OPTN

Request for Feedback

Update on the Continuous Distribution of Organs Project

OPTN Lung Transplantation Committee

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Update on the Continuous Distribution of Organs Project

Sponsoring Committee: *Lung Transplantation*
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Executive Summary

This request for feedback provides an update to the community about the continuous distribution of organs. Continuous distribution means replacing the current classification approach, which draws hard boundaries between types of patients (compatible vs. identical; sensitized vs not; inside a circle vs. outside), with a composite score that takes into account all of a candidate's characteristics. This score will be constructed with multiple attributes which align with NOTA and the OPTN Final Rule. This paper builds upon the 2019 concept paper[1] and contains updated information about the attributes that have been discussed by the Lung Committee (Committee)[2], how these attributes align with NOTA and the OPTN Final Rule, and how this work to date may influence the eventual conversion of other organs to continuous distribution. Finally, this paper provides an overview of the policy development approach and timeline for continuous distribution of lungs and other implementations, along with a request for community members to provide feedback in a prioritization exercise.

The end of this document has a glossary of terms to help readers.

[1] OPTN Thoracic Committee. 2019. *Continuous Distribution of Lungs, concept paper* available at: https://optn.transplant.hrsa.gov/media/3111/thoracic_publiccomment_201908.pdf.

[2] On July 1, 2020 the OPTN Thoracic Organ Transplantation Committee was split into separate Heart and Lung Transplantation Committees. Moving forward, the Lung Committee will sponsor this project. Prior to this, the majority of these discussions took place in either the former Lung Subcommittee of the Thoracic Transplantation Committee or the Continuous Distribution Workgroup under the Lung Subcommittee. For ease of reference, all references to those committees, subcommittees, and workgroups will collectively be referenced as the Lung Committee.

Background

Continuous distribution means replacing the current classification approach, which draws hard boundaries between types of patients (compatible vs. identical; sensitized vs not; inside a circle vs. outside), with a composite score that takes into account all of a candidate's characteristics. This score would be constructed with multiple attributes which align with NOTA and the OPTN Final Rule. To construct the score, the Committee must make two general decisions: 1) How much weight or importance to place on each attribute and 2) how to rate candidates within each attribute. Regarding the ratings, the Committee has been and will continue to work with OPTN and SRTR researchers to develop evidence based rating scales for each attribute. (For example, how much priority to give to a blood type O vs blood type AB candidate in order to provide equity in the system.)

As explained in the 2019 concept paper[3], hard boundaries create inequities for candidates on those edges. Candidates are placed into distinct classifications based upon their specific clinical criteria. Candidates are sorted within those classifications based upon medical priority and waiting time, but cannot move between classifications. For example, in **Figure 1** candidates A, B, and C are similar distances from the donor hospital but in different geographic zones. The current classification framework prioritizes zones before differences in medical urgency;[4] therefore, candidates A and C would receive the organ offer before candidate B. This happens regardless of any differences in medical urgency or candidate biology. By using a points-based framework instead of a classification-based framework, we can account for both considerations.

Figure 1: Hypothetical Candidates

Factors	Candidate A	Candidate B	Candidate C	Candidate D
Medical Urgency	Medium	High	Low	Medium
Distance from Donor Hospital	249 NM	251 NM	230 NM	300 NM
Candidate Biology (compatibilty)	Medium	Low	Medium	High
1 year survival after transplant	High	Medium	High	Low

[3] OPTN Thoracic Committee. 2019. *Continuous Distribution of Lungs, Concept Paper*.

[4] LAS is a composite score that contains measures for one-year waitlist mortality and post-transplant survival. In this way, lung allocation already has a composite score that weighs different attributes. Their experience developing this score is one of the reasons that lung is the first organ to transition to a continuous distribution framework.

These hard boundaries are inherent in a classification based system that prevents candidates from moving between classifications. The classification-based system, which currently precludes all patients in a lower classification from being prioritized ahead of any patients in a higher classification, irrespective of considerations regarding medical need, inequities in access, or benefit of transplantation. (See Error! Reference source not found..) A continuous distribution framework will eliminate hard boundaries resulting from the current system, in which candidates are grouped into classifications (e.g., adults in Zone A) and then sorted by their LAS within each classification. Instead, candidates will receive points for various attributes and all of these attributes can be considered as part of a composite allocation score. (See Error! Reference source not found..) A candidate's composite allocation score will determine the order in which the candidate will receive an organ offer.[5]

Figure 2: Sample Allocation Policy (Current)

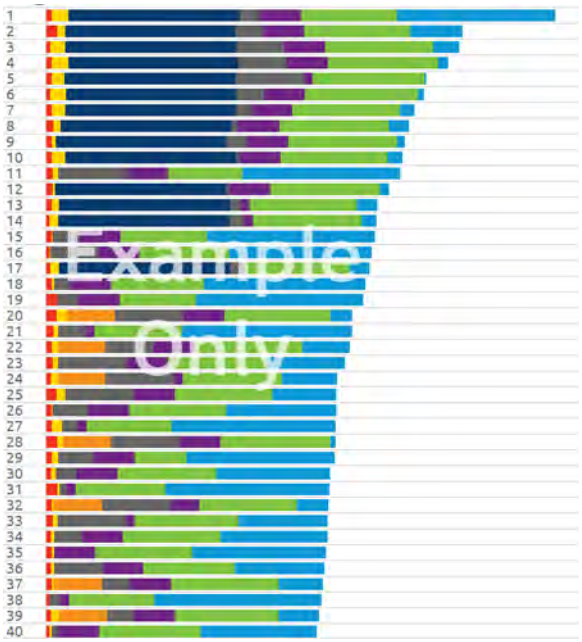
Note that candidates are placed into specific classifications and cannot move between them.

