OPTN Kidney and Pancreas Transplantation Committees
Utilization Considerations of Kidney and Pancreas Continuous Distribution Workgroup
Meeting Summary
January 25, 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 1/25/2023 to discuss the following agenda items:

1. Dual Kidney Finalization Discussion
2. Introduction: Kidney Minimum Acceptance Criteria Screening Tool

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

1. Dual Kidney Finalization Discussion

Staff provided a recap of prior Workgroup discussions on dual kidney and presented additional data related to dual kidney transplant density. The Workgroup continued discussions to finalize decisions about dual kidney criteria.

Presentation Summary:

The main goal of this 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 Workgroup agreed that, for donors of any Kidney Donor Profile Index (KDPI), OPOs may allocate the kidneys as dual once cold ischemic time (CIT) is four 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 also previously agreed on the following policy recommendations, such that once cold ischemic time (CIT) is four hours or greater, OPOs may allocate as dual once the below are met:

  o Donors KDPI 98-100 percent: no additional criteria required
  o Donors KDPI 86-97 percent: two of the below criteria must be met
  o Donors KDPI 60-85 percent: three of the below criteria must be met

The Workgroup agreed on eight specific criteria to qualify donors with a KDPI 60 percent or greater as eligible for 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
- 35-59 percent

The Workgroup reviewed additional data regarding dual and single kidney transplant density as shown in **Figure 1**.
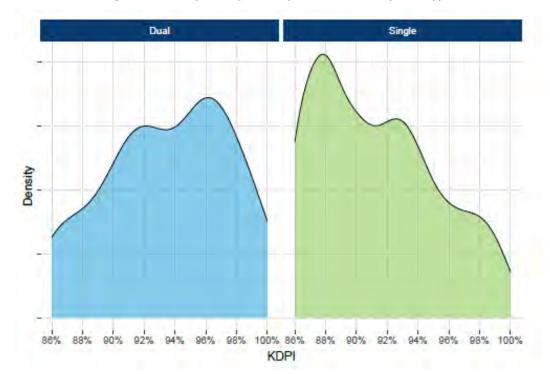
Figure 1: Kidney Transplants by KDPI and Transplant Type

Summary of Discussion:

One member noted that the data shown generally supports the highest KDPI split, but that the figures show a decline at 96 percent KDPI. The member added that the data also shows a decline in transplant density for single kidneys from 92 percent KDPI and greater. The Chair pointed out that the data in **Figure 1** is based on kidneys that were successfully transplanted. The Chair noted that dual kidney allocation is intended to reduce or prevent non-utilization, and that kidneys may be under-utilized in the highest KDPI range. The Chair added that it makes sense for these organs to be offered sooner in order

to encourage utilization. The Chair agreed that 95 or 96 percent KDPI may be a more appropriate cut off based on this data.

A member pointed out that it it may be easier to get consensus with the current KDPI categories. The member emphasized the fear of missing offers that often exists in transplant programs, who may say they are interested in transplanting these kidneys singly but may not actually be doing so. The Chair pointed out that the OPO *may* allocate these kidneys as dual, and would not be required to. The Chair continued that changing the KDPI cut off to 96 to 100 percent KDPI would only make it slightly easier for OPOs to allocate those kidneys as dual. The member agreed, adding that this could still have consensus.

The Chair pointed out that most of the highest KDPI kidneys are likely to hit one or two of theeight relevant criteria, particularly by four hours post-clamp.

One member noted that, in reviewing the data in terms of which kidneys could have been utilized as dual instead of not utilized, the cut off could be closer to 88 or 90 percent KDPI. This would align with the decline in single kidney transplant density shown in **Figure 1**. The member described the continuous fall from 88 percent to 100 percent KDPI, with no natural break point.

The Chair asked the Workgroup if they still felt that the highest KDPI should be separated out. The Chair asked what the likelihood would be that a KDPI 90 percent donor would not meet at least two criteria, and asked if there is a need to separate out the highest KDPI donors. A member responded that they didn't think there was a need to separate it out, particularly as some of these criteria filter into KDPI anyway. The member added that there may be a benefit to a simpler, more condensed policy. Another member agreed that it may not be necessary to introduce new KDPI thresholds. Another member agreed that consistency would be better.

