OPTN

Concept Paper

Continuous Distribution of Hearts Concept Paper

OPTN Heart Transplantation Committee

Prepared by: Eric Messick
UNOS Policy and Community Relations Department

Contents

Continuous Distribution of Hearts Concept Paper

Sponsoring Committee: *Heart Transplantation*
Public Comment Period: *July 27, 2023 – September 19, 2023*

Executive Summary

In August 2022, the Organ Procurement and Transplantation Network (OPTN) Heart Transplantation Committee (the Committee)[1] 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, 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 that simultaneously considers candidate and donor attributes. This points-based allocation system will create a more equitable and transparent allocation system. (See the Appendix for a glossary of terms.)

The purpose of the paper is to educate the community on the concept of continuous distribution, provide an update on the progress the Committee has made on the project thus far, and solicit feedback from the community on the Committee's work to date.

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

Background

In 2018, the OPTN Board of Directors sought a consistent allocation system to use across all organs and determined 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 result in more equity for candidates on the waitlist and increased transparency in the allocation of hearts. In addition, continuous distribution also 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] Heart is the fifth organ-specific OPTN committee to begin work on developing a continuous distribution allocation framework. In March 2023, continuous distribution of lungs was implemented.[4] In addition, the OPTN Kidney Transplantation Committee and OPTN Pancreas Transplantation Committee are collaborating on a project to convert the kidney and pancreas allocation systems to continuous distribution. In December 2021, the OPTN Liver and Intestinal Organ Transplantation Committee launched a similar effort.

Purpose

The purpose of the concept paper is two-fold. First, it is intended to educate and inform the heart transplant community on what continuous distribution is and the progress the Committee has made in developing a continuous distribution framework for the allocation of hearts.

Second, the Committee seeks feedback regarding the attributes identified for inclusion in the continuous distribution of hearts allocation framework. The Committee members request input on whether these are the correct attributes for prioritizing heart candidates, and whether other attributes should be included. The Committee is also seeking the community's feedback on their progress to date, the plan for the project moving forward, and any other relevant aspects of the larger effort to develop a points-based allocation system. This is not a final policy proposal, and the Committee has not finalized any specific decisions or recommendations. With such a significant change to the allocation system, community input is particularly important, and the Committee is eager for feedback from the transplant community.

The Committee requests community feedback on the ideas presented throughout the concept paper. However, the Committee is most interested in feedback on which attributes should be included in the first iteration of the continuous distribution framework. The attributes are described in more detail in subsequent sections of the document.

[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).

What is Continuous Distribution? [5]

A continuous distribution system prioritizes candidates based on a combination of points awarded for factors related to medical urgency, expected post-transplant outcomes, candidate biology, patient access, and the efficient management of organ placement. Current heart allocation policy does not include a factor for expected post-transplant outcomes.[6] The factors are also prioritized against each other, so that the primary factor carries the greatest weight, and no single factor can preclude a candidate from obtaining a greater prioritization ranking than another candidate. Classifications preclude a candidate from being prioritized ahead of other candidates who are assigned to a higher unit of classification. This scenario can occur despite other factors that suggest the candidate should be prioritized for transplant ahead of the other candidates.[7,8] In a point-based system, candidates will be ranked on a match run based on a combination of candidate and donor clinical characteristics, as well as placement efficiency. Each match run should result in a candidate receiving a different amount of total points due to changes in candidate-donor characteristics and placement efficiency factors.

There are many complex decisions that must be made to fully realize the potential of continuous distribution, and the Committee intends to seek the community's feedback throughout the development of this project. Such feedback is critical as the Committee seeks to develop a points-based system that increases flexibility of allocation by accounting for specific candidate characteristics, rather than requiring, for example, that allocation sort *all* blood type identical candidates ahead of *all* blood type compatible candidates. In this way, the framework is agnostic as to its goals and is flexible enough to achieve the desired outcomes of the community.

The goal of continuous distribution is to convert all aspects of heart allocation that rely on distinct classifications, such as distance between the recipient and donor hospitals, to a more flexible and transparent continuous distribution system.

Composite Allocation Score

A continuous distribution framework will rank candidates by a composite allocation score, or CAS, which aligns with the different requirements found in National Organ Transplant Act (NOTA) and the OPTN Final Rule. **Figure 1** shows the five sub-scores, or goals, constituting the overall CAS. These five goals are explained in more detail below.

[5] Continuous distribution aims to create a more fair and patient-focused system for organ allocation. For additional information regarding the continuous distribution allocation framework and the work of the OPTN, visit: https://optn.transplant.hrsa.gov/policies-bylaws/a-closer-look/continuous-distribution/ (Accessed May 9, 2023).

[6] As part of the OPTN Thoracic Transplantation Committee's development of the Proposal to Modify the Adult Heart Allocation System, the Committee considered whether post-transplant survival should be considered as part of the changes. At the time, the Committee determined that the appropriate data about post-transplant data was not being collected. The Committee recommended collecting such data moving forward. See *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 June 17, 2023), p. 5.

[7] J. J. Snyder et al., "Organ distribution without geographic boundaries: A possible framework for organ allocation," Am J Transplant 18, no. 11 (Nov 2018), https://doi.org/10.1111/ajt.15115.

[8] Jon Snyder, "Systems without Geographic Boundaries". Presented to the OPTN Ad Hoc Geography Committee meeting, March 26, 2018.

Figure 1: Components of Composite Allocation Score

Note: "Candidate biology" is also referred to as "Reducing biological disadvantages."

Medical urgency score: The Final Rule requires that allocation policies "seek to achieve the best use of donated organs"[9] and requires priority of organ allocation to be based upon "objective and measurable medical criteria."[10] OPTN policies use several different approaches to prioritize candidates based upon their medical urgency specific to each organ. Within the current heart allocation system, medical urgency already plays a prominent role. OPTN policy for the allocation of hearts classifies candidates' medical condition as statuses, with the sickest candidates receiving the highest priority status.[11] In October 2018, a new adult heart allocation system was implemented, which uses six statuses to categorize adult heart candidates based on their medical urgency. Within each status are multiple criteria designed to capture the types of therapies generally used to treat candidates who demonstrate the corresponding level of clinical priority. Pediatric candidates are prioritized within a three-tiered status system.

