OPTN

Briefing to the OPTN Board of Directors on

Continuous Distribution of Organs

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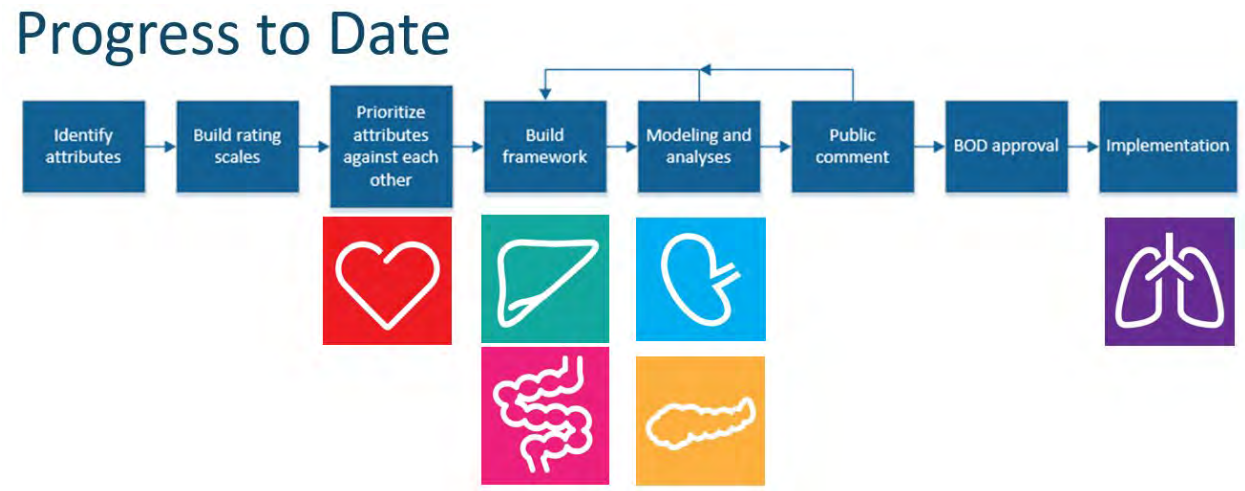
OPTN

Continuous Distribution of Organs

Board of Directors Date: December 4, 2023

Executive Summary

The OPTN is transitioning all organs to a new allocation framework entitled "continuous distribution." We have results from six months of the lung continuous distribution model while the other organs develop their models for future public comment and Board consideration. Consistent with the Expeditious task force, the committees are exploring new methods to incorporate and measure efficiency in the allocation system.



Kidney and Pancreas

In July 2023, the Kidney and Pancreas Committees received their second OASIM request results. The Committees reviewed the results and determined that the optimized policy scenarios successfully met many of their modeling objectives. However, some areas will require further evaluation, committee discussion, and collaboration with MIT to optimize further.

The Kidney Committee is optimizing policy scenarios to enhance access for high CPRA candidates (CPRA 99.9+ percent) while equalizing access across all CPRA groups. Additionally, the Committee is also investigating options to maintain high access for pediatric candidates while minimizing travel distance, as the SRTR modeling showed a significant increase in distance for these candidates.

The Pancreas Committee is discussing the inclusion of a medical urgency attribute and weight assignment for this attribute. Additionally, the Pancreas Committee is reevaluating the organ registration attribute weight to demonstrate an appropriate distribution between whole organs and islets and donor age/body mass index (BMI). The Committee will use candidate comparisons to determine weight assignments for these attributes.

