

OPTN Kidney & Pancreas Transplantation Committee Continuous Distribution Workgroup Meeting Summary April 29, 2022 Conference Call

Rachel Forbes, MD, Chair Oyedolamu Olaitan, MD, Vice Chair Martha Pavlakis, MD, Chair Jim Kim, MD, Vice Chair

Introduction

The Kidney & Pancreas Transplantation Committee Continuous Distribution Workgroup (the Workgroup) met via Citrix GoToMeeting teleconference on 4/29/2022 to discuss the following agenda items:

- 1. Kidney-Pancreas Simulated Allocation Model (KPSAM) Modeling Scenarios
- 2. Next Steps

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

1. Kidney-Pancreas Simulated Allocation Model (KPSAM) Modeling Scenarios

The Workgroup reviewed and finalized the modeling scenarios that will be submitted to the Scientific Registry of Transplant Recipients (SRTR) for the first round of modeling in the kidney and pancreas continuous distribution project.

The following are the proposed scenarios:

Scenario 1: Current Policy, Kidney Allocation System

• Uses current classifications to produce a baseline

Scenario 2: Combined Analytical Hierarchy Process (AHP) Results

- This run is the continuous distribution option closest to the community AHP results
- Incorporates some items the Committees and Workgroup have discussed incorporating into Continuous Distribution including expanded longevity matching, pediatric priority for sequence C kidneys from pediatric donors, and a steeper CPRA curve.
- In order to see a difference between solid organs and pancreas-islets, the assigned weight for organ registration and blood type (identical versus (vs.) compatible) is higher than five percent

Goal	Kidney alone	КР/РА/РІ 0%	
Medical Urgency	Medical Urgency 15%		
Transplant Outcomes	DR Matching 5% 0% Longevity 5%		
Candidate Biology	Blood Type 5% CPRA 15%	Blood Type Identical 15% CPRA 15%	
Patient Access	Pediatrics 15% Prior Living Donors 15% Waiting Time 10% KAL Safety Net 5%	Pediatrics 20% Prior Living Donors 20% Waiting Time 10%	
Placement Efficiency	Proximity Efficiency 10%	Organ Registration 10% Proximity Efficiency 10%	

Scenario 3: Increased Longevity

• This scenario increases the weight/importance of transplant outcomes from 10 percent to 40 percent divided between DR matching and longevity.

Goal	Kidney alone	КР/РА/РІ	
Medical Urgency	Medical Urgency 10%	0%	
Transplant Outcomes	DR Matching 20% Longevity 20%	0%	
Candidate Biology	Blood Type 3.3% CPRA 10%	Blood Type Identical 15% CPRA 15%	
Patient Access	Pediatrics 10% Prior Living Donors 10% Waiting Time 6.7% KAL Safety Net 3.3%	Pediatrics 20% Prior Living Donors 20% Waiting Time 10%	
Placement Efficiency	Proximity Efficiency 6.7%	Organ Registration 10% Proximity Efficiency 10%	

Scenario 4: Increased Placement Efficiency

• This scenario increases the importance of proximity efficiency from 10 percent to 30 percent.

Goal	Kidney alone	КР/РА/РІ 0%	
Medical Urgency	Medical Urgency 11.67%		
Transplant Outcomes	DR Matching 3.89% 0% Longevity 3.89%		
Candidate Biology	Blood Type 3.89% CPRA 11.67%	Blood Type Identical 11.67% CPRA 11.67%	
Patient Access	Pediatrics 11.67% Prior Living Donors 11.67% Waiting Time 7.78% KAL Safety Net 3.89%	Pediatrics 15.56% Prior Living Donors 15.56% Waiting Time 7.78%	
Placement Efficiency	Proximity Efficiency 30%	Organ Registration 7.78% Proximity Efficiency 30%	

Scenario 5

• For this scenario, the Workgroup had discussed the following options to model:

 Calculated panel reactive antibody (CPRA) scales – changes CPRA curve from Base 100 to Base 100,000 and will keep weights the same.

Goal	Kidney alone	кр/ра/рі 0%	
Medical Urgency	Medical Urgency 15%		
Transplant Outcomes	DR Matching 5% 0% Longevity 5%		
Candidate Biology	Blood Type 5% CPRA 15%	Blood Type Identical 15% CPRA 15%	
Patient Access	Pediatrics 15% Prior Living Donors 15% Waiting Time 10% KAL Safety Net 5%	Pediatrics 20% Prior Living Donors 20% Waiting Time 10%	
Placement Efficiency	Proximity Efficiency 10%	Organ Registration 10% Proximity Efficiency 10%	

• Harder to place kidneys – Increasing placement efficiency for hard to place kidneys (high KDPI) with donor weight modifiers.

