OPTN Kidney & Pancreas Transplantation Committee Continuous Distribution Workgroup
Meeting Summary
March 18, 2022
Conference Call

Rachel Forbes, MD, Chair
Oyedolamu Olaitan, MD, Vice Chair
Martha Pavlakis, MD, Chair
Jim Kim, MD, Vice Chair

Introduction

The Kidney & Pancreas Transplantation Committee Continuous Distribution Workgroup (the Workgroup) met via Citrix GoToMeeting teleconference on 3/18/2022 to discuss the following agenda items:

1. Project Outlines and Goals
2. Overview: SRTR Modeling Review of Kidney Pancreas Simultaneous Allocation Model (KPSAM) Metrics
3. Timeline and Next Steps

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

1. Project Outlines and Goals

The Workgroup reviewed the goal of the continuous distribution project, which is to change allocation from a classification-based system to a points-based system, and the identified attributes. The Workgroup is currently in the "build framework" phase of the project and gathering feedback from the community on the *Continuous Distribution of Kidneys and Pancreata Request for Feedback*.

Summary of discussion:

 There was no discussion.

2. Overview: SRTR Modeling Review of Kidney Pancreas Simultaneous Allocation Model (KPSAM) Metrics

A Scientific Registry of Transplant Recipients (SRTR) representative continued their overview of the simulation model building process, including verification, validation, and credibility processes. Staff then presented a set of draft modeling metrics for discussion.

Presentation summary:

The KPSAM simulation focuses on the allocation of organs, specifically the match run. A verification, validation, and credibility process is used to create the simulation and drive results.

Operational validation takes place with respect to the research question. To reduce bias, simulated scenarios are compared to a simulation of the historical cohort, which is the target of validation. Several factors are used for baseline historical cohort tuning:

- Transplant rate, time to transplant
- Human Leukocyte Antigen (HLA) matches by race
- Post-transplant survival by age

- Kidney Donor Profile Index (KDPI) by age
- Donor-recipient distance by geographic area

This validation can quantify variability and bias across metrics and subgroups. Metrics should not be used if they are not validated.

Conceptual model validation utilizes sub-models representing different components of the system:

- Waitlist sub-models for randomized donor arrivals, candidate history generation, etc.
- Statistical sub-models for offer acceptance, post-transplant outcomes, etc.

Draft Modeling Metrics:

The Workgroup was asked to consider two questions in considering modeling metrics: What data would help you determine whether one continuous distribution framework is better than another? How would you prioritize these metrics for the first round of modeling?

Potential Metrics:

- Post-transplant outcomes
  - Level of HLA mismatch
  - By Estimated Post-Transplant Survival score (EPTS) and KDPI
  - Donor and recipient age
- Candidate biology
  - Counts and percents of transplant and transplant rates across blood groups and calculated Panel Reactive Antibodies (cPRAs)
- Patient access
  - Waiting time and dialysis time
  - Vulnerable populations, including sex, race, ethnicity, and socioeconomic status
- Efficiency and travel
  - Organ travel distance
  - Organs within 250 nautical miles (NM) of the donor hospital, to figure out where we may see an increase in transportation via airline
- Additional considerations
  - Donors by different metrics
  - Waitlist mortality
  - Informative items helpful to decision making discussions

Medical urgency is not included, as this is a very small population of patients that may not be able to be captured in simulation.

Summary of discussion:

One of the Chairs remarked that distance to travel from donor hospital is important, and may be more important for kidney-pancreas (KP) and pancreas than kidney alone.

One member recalled the modeling presentation from the February 18 Workgroup meeting, noting that the majority of data collected is focused on one year outcomes, and the ability to predict longer term outcomes is less effective in some modeling. The member asked if this could impact longer-term post-transplant outcome metrics, as the goal of modeling is to find a frame similar to current allocation or simply not worse than the current allocation system. Staff responded to the member's second question, explaining that any new allocation framework should not negatively impact the system, and any indication of that in modeling would mean the Workgroup needs to go

back and consider how to shift the framework to remediate these potential impacts in the second round of modeling.

