OPTN ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

OPTN Pancreas Committee
Meeting Minutes
June 19, 2019
Conference Call

Jon Odorico, MD, Chair
Silke Niederhaus, MD, Vice Chair

Introduction

The OPTN Pancreas Committee (the Committee) met via Citrix GoTo teleconference on 06/19/2019 to discuss the following agenda items:

1. SRTR Presentation of Modeling

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

1. SRTR Presentation of Modeling

A member of SRTR presented an overview of the modeling results and committee discussion followed.

Data summary:

Simulated Allocation Models (SAMs)

SAMs make up a family of computer simulation programs developed by the SRTR. The family includes:

- LSAM: liver simulated allocation model
- TSAM: thoracic simulated allocation model
- KPSAM: kidney-pancreas simulated allocation model

SAMS take real candidate and donor information and use this to simulate allocation by applying new rules the committee would like to explore.

The software then outputs information on modeled results of new allocation rules, including the number of candidates transplanted, died waiting, and post-transplant deaths.

The models include some random components, reflecting uncertainty in:

- Acceptance decisions when an organ is offered to a potential recipient
- The unpredictable life expectancy that can result from undergoing or not undergoing transplant

To account for random variation, SRTR 'runs' the models several times with the same set of allocation rules, organs, and candidates to determine average outcomes

SAMs rely on aggregate historical data

- Can't predict changes in organ acceptance behavior or identify trends over time

SAMs work best for modelling small allocation changes applied to large patient groups

- Unlikely to give reliable predictions for small population subgroups; can't predict outcomes below an OPO level

SAMs assume standardized behavior

- Center and OPO-level variation in policy or practice is not modeled
- Directed/expedited allocations are not modeled

Organs are considered “discarded” after a fixed number (200) of declined offers, regardless of organ and donor characteristics

SAMs are not designed to predict an overall number of transplants

Overall SAMs are good tools to estimate relative magnitude/direction of possible effects of policy change. However, some policy changes may be justified even in the absence of clear simulation results.

Acceptance Model

The initial KPSAM report (submitted in December 2018) showed decreases in the number of transplants, potentially related to the inclusion of a local indicator in the offer acceptance models

In response, SRTR began investigating the effect of different decisions in the offer acceptance model on KPSAM results

- Presented two alternate acceptance models to the Kidney Committee, Pancreas Committee and Kidney-Pancreas (KP) Workgroup: candidate/donor model, and donor-only model. KP Workgroup voted that all new simulations be run with a donor-only acceptance model

All simulations were run using the donor-only acceptance model

Study Population

KPSAM input files were updated to include transplant candidates listed on the kidney, kidney-pancreas, or pancreas transplant waiting lists between January 1, 2017-December 31, 2017 and donors whose kidneys or pancreata were recovered for transplant in the same time period.

The results include all 10 iterations of each model.

Transplant Counts

Total transplants varied by less than 200 across all runs.

KI and KP/PA allocation systems are highly related, with KP/PA candidates receiving absolute priority over KI candidates through the first (formerly “local”) level of allocation.

KP candidates outnumber PA candidates by 3:1. Under broader sharing, KP candidates tend to benefit more than PA candidates.

In general, when the KP/PA and KI circles are of the same size, relatively more KP transplants are performed, and relatively fewer PA and KI transplants. In contrast, when the KP/PA circle is smaller than the KI circle, both KI and PA transplants decline less.

Travel Distance

Distance traveled is greatest in larger circles (e.g. 500 NM) and minimized in small circles (e.g. 150 NM).

Proximity points within the circle tend to reduce the distance traveled.

- For example, the median distance in run 500.500.0.8 for a kidney transplant was 303 NM, but in run 500.500.4.8 (which employed a maximum of 4 proximity points) the median distance for a kidney transplant was 199 NM.

The effect of proximity points outside the circle was less strong, likely because relatively few transplants were predicted there (10%-20%).

KP transplants traveled the shortest distances, and PA transplants traveled the farthest.

Subgroups of Note

Kidney transplant rates remained nearly constant under broader sharing

- Rates among pediatric candidates, female candidates, African American, and Latino candidates increased.
- Rates among highly sensitized candidates (80-99% cPRA) and candidate with >5 years of dialysis time increased.
- Small decreases in non-metropolitan candidates and EPTS <= 20% candidates.

