**OPTN Kidney and Pancreas Transplantation Committees**
**Utilization Considerations of Kidney and Pancreas Continuous Distribution Workgroup**
**Meeting Summary**
**December 14, 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 12/14/2022 to discuss the following agenda items:

1. Dual Kidney Data Review and Finalize Dual Kidney Criteria

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

## 1. Dual Kidney Data Review and Finalize Dual Kidney Criteria

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

The Workgroup also supported splitting KDPI categories as follows, based on data and clinical experience:

- 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 criteria must be met
    - Donors KDPI 60-85 percent: 3 criteria must be met

Today, the Workgroup will focus on kidneys KDPI 35-59 percent. Currently, kidneys in this category are able to be allocated as dual, but a different set of criteria may be necessary. The eight previously identified criteria may cause the kidneys to already have a higher KDPI than 35-59 percent. In the last meeting, the Workgroup suggested that post-OR information may be more impactful, such as biopsy results, anatomical abnormalities, or surgical damage.

Summary of Discussion:

The Chair noted that biopsy results may be foundational for the lower KDPI kidneys to identify the reason that the kidneys will not function well on their own. She stated that it would be very helpful to see the reasons why lower KDPI kidneys were placed as duals, and that biopsy results are probably the most likely reason. If one kidney of a pair within the low KDPI range was surgically damaged or had an anatomic abnormality, the other kidney would have been already allocated as a single. The Chair asked if the CIT should be the same as for higher KDPI kidneys at four hours, or if the time should be extended. Staff noted that in the Workgroup's last meeting, six hours of CIT for KDPI 35-59 percent was suggested. The Chair suggested that a benefit of a longer CIT requirement for lower KDPI kidneys is that the OPO would try to allocate as single for longer. A member suggested that the two hours may not make too much of a difference, and the Chair agreed. Keeping the CIT at four hours would be consistent with the scheme of criteria for the other KDPI categories. The Chair explained that OPOs would still be able to allocate as single regardless of what CIT cutoff the Workgroup chooses, and that it would be unlikely for an OPO to want to jump immediately to dual allocation for lower KDPI kidneys.

A member stated that four hours may not be enough time to properly attempt single allocation, noting that four hours CIT does not equal four hours of allocation. The Chair and this member discussed centers accepting kidneys pending biopsy as a common practice, but that allocation behaviors vary from OPO to OPO. The Chair noted that it would be unlikely for an OPO to give up on single allocation for low KDPI kidneys because it would be easier to move to dual, and that the criteria the Workgroup is trying to decide on is simply when the OPO can run the dual list.

A member suggested six hours. The Chair summarized, stating that there may not be a difference between six and four hours. The Chair then transitioned discussion to the criteria that kidneys KDPI 35-59 percent will need to meet to go to dual allocation.

Staff showed a slide with some possible criteria the Workgroup may want to include and noted that standardized biopsy reporting fields are currently being added to the OPTN Computer Systems. The

Chair stated that it would be helpful to know the weights of the criteria included in KDPI. Staff showed the proposed biopsy data fields for entry into the OPTN Computer Systems to help Workgroup members decide on criteria.

A member suggested that any arterial changes more than mild are concerning and may be a reason to expedite. This member also stated that kidneys with cortical necrosis or fibrin thrombi are notoriously hard to allocate, and that glomerulosclerosis acceptance practices vary by center. Staff asked what level of cortical necrosis would be concerning to centers, and this member answered that any cortical necrosis is concerning. The Chair asked this member what level of fibrin thrombi would be concerning, and the member answered that fibrin thrombi over 10 percent is a potential decline reason.

The Chair explained that it might make sense to allow OPOs to allocate low KDPI kidneys with a condition that makes them less likely to be accepted, such as surgical damage, more quickly to minimize CIT. A member stated that surgical damage makes their center less likely to accept a kidney at all, regardless of single or dual.

The Chair asked if a DCD donor should be a criterion. A member stated that this depends on warm ischemic time (WIT), but that limitations in monitoring technology sometimes present difficulties in determining WIT and prompt centers to accept kidneys with a higher WIT on paper. A member stated that to them, it did not make sense to include DCD as a criterion for the low KDPI kidneys. A member asked how many centers do uncontrolled DCD recoveries, and several members stated that in their experience, it was rare.

The Chair asked if members felt that any specific anatomical abnormalities are good indicators of needing to move to dual. A member asked if horseshoe kidneys, two kidneys that are fused at the base, count as dual allocation. A member stated that they believed horseshoe kidneys are only ever allocated as duals. No members had ever heard of splitting horseshoe kidneys. The Chair stated that in this case, it would make sense to add this into policy so that horseshoe kidneys are able to be allocated as duals. A member asked if the candidates that typical recipients of dual kidneys are would also be typical recipients for a horseshoe. A member stated that they believed the candidate population would be similar. Staff stated that clarification may be needed as to how horseshoe allocation works under current policy.