An SRTR representative answered the member's first question, noting that the model can project out long-term post-transplant graft and patient survival rates, and that is what the longer term metrics are built on. The representative noted that the model can show differences between current and proposed policy for things like total predicted life-years from transplant or graft years from transplant. Staff added that the statistical models make assumptions on what will occur in the future based on what has happened in the past, and there is a certain level of uncertainty when looking at those metrics. Staff noted that approaching the results with the correct mindset, knowing the results cannot be a perfect representation but still may be helpful for the Workgroup. Another SRTR representative added that 10-year outcomes specifically should be carefully interpreted.

One of the Chairs agreed, noting that cautious interpretation is important when the current baseline is not stable, recalling the models for the circles-based policy, which included a local and non-local preference. That set of modeling showed a decreased transplant rate. The next round of modeling removed the local presence, and the numbers were even. The Chair continued that the number of deceased donors was increasing nationwide steadily, making it difficult to understand whether the increased rate of transplant is due to the new policy or to generally increasing donors. The Chair remarked that, in reality, modeling can only go so far, but it is important to ascertain the best guess so that the new system can be built on data and estimations of how the new policies will impact these variables.

One member asked if Coronavirus Disease 2019 (COVID-19) would be reflected in the modeling, as well as recent changes to allocation towards a circles-based framework. An SRTR representative explained that these are counter-factual situations of what would have happened in the historical timeframe with the new rules, and won't necessarily predict what will happen in the future. The representative continued that there is no specific adjustment for COVID, because the results will just be considering what would have happened during the COVID period, had different allocation rules been in place. The representative continued that things needed to incorporate into the modeling to make predictive simulations of what will happen in the future would involve more assumptions, and would include waitlist trends and donor arrival trends. The representative noted that there isn't really a good way to model those things in addition to the historical scenarios.

One Chair commented that the Workgroup will need to look at the different models and decide what is best and how to improve on it. The Chair added that the follow up and post-implementation monitoring is important for these reasons – if the framework doesn't reflect the modeling or has negative impacts, changes will need to be made quickly.

Staff asked the Workgroup if there were any metrics missing, and if there were any additional metrics that could help the Workgroup make an informed decision from the modeling. One of the Chairs recommended including distance between when an organ travels via air versus ground transportation, as this could be more important than physical distance from donor hospital. Staff responded that this information is not currently available, and that there have been discussions about adding this to OPTN data collection. Staff added that the OPTN Operations and Safety Committee's project to collect logistical data related to organ allocation was just approved by the Board of Directors, and is currently undergoing Office of Management and Budget review. Once implemented, this kind of data can be collected and reviewed.

The Workgroup agreed that the drafted list of metrics is comprehensive and sufficient. Staff thanked the Workgroup and asked members to send any additional thoughts or suggestions.

3. **Public Comment Update & Next Steps**

The Workgroup discussed the project timeline, including several meetings in April to review the results from the analytic hierarchy process (AHP) exercise and public comment responses, make decisions on outstanding rating scales, finalize draft framework, and develop and submit the modeling request to the SRTR.

The Workgroup was encouraged to continue sharing and participating in the AHP exercise until public comment and the exercise close on March 23, 2022.

Summary of discussion:

There was no discussion.

The meeting was adjourned.

Upcoming Meetings

- April 8, 2022 (Teleconference)

Attendance

- **Workgroup Members**
  - Martha Pavlakis
  - Oyedolamu Olaitan
  - Aaron Wightman
  - Abigail Martin
  - Arpita Basu
  - Dave Weimer
  - Parul Patel
- **HRSA Representatives**
  - Adriana Martinez
  - Jim Bowman
  - Marilyn Levi
- **SRTR Representatives**
  - Grace Leyden
  - Ajay Israni
  - Jonathan Miller
  - Josh Pyke
  - Nick Wood
  - Tim Weaver
  - Warren McKinney
- **UNOS Staff**
  - Joann White
  - Lindsay Larkin
  - Rebecca Brookman
  - Alison Wilhelm
  - Amanda Robinson
  - James Alcorn
  - Joel Newman
  - Kaitlin Swanner
  - Kim Uccellini
  - Lauren Mauk
  - Lauren Motley
  - Ross Walton
  - Sara Booker
  - Matt Clark