

OPTN Kidney & Pancreas Transplantation Committee Continuous Distribution Workgroup

Meeting Summary

December 4, 2020

Conference Call

Silke Niederhaus, MD, Chair
Rachel Forbes, MD, Vice Chair
Vince Casingal, MD, Chair
Martha Pavlakis, MD, Vice Chair

Introduction

The Kidney & Pancreas Transplantation Committee Continuous Distribution Workgroup (the Workgroup) met via Citrix GoToMeeting teleconference on 12/4/2020 to discuss the following agenda items:

1. Welcome & Review of Project Goals
2. Update on Kidney Attributes
3. Update on Pancreas Attributes
4. Discussion: Kidney-Pancreas Attributes
5. Next Steps

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

1. Welcome & Review of Project Goals

The Workgroup reviewed the scope of the Continuous Distribution project as well as the objectives of the first phase of the project (identifying and categorization of attributes).

Summary of discussion:

There was no discussion.

2. Update on Kidney Attributes

Members reviewed the proposed attributes for the Kidney continuous distribution model.

Summary of discussion:

The Workgroup discussed the following proposed kidney attributes:

Medical Urgency: Prioritize those with high mortality due to imminent loss of dialysis

Attributes: Medical Urgency Status Definition

Post-transplant Survival: Increasing graft/longevity matching

Attributes: Human Leukocyte Antigens (HLA) Matching, Estimated Post-Transplant Survival (EPTS)

A member stated that it would be important for the committee to look at and come up with more updated data for HLA Matching. A member mentioned that the biggest advancement in immunologic matching technology is that being able to do it in deceased donors is not far away.

A member agreed and stated that the goal of this project is to set a framework that adapts with technology.

Candidate Biology: Increase transplant opportunities for patients who are medically harder to match

Attributes: Blood Type, Calculated panel reactive antibody (cPRA)

A member questioned whether the Kidney Continuous Distribution Workgroup had discussions regarding hypotensive candidates. The member stated that from experience with patients with a baseline blood pressure of 80s-90s systolic, they don't have good outcomes because the majority of donors are hypertensive.

Patient Access: Appropriate transplant access

Attributes: Pediatrics (age less than 18), Waiting Time, Prior Living Donors, Kidney after liver (Simultaneous Liver Kidney (SLK) Safety Net)

A member suggested considering very young pediatric donors since there are only certain centers that use organs from donors under age two or under a certain weight. The member stated that they are not sure when these kidneys should be split in order to maximize transplantation or if there's some type of expedited allocation for kidneys from very small, low weight donors for surgeons that aren't comfortable using them.

A member stated that some retrospective data on the splits showed that kidneys under 10 Kg were recommended to be split based on outcomes. The member mentioned that 10-20 Kg was the area of interest in the research and it was concluded that they can be split and used as separate kidneys. The member also stated that they use this as a guideline at their OPO for offering splits.

Placement Efficiency: Consider resource requirements required to match, transport, & transplant an organ

Attributes: Adult Dual, Travel (cost) efficiency

A member inquired about when other dual organs are going to be considered, such as heart-kidney. Staff explained that as each of the organs' continuous distribution model is discussed, the implications of multi-organ transplant will be discussed as well. Staff mentioned that there will be a transition for anything that is currently in policy, but heart-kidney multi-organ allocation won't be discussed until discussions about the continuous distribution model for heart start.

Staff stated that the new multi-organ allocation policy will be reviewed during the next Policy Oversight Committee (POC) call and members will be able to provide feedback then.

3. Update on Pancreas Attributes

Members reviewed the proposed attributes for the Pancreas continuous distribution model.

Summary of discussion:

The Workgroup discussed the following proposed pancreas attributes:

Avoiding organ wastage

Attributes: Islets, Facilitated pancreas

Medical Urgency: Prioritize sickest candidates first to reduce waiting list mortality

Attributes: Kidney-Pancreas (KP) versus (vs.) Pancreas vs. Islets

Post-transplant Survival: Prioritize candidates who are expected to survive for at least one year after receiving a transplant

Attributes: HLA Matching (0-ABDR), Distance*, Travel*

*Surrogates of ischemic time

Candidate Biology: Increase transplant opportunities for patients who are medically harder to match

Attributes: Blood Type, CPRA, C-Peptide

A member stated that c-peptide is usually in reference to very low Type I diabetics or high insulin resistant various forms of Type II diabetics and not thought as having meaningful differences in outcomes. The member questioned whether the Pancreas Continuous Distribution Workgroup was using c-peptide to differentiate between Type I vs. Type II diabetes and differentiate allocation based on that.