The Chair asked if the highest KDPI thresholds should be combined, such that a donor KDPI 86 to 100 needs to meet two criteria. The Chair asked if only one criteria should be met instead. The Chair agreed that the data shows a decline in utilization for single kidney closer to 88 or 90 percent KDPI, which is not much higher than KDPI 86 percent. A member responded that the requirement should be KDPI 86 to 100 and meeting two criteria. The member added that it was likely the highest KDPI kidneys would meet at least two criteria anyway. The member noted it should remain two criteria, as KDPI 86 to 100 percent is a large category, and a KDPI 86 is very different from a KDPI 98. The member added that it only makes sense to separate out the highest KDPI category if trying to encourage OPOs to move to dual allocation as fast as possible.

One member expressed support for condensing the highest KDPI thresholds and reducing criteria, such that the donor only needs to meet one criterion between KDPI 86 and the upper threshold.

Staff asked the Workgroup where the upper threshold should be. One member pointed out that the data shows an inflection between 88 and 90 percent KDPI. The member recommended that the Workgroup shift the threshold from KDPI 98 percent to 96 percent if they choose to maintain the highest threshold, which does not require the donor to meet any additional criteria. The member added that, if the highest category was combined to create a KDPI 86 to 100 category, then additional criteria should be met, as there is wide variation in medical complexity and organ quality in that category. The member pointed out that this is transplant density data, so there are still more single kidneys being transplanted than dual.

Staff asked the Workgroup if they would support splitting the KDPI thresholds into KDPI 86 to 95 and 96 to 100 percent, based on the data shown. The Chair remarked that the highest threshold could be 90 percent KDPI based on the data, but that it may be better to simply leave the KDPI category as 86 to 100 and require the donor to meet at least two criteria. The Chair added that the highest KDPI donors are

likely to meet at least two of the criteria chosen, and that it is preferable to simplify as much as possible. Other members agreed.

The Workgroup achieved consensus to condense the highest KDPI classifications, such that an OPO may allocate both kidneys as dual from a donor KDPI 86 to 100 if they meet at least two criteria and are four hours post-cross clamp.

One member noted that the KDPI 60-85 group needs to meet three criteria, and wondered if the acute criteria may be more applicable for this group. Staff shared that previously the Workgroup decided to split the KDPI 35-85 category into two groups, noting that the lower end of that group was unlikely to meet the chronic criteria. The Workgroup developed separate criteria that may be more applicable for dual kidney for lower KDPI donors.

A member remarked that the diabetes criterion could be too broad, and may ultimately apply to too many kidneys. The member shared that they have seen extreme hemoglobin A1c labs in both directions – patients with chronic diabetes may have just received a high volume transfusion and thus present with a normal hemoglobin A1c, while another patient who seems relatively healthy will have an extremely high A1c. The Chair explained that donors with a KDPI of 60 or greater will need to meet at least two or three criteria, and the cold ischemic time will need to be at least four hours. The Chair continued that, at four hours cold, an OPO will have had the opportunity to make offers. If the OPO has not yet found the appropriate candidatefor either kidney as single kidneys at four hours cold ischemic time, they may choose to offer duals if the donor meets the criteria. The Chair pointed out that donors for whom the hemoglobin A1c meets criteria but is not concerning will likely already have interest at four hours cold. Another member added that some programs may only focus on the KDPI of the kidney being offered versus the full anatomical profile. The Chair pointed out that the cold ischemic time requirement will help ensure OPOs have made some offers, and that the cold ischemic time requirement provides some balance to the overall criteria.

Staff asked the Workgroup about the hypertension criteria and related timelines. The Workgroup agreed that hypertension timelines should be:

- History of controlled hypertension greater than or equal to 10 years
- History of uncontrolled hypertension greater than or equal to 5 years
- History of hypertension greater than or equal to 5 years, unknown if controlled

2. Introduction: Kidney Minimum Acceptance Criteria Screening Tool

Staff introduced the Kidney Minimum Acceptance Criteria (KiMAC) screening tool and answered questions. The Workgroup provided insight on how the KiMAC could be best transitioned into a continuous distribution framework.

