OPTN

Request for Feedback

Update on Continuous Distribution of Hearts

OPTN Heart Transplantation Committee

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Contents

Update on Continuous Distribution of Hearts

Sponsoring Committee: *Heart Transplantation*
Public Comment Period: *January 23, 2024 – March 19, 2024*

Executive Summary

In August 2022, the Organ Procurement and Transplantation Network (OPTN) Heart Transplantation Committee (the Committee) initiated an effort to convert the current classification-based heart allocation system to a point-based framework, otherwise known as continuous distribution. The current 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. The composite allocation score simultaneously considers candidate and donor attributes. This points-based allocation system will create a more equitable, agile, and transparent allocation system. (See Appendix A for a glossary of terms.)

This request for feedback document is the next step following the Committee's initial concept paper, which was submitted for public comment during July – September 2023.[1] The request for feedback document is intended to supplement the concept paper by providing information about the Committee's activities since July 2023. It is also intended to inform the OPTN community about the Values Prioritization Exercise (VPE) available for members of the community to complete during January – March 2024. The VPE is a method of collecting community input regarding how certain aspects of heart allocation should be prioritized against each other. Additionally, the document describes the use of mathematical optimization to refine the Committee's initial ideas for attribute rating scales and, as with the initial concept paper, the request for feedback document solicits the community's feedback about the Committee's work to date and outlines the anticipated next steps for the Committee's activities.

[1] OPTN Heart Transplantation Committee, *Continuous Distribution of Hearts Concept Paper*, https://optn.transplant.hrsa.gov/media/ta4jlmpp/heart_cd-of-hearts-conceptpaper_pcsummer2023.pdf, (Accessed November 5, 2023).

Background

In 2018, the OPTN Board of Directors sought an allocation system that could be consistently implemented across all organs. The OPTN Board of Directors determined that a points-based continuous distribution framework would replace the current classification-based allocation systems.[2] 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 increase equity for candidates on the waitlist and increase transparency in the allocation of hearts. In addition, continuous distribution has more potential for flexibility in changing allocation through efficient policy development and implementation.

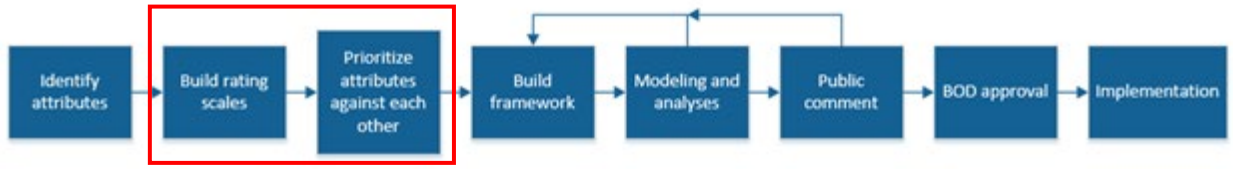
In August 2022, the Committee began developing a framework for the continuous distribution of hearts.[3] The Committee's efforts follow several other organ specific OPTN committees who have implemented or are developing continuous distribution allocation frameworks. For example, in March 2023, the policy changes associated with the continuous distribution of lungs were implemented.[4] In addition, the OPTN Kidney Transplantation and the OPTN Pancreas Transplantation Committees have been collaborating on a project to convert the kidney and pancreas allocation systems to continuous distribution.[5] In December 2021, the OPTN Liver and Intestinal Organ Transplantation Committee launched a similar effort.[6] The goal is to transition all organs to a continuous distribution allocation system.

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 perhaps the most significant change to heart allocation policy ever. This initial effort is largely focused on transitioning current policy into a continuous distribution framework, with the understanding that future refinements will be necessary. As first detailed in the July – September 2023 concept paper, the project will progress through several phases.[7] The phases are identified in **Figure 1** and explained in more detail in the remainder of this section.

[2] 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).
[3] Meeting Summary for August 16, 2022 meeting, OPTN Heart Transplantation Committee, https://optn.transplant.hrsa.gov/media/oqyfbjkh/20220816_heart_meeting-summary_final.pdf (accessed May 9, 2023).
[4] *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).
[5] OPTN website, https://optn.transplant.hrsa.gov/policies-bylaws/a-closer-look/continuous-distribution/continuous-distribution-kidney-and-pancreas/, Accessed November 5, 2023.
[6] OPTN website, https://optn.transplant.hrsa.gov/policies-bylaws/a-closer-look/continuous-distribution/continuous-distribution-liver-and-intestine/, Accessed November 5, 2023.
[7] *Continuous Distribution of Hearts Concept Paper*, OPTN Heart Transplantation Committee, July 27, 2023, https://optn.transplant.hrsa.gov/media/ta4jlmpp/heart_cd-of-hearts-conceptpaper_pcsummer2023.pdf (accessed November 13, 2023).

Figure 1: Project Plan Overview



The previous concept paper focused on identifying the attributes the Committee planned to discuss and asked for community feedback on which attributes should be included in the first iteration of continuous distribution.[8] Since that time, the Committee narrowed the list of attributes and moved forward with developing the rating scales. More information about the updated attributes and rating scales appears later in this section of the document.

For this cycle, the Committee is most interested in community participation in the Values Prioritization Exercise to inform the relative importance of the different attributes. This information will help guide the Committee in the optimization of the system.

Values Prioritization Exercise and Mathematical Optimization Will Assist In Prioritizing Attributes

After building the rating scale for each attribute, the Committee will then decide how much weight, or relative importance, each attribute should have within the composite allocation score. The Committee makes the decisions with input from the transplant community.

The Committee will utilize a number of tools to inform the discussion about attribute weights. The larger transplant community, including patients, is asked for their input via a structured exercise, called the values prioritization exercise (VPE).[9] The exercise asks participants for their opinion on how the different attributes should be weighed against each other in a quantitative and systematic fashion. The Committee will also work with experts in mathematical optimization to understand the tradeoffs between different attributes to help select the optimal combination of rating scales and weights.[10,1112] The Committee will utilize additional tools and consult with other subject matter experts as needed throughout this process.

Values Prioritization Exercise

The transplant community is asked to participate in a structured values prioritization exercise as part of this public comment cycle. This exercise utilizes analytical hierarchy process (AHP) methodology to aid in

[8] *Continuous Distribution of Hearts Concept Paper*, OPTN Heart Transplantation Committee, July 27, 2023.
[9] OPTN, *Continuous Distribution,* Help build the framework. Available at https://optn.transplant.hrsa.gov/policies-bylaws/a-closer-look/continuous-distribution/#CD_BuildTheFramework.
[10] 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.
[11] 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.
[12] 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.

values-based decision-making.[13] The OPTN requires specific expertise to participate in clinical, scientific, and operational discussions, even though everyone has valuable perspectives to contribute to the values debate. Combining the two discussions in previous projects made it more difficult for parts of the community to contribute their important perspectives to the discussion. Separating the discussions has allowed a broader and more diverse population to participate in the OPTN policy development process. AHP is a multi-criteria decision-making methodology that asks participants questions to compare the relative importance of a set of criteria through multiple pairwise comparisons.[14] The exercise asks participants for their opinion on how the different attributes should be weighed against each other in a quantitative and systematic fashion.

While the Committee is utilizing more traditional analytical methods to build rating scales (more detail provided below), weighing attributes against each other is values laden rather than only 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. Rather, such discussions are based on the values of the community and an effort to balance equity and utility in the organ allocation system. The values prioritization exercise is open to public participation as a structured way for the Committee to solicit feedback from the broader community on their priorities and what they value in the new allocation framework.[15,16] A similar approach was utilized by the OPTN Lung, Kidney, Pancreas, and Liver and Intestinal Organ Transplantation committees.[17]

In the values prioritization exercise, participants are asked to compare two attributes against each other and indicate which of the two is most important, as well as how important the attribute is when considering a candidate for organ transplant.[18] For example, **Figure 2** shows a sample pairwise comparison between two attributes in the values prioritization exercise used by the OPTN Liver and Intestinal Organ Transplantation Committee.

[13] OPTN, *Continuous Distribution,* Help build the framework. Available at https://optn.transplant.hrsa.gov/policies-bylaws/a-closer-look/continuous-distribution/#CD_BuildTheFramework.

[14] *See generally*, Lin, Carol and Harris, Shannon 2013. A Unified Framework for the Prioritization of Organ Transplant Patients: Analytic Hierarchy Process, Sensitivity, and Multifactor Robustness Study. Journal of Multi-Criteria Decision Analysis.

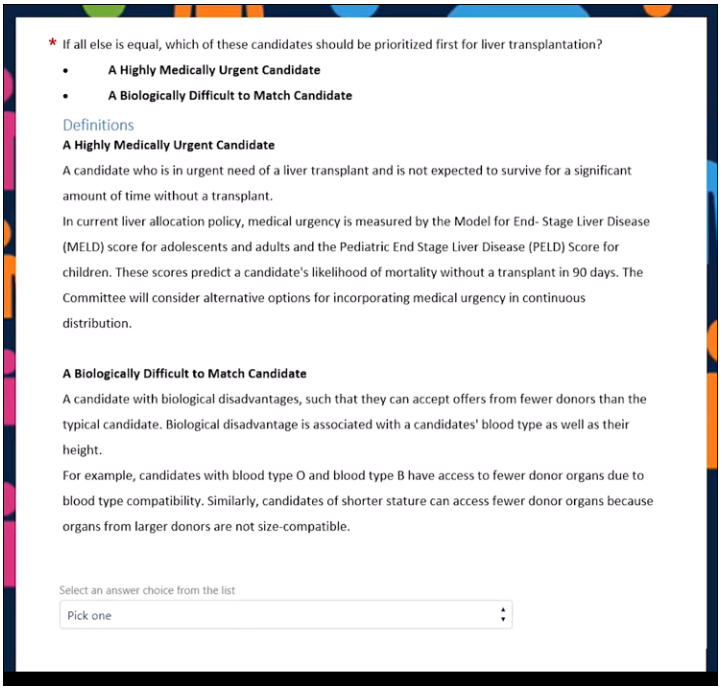
[15] *See generally* Mark, T. L., & Swait, J., 2004. Using stated preference and revealed preference modeling to evaluate prescribing decisions. Health economics.

