OPTN Liver and Intestinal Organ Transplantation Committee
Meeting Summary
April 19, 2024
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 WebEx teleconference on 04/19/2024 to discuss the following agenda items:

1. Patient Perspective: Medical Urgency Models
2. Medical Urgency Model Discussion

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

1. Patient Perspective: Medical Urgency Models

A member shared their experience with Model for End-stage Liver Disease (MELD) and Pediatric End-stage Liver Disease (PELD) and offered their input on the potential changes to a medical urgency score within liver continuous distribution.

Summary of discussion:

The presenting member stated that is important to provide specific parameters that patients can track, especially when hospitalized, in order to know how their scores, timing of potential transplant, and stability for transplant will all be impacted. Having something tangible to track may reduce some frustration or anxiety that patients experience. The member noted that the medical urgency score that allows for the most appropriate ranking is the best option and that when patients understand that the sickest patients get priority, it makes the more finite details of the medical urgency score less burdensome. The member stated that improved access for everyone remains the goal.

The presenting member stated that both Optimized Prediction of Mortality (OPOM) and Dynamic MELD (dynaMELD) models allow for honest conversations with patients when it comes to expectations for health status and potential outcomes following transplantation. The member added that a patient's mental status should be taken into consideration when more detailed medical discussions are required as a history of any condition that worsens with stress or impacts processing in combination with the mental load of a health crisis may increase medical treatment refusal. The member emphasized that using the patient's medical power of attorney is of the utmost importance when more complicated medical decisions need to be made. The member explained that discussions with the power of attorney or other family members/caregivers with some medical knowledge may be the difference between a compliant patient that is getting everything they need medically and a "combative" patient who declines treatments from misunderstanding or fear.

The Chair thanked the member for sharing their experience and input on the topic of medical urgency scores. The Chair asked what information did the presenting member track each day. The presenting member responded that they would reference the electronic medical record every day and review the

MELD score. The member added that they would then research how the changes in the MELD score may have changed the timeline for transplant. The member stated they would then compare this information to what their transplant team was also informing them.

A member asked how intuitive the scale of MELD scores is to patients (i.e. 6 to 40). The member asked whether it would be more helpful for patients if it was ranked as a percentile. The presenting member responded the MELD scale made sense to their family and they understood how certain MELD scores related to the urgency of transplant.

Another member commended the presenter for sharing their story.

2. Medical Urgency Model Discussion

The Committee discussed the various medical urgency models (OPOM, dynaMELD, and MELD/PELD). This discussion is a continuation of the information that was provided during the Committee's April 15, 2024 meeting.

Summary of discussion:

A member stated that liver candidates will often call the transplant program to ask for their current MELD score. The member explained that this information is currently easily calculatable for nurse coordinators to pass on to candidates and family members. The member expressed wanting to understand the feasibility of being able to continue to provide this service to patients with a score such as OPOM. The member added that it does seem to be too much change at once if the medical urgency score was to change from MELD at the same time liver continuous distribution is implemented but acknowledged that it is beneficial to consider all options.

Another member expressed that MELD 3.0 is very robust. The member sought to understand how dynaMELD performs for different populations. The member explained that some candidates present acutely at the hospital while others have been with the transplant program for a while, so understanding length of data collection on the impact of the score would be helpful. The member stated that OPOM is of interest because it may allow a better stratification of HCC candidates.

A member stated that the Committee should consider how fungible the liver allocation system should be. The member stated that the Committee needs to understand how policy would evolve and how changes to new scores like dynaMELD and OPOM could be incorporated and updated in future policies. The member reminded the Committee that updating MELD Na to MELD 3.0 took a fair amount of work and the Committee understood what needed to happen in order to make these changes in policy and the system. The member stated this will be different if a new medical urgency score is chosen. The member stated that it would be beneficial to have SRTR provide an analysis on the changes in survival for HCC and non-HCC candidates with a median MELD at transplant (MMaT) standard if there was a switch from MELD 3.0 to OPOM. The member stated it would be negligent if OPOM provided a huge survival advantage but was not pursued. The member added that it would also be important to review post-transplant outcomes. The member stated that an unintended consequence of switching to OPOM could be that there is a decrease in post-transplant survival due to HCC because the model favors more aggressive HCC tumors.

Another member noted interest in understanding how these new models respond to policy changes. The member stated that changing one variable in dynaMELD or OPOM would change the entire model. The member explained that it is worth considering how well could the Committee maintain this and whether it would be an issue if it was implemented into OPTN policy.

A member supported models that can be dynamic, adaptive, and incorporate exceptions to the best of its ability would be beneficial for liver continuous distribution and truly being able to identify medical urgency.

Another member stated they believe the Committee is in a good position since MELD 3.0 is so robust. The member stated that if the Committee ultimately decides that MELD 3.0 is the best model for the first version of continuous distribution then that remains a good solution. The member added that they like OPOM because it is modifiable. The member stated that OPOM focuses on non-HCC and HCC but the model provides a good platform to harness machine learning for further differentiation of waitlist mortality with exception candidates. The member does not agree that OPOM is less transparent or less interpretable. The member explained that the variables in OPOM are explainable, it is the output that gets complicated because of the machine learning. The member stated the Committee should be brave and since continuous distribution already incorporates so many changes, it makes sense to change the medical urgency score at the same time. The member added that OPOM incorporates MELD so it is a beneficial model to use when transitioning to a machine learning model because MELD and its variables can still be referenced.

