

Committee Update

Continuous Distribution of Hearts Update, Summer 2024

OPTN Heart Transplantation Committee

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Continuous Distribution of Hearts Update, Summer 2024

Sponsoring Committee: Heart Transplantation
Public Comment Period: July 31 – September 24, 2024

Executive Summary

This Committee update is the third in a series of reports prepared by the Organ Procurement and Transplantation Network (OPTN) Heart Transplantation Committee (Committee) describing the development of a continuous allocation framework for donor hearts.^{1,2} The update shares the results of the values prioritization exercise (VPE) which was available to the OPTN community from January 23 through March 19, 2024.³ Participants in the VPE were asked to decide, if all else is considered equal, which of two attributes is more important than the other when prioritizing a candidate for an organ.⁴ The update also describes the Committee's continued efforts developing attributes and rating scales. Additionally, the update seeks community feedback about both the VPE results and the attributes the Committee continues developing. Finally, the update outlines the expected next steps.

¹ *Concept Paper: Continuous Distribution of Hearts*, OPTN Heart Transplantation Committee, Public Comment: July 27 – September 19, 2023, https://optn.transplant.hrsa.gov/media/ta4ilmpp/heart_cd-of-hearts-conceptpaper_pcsummer2023.pdf (Accessed June 20, 2024). *Request for Feedback: Update on Continuous Distribution of Hearts*, OPTN Heart Transplantation Committee, Public Comment: January 23 – March 19, 2024,

https://optn.transplant.hrsa.gov/media/om4dqvbz/heart_cd_request-for-feedback_jan24pc.pdf (Accessed June 20, 2024).

² The OPTN Heart Transplantation Committee and the OPTN Lung Transplantation Committee were created on July 1, 2020, following the dissolution of the OPTN Thoracic Organ Committee.

³ "Community feedback needed on development of policy for continuous distribution of hearts," <https://optn.transplant.hrsa.gov/news/community-feedback-needed-on-development-of-policy-for-continuous-distribution-of-hearts/> (Accessed June 20, 2024).

⁴ "Continuous distribution – heart: 2. Build framework – in process," OPTN website: <https://optn.transplant.hrsa.gov/policies-bylaws/a-closer-look/continuous-distribution/continuous-distribution-heart/> (Accessed June 20, 2024).

Background

In 2018, the OPTN Board of Directors sought creation of an allocation system that could be consistently implemented across all organs. The OPTN Board of Directors determined a points-based continuous distribution framework would replace the current classification-based allocation systems.⁵ Developing and implementing a continuous distribution of hearts allocation framework aims to eliminate the hard boundaries between classifications in the current heart allocation system. Ultimately, transitioning to continuous distribution is expected to result in more equity for candidates on the waitlist while increasing transparency in the allocation of hearts. In addition, continuous distribution has more potential for flexibility in changing allocation through efficient policy development and implementation.

In August 2022, the Committee began converting the classification-based heart allocation system into a points-based continuous distribution allocation framework. The classification allocation system groups candidates into classifications based on medical urgency, whether they are adult or pediatric, blood type, and distance between donor and patient hospitals. Waiting time is then used to rank candidates within each classification. Continuous distribution implements a composite allocation score to prioritize candidates, simultaneously considering candidate and donor attributes. This points-based allocation system will create a more equitable and transparent allocation system. (See **Appendix A** for a glossary of terms.)

The Committee's efforts follow several other organ-specific OPTN committees who have implemented or are developing continuous distribution allocation frameworks. For example, in March 2023, the continuous distribution of lungs allocation framework was implemented.⁶ The OPTN Kidney Transplantation and the OPTN Pancreas Transplantation Committees have been collaborating to convert the kidney and pancreas allocation systems to continuous distribution.⁷ In December 2021, the OPTN Liver and Intestinal Organ Transplantation Committee launched a similar effort.⁸ The goal is to transition all organs to a continuous distribution allocation system. (See **Appendix B** for additional continuous distribution resources.)

Project Plan

The Committee is tasked with developing a comprehensive proposal for the continuous distribution of hearts. Considering the changes to the mechanism by which candidates are prioritized and the capability of modifying the system quickly, the effort represents a significant change in the allocation of donor hearts. Developing a continuous distribution of hearts allocation framework will progress through several phases, which are identified in **Figure 1**. The Committee has completed collecting public priorities. They are now preparing to collaborate with other groups in order to optimize the allocation score and perform modeling.

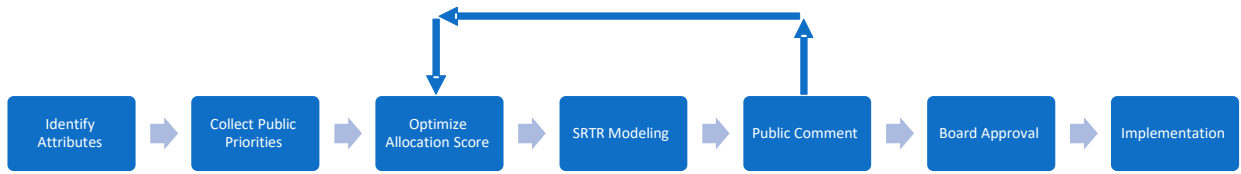
⁵ Executive Summary of the OPTN Board of Directors Meeting, December 3-4, 2018 meeting, https://optn.transplant.hrsa.gov/media/2787/board_executivesummary_201812.pdf (Accessed May 9, 2023).

⁶ *Briefing Paper: Establish Continuous Distribution of Lungs*, OPTN Lung Transplantation Committee, December 6, 2021, <https://optn.transplant.hrsa.gov/media/esjb4ztn/20211206-bp-lung-establish-cont-dist-lungs.pdf> (Accessed May 25, 2023).

⁷ OPTN website, <https://optn.transplant.hrsa.gov/policies-bylaws/a-closer-look/continuous-distribution/continuous-distribution-kidney-and-pancreas/> (Accessed November 5, 2023).