[16] *See generally*, Lin, Carol and Harris, Shannon 2013. A Unified Framework for the Prioritization of Organ Transplant Patients: Analytic Hierarchy Process, Sensitivity, and Multifactor Robustness Study. Journal of Multi-Criteria Decision Analysis.

[17] *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/fodja1ag/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/qrxnpv4n/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).

[18] "Continuous distribution," Organ Procurement & Transplantation Network, accessed November 12, 2023, https://optn.transplant.hrsa.gov/policies-bylaws/a-closer-look/continuous-distribution/#CD_BuildTheFramework.

Figure 2: Sample Pairwise Comparison



The results of the exercise will be considered by the Committee in conjunction with other information to determine the weight of each attribute and the overall composite allocation score. Participants are encouraged to leave comments explaining their decision-making as this information is helpful to the Committee's deliberations. The Committee will review the results stratified by different demographic categories. The results of the values prioritization exercise reflect the opinion of the community, which is valuable information for the Committee moving forward, but not the only consideration in proposing a first iteration of continuous distribution, as such the evidence supporting attributes will also be considered.

Optimization Analysis

In addition to the values prioritization exercise, the Committee also plans to collaborate with the Massachusetts Institute of Technology (MIT) on an optimization analysis. Optimization analysis applies artificial intelligence and machine learning to traditional policy simulations to allow for optimization of specific outcomes. 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 transplant.[19] The optimization analysis will allow the Committee to understand the relative weights they will need to consider for certain attributes in order to achieve a desired outcome.

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

Identify Attributes

The first step in the development of continuous distribution for hearts is identifying all attributes that should be included in the new allocation system.[20] This includes identifying the allocation attributes or factors in current policy. In addition, the Committee is also considering incorporating other attributes that do not exist in the current allocation. While the project's primary focus is converting the current system to continuous distribution, the Committee recognized the opportunity to improve the allocation system by including other important allocation factors; these will be discussed in more detail later in the concept paper. The Committee has finalized the list for inclusion in the first iteration of continuous distribution.

Based on the experiences of the other OPTN committees developing continuous distribution allocation frameworks, as well as their own judgment, the Committee identified the following criteria for considering whether an attribute should be included in the first iteration of continuous distribution of hearts:

- Exists in the current allocation framework
- Promotes consistency across all organ frameworks
- Support exists within the community for a specific solution
- Data and other evidence exist supporting a specific solution

It is important to acknowledge that it is not possible to include every potential attribute in the first version of continuous distribution. Potential attributes that would require new data collection, significant analysis, or consensus building, will be addressed in a future version because their development would likely delay the Committee's ability to develop a policy proposal in a timely manner. The Committee is interested in the community's feedback on which attributes should be added to the allocation system.

Build Rating Scales

In addition, the Committee began building the rating scales associated with each attribute, following release of the concept paper for public comment in July 2023. A rating scale is used tocompare candidates against each other for a specific consideration (ex. medical urgency). For example, all rating scales work on a 0-100% scale. The rating scale for each attribute will determine how many points out of the 100 percent each candidate will receive on the match run.

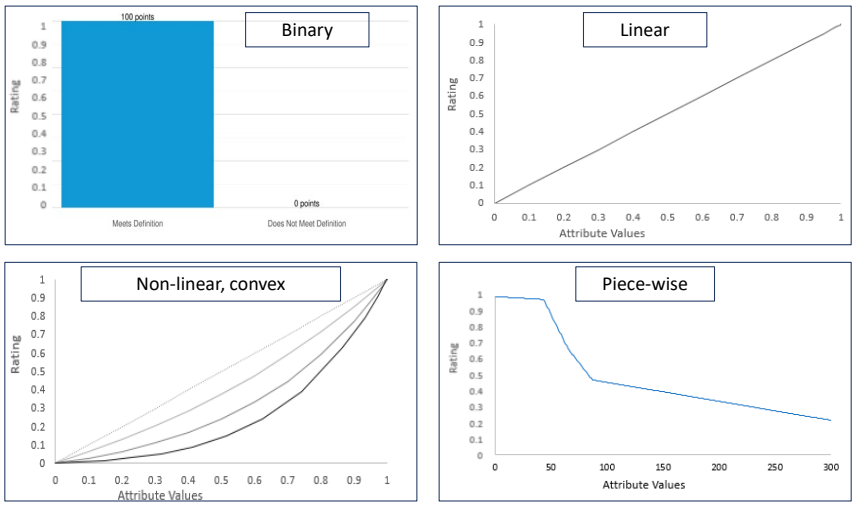
This represents just one example of a rating scale, and the Committee will go through a similar exercise for each attribute they intend to include in the first iteration of continuous distribution. Some rating scales, such as pediatric priority or prior living donors, will be simple, binary functions. However, other attributes will be more difficult. The Committee is using all available resources, relying heavily on traditional analytical methods and published research to develop rating scales for each attribute. Where possible, and in agreement with the Board's mandate for a more consistent organ allocation system, the Committee will utilize the analyses and precedents used in other continuous distribution proposals.

Each attribute reflects a way of prioritizing a specific factor or several factors considered critical to the equitable allocation of donor organs. A rating scale is used to operationalize the intended prioritization.

[20] Attributes are criteria used to classify then sort and prioritize candidates. Refer to *Appendix: Glossary of Terms* for more information.

Given their importance to the effectiveness of continuous distribution, the Committee spent a substantial amount of time developing rating scales for the identified attributes.[21] Generally speaking, rating scales represent how points will be assigned to individual candidates for each attribute. **Figure 3** provides examples of some rating scales. A binary rating scale is useful for awarding points when a condition is met or not met. For example, if a committee wants to provide priority to prior living donors, then the committee can create two groups: those candidates who are previous living donors, and those candidates who are not. The Committee can then award the attribute's points or priority to those who are prior living donors.[22]

Figure 3: Examples of Rating Scales



The Committee has identified preliminary rating scales for each of the attributes they have identified for potential inclusion in the continuous distribution of hearts framework. These rating scales are informed by current objective clinical or operational data. In some cases, they may have to rely on the Committee's experience and/or expertise. In addition to each purpose, the Committee will identify a metric of success for each attribute. This metric is used to evaluate the success of different rating scales. Later, the metric is used to identify optimized policy scenarios and evaluate the success of the implemented system.

Progress to Date

The Committee began discussing a continuous distribution allocation framework for hearts in August 2022.[23] Since then, the Committee has identified several attributes for inclusion in the first iteration of such a framework. Many of those attributes were identified in the Heart Committee's concept paper submitted for public comment in July 2023, and some have been identified since then based on public comment feedback and the Committee's continued work.[24] Several other potential attributes have been discussed. However, the Committee has decided not to include them as part of the first version of

[21] Rating scales describe how much preference are provided to candidates within each attribute. Refer to *Appendix: Glossary of Terms* for more information.
[22] Separately, the Committee will determine the maximum number of points available to those candidates who were prior living donors. These points are relative to the attribute of prior living donor – also known as the weight of the attribute.
[23] Meeting Summary for August 16, 2022 meeting, OPTN Heart Transplantation Committee, https://optn.transplant.hrsa.gov/media/ogyfbjkh/20220816_heart_meeting-summary_final.pdf (accessed December 7, 2023).
[24] *Continuous Distribution of Hearts Concept Paper*, OPTN Heart Transplantation Committee, July 27, 2023.

continuous distribution of hearts because they agreed only to include attributes that have sufficient supporting data. The Committee also agreed that future iterations of continuous distribution of hearts might include the additional attributes they discussed and other after sufficient data has been collected and analyses performed to support such inclusion.

The primary goal of this public cycle is to collect feedback from the community through the values prioritization exercise (VPE). To prepare those participants to make informed decisions, this request for feedback document presents the revised list of attributes, as well as the proposed rating scales; it also seeks feedback from the OPTN communityon those attributes and rating scales. Particularly, the Committee is interested if the community agrees that the chosen attributes are the most important aspects of heart allocation and appropriate for inclusion in the first version of the framework.

Additionally, the Committee has determined the general shapes of several attribute rating scales. At this stage of developing the framework, the Committee is more interested in whether the scales are mostly correct in terms of establishing priority within each individual attribute. Take, for example, some aspects of the medical urgency attribute for which the Committee seeks input. Is the priority associated with each medical urgency grouping mostly correct based on waiting list mortality rates and factors like time waiting since the adult heart allocation changes implemented in October 2018? In addition, are the differences between the medical urgency groupings mostly appropriate, such that the highest and second highest medical urgency groupings reflect a balance in priority?

More details on the Committee's discussions can be found in the subsections below. Specific feedback questions for the community appear in the Considerations for the Community section.

Attributes and Rating Scales for Heart Allocation

Table 1 identifies the list of attributes chosen by the Committee for inclusion in the initial continuous distribution of heart allocation framework. Additional information concerning the attributes the Committee considered but chose not to include in the initial framework is discussed in a later section.

Table 1: OPTN Heart Transplantation Committee Identified Attributes

	Medical Urgency	Post-Transplant Survival	Reducing Biological Disadvantages	Patient Access	Placement Efficiency
Attributes	• Medical urgency		• Blood type • Sensitization	• Priority for pediatric candidates • Priority for prior living donors	• Distance between transplant and donor hospitals

Medical Urgency

The OPTN Final Rule calls for allocation policies to "seek to achieve the best use of donated organs."[25] One way to achieve the best use of a donated organ is to transplant the organ into a candidate who has the greatest medical urgency. Also, the Final Rule calls for the OPTN to "[set] priority rankings … for

[25] 42 C.F.R. § 121.8(a)(2).

patients or categories of patients who are medically suitable candidates for transplantation to receive transplants. These rankings shall be ordered from most to least medically urgent…"[26]

The Committee identified the adult heart statuses, the pediatric heart statuses, and a candidate's time assigned to adult status 4 with a Left Ventricular Assist Device (LVAD) as the three primary factors they want addressed in the medical urgency attribute. Within each primary factor are one or more sub-factors.

