OPTN Kidney and Pancreas Transplantation Committees
Utilization Considerations of Kidney and Pancreas Continuous Distribution Workgroup
Meeting Summary
November 21, 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 11/21/2022 to discuss the following agenda items:

1. Welcome and Announcements
2. Recap: Dual Kidney Data Review
3. Discussion: Dual Kidney Criteria

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

1. Welcome and Announcements

Staff welcomed the Workgroup. There was no further discussion.

2. Recap: Dual Kidney Data Review

Staff provided a recap on data regarding dual kidney and prior Workgroup discussions on this topic.

Presentation Summary:

The main goal of this discussion is to dual kidney discussion is to transition dual allocation to a continuous distribution framework while addressing inefficiencies in the current system.

Previously, the Workgroup supported a new framework where dual kidneys are allocated from a specific dual kidney match run. Specific criteria will dictate when an Organ Procurement Organization (OPO) *may* begin allocating kidneys as dual, and the specifics of these criteria are up for Workgroup discussion.

The dual-specific match run will include only candidates opted in to receive dual kidney offers, carry over a subset of specific candidate refusals from the original match run, and utilize offer filters consistent with the offer filters model.

Staff outlined the focus for this meeting as the factors that make a single kidney difficult to allocate and accept and recapped what the workgroup had previously agreed upon:

- Criteria may differ between Kidney Donor Profile Index (KDPI)
  - Separate KDPI categories into KDPI 35-59 percent, 60-85 percent, and 86-100 percent
  - Donors with a lower KDPI may need to meet more criteria than donors with a higher KDPI to begin allocating as dual
- Cold ischemic time (CIT) is a critical consideration
  - Donors KDPI 60-85 percent: OPOs may not allocate as dual until at least four hours post cross-clamp
  - Donors KDPI 86-100 percent: OPOs may not allocate as dual until after organ recovery (OR)

- Post-OR information, such as biopsy results, should be considered

Data Summary:

A review of all deceased donor kidney transplants from 09/05/2019 to 04/29/2022 showed the following trends in donor metrics, which the Workgroup reviewed in a prior meeting:

- Serum creatinine was similarly distributed across KDPI categories 35-85 percent and 86-100 percent
- Dual kidney donors are more likely to:
    - Be a DCD donor, especially in KDPI 35-85 percent
    - Have a history of diabetes
    - Have a history of hypertension, especially in KDPI 35-85 percent
    - Have kidneys biopsied, and when biopsied have higher glomerulosclerosis

3. Discussion: Dual Kidney Criteria

The Workgroup transitioned to discussing specific criteria to determine when an OPO may begin allocating kidneys as dual from a dual kidney match run.

Summary of Discussion:

A member asked if the criteria would be double-counting some factors, such as donation after cardiac death (DCD), which is already accounted for in KDPI calculations. Staff answered that KDPI is calculated by age, weight, history of diabetes and hypertension, cause of death, and more. A member answered that in their interpretation, it may be important to include DCD as a separate criterion from KDPI, particularly as not all DCD kidneys will have a high KDPI. The member explained it is important to account for the factors that may motivate an OPO to move to dual allocation that are not accurately reflected in the KDPI score. Staff also pointed out that KDPI uses binary attributes (such as a yes/no for history of hypertension), while the dual kidney criteria selected by the Workgroup could allow for more nuance (such as history of uncontrolled hypertension 5-10 years).

A member stated that it may be better to keep things simple and focus on criteria that are not already accounted for by KDPI, such as biopsy results and cold ischemic time. This member suggested that the 98-100 percent KDPI kidneys are able to move right to dual. Another member agreed, stating that KDPI 86-100 percent kidneys are already extremely hard to allocate. One member pointed out that there may be pushback from the kidney community, as some programs may want to accept these organs as single. The member added that including KDPI calculation factors separately from KDPI will allow dual allocation to be more dynamic and better account for kidneys across a KDPI spectrum for which dual allocation may be appropriate.

A member asked if the Workgroup was setting policy or suggestions for OPOs, and staff responded that the Workgroup recommendations will move forward as policy.

Staff asked the Workgroup to focus on what criteria make sense specifically for KDPI 86-100 percent kidneys. A member suggested adding estimated Glomerular Filtration Rate (GFR) based on creatinine levels to accurately reflect projected nephron mass. A member explained that biopsy results are useful in determining single versus dual allocation but was unsure of how routinely biopsies are performed. Staff answered that biopsy of kidneys is common and that knowing sclerosis levels is important for acceptance, but it may be complicated for OPOs working with more rural donor hospitals, who may not have access to pathologist to perform the biopsy read.

