OPTN Kidney Transplantation Committee
Meeting Summary
August 15, 2022
Conference Call

Martha Pavlakis, MD, Chair
Jim Kim, MD, Vice Chair

Introduction

The Kidney Transplantation Committee (the Committee) met via teleconference on 8/15/2022 to discuss the following agenda items:

1. Welcome and Announcements
2. Operations and Safety Committee: *Redefining Provisional Yes and the Approach to Organ Offer and Acceptance*
3. Operations and Safety Committee: *Optimizing the Usage of Kidney Offer Filters*
4. Dual Kidney Allocation Data Request Discussion

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

1. Welcome and Announcements

Staff and Committee Leadership welcomed the Committee members, and shared that OPTN Public Comment is now open. The Chair explained that the cross-committee presentations are a great way to give OPTN Kidney Committee feedback, allowing the Committee to get more involved in OPTN work. The Chair encouraged the Committee to share their thoughts and feedback.

Summary of discussion:

There were no questions or comments.

2. Operations and Safety Committee: *Redefining Provisional Yes and the Approach to Organ Offer and Acceptance*

The Vice Chair of the Operations and Safety Committee presented the *Redefining Provisional Yes and the Approach to Organ Offer and Acceptance* concept paper.

Presentation summary:

"Provisional yes" is defined as when the transplant hospital notifies the OPTN or host organ procurement organization (OPO) that they have evaluated the offer and are interested in accepting the organ or receiving more information about the organ. This project seeks to improve processes to increase the efficiency of the organ offer, review, and acceptance system and reduce overall organ allocation time.

This concept paper will:

- Provide the community with an overview of the Operations and Safety Committee's progress to date on its efficiency project aimed to address inefficiencies related to provisional yes, including committee discussions on:
    - Identified challenges related to provisional yes

    - Proposed framework to organ offer, review, and acceptance system
- Introduce the concept of a three-tiered framework that aims to:
    - Provide outlined requirements for transplant programs
    - Allow transparency across OPOs and transplants programs
- Seek community feedback on the three tiered approach and associated responsibilities, time limit on offers within each tier, and the number of offers that can be sent within each tier

The Operations and Safety Committee identified a cyclical challenge related to provisional yes:

- OPOs send a high number of offers due to the high number of provisional yes responses, which do not result in final acceptance
- Transplant programs receive an overwhelming amount of organ offers and in response enter provisional yes in an effort to more appropriately manage the number of offers they receive

The Operations and Safety Committee developed the concept of a tiered framework. This framework would eliminate provisional yes and focus on the processes related to the organ offer, review, and acceptance system. Requirements within each tier would become more rigorous as a transplant program advances to each tier.

- Tier III: Initial Review of Organ Offer
    - Transplant programs will review and evaluate to determine if an offer immediately meets any of their internal refusal reason
    - This could streamline communications and notifications, such that programs may receive an electronic offer and provide a response
        - OPOs could be notified of offers that are turned down
- Tier II: Review and Evaluation of Organ Offers
    - In addition to requirements in Tier II, transplant programs will also:
        - Assess the candidate's medical suitability
        - Notify OPOs what additional information is needed to inform decision on organ offer
    - Includes two additional back up offers that will be considered for Tier I should there be an organ refusal
    - Time limit on offers: one hour
- Tier I: Final Review and Response to Organ Offer
    - In addition to requirements in Tier III and Tier II, transplant programs will also:
        - Assess histocompatibility
        - Confirm candidate availability
    - Transplant programs will finalize organ evaluation requirements, receive a primary or first back up offer for a specific candidate and provide a final response
    - One offer sent for each organ available in Tier I
    - Time limit on offers: one hour for the first offer, 30 minutes for subsequent offers

The tiered framework is still a concept, and additional feedback is welcome to help make further adjustments to the tiered framework and associated requirements. Additional considerations can include requirements for organ offers receive pre- and post-recovery and tools that could facilitate the proposed tiered framework.

