

OPTN Kidney Transplantation Committee

Meeting Summary

May 20, 2024

Teleconference

Jim Kin MD, Chair

Arpita Basu, MD, Vice Chair

Introduction

The OPTN Expedited Placement Workgroup (the Workgroup) met via teleconference on 5/20/2024 to discuss the following agenda items:

1. Welcome
2. Recap of Kidney Committee Approach and Timelines
3. Efficiency and Non-Use Goals in Continuous Distribution
4. Task Force Update: Expedited Placement Protocol #1
5. Recap of “Hard to Place” Definition Discussion to Date
6. SRTR Presentation: Cold Ischemic Time and Nonuse
7. OPTN Data Report: Kidney Match Run Center Refusal

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

1. Welcome

The Chair welcomed attendees to the call, noting his appreciation for everyone’s participation in an extended meeting with a full agenda.

2. Recap of Kidney Committee Approach and Timelines

The Committee reviewed their efficiency work to date and how these efforts fit into the Committee’s greater approach to addressing efficiency and non-use topics, including collaboration with the OPTN Expeditious Task Force.

Summary of presentation:

The Committee’s approach to incorporating the Board Resolution’s efficiency and non-use directives includes:

- Foundational Efficiency Work
 - Defining efficiency goals in Continuous Distribution (CD), just as other CD goals have been defined. As the Board of Directors’ resolution incorporated more foundational goals into the CD project, the Committee now has had to redefine what those efficiency goals translate to, revisiting some of the Committee’s previous work.
 - Defining “hard to place” kidneys
- Continuous Distribution Allocation Algorithm (match run order)
 - Development of additional efficiency-focused modeling tools with SRTR and MIT
 - Potential modifications to the structure of CD as the Committee considers how to address questions around modifying weights, rating scales, or even introducing new attributes.

- Operational Considerations of Kidney Allocation
 - The Expedited Placement Workgroup is focused on this task and will report back to the Committee. There is also conversation with the Expeditious Task Force as part of this process.
 - Released organs, dual kidney, review boards, KiMAC Screening and other areas will be explored regarding best way to promote utilization and functionality here.

Today’s meeting is meant to focus on finalizing defined efficiency goals in CD and continuing discussions to develop a definition of “hard to place” kidneys. The Committee will review relevant data regarding risk of non-use and cold ischemic time.

This summer, the committee will continue to focus on potential modifications to the algorithm and modeling potential changes specific to CD. The Chair will provide an update on these efforts to the Board of Directors during their June 2024 meeting and an update to the community on work done in the last year as part of the August public comment cycle.

Summary of discussion:

The Committee had no questions or comments.

3. Efficiency and Non-Use Goals in Continuous Distribution

The Committee reviewed their previous discussions and finalized efficiency and non-use goals in continuous distribution.

Presentation summary:

The OPTN Ethics Committee’s White Paper on the *Ethics of Continuous Distribution* established the following guiding principles:

- Utility- does the framework achieve the greatest good while reducing waste and promoting placement?
- Equity- does the framework achieve equitable allocation, and not disadvantage vulnerable candidates?
- Transparency and Autonomy- is the framework easily understandable, and does it promote participation in shared decision-making?

The September 5th OPTN Board of Director’s Resolution asked the Kidney and Pancreas Transplantation Committees to include analysis or understanding of the impact of the following in its CD proposal:

- Decreased nonuse/non-utilization of kidneys and pancreata
- Decreased out of sequence allocation of kidneys
- Consideration of expedited placement pathways for kidneys at high risk of non-use

The Committee has previously discussed the following key points and principles in consideration of achieving increased efficiency, decreased non-use, and decreased allocation out of sequence in Continuous Distribution:

- Improve placement efficiency: equitably allocate each organ to the most appropriate patient
 - Reduce cold ischemic time
 - Reduce number of offers required to place an organ
 - Reduce allocation out of sequence
 - Improvements to allocation algorithm and provision of alternate allocation pathways (operational)
- Reduce non-use

