At a glance

<u>Concept Paper</u>: Continuous Distribution of Lungs
<u>Sponsoring Committee</u>: OPTN Thoracic Organ Transplantation Committee

You may be interested in this concept if:

- You work for a transplant program
- You work for an OPO
- You are a transplant candidate or a family member of a transplant candidate

Here's the purpose of this document

In December 2018 the OPTN Board of Directors approved the continuous distribution framework for all organ allocation systems. Continuous distribution will prioritize waiting list candidates based on a combination of points awarded for factors related to medical severity, expected post-transplant outcome, the efficient management of organ placement, and equity. Continuous distribution will eliminate hard boundaries, which currently preclude a patient from being prioritized ahead of patients on the other side of the boundary.

Why this may matter to you

This model will eliminate hard boundaries and classifications that many people are accustomed to. It will also enable dynamic multi-factor allocation policies.

Tell us what you think about

- Do you understand the advantages of a points-based system versus the current classification-based system?
- Are there other measures of the efficient management of organ placement that should be taken into account in a points-based framework?
- What other issues should be considered to convert other organ systems to a points-based framework?
- What factors should be incorporated into the allocation of lungs within a continuous distribution framework?

OPTN

Concept Paper

Continuous Distribution of Lungs

OPTN Thoracic Organ Transplantation Committee

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Continuous Distribution of Lungs

Sponsoring Committee: *OPTN Thoracic Organ Transplantation Committee*
Public Comment Period: *August, 2, 2019 – October, 2, 2019*

Executive Summary

In December 2018, the OPTN Board of Directors selected continuous distribution for all organs. Continuous distribution will prioritize candidates on the match run based on a combination of points awarded for factors related to medical priority, expected post-transplant outcome, the efficient management of organ placement, and equity. Continuous distribution will eliminate hard boundaries, such as being more than 250 nautical miles from the donor hospital, which currently preclude a patient from being prioritized ahead of patients on the other side of a boundary.

This concept paper builds upon the work by the Ad Hoc Geography Committee and establishes a framework for the replacement of our current classification-based allocation system with a points-based allocation system. This framework is built on a new composite allocation score that weighs the OPTN final rule requirements that apply to the OPTN allocation system. All final rule requirements must be satisfied. Competing factors must be weighed such that the OPTN Board of Directors is satisfied that all of the regulatory requirements are all satisfied. This framework is intended to result in more equity for patients; more transparency into the allocation system; and more efficiency in developing organ allocation policies, implementing those policies, and achieving the goals of those policies. While the OPTN Thoracic Organ Transplantation Committee (hereafter, the Committee) and this paper focus on lung allocation, this framework will ultimately apply to all organs and all transplant candidates. The development of this new framework will utilize clinical and operational analysis in addition to values and legal analysis. The process for developing continuous, points-based priorities may benefit from the use of structured, analytical approaches such as multi-criteria decision-making (MCDM) methods and mathematical optimization. The OPTN is currently exploring the value of how such methods may lend to this project. This concept paper explains the progress made by the Committee to date and the anticipated process to develop the remainder of the proposal for lungs.

This document is a concept paper and not a policy proposal. Therefore, the committee has not developed any specific scoring model or policy language. The primary purpose of this paper is to solicit feedback and ideas on the approach, including appropriate factors to account for in a points-based allocation system.

What problem will this concept address?

The Committee is embarking on the initial steps of developing a proposal to implement the organ distribution framework selected by the Board of Directors: continuous distribution. This framework will eventually replace the current classification-based allocation system with a points-based allocation system. The current classification-based system contains several hard boundaries that inhibit optimal distribution. In selecting the continuous distribution framework, the Ad Hoc Geography committee noted the advantages of distance based circles for allocation over the use of DSA/regional boundaries for allocation; however, they also noted the potential inequities in geographic distribution caused by the use of distance based circles. (See below for examples.) We anticipate continuous distribution will ultimately result in more equity for patients in addition to more transparency into the system as well as efficiencies in policy development.

Ad Hoc Geography Committee & Unified Framework

The Ad Hoc Geography Committee was formed in December 2017 to examine the geographic distribution of organs. The Board charged the Committee with:

- Establishing guiding principles for the use of geographic constraints in organ allocation
- Reviewing and recommending models for incorporating geographic principles into allocation policies
- Identifying uniform concepts for organ specific allocation policies in light of the requirements of the OPTN Final Rule

On June 11, 2018, the OPTN Board of Directors adopted principles relating to geographic aspects of organ distribution to guide future organ transplant policy.[1] The Board of Directors also accepted the Ad Hoc Geography Committee's recommendation to request community feedback on the recommended distribution frameworks. The goal of the feedback was to identify a single, preferred distribution framework to be used across organs.

The OPTN currently uses multiple different frameworks to allocate organs. The Ad Hoc Geography Committee recognized "that from an overall network perspective, there is very little rationale for thoracic organs to be distributed based on a candidate's distance from the donor hospital, while all other organs are based on the candidate's location within an OPTN Region and DSA."[2] This variation in organ distribution frameworks created advantages and disadvantages for candidates based upon the distribution framework utilized for that particular organ type. Additionally, the use of a single framework would result in network efficiency (in the form of easier, consistent policy development, IT programming, and data analysis across organs). The Ad Hoc Geography Committee reviewed multiple distribution frameworks against the newly adopted Principles of Organ Distribution. In the fall of 2018, the Ad Hoc Geography Committee recommended continuous distribution as the preferred framework for all organs. The Ad Hoc Geography Committee believed that this framework best complied with the Principles of Organ Distribution and allowed a unified framework but also variation based upon organ specific clinical and operational considerations. After considering the public comment, the Board concurred with the committee and endorsed continuous distribution as the preferred framework.

[1] OPTN Ad Hoc Geography Committee, "Principles of Organ Distribution," (2018). https://optn.transplant.hrsa.gov/media/2506/geography_recommendations_report_201806.pdf.
[2] OPTN Ad Hoc Geography Committee, "Frameworks for Organ Distribution briefing paper," (2018).

