

OPTN Organ Procurement Organization Committee

Meeting Summary

August 17, 2022

Conference Call

Kurt Shutterly, RN, CPTC, Committee Chair

PJ Geraghty, MBA, CPTC, Vice Chair

Introduction

The OPTN Organ Procurement Organization (OPO) Committee (the Committee) met via Citrix GoToMeeting teleconference on 08/17/2022 to discuss the following agenda items:

1. Welcome and Introductions
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 welcomed the Committee members.

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*

The 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 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 received 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:

One member expressed support for the conceptual work, and asked how this concept differed from the current model, which creates a buffer between the offer and the decision makers. The member noted that this model seems to add an extra layer of buffer to the current system. The Operations and Safety Committee Chair explained that this would create explicit, specific expectations at each step in the offer process, with the program needing to indicate that each expectation has been met. If the program did not meet each expectation, the system would bypass them.

A member asked for clarification, and iterated their understanding that a program will need to sign off and indicate that they have completed specific steps within the timeframe, or the system will automatically bypass the program. The Operations and Safety Committee Chair confirmed this, adding that this would hold the programs responsible for evaluating offers in a timely fashion. The member asked if there would be an area in the match run or offer for the transplant center to specify the additional information they need, in order to streamline communication. The Operations and Safety Committee Chair explained that currently, the decision makers at transplant programs aren't reviewing offers until the morning or much later, as they are receiving too many offers, which can significantly slow the efficiency of the allocation process. The Operations and Safety Committee Chair continued, noting that this can do damage to an organ if it's been placed and recovered by adding unnecessary cold time.

One member noted that tier 3 is conceptually great, but would practically be similar to current offer and evaluation practices, with programs defaulting to saying yes. The member added that programs likely wouldn't begin evaluation until tier 2. The Operations and Safety Committee Chair acknowledged that this could happen, but noted that initial evaluation is an important step, and that hopefully the system will have more buy-in with the other steps and additional information requests. The Operations and Safety Committee Chair added that this project goes hand in hand with offer filters, and that effective offer filters allow programs to be held accountable for putting in provisional yes responses on offers that they never actually accept or transplant. The Operations and Safety Committee Chair noted that in those cases, the OPO has room to call on that program to code out for such offers at Tier 3. The member agreed that would be helpful. Another member agreed that offer filters will significantly improve allocation efficiency, particularly those based on historical data. Several members agreed.

A member explained that this is helpful when a transplant program wants to code out for all of their patients, but that it's also true that when a transplant program inputs a provisional yes for all of their patients, that's not genuine. The member asked if there was any consideration to limiting the number of provisional yes responses a program can enter on an offer. The Operations and Safety Committee Chair explained that transplant programs need to be on board with this as well, and that more limits could make this much more onerous on transplant programs. The Operations and Safety Committee Chair noted that this is iterative, and could be adjusted later.

The Chair remarked that everyone with a Tier 1 offer should be ready to accept the organ and have their recipient prepared to go to the operating room, to some degree. The Chair noted that all OPOs are experiencing issues with late turn downs, either due to recipient issues or the recipient receiving a better offer. The Chair expressed concern for prolonged decision making in Tier 2 and 3. The Operations and Safety Committee Chair noted that the tier 2 offers are meant to set a transplant program up well to accept a tier 3 offer, with some expectations met and the offer genuinely evaluated.

One member expressed concerns for additional time to allocation, and explained that there is a current issue with programs coding out offers patient by patient when those offers become primary, instead of evaluating the offer as a whole. The member continued that programs don't adhere to offer time limits,

don't evaluate back up offers as if they were primary, and don't properly check with patients, which causes issues particularly when an organ has to be shipped. The member expressed that this concept does not provide transplant center accountability for the current rules of allocation. Another member agreed, adding that this concept gives programs too much latitude. The Operations and Safety Committee Chair acknowledged there is a give and take to the offer and evaluation process, and that this would ultimately ask a lot more of transplant programs. By automatically bypassing programs and requiring response, the level of transplant program accountability and responsibility is increased.