Post-transplant survival score: The Final Rule requires the consideration of allocation policies that would avoid futile transplants.[12] In other words, a proposal should account for the likelihood of positive post-transplant survival outcomes. The organ-specific OPTN committees have chosen different ways to account for good post-transplant outcomes in their allocation policies. While OPTN lung policy specifically addresses post-transplant survival as a factor, heart policy addresses it indirectly. For example, greater ischemic time in transplanted hearts has been associated in the past with worse post-transplant survival rates.[13] OPTN heart policy accounts for ischemic time partly using the nautical mileage distance between the donor and candidate hospitals. Greater priority is given to those instances where the donor and candidate hospital are most approximate to each other. As part of their initial work, the Committee considered whether there are heart-specific attributes related to post-transplant survival that should be incorporated into the first version of a heart continuous distribution system. The Committee will continue exploring such options moving forward.

Reducing biological disadvantages score: The Final Rule calls for allocation policies to "promote patient access to transplantation."[14] Some candidates have difficulty finding a suitable donor due to biological incompatibilities. For example, heart allocation policy uses blood type compatibility between donors and candidates as a mechanism for prioritizing primary blood type candidates

[9] 42 C.F.R. § 121.8(a)(2).
[10] *Id.*at § 121.8(b)(2).
[11] OPTN Policy 6.1, *Adult Status Assignments and Update Requirements* and OPTN Policy 6.2, *Pediatric Status Assignments and Update Requirements* (March 16, 2023).
[12] 42 C.F.R. § 121.8(a)(5).
[13] Vladimir J. Lozanovski et al., "The Impact of Major Extended Donor Criteria on Graft Failure and Patient Mortality after Heart Transplantation," *Langenbeck's Archives of Surgery* 403, no. 6 (2018): pp. 719-731, https://doi.org/10.1007/s00423-018-1704-z.
[13] 42 C.F.R. § 121.8(a)(5).
[14] 42 C.F.R. § 121.8(a)(5).

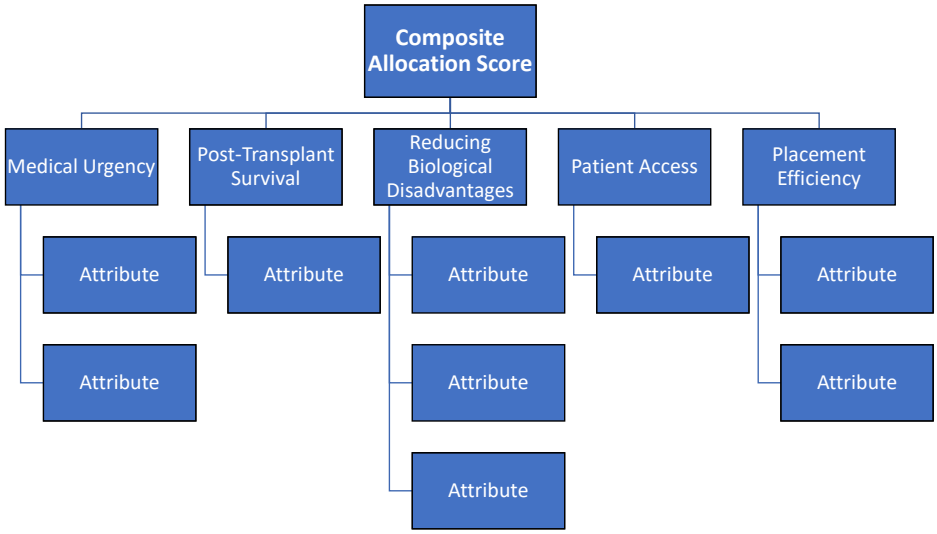
ahead of secondary blood type candidates.[15] Another example of reducing biological differences in transplantation access includes the calculated panel reactive antibodies (CPRA) sliding scale found in lung, kidney, and pancreas allocation policy.[16]

Patient access score: The Final Rule requires allocation polices be designed to "promote patient access to transplantation."[17] Additionally, NOTA requires that allocation policies "recognize the differences in health and in organ transplantation issues between children and adults throughout the system and adopt criteria, policies, and procedures that address the unique health care needs of children."[18] The prioritization of pediatric candidates in heart allocation and the prioritization of prior living donors in kidney allocation are examples of current OPTN policies that are designed to promote patient access to transplantation.[19]

Placement efficiency score: The Final Rule requires that organ allocation policies be designed to promote the "efficient management of organ placement."[20] Many things impact efficiency, such as the time it takes from organ offer to final acceptance, travel time between the transplant program and the donor hospital, and the costs associated with organ procurement and travel.

These five goals form the basis of the continuous distribution framework. Within each goal, the Committee has identified different attributes. Each attribute prioritizes candidates based on what the attribute is designed to accomplish. Candidates are assigned a certain number of points or a percentage of total points for each attribute. The attributes are then weighed against each other to calculate a CAS for each individual candidate at the time of the match run. Collectively, the attributes are used to form the CAS, which can be likened to a hierarchy, as depicted below in **Figure 2**.

Figure 2: CAS Hierarchy Depiction



[15] OPTN Policy 6.6.A, *Blood Type Matching Priority for Heart Offers.*
[16] OPTN Policy 8.2, *Table 8-2: Points for CPRA.*
[17] 42 C.F.R. § 121.8(a)(5).
[18] 42 U.S.C. § 274(b)(2)(M).
[19] OPTN Policy 8, *Allocation of Kidneys.*
[20] 42 C.F.R. § 121.8(a)(5).