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
13	Adult status 3 or pediatric status 1B and primary blood type match with the donor	500NM

Figure 3: Example Match Run (Proposed)

Each color represents a different attribute and the length of the bar shows the points credited to that attribute. Note that candidates receive points for multiple considerations and can move up or down depending on each attribute.



The Committee will use multiple methods, as explained later, to construct the weights or priorities for each attribute. The attribute weights and rating scales applied to each candidate will result in a composite allocation score. The match run in continuous distribution will then sort candidates based on their composite allocation score. This will allow the community to balance competing attributes and remove the inequities that exist with edge cases right now.

The Committee has worked since last fall to review the feedback from the concept paper, review additional attributes, and refine the concept for the composite allocation score. This paper provides an update on that analysis, the plan forward for the project, and a request for your participation in the project.

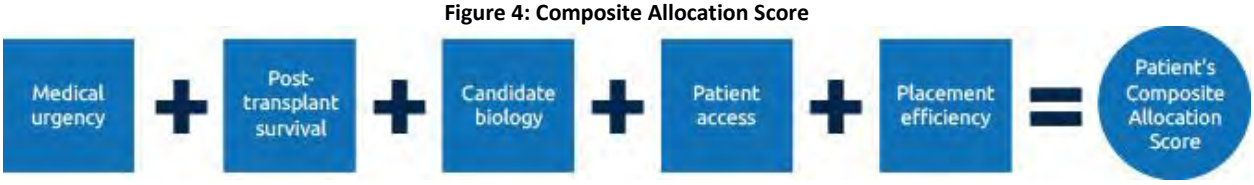
[5] OPTN Thoracic Committee. 2019. *Continuous Distribution of Lungs, Concept Paper*.

Composite Allocation Score

The Committee divided the composite allocation score into five broad goals and patient attributes within each goal. The goals, as described below, align with various requirements in NOTA and the OPTN Final Rule and are broad enough that they can be used across the different organ systems.

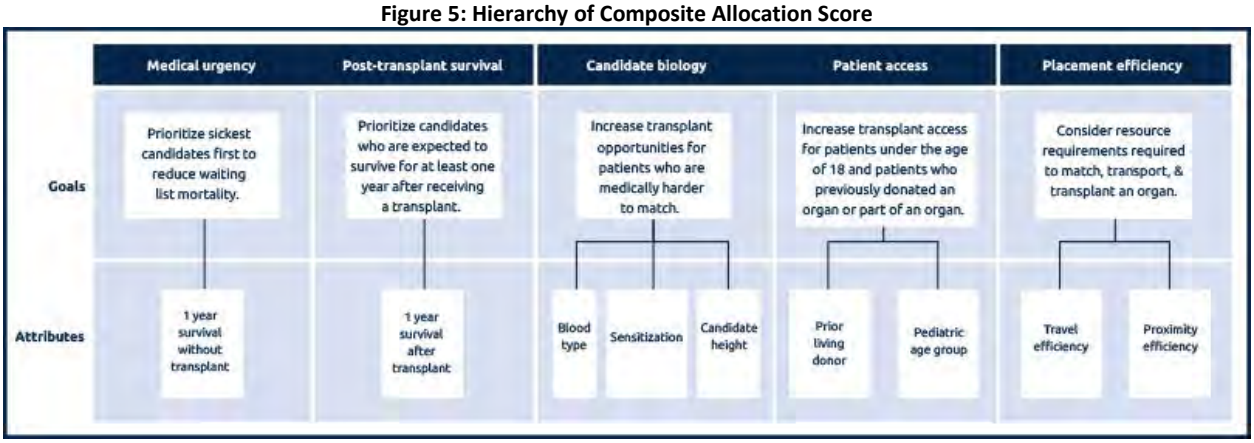
More specifically, continuous distribution will prioritize waiting list candidates based on a combination of points awarded for factors related to medical urgency, post-transplant survival, candidate biology, patient access, and the efficient management of the organ placement system.