⁸ OPTN website, <https://optn.transplant.hrsa.gov/policies-bylaws/a-closer-look/continuous-distribution/continuous-distribution-liver-and-intestine/> (Accessed November 5, 2023).

Figure 1: Developing a Continuous Distribution of Hearts Allocation Framework



The Committee’s previous updates detailed the attributes and rating scales being considered.⁹ For this public comment cycle, the Committee wanted to share the results of the VPE completed by the community during the January – March, 2024 public comment cycle. The results will help guide the Committee in the optimization of the system.

For this update, the Committee is interested in obtaining community feedback about the weights suggested by the values prioritization exercise. They also want to share with the community information about some of the attributes.

Progress to Date

Table 1 identifies the list of attributes chosen by the Committee for inclusion in the initial continuous distribution of heart allocation framework.

Table 1: OPTN Heart Transplantation Committee Identified Attributes

	Medical Urgency	Reducing Biological Disadvantages	Patient Access	Placement Efficiency	Post-Transplant Survival
Attributes	<ul style="list-style-type: none"> Adult statuses Pediatric statuses Waiting time on Left Ventricular Assist Device 	<ul style="list-style-type: none"> Blood type Sensitization 	<ul style="list-style-type: none"> Priority for pediatric candidates Priority for prior living donors Waiting time 	<ul style="list-style-type: none"> Distance between transplant and donor hospital 	

⁹ *Concept Paper: Continuous Distribution of Hearts*, OPTN Heart Transplantation Committee, Public Comment: July 27 – September 19, 2023, https://optn.transplant.hrsa.gov/media/ta4ilmpj/heart_cd-of-hearts-conceptpaper_psummer2023.pdf (Accessed June 20, 2024). *Request for Feedback: Update on Continuous Distribution of Hearts*, OPTN Heart Transplantation Committee, Public Comment: January 23 – March 19, 2024, https://optn.transplant.hrsa.gov/media/om4dqvbz/heart_cd_request-for-feedback_jan24pc.pdf (Accessed June 20, 2024).

Values Prioritization Exercise Participation, Results, and Next Steps

The values prioritization exercise is an opportunity to obtain feedback from patients and recipients, donors and their families, and transplant professionals about prioritizing the components of heart allocation. Medical urgency and priority for pediatric candidates were prioritized as most important. The Committee will use the VPE results when considering the most appropriate attribute weightings for continuous distribution of hearts.

VPE Participation

The values prioritization exercise asks participants to compare two attributes against each other and indicate the level of importance when considering a candidate for organ transplant. The exercise uses analytical hierarchy process (AHP) methodology to aid in values-based decision making.¹⁰ As part of the AHP methodology, participants are asked a series of questions to compare the relative importance of a set of criteria through multiple pairwise comparisons. The results of the comparisons are used as an additional input to inform the weight of each attribute. Ultimately, the Committee is responsible for determining the attribute weights to include in a policy proposal. Each organ-specific OPTN committee developing a continuous distribution framework employed a values prioritization exercise to gather public input regarding the weighting of their identified attributes.

The heart values prioritization exercise was open to the public on the OPTN website from January 23 to March 19, 2024. Prior to and during that time, the public was strongly encouraged to participate. Instructions for accessing the exercise were shared at each regional meeting and with OPTN committees. Outreach to stakeholder groups was performed and OPTN members were sent two emails asking them to participate.¹¹

While the Committee is utilizing more traditional analytical methods to build rating scales (refer to the Committee's first and second updates), weighing attributes against each other is values laden rather than a clinical or operational question. For example, finding the proper balance between equity and utility is a frequent discussion amongst the OPTN committees when developing organ allocation policies and cannot be solved with traditional analytical methods or clinical input. The VPE employed by the Committee was a structured way to identify the community's priorities in the new allocation

¹⁰ See generally, Lin, Carol S, and Shannon L Harris, "A Unified Framework for the Prioritization of Organ Transplant Patients: Analytic Hierarchy Process, Sensitivity and Multifactor Robustness Study," *Journal of Multi-Criteria Decision Analysis* 20, no. 3–4 (2013): 157–72, <https://doi-org.proxy.library.vcu.edu/10.1002/mcda.1480> (Accessed June 25, 2024).

¹¹ OPTN Communications, email to OPTN members, February 6, 2024. UNOS Communications, email to OPTN members, February 9, 2024.

framework.^{12,13} A similar approach was utilized by the OPTN Lung, Kidney, Pancreas, and Liver and Intestinal Organ Transplantation committees.¹⁴

Figure 2 shows a sample pairwise comparison between two attributes used as part of the Committee’s values prioritization exercise.¹⁵ In light of community feedback regarding a post-transplant survival attribute, the Committee included it for consideration with the VPE although it is not expected to be included in the first iteration of continuous distribution of heart.

Figure 2: Sample Pairwise Comparison

* If all else is equal, which of these candidates should be prioritized for heart transplantation?

- A highly medically urgent candidate
- A pediatric candidate

Definitions

A highly medically urgent candidate
A candidate who is in urgent need of a heart transplant and is not expected to survive for a significant amount of time without a transplant.

In current heart allocation policy, medical urgency is by statuses for adult and pediatric candidates. The Committee will consider alternative options for incorporating medical urgency in continuous distribution.

A pediatric candidate
A candidate aged less than 18 at time of being added to the waiting list. Heart allocation policy prioritizes pediatric candidates to address the unique needs of children. This includes recognizing the negative impact on childhood development that organ failure can have; as well as ethical principles such as the "fair innings" concept (children have yet to experience a full life); and the high value society places on children in general.

Assume this comparison is for the hearts that are prioritized for children. Currently, donors under age 18 years old are prioritized for children.

¹² See generally Mark, Tami L, and Joffre Swait, "Using Stated Preference and Revealed Preference Modeling to Evaluate Prescribing Decisions," *Health Economics* 13, no. 6 (2004): 563-73, <https://doi-org.proxy.library.vcu.edu/10.1002/hec.845> (Accessed June 25, 2024).

