

OPTN Kidney & Pancreas Transplantation Committee Continuous Distribution Workgroup

Meeting Summary

July 8, 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 07/8/2022 to discuss the following agenda items:

1. Welcome
2. Review and Discussion: Dual Kidney Allocation
3. Review and Discussion: Released Organs Allocation

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

1. Welcome

Kidney and Pancreas Committees Leadership welcomed the Workgroup members, and briefly reviewed the objectives and goals of the kidney and pancreas continuous distribution project.

Presentation Summary:

Continuous Distribution Version 1.0:

- Maps current policy to a continuous distribution framework with few modifications
- Minimal changes to current operational requirements as outlined in policy
- Utilizes data available to review

Future iterations or enhancements:

- May require new or additional policy considerations
- Substantial changes that would require additional review and modifications to current policy and operational requirements
- Data not current available, and additional research, data requests, or modeling required

Summary of discussion:

The Committee had no questions or comments.

2. Review and Discussion: Dual Kidney Allocation

The Committee discussed the current Dual Kidney Allocation policy, and how to transition dual kidney allocation to Continuous Distribution.

Presentation summary:

The former "double kidney allocation" policy listed specific clinical criteria to allow kidneys to be allocated as dual manually. This policy was developed prior to the development of the Kidney Allocation

System (KAS) and the Kidney Donor Profile Index (KDPI). Members reported that this policy was ambiguous, unclear, and out of date. Post-KAS implementation, dual kidney transplants declined to 0.9 percent of deceased kidney transplants one year pre-KAS, to 0.5 percent in the two years post-KAS. Dual kidneys were often offered after the list had been exhausted, leading to longer cold ischemic times (CIT).

The current policy was developed with the intent of reducing non-utilization of high KDPI kidneys through dual kidney transplantation, thereby increasing the number of transplants. Community feedback from 2017 indicated:

- Transplant programs and organ procurement organizations (OPOs) supported pre-recovery criteria to promote efficiency
- Support for modification of allocation tables to incorporate dual allocation onto a single match run
- Strong OPO support for more explicit direction on when to allocate kidneys as dual

The current dual allocation policy was implemented in 2018, incorporating a single match run and center opt-in to receive dual kidney offers.

Currently OPTN *Policy 8.6.A: Allocation of Dual Kidneys* allows KDPI 35-100 percent donor kidneys to be used for dual kidney transplants, and centers may opt candidates in to receive dual kidney offers. This means the same candidate can show up on the match run twice, first for a single kidney offer, then dual.

The two-year post implementation monitoring report for the current dual kidney allocation policy found that dual kidney transplants decreased. There were 252 total dual kidney transplants (0.83 percent of all deceased donor kidney transplants) in the two years pre-policy, and 198 total dual kidney transplants (0.55 percent of all deceased donor kidney transplants) in the two years post-policy. Of the latter, nearly half of all dual kidney transplants are being allocated to patients in a single kidney classification (44.44 percent). Feedback from the OPO Community indicates that this is happening:

- To avoid organ wastage due to increased ischemic time, late turndowns, etc.
- Because the match run is too long
 - Too many sequences before the OPO can offer the organ as dual
 - By the time an OPO offers in the dual classification, programs are declining offers they may have accepted at lower cold ischemic times
- OPOs want autonomy to determine when to begin offering duals
 - Main goal is to allocate kidneys singly, but at a certain point, dual allocation is more appropriate to placing kidneys

Summary of discussion:

One member explained that, in their experience within their OPO, their team will realize early on that most programs are not accepting the kidney in the single classifications, and start getting requests to place them as dual kidneys. The member continued that it would be helpful to have pre-operative criteria to switch over to dual allocation, but noted that it isn't often feasible to get pre-operative kidney biopsy results. The member recommended creating a process whereby a program could elect to utilize a single or dual kidney to transplant a patient who was listed for either, without penalty.

One of the Workgroup Chairs shared that, anecdotally, their program typically accept dual kidneys after the biopsy results have been released, post-recovery. The Chair commented that criteria would be helpful, as it makes sense in some cases to bypass single organ allocation and start offering dual kidneys. The Chair noted that it would be interesting to see how frequently kidneys were placed as dual from a single-classification sequence, as opposed to a dual kidney-classification sequence. A member

responded, sharing anecdotally that it is common for OPOs to allocate through some of a single classification and start getting interest in dual allocation. Once the kidney approaches seven or eight hours of cold time and flight opportunities are reduced, the OPO will move to dual allocation to ensure the kidney is placed. The member suggested a solution where the single-kidney only candidates are screened off of the match run, based on donor criteria. This would allow the OPO to allocate to dual kidney candidates directly. The member remarked that OPOs need to be able to allocate to dual kidney candidates faster than they currently can, based on donor age or interoperative findings. A Workgroup Chair agreed.