Attribute	KDPI 0-20%	KDPI 21-34%	KDPI 35-85%	KDPI 86-100%
Medical Urgency	1	1	1	1
HLA Matching	1	1	1	1
EPTS/KDPI	1	1	1	1
Blood Type	1	1	1	1
CPRA	1	1	1	1
Prior Living Donor	1	1	1	0
Pediatrics	1	1	0	0
KAL Safety Net	0	1	1	1
Qualifying Time	1	1	1	1
Proximity Efficiency	1	1	1	3

• Staff asked the Workgroup to decide which option they would prefer to model

Summary of discussion:

The following is a summary of the Workgroup's discussions for each scenario:

Scenario 1: Current Policy, Kidney Allocation System (KAS) 250

There was no discussion.

Scenario 2: Combined Analytical Hierarchy Process (AHP) Results

A member mentioned that they see a disparity between kidney alone and kidney-pancreas (KP)/pancreas/pancreas islets. The member noted that the Workgroup spent a lot of time discussing medical urgency, but they don't see an attribute that accounts for mortality for patients with Type I diabetes and the heightened preference for Type I diabetics compared to kidney alone candidates.

Staff stated that that is a great observation. Staff explained that, as they had put together this overall framework with five different goals, they recognized that not every organ is going to have equal weights across those five goals and that there will be some goals that organs don't have at all. For example, liver

doesn't have a scoring system for transplant outcomes. Staff mentioned that these differences across organs point to opportunities for the future, since currently there is not a preference in pancreas allocation for Type I diabetes.

A member inquired if there is a way in which estimated post-transplant survival (EPTS) could factor into preferentially allocating to those candidates with a better EPTS.

A member inquired if the question was referring to medical urgency for Type I vs. Type II diabetes or for kidney alone vs. KP. The member further commented KP already gets prioritization over kidney alone—that's why the Workgroup allocated medical urgency for pancreas allocation to zero, since there was not distinction between Type I and Type II diabetes. The member explained that, when it comes to medical urgency of diabetics with end stage renal disease (ESRD), the kidney will follow the pancreas and KP will have some priority over kidney alone candidates.

A member inquired if a 20 year old Type I diabetic would receive less priority than a 50 year old Type I diabetic. Staff explained that this is something the OPTN Pancreas Transplantation Committee has identified as a future project, which is to come up with a rating scale for pancreas medical urgency.

A Chair inquired if the member was referring to KP or kidney alone. The member mentioned that they were referring to both. The member stated that they understand that KP will be on a different list than kidney; however, the Workgroup had discussed the pancreas following the kidney and that would disadvantage the pancreas patients. The Chair explained that in the first iteration of continuous distribution the kidney would still follow the pancreas.

A Chair explained that the OPTN Pancreas Transplantation Committee had talked about getting some granularity with medical urgency, but couldn't really come up with enough data to justify adding points for Type I diabetes or hypoglycemic unawareness.

An SRTR representative inquired if the placement efficiency attribute is going to be defined as the acuity circles from the donor hospital or defined in other ways in the modeling. Staff explained that distance will be defined for pancreas as two parts:

- Organ registration to ensure solid organs like KP and PA come before islets
- Straight line distance between donor hospital and transplant hospital

Staff mentioned that the Workgroup had discussed other options, but there's benefit to gain by smoothing out the edges from acuity circles and it creates an easy process to add additional factors to placement efficiency in the future.

The Chair inquired how blood type identical came to have so much priority for KP/pancreas/islets. Staff explained that if the Workgroup really wants to distinguish between identical vs. compatible, which is different from the kidney rating scale, then they need more than five percent weight in order to see that impact.

A Chair inquired how much the Workgroup should be concerned about suggestions/changes that they have made that the community might not accept, therefore the modeling won't be acceptable. Staff stated that the Workgroup doesn't want to model something that won't be acceptable and inquired if there's something specific that the member believes the community won't accept. A Chair stated that blood type identical vs. compatible was brought to the OPTN Pancreas Transplantation Committee about five years ago and that idea was turned down. A Chair mentioned that the community may still not think that that's an acceptable approach.

Staff mentioned that the Workgroup spent half of the previous meeting on this topic and it seemed the Workgroup was pretty resolute with blood type identical vs. compatible for KP/pancreas/islets being

how they wanted to move forward. Staff emphasized that this is a different proposal than the blood type identical vs. compatible proposal brought to the OPTN Pancreas Transplantation Committee. The Workgroup models these scenarios in order to see what the impact of their decisions are and they can reassess from there.

The Chair mentioned that they think waiting time is more important for KP. The impact of pediatrics and prior living donors (PLD) is important, but there aren't a lot of pediatric KP candidates or PLD KP candidates. The Chair suggested that waiting time be placed at 15 percent and blood type identical be placed at 10 percent.

Staff explained that, when looking at weights, the Workgroup should not focus on how frequently an issue will arise, but instead focus on how important an issue is when it does occur.

