**OPTN Kidney and Pancreas Transplantation Committees**
**Utilization Considerations of Kidney and Pancreas Continuous Distribution Workgroup**
**Meeting Summary**
**July 14, 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 7/14/2023 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:

The Workgroup had no questions or comments.

**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:

As an example, staff posed the question "What is the intent or purpose of collecting these data elements?" Staff continued that an appropriate response could include "these data elements will be collected as part of the effort to automate the application of the KiMAC in a continuous distribution allocation framework for kidneys. This relates to efficient donor candidate matching and member/system performance."

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:

Members voiced their support for the example response given for the "purpose" of the potential data collection under discussion.

*Horseshoe Kidney*

The Workgroup began discussing "horseshoe kidney" as a potential data element. Staff asked the Workgroup if it would be necessary to include a second element allowing the Organ Procurement Organization (OPO) to indicate that the horseshoe kidney had been split. One member remarked that horseshoe kidneys are rare, and so it may not be necessary to have a data element to indicate that the

kidney was split. The Chair agreed and other members agreed. The Workgroup supported maintaining the question "Horseshoe kidney?" with "yes" and "no" response options.

One member asked if the horseshoe kidneys are split, should the OPO still indicate that those kidneys are horseshoe kidneys, and if that should change the way the screening is done. A member noted that, in most cases, the horseshoe kidney is split by the transplant program who has accepted it. The member continued that they haven't seen a horseshoe kidney that was split prior to final acceptance. The member added that there is often unusual anatomy involved with horseshoe kidneys, and that it would be highly unusual for a program to split the kidney and then released one of the moieties for re-allocation. The member shared that if one moiety is unable to be used, it will not be released and offered back out. The member concluded that it would be highly unusual for the horseshoe kidney to be split at recovery. The Chair agreed, and pointed out the rarity of horseshoe kidneys.

Staff asked if, based on the anatomy considerations, it is appropriate for an OPO user to indicate that a split horseshoe kidney was still a horseshoe kidney. A member agreed, noting that programs would still need that information to have informed decision making.

Staff shared the following definition for horseshoe kidney:

> *"A congenital abnormality in which the two kidneys fuse together during fetal development to create a horseshoe-shaped structure."*[1]

Multiple Workgroup members agreed that this definition was an appropriate industry standard definition, and that this would be understandable and useable to both transplant and OPO users.

Staff asked the Workgroup what the acceptable responses for this data element would be, particularly noting if the Workgroup felt that an "unknown" response option was necessary. Staff asked if this information is typically found upon procurement, or if this is typically seen in abdominal scans or other donor evaluation. One member noted that it varies, and that previously, it would be more likely to find this information out intra-operatively. However, it is more common for donors to have Computerized Tomography (CT) scans performed for various reasons, even outside of donor management. The member remarked that its most commonly found in the operating room. The Chair agreed that a donor's horseshoe kidney may be discovered either via abdominal scans or during recovery.

The Chair asked if this field is going to be a required field. If the field is optional, an "unknown" may not be necessary. The Chair continued that if the field is required, it may be important to have an "unknown option." A member agreed and noted that the tool should not be screening based on "unknown." The member also noted that, if possible, the field should be required to be answered as "yes" or "no" if a cross clamp date and time has been entered. Staff noted that this is not currently a functionality of the system, and that there could be concerns that a full anatomy and biopsy may not be available at time of cross clamp.

The Chair recommended putting "horseshoe kidney" in as an anatomy question and removing "unknown" as a response option. The Chair explained that this way, the OPO will fill this out once the information is known, at the time anatomy comes back. One member commented that currently, anatomy is not uploaded to the OPTN Donor Data and Matching System. Staff agreed that this would be one of the first discrete data elements related to organ anatomy.

