

**OPTN Kidney & Pancreas Transplantation Committee
Continuous Distribution Workgroup
Meeting Summary
October 1, 2021
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 10/1/2021 to discuss the following agenda items:

1. Review of Project Goals & Project Approach
2. Overview of Kidney after Liver (KAL) in Current OPTN Policy and Pancreas after Kidney (PAK) Attribute
3. Discussion: Recommendation of Rating Scale
4. Wrap Up & Next Steps

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

1. Review of Project Goals & Project Approach

The Workgroup reviewed the scope of the Continuous Distribution project, which is to change allocation from a classification-based system to a points-based system. The Workgroup is currently in the second phase of the project where they will be assigning values to the kidney and pancreas attributes and reviewing feedback on their concept paper, which was part of the Summer 2021 public comment cycle.

The following is the chronological process of developing the continuous distribution model for kidney and pancreas:

1. Attribute
 - a. Discuss each attribute individually
 - b. Ex: calculated panel reactive antibody (cPRA)
2. Rating Scale – where the Workgroup is currently
 - a. Determine rating scale for each attribute
 - b. Ex: Workgroup decides this should be a steep non-linear scale
3. Weight
 - a. Determine weight for each attribute compared to other attributes
 - b. Ex: Workgroup decides cPRA should count for 5% of total score
4. Build & Adjust
 - a. Use Workgroup's decisions to build draft framework and adjust as needed
 - b. Ex: Upon review, Workgroup decides to adjust weight to 10% of total score

Summary of discussion:

There was no discussion.

2. Overview of Kidney after Liver (KAL) in Current OPTN Policy and Pancreas after Kidney (PAK) Attribute

The Workgroup reviewed current OPTN Policy regarding kidney after liver (KAL) transplants, also known as the safety net, and discussed adding pancreas after kidney (PAK) transplant as a new attribute.

Kidney after Liver (KAL)

A prior liver recipient will receive priority for a kidney, according to *Policy 8.5.G: Prioritization for Liver Recipients on the Kidney Waiting List* if they meet both of the following criteria:

- Candidate is registered on the kidney waiting list prior to the one-year anniversary of the candidate's most recent liver transplant date
- At least 60 days, but not more than a year, after the candidate's liver transplant, one of the following criteria must be met:
 - Candidate has a measured or calculated creatinine clearance (CrCl) or glomerular filtration rate (GFR) less than or equal to 20 ml/min
 - Candidate is on dialysis

Pancreas after Kidney (PAK)

Discussions of potentially adding this attribute include the following:

- Waiting time for these patients tend to be longer after receiving kidney
- Should consider separating into subgroups
 - Pancreas after receiving a living donor kidney (potentially offer a safety net priority)
 - Pancreas after deceased donor kidney

Summary of discussion:

Kidney after Liver (KAL)

A member stated that the intent of the safety net was to avoid unnecessary simultaneous liver kidney (SLK) transplants for patients that had adequate renal function going into their liver transplant and to create some standardization across the country, which they believed the safety net has achieved.

A member requested clarification regarding who qualifies for the KAL safety net. For example, a potential transplant recipient may go into the operation with normal kidney function, be put on a complicated post-liver transplant treatment course, and then wind up on dialysis. The member commented in that situation, the liver recipient would qualify for the KAL safety net although they really should not. The member further emphasized that that would be no different than a potential transplant recipient going into a heart transplant and ending up with kidney failure or a member of the general population who had a complicated bypass surgery and ends up with kidney failure – those individuals don't receive priority compared to others who have been waiting on the transplant list. The member suggested that there be a modification to the current KAL safety net policy that excludes patients with some level of kidney function before their liver transplant. For example, a GFR of 40 would be high enough to be reasonable, but not so low to allow patients who shouldn't qualify to qualify for the KAL safety net.

A Scientific Registry for Transplant Recipients (SRTR) representative inquired what kind of priority is assigned to a kidney relisting if an SLK transplant is performed and the kidney is lost in the first 90 days due to primary non-function or technical loss. A member stated that a patient in this situation would have had enhanced priority for the kidney when they received the SLK transplant and, even though it's now a loss within 90 days, they should have the same priority for the kidney that they had prior to the

transplant. Members agreed it would be useful to have this clarification because they know of a couple of cases where centers have applied for the priority and the results have been variable.