Presentation summary:

The Kidney Minimum Acceptance Criteria (KIMAC) provides screening at the transplant program-level and is applied to "national" offers by the OPTN Contractor "National" offers are defined as offers made to candidates outside of 250 nautical miles of the donor hospital. This distance acts as a surrogate for "hard to place." The KiMAC is not applied to high calculated panel reactive antibody (CPRA) candidates or 0-ABDR mismatch candidates.

Transplant programs provide information about the kinds of offers they want to receive from more than 250 nautical miles away for their non-CPRA, non-0-ABDR mismatch candidates in the OPTN Waitlist System under "kidney program minimum" criteria. When the OPTN Contractor runs the KiMAC, the tool

will take this data and apply bypasses for programs who have indicated they would not accept and do not want to consider those donor kidneys.

In a continuous distribution framework, there will not be a clear "national" allocation. The OPTN Kidney Pancreas Continuous Distribution Workgroup determined that, because of this, OPOs will no longer be required to contact the Organ Center for assistance in allocating kidneys at a "national" level. As a result, however, the Organ Center will not always have an opportunity to apply this screening tool. The KiMAC tool will need to be transferred over to broader use in order to maintain efficiency on long match runs and avoid any increase in offers programs have indicated they are not interested in accepting. Application of the tool will need to be consistent across match runs and donors, and may need to mirror its existing state as close as possible.

Currently, the Organ Center manually enters screening criteria into the tool based on their knowledge of the donor and conversations with the host OPO. The tool exists separately from the donor record and does not update donor data. The KiMAC is applied after the match is run, and applies bypasses to all applicable candidates on the match at once. The KiMAC currently only updates if the OPTN Contractor updates the data entered and reapplies it to the match run. The KiMAC is applied at the following classifications:

- KDPI 0-20 percent: National pediatrics, after all inside circle candidates
- KDPI 20-34 percent: National pediatrics, after all inside circle candidates
- KDPI 35-85 percent: National candidates, after all inside circle candidates
    - Inside circle dual kidney candidates are not bypassed by the KiMAC tool
- KDPI 86-100 percent: National candidates, after all inside circle dual kidney candidates

In a future state, the KiMAC screening should be consistently applied across OPOs, donors, and matches. The Workgroup will later discuss how this screening can be integrated into the offer process, including potential integration into the electronic notification workflow. The Workgroup will also need to discuss new data collection in OPTN Donor Data and Matching System in order to capture information relevant to KiMAC screening.

Summary of discussion:

One member asked how KiMAC differs from offer filters, and asked if the KiMAC filters could be folded into the offer filters tool utilizing a distance factor as part of the filters. Another member agreed, noting that there are multiple different screening and filtering tools that a transplant program is responsible for. The member added that their program annually revisits their KiMAC responses, and that this is potentially redundant with the offer filters. The member commented that this redundancy indicates the potential to consolidate and streamline the offer filters tool, particularly as the "national" distinction goes away. The member recommended folding the KiMAC and offer filters tool into one system.

A member noted that the goal is to eventually require offer filters, and asked if that would be the primary filtering mechanism rather than KiMAC. Another member remarked that mandatory offer filters would involve utilizing historical program behavior to create a slightly looser filter, which would allow for slight deviations in the aggressiveness of program behavior.

One member agreed that KiMAC and offer filters are very similar and that there could be efficiency in streamlining, but that there could be significant allocation efficiency lost in doing so, particularly while KiMAC is mandatory and offer filters is not. The member noted that relying only on offer filters would leave OPOs in a situation where they are required to offer kidneys to a greater number of programs who are not interested in accepting them.

Staff presented a table explaining the difference between the KiMAC, Offer Filters, and Waitlist Acceptance Criteria, noting that each screening and filtering tool is applied differently and captures different information. Staff explained that the KiMAC screening may not be easily folded into offer filters, as this would require multiple long multi-factorial offer filters that include organ quality, distance, and candidate exclusion criteria. One such filter could be: "Filter kidney offers if KDPI greater than 50 percent *and* distance is greater than 250 nautical miles *and* donor age is greater than 60 years <u>unless</u> candidate is a 0-ABDR mismatch *or* candidate has a CPRA of 80 percent or greater."

