OPTN Kidney and Pancreas Transplantation Committees
Utilization Considerations of Kidney and Pancreas Continuous Distribution Workgroup
Meeting Summary
November 9, 2022
Conference Call

Valerie Chipman, RN, BSN, Chair

Introduction

The OPTN Utilization Considerations of Kidney and Pancreas Continuous Distribution Workgroup (The Workgroup) met via Citrix GoTo teleconference on 11/09/2022 to discuss the following agenda items:

1. Welcome and Announcements
2. Workgroup Purpose, Goals, and Scope
3. Dual Kidney: Data Review and Criteria
4. Closing Remarks

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

1. Welcome and Announcements

Staff and the Chair welcomed the Workgroup. There was no further discussion.

2. Workgroup Purpose, Goals, and Scope

Staff highlighted the purpose and goals of the Workgroup.

Presentation Summary:

Staff outlined the focus of the Workgroup, which is on aspects of kidney and pancreas allocation that fall outside the composite allocation score while transitioning to a continuous distribution framework. The scope includes mapping current policy to continuous distribution with minimal modifications. Further iterations and enhancements to "Continuous Distribution 1.0" will be necessary and should be expected.

Summary of Discussion:

There was no further discussion.

3. Dual Kidney: Data Review and Criteria

Staff presented the outcomes of the Workgroup's last meeting and prior discussions around dual kidney and the Workgroup discussed functionality and criteria.

Presentation Summary:

Staff reminded members that dual kidney is a classification for kidneys with Kidney Donor Profile Index (KDPI) 35-100 percent. The goal is to transition dual allocation into a continuous distribution framework. In Sequence C (KDPI 35-85 percent) of allocation, single offers are run first, then dual. In Sequence D (KDPI 86-100 percent), allocation runs single offers within 250 NM, then dual offers within 250 NM, and then single offers outside 250 NM, followed by dual offers outside 250 NM. Monitoring shows that nearly half of duals are allocated from single sequences, pointing to possible ineffectiveness of and inefficiencies in this policy.

Staff recapped the Workgroup's prior discussions regarding "pain points" in dual kidney, focusing on inefficiencies and the need for alignment between transplant program opt-in for dual kidneys and willingness to accept dual organs. The Workgroup decided to recommend a dual kidney offer filter to the OPTN Offer Filters Workgroup, which received the recommendation and plans to include in a proposal for the January 2023 public comment cycle.

Staff explained that discussion will now turn to the general inefficiency in dual kidney allocation and development of policy to address this and reminded the Workgroup of the option to build a policy to allocate dual kidneys in a dual-specific match run, which would include only candidates opted in to receive dual kidney offers. This would prevent candidates from appearing twice on the match run (which has been identified as inefficient in the current system) and provide more Organ Procurement Organization (OPO) flexibility. The Workgroup decided that donor criteria should determine when an OPO switches from a single allocation match run to a new dual allocation match run in a prior meeting.

A potential model policy was shown:

- OPOs can offer KDPI 35-85 percent kidneys with X, Y, and Z characteristics at their own discretion
- OPOs can offer KDPI greater than 85 percent kidneys with X and Y characteristics at their own discretion

Some of the donor criteria the Workgroup looked at in prior discussions included Donation after Cardiac Death (DCD donors), glomerulosclerosis, diabetes, and hypertension. Staff recapped that data showed serum creatinine was similarly distributed across KDPI 35-85 percent and 86-100 percent. Dual kidney donors are more likely to be a DCD donor, have a history of diabetes, have a history of hypertension, have kidneys biopsied, and when biopsied, have higher glomerulosclerosis.

Summary of Discussion:

A member described a concern that once the criteria for dual are met, there would be no possibility of single organ allocation even though certain candidates may be well-served by a single kidney that meets the dual criteria. This member asked if having the candidates appear twice on the match run actually allows for more efficient allocation because centers have the option to allocate as dual or single. The Chair explained that this is what the Workgroup is trying to work out, to decide when an OPO is allowed to allocate as dual and reduce the time it takes to go down a match run. She explained that a possible recommendation the Workgroup could make would be that OPOs must try to allocate off the single match run before going to dual, and that the Workgroup needs to work to define specific criteria so that OPOs are not going back and forth between dual and single match runs.

A member suggested looking at past data to determine which donor criteria are historically only allocated as dual to create a model where allocation goes straight to dual for these kidneys, adding that in continuous distribution, donors will be better matched to recipients, reducing OPO decision making about whether to allocate as dual or single. The Chair added that this would be good data to track, but that the focus of the current discussion is to determine what factors transplant centers use to decide when to allocate as dual.

One member added that the time it takes to go down the match run and the added cold ischemic time is the limiting factor for allocation in their experience. This member explained that it is hard to define criteria because what the individual conditions mean for each donor is very different (such as diabetes) and suggested including creatinine clearance to screen donors before the operating room (OR) and provide an accurate indication of nephron mass availability. Creatinine clearance was not included in the original data request.

The Chair asked if the workgroup wanted to recommend that an OPO cannot go to the dual list until the donor is in the operating room (OR). If the kidney is greater than KDPI 85, has poor biopsy results, and considering some of the other factors previously mentioned at OR, the OPO would have the option to move to the dual list. A member expressed support for this idea, explaining that the option to move to dual still preserves the ability to allocate as single.

