OPTN Kidney and Pancreas Transplantation Committees
Utilization Considerations of Kidney and Pancreas Continuous Distribution Workgroup
Meeting Summary
May 18, 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 5/18/2023 to discuss the following agenda items:

1. Discussion: Kidney Minimum Acceptance Criteria
2. Kidney Minimum Acceptance Application
3. KiMAC Criteria Review

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

1. Discussion: Kidney Minimum Acceptance Criteria

Staff provided a recap 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." 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 (NM) away for their non-100 percent 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 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.

The ultimate goal is to streamline filtering and screening tools into one easy to use system for transplant programs and OPOs. However, this will require a phased approach. The KIMAC tool will operate alongside Offer Filters and Acceptance Criteria in the first iteration of continuous distribution. The Workgroup is charged with determining how to best transition the KIMAC tool to a continuous distribution model in order to maintain efficiency.

Staff stated that the focus of this meeting is to determine where on the match run the KiMAC should apply. Currently, the KiMAC applies program-selected filters to candidates in national classifications and excludes "top of the match" candidates. Because distance plays such a large role in the current allocation system, "outside of 250 NM" can act as a surrogate for "hard to place" kidneys. Current Workgroup discussion is focused on how the application of this tool can be replicated in a continuous distribution framework. Some considerations include: maintaining the basic spirit and scope of the current application rules and applying the tool consistently across OPOs.

Several options for where on the match run the KiMAC should apply were presented:

- KiMAC applies to the entire match
- Continue the existing distance cutoff and exclude certain candidates from being bypassed (such as nearby candidates, candidates with a high CPRA, and prior living donors, for example)
- Apply at a set composite allocation score (CAS) cutoff
- KiMAC applies at a specific percentage of the match with the option to exclude certain candidate types from being bypassed

Staff explained that the recommended approach would be to have the KiMAC apply at a certain percentage of the match and exclude nearby and high CPRA candidates. This option leverages CAS which incorporates values judgements by the Committees and Workgroups developing kidney continuous distribution. Also, this option dynamically adjusts for differences in geography points and accounts for the same number of highly prioritized candidates from match to match. The percentage of the 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. Excluding specific candidate populations (such as high CPRA) ensures that those candidates are still receiving those offers.

Staff asked members if nearby candidates (within 250 NM) should be excluded from KiMAC bypasses. The Workgroup also needs to answer where the match percentage threshold should be set and at which percentage of the match run the KiMAC should be applied. To help with this, data was provided to the Workgroup.

The match run data analysis of current KiMAC application indicated that KiMAC bypasses should not begin applying until about eight percent of the match run has been offered to. The KiMAC bypasses will not apply to any candidates in the first eight percent of sequences regardless of distance, CPRA, and other factors. KiMAC bypasses will only apply to candidates at programs who have indicated they will not accept such donor organs on the last 92 percent of sequences, excluding candidates within 250 NM. Staff presented the data that allowed for these conclusions.

<u>Data summary:</u>

A subset of match runs where KiMAC was applied was analyzed with a cohort of March 15, 2021 through March 14, 2022. This encompassed about 5,000 match runs where the KiMAC was applied.

The median sequence number where KiMAC was applied was 814. Regions 2, 9, and 1 tend to use the KiMAC further down the match run than other regions. These regions are located in the Northeast. Staff noted that there is significant geographic variation. The interquartile range showed that the KiMAC applied from sequences 267 to 1778, demonstrating a large range.

This data was then converted into a percentage of the match run, which showed that a median of 7.6 percent of the match run had been covered by the time the KiMAC was applied. There is regional variation in this, and the interquartile range showed that the KiMAC was applied from 8.2 percent to 52 percent of the match runs.

Summary of discussion:

On the question of if nearby candidates (within 250 NM) should be excluded from KiMAC bypasses, a member stated that the KiMAC should not apply to these nearby candidates who have a high chance of being able to get to the kidney in time. Members agreed.

The Chair noted that the trend for Regions 2, 9, and 1 makes sense because there are multiple transplant centers and OPOs within 250 NM of that geographical area. A member suggested that the KiMAC should be applied to all match runs over 250 NM away. Staff noted that the idea behind using a percentage was that as the system transitions to continuous distribution, the importance of proximity efficiency may change over time, and the KiMAC should be flexible to any changes. Using a percentage of the match run helps to ensure that KiMAC is not screening out highly prioritized candidates. The member asked how the system would recognize candidates within 250 NM to be able to exclude them from KiMAC bypasses. Staff noted that the system can recognize distance and not screen those candidates.

Staff explained that while current system usage data indicates that KiMAC is applying at around eight percent of the match run, the Workgroup can recommend a less strict percentage, such as around 10 or 15 percent. The Chair noted that based on the experience with implementation of lung continuous distribution, the top eight percent of the match run in continuous distribution is expected to look very different than the current top eight percent. The Chair recommended using the eight percent as the percentage in transitioning the KiMAC, because even if some further away candidates wind up in the top eight percent, other candidates within 250 NM will not be bypassed. The Chair cautioned against broadening the KiMAC application too far to avoid decreasing utility of the tool.