As a transition step and to address immediate needs, in the summer of 2018, the organ specific committees were instructed to develop policy proposals to replace DSA and regional organ distribution using rationally-chosen and consistently applied boundaries, such as concentric circles. Multiple committees expressed interest in pursuing continuous distribution but, given the timelines set by the Board, it was impractical to develop continuous distribution frameworks in that time period. Instead, the analysis performed by those committees will help transition those organ systems first to concentric-circle based allocation and later transition to continuous distribution.

The purpose of this concept paper is to show how continuous distribution could work in lung allocation. The committee is seeking feedback and suggestions on the factors and other considerations with this model.

What is Continuous Distribution?

A continuous distribution system prioritizes waiting list candidates based on a combination of points awarded for factors related to medical priority, the efficient management of organ placement, expected post-transplant outcome, and patient access (equity). Continuous distribution will eliminate hard boundaries, which currently preclude a patient from being prioritized ahead of patients on the other side of the boundary.[3] By using this kind of calculation, there would not be hard boundaries, and candidates would be ranked on a match run based on a combination of their clinical and operational characteristics.

Composite Allocation Score

The National Organ Transplant Act of 1984, as amended, (NOTA) and the OPTN Final Rule contain multiple requirements for organ allocation policies, all of which must be addressed and balanced consistent with existing evidence and the expertise of the members of the OPTN Board and relevant committees. A continuous distribution policy would rank organ patients by a composite score that aligns with the different requirements found in NOTA and the OPTN Final Rule. Below are some potential considerations that could be included in a composite allocation score.

- **Medical urgency score:** The Final Rule requires that allocation policies "seek to achieve the best use of donated organs" and requires priority of organs based upon "objective medical criteria." OPTN policies use several different approaches to prioritize candidates based upon their medical urgency: MELD, PELD, heart statuses, etc.
- **Efficiency score:** The Final Rule requires that organ allocation policies be designed to promote the "efficient management efficiency of organ placement." The efficient management of the organ placement system can be impacted by many things. Some people have suggested that allocation systems that allocate organs quicker would lead to a more efficient system and could also decrease organ discards. There may be other factors that drive more efficient placement of organs. This model can accommodate those other factors and the committee is interested in feedback and suggestions on factors concerning the efficient management of organ placement.
- **Outcomes score:** The Final Rule requires that organ allocation policies be designed to avoid futile transplants. Another way to think about this is to consider post-transplant outcomes. OPTN policies use several approaches to consider post-transplant outcomes: EPTS, 0-ABDR, DR

[3] 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; Jon Snyder, "Systems without Geographic Boundaries" (paper presented at the OPTN Ad Hoc Geography Committee meeting, March 26, 2018).

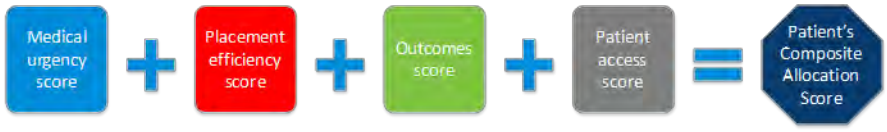
mismatch points, etc. The distance that an organ travels can impact the ischemic time on an organ which can impact the post-transplant outcomes for that transplant.

- **Patient access score:** The Final Rule requires that organ allocation policies be designed that would promote patient access to transplantation. OPTN policies use several approaches for this purpose: pediatric or age classifications, living donor priorities, multiorgan rules, calculated panel reactive antibodies (CPRA) points, median MELD at transplant (MMaT), etc.

Combining multiple scores together allows us to consider all of the factors that must be considered to satisfy the regulatory requirements for organ allocation policies. It will also allow us to understand the role of each score across the organs. (For example, do some organ systems place more importance on outcomes scores than other organs? If so, why?) Finally, by constructing the composite score around the goals in the OPTN Final Rule, the rationale for compliance will more explicitly align with the requirements in the OPTN Final Rule will be more clear.

Figures 1 and **2** shows how these scores could combine into a composite score. The committee will need to determine not only which components to include in a composite allocation score but also how much importance to place on each components. For example, one option would be four equally weighted components while another option could have more components with different weights.

Figure 1: Hypothetical Composite Allocation Score Comprised of 4 Factors with Equal Weights



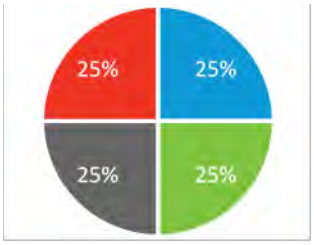
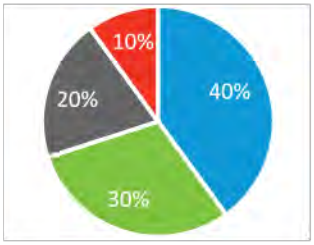


Figure 2: Hypothetical Composite Allocation Score Comprised of 4 Factors with Varying Weights



Discussions regarding continuous distribution originally focused on evolving from geographic zones to a scale for geographic distribution. Geography is currently woven throughout the allocation classifications, which makes it impossible to simply convert geographic proximity into points without also converting other classifications into points. Under the OPTN final rule, organ allocation policies cannot be based on a transplant candidate's place of residence or place of listing except to the extent required by other regulatory factors (i.e., avoiding organ wastage, avoiding futile transplants, promoting patient access, and promoting the efficient management of organ placement). There are many complex decisions that must be made to fully realize the potential of continuous distribution. Other organs already use scaled points to eliminate hard cutoffs. (For example, there is a scale for sensitization points used in kidney allocation.[4]) This concept of using points instead of hard boundaries could benefit other aspects of organ allocation, such as how candidate age groups are used. This is one of the benefits of the continuous distribution framework. It provides a framework to account for other variables to calculate a score for each candidate, besides proximity. **In this way, the move toward continuous distribution might best be described as a move from a classification-based framework to a points-based framework.**

Classification-based framework: A classification-based framework places similar candidates into classifications or groupings. Candidates are then sorted within those classifications. A candidate will only appear in the classification that is most beneficial to the candidate. This is the framework currently used to allocate organs.

