

**OPTN Thoracic Organ Transplantation Committee
Continuous Distribution Workgroup
Meeting Summary
May 21, 2020
Conference Call**

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Introduction

The Thoracic Committee's Continuous Distribution Workgroup met via Citrix GoTo teleconference on 05/21/2020 to discuss the following agenda items:

1. Lung Allocation Score (LAS) Refit
2. Analytical Hierarchy Process (AHP) Results

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

1. Lung Allocation Score (LAS) Refit

SRTR staff presented the LAS refit results to the Workgroup. SRTR refitted LAS after removing non-predictive covariates from the waitlist mortality and post-transplant mortality models, as previously directed by the Workgroup. Four covariates were removed from the waitlist mortality model and two covariates were removed from the post-transplant mortality model. The updated LAS calculations, referred to as "refit 2," were compared to LAS calculations based on models that included these six covariates, referred to as "refit 1." Since the covariates were not adding predictive value to the model before they were removed, there was little change between refit 1 and refit 2.

Summary of discussion:

A member said that when the public reviews this proposal, the conversation will go back to intuitively thinking about the cardiac index and central venous pressure (CVP) and how they affect diagnosis group B, which the Workgroup discussed extensively before deciding to remove those covariates from the model. A member pointed out that there is a more scatter in the plot for diagnosis group B between refit 1 and refit 2, and suggested that some candidates are better or worse off. SRTR staff agreed that some candidates might be better or worse off but that the difference is very small, and candidates with improved rankings had a larger magnitude change than those with worse rankings. The Workgroup agreed that no candidate is dramatically disenfranchised by removing those covariates from the model, and those who are impacted will likely be impacted positively. A member noted that they made other changes to benefit group B through factors other than the cardiac index and CVP. SRTR staff agreed, noting that the coefficients for all of the diagnosis group covariates changed, so it is possible that more of that data is being captured by the diagnosis group covariate, or by other covariates in the models. A member suggested that pulmonary artery (PA) pressure and mean PA pressure contribute to where the diagnosis group B candidates land in the models.

Next steps:

The Workgroup affirmed their support for sending the LAS update proposal out for public comment. A member noted that UNOS staff will need to clearly explain that the impact to candidates is minimal and that this is part of the ongoing process to make sure that the LAS reflects the most current data.

Members agreed that how the changes are described in the public comment proposal will be important, and said the proposal should include the original scatter data; explain why certain covariates are being removed; and explain how removal of those covariates did not change the bigger picture.

A member asked if SRTR looked at the scatter plots broken down by diagnosis groups. SRTR staff affirmed that they have. SRTR staff noted that they also looked at the univariate impact of these variables. If the univariate impact is considerable but the covariate isn't significant in the multivariate analysis, then that means other covariates are accounting for those factors. This type of information can help explain why covariates that seem important turn out not to be predictive in the models.

2. Analytical Hierarchy Process (AHP) Results

UNOS staff presented the Workgroup's results from the AHP exercise. UNOS staff noted that the AHP exercise will be shared with the transplant community during public comment this fall and wanted to make sure the Workgroup has a good understanding of each of the attributes.

Summary of discussion:

UNOS staff asked if it would be helpful to rename each of the goals to be more descriptive. For example, "reducing biological disadvantages in transplant access" is more descriptive than "medical urgency," which could be re-written as "reducing waitlist mortality." A member said this would be helpful since part of the challenge in the Workgroup's discussions is that everyone is coming from a different frame of reference. The Vice Chair agreed that clarifying the goals further will help the Workgroup gather more consistent answers from the community, particularly since opinions on post-transplant survival may vary depending on whether the respondent is thinking short-term or long-term. UNOS staff agreed to clarify these definitions further and to share updated versions with the Workgroup.

Medical Urgency vs. Pediatric Age Group

UNOS staff shared the Workgroup's responses to the pairwise comparison between medical urgency and pediatric age group. A member said that defining the goals further may make it harder to do the pairwise comparisons, like comparing reducing waitlist mortality to a pediatric patient getting priority.

