OPTN Kidney Transplantation Committee
Meeting Summary
May 23, 2023
Teleconference

Martha Pavlakis, MD, Chair
Jim Kim, MD, Vice Chair

Introduction

The Kidney Transplantation Committee (the Committee) met via teleconference on 5/23/2023 to discuss the following agenda items:

1. Welcome and Announcements
2. Released Organs
3. Kidney Minimum Acceptance Criteria
4. Dual Kidney

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

1. Welcome and Announcements

Committee Leadership welcomed the Committee members. Staff announced they were seeking committee volunteers to review data definition updates and confirm for clinical accuracy. These data definition reviews will be ad hoc.

Staff also reviewed an update to the timeline for the continuous distribution project. The *Continuous Distribution of Kidneys* proposal is now expected to be released for public comment in January of 2024. For the July 2023 public comment cycle, the Committee will release a request for feedback on operational topics.

Summary of discussion:

Two committee members volunteered to review data definition updates. There were no questions or comments.

2. Released Organs

The Committee reviewed recommendations on operational topics from the Utilization Considerations of Kidney and Pancreas Continuous Distribution Workgroup (the Workgroup), beginning with their recommendations on released organs.

Presentation Summary:

The Utilization Considerations Workgroup's (the Workgroup) focus is on the aspects of kidney and pancreas allocation that fall outside of the composite allocation score but require modification in order to transition to a continuous distribution framework. The Workgroup's goals are to map current policy to a continuous distribution framework with minimal changes to current operational requirements. Most new policy considerations or substantial changes to current policy and operational requirements are out of scope for the Workgroup but may be considered with future iterations of continuous distribution.

One of the topics discussed by the Workgroup was allocation of released kidneys and pancreata. For released pancreas, kidney-pancreas, and islets, the Workgroup recommended maintaining existing policy, meaning the host OPO may continue allocation according to the original match run, or allocate to a transplant candidate at the transplant program that originally accepted the organ.

For released kidneys, the Workgroup also recommends maintaining current policy of giving the host OPO the option to continue down the original match run or use a released kidney match run, which uses the current location of the kidney as the center of the allocation circle. Additionally, the Workgroup recommended incorporating an increased proximity efficiency weight for released match runs. Finally, the Workgroup also recommended carrying over certain refusals from the original match run to a released match run to increase efficiency of released organ allocation.

The Committee then reviewed a draft list of refusal codes recommended by the Workgroup to be carried over from an original match run to a released match run, including:

- Organ size, organ preservation, organ anatomical damage or defect, warm ischemic time, biopsy results, organ specific test results
- Candidate specific refusal reasons
- Histocompatibility related refusal reasons, excluding "no donor specimen for crossmatching"
- Disease transmission risk reasons
- Donor specific reasons, such as medical history, instability, prolonged CPR

The Workgroup requests further feedback from the Committee on whether refusals for "Other, specify" should be carried over to the released kidney match run.

Summary of discussion:

Committee members expressed support for the Workgroup's recommendations. For the "Other, specify" refusal code and whether that should be carried over to a released organ match run, a member supported carrying over the code. Another member asked what the code is typically used for. Staff responded since this is an open text field, the responses vary greatly and some programs are using this code as a default catch all. A member commented programs are likely using this code to refuse the offer for all candidates at their program. Another member agreed and commented in their experience, this code is often selected and filled out with a combination of concerns with the donor organ. Another member supported carrying over the code. The Committee was informally polled and unanimously supported carrying over the "Other, specify" code to a released kidney match run.

3. Kidney Minimum Acceptance Criteria

The Committee reviewed the Workgroup's recommendations on kidney minimum acceptance criteria screening.

Presentation Summary:

The Kidney Minimum Acceptance Criteria screening tool (KiMAC) provides screening at the transplant program-level and is applied to "national" offers by the Organ Center, excluding high CPRA and 0-ABDRmm candidates. Transplant programs are required to provide information annually about the kinds of offers they want to receive. This information is used to determine which programs should be bypassed when the KiMAC is applied.