- Particularly for KDPI 35+, and “hard to place” kidneys
- Maintain or improve post-transplant outcomes and waitlist mortality
 - Maximize survival benefit and realize increases in use without increasing delayed graft function and primary non-function.
- Increased incorporation of shared decision making
 - Alternate allocation pathways for a wide spectrum of organs can accommodate a diversity of patient preferences and transplant goals
 - Considerations and policies like high KDPI consent
- Understanding transportation as a balancing factor in equity and utility
 - Limits to transportation capacity are hard to define but can impact modeled equity gains, particularly those associated with increased travel distance
 - Consideration of feasibility of transportation associated with increased travel distances
 - Differing populations and geographies have different capabilities, considerations, and needs
- Accommodation of shifting program practices
 - Create solutions that allow program behaviors and acceptance patterns to shift

Summary of discussion:

One Committee member noted that these goals capture the Committee’s discussions and goals well. Other members agreed.

4. Task Force Update: Accelerating Kidney Placement Protocol #1

The Committee received an overview from Expeditious Task Force staff on the first accelerating kidney placement protocol. In January 2024, Committee members reviewed the expedited placement protocol variance proposal.

This new protocol is the Expeditious Task Force’s Rescue Pathways Workgroup’s first protocol recommendation. The Committee’s feedback will be recorded and submitted as public comment on this first protocol.

Summary of presentation:

This protocol is focused as a small-scale test of change that will follow the plan-do-study-act (PDSA) model. The PDSA approach will be important to working quickly to implement and test change while recognizing that improvements can be made as more is learned. This first protocol is not meant to push the needle, but rather to test this new process in a conservative manner.

The variance policy was approved in early April 2024. The Rescue Pathways Workgroup was initiated soon after and had a prioritized protocol in place by May 2. It was posted to the OPTN webpage several days later to seek comment and suggestions from the community, with a notice sent out to the community on May 15. A Town Hall will be conducted on this topic on May 20, with responses to questions posted online in a Frequently Asked Questions (FAQ) to ensure that all questions are answered. All feedback will be considered at the end of the comment period on May 30, with a planned Executive Committee vote on June 1. The intention is for this protocol to be implemented by the end of June 2024, after a three-week implementation period to onboard OPOs and transplant programs.

This first protocol is focused on pre-cross-clamp placement of Kidney Donor Profile Index (KDPI) 75-100 percent kidneys. In reviewing the Kidney Transplant Committee’s data report, it recognized the cut point at KDPI 70 percent but opted to utilize a more conservative threshold of KDPI 70-100 percent. OPOs will be required to make offers through the highest priority classifications, specifically:

- 75-85 percent KDPI through classification 26
- >85 percent KDPI through classification 19

These classifications include highly sensitized, 0-ABDR mismatch, medically urgent, and prior living donor candidates. It is not expected that requiring allocation through these classifications prior to expediting placement will contribute to reduce efficiency, particularly as these classifications typically include only a small number of highly prioritized candidates.

Once the participating OPOs have offered in standard allocation through these classifications, the OPOs will then begin allocating to programs on the “target list,” which includes participating programs. No less than two hours before OR time, the OPO will notify the target list of initiation of expedited allocation. Notification will be simultaneous to all programs on the target list, in order to alert the programs of the donor and allow them time to review donor information. OPOs may send out this notification in parallel with high priority classification offering. Programs on this target list will also receive notification once anatomy and biopsy information have become available on the OPTN Donor Data and Matching System. From this second notification, target programs will have 30 minutes to submit up to two potential recipients for whom the program would accept the offer. Once these responses are received, the OPO will make the primary offer to any candidates remaining in the required classifications per standard allocation protocol, and then make the primary offer to the highest ranking (by sequence number) candidate submitted by the target programs, in order of the candidates on the target list.

This protocol will employ 4-5 OPOs, to test both the protocol and the expedited placement variance process, to ensure maximization of variances. Participation in these protocols should expedite placement, not contribute to inefficiency in the system. The participating OPOs will vary across geographic location, population density, donor population considerations, and other factors. This first protocol will utilize minimal programming to create new bypass codes, to support monitoring and evaluation of the protocol’s use.