Kidney-Pancreas transplant rates increased globally under broader sharing

- African American, non-Latino, female and cPRA >=80% candidates received relatively more transplants.

Pancreas-alone transplant rates decreased globally under broader sharing

- Candidates aged >=35 years and candidates with cPRA >=80% had slightly more transplants, and candidates aged <35 years or with cPRA <80% fewer.

Conclusions

Total transplants varied by less than 200 across all runs

KI and KP/PA allocation systems are highly related, with KP/PA candidates receiving absolute priority over KI candidates through the first (formerly “local”) level of allocation

KP candidates outnumber PA candidates by 3:1. Under broader sharing, KP candidates tend to benefit more than PA candidates.

In general, when the KP/PA and KI circles are of the same size, relatively more KP transplants are performed, and relatively fewer PA and KI transplants. IN contrast, when the KP/PA circle is smaller than the KI circle, both KI and PA transplants decline less.

Summary of discussion:

One committee member asked if the cutoff for 200 organ offers is the same limit applied for the baseline SAM and therefore the baseline SAM is not real life data. The presenter for SRTR confirmed that is the case.

One committee member commented that while there is broader sharing with the larger 500 NM circles that there are also potential disadvantages. The member was concerned about an increase in the average cPRA as well as over-prioritizing sensitized patients. The member added that from a kidney-pancreas perspective, while 500 NM shares the most broadly there is an increase at all circle levels.

One committee member brought up a concern that even if kidney-pancreas is shared more broadly, that there is a potential for increased discards due to how far the organs will travel and surgeons are often desiring more ideal organs.

A UNOS staff asked why more broad distribution increased for kidney-pancreas but decreased for pancreas-alone. One committee member responded that it is common that pancreas transplants are only done by the more experienced surgeons and programs which are more limited in number compared to those that do kidney-pancreas transplants. In addition, another member added that some DSAs may be very reluctant to share kidneys outside the DSA whereas they may be more willing to share pancreata.

This member also expressed their support for the larger circle size of 500 NM in order to allow for larger or more “aggressive” centers to have the opportunity to transplant organs, while still giving priority to more local candidates.

One member asked a clarifying question regarding the larger 500 NM circle and the proximity points. A member of SRTR clarified that while proximity points inside the inner circle prioritize patients compared to those patients outside the circle, that there was not a significant difference in number of transplants performed compared to the 500.500.0.8. model.

One member asked for a clarification in the amount of net kidneys being transplanted for the model 500.500.08. It was clarified that the number of KP transplants were currently counted separate from the kidney-alone transplants and therefore the true total of kidney transplants overall would be a combination of the two figures.

A member of SRTR indicated that the range of net kidneys transplanted is very narrow among the models and only vary by about 60 transplants. The only model with a net positive is 500.150.0.8. Another member of SRTR cautioned committee members against relying too heavily on the exact transplant count as the small amount of variation between models was negligible and could easily be overcome by a change in acceptance behavior.

The Vice-Chair noted that while the OPTN Kidney Committee may prefer models where the kidney-alone transplant count does not decrease as much, that the kidney-pancreas transplant counts increased across the board and without a statistical significance between the models the Chair did not have strong oppositions to any models.

One member commented that if there was little significant difference between the models, that there was not strong reasons to expand to broader sharing and complicate the logistical issues that accompany farther travel distances.

The Committee members discussed the graph of violin plots demonstrating the estimated travel distance for each model, noting that those models with larger circles saw an increase in travel distance and as the circles were smaller so did the travel distance.

One member expressed concern over the waitlist mortality and graft failure rates for models with larger circle sizes. An SRTR staff member clarified that those rates are estimates to be taken with a grain of salt.

The Vice-Chair requested that the models be numbered as an alternative to using their full titles. SRTR said they would be able to accommodate.

Next steps:

The Committee will receive a deeper dive of the data by SRTR at their in-person committee meeting.

Upcoming Meetings

- June 25, 2019 – Full Committee Meeting
- June 26, 2019 – Kidney-Pancreas Workgroup Meeting