Staff mentioned that a kidney candidate who received a liver and kidney transplant from the same deceased donor will only qualify for the safety net if the candidate qualifies for kidney waiting time reinstatement according to *Policy 3.6.B.i: Non-function of a Transplanted Kidney*.

A Chair stated that the previous comments are highlighting areas of applications of this policy that aren't completely aligned with the original intent. A potential transplant recipient, who goes into the liver transplant with normal kidney function and then needs a kidney, receives priority from the safety net although the intent of the priority wasn't to make up for the patient not getting an SLK at the time. The Chair stated that these are both really important points that need to be addressed as the Workgroup moves forward.

Pancreas after Kidney (PAK)

A member clarified the distinction between receiving a pancreas after receiving a living donor kidney versus a pancreas after receiving a deceased donor kidney by stating that an SPK candidate who receives a living donor kidney is bringing a living donor kidney into the system when they could have been listed for an simultaneous pancreas kidney (SPK), which would have taken a kidney out of the system. The member further explained that providing these priority points would encourage living donor kidney transplants in potential SPK candidates.

An SRTR representative stated that, from what they remember of previous discussions, PAK would include a kidney safety net, which is slightly different from what is being described above. The SRTR representative further inquired whether, for pancreas transplant alone (PTA) patients with marginal kidney function and severe hypoglycemic unawareness who then go into renal failure, there should be a safety net for those patients to then receive kidney transplant because the worst situation is for them to be on dialysis and immunosuppression.

An SRTR representative stated that they aren't sure that the pancreas safety net should be considered a safety net, but instead pancreas priority points. However, the kidney safety net would truly function as a safety net to make sure pancreas alone patients who have a GFR of 30-40 and may end up needing a kidney after pancreas can receive the kidney.

A member inquired if it mattered how long ago the living donor kidney transplant occurred for the recipient to receive pancreas priority points. A Chair stated that this is a great question to discuss. The initial thought was that, if a patient on the kidney list receives a living donor kidney transplant and then needs a pancreas, that patient should receive extra points for a pancreas to come with or shortly after the kidney.

A member stated that, if their center has a patient that qualifies for a SPK transplant and they already have a living donor, they will list them for a SPK transplant and PTA so they don't lose waiting time. The member explained that the system works in such a way that waiting time for pancreas starts when the patient started dialysis or when they were listed for the SPK, so when their center performs the kidney transplant the patient keeps the time and isn't delayed in receiving a pancreas.

An SRTR representative mentioned the problems that may arise with the preemptive transplants that are done as living donor kidney transplants. The rate of preemptive transplants is higher with living donor kidneys and those patients will not have the advantage of dating back to start of dialysis time, but instead only to when they were listed, which may be a very short time since they found a living donor for the kidney. A member agreed and stated that the Workgroup needs to find a way to measure how

long patients have been diabetic or how acutely ill they are rather than have a blanket criteria for everyone.

An SRTR representative stated that, even if the Workgroup gave priority that were over inclusive, it wouldn't be contentious because it would be for PTA candidates and that pool is pretty small.

A Chair noted that their program, because of several disastrous outcomes, timed a PAK transplant pretty rapidly after the patient had received a living donor kidney transplant; however, their program repeated induction immunosuppression treatment and the patient actually had a 6-12 month waiting period between the living donor kidney and PAK transplant. The Chair wondered if allowing for very rapid PAK transplants might put some patients in a situation where they are receiving too much induction immunosuppression treatment right in a row. A member stated that that's why they like to do PAKs so closely together and they just don't repeat immunosuppression necessarily. For example, if the patient had a really strong depleting therapy for the kidney transplant, then the member would follow that therapy with basiliximab for the patient and that works very well.

A member also noted that the priority points wouldn't go away if a program chose to do the PAK transplant 6-12 months later – the points would be there and the program could inactivate the patient and when the patient is reactivated they would be at the top of the list.

An SRTR representative stated that PAK outcomes are worse once the candidate waits beyond a year for the pancreas.

