OPTN Kidney Transplantation Committee
In-Person Meeting Summary
October 8, 2024
Detroit, Michigan

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Introduction

The OPTN Kidney Transplantation Committee (the Committee) met in Detroit, Michigan on 10/8/2024 to discuss the following agenda items:

1. Continuous Distribution (CD) Overview
2. Review Public Comment Feedback: *Continuous Distribution of Kidneys Update, Summer 2024*
3. Discuss Updates to Kidney Expedited Placement Workgroup
4. Discussion: Finalize Hard-to-Place Definition and Efficiency Goals
5. Continuous Distribution Algorithm Efficiency Recap
6. Potential Efficiency Modifications to the Composite Allocation Score
7. Multi-Organ Allocation
8. Open Forum

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

1. Continuous Distribution Overview

The Committee received an overview the Continuous Distribution of Kidneys project and progress thus far. One goal of this meeting focused on incorporating increased efficiency in continuous distribution. It was noted as important for the group to have a clear understanding of work developed to date as a strong foundation.

Summary of Presentation:

Continuous distribution (CD) shifts organ allocation from a classification-based system to a points-based system. Each patient will be assigned a composite allocation score. The individual parts of this score are all aligned with requirements in the OPTN Final Rule, including medical urgency, post-transplant survival, candidate biology, patient access, and placement efficiency. The points-based approach allows for consideration of all of these elements together rather than separating them into categories and then preferentially ranking them. CD aims to remove these hard boundaries created by classifications, rather considering all the characteristics of a patient at one time when matching a donor with a potential recipient. The system is more equitable, more agile in adapting to changes in science, behavior, and community preferences.

The composition of a CD score was outlined for consideration. A rating scale is used to determine how candidates are ranked against each other for a given attribute. These scales may be binary, linear in nature, or be specific to candidate laboratory results. Attributes discussed by the committee for inclusion as part of the score include:

- Medical urgency
- DR matching
- Blood type

- Estimated post-transplant survival score (EPTS) and kidney donor profile index (KDPI) matching
- Calculated panel reactive antibody (CPRA)
- Pediatrics
- Prior living donors
- Safety Net
- Waiting time
- Proximity efficiency

The weight of each element is multiplied by the rating scale to determine the number of points that a candidate receives for a certain attribute. The Kidney Committee has discussed employing modifiers to preferentially give more points to candidates based upon donor characteristics. The attribute rating scale would be multiplied by the assigned weight and the donor modifier, based on the donor attributes.

$$\sum\{\text{Rating scale X Attribute weight X Donor Modifier}\} = \text{Patient's composite allocation score}$$

The Kidney Committee has identified the following attributes, based on each of the goals outlined in the Final Rule:

- Medical urgency:
  - Kidney medical urgency
- Post-transplant survival:
  - DR matching
  - EPTS/KDPI
- Candidate biology:
  - Blood type
  - CPRA
- Patient access:
  - Prior living donor priority
  - Pediatric priority
  - Safety net kidney
  - Waiting time
- Placement efficiency:
  - Proximity efficiency

The Kidney Committee initiated the Kidney Continuous Distribution project in September 2020, and by September 2023, was preparing to finalize the project. At this point, the Committee had identified 10 attributes and rating scales, submitted and reviewed two Organ Allocation Simulation (OASIM) modeling requests, and optimization work with the Massachusetts Institute of Technology (MIT) team to determine appropriate weights and rating scales to achieve Committee goals. The Committee also continued to develop operational approaches to support CD during this time, including review boards and updated definitions of kidney medical urgency, dual and en-bloc kidney allocation, removing requirement for Organ Center allocation to "national" kidneys and updating the KiMAC, released organ allocation, and multi-organ allocation.

To inform initial discussion of weights, the Committee sponsored a community-wide values prioritization exercise, the results of which were used to help determine the weights alongside modeling to determine the weights were functioning as desired.

The Committee developed kidney donor modifiers that allow certain candidates to receive more points based on a specific donor's characteristics. For example, for the highest KDPI kidneys, a donor modifier of 0 would be applied to pediatric and prior living donor priority, as these candidates would be expected not to accept offers of this type due to high priority on lower KDPI match runs.

The MIT team developed a dashboard to support policy optimization, allowing the Committee to establish specific constraints and goals, such as minimizing travel distance and reducing waitlist mortality. The dashboard develops optimized policies based on these constraints and goals. This optimization work informed the Committee's second OASIM request.

There were two principal areas of concern following the results of the second modeling request: (1) travel distance for pediatric recipients; and (2) reduced transplant rates for the most highly sensitized candidates (CPRA 99.9-100 percent) and equity in transplant rates between CPRA groups. The Committee requested feedback on these topics during the Summer 2024 public comment period.

In September 2023, the Committee received a directive from the OPTN Board of Directors to focus on efficiency in CD. The Kidney and Pancreas Committees were directed to incorporate the following goals into the CD project:

- Decreased non-use and non-utilization of kidneys and pancreata
- Decreased out of sequence allocation of kidneys
- Consideration of an expedited placement pathway for kidneys

Since that point, the Committee has shifted its focus over the last year towards efficiency, including establishing efficiency goals for CD that align with this directive:

- Improve allocation efficiency
- Maintain or improve post-transplant outcomes and waitlist survival
- Increase shared decision-making, incorporate transportation as a balancing factor in equity and utility
- Accommodate shifting program practices for sustainable transplant program growth.

In support of this work, the Committee has also requested that the SRTR assess feasibility of modeling use and utilization and look forward to seeing the results of this request soon. The Committee has reviewed data and literature in its efforts to build a foundation for understanding the drivers of non-use. The Committee began developing a data driven consensus definition of "hard to place" kidneys and was focused on development of a kidney expedited placement pathway through the Committee's Kidney Expedited Placement Workgroup.

The Committee's Summer 2024 public comment on Kidney CD provided an update on modeling and optimization, efficiency goals, defining hard to place, and early expedited placement discussions. It posed specific questions to readers regarding hard to place and expedited placement.

Summary of Discussion:

A Committee member requested clarity regarding SRTR modeling and MIT optimization. Historically, the SRTR has used the Kidney-Pancreas Simulated Allocation Model (KPSAM). Recently, the SRTR has focused on developing and transitioning to the Organ Allocation Simulation (OASIM) model. The MIT team supports the Committee utilizing these models to run thousands of potential policies, which can be compared to understand relationships and optimize for specific goals. MIT's dashboard leverages this to more visually demonstrate the interaction between the attribute weights, rating scales, and the outcomes.

The OPTN Lung Transplantation Committee utilized similar optimization to determine the appropriate weight for placement efficiency, noting the relationship between placement efficiency weight and waitlist deaths.

When Lung CD was being developed, they did not have the full benefit of the MIT optimizer, but did use it to help finalize some of their decisions. One of these was placement efficiency. The optimization tool

allows for the weights to be adjusted to better understand how the rest of allocation is impacted. The Chair added that the MIT dashboard allows the Committee to metaphorically "turn the dials" to see impact in real time versus waiting for additional rounds of modeling.

2. Review Public Comment Feedback: Continuous Distribution of Kidneys Update, Summer 2024

The Committee received an overview of feedback received on their recent Kidney CD update that was out for public comment from July-September 2024.

Summary of Presentation:

Seventy-four overall responses were received on the update, including written comments and sentiments collected at regional meetings. The bulk of these comments were submitted by transplant hospitals. Several themes were noticed in the feedback received, including:

- Continuous Distribution
    - General support for work to date
    - Modeling considerations
- Patient Focus
    - Priority for highly sensitized candidates
    - Pediatric priority and travel distance
    - Living donor priority
    - Patient and graft outcomes, program metrics, and risk adjustment
    - Transparency and shared decision-making
- Allocation Efficiency
    - Transportation, logistics, and cost
    - Broader distribution and impacts on non-use
    - Expedited kidney placement
    - Defining "hard to place"

For the theme of CD in general, OPTN Contractor staff shared that there is general support for CD to improve equity and efficiency from many stakeholders, including OPTN committees, regions, societies, and individual commenters. One society recommended monitoring the ongoing major changes that are happening across the donation and transplantation communities before continuing to shift to CD (e.g., OPTN Modernization, IOTA model, and OPO performance metrics). Commenters shared support for additional analyses and robust modeling to assess expected impacts of these proposed policy changes. There is support for consideration of increases in the number of kidney offers and expansion of travel in the modeling that was shared. Commenters also offered suggestions for how to assess impact on the most highly sensitized patients (99.9 percent CPRA) and to incorporate an equity metric for ABO weighted for population size.