The target list of participating transplant centers will be specific to each OPO, and the number of participating programs will vary. Target programs will be selected based on their previous acceptance practices and distance from the donor hospital. These distances may vary depending on transportation and logistical considerations. Ideally, this protocol will include 5-10 target programs per OPO, to ensure manageability of the protocol and working relationships can be maintained between participating programs and OPOs. Over time, iterations of this protocol may include more target programs, and allow programs the opportunity to opt in or out. For example, a program could opt in to be considered a target program for day time offers, but opt out at night due to travel limitations. The Rescue Allocations Pathways Workgroup has indicated a preference to balance previous acceptance practices and include programs that are hoping to accept these offers with less cold ischemic time.

To learn about the protocol experience, OPOs will meet monthly to review progress and provide status updates. Qualitative interviews may also be conducted to gather additional feedback. Results from the variance will be shared with participating OPOs. These results will also be shared with committees and the broader community.

The protocol will be monitored using OPO-identified results as well as aggregated results across all participating OPOs. These metrics will be broken into four sections:

1. National metrics (involving ALL OPOs, not just those participating in the proposal in the protocol) as compared to protocol-specific metrics
2. Usage of the protocol
3. Impacts on efficiency in placement
4. Impacts on equity

Broader sharing on the OPTN website is being discussed with HRSA, specifically regarding detail and frequency of reporting to be posted. The Task Force emphasizes the importance of transparency.

Two types of monitoring are planned:

- Stopping rules are non-negotiable- if thresholds are hit within metrics. These stopping rules were pre-determined before the protocol was developed. If these thresholds are hit, this is grounds to say that things are not going well and the protocol will be stopped. A short report examining the proportion of transplants to females, non-white, and pediatric candidates among participating OPOs (per Policy 5.4.G) will be reviewed weekly by a subgroup of the Expeditious Task Force's Expedited Placement Workgroup. This group will provide recommendations to the Executive Committee.
- Protocol-specific reporting will include in-depth monitoring of the success and potential unintended consequences of each protocol. This will be completed every other week for the first two months and then monthly thereafter. Reports will be posted on the Task Force, Kidney, and OPO SharePoint sites and presented to these committees upon request. Final monitoring reports will be posted to the OPTN website. A subgroup of the Expeditious Task Force's Expedited Placement Workgroup will review regularly and provide recommendations to the Executive Committee.

There has already been interest expressed by OPOs who wish to participate, but there will be a more formal call for participants that includes protocol expectations. The PDSA model will allow, if things are going well, for another iteration of this protocol with more OPOs and target programs.

Summary of discussion:

An incoming Committee member asked if kidneys being considered for expedited placement in this protocol will all be placed on pumps and biopsied. Staff noted that this will be an ongoing conversation between participating OPOs and their target list transplant programs, and that this could factor into opt in/opt out decisions for the target list depending on how OPOs plan to pump, and whether OPOs plan to transport organs on pump. OPOs will be required to biopsy certain organs per OPTN policy, but some kidneys may not meet this requirement; in this case, the OPO may choose to biopsy to support program decision making.

A Committee member asked whether target programs will be required to be within an OPO's donor service area, or if any center that has accepted organs from an OPO have the opportunity to participate. Staff noted that the workgroup is continuing to refine these factors in program selection, but that the Rescue Pathways Workgroup plans to have develop target lists based on known acceptance criteria and practices and invite centers to opt in or out depending on interest in participation. Members expressed support for a transparent method of program selection, including in allowing programs to shift practices to accept these organs.

An incoming Committee member noted a similar process in the European transplant system. In this system, initially only a few aggressive centers were accepting the kidneys; but as time went on other centers became aggressive in accepting the same type of kidneys. The incoming member noted that this type of protocol may encourage all centers to be more aggressive in the long run.

One member noted that most of the kidneys in this protocol will not go to pediatric candidates, due to the KDPI threshold used, and expressed concern that the proportion of pediatric transplants for participating programs may decrease, as the program may accept more kidneys overall. The member asked if the Rescue Pathways Workgroup has anticipated potential problems with this, including impact to pediatric waiting times. The member continued, asking if these considerations will be captured in the

monitoring plan. Staff responded that the Rescue Allocation Pathways Workgroup has discussed this topic and will be monitoring this, and that this is also one aspect of the “stopping rules” for this protocol. The member noted that it is important for the Rescue Allocations Pathway Workgroup to ensure negative impact to pediatric candidates is avoided and minimized.

