Pancreas Committee
Meeting Minutes
March 27, 2019
Chicago, IL

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Introduction

The Pancreas Committee (the Committee) met in Chicago, IL on March 27, 2019 to discuss the following agenda items:

1. Eliminate the Use of DSAs and Regions from Kidney and Pancreas Distribution
2. Continuous Distribution
3. Facilitated Placement 2 Year Data Review
4. Potential New Projects

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

1. Eliminate the Use of DSAs and Regions from Kidney and Pancreas Distribution

Members of the UNOS staff presented public comment analysis and the current state of the modeling request, followed by discussion by the Committee.

Data summary:

Public Comment Analysis:

Regional Feedback:

- Region 8 did not vote.
- 7 of 10 regions supported hybrid over fixed. (4,6, & 9 preferred fixed)
- The majority of regions preferred 150 NM or 500 NM.
- 9 out of 10 voting regions support separate systems
- The points preferences inside and outside the circle were as follows: steep, no points, and shallow

Committee Feedback:

- Minority Affairs Committee: impact on cost, variance in waiting time
- Transplant Administrators Committee: impact on low SES, impact on cost
- Organ Procurement Organization Committee: impact on cost; recommend improving efficiencies in current system;
- crossmatching may increase local import offer cases
- Look at how often kidney transplants go into original intended candidate
- Ethics Committee: concern about the balance of equity and utility, impact on rural communities
- Transplant Coordinators Committee: support for hybrid; impact on highly sensitized, HLA matching; make sure robust monitoring plan
- Pediatric Committee : give pediatrics more priority, such as KDPI 35.5> going to pediatrics at the local level above multi-organ
- Patient Affairs Committee: make more plain language; consider impact on wait time for donor families

Stakeholder Feedback:

- Association of Organ Procurement Organizations : support doing continuous distribution now
- National Kidney Foundation: make sure to consider impact on minorities/low SES
- American Society of Transplantation: concern about crossmatching, pediatrics, impact on access and utilization
- American Society of Transplant Surgeons: oppose 500 nm options, concern about impact on transplant rate/mortality, impact on safety, KDPI
- American Society for Histocompatibility and Immunogenetics: oppose b/c impact on medical judgment and organ wastage in Final Rule
- National Kidney Registry: room for increased efficiencies in current process; take into account

Trends:

- Support for hybrid model over fixed distance circles
- No clear preference for which proximity point combination is preferred
- Circle size: greatest support for 150, 500
- Support for pancreas having different first distribution circle than kidney
- Kidney and Pancreas will develop modeling proposal together but propose separate policy solutions in the fall

Themes:

- Concerns about increased travel/cost from broader sharing patterns
    - Different impact depending on organ/travel method: commercial v. charter
- Impact on socio-economically disadvantaged candidates
    - Scientific Registry of Transplant Recipients (SRTR) modeling didn't show an impact on low SES
    - Related concern about impact on waitlist mortality in certain geographic areas
- Movement towards continuous distribution
    - Ultimate goal to move toward continuous distribution and PC showed support for that
- Use population density instead of distance
    - Been considered, but extremely difficult to program and doesn't help geographic inequity
- Stratification by Kidney Donor Profile Index (KDPI)
    - Will be incorporated in continuous distribution but too complicated for current modeling
- Making sure pediatric priority in kidney addressed
    - Kidney Committee will include pediatric priority in request/their policy proposal
- Impact on virtual cross-matching
    - Not an impact on modeling, but a good question that could impact policy proposal put forward
- Impact on use of medical urgency at the 'local' level
    - Not an impact on modeling, but a good question that could impact policy proposal put forward

Modeling Request:

- Thursday 3.28.19 @ 5 pm EST: Final KP Call
- Monday April 1: submit request to SRTR
- Mid June-early/mid July:

    - Pancreas and Kidney Committees review modeling results
    - Pancreas and Kidney Committees separately determine how DSA/region should be replaced in their respective allocation systems, given modeling results
    - Pancreas and Kidney Committees submit separate policy proposals
- End of July: Policy Oversight Committee/Executive Committee meet
- August 2: Public comment starts

Metrics:

To add:

- Choropleth (heat) maps of median years of dialysis at transplant by candidate's listing DSA
- A similar concept to the "median MELD at transplant" used by the Liver Committee in their decision making
- Choropleth (heat) maps of median Calculated Panel Reactive Antibodies (cPRA) at transplant by candidate's listing Donor Service Area (DSA)
- cPRA is selected here because it is a continuous numeric patient characteristic that is given high allocation priority and for which broader sharing could be beneficial

To move to an appendix:

- Waitlist mortality rates by subgroups

To remove:

- Waitlist mortality counts by subgroup
- Prefer to show waitlist mortality RATES, which are adjusted for the size of the subgroup
- Transplant benefit metrics
- Not a primary goal of the policy at hand
- Time-consuming
- Not well-understood
- Can look at cross-tabulation of EPTS (<=20/>20%) and KDPI level, and transplants by dialysis time instead

Acceptance Models Update:

The initial Kidney-Pancreas Simulation 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.