For the August –September 2023 public comment period, the Committees released a *Committee Update* detailing their discussions leading into the second round of SRTR modeling.[1] Additionally, the Committees released an *Efficiency and Utilization in Kidney and Pancreas Continuous Distribution Request for Feedback,* which included a summary of discussions and specific feedback questions on the following operational topics:[2]

- Released Kidneys and Pancreata Allocation
- National Kidney Offers and Kidney Minimum Acceptance Criteria Screening
- Dual Kidney and En Bloc Kidney Allocation
- Facilitated Pancreas Allocation
- Mandatory Kidney-Pancreas Offers
- Considerations in Pancreas Medical Urgency

Summer 2023 Public Comment

The Committees released an update and Request for Feedback on kidney and pancreas continuous distribution. They focused on the multiple operational issues that necessitate changes when the kidney and pancreas systems transition to continuous distribution. Public comment feedback included general support for overall kidney and pancreas continuous distribution efforts and support for many of the potential operational solutions recommended by the Kidney and Pancreas Committees throughout the Request for Feedback.

Overall allocation efficiency was a key theme throughout public comment and regional meetings, with discussion emphasizing the importance of ensuring allocation and transportation efficiency, particularly

[1] SRTR modeling available at: https://optn.transplant.hrsa.gov/media/o52pegrg/kipacd_2023_01_analysisreport_2023_07_17.pdf.
[2] Summer 2023 Request for Feedback available at: https://optn.transplant.hrsa.gov/media/445objk1/kipa_cd-rff_pcsummer2023.pdf.

for "hard-to-place" kidneys. Many commenters supported an increased focus on improving system efficiency, addressing non-use, and incorporating such considerations into the continuous distribution framework. Commenters recommended further investigation and understanding of what is driving recent increases in non-use and out-of-sequence allocation (AOOS) of kidneys. Some commenters encouraged further understanding of changes to efficiency and utilization after the implementation of lung continuous distribution and circles-based kidney allocation, particularly incorporating lessons learned into a continuous distribution framework of kidney and pancreas allocation. Commenters also recommended focusing efficiency efforts on the following areas:

- Improving dynamics and communication between OPOs and programs
- Revisit and expand the KDPI calculation
- Increasing use of virtual crossmatch methods
- Establishing more dynamic, mandatory offer filters
- Investigating the measurability and limitations of the capacity of organ transportation systems

Feedback regarding released organ allocation was broadly supportive of the recommended framework, particularly for increased priority on proximity efficiency and for the "carry over refusals" functionality. Some commenters, including NATCO, recommended incorporating some form of transplant program backup, particularly for kidneys released with high cold ischemic times.

Similarly, feedback regarding the Kidney Minimum Acceptance Criteria Screening Tool (KiMAC) supported the framework recommended by the Kidney Committee. There were recommendations to simplify and condense available screening tools into one tool for program-specific filters and one for candidate-specific filters. Many commenters also supported further efforts to define "hard-to-place" kidneys clearly, particularly as the recommended KiMAC framework targets screening for "hard-to-place" kidneys. Commenters supported removing the requirement for OPOs to contact the OPTN Organ Center for assistance in allocating kidneys to candidates more than 250 nautical miles from the donor hospital.

Public comment feedback regarding dual kidney allocation emphasized the need to improve allocation for "hard-to-place" kidneys, including alternative allocation pathways for single kidney allocation. There was mixed support for using a separate match run to allocate dual kidneys, with those in support noting the need for mandatory offer filters and a "carry over refusal" functionality to ensure practical allocation efficiency. Others recommended allocating dual kidneys from the single kidney match run such that programs consider each offer for both single and dual kidney transplants, with the ability to decline and indicate interest separately. There was general support for OPO discretion and determining dual kidney eligibility based on donor- and organ-specific criteria. The American Society of Nephrology (ASN) did not support OPO discretion. Multiple commenters remarked that the highest KDPI kidneys could be allocated as dual immediately, at the OPO's discretion.

Several commenters also addressed the results of the second SRTR modeling request and the Committee Update, which summarized discussions leading to that request. Commenters supported increased pediatric transplant rates modeled by the SRTR but noted concern for significantly elevated pediatric travel distances. These commenters also noted concern for limitations of SRTR modeling, particularly in understanding the logistical impact of continuous distribution. Commenters expressed support for prior living donor, highly sensitized, and pediatric candidate priority weights, as well as

support for increased weight for proximity efficiency for high KDPI kidneys. Commenters noted the importance of ensuring that the continuous distribution framework does not widen disparities.

