OPTN Kidney and Pancreas Transplantation Committees
Utilization Considerations of Kidney and Pancreas Continuous Distribution Workgroup
Meeting Summary
August 25, 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 8/25/2023 to discuss the following agenda items:

1. Review Kidney Minimum Acceptance Criteria Screening Tool (KiMAC) in Continuous Distribution
2. Data Checklist: KiMAC
3. Finalize: KiMAC Data Collection Additions and Modifications

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 has been working 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

The Workgroup worked through the data checklist for data collection regarding anti-diabetic oral medication and insulin in the context of diabetes mellitus management.

Presentation summary:

Staff presented the following potential definition for anti-diabetic oral medication:

"Any oral pharmacological treatment used to manage and achieve glycemic control in diabetes patients. Oral medications (pharmacological treatments) to maintain and manage glycemic control in diabetes patients. This includes oral hypoglycemic medications such as: sulfonylureas, meglitinides, biguanides, thiazolidinediones, alpha-glucosidase inhibitors, DPP-4 inhibitor, SGLT2 inhibitors, and cycloset. Healthcare practitioners must encourage patients to combine lifestyle modifications with oral pharmacologic agents for optimal glycemic control."[1]

Summary of discussion:

One member agreed with the definition, but noted that the last sentence regarding lifestyle modifications may not be necessary. Staff asked if the Workgroup would prefer just the first sentence. The Chair agreed. Other members agreed that the first sentence is adequate, adding that listing all

[1] Oral Hypoglycemic Medications, Stat Pearls; https://www.ncbi.nlm.nih.gov/books/NBK482386/

potential options could hinder understandability as diabetes management options grow and change over time.

A member asked if it was necessary to specify “oral,” and staff noted that this was originally intended to differentiate oral medication from insulin. The Chair agreed, and noted that this definition makes sense for oral medications.

Staff asked if “yes,” “no,” and “unknown” were acceptable response options, with unknown applicable particularly if the donor’s history is unknown. Several members agreed. Staff asked if there are other instances where "unknown” is appropriate. The Chair remarked that unknown donor history is probably a sufficient and appropriate scenario for an “unknown” response, or if the family is unsure.

The Workgroup confirmed that use of oral anti-diabetic information is generally available in the donor’s medical and social history, and that this element would not require invasive or significant

Presentation summary:

Staff presented the following definition for diabetes managed with insulin:

“The use of injectable insulin to manage and maintain glycemic control in diabetes patients. This includes type I and type II diabetes.”

Summary of discussion:

The Chair remarked that it may not be necessary to include the last sentence in the definition, as it may not be necessary to specify all types of diabetes mellitus where insulin management is relevant. The Chair added that the definition could include “diagnosed with diabetes,” so that the diabetes diagnosis is clear and specific, and so this field wouldn’t apply to insulin used to manage the patient in the intensive care unit (ICU).

One member recommended removing the term “maintain” glycemic control, because it is hard to ascertain full control and the data element itself is more relevant to the attempt to manage glycemic control. The Chair agreed.

Staff noted that response options for this data element would include “yes,” “no,” and “unknown,” and asked the Workgroup if this was appropriate. The Chair agreed, noting that this aligns with the question regarding anti-diabetic oral medication.

The Workgroup agreed that this definition is clear and understandable. The Workgroup also agreed that this information is generally known, and that the “unknown” response option would allow this data to be appropriately reported if the information was not known. Staff asked the Workgroup if this information is easily discoverable, and asked the Workgroup to confirm that this would not require additional testing or invasive procedures. The Chair agreed and confirmed this.

3. Finalize: KiMAC Data Collection Additions and Modifications

The Workgroup holistically reviewed and finalized the previously discussed data collection related to the KiMAC, including where the element will be found on the donor record and finalized help documentation and definitions.

Presentation summary:

Donor has a horseshoe kidney – Yes, No

Help documentation and definition:

> "A horseshoe kidney is a congenital abnormality in which the two kidneys fuse together during fetal development to create a horseshoe-shaped structure.
>
> Indicate **Yes** if the donor is known to have a horseshoe kidney. Indicate **No** if the donor does not have a horseshoe kidney, or if it is unknown whether the donor has a horseshoe kidney (IE, the kidneys have not been visualized or an anatomical evaluation has not been performed."