A member explained that transplant programs already have the option to code out individual or for their whole center. The Operations and Safety Committee Chair agreed, noting that programs will typically input a provisional yes and not evaluate until the offer becomes primary. The member noted that programs will likely do the same thing in the conceptual model, such that they agree they have evaluated and are interested in the organ until the offer becomes a tier 1 offer, at which point they will decline the offer for what would be considered a tier 2 or tier 3 reason.

One member remarked that the best aspect of this concept paper is the automatic bypass based on offer time limits. The member explained that this reduces negotiation between the program and the OPO, and could bolster the expectations of each tier. The member noted that the automatic timeouts could be implemented without necessarily implementing a tiered system, particularly as the tier system essentially models the current evaluation system. The member added that the additional opportunities for programs to put information directly into the OPTN Donor Data and Matching System is helpful as well. The member reiterated that the most effective part of the concept is the enforcement of time limits, which holds transplant centers accountable and requires transplant programs to document themselves that they have fully evaluated the patient and are ready to move forward. The member added that transplant programs do typically wait until the offer becomes primary to evaluate an offer, which causes issues with the allocation process.

A member pointed out that tier 3 offers could be synonymous with offer filters already available. The member noted that, until centers change their behavior and get past the belief that they need to receive every possible offer for their patients, allocation will continue to be inefficient. The member shared that kidney discard rates are unacceptably high, and that every little attempt to improve this will make a difference. The member explained that, while 90 minutes may seem insignificant for a program to consider an offer, 90 minutes multiplied by thousands of patients on the kidney match equals a lot of time spent trying to place the organ. This results in high cold ischemic time and ultimately, non-utilization. The member noted that the holding of account needs to be shared equally between programs and OPOs, and that it's not sustainable to not make offer filters and other safe guards mandatory. The member added that lack of patient insurance or historical center acceptance behaviors are information that is available ahead of time, and can be used to improve efficiency. Another member agreed. The member shared that, despite offer filters being available to reduce transplant center offer work load, only 30 percent of programs are utilizing offer filters. The member noted that transplant programs need to be accountable to utilizing these tools and committing to system efficiency. The member added that, between acceptance criteria and offer filters, a tiered offer system is not necessary.

One member remarked that policy doesn't currently address the notify back up and notify primary buttons available within the match, and that policy should clarify when the clock starts on an offer. Currently, some programs don't believe the clock starts until the OPO and transplant program have discussed the offer via phone call. The member expressed concern that some coordinators rarely answer the phone as a result, and so further delay allocation. The member added that this problem is particularly exacerbated by contract coordinators, who create an additional buffer between OPOs and

decision makers at transplant programs. The member noted that automation will provide a neutral, agreed upon standardized clock. The member recommended ensuring that any policy provides clarity and accountability as to when the offer clock starts, so that the offer is not tied to a phone call. Another member agreed, adding that electronic notifications and the start of the offer evaluation period need to be clearly addressed in policy. Several members agreed. One noted that the addition of electronic notification while relying on a telephone call to start the clock doubled the expectations for OPOs. The Chair of the Operations and Safety Committee added that programs will be held accountable for each actionable piece of offer evaluation as well. Another member asked who would be holding programs accountable, adding that this should not be up to OPOs, and that accountability needs to be built into the system. Another member agreed. One member pointed out that OPOs are familiar with allocation analyst questions, and suggested that allocation analysts similarly could address transplant program behaviors that delay allocation, with some level of automation.

One member noted that accountability for transplant programs needs to be clearly defined and enforced. Several members agreed.

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

The 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?

Summary of discussion:

One member noted that allowing programs to remove filters makes the filter not mandatory. The Chair of the Operations and Safety Committee explained that there needs to be some degree of flexibility for transplant programs. The member noted that system inefficiency will not change until there is an increased degree of transplant program accountability.

A member expressed support for the inclusion of cold ischemic time as a filter, as well as cold ischemic time in the context of distance. The member noted that late declines could also be included in offer filters, such that programs could indicate that they would be willing to accept and recover themselves an organ four hours before planned organ recovery. The member explained that operating room and family timeframe restrictions can lead to post-recovery complications that offer filters could potentially help avoid. The Chair of the Operations and Safety Committee explained that this is just a first pass, but that the Operations and Safety Committee has discussed much more complex filters as well.

