

**OPTN Thoracic Organ Transplantation Committee  
Continuous Distribution Workgroup  
Meeting Summary  
April 16, 2020  
Conference Call**

**Erika Lease, MD, Committee Vice Chair**

## **Introduction**

The Thoracic Committee's Continuous Distribution Workgroup met via Citrix GoTo teleconference on 04/16/2020 to discuss the following agenda items:

1. COVID-19 Update
2. Rating Scale Data Request Update from Data Taskforce

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

### **1. COVID-19 Update**

UNOS staff presented an update on OPTN responses to COVID-19.

#### Summary of discussion:

The Workgroup did not have any questions or comments.

### **2. Rating Scale Data Request Update from Data Taskforce**

UNOS staff shared an update on the work of the Continuous Distribution Data Taskforce, including an overview of how the rating scales and prioritization exercise will feed into the composite allocation score. The Workgroup discussed how to align pediatric waitlist (medical) urgency with adult medical urgency, and whether the allocation model should estimate post-transplant survival beyond one year.

#### Summary of discussion:

#### *Pediatric Waitlist Urgency*

UNOS staff explained the proposed approach for aligning pediatric waitlist urgency (priority I and II) with adult medical urgency. A member asked how the Workgroup will estimate waitlist mortality for pediatric priority I and II patients. Another member asked if it would be appropriate to essentially recreate the lung allocation score (LAS) for pediatric candidates to assess waitlist mortality and post-transplant survival relative to the adult population, using data back to 2005. A member expressed concern that the data set is not large enough to produce reliable results. SRTR staff acknowledged that there is probably not enough data to compare one-to-one between pediatrics and adults, and SRTR would not be able to account for current practices that award priority to pediatric candidates. SRTR staff said they were not sure if there is a way to equate pediatric mortality to adult mortality.

The Workgroup discussed concerns about organ access for the population of candidates under age 12, noting that previous conversations between UNOS and HRSA determined that it is not appropriate to subdivide pediatric candidates (those under the age of 18). The Workgroup noted that the goal of prioritizing pediatric candidates (under age 18) overall is distinct from the Workgroup's goal of

prioritizing candidates under age 12, which is not acceptable to HRSA. SRTR staff agreed to evaluate how candidates under age 12 fare under this approach for aligning pediatric and adult medical urgency.

UNOS staff proposed a similar approach to aligning pediatric priority I and II with adult post-transplant survival. This led the Workgroup into a broader discussion of how post-transplant survival should factor into the composite allocation score.

### *Post-Transplant Survival*

The Workgroup noted that the current LAS estimates post-transplant survival at one year, and a member asked SRTR whether post-transplant survival should be estimated beyond one year. SRTR staff said that it may be advisable to look at post-transplant survival past one year to expand organ access to sicker patients by further stratifying the population. SRTR staff noted that there is not much difference in post-transplant survival at one year but there is more of a difference at three years after transplant. SRTR staff recommended estimating post-transplant survival based on population characteristics, noting that age is the best indicator of post-transplant survival when controlling for donor characteristics and other variables. SRTR staff explained that there is a big difference in post-transplant survival between those under age 65 and those age 65 and above, and 30% of candidates on the waitlist are over age 65. SRTR expressed support for weighting post-transplant survival more heavily than the LAS does currently.

UNOS staff noted that this would result in a big shift in allocation and that it may be a big change for the community, especially in conjunction with the shift to continuous distribution. SRTR staff responded that they have received a lot of feedback from the community to think about the allocation system in this way. A member said that since the Workgroup is already redesigning the whole system for continuous distribution, then it would make sense to make changes all at once, because it has taken the Committee a long time to get to this point of updating the allocation system following the establishment of LAS.

A member noted that the Committee must be able to model any changes to estimating post-transplant survival and demonstrate that it has validity. The member asked why age is a predictor of post-transplant mortality over age 65, and whether the relationship indicates the general mortality of the age group, or something specific to transplant. SRTR staff explained that the modeling is adjusted for every variable that the OPTN collects and age stands out as a predictive variable. A member said that the model would need to be adjusted for the general mortality of the age group. SRTR staff said that analysis has not been conducted. A member agreed that it would make sense to have longer-term survival built in to the model but was not sure it made sense to adjust for life expectancy.