In continuous distribution, kidney allocation will no longer have distinct "national" offers and OPOs will no longer be required to hand over allocation of these types of kidney offers to the Organ Center. The KiMAC tool will need to be updated for OPO use to ensure consistent application across match runs, maintain efficiency, and avoid an increase in unwanted offers. Ultimately, the goal is for filtering and

screening tools to be streamlined into one easy to use system for transplant programs and OPOs. However, this will require a phased approach and the current scope is to determine how to best transition the existing KiMAC tool to a continuous distribution model in order to maintain efficiency. The KiMAC tool will operate alongside Offer Filters and Acceptance Criteria. Some streamlining can be achieved initially in determining which criteria will be used by the KiMAC tool to screen and apply bypasses.

The KiMAC cannot be folded into Offer Filters at this time because:

- KiMAC is currently required for use by all transplant programs, while Offer Filters remains optional
- KiMAC provides a different, specific level of screening by applying only to the final classifications on the match run, for candidates outside of 250 NM
- The specific point on the match run at which KiMAC applies denotes that the organ is likely much harder to place, as many programs will have declined by this point

Table 1: Screening and Filtering Tools

Efficiency Tool Characteristic	KiMAC	Offer Filters	Kidney Donor Acceptance Criteria
What level of screening does this tool provide?	Screening questions answered based on program-level preferences	Screening questions answered based on program-level preferences, with ability to indicate candidate-based exclusion criteria	Screening questions answered by default with program-level preferences, but customizable candidate by candidate
What is the screening question being asked?	What is the minimum kidney donor characteristics that the program will accept for "national" offers?	What types of kidney donors will the program not accept?	What types of kidney donors will the candidate accept?
Is the tool required for use?	Transplant programs are required to provide responses to the questions and update annually	No requirement for use at this time	Transplant programs are required to provide responses to these fields on each candidate record
When is the tool applied?	Screening is applied *after* match is run, but before national offers are made	Screening is applied and updated as offers are sent out	Screening is applied when the match is run
How does the tool apply?	Applies as bypass	Applies as a bypass	Screens candidates from the match

			(candidates who would not accept the donor do not appear on the match run)
What offers does the tool apply to?	Applied for offers to candidates *outside* 250 NM; excludes 0-ABDRmm and 100 percent CPRA candidates	Applies to all offers unless the candidate meets the filter exclusion criteria	Applies screening to all matches, prior to offers being sent

The KiMAC tool will be automated in the continuous distribution framework, and will pull information directly from the donor record to apply bypasses to appropriate candidates based on program criteria selections and updated application rules. Transitioning the KiMAC tool in a continuous distribution framework will involve several elements, including:

- Determining how the tool is applied, or the logistics of OPO application (Automation, electronic notification workflow, applied via clicking a button, etc.)
- Determining who the KiMAC should apply to – how can we define "hard to place" in a continuous framework?
- Determining which screening elements should be carried over into the future state (Identifying which elements are already collected in Donornet, and which will require new data collection)

In considering where the KiMAC should apply, the Utilization Considerations Workgroup considered several potential options. After thorough discussion, the Workgroup's recommended approach is to apply the KiMAC tool at a certain percentage of the match, excluding candidates within 250 NM and 100 percent CPRA candidates. This approach approximates a definition of difficulty in placement based on placement metrics, meaning a certain percentage of the match run has been offered to and declined without successful placement of both kidneys. Using a percentage of the match run also dynamically adjusts for difference in geography and other factors influencing match size.

The Workgroup reviewed historical data on current KiMAC application, and determined the KiMAC tool should not apply to the first eight percent of the match run. Therefore, the Workgroup recommends applying the KiMAC tool once eight percent of the match has declined the offer, and will only apply to candidates at programs who have indicated they will not accept such donor organs. Additionally, the KiMAC tool would not apply to candidates at programs within 250 NM or 100 percent CPRA candidates.

