

**OPTN/UNOS Kidney Transplantation Committee
Meeting Minutes
March 25, 2019
Chicago, IL**

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

Introduction

The Kidney Committee met in Chicago, IL on 3/25/2019 to discuss the following agenda items:

1. Annual Kidney Donor Profile Index (KDPI) and Estimated Post Transplant Survival (EPTS) Mapping Table Updates
2. Dual Kidney and En Bloc Implementation Update
3. Public Comment Analysis and Discussion
4. Kidney-Pancreas (KP) Workgroup Status Report
5. Modeling and Proposal Discussion
6. Modeling Request
7. Waiting Time Modification Summary
8. Service Recognition and Incoming Roster
9. Wrap Up

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

1. Annual Kidney Donor Profile Index (KDPI) and Estimated Post Transplant Survival (EPTS) Mapping Table Updates

UNOS staff presented the annual changes to the mapping tables. It is a requirement for the committee to review the mapping tables every year before implementation. Background information was presented, and the current mapping table was shown.

A question was raised as to how the tables account for kidneys recovered but not transplanted. It was explained the Kidney Donor Risk Index (KDRI) is based only on donor factors and does not use outcomes.

Vote

Does the committee agree to adopt the new KDPI mapping table based on the year 2018 reference population?

- 100% voted yes
- 0% voted no
- 0% abstained

Vote

Does the committee agree to adopt the new EPTS mapping table based on the reference population (snapshot) of all adult kidney candidates on the waiting list December 31, 2018?

- 100% voted yes
- 0% voted no
- 0% abstained

2. Dual Kidney and En Bloc Implementation Update

UNOS staff presented an update on the implementation of the dual kidney and en bloc proposal implementation.

The project is expected to be implemented in the third quarter of 2019 and will be rolled out in two phases. The first phase will include waitlist changes and education for transplant hospitals followed by phase two a month later.

Summary of Discussion:

A Committee member asked if this was an opt-in or opt-out for the transplant hospitals. It was clarified this is an opt-in at the patient level. The Chair informed the Committee there will be a significant education effort for transplant hospitals.

Another Committee member asked if there is any way to prevent a potential delay by running a second match run for the second kidney once split. The Chair explained the delay is dependent on when the decision is made to split and whether it's before or after procurement. In addition there are few cases like this so the Committee will conduct continuous evaluation of the program.

3. Public Comment Analysis and Discussion

UNOS staff presented analysis of the public comment feedback in response to the *Eliminate the Use of DSAs and Regions in Kidney and Pancreas Distribution* concept paper.

The majority of regions preferred a hybrid framework and supported kidney and pancreas creating separate distribution systems. There was no clear preference on which proximity point combination is preferred. The community expressed concerns about increased travel from broader sharing patterns, socio-economically disadvantaged candidates, differences in population density.

Summary of Discussion:

Committee members discussed the themes and comments identified in the public comment analysis and their perception of comments heard at their regional meetings.

Some regional feedback identified by Committee members were:

- The concepts presented were difficult to understand
- Concern about cold ischemic time (CIT)
- Concern about decrease in transplant rates and counts in initial modeling
- Some regions expressed more support for no proximity points inside the circle
- Some regions preferred a small circle with steep points to localize organs
- Some regions preferred 250 nautical miles (NM) or larger circles
- Some regions showed strong sentiment for moving toward continuous distribution
- Concern about how a single framework can apply to different population densities nationwide

A Committee member stressed the importance of education and training for transplant hospital staff and patients for any framework that is chosen. There should also be education for committee members across all organs on modeling limitations and the modeling process.

Another Committee member cautioned against basing decisions on past behaviors considering transplant hospitals change surgeons which changes behaviors.

A Committee member asked for HRSA guidance on what the ultimate goal of the project should be as it relates to disparity. UNOS staff explained the mandate was to eliminate DSA and region

and the charge to create a rational definition of 'local' and consistent distribution system nationwide. HRSA staff explained they do not have an opinion specifically and supports the Committee following a systematic process to address the issue of DSA and region.

4. Kidney-Pancreas (KP) Workgroup Status Report

The Chair gave the Committee an overview of the KP Workgroup's efforts and decisions so far. The workgroup streamlined membership and added representatives from the Minority Affairs and Organ Procurement Organization (OPO) Committees. The workgroup met four times between February and March to review public comment feedback and decide on what to include in the new modeling request. The Workgroup will be exclusively modeling hybrid framework variations in the second round of modeling. Modeling variations will include circle sizes of 500NM, 250NM, and possibly 150NM, bandwidth permitting. The Workgroup also voted to increase the number of "steep" points awarded in variations both inside and outside of the circle.