We 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.

What does 'remain the same' mean?

- 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
- Assumptions: Local indicator

- 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.
- 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 schemes, a “local” organ offer is likely less important because local DSA no longer has an important role in allocation. Thus, we expect behavior to change in this respect.

Possible Models:

Due to these issues, we are considering two models without a local indicator:

Model 1

- Offer number
- Donor characteristics
- Candidate characteristics

Model 2

- Offer number
- Donor characteristics

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 polices
- Less likely to predict a decrease in transplant

In general, not much difference in transplant recipient characteristics in baseline runs

Modeling capacity

- SRTR will be able to run approximately 10 different KPSAM requests during the timeline allowed
- This allows for QA testing
- Rationale behind ranking requests in terms of priority and trimming metrics
- If time allows, optional metrics and requests
- Additionally, SRTR will rerun the report submitted in December 2018 using new donor-only acceptance models and will submit simultaneously with new report.

Summary of discussion:

Public Comment Analysis:

One member noted that data for Region 8 was not present. A UNOS staff member and committee representative noted that Region 8 did not take a vote on the provided Kidney-Pancreas questions. A committee member asked if it was possible to view the entirety of the public comments. A UNOS staff member explained that while public comment is closed that all

the comments are available for review on the website. One member noted that the majority of comments seem focused on kidney allocation than pancreas.

Another member noted that International Pancreas & Islet Transplant Association (IPITA) comments were not listed and a UNOS staff member responded that no comment from that organization had been received during the public comment period even though UNOS staff had reached out to them.

One member noted that many of the survey votes were from individuals who did not fully read the concept paper. Another member noted that the differences in region are often due to varying concerns in each region.

One member asked for clarification about the Kidney Committee's desire to increase the pediatric priority as part of the modeling request. Another member asked for clarification whether this would affect Kidney-Pancreas distribution – and the answer was no. The Pancreas Chair asked about the statement that including stratification by KDPI would be too complicated for the KPSAM modeling. A UNOS staff member explained that this issue of KDPI would be explained later on by a member of UNOS Research and SRTR. A committee member explained that liver is doing something similar for older aged donors. A UNOS staff member explained that the issue of KDPI is primarily regarding kidney allocation as it does not really affect simultaneous pancreas kidney transplant (SPK) which have been shown to have better than average KDPI. Thus the decision to add stratification by KDPI is one that will be determined by the Kidney Committee.

Modeling Request:

The Pancreas Chair noted that many members of the committee will be at IPITA around the time that the modeling results return July 2-5.

The Committee clarified how proximity points would work in a linear fashion rather than with large step offs. A UNOS staff member clarified that the allocation circles would be based off of the donor hospital rather than the recovery hospital. This decision was made in the hopes of equalizing access due to the fact that recovery hospitals tend to be centralized around metropolitan areas. Several members gave their opinion about the potential unfairness of giving proximity points starting directly from the donor hospital. The Vice Chair gave an example of their hospital which is located directly across the street from a donor hospital and that with any type of proximity points inside the allocation circle would give their patients even a minor advantage.

One member asked if time on dialysis still has the same impact on a diabetic as another patient with a less severe disease. The member felt that waiting time doesn't always capture degree of sickness. The Pancreas Vice-Chair pointed out that for this reason some simultaneous pancreas-kidney transplants (SPK) patients are listed pre-emptively before they qualify for dialysis waiting time. One SRTR member asked if the modeling could show metrics for both time on dialysis and time on the waiting list. Another member of SRTR said that the modeling could and would show both. The Pancreas Vice Chair spoke up in support of both metrics due to the inconsistencies when patients join the waiting list.

The Pancreas Chair asked if it was possible to have a partial local indicator in the acceptance model due to the fact that having a local offer does impact a center's decision to accept an organ. The SRTR presenter explained that while there was a nuance to the impact of local indicators that it is challenging to model accurately and avoid extremes. Another member commented that knowing the reputation and work of other transplant programs plays a role in their decisions on which organ offers to accept. The Pancreas Chair asked if the original five

models will be run again in the KPSAM without the local indicator. A member of SRTR clarified that not only will there be no local indicator but also no other indicators besides the donor characteristics.

