

**OPTN Kidney and Pancreas Transplantation Committees: Kidney-Pancreas
Continuous Distribution Workgroup
Meeting Summary
December 9, 2022
Conference Call**

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

Introduction

The Kidney-Pancreas Continuous Distribution Workgroup (the Workgroup) met via Citrix GoToMeeting teleconference on 12/09/2022 to discuss the following agenda items:

1. Review and Discussion: Organ Allocation Simulator (OASIM) Modeling Results

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

1. Review and Discussion: OASIM Modeling Results

Representatives from the Scientific Registry of Transplant Recipients (SRTR) presented the Pancreas and Kidney-Pancreas specific OASIM results.

Presentation summary:

Four continuous allocation scenarios were modeled, compared to a simulation of current policy. The scoring for each of the continuous allocation scenarios is based on a combination of rating scales, weights, and donor modifiers. Candidate biology, patient access, and placement efficiency are the attributes utilized for pancreas.

- Candidate biology:
 - Blood type
 - Calculated Panel Reactive Antibody (CPRA) – higher weight to higher CPRAs, with a steep line at about 80 percent CPRA
 - Each candidate has a CPRA score, representing their level of sensitization
- Patient access:
 - Pediatric – binary scale
 - Prior living donor – binary scale
 - Qualifying time – linear function with a steeper slope for less than five years, and a shallower slope for more than five years
 - Candidates beyond five years continue to receive additional points, just not as quickly a rate as the first five years
- Placement efficiency:
 - Proximity efficiency – piecewise linear
 - Fewer points awarded the further the program is from the donor hospital
 - Inner plateau up to 50 nautical miles (NM) where candidates all receive the same number of points

- Steeper slope in the 51 to 250 NM range, and a shallower slope from 250 NM beyond
- Whole pancreas score – binary scale
 - One point awarded for whole pancreas; zero for islet candidates

For pancreas, the most important scenarios are the “Combined Analytical Hierarchy Process (AHP) Weights” scenario and the “All Donor Efficiency Weights” scenario. The other scenarios are identical to the Combined AHP Scenario, as the variation in these scenarios were specific to Kidney-alone allocation. All Donor Efficiency includes increased weight for proximity efficiency. The only donor modifier used for Pancreas relates to whole pancreas transplantation versus pancreas islet candidates, such that islet candidates receiving preference for donor age 45 years or older or donor Body Mass Index (BMI) greater than 30.

OASIM modeling is limited by the size and demographics of the pancreas cohort:

- More than 95 percent of pancreas patients are between 18 and 65 years old
- Blood type AB patients are rare, and make up about 1 to 2 percent of the population

Summary of results:

- “All Donor Efficiency” scenario is associated with a significant decrease in travel distance without major differences in other outcomes
- Older candidates (greater than 65 years old) see a relative increase in transplant rates in all scenarios
- Blood type AB candidates see a relative decrease in transplant rates in all scenarios
- Even with higher transplant rates for KP compared to kidney alone models, the mortality on the waitlist for KP is still higher in all scenarios
- Pancreas utilization is highly dependent on acceptance behavior, which is not modeled in any scenarios

Summary of discussion:

One member remarked that these results were reassuring, particularly as they did not show substantial changes no matter which model was used. The member continued that these results particularly assuage the concerns that continuous distribution would harm certain groups or certain programs. An SRTR representative agreed, and noted that the only major difference is that the “All Donor Efficiency” scenario decreases travel time across all age groups. Otherwise, there are no major differences in the fundamental outcomes, particularly across racial disparities, demographic disparities, or access to transplant. The SRTR representative explained that it comes down to whether the Pancreas Transplantation Committee (the Pancreas Committee) considers distance traveled to be important. If so, the “All Donor Efficiency” model would be considered superior.

A member noted that the increase weight on proximity efficiency in the “All Donor Efficiency” scenario was critical to the decrease in distance traveled. The member noted that it would be helpful to know the volume of transplants and cost to the system, though it is understood that these things cannot be modeled. The member pointed out that it would be nice to follow that in post-implementation monitoring somehow. An SRTR representative pointed out that they often receive questions on projecting the volume or number of transplants. The SRTR representative explained that this would require a high number of assumptions, and that these assumptions could ultimately make any modeled estimate of expected number of transplants very misleading. Another SRTR representative agreed, noting that the more assumptions involved, the more extrapolation is required, particularly in terms of both Organ Procurement Organization (OPO) and transplant center behavior. The SRTR representative

noted that it is difficult at that point to present reliable information on changes in overall transplant volume. The member agreed, pointing out that the only way to know would be to implement the policy changes. An SRTR representative agreed, noting that post-implementation follow up is clearly worthwhile.

One SRTR representative recommended looking at historical trends in donor volume. The SRTR representative explained that, given the ongoing opioid epidemic, there has been an increasing number of donors every year for the last decade. The SRTR representative continued, adding that this trend could be extrapolated and that these trends are visible in the SRTR's annual data reports.

