

OPTN Lung Transplantation Committee**Meeting Summary****October 7, 2020****Conference Call****Erika Lease, MD, Chair****Marie Budev, DO, Vice Chair****Introduction**

The Lung Transplantation Committee met via Citrix GoTo teleconference on 10/07/2020 to discuss the following agenda items:

1. Proposal: *Incorporating COVID-19 Related Organ Failure in Candidate Listings*
2. Proposal: *Updated Cohort for Calculation of the Lung Allocation Score*
3. Revealed Preference Analysis: Introduction

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

1. Proposal: *Incorporating COVID-19 Related Organ Failure in Candidate Listings*

The Committee reviewed public comment feedback on the proposal *Incorporating COVID-19 Related Organ Failure in Candidate Listings* and voted to send the proposal to the OPTN Board of Directors for approval.

Summary of discussion:

This proposal would add COVID-19 related diagnosis codes for lung and heart. During public comment, members of the transplant community expressed support for continuing to monitor whether similar codes are needed for other organs, particularly kidney. Some members of the transplant community thought that diagnosis codes should be added for kidney at this time, but the Kidney Committee ultimately did not support adding these diagnosis codes because it is hard to determine if a kidney candidate is listed as a direct result of COVID-19. The Vice Chair said there was disagreement on whether kidney failure in COVID-19 patients was due directly to the viral infection or indicative of systemic inflammation. The Vice Chair said that diagnosis codes should not be added for kidney but agreed that diagnosis codes should be added for heart. The Chair agreed, noting that the Kidney Committee could choose to add diagnosis codes in the future as appropriate.

A member said there can be systemic effects on COVID-19 patients as treatment progresses and interventions like ventilators are used, and many of these patients end up on renal replacement therapy. The member supported following the Kidney Committee's decision but shared that some of his kidney colleagues favored adding COVID-19 diagnosis codes for kidney because they felt these candidates are being listed due to COVID-19, instead of hypertension or other issues. The Chair said the Kidney Committee's concern was that there is not enough data to be able to separate out whether a patient was critically ill because of COVID-19 infection or not. Feedback from nephrologists during the regional meetings was mixed. The Vice Chair said that these diagnosis codes for heart and lung can serve as a blueprint in the future for other organs.

A member asked how SRTR is going to analyze this data in terms of calculating the lung allocation score (LAS), given the small number of candidates. The Chair explained that these candidates will be grouped

into the same diagnosis codes under which they would have been listed without COVID-19 infection. If the population is large enough, SRTR can analyze this population separately. The member agreed that this is the best approximation for now, but said that the Committee will want to track this moving forward to ensure these diagnosis codes are reflective of the outcomes for these patients.

The Committee voted to send this proposal forward to the OPTN Board (16-yes, 0-no, 0-abstain).

Next steps:

The OPTN Board of Directors will consider the proposal during their 10/08/2020 meeting.

2. Proposal: *Updated Cohort for Calculation of the Lung Allocation Score*

The Committee reviewed public comment feedback on the proposal *Updated Cohort for Calculation of the Lung Allocation Score* and voted to send the proposal to the OPTN Board of Directors for approval.

Summary of discussion:

During public comment, the Cystic Fibrosis (CF) Foundation expressed concern about the impact on CF patients of removing the diabetes and forced vital capacity (FVC) variables from the waitlist mortality model. The Chair said it may not be clear to people that the Committee is not removing these variables from all calculations, but just those models in which the variables were no longer predictive. The Chair asked if SRTR looked at the impact of diabetes on CF patients, since SRTR evaluated the impact of removing variables on various patient groups. SRTR staff said they did not look at the impact of diabetes on CF patients in particular or by diagnosis group, but SRTR did evaluate the impact of each of the variables being removed as a univariate factor. While diabetes matters on a univariate case, it is not predictive when included in the full model because other factors are providing similar information in the model and accounting for the impact of diabetes. The Chair asked SRTR to look into this data to be able to share additional information with the CF Foundation.

Several stakeholders expressed support during public comment for evaluating longer-term post-transplant survival. A member asked if it is possible to add longer-term survival, such as three to five years, to the LAS, and if the Committee can explain to the community why the Committee is or is not making this change. The Chair explained that there are a few challenges. First, the most recent changes to lung allocation policy went into effect about three years ago, and data used for this analysis cannot cross allocation schemes. Second, the Committee is making many changes to the allocation framework with continuous distribution and there have been some concerns about making too many changes and not being able to predict what will happen. Later this fall, the Committee will start looking at additional data collection that would better predict post-transplant outcomes. The Chair expressed support for moving towards evaluation of longer term outcomes, but said it is not clear if it is possible to do that at this time, or if now is the right time to try to make these changes.

An attendee noted that based on previous conversations with SRTR, one additional challenge is the current method used for modeling. Because of the baseline survival curve, extending out post-transplant survival to three or five years may not actually change the pattern of candidate rankings very much. The Vice Chair added that the Committee has asked SRTR for a two-year post-transplant survival model. The Chair acknowledged the methodology issue and said that the Committee will need to do a project to come up with better data. A member agreed that the data collected by the OPTN is not very predictive of longer term post-transplant outcomes, and said it would be helpful to start identifying those variables. The member said it would be great for UNOS to consider other metrics besides survival to measure outcomes. The Chair agreed and said that the Committee will be tackling this issue later this year, when SRTR is working on modeling the continuous distribution framework.