Combining multiple attribute scores allows the OPTN to simultaneously utilize all the factors that must be considered to satisfy the regulatory requirements for organ allocation policies. It will also allow the OPTN to understand the role of each attribute score across organs. For example, some organ systems may place more weight on medical urgency than other organs. Finally, by constructing the CAS around the attributes, which are aligned with performance goals in the OPTN Final Rule, the rationale for compliance will more explicitly align with the requirements in the OPTN Final Rule.[21]

Figures 3 and 4 show how the current heart allocation system functions and how a potential heart allocation system utilizing a CAS could work. This is just a rough example and should be considered only for illustrative purposes. The figures depict how candidates could receive points for different attributes, which are then combined to calculate the overall CAS. The number of points given to each candidate would depend upon the candidate's specific situation, the rating scale for that attribute, and the amount of weight given to the attribute within the overall CAS.

Figure 3 depicts the current classification-based system which precludes all candidates in a lower classification from being prioritized ahead of any candidates in a higher classification, irrespective of other factors. For example, in the current allocation system, classifications are built around adult and pediatric heart statuses, blood type compatibility, and distance between the transplant hospital and the donor hospital. In this system, a candidate with an identical blood type to the donor will always be ranked ahead of a candidate with a compatible blood type when the two candidates are in the same allocation classification and have the same heart status assignment, irrespective of other factors.

Figure 3: Sample Allocation Policy (Current)

6.6.D Allocation of Hearts from Donors at Least 18 years Old

Hearts from deceased donors at least 18 years old are allocated to candidates according to *Table 6-7* below.

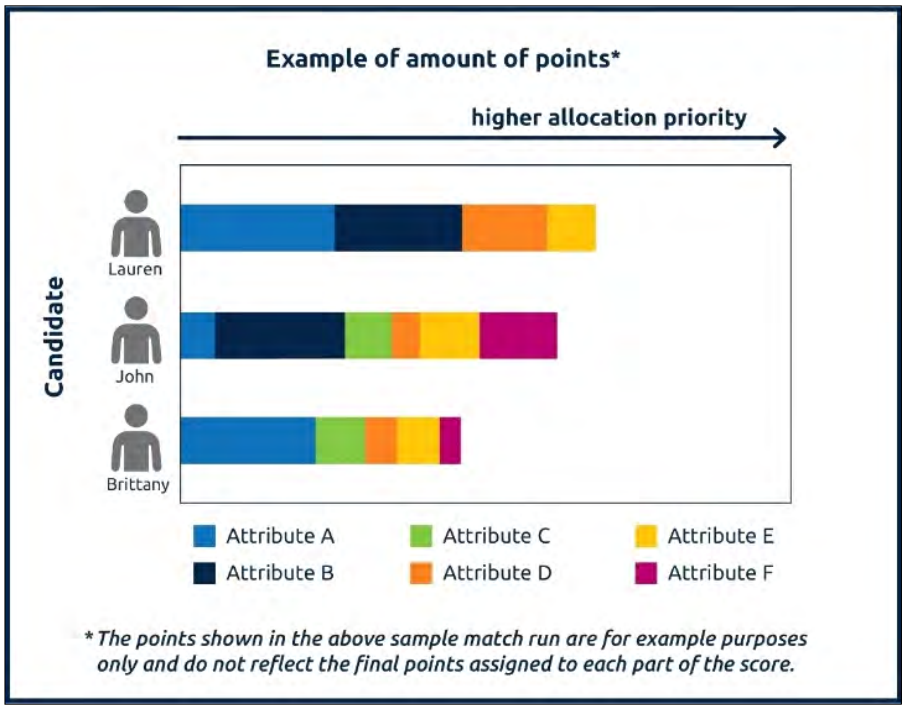
Table 6-7: Allocation of Hearts from Deceased Donors At Least 18 Years Old

Classification	Candidates that are within the	And registered at a transplant hospital that is at or within this distance from the donor hospital
1	Adult status 1 or pediatric status 1A and primary blood type match with the donor	500NM
2	Adult status 1 or pediatric status 1A and secondary blood type match with the donor	500NM
3	Adult status 2 and primary blood type match with the donor	500NM
4	Adult status 2 and secondary blood type match with the donor	500NM
5	Adult status 3 or pediatric status 1B and primary blood type match with the donor	250NM
6	Adult status 3 or pediatric status 1B and secondary blood type match with the donor	250NM
7	Adult status 1 or pediatric status 1A and primary blood type match with the donor	1000NM
8	Adult status 1 or pediatric status 1A and secondary blood type match with the donor	1000NM
9	Adult status 2 and primary blood type match with the donor	1000NM
10	Adult status 2 and secondary blood type match with the donor	1000NM
11	Adult status 4 and primary blood type match with the donor	250NM
12	Adult status 4 and secondary blood type match with the donor	250NM

[21] 42 C.F.R. § 121.8.

Figure 4 demonstrates how a points-based allocation system could prioritize candidates. (Figure 4 is for illustrative purposes only.) The figure is intended to show how the number of points given to a candidate varies depending upon the candidate's specific circumstances and donor characteristics in a points-based system. Each color represents a different attribute, and the length of the bar shows the points credited to that attribute. Candidates receive points for multiple considerations and can move up or down depending on each attribute. Under continuous distribution, classifications will no longer be used, and the allocation system will take a more nuanced approach to such cases by incorporating attributes using a points-based framework that considers multiple candidate characteristics simultaneously.