Summary of discussion:

Staff asked the Workgroup where the "horseshoe kidney" element should be located in the donor record. The Chair expressed support for putting this element in the "organ data" section of the donor record, noting that this may not always be known ahead of procurement. Another member agreed that this is generally discovered during organ recovery. The Chair noted that this could be seen on abdominal imaging, but that it makes sense for this information to be in the "organ data" section.

The Chair recommended that this data element be a check box instead of a "yes/no" question, noting that this is very infrequent and rare. The Chair noted that it would be unlikely for a coordinator to go back and input a "no" into the system post-recovery. The Chair added that this would be an unnecessary addition to post-recovery workflows, and that incorporating a check box would allow that step to only occur when relevant. Another member agreed that this data element will likely be left blank, and that it would be better to simply allow OPOs to indicate if present.

Staff updated the help documentation to reflect a checkbox based data element, such that help documentation includes:

> **Check the box** if the donor is known to have a horseshoe kidney. **Leave the box blank** if the donor does not have a horseshoe kidney, or if it is unknown whether the donor has a horseshoe kidney (IE, the kidneys have not been visualized or an anatomical evaluation has not been performed."

The Chair and another member agreed with the updated instructional documentation.

Presentation summary:

Kidney has infarcted areas – Yes, No

- Located in the organ data section
- Asked separately for left and right kidney

Help documentation and definition:

> Infarction is ischemic necrosis of the renal tissue
>
> Indicate **Yes** if any areas of infarction were visualized upon anatomic assessment. Indicate **no** if no areas of infarction were visualized.

As previously determined by the Workgroup, if the system cannot differentiate which kidney is being offered, the screening tool would not screen on infarcted areas unless both kidneys have infarcted areas indicated.

Summary of discussion:

The Workgroup agreed with the above format for data collection and screening on *Kidney has infarcted areas*.

Presentation summary:

Arterial plaque present at time of procurement – Yes, No

- If Yes, indicate *Type of plaque* – Soft, Hard
    - If Soft, indicate *Severity* – mild, moderate, severe
    - If Hard, indicate *Severity* – mild, moderate, severe, ulcerative
- This data element will be collected separately for the right and left kidneys
- This data element will be located in the organ data section of the donor record

Help documentation and definition:

> "Plaque in the renal artery, or artery atherosclerosis, is a mechanism of renal artery stenosis.
>
> Indicate whether plaque was visualized in the left/right renal artery upon anatomic assessment. If plaque was visualized, indicate the type of plaque, and then the severity."

As previously determined by the Workgroup, if the system cannot differentiate which kidney is being offered, the screening tool would screen on the best or mildest plaque input visualized. If one kidney has no plaque visualized, the system would not screen for hard plaque. If both kidneys have severe hard plaque visualized in the renal artery, the system would screen for severe hard plaque.

Summary of discussion:

The Workgroup agreed that this data collection aligns with how this information is typically collected on anatomy evaluations and in electronic donor records. One member noted that it may not be necessary to filter on some types of plaque, but supported maintaining screening if programs will use it.

A member pointed out that most renal anatomy sheets collected arterial and aortic plaque. Staff noted that currently, the KiMAC only provides screening on arterial plaque. Another member remarked that transplant programs care more about arterial plaque than aortic plaque. The member continued that it is appropriate to collect arterial plaque data for screening.

The Workgroup supported the above format for data collection for arterial plaque, including the definition and instructional documentation.

Presentation summary:

Does the donor have a known history of polycystic kidney disease (PKD)? – Yes, No

- Located in the medical and social history section of the donor record

Help documentation and definition:

> "Polycystic kidney disease (PKD) is a hereditary disease characterized by the progressive expansion of a large number of tightly packed cysts within the kidney.
>
> Indicate whether the donor has a known history of polycystic kidney disease. Indicate **yes** if the donor has been diagnosed with PKD, either in their medical history, upon donor evaluation, management, and/or organ procurement. Indicate **no** if the donor has no known history of polycystic kidney disease. Indicate **unknown** if the donor does not have a medical and social history, and has *not* been diagnosed with PKD upon donor evaluation, management, and/or organ procurement"

Summary of discussion:

Staff asked if unknown should be included as a potential response option, particularly in the case that the donor has an unknown medical and social history. Staff clarified that an "unknown" option typically provides more useful information, allowing OPOs to differentiate between "no" and "unknown." This would also align with how other questions in the medical and social history sections are asked. One

member responded that it would be difficult to have this be unknown, unless the donor had no known history at all. The member explained that this is typically asked in the medical and social interview with the family, and that the family is not always certain. The member explained that the screening tool should only screen if the answer is "yes," not if the answer is "no" or "unknown." The member supported making this question a check box, similar to horseshoe kidney. Another member agreed, noting that "no" and "unknown" are the same thing – if the history is not known, then there is no history of it. The member supported not including an "unknown" option.

