

OPTN Kidney & Pancreas Transplantation Committee Continuous Distribution Workgroup

Meeting Summary

January 21, 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 1/21/2022 to discuss the following agenda items:

1. Project Outlines and Goals
2. Discussion: Operational Components within Continuous Distribution Framework: Multi-Organ Transplantation (MOT)
3. Next Steps

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

1. Project Outlines and Goals

The Workgroup reviewed the goal of the continuous distribution project, which is to change allocation from a classification-based system to a points-based system, and the identified attributes. The Workgroup is currently in the "build framework" phase of the project.

Summary of discussion:

There was no discussion.

2. Discussion: Operational Components within Continuous Distribution Framework: Multi-Organ Transplantation (MOT)

The Workgroup received a presentation on the background of the kidney-pancreas allocation system and reviewed how current kidney-pancreas (KP) allocation works to inform their discussion.

The Workgroup reviewed how the Organ Procurement and Transplantation Network (OPTN) Lung Committee included multi-organ transplant (MOT) within the lung continuous distribution framework.

- Lung Committee reviewed data on:
 - Lung Allocation Score (LAS) of multi organ candidates who received MOT transplants
 - Projected distribution of composite allocation score (CAS) for lung candidates that need a second organ
- Transitional solution: CAS threshold
 - CAS threshold set at 28
 - Candidates above CAS of 28 would be offered the second organ
 - CAS 28 cut-off is used as a replacement for the LAS 35 threshold

The Workgroup was asked to provide feedback on the following guidelines for the MOT Committee to consider while they develop recommendations on how to incorporate kidney-pancreas (KP) allocation into the continuous distribution framework:

- How do we map current policy to the new continuous distribution system?
 - Recommended solution: Estimate the CAS for KP patients that are currently prioritized and define a CAS threshold for required KP shares
- What kidney alone candidates, if any, should be considered for required shares after KP candidates?
 - E.g., high calculated panel reactive antibodies (CPRA), pediatrics, etc.

Summary of discussion:

A Chair inquired if the age of 50 and body mass index (BMI) of 30 cut-offs still make sense in KP and pancreas allocation. Members stated that the OPTN Pancreas Committee had discussed the low utilization of KPs from donors over age 50 with a BMI greater than 30; however, there are opportunities for this in scenarios with local offers and the patient has a high CPRA. The OPTN Pancreas Committee had discussed changing the age threshold to 40 and gradually increasing priority for islet infusions as the donor age increases above 40; however, they didn't feel comfortable making that change without looking at more data.

A member mentioned that they had reviewed data from donors with a BMI of 30-35 and found that they did not have high risk of complications, so they thought that the candidates who received those organs would have acceptable outcomes. A Scientific Registry for Transplant Recipients (SRTR) representative inquired about the age of those donors. The member stated that the mean age of the donor group was 36.

A member noted that the reason the Workgroup is even discussing these cut-offs is for efficiency sake. Ideally, these higher age and higher BMI KPs would be placed, but the Workgroup should be cautious about making a decision on the age and BMI cut-offs without reviewing more data. The member also explained that there's an age and BMI cut-off so organ procurement organizations (OPOs) aren't offering KPs from donors of all ages and all BMIs, which would delay kidney allocation.

Staff explained, in the context of the first iteration of continuous distribution, the Workgroup most likely will not be able to address the age and BMI cut-offs due to the complexities and wanting to review additional data. Staff ensured the Workgroup that these cut-offs will stay at the forefront of discussions regarding pancreas and islet allocation.

A Chair mentioned that, in regards to MOT, the OPTN Pancreas Committee wants to make sure that all usable pancreata are being utilized, so they would like the significant priority that is granted to pancreata currently to be retained. The Chair asked for clarification on the guideline regarding how many KP candidates are prioritized ahead of kidney alone candidates and mentioned that, if KPs, pancreata, and kidneys are all on one list, it becomes difficult to salvage a pancreas for transplant since there are a variety of kidney patients also in the mix.

Staff explained that the current goal of the first iteration of continuous distribution is to keep the two list system – KP and pancreas on one list and kidney on the other list. Staff further clarified that this is a transitional solution and, since there will no longer be hard boundaries with classifications, the Workgroup is being asked to determine what level of CAS is required to offer the kidney and the pancreas to the same patient. Staff provided the following examples of how these classifications could be translated to CAS where it would be required to offer a KP:

- Average CAS score for patients that currently fall in those classifications

- Lowest possible CAS score that patients currently in those classifications could get
- A CAS score that would encompass 50 percent, for example, of the KP list before offering to kidney alone candidates

An SRTR representative inquired if it's possible to weigh proximity in a way that local pancreata within a reasonable cold ischemic time (CIT) still maintain that priority. The SRTR representative explained that most kidney and pancreata are likely to get used if they're local, but once they get beyond 12 hours of CIT it's unlikely they will be imported.

Staff explained that the Workgroup is inquiring about the amount of priority the proximity to the donor hospital should receive in the *Continuous Distribution of Kidneys and Pancreata Request for Feedback* and the Analytic Hierarchy Process (AHP) exercise, although that may look different between pancreas/KP and kidney allocation. Staff mentioned that, by translating these hard boundaries to CAS, two identical patients at 249 nautical miles (NM) and 251 NM will be treated similarly and won't have arbitrarily different levels of access, which is a problem under our current allocation system.