Staff asked if the Workgroup wanted to include an "unknown" response option. The Chair offered that, because horseshoe kidneys are so rare, the default assumption should be that the donor does *not* have

[1] National Cancer Institute; "Horseshoe Kidney Code;" **https://evsexplore.semantics.cancer.gov/evsexplore/concept/ncim/C3151383**

a horseshoe kidney. Another member agreed. The Chair added that the system should not screen or apply bypasses unless the OPO has indicated "yes." The Workgroup also agreed that, if the question is left blank, the system would assume the donor does *not* have a horseshoe kidney.

One member suggested that system not prompt the user to respond to that data element until the screening tool is applied. The member also suggested that this be able to be uploaded from electronic medical records. The member continued that potentially, unknown could be removed as a response option, especially if the field could be left blank. The member supported removing "unknown" as a response option and making the element not required, noting that the user could leave that field blank unless the donor had a horseshoe kidney. Staff noted that this could be feasible if the KiMAC would consider no response to indicate the donor does *not* have a horseshoe kidney.

The Chair offered that this element could be a check box instead, such that the OPO user is able to check the box if applicable, and otherwise it is assumed that the donor does *not* have a horseshoe kidney. The Chair continued that this field wouldn't be required.

Several Workgroup members noted that currently, horseshoe kidney is not collected in any electronic donor records. The Chair added that this information is typically shared in the "Donor Highlights" field.

The member noted that this could be easily added as a discrete field. Another member agreed.

The Workgroup agreed upon the responses in **Table 1**.

**Table 1: Horseshoe Kidney**

| Question | Response |
|---|---|
| What is the intent or purpose of collecting this specific data element? | This data element will be collected as part of the effort to automate the application of the Kidney Minimum Acceptance Criteria Screening Tool in a continuous distribution allocation framework for kidneys. This relates to member/system performance and efficient donor candidate matching. |
| Is there an industry-standard or established clinical definition for the data element?<br>(CMS, professional society, etc.) | "A congenital abnormality in which the two kidneys fuse together during fetal development to create a horseshoe-shaped structure" |
| What unit of measurement will be used? | Not applicable |
| What are the acceptable responses or response range for this data element? | • Yes (Kidneys are horseshoe kidneys; even if split)<br>• No (Kidneys are not horseshoe kidneys)<br>• Potentially, unknown (anatomical evaluation not yet complete)<br>If left blank, the assumption is the donor does not have a horseshoe kidney |
| What are the non-plausible value ranges for this data element? | Not applicable |

| | |
|---|---|
| If unknown values (e.g. missing, not reported, unknown) are acceptable responses, what instruction will be provided when/in what specific cases those values are appropriate? | If unknown or missing values, the system will assume the donor does *not* have a horseshoe kidney |
| For data elements that may change over time, what timeframe should be included in the label and definition? Should a date field also be included to capture the timing of measurement? | Not applicable |
| Is the definition easily understandable for the variety of people interacting with it? (coordinators, administrators, clinicians, data entry personnel) | Yes |
| Is this element widely available for the population of patients for which it is sought to be collected? | Yes |
| Does this element require additional testing (e.g. invasive procedure) or measurement that is not commonly done? | No; this would be known either as part of normal donor evaluation procedures or during procurement, with no requirement for additional testing |
| Are the data easily discovered by a clinical and non-clinical coordinator in EHR? | Not currently collected in electronic donor records, but could be added. |

*Polycystic Kidney Disease (PKD)*

Staff asked the Workgroup at what point it would be appropriate for an OPO user to indicate the donor has evidence of PKD – if the donor is known to have PKD due to recent genetic testing, or only if PKD has been visualized? One member remarked that typically, OPOs find out about that in the donor's medical and social history, particularly because it's known to run in families; the donor is typically evaluated for it prior to becoming a donor. The member added that this information is often in the donor's medical history or in the interview with the family. The Chair agreed.

