OPTN Kidney and Pancreas Transplantation Committees
Utilization Considerations of Kidney and Pancreas Continuous Distribution Workgroup
Meeting Summary
April 24, 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 4/24/2023 to discuss the following agenda items:

1. Dual Kidney: Carry Over Refusals
2. Kidney Minimum Acceptance Criteria (KiMAC)

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

1. Dual Kidney: Carry Over Refusals

Staff provided a recap the concept of carry over refusals and how they could work for dual kidney match runs as part of the transition to a continuous distribution framework. The Workgroup then reviewed and discussed specific carry over refusal codes that would be appropriate for a dual kidney match run.

Presentation summary:

Previously, the Workgroup discussed carrying over refusals as part of the solution for both released organ and dual kidney. In these cases, specific refusal codes would be "carried over" to the new match run (released organ or dual kidney). Meaning, candidates who have refused for specific, appropriate reasons would be screened from the released organs or dual kidney match run. The OPO would need to select which match run to carry refusals over from, in case multiple kidney matches are run. The focus of this meeting is to continue discussing carry over refusals for dual kidney. Previously, the Workgroup recommended that programs should be able to indicate whether they would accept an offer as dual for each candidate. Additionally, the Workgroup supported the following framework for dual kidney allocation:

1. In order to offer kidneys as dual, the host OPO would need to run a new, dual-specific match run
2. Specific criteria dictates *when* an OPO *may* begin allocating the kidneys as dual kidneys

The dual-kidney match run includes several efficiency considerations:

- Match run includes only candidates opted in to receive dual kidney offers
- Offer filters model takes dual kidney into account, and programs can build dual kidney specific filters
- Other screening tools, such as acceptance criteria and the kidney minimum acceptance criteria (KIMAC) tool, will also apply to the dual kidney match run
- Specific refusals will be carried over from the original match run to the dual kidney match run

Just like Released Organs, specific refusal codes would be "carried over" to the dual kidney match run

- Candidates whose transplant programs have refused the single kidney offer per a qualifying refusal reason would be screened from the dual kidney match run

- The organ procurement organization (OPO) would need to select which match run to carry refusals over from, in case multiple kidney matches are run
- OPOs would not be able to carry over refusals from system-locked matches, such as matches run before positive Hepatitis C (HCV) or Hepatitis B (HBV) results

Because a dual kidney offer is very different from a single kidney offer, most refusal reasons may not be appropriate to carry over to a dual kidney match run. Programs may be more willing to accept a dual kidney offer than a single kidney offer from medically complex donors. However, since the offer is still from the same donor, there may be certain refusal codes that are appropriate to carry over.

Previously, the Workgroup recommended that programs should be able to decline for a future dual kidney match at the time of the initial, single kidney offer and discussed adding this functionality to the OPTN Computer System. The recommendation for the first iteration of continuous distribution is to leverage the existing "donor refusal" functionality within the system and make improvements where necessary.

Staff explained the existing functionality of the donor refusal button, which allows programs to refuse current and future offers for a specific donor for all candidates for certain donor-specific codes by organ type. Programs will be able to decline the single kidney for specific candidates and have those refusals carry forward to the dual match via the proposed new functionality to carry over refusals. If a transplant program wants to decline for all candidates on a future kidney match, the recommendation is to use the donor refusal functionality. Staff asked members if separating "dual kidney" out as an organ checkbox would help encourage use of the tool, and if reworking the name "donor refusal" as well as the text description make the functionality clearer.

Summary of discussion:

Staff compared the list of refusals the Workgroup opted to carry over to the released kidney match run with the list of refusals the Workgroup opted to carry over to the dual kidney match run. Staff noted that the Workgroup decided to carry over "candidate requires different laterality" (code 723) on the released kidney match run, noting that this code is not typically relevant to kidney. The Workgroup also previously noted that this code is also particularly irrelevant to dual kidney, and decided *not* to carry over the code to the dual kidney match run. Staff asked the Workgroup why the response would be different, if the rationale is the same, and whether the Workgroup would like to choose a different option. One member noted that laterality is irrelevant entirely to dual kidney, and so it shouldn't carried over. The member noted that it could be argued that the code shouldn't be carried over to either match run, as it is more likely to be entered in error. The Workgroup agreed that refusals for "candidate requires different laterality" should *not* be carried over to the released organ match run.

Staff noted that the Workgroup decided code 728, "Candidate refused," should be carried over to the released organs match run, but not to the dual kidney match run, as the candidate may consider the dual kidney differently. A workgroup member remarked that this made sense. The Workgroup agreed.

