OPTN Kidney and Pancreas Transplantation Committees
Utilization Considerations of Kidney and Pancreas Continuous Distribution Workgroup
Meeting Summary
March 13, 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 3/13/2023 to discuss the following agenda items:

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

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." 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.

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

- Determining *who* the KiMAC should apply to – how can we 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

Summary of discussion:

The Workgroup had no questions or comments.

2. Kidney Minimum Acceptance Criteria Screening Elements

The Workgroup began reviewing and discussing which criteria the KiMAC tool should screen on in its future state.

Presentation summary:

The focus of this meeting is to determine which screening elements should be carried over into the future state. Some elements can be removed to streamline responses, while others provide significant benefits to efficiency and may need to be maintained. Currently, the OPTN Contractor creates a separate information record based on the donor's information when applying the KiMAC tool. In a future state, the information will be pulled directly from the donor's record in the OPTN Donor Data and Matching System, and the bypasses may be more automated. Some screening elements, if maintained, may require new data collection.

The Workgroup is asked to consider each screening element and determine whether the KiMAC should continue screening on these elements in a future state. The criteria have been separated into several categories for ease of discussion. These groups include:

- Consistently applied criteria
- Infectious disease and increased risk criteria
- Donor history and management
- Donation after circulatory death (DCD) related criteria
- Anatomy criteria
- Age-specific criteria

Consistently applied criteria are applied every time the KiMAC tool is used, and include:

- Donor age
- Creatinine clearance level based on serum creatinine upon donor admission
    - This is automatically calculated by the system based on the earliest creatinine
- Maximum acceptable peak creatinine level
    - System will be able to automatically determine peak creatinine level
    - Programs are able to select different maximum creatinine levels based on donor age
- Percentage glomerulosclerosis
    - Currently, this is one of the only biopsy data points collected in the OPTN Donor Date and Management System
    - Will need to determine which glomerulosclerosis score is used to screen if two biopsied kidneys are being offered
        - Currently, the KiMAC tool utilizes the higher (or worse) glomerulosclerosis score, while the Offer Filters tool uses the lower glomerulosclerosis score
- Cold ischemic time, based on time of arrival
    - Consistently applied, with more centers screened off as cold ischemic time increases
    - Currently, cold ischemic time is applied with an additional 6 hours, to account for additional time required in transportation. This practice was previously approved by the Kidney Committee more than 10 years ago.

- This was previously approved by the Kidney Committee when the KiMAC tool was first created
- The Workgroup will need to determine whether this is appropriate in a continuous system

Summary of discussion:

One member agreed that screening should be maintained for donor age, creatinine clearance, and maximum acceptable peak creatinine level. The member asked if programs are inputting valid criteria for these fields. Staff shared that these criteria are always applied, so it is harder to determine their measure of effectiveness. Staff noted that programs do enter thresholds for these criteria.

A member expressed surprise that the KiMAC tool utilizes creatinine clearance (CrCl), particularly because this is not shown in the OPTN Donor Data and Management System. Staff explained that this is calculated in the KiMAC tool itself, and is automatically calculated. The member asked which calculation is being used. Staff noted that they weren't certain at this time, but would look into it further.

The Workgroup agreed to maintain donor age, creatinine clearance based on serum creatinine upon donor admission, and maximum acceptable peak creatinine.

Staff introduced glomerulosclerosis as a screening tool, and explained that the KiMAC utilizes the highest of the two glomerulosclerosis scores when offering both kidneys at the approval and direction of the OPTN Kidney Transplantation Committee many years ago. Staff asked the Workgroup if they would like to maintain screening on percent glomerulosclerosis in the KiMAC tool, and if so, which score should be used to screen if both kidneys are being offered.

The Chair reminded that this tool will not be applied until quite a few centers have declined the organ. The Chair continued that if there is one kidney that is less medically complex, it will most likely have been placed by the time the KiMAC bypasses are applied. A member expressed support for maintaining screening on percent glomerulosclerosis. The member continued that it would be okay to utilize the worse of the two scores, but that there could also be an argument for taking an average of the two scores. The member noted that this would be complicated, and that for simplicity's sake, it would be appropriate to use the worse of the two glomerulosclerosis scores for screening when offering both kidneys. The Chair agreed that the higher of the two scores could be used, particularly because of when the KiMAC is expected to be applying bypasses. Another member remarked that two biopsies from the same donor can be drastically different, but that hopefully the kidney with the better biopsy score will be accepted. The member continued that the kidney with the higher glomerulosclerosis score will likely be the hardest to place anyway.