When considering the patient focus, there were a number of comments focused on highly sensitized candidates. There is consistent support for this most highly sensitized group of candidates maintaining a high priority on match run, with some support for increased weight on this attribute with updating the rating scale to ensure this is achieved. Commenters also shared support for further efforts to equalize access across CPRA groups, with a recommendation to consider further modifications to the rating scale to achieve this. The rating scale gives minimal variation in priority for candidates with CPRA less than 90 percent currently but does seem to provide slightly more equitability between groups than others. A member noted that the groups make sense clinically, but modeling does not always capture the future changes when behavior is impacted. There was concern that updated rating scales may disincentivize

programs from reporting unacceptable antigens, particular for those candidates who have a CPRA lower than 90 percent.

Comments were also received regarding pediatric and prior living donor priority. There was support for maintaining and ensuring high priority for both of these groups in CD. In particular, the community supported a high weight for pediatric priority, even with elevated modeled distances. OPTN Contractor staff reminded the Committee that the second round of SRTR modeling had considerably higher median travel distance for pediatric recipients by as much as 200 nautical miles for all modeled CD policies as compared to current policy. It is harder to rely on the numbers in modeling, and important to consider the relationships within the attributes. There was some preference to maintain the high pediatric weight despite these distances, allowing programs to utilize their filters or acceptance criteria to manage those offered volumes and distance traveled. One society comment recommended stratifying pediatric priority by distance. There was concern for potential center burden for offer filters and screening and recommended early and frequent monitoring to ensure pediatric access is efficient and high.

There was support for greater emphasis on graft survival and greater sharing of outcomes data. This was particularly true for "hard to place" organs. Members noted some concerns related to adverse outcomes as well as increased length of hospital stay, readmissions, long term care and frequent clinic visits and labs. All of these were seen as impacting both centers and patients. There were also comments regarding risk adjustment and program metrics. Multiple commenters recommended limiting penalties or negative impacts for programs that are accepting "hard to place" organs with known but unadjusted risks such as donor use of CRRT or acute kidney injury. There was also acknowledgment of both the clinical and financial burden for programs with respect to accepting "hard to place" kidneys, noting that it is riskier overall for them to accept them for their patients, their outcomes, and the financial impact on the program. Commenters suggested reducing program risks here to incentivize acceptance.

Support was shared for expanding shared decision making and organ preferences as an approach to increasing organ use. Commenters offered recommendations for improved tools and education for patients in understanding their relative priority and waiting times. Patient organ preferences may be an approach to increased organ use with thoughtful education to help patients better understand the variety of kidneys and the risk/benefit ratio involved in acceptance based upon their specific situation. Having this understanding and agreement may lead to a system that is truly matching organs with patients that are willing to accept them. There was also commenter support and emphasis on transparency in the kidney allocation process and policy. The OPTN Ethics Committee emphasized the need for balancing equity and transparency with efficiency goals in a holistic manner.

When considering efficiency in the system, there was high support and recognition for the Committee's discussions related to the drivers of non-use and recommendations to increase acceptance in organ use, including:

- Recommendations to support virtual crossmatch, including reporting of all anti-HLA specificities
- Recommendations to improve offer review, including provisional yes, and accountability for late declines
- Support for expanded and mandatory offer filters
- Support for standardization of biopsy and pump data
- Support for increasing emphasis on distance and reducing travel (and potentially increasing the weight on distance as an attribute)

There were comments shared related to increased offer volume and its impact on allocation efficiency. Additionally, there was a recommendation to incorporate candidate willingness to accept "hard to

place" kidneys within the allocation framework itself, assessing program organ acceptance as a function of expected acceptance.

There was some overall discussion of broader distribution in general and how this could be related to non-use. One commenter noted that the system may not have yet adjusted to increased offers, increased non-use, increased out of sequence allocation and expanded travel. The complexity of CD was acknowledged, and it was noted that the system would also impact the challenges listed here, requesting that the Committee consider this in its decision making. There was also comment recognizing that "despite more organs being available, not all organs are the right fit for patients who match them." CD provides an opportunity to match kidney and recipients more closely, but the nuance and complexity of the decision-making process was also acknowledged alongside kidneys traveling further and more medically complex kidneys generally experiencing more delayed allocation and cold time. The Center for Medicaid Services' Increase Organ Transplant Access (IOTA) model was also recognized as impacting offer acceptance for "hard to place" kidneys.

Commenters were largely supportive of the work done to date related to expedited placement pathways. One commenter did share that if programs were able to more thoroughly and rapidly review offers, expedited placement may not be necessary. Additionally, the was a recommendation to exclude pediatric donor organs from expedited placement pathways to ensure pediatric access. The key components of expedited placement identified by the Committee to date through extensive review of the literature and data received support for a standard, transparent and effective expedited placement pathway. Recommendations included considering logistical constraints, noting that transportation can be a limiting factor for a program to be aggressive in accepting offers. Cold ischemic time was also repeated by multiple commenters with respect to expedited placement emphasizing balance between ensuring rapid placement without extending cold time unnecessarily. There was support for ensuring that ample time is given for standard allocation attempts, with expedited placement not occurring earlier than 5 hours and not later than 9 hours post-crossclamp. Community feedback reflected support for ensuring that all post-recovery information is available before initiating expedited placement, as it must be rapid to be effective. Finally, commenters acknowledged that OPO behavior does inherently vary. OPO input is critical to effective expedited placement, especially in terms of having this post-recovery information readily available for consideration.

Summary of Discussion:

A Committee member asked if the group would begin focusing on solutions today. Transparency may lend itself to creative solutions to address concerns. Members discussed the challenges of interpreting transparency here. One member asked if increased shared decision making and transparency meant that the physician or surgeon calls the patient regarding every offer, noting impacts to efficiency. Patient education in understanding the risk/benefit ratio ahead of time would help the transplant center better understand a patient's transplant goals and interest in accepting a high KDPI kidney, and consider this on an offer-by-offer basis. The idea of a patient tool was discussed as something to make this more patient facing and intuitive. Giving patients access to this information could be a powerful visual statement of the offer and what the next steps and options are. This is not meant to pressure patients, but to help them understand the risk of life expectancy while continuing to wait for a lower KDPI organ. Committee members shared concerns that KDPI may be hurting some patients that are focused on "product quality" versus getting off a dialysis before it becomes too late.

Committee members recognized that patients may struggle with learning this information and making an offer decision in a short period of time, and noted that this type of individual discussion in real time would further slow organ placement. Education ahead of the offer is critical to understand the consequences of being more or less aggressive in considering offers will benefit patients and system

performance. Members shared experiences of having consent discussion every visit, while still struggling to help candidates understand the risks and benefits of higher KDPI kidneys. Health literacy here was noted as a challenge despite using the tools available to convey this information. Committee members agreed that education is critical prior to time of offer, and that education should take place earlier in the process through patient support groups and online tools to make sure everyone is comfortable and understanding of options.

A Committee member shared that his center uses graphs that show expected survival with transplant of kidneys with varying KDPIs, and recommended that the SRTR provide similar graphics to compare survival on dialysis over time. A higher KDPI kidney that may last 5 years may be far more preferable than the outcome of staying on dialysis for 5 years for many patients. The SRTR waiting time decision tool is used in this manner, but some Committee members noted that there are still situations where patients focus on the KDPI as an absolute determinant of a kidney's safety and longevity. Committee members acknowledged the stigma that seems to be placed on kidneys now as a result of the KDPI and the consent procedure for high KDPI, particularly when a high KDPI kidney may be the best possible match and main opportunity for transplant for some candidates. This is causing some patients to second guess the medical team. A comparison was made between going to a transplant center versus a cancer center. The member noted that patients recently diagnosed with cancer will ask about survival time estimates, but that this question is not asked with end stage renal disease patients. The member noted that patients should be asking how to get off of dialysis quickly. The member emphasized the importance of informed patient choice. Another Committee member added that it is important for candidates to understand the physiology of what their bodies are going through on dialysis and the true risk versus benefit of accepting a higher KDPI kidney versus continuing to wait for the "perfect" kidney. Education, whether printed or in phone application format, may be helpful in showing these opportunity costs, but getting individual patients to truly understand these issues is key.

