

**OPTN Kidney and Pancreas Transplantation Committees
Utilization Considerations of Kidney and Pancreas Continuous Distribution Workgroup
Meeting Summary
February 27, 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 2/27/2023 to discuss the following agenda items:

1. Kidney Minimum Acceptance Criteria Screening Tool
2. Application of the Kidney Minimum Acceptance Criteria Screening Tool

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

1. Kidney Minimum Acceptance Criteria Screening Tool

Staff provided an overview of the Kidney Minimum Acceptance Criteria (KiMAC) screening tool, and the Workgroup discussed how to transition the tool and its efficiencies 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" Kidneys. The KiMAC is not applied to high calculated panel reactive antibody (CPRA) candidates or O-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-O-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 wish 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, organ procurement organizations (OPOs) will no longer be required to contact the OPTN Contractor's 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 to programs that have indicated they are not interested in accepting these kidneys. 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.

Transitioning the KiMAC tool to a continuous distribution framework will involve several key decisions:

- Determining *who* the KiMAC should apply to – how we should define "had to place" in a continuous framework

- Determining *which* screening elements should be carried over into the future state
 - Some may require new data collection in the OPTN Donor Data and Matching System
- Determining *how* the tool is applied, or the logistics of OPO application

The focus of this meeting was determining *who* the KiMAC should apply to, or *where* on the match run the KiMAC bypasses should begin applying. Currently, the KiMAC applies program selected filters to candidates in national classifications, excluding “top of the match” classifications, such as candidates who have a 100 percent calculated Panel Reactive Antibody score (CPRA) and/or are a 0-ABDR mismatch with the donor. 100 percent CPRA and 0-ABDR mismatch candidates outside of 250 nautical miles are not bypassed by the KiMAC tool. Because distance plays such a large role in the current allocation system, “out of 250 NM” acts as a surrogate for hard to place kidneys. Programs take this into consideration when selecting the KiMAC filters. The KiMAC is currently 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, utilizing the same rules of application. Furthermore, a future state KiMAC should leverage the existing transplant program criteria in the OPTN Waitlist System, which were selected knowing that KiMAC only applies to national, non-high CPRA, non-0-mismatch offers, or generally hard to place kidneys.

Summary of discussion:

One member asked if the KiMAC applies organ offer filters that the program selects. Staff explained that the KiMAC is a separate tool from Offer Filters. Staff explained the difference between KiMAC, Offer Filters, and Waitlist Acceptance Criteria utilizing **Table 1**.

Table 1: Filtering and Screening Tools

KiMAC	Offer Filters	Waitlist 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 not accept	Describes the kidney donor that the candidate will accept
Transplant programs are required to provide answers and update yearly	No requirement for use at this time, though this may change in the future	Required fields on each candidate record
Applies as bypass	Applies as bypass	Screens candidates from the match (Candidates do not appear on match run)

Applied for offers outside of 250 NM, excludes “top of the match” candidates	Applies to all offers unless the candidate meets the filter exclusion criteria	Applies to all matches
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The member remarked that these tools seem redundant, and that these are duplicative functions. The member continued that if the transplant center is consistently answering those questions the same way, the same things could get filtered out. The member added that Offer Filters can be set up based on distance and time as well as donor characteristics, and asked if the KiMAC provides any additional benefit beyond the Offer Filter tool. Staff explained that the KiMAC is a different tool, and asks a different question from the Offer Filters tool, and is applied different ways. Staff added that responses to the KiMAC are currently required, where as Offer Filters are not currently required. The member recommended that attention should be focused on how to expand Offer Filters to include the functions of the KiMAC. The member explained that their program’s offer filters are very dynamic and incorporate cold ischemic time and distance, and that such filters are very helpful. The member agreed that the mandatory use of KiMAC is important to consider. Staff noted that some of the KiMAC screening may be achievable with many heavily dynamic and complicated offer filters.

The Chair pointed out that offer filters may be individualized for certain patients, whereas with hard to place kidneys, there is the potential for out of sequence or “aggressive” offers. The Chair asked if a lot of the KiMAC tool is meant to get at the kinds of donors that programs will accept for candidates further down the match run. The Chair explained that this tool is meant to increase efficiency for hard to place kidneys. The Chair agreed that some of this can be achieved with offer filters, but that the programming could be complicated. A member responded that aggressive placement is more discretionary and reduced via the use of filters or screening.