Next steps:

The KP workgroup will submit a joint modeling request in April and then draft proposals for fall public comment.

5. Modeling and Proposal Discussion

The Scientific Registry of Transplant Recipients (SRTR) staff gave an update on the metrics, acceptance models and the capacity for the new KP workgroup modeling request.

Metrics

To add:

- Choropleth (heat) maps of median years of dialysis at transplant by candidate's listing DSA
- Choropleth (heat) maps of median cPRA at transplant by candidate's listing DSA

To move to an appendix:

- Waitlist mortality rates by subgroups

To remove:

- Waitlist mortality counts by subgroup
- Transplant benefit metrics

Acceptance Models Update

The initial Kidney-Pancreas Simultaneous Allocation Model (KPSAM) report was negatively received due to notable 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 in December. SRTR staff were particularly interested in the effect of including or excluding certain types or groups of covariates from the models; for example, the effect of removing the local indicator.

Assumptions

Because offer acceptance models were created with historical data (match runs from 2017), they assume that acceptance behavior will 'remain the same' under the new allocation rules.

- The effects of candidate and donor characteristics are the same under new allocation systems

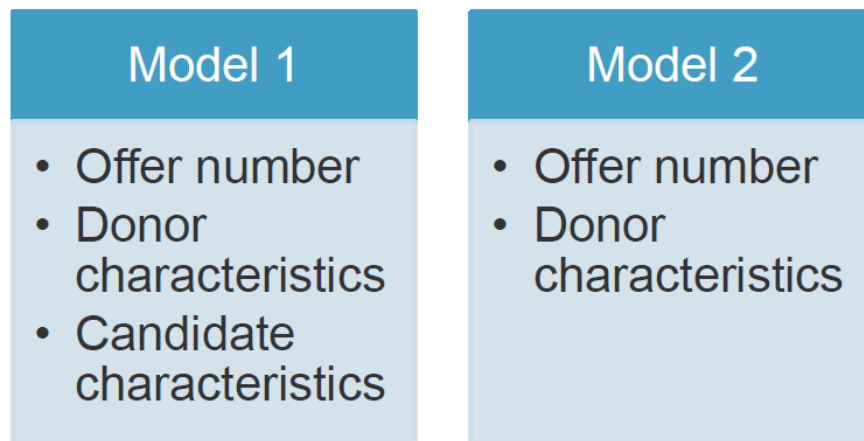
- The probability of acceptance at every offer number remains the same

The acceptance models from the December 2018 report included a “local” indicator. If an organ was offered from the local DSA, it was more likely to be accepted. SRTR staff explained this likely contributed to lower transplant counts because fewer offers at the beginning of the match run were made “locally” under broader sharing proposals.

Under the alternative allocation models, a “local” organ offer is likely less important because local DSA no longer has an important role in allocation. Thus, SRTR staff expects behavior to change in this respect.

Possible Models

Due to these issues, SRTR is considering two models without a local indicator:



Model 1 assumes that acceptance for different types of candidates, donors, and offer numbers is the same regardless of allocation policy.

- Differences in KPSAM results would be caused by (1) the different rankings of match runs and (2) whether the different allocation policies systematically caused certain candidates to move up or down the match run.
- More likely to predict a decrease in transplant

Model 2 assumes that acceptance for different types of donors stays constant regardless of allocation policy.

- Differences in KPSAM results would only be caused by the different rankings of match runs between allocation policies
- Less likely to predict a decrease in transplant

Modeling Capacity

SRTR will be able to run approximately 10 different KPSAM requests during the timeline allowed.

Additionally, SRTR will rerun the report submitted in December 2018 using new donor-only acceptance models and will submit both reports simultaneously.

Summary of Discussion:

The Chair addressed some feedback the Workgroup received related to the new modeling request and concern that the Workgroup is altering the modeling to achieve desired results. The

Chair and UNOS staff clarified the modeling is being refined to reach an optimal state and to make results as accurate as possible.

6. Modeling Request

UNOS staff gave an update to the Committee on what the KP Workgroup decided to include in the new modeling request.

Circle Sizes:

In order of preference for Kidney:

- 500 NM
- 250 NM
- 150 NM

In order of preference for Pancreas:

- 500 NM
- 150 NM
- 250 NM

Proximity Points:

UNOS staff tested some proximity point variations to demonstrate how different proximity points could affect patient scores. Some key takeaways from that analysis are:

- Regardless of proximity points, a patient cannot move from one classification to another. Proximity points simply “reshuffle” candidates against each other, in terms of identified characteristics as well as geography, within their classification.
- The higher the proximity points, the more geography may be valued over other factors such as Calculated Panel Reactive Antibody (CPRA), waiting time, and Human Leukocyte Antigen (HLA) mismatches. The Kidney Allocation System (KAS) currently gives points for these characteristics.
- The more proximity points awarded, the less broadly organs will be distributed within a circle.
- The bigger the circle/national space, the more impact proximity points has.

