

Meeting Summary

OPTN Kidney & Pancreas Transplantation Committee Continuous Distribution Workgroup Meeting Summary February 4, 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 2/4/2022 to discuss the following agenda items:

- 1. Project Outlines and Goals
- 2. Review of Current Kidney-Pancreas (KP) Multi-Organ Allocation Policy
- 3. Discussion: Operational Components within Continuous Distribution Framework: Multi-Organ Transplantation (MOT)
- 4. 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. Review of Current Kidney-Pancreas (KP) Multi-Organ Allocation Policy

The Workgroup reviewed current KP allocation policy.

Summary of discussion:

One Chair asked for confirmation that the Organ Procurement Organization (OPO) must allocate to the first four classifications of KP and pancreas potential transplant recipients (PTRs) before they can begin allocating the kidney as primary on the kidney alone list. Staff confirmed this is correct.

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

The Workgroup discussed several options for adapting Kidney-Pancreas (KP) multi-organ allocation policy for continuous distribution.

Data summary:

Current KP allocation policy establishes a threshold above which specific KP patients receive required KP offers. To accurately translate this policy into continuous distribution, the new KP allocation rule will

need to ensure as many candidates above the current threshold are still receiving a KP offer, but maintain OPO flexibility to move over to the kidney alone match run when appropriate. Specifically, there will need to be some kind of rule based on the composite allocation score (CAS). There are several options to adapt current KP policy for continuous distribution:

- Average CAS threshold the new rule would set a threshold based on the average simulated CAS of patients that fall above the current KP threshold. In this option, the highest CAS KP patient and that average CAS patient would likely receive the required KP share, but the patient with the lowest simulated CAS who currently receives a required KP offer, would no longer qualify for the required KP offer. There could also be patients with a high CAS who may not receive required KP offers in the current system, but would qualify under the new rule.
- Percentile CAS threshold the new rule would set a CAS threshold such that a certain percent, such as 90 or 95 percent, of the patients who would currently receive required KP offers would continue to receive required KP offers in the continuous distribution allocation system. The percentile can be drawn to balance efficiency as well. There could also be patients with a high CAS who may not receive required KP offers in the current system, but would qualify under the new rule. The Lung Committee decided to utilize a percentile threshold when looking at their own multi-organ allocation policies.
- Minimum CAS threshold the new rule would set a CAS threshold so that every patient who
 currently receive required KP offers would continue to receive require KP offers. This option
 would result in the most patients that currently do not receive required KP offers to receive
 required KP offers in the continuous distribution system. This option could be inefficient.

The new rule in continuous distribution will not be an exact translation, and there may be some situations where someone who would be offered a KP now would not be offered a KP in the new system. There also may be patients who would not receive a KP now, who would receive a KP offer in the new system.

Summary of discussion:

A Chair referenced discussions from the last meeting regarding a single match run for all organs being allocated, and asked for clarification on how such a match run would work and whether there would be separate organ specific match runs going forward. Staff explained that this project will focus on maintain individual match runs for pancreas/KP and kidney. Staff continued that there has been discussion about a future state with a combined organ match run, but current continuous distribution projects are focusing on individual organ specific match runs as exists in the current system. The Chair offered that this combined match run could essentially give heart patients a high number of points in order to place them ahead of kidney. Staff noted that the combined match run would involve a significant number of values decisions, but that it might not matter whether a kidney patient was ahead of a heart patient, since they don't need the same organ. Staff continued that potentially a highly sensitized or pediatric kidney patient could fall ahead of heart kidney patients, if that was how those values shake out. The values driving different organs' allocation are often different; heart allocation is typically driven by medical urgency, whereas that is not as critical a driver in kidney allocation. Staff continued that first, it is essential to define values and scales for all of the organs individually, including determining how to rank kidney patients against each other. Staff added that the Workgroup will need to ensure that KP patients still have access, and that the OPO can offer kidneys alone if they exhaust a certain amount of the match run. The Chair commented that currently, a kidney match is run, and a heart-kidney patient is very low on it, if on the match at all, but because of current multi-organ rules, a heart-kidney patient at the top of the heart match run could still receive the kidney, rendering the kidney match run irrelevant for at least one kidney. The Chair asked if this would be similar if multi-organ allocation policy keeps

priority for heart-kidney, lung-kidney, liver-kidney, and KP patients. Staff noted that a combined match run would likely require a series of complex conversations that the community is not necessarily ready to have ahead of organ-specific transitions to continuous distribution. The focus of the current meeting is prioritizing KP in the context of pancreas and kidney.