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

Example of a Hypothetical Points-Based Framework

To illustrate the challenges inherent in a classification-based system and the opportunities available in a points-based system, the following scenarios are presented. The candidates are hypothetical but the situations are representative of how the allocation of adult donor lungs currently functions.

Figure 1 is an example of how the points and attribute weights could work together to form a composite score. Consider the following overly simplified match run for a donor originating in Nashville, Tennessee. Each letter on the map represents a hypothetical lung candidate. The blue lines represent zone boundaries.

[4] OPTN Policy 8.3: *Kidney Allocation Points*.

Figure 1: Map of Hypothetical Candidates

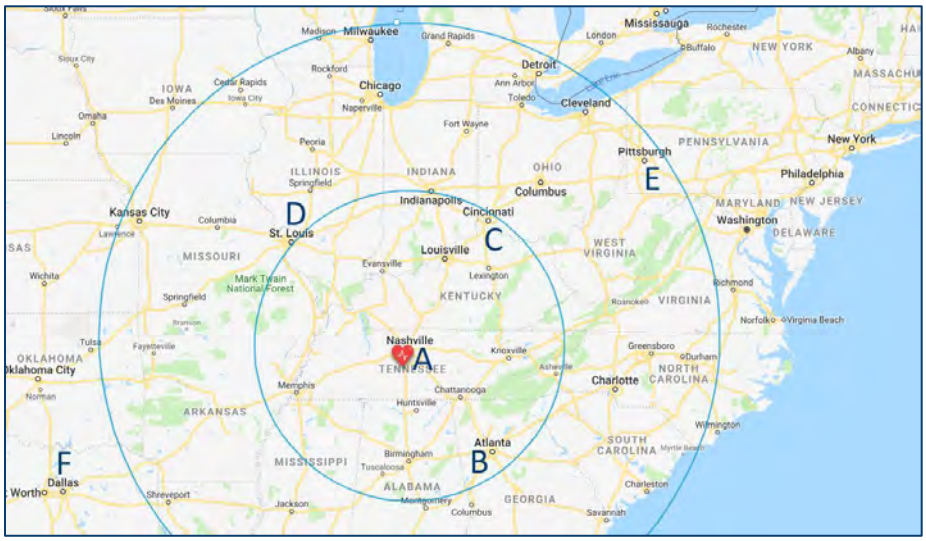


Table 1: LAS Scenario

Candidate	B	C	D
Medical Priority	LAS 38.02	LAS 38.03	LAS 90
Ischemic Time	2-hours	2-hours	2-hours

In **Table 1**, there is little difference between the proximity of the donor hospital to candidates B, C, and D; they all require a flight from Nashville, they all have airports capable of receiving charter aircraft, and they would all result in similar ischemic time for the organ. Using the current classification and zone framework, candidates B and C would be prioritized over candidate D. This occurs due to the placement of candidates B and C in one zone and candidate D in another zone. This is despite the roughly 50 point difference in LAS which is associated with a very large difference in expected net survival benefit of receiving a lung transplant versus remaining on the waiting list.[5] Using a points-based framework, these competing considerations could be balanced against each other.

Table 2: Blood Type Scenario

Candidate	D	E
Medical Priority	LAS 90	LAS 30
Blood Type	✔ Compatible	★ Identical
Ischemic Time	2-hours	2.5-hours

[5] Compare this hypothetical scenario with one of the allocation performance goals in the OPTN Final Rule. 42 C.F.R. Sec. 121.8(b)(2) "There shall be a sufficient number of categories (if categories are used) to avoid grouping together patients with substantially different medical urgency".

In **Table 2**, candidates D and E would be in the same geographic zone. Candidate D is a compatible blood type with the donor while candidate E is an identical blood type. The current classification framework prioritizes identical blood type matches over compatible matches within the same zone; therefore, candidate E would receive the organ offer before candidate D. This happens regardless of differences in medical priority. In this situation, candidate D's LAS is 60 points higher than candidate E yet D will receive the organ offer after candidate E. By using a points-based framework instead of a classification-based framework, we can account for both considerations.

Table 3: Waiting Scenario

Candidate	A	B	C
Medical Priority	LAS 38.01	LAS 38.02	LAS 38.03
Waiting Time	5-years	3-years	1-day

In **Table 3**, candidates A, B, and C all have similar LAS scores. If we assume that these candidates are in the same classification, then their order of allocation will primarily be determined by their LAS. Unlike kidney allocation points or the liver MELD score, the LAS is calculated to 16 decimal places; so slight differences in LAS can impact the order of allocation. Because of this, waiting time often does not impact the order of allocation for calculated LAS scores. Whereas, for those organs that do not calculate points to so many decimal places, waiting time is more likely to impact the order of allocation. By using a points-based framework, we can account for both considerations.

Table 4: Placement efficiency Scenario

Candidate	A	B	C
Medical Priority	LAS 38.01	LAS 38.02	LAS 38.03
Placement Efficiency	High efficiency	Medium efficiency	Medium efficiency

In **Table 4**, we see the same candidates with information about a hypothetical score for the efficient management of organ placement (placement efficiency). In **Figure 1**, all three candidates are within the same zone. In the current classification and zone framework, we prioritize between these candidates based upon their LAS. Since candidate C has the highest LAS, the organ offer would go to candidate C first. The LAS for these candidates are within a fraction of a point of each other and do not consider placement efficiency. By using a points-based framework instead of a classification-based framework, we can account for placement efficiency more effectively.

These hard boundaries combined together in the classification-based framework can lead to seemingly inexplicable conclusions that don't align with the ultimate goals of the lung allocation framework. We can better achieve these goals through a points-based framework. To determine the specific rankings for candidates, we must consider both: 1) how many points to give each candidate within each attribute (For example, how much preference is given for an LAS 90 versus an LAS of 70), and 2) how much priority is given to each attribute relative to other attributes. (For example, how important is a candidate's LAS score relative to additional ischemic time or blood type compatibility?) Combined, we will then generate a lung composite allocation score for each candidate.