A member explained that Type I candidates should have more priority than some Type II candidates since, currently in policy, there's no c-peptide requirement that a candidate must meet in order to receive priority for a KP or a pancreas. Another member mentioned that there tends to be a racial disparity between Type I and Type II – programs typically transplant Type I diabetics with KP, which creates a barrier for Type II African-Americans from getting a KP transplant.

A member stated that a precedent was set in pancreas allocation for Type I vs. Type II when the Board approved allocation based on c-peptide. If a candidate had a c-peptide greater than 2, then their body mass index (BMI) had to be non-obese in order to qualify for waiting time. The member stated that the Pancreas Continuous Distribution Workgroup's thought was that c-peptide is not as much Type I vs. Type II, but it's the physiology of Type I candidates. For example, if a candidate is a non-obese Type II diabetic, their physiology is more akin to Type I, minus the insulin deficiency, and there's not a modifiable risk factor that can be employed. The member explained that, in 2018, the BMI limit was removed so c-peptide no longer needed to be in the equation and this is being revisited by the Pancreas Continuous Distribution Workgroup.

A member emphasized that if there are racial implications to the policy then they should be addressed.

Patient Access: Increase transplant access

Attributes: Waiting Time, Age (Pediatric Prioritization), Prior Living Donor, Pancreas after kidney (PAK)

A member noted that the Pancreas Continuous Distribution Workgroup had discussed subdividing PAK into (1) PAK after deceased donor, which involves safety net rationale, and (2) PAK after living donor, which involves safety net rationale as well as benefits for patients who had received a prior living donor transplant. The member stated that they would be open to discussion regarding whether it should be in medical urgency or patient access.

Placement Efficiency

Attributes: Travel (cost) Efficiency

4. Discussion: Kidney-Pancreas Attributes

Both the Kidney Continuous Distribution Workgroup and the Pancreas Continuous Distribution Workgroup reviewed the current Kidney-Pancreas (KP) attributes that are included in OPTN policy.

Summary of discussion:

Medical Urgency: Amount of risk to a candidate's life or long term health without receiving an organ transplant

Attributes: KP vs. Pancreas vs. Islets

A member stated that the Kidney Continuous Distribution Workgroup modified the definition of medical urgency by adopting the kidney medical urgency policy, which is defined as inaccessibility to dialysis. The Kidney Continuous Distribution Workgroup discussed how it would be unusual to limit kidney prioritization for medical urgency to current kidney medical urgency policy, yet somehow allocate KPs based on anything else.

Another member stated that, for pancreas alone, the Pancreas Continuous Distribution Workgroup is trying to do exactly the opposite – looking at both life and potential long term health. The member mentioned that this is more difficult for pancreas since the details aren't as worked out as they are for kidney. The member explained that, at the moment, KP takes priority over pancreas alone and the mortality of patients, with diabetes and renal failure, who are in need of a pancreas is higher. The member inquired how to reflect that under medical urgency in an allocation system where waiting times are upwards of 8 years and patient survival, for some, at 8 years is dismal.

A member emphasized that they don't want to end up with a system where a candidate can only get a kidney under medical urgency attributes. If the candidate is about to run out of dialysis access and they need the KP it's a completely different definition.

Another member inquired if the Kidney Continuous Distribution Workgroup considered medical urgency based on waitlist mortality, similar to MELD. A member explained that taking candidates with the highest post-transplant mortality off the wait list is not the same as MELD, which suggests the candidate would die without the transplant. By prioritizing those with high post-transplant mortality, it's raising their risk of mortality with the transplant compared to what their mortality would be with just staying on dialysis. The member explained that the Kidney Committee rejected the idea of prioritizing the sickest dialysis patients who were at risk of dying within the next year from progressive complications of long term dialysis because those are the patients who have the worst outcomes.

