

OPTN Ad Hoc Multi-Organ Transplantation Committee Meeting Summary November 9, 2022 Conference Call

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Introduction

The Ad Hoc Multi-Organ Transplantation (MOT) Committee met via Citrix GoToMeeting teleconference on 11/9/2022 to discuss the following agenda items:

- 1. Scientific Registry of Transplant Recipients (SRTR) Kidney and Pancreas Continuous Distribution Modeling Results
- 2. Overview of Concept Paper: Identify Priority Shares in Kidney MOT Policies
- 3. Simultaneous Liver Kidney (SLK) Workgroup Update

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

1. SRTR Kidney and Pancreas Continuous Distribution Modeling Results

Representatives from the SRTR presented the Kidney and Pancreas Continuous Distribution Modeling Results.

Presentation summary:

Background and request:

- The Kidney and Pancreas Continuous Distribution Workgroup requested simulation results for 4 continuous allocation scenarios
- The continuous distribution framework for kidney transplants includes 5 components:
 - o Medical urgency
 - Post-transplant outcomes
 - Candidate biology
 - o Patient access
 - Placement efficiency
- The continuous distribution framework for pancreas, kidney-pancreas, and pancreas islets transplant includes 3 components:
 - Candidate biology
 - o Patient access
 - Placement efficiency

Scenarios run:

- Baseline scenario simulation runs of the current allocation rules were utilized as a baseline scenario for all simulation comparisons and as a means of tuning the overall simulation and its sub-models
- Combined Analytical Hierachy Process (AHP) based on weights informed by the values exercise completed by the Kidney and Pancreas Committee members and members of the community

- Increased Longevity increased weight on the longevity matching attributes, include Kidney Donor Profile Index (KDPI) to Estimated Post-Transplant Survival (EPTS) and DR locus matching
- All Donor Efficiency increased weight on placement efficiency
- High KDPI Efficiency donor modifiers increase efficiency weights for high KDPI donors

Summary – Kidney

- The Organ Allocation Simulator (OASim) has modeled a continuous distribution system that has eliminated hard boundaries of previous systems
 - Increased travel distance for all kidneys
 - Particular increase in travel distance for pediatric kidneys, whose priority for national kidneys was greater under the continuous distribution scenarios
 - Can manage travel distances by using increased weight on proximity efficiency
- Longevity matching of kidney is more precise under all continuous distribution scenarios compared to current policies
 - Higher KDPI kidneys go to older recipients
 - Longevity matching trend strongest under the increased longevity scenario
 - The continuous distribution longevity matching score gives priority for high EPTS, and generally older recipients for high KDPI kidneys
 - Different from current policy, under which there is no specific mechanism that pushes high EPTS candidates higher on the high KDPI match runs
- The lower weight on "qualifying time" for the "Increased Longevity" and "All Donor Efficiency" scenarios:
 - May explain the lower transplant rate for patients on dialysis for greater than 5 years
 - Led to unintended consequences of slightly lower rates for Black candidates, who tend to have longer dialysis time
 - Continuous distribution can be adjusted transplant rates for black candidates and candidates on dialysis for greater than 5 years are higher in scenarios with higher weight on qualifying time
- The continuous distribution scenarios showed lower transplant rates in some OPTN regions, but this was in regions with already high transplant rates, and brought these regions closer to transplant rates in many of the other OPTN regions

Summary – Pancreas and Kidney-Pancreas (KP)

- "All Donor Efficiency" scenario is associated with a significant decrease in travel distance without major changes in other outcomes
- Older candidates greater than 65 years old see a relative increase in transplant rates in all scenarios, more so in the all donor efficiency scenario
- Blood type AB appears to be associated with decreased transplant rates in all scenarios, but less so in the all donor efficiency scenario
- Candidates on the KP waiting list have a higher waitlist mortality than kidney-alone candidates in spite of a higher transplant rate

Summary of discussion:

A member asked whether impact on organ utilization was studied. The member pointed out that, under the current kidney and pancreas allocation policy, KPs are traveling greater distances, only for the pancreas to be declined upon arrival and the kidney transplanted into another recipient. The member asked if impact on pancreas utilization in particular could be shown. An SRTR representative responded that utilization cannot be modeled because behavior cannot be modeled. The SRTR representative explained that this modeling can only be based on historical data. The member asked if monitoring was done to understand the impact of pancreas utilization after the current policy was implemented, compared to the previous policy. The member said that geography and distance should play a larger role due to the combination of factors leading transplantable pancreata to ultimately not being transplanted.