¹³ See generally Lin and Harris, "A Unified Framework for the Prioritization of Organ Transplant Patients," *Journal of Multi-Criteria Decision Analysis* 20, no. 3-4 (2013): 157-72, <https://doi-org.proxy.library.vcu.edu/10.1002/mcda.1480> (Accessed June 25, 2024).

¹⁴ *Continuous Distribution of Lungs: Summer 2020 Prioritization Exercise – Community Results*, OPTN Lung Transplantation Committee, October 15, 2020, https://optn.transplant.hrsa.gov/media/4157/2020-10_report_community_ahp_prioritization.pdf (Accessed November 12, 2023). *Continuous Distribution of Kidneys: Winter 2022 Prioritization Exercise – Community Results*, OPTN Kidney Transplantation Committee, April 6, 2022, https://optn.transplant.hrsa.gov/media/fodia1ag/2022-kidney-report-on-public-ahp-prioritization_508-compliant.pdf (Accessed November 1, 2023). *Continuous Distribution of Pancreata: Winter 2022 Prioritization Exercise – Community Results*, OPTN Pancreas Transplantation Committee, April 7, 2022, https://optn.transplant.hrsa.gov/media/grxnpv4n/2022-pancreas-report-on-public-ahp-prioritization_508-compliant.pdf (Accessed November 12, 2023). *Continuous Distribution of Livers: Winter 2023 Values Prioritization Exercise – Community Results*, OPTN Liver & Intestinal Organ Transplantation Committee, January 2023, https://optn.transplant.hrsa.gov/media/0g5l3qpa/05122023_vpe_researchreport_final.pdf (Accessed November 12, 2023).

¹⁵ "Continuous distribution," Organ Procurement & Transplantation Network, https://optn.transplant.hrsa.gov/policies-bylaws/a-closer-look/continuous-distribution/#CD_BuildTheFramework (Accessed November 12, 2023).

Results of the Values Prioritization Exercise

Participation in the VPE totaled 702 responses. **Figure 3** indicates participation categorized by stakeholder type.

Figure 3: Heart VPE Participation by Stakeholder Type

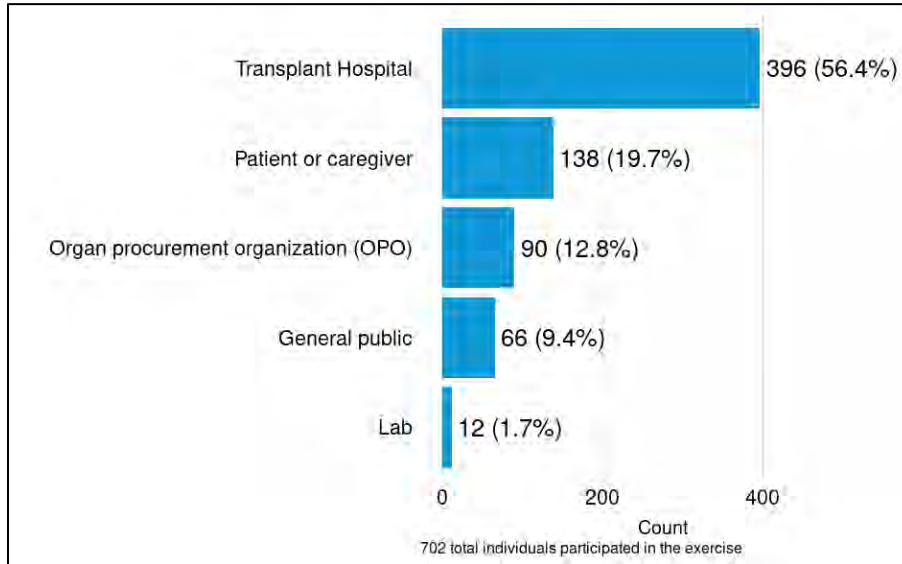
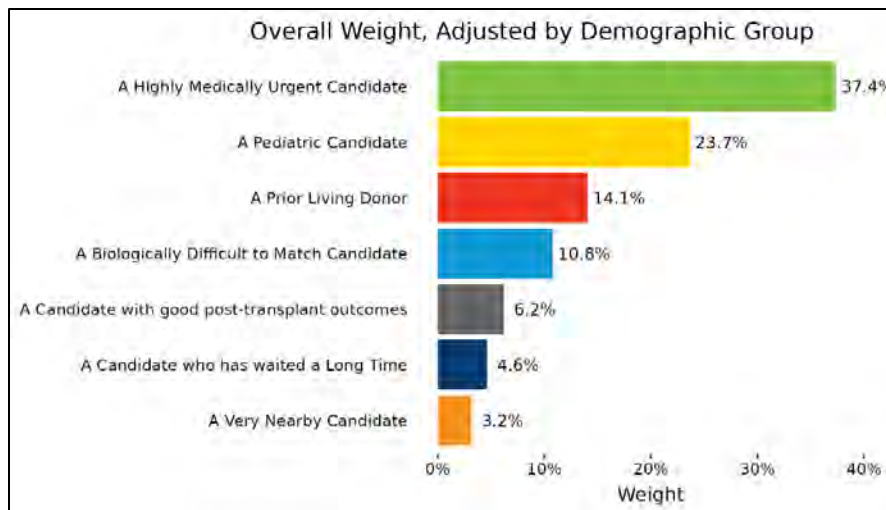


Figure 4 identifies each attribute included in the VPE and the overall relative weights based on the feedback received, and adjusted for the proportion of respondent types. The medical urgency attribute received the greatest weighting (37.4%) followed by priority for a pediatric candidate (23.7%). Both outcomes were largely expected by the Committee. While the community’s weighting of priority for a prior living donor (14.1%), was somewhat greater than expected, the Committee members stated that it made more sense considering the high volume of responses submitted by individuals identifying themselves as patient or caregiver. The members reasoned that patients and caregivers were likely to believe that donating an organ should be encouraged and receive additional priority as a result.

