OPTN Kidney and Pancreas Transplantation Committees
Utilization Considerations of Kidney and Pancreas Continuous Distribution Workgroup
Meeting Summary
August 11, 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 8/11/2023 to discuss the following agenda items:

1. Review Kidney Minimum Acceptance Criteria Screening Tool (KiMAC) in Continuous Distribution
2. KiMAC Data Checklist: Diabetes and Hypertension
3. KiMAC: Screening for Lateral Characteristics

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

1. Review Kidney Minimum Acceptance Criteria Screening Tool (KiMAC) in Continuous Distribution

Staff provided a recap of the Workgroup's effort to transition the KiMAC tool to a continuous distribution framework and introduced the OPTN Data Advisory Committee new data and data modification checklist process.

Presentation summary:

Previously, the Workgroup reviewed the full set of KiMAC criteria to determine which criteria are appropriate to continue screening on in a continuous distribution framework, including:

- Donor age
- Increased risk criteria (set of ten questions)
- HBsAg, HBV NAT, Anti-HCV, HCV NAT, Syphilis, HTLV I or II
- Creatinine clearance at admission
- Uncontrolled donation after cardiac death donor (DCD)
- Anatomy: horseshoe kidney, polycystic kidney disease, infarcted kidney, hard plaque and severity
- Hypertension and compliance
- Diabetes and management
- Peak creatinine
- Cold ischemic time
- Glomerulosclerosis

Many of the above criteria are already collected in the OPTN Donor Data and Matching System. For those that are not currently collected, data collection regarding the above elements will be added to the OPTN Donor Data and Matching System upon future implementation of the *Enhancements to OPTN Donor Data and Matching System Clinical Data Collection* and *Update Data Collection to Align with US Public Health Service Guideline, 2020* efforts. However, there are several data elements that will require new data collection in the OPTN Donor Data and Matching System. Furthermore, updating the KiMAC

tool will require modifications to phrasing and response options to a few screening questions in Waitlist for programs.

Automation of the KiMAC will require the following elements to be added to the OPTN Donor Data and Matching System:

- Horseshoe kidney? – yes/no
- Polycystic kidney disease? – yes/no
- (Asked separately for left and right) Kidney has significant infarction (greater than 20%)? – yes/no
- (Asked separately for left and right) Hard plaque in the renal artery at time of procurement? – No; mild; moderate; severe; ulcerative
- History of diabetes (duration) → diabetes currently or ever managed with oral medication? – yes/no
- History of diabetes (duration) → any periods of insulin dependence? – yes/no

The Workgroup will need to work through the OPTN Data Advisory Committee's data checklist process for adding and modifying data to the OPTN Computer System. This process ensures the quality of new data collection and modifications to data collection in the OPTN Computer System, with a focus on quality, consistency, understandability, usefulness, and trustworthiness of OPTN data. The process includes determining the purpose, availability or burden, reliability, and usability and conformity of each data element. The process also involves finding and building definitions for each data element.

Summary of discussion:

There were no comments or questions.

2. KiMAC Data Checklist: Diabetes and Hypertension

The Workgroup discussed screening considerations for diabetes and hypertension.

Presentation summary:

Current screening for diabetes and hypertension in the KiMAC tool is based on donor age, hypertension compliance and duration, and diabetes management and duration.

Previously, the Workgroup discussed diabetes screening based on management type, differentiating between insulin use and use of oral medication management. This would result in the following screening questions, with programs able to indicate different responses based on donor age less than 45 years, 45-54 years, 55-64 years, and greater than 64 years:

- Diabetic with any period of insulin dependence – 0-5 years, 6-10 years, greater than 10 years, will not consider
- Diabetic, with any use of oral medication management – 0-5 years, 6-10 years, greater than 10 years, will not consider

The Workgroup was asked if diabetes screening should be focused on diabetes management, or if it is more important to screen on type I vs. type II diabetes. Specifically, the Workgroup was asked if type of treatment is more important than the diagnosis.

Summary of discussion:

One member expressed support for maintaining screening based on how diabetes is managed. The member continued that the labels "type I" and "type II" are often inadequate labels. The member explained that there are many people who are typically considered type I diabetics who also develop insulin resistance, and then there are many type II diabetics who "become" "type I" diabetics. The member continued that categorizing these patients into these boxes is unnecessary, and diabetes management is much more objective.

The Chair remarked that the Workgroup previously agreed that insulin and oral medication use is more important than "type I" or "type II" diabetes.

Staff asked the Workgroup if it is important to maintain the language of "insulin dependence," which has been historically used to mean "type I" diabetes. Staff also asked the Workgroup if it is important to capture insulin use in the context of diabetes mellitus, or if insulin use should be captured separately. A member remarked that the verbiage should be the same as oral medication – such as "with use of insulin." The member also remarked that term "any" is not necessary and could be confusing; really, it's whether the donor is using insulin or not for diabetes management, not one-time instances of insulin use.