Summary of discussion:

The Committee discussed the Workgroup's recommendations. A member commented they support the ultimate goal of attempting to consolidate existing offer filters and screening into one tool and commented there should be more effort to make Offer Filters better for transplant programs. Staff commented some elements of the KiMAC's application rules, such as application outside of 250 NM and exempting certain candidate populations, can be recreated with the use of multi-factorial filters. However, this would require a significant number of complicated filters that could be burdensome to programs. The Workgroup discussed this as well, and noted that this could reduce efficiency provided by screening, particularly while use of Offer Filters is currently voluntary. Furthermore, the Offer Filters

utility cannot duplicate target screening for "hard to place" kidneys provided by KiMAC's application to candidates in the final kidney allocation classifications. The Vice Chair commented consolidating these tools would make it easier for programs. The Vice Chair also commented there should be more consideration for risks on the recipient side with these "hard to place" kidneys and a way for younger candidates to be opted out. A member commented transplant programs need to commit to using filters and screening tools on the front end to increase efficiency of the system. Another member agreed and commented programs owe it to the community to improve efficiency overall by using the tools available.

The Committee discussed who the KiMAC should apply to and the Workgroup's recommendations. Members commented the 0-ABDR mm exclusion should be removed to be consistent with the removal of 0-ABDRmm priority in the continuous distribution framework. Members agreed with maintaining candidate exclusions for 100 percent CPRA and candidates inside of 250 NM.

The Committee agreed with the recommended threshold of eight percent of the match run, excluding 100 percent CPRA candidates and candidates within 250 NM. A member suggested also including cold ischemic time (CIT) in addition to a percentage threshold as criteria for applying the KiMAC. Another member asked if CIT is currently one of the criteria for minimum acceptance criteria. Staff confirmed it is part of current criteria. Another member commented a difficulty with using CIT with 'hard-to-place' kidneys is by the time an OPO gets to programs on the list that would normally accept them, there is too much CIT on the donor kidneys for those programs to accept them. Another member commented the percentage and CIT should differ depending on whether the donor organ is pre or post-recovery. Another member suggested pre-recovery application of the KiMAC could be based on percentage of the match run, and post-recovery could be based on CIT.

Staff suggested the Committee could make initial recommendations and ask for feedback as part of the Request for Feedback going out in July. Committee members agreed to request feedback on the percentage threshold recommendation and whether the KiMAC should apply earlier on the match run once a certain CIT is reached.

4. Dual Kidney

The Committee reviewed the Workgroup's recommendations on dual kidney criteria and allocation.

Presentation Summary:

Dual kidney allocation is currently reserved for kidneys with a KDPI of 35-100 percent. Candidates who are opted in to receive dual kidney offers appear on the match run twice – once for single and again for dual. The policy's two-year monitoring report shows that 44.44 percent of dual kidney transplants were allocated from single kidney classifications – confirming that many dual kidney offers occur out of sequence, prior to allocation reaching the dual kidney classifications.[1] The monitoring report and anecdotal feedback demonstrate a need for a new system of dual kidney allocation. The Workgroup developed recommendations for transitioning dual allocation into a continuous distribution framework to address identified inefficiencies with minimal system impact.

For dual kidney allocation, the Workgroup recommends utilizing a new, dual-specific match run and specific criteria dictating *when* an OPO *may* begin allocation the kidneys as dual. OPOs would not be required to allocate kidneys as dual once criteria are met, but have the discretion to do so. The dual-specific match run would include only candidates opted in to receive dual offers. Additionally, transplant

[1] OPTN Descriptive Data Request. "Allocation of Dual and En Bloc Kidneys Two Year Post-Implementation Monitoring Report." Prepared for OPTN Kidney Transplantation Committee, March 18, 2022.

programs will have the ability to build dual-specific filters. Other screening tools such as acceptance criteria and the KiMAC will also apply to the dual kidney match run.

The Workgroup reviewed data on the characteristics of current dual kidney donors and recipients and found dual kidney donors were more likely to:

- Be a DCD donor, especially in the KDPI 35-85 percent group
- Have a history of diabetes
- Have a history of hypertension, especially in the KDPI 35-85 percent group
- Have kidneys biopsied, and when biopsied, have a higher glomerulosclerosis

The Workgroup developed sets of criteria to determine when an OPO *may* begin dual kidney allocation. Additionally, the Workgroup agreed criteria should differ between KDPI sequences, CIT is a crucial consideration, and post-recovery information (such as biopsy results) should be considered.