A member agreed and stated that proximity efficiency is much more important for pancreas than it is for kidney. The member stated that it may not be the same for islets, but for pancreas as a solid organ the proximity efficiency should be quite significant. An SRTR representative added that, in part, relates to the fact that if the donor is closer to the transplant center, then the transplant centers own team can procure the pancreas. A Chair mentioned there are also some ischemia issues related to pancreas.

A member stated that they believe proximity efficiency should be given more weight than waiting time because if a candidate has more waiting time but their center is further away, then the utilization of the pancreas will probably be more likely if it's kept closer.

Staff explained that one of the modeling scenarios is going to have a higher weight for proximity efficiency, but if the Workgroup still wants a higher weight for proximity efficiency in Scenario 2, then that can be adjusted.

Scenario 3: Increased Longevity

Staff inquired if the Workgroup wants to increase the weight for DR matching and longevity equally or do they want to put DR matching at 10 percent and longevity at 30 percent.

A member inquired how much significance the DR matching had on long-term outcomes. The member stated that, if DR matching wasn't significant, then they don't think DR matching and longevity need to be equal.

A member inquired if Scenario 2 is the baseline that the Workgroup will want to be able to compare the other scenarios to and the reason the other scenarios are extreme is to see the impact of those differences in weight. Staff stated that that is correct.

An SRTR representative stated that DR matching had a hazard ratio of about 1.5 for two matches compared to no matches.

Staff also mentioned that longevity matching was what the Workgroup looked at in regards to the relationship between kidney donor profile index (KDPI) and EPTS.

A Chair mentioned that they would like to see what longevity and DR matching look like equally because it is hard for them to identify one that is more important. There was no opposition from members.

Scenario 4: Increased Placement Efficiency

Staff explained that, for reference, lung has placement efficiency at 10 percent. This scenario allows the Workgroup to see the impact of increasing the priority for placement efficiency. Staff mentioned that it's important to have a good disparity between the scenarios in order to see the impact.

Staff inquired if the Workgroup, after seeing this scenario, still wants to adjust placement efficiency in Scenario 2.

A Chair stated that this seems like a big jump, when waiting time is only at seven percent. The Chair stated that waiting time should still be very important.

A member stated that, for lung, PLD was about 11 percent and inquired why PLD is placed at 20 percent when it happens probably once a year for pancreas, if at all. Staff explained that the weights aren't based on the frequency at which something happens, but instead how important it is when it does occur. Staff also mentioned that, based on the AHP results, the community felt that there should be a heavier weight for PLD when it occurs. The member stated that, for lung, PLD was only one-third as important as placement efficiency. Staff explained that that's correct – lung placed less weight on PLD; however, the weights don't have to be equal across all organs.

A Chair mentioned that there is higher weight for when there are PLD pancreas candidates and they should be given priority; however, the fact that this doesn't happen often isn't relevant. It can be argued that pancreata should not be prioritized for PLDs, but that decision is up to the Workgroup. There doesn't need to be consistency across organs – it depends on how the Workgroup feels and the AHP guidance that has been provided.

A member mentioned that when an attribute gets 20 percent, between pediatric and PLD, only 60 percent is left for all the other attributes. This de-emphasizes the Workgroup's ability to distinguish between the other characteristics. Staff explained that the Workgroup had discussed in September how important PLD priority is, so this is something the Workgroup had talked about and wanted represented in modeling. Staff also mentioned that this is just for the first round of modeling, so the Workgroup can get a sense of how to adjust from the results.

Staff also mentioned that having a really high weight for small sub-populations won't affect the ability of the score to distinguish between most of the other candidates, since they will still be scored by the same attributes. Staff explained that, even though the proportion of the score leftover will be less, the relative ranking and weights is what is important.

Scenario 5

A Chair inquired what members found more important to model for this first round. Staff also mentioned that the donor modifier for the harder to place kidneys option could be changed as well.

A Chair mentioned that there's probably too much priority for candidates with a lower CPRA and they would be more supportive of the most extreme CPRA scale.

Members stated that they liked the steeper CPRA curve as well. A Chair mentioned that there had been discussions about considering a separate attribute for CPRA 99-100 vs. another attribute that is weighted differently for CPRA 0-98 as a way to give highest priority for high CPRA patients.

Staff mentioned that the steeper CPRA curve better distinguishes between the high CPRA patients. Staff also explained that Base 100 was used in lung continuous distribution and the plan is to use Base 1,000 for kidney and pancreas continuous distribution. Staff inquired if members want to model a steeper CPRA curve as Scenario 5 or want a steeper CPRA curve in the baseline scenario.