Another Chair sought clarification on whether the KDPI of 75 percent was based on the KDPI at time of offer, time of organ recovery, or KDPI at time of match run, noting that KDPI can shift over time. Staff noted that the Rescue Allocation Pathways workgroup has not yet discussed this, and that this point will be taken back to that Workgroup. The Chair acknowledged that the KDPI will change over time, particularly with changing creatinine values, and could potentially increase or decrease after the match run has been generated. Another Committee member agreed and noted that match KDPI is determined prior to cross-clamp, and that the use of match KDPI may align best with the spirit of this protocol, since the objective is to begin expedited placement prior to recovery. Requiring the match to be re-run could complicate allocation and potentially lead to increased cold ischemic time.

Committee members agreed that it is important to know whether pumping will be mandatory or not within the protocol. It was suggested that centers would be more comfortable with accepting KDPI 75 percent kidneys if they were pumped, as the additional information may support acceptance decisions. An incoming Committee member acknowledged that kidneys from donation after circulatory death (DCD) donors are almost always biopsied and pumped. The incoming Committee member remarked that this could support increased placement within this protocol. Several members acknowledged significant variation in OPO pump practices, and that this could be considered in selection of participating OPOs. Staff noted that the monitoring plan includes use of pump, and that this data could be used to analyze whether pumping increases likelihood of offer acceptance. The Committee agreed, and a member noted that this could support increased pump use for hard to place kidneys moving forward.

Next steps:

Committee feedback will be submitted to the Expeditious Task Force.

5. Recap: “Hard to Place” Definition

The Committee continued discussions to develop a preliminary, data driven definition of “hard to place” kidneys.

Summary of discussion:

The Committee’s initial discussions to define “hard to place” and kidneys at increased risk of discard,” noted multiple pathways towards a hard to place definition:

- Clinical, characteristics-based definition – the aspects that may make an organ acceptable for a smaller pool of patients, with greater potential for limited longevity (Data was reviewed in February on characteristics of non-use investigated out of several clinical characteristics.)
- Allocation, logistical definition – based on allocation thresholds such as number of center or candidate declines, logistical barriers, etc.
- Cold ischemic time as a factor in both pathways

In March, the Committee noted that it may be that continued allocation, as indicated by offering further down the match run or a critical mass of declined offers, may be the strongest indicator of difficulty in placement. The Committee identified reinforcing loops such that clinical concern for graft function can contribute to longer allocation times and late acceptance; and longer allocation times contribute to increased cold ischemic time, which increases clinical concern for graft function. The Committee has

noted the importance of being able to identify these “hard to place” kidneys regardless of timing or organ recovery, noting that a more flexible, multi-pronged approach may be beneficial here.

Committee members were asked to keep this multi-pronged approach in mind as they reviewed the upcoming data presentations in this meeting. Allowing for recognition of clinical indicators, cold ischemic time and allocation indicators to define hard to place may help ensure increased risk on nonuse of kidneys. A multi-pronged approach can account for shifting organ and allocation scenarios and information that may be challenging to capture, such as transportation limitations. This approach will capture dynamic risk of nonuse over time, in real time, as organs are allocated. Flexibility will be encouraged in application to allow for the inherent variation across regions, donor populations, availability of transportation options, and other critical considerations.

Summary of discussion:

The Committee had no questions or comments.

6. Cold Ischemic Time and Non-Use

The Committee reviewed an analysis from the Scientific Registry of Transplant Recipients (SRTR) on the relationship between cold ischemic time and rate of non-use for kidneys.

Summary of presentation:

SRTR Contractor staff presented data meant to aid OPOs in determining when an expedited pathway should be considered for kidney allocation. Nonuse rates are very high and OPOs are using expedited placement at an increasing rate. Currently, around 16% of all transplant kidneys have been placed through an expedited pathway. Despite this, the number of unused kidneys is at an all time high. The challenge here is that there are currently no standard criteria for when OPOs decide to transition from a standard allocation pathway using the match run to expedited placement.

