

**OPTN Kidney and Pancreas Transplantation Committees
Utilization Considerations of Kidney and Pancreas Continuous Distribution Workgroup
Meeting Summary
February 8, 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 2/8/2023 to discuss the following agenda items:

1. Kidney Minimum Acceptance Criteria Screening Tool

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

1. Introduction: Kidney Minimum Acceptance Criteria Screening Tool

Staff provided an overview of the Kidney Minimum Acceptance Criteria (KiMAC) screening tool and explained the need for a transition of the tool. The Workgroup continued discussions on how to transition the tool and its application.

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. Because current allocation considers distance so strongly, "outside of 250 nautical miles" acts as a surrogate for hard to place kidneys, since generally this is the last couple of allocation classifications on the match run. The KiMAC is not applied to high calculated panel reactive antibody (CPRA) candidates or O-ABDR mismatch candidates in the higher classifications.

Transplant programs provide information about the kinds of offers they want to receive from more than 250 nautical miles away for their non- high 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 consider offers for those donor kidneys.

In a continuous distribution framework, there will not be a distinct "national" classification in allocation, and "national" candidates may be scattered across the match run. 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 for assistance in allocating kidneys at a "national" level. As a result, however, the OPTN Contractor 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.

While the longer term goal is to consolidate the different filtering, screening, and bypassing systems utilized by the OPTN Computer System, the tools will need to remain separate for the first iteration of

kidney continuous distribution. This is in part due to several differences between the tools in terms of their application, what they are screening for, use requirements, and their precision. **Table 1** illustrates these differences:

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 <i>candidate</i> 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 <i>after</i> 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	Screens candidates from the match (candidates do not appear on match run)
Applied for offers <i>outside</i> 250 NM; excludes “top of the match” candidates	Applies to all offers unless the candidate meets the filter exclusion criteria	Applies to all matches

Currently, the OPTN Contractor manually enters screening criteria into the tool based on their knowledge of the donor and conversations with the host OPO. The data entered into 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:

- Kidney Donor Profile Index (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.

Today’s discussion focuses on where the KiMAC tool should apply. The tool’s future state should leverage existing transplant program answers to the criteria in the OPTN Waitlist System, which were given knowing that the KiMAC tool is generally only applying to national, non-high CPRA and non-0-ABDR mismatch offers from medically complex donors with hard to place kidneys. Leveraging these

existing answers allows a baseline level of screening and efficiency to be maintained. Several options for where to apply the tool include:

- Applying the KiMAC tool to the entire match
 - This may not represent hard to place kidneys, and screening could be too aggressive
- Continue utilizing existing distance thresholds, excluding certain candidate types
 - Nearby candidates, high CPRA candidates, and O-ABDR mismatch candidates would not be bypassed by the tool
 - KiMAC would apply randomly, and potentially to top of match run candidates → thus not always representing “hard to place kidneys”
- Apply a set composite allocation score (CAS) cut off
 - Consistent application across match runs, but inflexible to the transplant candidate population appearing on each match run
 - Incorporates the values judgments inherent to the continuous allocation system
- KiMAC applies to a certain percentage of the match, with the option to exclude certain candidate types from being bypassed
 - Most closely approximates difficulty in placement while still avoiding screening of candidates that should receive offers for these organs (such as nearby, high CPRA, etc.)
 - Leverages CAS scores to a degree, thus incorporating values judgments inherent to a continuous distribution system
 - Cut off dynamically adjusts for differences in geographic and accounts for similar proportions of highly prioritized candidates from match to match
 - Staff recommended approach

Summary of discussion:

One member asked if OPOs currently apply this tool when making national level offers. Staff clarified that the OPTN Contractor applies this tool when making offers at a national level, due to the requirement for OPOs to hand over national allocation to the OPTN Contractor. Staff explained that, because this national distinction won't be a clearly delineated point on the match run, the OPTN Kidney Pancreas Continuous Distribution Workgroup has decided to remove this requirement. As a result, the efficiency provided by the KiMAC tool will be lost if the tool is not appropriately transitioned over. This efficiency will be particularly important with hard to place organs that are placed further down the match run.

One member asked when this tool is applied, and staff clarified that the KiMAC is applied after the match is run. Staff noted that the hope is to fold in the future application of the KiMAC tool into the electronic notification process, similar to how offer filters are applied now. The member asked how cold ischemia time and delays are anticipated, and if this tool would add another layer of delay in allocation or else increase the number of offers centers receive. Staff explained that hopefully, this would prevent delays in allocation and reduce the number of unwanted offers received by transplant programs. The tool will bypass programs who have indicated that they don't want the offer, and so reduce the number of offers that the OPO will need to make to allocate the kidney. This will reduce the time the OPO spends talking to and awaiting responses from programs who are not interested, and ultimately help to streamline allocation. The member agreed this made sense, and asked if it was possible that programs could receive some of these offers or be bypassed in real time, or even prior to organ recovery (OR). Staff agreed that yes, the hope is that the application of this tool would not include a cold ischemic time barrier. In its current state, the KiMAC applies at national offers, and for shorter match runs, allocation sometimes reaches that cut off point prior to organ recovery. Allocation still needs to be efficient at that

point – it is still a hard to place kidney that hasn't been placed, the kidney just hasn't been recovered yet.

