OPTN Kidney and Pancreas Transplantation Committees
Utilization Considerations of Kidney and Pancreas Continuous Distribution Workgroup
Meeting Summary
July 28, 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 7/28/2023 to discuss the following agenda items:

1. Review Kidney Minimum Acceptance Criteria Screening Tool (KiMAC) in Continuous Distribution
2. Data Checklist: KiMAC

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 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:

One member asked if programs and Organ Procurement Organizations (OPOs) still tested for HTLV, and whether or not screening for HTLV should be removed as a screening criteria. Staff responded that some OPOs do still test for this, and that HTLV test results are able to be reported in the donor record. Staff continued that programs are able to screen on this currently. Another member shared that OPOs that have tissue banks will test for HTLV, as it is a requirement for tissue donors.

A member asked how peak creatinine would be determined. Staff noted that the system would be able to determine the peak creatinine amongst the reported creatinine values. The member explained that peak creatinine can indicate different things in different donors – a young donor with great kidneys and temporary acute tubular necrosis (ATN) may have high creatinine that would not be relevant to how the kidney will function. The member continued that peak creatinine as a screening element without context may be less useful. The member explained that cold time, glomerular sclerosis, and diabetes history matter more to the potential function of the kidney. Staff noted that the KiMAC tool currently applies to the last two classifications on the match run, and that KiMAC is targeting hard to placed kidneys that haven't been placed after a percentage of the match run has received, reviewed, and declined the offer. Staff continued that by the time the KiMAC bypasses start applying, there has likely been some concern regarding the kidney.

One member suggested adding anuria as a potential screening criteria, noting that their program typically is more concerned about anuric donors with acute kidney injury (AKI) rather than a creatinine number. The member continued that urine output is not consistently captured in the donor record, which could make screening more difficult. Another member agreed that it is highly variable. The member noted that anuria would only be a helpful screening element if urine output was sufficiently rigorous as data point. Staff noted that urine output is not consistently entered into the donor record. Staff added that in the scope of the first iteration of the KiMAC in continuous distribution was to transition the tool, leveraging the existing responses programs have provided on the kinds of kidneys

they are willing to accept. Staff continued that this involves clarifying and removing existing elements, with new screening criteria an option for a later iteration.

A representative of the Scientific Registry of Transplant Recipients (SRTR) asked about pump numbers, noting that some programs use pump numbers to finalize acceptance decisions. The SRTR representative continued that each of these criteria are typically used in context with each other. The SRTR representative explained that most centers look at flow pump numbers, especially for DCD donors. Staff noted that adding new criteria for KiMAC screening is not currently in scope of transitioning the KiMAC. The SRTR representative explained that programs use flow and pump numbers as a screening criteria when evaluating offers. Staff noted that this is not currently part of the KiMAC tool. The Chair agreed, noting that pump numbers could actually be more ideal to screen on earlier on in allocation than where the KiMAC applies, and that pump numbers could be a better addition to offer filters. The Chair noted that there are other organ and donor information points that could be added to screening overall, not just the KiMAC. Another member remarked that pump numbers generally only become relevant after the kidneys have been on the pumps for a few hours, which results in longer allocation timelines overall. The Chair agreed, reiterating that adding new criteria is not within the scope of the first iteration of the KiMAC in continuous distribution. Staff noted that these ideas, particularly regarding anuria and flow can be recommended to the Operations and Safety Committee, which has worked closely with the offer filters project. Staff also noted that the Operations and Safety Committee currently has a concept paper out for public comment regarding potential data collection in the donor record, and recommended that Workgroup members review and leave individual comments on potential future OPTN Donor Data and Matching System Data Collection that could be used for screening and filtering.

The Chair commented that peak creatinine should be maintained, as programs may still use it for screening.

2. Data Checklist: KiMAC

The Workgroup began working through the DAC checklist, discussing the overall purpose for the data collection and then each individual data element.

Presentation summary:

The Workgroup may need to establish a workflow for several elements. For example, if the element is not required to be filled out, how can be the OPO indicate if the answer to a question is not known, or remove accidental indication of “yes” or “no?”

Summary of discussion:

Kidney has areas of infarction

Staff noted that infarction is currently asked on the KiMAC form as “will your center consider a kidney that has significant infarction (greater than 20 percent).” One member asked if the Workgroup had determined the 20 percent threshold, or if that was historical. Staff explained that this is how the question has been asked historically, and that there is limited documentation on how the 20 percent threshold was determined. Staff noted that the Workgroup will need to determine if that threshold is relevant or appropriate. The member remarked that most programs would be concerned about considerably less kidney infarction. The member explained programs are aggressive about different kinds of sclerosis, but that gross infarction of the kidney is typically a big red flag. The member recommended that the data element should be “kidney has gross infarction – yes/no,” noting that most programs are concerned about infarction at all. Another member agreed, noting that it’s not common to think of infarction in terms of numbers. A member continued that infarction is not very common, and that it’s relatively rare to see gross infarction.