The Pancreas Chair asked what the difference between the observed 2017 number of transplants and baseline number used. The SRTR presenter explained that the baseline model slightly over-predicted the actual number of transplants.

Another member of SRTR noted that it is possible that removing the local indicator could mark a sharp increase in kidney alone and SPK transplants that will be higher than reality. Due to this possibility, the SRTR member recommended that the Committee consider that this modeling may represent the other side of the extreme.

The SRTR presenter explained that one limitation of KPSAM is that it is difficult to account for multi-organ transplants. One member asked what the average number of heart-liver transplants are. Another member asked if the baseline is historical 2017 data. The SRTR presenter explained that while that data was used to inform the KPSAM, the methodology of KPSAM is to create a simulated baseline to replicate 2017 as closely as possible.

The Pancreas Chair noted that it may be helpful to see the changes among models as compared to the baseline. The Chair also asked how to account for the increase in organs transplants. The SRTR presenter explained that those are due to a decrease in discards. Another member of SRTR explained that the candidate characteristics can be very influential on the modeling and so removing them will impact the modeling results. By removing the candidate characteristics it assumes that with all other criteria held equal, programs will not be biased on which state the donor organ is coming from. However, the SRTR presenter wanted to note that the number of organ offers is still captured and accounted for.

One member brought up the disadvantage to programs that are on the coast and therefore have a partially empty allocation circle as opposed to those programs in the center of the country and have a full allocation circle. One member of the UNOS staff noted that coastal areas tend to be more populace than those areas in the center. The SRTR presenter explained that in order for the allocation circles to be more equal, the modeling would need to take into account population density. One committee member asked for clarification whether SPK transplants increased with broader allocation circles. The SRTR presenter confirmed that due to the current policy where kidney and pancreas are allocated together inside the “local” level that broadening that area likely will increase the number of SPK transplants.

The Pancreas Chair asked how the SRTR came up with the number ten as the number of possible models and whether the original five were included in that number. SRTR confirmed that the original five did not count towards the ten models, however that number includes both modeling for kidney and pancreas. The SRTR estimate was based on their experience from last run.

One SRTR noted that the greatest benefit to SPK candidates would be to have the largest allocation circle possible so that the kidney is following the pancreas farther. They also noted that any particular line tends to be arbitrary at the moment and when the Committee considers continuous distribution it will be important to determine a reasonable cut-off and a rationale for when kidneys will not follow pancreata.

One member of the committee noted that her center has experienced difficulties with liver procurement team’s unwillingness to also recover pancreata. They expressed that with increased distribution programs will need to rely more and more on other procurement teams which could prove an obstacle.

One committee member asked for a compelling reason to include proximity points inside an allocation circle. The Pancreas Vice Chair explained that it could depend on the circle size and that a 500 NM circle could merit some proximity points inside since the furthest reaches of the circle is nearly a 10 hour drive. One committee member felt that rather than using a linear distribution of proximity points, there could be merit to doing a fixed concentric circle model that awarded 2 proximity points to all candidates in the first 250 NM and then one to candidates in-between 250-500 NM and then no points outside of 500 NM. The Pancreas Vice Chair illustrated the different options for proximity points and the potential cliffs that can be caused by awarding in a non-continuous manner. The Pancreas Vice Chair felt that it was important that the committee not over-prioritize proximity by using linear inner points with smaller allocation circles, to the extent that even those who are a few miles closer to the donor hospital would be given an advantage.

A UNOS staff member clarified that continuous distribution is more complex than a simple linear line and would take into consideration other criteria besides proximity.

One member stated that the point of the new policy is to get rid of preference based on geography. Another member countered that the point of the policy is just to get rid of DSA because geography will still play a role in allocation. A UNOS member clarified that in addition to eliminating DSA and region that the point of the policy is to create a rational system for allocation.

A member of SRTR noted that the current system only allows patients to accumulate waiting time at one program per DSA and thus if the first allocation circle is 500 NM then patients will not be able to multi-accumulate waiting time within a 500 NM circle. One member felt that policy would need to be amended to allow patients to accumulate waiting time at multiple programs within a 500 NM circle. The Chair spoke up to note that the circle sizes are based on the donor hospital and therefore the current policy may be obsolete. A member of the UNOS staff expressed that the OPTN's official guidance has been to allow patients to multi-list as much as possible. Another member pointed out that being able to multi-list is not comparable to having waiting time at multiple centers. With this new change, it would benefit patients to have each program where they are listed to register their waiting time.

