

OPTN Lung Transplantation Committee

Meeting Summary

June 17, 2021

Conference Call

Erika Lease, MD, Chair

Marie Budev, DO, Vice Chair

Introduction

The Lung Transplantation Committee met via Citrix GoTo teleconference on 06/17/2021 to discuss the following agenda items:

1. Waitlist and Post-transplant Weighting
2. Efficiency Weighting
3. Organs Imported from Outside the United States
4. Clinical Value Update
5. Lung Review Board Exception Tiebreakers
6. Transition Plan
7. Continuous Distribution Public Comment Language Vote

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

1. Waitlist and Post-transplant Weighting

The results of the SRTR Thoracic Simulation Allocation Model (TSAM) showed the most noticeable gains in waitlist survival by using a 2:1 ratio and there were only minor changes to post-transplant survival based on 1:1 versus 2:1.¹ However, the highest gain in waitlist survival utilizing a 2:1 ratio are among candidates with both the worst waitlist survival and post-transplant survival. It was noted that the Final Rule asks that the goal is to achieve the best use of available organs through equity and utility. Also, Analytical Hierarchy Process (AHP) results from the community showed interest in increasing utility (increasing post-transplant survival).²

Summary of discussion:

Members expressed concern over moving to a 1:1 ratio due to a potential lack of relevant data collection or accuracy in the data regarding post-transplant survival. Members stated that all of the available options are a major improvement over the current system, but a desired outcome should include recipients getting the most life possible from their donor lungs. A member noted that they were initially supportive of a 1:1 ratio, but now supported 2:1 because it is difficult to predict post-transplant survival with how data is currently collected. An attendee mentioned that when you prioritize waitlist urgency you are transplanting more patients that have the shortest waitlist survival, but when using a 1:1 ratio patients that have longer post-transplant survival are getting the benefit. A member expressed

¹ "Continuous distribution simulations for lung transplant: Round 2, SRTR Data Request," OPTN, accessed June 30, https://optn.transplant.hrsa.gov/media/4646/lu2021_01_cont_distn_report_final.pdf

² Continuous Distribution of Lungs, Summer 2020 Prioritization Exercise – Community Results, October 12, 2020. https://optn.transplant.hrsa.gov/media/4157/2020-10_report_community_ahp_prioritization.pdf.

that continuous distribution shows tremendous progress since no matter which is chosen mortality is greatly decreased, but balancing should be done and that happens with the 1:1 ratio.

A member supported using the 2:1 ratio due to the patients seen with increased complexity more recently since the community may not have a grasp of their 5 year post-transplant survival yet. Another member that supported 2:1 stated that they did not feel there was enough accuracy when predicting post-transplant survival and referenced the example of coronary disease being a concern for complications post-transplant which is not collected currently which shows limitation in the data. The Chair mentioned that when looking at the results for transplant distribution by age group and seeing longer term outcomes being better for the 1:1 ratio while thinking about the Fair Innings Principle, they felt that post-transplant survival should receive the same weighting.³ SRTR staff noted that if the concern is net survival, over time more patients are surviving post-transplant which will add up over the years and acknowledged that models predict waitlist mortality than post-transplant survival, but at the time of allocation there are many variables not incorporated such as donor variables and operating room events and decisions have to be made by what is known about the patients. A member pointed out that when allocating for post-transplant survival in these scenarios, younger candidates have an increased transplant rate and those candidate tend to live longer.

A member asked for clarification on how these changes will be monitored after implementation including a review of the post-transplant outcomes to help understand the impact of the changes and to evaluate whether or not the best choices were made. It was clarified that the public comment proposal will include the cadence of post-implementation monitoring as well as which metrics would be the best to look at. It was also noted that the OPTN Policy Oversight Committee will have an additional monitoring that would be done post-implementation. A member explained that one of the benefits of continuous distribution is changes can be made more easily if a need is identified and that is a reassuring aspect of this system.

The Committee supported using a ratio of waitlist urgency to post-transplant survival of 1:1 for the public comment proposal, and asking for specific feedback on this ratio.

2. Efficiency Weighting

As weight for placement increases (10%, 15%, 20%):

- Variability in transplant rates by region increases (but still less variability than the current system)
- Post-transplant survival decreases
- Predicted waitlist deaths increase
- The percent of organs that fly and median travel distances decrease

Summary of discussion:

A member noted that if the Committee is in support of increasing the importance of post-transplant survival (1:1 ratio) the same logic should be applied to placement efficiency, which would mean using the lowest weight of 10%. A member stated that another factor is the regional transplant rates with the lower placement efficiency creating less variability across regions and the Vice Chair agreed. A member pointed out that the increase in weighting did lower the percent of organs that fly, but the benefits with the lower weighting of 10% is more important. Another member stated that waitlist mortality and post-transplant survival should account for 50% of the overall weighting and supported using a 10% weight

³ Williams, A., "Intergenerational Equity: An Exploration of the 'Fair Innings' Argument." Health Economics 6 (1997): 117-32.

for placement efficiency. A member asked for clarification on why post-transplant survival decreases with an increased weight for placement efficiency and it was clarified that as the weight is increased for placement efficiency weight is removed from what is allocated for waitlist mortality and post-transplant survival.