One of the Workgroup Chairs noted that typically, most of the dual kidneys transplanted at their program are requested from a single-kidney allocation sequence. The Chair continued that, by the time the offer would reach the same patient in the dual classification, the cold time would be too high. The Chair added that these kidneys are typically marginal kidneys to begin with, so reducing cold time is critical. The Chair asked the Workgroup for their thoughts about a threshold number of bypasses and specific criteria to allow the OPO to switch from single kidney allocation to dual kidney allocation.

A member shared that most dual kidneys used by their program would be considered high KDPI, or KDPI greater than 85 percent. The member remarked that there could be delay in allocation for kidneys with KDPI between 35 and 85 percent, and that this window should be shortened to reduce the amount of time those kidneys are allocated for.

Presentation Summary:

Dual Allocation in Continuous Distribution: Potential Options

- Flexible Dual Allocation – OPOs can offer duals when they choose, for donors meeting certain criteria and when candidates have opted in to accept dual kidney offers
- Dual Allocation Match Run – OPO runs a new, dual-only kidney match run at a time outlined in policy or at their discretion
- Dual as an Attribute – candidates who opt in to receive dual offers appear twice on the match: once as a single kidney candidate and once as a dual kidney candidates. The dual attribute is given a different points value

Summary of discussion:

One member remarked that, if flexible dual allocation was used, there would need to be a way to bypass or exclude single kidney only candidates within the match, which could have an impact on information technology (IT) resources. The member noted that this would be necessary in order to efficiently allocate dual kidneys. The member noted that the other two options would be preferable to the flexible dual allocation option, but that a separate dual allocation match run would need a clear, defined trigger within policy as to when an OPO could begin dual kidney allocation.

A Chair expressed support for a separate dual kidney match run, similar to the current policy for en bloc kidneys. The Chair suggested that an OPO could automatically run a dual kidney match run for certain donors, and if the kidneys are acceptable to use as a single kidney, a program could accept only one kidney instead of the dual kidney.

Another Chair pointed out that the flexible dual allocation option would require only one match run, which could improve efficiency, particularly with centers already indicating whether they are interested in dual kidney offers. The Chair noted that it will be key to define criteria that identifies donors for whom dual kidney allocation is appropriate. The Chair continued that this criteria could include biopsy results. The Chair pointed out an additional advantage of the flexible dual kidney allocation, in that it gives the OPO some discretion, which could improve efficiency and potentially reduce non-utilization.

One member pointed out that part of the reason there are so few dual kidney transplants is that current dual kidney allocation is very inefficient, and that OPOs struggle to place dual kidneys within policy.

3. Review and Discussion: Released Organs Allocation

The Workgroup discussed current Released Organ Allocation policy, and how to transition the policy to a Continuous Distribution framework.

Presentation summary:

OPTN *Policy 8.8: Allocation of Released Kidneys* allows the host OPO to continue allocation according to the original match run or allocate the kidney utilizing a released kidney match run, centered at the accepting transplant hospital. OPTN *Policy: 11.8 Allocation of Released Kidney-Pancreas, Pancreas, or Islets* allows the host OPO to continue allocation according to the original match run, or allocate the pancreas, KP, or islets to a potential recipient at the transplant program that originally accepted the organs.

At their June meeting, the OPTN OPO Committee provided the following feedback:

- Policy provides opportunity for more cold time
- No time requirement for transplant programs to decline offer and release back to the OPO to reallocate; transplant programs are releasing organs at extended cold times
- Maximization of marginal kidneys is most important for released organs
- Center back up should remain an option at OPO discretion

At the last Workgroup call, the Workgroup discussed the following:

- Released allocation is hard to standardize across organs – there will be differences between kidney and pancreas released organ policies
- Transplant center back up helps utilization
 - Concern raised for gaming if transplant center back up is an option
- Transplant center back up should depend on timing of relocation
- Monitoring would be needed with regards to where organs travel, discard rate, etc.

Released Organ Allocation in Continuous Distribution: Potential Options and Considerations:

- Kidney:
 - Option 1: Give the host OPO the option to continue allocation according to the original match run, OR use a released kidney match run, using the location of the kidney when it is released, with consideration for increased weight on placement efficiency on the released match run
 - Option 2: Incorporate center backup for more marginal kidneys, in addition to option 1
- Pancreas, KP, and Islets
 - Option: Maintain existing policy (OPO may continue allocation according to the original match run, or may use center back up)

Summary of discussion:

One member remarked that for OPOs, there is a real need to get released kidneys placed as quickly as possible, which can be challenging when a kidney is outside of the OPO's service area. The member continued that these are usually the cases where the kidney arrives at the transplant center and there is a positive crossmatch or some other issue that precludes the intended recipient from receiving the kidney. The member continued, noting that now the kidney was likely around 16 hours cold, and reallocation is challenging even in the best of circumstances. The member shared that the fastest and

most reliable way of ensuring a kidney is transplanted is to permit the transplant center to have a back-up candidate at that center. The member noted that the next best option would be to run a new match run based on the location of the kidney when it is released, with substantially more weight given to placement efficiency.