Figure 4: Composite Allocation Score



The hierarchy of the composite score shows goals, attributes, and rating scales. (See **Figure 5**.) The goals relate to the OPTN's goals for developing equitable allocation policies as defined by the OPTN Final Rule and are consistent across the organs. The attributes are the organ specific criteria that support each goal. Rating scales use data to score each candidate. Allocation policy goals – for example, prioritizing the most urgent patients and maximizing post-transplant survival – may be in tension, and continuous distribution aims to prioritize patients in a way that balances all five goals in a transparent way. The specific attributes, their weights, and their rating scales will be organ specific. The attributes align with the ethical principles of utility (for the purposes of this project, the hierarchy splits utility into medical utility and system efficiency) and equity.[6]

Figure 5: Hierarchy of Composite Allocation Score



In building the above hierarchy, the Lung Committee considered several attributes. The Committee began with the attributes that are in current policy then considered new attributes suggested during 2019 public comment. Below is an overview of those attributes the Committee is not anticipating to include in the composite allocation score. The attributes are further explained after the table.

[6] OPTN. 2020. *Ethics - Ethical Principles in the Allocation of Human Organs – OPTN* available at: https://optn.transplant.hrsa.gov/resources/ethics/ethical-principles-in-the-allocation-of-human-organs/.

Table 1: Attributes Considered by the Lung Committee but Not Anticipated to be Included

Goal	Attribute(s)
Maximizing organ use	Likelihood of acceptance, use of screening tools, use of OPTN efficiency tools,
Improve Post Transplant Survival	Ex vivo perfusion
Improve Post Transplant Survival	HLA matching
Improve Post Transplant Survival	Ischemic time
Improve Post Transplant Survival	Size matching
Candidate Biology	Multiorgan
Improve Patient Access	Age matching
Improve Patient Access	Waiting time Do not include as an attribute at this time, but continue to use as a tiebreaker
Improve Placement Efficiency	Likelihood of Placement
Improve Placement Efficiency	Aura placement
Improve Placement Efficiency	Population density

Medical Urgency

The first goal in the hierarchy of attributes is prioritizing medically urgent patients. The OPTN Final Rule calls for allocation policies to "seek to achieve the best use of donated organs."[7] One-way to achieve the best use of a donated organ is to transplant it 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…"[8] With this in mind, the Lung Committee looked to current policy for how to rank candidates according to medical urgency.

Current policy uses the Lung Allocation Score (LAS) for candidates 12 years and older.[9] The LAS is a composite score that considers each candidate's predicted waitlist mortality and post transplant survival. Candidates under 12 are allocated using priority levels 1 and 2; these work similarly to statuses in liver and heart allocation. Because lung policy currently uses these two different methods to rank the medical urgency of lung candidates 12 years and older versus those under 12, the Committee must decide how to compare these candidates. For example, what is the LAS equivalency of Priority 1 and 2? The Committee will review clinical data to compare the waitlist mortality of Pediatric Priority candidates with the waiting list mortality part of LAS among adult candidates. This analysis provides an evidence based way to compare the waitlist mortality of adult and pediatric patients. Importantly, pediatric

[7] 42 CFR Sec. 121.8(a)(2).
[8] 42 CFR Sec. 121.8(b)(2).
[9] OPTN Policy 10.1 *Priorities and Score Assignments for Lung Candidates.*

patients will also receive extra points associated with patient access, to ensure the unique needs of children are adequately considered in the new composite score approach. See below for more details.

It is also worth noting the Lung Committee is sponsoring a separate policy proposal to update the cohort and coefficients used to calculate the two parts (waiting list mortality; post-transplant survival) of LAS.[10] Part of those discussions involved whether to change from a one-year post transplant survival model to a three-year post transplant survival model. That change was out of scope for the project but the Committee is still interested in further evaluating that topic apart from the first iteration of continuous distribution. The OPTN Board of Directors last updated the LAS in 2012.[11] The new composite score will use these updated LAS components.

Other Organs

Other organs contain similar scoring systems for prioritizing candidates based upon medical urgency or waitlist mortality. For example, liver candidates are prioritized using the Model for End Stage Liver Disease (MELD) and Pediatric End Stage Liver Disease Model (PELD) systems, whereas heart candidates are prioritized using six statuses. All of these are meant to represent the medical urgency of those candidates.

Post Transplant Survival

The next goal in the hierarchy of attributes is post transplant survival. The OPTN Final Rule calls for allocation policies "to avoid futile transplant."[12] Placing organs into candidates predicted to have better post transplant survival and produce the most life years/benefit per organ is an attempt to avoid futile transplants. With this in mind, the Lung Committee looked to current policy for how to rank candidates according to post transplant survival.

As mentioned previously, the LAS is a composite score that contains measures for one-year waitlist mortality and post-transplant survival. The Committee will analyze the post-transplant survival of candidates that receive an LAS or a Pediatric Priority level. In this way, both adult and pediatric candidates will receive an evidence-derived score for estimated post transplant survival. Importantly, pediatric patients will also receive extra points associated with patient access, as described further below.

Some other organ specific policies already have scoring systems to predict post transplant survival or outcomes (ex. the use of EPTS in kidney allocation). For other organs, this is an opportunity for future enhancements to those systems. If an organ system currently does not have a scoring system to predict post transplant survival or outcomes, the effective weight of this attribute would be zero (0%) until they build an evidence based scoring system.

Other Attributes Considered

The Committee discussed other potential attributes related to post transplant outcomes, including:

- Ischemic Time and
- Candidate Height Matching.