A member stated that anatomy and surgical damage do not drive dual kidney allocation but that other factors that speak directly to kidney function do. One member stated that disseminated intravascular coagulation (DIC) on low KDPI kidneys could be a good indication to move to dual, but that that is usually a diagnosis made by the team receiving the kidney. A member agreed, stating that it is rare to read DIC on the report for a kidney in the OPTN Computer System as a potential receiving center, and that imaging and platelet counts usually signal DIC more than it is reported. A member suggested diffuse petechiae as a possible criterion, and it was added. Another member suggested poor pump numbers or a poor flush as criteria. Staff noted that in terms of policy, a specific qualifier would be needed for these attributes. A member added that the Workgroup could define pump parameters and that the kidneys would need to be on the pump for a specific amount of time, and the Chair agreed, noting that it is in the best interest of the OPOs to pump marginal kidneys if this is something that is included in policy. The Chair suggested looking at research to determine the specifics. A member suggested requiring the kidneys be pumped for at least three to four hours, with the flow less than 80 mL/min and the resistance higher than 0.4 mmHg/mL/min. This member stated, however, that for low KDPI kidneys with poor pump numbers, a problem with the pump may be to blame. The Chair noted that anything the Workgroup recommends will go out for public comment, allowing professionals and the public to weigh in.

A member stated that it is challenging to define when exactly it makes sense to move to dual. A member agreed, stating that the overall narrative donor is indicative of when to move to dual. The Chair responded, stating that the Workgroup is trying to make the policies make the most sense by dividing by KDPI. The Chair stated that the Workgroup may want to review the KDPI score calculations to further investigate criteria weighting.

A member stated that terminal creatinine does not tell the full story for a kidney because size of the donor also plays a role. The Chair stated that at six hours of CIT, OPOs would presumably have terminal creatinine, size of the donor, and age of the donor readily available and be trying to allocate as single. The Chair noted that OPOs would not wait until six hours to allocate.

A member suggested adding anuria to the list of criteria as it is written in the policy requiring procurement biopsy, and a member agreed. A member suggested similarly adding dialysis to the list, and it was added. The Chair asked if age should be on the list. A member described wanting to not make the criteria too complicated and suggested adding glomerulosclerosis to the list. Staff asked members if 10 percent glomerulosclerosis seemed reasonable, as indicated by relevant literature. A member stated that glomerulosclerosis is probably more impactful the higher the KDPI is and that it makes sense to have a higher requirement for lower KDPI kidneys. Members stated that biopsy results may be inaccurate and often do not tell the full story of kidney function.

A member suggested combining diffuse petechiae and fibrin thrombi into one criterion because they tell the same story about the kidney. The Chair suggested relying on fibrin thrombi greater than or equal to 10 percent rather than diffuse petechiae because diffuse petechiae will be difficult to qualify in policy language. The original member stated that including diffuse petechiae is important because it is a concerning finding.

Staff asked if the Workgroup felt comfortable moving forward with the initial list of criteria for KDPI 35-59 percent kidneys:

- Biopsy showing cortical necrosis on both kidneys
- Biopsy showing fibrin thrombi, greater than or equal to 10 percent, on both kidneys
- Anatomy findings of diffuse petechiae
- Biopsy showing vascular changes moderate to severe on both kidneys
- Biopsy showing glomerulosclerosis greater than 10 percent for both kidneys
- Donor on dialysis during hospital admission or during course of donor management
- Anuria: urine output of 100mL or less in 24 hours during hospital admission or during course of donor management

Members felt comfortable moving forward with this initial list, noting that edits or additions are likely needed.

The Chair asked members how many criteria from this list should be required for OPOs to move KDPI 35-59 percent kidneys to dual. A member stated that some criteria on the list, like cortical necrosis, are very rare. A member stated that any of these criteria alone would signal a need to move to dual. Initial consensus was reached to require one additional criterion to move to dual allocation.

**Upcoming Meeting**

- January 11, 2022

**Attendance**

- **Workgroup Members**
  - Valerie Chipman
  - Colleen Jay
  - Jillian Wojtowicz
  - Jaime Myers
  - Jason Rolls
  - Renee Morgan
- **HRSA Representatives**
  - Marilyn Levi
- **SRTR Staff**
  - Jonathan Miller
- **UNOS Staff**
  - Alex Carmack
  - Ben Wolford
  - Carol Covington
  - Kayla Temple
  - Keighly Bradbrook
  - Kieran McMahon
  - Kim Uccellini
  - Lauren Motley
  - Lindsay Larkin
  - Rebecca Marino
  - Thomas Dolan
  - Stryker-Ann Vosteen