Staff explained that some multi-factorial offer filters can get at some of the same screening provided by the KiMAC tool, but that it could require a significant number of multi-factorial filters, which is inefficient for the transplant program. Staff continued that while the offer filters tool can be very precise because of how multi-factorial it is, the KiMAC tool is typically applied after many programs have already declined the organ, which gets specifically at application for hard to place kidneys. While the KiMAC can be less precise than offer filters, it can reduce offers to programs who have already said they won’t accept the organ.

One member asked if the OPTN Contractor is already using the KiMAC when allocating kidneys nationally. Staff confirmed this, and explained that this tool is bypassing programs who have indicated that this donor, based on the donor’s characteristics, do not meet the minimum requirements for a donor kidney they would be willing to accept. The member asked if the KiMAC is applied manually. Staff explained that the OPTN Contractor will gather donor information and create a separate information file. This file is used by the system to determine which programs should be bypassed by the KiMAC tool. When the KiMAC is run, the system will automatically apply the bypass to appropriate sequences on the match. The member noted that the question being discussed today is when to initiate this, and commented that this is a tricky question to get consensus on. The member added that geographic location will make this complicated. The member shared that their OPO is located in the northeast, and has a high volume of transplant programs nearby. As a result, there is a significant amount of time before allocation reaches the “national” classifications. The member pointed out that other OPOs may not have as many centers nearby, and so reach “national” sequences quickly. The member recommended that application of the KiMAC should be left to OPO discretion, particularly as many OPOs are allocating kidneys prior to organ recovery. The member shared that their OPO sets the expectation that the programs interested and primary for the kidney have crossmatched their patients prior to organ

recovery. The member continued that once the kidney is 4 to 6 hours cold with no interest, that is when their OPO begins to allocate more aggressively. The member commented that this could be used to increase efficiency once allocation has proven to be more difficult.

2. Application of the Kidney Minimum Acceptance Criteria Screening Tool

The Workgroup discussed options for how the KiMAC will apply in a continuous distribution allocation system.

Presentation summary:

Options for where the KiMAC should apply in a continuous distribution allocation system include:

- KIMAC applies to entire match
 - Would not represent “hard to place” kidneys
 - Screening may be too aggressive and bypass candidates inappropriately
 - Would require programs to re-enter their KiMAC responses with the understanding that KiMAC would apply to whole match run
- KiMAC applies only to relevant candidates more than 250NM away, excluding certain candidate populations (“top of the match” candidates)
 - KiMAC would apply somewhat randomly – it could apply to candidates at the top of the match run and not at the bottom
 - May not represent “hard to place” kidneys
- KiMAC applies after a specific composite allocation score (CAS) threshold
 - Identifies as specific place on the match run after which KiMAC bypasses are applied, which encourages consistency across match runs
 - Inflexible to differences in the candidate population appearing on individual match runs
- Recommended approach: KIMAC applies at a certain percentage of the match with option to exclude certain candidate types from being bypassed
 - “Percentage of match run” approximates a definition of difficulty in placement based on placement metrics
 - A certain percentage of the match has been offered to and declined without successful placement of both kidneys
 - Defined point on match run leverages the CAS, which incorporates values judgements by Committee
 - Defined point on match run dynamically adjusts for difference in geography and other factors influencing match size
 - Excluding specific candidate populations ensures those candidates are still consistently receiving those offers

Summary of discussion:

One member remarked that this may be too complicated, and that three filtration systems is too many. The member recommended that the filtering system be condensed into one system, and that this can be modeled onto the current offer filters system. The member continued that programs should be able to have a listing default with the ability to make edits for each patient as they feel is appropriate. The member added that Offer Filters should also be expanded to include consideration for age or longevity parity, as programs should be able to filter out 60-year-old donor organ offers for 30-year -old recipients. The Chair agreed, noting that while this is the ultimate goal, it is not in scope for the first iteration of continuous distribution. The Chair remarked that not all transplant programs use the offer filters tool currently, and that with current practices in the community, it is appropriate to maintain the

KiMAC tool. The Chair agreed that future iterations should utilize one screening tool, but that currently, programs leave their criteria inappropriately wide out of fear of missing an offer. The member continued that this is something the community needs to work on.