Now consider how a composite score might prioritize these candidates. In **Table 5**, we see all of the candidates and their most relevant attributes.

Table 5: All Candidates and Their Attributes

Attribute	A	B	C	D	E	F
Medical Priority	LAS 38.01	LAS 38.02	LAS 38.03	LAS 90	LAS 30	LAS 70
Placement efficiency	High efficiency	Medium efficiency	Medium efficiency	Medium efficiency	Low efficiency	Low efficiency
Ischemic Time	30-minutes	2-hours	2-hours	2-hours	2.5-hours	3-hours
Blood Type	Compatible	Compatible	Compatible	Compatible	Identical	Compatible
Waiting Time	5-years	3-years	1-day	6-months	3-months	1-month
Highly Sensitized	No	Yes	No	No	No	No
Candidate Age Group	Pediatric	Pediatric	Adult	Adult	Adult	Adult

Next, we need to assign points for each of the attributes. **Table 6** shows some hypothetical points for each of the attributes in the above scenarios. For the sake of simplicity, all of the attributes in this scenario are rated from 0-100. LAS uses an increasing linear scale, placement efficiency groups candidates into high, medium, or low efficiency; ischemic time uses a decreasing scale; and blood type uses a binary 0/100 measure. Candidates with identical attributes will receive identical points for that attribute. How the committee will determine these points can be found later in this paper. In this example, we also assign a weight or importance to each attribute. For the sake of this example, we assign 40% of the composite score to medical urgency, 20% to ischemic time, 20% to candidate age, 9% to blood type compatibility, 5% to placement efficiency, 5% to sensitization, and 1% to waiting time.

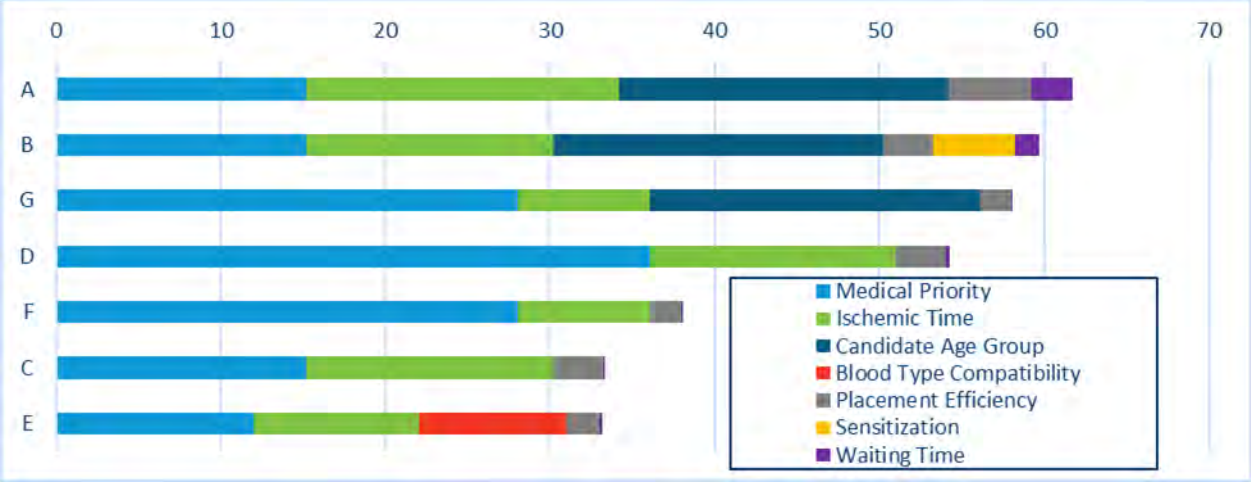
Table 6: Candidate points

Attribute	A	B	C	D	E	F
Medical Priority	15.2004	15.2008	15.2012	36	12	28
Placement efficiency	5	3	3	3	2	2
Ischemic Time	19	15	15	15	10	8
Blood Type	0	0	0	0	9	0
Waiting Time	2.5	1.5	0.001	0.25	0.12	0.04
Highly Sensitized	0	5	0	0	0	0

Attribute	A	B	C	D	E	F
Candidate Age Group	20	20	0	0	0	0

Figure 2 shows how a potential lung composite allocation score could function. Candidates receive points for each of the different attributes used to prioritize candidates. The amount of points given to each candidate depends upon the candidate's specific situation and the points assigned for that attribute. The maximum amount of points given for any attribute is determined by the importance assigned to that attribute. In the below example, the amount of waiting time points given to a candidate varies depending upon the candidate's specific circumstances. But the maximum amount of points given for waiting time is less than other attributes such as medical priority.

Figure 2: Example of a Lung Composite Allocation Score

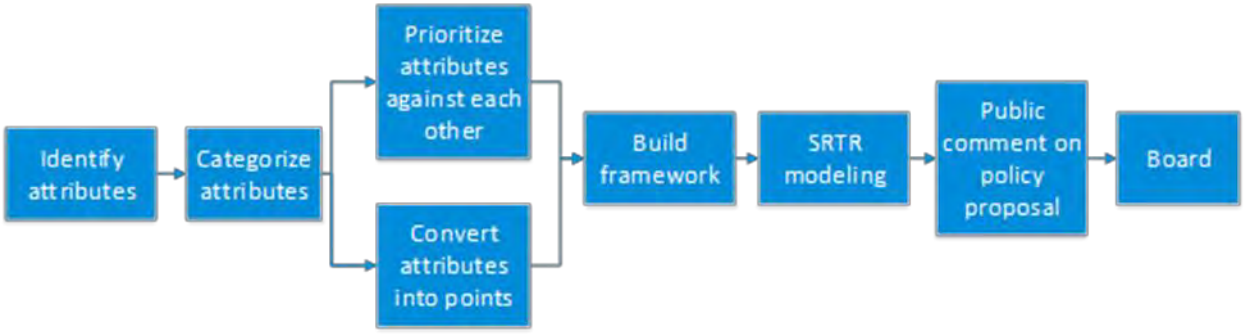


These hypothetical scenarios show the challenges and inequities caused by a classification-based system. A points-based system can overcome many of these challenges. Of course, OPTN allocation policies utilize more attributes than are included in the above scenarios.

