OPTN Kidney and Pancreas Transplantation Committees
Utilization Considerations of Kidney and Pancreas Continuous Distribution Workgroup
Meeting Summary
June 23, 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 6/23/2023 to discuss the following agenda items:

1. Update on Kidney Committee Review of Recommendations
2. Utilization Considerations and Public Comment Request for Feedback
3. Kidney Minimum Acceptance Criteria (KiMAC) Future State: Criteria Review
4. KiMAC Future State: Uncontrolled Donation after Cardiac Death (DCD) Definition

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

1. Update on Kidney Committee Review of Recommendations

Staff provided an overview of the Kidney Committee's feedback on the Workgroup's recommendations for transitioning and updating the KiMAC application rules, dual kidney allocation, and released kidney allocation.

Presentation summary:

The Kidney Committee supported the Workgroup's recommendation to carry over refusals from the original match run to the released kidney match run, including a recommendation that refusal code 798 (other specify) also be carried over.

The Kidney Committee supported the Workgroup's recommendation on KiMAC application in a continuous distribution framework, including the application of the tool at 8 percent of the match run, excluding CPRA 100 percent candidates and candidates within 250 nautical miles (NM) of the donor hospital. The Kidney Committee determined that 0-ABDR mismatch candidates should not be excluded from the KiMAC bypass, as continuous distribution of kidneys is expected to prioritize DR matching level, not 0-ABDR mismatches.

The Committee supported the Workgroup's recommended dual kidney framework, particularly with efficiency benefits for the dual kidney match run. The Committee was split on how to determine *when* an OPO may allocate kidneys as dual, and heavily discussed both the recommended criteria and other options, such as allowing dual kidney allocation after a percentage of the match run has been offered to and declined.

Summary of discussion:

There were no questions or comments.

2. Utilization Considerations and Public Comment Request for Feedback

Staff provided a brief update on the Kidney Committee's progress in developing the Continuous Distribution of Kidneys project. Staff also updated the Workgroup on the Committee's plan to release a request for feedback on efficiency and utilization in kidney and pancreas continuous distribution in the summer 2023 public comment period. The request for feedback will request community input on several operational topics, including:

- Released organ allocation
- National kidney offers
- KiMAC screening tool
- Dual kidney allocation
- En bloc kidney allocation
- Facilitated pancreas allocation
- Mandatory Kidney-Pancreas (KP) offers
- Other efficiency efforts, screening, and filters

Summary of discussion:

The Chair thanked the Workgroup for their work on several of these topics, noting the Workgroup's effort and dedication.

There were no further questions or comments.

3. Kidney Minimum Acceptance Criteria (KiMAC) Future State: Criteria Review

The Workgroup reviewed the full set of KiMAC criteria they had deemed appropriate to continue screening on in a continuous distribution framework, and discussed details related to diabetes management screening.

Presentation summary:

The Workgroup previously approved the following data elements for KiMAC screening in kidney continuous distribution allocation:

- Donor age
- Increased risk criteria (10 questions)
- Infectious disease screening, including: HBsAg, HBV NAT, Anti-HCV, HCV NAT, Syphilis, and HTLV I or II
- Creatinine clearance at admission
- Uncontrolled DCD
- Anatomy: horseshoe kidney, polycystic kidney disease, infarcted kidney, hard plaque and severity
- Hypertension and compliance
- Diabetes and related management
- Peak creatinine
- Cold time
- Glomerulosclerosis

Previously, the Workgroup supported maintaining diabetes screening questions, which were specific to diabetes management. Currently, the KiMAC screens on "donor who is insulin dependent" and "donor with diabetes and requires oral medication." The Workgroup was asked whether, in terms of screening, it is preferable to determine duration on insulin/oral medication (option 1) or if it is preferable to determine overall diabetes duration and general management type (option 2).

Option 1 focuses on duration of management, and related data may look like:

- Donor is diabetic; total duration of insulin dependence

- Donor is diabetic; total duration of oral medication management

Option 2 focuses on the duration of diabetes separate from diabetes management type. This option may allow for more accurate screening, as it may be difficult to determine duration of diabetes management from the donor's history. Option 2 data collection may look like:

- Duration of diabetes, with any insulin dependence
- Duration of diabetes, with any use of oral medication

Summary of discussion:

One member remarked that Option 2 makes the most sense, particularly in terms of the workload for the donor coordinators who are obtaining the donor's history.