The Chair expressed concern about applying the KiMAC tool at a certain percentage of the match run, particularly as OPOs are sometimes required to allocate very quickly, due to a variety of reasons including donor instability or timing constraints. In these scenarios, the Chair remarked that it may be appropriate to apply the KiMAC sooner.

One member suggested that it would be helpful to see what that percentage would look like based on real match runs. The member added that it is a little difficult to visualize without the data. The member agreed that the ultimate long-term solution is consolidation into one tool, potentially with layers. The member added that some characteristics are sensitive to time and distance, while others are not. The member continued that this could be built into a more nuanced, one size fits all solution. The member asked if members answer the KiMAC conservatively, so that they still receive the offers.

The Chair pointed out that some programs either worry about missing offers or have surgeons that disagree, and so the filters are left wider than the program's actual acceptance behavior. Another member agreed that this is a problem, particularly as not all programs and surgeons know their own filters well, and that there is limited consistency between filters. The member continued that there needs to be one filtering system that is regularly reviewed by the programs to ensure the filtering criteria are meaningful.

The Chair asked how the KiMAC can be built so that it can be appropriately consolidated into a single filtering tool later on. The Chair continued that by recommending a percentage of the match run to apply the tool at the criteria that should be used, the Workgroup can help determine the steps to a consolidated tool. A member recommended consolidating between listing defaults, offer filters, and the KiMAC into one list of criteria.

One member recommended applying the KiMAC after 4 hours to any appropriate program more than 250 nautical miles away. The Chair agreed that was a good option, to have the KiMAC apply based on a time frame, with exception for programs within 250 NM.

Staff shared how the KiMAC applies in the current state, and then explained how the KiMAC could work if applied at a certain percent of the match, such as 20 percent. The first 20 percent of candidates would not be bypassed by the KiMAC, while candidates after the 20 percent mark would be bypassed based on their programs' KiMAC selections. Candidates at programs within 250 NM could be exempted even if they are at a sequence after the 20 percent mark, as they would not be bypassed in the current system. Staff explained that distance won't be separating the match run into classifications, but it will be a consideration in continuous distribution, and the rating scale for distance gives fewer points for candidates beyond 250 NM. Staff added that the KiMAC is intended to apply to hard to place kidneys, and cold ischemic time does not always approximate this, which can be seen in cases like released organs, or cases where the organ has little interest prior to organ recovery. Staff added that the KiMAC tool is also not necessarily meant to move the organ into expedited allocation, but instead to increase allocation efficiency for hard to place kidneys on long match runs. Staff provided some scope to the discussion, noting that these decisions about how the KiMAC will apply will need to be made in order to eventually consolidate all three screening tools.

One member expressed concern about using distance in the screening tool, particularly with consideration of geographic equity. The member also disagreed with the recommended option, noting that a percentage of the match run doesn't really reflect a hard to place donor. The member continued that the highest quality kidneys don't require allocation through even the first 10 percent of sequences

– it will usually be accepted by the one of the first five candidates on the match run. The member added that 20 percent will look very different on different match runs, and that this should be investigated. The member also recommended mandating offer filters based on rolling historical data. The member continued that programs all receive offers differently, and that some programs have coordinators while others have surgeons take offer call. Regardless, not all those taking offer call will know their filters. The member continued that until offer filters is mandated, programs will still not choose to use strict enough filters. The member pointed out that the problem is that, out of 20,000 recipients on a match run, the OPO needs to quickly offer to the patient who will ultimately become the recipient of that organ. It is important to identify who will take the organ and offer to them as quickly as possible, and avoid offering to those programs who won't accept them.

The Chair remarked that this is currently applied when kidneys are turned over for national allocation. If that's the case, the KiMAC can be applied prior to cross clamp. The Chair continued that the percentage of the match run makes sense prior to cross clamp, but that post-cross clamp there are time concerns. The Chair continued that there are many transplant centers who are interested in more medically complex organs as long as the cold ischemia time is not too high. The Chair added that distance is important post-cross clamp as well. The Chair recommended using a percentage of the match run for application of the tool prior to cross clamp and applying the tool after a certain timeframe post-cross clamp. The Chair wondered what the percentage would be, and recommended investigating that data. The Chair continued that pre-cross clamp, there is less of a time crunch.

