

**OPTN Lung Transplantation Committee
Meeting Summary
February 18, 2021
Conference Call**

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

Introduction

The Lung Transplantation Committee met via Citrix GoTo teleconference on 02/18/2021 to discuss the following agenda items:

1. SRTR Continuous Distribution Modeling Results Overview

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

1. SRTR Continuous Distribution Modeling Results Overview

SRTR staff presented the first round of modeling results on continuous distribution of lungs.

Summary of discussion:

SRTR modeled four different continuous allocation frameworks using data from a cohort of candidates, recipients, and donors and their histories from January 1, 2018, to December 31, 2019. Thoracic Simulation Allocation Modeling (TSAM) simulates match runs and predict outcomes, including transplant and post-transplant death. Overall, waitlist deaths were cut in half in the 1:1 and 2:1 lung allocation score (LAS) scenarios, compared with current policy. This reflects a higher weight on preventing waitlist deaths and elimination of the 250 nautical mile (nm) boundary. Median donor-recipient distances increased relative to current policy. However, the S-shaped curve used for inefficiencies associated with distance served to increase the volume of nearby transplants while also increasing the volume of transplants at farther distances for the sickest candidates.

An attendee asked if SRTR has an idea how well these models predict reality, for example, based on modeling used for previous changes to lung allocation, to help manage expectations for how well the modeling predicts waitlist mortality and other outcomes. SRTR staff said they did a paper on that to evaluate how TSAM performed for the removal of donation service area (DSA) in lungs. That paper found that the numbers weren't perfect but the overall themes and directionality were supported by the observed data.¹ SRTR staff noted that the paper referred to an older version of TSAM, whereas TSAM was updated with a more current cohort for this round of modeling.

Data by LAS

Compared to current policy, the continuous allocation scenarios reduced waitlist deaths for high LAS (60+) candidates and increased transplant rates for high LAS candidates. The highest LAS candidates had the highest transplant rates overall. The proportion of low LAS candidates receiving transplants fell but the proportion of high LAS candidates receiving transplants increased. Organ travel distance by LAS

¹ Carli J. Lehr, Melissa Skeans, and Maryam Valapour, "Validating thoracic simulated allocation model predictions for impact of broader geographic sharing of donor lungs on transplant waitlist outcomes," *The Journal of Heart and Lung Transplantation* 39, no. 5 (2020): 433-440. <https://doi.org/10.1016/j.healun.2019.11.003>.

increased for high LAS candidates, with a sharp increase with an LAS of 50 or higher. For all continuous allocation scenarios, all organs were less likely to be flown for candidates with an LAS of less than 50 and more likely to be flown for candidates with an LAS greater than 60. Two-year post-transplant outcomes were similar across allocation scenarios and LAS groups.

A member noted that two-year post-transplant deaths did not vary much between current policy and the continuous allocation scenarios. The member suggested that the Committee implement continuous distribution for candidates with a higher LAS (over 60) but leave the current system in place for candidates with an LAS under 60.

A member was surprised that the modeling suggests that transplanting really sick candidates will result in similar outcomes in terms of two-year transplant deaths compared to transplanting candidates who are not hospitalized and are healthier at the time of transplant. An attendee said the post-transplant survival curves are a lot flatter in that there is less variation between candidates, but if the two-year mortality was broken down based on LAS, it might show worse outcomes for the high LAS recipients. SRTR staff shared a plot of two-year post-transplant death by LAS. The attendee observed that there is a slight difference by LAS but it is not a huge distinction. SRTR staff said they have seen that across TSAMs across the years, there tends not to be a lot of variation in post-transplant survival in the context of the model. The appendix of the report describes the factors that are included in those models so SRTR staff would appreciate feedback if members think something is missing. An attendee said there are probably risk factors that are not captured in the model.

A member said that if the system transplants fewer candidates with chronic obstructive pulmonary disease (COPD) who have a lower LAS, then they may have to wait behind idiopathic pulmonary fibrosis (IPF) candidates who get added to the list later, so the COPD candidates would have to wait longer. The member asked if there is a way to model that effect. SRTR staff said that TSAM is not able to model how the waiting list will change. The Chair noted that SRTR can look at the results by diagnosis group and that will help tease out some of those differences. A member said it is worth noting that candidates with a score of less than 35 are going to wait to get an offer until they get really sick and on a ventilator, or they are just going to be waiting for a really long time without getting an offer. It might be appropriate to have some sort of correction for wait list time.

A member asked if SRTR could look at five-year survival and asked why two years was selected. SRTR staff said that was the outcome that TSAM was able to produce but SRTR staff will be presenting some more information on next week's Subcommittee call on five-year post-transplant survival.

Data by Blood Type, Age, and Race

There were big drops in waitlist deaths among candidates of all blood types, especially among blood type O candidates, which declined by about 60 percent. There were reduced transplant rates for blood types A, B, and AB candidates, but increases in transplant rates for blood type O candidates. There were similar post-transplant mortality rates across all blood types. Pediatric waitlist deaths were low for the current system and remained low in all continuous allocation scenarios. Transplant rates increased in the 12-17 age group and dropped slightly in the 65+ age group, which may reflect the trends in transplant rates by LAS. The model saw an increase in donor-recipient distance for all ages within all scenarios. There was an apparent increase in post-transplant deaths among pediatric recipients, though this may be an artefact of the modeling. The post-transplant survival model for pediatrics is different from adults, and due to the small size of the pediatric population, the model is limited to one predictor, which is donor age greater than 20. SRTR staff suspects that the increase in predicted deaths is due to an increase in the average donor age for recipients age 12 to 17. SRTR staff did observe a significant increase in donor age in the modeling for recipients in this age group.

