OPTN Transplant Coordinators Committee
Meeting Summary
August 18, 2022
Conference Call

Stacy McKean, RN, Chair
Natalie Santiago-Blackwell, RN, MSN, Vice Chair

Introduction

The Transplant Coordinators Committee (the Committee) met via Citrix GoToMeeting teleconference on 08/18/2022 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*

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

1. Welcome and Introductions

Committee leadership and staff welcomed the Committee, and shared that OPTN Public Comment is now open and regional meetings are underway. Committee leadership encouraged members to engage in providing feedback on public comment items, and encouraged attendance at the in-person Committee meeting next month in Chicago, IL.

Summary of discussion:

The Committee had no questions or comments.

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

Staff 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 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 asked for clarification on the number of offers allowed in each tier, and staff clarified that there would be one offer for each organ available in tier 1; so if two kidneys were available, there would be two tier 1 offers. Tier 2 would be back up to all tier 1 offers. The Chair asked how this would affect lung allocation with respect to double lung, as an OPO may have two lungs to offer, but need to offer to candidates in need of a double lung. Staff responded that this offer limit mainly applies to the actual offering of the organs, and that an OPO could still make a primary double lung offer as appropriate per policy.

The Chair asked if tier 3 would be eliminated by offer filters, noting that mandatory offer filters would likely significantly reduce the need to determine if the offer does not meet the program's acceptance and consideration criteria. Staff agreed, noting that offer filters are very helpful to reducing the workload of a tier 3 offer, and that the mandatory offer filters and provisional yes concepts work hand in hand.

The Chair remarked that there are timeframes in policy to improve efficiency of offer acceptance and evaluation, but there is nothing to enforce those timeframes, nor a way to monitor adherence to the timeframes. The Chair asked if this project will include efforts to enforce and monitor compliance to the timeframes, to encourage efficiency and to ensure the timeframes are still reasonable and feasible. Staff shared that the Operations and Safety Committee has discussed this heavily, including responsibilities in each tier and ensuring accountability. The Operations and Safety Committee is still discussing whether these timeframes should be automated or documented in the system and monitored that way. Staff shared that the timeframes can be built into the system such that the system is driving the timeframes. The Operations and Safety Committee has discussed potentially incorporating an automated time out, so that a transplant center is bypassed when the time limit is exceeded. The Chair remarked that an automated time out bypass could be tricky, particularly if the transplant center's provisional yes is pending additional information from the OPO. The Chair added that transplant programs should not be bypassed while awaiting information that is reasonable to evaluate the offer.

The Chair noted that crossmatching should be required earlier in the allocation process, particularly as materials can take time to ship. The Chair added that programs should be running virtual crossmatches and identifying which patients need to be crossmatched early on in the evaluation process.

One member asked if special considerations would be made with regard to the offer evaluation time thresholds if an organ was turned down in the operating room. Staff shared that the Operations and Safety Committee has touched on it in their discussions, but the details haven't been finalized.

The Vice Chair asked if the Operations and Safety Committee is considering using simulation modeling or other testing before implementing potential changes. Staff shared that the Operations and Safety Committee is focusing on building the system up now, but will consider that recommendation. The Vice Chair added that it would be interesting to see the impact of the offer filters, particularly as the filters will likely have an impact on many of the issues addressed by the provisional yes concept. Another member agreed, adding that the Operations and Safety Committee should roll out filters for all of the organs before pursuing any major system change to the allocation process. The member continued that this concept will likely be expensive to implement, and that it would be preferable to address these issues in cheaper, more effective ways.

The Chair noted that tier 3 would be easily solved with the filters. The Chair asked if there would be a limit on the number of tier 3 offers. The Chair also asked if the number of offers was limited by offers to the recipient, or offers to the center, such that one center would receive the primary offer and would need to evaluate all of their patients. Staff explained that tier 3 is more program based, while tiers 1 and 2 are more candidate specific. The Operations and Safety Committee is still discussing whether there should be a limit on the number of tier 3 offers. The Chair offered that the Operations and Safety Committee should consider including tier 1 both the primary offer and the first back up to the primary offer, noting that the first backup needs to be ready to accept. Additional back up offers could be considered tier 2.

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

Staff 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.
    - o Recommended filters would be turned on by default
        - ▪ Programs would need to specifically opt out to disable the filters
    - o 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
    - o Based on prior organ offer acceptance and refusal behavior
    - o 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?