The SRTR sought to calculate the kidney nonuse rate as a function of time during the allocation process in order to help OPOs make an informed decision on when to transition to expedited placement that is informed by data. OPOs did not make offers in a one-by-one fashion down the match run, but rather send out offers in batches. For example, the OPO may send a batch notification to candidates at sequences 1-20 on the match run, notify the centers with candidates in these first 20 positions (e.g. Center A has candidates 1, 3-8, and 15; Center B has candidates 2 and 16-20; and Center C has candidates 9-14). All of these notifications happen almost simultaneously and are time stamped. If none are accepted, the OPO may then choose to notify sequences 21-100. The same rules apply, with notifications going to the center for all of their patients that fall within this sequence. As crossclamp occurs, the OPO continues to send out offer notifications, but perhaps the second kidney is never accepted. The time stamps are valuable here, as it notes that the OPO is still in the process of attempting allocation. The SRTR looked at the last offer notification time stamps on offers to determine a lower bound on when the OPO stops trying to place those kidneys. From this, they can calculate the nonuse rate of kidneys for which the donor’s last kidney offer notification occurred after accumulating cold ischemic time relevant to crossclamp.

Results were shared from a review of all kidneys recovered for the purpose of transplant between January 1, 2023, and January 1, 2024. Kidneys from donors with no offer notifications or missing crossclamp times were excluded from this sample. Based on this data, the rate of nonuse shows an inflection point at four hours post-crossclamp. The nonuse rate is always increasing, but a steep increase is noted at approximately this point in time. This may represent a signal for when OPOs should begin to deviate from the match run and pursue an expedited pathway if kidneys have not already been accepted.

It was acknowledged that nonuse varies dramatically by donor KDPI. Additional data was reviewed, stratifying donors by KDPI (0-20, 20-35, 35-85, and 85-100). High KDPI kidneys (85-100) are always difficult to place (nonuse rate is always high) and this remains true throughout the allocation timeline. Conversely low KDPI kidneys have a very low nonuse rate overall (2-7%). When the original analysis was repeated, stratified by KDPI, there is an inflection point across all KDPI groupings at the 3-5 hour post-crossclamp point.

SRTR Contractor staff summarized the data noting that, as allocation progresses, the risk of kidney nonuse increases, particularly after crossclamp. Some kidneys are always hard to place (e.g. high KDPI) while others (even low KDPI) can become hard to place if still being allocated several hours after crossclamp. This indicates that there may be a point in time where the OPO should be deviating from the standard match run and pursuing an expedited pathway. This review looked at a raw calculation stratified by KDPI. The Committee may wish to stratify this by other characteristics in the future (e.g. DCD versus DBD, etc.). An adjusted analysis could also be explored, taking into account donor age, cause of death, and other characteristics that might adjust this curve. However, regardless of KDPI, the inflection point happened at roughly the same time period for all, a few hours post-crossclamp. For all kidneys still offered from 5 hours post-crossclamp onward, the nonuse rate is 45%.

Summary of discussion:

An SRTR representative noted that non-use for low KDPI kidneys is usually due to anatomy concerns, and asked if this data could be evaluated to determine if kidneys with anatomy concerns could be expedited earlier than 5 hours post-cross clamp. The SRTR representative explained that the “reasons for non-use” data is vague and limited, but that anatomical concerns can directly result in non-use. The presenting SRTR representative responded and noted that the inflection point for increasing non-use occurred at around 4 or 5 hours post-cross clamp regardless of KDPI. The presenting SRTR representative continued that if an organ has not been accepted at 4 or 5 hours, the OPO should go to expedited placement.

A Committee members disagreed, noting that for kidneys with KDPI 35 and greater, with discard rate of 40% at time of cross clamp, earlier initiation of expedited placement may be necessary. They continued that if those organs haven't been placed by 3 hours post-cross clamp, expedited placement may be necessary, particularly with a 70 percent discard rate for high KDPI kidneys. The SRTR representative agreed and remarked that certain post-clamp information is not necessarily available within the initial hours post-cross-clamp. The SRTR representative explained that this information is often viewed as critical to making a final decision. The SRTR representative commented that if expedited placement could be initiated earlier with earlier final acceptance, that this data could support that.