Table 1: KiMAC vs. Offer Filters vs. Acceptance Criteria

KiMAC	Offer Filters	Acceptance Criteria
Answered on the program level	Answered on the program level with candidate-based exclusion criteria	Program defaults, but customizable candidate by candidate
Describes the minimum kidney donor that the program will accept for national offers	Describes the kidney donors that the program will <u>not</u> accept	Describes the kidney donor that the *candidate* will accept
TXCs are required to provide answers and update yearly	No requirement for use at this time – this may change in the future	Required fields on each candidate record
Applied *after* match is run before national offers are made	Applied and updated as offers are sent out	Applied when match is run
Applies as bypass	Applies as bypass (886)	Screens candidates from the match (candidates do not appear on match run)
Applied for offers *outside* 250 NM; excludes "top of the match" candidates	Applies to all offers unless the candidate meets the filter exclusion criteria	Applies to all matches

One member asked how OPOs are able to visualize the different screening tools at work. The Chair explained that one difficulty from the OPO perspective is that transplant programs have wide variation in their practices, with some programs casting their filter nets too wide out of the fear they will miss an offer, while at the same time not actually accepting those organs. The Chair explained that this results in a long match run with many programs that are not interested in the kidney – but who contribute to the cold ischemic time of an organ in asking to receive an offer they would not genuinely consider accepting. The Chair pointed out that having filtering and screening tools that apply at different points – such as when the match is run and after the match is run – can be helpful, but that these tools could eventually be streamlined. The Chair noted that the Waitlist Acceptance Criteria is important because it screens patients off the match run for an organ they would not accept, which reduces the match size and increases efficiency. The Chair explained that, at some point, OPOs know which centers are aggressive and will offer kidneys to those centers to avoid non-utilization. The member explained that placing kidneys aggressively like that should be avoided as much as possible.

One member recommended condensing the KiMAC and offer filters tool into one tool, in which each center could set inclusion and exclusion defaults for the whole center, and then utilize the Waitlist Acceptance Criteria to set patient specific parameters. The member noted that too many bypasses is unnecessary, and results in visual clutter when looking at long match runs. The member asked if such an option was within scope for the Workgroup, or if the Workgroup will need to focus on working with the current tools and optimizing them. Staff noted that, for now, the Workgroup's scope for the first version

of continuous distribution will be to optimize and transition the KiMAC tool into a continuous distribution framework. Staff noted that Workgroup feedback on how to streamline filtering and screening is being noted and recorded.

The Chair asked if, knowing that the KiMAC is available, whether there would be a need for the KiMAC tool if offer filters were appropriately used by transplant programs. The Chair asked if the two tools are similar enough in the questions they ask that one tool could be eliminated. The Chair recommended ensuring that all of these criteria are included in the offer filters tool and make the KiMAC criteria a mandatory part of the offer filters tool. The Chair added that this would consolidate the filtering mechanisms. Staff explained that there are key differences between the KiMAC and offer filters tool, and that the answer to that would be based on how well programs know their own behavior. Staff continued, explaining that offer filters are multifactorial, and that transitioning the KiMAC questions into offer filters would require a large series of complicated multifactorial filters in order to approximate the KiMAC's application. Staff added that offer filters are more nuanced and detailed, and to approximate the KiMAC in offer filters would ultimately be more time consuming and difficult for programs. Staff pointed out that another consideration is that there are the criteria on the KiMAC that are not currently collected in the OPTN Donor Data and Matching System, and will need to be added. Staff further explained that the Workgroup will need to determine which criteria to carry over into continuous distribution. Staff pointed out that the offer filters tool also applies across a broader range of kidney donors and most of the match run, while the KiMAC applies over only a portion of the match run and at a point where the OPO has allocated to all programs within 250 nautical miles. Staff concluded that though the two tools are similar, KiMAC and offer filters are capturing a different pool of donors and the questions asked are slightly different.

