OPTN Lung Transplantation Committee
Continuous Distribution Data Workgroup
Meeting Summary
September 10, 2020
Conference Call

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

Introduction

The Lung Transplantation Committee's Continuous Distribution Data Workgroup met via Citrix GoTo teleconference on 09/10/2020 to discuss the following agenda items:

1. SRTR Thoracic Simulation Allocation Modeling (TSAM)
2. Preview of Tableau Sensitivity Analysis Tool

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

1. SRTR Thoracic Simulation Allocation Modeling (TSAM)

SRTR staff presented on planning for TSAM output and the role of TSAM in predicting organ discard.

Summary of discussion:

Planning for TSAM Output

SRTR staff shared a list of stratification variables historically included in TSAM: age, sex, race, and ethnicity groups; diagnosis groups; status group; blood type; urbanicity; US location; distance: donor to recipient facility; Donor Service Area (DSA), state, and OPTN region; average annual center volume; and insurance status (public/private). Candidate height and Calculated Panel Reactive Antibody (CPRA) were not previously used in TSAM but are being considered in the continuous distribution framework. SRTR staff noted that the models cannot distinguish center-level practices, so acceptance models in TSAM are based on national data rather than DSA or state data.

SRTR staff shared a list of metrics historically calculated using TSAM stratification variables, including waitlist mortality (death counts and rates), transplants (counts and rates), one-year post-transplant mortality (death counts and rates), and median distance between donor and transplant hospital. Using the kidney-pancreas allocation simulator (KPSAM), SRTR has also reported distributions of time on the waiting list and variance in time on the waiting list.

SRTR staff noted that the TSAM was previously restricted to evaluating one-year post-transplant mortality. The Chair asked if it would be possible evaluate longer-term post-transplant mortality, perhaps out to three years. SRTR staff explained that the cohort of patients that could be used to estimate post-transplant mortality is limited to the time period between allocation changes in November 2017 and the start of the pandemic in March 2020. While evaluating three-year post-transplant mortality might not be possible, SRTR should be able to evaluate two-year post-transplant mortality. The Chair asked that SRTR evaluate both one-year and two-year post-transplant mortality if possible, with the ultimate goal of looking at longer-term outcomes. The Vice Chair asked at what point SRTR will be able to look at three-year outcomes. SRTR staff said they are evaluating the best way to incorporate outcomes data beyond on the start date of the national health emergency for COVID-19.

SRTR staff mentioned that the TSAM provides two-year output data for heart transplants, but the one-year and two-year data patterns looked exactly the same in terms of how the different simulations impacted certain groups. A member said the patterns may be different between heart and lung because some lung diagnosis groups, like cystic fibrosis (CF) patients, have almost twice the post-transplant survival as other diagnosis groups, and there seems to be either an age or disease interaction that changes over time. SRTR staff said that previous analysis of post-transplant survival by age and diagnosis group showed that the interaction was mostly based on age. Evaluating the data is complicated because the younger cohorts are primarily CF patients, and age and survival go hand-in-hand. SRTR staff offered to share that report with the Committee again.

Role of TSAM in Predicting Organ Discard

SRTR staff presented on the role of TSAM in predicting organ discard. The simulation allocation models (SAMs) use historical data to model what would have happened if a different allocation system had been in place. Historically, SAMs have been the primary tool of OPTN committees for understanding the potential effects of policy proposals.

The SAMs have three primary components: patient trajectories on the waiting list; offer acceptance; and post-transplant outcomes. The offer acceptance model predicts whether a patient will accept or decline an offer and interacts directly with the proposed allocation system. Accordingly, it plays a big role in determining both the number and distribution of transplants reported by the model for the different allocation schemes proposed by the committee.

In order to model offer acceptance, SRTR must identify donors for generating match runs; dynamically generate match runs based on the patients on the waiting list; and determine the candidates that accept the organ. Traditionally, SAMs create match runs for each recovered organ. However, there are more organs recovered than transplanted, so the SAMs need some way to determine which organs are transplanted and which are not. Accordingly, the SAMs traditionally have a process for "discarding" organs within the simulation, usually within the offer acceptance model.

The issue is that the offer acceptance model uses match run data, and the data do not indicate the point in the match run at which the OPO stopped offering the organ. In other words, SRTR has no good data on organ discard but the SAMs must model it. The SAMs adjust for this lack of data by truncating the match run after a certain number of offers, which is usually 50 for TSAM. This ad-hoc discard approach does not align with the discard process in the real world. For example, organs are regularly accepted and transplanted after these cutoffs. As a result, the number and distribution of transplants in the models for the proposed allocation policies depend on how SRTR implements the ad-hoc discard process.