A member asked for clarity on Option 2, asking if the question would be duration of diabetes, and then insulin use and oral medication were response options to a secondary question. Staff explained that in the screening tool, diabetes management is not a subset of a question, but instead the screening provided by the KiMAC is specific to management type. Staff noted that Option 2 identifies duration of diabetes and management separately; for example, a donor with an 8 year history of diabetes who has been on insulin for 3 months would select "insulin use" the same way a donor with an 8 year history of diabetes who has been on insulin for 6 years would select insulin use. Staff continued that Option 1is more discerning, in determining duration of time on insulin.

The Chair asked for further clarification, and staff provided another example. In this example, a hypothetical donor has a 9-year history of diabetes; the donor was on oral medication for two years and used insulin for seven years. In Option 2, the OPO would indicate duration of diabetes with any insulin dependence as 6-10 years and duration of diabetes with any use of oral medication as 6-10 years. In Option 1, the OPO would indicate total duration of diabetic insulin dependence as 6-10 years and total duration of diabetic oral medication use as 0-5 years.

Staff asked which is more clinically important – how long the donor was on insulin, or whether insulin was used in diabetes management at all in the context of the donor's duration on diabetes.

The Chair remarked that total number of years of diabetes and then whether insulin or oral medication were used seems more important. The Chair suggested collecting data regarding how long the donor is diabetic is important, and then a check box or a radio button of oral medication or insulin. A member agreed, noting that in terms of the questions asked in the donor history, it would make sense to go with Option 2. The member remarked that the related screening question would then be the program opting out of offers from donors in a certain age group who had a specific duration of diabetes and insulin use. The member remarked that Option 1 could be too detailed, and that duration on insulin or oral medication would likely make very minimal difference. The member also remarked that the donor's medical social history is not consistently reliable or fully accurate, particularly when considering the question in context with the entire donor population. The member concluded that it's likely more than sufficient to know whether the patient had diabetes, duration of diabetes, and whether or not they've taken insulin. The member remarked that insulin dependence and use isn't necessarily static, and that it is already going to be difficult to reliably ascertain whether the donor has or hasn't taken insulin to manage their diabetes, much less the duration of time on insulin.

The Chair remarked that Option 2 would make more sense, noting that it may not even be necessary to ask about oral medication management. A member agreed. Another member disagreed, noting that some diabetics manage their diabetes through diet and lifestyle, and that this population should be differentiated from those who have been using oral medication. The member noted that management

via diet and lifestyle is likely considered more benign than management via oral medication. The member agreed that Option 2 is the best option.

The Chair agreed that Option 2 is the better option, but that it could be altered to reduce confusion. The Chair suggested that the question flow would be donor is diabetic, duration, and then whether the donor has been insulin dependent. The Chair continued that it would be confusing for the question to be phrased as duration of diabetes with oral medication 0-5 and duration of diabetes with insulin dependence 0-5. The Chair continued that the math may be confusing there, and that it may be more clear to delineate duration of diabetes first off. The Chair supported the following format for data collection:

- Donor has diabetes (yes/no) →
    - If yes, duration?
    - If yes, donor has used insulin? Yes/No
    - If yes, donor has used oral medication? Yes/No

A member suggested that the KiMAC screening could work such that duration of diabetes was the criterion, and then duration of diabetes that includes insulin use. Staff shared the transplant center view of the KIMAC, and showed how the question would be asked for insulin dependence. Option 1 would be asked as "total duration of insulin dependence" and Option 2 would be asked as "duration of diabetes, with any insulin dependence." Staff continued, showing how the question would be asked for oral medication use, such that option 1 asks "total duration of oral medication management of diabetes" and option 2 asks "duration of diabetes with any use of oral medication management." The Workgroup supported option 2 for screening questions on both insulin dependence and oral medication management.

4. KiMAC Future State: Uncontrolled Donation after Cardiac Death (DCD) Definition

Staff briefly introduced the OPTN Data Advisory Committee process for adding, modifying, and removing OPTN data collection, highlighting the importance of clarity in data definitions. The Workgroup discussed a potential data definition for uncontrolled DCD and briefly discussed how anatomy specific data is collected by electronic donor records systems.

Presentation summary:

Many criteria to be used for screening in the future state of the KiMAC tool are already collected as donor data in the OPTN Donor Data and Matching System, or else are expected to be added to OPTN Donor Data and Matching System as part of implementation of other projects. Such projects include the Enhancements to OPTN Donor Data and Matching System Clinical Data Collection and the Update Data Collection to Align with United States Public Health Service (US PHS) Guideline, 2020.