A member stated that the willingness of centers to cross match plays a large role in this, as centers will crossmatch and be potential accepting recipients for kidneys at which their candidate is not at the top of the match run. A member suggested using previous center behavior to exclude centers that never do dual kidney transplants out of the match run. The Chair clarified that this has already been recommended to the Offer Filters Workgroup.

The Chair asked if the Workgroup felt if a time-based cutoff to switch to dual was appropriate and if OPOs should have discretion to switch to dual if they try to allocate as single before the OR (switch to dual after biopsy). A member described concern about constructing criteria as they may not apply for all transplant surgeons' habits or OPO tendencies and suggested leaving it up to OPOs with some guardrails in place. A member stated that the criteria decided upon would help reduce cold ischemic time and suggested using offer filters to screen programs who have accepted dual kidney offers in the past. This member added that there should be a time point at which a center is running down a single match run calling centers and not getting interest, they switch to dual, such as at six or eight hours of cold ischemic time. The Chair expressed support for this idea and added that higher KDPI kidneys should have a lower time cutoff. The Workgroup moved to recommend two different time cutoffs for the KDPI 35-85 percent and KDPI 85-100 percent groups.

The Chair asked members for their expertise in helping decide reasonable cutoff times for cold ischemic time. A member explained that the cutoff needs to provide enough time for obtaining biopsy results and suggested a four hour cut off. The Chair stated this sounded reasonable and that during the four hours, the OPO would be allocating off the single list. A member stated that in their experience, many single offers do not come to their center until five or more hours of cold time, and allocating a KDPI 50 or lower kidney as a dual based on cold time does not reflect the reality or goals of kidney transplant. A member suggested having a narrower range than 35-85 percent to better stratify within that group, and suggested different time cutoffs for KDPI 35-60 percent, 60-85 percent, and 85-100 percent.

The Chair asked members to describe their biggest areas of concern in accepting marginal kidneys as a dual transplant. A member responded that the 24-hour mark and distance from donor hospital are big decision makers. The Chair added that cross matching adds to this time, as many centers do still wait for physical cross-matches before the OR. A member asked what the lowest KDPI is that is typically allocated as dual and expressed that it is hard to decide a lowest allowable KDPI for dual allocation. The Chair explained that a way to ensure that the right kidneys are being allocated as dual versus single is to define clearly the criteria, requiring more criteria for lower KDPI kidneys to be met before dual allocation is permitted. Members expressed a desire for more data on KDPI and dual allocation to better decide. Staff explained that under current policy, dual is a classification only in KDPI 35-85 percent and in 86-100 percent. Staff showed a graph that demonstrates an increase in dual allocation around KDPI 50 and higher. The Workgroup agreed that based on this, a cutoff of KDPI 60-85 percent for dual allocation is reasonable.

The Workgroup then transitioned to discussing specific factors that may be included in dual kidney criteria. A member suggested for the KDPI greater than 85 percent group, 10-15 percent sclerosis should be a factor to transition to dual. A member explained that more details beyond the six or so criteria are necessary to decide on a kidney, and that in their experience, centers are willing to ignore bad biopsy results if the kidney is otherwise favorable. This member proposed having 20 percent sclerosis cutoff for

the KDPI 85 percent and up kidneys. The Chair asked if this is supported by the data and reminded members that this is one criteria of many. A member suggested using 15 percent sclerosis. Members discussed these three options. More centers might be willing to buy in to the policy if the number is higher. The Chair stated that 20 percent is a reasonable starting place, and then after implementation, acceptance data will be able to show if the cutoff needs to be higher or lower. The Workgroup moved to recommend a cutoff of at least one kidney with a biopsy showing sclerosis 20 percent or higher for the KDPI 85 percent and above group. A member asked if this could be added as an offer filter. Staff explained that offer filters are being worked on now by the Offer Filter Workgroup, and the criteria this Workgroup is focusing on is more aimed at determining when OPOs may start to allocate as duals.

A member asked how this would look from the OPO side. Staff explained that the criteria would not necessarily look like boxes to check off in the OPTN Computer System, but that an OPO could know that it meets the criteria and then switch over to dual. A member explained that automating this system may make it more efficient because of all the rules and factors for each organ. The Chair suggested having an alert in the OPTN Computer System when an OPO reaches the four-hour cutoff. Staff will discuss this with the service owners to see what is feasible from an information technology standpoint.

4. Closing Remarks

Staff stated that the Workgroup will finalize these discussions and begin discussing national kidney offers and the operationalization of the kidney minimum acceptance criteria screening tool in the next meeting. Staff thanked Workgroup members for their time and reminded them about the upcoming meeting on November 21, 2022.

Upcoming Meeting

- November 21, 2022

Attendance

- **Workgroup Members**
  - Valerie Chipman
  - Colleen Jay
  - Jillian Wojtowicz
  - Jason Rolls
  - Renee Morgan
  - Sharyn Sawczak
- **HRSA Representatives**
  - Jim Bowman
- **SRTR Staff**
  - Bryn Thompson
  - Jonathan Miller
  - Peter Stock
- **UNOS Staff**
  - Alex Carmack
  - Ben Wolford
  - Isaac Hager
  - Joann White
  - Joel Newman
  - Kayla Temple
  - Keighly Bradbrook
  - Kieran McMahon
  - Kim Uccellini
  - Lauren Mauk
  - Lauren Motley
  - Lindsay Larkin
  - Rebecca Marino
  - Sarah Booker
  - Stryker-Ann Vosteen
  - Thomas Dolan