The Operations and Safety Committee will review feedback from public comment and make adjustments as needed to the concepts presented.

Questions for considerations:

- Should there be different considerations for offers sent pre- and post-recovery? If so, what should those considerations be?
- Are there tools that should be considered that can help facilitate the three tiered model?

Summary of discussion:

The Chair thanked the Operations and Safety Committee for their work, and expressed concern that a tier III offer could become the new provisional yes, particularly if too many tier III offers are sent out and flood right into tier II. The Chair added that this will work differently for small programs, where one surgeon reviews all the offers directly, than for a larger, more resourced program that has a team of people paid to take organ offers through the night and only wake the surgeon when the kidney offer is more likely to become primary. The Chair added that this framework needs to work for both types of programs and everything in between. The Chair pointed out that there is a specific issue in defining how much time is allowed between tier III and tier II, and commented that 30 minutes is too short, as people may not physically be able to accomplish everything in that short a period of time.

One member shared that they take organ offers at their program, and that the proposed process could involve a significant increase in logging on to the OPTN Computer System, with a log-on for each tier. The member remarked that, logistically, this could be really complicated. The member shared that their program performs all of the responsibilities included in tier I, including virtual crossmatch and checking on the recipient, when they initially receive the offer. The member asked how the Operations and Safety Committee proposes holding programs accountable to these responsibilities, and ensuring that programs are assessing candidate's medical suitability. The presenter responded that a program could perform all of the tier I tasks up front in the three tier framework, and noted that they would share these concerns with the Operations and Safety Committee. The presenter also shared that the intent would be to find a way to hold people accountable to different tiers, but that this could be challenging.

One member shared that they take kidney offer calls, and expressed concern about potential enforcement of the three tier policy. The member noted that holding programs to decisions that are binding is the only way to get around the provisional yes problem. The member recommended including some language where OPOs can prioritize day time offers, as middle of the night provisional yes responses in particular contribute to increased cold ischemic time, as people forget about the offers and provide late, post-cross clamp declines. The member also suggested batched offering, such that the kidney is offered to recipients 1 through 7 on a match run, and if the first 7 programs don't respond, those programs are bypassed and recipients 7-14 are offered to, rather than sequential offerings that allow cold time to add up.

A member suggested performing some kind of simulation modeling as this moves forward, as this could help the Operations and Safety Committee define time limits and identifying areas causing preventable delays. Another member agreed, and asked if the Operations and Safety Committee has looked back to figure out exactly why this happens, and developed a list of reasons that informed the tiers. The member asked if there are problems centralized to certain transplant programs or regions of the country. The presenter explained that the Operations and Safety Committee reviewed several data requests, and did not identify any hot spots or problems with specific regions or programs. The Operations and Safety Committee did review data stratified by programs that took their own organ offer call and those that utilized an outside agency to screen offers, as well as offers sent during the day and those sent at night. The Operations and Safety Committee also reviewed decline codes for potential trends.

One member expressed agreement with other members' comments, and echoed concerns that tier III could become the new provisional yes, where people agree they've review information they haven't

reviewed. The member echoed that this problem is worse with offers sent late at night. The member also noted that the number of candidates to screen with each tier matters, and that this could look different for programs of different sizes.

3. Operations and Safety Committee: *Optimizing Usage of Kidney Offer Filters*

The Vice Chair of the Operations and Safety Committee presented the *Optimizing Usage of Kidney Offer Filters* concept paper.

Presentation summary:

The offer filters tool allows transplant programs to apply program-specific multi-factorial filters to bypass donor offers that they do not want to receive (currently voluntary). The goal of this project is to develop a more broadly utilized offer filter model that will create multi-factorial offer filters to filter off organ offers more precisely. The first iteration of this project will address kidney offer filters, and future iterations will address offer filters across all organs.