Summary of discussion:

One member shared that their center reviewed the offer filters for their program, and after looking at how the filters would apply over several potential donors and cases, noticed there is considerable overlap between offer filters, listing defaults, and acceptance criteria for kidney. The member noted that this approach is not very streamlined, and that their program doesn't want to have discrepancies between systems for accepting offers. The member continued that it became confusing to navigate three separate filtering systems, particularly as it came to filtering based on candidate and donor information. The member asked for clarification on how a program would notify the OPTN that it will opt out of default filters. Staff responded that a program could default through the same offer filters explorer that is available to programs now, and that in the default option, the program-specific filters would be preloaded in the offer filters tool based on historical acceptance behavior. Within that tool, the program could alter or turn off those filters. Staff agreed that, ideally, there is one tool for filtering, and that hopefully, offer filters can be expanded to absorb the acceptance criteria tools, which currently helps with screening from the match run and other tools. The member pointed out that all three tools have age-specific donor criteria as a filter, and that one tool could restrict on that while the others do not, and there could be misalignment between the tools. Staff clarified that each tool applies at a different time in the allocation process, and that acceptance criteria will screen certain candidates off the match when the match is executed, while offer filters applies as the OPO is offering, utilizing the most current donor information. Staff agreed that this process could be more streamlined. The member appreciated the clarification, and Staff confirmed that the offer filters will not prevent a candidate from appearing on the match run, but will appropriately bypass candidates as the OPO offers down the match run, based on the offer filter settings and donor information.

A member shared that bypassing on transplant program historical acceptance behavior could be difficult, particularly different surgeons at the same program can vary greatly in aggressiveness and willingness to transplant certain organs. The member provided an example, explaining that some surgeons are willing to accept donors with a drowning cause of death for a pediatric candidate, while others are not. The member noted that more aggressive surgeons could be upset at being screened from offers that they would seriously consider for their patients. Staff noted that the Operations and Safety Committee is seeking feedback on how often the filters should be re-evaluated and re-applied. Staff explained that, in the mandatory offer filter option, the mandatory filters would not apply as stringently, so that there is room for a program to accept organs outside of their historical behavior. The member recommended that offer filters be applied differently for pediatric candidates than for adult candidates. The member explained that their program is more conservative generally because they focus on pediatric patients, but that their program is generally more aggressive when considering offers for adult patients.

The Chair expressed support for a model that would provide programs the default filters, from which the program could modify, apply, or turn off those filters as necessary. The Chair explained that center behavior can change dramatically when gaining a new surgeon, particularly if that surgeon is more aggressive. The Chair emphasized the importance of flexibility for programs in changing their behaviors. Another member agreed, adding that this would reduce a lot of the leg work for the centers. Staff pointed out that this model is most aligned with the default option, and asked the Committee if they had any thoughts on how often the default filters should be reapplied and re-evaluated. Staff confirmed that the default filters would be specific to each program, based on that program's offer acceptance history.

4. Adjourn

Staff and Committee leadership thanked the Committee for joining, and encouraged members to attend the in person Committee meeting on September 27. Committee leadership also encouraged members to engage in public comment discussion, including reviewing and providing feedback on their assigned public comment item.

Summary of discussion:

The Visiting Board of Directors Member thanked the Committee for their discussion and engagement, and asked if the Committee members had any concerns to take back to the Executive Committee or the Board of Directors. The Chair thanked the Visiting Board Member for their participation and their offer, and recommended that Committee members reach out with any thoughts.

Upcoming Meeting

- September 27, 2022 – In Person, Chicago, IL

Attendance

- **Committee Members**
  - Stacy McKean
  - Natalie Santiago-Blackwell
  - Angele Lacks
  - Ashley Anne Hamby
  - Ashley Cardenas
  - Brenda Durand
  - Donna Campbell
  - Karl E. Neumann
  - Kelsey McCauley
  - Madison Salazar
  - Melissa Walker
  - Sergio Manzano
  - Valinda Jones
- **HRSA Representatives**
  - Megan Hayden
  - Vanessa Arriola
- **UNOS Staff**
  - Kayla Temple
  - Alex Carmack
  - Joann White
  - Lauren Mauk
  - Shelby Jones
  - Terry Cullen