2. Kidney Minimum Acceptance Application

The Workgroup considered when the KiMAC tool should apply in further detail.

Presentation summary:

Some limitations and considerations in deciding where the KiMAC tool should apply were introduced to the members:

- Regions vary in where the KiMAC was applied in terms of sequence number
- The KiMAC applied on average about eight percent into the match run (but, this does not mean that all candidates after eight percent of the match run will be bypassed)
- Centers always have the option to open up the KiMAC criteria to minimize screening
- The percentage at which the KiMAC applies can be adjusted post-implementation, if needed
- The percentage of the match run based on sequence number reflects prioritization based on current allocation and will not need to be changed if new CAS formulas are implemented

Members were asked to think about these considerations and revisit the staff recommendation for having the KiMAC apply at eight percent of the match presented earlier in the call.

Members were also asked to consider the following questions:

- Should 100 percent CPRA candidates be excluded from the KiMAC bypass?
- Should 0-ABDR mismatch candidates be excluded from the KiMAC bypass?

Staff noted that 0-ABDR mismatch priority will not be included in kidney continuous distribution.

Summary of discussion:

The Chair asked if this system will be automated, and staff answered that the system is expected to be fully automated such that when the percentage of the match run is met, the KiMAC will apply automatically. The Chair explained that this recommendation makes sense and should help with efficient placement of organs while retaining transplant program's options to set their own criteria. Two members agreed with having the KiMAC apply at eight percent, explaining that the data supports this. A member noted that the "national offer" classification would no longer exist under continuous distribution. The recommendation that KiMAC bypasses should not begin applying until eight percent of the match run has been offered to will be brought forth to the Kidney Committee for review, and the community will be able to weigh in on this through public comment.

On the question of if 100 percent CPRA candidates should be excluded from the KiMAC bypass, the Chair asked if these candidates would already be at the top of the match run due to the priority associated with the attribute. Staff answered that this is expected, however, because CAS takes into account all the attributes, it wouldn't be possible to guarantee that 100 percent of the candidates with 100 percent CPRA would be accounted for in the top eight percent of the match. However, a CAS calculator is in progress that could check against historical data. The Chair explained that although the top eight percent *should* account for highly sensitized candidates, the Workgroup should make sure that these candidates aren't accidentally skipped over. The Chair recommended excluding 100 percent CPRA candidates from the KiMAC bypass.

On the question of if 0-ABDR mismatch candidates should be excluded from the KiMAC bypass, a member explained that acceptance practices for 0-ABDR mismatch on "hard to place" kidneys are highly variable, however, it may be worth excluding 0-ABDR mismatch candidates for consistency with prior policy. The Chair agreed, and noted that the modeling would probably show that 0-ABDR mismatch patients will already fall in the top eight percent, however, keeping the KiMAC consistent with current policy would be preferable.

3. KiMAC Criteria Review

The Workgroup discussed which criteria should be carried over to the updated KiMAC.

Presentation summary:

The Workgroup needs to determine which criteria should be carried over into the updated KiMAC. For the first iteration of continuous distribution, existing data points entered by transplant programs will be leveraged. The effectiveness of each criterion is determined based on the median percentage of transplant programs bypassed from a match run. In reviewing the criteria, members were asked to keep in mind that some criteria will require new data collection. Members were asked to consider the following questions:

- Which screening elements should be carried over into the future state?
- Which elements provide significant efficiency benefit and should be used to screen under continuous distribution?
- Which elements provide little benefit, and could be removed to streamline transplant program responses?

Summary of discussion:

Staff showed a worksheet with the criteria for the Workgroup to discuss. The Workgroup began discussion with the donation after circulatory death criteria, and Workgroup discussion is noted in the "notes" section of the tables below:

Table 1: KiMAC Screening Criteria (Donation after Circulatory Death)

Item as it appears in KiMAC: was the kidney recovered from:	Responses	Notes	Currently Collected?	Include or Remove?
A controlled DCD donor?	Yes/no	Screens a maximum of 3 programs when applied (median of 0% of programs) Workgroup members elected to remove as this does not screen a high number of candidates.	Mod Req	Remove
An uncontrolled DCD donor?	Yes/no	Screens a median of 58% of programs when applied, but is extremely rarely applied. The Workgroup elected to include this, as some centers are piloting programs from uncontrolled donors. Members noted that this may become more common in the future. The Workgroup members had conflicting definitions of an uncontrolled DCD donor, and agreed that there will be a need to determine specific definition of uncontrolled DCD donor.	Mod Req	Include
A DCD donor with no kidney biopsy report?	Yes/no	Currently, DCD Status is collected, and whether the biopsy was performed is collected. However, not all OPOs directly report biopsy performance in this way, which may lead to inappropriate application. Staff noted that data is limited for this element so it is hard to determine if this is an effective screening tool. Members elected to remove, noting that the biopsy policy already requires to disclose the biopsy where appropriate.	Mod Req	Remove

