OPTN Kidney and Pancreas Transplantation Committees
Utilization Considerations of Kidney and Pancreas Continuous Distribution Workgroup
Meeting Summary
April 3, 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 4/3/2023 to discuss the following agenda items:

1. Released Organs: Carry Over Refusals
2. Dual Kidney: Carry Over Refusals

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

1. Released Organs: Carry Over Refusals

Staff provided an overview of the concept of carry over refusals and how they could work for released organ 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 released organ 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 kidney 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 Workgroup will first focus on carrying over refusals for released organ match runs.

The proposed solution for released Kidney match runs mirrors current policy, with a few additional efficiency considerations. If a program accepts and later declines an organ, the OPO will have the option to continue allocation via the original match run, or allocate the kidney via a released organ match run. Previously, the Workgroup agreed the released kidney match run should have an increased weight on placement efficiency and carry over refusals from the initial match run.

Because a released kidney offer is very similar to the original organ offer, and the OPO has the option to allocate from the original match run, carrying over a majority of refusal codes may be appropriate.

Summary of discussion:

One member asked why some refusal reasons shouldn't be carried over, particularly in the context of a released kidney, noting that refusals should always re-apply again for released kidney. The Chair remarked that most of the refusal reasons should be carried over, particularly donor quality refusals. The Chair noted that if the kidney happens to be closer to a program who has already refused it and the logistic situation has changed, the potentially the program may be interested in accepting the organ they previously declined.

A member recommended that the Workgroup review some of the refusal reasons that may make the most sense to carry over first. Staff provided an example, noting that a positive physical crossmatch will still be an issue preventing acceptance of the kidney for that candidate when the organ is released.

Donor and Candidate Matching Refusal Reasons

Staff asked about "donor age" (code 700) and "organ size" (code 701) refusal codes. The Chair remarked that both should be carried over, since this will not change when the organ is released.

One member noted that consideration of donor age is different for their program when the organ is closer than when the organ is several states away, particularly considering potential cold ischemic time for older donors. Staff asked if the refusal reason would then be donor age, or instead relate to transportation, noting that scenario would likely be a decline due to expected cold time. The member noted that not all coordinators enter the refusal codes appropriately.

One member noted that potentially, all or none of the codes should be carried over. Another member noted that this would automatically prevent those candidates from appearing on the released match. The Chair remarked that this will save time for the OPO and the transplant programs, and noted that organ specific, donor specific, and histocompatibility specific refusal codes relate to aspects of the donor that are not going to change when the offer is released. The Chair continued that cold ischemic time and logistics are the only aspects that could change. The Chair remarked that the Workgroup should default more to carrying over refusals so that programs are not re-reviewing offers that they have already seen and declined for. One member agreed, but noted that major shifts in logistics could change the consideration, although it's likely that a kidney that has traveled a great distance now has a fair amount of cold ischemic time.

A member asked how often the released organ match run is used, noting that many OPOs don't opt to utilize the released organ match run unless the kidney has been shipped a great distance, because that is where the allocation will be dramatically different from the original match run. The Chair agreed. The member remarked that the OPO prefers to use the original list when the organ is nearby because they don't expect allocation to shift dramatically. The member noted that timing, preservation, distance, and logistics are the things that would change in a released match run.

The Chair remarked that if the kidney has been shipped a great distance, it is not likely that many of the programs have responded anyways, as it is likely that the organ was accepted by a highly sensitized patient far away from the donor. The Chair remarked that most refusal codes should be carried over.

Organ Specific Refusal Reasons

The Chair remarked that refusals for "organ preservation: unacceptable method or findings" (710) and "organ anatomical damage or defect" (code 711) should be carried over to the released organ match run, as this will not change when the offer is released. The Chair added that refusals for "warm ischemic time too long" (713), "biopsy results unacceptable" (715), "organ specific test results not available" (716), and "unacceptable organ specific test results" (717) should also be carried over, as this will not change. The Chair remarked that time is of the essence for released organ allocation. Another member agreed that any refusals reflecting information that was known at the time of initial offer should carry over again, and that time and distance are the only considerations that will really change.