The Workgroup recommended the following sets of criteria:

Once CIT is four hours, an OPO may offer both kidneys as dual from any donor who meets at least one of the below criteria:

- Biopsy: Cortical Necrosis present on both kidneys
- Biopsy: Fibrin Thrombi present, greater than or equal to 10%, on both kidneys
- Biopsy: Vascular Changes moderate or severe, on both kidneys
- Biopsy: Glomerulosclerosis 20% or greater on both kidneys
- Donor on dialysis during current hospital admission or in the course of donor management
- Anuria, or urine output of 100 ml or less in 24 hours during current hospital admission or in the course of donor management

Once CIT is four hours, an OPO may offer both kidneys as dual from KDPI 60-85% donors who meets at least three of the below criteria:

- DCD
- Donor age 60 or greater
- Terminal serum creatinine > 1.5 mg/dL
- CVA as mechanism of death
- History of Hypertension
- Controlled hypertension: greater than or equal to 10 years
- Uncontrolled: greater than or equal to 5 years
- Unknown if controlled vs. uncontrolled: greater than or equal to 5 years
- Any history of diabetes or HbA1c > 6.5 during donor evaluation or management
- Glomerular sclerosis greater than 10% on at least one kidney
- Renal biopsy findings of vascular changes moderate or severe on at least one kidney

Once CIT is four hours, an OPO may offer both kidneys as dual from KDPI 86-100% donors who meets at least two of the below criteria:

- DCD
- Donor age 60 or greater
- Terminal serum creatinine > 1.5 mg/dL
- CVA as mechanism of death
- History of Hypertension
- Controlled hypertension: greater than or equal to 10 years

- Uncontrolled: greater than or equal to 5 years
- Unknown if controlled vs. uncontrolled: greater than or equal to 5 years
- Any history of diabetes or HbA1c > 6.5 during donor evaluation or management
- Glomerular sclerosis greater than 10% on at least one kidney
- Renal biopsy findings of vascular changes moderate or severe on at least one kidney

Additionally, the Workgroup recommends carrying over certain refusals to the dual-specific match run, similar to released organs.

Summary of discussion:

The Committee discussed the Workgroup's recommendations. The Committee agreed with the Workgroup's recommendations for carry over refusal codes for a dual kidney match run. For the "Other, specify" refusal code, the Committee supported not carrying this code over to a dual kidney match run.

In reviewing the Workgroup's recommendations on dual kidney criteria for higher KDPI kidneys, a member commented the size of kidneys could also be a consideration. Staff commented the Workgroup did discuss size of kidneys and determined that is a transplant program decision on size matching with their candidate. The Workgroup's focus was on creating criteria for when the OPO may run a dual kidney match run.

The Chair commented glomerular sclerosis of more than 10 percent on one kidney seems like a low number. Staff commented this recommendation was based on a study which found that there was a plateau of effects on transplant outcomes at about 10 percent.[2] Members suggested raising this threshold to 15-20 percent which would be more of a moderate level of glomerular sclerosis. Another member commented biopsy results are typically not available until there is CIT on the kidneys, and the decision to switch to a dual offer should be based upon biopsy results immediately when the results come back. The member further noted that kidneys with high glomerular sclerosis and arterial disease would likely not be placed as single kidneys. Another member agreed and commented the threshold for when to allocate as dual should be more liberal than restrictive to give OPOs the latitude to place the kidneys at programs that will take them. Other members agreed and noted placement of these 'hard-to-place' kidneys should be prioritized. The Vice Chair agreed and noted the decision to accept kidneys as dual is largely based on biopsy and anatomy results, and OPOs should be given the flexibility to move to dual allocation once biopsy results return if results are concerning. Members commented OPO discretion is important to ensure utilization.

The Vice Chair asked how many dual kidneys were transplanted within the data cohort. Staff clarified within the time period the Workgroup evaluated, 278 of 47,443 kidney transplants (less than one percent) were dual kidney transplants.