Other screening criteria will require new data collection to be added to the OPTN Donor Data and Matching System, as well as modifications to phrasing and response options to screening questions in the OPTN Waitlist System. These updates and modifications to OPTN data collection will require review of each element according to the OPTN Data Advisory Committee data collection process. This process helps to ensure quality, consistency, understandability, usefulness, and trustworthiness of OPTN data. The process includes determining the purpose, availability or burden, reliability, usability, and conformity of each data element. The DAC process also involves building definitions for each data element.

In order to ensure understandability, consistency, and usefulness in screening on "uncontrolled DCD," the Workgroup may need to develop a definition of "uncontrolled DCD."

Upon implementation of the OPTN Organ Procurement Organization (OPO) Committee's *Enhancements to OPTN Donor Data and Matching System Clinical Data Collection Proposal,* a new question will be added for "Controlled DCD," with "yes" and "no" response options. This question will be a child question of "DCD – yes/no."

The OPO Committee proposed the following definition of "controlled DCD" as part of the *Enhancements* proposal: "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 was asked two questions:

- Is it appropriate that a patient for whom "Controlled DCD" is marked "No," would be considered an uncontrolled DCD donor for the purpose of KiMAC screening?
- Is a separate definition needed for "uncontrolled?"

The Workgroup was also asked how anatomy data is collected in electronic donor records, and whether there was a standardized way anatomy should be collected.

Summary of discussion:

One member remarked that the definition of controlled DCD should be updated to reflect the patient is in the intensive care unit (ICU) or in the operating room (OR), as some DCD donors are withdrawn in the OR. The member continued that this definition is not clear here. The Chair noted that withdrawal can occur in the ICU or in the post-anesthesia care unit (PACU), as well as the OR.

A member noted that uncontrolled needs to be defined as well, particularly as different professionals may interpret uncontrolled DCD differently, and there needs to be consistency. Another member agreed, noting that "uncontrolled DCD" is not currently well defined, and that they are not aware of a standard technical definition. The member noted that uncontrolled DCD can sometimes be more of a "you know it when you see it" situation. The Chair agreed. The Chair continued that controlled DCD is a planned withdrawal of mechanical ventilation and uncontrolled DCD is a situation in which that planned withdrawal did not happen. The Chair explained that the definition may require a larger scope to build consensus.

One member offered that the DCD definition could include an unstable or expedited DCD and a donor who is in cardiac arrest upon arrival. The member continued that unstable DCD cases are more similar to controlled DCD than the donor who is in cardiac arrest on arrival.

Another member suggested that the definition could be that, in order to be considered a controlled DCD donor, the patient must come to the care withdrawal area not in a state of arrest, and all the traditional steps in the DCD process must be accomplished, including paperwork, heparin, etc.

The Chair offered that adding the word planned to the definition of controlled DCD would be appropriate – controlled DCD is a planned withdrawal of life-sustaining mechanical ventilator care. The Chair remarked that a controlled DCD is planned, and that this is very different than an uncontrolled DCD. The Chair continued that uncontrolled DCD will have a wide definition, while controlled is more specific.

Staff shared the Maastricht classifications (**Table 1)** from Koostra et al's "Categories of Non-Heart Beating Donors" study, as delineated in a recent study by Park et al.[1,2]

Table 1: Maastricht Classification of DCD

Category	Definition	Type of DCD
I	Dead on arrival: (1) Cardiocirculatory death outside hospital with no witnesses. Totally uncontrolled (2) Cardiocirculatory death outside hospital with witnesses and rapid resuscitation attempt.	Uncontrolled
II	Unsuccessful cardiopulmonary resuscitation : witnessed cardiac arrest outside the hospital with unsuccessful cardiopulmonary resuscitation	Uncontrolled
III	Cardiac arrest following the withdrawal of life-sustaining treatments but not considered to be brain dead	Controlled
IV	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	Uncontrolled
V	Cardiac arrest in hospital patients	Uncontrolled

The Chair noted that the Maastricht definition of controlled DCD is appropriate, and offered "planned withdrawal of life sustaining treatments with the authorization of family for the intent to pursue organ donation."

One member offered that the definition of "controlled DCD" should align with the Maastricht III classification, which aligns with the Workgroup's previous comments. The member continued that the Workgroup could potentially add the word "planned" if needed for clarity. The member continued that uncontrolled would then be defined as any DCD donor not fitting that definition of controlled DCD, and include the Maastrict I, II, IV and V classification.

