

## **OPTN Liver and Intestinal Organ Transplantation Committee**

### **Meeting Summary**

**May 3, 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 05/03/2024 to discuss the following agenda items:

1. Continuous Distribution: Medical Urgency Attribute

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

#### **1. Continuous Distribution: Medical Urgency Attribute**

The Committee continued to discuss various medical urgency models and decided on which to incorporate into the first version of liver continuous distribution.

#### Summary of discussion:

**The Committee has opted to use model for end-stage liver disease (MELD) and pediatric model for end-stage liver disease (PELD) as the medical urgency models to incorporate into the first version of liver continuous distribution.**

The Vice Chair indicated that they would like to proceed with MELD and PELD based on the data that was previously reviewed. The Vice Chair stated it will be important to work on incorporating the standard exceptions and hepatocellular carcinoma (HCC) stratification later. They added that many exceptions can fit into different goals, such as post-transplant survival or access to transplant, but that may reframe exceptions, thus making creating a better system. One member concurred that in terms of medical urgency models, MELD/PELD is ideal, especially when considering that many complexities will be added to a continuous distribution system. They noted that the optimized prediction of mortality (OPOM) model interdigitated HCC exceptions, which was enticing, therefore they advised comparing the performance of OPOM to however the Committee determines to approach HCC exceptions. Additionally, the member questioned how the Committee will undertake Status 1A and 1B candidates. The Chair reminded the Committee that they had previously discussed during the values prioritization exercise (VPE) having these candidates appear at the top of match runs.

Another member advocated for moving forward with OPOM, noting that the foundation of the modeling is MELD 3.0, but allows the interdigitation of HCC candidates. The member stated that this framework for interdigitation could be applied to other exceptions instead of the Committee determining scores for each diagnosis. They continued advocating for the use of OPOM by stating that it is more dynamic and future-oriented, therefore the Committee should consider investigating this model further.

A member voiced their preference for MELD, as they felt the data presented demonstrated its success, especially with the recent implementation of MELD 3.0. The member added that they felt that working through how exceptions could be incorporated into a continuous distribution framework would be a good exercise for the Committee to participate in. Another member agreed that MELD 3.0 should be utilized in the first version of continuous distribution because the other medical urgency models did not appear to have vastly superior outcomes or results. The member added that the MELD 3.0 is a model that the community is already familiar with which is beneficial during such a large change to the allocation system.

A member stated that since continuous distribution will change many factors, it may be beneficial to continue to utilize MELD 3.0 as the medical urgency score since it has continued to perform well. The member added that utilizing MELD 3.0 will also be helpful when evaluating the effectiveness of continuous distribution and analyzing what factors can be attributed to success. The member stated that it will also be important to continue to analyze the opportunity to implement more dynamic systems.

Another member advocated for the use of MELD 3.0 in the first version of continuous distribution. The member underscored the importance of interdigitating HCC exceptions, however, noted that the Committee should revisit that at a later time, ideally once they have had the opportunity to critically think about what that would look like for that population and the consequences that may result. The Vice Chair encouraged the Committee to think about how HCC candidates will be better prioritized, as not all HCC candidates may be ideal transplant recipients. The Chair stated that the OPOM model appears to interdigitate HCC candidates based on medical urgency and does not necessarily incorporate futility considerations as the Vice Chair is suggesting. Another member responded that the criteria for an HCC exception should cap the excess post-transplant risk.

A member noted that stratification by urgency is different than interdigitation. The member explained that stratifying involves grouping HCC candidates within their own risk while interdigitation compares HCC candidates with similar mortality to candidates with non-HCC exceptions. The Chair noted that the Committee could further discuss HCC stratification and determine whether more access to transplant is needed or whether post-transplant survival or medical urgency needs additional consideration, then the Committee could figure out how to award points within a continuous distribution system.

One member pointed out that the terminology of “exceptions” will change, as these standard exceptions will be incorporated into the composite allocation score through various means such as additional points through patient access rather than all being tied to a MELD or PELD score like the current allocation system. One member agreed, citing that the Committee should begin feeling comfortable with a different term rather than exceptions, and suggested potentially using the phrase “diagnosis priority points” or something that implies the current candidate status and diagnosis. The Chair suggested “clinical condition points”.

The visiting board member stated that the Committee should make the decision that best serves patients while also considering any unintended consequences. The visiting board member indicated support for MELD and PELD because the continuous distribution system is very complex and more complexity might not be beneficial at this point in time.

A member stated that OPOM and dynaMELD have not presented enough data on the pediatric population and therefore would support using MELD and PELD. The member added it is important to continue to learn and explore technological advancements and opportunities for medical urgency models in the future but it may not be worth the time to explore them at the same time developing a new allocation system.

Another member agreed with the other members in support of the use of MELD. The member stated that the data reviewed did not present a compelling reason to switch medical urgency models. The member added that with the switch to continuous distribution it would make sense to develop a stepwise approach to avoid any unintended consequences. The member support continuing to maintain a relationship with the other medical urgency model teams in order to further develop and understand innovations.

A member stated that due to the complexity of developing a new allocation system, they are in support of continuing the use of MELD and PELD. The member stated that OPOM and dynaMELD show promise and may be emblematic of where liver allocation is headed in the future.

The Chair of the OPTN Pediatric Transplantation Committee agreed with several other members' rationale for supporting the continued use of MELD/PELD. The OPTN Pediatric Transplantation Committee Chair emphasized the importance of utilizing the continuous distribution framework to categorize exceptions to align with their true purpose rather than attaching them all to a medical urgency score. They also noted the importance of ensuring MELD and PELD continue to be calibrated to each other, really thinking about adjusted expected waitlist mortality for the pediatric population. They stated that the same exercise for considering how to incorporate exceptions will need to be performed specific to the pediatric population.

The Chair summarized that the majority of the Committee appears to support utilizing MELD and PELD in the first version of continuous distribution and the interest in continuing to explore OPOM or dynaMELD for future iterations. The Chair stated that these models could also help the Committee consider how to approach other standard exceptions.

Next steps:

The Committee will move forward with MELD and PELD as their medical urgency model attribute. The Committee will revisit the HCC stratification attribute.

**Upcoming Meetings**

- May 17, 2024 @ 2 PM ET (teleconference)
- June 7, 2024 @ 2 PM ET (teleconference)

## Attendance

- **Committee Members**
  - Scott Biggins
  - Shimul Shah
  - Aaron Ahearn
  - Allison Kwong
  - Chris Sonnenday
  - Christine Radolovic
  - Jenn Muriett
  - Joseph DiNorcia
  - Kathy Campbell
  - Neil Shah
  - Omer Junaidi
  - Sophoclis Alexopoulos
  - Vanessa Cowan
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Jack Lake
  - Katie Audette
  - Nick Wood
  - Tim Weaver
- **UNOS Staff**
  - Ben Schumacher
  - Cole Fox
  - Erin Schnellinger
  - Kayla Balfour
  - Laura Schmitt
  - Meghan McDermott
  - Niyati Upadhyay
  - Susan Tlusty
- **Other**
  - Emily Perito (Chair, OPTN Pediatric Transplantation Committee)
  - Jennifer Lau (visiting board member)