Peer education was also discussed as an opportunity here, with those who have received high KDPI kidneys sharing their experience. This would provide a living example that could be powerful to patients. Committee members talked about the need for education and the type of education needed related to CD in general to help explain this new allocation system as well as destigmatize high KDPI kidneys. There was agreement that it must be straightforward and easy to understand. A Committee member recognized the emotional and mental status of some individuals who have just been diagnosed and are dealing with dialysis. Patient education should provide patients with an understanding what their future looks like remaining on dialysis while waiting for a lower KDPI kidney versus accepting a high KDPI kidney more quickly, in terms that are less academic and more digestible. One member recommended graphics to demonstrate statistics. Utilizing patients and patient groups to help here in addition to changing how the transplant professionals communicate is critical to success.

Committee members talked about offer evaluation for the individual patients based on their situation and needs, noting that the "best matched organ" is very tailored based on antibodies, number of prior transplants, dialysis time, anatomy, and other factors. Rather than focusing on the quality of the kidney, perhaps the focus should be on the best window of opportunity to get a transplant earlier, before risk associated with transplant is elevated.

A meeting participant noted the value of a verbal discussion early in the process with candidates awaiting transplant regarding their interest in accepting higher risk, "hard to place" kidneys. Committee members agreed that they recognize these kidneys, some of which have high KDPI due to donor age, but may still be a good match for certain candidates. Having a list of candidates who are understanding that these kidneys may not have as good a function immediately but may still be a good match for them related to their individual circumstances would be valuable. While this verbal agreement to consider

such offers does not constitute a consent process, the pre-identification of these patients who are open to these offers will help allocate the "hard to place" kidneys more efficiently without adding unnecessary cold ischemic time. A patient representative noted that these conversations need to take place with patience and compassion and meet the individual candidate where they are to help them and their caregiver(s) understand the decision and see the team effort.

This education may also need to extend to community nephrologists as well, as some candidates also received mixed messages or misinformation from them or their primary care physicians that may impact their decision making. The knowledge gap even amongst peers was recognized here and needs to be addressed through education so this may then trickle down. Otherwise, the kidney transplant community is putting too much pressure on peer-to-peer patient education to manage these discussions. The information also needs to be reiterated, and most patients are seen at the transplant center on an annual basis leading up to transplant. Committee members considered how to hold community nephrologists accountable for understanding KDPI and CD when some transplanter colleagues are not doing a good job in these communications either. A member questioned whether OPTN and SRTR materials could be shared with dialysis units as well to help educate candidates, perhaps even making it a quarterly requirement. This could be incentivized in some way for delivery. Additionally, the transplant community is working to engage more with the community nephrologist community to help with education.

A Committee member suggested that he believes a huge part of organ non-use is related to allocation inefficiency. CD is hoped to address much of this, but acceptance behavior must be addressed as well to truly improve the system. One member asked if offer filters will be mandatory, or if the OPTN will incorporate center acceptance behavior into allocation algorithms to ensure kidneys are offered to those programs most likely to use them.

Committee members discussed the challenges in using KDPI in longevity matching, noting that KDPI is a crude measure of graft survival and quality, and was initially only used to match kidneys expected to function longest with patients expected to survive the longest and receive the maximum benefit of the organ. It has now been extrapolated to use for different things. The member remarked, when considering CD, that it may be time to eliminate the high KDPI consent requirement. While the consent form was created with the intent for greater transparency, it has created fear or stigma with these kidneys in some cases. Education can be substituted here to increase transparency and shared decision making. Committee members questioned whether candidates understood that not signing this form prevents them from receiving some kidney offers.

Eliminating the high KDPI consent form will require replacing this with specific conversation or education. Members noted that this is something that the Committee could standardize, and policy could be mandated that it is shared as part of the acceptance process similar to an attestation that donor risk factors were discussed. Committee members concurred that patient experience will be more powerful than any standard education that is provided. A Committee member noted that patients often don't understand the decisions being made in their interest. Helping patients to clearly understand their role in medication adherence and self-care and sharing patient experience and success with high KDPI organs is critical strong patient education on this topic.

A Committee member noted his excitement about CD, suggesting that it is the most nimble system that has been developed and can be fine tuned year over year based on outcomes and responding to public need. With all the work that is being put into it, EPTS and KDPI are still being used and there is some agreement that these calculations could be improved. The member asked if these systems could be updated, even with recognition that these calculations inform allocation significantly.

OPTN Contractor Staff noted that it will be beneficial to explore this idea with the Patient Affairs Committee as it considers next steps.

Next Steps:

Committee members wish to explore elimination of the high KDPI consent form in favor of an attestation of understanding of potential risks and benefits to accepting these kidneys.

Committee members wish to explore a multi-pronged proposal for patient education regarding high KDPI and/or "hard to place" kidneys that includes both health literacy appropriate clinical education as well as patient-to-patient peer education and sharing in a more holistic manner to reduce the perceived stigma related to these organs and refocus on the benefits of their use versus remaining on the waitlist and dialysis over time.

3. Kidney Expedited Placement Update

The Committee received an update regarding ongoing efforts focused on expedited placement of kidneys.

Summary of Presentation:

The OPTN has had three different groups working on expedited placement overall:

- Expeditious Task Force's Rescue Pathways Workgroup – working to develop, operate, test, and analyze different kidney expedited placement protocols on a small scale via the expedited placement variance
- Kidney Committee's Expedited Placement Workgroup – performed literature review on expedited placement frameworks, developing potential protocol for recommendation, maintaining aware ness of protocols tested, and considering requirements for implementation of expedited policy in KAS250 and CD. This group is positioned to develop policy and systems requirements to transition to expedited placement policy
- Ethics Committee - developing ethical analysis related to expedited placement

Current OPTN efforts on the expedited placement variance policy have been put on hold at HRSA's request, upon receipt of a critical comment[1] on this topic. With no clear timeline for potential testing via the expedited placement variance in place, there has been some discussion to pivot to begin development of an expedited placement policy. The Workgroup has done a substantial amount of work in this area both in researching how other transplant systems handle expedited placement and defining key components of expedited placement. Next steps will involve exploring operational details necessary to make the system work, such as trigger points for initiating expedited placement. Committee leadership has discussed moving forward with proposal development, with a target goal of a summer 2025 public comment. This is expected to involve creating the expedited pathway to function with current kidney allocation while recognizing that minor modifications will be needed to make this pathway operable for CD. For example, this may involve ensuring standard offers are made through a specific classification of patients before moving to an expedited pathway in the current system while offering to patients with a composite allocation score above a to-be-determined threshold before initiating expedited placement in CD.

[1] https://optn.transplant.hrsa.gov/media/q2qiywew/08302024-aoos-critical-comment-letter-to-optn-508.pdf. Accessed on 10/18/2024.

Summary of Discussion:

One Committee member questioned whether expedited placement will be necessary in CD. The Chair noted that while the need for this expedited pathway could be expected to be less, Continuous Distribution as currently developed does not account for center acceptance behavior, and offer filters may not be mandatory at that point. While this pathway may become obsolete as CD is finetuned with time, Committee members were supportive of creating this pathway for helping to allocate "hard to place" organs.

Committee members voiced disappointment that the expedited placement protocol pilots are not a viable path forward at this time, as they note that both logistical concerns and benefits could be identified before advancing a public comment proposal. This would allow for not only testing in a small number of OPOs, but also of testing variations of the proposed expedited pathway itself. OPTN Contractor staff noted that, while variance testing is paused, there is support from the OPTN Board of Directors to continue with the standard policy development process. This has been the normal iterative process for OPTN policy development, which has not typically utilized the testing incorporated as part of the protocol pilots.