SRTR staff proposed a new approach to modeling organ discard, which is for the SAMs to create match runs for each *transplanted* organ, rather than each *recovered* organ, and never truncate the match run. The advantages of this approach are that it would avoid arbitrary design decisions in estimating organ discard and it aligns more closely with available data on organ discard. The disadvantage of this approach is that some proposed allocation systems may have fewer estimated transplants because no offer on the match was accepted. The Chair and the Vice Chair supported this approach for TSAM. The Vice Chair said the current approach does not account for back-up offers, and there are other organs that would be offered further down the sequence and would not be discarded, so it makes sense not to use a cutoff on the match run.

A member asked if SRTR has a way to capture organs that would have been accepted if an appropriate candidate was available. SRTR staff said SAMs are run multiple times, so hopefully that sort of effect would be captured through multiple iterations. The member asked if SRTR has a sense of how much the likelihood of acceptance of organs discarded in the current model compare to likelihood of acceptance

for accepted organs. SRTR staff did not know the answer for lungs, but for kidney, the difference is apparent for kidneys with lower donor quality. The member said it might be reassuring if SRTR can demonstrate that organs discarded by the modeling are organs that are unlikely to be transplanted anyway. If the modeling discards good organs that could have been used, that would be concerning.

The member asked if the proposed approach would underestimate the impact of policy changes by eliminating potential donors who might have been used in other circumstances. UNOS staff said that for kidney, most discards happen because there is no acceptance, whereas lungs, they are generally accepted and the discard happens after that, so there is some data that an acceptance was received prior to the discard. UNOS staff asked if it was worth using data on lung donors for which there was a final acceptance on the match run, even if it may have been discarded afterwards. SRTR staff said they would need a separate model to capture whether an organ was transplanted or discarded after acceptance. UNOS staff agreed that the separate model would be needed if the goal is to accurately predict the number of transplants, but the proposed approach will moderately underestimate transplants. However, since the same approach is being used to compare current policy to proposed policy, then the focus is comparing the relative difference in the number of transplants rather than the actual baseline. SRTR staff said this approach standardizes what is being compared across different allocation policies, and that is generally a bad idea to focus on the total number of transplants estimated by the SAMs. It is more useful to focus on who is getting transplanted, and whether those are the people intended to receive transplants. The member said he had been under the impression that SRTR was changing the model from looking at all potential donors, including lungs not recovered for transplant, to only looking at organs transplanted. Since the current approach looks at all organs recovered for transplant, any donor bias would be a marginal number. HRSA staff asked for the discard rate for lungs. UNOS staff said the rate is generally about 5-7%, with higher rates for lungs that are perfused or donated after cardiac death.

Next steps:

SRTR staff asked members to provide feedback on TSAM stratification variables and metrics within the next week. The Workgroup supported SRTR's recommendation for modeling organ discard in TSAM.

2. Preview of Tableau Sensitivity Analysis Tool

UNOS staff previewed a sensitivity analysis tool that the Committee will use to refine the weights assigned to attributes in the composite allocation score.

Summary of discussion:

UNOS staff explained that old match run data was uploaded into the tool. Since it is known how those candidates were ranked on the match run, users can see how their ranks on the match run change when using the composite allocation score by varying the weights of each attribute in the tool. Users can see how the results differ by changing either the rating scales or the weights on the rating scales. Users can also view the rating scales that have been incorporated into the tool and select characteristics for a sample candidate. Members said the tool will be helpful.

Next steps:

The sensitivity analysis tool will be shared with the Committee following review of the transplant community prioritization exercise results.

Upcoming Meeting

- September 17, 2020 (Lung Committee)

Attendance

- **Workgroup Members**
  - Erika Lease, Committee Chair
  - Marie Budev, Committee Vice Chair
  - Alan Betensley
  - Whitney Brown
  - Rocky Daly
  - Ryan Davies
  - Marc Shecter
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
  - Adriana Martinez
- **SRTR Staff**
  - Yoon Son Ahn
  - Katie Audette
  - Melissa Skeans
  - Maryam Valapour
  - Andrew Wey
- **UNOS Staff**
  - James Alcorn
  - Julia Chipko
  - Rebecca Goff
  - Elizabeth Miller
  - Leah Slife
  - Darren Stewart
  - Kaitlin Swanner
  - Susan Tlusty
  - Sara Rose Wells
  - Karen Williams
- **Other Attendees**
  - Jennifer Schiller