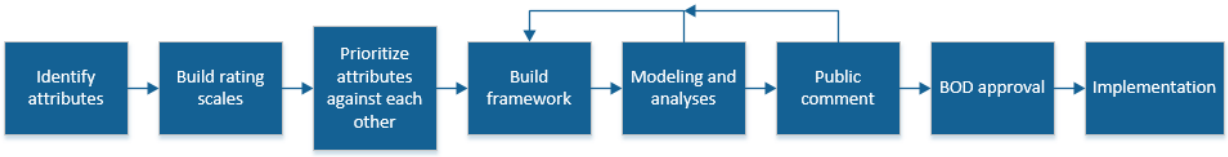
Figure 4: Example of a Composite Allocation Score Match Run



Project Plan

The Committee is tasked with developing a comprehensive proposal for the continuous distribution of hearts, an effort that represents perhaps the most significant change to heart allocation policy. This initial effort is largely focused on translating current policy into a continuous distribution framework, with the understanding that future refinements will be necessary. At the same time, it is equally important to recognize the benefit of moving quickly to the new allocation framework because it lends itself better when it comes to accommodating such dynamic changes. The project will progress through several phases, as seen in **Figure 5**. Each step is explained in more detail below.

Figure 5: Project Overview



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.[22] 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 primary focus of the project is converting the current system to continuous distribution, the Committee recognized the opportunity to improve the allocation system through the inclusion of other important allocation factors, these will be discussed in more detail later in the concept paper. The Committee focused its early efforts on developing the list of attributes and is close to finalizing the list for inclusion in the first iteration of continuous distribution.

Attributes meeting the following criteria should be considered for inclusion in the first version 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

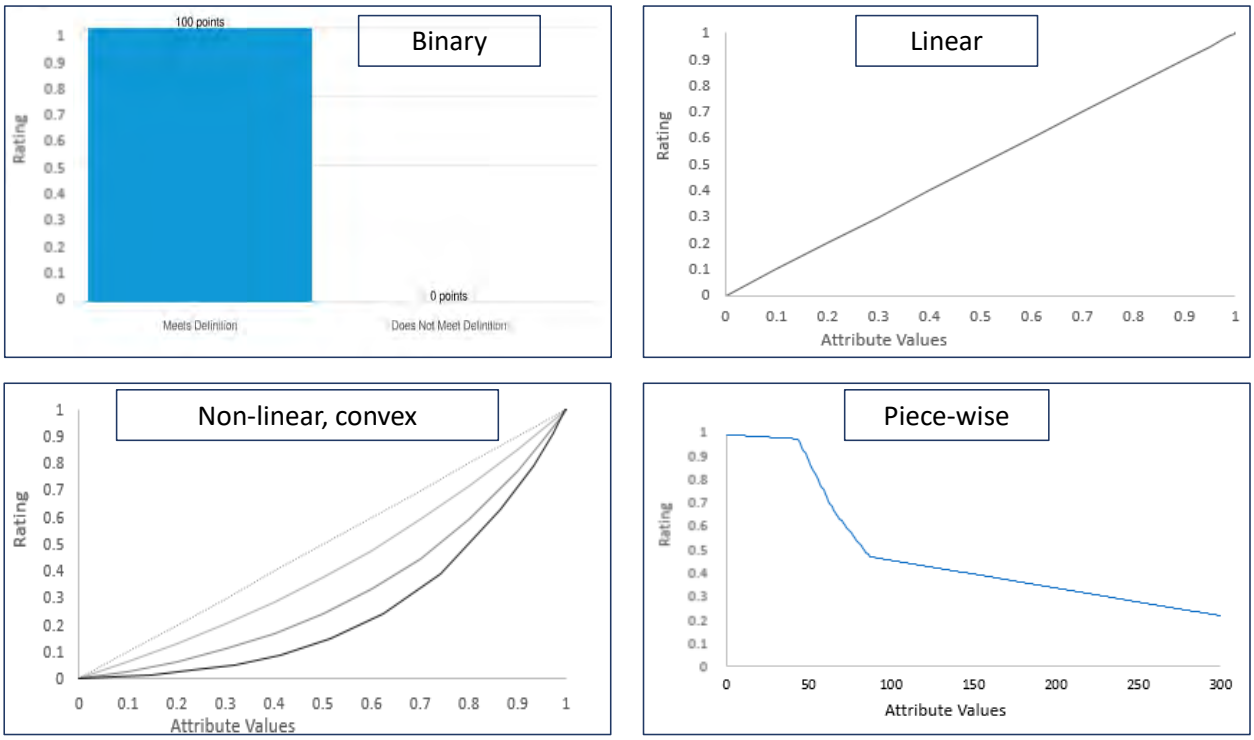
At the same time, it is not possible to include every potential attribute in the first version of continuous distribution. Potential attributes that would require new data collection, analysis, or consensus building, should be addressed in future version. The Committee is interested in the community's feedback on which attributes should be added to the allocation system.

Build Rating Scales: Every attribute requires a method to distinguish candidates according to that attribute's purpose – otherwise known as a rating scale. Developing a clear purpose and rating scales for each attribute is the Committee's next task.[23] Generally speaking, rating scales represent how points will be assigned to individual candidates for each attribute. **Figure 6** 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.[24] The Committee will construct rating scales for each of the attributes included in the continuous distribution of hearts. These rating scales will be built from objective clinical or operational data as much as possible. In some cases, they may have to rely on the

[22] Attributes are criteria used to classify then sort and prioritize candidates. Refer to *Appendix: Glossary of Terms* for more information.
[23] Rating scales describe how much preference are provided to candidates within each attribute. Refer to *Appendix: Glossary of Terms* for more information.
[24] 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, not relative to the maximum number of total composite allocation score points.