Adult Heart Statuses

Heart policy relies heavily on the type of therapeutic intervention used as a measure of disease severity, and thus, medical urgency. In 2018, policy changes were implemented to better stratify adult heart candidates based on their medical urgency.[27] Prior to the changes, it was determined that the waitlist mortality rates of candidates assigned to the highest priority status were dissimilar enough to warrant creation of additional heart statuses.

Adult heart candidates listed at status 1 receive the highest priority in allocation policy, with status 2 candidates receiving the second highest priority with each successive status receiving less priority through adult heart status 6. As part of the Committee's work on continuous distribution, they reviewed the waitlist mortality rates presented in the *Three- Year* and *Four-Year Monitoring of the Heart Allocation Proposal to Modify the Heart Allocation System* reports.[28] **Table 2** indicates the waitlist mortality rates associated with the adult heart statuses reported in the *Three-Year* monitoring report. The era represents October 18, 2018 – October 17, 2021. The members agreed that, overall, policy modifications implemented in 2018 had achieved their intended purpose. The three most medically urgent statuses in the new classification system appropriately reflected the waitlist mortality rates as expected. In addition, transplant rates had remained relatively the same. The Committee members believe that the mortality rates serve as an excellent starting place by which to transition the adult heart statuses into a points-based allocation framework, as well as published research on the topic.[29]

[26] 42 C.F.R. § 121.8(b)(2).

[27] *Briefing Paper: Proposal to Modify the Adult Heart Allocation System*, OPTN Thoracic Organ Transplantation Committee, December 2016, https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/modify-adult-heart-allocation-2016-2nd-round/ (Accessed December 8, 2023).

[28] OPTN Descriptive Data Request, "Three-Year Monitoring of Heart Allocation Proposal to Modify the Heart Allocation System," Prepared for OPTN Heart Transplantation Committee meeting, October 11, 2022, https://optn.transplant.hrsa.gov/media/hx1pr13a/data_report_heart_committee_3yr_rpt1_508_compliant.pdf (Accessed May 9, 2023), pp. 27-32. OPTN Descriptive Data Request, "Four-Year Monitoring of Heart Allocation Proposal to Modify the Heart Allocation System," Prepared for OPTN Heart Transplantation Committee meeting, the March 29, 2023, https://optn.transplant.hrsa.gov/media/asdpqli5/data_report_heart_committee_4yr_rpt1.pdf (Accessed May 9, 2023), pp. 29-36.

[29] Kiran K. Khush, Alexander T. Sandhu, and William F. Parker, "How to Make the Transplantation Allocation System Better," *Journal of the American College of Cardiology*, Vol. 11, no. 5, 2023: pp. 516-519. https://doi.org/10.1016/j.jchf.2022.11.029

Table 2: Deaths per 100 Active Patient-Years Waiting by Adult Medical Urgency Status

Adult Status	Criteria	Description	Deaths per 100 Active Years Waiting
2	1	Non-dischargeable, surgically implanted, non-endovascular Left Ventricular Assist Device (LVAD)	154.23
1	2	Surgically implanted non-endovascular biventricular support device	137.44
1	4	Exception	90.73
1	1	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO)	82.47
1	3	BiVentricular Assist Device (BiVAD)/Ventricular Episodes	55.64
2	6	Ventricular Tachycardia (VT) or Ventricular Fibrillation (VF)	25.81
3	5	Mechanical Circulatory Support Device (MCSD) with right heart failure	23.92
2	4	Percutaneous endovascular MCSD	18.73
2	2	Total Artificial Heart (TAH), BiVAD, Right Ventricular Assist Device (RVAD), or VAD for single ventricle patients	17.55
3	2	Multiple/single high dose inotrope and hemodynamic monitoring	10.09
2	7	Exception to status 2 criteria	9.68
4	6	Retransplant	7.45
2	5	Intra-Aortic Ballon Pump (IABP)	6.75
3	13	Exception to status 3 criteria	6.63
4	2	Inotropes without hemodynamic monitoring	5.24
4	4	Ischemic heart disease with intractable angina	3.90
4	3	Congenital heart disease	3.50
4	7	Exception to status 4 criteria	2.93
4	1	Dischargeable LVAD without discretionary 30 days	1.82
3	4	MCSD with pump thrombosis	1.68
4	5	Amyloidosis/hypertrophic/restrictive cardiomyopathy	1.19
3	6	MCSD with device infection	1.09

Note: Represents October 18, 2018 – October 17, 2021.

The Committee also intends to use the medical urgency attribute to improve access for certain candidates who may need additional prioritization beyond that provided in the current allocation system. As part of the heart allocation policy changes implemented in October 2018, the Heart Committee (then the OPTN Thoracic Transplantation Committee[30]) created guidance documents to assist the adult heart regional review boards with standardizing decision-making for adult CHD exception requests. These include congenital heart disease (CHD); Hypertrophic and Restrictive Cardiomyopathy (HCM/RCM); and re-transplant and Cardiac Allograft Vasculopathy (CAV). According to the CHD guidance document, during development of the policy changes, the Committee received feedback from the heart transplant community that adult congenital heart disease candidates may be disadvantaged by the new system.[31] The guidance document contains recommendations for which status priority a transplant program should request based upon established clinical criteria. A guidance

[30] The OPTN Thoracic Transplantation Committee was dissolved July 1, 2020, and the OPTN Heart Transplantation Committee and the OPTN Lung Transplantation Committee were implemented in its place.

[31] OPTN Thoracic Transplantation Committee, *Review Board (RB) Guidance for Adult Congenital Heart Disease (CHD) Exception Requests*, December 2017, https://optn.transplant.hrsa.gov/media/2349/thoracic_guidance_201712.pdf (accessed May 14, 2023).

document created to address candidates with HCM or RCM contains similar recommendations for which status priority to request. After careful consideration, the Heart Committee decided that the CHD and HCM/RCM recommendations should be integrated in heart allocation policy as part of the initial version of continuous distribution. The members agreed to use the adult heart status recommended in the documents to align such candidates' priority on a continuum for medical urgency.

As part of current heart policy, a candidate who was previously transplanted and who has evidence of CAV may be assigned to adult heart status 4. The Committee members discussed whether such candidates are receiving the appropriate level of priority. It was acknowledged that re-transplantation is associated with inferior short-term and long-term survival when compared with primary heart transplantation, and its use remains controversial.[32] In part, the poorer outcomes result from the rapid deterioration such candidates experience after developing CAV. However, it has been shown that survival with re-transplantation can approach that of primary transplantation when patients are appropriately selected.[33] The Committee considered the circumstances and determined to incorporate additional priority for candidates needing re-transplantation. The members agreed that candidates who meet certain identified eligibility criteria for allograft failure or severe CAV as demonstrated by angiography or intravascular ultrasound (IVUS) should receive additional priority in the first iteration of continuous distribution of hearts.

Pediatric Heart Statuses

Statuses also prioritize pediatric heart candidates; however, there are only three pediatric heart statuses. (In addition to the medical urgency concerns associated with pediatric heart candidates, there is also concern from an access perspective, which is discussed in more detail later in the document.) As a result of having fewer statuses, it is widely believed that heart allocation policy does not stratify the medical urgency of pediatric candidates as well as it does for adult heart candidates.[34] During their discussions, the Committee members agreed that pediatric status 1A, the highest pediatric priority status, is comprised of candidates with wide differences in their medical urgency.[35] This is similar to the circumstances that led the Committee to create the additional adult heart statuses that were implemented in October 2018. As part of their effort to develop a continuous distribution framework, the Committee seeks to accomplish two goals related to the pediatric statuses: better stratify status 1A candidates based on medical urgency and align pediatric and adult candidates on a single medical urgency scale.

The medical urgency of pediatric heart candidates is reflected in three statuses: 1A, 1B, and 2. Candidates assigned to pediatric status 1A have the highest medical urgency. They typically receive organ offers before status 1B candidates, who typically receive offers before status 2 candidates. **Table 3** shows the waitlist mortality rates for pediatric heart candidates pre- and post-implementation by medical urgency status and era, as well as by candidate age.

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[32] Maya H. Barghash and Sean P. Pinney, "Heart Retransplantation: Candidacy, Outcomes, and Management," *Current Transplantation Reports* 7, no. 1 (2020): 12–17, https://doi.org/10.1007/s40472-019-00257-y.

[33] Barghash MH, Pinney SP, Heart Retransplantation: Candidacy, Outcomes, and Management, Curr Transplant Rep, 2020;7(1):12-17. doi: 10.1007/s40472-01900257-y. Epub 2019 Dec 17. PMID: 32435573; PMCID: PMC7223608.

[34] Meeting Summary for March 21, 2023 meeting, OPTN Heart Transplantation Committee, https://optn.transplant.hrsa.gov/media/hxmhtype/20230321_optn-heart-committee_meeting-summary.pdf (accessed December 21, 2023).

[35] *Briefing Paper: Proposal to Modify the Adult Heart Allocation System*, OPTN Thoracic Transplantation Committee, December 2016, https://optn.transplant.hrsa.gov/media/2006/thoracic_brief_201612.pdf (Accessed December 7, 2023).

Table 3: Deaths per 100 Active Patient-Years Waiting by Pediatric Medical Urgency Status

Pediatric Status	Criteria	Description	Deaths per 100 Active Years Waiting
1A	1	Peds – Continuous mechanical ventilation	194.74
1A	5	Peds – Mechanical Circulatory Support Device (MCSD)	57.62
1A	3	Peds – Ductal dependent pulmonary/systemic circulation	43.89
1A	4	Peds – Congenital heart disease	43.23
1A	6	Peds – Exception to status 1A criteria	21.24
1B	1	Peds – Inotropes	6.24
1B	3	Peds – Exception to status 1B criteria	4.00
2	2	Peds – No criteria	1.69

Note: Represents October 18, 2018 – October 17, 2021.