The goal for developing this proposal would be a summer 2025 public comment proposal. This would allow the Committee time to build the process out, consider programming requirements, and allow the OPTN Policy Oversight and Executive Committees time to consider impact to resources. As the Expedited Placement Workgroup worked to develop its own variance proposal for the Expeditious Task Force protocol, a number of these details have already been discussed. This project would not be starting from step one, with a significant review of the literature and thoughtful discussions regarding what would trigger the expedited placement pathway. Members suggested that the initial protocol put forth by the Expeditious Task Force was relatively straightforward in its approach. A Committee member noted that the Expedited Placement Workgroup had incredible conversations in developing its ideas to address efficiency and inequity. All Committee members were encouraged to share their ideas with the full Committee. The OPTN Recovery and Usage Map (RUM) Report may also serve as a resource as the Committee completes this work, as it shows existing acceptance behavior patterns. The Workgroup has seen a demonstration of this report, and several Committee members expressed interest in a brief introduction.

OPTN Contractor staff provided a brief demonstration of the RUM Report. This report considers a rolling two-year cohort that is updated weekly on Mondays. The report looks back, by organ, at usage and non-usage rates and maps. It allows for visualization of how many organs are transplanted and also non-use rates for all the different DSAs. The map includes filters and allows for reviewing various metrics and what centers are accepting organs based upon these filters. For example, non-use rates for all DSAs could be used as well as number of donors recovered, number of kidneys recovered, number of kidneys transplanted, kidney discard rate, and kidney utilization rate for a specific OPO. The user can look at DCD donors or switch to KDPI and see what centers are accepting these types of organs. Committee members agreed that this tool will be a key part of expedited allocation policy development, as it helps to better understanding of acceptance behavior.

A member suggested a two-tiered system where expedited allocation is opened to centers within 250 nautical miles regardless of organ acceptance behavior to satisfy equity and then moving to centers with a proven track record of utilizing "hard to place" kidneys to avoid organ nonuse. The Workgroup had discussed a process where then centers may identify two candidates on their waitlist they would be willing to accept the kidney for in a specific time limit. The OPO would ultimately review all names submitted in the specified time period and allocate to the recipient(s) identified highest on the wait list. The Workgroup had previously discussed a number of potential characteristics both pre- and post-

crossclamp that may develop into these triggers. Cold ischemic time has received support as a trigger for the pathway but was not preferred as the only trigger. There are pre-recovery characteristics that may also be used to identify "hard to place" kidneys. In some cases, a donor might meet two or three criteria rather than waiting for a specific cold ischemic time accrual to move to the expedited pathway. Committee members acknowledged the complexities of identifying the characteristics (and seeking full community agreement on them) versus simply identifying a sequence number on the match run where allocation moves to an expedited pathway. The Workgroup had reviewed variables with a high predictability of turndowns. A logistic regression was also completed and previously reviewed as part of the "hard to place" discussions to better understand what clinical characteristics might consistently be reflected in these kidneys outside of high KDPI alone

4. Discussion: Finalize Hard to Place

Committee members continued discussion regarding finalizing pre- and post-crossclamp clinical factors valuable in identifying "hard to place" kidneys.

Summary of Presentation:

As the Committee is now focused on a policy development project here rather than small scale testing of a protocol, members were asked to focus on a preliminary definition to establish a specific, clear standard describing which kidneys are "hard to place." This definition will be used to identify organs what are at increased risk of non-use.

Committee members were asked to discuss characteristics and potential drivers of non-use to support development of approaches that will improve the likelihood of transplanting these organs. The goal of today's discussion is to finalize the "hard to place" definition and shift focus to application in CD.

In KDPI 50-75 percent, the following items were acknowledged as independently associated with non-use:

- Kidneys biopsied
- History of hypertension
- Hepatitis B positive
- Diabetes with duration of 5 years or more
- Donor median age 51 years
- DCD donors

In KDPI 76-100 percent, the list of clinical criteria independently associated with non-use included:

- History of hypertension
- Hepatitis B or C positive
- Diabetes duration unknown and duration of 5 years or more
- Donor age median 612 years
- DCD donors

The risk of non-use was noted as highest for the highest KDPI kidneys. Risk of non-ruse increases at 6 hours of cold ischemic time. Limitations in transportation and logistics were noted as increasing risk of non-use. Also, the great number of candidate and program declines can also indicate (influence) increased non-use.

Public comment feedback indicated support for a data-driven definition of "hard to place" with commenters recognizing the benefit of standardization and transparency as well as early identification of these organs. Commenters also acknowledged the difficulty to granularly define, with combinations

of clinical factors. There was support that "hard to place" should not be defined by a single criterion such as cold ischemic time, but more holistically. Commenters placed emphasis on post-recovery information in identifying these kidneys and recognized the limited post-recovery data collection in Donor Data and Matching system, specifically related to anatomy. Individual clinical, anatomy, allocation threshold, and cold ischemic time recommendations discussed later in evaluation a "hard to place" definition. The following anatomical items were shared as part of public comment:

- Multiple vessels (3+)
- Inadequate vessel length
- Vascular anomalies
- Multiple ureters
- Ureter length and size mismatch
- Ureter injury
- Stripped ureters
- Surgical damage
- Capsular tear
- Trauma to parenchyma or vasculature
- Presence of hematomas
- Arterial plaque, including ulcerative arterial plaque
- Petechiae
- Poor flush quality
- Discoloration and mottling
- Multipole cysts, suspicious cysts
- Excessive dense fat

The following clinical factors were emphasized in public comment as indicative of "hard to place" kidneys:

- High KDPI 90/95-100 percent
- Support for KDPI stratification
- Donor age, including 60+ years
- Distance
- Diabetes
- Hypertension
- Increasing or elevated creatinine
- Pump parameters
- DCD status
    - Warm ischemic time >30 minutes
- Donor use of hemodialysis/CRRT
- Serologies
- Donor acute kidney injury history
- Biopsy results:
    - High percentage of glomerulosclerosis
    - Severe arterial disease
    - Severe interstitial fibrosis
    - Evidence of thrombotic microangiopathy (TMA)

Commenters largely noted that cold ischemic time (CIT) alone does not define kidneys as "hard to place." Post-recovery evaluation varies and informs clinical aspects of difficulty in placement. Cold ischemic time was noted as valuable as a consideration in defining "hard to place," particularly in combination with clinical and allocation factors. Commenters did note that increased cold ischemic time as a result of late turn downs should not result in expedited placement.

In considering the thresholds of cold ischemic time, ranging from 5-9 hours, commenters suggested that 5 hours might be a tight timeframe, as post-recovery information sharing varies broadly across OPOs. There was agreement that 9-12 hours is too long and does not allow for added CIT building during transportation time. Most commenters were supportive of a threshold between 6-8 hours, with a recommendation to ensure that organs are accepted and transported in a window between 12-24 hours of CIT.

Mixed feedback was received on allocation thresholds, with support for utility of declines as relevant data points to understanding ease of organ placement. Concern was shared that identifying a specific sequence number or number of program declines to initiate expedited placement is arbitrary. Commenters did acknowledge the decline "domino effect" in organ allocation but suggested that this

pattern may look different depending on program density and geographic region as well. There was slightly more support for thresholds based on sequence number of programs having declined an offer, as opposed to number of programs declining, which was thought to be driven by surgeon behavior. There was a recommendation to strategy by KDPI and potentially distance.

Sequence number thresholds discussed in public comment included moving to expedited placement at sequence 50, 200, 250, 350, 500, and sequence 100 with 2 program declines for all potential candidates. Recommended potential thresholds based on program declines included 5 centers (similar to the European rescue allocation pathway closely studied by the Expedited Placement Workgroup), 25 programs, all programs within 250 nautical miles (with range varying greatly here in different regions of the country where that could include one or two programs in some cases and 70 in others). There was also a recommendation to make sure that any definition of center decline did not include a single candidate (specially prioritized candidates as an example).