How will this concept be developed?

This concept for the continuous distribution of lungs will require several phases. To develop this concept, the Committee constructed a continuous distribution workgroup (hereinafter, the workgroup) comprised of members of the Lung Subcommittee as well as additional experts in lung transplantation. **Figure 3** shows the overall plan for the project. Each step is explained below.

Figure 3: Project Overview



- **Identify attributes**: We must first identify all of the ways that OPTN policy classifies and sorts lung candidates. This includes LAS, candidate and donor age, blood type matching, waiting time, etc. We could potentially add attributes though that would likely make the transition to continuous distribution longer.
- **Categorize attributes:** Once we identify individual attributes, we then need to categorize the attributes according to their purpose in organ allocation. We'll use the permissible considerations set by the OPTN Final Rule to categorize the attributes.[6] This includes the best use of organs, avoiding wastage, the efficient management of organ placement, etc.
- **Convert attributes into points:** Each attribute must be converted into points that allows us to prioritize candidates. To convert each attribute to a scale, we first look at how the attribute is used. Is it a score? Are the relative differences in points linear or some other function? If they are categories, can we smooth the hard boundaries between those categories? Next, we determine how we sort the categories for allocation. In setting these points, we will use objective clinical or operational data as evidence as much as possible.
- **Prioritize attributes against each other**: Separately, the committee must weigh the relative importance of each attribute against each other. This is a values and compliance issue – as opposed to clinical or operational issue. For this reason, it will benefit from a different analytical approach. See below for more information.
- **Build framework:** Using the points and attribute weightings from the previous steps, we will then construct a composite score for lung allocation.
- **SRTR modeling:** The SRTR will then model the new framework.[7]
- **Public comment on policy proposal and Board consideration:** Once SRTR modeling is complete, the proposal will follow the normal OPTN processes. This will include additional committee discussions, community education and feedback, public comment for a policy proposal, and eventually a Board decision.

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.

[6] 42 C.F.R. Sec. 121.8(a).

[7] The SRTR is the Scientific Registry of Transplant Recipients. They provide statistical and other analytic support to the OPTN for purposes including the formulation and evaluation of organ allocation and other OPTN policies.

What could be included in a composite allocation score?

The workgroup began analysis by looking at current lung allocation policy to see how it categorized and sorted lung candidates. **Figure 4** is a graphical representation of the first eight classifications in Table 10-9 found in *Policy 10.4.C: Allocation of Lungs from Deceased Donors at Least 18 Years Old*, which shows candidates categorized by geography, age, blood type, and medical priority. Reading the remainder of the policy, we also see that candidates are prioritized based upon waiting time and sensitization.[8]

Figure 4: Table 10-9: Allocation of Lungs from Adult Donors

Classification	Candidates that are	And registered at a transplant hospital that is within this distance from the donor hospital
1	At least 12 years old blood type identical to the donor	250NM
2	At least 12 years old blood type compatible with the donor	250NM
3	Priority 1 and *one* of the following: • Less than 12 years old and blood type identical to the donor • Less than 1 year old and blood type compatible with the donor • Less than 1 year old and eligible for intended blood group incompatible offers	250NM
4	Priority 1 and *one* of the following: • At least 1 year old and blood type compatible with the donor • At least 1 year old and eligible for intended blood group incompatible offers	250NM
5	Priority 2 blood type identical to the donor	250NM
6	Priority 2 blood type compatible with the donor	250NM
7	At least 12 years old blood type identical to the donor	500NM
8	At least 12 years old blood type compatible with the donor	500NM

The committee will work to convert these attributes from a classification-based system to a points-based system. To do so, they will first need to construct a points system for each attribute. Below is a summary of considerations. The committee would like feedback on this:

- **Medical Urgency:** Lung candidates are prioritized using two different systems: The Lung Allocation Score (LAS) for candidates 12-years old and above and pediatric priorities for candidates under 12. (Pediatric priorities function similarly to statuses in heart and liver allocation.) The committee will need to determine how to compare the relative medical priority of an LAS candidate against a pediatric priority 1 or 2 candidate. Similarly, the committee will need to determine the relative difference between LAS scores. The committee will also need to decide whether to maintain LAS as a single attribute or separate it into its two components for waitlist mortality and post-transplant survival.
- **Age:** Candidate age is currently used to prioritize younger candidates (under 12 years old before 12-17 then 18 years and older) for lungs from pediatric donors and prioritize older candidates (12 years or older) for lungs from adult donors.[9] This creates some hard boundaries in lung allocation. (For example, an 11-year old candidate will always receive the organ offer for lungs from donors less than 18 years old before a 12-year old candidate at similar distances – no

[8] OPTN Policies 10.2.A *Allocation Exception for Highly Sensitized Patients* and 10.4.A *Sorting Within Each Classification*.
[9] OPTN Thoracic Transplantation Committee, "Proposal to Modify Pediatric Lung Allocation Policy" briefing paper (December 2015). See also 42 U.S.C. Sec. 274(b)(2)(M). The OPTN shall "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."

matter any difference in medical priority.) The committee has multiple options for smoothing age classifications. The committee has not yet made decisions regarding the use of age. Similar to lung, age is used in almost of all of the organ systems to classify donors or candidates. Before the committee makes decisions regarding the use of age, they will consider other attempts by the OPTN to use age in organ allocation.[10]

- **Blood Type:** Blood type is an attribute which includes both candidate and donor information. Lung allocation classifies candidates according to identical, compatible, intended incompatible, and incompatible blood type matches. The workgroup agreed to continue categorizing candidates into these three categories with a preference given to identical matches. With the exception of intended incompatible blood type matches, points are not given to incompatible matches because these are screened off the match run and do not receive any organ offers.
- **Waiting Time:** Waiting time is used as a tiebreaker in current lung allocation.[11] Because LAS is calculated to 16 decimal places, it is rare that waiting time is ever needed to break a tie LAS; however, waiting time is often used to break ties between pediatric priorities. Waiting time is used due to a sense of fairness or to promote patient access. Waiting time is already captured along a scale with priority given to candidates with more waiting time. A points-based model could similarly give little weight to waiting time and prioritize candidates with more waiting time.