An SRTR representative pointed out that significant assumptions regarding center behavior would need to be made in order to project transplant volume. The SRTR representative explained that how these changes will reflect in the results produced by the OASIM, with higher transplant rates for high CPRA and older candidates. The SRTR representative noted that, if center behavior still dictates that programs are only likely to accept organs from nearby donors and decline organs further away, transplant rates for those patients may not change as much, as that increase in transplant rate is largely driven by increased distance. The SRTR representative pointed out that these things are expected when continuous distribution is implemented no matter which scenario is chosen. The SRTR representative continued that these results at least provide an understanding as to whether there could be system-driven disparities in access, particularly in terms of population groups and primary outcomes between scenarios, so that the Pancreas Committee and the Workgroup may make an informed decision moving forward.

An SRTR representative addressed cost to the system, noting that cost is divided into two components: the cost of procurement and transportation, and the cost post-transplant. The SRTR representative noted that shorter organ travel distances will marginally decrease transportation costs. The SRTR added that the surrogate for post-transplant costs would be graft success or graft outcomes. The SRTR representative noted that graft outcomes were not specifically reported as part of modeling, but mortality was, and it was not different between scenarios.

One member pointed out that another area where center behavior is strongly influential is transplant rates for blood type AB patients. The member noted that the results show decreased transplant rates for these patients. The member explained that this could be because AB patients receive so many offers that programs may be more inclined to bypass less than perfect offers for these patients, in the interest of waiting for a better offer. The member noted that this is an example of center behavior playing out differently than the modeling results show. An SRTR representative agreed.

Another SRTR representative noted that the big driver in center-level variation is not usually the allocation system, but the transplant center's behavior. The SRTR representative explained that aggressive transplant teams that accept lower quality organs will have higher overall center activity, and that this is far more impactful to the program than allocation system changes.

One of the Chairs noted that the biggest takeaway is that there is not a huge difference between the modeled scenarios, particularly with respect to transplant rate. The Chair expressed support for decreased travel distance in the "All Donor Efficiency" scenario. The Chair pointed out that transplant rate seems to be lower for non-metropolitan versus metropolitan. The Chair noted that this distinction is likely between metropolitan programs and non-metropolitan programs, and asked how these distinctions are defined. The Chair asked if "non-metropolitan" was synonymous with "rural." An SRTR representative explained that "metropolitan" and "non-metropolitan" are based on the patient's reported zip code of residence, and that these transplant rates are at a patient level. The distinction comes from the "metropolitan" designation of the patient's zip code. The SRTR representative added

that travel distance is calculated based on the distance between transplant center and the donor hospital. Another SRTR representative explained that the difference in transplant rates for “non-metropolitan” and “metropolitan” patients could be explained by two things. The first is that there are not as many pancreas transplant programs as kidney transplant programs, and as such, they are restricted generally to large centers more likely to be located in metropolitan areas. These areas may naturally have a larger patient base, and this could account for baseline differences even in current policy, where “metropolitan” patients have higher access. The second is that, for a given center, the patients who live far away from a center may not have access to the same offers. The SRTR representative explained that those patients who have to make long drive to reach the transplant program will not have access to as many organs, because they will not be able to accept offers that are already clamped or going for recovery soon. The SRTR representative explained that these factors could play into the difference in transplant rates, and that this difference could be contributed to the distribution of transplant centers and the distribution of patients in a transplant program’s area.

One of the Chairs addressed the discussion question regarding which metrics are most important for measuring the success of a new allocation system, noting that the metrics shown by the SRTR were important. The Chair noted that equity, transplant rates, and waitlist mortality are all critical. The Chair added that non-utilization rate would be nice, but that this would not be able to be evaluated until post-implementation. An SRTR representative noted that this question was posed to see if the Workgroup had any thoughts on particular metrics.

An SRTR representative noted that, over the next few weeks, the Kidney and Pancreas Transplantation Committees will need to make decisions about what changes will be included for the next round of modeling. The SRTR representative noted that the second modeling request will exclude multi-organ listings for isolated pancreas patients, such that it reflects pancreas transplantation alone. The SRTR representative reminded the Workgroup that these weights and rating scales can be tweaked. The SRTR representative noted that the Workgroup could decide to pursue correcting a discrepancy in one area, and the SRTR could provide some guidance in what areas could be tweaked to correct the discrepancy.

A Chair thanked the SRTR and the Workgroup for their work and noted that discussions will continue moving forward.

Next steps: The Kidney and Pancreas Transplantation Committees will continue to review attributes, including rating scales and weights, and develop a second modeling request. The Workgroup will be updated throughout this process. An update on the progress of Kidney and Pancreas Continuous Distribution development effort will be released for the January 2023 Public Comment cycle.

Upcoming Meetings

- December 16, 2022

Attendance

- **Committee Members**
 - Martha Pavlakis
 - Rachel Forbes
 - Oyedolamu Olaitan
 - Jim Kim
 - Abigail Martin
 - Caitlin Shearer
 - Parul Patel
 - Peter Lalli
 - Rachel Engen
 - Todd Pesavento
- **HRSA Representatives**
 - Jim Bowman
- **SRTR Staff**
 - Ajay Israni
 - Bryn Thompson
 - Jon Miller
 - Raja Kandaswamy
- **UNOS Staff**
 - Joann White
 - Lindsay Larkin
 - Kayla Temple
 - Keighly Bradbrook
 - Kieran McMahon
 - Kim Uccellini
 - Sara Moriarty
 - Sarah Booker
 - Thomas Dolan
 - Lauren Motley
 - Ben Welford
 - Carly Layman
 - Carol Covington
 - James Alcorn