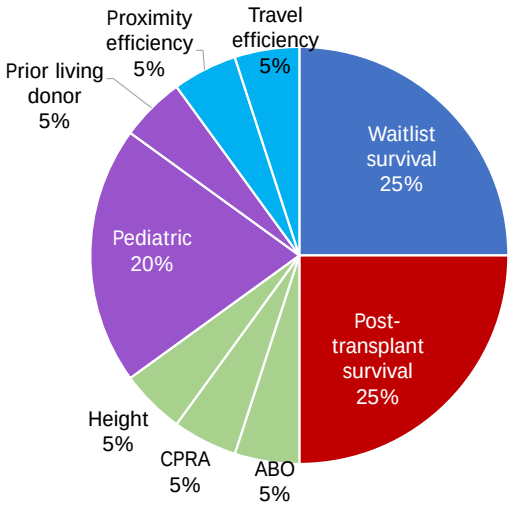
Committee's experience and/or expertise. In addition to each purpose, the Committee will identify a metric of success for each attribute. This metric is used to evaluate the success of different rating scales. Later, the metric is used to identify optimized policy scenarios and evaluate the success of the system.

Figure 6: Examples of Rating Scales



Prioritize Attributes Against Each Other: 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. For example, **Figure 7** shows the weights assigned to each attribute and goal within the lung continuous distribution allocation system.

Figure 7: Percent of Lung Composite Allocation Score (by Attribute)



Attribute	Attribute Weight
Waitlist survival	**25%**
Post-transplant survival	**25%**
ABO	**5%**
CPRA	**5%**
Height	**5%**
Pediatric	**20%**
Prior Living Donor	**5%**
Placement Efficiency	**5%**
Travel Efficiency	**5%**
Total	**100%**

The Committee will utilize a number of tools to inform the discussion about attribute weights. The larger transplant community will be asked for their input via a structured exercise, called the values prioritization exercise (VPE).[25] 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.[26,27,28] The Committee will utilize additional tools and consult with other subject matter experts as needed throughout this process.

Build Framework: After constructing the attribute rating scales and determining the weights, the Committee will create a single comprehensive allocation framework. In addition to attributes, rating scales, and weights, the Committee will also need to consider how to incorporate donor factors, as well as operational components like screening and review boards. The committee will work with experts in mathematical optimization to iterate through thousands of potential policy scenarios and identify optimal scenarios that meet the community's needs.

Modeling and Analysis: The Committee will then submit their proposed framework to the Scientific Registry of Transplant Recipients (SRTR) for allocation simulation modeling analysis to understand the impact of the proposal on candidates and recipients. The Committee will review the results and use them to finalize decisions when developing a policy proposal. If not satisfied with the predicted outcomes, the Committee can consider tweaking the framework and re-submitting for additional modeling.

---

[25] OPTN, *Continuous Distribution,* Help build the framework. Available at https://optn.transplant.hrsa.gov/policies-bylaws/a-closer-look/continuous-distribution/#CD_BuildTheFramework.
[26] Darren E. Stewart et al., "A Revealed Preference Analysis to Develop Composite Scores Approximating Lung Allocation Policy in the U.S.," *BMC Medical Informatics and Decision Making* 21, no. 1 (June 2021), https://doi.org/10.1186/s12911-020-01377-7.
[27] Theodore P Papalexopoulos et al., "Ethics-by-Design: Efficient, Fair and Inclusive Resource Allocation Using Machine Learning," *Journal of Law and the Biosciences* 9, no. 1 (January 2022), https://doi.org/10.1093/jlb/lsac012.
[28] 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.

Public Comment: Once SRTR modeling is complete and the Committee is supportive of the proposed policy framework, the proposal will be submitted for public comment. If community feedback suggests that the framework needs additional work, the Committee could again revise the proposal and submit it again for public comment at a future date.

BOD Approval and Implementation: After public comment feedback is considered and if the proposal is finalized by the Committee, the proposal will move to the BOD for final consideration and approval. Once approved by the BOD, the proposal will be implemented in the OPTN computer system. Any new data collection could require OMB approval and delay the implementation of the proposal.

At multiple steps throughout the project, the OPTN will provide education to and solicit feedback from the transplant community. These outreach efforts include the release of this concept paper and will continue through the lifecycle of this project.

Progress So Far

The Committee began discussing a continuous distribution allocation framework for hearts in August 2022 and is currently in the first phase of identifying attributes related to heart allocation. The major goal of this concept paper is to present the list of attributes identified to date and obtain community feedback about the appropriateness of their inclusion. More details on the Committee's discussions can be found in the subsections below. Specific feedback questions for the community appear in the Conclusion section.

Identifying Attributes

As part of the first phase of the project, the Committee reviewed the five goals used across organs to organize the continuous distribution discussion. These goals and their definitions are outlined in **Table 1** below.

Table 1: Goals for Heart Continuous Distribution Allocation

Goals	Medical Urgency	Post-Transplant Survival	Reducing Biological Disadvantages	Patient Access	Placement Efficiency
	Prioritize those with highest risk of mortality on the waitlist	Increasing graft and recipient post-transplant survival	Increase transplant opportunities for candidates who are medically harder to match	Appropriate transplant access for all candidates	Consider resource requirements required to match, transport, and transplant an organ

The Committee reviewed how other organ systems categorized their attributes. Members then undertook a similar effort to identify and categorize attributes that are specific to heart allocation. The Committee started by identifying attributes that exist in the current heart allocation policy, before discussing attributes that are not currently in policy but should be considered for inclusion in the continuous distribution framework. **Table 2** shows a list of the attributes and their associated goal as identified by the Committee. The attributes are further grouped by those attributes in current policy

versus those attributes not in current policy, which will be considered for inclusion in the continuous distribution framework.

Not every attribute listed in the table will be included in the first iteration of continuous distribution of hearts. Currently, the Committee is reviewing available data and literature to determine which attributes can and should be incorporated into the first version of continuous distribution. Post-transplant survival as a potential attribute is discussed in more detail later in the concept paper. Importantly, the Committee seeks community feedback on the identified attributes (and those not identified in the concept paper) to assist in the future Values Prioritization Exercise.