Staff asked if, based on this, "evidence of polycystic kidney disease" is preferable to "polycystic kidney disease visualized," and asked if it matters how far PKD has developed. A member commented that the number of cysts and the age of the donor likely play a role, noting that it's not uncommon to see radiographic criteria for PKD met, as there is a fairly low threshold, although that is typically outside of the setting of deceased donation.

Staff presented two scenarios – one where the donor has severe PKD, with many cysts visualized on anatomy, versus a donor who has PKD in their family history but did not meet the radiographic criteria for PKD. Staff noted that in the former, it is likely that the OPO user would indicate that the donor has PKD. Staff asked if it is appropriate to indicate PKD in the latter scenario. One member agreed that PKD should be indicated in the latter scenario. Another member offered that if there are multiple cysts bilaterally and there is a family history, this should be considered. The member asked how the system is currently screening on PKD. Staff explained that the OPO would have indicated the donor has polycystic kidney disease in the Donor Highlights or upon referral, and that the OPO determines whether it is appropriate to screen on PKD.

The Workgroup agreed it is appropriate to indicate PKD if the donor has been diagnosed with PKD in their medical history. A member offered that it would also be appropriate to indicate this if there is presence of bilateral cysts and a family history of PKD. Another member agreed. The Chair pointed out that this is a medical diagnosis, and that the OPO's medical director should be making the call if the donor does not have a previous diagnosis. Staff summarized the following scenarios in which it would be appropriate for the OPO user to indicate the donor has PKD:

- If the donor has been diagnosed with PKD in their medical history
- If the donor has presence of bilateral cysts on imaging and family history of PKD
- If the donor is medically diagnosed with PKD upon donor evaluation or management, or organ recovery

The Workgroup agreed. Staff asked if the OPO would approach a clinician or medical director about PKD if the donor has the presence of bilateral cysts on imaging and a family history of PKD, and if it is appropriate to assume that the PKD would be diagnosed at that point. Members agreed. A member noted that the diagnosis may not be made by some one on site, but that the medical director would need to make that decision. The Chair agreed that there would be a consultation, and that this information would be presented in the donor's medical record.

Staff asked the Workgroup where this field should be on the Donor Record, noting that this may be less relevant to anatomy and more relevant to general donor information. A member recommended adding this to the other questions related to the donor's medical and social history, on the primary page in the donor record.

A member remarked that PKD is not very common. The member suggested adding another element to indicate history of kidney disease, noting that this is much more common, and that this could be inclusive of PKD. The Chair asked if this element would then have further data elements on potential kidney diseases as child questions. The member responded that this could become overly detailed, but just having one element to indicate and screen on history of kidney disease. Another member responded that PKD is well defined and specific, whereas general kidney disease could be inclusive of a range of issues, some of which are reversible and others could be more chronic and damaging.

Staff shared two definitions of polycystic kidney disease:

> *"Polycystic Kidney Disease is a usually autosomal dominant and less frequently autosomal recessive genetic disorder characterized by the presence of numerous cysts in the kidneys leading to end-stage renal failure."*[2]

[2] National Cancer Institute, "Polycystic Kidney Disease;" https://evsexplore.semantics.cancer.gov/evsexplore/concept/ncim/C0022680

*"PKD is a hereditary disease characterized by the progressive expansion of a large number of tightly packed cysts within the kidney. There is an autosomal recessive form appearing in childhood, and a more frequent autosomal dominant form appearing later in life."*[3]

A member noted that both definitions are accurate and appropriate. The Chair offered that the second definition could be more appropriate for usability and understandability, and recommended shortening the second definition to only the first definition. The Chair continued that the autosomal dominant and recessive aspects are not as necessary for the purposes of deceased donation. Other members agreed. The Workgroup agreed this definition was easily understandable.

The Workgroup agreed this element does not have any relevant units of measurement.