Staff explained that the Scientific Registry of Transplant Recipients (SRTR) kidney-pancreas simulated allocation model (KPSAM) will require a specific rule for KP allocation, including when to switch between the KP match run and the kidney match run. Staff asked the Workgroup how to best translate current KP allocation policy to continuous distribution. Staff noted that the Workgroup will send their recommendations for the Ad Hoc Multi-Organ Transplantation (MOT) Committee to discuss and provide further recommendations for the Workgroup to consider.

One member remarked that CAS will potentially change based on factors like distance and antigen matches, and that different candidates will come up with different CAS scores depending on the donors. The member continued that setting a minimum threshold could result in donors for which no KP patients meet the threshold. Staff agreed that this was a possibility, and shared that the Lung Continuous Distribution team ended up seeing a right skewed distribution, where there was a tail of folks with very low CAS, indicating that a percentile was the most appropriate. Staff continued, noting that the data can help reassure that such a situation doesn't occur.

One of the Chairs asked if the KP and pancreas match run will have different allocation sequences based on body mass index (BMI) and age criteria. Staff explained that the difference between the two KP/pancreas allocation sequences is where islets fall, and that this can be translated into continuous distribution through a pancreas islet attribute so that islet candidates have a boost for donors that have more difficulty with solid pancreas placement. The Chair noted that choosing a threshold will be difficult without knowing what the simulated CAS are, and that the rule should be consistent with the current rule as much as possible. Staff asked the Workgroup to find consensus on the concept for the new rule based on what is reasonable, contingent on the data. Making a decision conceptually on the front end will allow for more efficient tweaking and finalizing. Staff pointed out that this will be a preliminary decision. The Chair agreed that the new rule should be similar to current policy, and balance system efficiency in allowing an OPO to shift allocation towards kidney alone if the pancreas is not accepted.

Staff asked the Workgroup if there was a sense of what kind of rule could be considered similar enough to current KP allocation policy, and if there were particular patient groups where KP allocation should operate differently. One of the Chairs remarked that a high percentage of KP candidates currently receiving required offers, somewhere over 90 percent, would be reasonable.

One Chair asked if facilitated pancreas placement will also transition to the continuous distribution system. Staff shared that based on previous discussions, facilitated pancreas will likely remain operationalized in continuous distribution. The Chair commented that those OPOs hoping to place a pancreas will go to the extra effort to do so after they have offered through the required KP patients. The Chair continued that once an OPO has offered through a high percentage of potential transplant recipients, it seems suitable for the OPO to offer to the kidney alone list or pursue facilitated pancreas.

One of the Chairs asked about the concept of targeting to keep KP allocation roughly similar to current KP transplant levels. The Chair offered a scenario where a patient listed for a KP approaching the year in which they would typically receive a required KP offer would then have their access dramatically reduced with implementation. Another Chair agreed with keeping KP allocation policy similar to the current policy for simplicity's sake, and commented that there may not be much time to get data and make major changes. A third Chair remarked that the initial idea was to translate current allocation over

to continuous distribution with limited differences. The Chair added that adjustments will be easier to make in a continuous distribution allocation model.

4. Next Steps

The Workgroup's recommendation will be sent on to the Ad Hoc MOT Committee for additional input. The Ad Hoc MOT Committee will also review and provide feedback on the Continuous Distribution request for feedback.

The meeting was adjourned.

Upcoming Meetings

• February 18, 2022 (Teleconference)

Attendance

• Workgroup Members

- o Martha Pavlakis
- o Rachel Forbes
- o Oyedolamu Olaitan
- o Abigail Martin
- o Amy Evenson

UNOS Staff

- o Joann White
- o Lindsay Larkin
- o Rebecca Brookman
- o Kayla Temple
- o Anne McPherson
- o Ross Walton
- o Amanda Robinson
- o Kaitlin Swanner
- Lauren Motley
- o Sarah Booker

Due to technological issues, the full attendance list for the Kidney Pancreas Continuous Distribution Workgroup meeting on 2/4/2022 could not be recorded.