The Chair asked for clarification on the term "subgroups" for metrics. The SRTR presenter explained that those subgroups consist of vulnerable populations, ethnic populations, etc. One member asked if donation after circulatory death (DCD) donors would be captured with some other metrics. The SRTR presenter explained that the metric would be captured with time permitting. A committee member expressed dissatisfaction at that metric not being higher prioritized.

The Pancreas Vice Chair expressed concern that the median dialysis time or variance of median dialysis time does not capture SPK candidates who are listed pre-emptively and have longer waiting time but are not necessarily on dialysis. A UNOS staff member took note of that and the possibility of adding a broader waiting time metric.

The Pancreas Chair asked for clarification whether the increase of pediatric priority still falls after the SPK prioritization, which was confirmed. The Pancreas Vice Chair asked which of the models the Pancreas Committee preferred. One committee member commented that it depends on the type desired outcomes. One committee member felt that the modeling requests should be more focused on organ utilization rather than appealing to certain acceptance behaviors. Another committee member explained that there are so many different factors in recovery, procurement and acceptance practices that are difficult to capture or take into considerations. The Pancreas Chair expressed that the best way to maximize SPK transplants is by increasing

the circle size in which SPK transplants are prioritized. They noted that some geographical areas may have significant differences between 250 and 500NM, although 500 NM is often a feasible 8-10 hour drive.

The Chair asked why there were no models that the pancreas circle is larger than the kidney circle. A member of the UNOS staff explained that they felt that an allocation system that had a larger pancreas circle over a kidney circle would be unpopular with the community especially considering the respective ischemic times. Another member of the committee expressed that his region supported a larger pancreas circle and a smaller kidney circle. One committee member noted that the support for such a system might be out of a desire to not disrupt or increase sharing among kidneys which are extremely common transplants but less concern for pancreata which are of greater supply and less demand. One member spoke in support of a 500 NM circle but noted that pancreata are less likely to be used outside of 250 NM circle and therefore it may be advantageous to consider a soft circle with proximity points to favor candidates in a 250 NM circle.

The Pancreas Vice Chair spoke that while the committee may be interested in 4 proximity points inside the circle, they do not like a linear distribution of points and prefer a flat distribution. Another member asked if that proposition is similar to a 250 soft circle with no proximity points inside, followed by a slope out to a 500 NM circle. The Pancreas Vice Chair explained that one of the significant differences is that a 250 NM circle would limit the coupling of the KP.

A UNOS staff member asked the rationale of having a slope outside of 250 NM. The Chair explained that 250 NM is a feasible 5 hour drive. The Pancreas Vice Chair spoke about concern of a “zone of irrelevance” where the travel distance is not significant in allocation and thus shouldn’t be a prioritized factor. An SRTR member noted that nautical miles differ from driving miles and therefore 250 NM may be a larger area than traditional 250 driving miles. The Pancreas Vice Chair noted that it may be advantageous to then consider 150 NM as a “zone of irrelevance”. The committee debated whether 250 NM or 150 NM was more appropriate as a “zone of irrelevance”. Multiple committee members explained their experience with procuring organs. It was agreed that 150 NM was similar to 2 driving hours.

SRTR asked to confirm what type of models were being requested. A UNOS staff member explained that since the KP workgroup was finalizing the modeling request the next day, it is significant to ask for specific models. The UNOS staff member summarized the main priorities of the Committee: to model a system in which the kidney circle is smaller than pancreas circle and to model a “zone of irrelevance” by having fixed proximity points in a soft circle. It was noted that it would be difficult from the perspective of the Final Rule to justify a smaller circle for kidney than for pancreas due to the ischemic times of the different organs. A committee member noted that there are many more kidney programs than pancreas programs, which is an argument for broader sharing of pancreata.

A member of SRTR pointed out the importance of working with the Kidney Committee when creating the modeling requests due to how inter-connected the systems are. One committee member suggested that the Kidney Committee could also propose a zone of irrelevance. A UNOS staff member asked if the Pancreas Committee would recommend a “zone of irrelevance” for Kidney Committee as well. The Pancreas Committee felt that they support the suggestion to the Kidney Committee but also recognizes that they cannot determine modeling for the Kidney Committee.

The Committee expressed a desire for a straw vote regarding some of the modeling options they discussed.