The Chair shared that the Region 2 meeting did not see a lot of push back on mandatory offer filters, even from transplant programs. The Chair expressed support for some kind of mandatory offer filters.

One member explained that the main issue is getting programs over the hump of sitting down and setting the offer filters up, and that this is why mandatory applied filters is the only way to make offer filters work. The member continued, pointing out that programs are in support of filters, but in practice, few programs utilize the filters. The member added that this makes no sense, particularly given the complaints about the volume of offers, and that making filters mandatory would improve this. The Chair of the Operations and Safety Committee shared that his program has been utilizing the filters, and offered that one option could be requiring programs to show that they considered offer filters and sorted through their offer data. The member agreed, adding that programs that have utilized the filters have had a great experience with them.

Staff clarified that there are three options being presented: voluntary offer filters, default filters (transplant program can turn filters off or edit them manually), or mandatory filters (program must utilize some form of filters and cannot turn them off).

A member expressed support for default filters, noting that many programs may not have had the time to sit down and evaluate offer filters. The default filters will force programs to look into the filters, and could encourage programs to start utilizing them. The member added that programs don't avoid offer filters out of malicious intentions, just that they may not have had the time to address them. Another member agreed, noting that the default option would force programs to use the tool without requiring specific filters. The member added that once something like default offer filters are in place, mandatory offers could be figured out in the future.

One member recommended some kind of policy that requires programs to try offer filters for a specific period of time, such as two weeks, to see how the filters work and how it affects their workflows.

Staff asked when filters should be re-evaluated or reapplied as a default for programs, and how often they should be recalculated. One member recommended reapplying offer filters more often than once a

year. The member remarked that this could be more difficult for smaller programs, but added that programs need to be required to use offer filters to some degree. The member noted that, if offer filters were made mandatory, programs could maybe appeal certain filters, but that programs shouldn't be allowed to opt out of utilizing the filters.

A member remarked that basing mandatory offer filters on the last two years of data may be unfair, as programs were a lot more conservative in the COVID-19 era than they would have been otherwise.

One member expressed support for mandatory filters and for consideration of what filters will be most effective for the programs. The member explained, with the default option, programs could end up reverting to only using ineffective filters. The member wondered to what degree current users are utilizing offer filters, and if those programs are considering how effective their filters are.

A member expressed support, noting that OPOs want organs to be placed with the appropriate recipient as quickly as possible. The member added that mandatory filters will help programs manage their list.

One member pointed out that there needs to be some mechanism of flexibility, to allow programs to change their accept practices and demonstrate changes in behavior. The member provided an example – a program that never used to accept DCD offers should be able to remove the DCD offer filter and receive DCD offers for a period of time, to allow them to demonstrate changes in behavior. Another member agreed that was reasonable.

One member remarked that voluntary filters have made little difference, and expressed support for mandating reasonable filters based on center behavior and data evidence. Several members agreed.

Upcoming Meeting

- September 21, 2022 – Teleconference
- October 6, 2022 – Richmond, VA

Attendance

- **Committee Members**
 - Kurt Shutterly
 - Bruce Nicely
 - Chad Ezzell
 - Clint Hostetler
 - Donna Smith
 - Doug Butler
 - Erin Halpin
 - Judy Storfjell
 - Leslie McCloy
 - Lindsay Larkin
 - Meg Rogers
 - Samantha Endicott
 - Sharyn Sawczak
 - Valerie Chipman
- **HRSA Representatives**
 - Vanessa Arriola
 - Jim Bowman
 - Marilyn Levi
- **SRTR Staff**
 - Katie Audette
 - Nick Wood
- **UNOS Staff**
 - Robert Hunter
 - Kayla Temple
 - Courtney Jett
 - Joann White
 - Katrina Gauntt
 - Kevin Daub
 - Krissy Laurie
 - Lauren Mauk
 - Lauren Motley
 - Ross Walton
 - Sarah Booker
 - Taylor Livelli
 - Thomas Dolan
- **Other Attendees**
 - John Lunz