The member also recommended removing the word "management" from how the oral medication question is phrased. Staff asked how it should be indicated that the oral medication was used to maintain diabetics, or if there is a different set of specific language to indicate the type of oral medication intended here. Another member remarked that "management" is necessary to ensure clarity that the medication is related to diabetes. The Chair agreed, noting that perhaps the question could be phrased more simply. The Chair continued that some donors have insulin drips in the ICU and are not diabetic, just to help manage the donor, and that it is important the insulin and oral medication is related to diagnosed diabetes. A member offered the word "chronic" for insulin use, to differentiate. The Chair recommended "daily." Another member disagreed, noting that "diagnosed with diabetes with insulin use" is likely sufficient, and that additional labels could be confusing. One member expressed support for oral medication to include "anti-diabetic" to clarify.

One member asked if it was necessary to indicate diabetes mellitus. Staff noted that there has been a recommendation to clarify diabetes mellitus, to avoid confusion with other kidneys of diabetes. The Workgroup agreed.

Staff asked the Workgroup whether it's more critical to capture use of insulin in general, or if insulin use should be a child question of diabetes, to indicate the insulin is used for diabetes management. The Chair recommended that "insulin use" be a child question of diabetes, and added that help documentation could also help clarify.

Staff offered that "diabetes management" could lead into the insulin and oral medication questions. The Chair agreed that makes sense. The Workgroup agreed.

One member asked if the KiMAC currently screens on compliance for diabetes care, and staff noted that there is no compliance screening for diabetes, just management type. The member noted that compliance is important to consider, and added that many evaluating surgeons look at hemoglobin A1c levels, although they can be erroneous. The member continued that it may not be helpful to add another layer of complexity, but that there could be value to considering compliance with diabetes medication. The Chair responded that information may be unreliable, and donor families may not know that. The Chair added that compliance is subjective, and it is difficult to reliably determine this. The Chair agreed the A1c is more helpful. The member agreed. Another member remarked that A1c can be unreliable, especially if the donor had a blood transfusion.

A representative of the Health Resources and Services Administration (HRSA) asked if it would matter how long a donor was on insulin or if the donor had originally been put on oral medication, and if these are criteria that would make sense as a filter. The HRSA representative continued, asking if that really made a difference in determining whether or not to accept the kidney, and if that information is clinically relevant. Staff explained that the question has been asked this way is because the Workgroup determined that management type for diabetes in combination with duration of diabetes was more relevant and accurate for screening than duration of diabetes management. The HRSA representative continued, asking if this information is helpful or relevant to the clinical decision making to accept a kidney. A member responded that more information is typically preferable, but that becoming overly granular may not be helpful or accurate when considering donor history. The Chair also noted that this is for the KiMAC, which is for hard to place kidneys with a significant amount of declines. The Chair asked the Workgroup to consider what would be helpful to help bypass centers who would not accept the kidney.

Presentation summary:

Current screening for diabetes and hypertension in the KiMAC includes the following duration designations: 0-5 years, 6-10 years, 11-20 years, greater than 20 years, and will not consider. Previously, the Workgroup discussed condensing these response options to align with how diabetes and hypertension duration are currently collected in the OPTN Donor Data and Matching System. Currently, the OPTN Donor Data and Matching System collect the following:

- History of Diabetes – No; Yes, 0-5 years; Yes, 6-10 years; Yes, greater than 10 years; Yes, duration unknown; unknown
- History of hypertension – No; Yes, 0-5 years; Yes, 6-10 years; Yes, greater than 10 years; Yes, duration unknown; unknown

The Workgroup was asked to confirm whether the KiMAC screening tool should be updated to align with the OPTN Donor Data and Matching system's method of collecting diabetes and hypertension data, or if the OPTN Donor Data and Matching system should be updated to increase granularity of diabetes and hypertension duration.

Staff shared that about 70 transplant programs use the more granular 11-20 years for controlled hypertension, and about 60 transplant programs use the more granular 11-20 years for uncontrolled hypertension. There are about 108 programs using 11-20 years as their threshold across both diabetes question. This means that the program would accept an offer from a donor with 11-20 years (up to 20 years) of uncontrolled hypertension, but not from a donor with more than 20 years of hypertension.

Summary of discussion:

The Chair expressed a preference to maintain what is currently collected in the OPTN Donor Data and Matching System. The Chair continued that it does seem like there are enough transplant programs using the more granular system to make a difference, and asked the Workgroup what their preference would be, or if programs could just indicate they would accept a donor with any duration of hypertension or diabetes. The Chair explained that the granularity being used in the KiMAC should be maintained, and the OPTN Donor Data and Matching System should be updated. A member countered that this may not be a good enough reason to change the response options in the OPTN Donor Data and Matching System. The Chair remarked that hypertension and diabetes are likely more important, particularly for hard to place kidneys.

Staff explained that offer filters can screen on diabetes using the granularity of response options that the OPTN Donor Data and Matching System provides. The Chair noted that if these centers are using

offer filters this way, then maybe it would be better to leave the OPTN Donor Data and Matching System response options alone. A member remarked that the duration should be the same across the board. The Chair remarked that the KiMAC should align with Offer Filters. The Workgroup expressed support for condensing the granularity of response options for diabetes and hypertension durations into 0-5 years, 6-10 years, greater than 10 years, and will not consider.