One member noted that it is interesting for the inflection point to apply across the KDPI spectrum. The member continued that KDPI is only a partial grading system, and that KDPI does not consider anatomic and other clinical information that may impact an organ's potential function or longevity. The member explained that gaps in the data may make it more difficult to understand why organs are not being transplanted on a larger scale. The member expressed support for expanding this analysis to look at anatomy, pump, and biopsy. The member also expressed interest in whether the relationship between cold ischemic time and non-use rate changes based on the time of day of recovery and allocation. The presenting SRTR representative explained that this analysis looks at batch notifications, as opposed to individual offers. The SRTR representative noted that the OPO could send out an offer at 4 PM and then 2AM the next day, and so it can be difficult to define timing of allocation.

One member asked what the sample size was for low KDPI non-use, and if late turn downs were incorporated in this data. The presenting SRTR representative presented two graphs, one showing the

number of kidneys not placed over time. The member asked if late turn downs are incorporated in the data. The SRTR representative confirmed that late turn downs are captured in this analysis, as OPO notification after late turn down would be captured in the data set. The member asked if this analysis determined what percentage of non-used low KDPI kidneys were initially allocated to multi-organ transplants. The SRTR representative explained that the analysis did not look at that.

The Chair wondered if the relationship between cold ischemic time in non-use has changed drastically over time. The SRTR representative agreed that this has shifted slightly over time, and shared that this analysis was initially performed for 2022 or 2021, and that the inflection point may have occurred slightly later in allocation.

The Chair pointed out that program and OPO behavior is reflected in this analysis, with 5 hours post-cross-clamp being a time that programs typically begin to make final decisions in term of acceptance or decline. The Chair explained that reasons for non-use for low KDPI kidneys is largely due to anatomy concerns, but may also include other clinical donor factors, including donor on dialysis or CRRT. The Chair offered that, if necessary, the Committee could evaluate refusal codes for non-used low KDPI kidneys. The SRTR representative noted that the main question for the Committee is what they hope to gain by evaluating this information, adding that this analysis was meant to support decision pathways for OPOs trying to ensure organ placement and transplant. The SRTR representative remarked that this information intends to support balancing equity and utility, while ensuring utilization of recovered organs. The SRTR representative continued that this data can support OPOs to better refine when deviation from standard allocation may be appropriate.

One member shared that one OPO they work with begins expediting allocation for DCD donors at 4 or 5 hours of cold ischemic time, particularly if there are other clinical concerns. The member continued that allocation out of sequence does not currently ensure equity, and that it is important for expedited placement pathways to drive equitable increases in utility. The member continued that OPOs have become much more aggressive in attempting to ensure transplant of recovered organs, and that it is important for programs not to be penalized for accepting out of sequence offers. The member expressed support for early intervention and expedited placement for high KDPI kidneys. The SRTR representative agreed that the data supports earlier initiation of expedited placement for high KDPI kidneys and noted that waiting for 5 hours post-cross clamp before initiation of expedited placement may be conservative.

One member remarked that 5 hours post-recovery is very early, especially across the broad range of KDPI. The member added that the post-cross-clamp move to expedited allocation is much simpler to understand, and the data supports initiation of expedited placement at 4 or 5 hours of cold ischemic time. The member continued that it is much more challenging to open up expedited placement prior to organ recovery, particularly without a straightforward, simple trigger. The SRTR representative agreed that pre-cross-clamp expedited placement is also complicated by the fact that organ recovery times can be and may need to be shifted. The SRTR representative pointed out that, because expedited placement is not currently codified in OPTN Policy, OPOs may be initiating their own expedited or aggressive placement processes at varying and inconsistent times. The SRTR representative continued that this data would support reduced variation in initiation of expedited placement, potentially resulting in a greater number of organs placed and transplanted. The member agreed, noting that there is significant variation in OPO expedited placement processes. The SRTR representative continued that data driven initiation criteria is helpful to providing consistency for transplant programs evaluating these offers.

One member asked if this data has been shared with Association for Organ Procurement Associations (AOPO). An incoming Committee member shared that AOPO has had this data. The incoming Committee member shared that personnel who take organ call fundamentally understand this process and its pain

points better than those who do not take organ call. The incoming Committee member expressed that, at some point in allocation, it is important to ensure the recovered kidney is transplanted, even if out of sequence allocation is necessary to ensure utilization. The incoming Committee member continued that this is important as the transplant system is recovering and transplanting increasingly medically complex donors.

