OPTN Thoracic Organ Transplantation Committee
Continuous Distribution Data Taskforce
Meeting Summary
March 11, 2020
Conference Call

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Introduction

The Thoracic Committee's Continuous Distribution Data Taskforce met via Citrix GoTo teleconference on 03/11/2020 to discuss the following agenda items:

1. Discussion of Attribute Rating Scales

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

1. Discussion of Attribute Rating Scales

UNOS staff described the purpose of the Continuous Distribution Data Taskforce (Taskforce), which is to make recommendations to the Continuous Distribution of Lungs Workgroup (Workgroup) regarding development of rating scales for attributes that will factor into the composite allocation score for lungs. UNOS staff explained how the rating scales impact the composite allocation score and requested feedback from the Taskforce regarding development of the medical utility score (MUS), which combines the medical urgency and post-transplant survival components of the composite allocation score.

Summary of discussion:

A member asked for clarification about how the Analytical Hierarchy Process (AHP) exercise fits in the process of developing the composite allocation score. UNOS staff explained that AHP is intended to help weigh the attributes for which there is not clinical data, like comparing the importance of medical urgency to post-transplant survival, whereas attributes supported by clinical data will be weighed based on rating scales developed using variables like ischemic time, candidate size, and sensitization.

A member asked if there is external guidance from the Final Rule or the National Organ Transplant Act (NOTA) regarding the components of the composite allocation score and how they should be weighed against each other. UNOS staff highlighted three lessons from these sources that can serve as guidance. First, both sources generally say that if all else is equal, candidates should be prioritized according to medical urgency. Second, the guidance says that geography – where a candidate is registered or where they live – should not play much of a factor into whether a candidate receives an organ offer. Finally, the guidance says that the system needs to consider both equity and utility, but does not specify how these factors should be weighed against each other. UNOS staff noted that the Final Rule and NOTA list other goals but there is no hierarchy of the goals except as otherwise indicated.

A member asked how current policy fits into this framework. UNOS staff shared that UNOS has contracted with an external research firm to convert the current allocation system into points so that it can be compared to the composite allocation score in development by the Workgroup.

A member asked if all of the constants included in the composite allocation score equation are linear. UNOS staff explained that it depends on the attribute, as some attributes are binary and some could be nonlinear.

UNOS staff explained how lung allocation score (LAS) is calculated currently and how the Workgroup will use AHP and rating scales to develop a MUS, which is essentially a new LAS. The LAS is comprised of two components: a waitlist urgency measure (WLAUC) and a post-transplant survival measure (PTAUC). WLAUC is the estimated survival days within one year if the candidate does not receive a transplant. PTAUC is the estimated survival days within one year with a transplant. The LAS is intended to reduce waitlist mortality by placing more weight on the waitlist urgency measure (2/3 for waitlist urgency vs. 1/3 for post-transplant survival). LAS applies to candidates ages 12 and older. Younger patients are not assigned an LAS because the population is so small that it is difficult to estimate LAS, so candidates under age 12 are assigned either priority I or II. The Continuous Distribution project provides an opportunity to revisit how waitlist urgency and post-transplant survival are weighted, and the AHP results can help the Workgroup evaluate if and how to adjust these weights. UNOS staff believe that the best approach to developing the MUS may be to integrate pediatric priority into WLAUC, and to integrate pediatric priority and cold ischemic time into PTAUC.

UNOS staff explained that there are three key questions for developing the MUS. First, the Taskforce must determine how to calibrate pediatric priority onto the same waitlist urgency and post-transplant survival scales used for adults. Second, the Taskforce must determine how to calibrate lung ischemia time onto the post-transplant survival scale. Finally, the Taskforce must determine how to predict or estimate ischemia time for lung candidates on the match run based on donor and transplant hospital locations. To help answer some of these questions, UNOS staff and SRTR are working together on a proposed data request for Workgroup leadership review and approval. UNOS staff requested feedback from the Taskforce regarding the approach for developing MUS.