An attendee asked if SRTR looked at waiting list mortality rates instead of deaths in counts, since the size of the pediatric waiting list is so small compared to the adults. SRTR staff explained that waiting list mortality rates are independent of the transplant rate. Waiting list mortality rate is equal to deaths divided by the time waiting on the list, so the waiting list mortality rate may not change if candidates are getting transplanted faster and there are fewer deaths. The attendee agreed and said that for the waiting list mortality rate to be relevant, there must be a relatively constant transplant rate to compare the different groups. If the transplant rates are different, then the exposure time on the waiting list is going to differ for reasons other than the underlying causes of mortality. However, one waiting list death in the 0-11 age group may be a significant percentage of the candidates waiting relative to one waiting list death in the 18-24 age group. It may be important to provide that context when presenting this to the community.

A member noted that the modeling shows distribution of lower quality organs to the 12 to 17-year-old age group, and perhaps the Committee should give preferential treatment for that group to receive organs from donors under the age of 18. SRTR staff said the 12 to 17-year-old age group has pretty large priority for those organs in these scenarios but what TSAM is struggling with is that 12 to 17-year-olds suddenly have much more priority for a lot more adult organs, which is not something that exists in current allocation, so it is hard to model what would happen in terms of offer acceptance. The member asked why SRTR staff feels this group has high priority in the current allocation system. SRTR staff explained that in the current system, pediatric candidates (under age 18) have priority for pediatric donor organs. UNOS staff asked if the offer acceptance model in TSAM includes differences in donor-recipient height. SRTR staff said that the offer acceptance model includes height and donor age, but these match runs do not look like anything that would be observed under current policy.

HRSA staff asked how the actual numbers of pediatric recipients in the model compare to the current system in terms of volume. SRTR staff explained that the number of patients in the model is the same across all of the scenarios and the acceptance models determine who get the transplants. HRSA staff asked if the actual counts of pediatric candidates who received transplants increased. An attendee explained that transplant counts increased for pediatric candidates. HRSA staff said if transplants increase in a population, then even if the same percentage died in two years, then the actual count of deaths go up. An attendee said the question is whether the age of the donor mortality data is having the effect that the Committee thinks it should in the simulation. HRSA staff asked this question because there was concern previously over a liver allocation change regarding a small number of death counts because people were concerned about the geographical distribution of those predicted deaths. SRTR staff mentioned that those data are available for review in the full report.²

Data by Diagnosis Group

Overall waitlist deaths were cut in half, but this varied by diagnosis groups. There was a bigger reduction in deaths for diagnosis group C and D than diagnosis group B. There was also a decrease in transplant rates for diagnosis group B in all continuous distribution scenarios but there was an increase in transplant rates for diagnosis group C in all continuous distribution scenarios. These rates are driven largely by waitlist severity, so the decline in transplants in diagnosis group B could be based on LAS, since group B has fewer patients in the highest LAS category. The model saw an increase in donor-recipient distances travelled for diagnosis groups B, C, and D, and similar distances travelled for diagnosis group A. There was similar two-year transplant mortality across all diagnoses and scenarios.

² Andrew Wey et al., "Continuous distribution simulations for lung transplant," Scientific Registry of Transplant Recipients, accessed March 15, 2021, https://optn.transplant.hrsa.gov/media/4450/lu2020_05_cont_distn_srtr_1.pdf.

There was more variation between the scenarios based on diagnosis group relative to the other subgroup analyses.

Next steps:

The Committee will dive deeper into these results on future committee meetings to work on refining a proposal for a second round of modeling by SRTR. Members were encouraged to submit questions and feedback over email in the interim.

Upcoming Meetings

- February 25, 2021 (Subcommittee)
- March 10, 2021 (Committee)
- March 18, 2021 (Committee)

Attendance

- **Committee Members**
 - Erika Lease, Chair
 - Marie Budev, Vice Chair
 - Alan Betensley
 - Whitney Brown
 - Ryan Davies
 - Cynthia Gries
 - Julia Klesny-Tait
 - Jasleen Kukreja
 - Denny Lyu
 - Dan McCarthy
 - John Reynolds
 - Marc Schechter
 - Nirmal Sharma
 - Kelly Willenberg
- **HRSA Representatives**
 - Jim Bowman
 - Marilyn Levi
- **SRTR Staff**
 - Yoon Son Ahn
 - Katie Audette
 - Ajay Israni
 - Melissa Skeans
 - Maryam Valapour
 - Andrew Wey
- **UNOS Staff**
 - James Alcorn
 - Julia Chipko
 - Rebecca Goff
 - Elizabeth Miller
 - Amanda Robinson
 - Janis Rosenberg
 - Darren Stewart
 - Kaitlin Swanner
 - Susan Tlusty
 - Sara Rose Wells
 - Karen Williams
- **Other Attendees**
 - Sommer Gentry
 - Michelle Munson
 - Masina Scavuzzo
 - Jennifer Schiller
 - Stuart Sweet