What was the duration of hypotension (< 90 mm/Hg systolic) prior to cardiac arrest?	XX minutes (Range 0-999)	Members elected to remove this, noting that current usage data is unclear about whether this is an effective screening tool, and that it would be difficult to collect this data moving forward.	Mod Req	Remove

Table 2: KiMAC Screening Criteria (Donor Age Specific)

Item as it appears in KiMAC: identify the duration of any of the specified circumstances for the donor:	Responses	Notes	Currently Collected?	Include or Remove?
History of hypertension and compliant with medication?	• 0-5 years • 6-10 years • 11-20 years • >20 years	History of HTN (with duration) and compliance collected, but the duration options differ between KIMAC and donor record. The Workgroup was in favor of modifying KIMAC to match donor record (remove 11-20 years and >20 years options). Staff noted that duration of compliant vs. duration non-compliant is not collected. Members noted that the duration of hypertension and diabetes sometimes varies in reliability due to variability in reporting. Staff noted that a priority in the future system will be reliability and interpretability. This element screens a median of 79-98% of programs depending on donor age. Members noted that the hypertension by age group is helpful in the current screening tool and that it makes sense to keep this element moving forward.	Mod Req	Include

History of hypertension and with periods of non-compliance within the last 5 years?	• 0-5 years • 6-10 years • 11-20 years • >20 years	Screens a median of 73-86% of programs depending on donor age. The Workgroup in favor of modifying KIMAC to match donor record (remove 11-20 years and >20 years options) and keeping this as a screening element.	Mod Req	Include
Insulin dependent diabetic?	• 0-5 years • 6-10 years • 11-20 years • >20 years	Duration diabetes is collected, but duration options differ between KIMAC and donor record. Workgroup was in favor of modifying KIMAC to match donor record (remove 11-20 years and >20 years options). Insulin vs. oral medication not collected; duration insulin vs oral medication not collected. Members noted that this was an important distinction clinically. This element screens a median of 75-90% of programs depending on donor age. Members agreed this is important to include.	Mod Req	Include
Diabetic and requires oral medication?	• 0-5 years • 6-10 years • 11-20 years • >20 years	Screens a median of 67-80% of programs depending on donor age. Workgroup in favor of modifying KIMAC to match donor record (remove 11-20 years and >20 years options) and keeping this element as it screens many programs and is important clinically.	Mod Req	Include

Table 3: KiMAC Screening Criteria (Duration of Cardiac Arrest)

Item as it appears in KiMAC: identify the duration of cardiac arrest (downtime) for the donor:	Responses	Notes	Currently Collected?	Include or Remove?
• With CPR?	• <10 min • 10-15 min • 16-20 min • 21-30 min • >30 min	Currently, "Downtime" is collected but not with CPR or without CPR – may need additional fields to separate them out. Screens a median 75-97% of transplant programs, depending on duration. The Workgroup remarked that downtime generally has varying reliability, as this information is collected in the field, typically. The Workgroup noted that this field is likely too unreliable to screen on. Therefore, the members elected to remove this element.	N	Remove
• Without CPR?	• <10 min • 10-15 min • 16-20 min • 21-30 min • >30 min	Screens a median of 70-85% of transplant programs, depending on duration The Workgroup remarked that downtime generally has varying reliability, as this information is collected in the field, typically. The Workgroup remarked that this field is likely too unreliable to screen on.	N	Remove

Members had previously discussed the other KiMAC screening elements. There was no further discussion.

Next steps:

These recommendations will be taken to the Kidney Committee for further discussion and finalization.

Upcoming Meeting:

- June 12, 2023

Attendance

- **Workgroup Members**
  - Colleen Jay
  - Jason Rolls
  - PJ Geraghty
  - Renee Morgan
  - Jillian Wojtowicz
  - Valerie Chipman
  - Sharyn Sawczak
- **HRSA Staff**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Jonathan Miller
- **UNOS Staff**
  - Kayla Temple
  - Lindsay Larkin
  - Ben Wolford
  - Carly Layman
  - Carol Covington
  - Cassandra McCharen
  - Joel Newman
  - Kaitlin Swanner
  - Keighly Bradbrook
  - Kieran Mcmahon
  - Kimberly Uccellini
  - Laura Schmitt
  - Lauren Mauk
  - Mariah Huber
  - Melissa Lane
  - Rebecca Fitz Marino
  - Ross Walton
  - Sarah Booker
  - Shavon Goodwyn
  - Tamika Watkins
  - Thomas Dolan