OPTN Lung Transplantation Committee
Meeting Summary
March 18, 2021
Conference Call

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

Introduction

The Lung Transplantation Committee met via Citrix GoTo teleconference on 03/18/2021 to discuss the following agenda items:

1. 5-year Post-transplant Survival Modeling Results
2. Introduction to Continuous Distribution: Tradeoff Curves

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

1. 5-year Post-transplant Survival Modeling Results

SRTR Staff presented the 5-year post-transplant survival model results and requested Committee feedback on specific topics.[1]

Summary of discussion:

The Effect of Creatinine

The current post-transplant mortality model sets the effect of creatinine value to 0 for candidates younger than 18 years old, while the 5-year post-transplant mortality model used the same creatinine effect for all age groups. SRTR staff requested the Committee's feedback on whether or not it is appropriate to have a creatinine effect for candidates less than 18 years old, and if not, should the effect be 0 or should the creatinine be transformed to eGFR?

An attendee mentioned that pediatric creatinine levels can be complex, but did not recall why the value was previously set this way. It was discussed how pediatric candidates can have changes in creatinine that do not translate exactly to how it is evaluated for adults since a growing child would have changes in predicted creatinine where adults will be relatively stable which is likely the reason for the previous decision. The Chair asked if the attendee would support leaving this value set at 0, and they mentioned that they would have to consider the all the information. The attendee asked for clarification on whether or not pediatric candidates have an advantage with lower creatinine because that may not be the best practice. SRTR reviewed the figure showing the effect of serum creatinine (CR) there was support for keeping things as they have been with the prior model.

[1] Andrew Wey, PhD, Melissa Skeans, MS, Maryam Valapour, MD, MPP, and Katie Audette, MS, "The impact of extending follow-up for the PTAUC model from 1 year to 5 years after transplant." SRTR Report. February 17, 2021.

The Effect of O_2

SRTR staff explained that O_2 had relatively small effects, but requested Committee feedback on whether or not it should be separated into two effects or is it appropriate to have a single effect for O_2? Previous feedback included removing O_2 for the post-transplant mortality model.

The Chair reminded the Committee of the lack of standardization for capturing O_2 currently and that she was not comfortable with giving different values to different diagnoses groups and also that O_2 probably would not be easily removed from the post-transplant mortality model without impact when it is still included in the waitlist mortality model. A member stated that if there is not much effect of this value and there is opportunity for members to manipulate the values to benefit the candidate since there is no standardization they would be in favor of removing it. A member mentioned that it may be problematic to pull it for the post-transplant mortality model due to a lack of standardization while leaving it for the waitlist mortality model, but could remove it if the effect was minimal and rankings did not change. SRTR staff stated they did review the effects of the rest of the post-transplant mortality model does not really change if O_2 is removed. Overall, the Committee supported removing O_2 for the post-transplant mortality model due to the possible inconsistencies for reporting this data. Committee Leadership included that a future aspect of the project would be to include how to improve consistency among members for capturing these results for future use.

The Effect of the Six-Minute Walk

The effect for the six-minute walk has a sudden increase after 1,600 feet which is driven by a small proportion of recipients (1.7% of the cohort). It was clarified that it is implausible that the increase would happen realistically and that it may be the result of data entry errors. For the purpose of the post-transplant mortality model, it may be best practice to limit the six-minute walk to 1,600 feet which would also be included in the next Thoracic Simulation Allocation Model (TSAM). SRTR staff stated that analytical approaches could be developed to remedy the effect, but that would not be feasible for the current continuous distribution timeline. HRSA staff asked for clarification on whether or not a lung candidate could complete a 1,600 foot walk and what would their medical status be if they could complete it. The Chair confirmed that those candidates would likely be lower on the lung allocation score (LAS) scale which may be why there are so few of these candidates represented in the data. The Committee was in support of capping the length of the six-minute walk at 1,600 feet.

Review the remaining factors included in the 5-year Post-transplant Mortality Model

The Committee received an overview of the project roadmap which included an introduction to the effects of age, cardiac index (CI), ventilation status, diagnosis group, bronchiectasis, lymphangioleiomyomatosis (LAM), obliterative bronchiolitis (OB), pulmonary fibrosis (PF) (not idiopathic), sarcoidosis, and functional status.