Staff noted that the KiMAC would not screen on "unknown" if an unknown option was included. Staff added that this could impact the quality of the data with limited additional data burden. A member noted that the data could be more questionable if "unknown" was added, adding that instances where it's unknown should really be considered a "no." The member continued that many donor families also conflate "no" and "unknown," and that this puts the OPO in a position where they have to interpret whether there is no history or an unknown history.

One member offered that there could be increased clarification on medical and social history data elements in general, such that "unknown" should only be used if the donor does not have a history at all, because the family has no idea of the donor's history or else the medical social interview cannot be completed. The member continued that this would be very rare.

Staff asked if there is an instance where "unknown" would be necessary. A member noted that the only instance where unknown would be appropriate is if the donor does not have a medical and social history. The member recommended adding that the OPO was unable to perform a donor risk assessment index interview or risk assessment interview to the help documentation for "unknown." The member suggested the following update to the instructional documentation:

"Indicate **unknown** if the OPO was unable to complete a donor risk assessment interview (DRAI), the donor does not have a medical and social history, and has *not* been diagnosed with PKD upon donor evaluation, management, and/or organ procurement"

The member recommended expanding similar language across the instructional documentation for the other questions asked in the donor medical and social history.

The Workgroup supported the following format for data collection regarding PKD, understanding that the KiMAC tool would only screen when the donor was indicated to have a known history of PKD:

Does the donor have a known history of polycystic kidney disease (PKD)? – Yes, No, <u>unknown</u>

- Located in the medical and social history section of the donor record

Help documentation and definition:

> "Polycystic kidney disease (PKD) is a hereditary disease characterized by the progressive expansion of a large number of tightly packed cysts within the kidney.
>
> Indicate whether the donor has a known history of polycystic kidney disease. Indicate **yes** if the donor has been diagnosed with PKD, either in their medical history, upon donor evaluation, management, and/or organ procurement. Indicate **no** if the donor has no known history of polycystic kidney disease. Indicate **unknown** if the OPO was unable to complete a donor risk assessment interview (DRAI), the donor does not have a medical and social history, and has *not* been diagnosed with PKD upon donor evaluation, management, and/or organ procurement."

<u>Presentation summary:</u>

Diabetes mellitus → *Managed with antidiabetic oral medication* – Yes, No, Unknown

- Located in the medical and social history section of the donor record

Definition and help documentation:

> "Antidiabetic oral medication is any oral pharmacological treatment used to manage glycemic control in diabetes patients.
>
> Indicate **yes** if the donor has been prescribed anti-diabetic oral medication in order to manage their diabetes, regardless of compliance. Indicate **no** if the donor has never been prescribed anti-diabetic oral medication in order to manage their diabetes. Indicate **unknown** if it is unknown whether the donor has managed their diabetes via oral medication."

Summary of discussion:

One member supported the above format for data collection regarding anti-diabetic oral medication.

Staff asked the Workgroup if "managed" is the appropriate terminology, or if it implies compliance. One member remarked that "prescribed" could be substituted. A member noted that "prescribed" does not necessarily mean that the donor was actually compliant with the prescribed medication, and that this needs to be made clear. The Chair agreed, noting that it is hard to verify compliance in any case. Another member remarked that non-compliant but identified as needing medication would be concerning, and that this would be an acceptable instance to screen if there are concerns for donor quality. The member continued that a donor with a need for the medication who was not compliant would likely have increased risk of renal damage than a donor who was compliant.

The Chair pointed out that the OPO will likely indicate "yes" here if the patient had ever been prescribed oral medication to manage diabetes, regardless of whether the patient is currently managing their diabetes in this way.

The Workgroup agreed to phrase the question as "has the donor been prescribed antidiabetic oral medication."

