

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

Nicole Turgeon, MD, Chair Vincent Casingal, MD, Vice Chair

Introduction

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

- 1. Welcome & Opening Remarks
- 2. Review of Scientific Registry of Transplant Recipients (SRTR) Modeling Results
- Removing Donation Service Area (DSA) and Region from Kidney Allocation Modeling Discussion
- 4. Removing Donation Service Area (DSA) and Region from Kidney Allocation Preferences Discussion
- 5. Outreach Strategy

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

1. Welcome & Opening Remarks

The Committee Chair and UNOS staff welcomed committee members and stakeholders to the meeting, gave an overview of the agenda, and encouraged all to participate fully in the day's work.

UNOS staff also reviewed some of the reasons the committee embarked on this project to remove Donation Service Area (DSA) and region from kidney allocation. When looking at the Access-to-Transplant Score (ATS) and the contributing factors of disparity in equity in access to kidney transplantation over time, DSA has remained the number one factor of inequity in the system.

2. Review of Scientific Registry of Transplant Recipients (SRTR) Modeling Results

SRTR staff reviewed the findings of the Kidney Pancreas Simulated Allocation Model (KPSAM) report previously presented on the June 17, 2019 Committee call. UNOS staff also presented some supplemental data slides to highlight key metrics from the KPSAM modeling report.

Discussion:

A committee member asked how well the modeling can predict outcomes. SRTR staff explained based on retrospective comparisons, the modeling is good at predicting the magnitude and direction of changes, but not good at giving exact measurements.

Another committee member asked if there is a way to collect data related to acceptance behavior so the models can better predict behavior changes. UNOS staff explained the OPTN does not currently collect acceptance or decline reasons and to do so would require a large systems based effort.

The Chair clarified for the committee that when looking at the modeling results, multi-organ transplants come before kidney alone in allocation which is why the modeling shows an increase in the transplant counts for kidney-pancreas (KP) because they are given more access. According to OPTN policy the kidney follows the life-saving organ (ex. heart, lung).

Submitted: 07/08/2019

A stakeholder asked at the individual patient level, what the effect is of having a large number of proximity points outside of the circle and if they produce issues of equity at the border of the circle. SRTR and UNOS staff clarified although the proposed models are not continuous distribution circles, patients inside the circle will always have priority over candidates outside of the circle, except for mandatory national shares, as noted in policy. The Chair further explained the committee recognizes this "cliff" is a limitation of the model, but the framework chosen will be a step moving toward continuous distribution.

The committee had several questions regarding the average time on dialysis at transplant data. SRTR and UNOS staff clarified that output figures represent increases in access for patients with long dialysis times and should not be interpreted to mean that a candidate would have to wait longer on dialysis before receiving greater access to transplant.

The Vice Chair asked what populations are affected negatively in the modeling and how much they were affected. SRTR staff informed the committee according to the modeling, older adults and white candidates showed a small decrease in transplant rates. Also there was little increase for Medicaid patients and little decrease for private insurance; Medicare patients stayed constant throughout models. When looking at urbanicity, all but the metropolitan population showed a small decrease in transplant rate. The urbanicity data is determined by the candidate's zip code at time of listing and their categorization comes from U.S. census data. The Vice Chair emphasized the Committee must make sure the framework chosen does not disadvantage or advantage any population too much. However, though small decreases in transplant rate in non-metropolitan areas were observed, the output appeared to show greater equity in access across all urbanicity types.

UNOS staff highlighted that the KPSAM modeling assumes organs are discarded after sequence 200 in the match run. The Vice Chair asked if the modeling stops at sequence 200, how that effects the depictions of urbanicity. UNOS staff informed the committee that the vast majority of organs are accepted prior to sequence 200.

UNOS staff also highlighted the baseline transplant rates by DSA which shows large disparity across all DSAs. By depicting the same DSAs using some of the model frameworks, the transplant rate becomes more equitable across the DSAs.

3. Removing Donation Service Area (DSA) and Region from Kidney Allocation – Modeling Discussion

The Chair asked the committee members and stakeholders their initial thoughts on the modeling results. Participants had the following comments:

- The Committee should make sure the gains in reductions of disparities seen post the implementation of the Kidney Allocation System (KAS) are not taken away by the new framework.
- The impact of broader distribution would be different for different Organ Procurement Organizations (OPOs). It will have more of an effect on OPOs that don't usually have organs travel far.
- There is a lack of meaningful difference between all the models in terms of variance in transplant rate, transplant count, and other key metrics.
- The models that can be immediately eliminated would be the 150 nautical miles (NM) circles as they actually increase variance in transplant rates across DSAs.
- The Committee will need to consider logistics when considering models.
- Suggestion to start with a smaller circle then extend the circle over time if data supports expansion.