Figure 4: Overall Weights of Heart Attributes in VPE, Adjusted for Stakeholder Type



Prior to the exercise being made available to the public, the Committee members expected that the community’s weighting of a candidate with good transplant outcomes and a candidate who has waited a long time would place the factors somewhere in the middle of the weightings, if not higher. The low weight assigned to post-transplant outcomes was somewhat surprising; however, the Committee also indicated it aligned with the feedback received during the January to March 2024 public comment cycle. The comments submitted to the OPTN website and made during regional meetings mostly concurred with the Committee’s position that the first iteration of CD of hearts may not be the appropriate time to develop such an attribute.¹⁶ Committee members also indicated that the community’s weighting of the very nearby candidate factor, a proxy for proximity efficiency, appeared low given the importance associated with improving the efficiency of organ allocation overall. The members also suggested that the proximity efficiency attribute may need to have a somewhat higher weighting if it is to improve efficiency.

Table 2 identifies the overall rating preferences categorized by the participation group. As the ratings demonstrate, there is mostly agreement across the groups in how the factors should be prioritized. For instance, all the groups ranked the factors in the same order. This has not always been the case when other OPTN committees used the VPE. Results of the Liver and Intestinal Organ Committee’s VPE found differences in how the patient and caregiver group prioritized their factors compared to the transplant hospital professional group.¹⁷ The relatively similar percentages shown in Table 2 also indicates the participant groups largely agreed with how much more or less priority should be given to each factor.

Table 2: Ratings by Participation Group

Factor	Patient or Caregiver (N=138)	General Public (N=66)	Transplant Hospital Professional (N=396)	OPO Professional (N=90)	Laboratory Professional (N=12)
A highly medically urgent candidate	37.5%	36.5%	37.2%	37.9%	37.8%
A pediatric candidate	22.4%	24.5%	24.9%	24.5%	22.2%
A prior living donor	13.8%	14.9%	13.8%	14.2%	13.7%
A biologically difficult to match candidate	10.9%	10.1%	10.4%	10.8%	11.8%
A candidate with good post-transplant outcomes	6.7%	6.3%	6.2%	5.6%	6.4%
A candidate who has waited a long time	5.0%	4.8%	4.7%	4.3%	4.4%
A very nearby candidate	3.6%	3.0%	2.9%	2.8%	3.6%

¹⁶ See the comments associated with the *Update on Continuous Distribution of Hearts* webpage. Available at: <https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/update-on-continuous-distribution-of-hearts/#ProposalComments> (Accessed June 20, 2024).

¹⁷ *Committee Update: Update on Continuous Distribution of Livers and Intestines*, OPTN Liver and Intestinal Organ Transplantation Committee, July 2023, pp. 14-16, https://optn.transplant.hrsa.gov/media/enuh5qmk/liver_cd_update_incorporatehrsacomments_pcsummer2023.pdf (Accessed on June 21, 2024).

Given the relatively low priority given to the “very nearby candidate,” the Committee is interested in additional public feedback concerning the proximity efficiency attribute and rating scale, especially from OPO and transplant hospital professionals. In developing the rating scale, the Committee focused on disincentivizing organs traveling great distances. There was some level of expectation that the public would prioritize the attribute more highly. Therefore, the Committee wants to better understand the public’s reasoning. Especially given that donor lungs are traveling farther, and more transplant programs are receiving donor lung offers in the first 12 months following the implementation of continuous distribution of lungs in March 2023 than in the 12 months prior to implementation.¹⁸

The Committee will continue referencing the quantitative and qualitative VPE results when weighting each attribute for consideration as part of the mathematical optimization and for future modeling activities.

Next Steps

The VPE results were shared with the Committee in May and June, 2024. The results were also adjusted for respondent type and stratified by different demographic categories. In addition to the weighting, participants were encouraged to leave comments explaining their decision-making as such details are helpful to the Committee’s deliberations. The Committee is and will continue considering the results in conjunction with other information to determine the weight of each attribute and the overall composite allocation score.

Along with the VPE results, the Committee will use additional information and tools and consult with other subject matter experts, including Massachusetts Institute of Technology (MIT) for mathematical optimization and the Scientific Registry of Transplant Recipients (SRTR) for policy simulation. These collaborations will help refine the weighting of the attributes for an appropriate balance reflecting community and Committee prioritization.

Performing a mathematical optimization analysis of potential approaches to weighting the attributes is an important next step in the Committee’s efforts. Mathematical optimization analysis applies artificial intelligence and machine learning to traditional policy simulations to allow for optimization of specific outcomes. Optimization analyses can be completed fairly quickly, allowing for a more iterative and flexible approach to policy development. The results assist the Committee understand the tradeoffs between different attributes to help select the optimal combination of rating scales and weights.^{19,20,21} For example, the OPTN Lung Transplantation Committee used the optimization analysis to choose a relative weight of 20 percent for pediatric priority, as the analysis showed that setting the weight for this attribute at 20 percent would likely achieve the desired transplant rate for the pediatric population and any increase in the weight above 20 percent was unlikely to have much impact on pediatric access to

¹⁸ *Lung Continuous Distribution One Year Monitoring Report*, OPTN Lung Transplantation Committee, May 9, 2024, pp. 54 and 61, https://optn.transplant.hrsa.gov/media/enuh5qmk/liver_cd_update_incorporatehrsacomment_psummer2023.pdf (Accessed on June 21, 2024).

¹⁹ T. Papalexopoulos et al., “Reshaping National Organ Allocation Policy,” *Operations Research*, Published Online November 20, 2023, 0(0). <https://doi.org/10.1287/opre.2022.0035>.

²⁰ T. Papalexopoulos et al., “Applying Analytics to Design Lung Transplant Allocation Policy.” *INFORMS Journal on Applied Analytics*, 53, no. 5 (2023): 350–58. <https://doi.org/10.1287/inte.2023.0036>.