The Vice Chair asked to clarify the effect of sarcoidosis with a pulmonary artery pressure (PA) greater than 30 mmHg versus a PA of less than 30 mmHg and it was noted that a PA greater than 30 mmHg shows an effect that is significantly smaller than seen when the candidate's PA is less than 30 mmHg . It was clarified that the Updating Mortality Models Subcommittee looked at this in detail and concluded that it would be valuable to leave this in the 5-year post-transplant mortality model with continuous distribution.

The Committee was asked if they were supportive of using the 5-year post-transplant mortality model. An attendee mentioned that they have not seen much information on the performance of the model considering the data will be far into the future. SRTR staff stated that the performance has a very small decrease moving from 1 to 5-years. An attendee asked if there were any substantial changes in rankings

and SRTR noted that they were statistically similar in their rankings. UNOS staff asked about alignment to the TSAM for pediatric recipients age 0 to 11 for the 5-year model and SRTR staff said they used the adult post-transplant mortality model but the future plan would be to update previous analysis where the post-transplant mortality model was calculated for status 1 and 2 candidates and adjust that to 5-year model instead of the previous 1-year model. It was noted that the Committee would likely need to revisit this alignment in the future to make sure they are comfortable with the results. Overall, the Committee was supportive of moving forward with modeling for longer term post-transplant outcomes.

2. Introduction to Continuous Distribution: Tradeoff Curves

MIT consultants presented on Tradeoffs through Optimization for Continuous Distribution and introduced how optimization and artificial intelligence could be used to help the Committee weigh different attributes for continuous distribution. These methods could help hone in on ideal attribute weighting as well as identify areas of diminishing returns and mitigation strategies. UNOS staff summarized how the MIT work can help facilitate Committee decisions with different policy options when requesting the next SRTR models especially in regards to attribute weights and their points of diminishing returns.

Summary of discussion:

A member agreed that this information will be useful since most of since most of the attribute weights are abstract so it would be helpful to see inflection points and where benefits cease since that will aid in making more informed decisions. A member asked for clarification on the effects of using an older cohort in relation to travel since that practice is different currently and it was clarified that the model is using 2009-2011 waitlist data, but it is using current policy. A member asked why they could not use a post-2018 dataset since they felt looking for diminishing returns with a newer dataset would be helpful. MIT consultants stated that they would ideally perform those analyses in the future, but they would not be able to provide those results by the April 2021 deadline. However, they offered to provide a sample of results with the newer cohort to validate the results from the older cohort to add assurance for the Committee. A member had an interest particularly in the potential impact that these results may have on candidates in rural areas as to not disadvantage more rural candidates.

Next steps:

The Committee is set to choose the final set of policy options for SRTR to model by April 1, 2021 and the Committee will review the final modeling results and choose an option by May/June 2021 to send for public comment.

Upcoming Meetings

- March 25, 2021 (Committee)
- March 31 & April 1, 2021 (Committee)

Attendance

- **Committee Members**
  - Erika Lease, Chair
  - Marie Budev, Vice Chair
  - Alan Betensley
  - Whitney Brown
  - Julia Klesny-Tait
  - Denny Lyu
  - Nirmal Sharma
  - Kelly Willenberg
  - Kenneth McCurry
  - Michael Mulligan
  - June Delisle
  - Daniel McCarthy
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Katie Audette
  - Melissa Skeans
  - Maryam Valapour
  - Andrew Wey
  - Jon Snyder
  - Ajay Israni
- **UNOS Staff**
  - James Alcorn
  - Julia Chipko
  - Rebecca Goff
  - Elizabeth Miller
  - Janis Rosenberg
  - Susan Tlusty
  - Sara Rose Wells
  - Krissy Laurie
  - Leah Slife
  - Amanda Robinson
  - Darren Stewart
- **Other Attendees**
  - Ted Papalexopoulos
  - Nikos Trichakis
  - Stuart Sweet
  - Jodi Bell
  - Carli Lehr
  - Paul Gunsalus
  - Jarrod Dalton
  - Jennifer Schiller
  - Masina Scavuzzo
  - Lyla Mourany