3. KiMAC: Screening for Lateral Characteristics

The Workgroup discussed how to screen when characteristics may differ from one kidney laterality to the other.

Presentation summary:

"Areas of infarction" and "Plaque in the renal artery" will need to be collected for both the left and the right kidney separately, as they may differ.

Currently, the system cannot determine which kidney is being offered. Acceptances are not consistently entered during allocation, particularly with multi-organ allocation; this makes tracking which kidney is being offered and available difficult to track.

The Workgroup was asked how the system should screen when there are characteristics that vary laterally. If the Workgroup chose for KiMAC to screen more conservatively, the tool would not screen on infarction unless infarction was present for both kidneys, and the milder response for plaque would be used to screen. If the Workgroup chose for the KiMAC to screen more aggressively, the KiMAC will screen on the worse result, with infarction screening if present on either kidney, and the more severe plaque will screen regardless of whether it is present or visualized on the other kidney.

Summary of discussion:

One member remarked that screening should be conservative if laterality can't be determined, but that it would be a worthwhile endeavor for the OPTN Donor Data and Matching System to be able to determine the laterality. The Chair agreed that ideally, the system can determine which kidney is being offered.

The Chair remarked that it is more likely that the less marginal kidney would have been placed, and the kidney that is more concerning is still being offered. The Chair added that this tool won't be used until a number of declines have been sent already. The Chair supported screening more aggressively. A member responded to the Chair, but noted that this may not be true in all cases. The member remarked that using more conservative screening rules may also result in more aggressive screening choices for programs, who may be concerned they may miss an offer for a kidney that is not infarcted due to the other having infarction. The member added that is not uncommon for a set of kidneys to have disparate characteristics.

The Chair remarked that it may not make sense to even ask questions regarding infarction if the screening won't apply in many cases where it is relevant. The Chair continued that it's important to bypass the programs that would not accept the organ. A member responded that the conservative screening is less efficient, but that more aggressive screening may be inappropriate and discourage use of appropriately selected screening criteria. The member noted that it's an easier determination if both the organs are bilaterally diseased. The member expressed support for more conservative screening rules. The Chair reiterated that it is more likely the less marginal kidney will be placed and the other kidney being allocated will have these characteristics. The Chair asked how likely it would be that one kidney has concerning characteristics and the other doesn't, where both kidneys are being allocated at the point at which the KiMAC applies. The Chair agreed that it makes sense to use conservative

screening rules if programs' behavior will be changed and result in less effective screening. A member that aggressive screening rules just need to be clear, so that programs understand what offers they will be bypassed for. The Chair agreed that perception is important, and that the tool should be used.

The Workgroup expressed support for utilizing more conservative screening rules in the case of lateral characteristics.

Staff asked the Workgroup if they have any ideas on how the system should be differentiating which kidney is being offered. Staff noted that there is currently a pop-up screen when an Organ Procurement Organization (OPO) user hits the "electronic notification" button, where OPOs are able to input data. Staff asked if it would make sense for laterality of kidney(s) offered to be reported here.

The Chair remarked that it could be more automated, once the acceptance has been entered into the OPTN Donor Data and Matching System. Staff explained that acceptances are not consistently entered in the system, and are often not entered immediately upon acceptance. Staff asked if it could be a separate match for each kidney. The Chair recommended against two separate kidney matches, particularly because programs will often have choice of which kidney, but won't determine which kidney they want to accept until after organ recovery. Another member agreed that separate kidney match runs would result in an enormous offer burden for transplant centers. This could double the offer volume, particularly when not all of these offers will result in a transplant. The member continued that this needs to be efficient without significantly increasing the workload. The Chair recommended an option where the right kidney acceptance is input into the match, and that would trigger the system to know that the left kidney is being offered. The Chair continued that this would be most applicable for the KiMAC. The Chair continued that potentially there is an option for the OPO to create a separate match run, and that could be more efficient, as it would be based more on OPO discretion. The Chair added that refusals could carry over from the combined match run.

Upcoming Meeting: August 25, 2023

Attendance

- **Workgroup Members**
  - Valerie Chipman
  - Colleen Jay
  - Carrie Jadlowiec
  - Rebecca Baranoff
- **HRSA Staff**
  - Marilyn Levi
- **SRTR Staff**
  - Bryn Thompson
  - Jon Miller
  - Peter Stock
- **UNOS Staff**
  - Kayla Temple
  - Lauren Motley
  - Lindsay Larkin
  - Joann White
  - Ben Wolford
  - Carlos Martinez
  - Carly Layman
  - James Alcorn
  - Joel Newman
  - Kaitlin Swanner
  - Keighly Bradbrook
  - Kieran McMahon
  - Krissy Laurie
  - Rebecca Fitz Marino
  - Sevgin Hunt
  - Thomas Dolan
  - Valerie