Summary of Discussion:

The Workgroup Chair recognized that cold ischemia time seems to be indicative of a clear post-crossclamp indicator but should not be the only one used to identify "hard to place" kidneys. Pre-crossclamp indicators or triggers were noted as more challenging to specifically define. The idea of a sequence number trigger was discussed. A Committee member suggested that meeting 2 or 3 clinical factors prior to crossclamp for recognition of "hard to place" kidneys will allow for expedited placement a lot sooner and a higher chance of avoiding non-use; however, Committee members acknowledged the risk of getting too prescriptive in identifying these triggers. Members also acknowledge the challenge of getting full community agreement on these factors as well.

Committee members agreed that a straightforward approach is critical to public understanding and equitable administration of any expedited placement pathway. One member questioned whether the system should simply be triggered based upon cold time, noting that this represents the main group of non-used kidneys being targeted.

Kidney non-use by time from crossclamp and stratified by KDPI had been previously considered by the Expedited Placement Workgroup. Non-use in the highest KDPI kidneys remained relatively consistent. When considering the different KDPI quartiles, an inflection point for non-use appeared at 5-6 hours post-crossclamp. Some public comment feedback on this point noted that moving to expedited placement before 5 hours post-crossclamp may be premature while waiting beyond 9 hours post-crossclamp would be futile. A Committee member shared that the problem with using cold ischemia time on any given kidney is that some OPOs allocate kidneys prior to crossclamp, and others don't even start allocating until afterwards. The member asked if allocation could be required prior to recovery. The member expressed concern that otherwise, this may create incentive for OPOs to wait for this 5–6-hour post-crossclamp trigger and allocate the organs quickly without having to consistently follow the match run. OPO challenges regarding uncontrolled DCD donors, travel to outlying, smaller donor hospitals, and delayed test results were acknowledged as reasons that allocation may begin post-crossclamp for some kidneys.

One member acknowledged the RUM report, noting that this report evaluates serologies, body mass index, KDPI, history of hypertension, and diabetes. The member noted that these are examples of donor information known prior to recovery that may impact acceptance.

Recognizing that the current OPTN data set is incomplete related to anatomy, a Committee member asked what three pre-crossclamp donor variables correlate mist highly with non-use. The member noted that if this can be determined, there may be no need for a pre- and post-crossclamp system for recognition and trigger expedited placement. Committee members agreed that some of the items in the

regression modeling, such as terminal creatinine and median age, do not necessarily directly transplant to explicit criteria for “hard to place.”

A Committee member suggested that a simple path may be that, if a kidney is biopsied and there is 25% glomerulosclerosis and other agreed upon factors present, this would be considered a “hard to place” kidney that triggers expedited placement. This would allow for uniform application. A member noted that the Committee is trying to do two different things here- trying to identify hard to place organs mid-recovery and trying to predict which organs may become hard to place. A member noted that you can identify hard to place by how many people or centers have declined a kidney or the amount of cold ischemic time accrued on a kidney. Predicting hard to place should be based on clinical criteria, and could help OPOs start planning ahead to allocate these kidneys successfully. Committee members agreed that the definition must be clear cut, including either 6 hours cold ischemic time (post-crossclamp) or the identified factors.

Committee members were asked to consider what is predictive of “hard to place” versus what identifies these kidneys in real time after placement efforts are underway. The Chair recognized the differences in these two categories of the definition and encouraged Committee members not to be overly prescriptive in thinking through this, as any kidney becomes hard to place if it is not placed. To start the discussion, he asked Committee members to consider at what point a kidney becomes hard to place before then considering clinical characteristics that might predict this outcome.

Cold ischemic time is an important factor here. Committee members were asked for their opinions on whether this, allocation sequence number, or number of program declines might best satisfy the definition of a trigger for expedited placement here.

Pre-crossclamp variables should be a maximum of three and data driven.

SRTR defines “hard to place” as beyond sequence 100 in the program specific reports. Committee members suggested that the definition be aligned here since it is already a metric in use and suggested that centers not be penalized for outcomes when using these more challenging kidneys. This was noted as impacting center decision making, with fear of accepting the kidney due to the risk of it potentially failing. Smaller centers are often more conservative here due to the smaller number of patients in their overall denominator. Additionally, smaller centers often do not even receive these more aggressive, hard to place offers when larger centers who are known to be more aggressive decline them.

A member noted that looking at cold time accrued at time of offer as a trigger must be considered carefully as well. He suggested not going beyond six hours due to the impact of travel time added to this. If all “local” programs have declined and cold time is already accruing to a certain trigger (e.g., 6 hours CIT), one must then consider the time for getting the kidney to a program willing to accept it. This will most likely involve flights (outside of drivable distance). If accepted at 6 hours CIT, another 12-18 hours may accrue as flights are being secured. Cold time could easily be 24 hours or more if an offer is received in the evening and you are awaiting a commercial flight the next day. This scenario often leads to declines.

A suggestion was made to explore risk adjustment for “hard to place” kidneys that are transplanted. It was noted that this would be helpful to centers not only with SRTR metrics but also with payors, especially for smaller and even medium volume centers.

A member noted that the goal of 60,000 kidneys a year set by the OPTN Expeditious Task Force is only going to be reached using the highest KDPI kidneys. If centers don’t feel like they can risk accepting and using them or they are penalized for their use, this could lead to centers shutting down due to financial issues or closures due to metrics, which will only further challenge the delivery of this goal. A Committee

member questioned whether patients should be compared to those on dialysis from a metrics standpoint rather than transplant programs being compared to one another. This is important for the general public and the SRTR to understand. Another member noted that the SRTR and the OPTN are already moving in the direction of helping in this area. The Chair noted that developing a consensus definition will only help the SRTR if they are able to risk adjust these donors, and this risk adjustment model is updated on a rolling basis. This would be expected to encourage centers to use these more marginal donor kidneys because they won't impact the program's outcomes as much.

In identifying a hard-to-place definition for kidney post-recovery, the Committee discussed:

- Cold ischemic time, using 6 hours of cold time as a trigger to identify a hard-to-place kidney
    - Members recognized that there must be consideration for transportation as part of the timing of allocation here, noting that there could be many more hours of cold time anticipated based upon transportation needs and distance.
    - The 6-hour cold ischemic time decision point is based on SRTR non-use and not an arbitrary number. It was based on an infection point noted at the 5–6-hour mark.
    - This was supported in public comment feedback.
- Allocation threshold
    - SRTR definition- sequence 100 on the match run is reached
    - Some concerns that this is arbitrary and can be impacted by the number of centers in an area (e.g., 1 or 2 centers in the first 100 offers versus 10+ depending on location)
    - There appeared to be preference for cold ischemic time over allocation threshold due to geographic variability within public comment
    - It was acknowledged that OPOs have their own triggers currently in use (e.g., clinical triggers, cold time triggers, allocation threshold triggers. OPOs are developing their own models to determine what may best benefit their percentage of placement of these hard-to-place kidneys. What works for one OPO may not be preferred or supported by another.

In predicting hard-to-place kidneys, considering pre-recovery clinical characteristics predictive of "hard to place" (as defined by difficulty in placement, or lack of placement by certain points in allocation efforts), the Committee recognized that many of these characteristics are already incorporated into the KDPI score. Committee members agreed that they still consider a number of these clinical characteristics when receiving an organ offer despite inclusion in KDPI. Topics of focus included:

- Donor age
- High KDPI (there was support in public comment for stratifying based upon KDPI). The data showed that non-use is higher than the national average at about 70-79 percent KDPI. The mean non-use rate of kidneys with a KDPI of 90-100 percent was over 60 percent.
    - A Committee member disagreed, noting that not all recovered kidneys are transplantable. There is a subset of organs that will never be utilized whether its allocation is expedited or not. These are organs that probably would not have been recovered in years past. Now they are being recovered and we are trying to get programs to transplant them. Another member suggested there is value in learning what hard-to-place kidneys are not used at all as well, as this may be helpful to OPOs regarding not pursuing some donors.