Staff shared that the OPTN Task Force's Rescue Allocation Pathways Workgroup and the Kidney Expedited Placement Pathways Workgroup are working collaboratively towards expedited placement solutions.

The Chair noted that the Committee will continue these discussions at their next meeting.

7. OPTN Data Report: Kidney Match Run Center Refusal

The Committee reviewed the results of their March 2024 data request to explore center declines as part of their work to define "hard to place" kidneys.

Summary of presentation:

This Committee requested this data at their March meeting, to understand trends in program declines.

Currently there is no universal definition for a center decline on a match run. For the purposes of this data review, four definitions were evaluated:

- Range refusals – program enters a decline response simultaneously for multiple candidates on the match run
 - This response does not need to be for all candidates on the match run and it does not always mean that these candidates received the offer yet
 - Centers could have more than one range refusal.
 - For the purposes of this request, a center was defined as having a center decline per this definition if it had one or more range refusals.
- Center Decline (>50%) – center declines for 50+% of its candidates on the match run
- Center Decline (>75%) – center declines for 75+% of its candidates on the match run
- Center Decline (100%) – center declines for all of its candidates on the match run

Definitions are very similar in reviewing the match run data. On average 3-4 centers on a match run enter center declines under these definitions. This translates to about 25-38 percent of centers appearing on the match run and entering declines based upon these definitions.

When breaking this out by KDPI, we see that higher KDPI is associated with a higher number of center declines. The data was also reviewed by post-crossclamp matches. As expected, post-cross-clamp offers had a higher number of center declines when compared with matches run prior to cross-clamp.

On average, a program's center decline accounts for 30-35 percent of a center's candidates, based on the definitions investigated. For match run location, 50 percent of candidates in a center decline were in later sequence numbers 1,100-10,000.

Summary of discussion:

One member asked if this data is a way to determine how centers are turning down these organs. Staff explained that this data request was to understand how centers behave currently, and to understand if a definition of hard to place based on the number of centers declined could be utilized in the US transplant system, similar to that utilized in the European transplant system. Staff continued that the Committee could see that on average, about 3-5 centers are putting in full declines, particularly on KDPI 86-100 match runs. Staff remarked that the number of centers having declined for all candidates on the

match run could indicate that the organ is hard to place – because the organ is being declined. Staff continued that center decline could be a surrogate indicator for concern.

One member expressed support for Offer Filters, noting that Offer Filters should be made more robust, with candidate and donor criteria and transmission risk criteria. The Chair agreed. Staff noted that enhancements to the Kidney Offer Filters system are incoming, and that these enhancements were delayed by the OPTN Board of Directors to prioritize implementation of offer filters for other organs. The Vice Chair added that beyond tweaking offer filters, the OPTN should focus efforts on ensuring centers utilize the offer filters tool. The Vice Chair expressed support for mandatory requirement for use. Staff shared that the OPTN Operations and Safety Committee has proposed and received Board Approval for Default Filters, which allows the system to build and establish a set of recommended filters for programs. Programs will need to evaluate these filters every 6 months and determine which filters they want to remove. Staff shared that the Operations and Safety Committee does ultimately want to move towards a mandatory offer filters model.

Staff noted that this data could support a way of initiating expedited placement prior to cross clamp – if 3-5 programs have declined for all of their patients prior to cross clamp, there is likely an indication that the organ has concerning risk factors. A member agreed.

The Chair asked if the center declines information was stratified by time of decline. Staff noted that this analysis did not incorporate time.

Upcoming Meetings

- June 10, 2024

Attendance

- **Committee Members**
 - Jim Kim
 - Arpita Basu
 - Jason Rolls
 - Steve Almond
 - George Surratt
 - Eloise Salmon
 - Curtis Warfield
 - Patrick Gee
 - Marian Charlton
- **HRSA Representatives**
 - James Bowman
- **SRTR Staff**
 - Bryn Thompson
 - Jonathan Miller
 - Grace Lyden
 - Nick Wood
 - Peter Stock
- **UNOS Staff**
 - Kayla Temple
 - Shandie Covington
 - Kaitlin Swanner
 - Jadia Bruckner
 - Lauren Motley
 - Thomas Dolan
 - Houlder Hudgins
 - Keighly Bradbrook
 - Carly Layman
- **Other**
 - Prince Anand