The Chair noted that "actual or projected cold ischemic time too long" (712) and "biopsy not available" (714) refusals relate to circumstances that could change. The Chair continued that cold ischemic time may be shorter than originally anticipated with the kidney in a new location, and that the accepting program may have performed a biopsy. The Chair remarked that codes 712 and 714 should not be carried over. A member remarked that the system should allow OPOs to note if a biopsy became

available, and carry over code 714, “biopsy not available,” if biopsy results are still not available. Another member noted that this is likely rare enough that it may not justify the additional complexity to the system. The Chair agreed.

A member noted that the programs within 250 nautical miles will be different programs from the original match run, and that carrying over refusals may not be as helpful. The Chair agreed, but added that, just in case the released match run is needed, this will help reduce unnecessary offers and calls. The Chair added that time is crucial in released organ allocation.

Candidate Specific Refusal Reasons

A member remarked that “candidate transplanted or pending transplant” (721) should not be carried over, noting that the potential recipient’s previous offer may have fallen through. The Chair agreed.

One member noted that refusals for “candidate temporarily medically unsuitable” (720) should be carried over, noting that this will not likely change in the time between initial offer and released organ allocation. The Chair agreed.

Members agreed that refusals for “candidate requires a different laterality” (723) should be carried over, noting this is not often relevant for kidney and not likely to change. Members agreed that refusals for “candidate requires multiple organ transplant” (724) and “candidate’s condition improved, transplant not needed” (722) should be carried over, noting that these are not likely to change when the organ is released. Members also agreed that refusals for “epidemic/pandemic – candidate” (725) and “candidate temporarily ineligible due to insurance or financial issue” (726) should also be carried over, as these are also not likely to change when the organ is offered as a released organ.

One member recommended that “candidate unavailable” (727) should not be carried over, as the candidate may not have been reachable by the transplant program before, but that the transplant program may be able to contact them now.

The Chair recommended that refusals for “candidate refused” (728) should be carried over, since the candidate’s refusal is unlikely to change when the offer for the released kidney. Members agreed.

Histocompatibility Refusal Reasons

Workgroup members agreed that a positive physical crossmatch would remain positive when the organ is released and thus still prevent the program from accepting and transplanting the organ for the refused candidate. The Workgroup agreed that “positive physical crossmatch” (code 732) should be carried over to the released organ match run.

One member remarked that refusals for “no candidate serum for crossmatching” (730) should be carried over, as this will not likely change that quickly.

A member remarked that refusals for “no donor specimen for crossmatching or no time to crossmatch” (731) should not be carried over, noting that the circumstances may have changed, and that post-recovery there may be more donor specimen available, particularly with additional blood or nodes available post-recovery. Members noted that there may have been additional time to obtain specimen in the post-recovery period. The Workgroup agreed code 731 should not be carried over.

Members agreed that refusals for “positive virtual crossmatch/unacceptable antigens” (733) and “number of HLA mismatches is unacceptable” (734) should carry over, as this will not change in the context of the kidney being a released organ.

Disease Transmission Risk

Members agreed that refusals for “Public Health Service (PHS) risk criteria or social history” (740), “positive infectious disease screening test” (741), “donor infection or positive culture” (742), “malignancy or suspected malignancy” (743), and “epidemic/pandemic-donor” (744) should be carried over to the released kidney match run. Members noted these factors will not change when the offer becomes a released offer.

Donor Specific Refusal Reasons

Members agreed that the donor’s medical history will not change, and recommended that refusals for “donor medical history” (750) be carried over.

The Chair remarked that refusals for “donor instability or high vasopressor usage” (751) and “prolonged downtime or CPR” (752) would not change when the organ offer became released. Members agreed. A member remarked that “donation after circulatory death (DCD) donor neurological function/not expected to arrest” (753) would not be applicable if the organ is released, as released allocation would be occur after the donor arrested and kidney was recovered. The member then noted that potentially, the program may still be interested in the organ if the donor arrested in a short amount of time. The Workgroup agreed not to carry over code 753.

Logistics Refusal Reasons

The Workgroup agreed that code 760, “resource time constraint,” and code 761, “donor family time constraint,” should not be carried over, noting that the logistical considerations may be different post-recovery. Another member noted that some of these may not be applicable, and so shouldn’t be carried over. The Chair agreed.

The Workgroup agreed that refusals for “recovery team availability” (762) should not be carried over, as the logistical considerations are different post-recovery. The Workgroup agreed that refusals for “transplant team or transplant facility availability” (763) and “transportation availability” (764) should also not be carried over, as these considerations may change.