A member asked for further explanation of how the KiMAC tool differs from the offer filters tool, particularly as the offer filters tool takes into account distance and they will be applying to the match run at the same time. The member commented that, if the goal is to move allocation of hard to place kidneys, then a specific point on a match run may not speak to that as much as kidney characteristics would. The member suggested using the KiMAC if the kidney meets certain criteria, and so applies based on the kidney quality. Staff explained the differences between the tools utilizing **Table 1**, emphasizing that the KiMAC tool has a requirement for programs to enter their preferences, whereas programs are not required to use offer filters. Staff continued that the KiMAC references more hard to place kidneys, which means that programs are entering preferences such as “not interested in accepting donor after cardiac death (DCD) with 45 minutes of warm ischemic time that is being offered nationally”, as an example. Staff explained that this is a single criteria, but that this national offer means that the offer has been made to a lot of candidates and is thus hard to place. If offer filters were to consume the KiMAC tool, it would require a great number of complicated multifactorial filters. Staff explained that the offer filters tool can get granular and specific, whereas what programs are inputting in the system for KiMAC are a little more overarching. The member asked why a less precise screening tool would be used when a more precise tool is available. Staff explained that optimally, both would be used, as they ask different questions. Staff explained that, while KiMAC is a more blunt tool, it allows programs to cover a larger range of offers for specifically hard to place organs, and thus have a broader impact. Staff also noted that future iterations will expand offer filters, but that currently KiMAC asks several additional more clinical questions compared to offer filters, and that is also part of the conversation moving forward. Staff explained that how the KiMAC tool applies today is not how it would apply in future iterations, and that the goal is to streamline the KiMAC's application into the organ offer process.

Staff posed the question differently, and asked the Workgroup how to mirror the current application of the KiMAC in a continuous distribution system if there are no classifications. Staff asked how to ensure the highest priority candidates are not bypassed by the tool, while still maintaining system efficiency and bypassing programs who won't accept these kidneys. Staff further explained the recommended approach, noting that excluding certain candidate populations from the tool will ensure that these candidates still receive these offers, but the tool itself won't start applying until at least a certain percentage or proportion of the match run has been offered to.

A member commented that a kidney is hard to place based on kidney characteristics, not by how far allocation has gone down a match run. The member continued that by applying the tool at a certain percentage of the match, this could be applied after any number of offers. The member expressed support for applying this to the whole match with some candidate exclusions if the kidney meets certain criteria. The hard to place kidneys would be represented in the criteria used to qualify which match runs the tool applies to. Staff asked what the criteria to define hard to place would be. Staff noted that it can be difficult to define this criteria, and that it is almost impossible to ensure that every hard to place kidney is included in that list. Staff explained that the percentage of the match run concept creates a definition of hard to place that is based on placement characteristics instead of donor or organ characteristics. The kidney is a known hard to place kidney because it has not yet been placed and there is difficulty in placing it, despite offering to a significant portion of the match run. The member agreed that this makes sense.

The member asked how an OPO would know when to apply the tool. Staff noted that the Workgroup will talk about how to best operationalize this, but the hope is to automate this as much as possible so the system knows when to apply the tool and applies it appropriately.

One member asked if there will be something built into the system that will reconcile differences between what programs have put their offer filters versus their KiMAC. Staff explained that the two tools ask slightly different questions, and that the system will screen appropriately. If the KiMAC tool has been told to screen very rarely but the offer filters tool has been told to screen a lot, the system will screen a lot. If a program hasn't used the offer filters tool but has restrictive KiMAC settings, the system will still screen according to the KiMAC but won't apply any offer filter bypasses for the program.

Next steps:

The Workgroup will continue discussions on the KiMAC tool and how to transition its application in a continuous distribution framework.

Upcoming Meeting

- February 27, 2022

Attendance

- **Workgroup Members**
 - Carrie Jadlowiec
 - Nikole Neidlinger
 - Renee Morgan
 - Sharyn Sawczak
- **HRSA Representatives**
 - Jim Bowman
 - Marilyn Levi
- **SRTR Staff**
 - Ajay Israni
 - Bryn Thompson
 - Grace Lyden
 - Jon Miller
- **UNOS Staff**
 - Kayla Temple
 - Lauren Motley
 - Lindsay Larkin
 - Melissa Lane
 - Joann White
 - Thomas Dolan
 - Sarah Booker
 - Keighly Bradbrook
 - Kieran McMahan
 - Krissy Laurie
 - Lauren Mauk
 - Austin Chapple
 - Carly Layman
 - Carol Covington
 - James Alcorn
 - Joel Newman