Ongoing Committee Efforts

Kidney and Pancreas Review Boards

Throughout the last year, the Kidney and Pancreas Committees have also collaborated with the OPTN Transplant Coordinator and Administrator Committees to build organ-specific review board frameworks. These review boards will align with the cross-organ framework developed in 2018. The Kidney and Pancreas Review Board Workgroup established a recommended framework throughout fall 2022 and spring 2023. The Kidney Committee reviewed and approved the finalized Kidney Review Board framework this fall.[3] The Pancreas Committee also reviewed and approved the finalized Pancreas Review Board framework this fall.[4]

Kidney Medical Urgency

In alignment with the incoming Kidney Review Board, the Kidney Medical Urgency Workgroup has been working to update the kidney medical urgency definition outlined in OPTN policy. The Kidney Medical Urgency Workgroup has reviewed data regarding the use of the current kidney medical urgency status and began to discuss which types of medical urgency scenarios may be appropriate for review by a Kidney Review Board to ensure the medical urgency status continues to be used appropriately.

Pancreas Medical Urgency

Currently, pancreas policy does not include medical urgency. The Pancreas Committee discussed and decided to include medical urgency as an attribute available as an exception. Including medical urgency in this capacity will provide a pathway for medically urgent candidates and information to help further define pancreas medical urgency or criteria based on cases presented to the Pancreas Review Board.

Public comment provided mixed sentiment for including pancreas medical urgency in the continuous distribution framework. For those opposed to including pancreas medical urgency, there was sentiment that this was irrelevant to pancreas candidates due to technological advancements (ex., continuous glucose monitoring (CGM)). For those in support of including pancreas medical urgency, there was agreement in allowing an exception pathway for pancreas candidates that may be deemed medically urgent. Additionally, there was agreement in including hypoglycemia unawareness to the criteria for pancreas medical urgency.

The Committee reviewed the public comment feedback and decided to include medical urgency as an attribute for pancreas allocation. The Committee is working to develop guidelines regarding pancreas medical urgency exception requests for the Pancreas Review Board and will determine which data should be collected to assess medical urgency further. As mentioned previously, the Committee will also need to determine the appropriate relative weight assigned to the Medical Urgency attribute.

Utilization Considerations of Kidney and Pancreas Continuous Distribution Workgroup

The Utilization Considerations of Kidney and Pancreas Continuous Distribution Workgroup, which developed many recommendations in the most recent *Request for Feedback,* continued to meet through summer 2023. The Utilization Considerations Workgroup's efforts focused on additional data collection

[3] OPTN Kidney Transplantation Committee Meeting Summary, August 21, 2023.
[4] OPTN Pancreas Transplantation Committee Meeting Summary, September 11, 2023.

and data modifications to streamline and automate the Kidney Minimum Acceptance Criteria tool for use in the continuous distribution of kidney allocation.

In September, the OPTN Board of Directors approved the creation of a task force dedicated to investigating and coordinating an effort to address efficiency and reducing non-use in the organ transplant system.[5] The Board also approved a resolution directing the Kidney and Pancreas Committee to ensure the continuous distribution proposal considers how the framework will impact:

- Decreased non-use and 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

This Board resolution also relieved the Kidney and Pancreas Committees of their prior commitment to submit a proposal for consideration to the OPTN Board at the June 2024 meeting.

In keeping with this Board resolution, the Committee began discussing how to address the goals mentioned above at their in-person meeting on October 11, 2023. The Committee utilized break-out groups to gather feedback, considerations, and ideas regarding general allocation efficiency, defining "hard-to-place" kidneys, expedited kidney placement pathways, shared decision-making, and communicating efficiency. Committee discussions highlighted the intersectionality of multiple factors, stakeholders, and pain points in the organ procurement, allocation, and transplant system. The Committee emphasized the need for a coordinated strategic effort to address these factors, as well as to define efficiency and establish achievable, direct objectives and goals.