Staff noted that it may not be appropriate to carry “exceeded policy defined response time (OPO only)” (765), as this could disadvantage the patient and prevent them from receiving the offer inappropriately. Members agreed that refusals for code 765 should not be carried over.

Other Refusal Reasons

One member remarked that refusals for “disaster emergency management consideration” (790) should not be carried over, as these considerations could change and it is not always clear what kind of emergency management was required. One member remarked that disaster or emergency may also result in another code being more appropriate, such as prolonged cold ischemic time.

One member remarked that programs use “Other specify” (code 798) at random, and may use 798 as a “catch all” instead of selecting one of the appropriate refusal codes. The member continued that not carrying over 798 will likely reduce efficiency significantly. The member recommended carrying over refusals for code 798. The Chair agreed, noting that programs are required to input a text description, and that at that point, the program likely does not want to review the offer again. Another member remarked that the message input doesn’t always make sense or provide rationale. Several members agreed that code 798 should be carried over.

A member asked if the system requires the OPO to input a reason the released organ match is being run, and staff confirmed that the system does not require rationale to run a released organ match run.

2. Dual Kidney: Carry Over Refusals

Staff introduced carry over refusals in the context of dual kidney, and the Workgroup began discussions on which refusal codes may be appropriate to carry over to a dual kidney match run.

Presentation summary:

Previously, 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
    - Improved efficiency for the original, single kidney match run and dual kidney match run:
        - Candidates only appear once on the original match run, which reduces calls and increases efficiency
        - Dual kidney match run includes several layers of efficiency, including filtering and screening
2. Specific criteria dictates *when* an OPO *may* begin allocating the kidneys as dual kidneys

The dual kidney match run includes several efficiency considerations, including:

- Match run includes *only* candidates opted in to receive dual kidney offers
- Offer filters model takes dual kidney into account, and programs will be able to build dual-kidney specific filters
    - Other screening tools 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

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, the offer is still from the same donor – there may be certain refusal codes that are appropriate to carry over. There are efficiency benefits to be gained from *not* offering to a candidate who would *not* accept the organ *for the same reason.*

Summary of discussion:

The Workgroup agreed that candidates for whom refusals were carried over should not appear on the dual or released organ match runs, in order to reduce visual clutter on these match runs.

The Chair remarked that it would be easier to provide programs with a way to indicate whether they are interested in accepting the offer as a dual offer on the single kidney match run. Another member agreed, noting that programs consider this option up front. The Chair continued that OPOs hear that the program would be interested in the dual offer prior to reaching the dual classifications. The Chair continued that rather than having to re-allocate, it may be easier to give programs the ability to indicate their dual interest upfront. Another member remarked that this would significantly improve dual allocation efficiency. The Chair offered that this could be a radio button or else a refusal code that programs could enter as a secondary refusal to indicate interest.

A member noted that the number of programs declining for single but expressing interest in dual could also be a criterion for initiating dual allocation. Other members agree. One member notices that this would give OPOs more information earlier on.

Staff remarked that this concept can be brought back to determine potential feasibility. The Workgroup agreed to work through the refusal codes in the mean time, and adjust a final recommendation once feasibility of program indication of dual interest. The Workgroup agreed a radio button for programs to indicate dual interest would be useful.

Donor and Candidate Matching Refusal Reasons

One member remarked that refusals for "donor age" (700) and "organ size" (701) should not be carried over to the dual kidney match run, as these considerations may change in the context of greater nephron mass. Other members agreed, and one member remarked that donor age and organ size could be considered indicators for potential dual kidney transplant.

Organ Specific Refusal Reasons

A member remarked that refusals for "organ preservation: unacceptable methods or findings" (710) should not be carried over, as dual kidney may change this consideration. Other members agreed.

One member remarked that "organ anatomical damage or defect" may be appropriate to carry over, as this complexity could increase in the context of two organs. Others agreed that refusals for "organ anatomical damage or defect" (711) should be carried over.

A member noted that "actual or projected cold ischemic time too long" should be carried over, as that dual kidney transplantation can take twice as long, with two organs needing to be surgically implanted. Other members agreed that "actual or projected cold ischemic time too long" (712) should be carried over.