An SRTR representative shared that the OPTN Pancreas Transplantation Committee is focused on reducing the travel distance for pancreas and KP, and that they understand pancreata are more likely to be used locally when the program's team recovers and transports the organ. The SRTR representative pointed out that the "All Donor Efficiency" scenario was the only scenario which showed a difference from the "Combined AHP" scenario in weights for pancreas and KP allocation. The SRTR representative explained that the "All Donor Efficiency" scenario showed reduced median travel from 155 to 108 miles. The SRTR representative continued that these are median distances that represent a lot of pancreata that could now be driven instead of flown. Another SRTR representative pointed out that the distance traveled for pancreas alone was greater in all scenarios. The member explained that many regions don't have centers that perform pancreas transplants. The SRTR representative explained that this impacts the modeling, and shared that they believe the modeling shows greater distance traveled for isolated pancreas as a result of this regional and geographic variability.

A member explained that pancreas and KP allocation needs to be about giving programs the ability to be successful by allowing them to recover the organs themselves. The member added that, as an Organ Procurement Organization (OPO) professional, OPOs hear all the time that the transplant program would be interested if they could get to the donor and recover themselves. The member explained that current allocation of pancreata and KP limits pancreas programs located in a small geographic area around the donor hospital because the organs are being allocated to programs who will never actually accept the pancreas first. An SRTR representative noted that this concern was brought up at the OPTN Pancreas Transplantation Committee meeting. Another SRTR representative agreed that it should be more accessible for the accepting center to procure themselves, noting that the variability in training and procurement techniques is currently so wide that many people are not comfortable accepting a pancreas procured by someone else.

An SRTR representative noted that the reason pancreata travel longer distances is because the centers that perform pancreas-alone transplants are typically more aggressive, and can make acceptance decisions using a photo or a video of the organ. The SRTR representative added that this trend is still currently evolving, with pancreata accepted from 300 nautical miles (NM) away often requiring costly charter flight transportation. The SRTR representative noted that it is becoming increasingly expensive to charter flights, and more centers look to share costs with the offering OPOs. The SRTR representative added that these factors influence behavior and make it difficult to model. A member responded that the challenge with splitting the cost of pancreas transportation is that pancreata have the lowest utilization rate of an organ procured for transplant. The member continued that OPOs are aware of this going into these conversations, and it can be hard to commit to such a steep financial commitment without certainty the organ will actually be utilized.

One member shared that the modeled pediatric transplant rates were exciting at first glance, but that the related increased travel distances for pediatric transplants were disheartening. The member agreed that behavior cannot be modeled, but pointed out that these distances were not realistic when considering pediatric transplantation. The member continued that most pediatric programs may not accept kidneys from 1000 miles away, and that this practice should not necessarily be encouraged, as increased cold ischemic times can impact patient outcomes and have been linked to delayed graft function. The member asked if there was a way to get a sense of how much the elevated pediatric kidney transplant rates are related to the unrealistically high travel distances. An SRTR representative

responded that there was an increased weight on pediatric patients. Another SRTR representative noted that the pediatric rating scale is binary, and some of these increases are due to removing current existing hard boundaries. The SRTR representative explained that the pediatric transplant rate and travel distances are not separated out categorically, but that a full distribution of travel distances could be possible in the second round of modeling. The member asked if behavioral guardrails could be built in, such as only having offers within a specific NM range considered accepted. The SRTR representative responded that anything involving modeling behavior requires a different level of validation that is not feasible on a short timeline, but that the OASim software is flexible for this, and this could be an ongoing area of evaluation. The SRTR representative reiterated that behavior cannot be simulated at this time.

A member agreed with concerns regarding travel distance for pediatric kidneys, sharing that this is one of the biggest complaints at their program. The member explained that the current allocation system broadened the distance that kidneys travel for pediatric recipients. The member continued that transplant rates did not increase because behavior had to change. The member also pointed out that, when the new allocation system was implemented, the number of organ offers that centers received drastically increased within the 250 NM range, and OPOs had to work with significantly more programs in order to place an organ. The member expressed concerns that OPOs will need to send more offers and coordinate with even more programs before an organ can be successfully placed. The member asked if there was a sense of the number of offers and related allocation efficiency. An SRTR representative responded that the modeled current policy puts median travel distance at 158 NM, while the "Combined AHP" scenario and "Increased Longevity" scenarios have median travel distances up to 770 NM. The SRTR representative explained that, even though these numbers look high, they will not be, because programs will not accept quite so many kidneys from such long distances. The SRTR representative pointed out that the "All Donor Efficiency" model, the median distance is only 205 miles, and pediatric transplant rates shift from 0.441 to 0.49. The SRTR representative continued that these weights can be tweaked to achieve different results.