The Committee supported placement efficiency having a weight of 10% (5% for travel efficiency and 5% for proximity efficiency).

3. Organs Imported from Outside the United States

The Committee supported using the location of the closest U.S. donor hospital to the foreign donor hospital for calculating proximity efficiency for those scores.

4. Clinical Update Schedule

The Committee previously discussed the timing of required clinical updates should occur (every 28 days versus six months) and what types of updates will be required instead of using the Lung Allocation Score (LAS) as the threshold.

Summary of discussion:

The Committee reviewed the suggested change of including any patients with a high flow nasal cannula instead of using a 70% FIO₂ cutoff due to the challenges of converting the percent to liters depending on the oxygen delivery device and members supported this option.

5. Lung Review Board Exception Tiebreakers

The current process is for ties to be auto-declined on the initial tie and auto-approved if tied again on the appeal. Future options include using the Lung Review Board (LRB) Chair to break ties or default to auto-approval on the initial tie.

Summary of discussion:

The Chair and Vice Chair stated that if half of the case reviewers felt the exception should be granted, they would be in support of an auto-approval to give the patient the benefit. The Vice Chair felt that as a past LRB Chair being a tie-breaker would be a difficult role and stated that they would likely vote in favor of the patient. A member felt that someone with leadership and experience should break the tie since the exceptions will not expire and the patients who will not receive offers due to the granting of exceptions should be considered. The Vice Chair noted that there should be a level of expertise assumed with the reviewers and if half of the reviewers approve the request their expertise should be recognized. The Committee supported LRB exception request ties defaulting to an auto-approval.

6. Transition Plan

The Committee was asked if there is a need for a transition plan for any groups that would possibly be disadvantaged by the changes that need to be protected or adjusted for as part of the move to continuous distribution.

Summary of discussion:

The Chair noted that they had given considerable thought to this and could not think of a group that would require a transition plan since the changes should be an improvement overall. A member asked if there was a way to account for patients with certain diagnoses (Alpha-1) and the Chair clarified that unfortunately specific diagnoses cannot be looked at and it does not appear that any of the diagnoses

groups are disadvantaged as a whole. A member noted that transplant rate did decrease slightly and SRTR staff clarified that transplant rate declines, but only because patients who can wait, wait longer for transplant. It was also clarified that there is a different coefficient for Alpha-1 patients so that they are differentiated from all chronic obstructive pulmonary disease (COPD) patients.

A member asked if there is any information on how continuous distribution will effect patients with certain socioeconomic statuses and SRTR staff clarified that there are not great data available for that and often those disparity issues occur with referral and is not captured with waitlisted patients. SRTR staff offered to look into insurance status data to see if that would help predict possible disparity.

7. Continuous Distribution Public Comment Language Vote

The Committee voted with 13 yes, 0 no, and 0 abstentions in support of sending the Continuous Distribution of Lungs proposal with the policy language sent for review prior to the meeting with the changes included as decided during the meeting.

Upcoming Meetings

- July 15, 2021 (Committee)
- July 22, 2021 (Subcommittee)

Attendance

- **Committee Members**
 - Erika Lease, Chair
 - Marie Budev, Vice Chair
 - Alan Betensley
 - Denny Lyu
 - Cynthia Gries
 - John Reynolds
 - Julia Klesney-Tait
 - Nirmal Sharma
 - Whitney Brown
 - Kelly Willenberg
 - June Delisle
 - Ryan Davies
 - Daniel McCarthy
 - Kenneth McCurry
 - Staci Carter
- **HRSA Representatives**
 - Jim Bowman
- **SRTR Staff**
 - Katie Audette
 - Melissa Skeans
 - Maryam Valapour
 - Yoon Son Ahn
 - Andrew Wey
- **UNOS Staff**
 - James Alcorn
 - Elizabeth Miller
 - Janis Rosenberg
 - Susan Tlusty
 - Sara Rose Wells
 - Krissy Laurie
 - Tatenda Mupfudze
 - Darren Stewart
 - Kristina Hogan
 - Leah Slife
- **Other Attendees**
 - Dave Weimer
 - David Robinson
 - Masina Scavuzzo
 - Sommer Gentry
 - Stuart Sweet
 - Matt Hartwig