The Committee recognized the pressure that OPOs are under to recover every donor organ and the tension between their metrics and the transplant center outcomes metrics. Another Committee member questioned how much cold time these unused kidneys had accrued before they were offered

to a center that might have used them. This is a challenging question to answer but would be instructive to the process.

Committee members suggested focusing on the success stories from out of sequence allocation of high KDPI kidneys where recipients are doing great post-transplant rather than focusing on the non-use. This may encourage others to think more about accepting these organs. A Committee member noted the importance of defining hard to place, then accurately be able to predict it, and then follow with a quality assessment to see if the predictions were correct and hold the community accountable. The member was supportive of both cold time and allocation sequence thresholds but noted that simple regression models are important to see what predicts this and use the predictive model to activate the expedited pathway as needed.

Committee members talked about the importance of alignment between what predicts "hard to place" and the filters available to centers receiving offers. If centers put those filters on automatically, it indirectly makes it part of the expedited pathway. As an example, if a center is not willing to accept a DCD donor over 60 years of age and this is reflected in the filters, then filtering will support streamlining offers to programs that would accept them. Default offer filters are forthcoming, but a member suggested that the filters should correlate with these clinical characteristics to help streamline the allocation process. An OPO representative noted that the ideal would be for the match run to match organ acceptance/usage behavior based upon previous acceptance history. This would put the patients most likely to accept these organs at the top of the list and this would improve the hard-to-place kidneys' chances of allocation by reducing cold ischemic time.

After lunch, Committee members returned to this discussion with a focus on clinical factors that predict the likelihood of hard-to-place kidneys. Committee members revisited the clinical factors emphasized in public comment feedback, noting that with the exception of the warm ischemic time associated with DCD status and biopsy results, all of this information is known pre-crossclamp. The following also includes factors recommended in public comment:

- High KDPI 90/95-100 percent
    - Support for KDPI stratification
- Donor age, including 60+ years
- Distance
- Diabetes
- Hypertension
- Increasing or elevated creatinine
- Pump parameters
- DCD status
    - Warm ischemic time greater than 30 minutes
- Donor use of hemodialysis/CRRT
- Serologies
- Donor acute kidney injury history
- Biopsy results:
    - High percentage of glomerulosclerosis
    - Severe arterial disease
    - Severe interstitial fibrosis
    - Evidence of thrombotic microangiopathy (TMA)

The Chair asked Committee members if they were more comfortable with a broad or narrow KDPI definition here. A Committee member asked if the OPTN collected characteristics of kidneys that were not used. This data has already been reviewed by the Committee, reflecting that more than 50 percent of centers decline kidneys in the 86-100 percent KDPI range are declined by centers for all of their patients. Members suggested that a broader definition would give OPOs more flexibility. Committee members were also asked to consider this from a transparency perspective. The definition is important, as it is needed for the SRTR to help build metrics in this area. This could be a narrow approach or a list of some characteristics that would be included in this predictive definition.

Committee members discussed a two-pronged approach may be reasonable. One member offered that the first part of the approach could be decline for all potential recipients within 250 nautical miles. A member cautioned that the length of the list for 250 nautical miles will vary greatly by region of the country, where this could mean 4-5 centers for one OPO or more than 25 centers for another. This has been an ongoing topic in the Expedited Placement Workgroup, as this would be an approach that is unevenly applied across OPOs, and the effect will not be the same in expediting placement.

Members revisited the idea of sequence numbers again but acknowledged that a similar issue applies. A more rural OPO may only have 3-4 centers in its first 100 potential recipients on the match run while an OPO in an urban area may still be offering to more centers and more aggressive centers in this first 100 offers. These centers may take time looking at the offer or want more data, so the two OPOs do not get to the same point of expedited allocation at the same time. Members circled back to the Eurotransplant's Recipient-Oriented Allocation (REAL) System model for expedited placement that is triggered on number of centers that have declined for all patients. A Committee member shared that economists at Stanford have looked at this using blocks of turndowns. If Center A declines for their ten patients and Center B turns down the offer for its next 10 patients, the OPO would reach a threshold of a certain number of blocks of turndowns and then initiate the expedited placement pathway for a hard-to-place kidney.

Committee members asked if modeling could be done to determine the appropriate sequence number or number of center refusals for all patients per OPO based on number of centers to make the system function evenly nationwide. OPTN Contractor staff noted that this might be challenging to do, as the information available in the middle of allocation looks very different than the final Deceased Donor Registration form that is submitted and the match run with all of the declines and the organs that have been accepted. It is not clear to identify the point (after the fact) where perhaps redirecting allocation may have enhanced chances of successful allocation or prevented non-use.

Members talked about the right number of program declines to include in a definition. Number of center declines could make expedited placement dependent on how many patients that center has on the match run. This could also vary greatly depending on center size and location. A member suggested that it may have to be some combination of factors. Committee members were hesitant to require centers declining for all candidates, as there could be a yes at the end of the list for a hard to match candidate. Equally, if three different centers are represented in the first three organ offers, you would not want this to be a trigger to move to expedited allocation. A member also noted that the decline codes will have to be considered if the trigger will be one patient per center turn downs and not blocks of patients, as those declines could be candidate related (e.g. already been transplanted, not medically ready) and not indicative of hard-to-place kidneys.

A Committee member noted the importance of not only setting the definition but also assessing it every year. If large numbers of kidneys are being put into an expedited placement pathway, then something in the definition or system is not working properly. Any initial selection here will be somewhat arbitrary-whether it is sequence 100 from the SRTR definition or a specific number of centers.

Because sequence 100 is already defined as hard to place by the SRTR, the Committee supported using this as a starting point. This, in conjunction with cold ischemic time as post-recovery triggers to identify hard-to-place kidneys and initiate expedited placement are both backed by data. Both can be re-evaluated and recalibrated as the Committee learns more about their impact on allocation over time.

The Committee agreed upon sequence number 100 or cold ischemic time of 6 hours as triggers to identify hard-to-place kidneys post-crossclamp and to initiate expedited placement in order to avoid non-use.

For pre-crossclamp predictors of hard-to-place kidneys, Committee members acknowledged that anatomy, biopsy, and post-recovery information are more challenging to use as predictive but there are a small number of anatomical considerations that could be listed. Some committee members favored a broader anatomical considerations category here rather than getting prescriptive- as a list would not necessarily be exhaustive.

Committee members discussed whether this should apply to pediatric candidates and to pediatric donors. Members suggested the cold time trigger may still be valuable here post-crossclamp, but all recognized the importance of adhering to the match run for pediatric candidates.

Members also discussed the importance of completing zero antigen mismatch and other critical offers before initiating any expedited pathway. OPTN Contractor staff noted that this is something that the Workgroup has discussed and will be bringing to the full Committee for consideration before it was to go out for public comment.

The Committee was asked whether a KDPI stratification or a KDPI minimum should be considered here. Members noted that KDPI alone should not be a factor that identifies hard-to-place kidneys but should also require another attribute from the list of predictors. Committee members also discussed a scenario where a KDPI 30 donor met the hard-to-place definition. In this case, offers would still need to be placed for priority candidates (e.g., high CPRA, zero antigen mismatch, prior living donors, pediatric candidates). Committee members agreed that expedited placement should include carve outs to ensure priority populations receive the offers prior to initiation of expedited placement.

Committee members suggested that a donor must meet a to be determined number of the following clinical factors discussed:

- Donor age
- Diabetes for 5 years or more
- Hypertension (duration or medically controlled will be helpful but this data is not currently collected)
- DCD
- Biopsy results: glomerulosclerosis >10%
- Donor use of CRRT (no specific data collected on this currently, but serves as a surrogate for AKI)

Committee members agreed that they do not want to be overly aggressive in classifying kidneys as hard to place, as this will lead to more allocation out of sequence through the expedited allocation pathway. The importance of closely monitoring the impact of the initial definition was reiterated. There was a question on how this will be checked to determine that it is working correctly.

The Chair noted that this provides a good starting point, suggesting that the list can be reviewed to determine what combination of factors is more predictive of hard to place and non-use. Data on CRRT is not currently collected, but this may serve as a surrogate for other issues related to AKI and terminal creatinine.