Staff asked the Workgroup about refusal code 731, "no donor cells or specimen for crossmatching," which the Workgroup opted to carry over to the released organ run but not the dual kidney match run. Previously, the Workgroup noted that in a dual kidney scenario, the organ is clearly post-recovery and it may be possible to get donor specimen, including nodes, where it wasn't before. The Workgroup agreed that code 731 should not be carried over to neither the dual kidney match run nor the released kidney match run.

Staff asked about code 798, "Other specify," noting that the Workgroup felt that code 798 could go either way. Previously, the Workgroup commented that there isn't a way to identify the reason entered,

but that in practice, programs are using this code as a catch all, instead of using a more appropriate and specific decline code. The Workgroup also remarked that it is likely that the program wouldn't want to receive the offer again, but the lack of specificity makes it hard to determine this consistently.

One member remarked that "Other specify" should not be used as a primary refusal code, and that this code should be carried over to the dual kidney and released organ match runs to help discourage this practice. Another member noted that this should likely be consistent across released and dual kidney match runs. One member pointed out that it would be the more conservative choice would be to not carry refusals for "other specify" over, since it could be argued either way. Another member agreed. One member remarked that this is fine, but that not carrying over these refusals may increase inefficiency, as some programs are using the refusal code inappropriately. The Workgroup decided to tentatively not carry this code over to either match run, and request additional consideration from the Kidney Committee in their review.

2. National Kidney Offers and the Kidney Minimum Acceptance Criteria Screening Tool

The Workgroup continued discussions on criteria utilized by the Kidney Minimum Acceptance Criteria screening tool.

Presentation summary:

The Kidney Minimum Acceptance Criteria (KIMAC) provides screening at the transplant program-level and is applied to "national" offers by the OPTN Contractor. "National" offers are defined as offers made to candidates outside of 250 nautical miles of the donor hospital. This distance acts as a surrogate for "hard to place." The KIMAC is not applied to high calculated panel reactive antibody (CPRA) candidates or 0-ABDR mismatch candidates.

Transplant programs provide information about the kinds of offers they want to receive from more than 250 nautical miles away for their non-CPRA, non-0-ABDR mismatch candidates in the OPTN Waitlist System under "kidney program minimum" criteria. When the OPTN Contractor runs the KiMAC, the tool will take this data and apply bypasses for programs who have indicated they would not accept and do not want to consider those donor kidneys.

In a continuous distribution framework, there will not be a clear "national" allocation. The OPTN Kidney Pancreas Continuous Distribution Workgroup determined that, because of this, OPOs will no longer be required to contact the Organ Center for assistance in allocating kidneys at a "national" level. As a result, however, the Organ Center will not always have an opportunity to apply this screening tool. The KiMAC tool will need to be transferred over to broader use in order to maintain efficiency on long match runs and avoid any increase in offers programs have indicated they are not interested in accepting. Application of the tool will need to be consistent across match runs and donors, and may need to mirror its existing state as close as possible.

The ultimate goal is to streamline filtering and screening tools into one easy to use system for transplant programs and OPOs. However, this will require a phased approach. The KIMAC tool will operate alongside Offer Filters and Acceptance Criteria in the first iteration of continuous distribution. The Workgroup is charged with determining how to best transition the KIMAC tool to a continuous distribution model in order to maintain efficiency.

The Workgroup will recommend which criteria should be carried over into the updated KIMAC tool. To inform these discussions, each data point is evaluated for effectiveness based on median percentage of transplant programs bypassed from a match run. In reviewing the criteria, Workgroup members were

asked to consider which elements provide significant efficiency benefit that should be carried over, or those elements that provide little efficiency benefit and could be removed to streamline transplant program responses.

Summary of discussion:

Infectious disease related questions

Staff asked the Workgroup if screening for hepatitis B core with differentiation for IgG and IgM testing, noting that this screening element predates the use of total hepatitis B core testing. One member remarked that they were unsure as to whether this differentiation is crucial. Staff explained that there are three questions related to hepatitis B testing in the KiMAC tool:

- Hepatitis B surface antigen (HBsAg)
- Hepatitis B core antibody with no IgG/IgM testing
- Hepatitis B core antibody with IgM testing

Staff noted that the waitlist acceptance criteria already screens on hepatitis B core positive, and that a positive hepatitis B result would require a re-run of the match due to new information, which would trigger the waitlist acceptance criteria screening.

One member noted that the IgM test is not technically required per OPTN Policy if the hepatitis B core test is used, so most OPOs are not likely providing that result separately anyway. Another member explained that a positive hepatitis B core means that the patient had a potential history of a hepatitis B infection, but not an active infection, which could potentially re-activate. The member noted that it may not be necessary to have that level of specificity in terms of IgM and IgG when screening. A member remarked that the screening tool shouldn't include hepatitis IgM/IgG questions. Another member agreed that the hepatitis B core antibody with IgM and without IgM/IgG testing screening questions should be removed. The member explained that active hepatitis B is indicated by a positive HBsAg result. The member continued that, based on current hepatitis B testing requirements, the hepatitis B core antibody with no IgG/IgM and with IgM testing questions are not useful.