A Chair agreed the Workgroup could use the steeper CPRA curve for the baseline scenario and then model harder to place kidneys in Scenario 5. Staff mentioned that the CPRA curve in the baseline model can be changed. Staff mentioned that a CPRA curve of Base 100 is closest to what is currently in policy, and that Base 1,000 is what is used in the baseline scenario for kidney and pancreas modeling.

A Chair stated that, in general, it would be nice if points reflected a candidate's proportionate access to transplant.

A member stated that they thought there was data to show that current allocation with PRA preferentially gave kidneys to patients and didn't change their waiting time very much.

A member inquired if focused proximity means looking at proximity for high KDPI kidneys, donation after circulatory death (DCD) kidneys and/or the pancreas or does it mean broad proximity. Staff explained that they are more focused on high KDPI kidneys, but could also focus on the pancreas as the member mentioned at a later time.

A member inquired if the Scenario 2 curve is going to include a steeper CPRA curve. Staff mentioned that they are asking members to vote on what they want to model for Scenario 5. The member inquired if the Scenario 2 curve is steeper than what is currently in policy. Staff stated that this is correct.

The Workgroup members voted on whether they wanted the last modeling scenario to look at either:

- Steepest CPRA scale 6 votes
- Harder to place kidneys (focused proximity efficiency) 7 votes

A member mentioned that they would prefer to have the steepest CPRA curve in the baseline scenario and use placement efficiency for Scenario 5.

A member inquired, since this modeling is being done equally, if the Workgroup will be able to uncouple kidney modeling from KP/pancreas/islets if they find that one scenario is more advantageous for pancreas or vice versa. An SRTR representative stated that the two systems are interdependent so, from a modeling perspective, it won't be possible to take two different scenarios and mesh them together. The SRTR representative also mentioned that there seemed to be another question of whether it would be feasible to take rules from one policy scenario and rules from another to combine them for a future modeling scenario. The SRTR representative stated that there's no technical reason SRTR can't do that, but wanted Staff's insight on their plans regarding how to handle the future modeling process.

Staff explained that they expect the Workgroup will learn from the differences between the kidney and KP/pancreas/islets match runs and that is how they will determine to adjust.

Staff summarized that the Workgroup decided to use Scenario 5 for harder to place kidneys (focused proximity efficiency) and the Workgroup can do something similar for harder to place pancreata.

A Chair stated that, for hard to place KP/pancreas/islets, they aren't sure proximity is necessarily a problem and don't think it's going to help get those KP/pancreas/islets transplanted.

Staff summarized the scenarios that the Workgroup had agreed to for modeling:

- Scenario 1: true baseline
 - o Model current policy and classifications
- Scenario 2: baseline AHP results
- Scenario 3: increased longevity
- Scenario 4: increased placement efficiency
- Scenario 5: increased placement efficiency for hard to place (high KDPI) kidneys

Staff clarified that the current plan is to use Base 1,000 for the CPRA scale in Scenario 2. Staff inquired if the Workgroup wanted to keep Base 1,000 or model a steeper CPRA curve for Scenario 2.

Members voted on the CPRA curve that they would prefer to use in Scenario 2:

• Base 10,000 – 1 vote

- Base 100,000 6 votes
- Base 100,000,000 4 votes

Staff summarized that the Workgroup decided on using Base 100,000 CPRA curve for Scenario 2 in the first round of modeling.

There was no further discussion.

2. Next Steps

Staff expressed appreciation for the participation of the Workgroup and will finalize and submit these modeling scenarios to SRTR for the first round of modeling.

Upcoming Meetings

• May 20, 2022 (Teleconference)

Attendance

Workgroup Members

- o Rachel Forbes
- o Martha Pavlakis
- o Oyedolamu Olaitan
- o Jim Kim
- o Aaron Wightman
- o Abigail Martin
- o Amy Evenson
- o Arpita Basu
- o Bea Concepcion
- o Caitlin Shearer
- o Cathi Murphey
- o Dave Weimer
- o Elliot Grodstein
- o John Barcia
- o Pradeep Vaitla
- o Silke Niederhaus
- o Todd Pesavento

• HRSA Representatives

- o Jim Bowman
- o Marilyn Levi

• SRTR Representatives

- o Bryn Thompson
- o Grace Lyden
- o Jonathan Miller
- o Josh Pyke
- o Nick Wood
- o Peter Stock
- Raja Kandaswamy
- o Tim Weaver
- UNOS Staff
 - o Joann White
 - o Lindsay Larkin
 - o Rebecca Brookman
 - o Kayla Temple
 - o Ross Walton
 - o Amanda Robinson
 - o Darren Stewart
 - o James Alcorn
 - o Joel Newman
 - o Kaitlin Swanner
 - o Kim Uccellini
 - o Laura Schmitt
 - o Lauren Mauk
 - o Melissa Lane
 - Rebecca Fitz Marino

- o Sarah Booker
- o Tina Rhoades