

**OPTN Kidney and Pancreas Transplantation Committees
Utilization Considerations of Kidney and Pancreas Continuous Distribution Workgroup
Meeting Summary
January 11, 2023
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 1/11/2023 to discuss the following agenda items:

1. Dual Kidney Criteria Discussion

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

1. Dual Kidney Data Criteria Discussion

Staff provided a recap on data regarding dual kidney and prior Workgroup discussions on this topic, and then the Workgroup worked to finalize decisions about dual kidney criteria.

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. This will allow greater OPO flexibility and ensure a more efficient system.

Staff outlined the focus for this meeting as finalizing Workgroup's recommended criteria and policy for when an OPO may begin allocating kidneys as duals.

Previously, the Workgroup agreed on eight total criteria for moving to dual kidney allocation:

- DCD donor
- Donor age 60 or greater
- Terminal serum creatinine greater than 1.5 mg/dL
- Cerebrovascular accident (CVA) as mechanism of death
- History of hypertension
 - History of controlled hypertension greater than 10 years
 - History of uncontrolled hypertension greater than 5 years
 - Unknown history of hypertension greater than 5 years
- Any history of diabetes or a hemoglobin A1C level (HbA1c) greater than 6.5 percent during donor evaluation or management

- Glomerulosclerosis greater than 10 percent on at least one kidney
- Renal biopsy findings of vascular changes moderate or severe on at least one kidney

The Workgroup also supported splitting KDPI categories as follows, with the KDPI 60-85 split based on clinical data.

- 98-100 percent
- 86-97 percent
- 60-85 percent
- 35-59 percent

The Workgroup also previously agreed on the following policy recommendations:

- Once cold ischemic time (CIT) is four hours or greater, OPOs may allocate as dual once the below are met:
 - Donors KDPI 98-100 percent: no additional criteria required
 - Donors KDPI 86-97 percent: 2 of the above criteria must be met
 - Donors KDPI 60-85 percent: 3 of the above criteria must be met

The Workgroup was asked to discuss several questions:

- What justifies the KDPI 98-100 percent split? Are these kidneys that much more difficult to allocate?
- What rationale justifies the KDPI 60-85 percent split?

Summary of Discussion:

One member noted that KDPI 98, 99, and 100 percent kidneys are incredibly hard to allocate. It was clarified that the OPO will not be required to switch to dual kidney allocation, but instead have the opportunity to begin offering dual at 4 hours or greater CIT. The member added that this is reasonable particularly because OPOs will not be required to offer dual at these criteria, noting that historically these kidneys are more likely to not be utilized. The Chair agreed that OPO autonomy to determine when to switch to duals after 4 hours CIT is the key. The Chair noted that the data previously presented did not have a clear line for the highest KDPI kidneys, but that from clinical and allocation experience, the highest KDPI kidneys are the most difficult to place. The Chair added that the 98, 99 and 100 percent KDPI distinction somewhat aligns with the highest distinctions used in calculated panel reactive antibody (CPRA) classifications, and so the kidney transplantation community is already familiar with these splits. The Chair added that this highest classification is split out so as to reduce any barriers to placing these difficult to place kidneys.

The Chair noted that the dual kidney transplant density data indicated a more natural distinction at KDPI 60 percent. The Chair added that KDPI 60 to 85 percent is a more natural split, justified by the data and the KDPI 85 percent distinction already designated in kidney allocation.

One member asked if the Workgroup evaluated the characteristics of kidneys previously placed as dual. The Chair explained that the Workgroup did evaluate this data, particularly specific to hypertension, diabetes, age and KDPI, and that this data played into the criteria the Workgroup has developed thus far. The Chair noted that the research did not get granular enough to justify the KDPI 97 to 100 percent split. The Chair added that if, as an OPO allocating these kidneys, they have interest in one kidney, they will continue down the single kidney match run regardless of whether the criteria has been met. If the OPO were to switch to dual allocation, they would run a new list, not just bypass.