The Committee discussions addressed a breadth of ideas and considerations related to non-use, with the consensus that alternate approaches to allocation for "hard-to-place" kidneys may be appropriate, as well as general system improvements to improve overall allocation efficiency. One system improvement discussed by the Committee was an expansion of offer filters, particularly to incorporate age matching, KDPI/EPTS matching, and more detailed, dynamic clinical attributes. The Committee also noted that expanded offer filters should include a more robust ability to target filtering for different candidate groups, allowing for varying filter thresholds. Regarding general efficiency, the Committee recognized the value of understanding different OPO practices and what factors may necessitate variation in OPO practices and behaviors. The Committee agreed that it is important to define "efficiency" clearly and that this definition should consider how to get an organ to the most appropriate candidate at the center that will accept and transplant that organ. The Committee agreed that it is critical to balance efficiency and equity appropriately.

The Committee highlighted the need to identify and clearly define "hard-to-place" organs, particularly in the context of a potential expedited placement policy. The Committee recognized that many characteristics in varying combinations may influence which kidneys may require expedited placement and that there may be instances where broader program and OPO autonomy may promote organ use. The Committee also recognized that specific policy requirements, such as biopsy requirements, may impact whether an organ becomes "hard-to-place." The Committee similarly recognized that limitations in transportation capabilities may impact whether an organ becomes "hard-to-place."

[5] OPTN Board of Directors Meeting Summary, September 5, 2023

In discussing expedited kidney placement pathways, the Committee agreed that keeping "hard-to-place" kidneys closer to the donor hospital may not be more efficient, particularly with variations in program acceptance practices and behaviors. One Committee member commented that the recovery and usage map (RUM) report is a helpful tool to balance equity and efficiency in expedited placement, allowing OPOs to determine which programs have historically accepted an organ based on the organ and donor characteristics while still offering to candidates at those programs based on the order of candidates and programs on the match. The Committee recommended efforts to establish best practices among OPOs to encourage equity and efficiency to be appropriately balanced during expedited allocation practices. The Committee also discussed the potential for a process to hold programs accountable for multiple or consistent late declines.

The Committee discussed the transportation system's capacity as a fundamental and infrastructural limitation. The Committee recognized that transportation capacity is limited and varies considerably based on geography and timing, but this impacts an organ offer's feasibility to lead to a transplant. The Committee highlighted the need for improved metrics to understand the logistical impacts of various allocation systems, as well as the impacts of transportation on allocation. The Committee remarked that this analysis may also need to consider costs and cost savings to OPOs, programs, CMS, and the healthcare system as a whole. In considering the infrastructure of the transplant system, the Committee also acknowledged that increased organ volumes result in increased stress on all resources, including recovery, surgeon and personnel, program, and transportation resources. The Committee also noted that certain aspects of transplant system infrastructure could be modified to improve outcomes, such as incentivizing organ pumps. Finally, the Committee reflected that the metrics and goals for OPOs and transplant programs are not aligned, contributing to inefficiency.

Finally, the Committee discussed how shared decision-making and patient voice can be incorporated to improve efficiency in the transplant system. The Committee agreed that shared decision-making requires ample and navigable patient education, allowing patients to learn at their own pace. Educational materials should also be culturally competent and available in multiple languages to ensure patient accessibility. The Committee discussed that shared decision-making could be leveraged in allocation, allowing patients to determine how they would prefer to balance the longevity of a potential transplant versus receiving a transplant (and thus getting off of dialysis) quickly, with consideration for what is clinically feasible, safe, and appropriate. The Committee also noted that shared decision-making should include the referring nephrologist and patient care teams. The Committee recommended that the OPTN Expeditious Task Force consider how patient education and shared decision-making can affect efficiency efforts.