Staff asked the Workgroup if the numeric threshold for infarction is helpful. A member noted that any evidence of gross infarction will be a red flag for most centers, and that the 20 percent distinction is not necessary. A member pointed out that it would be hard to determine what 20 percent infarcted meant, and if this would be determined by surface area or another consideration.

The Chair commented out that "gross infarction" requires the OPO to make a clinical determination as to what that means. A member pointed out that the back table recovery would be done by the recovering physician, and another member agreed that this would be a donor surgeon call. The Chair explained that the OPO will still need to ask the recovering surgeon if they consider the infarction to be gross, versus a percentage that the recovery surgeon would need to indicate. The Chair continued that gross infarction is not currently being reported. One member remarked that they are never asked about a percentage of infarction upon anatomical evaluation, but instead are simply asked if there is infarction present, as a yes/no question. The member offered that the donor record data collection could align with that data collection in anatomy reports – "any infarcted areas? – Yes/No." Another member agreed, noting that the threshold and "gross" could be omitted in favor of "any infarcted areas." The Chair agreed that this question is sensible and straight forward for OPOs. A member agreed, adding that gross is only helpful to avoid splitting hairs over microscopic and gross infarction; it would need to be definitive, clearly visualized infarction. The Chair agreed, that clear, objective language is the most useful.

Staff asked if the language should be "evidence of infarction" or "kidney has infarcted areas." One member remarked that the language should be "kidney has infarcted areas," which aligns with the question asked of recovering surgeons upon anatomical evaluation. Another member agreed that this is the standard language on OPO anatomy forms, with a simple "Yes/No" response. Other members agreed. The Chair recommended that the data collection for infarcted kidney be separate for left and right kidneys, such that OPOs could indicate one kidney has infarction and the other does not. A member pointed out that there are currently very limited fields for Kidney organ data, and currently only includes minimal biopsy fields and pump values. The member continued that most kidney anatomy information is uploaded to the donor record as an attachment.

Staff asked if there would be any concern that the KIMAC would be screening too aggressively if there was only a small spot of infarction. The Chair pointed out that, based on how the KiMAC is applying, that the way the question is worded is appropriate, particularly as at that point, there are enough concerning factors that other programs are no longer interested. A member agreed, noting that this question should remain binary.

One member asked how the tool would screen if one kidney is infarcted and the other is not, especially if both kidneys are being allocated. Staff explained that this question would be asked separately for the left and the right kidney, and asked the Workgroup how they think the tool should screen, particularly in consideration for how the KiMAC is applying. The Chair remarked that if both kidneys are available, programs shouldn't be bypassed just because one kidney has infarction, as they may be interested in the kidney without infarction. The Chair remarked that they should be allocated separately. Staff remarked that the current application of the KiMAC is manual enough in nature to ensure that screening for infarction is not inappropriately applied if only kidney is infarcted. When the KiMAC is automated, it may be necessary to have a rule for how to screen on differing lateral characteristics. Staff noted that currently, the system is not currently able to determine which kidney is being offered, particularly because acceptances of kidneys on non-kidney match runs (such as in the case of heart-kidney acceptances), are not consistently entering kidney acceptances. The Chair noted that there are pros and cons to both. A member remarked that they would want to get the offer for the non-infarcted kidney even if the other was infarcted. The member remarked that it could be fair to consider that the non-

infarcted kidney may have already been placed and allocated by the time the KiMAC tool applies, and so it could be appropriate to screen on infarction if only one kidney is infarcted. Staff noted that the Workgroup can circle back to this later, and consider the question in context with other lateral screening criteria. The Chair agreed.

Staff shared two definitions of infarction:

> *Ischemic necrosis of the kidney caused by interruption of the blood supply to the area*[1]
>
> *Renal infarction is a rare ischemic event or insult caused by the complete or partial occlusion of the main renal artery or its segmental branches, which may ultimately lead to the ischemic necrosis of renal tissue.*[2]

Staff asked the Workgroup if either definition was appropriate and accurate. One member asked what the purpose of the definition is. Staff explained that each data element in the OPTN Computer System needs to incorporate a definition for understandability and consistency. The member remarked that the first definition is the slightly briefer. Another member recommended the last line of the second definition, "ischemic necrosis is concern for ischemic necrosis of renal tissue," noting that cause is not relevant. The member noted that the definition should be simpler. Another member remarked that it is important that members don't get confused between infarction and acute tubular necrosis, which are separate concerns. The member recommended including the word "gross" in the definition, noting that renal infarction is large scale, not microscopic. Staff continued that the definition would then be "ischemic necrosis of renal tissue." Staff asked the Workgroup if they felt the definition of infarction is usable and understandable.

The Workgroup confirmed that there is no relevant unit of measurement, and that the acceptable response options include "yes" and "no." Staff asked the Workgroup if there needs to be an "unknown" response option. A member pointed out that this should be a yes/no answer given by the recovery surgeon at the time of anatomical assessment. The member remarked that while there could be infarcted areas under uncleaned fat that the recovery surgeon couldn't see, the recovery surgeon still needs to make a clear determination. The member recommended "yes" and "no" response options only. Another member agreed, pointing out that even small areas of infarction could be related to much larger, deeper damage of the organ that can't be visualized.