Ischemic Time

The Committee researched and debated whether to include predicted ischemic time into this goal. Their original hypothesis was that increased distance between the donor hospital and transplant hospital

[10] OPTN, *Updated Cohort for Calculation of the Lung Allocation Score (LAS).* August 2020.
[11] OPTN. 2012. *Proposal to Revise the Lung Allocation Score (LAS) System Briefing Paper*.
[12] 42 CFR Sec. 121.8(a)(2).

would mean longer ischemic times and poorer post-transplant outcomes for the recipient. For example, **Figure 6** represents the logic of the argument: As travel distance increases, the mode of transportation changes from driving flying; this impacts the speed of travel and total transit time; increased transit time relates to increased ischemic time; and increased ischemic time relates to transplant outcomes. The Committee therefore sought a rating scale that would rank candidates based on their predicted travel-related ischemic time and post-transplant outcomes.

Figure 6: Ischemic Time

Discussions focused on how to predict ischemic time with information known at the time of the match run. SRTR staff presented a method for predicting ischemia time based on information known at the time of the match run. Since ischemia time is not known at the time of the match run, ischemia time must be estimated based on a variable that is known, like distance. SRTR analysis showed there is much variability in the relationship between ischemia time and distance but there is an upward trend, and the average ischemia time is higher for transplants at 1,000 miles than at 100 miles.[13] The upward trend is mostly linear after 500 miles. The high variability in the relationship between ischemia time and distance causes concern for using straight line distance, or transit time as predictors for post transplant outcomes. (See Error! Reference source not found..) At shorter distances, ischemia time differs based on variables that have nothing to do with distance, like the complexity of the transplant procedure. In these situations, it is the patient's circumstances that dictate the ischemia time and the outcome, not the distance. While longer ischemia times could impact outcomes in some situations, this is not reflected in OPTN data because transplant programs do not accept organs when ischemia time is expected to be problematic. After much discussion, the challenges in accurately predicting travel-related ischemia time and the low correlation between ischemic time and either straight line distance or predicted travel time provided reason for the Committee to exclude ischemic time in the composite allocation score at this time.

[13] SRTR. 2020. *LU2020_01, Data Request from the Continuous Distribution Workgroup of the OPTN Thoracic Committee*.

Figure 7: Predicting CIT from Distance[14]

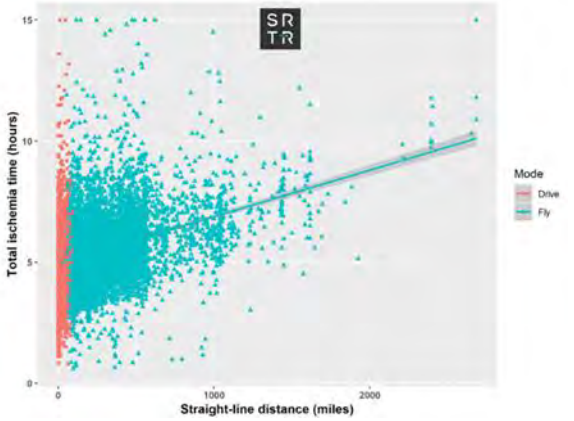
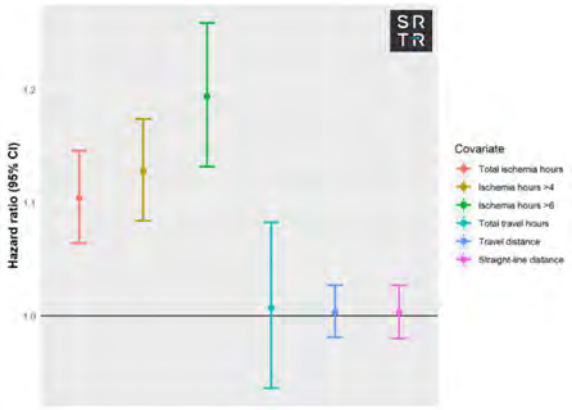


Figure 8: Functional Form of Ischemia / 1-Year Survival Relationship[15]



The effect of different donor characteristics and ischemic time were also evaluated through SRTR data and literature.[16] In reaching its decision to not include travel-related ischemic time in the composite allocation score, the Committee also took into account findings from the Mulhivill paper which concluded, "Neither ischemic time nor interaction of ischemic time and donor age were significantly associated with overall survival. There does not appear to be an interaction between donor age and ischemic time."[17]

Though SRTR analyses revealed a positive, statistically significant relationship between total ischemic time and lung recipient survival, the same analysis found no relationship between distance and lung recipient survival.[18] After extensive discussion, the Committee determined that this observed relationship reflected non-travel related ischemia associated with unmeasured causes related to patient acuity and surgical complexity, and the association between travel-related ischemia and post-transplant outcomes was weak or non-existent.