Presentation summary:

Diabetes mellitus → *Managed with insulin* – Yes, No, Unknown

- Located in the medical and social history section of the donor record

Definition and help documentation:

> "Injectable insulin may be used to manage glycemic control in diabetic patients.
>
> Indicate **yes** if the donor has ever been prescribed regular insulin to manage their diabetes, regardless of compliance. Indicate **no** if the donor has never been prescribed insulin to manage their diabetes. Indicate **unknown** if it is unknown whether the donor has managed their diabetes via insulin."

Summary of discussion:

Staff asked the Workgroup if "managed" is the appropriate terminology, or if it implies compliance. Staff also asked the Workgroup how insulin use should be defined, and whether this should be any insulin use to manage a patient's diabetic episodes, or if this should really focus more on regular insulin use.

The Chair remarked that prescribed insulin is much easier to verify. The Chair continued that "prescribed with insulin" makes sense, and recommended that the definition align with the other definition for antidiabetic oral medication.

The instructional documentation was updated to include the following: "Indicate **unknown** if it is unknown whether the donor has been prescribed insulin to manage their diabetes."

The Workgroup supported the updated format for data collection for diabetes management via insulin use.

Staff presented samples for how each data element would appear in the OPTN Donor Data and Matching System. The Workgroup had no questions for comments.

Staff asked the Workgroup if any of the discussed data collection will need to be added to the deceased donor registration form, noting that the original purpose of this data collection was for screening at time of allocation. Members supported not adding these data elements to the deceased donor registration form.

Presentation summary:

Previously, the Workgroup discussed modifications to the definition of an incoming data element for "controlled donation after circulatory death (DCD)," to clarify uncontrolled DCD scenarios.

The current definition is as follows: "a controlled DCD donor is a donor whose life sustaining treatment will be withdrawn and whose family gave written consent for organ donation in the controlled environment; a donor awaiting circulatory arrest; patient on intensive care unit with non-survivable injuries who have withdrawal of life sustaining treatment."

The Workgroup discussed the following addition to the current definition: "Indicate **yes** if the donor is a controlled DCD donor. This is defined as those situations where the donor experiences cardiac arrest following the withdrawal of life sustaining treatments, but not considered to be brain dead. Indicate **no** if the donor is an uncontrolled DCD donor. This includes situations where:

- Cardiac arrest in the process of the determination of death by neurological criteria after brain death or after such determination has been performed, but before being transferred to an operating room
- Cardiac arrest in hospital patients."

Summary of discussion:

The Chair and other members expressed support for this modified help documentation and definition.

Presentation summary:

Staff presented a sample form of how the updated KiMAC questionnaire will look in the OPTN Waitlist System, as shown in **Tables 1-5**. Staff noted that data definitions in the KiMAC questionnaire will align with those included in the OPTN Donor Data and Matching System, so that programs understand how the data used for screening will be entered.

Table 1: KiMAC Questionnaire: Donor History and Management

Item	Response Options
What is the maximum age your center will consider?	XX years
Will your center consider kidneys from a donor with any of the following exposures within the last 30 days?	

• Sex (i.e. any method of sexual contact, including vaginal, anal, and oral) with a person known or suspected to have HIV, HBV, or HCV infection	Yes/No
• Man who has had sex with another man	Yes/No
• Sex in exchange for money or drugs	Yes/No
• Sex with a person who had sex in exchange for money or drugs	Yes/No
• Drug injection for non-medical reasons	Yes/No
• Sex with a person who injected drugs for nonmedical reasons	Yes/No
• Incarceration (confinement in jail, prison, or juvenile correction facility for ≥ 72 consecutive hours	Yes/No
• Child breastfed by a mother with HIV infection	Yes/No
• Child born to a mother with HIV, HBV, or HCV infection	Yes/No
• Unknown medical or social history	Yes/No
Will your center consider kidneys from a donor with a positive result from any of the following infectious disease tests?	
Hepatitis B Surface Antigen?	Yes/No
HBV NAT?	Yes/No
Anti-HCV?	Yes/No
HCV NAT?	Yes/No
HTLV I or II?	Yes/No
Syphilis?	Yes/No
What is the minimum donor creatinine clearance level either measured or estimated based on serum creatinine upon donor's admission that your center will consider?	XX ml/min corrected to 1.73 M^2
Will your center consider an adult kidney donor with a known history of polycystic kidney disease?	Yes/No/unknown

