OPTN Lung Transplantation Committee Meeting Summary June 10, 2021 Conference Call

Erika Lease, MD, Chair Marie Budev, DO, Vice Chair

Introduction

The Lung Transplantation Committee met via Citrix GoTo teleconference on 06/10/2021 to discuss the following agenda items:

1. SRTR Thoracic Simulation Allocation Model (TSAM) Results

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

1. SRTR Thoracic Simulation Allocation Model (TSAM) Results

SRTR representatives presented an overview of the results for discussion of the six simulations requested by the Committee for lung continuous distribution allocation.¹ The Committee previously set attribute weights and requested TSAM results for the current rules and six continuous distribution scenarios.²

Summary of results:

Overall Outcomes by Scenario

These scenarios compared the current allocation system to six scenarios that included weighting placement efficiency at 10%, 15%, and 20% with both a waitlist urgency and post-transplant survival ratio of 1:1 and 2:1. Pediatric priority, candidate biology, and prior living donor priority weights were held constant for all scenarios. This TSAM utilized a five year post-transplant survival, but the TSAM cohort is smaller and more recent than five years which limits the predicted post-transplant survival to two years. The outcome categories included transplant rate, waitlist mortality count, the percent of recipients who died by two years post-transplant, the median donor-recipient distance in nautical miles (NM), and the percent of organs expected to fly (distance greater than 75 NM).

Compared to current allocation, continuous distribution resulted in a 36 to 47% decrease in waitlist mortality, equal two year post-transplant survival outcomes, an increase in median donor-recipient distance, and a lower proportion of donor organs that are expected to fly and this decreases more as weight is increased for placement efficiency. Currently, the majority of transplants occur within 50 NM and under continuous distribution, most transplants will happen at a distance of 100 to 250 NM. Waitlist mortality decreased the most when waitlist urgency was given the most weight (2:1) and placement efficiency was weighted at 10%.

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 "OPTN Lung Transplantation Committee Meeting Summary (March 31, 2021),"OPTN, accessed June 30, https://optn.transplant.hrsa.gov/media/4579/20210331_lung-meeting-summary.pdf

Results by Age Group

The results by age group showed that there was a decrease in waitlist mortality for adult candidates, an increase in transplant rates for adolescents and children under the age of 12 while transplant rates decreased for candidates over the age of 50. The donor-recipient distance for all age groups increased across all of the scenarios. The results also showed an increase in the two year post-transplant mortality among pediatric recipients, but this is likely due to a modeling artifact related to an increase in adult donors in the simulations.

Results by Waitlist Urgency Quartile

Compared to the current allocation system, waitlist mortality decreased for the candidates with the most waitlist urgency and transplant rates increased for the most urgent candidates while decreasing for candidates with lower waitlist urgency. The donor-recipient distance increased for candidates with higher waitlist urgency and remained the same or decreased for other candidates. The two year post-transplant mortality remained similar to the current allocation system across all waitlist urgency quartiles.

Results by Post-Transplant Survival Quartile

Waitlist mortality decreased for all post-transplant survival quartiles with the largest decrease occurring for the quartile with the worst predicted post-transplant outcomes. The transplant rate increased for the quartile with the best predicted post-transplant survival and decreased for the quartiles with lower predicted post-transplant survival. The donor-recipient distance for all quartiles increased with a larger increase seen with the quartiles with lower predicted post-transplant outcomes. The two year post-transplant mortality was equal to the current allocation system for all quartiles and scenarios.

Results by Lung Allocation Score (LAS)

The continuous distribution allocation results showed a decrease in waitlist mortality for candidates with high LAS (60+) compared to the current allocation system. There was an increase in transplant rates for high LAS candidates and a decrease or no change in the transplant rates for candidates with a low LAS. The donor-recipient distance increased for candidates with a high LAS and did not change or deceased for candidates with a low LAS. Two year post-transplant mortality showed no change across LAS groups and scenarios.

Results by Diagnosis Group

The results showed that there was a decrease in waitlist mortality for Group B with larger decreases in waitlist mortality for Groups C and D. There was an increase in transplant rate for Group C, a decrease for Group D, and no change or decrease for Groups A and B. The donor-recipient distance for Groups C and D increased, remained the same or decreased for Group A, and remained the same or increased for Group B. The two year post-transplant mortality remained the same for all diagnosis groups and scenarios.

Results by Transplant Hospital Volume

The modeling results by center volume showed that waitlist mortality decreased for all volume groups across transplant hospitals. The transplant rates increased for lowest volume (1-15 transplants per year) transplant hospitals and decreased for other volume groups (16-101+ transplants per year). The donor-recipient distance for all volume groups increased with the largest increase occurring for lowest volume centers. The results did show a modeling artifact of a two year post-transplant mortality increase for the lowest volume center, but no change for centers that perform more than 15 transplants per year.

Summary of Discussion:

Committee members generally considered the results positive for all of the modeled options, with improvements in mortality and outcomes measures. The Committee also found the presentation helpful for interpreting the results. An attendee and the Vice Chair recommended drawing a table, or printing the slides and highlighting as useful ways to process the results, and possibly dedicating an hour or so a day to consider the results and their implications.

The Committee considered that there might be reasons to be conservative with changes to elements such as efficiency, since some elements are not able to be modeled, in order to avoid unintended consequences.

The SRTR representatives asked if there was additional information that would be helpful in deliberating. One Committee member asked for additional consideration of the results by geographic area. Another asked for assistance regarding which differences were clinically significant. An SRTR representative suggested one way might be to focus on age and diagnosis group information and compare it to clinical experience. She also noted that there is more variation between scenarios in Diagnosis Group D, and in Diagnosis Group D there are diagnoses with larger age variation.

Another member asked if there was stratification by specific clinical markers, and the SRTR representative responded that it was beyond the capability of TSAM because the samples become too small when stratified to that level. Additionally, TSAM is only able to stratify categorically, not continuously. However, the waitlist mortality and post-transplant survival analyses are able to provide some insight into the impact by urgency of illness. The larger differences in transplant rates and waiting list deaths are seen among the sickest patients when viewed this way.

The Committee discussed the fact that results were not stratified by insurance status, and requested that additional information from the SRTR. Although it is not a perfect measure of socio-economic status impact, the Committee was interested in at least reviewing it, since it is available in the data set, to make sure there is no disadvantage to patients on Medicaid.

Next steps:

Committee members will receive the presentation slides, a summary of decisions so far, and draft policy language for review prior to the next meeting. During the next Committee meeting, the Committee will consider the weight of placement efficiency and the utilization of the 2:1 versus 1:1 ratio.

Upcoming Meeting

• June 17, 2021 (Committee)

Attendance

- Committee Members
 - o Erika Lease, Chair
 - Marie Budev, Vice Chair
 - Alan Betensley
 - o Denny Lyu
 - Cynthia Gries
 - o John Reynolds
 - Julia Klesney-Tait
 - Nirmal Sharma
 - o Whitney Brown
 - o Kelly Willenberg
 - o June Delisle
 - o Ryan Davies

• HRSA Representatives

- o Jim Bowman
- o Marilyn Levi
- o Adriana Martinez
- SRTR Staff
 - Katie Audette
 - o Melissa Skeans
 - o Maryam Valapour
 - o Yoon Son Ahn
- UNOS Staff
 - o James Alcorn
 - o Elizabeth Miller
 - o Janis Rosenberg
 - o Susan Tlusty
 - Sara Rose Wells
 - o Krissy Laurie
 - Tatenda Mupfudze
 - Holly Sobczak
- Other Attendees
 - o Dave Weimer
 - o Jon Miller