  Alternatively, some workgroup members have mentioned that waiting time could receive no points in the composite score and continue to be used as a tie-breaker in the event that the composite score results in a tie. While it is unlikely that ties would exist in this new framework, the potential does exist. For that reason, the OPTN will need to identify a system for breaking ties in candidate scores.
- **Sensitization:** OPTN policy permits highly sensitized lung patients to be prioritized for allocation.[12] The reason for this policy is to grant greater access for these candidates who might otherwise struggle to receive organ offers. Right now, the policy requires hospitals to receive agreement from transplant programs who registered the candidates higher on the match run. Because a points-based framework will be less static than a classification-based framework, the committee will need to discuss how to operationalize this policy in the context of a points-based framework. In the long term, the lung community might wish to pursue a sensitization scale similar to the CPRA sliding scale used in kidney allocation.[13]
- **Proximity:** Current lung allocation policy uses proximity between the donor hospital and transplant hospital to place candidates into geographic zones. While the efficient management of organ placement encompass multiple factors, proximity is the only factor of placement efficiency included in the current lung allocation policies. Candidates in zones closer to the donor hospital are currently prioritized over candidates in zones that are further from the donor hospital. Geographic proximity is not a specific consideration under 42 C.F.R. 121.8. Instead, geographic proximity (e.g., distance between donor and transplant candidate's hospital) may be considered to the extent necessary to satisfy other requirements in the Final Rule: e.g., efficient management of organ placement and the avoidance of futile transplants due to increased ischemic time. Transportation costs and ischemic time generally increase as

[10] Benjamin Eidelsen, "Kidney Allocation and the Limits of the Age Discrimination Act," *Yale Law Journal* 122, 6 (2013). Govind Persad, "Evaluating the Legality of Age-Based Criteria in Health Care: From Nondiscrimination and Discretion to Distributive Justice," *Boston College Law Review* 60, 889 (2019). S. C. Sweet and M. L. Barr, "Pediatric lung allocation: the rest of the story," *Am J Transplant* 14, no. 1 (Jan 2014), https://doi.org/10.1111/ajt.12546.

[11] OPTN Policy 10.4.A: *Sorting Within Each Classification*.

[12] OPTN Policy 10.2.A*: Allocation Exception for Highly Sensitized Patients*.

[13] OPTN Policy 8.4: *Kidney Allocation Points*.

the distance between the donor and transplant hospitals increase but these are not always directly related. In a points-based system, we can more directly estimate and consider the transportation efficiency and the impact of ischemic time. The committee is interested in feedback on the best ways to incorporate proximity and the efficient management of organ placement in a points based system.

The increased flexibility inherent in a points-based framework will allow new attributes or more nuance to be added more easily. The current project will focus on converting and smoothing existing policy concepts into a points-based framework for lung and new attributes would not be added to the system at this time unless they were needed to smooth existing cliffs. However, below are some potential attributes that could be included in the future.

- **Vulnerable populations:** Several committees have discussed how to promote access to transplant for different vulnerable populations. Using a classification-based framework, committee have created new classifications for vulnerable populations then decided where to place those classifications relative to other classifications. Using a points-based framework, points could potentially be granted to vulnerable populations in order to provide equity in access to transplant. Within the lung community, recent conversations have also discussed access for short-statured candidates.[14] If these were shown to have disparate access to transplant, then these could align with the Final Rule's consideration for allocation policies "to promote patient access to transplantation."[15]
- **Changes in Transportation Practices:** The last few years have seen advances in transplant that have the potential to impact the cost, the clinical impact of, or the length of time to transport organs. These advances include the use of donor recovery centers, organ perfusion, and drones.[16] A classification-based framework that uses zones or hard boundaries cannot easily incorporate these new advances. A points-based framework that separates geographic considerations into clinical outcomes and the efficient management of organ placement can more easily accommodate these changes.
- **Cross Organ Considerations**: One of the challenges in multi-organ allocation is comparing the medical priority of candidates using organ specific definitions of medical priority.[17] Using a common points-based framework will allow easier comparison of candidates across organ types. This will also allow common reviews of system and member performance across organ types.
- **Donor Specific Factors:** Most organs have different allocation algorithms for different classes of donors.[18] The OPTN classifies lungs based upon the age of the donor. A points-based framework could maintain similar points for common attributes across all donors and change only those points scales that are relevant for differences in donors. For example, if the ischemic time limits

[14] J. L. Sell et al., "Short Stature and Access to Lung Transplantation in the United States. A Cohort Study," *Am J Respir Crit Care Med* 193, no. 6 (Mar 2016), https://doi.org/10.1164/rccm.201507-1279OC.

[15] 42 CFR Sec. 121.8(a)(5).

[16] M. Doyle et al., "Organ Donor Recovery Performed at an Organ Procurement Organization-Based Facility Is an Effective Way to Minimize Organ Recovery Costs and Increase Organ Yield," *J Am Coll Surg* 222, no. 4 (Apr 2016), https://doi.org/10.1016/j.jamcollsurg.2015.12.032. A. S. Barbas et al., "Ex-vivo liver perfusion for organ preservation: Recent advances in the field," *Transplant Rev (Orlando)* 30, no. 3 (07 2016), https://doi.org/10.1016/j.trre.2016.03.002. (regarding the use of organ perfusion). J. R. Scalea et al., "An Initial Investigation of Unmanned Aircraft Systems (UAS) and Real-Time Organ Status Measurement for Transporting Human Organs," *IEEE J Transl Eng Health Med* 6 (2018), https://doi.org/10.1109/JTEHM.2018.2875704.(regarding the use of drones).