²¹ M. Mankowski et al., “Designing Continuous Distribution for Liver Allocation [abstract],” *Am J Transplant*, 2022; 22 (suppl 3), <https://atcmeetingabstracts.com/abstract/designing-continuous-distribution-for-heart-allocation/> (Accessed July 5, 2022.)

transplant.²² The Committee will share the optimized attribute weights and ratings scales with the Scientific Registry of Transplant Recipients (SRTR) for modeling to determine the impact on candidates.²³

Ongoing Attribute Discussions

In addition to VPE, the Committee also continues reviewing their previous decisions concerning attributes and rating scales based on additional public feedback and other new information. Following the January – March, 2024 public comment cycle, the Committee revisited the following attributes:

- Medical urgency
- Placement efficiency
- Post-transplant survival

Overview of Public Comment Feedback from January – March, 2024

A total of 75 comments were received in response to the Committee’s request for feedback document, what was available for public comment from January 23 through March 19, 2024.²⁴ The comments received represented all member types, with the greatest participation coming from individual respondents, those who submitted a comment under their own name rather than on behalf of a professional society, transplant program, OPO, etc. **Table 3** indicates the number of comments received by how the commenter described themselves. Individuals and anonymous commenters accounted for 43 comments received, or almost 58 percent of the total. (It is likely that most of the anonymously submitted comments represent the ideas of a single individual, some may not and; therefore, were not combined with the comments submitted by someone who provided their name.)

Table 3: Number and Percentage of Comments Received by Commenter Type, January 23 – March 19, 2024

Commenter Type (Self-identified)	# of Comments	% of Total Comments
Individuals	22	29.3%
Anonymous	21	28.0%
OPTN Regions	11	14.7%
Professional Societies	7	9.3%
OPTN Committees	6	8.0%
Industry / Business	3	4.0%
Organ Procurement Organizations	2	2.7%
Transplant programs	2	2.7%
Patient / Donor groups	1	1.3%
Total	75	100.0%

²² *Briefing Paper, Establish Continuous Distribution of Lungs*, OPTN Lung Transplantation Committee, Public Comment Period August 3, 2021 – September 30, 2021. <https://optn.transplant.hrsa.gov/media/esjb4ztn/20211206-bp-lung-establish-cont-dist-lungs.pdf>.

²³ “Continuous distribution – kidney and pancreas: 3. Modeling and analysis – in process,” Organ Procurement & Transplantation Network, <https://optn.transplant.hrsa.gov/policies-bylaws/a-closer-look/continuous-distribution/continuous-distribution-kidney-and-pancreas/>. (Accessed June 20, 2024).

²⁴ See the comments associated with the *Update on Continuous Distribution of Hearts* webpage. Available at: <https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/update-on-continuous-distribution-of-hearts/#ProposalComments> (Accessed June 20, 2024).

It is important to consider the demographics participating in public comment relevant to this proposal thereby ensuring the ultimate recommendation to the Board represents all stakeholders, even those whose volume of participation may be lower. The substance of each comment should be considered, with the volume of comments as a factor but not dispositive of the opinions represented.

Suggestions for Improving How Medical Urgency Is Determined

The last request for feedback document received a large number of comments about the current urgency statuses. Specifically, commenters were concerned that what they believe are deficiencies in the current allocation framework will be replicated in continuous distribution. For instance, several commenters recommended that the Committee consider realigning the urgency associated with Intra-Aortic Balloon Pumps (IABP) to status 3 or lower. Several others indicated that greater urgency should be provided to individuals with LVADs who are experiencing complications. Multiple comments targeted how the current allocation framework prioritizes pediatric candidates. The OPTN Pediatric Committee (Pediatric Committee) commented that smaller-size pediatric candidates who are ineligible for device support do not appear to be addressed as part of the continuous distribution framework. The Pediatric Committee also strongly recommended that the priority pediatric candidates receive for pediatric donor hearts in the current allocation framework be included in the continuous distribution allocation framework.

Others expressed concerns that current heart allocation policy relies too heavily on the type of device or therapy for determining medical urgency, and that this will continue in continuous distribution, at least initially. Such concerns are not new. During development of the allocation changes implemented in October 2018 concerns were raised about the potential for transplant programs to utilize “invasive procedures and mechanical support techniques” to increase candidates’ waiting list priority ahead of treating their clinical condition.^{25,26}

In response to the Committee’s January 2024 public comment document, commenters pointed out that the changes implemented in October 2018 may have led to an over-prioritization of temporary support devices. The American Society of Transplant Surgeons (ASTS), the American Society of Transplantation (AST), and others recommended adopting physiological variables to better stratify medical urgency. Several comments suggested the Committee consider approaches similar to the French Candidate Risk Score (CRS) and a proposed U.S. CRS. Both the French and proposed U.S. candidate risk scores rely on a mixture of clinical, laboratory, and hemodynamic variables to prioritize candidates. In terms of the reliance on device type, the proposed U.S. CRS only includes whether a candidate previously or is currently supported by a temporary mechanical device and whether a candidate is currently supported by a durable LVAD as part of the medical urgency score. This is different from current heart allocation policy which focuses mostly on the device type and/or type of support to determine medical urgency. The Committee received a presentation about the proposed U.S. CRS during their March 2024 in-person meeting. The members agreed to continue reviewing the advantages and disadvantages of the proposed U.S. CRS for consideration as part of a future iteration of continuous distribution of hearts, but it would be unlikely for the first iteration. The Committee concurred it would be better to continue pursuing the

²⁵ Davies, Ryan R, et al, “The New United States Heart Allocation Policy: Progress through Collaborative Revision,” *The Journal of Heart and Lung Transplantation* 36, no. 6 (2017): 595–96. <https://doi.org/10.1016/j.healun.2017.03.010> (Accessed June 21, 2024).

²⁶ *Modify Adult Heart Allocation 2016 Second Round*, OPTN Heart Transplantation Committee, December 2016, see public comments at: <https://optn.transplant.hrsa.gov/policies-by-laws/public-comment/modify-adult-heart-allocation-2016-2nd-round/#Comments> (Accessed June 25, 2024).

approach they have been working on for some time of transitioning the existing status and criteria to a continuous rating scale.