A member mentioned that medical urgency can be more than just simply running out of access. The Kidney Continuous Distribution Workgroup took a very narrow view of it because there's a tipping point where prioritizing the absolute sickest candidates is wasting kidneys. Another member noted that the liver community may look at this differently – they prioritize the sickest patients because they have the highest waitlist mortality.

A member noted that the kidney community views post-transplant mortality differently because there is dialysis.

Another member suggested that this could be a future project for the Kidney Committee once continuous distribution is established. There may be some benefit to think about prioritizing patients on the kidney list who have a higher waitlist mortality, but may do quite well with a transplant when they start dialysis or first get listed and would have had a much better long-term outcome. The member mentioned that, on the other hand, there are other patients on the kidney list that are so healthy they can tolerate dialysis for probably many more years. It was noted that dialysis is a long-term back up option that can fit into end of life care and decision making, but a member inquired where the turning point is.

A member mentioned that the examples they are thinking of is a patient with Type II diabetes and a BMI where the program doesn't want to transplant them or a patient with Type I diabetes and an obese BMI. These patients have a much higher wait list mortality and would do very well with a kidney transplant early on, but the post-transplant survival with kidney declines after 10 years.

A member noted that KP patients are transplanted quicker than kidney patients, so they are already getting some priority because they do very poorly on the wait list. Members agreed that KP patients are

already getting priority, but inquired if patients already on dialysis need more priority than patients who are not yet on dialysis. A member stated that the Pancreas Continuous Distribution Workgroup wanted KP patients to keep their priority over pancreas alone patients. Members suggested that the Kidney Committee consider how kidney alone candidates, who may have worse wait list mortality due to other comorbidities, would be prioritized long term.

Staff stated that it's important to remember that there is a current prioritization for KP candidates, but the exercise is to question why that prioritization is in the current policy. Staff inquired if the current prioritization of KP candidates is because of a medical urgency difference.

A member mentioned that, currently, the kidney either goes to the combined kidney and KP list or it stays on the kidney list. The member explained that when the Pancreas Continuous Distribution Workgroup was discussing medical urgency for KP candidates, they were referring to after the kidney goes to the KP list, not beforehand. The member mentioned that the medical urgency status for kidney and pancreas candidates may not need to be exactly aligned, as long as it's maintained that medical urgency occurs after the kidney goes to either the pancreas list or stays on the kidney list. A member noted that, for example, the medical urgency for a Type I candidate on dialysis with hypoglycemia unawareness, with or without failing dialysis access, is very different from a patient who does not have hypoglycemia unawareness and can stay on dialysis.

Staff mentioned that, during conversations with the Lung Committee about post-transplant outcomes, it was realized that there's a difference between what can be measured short-term versus long-term. Different weights could be given to a short term outcome versus a long term outcome and it may be similar for medical urgency. Staff inquired whether the Workgroup is talking about the same general concept for medical urgency or is the reason KP candidates are prioritized because it's harder to find a match – then it's a patient access issue or a different type of goal opposed to medical urgency.

Staff will update the spreadsheet of attributes and the Workgroup will continue the discussion of KP medical urgency attributes during their next call.

Upcoming Meetings

- December 18, 2020 (Teleconference)

Attendance

- **Committee Members**
 - Martha Pavlakis
 - Silke Niederhaus
 - Rachel Forbes
 - Vince Casingal
 - Abigail Martin
 - Alejandro Diez
 - Amy Evenson
 - Arpita Basu
 - Bea Concepcion
 - Caitlin Shearer
 - Cathi Murphey
 - John Barcia
 - Parul Patel
 - Peter Kennealey
 - Peter Stock
 - Raja Kandaswamy
 - Todd Pesavento
- **HRSA Representatives**
 - Jim Bowman
 - Marilyn Levi
 - Raelene Skerda
- **SRTR Staff**
 - Bryn Thompson
 - Jonathan Miller
 - Nick Salkowski
- **UNOS Staff**
 - Joann White
 - Lindsay Larkin
 - Kiana Stewart
 - Rebecca Brookman
 - Amanda Robinson
 - Ben Wolford
 - Betsy Gans
 - James Alcorn
 - Joel Newman
 - Lauren Motley
 - Nang Thu Thu Kyaw
 - Olga Kosachevsky
 - Ross Walton
 - Kerrie Masten