- Concern about kidney-pancreas (KP) candidates pulling too many organs from kidney alone candidates.
- Proximity points may introduce geographic disparity in a new way.
- When this data is released it should to be distributed and written in a way to make it easy to discuss with patients and staff. It's important to be able to explain these potential changes in a coherent way.
- Concern about if proximity points unfairly advantage centers next door vs. down the street.
- Concern over cold ischemic times (CIT), cost, and distance with broader distribution. These should be carefully considered.
- The Committee should consider models that share more broadly while maximizing efficiency and innovation.
- Pre-transplant cross-matching would be logistically harder if it goes further away.
- Allocation policies need to be justified based on the Final Rule.
- Steep proximity points may increase organ donation because of the direct impact to the community.
- Suggestion to create a liquid, fluctuating model and adjust as needed. The Committee should consider the future end goal and plan back from there.
- Suggestion to choose the least disruptive model.

There was discussion on prioritization for pediatric candidates. A stakeholder suggested the Committee should evaluate fully what the impact would be on pediatric candidates and prepare for questions on this issue at upcoming regional meetings. Another stakeholder recommended pediatric candidates should be prioritized above multi-organ candidates. The Chair and Vice Chair clarified although this is an important consideration, this particular reprioritization is not in the purview of the current project. SRTR staff further clarified that according to KPSAM modeling, pediatric candidates are projected to benefit when sharing is broadest.

4. Removing Donation Service Area (DSA) and Region from Kidney Allocation – Preferences Discussion

The Chair updated the Committee on the Pancreas Committee's modeling discussions. The Pancreas Committee eliminated both of the 150NM models and thinks the vast majority of KPs should stay local while allowing broad sharing for pancreas alone. The Chair emphasized the need to have both committee's proposals make sense and work together.

The Chair held an informal poll to eliminate the 150NM models from consideration. The committee members and stakeholders unanimously agreed.

The Chair then asked the committee members and stakeholders to select their top preference to narrow down to the four top models for discussion.

- 500.500.0.8 (2 votes)
- 500.500.4.8 (3 votes)
- 500.150.0.8 (0 votes)
- 250.250.2.4 (6 votes)
- 250.250.0.8 (4 votes)
- 250.150.0.8 (0 votes)
- 500.500.step150 (1 vote)
- 500.500.step250 (0 votes)

The committee members and stakeholders then discussed justifications for the different models:

- 250.250.2.4 and 250.250.0.8
 - Least disruptive to status quo
 - Least disadvantages to vulnerable populations
 - Would mitigate cost increases for travel distance
 - o Allows a first step which can be expanded on over time
- 500.500.0.8 and 500.500.4.8
 - Largest distribution
 - o Equitable over the greatest distance
 - o Broadest distribution without overwhelming the system

The committee members and stakeholders agreed all four variations would satisfy the current charge to move away from DSA based policy. The Chair reiterated that any change that is made needs to be in the right direction and there can't be change without some level of disruption.

There was discussion surrounding kidney distance travel and cold ischemic time. UNOS staff informed the committee members and stakeholders that there are currently national shares for deceased donor kidneys with high Calculated Panel Reactive Antibodies (CPRA). When looking at the distance traveled by deceased donor kidneys by CPRA category, the median distance traveled for a CPRA 100% kidney is 688NM compared to 60NM for kidneys with CPRA less than 100%. When looking at the same data comparing CIT, CPRA 100% kidneys have a median of 21 hours of CIT while CPRA kidneys less than 100% have a median of 16 hours of CIT. Furthermore, according to the KPSAM modeling report the percent of organs traveling more than 250NM would decrease for all of the 250NM variations when compared to baseline.

The committee members and stakeholders then discussed their preferences for proximity points within the four selected models. There was overall preference for the variations with proximity points.

The committee members and stakeholders then selected their top framework preferences for the 500NM variations.

- 500.500.0.8 (8 votes)
- 500.500.4.8 (11 votes)

The committee members and stakeholders then selected their top framework preferences for the 250NM variations.

- 250.250.2.4 (12 votes)
- 250.250.0.8 (7 votes)

The committee members and stakeholders then selected their top preference between the two top frameworks.

- 500.500.4.8 (11 votes)
- 250.250.2.4 (10 votes)

UNOS staff reported the Pancreas Committee selected the same two variations as the Kidney Committee.

Next Steps

UNOS staff will take all of the participant's feedback and available data to develop a thorough comparison between the two top frameworks compared to baseline. The committee members and stakeholders will evaluate the compiled information on the next Kidney Committee call.

5. Outreach Strategy

UNOS staff presented the strategy going forward for stakeholder and community engagement. The goal is to solicit feedback from a wide audience and keep stakeholder organizations and other relevant associations and organizations engaged.

UNOS staff has been in discussions with transplant professionals, committee alumni, board members, stakeholder organizations and patient and family networks throughout the development process.

Committee members recommended in addition to already identified organizations, to also engage the National Kidney Foundation, DonateLife, and the pediatric community of the American Transplant Congress.

Webinars are also being developed for both the kidney and pancreas to update the community on the committee's efforts and to solicit further feedback. There will also be subsequent articles and updates sent through newsletters and posted on relevant websites. The upcoming regional meetings will also hold kidney-pancreas specific breakout sessions to foster a more engaged and focus discussion surrounding the proposals.

Upcoming Meetings

- July 8, 2019 Teleconference
- July 15, 2019 Teleconference