Candidate Height Matching

The Committee discussed the role of size matching at their in-person meeting last fall.[19] Size matching is part of UNet's℠ donor screening criteria and serves a significant role in hospital acceptance practices but current lung allocation policy does not use it to prioritize candidates. The Committee agreed with the literature which showed size matching holds promise for predicting post-transplant outcomes[20] But

[14] Id., Figure 3.
[15] Id., Figure 8.
[16] Meyer, et. al. 2000. *Effect of Donor Age and Ischemic Time on Intermediate Survival and Morbidity after Lung Transplantation*." Mulvihill, et. al. 2017. *The association of donor age and survival is independent of ischemic time following deceased donor lung transplantation*.
[17] Id.
[18] SRTR (2020).
[19] OPTN. Oct. 17, 2019. *Minutes of Thoracic Committee*, available at: https://optn.transplant.hrsa.gov/media/3330/20191017_thoracic-committee_minutes.pdf.
[20] Eberlein, Michael, and Robert M Reed. 2016. *Donor to Recipient Sizing in Thoracic Organ Transplantation*. World Journal of Transplantation 6 (1): 155–64. https://doi.org/10.5500/wjt.v6.i1.155. Keeshan, Britton C., Joseph W. Rossano, Nicole Beck, Rachel Hammond, James Kreindler, Thomas L. Spray, Stephanie Fuller, and Samuel Goldfarb. 2015.*Lung Transplant Waitlist Mortality: Height as a Predictor of Poor Outcomes*. Pediatric Transplantation 19 (3): 294–300. https://doi.org/10.1111/petr.12390.

the Committee nonetheless agreed that this wasn't a necessary additional and would require extensive analysis right now so it will not include size matching at this time but might include it in a future change to lung allocation.

Candidate Biology

The next goal in the hierarchy of attributes is candidate biology, or increasing transplant opportunities for patients who are medically harder to match. The OPTN Final Rule calls for allocation policies to "promote patient access."[21] Some candidates have difficulty finding a suitable donor due to biological incompatibilities. The OPTN has long used different mechanisms, for example the CPRA sliding scale in kidney allocation policy, to reduce these biological differences in transplant access.[22] With this in mind, the Lung Committee looked to current policy for 1) which disadvantages to include and 2) how to prioritize candidates according to their candidate biology. After much discussion, the Committee agreed to include the following three disadvantages:

- Blood type
- Highly sensitized
- Candidate height

Other organs

The topic of candidate biology that affects differences in transplant access is not unique to lung allocation. Every organ system includes some attempt to reduce these differences. The approaches used to address these differences in lung allocation can be replicated using clinical data or different attributes for other organs.

In this way, it is a data driven decision about how to prioritize candidates according to different heights, blood types, or sensitization levels and how much priority to give for height vs. blood type or sensitization. It is then a values laden question about how much weight should be given to Decrease Biological difference in transplant allocation vs. placement efficiency, medical urgency, or post-transplant outcomes.

Because all three attributes consider the same clinical issue (disadvantages in transplant access due to biological incompatibility with donors), we can use clinical data to inform the degree to which these attributes and their levels should be prioritized in the composite allocation score. OPTN data can show the factors which influence a candidate's access to transplant.[23] These data can also show the relative importance of each factor in determining a candidate's access. This relative importance can be used to empirically weigh these attributes.

Blood Type

The Committee discussed the role of blood type in lung allocation. Lung allocation currently classifies candidates according to identical, compatible, intended incompatible, and incompatible blood type with the donor matches. This general framework has been in place since the earliest lung allocation policies.[24] The Committee discussed whether the purpose of these policies was to promote post-transplant

[21] 42 CFR Sec. 121.8(a)(5).
[22] OPTN Policy 8.3, Table 8-2 *Points for CPRA.*
[23] OPTN. 2020. *Access to Transplant: Lung Equity Dashboard*, available at: https://insights.unos.org/equity-in-access/.
[24] Egan, T.M., Murray, S., Bustami, R.T., Shearon, T.H., McCullough, K.P., Edwards, L.B., Coke, M.A., Garrity, E.R., Sweet, S.C., Heiney, D.A. and Grover, F.L. 2006, *Development of the New Lung Allocation System in the United States*. American Journal of Transplantation, 6: 1212-1227. https://doi:10.1111/j.1600-6143.2006.01276.x

outcomes or to provide equity in the system. The Committee reviewed relevant articles and agreed the purpose for distinguishing candidates based on blood type was to promote patient access and provide equity in the system, not due to post-transplant survival concerns.[25] The composite scoring system will award differential point values for A, B, AB, and O patients based on clinical data reflecting the portion of available lung donors with which each group is blood type compatible.

The framework of prioritizing identical donors over compatible donors is found in other organs. Similarly, some of the other organ systems also contain a preference for blood type O candidates to provide equity in the system. The analysis performed for the continuous distribution of lungs provides a framework for how this analysis can be performed for other organ systems as well.