[17] OPTN Ethical implications of multi-organ transplants (2019) available at: https://optn.transplant.hrsa.gov/media/2989/ethics_boardreport_201906.pdf.

[18] OPTN Policy 8.5.B *Deceased Donor Classification* (description of classifying kidneys by KDPI).

for Donation after Circulatory Death (DCD) organs are different than donation after brain death organs, then the points for ischemic time should change for those organs; but the other points need not change as well.

- **Likelihood of Acceptance:** One perceived advantage of limiting ischemic time is that hospitals are more likely to accept organs with less ischemic time. These acceptance behaviors, which could change, also raise the prospect that points could be used to account for offers that are likely to be declined in order to gain efficiencies in the organ placement system. For example, facilitated pancreas offers could operate through the use of points.[19] These would align with the Final Rule's requirements that organ allocation policies be designed to avoid wasting organs and promote the efficient management of organ placement.[20]
- **Concurrent Offers:** Similarly, some members have opined that the number of transplant programs receiving organ offers at the same time increases complexity in the organ placement system and is inefficient. If so, then effort could be made to decrease the number of transplant programs who receive organ offers at the same time.
- **Size Matching:** Some research has shown the improved outcomes for certain organs where the size for the organ matches the size needs for the candidates.[21] In the same manner that we use HLA matching to improve transplant outcomes, points could be used for size matching to improve transplant outcomes.

How might each attribute be evaluated?

As briefly described above, the workgroup developed a four step process to evaluate each of the attributes.

1. If the attribute currently exists in OPTN policy, how is it used for allocation? In other words, is it a scale like LAS or does it use categories like geographic zones, blood type compatibility, and age?
2. Why is the attribute used in allocation? We'll connect the purpose of each attribute to a permissible consideration in the OPTN Final Rule.[22] This will be helpful to understanding whether the allocation system meets the overall goals for the OPTN and whether a policy complies with the regulatory requirements.
3. For attributes that use categories with hard boundaries, can the attribute be broken into smaller groups? Or are there options for smoothing the boundaries between these groups?
4. Within the attribute, how should candidates be prioritized? For example, identical blood type matches are prioritized over compatible blood type matches.

From this analysis, staff and the committee will construct a system for assigning points for each attribute. Points could be expressed as a function or a schedule of discrete points. These functions do not need to be linear. In keeping with the requirements for evidence based allocation policies, clinical and operational data will be used as much as possible to determine the specific point assignment. (For example, medical priority, outcomes, cost, etc.) For attributes that do not lend themselves to clinical or

[19] OPTN Policy 11.6: Facilitated Pancreas Allocation.
[20] 42 C.F.R. Sec. 121.8 (a)(5).
[21] M. Eberlein and R. M. Reed, "Donor to recipient sizing in thoracic organ transplantation," *World J Transplant* 6, no. 1 (Mar 2016), https://doi.org/10.5500/wjt.v6.i1.155, https://www.ncbi.nlm.nih.gov/pubmed/27011913. J. B. Barnard et al., "Size matching in lung transplantation: an evidence-based review," *J Heart Lung Transplant* 32, no. 9 (Sep 2013), https://doi.org/10.1016/j.healun.2013.07.002.
[22] 42 C.F.R. Sec. 121.8.

operational analysis, (for example, waiting time), consensus building methods are used to build their points.

How might the attributes be compared against each other?

Before we can develop the new framework, the committee, with input from the community, will need to determine the importance of each attribute against each other. While the preceding analysis used traditional analytical methods to determine how to smooth and prioritize categories of candidates, the next analysis will require a different method. The task of weighing attributes against each other is a values laden and compliance rather than a clinical or operational question. For example, the proper balance between equity and utility is a frequent discussion amongst the committees when they develop organ allocation policies. The OPTN Final Rule contains requirements that apply to permissible considerations for setting organ allocation policies and the OPTN has adopted principles that espouse the values held by the organization.[23]

The field of operations research provides several methods for multi-criteria decision making (MCDM) that may be of use for developing organ allocation policies. Broadly speaking, they require the transplant community to express the relative importance for the attributes to achieve a given goal within any specified constraints. The requirements for the system are expressed in the OPTN Final Rule. Guidance for the relative importance of these requirements can be found in the OPTN Final Rule and principles adopted by the OPTN. The workgroup can refine the relative importance of these attributes either by revealing them through past decisions and/or by stating them through different experiments. These levels of importance can then become the coefficients in a composite score for organ allocation. This framework will allow the Board and committee to tailor the composite allocation score to meet the needs of the transplant community for each of the organs.

The process to solicit and memorialize these preferences must achieve several goals:

1) *Replicable*: If the committee discussed this same topic next year (with the same data), they should arrive at the same conclusion. Otherwise, the personal preferences of the committee members are biasing the results. Therefore, for decisions which are not clinical or operational, they must properly reflect the values of the transplant community.
2) *Participation*: It allows members of the transplant community to participate in the policy development process.
3) *Transparent*: It allows people to understand how their input impacted the outcome.
4) *Cross-Organ*: The move to continuous distribution will expand to other organs. Therefore, we want a methodological approach that can be repeated with other organs.
5) *Consistent with OPTN's Obligations*: The final policies must be consistent with the OPTN's obligations in NOTA and the OPTN Final Rule. Any new policy must be justified in light of the statutory and regulatory requirements.

[23] OPTN Ethics Committee, "Ethical Principles in the Allocation of Human Organs briefing paper," (2015). OPTN Ad Hoc Geography Committee, "Frameworks for Organ Distribution briefing paper." (2018). OPTN Pediatric Transplantation Committee, "Ethical Principles of Pediatric Organ Allocation briefing paper," (2014).