Staff asked the Workgroup about appropriate response options, offering "yes," "no," and "unknown" as potential response options. Staff also asked the Workgroup if this data element should be required, particularly as requiring OPOs to rule out PKD could be burdensome. One member remarked that "unknown" should be avoided, and recommended phrasing the question as "does the donor have a known history of polycystic kidney disease," with only "yes" or "no" response options. The Chair agreed – it is known history has an indication of yes, and then the system can assume that the donor does *not* have PKD if it has not been indicated. The Chair noted that in this case, this question should not be a required data element. The Chair added that checkmarks are helpful here, and preferable to the radio button or drop down. The Workgroup agreed that "unknown" should *not* be a response option.

The Workgroup agreed that this element would not change over time.

Staff asked the Workgroup if this would be generally known, or if this would require additional testing that is not commonly done. The Chair noted that the testing and interviews required would be within the realm of current testing, as this would likely be in the donor's medical or social history. A member agreed, noting that this would either be known, or not. The member added OPOs will not likely be performing genetic testing for PKD on donors. Another member added that potential PKD could be seen with an ultrasound or CT scan, as genetic testing timelines wouldn't align with donation timing. The Chair added that it is generally very clear and easy to find if the donor has a history of PKD.

A member noted that history of PKD is not currently a discrete field in the electronic donor records, but that it would be easily added as a discrete field. Another member agreed.

The Workgroup agreed upon the responses in **Table 2**.

**Table 2: Known History of Polycystic Kidney Disease**

| Question | Notes |
|---|---|
| What is the intent or purpose of collecting this specific data element? | This data element will be collected as part of the effort to automate the application of the Kidney Minimum Acceptance Criteria Screening Tool in a continuous distribution allocation framework for kidneys. This relates to member/system performance and efficient donor candidate matching. |

[3] Unified Medical Language System, "Polycystic Kidney Disease," CSP

| | |
|---|---|
| Is there an industry-standard or established clinical definition for the data element? | PKD is a hereditary disease characterized by the progressive expansion of a large number of tightly packed cysts within the kidney. |
| What unit of measurement will be used? | Not applicable |
| What are the acceptable responses or response range for this data element? | • Yes<br>• No<br>This element should not be required; if the OPO is not sure, they can indicate No unless the OPO has found evidence or a known history of PKD. |
| What are the non-plausible value ranges for this data element? | Not applicable |
| If unknown values (e.g. missing, not reported, unknown) are acceptable responses, what instruction will be provided when/in what specific cases those values are appropriate? | Not applicable |
| For data elements that may change over time, what timeframe should be included in the label and definition? Should a date field also be included to capture the timing of measurement? | Not applicable |
| Is the definition easily understandable for the variety of people interacting with it? (coordinators, administrators, clinicians, data entry personnel) | Yes |
| Is this element widely available for the<br>population of patients for which it is sought to be collected? | Yes, this information would generally be known either during donor evaluation or else at time of procurement. Often familial, medical history. This could also be discovered on CT scans. |

| | |
|---|---|
| Does this element require additional testing (e.g. invasive procedure) or measurement that is not commonly done? | Testing should be within the realm of what is already performed for organ/donor evaluation. OPOs should and will not be required to perform genetic testing to rule out PKD. |
| Are the data easily discovered by a clinical and non-clinical coordinator in EHR? | If patient has a history of PKD or a family history, this information will be clear and discoverable in the medical history or in the medical social history interview. This information is not currently collected in electronic donor records. |

**Upcoming Meeting:**

- July 14, 2023

**Attendance**

- **Workgroup Members**
  - Valerie Chipman
  - Carrie Jadlowiec
  - Jill Wojtowicz
  - PJ Geraghty
- **HRSA Staff**
  - Marilyn Levi
- **UNOS Staff**
  - Kayla Temple
  - Lindsay Larkin
  - Joann White
  - Keighly Bradbrook
  - Kieran McMahon
  - Krissy Laurie
  - Lauren Mooney
  - Lauren Motley
  - Lauren Mauk
  - Carly Layman
  - Rebecca Fitz Marino
  - Sevgin Hunt
  - Thomas Dolan