The member added that this could be for pancreas as well, but that the odds of placing a pancreas at that level are daunting. A Workgroup Chair agreed that transplant center back-up makes the most sense for pancreas, as the pancreas would be unlikely to go to another center irrespective of the reason the organ was declined.

One of the Workgroup Chairs asked for clarification on which OPO is considered the host OPO, and staff clarified that the host OPO is the OPO responsible for managing the donor, recovery, and initial allocation of the kidney.

A Workgroup Chair remarked that the discretion for released organ allocation should remain with the host OPO. The Chair noted that efficiency should be prioritized, particularly with higher KPDI kidneys and those with long cold ischemic times, and that a new released organ match run should be centered around the intended recipient's hospital.

Another Workgroup Chair commented that many of these points were discussed when the released organs policy was last updated, with the removal of donor service area and regions. The Chair pointed out that how the kidney should be reallocated is dependent on the quality of the donor – younger or lower KDPI donor kidneys can tolerate more cold time, and could potentially be reallocated from the original match run, or be allocated back across the 250 nautical mile radius around the original donor hospital. A more marginal donor kidney won't tolerate as much cold time, and should be reallocated as efficiently as possible. The Chair explained that this is why there are options for reallocation. The Chair also shared that the idea of transplant center back up triggered concerns related to gaming, such that a center accepted a kidney at a higher sequence with the intention of transplanting it into a patient much further down the match run.

A Workgroup Chair asked if this discussion is to change the current policy, or if this discussion is to create a new attribute for released organs. Staff clarified that this discussion is to determine if the current released organ policy is sufficient to transition over to a continuous distribution framework, or if additional changes need to be considered. Staff clarified that the only attribute piece relates to potentially increasing the weight of placement efficiency for released organ match runs, to encourage efficient allocation. The Chair agreed that makes sense, but expressed confusion regarding changing the weight of placement efficiency, noting that the weight would be set on the original match run, since the match runs are static, not dynamic. Staff explained that the composite allocation score is candidate-specific, and the placement efficiency score could change depending on the candidates on the released match run. When a new, released-organ specific match is run, that match run could be centered around where the kidney physically is, and have greater weight given to placement efficiency. Another Chair agreed that makes sense, noting that the points the candidates would receive on the new, separate, released organ match run would change based on the weight given to placement efficiency. This would give a lot of weight to placement efficiency, to prioritize candidates closer to the recipient hospital in order to decrease cold ischemic time.

One of the Workgroup Chairs recommended not utilizing transplant center back up for released kidneys, particularly since the original intended recipient's hospital would need to run a crossmatch anyway, and there would be time to run a released organ match run.

Another Workgroup Chair remarked that the first option would make sense for kidney reallocation, so an OPO could run a released organ match run with a higher weight on placement efficiency. The Chair

expressed support for allowing the OPO to both continue reallocation from the same match, or to run a released organ match run with a higher weight on placement efficiency.

A Workgroup Chair explained that the host OPO could release the organ to the intended recipient program's OPO for reallocation. Staff clarified that the host OPO releasing an organ to an importing OPO was called local back up, and that local back up is no longer a part of reallocation policy for kidneys. Local back up was removed with the removal of DSAs, and the host OPO remains responsible for the reallocation of released organs. The Chair agreed, and emphasized that it is important for the released organ match run to be centered around the kidney's physical location, in order to increase efficiency. The Chair noted that increased weight for placement efficiency would also increase allocation efficiency.

The Workgroup agreed that current pancreas reallocation policy is still appropriate, and that kidney reallocation policy should include an option for a released organ match run centered around the initial intended recipient hospital, with an increased weight for placement efficiency.

Upcoming Meetings

- July 15, 2022 (Teleconference)

Attendance

- **Workgroup Members**
 - Oyedolamu Olaitan
 - Jim Kim
 - Alejandro Diez
 - Bea Concepcion
 - PJ Geraghty
 - Parul Patel
 - Peter Lalli
 - Rachel Engen
 - Todd Pesavento
- **HRSA Representatives**
 - Jim Bowman
- **SRTR Representatives**
 - Bryn Thompson
 - Jon Miller
 - Raja Kandaswamy
- **UNOS Staff**
 - Joann White
 - Lindsay Larkin
 - Ross Walton
 - Sarah Booker
 - Stryker Ann Vosteen
 - Kayla Temple
 - Keighly Bradbrook
 - Lauren Mauk
 - Lauren Motley
 - Joel Newman
 - Alison Wilhelm
 - Carol Covington
 - James Alcorn