Table 2: OPTN Heart Transplantation Committee Identified Attributes

	Medical Urgency	Post-Transplant Survival	Reducing Biological Disadvantages	Patient Access	Placement Efficiency
In Current Policy	• Adult statuses • Pediatric statuses • Re-transplant		• Blood type	• Waiting time • Priority for pediatric candidates	• Distance between transplant and donor hospitals
Not in Current Policy	• Congenital heart disease • Hypertrophic/Restrictive cardiomyopathy • Cardiac Allograft Vasculopathy • Waiting time on Left Ventricular Assist Devices		• Sensitization	• Priority for prior living donors	

Medical Urgency

The OPTN Final Rule calls for allocation policies to "seek to achieve the best use of donated organs."[29] 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 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…"[30]

Within current policy, the Committee identified the following attributes related to medical urgency:

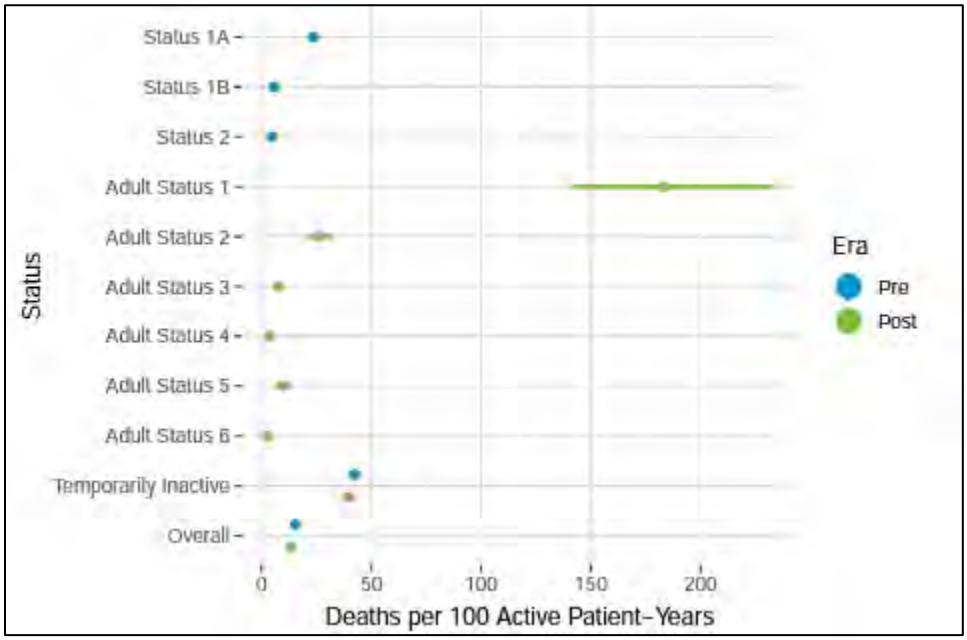
[29] 42 C.F.R. § 121.8(a)(2).
[30] 42 C.F.R. § 121.8(b)(2).

Adult Heart Status

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. 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.

As part of the Committee's work to date 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.[31] For example, **Figure 8** indicates the waitlist mortality rates associated with the adult heart statuses reported in the Four-Year monitoring report. The pre-implementation era represents October 18, 2015 – October 17, 2018, and the post-implementation era represents October 18, 2018 – October 17, 2022. 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.[32]

Figure 8: Deaths per 100 Active Patient-Years Waiting by Adult Medical Urgency Status and Era



[31] 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.

[32] 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

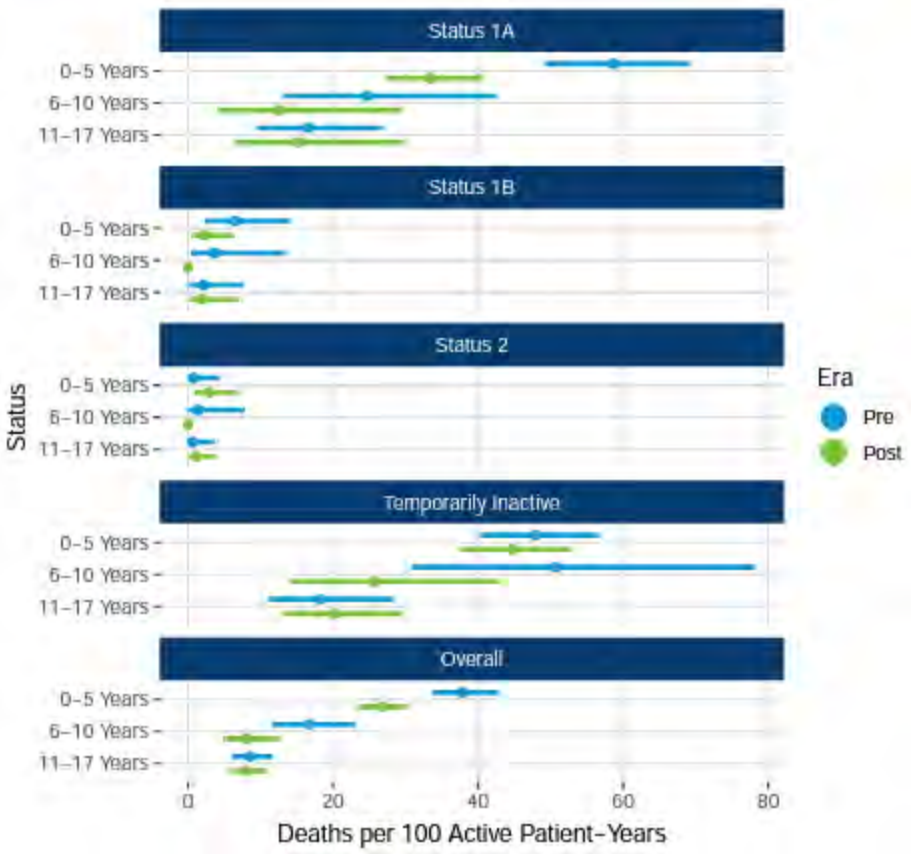
Note: Pre-era represents October 18, 2015 – October 17, 2018. Post-era represents October 18, 2018 – October 17, 2022.