A member added that pump numbers should be considered for this group, and members discussed difficulties with obtaining pump numbers or poor pump compliance.

A Health Resources and Services Administration (HRSA) representative asked about usage of estimated GFR in the case of donors with acute kidney injury (AKI), sepsis, trauma, or another condition that may cause a donor to have lower initial GFR but ultimately resolve with recovery. A member answered that this is a question of which GFR should be utilized, and that more discussion is needed on this topic. Two members suggested that the GFR could be calculated in the OPTN computer system, not by the OPOs, to ensure standardization. Staff discussed difficulties in relying on GFR calculations, because these are in the process of being modified and controversial. Members agreed that GFR can be added to the list at a later date.

A member suggested that for the KDPI 86-100 percent kidneys, only one criterion must be met to move to dual to ensure that OPOs have adequate pathways to move to dual. Staff explained that, based on the current list of criteria, this could mean that KDPI 86-100 percent kidneys may only need to be post-recovery. Staff pointed out that biopsy and pump parameters may only be available post-recovery as well. A member voiced support for this idea, pointing out that dual allocation is most often a last resort for OPOs and that the pathway should be open for them to utilize it as such.

A member suggested that for KDPI 98-100 percent, OPOs may allocate as dual immediately after cross-clamp and for KDPI 86-97 percent, OPOs may move to dual post cross-clamp and having met one additional criterion.

A member suggested having a criterion be glomerulosclerosis greater than 20 percent to account for older patients with low nephron mass. A member agreed with accounting for these patients but suggested 10 percent glomerulosclerosis. Members discussed adding age, vascular changes, and anatomy as possible criteria. Anatomy-based criteria, such as color and plaque, may be difficult to include because they are subjective. A member suggested adding warm ischemic time (WIT) greater than 45 minutes for DCD donors.

A member suggested having a very generic criterion, such as “challenging to place kidneys” to allow for OPO flexibility. Staff explained that maximum OPO flexibility could look like only requiring KDPI 86-100 percent kidneys be clamped to move to dual. A member stated a concern that this may increase dual transplantation of kidneys that should have been placed singly. A member explained that in their experience, it is more work for OPOs to allocate as dual so OPOs will allocate as single whenever possible. This member stated that in the rare case that a center accepts an offer as dual but for some reason only actually transplants a single kidney, that the unused kidney should be released for reallocation. These members discussed issues surrounding patient consent for high KDPI kidneys and dual and how they differ by centers. Staff explained that OPTN policy requires written candidate consent to receive high KDPI kidney offers, but that programs can opt candidates into receiving dual kidney offers without initial written consent.

A member explained that the clearer the policy is, the better, because it will avoid escalation and exception pathways. A member asked about cases that would not fit into the “boxes” created by the criteria aligning with KDPI, such as a 40-year-old with a WIT of 90 minutes. Staff explained that establishing a wider set of criteria will allow for greater OPO discretion and help account for a greater number of donors.

The Workgroup concluded the discussion by agreeing on the following criteria for when an OPO *may* allocate kidneys from the following donors as dual kidneys:

- For donors KDPI 98-100 percent, once kidneys are cross-clamped (post-OR)
- For donors KDPI 86-97 percent, once kidneys are cross-clamped (post-OR) and meet at least one of the criteria below:
    - Biopsy showing glomerulosclerosis 10 percent or above

- Biopsy showing vascular changes moderate or severe
- DCD donor with WIT greater than or equal to 45 minutes
- Age 60 or greater

Upcoming Meeting

- December 7, 2022

Attendance

- **Workgroup Members**
  - Colleen Jay
  - Jaime Myers
  - PJ Geraghty
  - Renee Morgan
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Bryn Thompson
  - Jonathan Miller
- **UNOS Staff**
  - Alex Carmack
  - Ben Wolford
  - Carly Layman
  - Carol Covington
  - Joel Newman
  - Isaac Hager
  - Kayla Temple
  - Keighly Bradbrook
  - Kieran McMahon
  - Kim Uccellini
  - Lauren Motley
  - Lindsay Larkin
  - Rebecca Marino
  - Sarah Booker
  - Thomas Dolan
  - Stryker-Ann Vosteen
  - Tommie Dawson
  - Shavon Goodwyn