Highly Sensitized

Lung allocation policy currently prioritizes highly sensitized lung candidates.[26] This policy aim 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. Also, public comment from 2018 and recent literature shows the community's wish to address this issue.[27]

The Committee reviewed relevant literature and similar policies in other organs and agreed that use of the CPRA sliding scale should be developed as the basis for assigning points to highly sensitized candidates based on sensitization level. While members are not required to submit unacceptable antigen information similar to kidney candidates,[28] a CPRA can be calculated for those candidates that do enter the information. Literature shows that while the CPRA was designed with kidney candidates in mind, it is a good predictor of the level of sensitization in thoracic candidates.[29] This model could be expanded to other organs (ex. liver or heart) that do not have points based mechanisms for prioritizing highly sensitized candidates. This approach also could be used to smooth out the CPRA points curve used in kidney allocation and address the issue about access for the most highly sensitized candidates. Therefore, the Committee agreed to include priority points dependent on the sensitization level of candidates.

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[25] Barac YD, Mulvihill MS, Cox ML, et al. 2019 *Implications of blood group on lung transplantation rates: A propensity-matched registry analysis*. J Heart Lung Transplant. 38(1):73-82.

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

[27] OPTN. 2018. *Modifications to the distribution of deceased donors lungs, briefing paper*, available at: https://optn.transplant.hrsa.gov/media/2523/thoracic_boardreport_201806_lung.pdf.
Ericheok Tague LK, Witt CA, Byers DE, et al. 2019. *Association between Allosensitization and Waiting List Outcomes among Adult Lung Transplant Candidates in the United States*. Ann Am Thorac Soc. 16(7):846-852.

[28] OPTN Policy 4.3.B *HLA Typing for Candidates*

[29] Kucheryavaya A, Callahan L Robbins, Edwards L. 2015. *Kidney Vs. Heart Calculated PRA (CPRA) for Sensitized Heart Candidates: Does Donor Ethnic Distribution Make a Difference?* [abstract]. Am J Transplant. 15 (suppl 3), available at https://atcmeetingabstracts.com/abstract/kidney-vs-heart-calculated-pra-cpra-for-sensitized-heart-candidates-does-donor-ethnic-distribution-make-a-difference/. Kransdorf EP, Kittleson MM, Patel JK, Pando MJ, Steidley DE, Kobashigawa JA. 2017 *Calculated panel-reactive antibody predicts outcomes on the heart transplant waiting list*. J Heart Lung Transplant. 36(7):787-796. Barac, Y.D. et al. 2019. *High Calculated Panel Reactive Antigen (cPRA) is Associated with Decreased Rates of Transplantation and Increased Waitlist Mortality in Lung Transplantation: A UNOS/OPTN Registry Analysis*. The Journal of Heart and Lung Transplantation, Volume 38, Issue 4, S148. https://doi.org/10.1016/j.healun.2019.01.353

Candidate Height

As mentioned above, the Committee agreed with the literature that showed size matching holds promise for predicting post-transplant outcomes.[30] However, the Committee also agreed this would require extensive analysis right now so excluded size matching at this time. Separately, literature shows that a candidate's height can influence their access to transplant.[31] Therefore, the Committee agreed to include priority points dependent on the candidate's height alone, not the relationship between the candidate and donor heights.

Patient Access

The next goal in the hierarchy of attributes is ensuring patient access according to the OPTN Final Rule requirement for allocation policies to "promote patient access."[32] Across the organs, OPTN policy currently prioritizes access for two candidate populations:

- Candidate age groups
- Prior living donors

Candidate Age Groups

The Committee discussed the role of age in lung allocation. 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 prioritizes older candidates (12 years or older) for lungs from adult donors.[33] The OPTN Board adopted these policies in 2015 to address the barriers to transplantation that pediatric candidates face.[34] Currently, age distinguishes candidates into classifications before medical urgency is considered. For lungs from donors younger than 18 years old, an 11-year old candidate will generally receive the organ offer before a 12 to 17-year old candidate at similar distances – irrespective of any difference in medical urgency. The prioritization for lungs from older adult donors also uses age classifications to generally prioritize adults and adolescents (aged 12-17 at the time of the offer) over pediatric candidates.

Similar to lung, age groups are used in almost of all the organ systems to classify donors or candidates, most notably to award priority for pediatric candidates. Before the Committee makes final decisions about the use of age, they will consider previous attempts by the OPTN to use age in organ allocation.[35] In 2011, HHS Office of General Counsel and Office of Civil Rights provided advice about the use of age in

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[30] Eberlein, Michael, and Robert M Reed. 2016. *Donor to Recipient Sizing in Thoracic Organ Transplantation*. World Journal of Transplantation 6 (1): 155–64. https://doi.org/10.5500/wjt.v6.i1.155. Keeshan, Britton C., Joseph W. Rossano, Nicole Beck, Rachel Hammond, James Kreindler, Thomas L. Spray, Stephanie Fuller, and Samuel Goldfarb. 2015. *Lung Transplant Waitlist Mortality: Height as a Predictor of Poor Outcomes*. *Pediatric Transplantation* 19 (3): 294–300. https://doi.org/10.1111/petr.12390.

[31] Sell, Jessica L., et. Al. 2016. *Short Statute and Access to Lung Transplantation in the United States: A Cohort Study*. American Journal of Respiratory and Critical Care Medicine 193(6): 681-88.