Next Steps:

The Committee requested additional data to help determine thresholds for donor age and hypertension in order to finalize its predictive criteria definition.

5. Continuous Distribution Efficiency Recap

The Committee received an overview of efficiency in Continuous Distribution.

Summary of Presentation:

The Committee's initial goal was to transition the current classification system into a continuous distribution framework. Each part of the composite allocation score for CD aligns with requirements of the Final Rule. Placement efficiency is built into the equation used for a patient's composite allocation score. This is to ensure that organs are able to be utilized and logistically carrying out these transplants. Up until September 2023, placement efficiency was incorporated into the score based solely on distance. Donor weight modifiers were also employed to allow kidney allocation to be a bit more nimble. This helps avoid, for example, offering KDPI 95 percent kidneys to pediatric recipients, knowing that they would be far less likely to accept those organs.

There were a number of operational considerations that played into placement efficiency of the overall allocation system as well. The Committee was tasked with considering dual kidney, en bloc, kidney Minimum Acceptance Criteria (KIMAC), and released kidney in how to efficiently place organs. The Committee developed approaches and requested public comment feedback on these operational aspects of kidney allocation..

In September 2023, the OPTN Board of Directors asked the Committee to consider how CD could impact efficiency by:

- Reducing non-use and non-utilization of kidneys
- Reducing out of sequence allocation of kidneys
- Incorporating expedited placement pathways for kidneys at high risk of non-use

The Committee submitted a data request to the SRTR in February 2024 to assess feasibility of modeling non-use and non-utilization. In the months that followed, the Committee's Expedited Placement Workgroup laid the structural foundation for developing expedited placement policy. Today's work provides consistency in recognizing hard-to-place kidneys and when it is acceptable to move to an expedited pathway for allocation to avoid non-use and place these organs with candidates who would benefit from receiving them.

There may be other opportunities to incorporate efficiency into the allocation algorithm/score. The Committee reviewed six different ideas during the meeting to become familiar with these concepts and provide preliminary feedback.

Summary of discussion:

There were no questions or comments.

6. Potential Efficiency Modifications to the Composite Allocation Score

The Committee explored possible efficiency modifications to the composite allocation score (CAS). Members were encouraged to flag items that they wish to talk about in detail but also reminded that there may be more to come and some of these topics were previously discussed during this meeting during the course of Committee conversation.

Summary of Presentation:

Six potential efficiency modifications were shared with the Committee for consideration:

1. Update the placement efficiency rating scale

   The Committee has already received public comment feedback in this area. There may need to be more emphasis on keeping organs closer and reducing travel. The current proximity efficiency rating scale was shown, utilizing a piecewise linear slope that provides similar but

decreasing priority for candidates within 250 nautical miles, less priority for candidates between 250 and 500 between 85 and 25 percent of total proximity efficiency points, and then decreasing priority for candidates beyond 500 nautical miles.

The Committee could decide to increase the weight on proximity efficiency, changing the shape of the rating scale to give more priority to candidates who are closer to the donor hospital (with a steeper drop off in points as candidates get farther away from the donor hospital).

2. Additional donor modifiers for "hard to place" kidneys

   Currently, there are donor modifiers planned for 86-100% KDPI kidneys. Candidates who are unlikely to accept those kidneys (e.g. pediatric, prior living donor) receive less points on match runs for those kidneys. A suggestion was offered to add donor modifiers for other "hard to place" kidneys, creating a new allocation sequence for types of kidneys with more specific characteristics that aren't accounted for in KDPI.

   The Committee has also tested increasing the weight, using a nonzero donor modifier and multiplying for travel distance for the highest KDPI kidneys to see an impact to reduce travel distance for these kidneys. The Committee has explored donor modifiers based on KDPI and age but could decide to add modifiers based on other hard-to-place attributes. The Committee would have to evaluate the value of adding donor modifiers versus the expedited placement pathway.

3. Inverse qualifying time for "hard to place" kidneys

   This would invert or significantly alter how waiting time is prioritized for the hardest to place kidneys. Traditionally, the higher the waiting time or qualifying time you have, the more points you receive- meaning your ranking is higher on the match run in current allocation.

   This modification would add an inverse scale to replace the qualifying time scale for hard-to-place kidneys so that candidates with less waiting time would be prioritized for the hardest to place organs. The concept here is that those candidates with less time on dialysis may be a better match for these more medically complex organs. This is matching a less medically complex candidate with the organ and getting them off of dialysis earlier while ensuring that the organ is used.

4. Re-evaluate consent for high KDPI and "hard to place" kidneys

   Currently, there is an informed consent process for kidneys with a KDPI greater than 85 percent. The Committee discussed this topic today, noting that it may stigmatize usable organs, becoming more detrimental than helpful.

   This modification involves changes to policy to better support shared decision-making on high KDPI and/or hard-to-place kidneys. The suggestion of an "opt in" versus informed consent that requires education versus informed consent.

5. Add interaction with distance in other parts of the allocation score

   This was described as an attribute to attribute interaction. All of the attributes have a rating scale and weight and potentially a donor modifier. They all work together based upon these components. In pediatrics, particularly for priority populations, we are seeing very high travel distances being modeled and simulated. The Committee could consider adding a distance component to this attribute. Currently, the pediatric rating scale is binary, so pediatric candidates are either receiving priority or they are not. Adding a secondary component or attribute here could include offering more priority to a pediatric candidate with 100 nautical miles of the donor hospital (as an example). This stratification of pediatric priority by distance would be expected to improve offer efficiency and reduce travel time.

6. Add "likelihood of acceptance" attribute to allocation score

   This proposed modification would give more points to candidates registered at transplant programs that are more likely to accept organ with specific donor or organ characteristics. This attribute would assign priority based on a program's history of accepting the type of organ being offered, utilizing the donor's specific characteristics. The scope here could be limited to higher KDPI and hard-to-place kidneys.

Summary of Discussion:

For option 1, a Committee member asked how the initial scale was developed. OPTN Contractor staff confirmed that it was a decision based upon the 250 and 500 nautical miles and committee discussions regarding exploring switching to circles-based kidney allocation and based on organ placement data. The inflection points were semi-data driven and the slopes were based on Committee judgment.

For option 2, Committee members briefly opined whether donor modifiers would be more or less helpful than an expedited pathway, noting that expedited placement could more readily and flexibly achieve increased offer efficiency. A member added that, with consideration for offer filters, expedited placement may be more worthwhile than donor modifiers.

For option 3, the Committee considered potential ethical concerns, noting the importance of careful consent and shared decision making. The Committee noted potential impact to candidates who are in the middle range of waiting time who may have decreased priority.

For option 4, a member noted that earlier transplant with a greater risk of delayed graft function for a couple of weeks as compared to waiting longer on dialysis to get a better quality kidney. The question then becomes graft survival. There was concern that regularly published OPTN data based upon KDPI of kidneys transplanted to show the curve of graft survival based on candidate age would be an incredible asset in having these discussions in a meaningful way.

For option 5, a Committee member questioned the benefit of such a modification. With the general quality of pediatric organs being high, there was concern that offering priority based upon location may disadvantage other pediatric candidates on the match run. One member noted concern that such a change could actually making waiting time worse for pediatric candidates in some areas of the country based upon lower rates of pediatric deaths in some parts of the country. A member recognized the OPTN Pediatric Committee was more in favor of adjusting offer filters to address this concern rather than modifying the CD formula as a whole.

For option 6, Committee members questioned whether this might perpetuate any inequity as it would funnel these hard to place or high KDPI organs to more aggressive centers. This would be perpetuated as more and more organs are received and transplanted. A member suggested that this may also help to

change behavior, encouraging other centers to be more aggressive in considering offers. Transparency was noted as critical here, as centers would need to know that they are missing out on offers versus this happening in the background. This would create a huge opportunity for transplant center education. An example of monthly emails to specific programs noting that they had missed out on 100 kidney offers and of those offers, 89 of the kidneys were transplanted successfully. This would drive programs to reconsider their practices.