Pediatric Heart Status

Heart allocation policy better stratifies the medical urgency of adult candidates than it does pediatric candidates. Adult candidates' medical urgency is captured across six statuses. By contrast, pediatric candidates are classified within three statuses. 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. 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. **Figure 9** 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.

Figure 9: Deaths per 100 Active Patient-Years Waiting by Pediatric Medical Urgency Status and Era



Note: Pre-era represents October 18, 2015 – October 17, 2018. Post-era represents October 18, 2018 – October 17, 2022.

Status 1A is comprised of five criteria, of which hospital admission is an eligibility requirement of four. 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. According to the Committee members, although grouped under a single status, the status 1A criteria represent substantially different levels of urgency, beyond whether or not hospitalization is involved. The Committee, with assistance from OPTN Pediatric Committee members and other professionals in the pediatric heart community, have already begun mapping a conversion of the criteria within statuses 1A and 1B into 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.[33] 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.

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 better stratifying pediatric candidates by their clinical conditions will have similar positive results.[34] 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. Critically ill children of smaller sizes (measured as body surface area) can have wait times of 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 high risk of waitlist mortality, but do not have adequate mechanical or medical support options available to them.

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

[33] 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).
[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 June 20, 2023).

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.

Congenital Heart Disease (CHD) and Hypertrophic and Restrictive Cardiomyopathy (HCM/RCM)

As part of the heart allocation policy changes implemented in October 2018, the Heart Committee (then the OPTN Thoracic Transplantation Committee[35]) created guidance documents to assist the adult heart regional review boards with standardizing decision-making for adult CHD exception requests. 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.[36] The guidance document contains recommendations for which status priority a transplant program should request based upon established clinical criteria. A guidance 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 addressed 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.

Re-Transplant and Cardiac Allograft Vasculopathy (CAV)

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.[37] 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.

Waiting Time Accrued With an Implanted Ventricular Assist Device (VAD)

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 for mortality increases over time, regardless

[35] 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.
[36] 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).
[37] 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.

of the presence or absence of device complications.[38,39,40,41] Additionally, the longer someone is supported by a MCSD, the greater the hazard of developing a device-related complication that can impact patient survival and/or candidacy for transplant.

In making their decision to provide additional priority to candidates supported by the MCSDs, the Committee members also cited the following circumstances. 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. 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.

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. The Committee members asked for additional information related to the waiting time rating scale previously considered by the Pancreas Committee. That scale consists of a linear rating scale up to a threshold value, that then converts to a curved rating scale.[42] Candidates below the threshold receive priority in a linear fashion. Candidates above the threshold receive priority more slowly based on the curve.

Post-Transplant Survival

The OPTN Final Rule calls for allocation policies "to avoid futile transplants."[43] 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.[44,45] 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.

---

[38] 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.

[39] 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.

[40] 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.

[41] 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.

[42] *Public Comment Committee Update: Update on Continuous Distribution of Kidneys and Pancreata*, OPTN Kidney & Pancreas Transplantation Committees, August 3, 2022 – September 28, 2022, pp. 22-23, https://optn.transplant.hrsa.gov/media/ha2mpuor/continuous-distribution-of-kidneys-and-pancreata_comm-update_summer-2022.pdf.

[43] 42 C.F.R. § 121.8(a)(5).

[44] Meeting Summary for March 29, 2023 meeting, OPTN Heart Transplantation Committee, https://optn.transplant.hrsa.gov/media/hkqcif42/20230329_heart_in-person-meeting-summary-final.pdf (Accessed June 20, 2023).

[45] 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).

While there is no factor for post-transplant survival in the current heart allocation system, the Committee acknowledges the importance of such an attribute as part of a continuous distribution allocation framework. To date, the Committee discussed the advantages and disadvantages of creating a post-transplant survival attribute for inclusion in the first version of continuous distribution of hearts. More conversations will occur in the future. As part of this concept paper, the Committee is seeking the community's feedback on whether post-transplant survival should be a factor in the first version of Heart CD, and if so, how might such an attribute be incorporated. In particular, 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.

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 existing heart-specific model that could be readily adapted for inclusion in continuous distribution of hearts made the Committee members 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. 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, current OPTN liver policy does not have a post-transplant survival model, and that the Liver Committee was initially thinking they would not address outcomes as part of their initial continuous distribution effort. After those discussions a post-transplant model for liver has been published that the Committee will likely consider.[46]

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. As was described previously, there are advantages to first transitioning the existing framework to a continuous distribution allocation framework and then changing components of the framework to take advantage of the improved efficiencies of policy development and implementation.

[46] 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).

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

Blood Type

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.

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.[49] 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.

---

[47] 42 U.S.C. § 274(b)(2)(A)(ii).
[48] 42 C.F.R. § 121.8(a)(5).
[49] 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.

Patient Access

The OPTN Final Rule requires allocation policies to "promote patient access to transplantation,"[50] 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 address the unique health care needs of children."[51] 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 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. 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. All other candidates will receive no benefit. 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 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 is supported by the OPTN Ethics and OPTN Living Donor Committees.[52,53] Further, there are both ethical and legal justifications for providing a form of priority for prior living donors.[54]

---

[50] 42 C.F.R. § 121.8(a)(5).
[51] 42 U.S.C. § 274(b)(2)(M)
[52] 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).
[53] 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).
[54] *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).

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.

Waiting Time

The Committee is still considering the most appropriate way to address candidate waiting time as part of heart continuous distribution. Under the current allocation system, waiting time for heart candidates begins when the candidate is first registered as an active candidate on the waiting list.[55] Candidates are sorted within each classification by the total amount of waiting time that the candidate has accumulated at that status.[56] Waiting time does not accrue while a candidate is inactive, and this applies to adult and pediatric candidates.[57] The Committee may modify this approach so that waiting time reflects the total amount of time spent on the waiting list, whether it was at an active or inactive status. The Lung Committee chose to use total waiting time as a composite allocation score tiebreaker as part of lung continuous distribution.[58] However, both the Kidney and Pancreas Committees are considering addressing waiting time as individual attributes in their respective continuous distribution allocation frameworks.

