OPTN Kidney and Pancreas Transplantation Committees
Utilization Considerations of Kidney and Pancreas Continuous Distribution Workgroup
Meeting Summary
December 7, 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 12/07/2022 to discuss the following agenda items:

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

Staff provided a recap on data regarding dual kidney and prior Workgroup discussions on this topic. The Workgroup discussed specific criteria to determine when an OPO may begin allocating kidneys as dual from a dual kidney match run.

Presentation Summary:

Staff explained that the goal of dual kidney discussion is to transition dual allocation to a continuous distribution framework while addressing inefficiencies in the current system. Dual kidneys appearing on the single kidney match run results in a match run lengthen the match run, resulting in inefficient allocation.

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.

Prior Workgroup discussions indicated a need for balance between having enough criteria so that allocation can begin swiftly where appropriate, and ensuring that single kidney allocation is adequately attempted. Staff explained the focus for this meeting as "casting a net" wide enough to capture most cases where dual kidney allocation would be appropriate, and then the Workgroup will "draw the net" to indicate the number of criteria that will be required for an OPO to move to dual allocation. The number of criteria may be different for different Kidney Donor Profile Index (KDPI). Staff showed some sample criteria to allow members to get a sense of what this might look like on paper.

Previously, the Workgroup identified the following criteria as important in dual kidney allocation:

- Cold ischemic time
- Warm ischemic time
- Biopsy showing vascular changes moderate or severe
- Donor age 60 or greater

Summary of Discussion:

A member asked if the Workgroup would be further discussing criteria such as hypertension and diabetes that may already be accounted for in the Kidney Donor Profile Index (KDPI) calculator. Staff explained that it might be most helpful to include any and all criteria that may be important at first, and then the Workgroup can pare down the list. The Chair noted that because KDPI does not break down hypertension and diabetes by number of years and controlled versus uncontrolled, it makes sense to include more stringent criteria relating to those factors. A member suggested using cutoff values that clinicians are already familiar with or criteria that are already in the OPTN computer systems when making these criteria.

The Chair stated that one criterion should be cold ischemic time of 4 hours. A member suggested terminal serum creatinine greater than 1.5 mg/dL. Members discussed what value makes sense for hypertension and initially landed on controlled hypertension of greater than ten years and uncontrolled or unknown history of hypertension greater than five years. A member asked if an unknown history of hypertension increases KDPI. Staff answered that unknown history of hypertension does increase KDPI slightly. After further discussing, the Workgroup decided to not include unknown hypertension with uncontrolled hypertension, because a history of hypertension would be evident in some of the other factors included in the list of criteria. The Chair noted that these values may need to be adjusted in future iterations.

Members discussed adding cause of death of cerebrovascular accident (CVA) as a criterion. For history of diabetes, members discussed alignment with clinical values already in use at transplant centers to aid centers with implementation and ways to gauge risk without necessarily knowing the history of diabetes. After discussion, members landed on having the criterion be any history of diabetes or unknown history of diabetes with a Hemoglobin A1c (HbA1c) value greater than 6.5 percent upon hospital admission or during donor management. A member suggested adding proxies for diabetes, such as protein in the urine or elevated blood glucose upon admission. The Chair stated that these criteria may be too complicated and that it may be better to rely on patient history and/or a hemoglobin A1C lab value to determine history of diabetes. A member added that this makes sense, because obtaining the hemoglobin A1c value is standard in donor management. The Chair added that it would be in the center's best interest to obtain the lab value when diabetes history is unknown.

The Chair pulled up kidney biopsy criteria to help inform discussion on dual kidney criteria. A member suggested using the same criteria as for kidney biopsy, such that if a donor meets the biopsy criteria and the kidneys have not been allocated as singles at the four-hour mark, that OPOs may move to allocation as dual. This member noted that the biopsy criteria are very similar to things the Workgroup had discussed for reasons to move to dual. Staff noted that some criteria for biopsy are not collected as OPTN data.

Staff asked if members would prefer specific biopsy information callouts to include on the dual kidney criteria list. The Chair indicated that specific biopsy results, such as vascular changes and glomerulosclerosis, should be included on the list.

Data indicates that glomerulosclerosis 6-10 percent kidneys are more likely to be allocated as dual. One member remarked that this seemed low in their experience. Members initially agreed on using biopsy results of glomerulosclerosis greater than 15 percent, noting that this is one criterion of many that OPOs can use to move to dual and that this number can be adjusted after public comment feedback. Staff pointed members to some relevant literature and noted that data may support a lower cutoff. The Chair described the importance of getting this number right, as many transplant centers accept organs pending biopsy. The criteria here would be what OPOs are allowed to do, keeping in mind that if they have centers that entered provisional yes, the preferred option would be to allocate the kidneys as singles. The Workgroup later agreed to include glomerulosclerosis greater than ten percent on at least one kidney as a criterion.