A Chair inquired if the Workgroup is being asked to determine a CAS score for KP allocation that is aligned with kidney allocation. Staff explained that KP patients have high waiting list mortality and issues with utilization, which is why they are prioritized the way they are currently, and the Workgroup wants to maintain that level of access in the continuous distribution framework; however, OPOs are going to need to know when they can switch over to the kidney alone match run. Staff mentioned that translating the current KP priority into CAS would be the most reasonable way to transition the KP priority to continuous distribution.

A member emphasized that the importance of defining a CAS score is so OPOs don't spend 24 hours trying to place the pancreas and lose the opportunity to place the kidney.

An SRTR representative inquired if it's possible to use a graduated score after the 250 NM, so KP patients start receiving less points the further away they are from 250 nautical miles (NM) until it tapers off at zero. The SRTR representative emphasized the importance of the preservation of local offers being exhausted, then KP patients can receive the graduated points after 250 NM before OPOs can go to the kidney list.

A Chair noted that, outside of the populated areas on the coasts, the 250 NM local offers isn't really relevant because centers aren't as close together. The Chair mentioned that they don't think the distance will be much of an issue and the community already has practice from their experience with acuity circles.

A member suggested that it would be helpful to know how many of the pancreata that are offered are accepted beyond 250 NM and if it is the same centers that are accepting them.

An SRTR representative cautioned against putting KPs and kidneys on one match run in future iterations of continuous distribution because the kidney list is so large that it would engulf the small pancreas population that is waiting.

A member inquired about how the OPTN MOT Committee will handle heart-kidney, since the heart-kidney patient would have to receive significant priority if they were put on the kidney list for similar reasons as above. A member mentioned that the OPTN MOT Committee is looking forward to answering this question in a later phase of their project. The member stated that OPOs really want guidance on the order in which to allocate organ combinations for MOT candidates, but it will be similar to what the Workgroup is discussing now – not exhausting the whole KP list until going to the kidney list.

Staff inquired if the Workgroup agrees with referring these guidelines to the OPTN MOT Committee to assist in the development of their recommendations for KP allocation in continuous distribution.

A member stated that, from their experience, the general sentiment of the OPTN MOT Committee is to standardize policy across the board and they're concerned that by deferring this the importance of keeping the kidney with the pancreas in KP allocation would be lost. The member suggested that pancreata should be viewed in the same way that lungs or hearts are – they are organs that are prioritized with the kidney.

An SRTR representative stated that if a patient is allocated a heart, but also needs a kidney, then the kidney will be offered to that patient regardless. The SRTR representative inquired if that's going to be changed by the OPTN MOT Committee.

A member stated that won't be changed by the OPTN MOT Committee. The OPTN MOT Committee is trying to provide guidance to OPOs on which patients receive the two kidneys. For example, if the first patients on the heart list, lung list, and liver list are all also listed for a kidney, some OPOs could offer first to the heart patient and some could offer to the liver patient. If KP is added into the mix, then there are four patients that could receive the kidney yet there is currently no guidance on who OPOs should offer to first.

A member mentioned that the Workgroup has been talking a lot about KP and its effect on kidney and inquired how much it affects the pancreas list when pancreata are offered to liver-intestine patients. An SRTR representative stated that they haven't seen that to cause a big impact on pancreas availability, since liver -intestine is a small subset of the overall transplant population. The SRTR representative mentioned that if there's an opportunity to do a liver-intestine transplant, then typically programs will forego the pancreas, since liver-intestine is such a specialized population with multi-organ failure.

Staff stated that if the Workgroup does prioritize proximity and CPRA very highly for KP and pancreas patients, that will increase the CAS for patients that are closer to the donor hospital and the patients that are above the defined CAS threshold will receive the kidney.

There was no further discussion.

3. Next Steps

The Workgroup will continue the MOT discussion during their next meeting and finalize the guidelines to provide to the MOT Committee for their review and further recommendations.

The meeting was adjourned.

Upcoming Meetings

- February 4, 2022 (Teleconference)
- February 18, 2022 (Teleconference)

Attendance

- **Workgroup Members**
 - Martha Pavlakis
 - Rachel Forbes
 - Jim Kim
 - Oyedolamu Olaitan
 - Aaron Wightman
 - Abigail Martin
 - Amy Evenson
 - Beatrice Concepcion
 - Caitlin Shearer
 - Dave Weimer
 - Lynsey Biondi
 - Maria Friday
 - Parul Patel
 - Peter Kennealey
 - Pradeep Vaitla
 - Rachel Engen
 - Tarek Alhamad
 - Todd Pesavento
 - Vincent Casingal
- **SRTR Staff**
 - Bryn Thompson
 - Grace Lyden
 - Jonathan Miller
 - Raja Kandaswamy
- **HRSA Representative**
 - Jim Bowman
 - Marilyn Levi
 - Vanessa Arriola
- **UNOS Staff**
 - Joanne White
 - Lindsay Larkin
 - Rebecca Brookman
 - Kayla Temple
 - Anne McPherson
 - Ross Walton
 - Amanda Robinson
 - Darby Harris
 - Kaitlin Swanner
 - Laura Schmitt
 - Lauren Motley
 - Sarah Booker
 - Susan Tlusty