There is also opportunity to create repercussions for centers not using organ filters. An example of a surgeon moving to a different center and a historically conservative transplant program now becomes aggressive in their offer acceptance. Allowing them the luxury of adjusting their filters may be a better way to address this than at the match run level where centers have no control. Appropriate use of the organ offer filters would negate the need for this type of modification. A member also asked about the proportion of HLA labs that are not leveraging virtual crossmatch. This has made the post crossclamp offers manageable, noting that the added cold time while waiting four fours for flow results would be detrimental. Committee members discussed the benefits of this approach, even with considering offers for highly sensitized candidates. OPTN Contractor staff shared that this data had been shared at the 2024 American Transplant Congress. Approximately 40 percent of transplants in 2023 utilized a virtual crossmatch. Data collection in this area continues. A Committee member suggested that this number should be much higher.

The OPTN Histocompatibility Committee, in conjunction with the Expeditious Task Force, will be offering a webinar on virtual crossmatching to help facilitate greater use from both the laboratory side as well as the kidney programs. There is hope that this may address reservations or hesitancy in this area. While there is no move to be prescriptive regarding practices at this time, the Committee will state that it generally supports the use of virtual crossmatch and that this should be addressed in program and lab transplant agreements. The webinar will cover new changes coming from Clinical Laboratory Improvement Amendments (CLIA) that give greater permissibility for virtual crossmatch to be used as a final immunological assessment to be used prior to going forward with transplant.

Members suggested that number 6 may catch the most attention from both an equity and ethics standpoint, and recommended seeking feedback from the OPTN Ethics Committee.

7. Multi-Organ Allocation

Committee members received an update regarding progress to date on multi-organ allocation.

Summary of Presentation:

OPOs may run a total of 10 different match runs, including kidney-pancreas, kidney alone, pancreas alone, heart-alone, lung-alone, and heart-lung match runs. Current policy does not require OPOs to work through these match runs in any particular order, though allocation must follow the match run order. Current multi-organ allocation policy does not delineate a clear way for OPOs to prioritize certain multi-organ combinations, and does not establish instances where single-organ potential recipients have priority in offer access over multi-organ patients.

While OPTN policies have historically required some multi-organ offers to ensure candidates have access to transplant, not all donors can donate to candidates who need multiple organs and some multi-organ candidates cannot accept a single organ transplant. For multi-organs, OPOs generally place thoracic organs first and then move to abdominal organs. Kidneys may often be allocated off of these other organ match runs before they are offered to kidney alone or kidney-pancreas candidates.

One of the goals of the multi-organ allocation project is to ensure that the most highly prioritized kidney alone candidates are getting some of these offers versus the donor kidneys being pulled away by a

multi-organ candidate who is most likely going to receive another suitable offer shortly thereafter. This proposal seeks to promote equity between multi- and single-organ candidates and standardization in how OPOs manage allocation from donors from whom multiple organs are available. The scope of this effort is to direct OPOs on how to prioritize multi-organ and single-organ candidates on different match runs by prescribing the order that the OPOs work through the match runs. This would not impact the ranking order developed in organ-specific policies.

A timeline for the project was shared. The OPTN Multi-Organ Transplant Committee (MOT) has been working on this effort since Policy Oversight Committee approval in October 2022. The MOT Committee is currently in the process of developing final allocation algorithms and is aiming to have an update for public comment in January and a policy proposal out for public comment in July 2025.

The MOT envisions the policy working as outlined: the OPO will determine which organs they plan to offer from the donor as they work through their donor evaluation. From here, all donor information, inc including the organs to be allocated, will be entered into the OPTN Computer System. The OPTN Computer System will then generate a plan that will tell the OPO which organ match runs to work through in specific order based on the relevant MOT allocation algorithm. Examples of how this would work were shared with the Committee. This will involve moving back and forth through the match runs to ensure that offers are made in various classifications in the specified order.

Specific to kidney placement, the OPO will work through the most medically urgent liver, heart, and lung candidates first. It is possible that a kidney could be placed with one of these organs off of these match runs, but then the OPO would have to move to the kidney match run to make offers to the most highly sensitized and most prioritized kidney only candidates before proceeding to make offers off of other match runs. The initial draft of the MOT allocation algorithm was reviewed with the kidney. It includes 34 classifications across different organ match runs, assuming a brain-dead donor aged 18-69 with a lower KDPI. The lung composite allocation score threshold is still in discussion, but the MOT Committee is recommending splitting that into a higher urgency and less urgency group.

Different organs will have different sequences based upon donor characteristics. Kidney allocation will be determined by donor age and KDPI score. There are currently six algorithms that cover about 96 percent of the donors who donated organs to multi-organ candidates. The MOT Committee continues to work on these algorithms and other policy questions, like incorporating eligibility criteria for multi-organ offers. There are currently eligibility criteria in policy for liver-kidney, heart-kidney, lung-kidney, so there is a need to determine how those existing policies get folded into this framework. The MOT Committee will meet on October 30 in person to continue these discussions and finalize a lot of policy questions for the January 2025 update.

Summary of Discussion:

A Committee member asked if one allocation list will be generated here that directs the OPOs regarding allocation, and OPTN Contractor staff noted that this is still being determined, though user interviews have been conducted. These interviews have yielded feedback from OPOs users are frequently confused regarding the required order of allocation and currently having to develop these allocation plans manually, which may involve in-house templates and require significant input from the administrator on call. The idea is to develop a standardized order provided by the OPTN Computer system that would direct OPOs how to work through this using the traditional match runs that they generate. It is thought that it will be easier to work through by sequence number rather than classification, as the classifications are not always clearly annotated on the match runs. For this reason, the MOT Committee opted for a more complex IT solution, which generates an allocation plan for the specific donor and relevant match runs. This allows the OPO users to integrate the allocation plan with the match page and

track progress against their allocation to plan. The goal is to standardize the process so OPOs are not left to make these decisions and centers have more transparency in understanding where their patients land in the allocation plan and will not argue with the OPO about offer order. The MOT Committee presented to the OPO Committee to get feedback on making this a functional plan, and it will continue to evolve based upon feedback.

A Committee member questioned how this would expand allocation time, noting an example of having to work through so many heart and lung offers that could pull a liver, that liver only allocation cannot be started for hours into the overall allocation process. This is meant to simplify the process overall, as there are smaller numbers to work through in these priority categories. The Multi-Organ Committee's Lung Work Group has been asked to identify thresholds that are higher than the current ones. The intent is to keep these priority offers somewhat limited in scope so that OPOs can get through them efficiently. The goal is not to slow things down. The MOT Committee has requested data to better understand, on average, how many candidates are falling into these classifications on the match run. This is expected to give the committee a better sense of what their intended plan will look like in practice.

A meeting participant noted that, even with a standardized list, the organ won't be allocated until they are in the operating room. If they get into the operating room, and the heart-liver team does not like the looks of the liver and decides not to use it, that becomes a problem. Now there is reallocation and post-crossclamp organ offers. This concept was noted as helping but will not completely solve the multi-organ allocation problem.

Upcoming Meetings

October 28, 2024
November 18, 2024

Attendance

- **Committee Members**
  - Jim Kim
  - Arpita Basu
  - Kristin Adams
  - Prince Anand
  - Toni Bowling
  - Leigh Ann Burgess
  - Jesse Cox
  - Patrick Gee
  - Tania Houle
  - Christine Hwang
  - John Lunz
  - Marc Melcher
  - Jason Rolls
  - Reza Saidi
  - Eloise Salmon
  - Chandrasekar Santhankrishnan
  - Curtis Warfield
- **HRSA Representatives**
  - James Bowman
- **SRTR Staff**
  - Bryn Thompson
  - Jonathan Miller
  - Grace Lyden
  - Peter Stock
- **UNOS Staff**
  - Kayla Temple
  - Shandie Covington
  - Kaitlin Swanner
  - Sarah Booker
  - Houlder Hudgins
  - Meng Li
  - Keighly Bradbrook
  - Ross Walton
  - James Alcorn
  - Lauren Motley
  - Thomas Dolan