The Workgroup agreed to maintain screening on percentage glomerulosclerosis, and to utilize the higher percent glomerulosclerosis if both kidneys are being offered and both kidneys have been biopsied.

Staff explained that currently, the cold ischemic time is calculated with an additional 6 hours, which is meant to be inclusive of time for travel, particularly as these organs are expected to travel greater distances. The 6 hours is based on one hour for pick up, one hour to drive, an hour long lockout prior to the flight departure time, and then one hour for offloading, one hour to pick up, and then an hour to drive the organ to its final destination. Staff added that this rule was originally approved by the OPTN Kidney Transplantation Committee. Staff asked the Workgroup if they would like to maintain screening based on cold ischemic time, and whether the Workgroup would like to utilize the same application rule to approximate cold ischemic time upon arrival.

One member expressed uncertainty about adding 6 hours to the cold ischemic time, noting that the actual projected cold ischemic time is more important, and that this rule may be too blunt. The member

noted that this application rule could be maintained. Another member pointed out that in Continuous Distribution, it will not be as obvious where the organs will be offered, so it may not be appropriate to utilize the additional 6 hour rule. The member added that this could also confuse the transplant programs as well. A member agreed, adding that actual cold ischemic time would make sense. The member continued that ideally, programs would be able to select a cut off based on time and distance, which Offer Filters does include. The member shared that it does still take at least 6 hours to receive an organ from a neighboring state, but noted that actual cold ischemic time will be clearer and more transparent. The Chair pointed out that this will be applied after a good number of centers have declined. Staff added that the Workgroup may decide that any candidate within 250 NM is not bypassed by the KiMAC tool at all, and that it may be hard to answer this question while it is unclear how the tool is applying.

The Chair expressed support for not applying the KiMAC bypasses within 250 NM and include the additional 6 hours to project cold ischemic time when applying the bypass. The Chair agreed that past 250 NM, when a flight is involved, it could be efficient to keep the transportation timeframe in place. A member recommended keeping cold ischemic time and distance separate, instead of attempting to estimate the effect of distance on cold ischemic time in a blunt and general way. The member explained that six hours means something different to each program, particularly depending on the time of day, the day of the week, and the season. The member expressed support for utilizing actual cold ischemic time and allowing the program to make that determination for themselves. Another member agreed, noting that the 6 hour rule makes a prediction that cannot be guaranteed, particularly given the wide variability in transportation feasibility and times. Another member agreed.

The Workgroup agreed to maintain screening on cold ischemic time utilizing actual cold ischemic time.

Presentation summary:

The following increased risk criteria are currently included in KiMAC screening, based on the United States Public Health Service (PHS) Increased Risk Guidelines.[1] To be utilized for screening, the following criteria must be applicable within the last 30 days:

- Sex with a person known or suspected to have HIV, HBV, or HCV infection
- Sex with a person who had sex in exchange for money or drugs
- Sex with a person who injected drugs for nonmedical reasons
- Child born to a mother with HIV, HBV, or HCV infection
- Child breastfeed by a mother with HIV infection
- Unknown medical or social history
- Man who has had sex with another man
    - Previously, this criterion was “man who has had sex with another man in the last 5 years”
- Sex in exchange for money or drugs
- Incarceration for greater than or equal to 72 consecutive hours
- Drug injection for nonmedical reasons, current or past

The following increased risk criteria are rarely selected to screen by transplant programs, and when applied, screen a median of less than 5 percent of transplant programs:

- Unknown medical or social history

[1] https://www.cdc.gov/transplantsafety/hc-providers/guidelines.html

- Man who has had sex with another man
- Sex in exchange for money or drugs
- Incarceration for greater than or equal to 72 consecutive hours
- Drug injection for nonmedical reasons, current or past

Summary of discussion:

One member asked if the more effective questions were more commonly applied, and staff explained that more effective increased risk criteria were not necessarily more common, just that they screened a greater number of programs when they are applied. The member pointed out that these things are all known prior to the kidney being recovered, and between acceptance criteria and offer filters, it may not be necessary to maintain this screening in the KiMAC tool. The Chair agreed, and asked if Offer Filters asks each increased risk question individually. The Chair continued that if Offer Filters or Acceptance Criteria include these, then it wouldn't be necessary to ask these questions on the KiMAC. The Chair continued that it could be simpler to remove all of these questions for the sake of simplification, particularly because it is not necessary to screen on these elements twice.