The Chair noted that some of these criteria could be folded into the Waitlist Acceptance Criteria, and be applied when the match is run. The Chair remarked that it wastes time to put candidates on the match run if the system knows the candidate will not accept these kidneys. Another member agreed, and asked why the system utilizes the bypasses as opposed to screening off the match run. The member asked if the bypass codes waste time for the OPO, or if the OPO simply sees the bypasses apply to the match run. The Chair explained that the OPO can see the bypasses on the match run, but that it does waste time for the OPO professionals. The Chair noted that applying a lot of bypasses also introduces potential for error, where OPOs may miss a non-bypassed candidate on a long list of bypasses. The Chair recommended reducing that potential for error by reducing the patients appearing on the match run as much as possible, which can be done by frontloading some of the waitlist criteria screening. The Chair also recommended focusing on screening candidates from appearing on the match run where possible, and applying bypasses based on information that becomes available after the match is run. The Chair recommended that offer filters provided the candidate-specific flexibility as well.

Another member agreed that expanding the Waitlist Acceptance Criteria is beneficial because it is patient specific, which allows clinicians to make decisions for the individuals. The member agreed that efficiency should incorporate screening where possible. The member also supported mandatory offer filters, particularly since the match runs are extremely long and complicated. The member added that utilizing screening and filtering means that programs receive fewer offers they are not interested in. The Chair added that there is a benefit as well for programs to receive the offers they are interested faster, with fewer not interested programs and candidates who will receive and decline the offer before the programs and candidates that would accept.

The Chair explained that calling centers, talking to coordinators, and waiting for coordinators to calling their surgeons can be time consuming. The Chair added that eliminating or limiting as many of those interactions as possible in the interest of allocating the kidney to the program and candidate who will

ultimately accept the organ, noting that this is beneficial for both programs and OPOs. The Chair remarked that it is important to be sensitive to programs who are concerned about missing potential offers, and that this can be addressed by incorporating flexibility with patient-specific Waitlist Criteria and efficiency focused offer filters.

A member pointed out that the global problem is less that OPOs are offering to centers who have indicated they are not interested in such an organ, and more that programs are reluctant to indicate aggressive enough filters. The member shared that their program is aggressive, with an observed acceptance rate that is double their expected acceptance rate; despite this, their program is still turning down 80 percent of offers based on the nature of kidney offers. The member noted that their program may underutilize offer filters, but offer filters has yet to incorporate critical nuance about expected travel times, which vary based on where the kidney is. The member added that there are many interacting factors and that acceptance decisions are very patient-specific. The member also noted that expecting programs to constantly keep filters updated for each patient based is not realistic, particularly as patient information is ever changing. The member noted that it would be incredibly difficult to keep up with. The member shared that their program evaluates their patients on each pre-organ recovery match run ahead of time, and that this practice encourages efficiency. The Chair agreed, noting that anything requiring programs to go in and make updates to their existing waitlist population is challenging, and that filtering and screening requirements will need to take that into consideration. Another member agreed, and expressed support for the practice of programs reviewing all of their candidates that appear on the match run. The member shared that some programs in their area have this practice, and are able to quickly code out for patients they would not accept the organ for and perform a virtual crossmatch for patients they would be interested in accepting for. The member noted that this practice greatly improves allocation efficiency. The member explained that other programs evaluate and code out for their candidates individually, which significantly delays allocation, with detrimental impact to the organs and the programs that ultimately accept them. The member added that this ultimately hurts other programs the most.

One member expressed support for the offer filters concept, and recommended that offer filters include some kind of filter for parity of KDPI and patient estimated post-transplant survival (EPTS), or some sort of donor-recipient matching. The member explained that programs have to code out offers from higher KDPI donors for patients that are not appropriate recipients. The member concluded that offer filters could eliminate some of these offers.

Upcoming Meeting

- February 8, 2022

Attendance

- **Workgroup Members**
  - Valerie Chipman
  - Colleen Jay
  - Jason Rolls
  - Sharyn Sawczak
  - Renee Morgan
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Bryn Thompson
  - Jon Miller
- **UNOS Staff**
  - Kayla Temple
  - Thomas Dolan
  - Keighly Bradbrook
  - Kieran McMahon
  - Kim Uccellini
  - Krissy Laurie
  - Lauren Motley
  - Lindsay Larkin
  - Alan Nicholas
  - Ben Wolford
  - Carly Layman
  - Carol Covington
  - Joel Newman
  - Mariah Huber
  - Melissa Lane