Status 1A is comprised of five criteria. Hospital admission is an eligibility requirement for four of the five status 1A criteria. Status 1B is comprised of two criteria, neither of which requires hospital admission for eligibility. Candidates who are less than 18 years old at the time of registration and do not qualify for status 1A or status 1B may be assigned to pediatric status 2.[36] The five status 1A criteria represent substantially different levels of medical urgency, as reflected by the waitlist mortality rates identified in Table 3 and according to the Committee members. The committee has collaborated with the OPTN Pediatric Committee and other professionals in the pediatric heart community to map criteria within statuses 1A and 1B onto a points-based allocation framework. They propose aligning the five sub-criteria within status 1A more closely with the medical urgencies associated with the adult heart statuses. For instance, the status 1A sub-criterion addressing continuous mechanical ventilation will be aligned closely with the use of VA ECMO for adult candidates.[37] The committees see continuous distribution as an opportunity to map pediatric urgency onto the same scale used for adult candidates, but with greater granularity, and using similar nomenclature and criteria. The committees also acknowledge that such a change represents a large departure from current policy. They also agree that this is the appropriate time and vehicle for making the change because the differences in medical urgency have been a concern of the pediatric heart community in the past. Nonetheless, any changes will need to be thoroughly reviewed for potential disadvantages and those disadvantages addressed as best as possible. In order to identify any resulting issues, new data collection may also be required ahead of any changes being implemented.

Just as the creation of more granular adult heart statuses succeeded in shortening wait times for the most urgent adult candidates, the Committee strongly believes that better stratifying pediatric candidates by their clinical conditions will have similarly positive results.[38] In addition, the Committee has identified an opportunity to improve waitlist mortality for a small group of very ill pediatric patients by identifying a group similar to adult status 1. According to several members of the Heart and Pediatric committees, critically ill children of smaller sizes (measured as body surface area) can have wait times of

[36] OPTN *Policy 6.2.A: Pediatric Heart Status 1A Requirements*, https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf (Accessed December 7, 2023).
[37] Meeting Summary for March 21, 2023 meeting, OPTN Heart Transplantation Committee, https://optn.transplant.hrsa.gov/media/hxmhtype/20230321_optn-heart-committee_meeting-summary.pdf (accessed June 20, 2023).
[38] Meeting Summary for March 21, 2023 meeting, OPTN Heart Transplantation Committee, https://optn.transplant.hrsa.gov/media/hxmhtype/20230321_optn-heart-committee_meeting-summary.pdf (accessed June 20, 2023).

many months in certain OPTN regions due to a lack of suitable donors, exacerbating risk of wait list mortality for the sickest patients. The shortage of donors means that even with establishment of an adult status 1 equivalent, pediatric patients at this high urgency may not have acceptable wait times and may still experience substantial waitlist mortality.

Pediatric status 1B, which encompasses patients similar to adult statuses 3 and 4, includes both inpatients and outpatients, making it more challenging to determine the appropriate level of priority that should be assigned. Status 1B encompasses a wide spectrum of clinical situations, including inpatients on inotropic therapy with cardiomyopathies, patients with complications of single ventricle physiology, and outpatients with risk of decompensation or few medical options for therapy. The Committee acknowledged that some status 1B outpatients are at elevated risk of waitlist mortality, but do not have adequate mechanical or medical support options available to them.[39]

Additionally, OPTN pediatric exception guidance documents make suggestions to National Heart Review Board for Pediatrics reviewers about how to consider whether the requested status is appropriate given the clinical conditions described. The guidance documents address certain disease states, including restrictive and hypertrophic cardiomyopathy, non-pump related single ventricle heart disease failures, and inotrope dependent cardiomyopathies with end-stage organ dysfunction. The Committee intends to incorporate the clinical conditions more directly in allocation policy through the continuous distribution framework. The members indicated such a change should help minimize exception requests, as well.

Several of the attribute-specific comments submitted during public comment recommended that the Committee consider how pediatric candidates will be impacted by the changes. For example, the OPTN Pediatric Transplantation Committee's comment reported that the members were very interested in the transition and mapping of current medical urgency to a continuous scale in which each condition and the associated waitlist mortality falls somewhere on the curve.[40] The Pediatric Committee underscored that this represents a large change in how medical urgency will work for pediatric candidates, and it is important for the Heart Committee to model how these pediatric urgency points will sort against other children and also against adults. According to the Pediatric Committee, an increase in composite allocation score points may not translate directly to an increase in transplants for children, especially for those children who may receive less medical urgency points than they do currently via the current status system. The Pediatric Committee recommended that the Heart Committee model or simulate such changes and their outcomes before implemented as part of continuous distribution. The Heart Committee agrees with the need to perform such analyses, and also is aware that the small numbers of pediatric heart candidates within the different statuses and criteria also make it challenging to get a complete picture of the impact of such changes.

Feedback provided by the Transplant Coordinators Committee (TCC) also addressed how realigning medical statuses on a continuous rating scale might impact pediatric candidates.[41] For example, part of

[39] Meeting Summary for March 21, 2023 meeting, OPTN Heart Transplantation Committee, https://optn.transplant.hrsa.gov/media/hxmhtype/20230321_optn-heart-committee_meeting-summary.pdf (accessed June 20, 2023).
[40] OPTN, Public Comment webpage, *Continuous Distribution of Hearts Concept Paper*, OPTN Pediatric Transplantation Committee comments submitted September 13, 2023, https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/continuous-distribution-of-hearts/#ProposalComments, (accessed November 13, 2023).
[41] OPTN, Public Comment webpage, *Continuous Distribution of Hearts Concept Paper*, OPTN Transplant Coordinators Committee comments submitted August 28, 2023, https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/continuous-distribution-of-hearts/#ProposalComments, (accessed November 13, 2023).

the TCC comment recommended including growth parameters for pediatric candidates within the medical urgency attribute. The TCC comment also recognized that the proposal appears to realign pediatric statuses to be more like the adult statuses but cautioned that pediatric candidates with a durable ventricular assist devices (VADs) are at a much higher advantage than other pediatric candidates with VADs who are not dischargeable. It was also questioned whether pediatric wait time for durable VAD is as relevant. A similar comment stated that the pediatric heart transplantation urgency strata are too broad, specifically status 1A, and CD should allow for enhanced prioritization for allocation on features associated with high risk of waitlist mortality rather than time accrued at urgency status.

Waiting Time Accrued at Adult Heart Status 4 With an Implanted Ventricular Assist Device (VAD)

Another important aspect of allocation policy that the Committee is addressing involves the impact candidates experience when assigned to adult status 4 with a LVAD for an extended period. The heart community has expressed concern that such candidates are likely to be clinically stable for extended periods of time, but eventually suffer device infections or device failures that require them to be assigned to a much higher priority status. In some cases, such candidates are removed from the waiting list for being too sick to transplant. According to Committee members, transplant programs have become increasingly reluctant to assign a candidate to status 4 with a LVAD because of the long period of time before such candidates are transplanted. A 2021 study reported that before implementation of the heart policy changes in October 2018, nearly one of two heart transplant patients was supported by a LVAD, but the proportion decreased to one of four following implementation. The report suggested that reasons for the change include wanting to avoid surgery for implanting the LVAD, avoid the risk of complications with the LVAD, and the prolonged waitlist times such candidates experience in the current allocation system.[42]

Patients with an implanted Left Ventricular Assist Device (LVAD) are assigned to adult heart status 4. The level of priority is associated with the stability and longevity of the LVAD. The current heart allocation framework is appropriately reactive to complications associated with LVADs and other mechanical circulatory support devices (MCSD). Such complications are accounted for within adult heart statuses 2 and 3. Nonetheless, the allocation framework does not proactively address the development of MCSD-related complications and associated mortality over time. The Committee members agreed that additional priority should be given to candidates who are supported by a durable MCSD the longer they are listed for transplant, regardless of whether a device complication is experienced. Published research indicates that for patients with durable MCSD, the hazard ratio for mortality increases over time, regardless of the presence or absence of device complications.[43,44,45,46] Additionally, the longer someone is supported by a MCSD, the greater the likelihood of developing a device-related complication that can impact patient survival and/or candidacy for transplant.

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[42] Clerkin et. al., "Impact of Temporary Percutaneous Mechanical Circulatory Support Before Transplantation in the 2018 Heart Allocation System," *J Am Coll Cardiol HF*, 2021;10:12-23.
[43] Imad M. Hariri et al., "Long-Term Survival on LVAD Support: Device Complications and End-Organ Dysfunction Limit Long-Term Success," T*he Journal of Heart and Lung Transplantation* 41, no. 2 (2022): 161–70, https://doi.org/10.1016/j.healun.2021.07.011.
[44] James K. Kirklin et al., "Eighth Annual INTERMACS Report: Special Focus on Framing the Impact of Adverse Events," *The Journal of Heart and Lung Transplantation* 36, no. 10 (2017): 1080–86. https://doi.org/10.1016/j.healun.2017.07.005.
[45] Palak Shah et al., "Twelfth Interagency Registry for Mechanically Assisted Circulatory Support Report: Readmissions After Left Ventricular Assist Device," *Ann Thorac Surg* 113, no. 3 (2022): 722–37, https://doi.org/10.1016/j.athoracsur.2021.12.011.
[46] Jeffrey J. Teuteberg et al., "The Society of Thoracic Surgeons Intermacs 2019 Annual Report: The Changing Landscape of Devices and Indications," *Ann Thorac Surg* 109, no. 3 (2020): 649–60. https://doi.org/10.1016/j.athoracsur.2019.12.005.

The Committee proposes giving such candidates additional priority within the medical urgency attribute by allocating an additional percentage of points on the rating scale for each year a candidate is assigned to adult status 4 while having an implanted LVAD. The Committee members concurred that such candidates would receive an additional five percentage points on the priority rating scale for each year of assignment. The additional benefit would be capped at six years of waiting at status 4 with an implanted LVAD, or a total of 30 additional percentage points. The members also agreed that the candidates will be allowed to keep the additional percentage points regardless of whether a candidate is assigned to status 4 or any other status. Furthermore, the Committee discussed whether such candidates should be allowed to receive more medical urgency priority points than candidates assigned to the highest medical urgency grouping. The Committee seeks community feedback concerning the question.

In making their decision to provide additional priority to candidates supported by the MCSDs, the Committee also cited the following circumstances. Improving the feasibility of LVAD as a bridge to transplant will improve patient and medical provider acceptance of the use of durable LVAD for advanced heart failure patients who may not achieve rapid transplant. Given quality of life constraints on present durable MCSD, the patient's willingness to undertake durable MCSD support based on the transplant program's recommendation deserves to be recognized.