The Workgroup agreed that "hepatitis B core antibody with no IgG/IgM testing" and "hepatitis B core antibody with IgM testing" should be removed from future KiMAC screening.

Staff noted that some of the infectious disease screening questions currently utilized by the KiMAC tool are also included in waitlist acceptance criteria screening. Staff asked if there is a need to keep some of these infectious disease screening questions in the KiMAC tool and in the Waitlist Acceptance Criteria screening, specifically test results for the following:

- Hepatitis B NAT (HBV NAT)
- Hepatitis C antibody (Anti-HCV)
- Hepatitis C NAT (HCV NAT)

Staff noted that currently, HBV NAT is an effective screening criterion, and when applied, screens off a median of 82 percent of programs. Anti-HCV is less effective as a screening criterion, and when applied, screens off a median of less than 5 percent of programs. When applied, positive HCV NAT screens a median of 33 percent of programs.

One member remarked that HBV NAT, anti-HCV, and HCV NAT screening should continue to be utilized by the KiMAC tool. Another member agreed, noting that these criteria seem to screen efficiently.

The Workgroup decided to maintain screening on HBV NAT, anti-HCV, and HCV NAT. Going forward, the KiMAC tool would screen on the following infectious disease questions:

- Hepatitis B surface antigen (HBsAg)
- Hepatitis B NAT (HBV NAT)
- Hepatitis C antibody (Anti-HCV)
- Hepatitis C NAT (HCV NAT)
- Human T-cell Lymphotropic Viruses type I and II (HTLV-U/II)
- Syphilis

Donor history and management related questions

Staff asked the Workgroup about "unknown cause of death" and "meningitis as cause of death" criteria, both of which may require modification to data collection in the OPTN Computer System if maintained in the KIMAC screening. One member remarked that both instances are highly uncommon, and recommended removing these criteria. Another member agreed that these are likely very infrequent, and thus screening on these criteria would not provide additional efficiency to the system. A member remarked that additional data collection will require maintenance in the future. One member noted that programs may be wary of unknown cause of death.

The Workgroup decided to request additional input from other Workgroup members at the next meeting before finalizing a decision on "unknown cause of death" and "meningitis as cause of death."

Staff asked the Workgroup about "maximum levophed dosage," "maximum levophed duration," and "average dopamine dosage over the last 12 hours of donor management" screening criteria. Staff noted that the levophed and dopamine criteria would require additional system complexity to automate screening. Staff also noted that these criteria are not frequently used to screen, and so do not provide significant efficiency benefit. One member remarked that the levophed and dopamine criteria should be removed, particularly if they will require additional system complexity with limited benefit. Other members agreed.

The Workgroup agreed to remove screening on "maximum levophed dosage," "maximum levophed duration," and "average dopamine dosage over the last 12 hours of donor management."

Staff asked the Workgroup about the "adult donor had prolonged hypotension (<70 mm/Hg systolic)" screening criterion. Staff noted that maintaining screening on this criterion would require additional data collection in the OPTN Computer System, and could be a significant system effort. Staff added that this element is not frequently used in current KiMAC screening, and so provides little screening benefit. One member wondered if the response options to this criterion could be simplified, in order to reduce some of the overall complexity. The member noted that the element may not provide much screening benefit, even with simplification. The member recommended removing screening for "adult donor had prolonged hypotension." One member remarked that it is hard to tell how program responses to this question look, and that it may be helpful to understand the distribution of program responses. The Workgroup decided to continue discussing "adult donor with prolonged hypotension" at the next meeting.

Upcoming Meeting

- May 8, 2023

Attendance

- **Workgroup Members**
  - Jaime Myers
  - Jillian Wojtowicz
  - PJ Geraghty
  - Nikole Neidlinger
  - Renee Morgan
- **HRSA Staff**
  - Jim Bowman
  - Arjun Naik
- **SRTR Representatives**
  - Ajay Israni
  - Jonathan Miller
- **UNOS Staff**
  - Kayla Temple
  - Kieran McMahon
  - Kimberly Uccellini
  - Krissy Laurie
  - Lauren Motley
  - Tamika Watkins
  - Lindsay Larkin
  - Maria Huber
  - Melissa Lane
  - Rebecca Fitz Marino
  - Ben Wolford
  - Carly Layman
  - Carol Covington
  - James Alcorn
  - Ross Walton
  - Sara Moriarty
  - Sarah Booker
  - Shavon Goodwin
  - Tommie Dawson
  - Thomas Dolan