This concept paper will provide the community with an update on the Operations and Safety Committee's ongoing work on kidney offer filters, increase awareness on the benefit of offer filters usage, and seek community feedback on potential options to increase utilization and system benefit of kidney offer filters. The concept paper also provides data from the pilot program and voluntary rollout of kidney offer filters.

Offer filters is one of the many strategies for increasing the efficiency of organ placement. Usage of offer filters can increase the number of transplants and decrease cold time by getting to organ offer acceptances faster. This project presents two options that will allow transplant programs to create multi-factorial offer filters to filter off their organ offers more precisely.

The Operations Committee is presenting and seeking feedback on two offer filter options. All filters model decisions will be data driven and determined by historical organ offer data analysis.

- Default filters – one option is to have the system automatically enable model identified filters by default, instead of having kidney transplant programs opt in to enable them.
    - Recommended filters would be turned on by default
        - Programs would need to specifically opt out to disable the filters
    - Transplant programs would have the ability to turn off filters and/or adjust recommended offer filter criteria
- Mandatory offer filters – one option is to apply the model identified filters on match runs for kidney transplant programs based on previous organ offer acceptance and refusal behavior, without granting programs the ability to adjust or remove model-identified filters
    - Based on prior organ offer acceptance and refusal behavior
    - Developing pathways to demonstrate changes in behavior
        - Using a model filter to develop more restrictive criteria:
            - Distance
            - Cold ischemic time
            - Mixture of all criteria

The parameters used by the system to identify program specific offer filters are an evidence threshold. This includes:

- Kidney offers from the past two years
- Only donors that were eventually accepted
- Only offers up to and including final offer acceptance

- Must filter at least 20 donors
- Must have 0 acceptances
- No candidate parameters are included

The Operations and Safety Committee has developed several options to allow programs to demonstrate behavioral change:

- Option 1: Offers that are far away
    - Donor hospital distance could be used to make the mandatory filters less restrictive by increasing the distance by 250 nautical miles (NM) from the model identified filter
    - Example model identified filter: distance exceeds 325 NM *and* offer timing is post-cross clamp → mandatory filter: distance exceeds 575 NM *and* offer timing is post-cross clamp
- Option 2: Cold ischemic time at time of offer
    - Cold ischemic time could be used to make the mandatory filters less restrictive by increasing cold ischemic time by 5 hours
    - Example model identified filter: distance exceeds 325 NM *and* offer timing is post-cross clamp → mandatory filter: distance exceeds 325 NM *and* cold ischemic time at time of offer exceeds 5 hours
- Option 3: Criteria-specific adjustments
    - Each criteria could be adjusted to make it less restrictive by increasing distance by 250 NM, increasing cold ischemic time by 5 hours, increase donor KDPI by 5 percent, increasing donor age by 5 years, and increase history of hypertension by 5 years
    - Example model identified filter: distance exceeds 325 NM *and* offer timing is post-cross clamp → mandatory filter: distance exceeds 575 NM *and* cold ischemic time at time of offer exceeds 5 hours
    - Example model identified filter: donor KDPI exceeds 15 percent *and* offer timing is post-cross clamp → mandatory filter: donor KDPI exceeds 20 percent *and* cold ischemic time at time of offer exceeds 5 hours

The Committee will review feedback from public comment and make adjustments as needed to the proposed concepts.

Questions for consideration:

- Should OPTN policy promote increased filter use? If so, which option outlined in the concept paper do you support?
- What is the appropriate threshold for applying a filter?
- Should the filter be mandatory? If so, can a program request removal under certain circumstances?
- Should the filter be removable by the program? If so, should the filter reset if the center continues to decline the organs?
- Should certain hard to match candidates never be subject to having offers filtered?
- How often should the acceptance data be re-evaluated for transplant programs in order to adjust the model identified offer filters?