Commenters pointed to other evidence indicating over-reliance on heart devices. One commenter stated that the high volume of exception requests is an indicator that the device-based statuses and criteria are not accurately capturing medical urgency. Others suggested that the volume of exception requests reveals the inefficiencies resulting from the current device-heavy approach. For example, transplant programs must divert time and resources from patient care in order to prepare and submit exception requests. Exception requests may result in subjective application of policy to similar cases. The Committee discussed strategies for addressing the high volume of exception requests during their March 29, 2024 in-person meeting and are likely to pursue changes improving the transparency and accountability of such requests.²⁷

Concerns About Potential Unintended Consequences from Proposed Placement Efficiency Attribute

Comments supported the Committee's efforts to design the placement efficiency attribute in a way that limits the potential for donor organs 'crisscrossing' in the air while still permitting broader sharing. Nonetheless, several comments recommended that the Committee be wary of unintended consequences arising from including the proximity efficiency attribute. In particular, multiple comments cautioned that smaller transplant programs could be disadvantaged if the attribute provides too much benefit to programs that can afford the new organ care systems and therefore travel longer distances to procure donor hearts.^{28,29} A commenter stated that there "has to be priority given to a donor heart in close proximity to recipient (like < 250 NM). [N]ot sure the current proposal of having the same priority for up to 500 NM and then a linear decrease to 0 [priority] at 1500 NM makes sense." The Committee intends to continue discussing the most appropriate way to address placement efficiency, as well as use mathematical optimization to refine what the appropriate cut-off point should be for assigning priority.

Committee Agreement Not to Include a Post-Transplant Survival Attribute in the First Iteration of Heart CD

Since starting development of heart continuous distribution, the Committee has discussed on several occasions whether a post-transplant attribute should or can be included with the first iteration of a policy proposal. The Committee's initial concept paper specifically asked for community feedback on the matter.³⁰ The Committee's second update to the community asked if the attributes identified were

²⁷ Meeting Summary for March 29, 2024 meeting, OPTN Heart Transplantation Committee, https://optn.transplant.hrsa.gov/media/pfpcrcz4/20240329_heart_committee-meeting-summary.pdf (Accessed June 21, 2024).

²⁸ The introduction of organ transportation devices recently provides opportunities to greatly increase the distances organs can safely travel from donor to recipient. Such devices included, but not limited to: Paragonix LUNGguard system, Paragonix SherpaPak Cardiac Transport System, and the TransMedics Organ Care System.

²⁹ Pullen LC, New Organ Transport Technology is a Game Changer," *Am J Transplant*, 2022; 22:1285-1286. <https://doi.org/10.1111/ajt.16655>

³⁰ *Continuous Distribution of Hearts Concept Paper*, OPTN Heart Transplantation Committee, July 27, 2023, pp. 26-7, https://optn.transplant.hrsa.gov/media/ta4ilmpp/heart_cd-of-hearts-conceptpaper_psummer2023.pdf (Accessed June 21, 2024).

appropriate and whether any others should be considered.³¹ Multiple comments were submitted to the OPTN website about the topic during the January 24-March 19, 2024 public comment cycle. Several regional meeting speakers also addressed it. At least 20 comments submitted to the OPTN website during that period pertained to whether the Committee should address post-transplant survival as part of the first iteration of continuous distribution of hearts. Of those, 12 comments recommended not including it in the first version, while 6 comments recommended including it now. (Two other comments addressed post-transplant survival, but not whether to include it now or later.)

The American Society of Transplantation (AST) and the American Society of Transplant Surgeons (ASTS) took opposite views on the whether post-transplant survival should be addressed in the first iteration. AST stated that “post-transplant survival is an appropriate attribute to consider; however, it should not be included in the first version of heart continuous distribution.”³² AST’s response listed multiple reasons for its decision, including that post-transplant survival is variable based on patient co-morbidities, in-hospital status, the levels of transplant program expertise, and other reasons. On the other hand, ASTS recommended the Committee “should strongly reconsider inclusion of posttransplant survival in the Heart CD model as this is the most important metric for potential recipients and donor families.”³³

Most commenters agreed that the Committee should be working on developing a post-transplant survival attribute as soon as possible. For instance, respondents recommended the Committee should undertake these steps right away:

- Identify and collect data elements most appropriate to help optimize patient outcomes
- Consider different post-transplant survival metrics for different categories of recipients

When developing the values prioritization exercise, the Committee considered whether to include post-transplant survival as one of the factors even though there was agreement that it should not be included as an attribute in the first version of heart continuous distribution. Members discussed how post-transplant survival is perhaps the most important factor they consider for each of their candidates, and as a result, the community would likely prioritize it fairly high relative to the other VPE factors. Members were concerned that including it as a VPE factor when it is unlikely to be included in the first iteration of heart continuous distribution would skew the overall VPE results and make them less useful.

At the same time, the Committee was aware that the OPTN Liver and Intestinal Organ Transplantation Committee (Liver Committee) had not included a post-transplant survival attribute in its values prioritization exercise. Community feedback questioned the Liver Committee’s decision. With the Liver Committee’s experience in mind, the Committee decided to include a post-transplant survival attribute with the heart VPE despite their stated concerns.

³¹ *Request for Feedback: Update on Continuous Distribution of Hearts*, OPTN Heart Transplantation Committee, January 23, 2024, p. 30, https://optn.transplant.hrsa.gov/media/om4dqvbz/heart_cd_request-for-feedback_jan24pc.pdf (Accessed June 21, 2024).

³² See the comments associated with the *Update on Continuous Distribution of Hearts* webpage. Available at: <https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/update-on-continuous-distribution-of-hearts/#ProposalComments> (Accessed June 20, 2024).

³³ See the comments associated with the *Update on Continuous Distribution of Hearts* webpage. Available at: <https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/update-on-continuous-distribution-of-hearts/#ProposalComments> (Accessed June 20, 2024).