One member offered a suggestion, wondering if it would improve community buy in to focus on the high KDPI organs first, which have greater rates of non-utilization. The member noted that it can be easy to get lost in the weeds, and that many surgeons may have fear of missing out on an offer. The member added that it may make more sense to take it one piece at a time. The Chair noted that this was a great point, but that continuous distribution will need to encompass some of these middle range KDPI kidneys for which dual allocation may also be appropriate to ensure utilization. The Chair added that the currently, dual kidney allocation occurs on the same match run as single kidney allocation, which reduces the efficiency of both single and dual kidney allocation. The Chair pointed out that, it is important for OPOs to have the option, and that it is better for the OPO to place two kidneys with two separate candidates than to place two kidneys as dual to the same candidate. The Chair noted that an OPO is not likely to place kidneys as dual if they have interest in single placement. The Chair reiterated that the OPO is not expected or required to switch to dual kidney placement once criteria is met, only that they have the option to.

Staff summarized the Workgroup's comments, with the justification for 60 to 85 percent based on the point at which there is an increasing density for dual allocation at around KDPI 60 percent. The justification for splitting out KDPI 98 to 100 percent is based on clinical and allocation experience. The Workgroup agreed. Staff asked the Workgroup if it justified to treat the 98 to 100 percent KDPI kidneys the same as 86 to 97 percent kidneys, knowing that those donor kidneys are likely to meet at least two of the listed criteria anyway.

One member asked if the OPTN could provide more granular data on the discard rate of the highest KDPI kidneys. The member noted that they believe those numbers would confirm the clinical and anecdotal experience. The member also noted that organs at greater longevity risk necessarily need faster allocation. The member pointed out that what is happening now is that the offer is too cold and too far away for the program to accept, even if they would have been interested in a dual kidney offer. The Chair agreed. The Chair noted that it may not be necessary to split out the highest KDPI group (KDPI 98-100 percent), particularly if it is going to confuse the community. The Chair agreed that it may be appropriate to leave the category as 86 to 100 percent KDPI with 2 criteria met, as those highest KDPI donors are so likely to meet at least two criteria any way. A member expressed support for this.

The Chair pointed out that OPOs are often prompted to move to dual kidney due to the transplant programs they speak to, who ask to receive the single offer as a dual offer. The Chair noted that the separation of KDPI 98 to 100 would give them the opportunity to move to dual kidney faster, which could make a difference.

One member suggested removing the cold ischemic time requirement from the highest KDPI kidneys, which would make them eligible for immediate dual kidney allocation. The Chair noted that previous discussion on this option resulted in some feedback that transplant programs may want to see the biopsy anyway before deciding to accept or decline on a single offer. The four hour time frame allows time for some single allocation and for the biopsy results to be returned. The member noted that the wait for biopsy results could become four hours of dead time, where the OPO cannot continue primary allocation. Another member comment that programs want to see the biopsies and potentially some early pump numbers. The member added that there can be dissonance between how surgeons talk about offer acceptance and the offers they actually accept.

Staff summarized the Workgroup's discussions, noting that the 98-100 KDPI category could be combined with the 86-97 percent KDPI category for the purposes of simplification, but that more granular data should be evaluated first. Staff shared data from the Kidney circles based distribution monitoring report, which showed higher non-utilization for KDPI 86 to 100 percent kidneys, but does not show more

granular data with respect to the highest KDPI. The Chair expressed support for more granular data. The Workgroup agreed.

Presentation summary:

For donors KDPI 35-59%, OPOs may allocate as dual once CIT is four or six hours or greater and at least one of the below criteria are met:

- Cortical necrosis present on both kidneys
- Fibrin thrombi present, greater than or equal to 10 percent on both kidneys
- Vascular changes moderate or severe on both kidneys
- Glomerulosclerosis 20 percent or greater on both kidneys
- Anatomy: presence of diffused petechiae
- Donor on dialysis
- Anuria, or urine output of 100ml or less in 24 hours during current hospital admission or in the course of donor management

The Workgroup was asked to discuss several questions:

- Should presence of diffused petechiae be included? This could be very subjective and may be difficult to define and measure, as well as ensure compliance for policy purposes
- Should the KDPI 35-59 percent criteria allow the OPO to allocate as dual once CIT is greater than or equal to four hours or six hours?