A member noted that pediatric priority in the current system has two components: weighting based on medical urgency (priority I vs. priority II) and weighting candidates under age 12 relative to candidates over age 12 relative to adults. The member asked for clarification about which components of pediatric priority will be incorporated into the MUS. UNOS staff explained that calibrating pediatric priority I and II onto the same medical urgency scale and post-transplant survival scale as adults is distinct from the pediatric priority that is to be awarded for candidates under age 18 based on ethical reasons and federal guidance. The MUS will award pediatric candidates points for medical urgency and post-transplant survival just like adults, and pediatric candidates will be separately awarded a boost as determined by the Workgroup.

The member expressed concern that if the pediatric boost applies to all children under 18 equally, then the OPTN has lost the opportunity to distinguish priority between children under age 12 and children ages 12 and older. UNOS staff acknowledged that this is an important point to consider and shared that HRSA staff have previously recommended adhering to the definition of age as it sits in NOTA, which defines pediatrics as those under age 18. The member noted that the OPTN has made efforts over the last several years to improve lung allocation for candidates under age 12 and expressed concern that the composite allocation score will not be able to account for these efforts. UNOS staff noted that they are evaluating additional approaches to ensure the composite allocation score appropriately prioritizes candidates under age 12. UNOS staff also noted that part of this process will include a sensitivity analysis that will look at how match runs change with different profiles of patients and donors to make sure it is generating desirable results based on existing allocation policy before the composite allocation score is handed over to SRTR for simulation.

The Taskforce discussed how to calibrate pediatric medical urgency so that it can be compared to adult medical urgency. UNOS staff explained that the OPTN must estimate the waitlist mortality for pediatric priority I and priority II candidates on the same WLAUC scale that is used for adults in LAS. The medical urgency rating scale is a value between 0 and 1, where 0 refers to 0 days of survival without a lung

transplant and 1 refers to 365 days of survival without a lung transplant. The scale is linear, so each day of survival is equally valued. UNOS staff intends to use SRTR modeling to estimate how many days of survival pediatric priority I patients have compared to pediatric priority II patients.

One member asked UNOS staff if they were confident that using available data would yield a statistically clean assessment of how to place priority I/II pediatrics on the curve. UNOS staff acknowledged that there is a sample size challenge and noted that this question is included in the working data request for SRTR to evaluate the level of uncertainty and the size of the cohort needed for this analysis. UNOS staff acknowledged that there will be more uncertainty for pediatric candidates than for adults. The member suggested that the models would have wide confidence intervals for pediatric coefficients, which is why pediatrics have been handled separately in the past. UNOS staff acknowledged the concern and suggested that the Taskforce wait to review the results of the modeling and then consider whether alternate methods will need to be used to account for pediatric candidates.

The Taskforce discussed the rating scale for post-transplant survival, which would be comprised of the PTAUC scale, pediatric priority, and a scale for cold ischemic time. For this rating scale, a score of 0 indicates 0 days of survival post-transplant and a score of 1 indicates 365 days of survival post-transplant. Incorporating ischemic time is expected to reduce estimated post-transplant survival at higher levels of cold ischemic time.

Another member asked if the scale should be linear. UNOS staff explained that either of these two scales could be comprised non-linearly, which may be a value judgment if certain days are valued more than others. Alternatively, after the factors have been combined into the MUS, a non-linear transformation could be applied on top of that score. For now, UNOS staff are assuming linearity because that is how LAS currently functions. UNOS staff explained that the nonlinear clinical models, like PTAUC and Cox models, underpin the variables feeding in to the rating scales. The Taskforce members expressed interest in seeing the intermediate steps to transform the clinical data into the rating scales in order to evaluate whether the approach makes sense.

HRSA staff noted that OPTN policy changes could also influence the nonlinearity of the rating scales. For example, if the OPTN were to introduce a futility deterrent, that would flatten the curve for post-transplant survival. UNOS staff agreed that the continuous distribution framework offers the flexibility to incorporate value judgments in different ways.

Next steps:

The Taskforce will reconvene on March 12, 2020, to continue the discussion on attribute rating scales and to consider whether donor type by total ischemic time interactions should be considered at this stage of the Continuous Distribution of Lungs project.

Upcoming Meetings

- March 12, 2020
- April 9, 2020