As previously indicated, the community’s weighting of the attribute was relatively low. Additionally, all of the participant groups rated it as only the fifth most important factor. The members agreed that the low weighting was additional evidence supporting their position.³⁴

In the course of developing this update, the Committee agreed that a post-transplant survival attribute will not be included in the first iteration of continuous distribution of hearts citing several of the previously discussed reasons.³⁵ Chief among them is the lack of an existing model that the community would quickly coalesce around and support. They also pointed to the feedback received during the two previous public comment cycles and regional meetings recommending that it should not be included as an attribute in the first version of heart continuous distribution.

The Committee is considering how to develop a post-transplant survival attribute for inclusion in a future version of continuous distribution, but development may not occur until after the first version of heart continuous distribution has been completed.

NOTA and Final Rule Analysis

The Committee submits this update describing recent activities and information gathering under the authority of the National Organ Transplant Act (NOTA), which requires the OPTN to “establish...medical criteria for allocating organs and provide to members of the public an opportunity to comment with respect to such criteria,”³⁶ and the OPTN Final Rule, which states “The OPTN Board of Directors shall be responsible for developing...[p]olicies for the equitable allocation of cadaveric organs.”³⁷ This request for feedback identifies potential OPTN policy changes that will result in a more equitable and agile heart allocation system.

The Final Rule requires that when developing policies for the equitable allocation of cadaveric organs, such policies must be developed “in accordance with §121.8,” which requires that allocation policies “(1) Shall be based on sound medical judgment; (2) Shall seek to achieve the best use of donated organs; (3) Shall preserve the ability of a transplant program to decline an offer of an organ or not to use the organ for the potential recipient in accordance with §121.7(b)(4)(d) and (e); (4) Shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate; (5) Shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement;...(8) Shall not be based on the candidate's place of residence or place of listing, except to the extent required by paragraphs (a)(1)-(5) of this section.”³⁸ While this request for feedback document does not propose policy changes at this time, the concepts presented in this paper:

Are based on sound medical judgment:³⁹ The construction of the individual ratings scales and weights will be based on objective data, including simulation modeling and published research. The Committee will rely upon peer-reviewed literature and data analyses as well as their own clinical experience and judgment in making determinations regarding assigning weights and ratings to each attribute.

³⁴ Meeting Summary for June 12, 2024 meeting, OPTN Heart Transplantation Committee,

³⁵ Meeting Summary for June 12, 2024 meeting, OPTN Heart Transplantation Committee,

³⁶ 42 U.S.C. § 274(b)(2)(B).

³⁷ 42 C.F.R. § 121.4(a)(1).

³⁸ 42 C.F.R. § 121.8(a).

³⁹ 42 C.F.R. § 121.8(a)(1).

Seek to achieve the best use of donated organs:⁴⁰ One of the best uses of a donated organ is that it is transplanted according to medical urgency. This clause of the OPTN Final Rule will be considered as the Committee prioritizes the weight of the attributes under Medical Urgency. Before the policy proposal is released for public comment, it will be modeled by the SRTR to assess its impact on waitlist mortality. If necessary, the Committee will adjust the weighting of the attributes.

Are specific for each organ:⁴¹ In this case, hearts.

Are designed to avoid wasting organs:⁴² The Committee included the proximity efficiency attribute in part to address increased organ utilization. Additionally, before the policy proposal is released for public comment, it will be modeled by the SRTR to assess the impact on organs recovered for transplant, but not transplanted, as well as the impact on total number of transplants. If necessary, the Committee will be able to adjust the weighting of the attributes to balance the number of transplants against other attributes.

Are designed to... promote patient access to transplantation:⁴³ The Committee identified several attributes that specifically ensure similarly situated candidates have equitable opportunities to receive an organ offer. This includes the two attributes of priority for pediatric candidates and priority for prior living donors, which are associated with the Patient Access goal. It also includes the two attributes of blood type and sensitization, which are aligned with the goal of Reducing Biological Disadvantages. The inclusion of these attributes is likely to increase access to transplantation for these candidates.

Are designed to... promote the efficient management of organ placement:⁴⁴ The Committee will consider indicators of efficiency associated with procuring and transplanting hearts, including efficiencies involved with procuring methods of transportation, such as chartered plane flights, and the proximity between the donor and transplant hospitals. Additionally, work from the Expedient Taskforce could influence additional attributes related to efficiency.

Not be based on the candidate's place of residence or place of listing, except to the extent required [by the aforementioned criteria]:⁴⁵ The Committee is considering the candidate's place of listing only to the extent that is required for the purpose of achieving efficient placement of the organs, specifically for proximity efficiency.

Consider whether to adopt transition procedures:⁴⁶ A Similarly, exception candidates might need a process to transition to the new system. This would allow members and patients time to prepare for these changes.

⁴⁰ 42 C.F.R. § 121.8(a)(2).

⁴¹ 42 C.F.R. § 121.8(a)(4).

⁴² 42 C.F.R. § 121.8(a)(5).

⁴³ 42 C.F.R. § 121.8(a)(5).

⁴⁴ 42 C.F.R. § 121.8(a)(5).

⁴⁵ 42 C.F.R. § 121.8(a)(8).

⁴⁶ 42 C.F.R. § 121.8(d)(1). The Final Rule requires the OPTN to "consider whether to adopt transition procedures that would treat people on the waiting list and awaiting transplantation prior to the adoption or effective date of the revised policies no less favorably than they would have been treated under the previous policies" whenever organ allocation policies are revised.

Conclusion

The Committee update is intended to share the values prioritization exercise results and some of the general themes from the last public comment cycle that the Committee continues reviewing. Additionally, the Committee seeks community feedback about both topics. The Committee will continue engaging with the community and providing public updates as part of its on-going activities developing the first iteration of heart continuous distribution.

Considerations for the Community

The Committee seeks feedback regarding the following continuous distribution topics:

- Overall, do you agree with the general priority of attributes as identified by the VPE results? Why or why not?
- Do you agree with the relatively low prioritization of the proximity efficiency attribute suggested by the VPE results?
- How should the Committee consider the use of new perfusion technologies and their impact on travel distance?
- Is there any additional information the OPTN could provide to help you better understand the concepts associated with the continuous distribution framework for organ allocation? (Note: The Committee is very interested in hearing from those with a personal connection to organ donation and transplantation.)