Another member expressed support for looking at longer post-transplant survival time frames since post-transplant and waitlist survival are separate in the continuous distribution model. UNOS staff explained that the decision about how to weight waitlist survival and post-transplant survival will come from the prioritization exercise, and what the Workgroup needs to decide now is how to align pediatric priority I and II and whether SRTR should look at incorporating longer-term outcomes into the model.

The Vice Chair acknowledged the clinical importance of looking at survival in longer terms but also expressed concern that such a big change could be too much for the community for this iteration of the composite allocation score. A member expressed concern about the possibility that certain criteria like being on extracorporeal membrane oxygenation (ECMO) would penalize a candidate even if the transplant program thought that ECMO would give the patient the best chance of a good outcome.

A member asked SRTR staff if they thought they would be able to provide a model accounting for longer-term post-transplant survival that would be acceptable to the transplant community. SRTR staff noted that this work has not yet been done. A member said that this question has been asked since the LAS was developed, and he was under the impression that one-year survival remained in the LAS

because one-year survival is not that different from three-year survival. SRTR staff explained that the candidate cohorts are completely different than when LAS was first developed so the modeling needs to be completed again. SRTR staff noted that if the current post-transplant survival model were updated to three-year survival, the current ranking of the candidates would not change because the model is a proportional hazards model, though the spread of the candidates may change. If SRTR chose a different modeling approach other than a proportional hazards model, that would be a significant change. SRTR staff also noted that the WLAUC would not be on the same scale as the PTAUC, since the waitlist urgency measure is on a one-year scale.

UNOS staff asked SRTR how difficult it would be to evaluate one-year versus three-year models for the WLAUC and PTAUC. SRTR staff said that the models have been constructed to be as current as possible for one-year post-transplant survival whereas they would have to go back farther in the data to assess three-year post-transplant survival. The challenge for SRTR would be building the model based on a larger cohort of patients.

UNOS staff noted that a public comment proposal to update LAS is slated for fall public comment and asked if the Workgroup would prefer that SRTR take the time to focus on one-year versus three-year post-transplant survival. The Workgroup recommended proceeding with the updates to LAS and continuing to consider the possibility of including longer term post-transplant survival in continuous distribution. UNOS staff noted that there were two reasons for updating LAS: (1) it was long overdue, and (2) having a stable formula for the LAS provides a foundation for aligning pediatric priority I and II candidates with LAS patients. Accordingly, the pediatric priority analysis cannot be completed until the LAS updates are complete. UNOS staff recommended that SRTR run the waitlist model for one year and the post-transplant survival for one year and three years, and then the Workgroup will be able to assess how the pediatric priorities I and II fall out in the model.

A member expressed concern that one number would be assigned to all of the pediatric patients in the priority I group and one number would be assigned to all the pediatric patients in the priority II group, whereas a better model would have a spread of values for pediatric priority. The member asked how the Workgroup can ensure that pediatric patients will not be disadvantaged compared to current state. UNOS staff suggested allowing SRTR staff to run the analysis on pediatric priority for the Workgroup to evaluate. The Workgroup agreed with this approach.

SRTR staff asked the Workgroup how they would evaluate whether the one-year or three-year model is better. A member said that if the predictive values and statistical validity are comparable but the spread of values is broader in the three-year model, than the three-year model would be better. The member explained that the problem with the current model is that there is not much to distinguish between candidates. SRTR staff noted that the spread may not be more distinct in the three-year model once it is scaled to the one-year model.

#### Next steps:

UNOS staff and SRTR staff will discuss potential options and assess their impact on the LAS update and continuous distribution project timelines to share with the Workgroup for consideration.

#### **Upcoming Meetings**

- May 21, 2020
- June 18, 2020