Lung

Continuous distribution of lungs was implemented on March 9, 2023.[6] In the first six months following implementation, lung transplants increased by 11.2% (from 1387 to 1543), and removals from the waiting list due to death or too sick decreased by 26.1% (from 111 to 82) relative to the six months

[6] "Establish Continuous Distribution of Lungs," OPTN, Policy Notice, available https://optn.transplant.hrsa.gov/media/b13dlep2/policy-notice_lung_continuous-distribution.pdf.

preceding the policy change.[7] In the first six months following implementation, median waiting times were the shortest for the most medically urgent candidates. Specifically, the median time waiting for a transplant was six days for candidates with 2.5 or more medical urgency points at the time of listing. The median travel distance between the donor and transplant hospitals increased from 195 to 353 nautical miles, consistent with what was expected based on the simulation modeling completed during policy development.[8]

In the first three months following implementation, monitoring data showed that blood type O transplants decreased after implementation compared to the three months before.[9] In contrast, the simulation modeling estimated that blood type O transplants would increase under the continuous distribution policy.[10] It was determined that the simulation modeling did not incorporate incompatible blood type screening rules, thereby overestimating transplant volume for blood type O candidates. The OPTN released a proposal for a special public comment period in the summer of 2023 to improve access to transplant for blood type O candidates and to provide more proportional access to transplant for candidates of all blood types.[11] The proposal was strongly supported in public comment;[12] approved by the OPTN Board of Directors; and implemented on September 27, 2023.[13] While allocation changes have historically taken multiple years for policy development and implementation, the OPTN was able to develop and analyze solutions, get public comment feedback and Board approval, and implement this change in less than three months due in part to the inherently more agile design of the continuous distribution framework.

While the continuous distribution allocation system is achieving many of its stated goals, including reducing waiting list mortality and prioritizing transplants for the most medically urgent candidates, transplant programs and organ procurement organizations (OPOs) have reported challenges adjusting to redistributed organ offer patterns across the country and more complex allocation logistics. Based on these concerns, the OPTN Lung Transplantation Committee established the Lung Allocation Efficiency Workgroup, comprised of Lung and OPO Committees members, in June 2023[14] to review data on lung allocation and potential solutions to address inefficiencies. As a result, the committee is preparing a proposal for January 2024 public comment.