Summary of Discussion:

It was clarified that en bloc allocation is not considered dual kidney for the purposes of dual kidney allocation, and that en bloc allocation only applies to donors weighing less than 18 kilograms. These kidneys are allocated as if they were 0 to 20 percent KDPI kidneys, with masked KDPI because it's not accurate given their size, and their calculated KDPI doesn't align with their outcomes.

Staff asked about the inclusion of diffused petechiae.

One member shared that they are less practiced in utilizing dual kidneys for kidneys with potential acute kidney injury (AKI) that may not recover. The member agreed that diffused petechiae is a subjective criterion, but argued that biopsy results are also subjective and vary greatly. The member expressed support for dropping diffused petechiae as a criterion.

Another member noted that frozen biopsies can be subjective, but that OPOs obtain them anyway and that they are already used in the system. The member continued that people understand biopsies for what they are. The member agreed that petechiae may be too subjective of a criterion, and that other potential criteria like flush are equally subjective. The member agreed that diffused petechiae could be dropped from the list.

One member asked what options an OPO will have if they encounter a low KDPI donor with some other issue that impacts their kidney placement that this Workgroup did not foresee. The member suggested that policy include some kind of "escape hatch" for OPOs to move to dual allocation for donors with a series of declines. The member offered pointing to a specific point on a match run or allocation to say that once an OPO has not gotten any interest, they may start dual allocation at this point. The Chair agreed that this is reasonable. The Chair added that OPOs cannot currently offer dual kidneys in a timely manner, at least within policy. The Chair noted that this criteria allow OPOs the option to transition to dual kidney when they feel it is necessary and appropriate.

The Chair agreed with the removal of diffused petechiae.

The Chair remarked that OPOs should be allowed to move to dual kidney allocation at 4 hours cold ischemic time, in order to maintain consistency. The Chair added that it is important for dual kidney allocation to occur in a timely fashion, and that OPOs won't be thinking about dual kidney allocation if one kidney is already placed or if they have interest in single placement for the kidneys. The Chair noted that, for lower KDPI kidneys, they are likely to have interest by 4 hours cold ischemic time. Another member agreed. One member agreed, noting that consistency improves understandability. Others agreed.

The Chair also expressed support for providing OPOs the option to move to dual kidney allocation for any kidney at certain allocation benchmarks. The Chair added that there could be factors that the Workgroup hasn't thought of or that are revealed in new research, and that policy should be flexible enough to allow dual kidney allocation outside of this. Another member agreed, noting that OPOs should not be limited. The Chair remarked that the KDPI 35-59 criteria should be utilized to allow OPOs to allocate as dual once CIT is 4 hours or greater, but that OPOS should also have a separate point at which they can run the dual kidney list with no additional outside factors.

Staff summarized, noting that the Workgroup supports allowing OPOs to allocate KDPI 35-59 percent kidneys as dual once they meet one of the previously mentioned criteria and the CIT reaches 4 hours. The Workgroup also supports removing diffuse petechiae as a criterion.

Staff asked the Workgroup if the AKI-based criteria for KDPI 35-59 percent should apply to donors with a KDPI of 60 or greater. A member agreed that the AKI-based criteria would be relevant for the higher KDPI donors as well. Another member agreed, noting that these criteria should apply to all the higher KDPI donors and categories. The member added that the fewer categorizations the better. The Chair agreed, noting that a donor of any KDPI with one of these criterion would be concerning. The Chair pointed out that lower KDPI kidneys are extremely unlikely to have any of these, and are also unlikely to be biopsied anyway. The Chair suggested removing the KDPI aspect of these criterion, and instead allowing OPOs to offer donors kidneys as dual for any donor meeting at least one of these criteria, once CIT reaches 4 hours. Another member agreed. Staff noted that this would be a deviation from the current dual kidney policy. The Workgroup agreed that any donor who meets at least one of the AKI-based criteria could be allocated as dual kidney once CIT is at least 4 hours. One member pointed out that OPOs have an incentive to allocate both kidneys to separate candidates anyway. The Chair noted that it is incredibly unlikely for a KDPI 0-34 donor to meet of these criteria anyway, and if they did – it could be cause for significant concern.