The Committee recommended that the level of priority be continuous in nature and in proportion to the candidate's time supported by the MCSD. Nonetheless, a peak will likely need to be established for those experiencing extreme durations of support.

Table 4 represents the Committee's early attempt to think about medical urgency groupings. These are very preliminary groupings, and the Committee is aware that they will need to make greater analysis and community input before a policy proposal is developed.

Table 4: Potential Medical Urgency Groupings for Consideration

Medical Urgency Grouping	Percentage of Priority Points	Adult Criteria	Pediatric Criteria[a]
1	100%	ECMO, Non-dischargeable VAD, MCSD and arrhythmia	ECMO (1A EB), SVAD (1A EO), VAD with life threatening arrhythmias (1A EO)
2	60%	Non-dischargeable LVAD, TAH, MCSD+malfunct., perc. endo. MCSD, IABP	CHD on inotropes (1A), Ductal dependent Single V (stent or PGE1) (1A), Inotrope and vent dependent (1A, EB), nondischargeable VAD (1A), Poor VAD cand: RCM/HCM inpatient <10kg (1Ae EB), inotropes inpatients <10kg (1Ae)
3	> 60% - ≤ 41%	None	Severe CAV inpatient (1Ae), RCM/HCM on HD inotropes or syncope etc or PVR>6 Wui (1Ae), single ventricle other complications inpatient (1Ae)
4	40%	LVAD and complication, inotropes w monitoring	Inpatient dischargeable VAD (1A), DCM high dose inotropes inpatient (1Ae), HCM/RCM inpatient other (1Ae)
5	> 40% - ≤ 21%	None	Outpatient VAD, < 1.3m^2 (1A, EO)
6	20%	LVAD, inotropes wo monitoring, HCM, RCM, CHD, Re-Tx, IHD w angina	Outpatient VAD >1.3m^2 (1A, EO), Congenital Heart Disease (adult 4), Fontan complications outpatient (1Be), severe CAV outpatient w/ stent/CABG (1Be)
7	10%	Multi-organ Tx	Multiple organ listing, not meeting higher criteria
8	0%	Others	Other pediatric candidates, not meeting higher criteria

Notes: The medical urgency groupings represent most urgent (1) to least urgent (8). EB indicates pediatric heart candidates who have proposed higher levels of medical urgency because of Evidence Basis of excess waitlist mortality. EO indicates pediatric heart candidates whose medical urgency groupings are adjusted based on the experience and expertise of the Committee. Candidates who qualify for exceptions according to OPTN-approved guidance documents are indicated by "e."
[a] The identified pediatric criteria reflect a combination of criteria identified in OPTN policy, circumstances identified in OPTN-approved guidance documents, and the experience and expertise of the Committee, particularly the members who are pediatric heart surgeons and cardiologists. The criteria and associated medical urgency grouping should strictly be considered as the Committee's preliminary effort at categorization prior to any simulation modeling being performed.

Reducing Biological Disadvantages

NOTA requires the OPTN to consider candidates "whose immune system makes it difficult for them to receive organs,"[47] and the OPTN Final Rule calls for allocation policies to "promote patient access to transplantation."[48] Some candidates have difficulty finding a suitable donor due to biological incompatibilities and the OPTN has long used different mechanisms to equalize access to transplant for biologically disadvantaged candidates, such as CPRA in kidney allocation and prioritizing candidates with specific blood types for certain donors.

The Committee identified one attribute in the current allocation system that aims to reduce biological disadvantage – candidate blood type. As part of their earliest discussions of potential attributes, the Committee also identified sensitization, or how likely rejection of non-self Human Leukocyte Antigens

[47] 42 U.S.C. § 274(b)(2)(A)(ii).
[48] 42 C.F.R. § 121.8(a)(5).

(HLA) is to occur, as biological disadvantage that should be addressed as part of the initial iteration of heart continuous distribution.

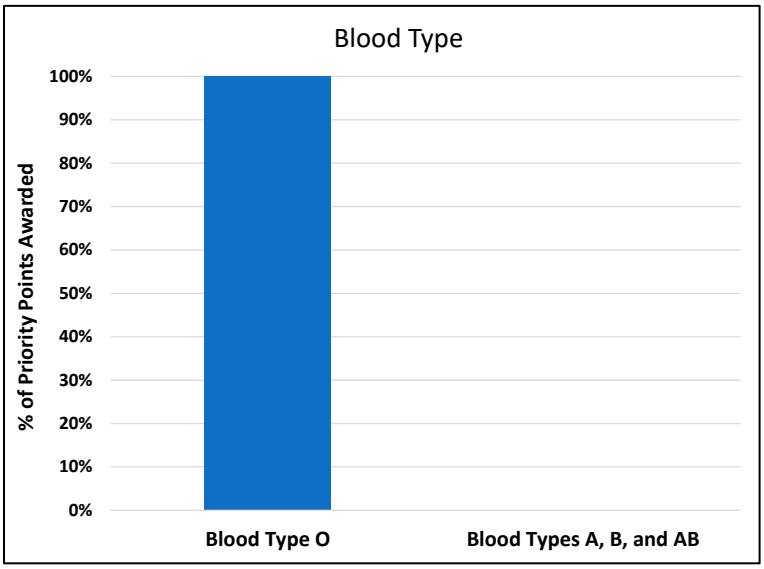
Blood Type

Blood type plays two roles in current policy. The first role is patient safety: certain blood types are only compatible with certain other blood types. Death can occur if an organ with an incompatible blood type is transplanted into a recipient. The second role is to promote equity in access to transplant as mentioned above. Screening rules for compatibility can achieve the patient safety goal while this attribute aims to address issues of equity.

In the current allocation system, blood type is a factor associated with both the candidate and the donor. Heart policy classifies candidates according to primary and secondary blood type groups. In addition, pediatric candidates who meet certain criteria are eligible for compatible blood type donor organs, as well as intended incompatible (ABOi) blood type donor organs. Current policy does not provide additional priority for candidates based solely on blood type.

As part of their deliberations involving how to prioritize blood type, the Committee decided that for the first attempt at determining how much priority to give, that blood type O candidate would receive 100 percent of the priority points, as shown in **Figure 4**. The members pointed out that blood type O candidates face the toughest competition for donor hearts and that blood type AB candidates are at a huge advantage in terms of access to donor hearts.[49]

Figure 4: Potential Rating Scale for Blood Type Attribute[50]



[49] Meeting Summary for September 22, 2023 meeting, OPTN Heart Transplantation Committee, https://optn.transplant.hrsa.gov/media/4dgpvbr5/20230922_optn-heart_meeting-summary_final.pdf (Accessed December 8, 2023).

[50] Meeting Summary for September 22, 2023 meeting, OPTN Heart Transplantation Committee, https://optn.transplant.hrsa.gov/media/4dgpvbr5/20230922_optn-heart_meeting-summary_final.pdf (Accessed December 7, 2023).

An analysis of the ratio of heart candidates ever waiting to eligible donors recovered in 2022 by blood type underscores this point. According to the analysis, the ratio of blood type O candidates to compatible blood type donors was 1.905, so almost two candidates for every compatible donor heart. On the other end of the spectrum, the ratio of blood type AB candidates to eligible donors was calculated as 0.063, so every blood type AB candidate had access to multiple donor hearts.

Based on the results of the analysis, the Committee considered adopting a scale by which blood type O candidates would receive 100 percent of the prioritization, blood type A candidates would receive substantially less priority, followed by blood type B candidates with even less priority. Finally, blood type AB candidates, the group eligible for all blood type donor hearts, would receive zero percent of the prioritization.

During that discussion, the Committee began to coalesce around the importance of ensuring that blood type O candidates' access to donor hearts is protected by the rating scale. As a result, that meant potentially scaling the prioritization given to blood type O candidates so high that other blood type candidates could not overcome that priority. Ultimately, the Committee decided to advance as a primary option providing all of the prioritization to blood type O candidates, and giving candidates with other blood types no priority. All of the Committee's efforts at determining how much priority to give are preliminary. Final values are all contingent upon simulation modeling, which will occur sometime in the future. The issue of seeking equity in access regardless of a candidate's blood type occurs across multiple organs. Optimization and simulations from other organs can help the OPTN and the Committee identify an optimal rating scale for hearts and a consistent approach to use across the organs.

Sensitization

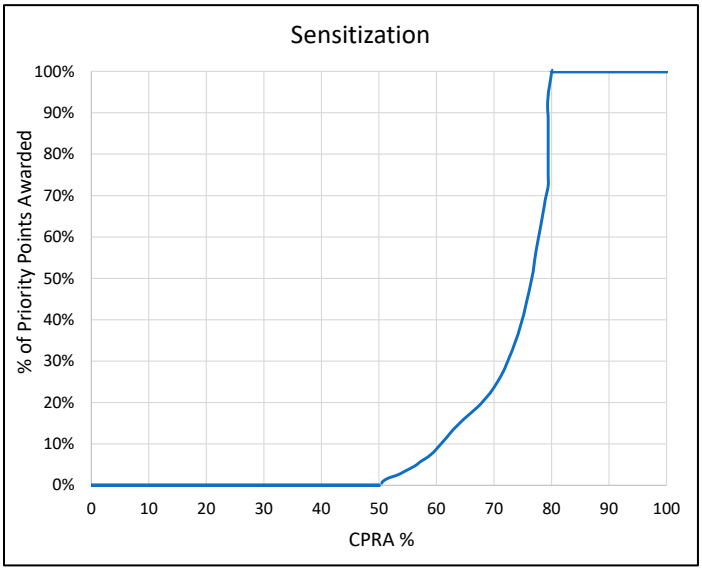
Antigens, also known as human leukocyte antigens (HLA), are proteins on most cells in the body that act as genetic identification labels. The immune system uses HLA to distinguish itself from foreign peptides. When a candidate has antibodies to non-self HLA, the candidate is considered "sensitized." Such antibodies could destroy a newly transplanted donor organ. Sensitization is a major challenge in organ transplantation because its presence can restrict a candidate's access to the donor pool resulting in longer wait times, and subsequently increased risk of waitlist mortality.[51] Calculated panel reactive antibody (CPRA) values are a measurement of sensitization that directly estimate the proportion of donors with which an HLA-sensitized candidate is HLA incompatible.