<u>Summary of discussion:</u>

One member shared that their program utilizes these filters. The member recommended that navigational routes be considered as a potential filter. The member shared an example of a kidney offered from another state, which would not have been able to arrive at the program by air travel until

at least 20 hours later, due to lack of connecting flights. The member shared that they ended up driving the organ 10 hours, and that these kinds of considerations should be taken into account with offer filters. The member expressed support for making offer filters mandatory, but noted that this could be too aggressive, particularly for smaller programs. The member remarked that the intent of this proposal and provisional yes is so that more aggressive programs, who are willing to take a chance on a kidney that wasn't accepted locally, to be offered those kidneys within an acceptable timeframe to allow transplantation at a lower cold ischemic time. The member noted that, at the end of the day, it becomes a navigational issue, and that most of the time, their program is declining organs because they can't travel to their program in a reasonable timeframe.

A member expressed support for mandatory offer filters, but noted that programs need to be able to change the filters, and that the filters themselves shouldn't be based on historical data alone. The member emphasized that the program should have the ultimate right to change their filters. The member added that, based on the parameters shown, there are other aspects of an organ that may make it seem like the program is turning down a good kidney, when in reality there are issues with the anatomy or with the travel logistics. For example, an organ can seem like a great offer, but could have four arteries and not be a good match for a five kilogram pediatric candidate.

One member expressed support for the offer filters tool, and shared that their program has had a positive experience with the filters. The member asked the Operations and Safety Committee to consider what patients should be made aware of with regard to filters – if a program is using filters or filters become mandatory, this needs to be communicated with patients to let them know that certain types of kidneys will not be offered to them due to filtering. The member asked how the Operations and Safety Committee plans to ensure that patients are aware of what kind of offers the program is filtering out. Another member agreed.

A member recommended including some way to educate programs as well on how offer filters affects odds ratios for organ acceptance, as many people are under-informed when it comes to how new acceptance rates are viewed and tabulated. A Scientific Registry of Transplant Recipients (SRTR) representative agreed, echoing that many programs don't realize that filters exclude organs from the offer acceptance metric, and that offers that are filtered are not counted in that metric. The SRTR representative explained that it is important for programs to remove offers that will not be accepted, based even in their historical data. The SRTR representative agreed that it could be worthwhile to emphasize this for all programs.

4. Dual Kidney Allocation Data Request Discussion

Staff presented recent discussions from the Kidney and Pancreas Continuous Distribution Workgroup on transitioning dual kidney allocation to a continuous distribution framework, including a data request on current dual kidney allocation.

Presentation summary:

Dual allocation overview:

- Dual is a classification for kidneys with KDPI 35-100 percent (Sequence C and D)
    - Centers opt in candidates to receive dual offers
    - Candidates appear twice on match run – once for single and again for dual
- Monitoring report shows nearly half (44.44 percent) of duals are allocated from the single sequences
    - Done to avoid organ wastage (cold ischemic time, late refusals, etc.)
    - Match run is too long

- Goal: transition dual allocation into a continuous distribution framework
    - Address identified inefficiencies with minimal system impact

The Kidney and Pancreas Continuous Distribution Workgroup and the OPO Committee Leadership provided feedback:

- Support for dual-accepting candidates appearing once on the match run
- Support for OPO discretion
- Need for system tools to be able to exclude single-offer only candidates
- Need for education for transplant programs on opting candidates in for dual offers
- Support for clear policy threshold to be able to offer dual

The Kidney and Pancreas Continuous Distribution Workgroup considered developing criteria to allow an OPO to offer donor kidneys as dual.