One member recommended a two-factor rule, where the KiMAC is applied based on a certain combination of cold time and the donor's Kidney Donor Profile Index score (KDPI). The member continued that at that point, the kidney just needs to be allocated quickly. The Chair added that poor biopsy results can also shift the approach to allocation necessary, as programs who were previously interested are now concerned about acute damage and other factors.

A member asked if aggressive or open organ offers are increasing, particularly as the pressure on OPOs to procure and place more organs has increased due to changes in regulations. The member asked if there were any OPTN policies that support when an OPO can make open or out of sequence organ offers, and if there is any uniformity to out of sequence allocation offers. The Chair explained that every OPO has slightly different practices and different expedited processes. The Chair added that, if necessary, their OPO creates a set of bypass codes. The Chair agreed that some OPOs are placing kidneys via aggressive offers more frequently, and that some of this is due to programs becoming more aggressive as well. The Chair remarked that it would be ideal if the KiMAC could help bypass the programs who are not as aggressive or interested in accepting the organ. Another member agreed that current OPTN Policy does not support out of sequence allocation.

Staff provided some context of the KiMAC tool, and explained that one goal of the KiMAC could be to reduce out of sequence allocation, particularly because transplant programs have already indicated that they are not interested in these offers. The tool applies bypasses that the program has already agreed to and within bounds of OPTN policy, and the tool allows for more efficient allocation in a community consensus way, with consistent application. Staff added that maintaining the KiMAC tool will allow OPOs to avoid offering to programs who have said they are not interested in accepting those offers, particularly as the KiMAC is currently required for use by transplant programs. Staff noted that OPTN Policy follows the Final Rule and NOTA, and that this requires OPTN policy only to consider geography where necessary. Staff explained that typically, ensuring utilization of organs falls within the necessary use of geography.

The Chair asked if the KiMAC is similar to the expedited liver tool. Staff explained that how the tool applies and whether it will be automated will need to be decided by the Workgroup. Before that point,

the Workgroup will need to figure out how the tool will apply. A member remarked that once these filters are consolidated and well used, hopefully OPOs won't need to make aggressive offers any more.

A member remarked that where on the match run the KiMAC is applied should be a function of cold ischemic time and KDPI, as that is where the urgency is. The Chair pointed out that it would be important to be able to run this tool prior to cross-clamp, and agreed that application post-cross clamp may need to be different. The Chair agreed that a percentage should be used prior to cross clamp, and that post-cross clamp the trigger could be some version of cold ischemic time. Another member agreed, noting that it would be appropriate to use a percentage of the match run pre-clamp, particularly if the OPO is allocating without interest prior to recovery. The member agreed that those are hard to place kidneys, and those match runs definitely need a filtering system. The member agreed that post-cross clamp, a KDPI and cold time factor could also be helpful. The member recommended review of a visual of how the current KiMAC operates so that everyone understand what this would look like.

One member remarked that cold time is the biggest concern, and that efficient allocation and transportation are critical to ensuring utilization.

Upcoming Meeting

- March 13, 2023

Attendance

- **Workgroup Members**
 - Valerie Chipman
 - Colleen Jay
 - Jason Rolls
 - Sharyn Sawczak
 - Renee Morgan
 - Nikole Neidlinger
 - PJ Geraghty
- **HRSA Representatives**
 - Jim Bowman
 - Marilyn Levi
- **SRTR Staff**
 - Ajay Israni
 - Bryn Thompson
 - Jonathan Miller
 - Peter Stock
- **UNOS Staff**
 - Kayla Temple
 - Keighly Bradbrook
 - Kieran McMahon
 - Kimberly Uccellini
 - Lauren Mauk
 - Lauren Motley
 - Lindsay Larkin
 - Melissa Lane
 - Austin Chapple
 - Sarah Booker
 - Thomas Dolan
 - Carly Layman
 - Carol Covington
 - James Alcorn
 - Joann White