OPTN ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

OPTN Pancreas Transplantation Committee
Meeting Minutes
June 25, 2019
Baltimore, MD

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Introduction

The Pancreas Transplantation Committee (hereafter the Committee) met in Baltimore, MD on 06/25/2019 to discuss the following agenda items:

1. SRTR Modeling Results- Deeper Dive
2. Removing DSA and Region from Pancreas Allocation – Elements of a Policy Solution Aligning with the Final Rule
3. Outreach Strategy

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

1. SRTR Modeling Results- Deeper Dive

An SRTR representative presented the most recent KSAM results on the effect of removing Donor Service Area (DSA) and region from kidney, pancreas, and kidney-pancreas OPTN allocation policy.

Data summary:

The KPSAM results showed little variation in the total number of transplants for kidney and kidney-pancreas (KP). Overall the number of kidney and pancreas-alone transplants were projected to decrease, and the number of KPs were projected to increase. The change in transplant count for the respective organ combinations was less for smaller sized circles. The modeling showed greater distance traveled for larger circles across organ type. More kidney candidates with longer dialysis time were shown to be transplanted. The full modeling results are available on the OPTN website.

Next Steps:

The Committee will further discuss the models and work towards a solution.

1. Removing DSA and Region from Pancreas Allocation – Elements of a Policy Solution Aligning with the Final Rule

The Committee reviewed SRTR modeling and discussed at length the optimal replacement for DSA and region in OPTN pancreas policy.

Summary of discussion:

The Committee reviewed and discussed the SRTR modeling results on replacing DSA and region with nautical mile distances from the donor hospitals with proximity points. The Committee agreed that the models were very similar and the discussion should center on compliance with the Final Rule. A concern was expressed that pancreas-alone numbers are decreasing outside of any changes to policy and any options chosen should not disadvantage pancreas-alone. However, Committee members noted that pancreas-alone transplants occur at programs that tend to be more aggressive and such behavior characteristics are difficult to model in the KPSAM. Because more aggressive pancreas programs could still accept and transplant pancreas-alone, the drop in pancreas-alone transplants may not occur in the

way the modeling indicates could happen. Because of this and because most pancreata are transplanted as KPs (about 80%), the Committee agreed to focus the discussion around the impact on KPs

Certain members favored a smaller circle size such as 150 nautical miles (NM) because it would be more cost effective. It is difficult for the Committee to fully review the impact of cost on members because limited data is collected on the travel and recovery cost of organ procurement and transplantation. The Committee considered impact on graft survival and ischemic time for greater distances traveled. Patient survival was not shown to be significantly impacted in the KPSAM projections (which were limited to 1 year post-transplant).

The Committee discussed further the relationship between ischemic time and travel distance. Specifically, whether ischemic time limit the distance traveled and the circle size chosen. Committee members indicated the answer was "not necessarily." Most pancreata are transplanted locally – but certain more aggressive programs do accept pancreata from further away and successfully transplant the organs. The Committee considered that a 500 NM circle with proximity points inside the circle would concentrate acceptance to programs closer to the donor hospital while still allowing more aggressive programs the opportunity to transplant pancreata from farther away. This could increase competition with less aggressive programs, which could help with utilization by encouraging less aggressive programs to consider viable pancreata they may not have otherwise. Utilization has been a longstanding problem in the pancreas transplant community. Committee members also considered that a larger circle could allow programs to work with different Organ Procurement Organization (OPOs) if they are facing issues with the OPO in their DSA.

There was also interest in a different proximity points system in which points taper logarithmically instead of linearly. The Committee could consider this option when it considers how to move from a circle-based distribution system to a continuous distribution system. However, it will not be included in the proposal in the fall due to added complexity and the need for further review.

The Committee discussed feedback received from the Kidney Committee colleagues regarding concern about increased access for type 2 candidates with broader distribution of KP transplants. The Committee considered that type 2 versus type 1 diabetes is itself perhaps an inappropriate distinction that is not particularly useful. Several Committee members noted how the distinction between type 1 and type 2 candidates is not rigid as insulin resistance can occur in either group, depending upon how the "types" are defined. Instead the more relevant data relates to the metabolic nature of the patient. Committee members also noted that it is still up to the surgeon's discretion whether the candidate should be transplanted, and not all type 2 candidates from the kidney waiting list would be transplanted with KP, only the ones that the surgeon considers medically appropriate.

The Committee took a straw poll vote and indicated a strong support for a 500 NM circle for pancreas, with up to 4 points inside the circle and 8 points outside the circle. This reflects the Committee sentiments that ischemic time not an absolute barrier to distributing pancreata out to 500 NM, pancreas-alone can travel farther currently, and aggressive programs may accept further KPs as well. The proximity points would provide balance to the farther distance by prioritizing those candidates closer to the donor hospital. As a second choice, the Committee indicated support for a 250 NM circle with 2 points inside and 4 points outside the circle. In both votes clear majorities spoke to the preferred options; 2 members preferred a smaller circle of 150 NM because of concerns about cost effectiveness.

The Committee also reviewed how facilitated placement in pancreas allocation may need to change. Currently in pancreas allocation, the host OPO or the UNOS organ center can make offers to a list of facilitated pancreas programs (defined as transplanting 5 imported pancreata in the last 2 years) if the local/DSA offers have been exhausted and the OPO is 3 hours or less from the operating room to

procure the pancreas. Because "facilitated placement" is defined by DSA in policy, this section of policy will need to be changed. It could be changed to a NM distance from the transplant program, and it could be modified according to the number of pancreata that need to be transplanted from beyond a NM distance. The Committee asked the UNOS research scientist to gather data regarding the number of qualifying facilitated programs if DSA were changed to 500 NM in policy. The Committee will discuss this data during its July 10 call.

Next steps:

The Committee will continue discussion and potentially vote on policy language on a July 10 teleconference. If consensus or quorum is not reached on the July 10 call, the Committee will utilize a July 17 teleconference to vote on the proposed changes to send out for public comment.

2. Outreach Strategy

UNOS staff presented their strategy for stakeholder communications.

Summary of discussion:

UNOS goals for community engagement include transparency, involving stakeholders early on in the process, and asking for frequent feedback. The targeted audiences are transplant professionals, committee alumni, Board of Directors, stakeholder organizations, and patients/families of patients. UNOS staff listed stakeholder organizations/societies as potential partners and asked for input from committee members. Members suggested connecting with the National Kidney Foundation (NKF), Transplant Recipients International (TRIO), and the American Diabetes Association (ADA). Members were also asked to keep their ears open for feedback during an upcoming International Pancreas and Islet Transplant Association (IPITA) conference and within their home institutions.

UNOS staff presented their plan for outreach pre through post- public comment. This plan emphasized the need for increased solicitation of feedback. Members were asked to assist with efforts through webinars, email updates, and 1:1 outreach. Changes to regional meetings and the fall 2019 schedule were discussed.

Next Steps:

Committee members were asked to reach out to UNOS staff with ideas for engaging the community.

Upcoming Meetings

- July 10, 2019 (teleconference)
- July 17, 2019 (teleconference)
- August 21, 2019 (teleconference)