Potential criteria:

- Recipient criteria: age, calculated panel reactive antibodies (CPRA), primary diagnosis, estimated post-transplant survival (EPTS), dialysis time, blood type
- Donor criteria: age, completed biopsy, donor after circulatory death, serum creatinine, glomerulosclerosis greater than X value, diabetes, hypertension

Potential data request:

- What candidates are currently taking single vs. dual kidneys by KDPI group?
    - Metric: kidney transplant recipients by KDPI group and single vs. dual kidney (excluding en bloc)
    - Stratify by recipient characteristics, KDPI, and single vs dual: age, CPRA, primary diagnosis, EPTS, dialysis time, DR human leukocyte antigen (HLA) mismatches, bllod type
- What donors are being allocated as single vs dual by KDPI group?
    - Metric: deceased kidney donors by KDPI group and single vs. dual kidney transplant, excluding en bloc
    - Stratify by donor characteristics, KDPI, and single vs. dual: age, completed biopsy, DCD, serum creatinine, glomerulosclerosis, diabetes, hypertension

<u>Summary of discussion</u>:

The Vice Chair recommended including data on how many donors with a KDPI between 35 and 85 were transplanted as dual. The Vice Chair remarked that there must be either some biopsy findings or other donor characteristics that should be incorporated, and asked if that data could be pulled as well. The Vice Chair estimated that the bulk of dual kidney transplants are from donors with a KDPI 85 percent or higher, just due to the nature of those high KDPI donors. Staff shared the potential data request, and remarked that it may not be possible to dig into specific biopsy results, but that the data request can look at whether a biopsy was completed or not.

One member shared that, as a patient, they were offered a two for one transplant, based on the size of the kidneys and their size as a recipient. The member shared that those kidneys weren't able to be transplanted due to poor biopsy results, but that they found out years later, those kidneys had been declined by 7 other recipients. The member shared that, at the time, their program had told them they would be likely to receive a kidney in less than 3 months, but that they didn't end up receiving another offer until much later. The member emphasized that there is a lack of patient education about transplantation, particularly when it comes to dual kidney offers, and that it would be advantageous to get transplant programs to talk to their patients about this during initial consultation. The member

concluded that there needs to be clarity and more educational information for patients to consider something like this. Staff thanked the member for their perspective, and noted that this comment gets back to the issue of balancing utility and equity when it comes to developing this policy. Staff agreed that patient education would be important. The Chair thanked the member for their comments, noting that it highlights the challenge that patients and their programs face in making these decisions in the middle of the night. The Chair agreed, that ideally, these options are discussed well in advance, so that patients may make more informed decisions ahead of time.

The Chair remarked that clumping KDPI 35 to 85 percent kidneys together in one group makes it difficult to have just one approach. Staff clarified that this data will also be stratified across a continuous distribution of KDPI.

5. Continuous Distribution Workgroup Updates

Staff shared an update on the Continuous Distribution Workgroup, from which two additional spin off workgroups are being formed, to support maintaining the project timeline and ensure each topic is addressed appropriately.

The Operational Considerations Workgroup will focus on operational components and system functions outside of the composite allocation score, such as dual allocation, kidney minimum acceptance criteria screening tool, and facilitated pancreas. The Review Board Workgroup will focus on the development of review boards for both kidney and pancreas. All Workgroup recommendations will be reviewed by the Kidney and Pancreas Committees for endorsement.

Summary of discussion:

There were no questions or comments.

Upcoming Meetings

- September 19, 2022 – Teleconference
- October 14, 2022 – Chicago, IL

Attendance

- **Committee Members**
  - Martha Pavlakis
  - Jim Kim
  - Arpita Basu
  - Bea Concepcion
  - Caroline Jadlowiec
  - Elliot Grodstein
  - Jesse Cox
  - Marian Charlton
  - Patrick Gee
  - Precious McCowan
  - Sanjeev Akkina
  - Stephen Almond
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Bryn Thompson
  - Grace Lyden
  - Jon Miller
- **UNOS Staff**
  - Kayla Temple
  - Keighly Bradbrook
  - Kim Uccellini
  - Ben Wolford
  - Carly Engelberger
  - James Alcorn
  - Joann White
  - Krissy Laurie
  - Lauren Motley
  - Matt Belton
  - Rebecca Fitz Marino
  - Ruthanne Leishman
  - Sara Moriarty
  - Stryker-Ann Vosteen
- **Other Attendees**
  - Kimberly Koontz