

OPTN Lung Transplantation Committee

Meeting Summary

September 16, 2021

Conference Call

Erika Lease, MD, Chair

Marie Budev, DO, Vice Chair

Introduction

The Lung Transplantation Committee met via Citrix GoTo teleconference on 09/16/2021 to discuss the following agenda items:

1. Public Comment Update
2. Continuous Distribution Decimal Precision
3. Vice Chair Nomination and Selection Process
4. Updates for the Pending Implementation for Changes to the Lung Allocation Score (LAS)

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

1. Public Comment Update

The Committee received an update regarding the public comment feedback for the *Establish the Continuous Distribution of Lungs* proposal submitted through the beginning of September 2021 including OPTN Regional Meeting sentiment. Overall, the proposal is generally supported with themes of the feedback including post-transplant outcomes, travel, pediatrics, possible impacts for candidates with lower lung allocations scores (LAS), and request for close monitoring post-implementation. Of all of the sentiment received at Regional Meetings to date there has been only one oppose submitted. The OPTN member representative who opposed noted concerns over priority for candidates aged 0-11 years old, the lack of incorporation of explicit timelines for updates, and the impact on small volume programs.

Summary of discussion:

Members who have already presented to their regions noted that there were a number of questions relating to general inefficiencies in allocation and multi-organ transplant, but agreed that overall there was general support at the meetings. The Chair noted that since lung presented after the OPTN Kidney and Pancreas Committees there were quite a few questions regarding their continuous distribution projects or continuous distribution in general and not many questions specific to lung. They also mentioned that some of the general feedback came from organ procurement organizations (OPO) regarding organ allocation inefficiencies occurring currently from a structural standpoint, but the Chair felt unsure about how much of that would be in scope for continuous distribution. A member stated they also received questions from OPOs, but more specifically about potential inefficiencies for allocating across thousands of miles. Other Committee members who have presented at Regional Meetings noted that multi-organ transplantation and the use of a 5-year post-transplant outcome had also been brought up.

The Vice Chair asked for more information regarding the feedback received for the consideration of a serum sharing requirement for cross-matching due to its impact on placement and whether or not that recommendation was to include the requirement at the OPO level. The Chair presumed that it would be

at the OPO level, but explained that it is not part of this proposal and is related to the general concerns over inefficiencies that OPOs are currently experiencing. The Committee noted the comment concerning potential impact on candidates with lower LAS, but the Chair stated that the modeling would suggest that there should not be a significant reduction in transplant rates with that group. A member mentioned that there was a small increase in mortality, however, the Committee have to acknowledge that there may be a bit of an impact but they feel it is not significant compared to the other gains they feel are beneficial.

The Vice Chair noted that there is a theme of potential impacts of travel and explained that this topic may be confusing to members, so clearing up the messaging may be helpful. The Chair mentioned that the modeling suggests that the number of flights is not increasing, but there is a longer distance traveled when flying. The Chair also mentioned that OPOs expressed concern over the ability to find flights and provisional yeses, however, these are still process related issues. The Vice Chair asked if the Committee needs to look at the impacts on smaller volume programs, and members noted that the Committee did review that, but agreed having that information on hand would be helpful for when these questions arise. HRSA staff mentioned that some of these themes came up with the changes in liver allocation since they also saw a potential increase in flight distance but not number of flights, so it may be helpful to review since the impact can be difficult to predict. HRSA staff also mentioned that the potential impact on small volume centers was also raised with liver allocation, and that has not been seen at about 15 months post-implementation.

A member mentioned that they gave a presentation at their center and someone had brought up the possibility of potential gaming by listing a 17 year old candidate sooner than necessary to gain the pediatric points. Committee members noted that this is such a small population so the risk is low, but agreed that it something to watch for. Another member stated they were asked about expiration of pediatric points after the candidate turns 18 years old, and it was clarified that they would not lose them. However, if you remove a pediatric candidate from the waiting list and add them after they turn 18 years old they would no longer have the pediatric points. The Committee discussed the feedback regarding pediatric access to pediatric organ offers and the Chair noted that pediatric patients are most often at the top of the list so they will get first access to those offers. A member stated that it is fair to say that pediatric donor lungs are higher in quality, so they wondered if there was a mechanism that could be put in place to help ensure those offers go to pediatric candidates. HRSA staff noted that there may be a way to evaluate and assess the quality of donor lungs similarly to the Kidney Donor Profile Index (KDPI).¹ The Committee also discussed the concern expressed over the removal of the distinction between 0-11 year old and 12-17 year old candidates and it was clarified that the youngest of those candidates will still get the total of the pediatric points and would likely also get points for height. A member stated that the modeling showed a significant increase across all pediatric candidates.

The Committee discussed the feedback regarding the timeline for monitoring and possible revisions and it was clarified that that is available in the proposal with the plan to monitor at three months, six months, one year, two years, and three years post-implementation.

2. Continuous Distribution Decimal Precision

The Committee received a presentation on recommendations for decimal precision so that there is very low likelihood of a tie. The waitlist mortality, post-transplant outcomes, candidate biology, and placement efficiency scores are recommended to have four decimal values with the candidate access

¹ A Guide to Calculating and Interpreting the Kidney Profile Index (KDPI), OPTN, accessed October 14, 2021, https://optn.transplant.hrsa.gov/media/1512/guide_to_calculating_interpreting_kdpi.pdf.

score being an integer. An integer is recommended for nautical miles by rounding to the nearest nautical mile. The recommended decimal values for biological disadvantages range from four to six decimal places. The recommendation for waitlist and post-transplant values are 16 decimal places for the coefficients, six decimal places for baseline survival functions, and integer days for expected survival. The Committee supported the recommendations as presented.

3. Vice Chair Nomination and Selection Process

UNOS staff provided an overview of the process for the nomination and selection of the Committee's next Vice Chair. The goals for the nomination process are to increase transparency, promote inclusiveness, and provide a thorough review and vetting of the Vice Chair candidates. The call for interest will be sent out in October and will be sent to current Committee members and members who have served on the Committee within the last five years.

4. Updates for the Pending Implementation for Changes to the Lung Allocation Score (LAS)

Changes to the LAS as part of the Updated Cohort for Calculation of the Lung Allocation Score (LAS) project will be implemented September 30, 2021 which does change candidate scores. A communication will be sent to lung transplant programs explaining the changes and members are able to reach out to UNOS staff if they have any questions. The Vice Chair requested a patient letter for these changes since they may want to have more explanation about the updated LAS and new calculations.

Upcoming Meetings

- September 23, 2021 (Subcommittee)
- September 27, 2021 (Committee)

Attendance

- **Committee Members**
 - Erika Lease, Chair
 - Marie Budev, Vice Chair
 - John Reynolds
 - Julia Klesney-Tait
 - Whitney Brown
 - Errol Bush
 - Scott Scheinin
 - Pablo Sanchez
 - Jasleen Kukreja
 - Karen Lord
 - Dan McCarthy
- **HRSA Representatives**
 - Jim Bowman
- **SRTR Staff**
 - Katie Audette
 - Andrew Wey
 - David Schladt
- **UNOS Staff**
 - Elizabeth Miller
 - Janis Rosenberg
 - Susan Tlusty
 - Sara Rose Wells
 - Krissy Laurie
 - Tatenda Mupfudze
 - Holly Sobczak
 - Leah Slife