NOTA & OPTN Final Rule

Organ allocation policies are governed by NOTA and the OPTN Final Rule.[24] A critical objective of the Final Rule is to achieve the most equitable and medically effective use of donated human organs.[25] Towards that goal, the Final Rule directs provides that organ allocation policies cannot be based on a transplant candidate's place of residence or place of listing except to the extent required by other regulatory factors (i.e., avoiding organ wastage, avoiding futile transplants, promoting patient access, and promoting the efficient management of organ placement).[26] The proposed concept will allow a much more transparent nexus between any adopted policy and the legal requirements in the OPTN Final Rule. These will include requirements that the allocation policies:

- **Be based on sound medical judgment:** The construction of the individual points will be based on objective clinical and operations evidence. Because each attribute will have its own points, it will be easier to update the points as medical practice changes. It will also allow us to more easily identify clinical differences and similarities between organs.
- **Seek to achieve the best use of donated organs:** One of the potential attributes for any composite allocation score is medical urgency. As much as possible, the score will prioritize candidates based upon their medical urgency.[27] Before the policy proposal is released for public comment, it will be modeled by the SRTR to assess its impact on waitlist mortality and post-transplant outcomes. If necessary, the committee will be able to adjust the weighting of the attributes to balance these outcomes.
- **Be designed to avoid wasting organs:** In addition to being required under the OPTN Final Rule, a strategic goal of the OPTN is to increase the number of transplant. A key strategy to achieve this goal is to decrease the number of organ discards. As mentioned above, points could be assigned to candidates more likely to accept organs at risk of discard. Before the policy proposal is released for public comment, it will be modeled by the SRTR to assess its impact on the 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.
- **Be designed to…promote patient access to transplantation:** The committee agreed that variation in waitlist mortality can be used to assess whether any patient populations require points to provide equity in access to transplantation. When looking at any of the attributes under patient access above, we can use this common definition of access to determine the points and weights for the attributes.
- **Be designed to…promote the efficient management of organ placement:** The committee will consider both how current allocation policies promote the efficient management of organ placement and how new organ allocation policies could consider the efficient management of organ placement. The efficiency management of organ placement can be impacted by many thing. Some people have suggested that allocation systems that allocate organs quicker would lead to a more efficient system. The current policies consider geographic proximity in order to satisfy other regulatory requirements.[28] Travel costs may have a more direct impact on the efficient management of the organ placement system than the current geographic zones. A

[24] 42 U.S.C. Sec. 273 and 42 C.F.R. Sec. 121.8.

[25] 64 Fed. Reg. 56,650 (October 20, 1999).

[26] 64 Fed. Reg. 56,651 (October 20, 1999).

[27] See the allocation performance goals found in the OPTN Final Rule. 42 C.F.R. Sec. 121.8(b)(2) "These rankings shall be ordered from most to least medically urgent".

[28] 63 Fed. Reg. 16,315. "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." (April 2, 1998).

points-based system can accommodate multiple factors related to efficiency and will more directly connect those factors with these Final Rule provisions. Furthermore, the committee will weigh this attribute only as much as necessary so that organs are distributed as broadly as feasible. The committee would welcome feedback on any additional attributes to be considered to account for the efficient management of the organ placement system.

- **Not be based on the candidate's place of residence or place of listing, except to the extent required [by the aforementioned criteria]:** The committee will consider the level of importance to be placed on each of the attributes. The attributes related to placement efficiency and ischemic time are related to the candidate's place of registration.
- **Consider whether to adopt transition procedures:** A points-based framework will facilitate the use of transition procedures for existing candidates. For example, let us consider what would happen if the current framework places 50% of the weight for the composite score on ischemic time and that changes to 30% in the future. Without a transition procedure, OPOs and programs will need to interact with different programs immediately. In a points-based framework, the framework could incrementally change the weight from 50% to 30% over a set period. This would allow members and patients time to prepare for these changes.

Next Steps

After public comment, the workgroup will review feedback on the concept paper. They will use this to continue their work building the points, weighing the attributes, and refining their overall approach to this project. As mentioned above, the workgroup has begun work developing the points for the various attributes. Following that work, we will weigh the attributes against each other. Once those two steps are combined, the workgroup will develop the framework for a composite score to distribute lungs. The project will then follow traditional OPTN processes for developing organ allocation policies at this point. The SRTR will model one or more frameworks under consideration by the workgroup. The committee will continue to educate and solicit feedback from the community on these concepts as this project develops. All of these things will be done only after comments from the community are assessed and incorporated.

As also mentioned above, continuous distribution is the preferred allocation framework for the future. Work will begin in the other organ specific committees after the close of public comment on this concept paper. The process will look similar to the progress on this project to date. The committees will identify the current attributes used for prioritizing candidates then classify them according to the purposes in the OPTN Final Rule. We will then build points for those attributes. For attributes that are similar to those used in lung allocation, we will begin with the points selected by the lung workgroup then make changes according to any clinical differences between organs. Finally, those committees will follow a similar process for weighing the different attributes. The work for this suite of projects could take several years.

Summary

The continuous distribution framework has the potential to restructure the concept of a match run and its classification-based framework and therefore will create a significant change in the framework of organ allocation in the United States. Moving forward, candidates will be prioritized in a more flexible manner with attributes that more closely connect to the OPTN's obligations under NOTA and the OPTN Final Rule. This new framework will permit the transplant community to see how much weight is placed on each attribute. By separating the specific attributes and developing attribute specific points, we will

be able to have more flexible solutions for how we prioritize certain patient populations, thereby improving equity in access to organ transplantation.

This new framework will also require the community to reconsider how it develops organ allocation policies. This requires us to balance the need for evidence-driven decisions based in clinical and operational data with the inherently values-based decisions concerning the multiple goals of a national, organ allocation system. While this concept paper focuses on lung allocation, it will eventually impact all organ transplantation systems.

We invite all comments and suggestions on this concept paper. In reviewing this concept paper, we encourage readers to consider the following questions:

- Do you understand the advantages of a points-based system versus the current classification-based system?
- Are there other measures of the efficient management of organ placement that should be taken into account in a points-based framework?
- What other issues should be considered to convert other organ systems to a points-based framework?
- What factors should be incorporated into the allocation of lungs within a continuous distribution framework?