One member asked if a KDPI 20 kidney with rising creatinine or evidence of purple changes would be biopsied, noting that OPOs are requested biopsy often. Another member pointed out that if the kidney is purple and creatinine is not normal, the KDPI will likely be much higher. The member added that if a biopsy is done anyway and concerning findings are found, the OPO would likely want the option to allocate as duals in order to avoid non-utilization. The member expressed support for allowing this criteria to apply to donors with any KDPI, once CIT reaches 4 hours cold. The Workgroup agreed.

A member wondered if the glomerulosclerosis criterion should be removed from the list. The member pointed out that a biopsy finding of 30 percent glomerulosclerosis on a 20 year old donor with a normal creatinine would likely be the result of a poor biopsy, not of some other concerning finding. The member continued that this would not be a reason to trigger dual kidney allocation. The member added that glomerulosclerosis is chronic and likely shouldn't be included in this list. The Chair noted that the OPO would still need to allocate for 4 hours, and that surgeons would tell them that soon. The Chair pointed out that it would be likely for the OPO to interest in at least one kidney if that were the case. The Chair added that it is important for OPOs to have the option to allocate as dual in case there are issues with single allocation. The member responded that the list should focus on AKI criteria, and

chronic indicators should be removed – such as glomerulosclerosis and vascular changes – as these indicators mean different things for older donors.

The Chair asked the Workgroup if they would be concerned about a KDPI 45 kidney that ends up having biopsy results with poor glomerulosclerosis and or vascular changes findings. One member responded that it matters who the donor is. For example, a 30 year old donor with type 2 diabetes for the previous 5 years would not likely actually have that much chronic damage. That result would be more believable on a donor with extended diabetes and no blood sugar control. The member explained that glomerulosclerosis findings in a kidney with no reason for chronic kidney disease or chronic kidney damage would likely be the result of a poor biopsy sample. The member added that it is less common for vascular changes to be misleading, but that donor context is very important. The member concluded that anomalous findings are more likely the result of poor biopsy sample or read. The Chair asked if others would agree. The member noted that a lot of surgeons are wary of any negative result or indicator, but that these two criteria do not align with AKI or AKI concerns. The member added that poor glomerulosclerosis or vascular changes results are poor likely to be poor quality biopsy than indication of any actual chronic damage for lower KDPI donors.

The Chair pointed out that an OPO who receives these results for a low KDPI kidney could be stuck allocating them as single kidneys despite having no interest if there is no option for dual kidney allocation. A member agreed, but noted that 4 hours is not necessarily sufficient time to rule out local interest in the single kidney offers. The Chair pointed out that this is earliest time the OPO could switch to dual kidney allocation, but that it is unlikely they would switch too early.

The Workgroup agreed to ask the Kidney Committee and community for their input on the inclusion of vascular changes and glomerulosclerosis in the criterion applying to any donor.

Upcoming Meeting

- January 25, 2022

Attendance

- **Workgroup Members**
 - Valerie Chipman
 - Colleen Jay
 - Jill Wojtowicz
 - Jason Rolls
 - Sharyn Sawczak
- **HRSA Representatives**
 - Jim Bowman
- **SRTR Staff**
 - Bryn Thompson
 - Jon Miller
- **UNOS Staff**
 - Kayla Temple
 - Thomas Dolan
 - Keighly Bradbrook
 - Kieran McMahon
 - Krissy Laurie
 - Lauren Motley
 - Lindsay Larkin
 - Austin Chapple
 - Sarah Booker
 - Carly Layman
 - James Alcorn
 - Joel Newman