One member remarked that refusals for "warm ischemic time too long" (713), "biopsy results not available" (714), and "biopsy results unacceptable" (715) should not be carried over to the dual kidney match run. The member remarked that clinical considerations of a dual kidney transplant may mitigate these concerns. Others agreed. A member pointed out that biopsy results may be available later where they weren't before the dual kidney offer.

A member commented that "unacceptable organ specific test results" (717) should not be carried over, particularly as these considerations could change in the context of dual kidney offer.

The member noted that "organ specific test results not available" (716) could be carried over, as it is possible those results may remain unavailable. Another member agreed that if the results were not available at time of offer, they would not like be available later. Others agreed.

Candidate Specific Refusal Reasons

Members agreed that refusals for "candidate temporarily medically unsuitable" (720) should be carried over, as this consideration is not likely to change in the context of a dual offer.

Members agreed that refusals for "candidate transplanted or pending transplant" (721) should not be carried over, as the candidate's offer may have fallen through. The Chair remarked that potentially, refusals for 721 should be carried over, particularly as this is unlikely that the candidate would pending transplant and now accepting for duals. Another member explained that the other offer may have fallen through, and the program is interested in accepting the dual offer.

A member remarked that refusals for "candidates condition improved, transplant not needed" (722), "candidate requires different laterality" (723), and candidate requires multiple organ transplant" (724) should be carried over to the dual kidney match run, as these are not likely to change.

Members agreed that refusals for "candidate temporarily ineligible due to insurance or financial reason" (728) should be carried over, as this is unlikely to change in the context of a dual offer.

One member asked if a transplant program would offer a dual kidney to a candidate who had declined the organ as single. The Chair remarked that refusals for "candidate refused" (728) should be carried over, since it is unlikely the candidate would accept the dual if they refused the single.

The Workgroup agreed not to carry over refusals for “candidate unavailable” (727) , as the candidate may not have been able to be reached before, but may be reachable now.

Histocompatibility Related Refusal Codes

The Chair recommended carrying over all histocompatibility related refusals, as none of these are expected to change in the context of a dual kidney. This would include the following codes:

- 730 – no candidate serum for crossmatching
- 731 – no donor cells/specimen for crossmatching
- 732 – positive physical crossmatch
- 733 – positive virtual crossmatch/unacceptable antigens
- 734 – number of HLA mismatches is unacceptable

Another member agreed, noting that these are not going to change for dual.

Disease Transmission Risk Refusals

The Workgroup agreed all disease transmission risk related refusals should be carried over to the dual kidney match run, as the context of dual kidney transplantation will not likely change the risk of disease transmission. This would include the following refusal codes:

- 740 – PHS risk criteria or social history
- 741 – positive infectious disease screening test
- 742 – donor infection or positive culture
- 743 – malignancy or suspected malignancy
- 744 – Epidemic/Pandemic – Donor

Donor Specific Refusals

The Workgroup agreed that none of the donor specific refusal codes should be carried over to the dual kidney match run, as all of these factors may be considered differently in the context of a dual kidney offer as opposed to a single kidney offer. The following refusal codes will not be carried over to the dual kidney match run:

- 750 – Donor medical history
- 751 – donor instability/high vasopressor usage
- 752 – prolonged downtime/CPR
- 753 – DCD donor neurological function/not expected to arrest

Logistics Refusals

One member remarked that “donor family time constraint” (761) and “recovery team availability” (762) should not be carried over, as this may no longer be an issue.

<u>Next Steps:</u>

The Workgroup will continue to work through carry over refusals on their next meeting.

Upcoming Meeting

- April 10, 2023

Attendance

- **Workgroup Members**
  - Valerie Chipman
  - PJ Geraghty
  - Renee Morgan
  - Sharyn Sawczak
  - Colleen Jay
  - Jason Rolls
  - Nikole Neidlinger
- **SRTR Staff**
  - Jon Miller
- **UNOS Staff**
  - Kayla Temple
  - Kieran Mcmahon
  - Joann White
  - Thomas Dolan
  - Lindsay Larkin
  - Lauren Motley
  - Sarah Booker
  - Keighly Bradbrook
  - Lauren Mauk
  - Melissa Lane
  - Carol Covington
  - Ross Walton
  - Ben Wolford