A member suggested CIT could be a trigger for allocating as dual post-recovery. Another member expressed concern for basing dual criteria on biopsy results due to variability in reads by pathologists and the time it takes to get biopsy results back, and supported giving more importance to CIT. A member responded reported biopsy results play a large role in post-recovery kidney acceptance behavior. For pre-recovery allocation, the member commented determining criteria is difficult due to the potential large number of provisional acceptances of the offer the OPOs will need to work through before switching to dual allocation. Another member suggested transplant program's request for dual over single could be another criteria to prompt facilitation for those kidneys. A member commented

[2] Stewart et al, "The Independent Effects of Procurement Biopsy Findings on 10 Year Outomces of Extended Criteria Donor Kidney Transplants," Kidney International Reports, 2022.

basing criteria on a specific CIT threshold could be difficult due to geographic variability and transplant program density across regions. A member suggested allowing OPOs to have the discretion to allocate kidneys as dual at any point post-recovery. Another member suggested allowing OPOs to allocate high KDPI kidneys as dual from the beginning of the match run.

The Committee was informally polled on whether they would recommend no time requirement or a post-recovery requirement. The Vice Chair commented it's difficult to determine appropriate clinical criteria prior to recovery. A member commented the threshold should differ depending on the kidney's KDPI and supports a more liberal threshold for the highest KDPI kidneys. Another member commented kidneys with good biopsy results should still be allocated as single. A member commented there should be flexibility for high KDPI kidneys or kidneys from older donors.

The Committee focused on KDPI 86-100 criteria and some members recommended allowing OPOs to use a dual kidney match run prior to recovery. Other members commented there should be some specific criteria prior to being able to allocate as dual to incentivize OPOs to attempt to place kidneys as single first. When discussing if there should be specific pre-recovery clinical criteria to be able to switch to dual, members commented the criteria presented could result in a lot of high KDPI kidneys being allocated as dual, resulting in less individuals being transplanted. The Vice Chair commented pre-recovery, there is more time available for single allocation attempts prior to switching to dual allocation. The Vice Chair recommended exploring a percentage threshold for when the OPO can switch to a dual match run, similar to the application of the KiMAC tool. Other members agreed with this recommendation.

Staff suggested the Workgroup's and Committee's recommendations could both be presented in the Request for Feedback going out in July. Committee members agreed to request feedback on both sets of recommendations for dual kidney allocation.

Next Steps:

The recommendations from the Workgroup and the Committee will be detailed in a Request for Feedback that will be released for public comment in July 2023.

Upcoming Meetings

- June 22, 2023 – Conference Call

Attendance

- **Committee Members**
  - Martha Pavlakis
  - Jim Kim
  - Arpita Basu
  - Asif Sharfuddin
  - Chandrasekar Santhanakrishnan
  - Beatrice Concepcion
  - Elliot Grodstein
  - Patrick Gee
  - Precious McCowan
  - Carrie Jadlowiec
  - Jason Rolls
  - Jesse Cox
  - Steve Almond
  - Tania Houle
  - Kristen Adams
  - Marian Charlton
  - Marilee Clites
  - Sanjeev Akkina
  - Oscar Serrano
- **HRSA Representatives**
  - Shelley Grant
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Ajay Israni
  - Bryn Thompson
  - Grace Lyden
  - Jonathan Miller
  - Ryo Hirose
  - Jodi Smith
- **UNOS Staff**
  - Kayla Temple
  - Lindsay Larkin
  - Kieran McMahon
  - Ben Wolford
  - James Alcorn
  - Joann White
  - Lauren Motley
  - Thomas Dolan
  - Carly Layman
  - Kaitlin Swanner
  - Keighly Bradbrook
  - Kimberly Uccellini
  - Mariah Huber
  - Rebecca Fitz Marino

    - Ross Walton
    - Sara Moriarty
- **Other**
    - Caitlin Peterson
    - Dave Weimer
    - John Lunz
    - Leigh Burgess
    - Aparna Sharma
    - Rachel Engen