Staff continued that the definition will need to align as much as possible with clinical standards, and asked if the Workgroup supported starting with the Maastricht classifications for building the definition of uncontrolled DCD, such that controlled DCD is Maastricht classification III, and uncontrolled includes Maastricht I, II, IV, and V and other non-Maastricht III scenarios.

One member continued that each scenario and hypothetical posited during the meeting would fit in the one of the four "uncontrolled" classifications. The member supported utilizing the Maastricht classifications in developing the definition for "uncontrolled DCD." The Chair agreed and noted that

[1] Kootstra G, Daemen JH, Oomen AP. Categories of non-heart-beating donors. Transplant Proc. 1995 Oct;27(5):2893-4. PMID: 7482956.

[2] Park H, Jung ES, Oh JS, Lee YM, Lee JM. Organ donation after controlled circulatory death (Maastricht classification III) following the withdrawal of life-sustaining treatment in Korea: a suggested guideline. Korean J Transplant. 2021 Jun 30;35(2):71-76. doi: 10.4285/kjt.21.0004. PMID: 35769520; PMCID: PMC9235338.

classifications III, IV, and V are really the most common scenarios. A member agreed, pointing out that classification I is incredibly unlikely in the context of organ donation. The Chair continued that classification II is also unlikely, particularly if the donor is arresting outside of the hospital. The Chair concluded that Maastricht classifications IV and V are the scenarios that should be utilized in the definition. A member agreed that Maastricht classification III represents controlled DCD, and IV and V represent uncontrolled DCD.

The Chair reiterated that controlled DCD is inherently planned as a process. The Chair also noted that location should not be included in the definition of controlled or uncontrolled DCD, particularly as there are multiple locations where the OPO may pursue withdrawal of life-sustaining treatments. The Chair continued that if it's planned, it doesn't matter where the withdrawal is done.

Staff asked the Workgroup if there is a standard for how anatomy data is collected, particularly with respect to horseshoe kidney, polycystic kidney disease, infarction, and plaque. One member remarked that most OPOs use similar anatomy sheets, and that anatomy is relatively consistently reported. The Chair agreed that there is generally consistency in how it's collected. The member offered that the order of what's reported in terms of measurements, arteries, veins, are generally the same. The Chair continued that the anatomy reports may vary, but maintain a degree of consistency across electronic medical records systems and OPOs.

The Chair remarked that reporting of abnormalities such as horseshoe or polycystic kidney may be more inconsistent, but more general anatomy information is much more standard. The Chair continued that such information would likely be documented in the donor highlights.

One member pointed out that every OPO is not using the exact same form, but that each form is similar and reporting basically the same information. The member continued that horseshoe kidney would be documented in the comment box. The member noted that it's more important whether the electronic donor record would be able to upload directly to the OPTN Donor Data and Matching System. The member added that some OPOs may attach that information separately if it does not upload.

A member remarked that this form is often a piece of paper that is filled out during organ recovery and later scanned and uploaded as an attachment. The member continued that it may also have the biopsy information transcribed at the bottom. The Chair pointed out that anatomy report is likely similar across systems and OPOs based on the information OPOs are required to report, what is collected in the OPTN Computer System, and what OPOs are often asked during offer evaluation. The Chair continued that the consistency is occurring as a result of general standard practice in terms of aligning with electronic medical records. Another member added that most OPOs are probably moving away from paper forms over entering the data directly in the donor medical record, but that the anatomy information gathered and reported is likely all very similar.

Upcoming Meeting:

- July 14, 2023

Attendance

- **Workgroup Members**
  - Valerie Chipman
  - Collen Jay
  - Jaime Myers
  - Jason Rolls
  - Jill Wojtowicz
  - Nikole Neidlinger
  - Sharyn Sawczak
- **HRSA Staff**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Bryn Thompson
  - Jon Miller
- **UNOS Staff**
  - Kayla Temple
  - Lindsay Larkin
  - Ben Wolford
  - Carly Layman
  - James Alcorn
  - Joann White
  - Kaitlin Swanner
  - Keighly Bradbrook
  - Kieran McMahon
  - Kimberly Uccellini
  - Krissy Laurie
  - Lauren Mauk
  - Rebecca Fitz Marino
  - Ross Walton
  - Sarah Booker
  - Thomas Dolan