Table 2: KiMAC Questionnaire: Anatomy Questions

Item	Response Options
Will your center consider an adult kidney donor with any of these abnormalities:	
• Horseshoe kidney?	Yes/no
• Kidney has infarcted areas?	Yes/no

Will your center consider a kidney from a donor with hard plaque in the renal artery described as:	
• Mild	Yes/No
• Moderate	Yes/No
• Severe	Yes/No
• Ulcerative	Yes/No

Table 3: KiMAC Questionnaire – DCD Questions

Item	Response Options
Will your center consider a kidney recovered from an uncontrolled DCD donor?	Yes/No

Tables 4-5: KiMAC Questionnaire – Age Specific Questions

Identify the duration for which your center will consider donor kidneys for the specified circumstance:

For donors aged:	<45 years	45-54 years	55-64 years	>64 years
With a history of hypertension and compliant with medication?	0-5 yrs 6-10 yrs >10 yrs Will not consider	0-5 yrs 6-10 yrs >10 yrs Will not consider	0-5 yrs 6-10 yrs >10 yrs Will not consider	0-5 yrs 6-10 yrs >10 yrs Will not consider
With a history of hypertension and any periods of non-compliance?	0-5 yrs 6-10 yrs >10 yrs Will not consider	0-5 yrs 6-10 yrs >10 yrs Will not consider	0-5 yrs 6-10 yrs >10 yrs Will not consider	0-5 yrs 6-10 yrs >10 yrs Will not consider
With diabetes duration, and donor has been prescribed antidiabetic oral medication for management	0-5 yrs 6-10 yrs >10 yrs Will not consider	0-5 yrs 6-10 yrs >10 yrs Will not consider	0-5 yrs 6-10 yrs >10 yrs Will not consider	0-5 yrs 6-10 yrs >10 yrs Will not consider
With diabetes duration, and donor has been prescribed insulin for management	0-5 yrs 6-10 yrs >10 yrs Will not consider	0-5 yrs 6-10 yrs >10 yrs Will not consider	0-5 yrs 6-10 yrs >10 yrs Will not consider	0-5 yrs 6-10 yrs >10 yrs Will not consider

Enter the appropriate criteria your center will consider for each of the following questions

For donors aged:	<45 years	45-54 years	55-64 years	>64 years
What is the maximum acceptable peak serum creatinine level?	XX mg/dl	XX mg/dl	XX mg/dl	XX mg/dl

What is the maximum cold ischemic time on cold storage?	XX hrs	XX hrs	XX hrs	XX hrs
What is the maximum acceptance percentage of global glomerulosclerosis for a biopsied kidney?	XX %	XX %	XX %	XX %

Summary of discussion:

Staff noted that previously, the Workgroup supported removing screening for soft arterial plaque. However, since the Workgroup has determined that it is appropriate to also collect data for soft arterial plaque, staff asked the Workgroup if soft arterial plaque should be removed as a screening criterion. One member supported removing soft plaque as a screening criterion, noting that soft plaque is fairly common and rarely concerning. The Chair agreed.

The Workgroup agreed to remove screening for soft arterial plaque.

Staff asked the Workgroup whether it was appropriate for the screening tool to screen on the better (milder) of two glomerulosclerosis percentage results, as opposed to more aggressively screening on the worse (more concerning) of the two results. One member expressed support for more conservative screening, screening on the milder result. Another member agreed, noting there can be extreme differences in biopsy results. Staff noted that this aligns with the screening decision the Workgroup made for other lateral characteristics.

Upcoming Meeting: TBD

Attendance

- **Workgroup Members**
  - Valerie Chipman
  - Jillian Wojtowicz
  - PJ Geraghty
  - Tania Houle
  - Colleen Jay
  - Jamie Myers
  - Nikole Neidlinger
- **HRSA Staff**
  - Jim Bowman
- **SRTR Staff**
  - Jon Miller
  - Bryn Thompson
- **UNOS Staff**
  - Kayla Temple
  - Lauren Motley
  - Lindsay Larkin
  - Lauren Mooney
  - Kieran McMahon
  - Mariah Huber
  - Thomas Dolan
  - Joann White
  - Kaitlin Swanner
  - Laura Schmitt
  - Joel Newman
  - Krissy Laurie
  - Carlos Matinez
  - James Alcorn