A member agreed that if the Committee ultimately decides to remain with MELD that they are in a good space because it holds up and the recent changes to MELD 3.0 have continued to be positive and helped address equity. The member stated that they like dynaMELD and the neural networks as well as the model gives priority to the cholestatic group which is a current deficiency. The member stated their concern about dynaMELD is the change variables given how rapidly sick some of the liver candidates can get and whether that may over or underestimate mortality just based on change. The member stated they liked the idea of SHAP values and how beneficial that could be when explaining the impact of certain variables on a candidate's score. A member disagrees and states that they are concerned about the transparency of OPOM due to the number of variables and it seems as if it could change at any moment. The member agreed that reviewing post transplant outcomes for HCC recipients under OPOM is very important. The member stated that OPOM did not incorporate transplanted patients so it will be difficult to determine.

A member agreed that MELD 3.0 has a good backbone. The member stated they like the modularity of OPOM and the ability to interdigitate HCC candidates in a more dynamic way. The member stated the backbone of OPOM is MELD 3.0. The member stated that OPOM incorporating HCC is an example of how an exception case can be interdigitated using machine learning into the allocation system. The member emphasized that the focus of this conversation is acuity, not post-transplant outcomes, so the Committee should be assessing how these models are able to differentiate acuity between candidates. The member stated that this is a great opportunity to be aspirational about this because the future is a dynamic and adaptable scoring system.

Another member agreed.

A member stated that they were cautious with the change from MELD Na to MELD 3.0 due to potential unintended consequences that could have occurred. The member explained that was a small change in comparison to what is currently under discussion and agreed with not changing the medical urgency score at the same time as continuous distribution because they do not know what the consequences could be. The member stated that if it were not for the continuous distribution project, there would not be an impetus to change MELD 3.0. The member stated there is a lot of room for unintended consequences and it is a bit high risk. The member stated that if the Committee remains interested in HCC stratification, there are several models available that the Committee could consider incorporating as an additional attribute. The member stated that determining a model for HCC stratification is nuanced. In addition to considering transplant survival, candidates will get more points for having a

larger tumor and could that disincentivize locoregional therapy treatment. The member stated that the dynamics are very challenging which is why the score for HCC candidates has been static for so long.

Another member stated that liver continuous distribution will likely not be implemented for several more years. The member stated that whatever system is decided upon has to be adaptable because the field may look different. The member explained that particularly in relation to medical urgency models, they must be adaptable such that if a variable is removed it does not yield a completely different result. The member stated with the changing technology such as machine perfusion, HCC may not be as much of an issue in several years as it is now.

The Vice Chair stated the MELD 3.0 has shown its strengths and that the current system is great. The Vice Chair stated that they would like to see how the exceptions could be modeled better. The Vice Chair wondered whether machine learning could be utilized to stratify each disease within MELD. The Vice Chair agreed that the HCC is tricky. The Vice Chair stated concern that OPOM excludes candidates who received transplants within 90 days. The Vice Chair stated that their transplant program does not have candidates often waiting longer than 90 days so how does OPOM work for a programs with similar wait time experiences. The Vice Chair stated they are not convinced that OPOM is valuable since MELD scores are becoming more even around the country and wait times are shortening as well.

A member stated that the Committee needs to consider how the most vulnerable patient populations would receive and be explained this information if a new medical urgency model is chosen. The member stated that the most vulnerable groups that have been historically disenfranchised and marginalized must be considered. The member added their encouragement learning the persistent strength of MELD 3.0.

Another member agreed that there may be too many changes all at once. The member noted that the other models are based on outcomes dictated by MELD scores so it would be helpful if data was collected from one or both models in a prospective way. The member explained that then when considering changes for continuous distribution 2.0 there will be prospective data to analyze the models against MELD in a continuous distribution system. The member noted they are concerned with the branching logic in OPOM as it still has distinctive cut offs where very different outcomes could occur with a very small change. The member noted a preference to neural networks over machine learning but emphasized the need for prospective evaluation of the models.

Next steps:

The Committee will continue discussing medical urgency models and determine whether OPOM or dynaMELD warrant incorporation into the first version of continuous distribution. If so, the Committee will work with SRTR to conduct further analysis for comparison and evaluation.

Upcoming Meetings

- May 3, 2024 at 2 pm ET (teleconference)

Attendance

- **Committee Members**
  - Aaron Ahearn
  - Allison Kwong
  - Cal Matsumoto
  - Colleen Reed
  - Joseph DiNorcia
  - Kym Watt
  - Lloyd Brown
  - Neil Shah
  - Omer Junaidi
  - Scott Biggins
  - Shimul Shah
  - Sophoclis Alexopoulos
  - Tovah Dorsey-Pollard
  - Vanessa Pucciarelli
- **HRSA Representatives**
  - Jim Bowman
- **SRTR Staff**
  - Jack Lake
  - Katie Audette
  - Nick Wood
  - Tim Weaver
- **UNOS Staff**
  - Benjamin Schumacher
  - **Betsy Gans**
  - Cole Fox
  - Erin Schnellinger
  - Kayla Balfour
  - Laura Schmitt
  - Meghan McDermott
  - Niyati Upadhyay
  - Susan Tlusty