Appendix A: Glossary of Terms

The following terms are used throughout the concept paper.

Attribute: Attributes are criteria used to classify, sort, and prioritize candidates.

Classification-based framework: A classification-based framework groups similar candidates into classifications or groupings. The candidates are then sorted within those classifications. This is the framework currently used to allocate organs.

Composite Allocation Score: A composite allocation score combines points from multiple attributes together. This concept paper proposes the use of composite allocation scores in a points-based framework.

Concentric Circles: This distribution framework utilizes the distance between the donor hospital and the candidate's transplant hospital to prioritize organ offers to candidates. These distances are grouped into zones at specific nautical mile distances.

Calculated Panel Reactive Antibody (CPRA): The percentage of deceased donors expected to have one or more of the unacceptable antigens indicated on the waiting list for the candidate. The CPRA is derived from HLA antigen/allele group and haplotype frequencies for the different ethnic groups in proportion to their representation in the national deceased donor population.

Exception: When A method for a transplant program to request that a candidate be assigned to a heart status because the candidate does not meet the criteria in policy, but the program believes, using acceptable medical criteria, that the candidate has an urgency and potential for benefit comparable to that of other candidates at the requested status. For certain exception requests, a candidate must be admitted to the transplant hospital that registered the candidate on the waiting list in order to be eligible.

Framework: A collection of policies and procedures used to distribute organs. Examples include concentric circles and continuous distribution.

Goals: Five goals constitute the overall composite allocation score. These goals align with the requirements in NOTA and the OPTN Final Rule: Medical urgency, post-transplant survival, Reducing biological disadvantages, Patient access, and Placement efficiency.

Human Leukocyte Antigen (HLA): A type of molecule found on the surface of most cells in the body. Human leukocyte antigens play an important part in the body's immune response to foreign substances.

Ischemic Time: Ischemic time is broken into three subparts: procurement, transit, and transplant time. Procurement time begins at cross-clamp and ends at transit departure time. OPO and procurement practices, among other things, influence procurement related ischemic time. Transit time is the time in between departure from the procurement location and delivery at the transplant hospital. Transplant time is then the time between delivery at the transplant hospital and the start of anastomosis.

NHRB for Pediatrics: National Heart Review Board; A review board of members drawn from a nationwide pool of heart transplant physicians and surgeons, who review non-standard exception requests from transplant programs for candidates whose calculated MELD score or PELD score does not accurately reflect the candidate's medical urgency for transplant.

Points-based framework: A points-based framework gives each candidate a score or points. Organs are then offered in descending order based upon the candidate's score. This concept paper proposes a points-based framework for organ allocation.

Rating Scale: A rating scale describes how much preference is provided to candidates within each attribute. Applying the rating scale to each candidate's information and combining it with the weight of the attribute results in an overall composite score for prioritizing candidates.

Regional Review Boards: A review board of members drawn from a pool of heart transplant physicians and surgeons within an OPTN region, who review non-standard exception requests submitted by transplant programs for assigning a candidate to an adult heart status. The transplant program is expected to demonstrate, using acceptable medical criteria, that the candidate for whom the exception request is being submitted has an urgency for benefit comparable to that of other candidates at the requested status.

Revealed Preference: A revealed preference analysis looks at actual decisions to determine the implicit preferences of the decision maker. This is compared with a stated preference analysis (for example, AHP) that asks the decision maker to state their preferences in an experiment.

Values Prioritization Exercise (VPE): VPE is an example of a stated preference analysis. This analysis asks participants to state their preferences in a pairwise comparison. VPE may also be referred to as an Analytical Hierarchy Process (AHP).

Weight: Weights are the relative importance or priority of each attribute toward our overall goal of organ allocation. Combined with the ratings scale and each candidate's information, this results in an overall composite score for prioritizing candidates.

Appendix B: Continuous Distribution Resources

For additional information regarding the continuous distribution allocation framework and the efforts of the OPTN, visit: [Continuous distribution](#)⁴⁷.

The OPTN Heart Transplantation Committee released an initial continuous distribution concept paper addressing the Committee's activities during the July – September 2023 public comment cycle. The concept paper and background materials can be accessed on the OPTN website: [Continuous Distribution of Hearts](#)⁴⁸.

Other organ-specific continuous distribution resources are available on the OPTN website, including:

- [Continuous distribution - lung](#)⁴⁹
- [Continuous distribution - kidney and pancreas](#)⁵⁰
- [Continuous distribution - liver and intestine](#)⁵¹

[Ethical Considerations of Continuous Distribution in Organ Allocation White Paper](#)⁵²

⁴⁷ OPTN website, <https://optn.transplant.hrsa.gov/policies-bylaws/a-closer-look/continuous-distribution/> (Accessed November 5, 2023).

⁴⁸ OPTN website, <https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/continuous-distribution-of-hearts/> (Accessed November 5, 2023).

⁴⁹ OPTN website, <https://optn.transplant.hrsa.gov/policies-bylaws/a-closer-look/continuous-distribution/continuous-distribution-lung/> (Accessed November 5, 2023).

⁵⁰ OPTN website, <https://optn.transplant.hrsa.gov/policies-bylaws/a-closer-look/continuous-distribution/continuous-distribution-kidney-and-pancreas/> (Accessed November 5, 2023).

⁵¹ OPTN website, <https://optn.transplant.hrsa.gov/policies-bylaws/a-closer-look/continuous-distribution/continuous-distribution-liver-and-intestine/> (Accessed November 5, 2023).

⁵² *Ethical Considerations of Continuous Distribution in Organ Allocation*, OPTN Ethics Committee, https://optn.transplant.hrsa.gov/media/mjzfpb3h/ethical-considerations-of-continuous-distribution-in-organ-allocation_whitepaper.pdf (Accessed November 5, 2023).