CPRA is included as an attribute in lung continuous distribution and is used in the current kidney allocation framework. However, CPRA is not currently used in heart allocation policy, in part because of the challenges associated with establishing an evidence-based threshold for what constitutes a "highly sensitized" candidate. The Committee expressed an interest in prioritizing sensitized candidates in the first version of heart continuous distribution. Similar to other organs, candidates would qualify for priority when their transplant programs list the unacceptable antigens in the OPTN Computer System. Because listing unacceptable antigens results in a candidate being excluded from match runs involving donors with those HLA types, this approach incentivizes programs to list only those truly clinically significant antigens.

[51] Monica M. Colvin et al., "Sensitization in Heart Transplantation: Emerging Knowledge: A Scientific Statement From the American Heart Association," *Circulation*, 2019; 139:e553-e578. https://doi.org/10.1161/CIR.0000000000000598.

During Committee deliberations regarding how to build the sensitization rating scale, members agreed to start with a piecewise scale, potentially similar to the one shown in **Figure 5**. With the understanding that current decisions are contingent on future data modeling, members agreed that candidates whose sensitization is less than 50 percent would receive no prioritization, as reflected by the first segment of the scale. The next segment of the scale is where priority points start being awarded for candidates whose sensitization is at least 50 percent, and candidates whose sensitization is just below 80 percent, will be awarded almost all of the priority points available. Candidates whose sensitization is calculated at 80 percent or greater would be awarded 100 percent of the available prioritization points. The Committee members noted that the decision to use a 50 percent sensitization threshold for candidates to start receiving points was supported by data showing an increased risk of removal from the waitlist for candidates with a CPRA greater than 50 percent. It was suggested that the curve should be steep above 80 percent sensitization, with candidates getting sharply more points as sensitization increases past that point. The Committee emphasized the importance of including sensitivity in the model and determining the shape of the distribution curve for allocation points. It was further pointed out that that modeling could help shape the curve to align with the Committee's goals. Similar to the shape of the blood type rating scale, this issue occurs across multiple organs. Optimization and simulations from other organs can help the OPTN and the Committee identify an optimal rating scale for hearts and a consistent approach to use across the organs.

Figure 5: Potential Rating Scale for Sensitization Attribute[52]



Patient Access

The OPTN Final Rule requires allocation policies to "promote patient access to transplantation,"[53] and NOTA requires the OPTN to "recognize the differences in health and in organ transplantation issues between children and adults throughout the system and adopt criteria, polices, and procedures that

[52] Meeting Summary for September 22, 2023 meeting, OPTN Heart Transplantation Committee, https://optn.transplant.hrsa.gov/media/4dgpvbr5/20230922_optn-heart_meeting-summary_final.pdf (Accessed December 7, 2023).

[53] 42 C.F.R. § 121.8(a)(5).

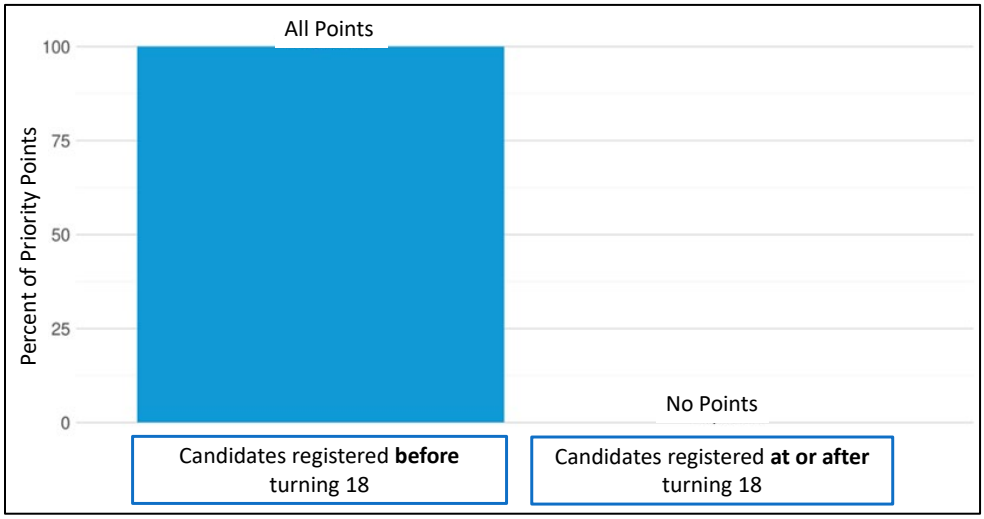
address the unique health care needs of children."[54] Accordingly, the patient access goal is intended to ensure appropriate access to transplant for all heart transplant candidates. Within patient access, the Committee identified several factors for consideration as attributes that will be discussed in this section.

Priority for Pediatric Candidates

Pediatric heart candidates receive some additional priority in the current allocation framework. For example, pediatric candidates experience limited access to donor hearts as a result of the lack of suitable donors. To increase access, pediatric candidates as a group are included in some of the higher classifications for receiving offers involving adult donor hearts. After consideration, the Committee members agreed to provide additional priority to pediatric candidates as part of heart continuous distribution. The prioritization for being a pediatric candidate is provided in addition to the priority for medical urgency the Committee determined to provide pediatric candidates. Therefore, the Committee determined that pediatric candidates receive a certain among of priority for medical urgency, which was previously discussed, and also receive additional priority for being pediatric.

The Committee is proposing that pediatric candidates receive a set amount of priority points based solely on being registered on the waiting list prior to turning 18 years old (**Figure 6**). This is consistent with the recommendations of the OPTN Pediatrics Committee and the discussions from the other organ specific committees that are transitioning to continuous distribution. The intent is to continue seeking ways to increase pediatric candidates' access to donor hearts. Consistent with other organs, the Committee agreed to use a binary rating scale (yes or no). Therefore, candidates who are less than 18 years old at the time of registration will receive the full benefit associated with the attribute. As under current policy, a pediatric candidate (e.g., a candidate registered prior to turning 18 years old) would maintain the status even after turning 18 years old as long as they remain on the waiting list with no breaks in their registration. Candidates registered on the day they turn 18 years old or later receive no benefit.

Figure 6: Proposed Rating Scale for Pediatric Priority



[54] 42 U.S.C. § 274(b)(2)(M)

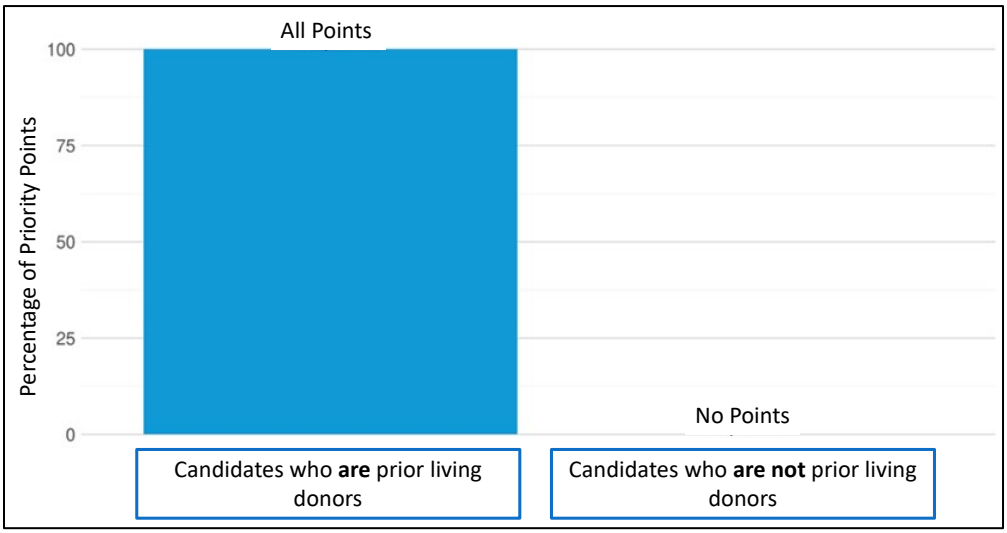
A question was raised that use of a binary rating scale does not account for differences in the time candidates have been registered on the waiting list, and as a result, may disadvantage candidates with greater waiting time. As part of their work, the Committee identified waiting time as a separate attribute for inclusion in the first iteration of the continuous distribution allocation framework, and the attribute will prioritize candidates based on waiting time.

Priority for Prior Living Donors

The Committee also decided to provide priority in the allocation system for prior living donors. In the current heart allocation system, prior living donors are not provided any form of additional priority. However, in the current kidney allocation system all prior living donors, regardless of which organ they donated, receive priority. Similarly, continuous distribution of lungs includes additional points for prior living donors, again, regardless of which organ the candidate previously donated. Prioritizing prior living donors previously was supported by the OPTN Ethics and OPTN Living Donor Committees.[55,56] Further, both ethical and legal justifications for providing a form of priority for prior living donors were identified during the development of the continuous distribution of lungs framework.[57]

Consistent with other organs, the Committee agreed to use a binary rating scale (yes or no) for prioritizing prior living donors. Candidates who are prior living donors will receive the full benefit associated with the attribute. All other candidates will receive no benefit. **Figure 7** reflects the Committee's proposed rating scale for the priority for prior living donor attribute.

Figure 7: Proposed Rating Scale for Priority for Prior Living Donors



During the July – September 2023 public comment period, the Ethics Committee raised questions about whether CD of hearts should provide additional consideration for prior living donors. Ethics Committee members were concerned that giving additional priority to prior living donors may affect candidate

[55] Meeting Summary for March 11, 2021, OPTN Ethics Committee, https://optn.transplant.hrsa.gov/media/4533/20210311_ethics_meeting_summary.pdf (Accessed May 25, 2023).
[56] Meeting Summary for May 12, 2021, OPTN Living Donor Committee, https://optn.transplant.hrsa.gov/media/4656/20210512_ldc_summary.pdf (Accessed May 25, 2023).
[57] *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).

populations unequally, especially minority and marginalized populations that typically have lower rates of living donation.[58] The Ethics Committee added that giving priority to living donors who are listed for a different organ than they previously donated may require additional consideration.[59] After considering the Ethics Committee's feedback, the Committee decided to keep the prior living donor attribute unchanged.