The member said that completing the AHP exercise was not confusing but now it is confusing to think about it in terms of lung pediatric priority 1 and 2. Another member asked how the Workgroup will ensure that pediatric patients and those under age 12 are not disadvantaged in this new framework, and how the Workgroup can honor the current policy that promotes access for candidates under age 12. The member found the AHP exercise difficult to navigate because it cannot be applied directly to the current system. UNOS staff agreed this is a different construct and noted that the forthcoming revealed preference analysis will show how the current allocation system prioritizes these attributes. UNOS staff also shared that members of the Policy Oversight Committee (POC) had asked if the purpose of the exercise is to pick one candidate over another or to think about what is important for the entire system. Earlier instructions provided by UNOS encouraged people to think about the comparisons at a candidate level, but the POC favored thinking about the system as a whole.

A member noted that a lot of respondents submitted comments about the arbitrary age cut-off (e.g. a 17-year-old is treated differently than a 19-year-old) and wondered if that influenced the responses to this pairwise comparison and contributed to the wide range of opinions. UNOS staff said that is an important point but noted that from a legal perspective, there is concern about compliance with the Age Discrimination Act. By law, there must be a reason for making distinctions in age for access to goods. The National Organ Transplant Act (NOTA) gives the OPTN permission to make distinctions for pediatric candidates, but the OPTN must have a clinical reason to make other distinctions based on age. However, UNOS staff noted that this may not be the end of the conversation about age, especially since

committees that will be working on continuous distribution for other organs will also be grappling with this issue. A member guessed that the data on LAS would not favor younger adults over older adults. The member suggested breaking down the reason for that clause regarding children to see if there is another way to break out age that does not include a sharp boundary.

Medical Urgency vs. Post-Transplant Survival

UNOS staff asked the Workgroup how they envision asking questions about post-transplant survival, particularly whether post-transplant survival should refer to one-year survival or long-term survival. The Vice Chair says it should be long-term if it is truly a values discussion about global concepts. However, if the goal of the exercise is to hone in on the attributes that will be in the composite allocation score, then the exercise should focus on one-year survival. The Vice Chair said that the thought processes for clinical decision-makers is very different for a patient who may only survive a few weeks on the waitlist and will live one year after transplant versus a patient who is less urgent but is more likely to live 10 years after transplant.

A member said that SRTR modeling has shown that the time frame for evaluating post-transplant survival will not necessarily impact how candidates are ranked on the waiting list. The Vice Chair agreed but explained that the survival timeline does make a difference in terms of how people will respond to the pairwise comparison. The member said it is not clear that the Workgroup needs to focus on the number in terms of year of survival, rather than thinking about if this person is likely to do well after transplant or not likely to do well, compared to if this person is likely to die on the waitlist versus not, and who is prioritized.

Another member expressed preference for more of a value-based approach. The member noted that age does impact post-transplant survival. The member acknowledged the limitations of the LAS models but would like the OPTN to get to a point where post-transplant survival can be estimated at greater than one year. UNOS staff agreed that focusing on the high-end goal makes sense at this stage, and noted that the OPTN will be able to update the post-transplant survival attribute in the future if the OPTN is able to model longer-term survival.

Medical Urgency vs. Reducing Biological Disadvantages in Transplant Access

The members like how “reducing biological disadvantages in transplant access” is defined and agreed to keep it as written.

Medical Urgency vs. Prior Living Donors

A member expressed support for giving some priority to living donors. The member noted that medical urgency takes priority over everything, which is appropriate since those are the sickest patients, but transplant programs may also make decisions about giving organs to patients who are more likely to survive after transplant. With these ideas in mind, the member felt conflicted about choosing between medical urgency and prior living donors. UNOS staff pointed out that prior living donor prioritization does not exist in current lung allocation policy, so it can be difficult to figure out how to factor in a new attribute, particularly for a small population of candidates.

Medical Urgency vs. Travel Efficiency

UNOS staff noted that the travel efficiency definition will likely change prior to public comment. UNOS staff explained that this attribute only included cost initially, but the Continuous Distribution Data Taskforce is starting to consider other possible efficiency measures, like time away from the operating room for surgeons, or prioritizing local recovery. A member noted that those are real constraints that

can conflict with the ethically preferred choice, for example, if a program does not have the budget or time to travel to another state for an organ.

Next steps:

UNOS staff will update the attribute definitions and the AHP exercise, and the Workgroup will be asked to complete the AHP exercise again. UNOS staff will solicit feedback from the transplant community on priorities via the request for feedback paper and the community AHP exercise that will be released during the OPTN public comment period starting in August 2020.

Upcoming Meeting

- June 18, 2020