Another SRTR representative agreed that increased calls can be difficult, but that an increase in offers can be a good thing at an individual program level. The SRTR representative continued that programs need a better mechanism to triage these calls more efficiently.

One member noted support for increased transplant rates for pediatric patients, but expressed concern about decreased transplant rates for patients aged 18 to 35. The member explained that these are typically pediatric patients who have managed their illness well and may only need their first transplant after 18, or else these are pediatric patients in need of a second transplant. The member expressed additional concern for several other groups that could be potentially disadvantaged, including highly sensitized candidates, blood type AB candidates, candidates with prolonged dialysis time, and Black candidates. The member continued that there seem to be several red flags in terms of worsening disparities without a proven increase in transplant rate or decreased waitlist mortality. The member continued that the allocation scenarios seem insufficient to achieve these goals. An SRTR representative explained that this models a continuous distribution system that can be managed and tweaked. If the continuous distribution system is tweaked to highlight increased longevity, the rates are higher for the 18-35 age group than they are under the current allocation system model. The SRTR representative pointed out that prolonged dialysis patients and Black candidates saw increased transplant rates in some scenarios. Staff added that the concept of this modeling request was to determine if the policy framework would respond to the attribute weights. An SRTR representative explained that the Kidney and Pancreas Committees are discussing these results robustly to generate a second modeling request based on these results and what may need to be changed. The member continued that these scenarios are not the final proposal.

One member asked what the model reported for long term patient outcomes, including how long patients live with these transplants. The member explained that this is what patients are typically focused on. An SRTR representative explained that this is in the supplementary data, and that the ten year outcomes were built with outcomes data from 2007 to 2021, and should be reviewed with a grain of salt. Another SRTR representative added that, in a nutshell, the ten year outcomes results showed that rates of graft failure were slightly higher for older age groups under the "Increased Longevity" scenario and unchanged for younger age groups, relative to the modeled current allocation policy. This information is available in the full report. The Chair shared that this presentation was cut down some, in order to ensure adequate time for discussion.

Staff shared that the Kidney and Pancreas Committees will be submitting a second modeling request, and asked Committee members to send any additional feedback or questions.

2. Overview of Concept Paper: Identify Priority Shares in Kidney MOT Policies

Staff asked the Committee to read the drafted concept paper and provide any feedback, including questions for the community or literature that should be included in the concept paper.

Summary of discussion:

The Committee had no questions, comments, or concerns.

3. Simultaneous Liver Kidney (SLK) Workgroup Update

Staff shared a brief update on the SLK Workgroup, which met recently to review data and discuss final recommendations. The SLK Workgroup has ultimately recommended expanding the required share circle size for SLK offers to 500 NM for qualifying SLK patients who are Status 1A or 1B, or have a Model for End-stage Liver Disease (MELD) score of 29 or greater.

Summary of discussion:

The Chair shared that the data reviewed by the SLK Workgroup clearly showed a gap and regional inequity, and that the SLK Workgroup agreed that expanding the required share circle to 500 NM would resolve some of this. The Chair shared a point made by one of the SLK Workgroup members, that expanding to 500 NM and leaving permissibility at 501 NM could ultimately recreate this variability with a smaller pool of patients. The Chair continued that, for now, the SLK Workgroup is recommending maintaining permissibility of SLK shares beyond 500 NM.

Next steps:

The Committee will review the SLK Workgroup's recommendation and relevant data at their next meeting.

Upcoming Meetings

• December 14, 2022

Attendance

• Committee Members

- o Lisa Stocks
- o Chris Curran
- o Dolamu Olaitan
- o Shelley Hall
- o Jim Sharrock
- o Kenny Laferriere
- o Marie Budev
- o Nicole Turgeon
- o Rachel Engen
- o Sandra Amaral
- o Valerie Chipman
- Vince Casingal
- HRSA Representatives
 - o Jim Bowman
 - o Marilyn Levi
- SRTR Staff
 - o Bryn Thompson
 - o Raja Kandaswamy
 - o Peter Stock
 - o Jonathan Miller
 - o Katie Audette
- UNOS Staff
 - o Kaitlin Swanner
 - o Kelsi Lindblad
 - o Kayla Temple
 - o Erin Schnellinger
 - o Ben Wolford
 - o James Alcorn
 - o Matt Cafarella
 - Paul Franklin