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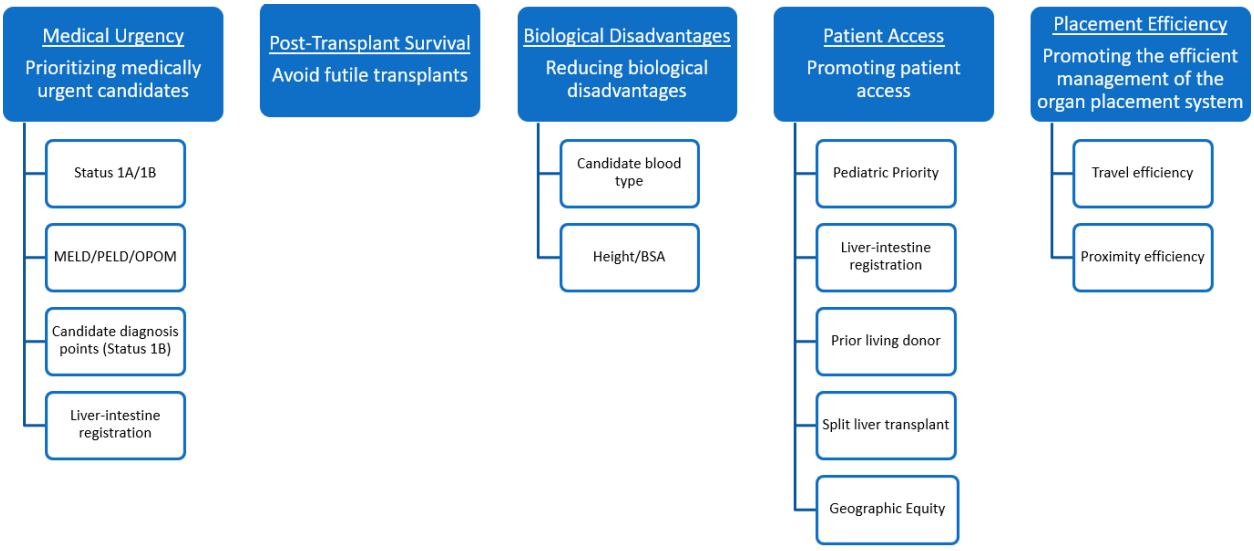
[7] "Lung Continuous Distribution Six Month Monitoring Report," OPTN, October 27, 2023, available https://optn.transplant.hrsa.gov/professionals/by-organ/heart-lung/lung-continuous-distribution-policy/.
[8] "Continuous distribution simulations for lung transplant: Round 2," SRTR, June 10, 2021, available https://optn.transplant.hrsa.gov/media/4646/lu2021_01_cont_distn_report_final.pdf.
[9] "Lung Continuous Distribution Three Month Monitoring Report," OPTN, July 13, 2023, https://optn.transplant.hrsa.gov/media/fzhh1e5r/data_report_lung_committee_cd_07_13_2023.pdf. The pre-policy era was December 7, 2022 – March 8, 2023, and the post-policy era was March 9, 2023 – June 8, 2023.
[10] Id.
[11] "Modify Lung Allocation by Blood Type," OPTN, Public Comment Proposal, available https://optn.transplant.hrsa.gov/media/5xjpasun/lung_blood-type_special-pc-summer-2023.pdf.
[12] "Modify Lung Allocation by Blood Type," OPTN, Briefing Paper, available https://optn.transplant.hrsa.gov/media/acjaszq0/lung_blood-type_bp_sep-2023.pdf.
[13] "Modify Lung Allocation by Blood Type," OPTN, Policy Notice, available https://optn.transplant.hrsa.gov/media/rrkeagop/policy-notice_lung-blood-type_sep-2023.pdf.
[14] OPTN Policy Oversight Committee Meeting Summary for June 12, 2023, available https://optn.transplant.hrsa.gov/media/kqgp2aus/20230612_poc-meeting-summary.pdf.

Liver and Intestine

The OPTN Liver & Intestinal Organ Transplantation Committee submitted a concept paper to the July – September 2023 public comment period, which provided an update on the progress to date regarding the development of liver continuous distribution.[15] The paper detailed the results of the values prioritization exercise, which was open for public participation during the January – March 2023 public comment period.[16] The committee is considering attributes outlined in **Figure 1**, and the concept paper provided an update on recent discussions related to medical urgency, post-transplant survival, and geographic equity. An update on the work towards the mathematical optimization dashboard was also detailed.

Figure 1: Liver CD Goals and Attributes



Public comment feedback agreed with the Committee's decision to analyze both medical urgency scores, Model for End-stage Liver Disease (MELD) and Optimized Prediction Of Mortality (OPOM) in the mathematical optimization analysis to understand the impact prior to deciding which medical urgency score to input into a liver composite allocation score (CAS). Additional feedback on medical urgency emphasized the importance of having medical urgency as a highly weighted attribute in the CAS as it would approximate the current system and align with the Final Rule. Public comment also recommended several special considerations regarding the medical urgency attribute and the pediatric populations. The Committee will continue to engage with pediatric specialists to ensure the liver continuous distribution system does not disadvantage pediatric candidates.

[15] OPTN Liver & Intestinal Organ Transplantation Committee, *Update on Continuous Distribution of Livers and Intestines, 2023,* Concept Paper. Public comment period: July 27, 2023 – September 19, 2023. Available at https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/update-on-continuous-distribution-of-livers-and-intestines-2023/.

[16] For more information on the liver values prioritization exercise, please reference https://optn.transplant.hrsa.gov/media/0g5l3qpa/05122023_vpe_researchreport_final.pdf.