Another criterion that was added to the list was being a donation after cardiac death (DCD) donor.

The Chair and a member noted that when discussing these criteria, it is important to remember that until the four-hour cold time mark, the OPO would be allocating off the single match run, and that at the four-hour mark, it the OPO *may* begin dual allocation, but is not required to.

At the end of the discussion, the criteria for moving to dual kidney were as follows:

- Cold ischemic time greater than or equal to four hours (post-recovery)
- A DCD donor
- Donor age 60 or greater
- Terminal serum creatinine > 1.5 mg/dL
- History of hypertension
    - History of controlled hypertension greater than ten years
    - History of uncontrolled hypertension greater than five years
    - Unknown history of hypertension
- Any history of diabetes or HbA1c > 6.5 percent during current hospital admission or in the course of donor management
- CVA as cause of death
- Glomerulosclerosis greater than ten percent on at least one kidney
- Renal biopsy vascular changes moderate or severe on at least one kidney

The Workgroup then transitioned to discussing how many criteria should be required for each KDPI grouping. Staff reminded members that previously the Workgroup had agreed that for donors KDPI 98-100 percent, OPOs may move to dual immediately once kidneys are clamped and do not have to meet any additional criteria. Members discussed this, and recommended that for consistency and to ensure that OPOs attempt single allocation, it makes more sense to allow OPOs move to dual for KDPI 98-100 percent after four hours cold ischemic time. The Chair explained that the 98-100 percent KDPI grouping makes sense because those very high KDPI kidneys are challenging to place.

The Workgroup agreed that cold time of four hours or more should apply to all KDPI groupings and that the additional criteria would be required on top of that.

For 86-97 percent KDPI kidneys with cold time greater than or equal to four hours, a member suggested requiring two additional criteria. Other members agreed. Staff noted that candidates have to opt in to dual kidney and high KDPI kidneys, which further narrows the list. The Chair added that these candidates who opt in are usually diabetic or older.

A member asked if the OPTN collects data on how many candidates are willing to accept duals. Staff responded that they would check on this. The Chair added that there is an option to say no to duals upon listing, but that most centers check yes to duals for marginal candidates anyway. The original

member added that in their experience, centers don't consent patients for duals until there is a dual offer on the table.

For KDPI 60-85 percent kidneys, the Chair initially suggested requiring three additional criteria. A member stated that three sounded reasonable out of the seven total criteria. The Workgroup agreed that three is the appropriate number for KDPI 60-85 percent kidneys. The Chair emphasized that this still would be an OPO option, not a requirement.

A member asked how this would work operationally in the OPTN computer systems. Staff answered that the details are still being worked out from an information technology (IT) standpoint, but that it might make sense to have a more manual process to match existing functioning and not limit OPOs. However, this would be thoroughly discussed before any decisions are made.

The Workgroup began discussing criteria for KDPI 35-59 percent kidneys, and staff noted that under current policy, these kidneys are sometimes allocated as duals. A member suggested requiring more than three criteria. The Chair suggested extending the cold ischemia time and potentially requiring a high number of criteria. A member supported this idea. A member stated that if it is taking a long time to place a low KDPI kidney, there is a problem with the kidney, and the Chair suggested looking into data describing the problems typically associated with low KDPI kidneys allocated as duals.

The Chair explained that if some of the criteria on the list are met, the kidney would not appear in the low KDPI category anyway. A member suggested surgical damage, poor pump numbers, and anatomical abnormalities as potential reasons for low KDPI kidneys allocated as duals. The Chair noted these would need to affect both kidneys, otherwise one kidney would have been allocated already.

The Workgroup will continue to discuss this topic at their next meeting.

3. Closing Remarks

Staff thanked Workgroup members for their time and reminded them about the upcoming meeting on December 14, 2022.

Upcoming Meeting

- December 14, 2022

Attendance

- **Workgroup Members**
  - Valerie Chipman
  - Ajay Israni
  - Jillian Wojtowicz
  - Jason Rolls
  - Sharyn Sawczak
  - Renee Morgan
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Bryn Thompson
  - Jonathan Miller
  - Peter Stock
- **UNOS Staff**
  - Alex Carmack
  - Kayla Temple
  - Keighly Bradbrook
  - Kieran McMahon
  - Joann White
  - Lauren Motley
  - Lindsay Larkin
  - Sarah Booker
  - Thomas Dolan