Placement Efficiency

The OPTN Final Rule does not define the "efficient management of organ placement." [60] However, the Federal Register preamble of the OPTN Final Rule can provide some guidance for interpreting this clause. It states:

> Broad geographic sharing should not come at the expense of wasting organs through excessive transportation times. Efficient management of organ allocation will sometimes dictate less transportation when the highest-ranking patient can wait a day or two for the next available organ. Sound medical judgment must be exercised before a final decision on whether to transplant a particular organ into a particular patient.[61]

The placement efficiency goal encompasses the number of resources required to identify a suitable candidate willing to accept the organ and procure the organ for transplant.

Placement efficiency is factored into the current heart allocation system by using concentric circles and prioritizing candidates closer to the donor hospital when other factors are similar. However, the Committee has an opportunity to consider the impact of placement efficiency in a more nuanced way within continuous distribution.

It is important to reiterate that the goal of continuous distribution is smarter distribution, not necessarily broader distribution of hearts. One intent of continuous distribution is to remove the hard boundaries between classifications in the current allocation system, such as concentric circles. Removing these concentric circles does not necessarily mean that continuous distribution will result in hearts being allocated over larger areas for all donors and candidates; instead, continuous distribution should permit broader access for the most urgent candidates and more localized allocation for organs that cannot travel as far. The transition to a points-based framework allows the Committee and the community to consider the impact of placement efficiency with more precision.

The Committee has identified proximity efficiency as an attribute within the placement efficiency goal. Proximity efficiency was included within the continuous distribution of lungs policy that was recently approved by the OPTN Board of Directors and implemented in March 2023, and is being considered as an attribute by the other committees developing continuous distribution allocation frameworks.

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[58] OPTN, Public Comment webpage, *Continuous Distribution of Hearts Concept Paper*, OPTN Ethics Committee comments submitted September 7, 2023, https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/continuous-distribution-of-hearts/#ProposalComments, (accessed November 13, 2023).
[59] OPTN, Public Comment webpage, *Continuous Distribution of Hearts Concept Paper*, OPTN Ethics Committee comments submitted September 7, 2023.
[60] 42 C.F.R. §121.8(a)(5).
[61] 63 FR 16315 (1998).

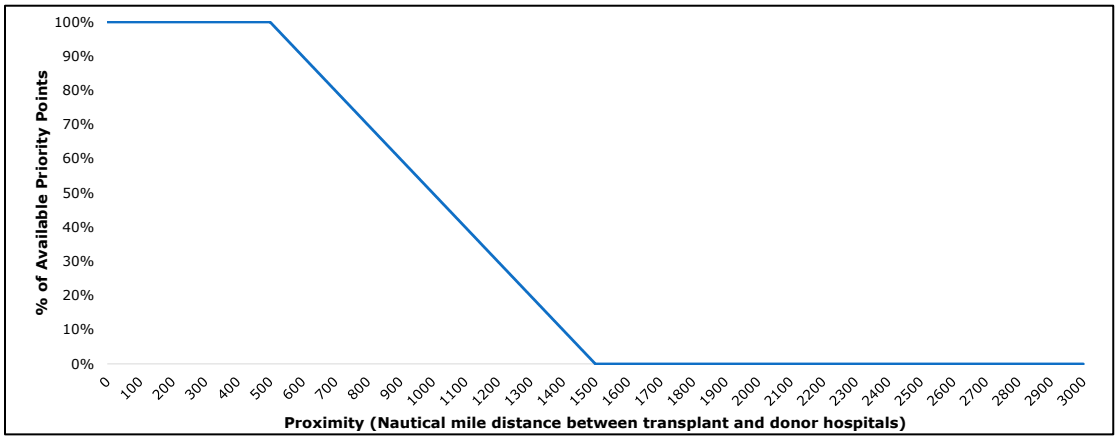
The recently established OPTN Expeditious Taskforce has begun discussions regarding other methods to improve the efficiency of the organ placement system and additional metrics of efficiency. The kidney and liver committees are discussing additional attributes related to these discussions. While the recovery and placement of thoracic organs differs from abdominal organs, some of these attributes might be useful to improve the efficiency of the heart placement system. If so, they could be discussed by the Committee in the future.

Proximity Efficiency

Importantly, geographic proximity (e.g., distance between donor and transplant candidate's hospital) may be considered to the extent necessary to satisfy requirements in the Final Rule. This includes consideration of the efficient management of organ placement and the avoidance of futile transplants due to increased ischemic time.[62] The proximity efficiency attribute measures the efficiency of transporting hearts shorter distances as opposed to decreased transportation costs. These include differences such as the time in transit for transplant teams, additional effort required to coordinate longer travel, and differences in the chance of something going wrong in transit the farther the personnel and heart must travel. The Committee will consider how to incorporate this attribute in the continuous distribution-based system and is seeking community feedback on the topic.

The Committee has initially determined that a piecewise linear rating scale best represents the priority they want assigned to a proximity efficiency attribute (**Figure 8**). The Committee developed a rating scale consisting of three linear segments.[63] The first segment extends from zero to 500 nautical miles (NM). In this segment, candidates located 500 NM or less receive 100 percent of the available priority points. In current heart allocation policy, 500 NM is also used in the first classification rows, so in that way the Committee's choice continues that amount. The next segment is represented linearly. Prioritization decreases linearly from 500 NM to 1,500 NM. The third and final segment starts at 1,500 NM and extends to the greatest distance possible. Candidates whose transplant hospital is 1,500 NM miles or more from the donor hospital receive no priority points.

Figure 8: Sample Proximity Efficiency Rating Scale



Note: June 20, 2023, OPTN Heart Transplantation Committee meeting.

[62] 42 C.F.R. § 121.8(a)(8).

[63] Meeting Summary for June 20, 2023 meeting, OPTN Heart Transplantation Committee, https://optn.transplant.hrsa.gov/media/rmjf4lns/20230620_optn-heart-committee_meeting-summary_final.pdf (accessed November 12, 2023).

The Committee concurred that there is little difference between driving and flying when procuring donor hearts, and that is more likely a program will fly for a donor heart. According to several Committee members, this is true for transplant programs in major urban areas where a transplant program is likely to travel by helicopter rather than drive as a result of potential traffic issues. Committee members also agreed that an important consideration of their proximity efficiency attribute is limiting programs from traveling great distances to obtain organs. Members cited the median distance traveled in the three-year monitoring report as evidence that the allocation policy changes implemented in October 2018 and the subsequent changes implemented with the removal of DSA as an allocation factor have resulted in a generally acceptable travel distance with the heart transplantation community.[64] As previously stated, all of the Committee's preliminary decisions will go through optimization and simulation analyses in order for the Committee to consider what changes might result.

Attributes Considered, But Not Included at This Time

Throughout the Committee's development of potential attributes, the members have been particularly focused on including attributes they anticipate having a substantial benefit for a new allocation framework while also being more easily incorporated into such a framework. From the project's outset, transitioning the current classification-based system into a points-based system was expected to be extremely challenging. As a result, the Committee has recognized a need to limit the first iteration of continuous distribution of hearts to those attributes that would add benefit without increasing complexity of the project.

Post-Transplant Survival

The OPTN Final Rule calls for allocation policies "to avoid futile transplants."[65] This is accomplished, in part, by improving long-term survival after transplant. The lung continuous distribution allocation framework includes a post-transplant survival attribute addressing a candidate's likelihood of survival for five years after receiving a transplant. There appears to be increased community support, especially among patients, patient families, and donor families, that post-transplant survival should be addressed in each of the initial continuous distribution allocation frameworks.[66, 67] It was brought to the Committee's attention that members of the OPTN Board of Directors have had conversations about attributes like post-transplant survival, and outcomes generally.[68]

As part of their earlier deliberations pertaining to a post-transplant survival attribute, the Committee identified several factors that gave them pause for addressing it now. For instance, the lack of an

[64] OPTN Descriptive Data Request, "Three-Year Monitoring of Heart Allocation Proposal to Modify the Heart Allocation System," Prepared for OPTN Heart Transplantation Committee meeting, October 11, 2022, https://optn.transplant.hrsa.gov/media/hx1pr13a/data_report_heart_committee_3yr_rpt1_508_compliant.pdf (Accessed May 9, 2023)

[65] 42 C.F.R. § 121.8(a)(5).

[66] Meeting Summary for March 29, 2023 meeting, OPTN Heart Transplantation Committee, https://optn.transplant.hrsa.gov/media/hkgcif42/20230329_heart_in-person-meeting-summary-final.pdf (Accessed June 20, 2023).

[67] Public comment submitted by James Sharrock to the OPTN website on March 12, 2023 regarding the OPTN Liver and Intestinal Organ Transplantation Committee's document *Update on Continuous Distribution of Livers and Intestines*, https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/update-on-continuous-distribution-of-livers-and-intestines/ (accessed June 20, 2023).

[68] Meeting Summary for March 29, 2023 meeting, OPTN Heart Transplantation Committee, https://optn.transplant.hrsa.gov/media/hkgcif42/20230329_heart_in-person-meeting-summary-final.pdf (Accessed June 20, 2023).

existing heart-specific model that could be readily adapted for inclusion in continuous distribution of hearts made the Committee somewhat reluctant to move forward. Without a model that already exists and has garnered community consensus, the Committee would need to develop one on its own or adapt an existing model designed for another organ to heart. In addition, the complexity associated with how to integrate such a model in CD also contributed to the Committee suggesting the attribute be addressed in the future. For instance, should such a model use 1-year, 3-year, or 5-year survival outcomes, and how might that choice impact the medical urgency attribute? The role of mechanical devices in heart policy makes it difficult to create such a model because of how devices can be combined with medications to create multiple therapeutic treatment alternatives. It was pointed out that the Lung Committee was able to rely on the post-transplant outcome model that existed as part of the Lung Allocation Score when they created their continuous distribution allocation framework. In contrast, the Liver and intestine Committee initially chose not to include a post-transplant attribute with their first iteration of continuous distribution, in part, because no model existed. Subsequent to that decision, a model was identified that could potentially be adapted for use in liver allocation policy, and the Liver and Intestine Committee was considering it more closely.[69] The Committee also stated that including post-transplant survival in this version of continuous distribution could have unintended consequences. For instance, it was pointed out if a transplant program is under the impression that its program-specific score will be impacted by a post-transplant survival metric, the program may make strategic priority decisions that reduce candidate access to transplantation.