Attributes

The Committee continues refining the attributes in **Figure 1** and determining how to assign points. This information is being incorporated into a mathematical optimization dashboard that the Committee will utilize to determine focus areas for improvement and facilitate decision making regarding rating scales and weights for each attribute.

Post Transplant Survival

Regarding post-transplant survival, most community feedback affirmed the Committee's decision not to incorporate a post-transplant survival attribute in the first iteration of liver continuous distribution. Some community members – notably from the patient community – continue to express the importance of including post-transplant outcomes in organ allocation. The Committee will continue to monitor whether a post-transplant survival model is developed and validated that could be incorporated into future versions of liver continuous distribution frameworks.

Geographic Equity

Additionally, public comment supported the inclusion of a geographic equity attribute but sought more information on how it would be incorporated into a CAS. Since the release of the summer 2023 concept paper, the Committee continued to discuss geographic equity. Historically, broader distribution has been a tool utilized to improve geographic equity. The committee discussed utilizing population density or supply/demand as potential attributes to improve geographic equity. Currently, the committee is focused on incorporating population density as an attribute to improve geographic equity.[17]

Utilization and Placement Efficiency

Further discussions since the concept paper's time include identifying a new attribute: utilization efficiency. This new attribute aligns with another emergent theme from public comment: improving efficiency in organ allocation. Public comment highlighted the importance of understanding lessons learned from lung continuous distribution, the impact of a future liver continuous distribution system on efficiency, addressing current issues with organ allocation and distribution, and prioritizing solutions for improving efficiency in the continuous distribution project.

The Committee has stated that the purpose of the utilization efficiency attribute is to increase efficiency in the organ placement system by making medically complex liver offers easier to place. The Committee defines medically complex livers as those from DCD donors or those from donors over the age of 70. This definition is similar to the current system; however, the Committee is also interested in incorporating other indicators, such as fat content. The information must be known at the time of a match run to be incorporated into a CAS, so the Committee acknowledges that including fat content in the definition of a medically complex liver offer may be part of a future version of continuous distribution.

As noted, the donor side of the utilization efficiency attribute has been defined, and the Committee is currently discussing the candidate side (i.e., how to assign points to candidates to make medically

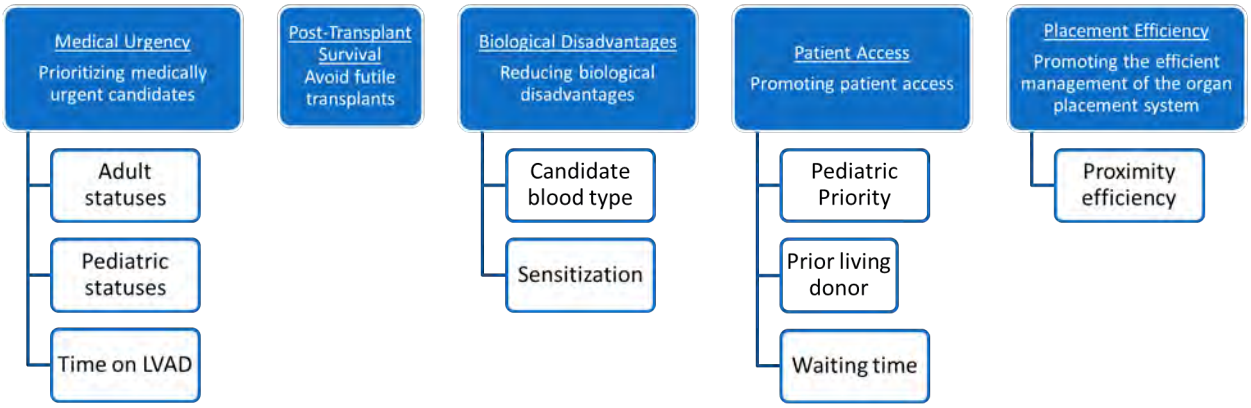
[17] OPTN Liver & Intestinal Organ Transplantation Committee Meeting Summary for October 6, 2023.

complex livers easier to place). Several options are under consideration, and an approach to applying a utilization efficiency attribute across organ types is a priority.