[32] 42 CFR Sec. 121.8(a)(5).

[33] OPTN Thoracic Transplantation Committee. Dec. 2015, *Proposal to Modify Pediatric Lung Allocation Policy briefing paper*.

[34] OPTN, Dec. 2015. *Proposal to Modify Pediatric Lung Allocation Policy policy notice*, available at: https://optn.transplant.hrsa.gov/media/2075/policynotice_20151201_ped_lung_policy_changes.pdf.

[35] Eidelsen, Benjamin, 2013. *Kidney Allocation and the Limits of the Age Discrimination Act*, Yale Law Journal (2013). Persad, Govind. 2019. *Evaluating the Legality of Age-Based Criteria in Health Care: From Nondiscrimination and Discretion to Distributive Justice*, Boston College Law Review. Sweet SC, Barr ML. 2014. *Pediatric lung allocation: the rest of the story*. Am J Transplant. 14(1):11-2.

kidney allocation. "[HRSA] shared that according to the stipulations in the [Age Discrimination] Act[36], age may be used if it is a proxy for medical variables. Therefore, the use of age in the calculation of estimated post transplant survival (EPTS) was not of concern because the evidence has shown that age is a suitable proxy for variables such as cardiovascular disease which are not available in the OPTN dataset. However, in the [kidney] concept document, the use of age matching within 15 years appeared to be arbitrary in that candidates who are sixteen years older or younger than a donor are not substantially clinically different than those who have 14 years of age difference." [37]

For these reasons, the Committee has favored a points based system that distinguishes candidates that are under 18 years old from those that are at least 18 years old. This would remove the priority granted to candidates 12-17 years old. Drawing the line at 18 years old is consistent with NOTA's requirement to "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.."[38] This is also consistent with the OPTN's Ethical Principles of Pediatric Organ Allocation, which concludes: "Drawing from regulatory guidance and ethical principles, we find that there is a reasonable basis for giving preference to pediatric transplant candidates for allocation. This preferential allocation must take into account the organ-specific clinical context faced by candidates of all ages."[39] Therefore, the committee agreed to provide priority for candidates under 18 at the time of organ offers but not further distinguish between candidates 0-11 and 12-17. While this eliminates one type of priority for pediatric candidates, these candidates should not have decreased access to transplant so long as the attribute for pediatric priority is sufficiently large.

The Committee has also agreed to provide this same pediatric priority for both pediatric and adult donor lungs. This may decrease access to adult donor lungs for adult candidates, however any impact is expected to be small due to the lung waiting list having relatively few pediatric candidates. The impact of this decision is expected to be beneficial for taller pediatric candidates but not very impactful on adult candidates due to the relatively small number of pediatric candidates compared to adult candidates.

Prior Living Donors

Living donation is generally considered to be safe and end stage organ failure is relatively rare among living donors.[40] Starting in 1996, prior living donors have received priority for kidney transplants.[41] To be consistent with kidney allocation policy, the Committee favors adding priority points for prior living donors.[42] Living lung donation is rarely performed in the United States.[43] However, living donors can donate a portion of their lung and could need a subsequent lung transplant. The Committee agreed to

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[36] 42 U.S.C. §§ 6101-6107 (2006).
[37] OPTN Kidney Transplantation Committee. Aug. 26, 2011. *Meeting Minutes*.
[38] 42 USC Sec. 274(b)(2)
[39] Available at: https://optn.transplant.hrsa.gov/resources/ethics/ethical-principles-of-pediatric-organ-allocation/.
[40] Wainright et al. 2017. *The Impact of the New Kidney Allocation System on Prior Living Kidney Donors' Access to Deceased Donor Kidney Transplants: An Early Look. Transplantation.* 17: 1103-111. https://doi: 10.1111/ajt.14102 *citing* Muzaale AD, Massie AB, Wang MC, et al. 2014. *Risk of end-stage renal disease following live kidney donation*. JAMA 311: 579– 586. and Mjoen G, Hallan S, Hartmann A, et al. 2014. *Long-term risks for kidney donors*. Kidney Int. 86: 162– 167.
[41] Smith JM, Biggins SW, Haselby DG, et al. 2012. *Kidney, pancreas and liver allocation and distribution in the United States*. Am J Transplant. 12(12):3191-212. https://doi.org/10.1111/j.1600-6143.2012.04259.x
[42] OPTN Policy 8.3: *Kidney Allocation Points*. During its June 26-27, 1996 meeting, the Board first adopted a change permitting the assignment of points to kidney candidates that are prior living donors.
[43] Domino donors also occur. However, since this donors also receive a transplant at the time of those donation, we might not want to include them in this category.

add priority for *all* prior living donors of any solid organ, not just a partial lung, to be consistent with the kidney allocation policy.