It was suggested that the Committee could make a commitment to review data that is believed to be associated with post-transplant survival on a regular timeframe. The Committee could also consider if the outcome information provided in the monitoring report is sufficient, or if more data elements should be collected. The Risk Stratification Data (RSD) collected on the justification forms was intended to inform a Heart Allocation Score, similar to the prior Lung Allocation Score, and includes data fields associated with post-transplant survival. It was mentioned that the Committee could request the RSD data be analyzed with the intention of creating a post-transplant outcome model; however, given the time needed to develop and test such a model, it still might not be available for inclusion in this first version of continuous distribution.

Still, the Committee members agreed that it was important to ask for community feedback during the July – September 2023 public comment cycle as to whether an attribute for post-transplant survival should be included in the first version of a continuous distribution allocation framework. The responses received during public comment were mixed about whether to include such an attribute now, or as part of a future version of continuous distribution of hearts. Among the comments, eight respondents addressed the question, with five indicating it should not be addressed as part of this iteration; and three indicating it should be. Feedback from those opposed to its inclusion cited the lack of available data and/or metrics by which to measure post-transplant survival success among heart and heart-lungs recipients. Others highlighted the lack of a validated model for survival. The American Society of Transplantation (AST) was among those against including it in the first iteration. AST recommended that the Committee review the new French heart allocation system which accounts for donor and recipient variables that are used, along with other considerations, to assess post-transplant survival.[70] Another commenter was against inclusion now, because “the cardiology community does not have a single

[69] Meeting Summary for April 3, 2023 meeting, OPTN Liver and Intestinal Organ Transplantation Committee, https://optn.transplant.hrsa.gov/media/0bvligm5/20230403_lic_summary_final.pdf (Accessed June 20, 2023).
[70] C. Jasseron et al., “Impact of the New French Heart Allocation System on Post-Transplant Mortality,” *The Journal of Heart and Lung Transplantation*, 40, no. 4 (2021): S252-S252. https://doi-org.proxy.library.vcu.edu/10.1016/j.healun.2021.01.720

survival calculation that accounts for all cardiology patients. The survival calculations have changed and grown over the years, but they don't take into consideration a lot of factors like inotropes, LVAD's or newer medications."

Among those who favored inclusion of a post-transplant survival attribute with the first iteration of heart continuous distribution, one respondent pointed out that it could potentially "limit the application of temporary support devices with less positive impact on post-transplant outcomes than placement of more durable VADs."

Generally, the respondents suggested that the Committee should:

- Initiate an effort to develop a post-transplant survival metric for inclusion in a future iteration of continuous distribution of hearts.
- Identify and collect the data elements most appropriate to help optimize patient outcomes.
- Consider whether different categories of recipients should be represented by different metrics, given that survival varies across centers and sometimes within various subsets of diagnoses.

Following the July – September public comment cycle, the Committee revisited their decision and agreed that the lack of data and existing models recommend not including a post-transplant attribute for the allocation system's first iteration. However, they did agree that it was appropriate to include as part of the Values Prioritization Exercise. Including it in the VPE permits the community to weigh in on the relative importance of post-transplant outcomes in a future iteration of CD of hearts,.

The Committee acknowledges the importance of including such an attribute as part of a continuous distribution allocation framework at some point in the future. The Committee will continue having conversations about such an attribute as they move forward with their work, but those conversations are likely to focus on identifying potential models that might fit the heart community's needs. The Committee still seeks community feedback as part of this document and through the Values Prioritization Exercise. The Committee is interested in existing models or solutions that could be adapted for use in heart allocation, especially where there is consensus around the validity of such models. In addition, the Committee is interested in feedback from donor families and patients and their families and caregivers about how important post-transplant survival is to them as a factor in a future composite allocation score.

Priority for Candidates Whose Stature Makes It Challenging to Find Suitable Donor Organs

During public comment, five respondents suggested including some amount of priority for candidates whose size makes it difficult to find a match. The OPTN Pediatric Transplantation Committee's comment stated that while all children deserve allocation priority, there are specific considerations for patient access and waitlist mortality that may be better captured with the ability to include age and weight in the allocation scheme. The Pediatric Committee further stated that the use of total cardiac volume could serve as a proxy for size matching. Another respondent asked if size matching of pediatric candidates should be considered to accommodate both age and size of such candidates.

The Committee also considered these comments, and like post-transplant survival decided prioritizing such candidates is not appropriate. Several Committee members stated that the issue is that candidates whose very large or very small stature makes finding suitable donor organs difficult will only be competing against each other for such organs. Such candidates are unlikely to compete against average-

sized adults for organs. Therefore, any priority they would receive does not increase their access to more donor hearts. The Committee concurred that development of a prioritization attribute is unwarranted for this group of patients. Moreover, they agreed that it should not be included as part of the Values Prioritization Exercise.

NOTA and Final Rule Analysis

The Committee submits this request for feedback document 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,"[71] 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."[72] This request for feedback identifies potential OPTN policy changes that will result in a more equitable, agile, and transparent 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."[73] 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:[74] 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.

Seek to achieve the best use of donated organs:[75] 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:[76] In this case, hearts.

[71] 42 U.S.C. § 274(b)(2)(B).
[72] 42 C.F.R. § 121.4(a)(1).
[73] 42 C.F.R. § 121.8(a).
[74] 42 C.F.R. § 121.8(a)(1).
[75] 42 C.F.R. § 121.8(a)(2).
[76] 42 C.F.R. § 121.8(a)(4).

Are designed to avoid wasting organs:[77] The Committee included the proximity effiency 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:[78] 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:[79] The Committee will consider indicators of efficiency associated with procuring and transplanting hearts, including travel costs and the proximity between the donor and transplant hospitals. Additionally, work from the Expeditious 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]:[80] 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:[81] A points-based framework will facilitate the use of transition procedures for existing candidates. For example, the OPTN may be able to compare the policy proposal with modeling to determine who is impacted and if there is a need for transition procedures. 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.

Conclusion

In August 2022, the Committee began developing a continuous distribution allocation framework, to transition away from the classification-based system currently in place. Continuous distribution implements a composite allocation score to prioritize candidates that simultaneously considers candidate and donor attributes. The attributes reflect the Committee's decisions on how best to prioritize heart patients on the waiting list. The points-based allocation system that continuous distribution represents will create a more equitable and transparent allocation system. The purpose of the concept paper is to educate the community on continuous distribution, provide an update on the

[77] 42 C.F.R. § 121.8(a)(5).
[78] 42 C.F.R. § 121.8(a)(5).
[79] 42 C.F.R. § 121.8(a)(5).
[80] 42 C.F.R. § 121.8(a)(8).
[81] 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.

progress the Committee has made on the project thus far, and solicit feedback from the community on the Committee's work to date.

As noted throughout the concept paper, the Committee is still in the initial stages of this project and no decisions or recommendations have been finalized. For this cycle, the Committee is most interested in community participation in the Values Prioritization Exercise to inform the relative importance of the different attributes. This information will help guide the Committee in the optimization of the system. The Committee is also focused on deciding which attributes to include in the first version of continuous distribution. Therefore, the Committee is interested in community feedback on the proposed attributes. At later points in the development of the project, the Committee will seek more specific feedback on rating scales, weights, and other operational aspects of the effort.

Considerations for the Community

The OPTN Heart Transplantation Committee seeks feedback regarding the following questions:

- Should candidates assigned to adult heart status 4 using the LVAD criterion be allowed to receive a higher percentage of medical urgency priority points than candidates assigned to the highest medical urgency rating groups, such as candidates on VA ECMO?
- Are the attributes the Committee has identified for inclusion in the first version of the continuous distribution of heart allocation framework appropriate? Do you agree with the Committee's decision to include each attribute in the first version of Heart CD? Why or why not?
- Are there other attributes that the Committee should consider when developing the first version of the continuous distribution of heart allocation framework, and why? What data analysis of information is available to support their inclusion?
- Considering the individual attributes, what information should the Heart Committee use to evaluate success toward the outcome of that specific attribute?
- Are there any allocation factors or attributes in current heart allocation policy that should not be included in the first version of continuous distribution? Why?
- From the patient, donor, family perspective, what do you consider to be the most key factors for allocating donor hearts?

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[82]

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[83]

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

- Continuous distribution - lung[84]
- Continuous distribution - kidney and pancreas[85]
- Continuous distribution - liver and intestine[86]
- Ethical Considerations of Continuous Distribution in Organ Allocation White Paper[87]

[82] OPTN website, https://optn.transplant.hrsa.gov/policies-bylaws/a-closer-look/continuous-distribution/, Accessed November 5, 2023.
[83] OPTN website, https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/continuous-distribution-of-hearts/, November 5, 2023.
[84] OPTN website, https://optn.transplant.hrsa.gov/policies-bylaws/a-closer-look/continuous-distribution/continuous-distribution-lung/, Accessed November 5, 2023.
[85] OPTN website, https://optn.transplant.hrsa.gov/policies-bylaws/a-closer-look/continuous-distribution/continuous-distribution-kidney-and-pancreas/, Accessed November 5, 2023.
[86] OPTN website, https://optn.transplant.hrsa.gov/policies-bylaws/a-closer-look/continuous-distribution/continuous-distribution-liver-and-intestine/, Accessed November 5, 2023.
[87] OPTN Ethics Committee, *Ethical Considerations of Continuous Distribution in Organ Allocation*, https://optn.transplant.hrsa.gov/media/mjzfpb3h/ethical-considerations-of-continuous-distribution-in-organ-allocation_whitepaper.pdf, Accessed November 5, 2023.