
- How long would it take liver programs to transition back to regularly scheduled clinical updates?

Summary of discussion:

A member reported that his or her center is back to regular operating procedures and that four weeks would be a suitable transition time to repeal the COVID- 19 emergency policy action. Another member agreed and added that some candidates are still reluctant to come in due to COVID- 19.

Next steps:

The Executive Committee will use this feedback to help determine the best course of action for the repeal of the COVID- 19 emergency policy action.

7. Pediatric End-Stage Liver Disease (PELD) Project Update – Discussion Item

The Committee received an update on the PELD/Status 1B project including a PELD refit and scaling presentation from the SRTR.

The Committee considered the following:

- Reparameterizing PELD factors and adding eGFR or Creatinine factors improved overall ability of PELD to discriminate on risk mortality.
- Age and Growth Failure are continuous variables.
    - No large drop in PELD for small changes in age, weight, or height.
- Candidates with higher Serum Creatinine (or lower eGFRs) would benefit from adding a Creatinine (or eGFR) factor.

Summary of discussion:

A member asked for an explanation as to how the original PELD grew to be more inaccurate over time. The presenter responded that this could be a result of a changing pediatric transplantation population. Another member noted that between estimated glomerular filtration rate (eGFR) and creatinine, creatinine may be simpler to use. The presenter agreed, reporting that using eGFR degrades the impact of age and height as factors. A member asked if differences in sex for PELD have a similar impact as they do for MELD. A member responded that most differences in sex emerge post-puberty, so they are not evident for most pediatric patients 0-12 years old. A member asked if there was a way to know how many viable offers were made to the 400 pediatric patients who died on the list. The presenter responded that while the Scientific Registry of Transplant Recipients (SRTR) does not currently have this data, it would be helpful in understanding pediatric programs' acceptance behavior.

Next steps:

The work group will consider this feedback as they update the PELD.

8. Model for End-Stage Liver Disease (MELD) Project Update – Discussion Item

The Committee received an update on the MELD project and consider the following feedback questions:

- Does the Committee agree with the primary outcome (waitlist mortality) for the MELD project?
- Feedback on MELD 3.0?
- Adolescent candidates: while updating MELD and PELD, it is a perfect time to re- examine use of MELD for adolescent candidates
    - If sex is included as a variable in the updated MELD, could it disadvantage adolescent males with low muscle mass?

Summary of discussion:

A member commented that they would not favor including albumin in the MELD 3.0 equation due to its therapeutic use and the potential to disadvantage patients with renal failure. The presenter noted that if the new MELD uses time varying covariates, the factors would look similar to the presented MELD 3.0 model, but it would take all MELD updates into account for a potentially more accurate prediction. A member asked what steps could be taken to allocate smaller donors to small women. A member responded that this was discussed in the work group and could be considered as a separate allocation project. A member voiced support for the MELD 3.0 model. A member asked if the community may be concerned that tall women may be over prioritized when compared to other candidates. Another member commented that this should be included in the modeling. The member explained that because men naturally have more creatinine, their MELD score will be more accurate even when compared to tall women. A member commented that should it fit into the timeline, the workgroup could consider using time variant covariates. Additionally, adolescents should be considered when updating the MELD.

Next steps:

The work group will consider this feedback as they update the MELD.

9. Data Monitoring Reports – Discussion Item

The Committee reviewed the ABO blood type variance monitoring report and considered the following:

- Some potential evidence that it provides the intended benefit and access for candidates listed on these islands.
- There has been an increase in new additions to the liver waiting list in Hawaii with blood type A since implementation.

Summary of discussion:

A member commented that small numbers make it difficult to draw conclusions about the effectiveness of the variance at this time. This member confirmed that the variance will need to be evaluated next year to determine if it should be continued. A member suggested that the Committee should meet with representatives from Hawaii and Puerto Rico to discuss the future action on this variance.

Next steps:

The Committee will evaluate the variance for extension and consider if it should be developed into policy.

10. Updating Diagnoses on the Transplant Candidate Recipient (TCR) Form - Discussion Item

The Committee discussed updating the diagnoses on the transplant candidate registration form to better capture alcohol-associated liver diseases. The goal of the potential future project is to update liver diagnoses on TCR to allow for more complete and accurate data collection on transplant candidates/recipients with alcohol – associated liver diseases.

Summary of discussion:

A member reported that a change in codes on the TCR is essential, otherwise programs will continue to use the incorrect codes and contribute to the collection of inaccurate data. This member voiced support for the proposed diagnoses: alcohol-associated cirrhosis and alcohol-associated cirrhosis or hepatitis with less than 6 months of abstinence. A member asked if programs may be reluctant to pick the diagnosis code denoting less than 6 months of abstinence as some insurance companies will not pay without a waiting period. A member responded that the Committee should ask programs about any

barriers to adding these diagnoses. A member commented that while most of his or her program's candidates do meet the abstinence period, they are unsure if and how those who do not are coded.

Next steps:

UNOS staff will work to develop a pathway for updating these diagnoses and update the Committee.

Upcoming Meetings

- May 7, 2021

Attendance

- **Committee Members**
  - Pete Abt
  - Diane Alonso
  - Sumeet Asrani
  - Kimberly Brown
  - Derek DuBay
  - James Eason
  - Alan Gunderson
  - Julie Heimbach
  - Bailey Heiting
  - Jennifer Kerney
  - Shekhar Kubal
  - Ray Lynch
  - James Markmann
  - Greg McKenna
  - Mark Orloff
  - James Pomposelli
  - Jorge Reyes
  - James Trotter
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Michael Conboy
  - John Lake
  - Adriana Martinez
  - David Schladt
  - Tim Weaver
- **UNOS Staff**
  - Nicole Benjamin
  - Sarah Booker
  - Matt Cafarella
  - Betsy Gans
  - Chelsea Haynes
  - Alesha Henderson
  - Jason Livingston
  - Joel Newman
  - Samantha Noreen
  - Kelley Poff
  - Matt Prentice
  - Liz Robbins
  - Niyati Upadhyay
  - Leah Slife
  - Karen Williams
- **Other Attendees**
  - Samantha Delair

- Emily Perito (OPTN Pediatric Transplantation Committee)
- James Sharrock (visiting Board member)