The Workgroup confirmed that there is no timeframe to this data element. Staff asked the Workgroup if this data element would require any additional invasive testing beyond routine evaluation and donor testing. A member agreed that this does not require any additional invasive testing beyond the general anatomy evaluation, and that this information would be widely available for all deceased kidney donors upon organ recovery.

Staff asked the Workgroup if this data is easily discovered by a clinical and non-clinical coordination in the electronic medical record or electronic donor record. A member agreed that this is true, as long as the coordinator understands that this information is determined upon anatomical evaluation.

Hard plaque in the renal artery at time of procurement

Staff noted that this question would be asked separately for the left and right kidneys. Staff asked the Workgroup if it is appropriate to delineate "at time of procurement," to ensure this question is answered based on the anatomical evaluation performed immediately post-recovery. A member agreed,

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[1] National Cancer Institute, "Renal Infarction." https://evsexplore.semantics.cancer.gov/evsexplore/concept/ncim/C0035085
[2] Mulayamkuzhiyil and Leslie, "Renal Infarction," StatPearls: https://pubmed.ncbi.nlm.nih.gov/35881744/#:~:text=Renal%20infarction%20is%20a%20rare,or%20an%20in%2Dsitu%20thrombosis.

noting that it's mostly important to know what the recovering surgeon has to say. The member added that this is standard evaluation of kidney anatomy. A member remarked that some OPOs recover kidneys en-bloc, which makes evaluating arterial plaque more difficult.

Staff shared a definition for "hard plaque," noting that this a function of renal artery stenosis:

> *Hard plaque in the renal artery, one mechanism of renal atherosclerosis, also called renal artery stenosis (RAS). Renal artery stenosis is the narrowing of a main artery in the kidney.*[3]

One member remarked that hard plaque and renal artery stenosis are not exactly interchangeable, as renal artery stenosis can occur in young health people with fibromuscular issues or apply to different things. The member continued that renal arterial disease, or renal artery atherosclerosis would cover it. Another member pointed out that defining a simple word such as plaque should not require such a complex word like atherosclerosis. The member pointed out that this definition could be generally simpler, and that plaque is much easier to understand than heavily clinical terminology. Another member noted that plaque and hard plaque are generally descriptive terms, and recommended using the simplest terms. Staff offered a definition that was more instructional – "hard plaque has been visualized in the renal artery." A member noted that "hard or severe" should be included.

A member recommended that the data elements follow a similar order to how the arterial plaque information is currently collected on most anatomical evaluation sheets, such that the questions are answered by whether there is plaque, if the plaque is hard or soft, and then severity of the plaque. Staff shared how the question is asked in a sample anatomy sheet, noting that this follows the member's recommendation. A member remarked that most anatomy forms ask the question that same way, and recommended that the question be structured similarly in the donor record in the OPTN Donor Data and Matching System.

Staff asked if the Workgroup would want to continue screening on soft plaque if that data could be collected for the presence of soft plaque. One member noted that this wouldn't be necessary.

Staff noted that whether there is a level of subjectivity to this anatomical evaluation, and if there is ever a question if the plaque is soft or hard. A member remarked that there is subjectivity to it, but that the recovering surgeon has to make a clinical determination.

Staff asked which degrees of severity should be included, noting specifically that currently KiMAC provides screening options for mild, moderate, and severe for soft plaque, and options for mild, moderate, severe, and ulcerative for hard plaque. A member agreed that those are appropriate. The member noted that some anatomy forms don't distinguish between severe and ulcerative, and that it could be potentially simplified to none, mild, moderate, and severe. The member noted that ulcerative could be considered "severe," and that if simplification was needed, ulcerative could be removed. Another member recommended maintaining ulcerative as a response option.

Staff asked the Workgroup if "unknown" should be an appropriate response option. One member noted that the recovery surgeon has to give an answer – it cannot be unknown. The Chair agreed.

The Workgroup confirmed that this data element would not change over time, and that this information is widely available for deceased kidney donors. The Workgroup also confirmed that this would not require any additional invasive testing beyond the standard recovery anatomical evaluation. The Workgroup confirmed that this information would be easily discovered in the donor's electronic record and on the anatomy sheet.

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[3] National Cancer Institute, "Renal Artery Stenosis." https://evsexplore.semantics.cancer.gov/evsexplore/concept/ncim/C0035067

Upcoming Meeting: August 11, 2023

Attendance

- **Workgroup Members**
  - Valerie Chipman
  - Colleen Jay
  - Tania Houle
  - Jason Rolls
  - Jillian Wojtowicz
  - Sharyn Sawczak
- **HRSA Staff**
  - Marilyn Levi
  - Peter Stock
- **SRTR Staff**
  - Bryn Thompson
  - Jon Miller
  - Peter Stock
- **UNOS Staff**
  - Kayla Temple
  - Lindsay Larkin
  - Joann White
  - Lauren Motley
  - Tamika Watkins
  - Kaitlin Swanner
  - Kieran McMahon
  - Krissy Laurie
  - Lauren Mauk
  - Ben Wolford
  - Rebecca Fitz Marino
  - Sarah Booker