Staff explained that Offer Filters includes a question as to whether or not the donor meets any of the PHS Increased Risk criteria, but the discrete increased risk criteria are not included in offer filters.

A member commented that programs may not fully understand the difference between all of the screening tools. The member recommended that programs receive increased education on the different tools and how they are applied. The Chair agreed.

A representative from HRSA explained that the PHS Guidelines were recently updated in 2020, and included an adjusted list of criteria. The HRSA representative asked if these criteria are used in the Waitlist Acceptance Criteria. Staff explained that some increased risk information may not become available in some cases until after the match is run, such as if the donor's medical and social history becomes available much later. The HRSA representative noted that HIV, Hepatitis B, and Hepatitis C screening is performed before the match is run, so this would relate more to window period infections, before the PCR tests are positive. The HRSA representative explained that there is a post-transplant monitoring process in place where HIV, Hepatitis B and Hepatitis C are repeated regularly post-transplant. The HRSA representative recommended looking further into this list, noting that removing some elements could cause confusion.

The Chair expressed that more conservative transplant programs may be screened off via other KiMAC criteria, and that more aggressive centers will have wider criteria selections. The Chair continued that programs that are more conservative about increased risk are also more conservative in other areas. The Chair added that utilizing these criteria as discrete questions in the KiMAC tool could be overly complicating.

Staff explained that these questions are currently used by the KiMAC tool, and that programs may select KiMAC criteria based on specific increased risk questions. Staff added that the KiMAC is the only area that programs can select criteria based on discrete, specific increased risk questions.

The Chair pointed out differences between screening effectiveness between certain criteria, noting that it is interesting to see that "non-medical drug injection" is less effective as a screening criteria than "sex with a person who injected drugs for non-medical reasons." The Chair remarked that it is interesting programs would want to differentiate between these criteria. Another member agreed, adding that if the donor meets one of the increased risk criteria, they are considered increased risk, and all increased risk is considered the same. The member continued that it should be the same on the transplant program side. The Chair remarked that there may be statistical differences in level of risk, and that

programs may have their own practices informed by literature and data on increased risk. The Chair continued that research shows that increased risk donors still have a much lower risk of transmission, particularly with current testing practices.

One member pointed out that if any increased risk criteria are present, then the donor is increased risk, and in that effect, each increased risk criteria essentially carries the same weight. The member continued that if this is the only place that programs can screen individually, then it may be appropriate to leave these in the KiMAC as they are, particularly if programs want to set specific criteria. The member continued that this would also make sense if the Offer Filters tool currently allows programs to indicate that they will not accept increased risk organ offers. The member also added that as the science behind these diseases evolves, it may be that some increased risk factors are less relevant than others, and it may be helpful for programs to be able to indicate which increased risk offers they are not interested in receiving. Another member pointed out that by maintaining the discrete increased risk questions, the OPO will have an easier time getting the organ placed, as they may be able to screen more effectively.

The Chair expressed support for the Workgroup to maintain all of the discrete increased risk questions or remove all of them from the KiMAC tool entirely. The Chair continued that the criteria should align with the PHS Increased Risk Guidelines. The HRSA representative agreed, noting that each of the increased risk criteria are considered clinically important. Another member agreed that all of the increased risk questions should be maintained in the KiMAC tool.

The Workgroup agreed to maintain screening for each increased risk criteria in the KiMAC. Staff noted that some of these questions may require additional data collection in the OPTN Donor Data and Matching System. The Chair agreed, and noted that the Workgroup can continue to discuss this potential data collection.

Upcoming Meeting

- April 3, 2023

Attendance

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