Zone of irrelevance:

Yes – 16 (unanimous)

No - 0

Stepwise or sloping off:

Step - 10

Slope - 6

Size of zone:

150 - 12

250 – 3

Abstain - 1

500 pancreas, 150/250 kidney circle:

Yes – 15

No – 1

Which model option is most important:

Zone – 9

Step/Slope – 0

Size of Zone – 0

Larger Pancreas - 6

Next steps:

The members of the Pancreas Committee will take the suggestions back to the KP Workgroup which will finalize the modeling request on Thursday 3/28/2019. The KP Workgroup will then submit request to SRTR on Monday, April 1st.

2. Continuous Distribution

A UNOS staff member gave an overview of continuous distribution.

Summary of discussion:

One member asked how one national model would work when states and areas vary widely by demographics, populations, etc. A UNOS staff member said that this type of model is flexible enough to incorporate solutions to different variations. A couple members expressed support for the continuous distribution model. One member commented that there are three different domains to consider such as patient severity, availability of surgeons and recipient acceptance criteria. A UNOS staff member noted that distance does not need to be a factor in this distribution system but that it is the closest proxy we have for cold ischemic time. The Pancreas Vice Chair pointed out that it is not beneficial to estimate cold time because much of the cold time is built up during travel logistic issues and often travel time is the most accurate proxy metric. The Pancreas Chair noted that it will be notable for the Committee to review any concept paper about continuous distribution that comes out in the fall.

3. Facilitated Placement 2 Year Data Review

A UNOS staff member presented on the data of facilitated placement allocation policy.

Summary of discussion:

One member asked why the amount of OPOs in the program decreased in the second year of the program. No members had any specific theories.

Next Steps:

The Committee has fulfilled its two-year review post-implementation of this project by reviewing the data at this meeting, and will not review it at subsequent in-person meetings.

4. Potential New Projects

The committee discussed potential new projects.

Data summary:

Here are the project ideas of the Pancreas Committee from the last in-person meeting in October 2019:

- Best practices for growing pancreas programs
- COIIN project for pancreas
- Guidance on when to transplant a type 2 diabetic candidate
- Mathematical optimization of pancreas allocation: using a score system (e.g., including
- CIT, diabetes acuity score, surgical risk score, patient preferences for islet or pancreas, biological match, etc.)
- Increased access for sensitized pancreas candidates
- Vessel sharing practices and impact on pancreas discard rate

Current OPTN Goals

- **Increase the Number of Transplants**
- **Increase Equity in Access to Transplants**
    - Currently over-allocated by 20%
- **Improve Waitlisted Patient, Living Donor, and Transplant Recipient Outcomes**
    - Over allocated by 3%
- **Promote Living Donor and Transplant Recipient Safety**
- **Promote the Efficient Management of the OPTN**

Summary of discussion:

The Chair expressed a desire to focus on projects that are both feasible and high impact. The Vice Chair expressed that while the Committee will be dealing with a lot of geography projects that the Policy Oversight Committee is also open to other project ideas depending on their allocation. Additionally, the Vice Chair mentioned that pediatric SPK candidates do not currently receive priority on the list as well as high CPRA candidates. The Vice Chair noted that the mathematical optimization of pancreas allocation will probably be largely accomplished by continuous distribution.

- One member suggested providing guidance on type 2 diabetic candidates because current listing criteria vary.
    - The Chair asked for clarification on whether that would be a policy or white paper. The member clarified that it would be a white paper seeking to clarify which type 2 diabetic candidates are most benefited. The Chair asked whether this was the right time for the paper and whether the committee could benefit from gathering and reviewing more granular data.
- One member suggested a project focused on best practices around live donors as a part of the project idea “best practices for growing pancreas programs”.

    - The Chair recommended reading a paper on growing pancreas programs that had been recently published.
- One member suggested that the Committee focus more on increasing pancreas alone transplants (PA) rather than SPK. The Chair noted that their program has increased their number of PA transplants.
    - Another member noted that other centers struggle with PA transplants because of the lack of referrals. Another member explained that it is difficult to convince patients to switch from islet transplants to pancreas transplants because of the complexity of the surgery.
- One member expressed support for a collaborative improvement project for pancreas which would include an element involving best practices.
    - One member expressed dissatisfaction that there was a lack of explanation about the criteria for choosing programs in the last collaborative improvement project. The Chair asked what the next steps for moving forward with such a project would be. A UNOS staff member named another staff member that is in charge of operating such projects.

The Chair expressed support for polling the Committee members their top three preferences for new projects.

Upcoming Meetings

- April 17, 2019 (teleconference)
- May 15, 2019 (teleconference)
- June 19, 2019 (teleconference)