UNOS staff then informed the Committee what proximity point variations the KP Workgroup voted to include the new modeling.

Inside the circle (Local):

- No points (86% voted this should be an option)
- Two variations (86% voted in favor of options) in order of priority:
 - 4
 - 10

Outside the circle (National):

- Two variations (86% voted in favor of options) in order of priority:
 - 8
 - 20

Metrics and Subgroups

KP/pancreas/kidney will have the same metrics for these selected circle sizes for our hybrid framework. SRTR bandwidth will be dependent on number of circle variations, number of proximity point variations, and what metrics/stratifications should be included.

Metrics to include in new modeling request:

- Count (%) of transplants
- Transplant rates
- Time on dialysis (days) distribution at transplant
- Organ travel distance distribution (NM) for transplants
- Percent of organs traveling over 250 NM
- Count (%) of waitlist deaths
- Waitlist mortality rates – (subgroups in appendix)
- One year post-transplant graft survival rates (time permitting)
- One year post-transplant patient survival rates (time permitting)

Metrics by DSA to include in new modeling request:

- Transplant rates
- Variance in transplant rates
- Variance of median dialysis time (days) at transplant
- Change in count (%) of waitlist deaths
- Waitlist mortality rates (overall only)

Subgroups to include in new modeling request:

- Vulnerable populations:
 - race/ethnicity, age, blood type, CPRA (0-80, 80-90, 90-94, 95-97, 98, 99, 100), diagnosis
 - gender, ABDR mismatch (time permitting)
- SES related: insurance status, median income by recipient zip code, urbanicity
- KDPI: 0%-20%, 21%-34%, 35%-85%, 86%-100% (transplant only)
- EPTS: 0%-20% vs. 21%-100%
- Geographic: local/regional/national, OPTN region, DSA
- Donor type: DCD vs not (transplant only – time permitting)

Pediatric Priority

The Chair updated the Committee on the Workgroup's decisions on pediatric priority to include in the new modeling. The KP Workgroup voted to leave pediatric priority as is given the increased access under the new geographic boundary.

Summary of New Modeling Request

Circle sizes (NM)

- 500, 250, 150

Proximity points

- Inside circle: 0, 4, 10
- Outside circle: 8, 20

Updated acceptance model for KPSAM

- Remove local indicator and include only offer number and donor characteristics (no candidate characteristics)
- Differences in KPSAM results would only be caused by the different rankings of match runs between allocation policies

Summary of Discussion:

One Committee member expressed concern over the 500 NM circle to be modeled and its effect on rural patients and smaller transplant programs. The Chair reminded the Committee no decisions have been made yet and it's possible some programs will be over or under advantaged.

Another Committee member said the Workgroup should be conscious of how these decisions will effect cost for transplant hospitals.

A Committee member asked how many kidneys are allocated via the UNOS Organ Center versus allocated by OPOs. UNOS staff clarified the UNOS Organ Center allocates a small percentage of kidneys because they only allocate the mandatory national shares.

A Committee member asked why travel data is not available. UNOS staff clarified travel data is not currently collected in the OPTN database. However, the Operations and Safety Committee is looking into the best way to collect this information.

The Committee discussed modeling different pediatric priority scenarios. The Chair shared the KP Workgroup was split between two options and therefore Committee input is requested. The Committee was presented with two options:

- Leave pediatrics as is given increased access under new geography boundary in original modeling
- Move prior living donor and local pediatrics priority under highly sensitized candidates and above 0-ABDRmm under Sequence A and Sequence B

Vote

Move prior living donor and local pediatrics priority under highly sensitized candidates and above 0-ABDRmm under Sequence A and Sequence B

- 78% voted yes
- 11% voted no
- 11% abstentions

7. Waiting Time Modification Summary

The Committee was provided copies of the Waiting Time Modification Report for review.

There were no comments from the Committee.

8. Service Recognition and Incoming Roster

UNOS staff gave an overview of the committee roster changes effective July 1, 2019.

There were no comments from the Committee.

9. Wrap Up

One Committee member raised a reoccurring issue they have witnessed where an OPO sends bloodwork to an HLA laboratory without notifying the lab the donor is a previous organ recipient. This is problematic because the previously transplanted organ could have a different HLA blood type than the donor. When this has occurred the lab had to initiate a new match run for the correct HLA blood type of the organ, not the type of that particular donor.

The Chair informed the Committee there will be an update on Simultaneous Liver Kidney implementation in April.

Upcoming Meeting

- April 15, Teleconference