The Committee voted to send this proposal forward to the OPTN Board (16-yes, 0-no, 0-abstain).

Next steps:

The OPTN Board of Directors will consider the proposal during their 12/07/2020 meeting.

3. Revealed Preference Analysis: Introduction

UNOS staff presented an introduction to the revealed preference analysis that will be presented by staff from RTI International on the Lung Committee's call on 10/08/2020.

Summary of discussion:

UNOS staff explained how the revealed preference analysis can help the Committee to understand the value judgments built into current policy, and how that can inform development of the continuous distribution framework. Current lung allocation policy is classification-driven. One of the advantages of shifting to a continuous distribution framework is the elimination of edge cases, which occur when hard boundaries create allocation choices that might not be ideal. For example, a candidate in classification #1 may receive priority over a much more medically urgent candidate in classification in #2. Another advantage is of the continuous distribution framework is the ability to update the attributes of a composite allocation score and the relative weight of each attribute over time. A third benefit of the continuous distribution framework is transparency in terms of quantifying the value judgments that are built into the system, for example, understanding the degree to which policy values each attribute, including medical urgency, post-transplant survival, candidate biology, proximity, and pediatric priority.

The purpose of the revealed preference analysis is to estimate how much current policy values these attributes. The analysis provides a baseline for comparison when selecting the weights for each attribute in the continuous distribution framework. This baseline can also be compared to the results of the community analytical hierarchy process (AHP) exercise results. The purpose of the AHP exercise was to help reimagine what these value judgments should be in future policy.

The revealed preference analysis used lung match runs to generate "data" revealing the value judgments, or preferences, embedded in current policy. Characteristics of candidates ranked ahead of other candidates reflect those embedded preferences, or policy value judgments. The revealed preference analysis also helps to demystify the composite score approach by showing how a composite score can approximate the current system, and provides a potential policy option that reflects the essence of the current, classification-based system but removes hard boundaries and edge cases.

The importance of distance varies in current policy. Because there are hard boundaries based on distance, distance is infinitely important between these zones. However, within a zone, distance has zero importance, because candidates are ranked based on LAS and other factors. To account for this in the revealed preference analysis, the estimated coefficient for distance reflects a blended average of "zero importance" and "infinite importance" across the proximity spectrum.

UNOS staff highlighted three key takeaways from the report:

- Current policy can be approximated by a smooth, continuous score reasonably well
- The score can be used to derive weights reflecting the relative contribution of each attribute
- The score provides "exchange rates" expressing the relative value of each factor compared to another

Exchange rates reflect the change in one attribute that is equivalent to a change in another attribute in terms of the effect on the composite score. For example, if being 400 miles closer to the donor hospital

results in a one-point increase in the composite score, and a 30-point increase in LAS also results in a one-point increase, then the distance/LAS exchange rate is $400/30 = 13.3$ miles per LAS point.

In addition to exchange rates, the Committee can also use relative contribution weights to assess the impact of different attributes. Relative contribution weights reflect the proportion of the maximum possible difference in candidate scores potentially contributed by each attribute. For example, if two candidates' scores can differ by as much as 5 points, and differences in LAS can contribute up to 2 points, then LAS would have a relative contribution weight of 40%.

Next steps:

Staff from RTI International will present the revealed preference analysis report to the Committee on 10/08. UNOS staff asked the Committee to review the executive summary of the report in advance.

On 10/15, the Committee will review the community AHP results and compare them to the revealed preference analysis. On 10/21 and 10/23, the Committee will discuss the AHP results in detail; retake the AHP exercise; and aim to determine policy options for SRTR modeling.

Upcoming Meetings

- October 8, 2020 – Lung Committee
- October 15, 2020 – Lung Committee
- October 21, 2020 – Lung Committee

Attendance

- **Committee Members**
 - Erika Lease, Committee Chair
 - Marie Budev, Committee Vice Chair
 - Alan Betensley
 - Whitney Brown
 - Staci Carter
 - June Delisle
 - Mindy Dison, visiting Board member
 - Cynthia Gries
 - Julia Klesney-Tait
 - Jasleen Kukreja
 - Dennis Lyu
 - Daniel McCarthy
 - Kenneth McCurry
 - Michael Mulligan
 - John Reynolds
 - Marc Schechter
 - Nirmal Sharma
 - Kelly Willenberg
- **HRSA Representatives**
 - Jim Bowman
- **SRTR Staff**
 - Yoon Son Ahn
 - Katie Audette
 - Melissa Skeans
 - Andrew Wey
- **UNOS Staff**
 - James Alcorn
 - Nicole Benjamin
 - Julia Chipko
 - Craig Connors
 - Shannon Edwards
 - Rebecca Goff
 - Elizabeth Miller
 - Janis Rosenberg
 - Leah Slife
 - Darren Stewart
 - Kaitlin Swanner
 - Susan Tlusty
 - Sara Rose Wells
 - Karen Williams
- **Other Attendees**
 - Masina Scavuzzo
 - Jennifer Schiller
 - Stuart Sweet