Staff summarized that the focus for PAK is specifically pancreas after receiving a living donor kidney and potentially offering priority points on the pancreas list, since they already have a kidney. Staff inquired if the Workgroup had a sense of whether they would want to prioritize PAK transplants after living donor kidney transplants over PAK transplants after deceased donor kidney transplants or vice versa, given that in all other aspects the patients were identical.

An SRTR representative stated that, based on discussions, it seems the Workgroup would want to prioritize PAK transplants after living donor kidney transplants; however, the Workgroup hasn't discussed PAK transplants after deceased donor kidney transplants yet.

A member noted that there are kidney candidates that don't find a living donor and aren't medically stable enough to receive an SPK transplant. It's not uncommon for centers to perform the deceased donor kidney transplant, observe how well the recipient does, and then consider the option of a pancreas transplant. The member stated that these patients may have a short window of time as well for when they need the pancreas transplant. It was suggested that the PAK transplant after deceased donor kidney transplant attribute should be discussed by the OPTN Pancreas Transplantation Committee, since this would prioritize these patients over pancreas alone candidates.

A member suggested that the Workgroup should also consider demographics that historically don't have a lot of living donors, just to make sure that they are not disadvantaged. Staff stated that there may be additional criteria other than just being a recipient of a living donor kidney.

3. Discussion: Recommendation of Rating Scale

The Workgroup reviewed the following recommended rating scale for KAL and PAK:

- Binary (Yes/No) scale for both kidney and pancreas based on qualifying criteria

The Workgroup provided feedback on the following discussion questions:

- Should KAL maintain the existing kidney donor profile index (KDPI) threshold (KDPI greater than or equal to 35%)?

- What qualifies a candidate for PAK?

Summary of discussion:

A member stated that patients who qualify for simultaneous liver kidney (SLK) transplants have a GFR of 25 for acute renal failure and a GFR of 30 for chronic renal failure. Likewise, the member wondered if there might be a higher GFR threshold that would qualify candidates who need a pancreas, but don't have a GFR that qualifies them for a kidney, for a SPK. The member further explained that it would be for patients who medically qualify for a pancreas transplant and also have chronic renal failure, but they may not meet the GFR threshold of 20. The member suggested raising the SPK GFR threshold to 25 or 30, which would align with what happens when a patient receives an SLK transplant.

An SRTR representative mentioned that there are two points in favor of that suggestion: (1) the accelerated loss of GFR in Type I diabetics once they hit a GFR below 30, and (2) the candidates who have severe hypoglycemic episodes or hypoglycemic unawareness with a GFR of 30 and have a significant risk of stroke need a PTA. The SRTR representative stated that if these candidates did receive a PTA, then their kidneys are likely to start failing and they'll need a kidney. The SRTR representative agreed with having a GFR threshold of 30 and below so these patients would qualify for an SPK transplant with better outcomes and if a patient had a GFR above 30 then they would have the kidney safety net if the kidney fails within one year after transplant.

A Chair stated that they would assume there would be some pushback from pediatricians in the community because of the multi-organ transplant priority for SPKs.

A member inquired about the reason for wanting to increase the SPK GFR threshold. A member stated that the concern is that if a patient receives a pancreas transplant and their GFR is 29, then they don't qualify for a kidney transplant; however, most practitioners feel that, with that amount of immunosuppression, the patient might end up with renal failure and all the patient has received at that point in time is a pancreas.

A member noted that another opportunity this presents is to potentially consider a safety net situation for the other organs similar to what is in place for liver. It was noted that the OPTN Ad Hoc Multi-Organ Transplantation Committee is discussing that and will be looking for feedback from the Workgroup and organ-specific committees.

A member expressed concern that, from the pediatric perspective, having poor kidney function can really have detrimental effects on a pediatric patient's growth and development well before they reach a GFR of 20. The member stated that they are concerned that higher GFRs are used to get adult patients listed for multi-organ transplants, but the use of higher GFR thresholds isn't offered to other categories of patients.

A Chair agreed with the pediatric concern and cautioned the Workgroup on modeling multi-organ combinations off of current SLK and safety net policies because the current policies may need to be revised.