Heart

During the July – September 2023 public comment period, the OPTN Heart Transplantation Committee submitted a concept paper describing the Committee's activities in developing an initial continuous distribution of hearts allocation framework. **Figure 2** reflects the attributes the Committee discussed in the concept paper. The concept paper also provided information about the Committee's discussions and initial activities identifying the types of rating scales envisioned for some of the attributes.

Figure 2: Heart CD Goals and Attributes



The Committee reviewed the general themes and specific feedback received during public comment and considered the information during their ongoing deliberations on attributes and potential rating scales. A primary theme emerging from community input involved considering how the transition to a continuous distribution of heart allocation framework will impact pediatric candidates. Such comments were associated with almost all identified attributes but focused on the medical urgency attribute. For instance, the comments provided by the Transplant Coordinators Committee (TCC) addressed how realigning medical statuses on a continuous rating scale might impact pediatric candidates. Part of the comment recommended including growth parameters for pediatric candidates within the medical urgency attribute. TCC members also commented that the proposal appears to realign pediatric statuses to be more like the adult statuses but cautioned that pediatric candidates with durable ventricular assist devices (VADs) are at a much higher advantage than other pediatric candidates with VADs who are not dischargeable. Other comments addressing pediatric candidates and the medical urgency attribute questioned whether pediatric wait time for durable VAD is as relevant. A comment supporting the Committee's planned transition to continuous distribution stated that the pediatric heart transplantation urgency strata are too broad, specifically status 1A, and that continuous distribution

should allow for enhanced prioritization for allocation on features associated with a high risk of waitlist mortality, rather than time accrued at urgency status.

The Heart Transplantation Committee also discussed the potential for creating attributes not included in the current heart allocation policy. During several meetings, the Committee has spent time discussing the advantages and disadvantages of trying to include a post-transplant survival attribute at this stage of their work. The members agree that the lack of a fully researched and accepted post-transplant survival model by the community is a significant hurdle to including something at this stage. Nonetheless, the Committee also appreciates that this topic is important to members of the transplant community and agrees to revisit the topic so that they consider whether circumstances have changed in ways that make inclusion more acceptable.

The Committee also began discussions about potential efficiency-related attributes, in addition to the proximity efficiency attribute they previously identified to include in this version of CD of hearts. The members acknowledged that there might be opportunities to improve the allocation efficiency of donor hearts beyond the distance between donor and recipient hospitals. For example, the members indicated that the development and implementation of offer filters might improve allocation efficiency by permitting a transplant program to identify specific donor characteristics that the program will always or never accept. Such filters might improve organ allocation by including fewer candidates on a match run while at the same time increasing the likelihood that an offer will be accepted earlier in the match run.

As part of the January – March 2024 public comment cycle, the Committee intends to submit a request for feedback document. The Committee is also preparing to release its first public prioritization exercise during the same public comment cycle. Like the prioritization exercises performed by other OPTN committees developing continuous distribution allocation frameworks, the Heart Committee will employ the Analytic Hierarchy Process (AHP). The AHP methodology elicits community feedback to help inform the development of the continuous distribution of hearts allocation framework. As part of AHP, a participant is asked to compare two "patient profiles" against each other and select the level of importance the participant believes appropriate when considering a typical heart candidate for transplant. Along with other information, the Committee will use the AHP results to help guide their deliberations about the attribute weights and the overall score.

The Committee members also expect to work with the Massachusetts Institute of Technology (MIT) to optimize the priority associated with each attribute. MIT has worked with the other OPTN committees developing continuous distribution allocation frameworks to perform a mathematical optimization that iterates through a vast number of alternative prioritization approaches based on the desired outcomes identified by the community.

The Heart Transplantation Committee will continue to engage the community in developing the continuous distribution allocation framework, and will inform the community of the project's progress and incorporate feedback as appropriate.