Placement Efficiency

The OPTN Final Rule does not define the "efficient management of organ placement." [59] 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.[60]

The placement efficiency goal encompasses the amount 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

[55] OPTN Policy 6.5, *Waiting Time.*
[56] OPTN Policy 6.6.C, *Sorting Within Each Classification.*
[57] OPTN Policy 6.5, *Waiting Time.*
[58] *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).
[59] 42 C.F.R. §121.8(a)(5).
[60] 63 FR 16315 (1998).

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.

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.[61] 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.

Next Steps

As described previously, the Committee is still in the early phases of this project and much work remains to be done. The Committee recently began considering the methods by which they would prioritize candidates within each of the attributes they identified. The Committee may be able to benefit from the methods and rating scales created by the other OPTN Committees developing continuous distribution allocation frameworks.

Again, the primary goal of this project is to convert the current classification-based system into a points-based framework. While the Committee has largely established the specific attributes they want to include in the first version of heart continuous distribution, they are not precluded from re-considering those chosen attributes. Furthermore, the Committee has the opportunity to include new attributes, such as post-transplant survival, as they continue developing the new allocation system. Revising identified attributes or considering new attributes must be tempered against the reality that it is not feasible to incorporate every possible attribute into this first version of heart continuous distribution. Any attempt to do so would delay the immediate benefits of transitioning to a continuous distribution framework.

Also, like the other organs transitioning to continuous distribution, the Committee expects to work with experts in mathematical optimization to understand the tradeoffs between the attributes and select the optimal combination of rating scales and weights.[62,63] The Committee has begun to focus its work on the inputs that will go into the mathematical optimization tool. At a high level, for each attribute, the

[61] 42 C.F.R. § 121.8(a)(8).
[62] Theodore P Papalexopoulos et al., "Ethics-by-Design: Efficient, Fair and Inclusive Resource Allocation Using Machine Learning," *Journal of Law and the Biosciences* 9, no. 1 (January 2022), https://doi.org/10.1093/jlb/lsac012.
[63] 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.

Committee will need to determine a specific outcome measure to quantify the impact of the attribute in the optimization tool and decide on a general method by which points will be assigned for each attribute. Ultimately, mathematical optimization will identify the policies which most closely achieve the Committee's desired outcomes. The Committee will use all available data and subject matter expertise throughout these steps, and will continue to seek community feedback as the project progresses.

Once the Committee constructs rating scales and attribute weights, they will then build the overall framework for the continuous distribution system.

Additional Considerations

In addition to the attributes, the Committee must address the operational aspects of moving from a classification-based system to a points-based system. For example, the Committee must evaluate the existing adult and pediatric status exception process into continuous distribution. Transplant programs can submit exception requests on behalf of their candidate for assignment at a specific status when the program believes, based on accepted medical criteria that a candidate's medical urgency and potential for benefit is not accurately captured by the standard criteria. The review board framework – or chiefly the ability of transplant programs to request changes to their candidates' prioritization and for that request to be evaluated by a group of peers – is an important part of current heart allocation. The ability of a candidate to receive the level of priority commensurate with his or her clinical condition will remain an important aspect of heart continuous distribution. The Committee will continue to utilize some form of review board to evaluate instances where a candidate's clinical situation is not appropriately represented by their CAS. It is also an important consideration in the other continuous distribution frameworks being developed. As a result, maintaining consistency across the frameworks is equally important.

The Committee will also address situations where recipient and donor factors currently combine as a factor in heart allocation. For instance, priority is given to candidates at transplant hospitals closer to the donor hospital in current policy. Similarly, whether a candidate is considered a primary or secondary blood type match with the donor is integral in determining the candidate's classification priority. The Committee has not yet discussed how to incorporate such donor factors in the heart continuous distribution system. However, they will have the opportunity to adjust attribute rating scales and/or weights based on different donor factors. The OPTN Kidney and Pancreas Committees have been considering how to address donor factors in their continuous distribution allocation frameworks, and the Committee may be able to build upon those ongoing efforts.

NOTA and Final Rule Analysis

The Committees submit this concept paper under the authority of 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."[64] 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

[64] 42 C.F.R. § 121.4(a)(1).

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."[65] While this paper does not propose policy changes at this time, the concepts presented in this paper:

Are based on sound medical judgment:[66] 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:[67] 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:[68] In this case, hearts.

Are designed to avoid wasting organs:[69] The Committee identified multiple attributes specifically designed to increase donor 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:[70] 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:[71] 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.

[65] 42 C.F.R. § 121.8(a).
[66] 42 C.F.R. § 121.8(a)(1).
[67] 42 C.F.R. § 121.8(a)(2).
[68] 42 C.F.R. § 121.8(a)(4).
[69] 42 C.F.R. § 121.8(a)(5).
[70] 42 C.F.R. § 121.8(a)(5).
[71] 42 C.F.R. § 121.8(a)(5).

Not be based on the candidate's place of residence or place of listing, except to the extent required [by the aforementioned criteria]:[72] 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:[73] 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 the results of a revealed preference analysis and 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 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 early stages of this project and no decisions or recommendations have been finalized. The Committee has primarily focused on deciding which attributes to include in the first version of continuous distribution. Therefore, the Committee is most 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.

The Heart Committee seeks feedback on the following questions:

- 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?
- Should the Committee create an attribute for post-transplant survival for inclusion in the first version of the continuous distribution of heart allocation framework? Why or why not? What, if any, predictive models should the Committee consider for use?
- 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?

[72] 42 C.F.R. § 121.8(a)(8).

[73] 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.

- 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 important factors for allocating donor hearts?

Appendix: 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.