Staff summarized that the Workgroup agrees with the binary scale recommendation for KALs, agrees with maintaining the existing kidney donor profile index (KDPI) threshold for the KAL safety net, and suggests that there should be more discussion around SLK to also bring back to the MOT Committee. The Workgroup also suggested having the OPTN Pancreas Transplantation Committee discuss the PAK attribute further during their next meeting.

A member inquired about whether maintaining the KDPI threshold was only dependent on if kidneys are allocated according to sequence. The member further elaborated by stating that, with continuous

distribution, KDPI would also be weighted as an attribute and wondered why the Workgroup would need to consider the KDPI threshold for safety net allocation, especially if safety net status could be its own attribute.

Staff clarified that the question of whether to maintain the KDPI threshold for KALs or not was really asking whether the Workgroup thought that KAL patients should be prioritized on every match run regardless of the quality of the kidney since the current KDPI threshold does serve a purpose.

A member inquired if pediatric patients need to receive kidneys with KDPIs under 35 as a first run. A member stated that pediatric patients do get some priority for kidneys with KDPIs under 35 percent; however, that concern is that KDPI is a donor attribute and is not accurate for donors who are within the pediatric age range, so it's not very predictive of the quality of the kidney. The member continued by stating that pediatric recipients do get priority for any kidney with a KDPI 35 percent or less and there are some centers who might take a high KDPI kidney if the donor was 12 years old because they know that KDPI is not a good measure of quality.

A member proposed that, for KAL transplants, the Workgroup consider changing the KDPI threshold to 35 percent or greater so those kidneys with a KDPI less than 35 percent could potentially go to pediatric patients.

Staff explained that, based off of original kidney sequence discussions, there had been mixed public comment feedback on whether to include the safety net in Sequence B or not; however, after looking at data, the OPTN Kidney Transplantation Committee observed that the majority of kidneys allocated were allocated through Sequence B and C and thought removing it would reduce access so they decided to include the safety net in Sequence B in the final proposal.

A Chair emphasized that some of the KAL candidates are young liver patients who would then need a safety net and would benefit from high quality kidney that lasts a long time. A member noted that pediatric patients are prioritized above safety net patients in Sequence B.

Staff emphasized that the real question about the KAL KDPI threshold is whether there are certain circumstances where the Workgroup would want patients who qualify for KAL to be prioritized over all other kidney candidates, given that all other aspects of the patients are identical. Staff summarized by stating it sounds like the Workgroup agreed that in certain circumstances they should be prioritizing the KAL patients.

A member stated that an argument for giving liver patients some priority is that the transplant community wants to be good stewards of the resources that a patient has already received. A member mentioned that part of the reason for giving priority to KALs was to reduce the drive for so many SLKs, so it was a promise that a patient could get a kidney quickly if they ended up requiring dialysis or having end stage renal issues. The member stated that they don't think moving the safety net to just Sequence C and D is achieving that goal.

Staff summarized that the Workgroup agreed with the rating scale for KAL, but there needed to be more discussions about the criteria to qualify for KAL.

4. Wrap Up & Next Steps

The Workgroup will review the feedback provided from the OPTN Pancreas Transplantation Committee on the PAK attribute.

Upcoming Meetings

- October 15, 2021 (Teleconference)

Attendance

- **Workgroup Members**
 - Martha Pavlakis
 - Rachel Forbes
 - Jim Kim
 - Oyedolamu Olaitan
 - Abigail Martin
 - Alejandro Diez
 - Arpita Basu
 - Dave Weimer
 - Peter Kennealey
 - Parul Patel
 - Pradeep Vaitla
 - Silke Niederhaus
- **SRTR Staff**
 - Ajay Israni
 - Bryn Thompson
 - Jon Miller
 - Raja Kandaswamy
- **UNOS Staff**
 - Joann White
 - Rebecca Brookman
 - Lindsay Larkin
 - Kayla Temple
 - Ross Walton
 - Amanda Robinson
 - Ben Wolford
 - Darby Harris
 - Eric Messick
 - James Alcorn
 - Lauren Motley
 - Sara Moriarty
 - Sarah Booker
- **Other Attendees**
 - Chris Curran
 - Kurt Shutterly
 - Warren McKinney