Since 1996, the transplant community has repeatedly expressed, that in their medical judgement, prior living donors should be prioritized for transplant. While developing the Revised Kidney Allocation System (KAS), the Kidney Committee states that "[P]rior living donor priorities were determined to be important not only from the standpoint of patient care, but also from a public perception standpoint."[44] In response to a 2012 public comment proposal that clarified this prioritization, the Ethics Committee noted that "[u]nder the same principles that support the priority for kidney allocation, there should be consideration to grant priority for living donors of other organs."[45] The Living Donor Committee commented that, "[t]he Committee also questioned if prioritization (special exception points) should be provided for prior liver (and/or lung) donors who may need to be listed for liver (or lung) transplant." In 2015, "The Joint Societies Work Group previously developed recommendations for living liver donor consent, medical evaluation as well as living donor follow-up; the work group also identified a possible need for a policy to prioritize prior living liver donors who need a liver transplant, similar to the priority provided to living kidney donors who subsequently need a kidney transplant."[46] In 2019, the Kidney Committee released a public comment proposal that, among other things, impacted the prioritization of prior living donors. Public comment showed positive support for prioritizing prior living donors.[47]

This attribute is in alignment with NOTA and the OPTN's Final Rule requirement to develop organ allocation policies based upon sound medical judgment and achieve the best use of organs. The record shows that reasonably prudent physicians, knowledgeable about transplant and the allocation system, agree with this prioritization. In 2012, when the Ethics Committee was reviewing (KAS), they noted that prioritization of prior living donors was a utility component when discussing the utility vs. equity balance in KAS.[48] This is relevant in that it further cements that this attribute helps achieve the best use of organs, which is a requirement in the OPTN Final Rule for allocation policies.

Waiting Time

Waiting time is used as a tiebreaker in current lung allocation.[49] 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 some weight to waiting time and prioritize candidates with more waiting time.

After discussion, the Committee agreed *not* to include waiting time as an attribute but instead favored its continued use as a tiebreaker if the composite allocation score results in a tie. While it is unlikely that ties would exist in this new framework, the potential does exist – most commonly for review board exceptions. This decision is also consistent with published literature on the role of waiting time in organ allocation. A report commissioned from the Institute of Medicine states that organ allocation should be

[44] OPTN. Dec 13, 2006. *Kidney Committee Report to Board*.
[45] OPTN. April 2, 2012 *Minutes from Meeting of Ethics Committee*.
[46] *Letter from Liver Committee to Living Donor Committee*, Feb 23, 2015. Note: The Joint Societies contained representatives from the American Society of Transplant Surgeons, the American Society of Transplant, the National Association of Transplant Coordinators, the OPTN, and HRSA.
[47] OPTN. Aug. 19, 2019. *Minutes from Meeting of Kidney Transplantation Committee*.
[48] OPTN. Oct. 3, 2012 Minutes of Ethics Committee.
[49] OPTN Policy 10.4.A *Sorting Within Each Classification*.

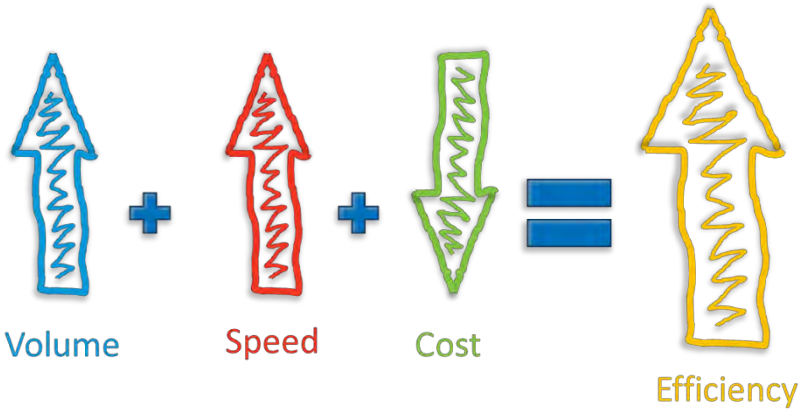
based on measures of medical urgency, while avoiding futile transplants, and *should minimize the effect of waiting time*.[50] A 2005 article stated, "An allocation system that is based on accumulated waiting time favors patients who are 'well enough' to wait the longest. A corollary is that patients with seniority in the current allocation scheme may have a better chance of longer survival time without undergoing transplantation, which was a finding both in the study by Hosenpud *et al* (6) and in analyses performed by the Lung Allocation Subcommittee.[51] For these reasons, the Committee decided to keep waiting time for breaking ties in candidate scores but not to include it as a weighted attribute.

Promoting the Efficient Management of Organ Placement

The next goal in the framework of attributes is increasing the efficient management of organ placement [52] The OPTN Final Rule does not define the "efficient management of organ placement." However, a Federal Register notice related to the development of the OPTN Final Rule can provide some guidance for interpreting this clause. It stated:

> 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.[53]

In considering attributes for efficiency, the committee discussed that it means to have an efficient organ placement system.[54] Efficiency can be thought of as increased volume/output (ex. more transplants), faster cycle times (ex. placement times or transportation times), or lower costs (ex. discards, or surgeon time). These three concepts usually require trade-offs. This is similar to the trade-offs between cost, quality, and speed in project management.[55]



In continuous distribution, we've been talking about the trade-offs between medical priority, equity, and system efficiency.

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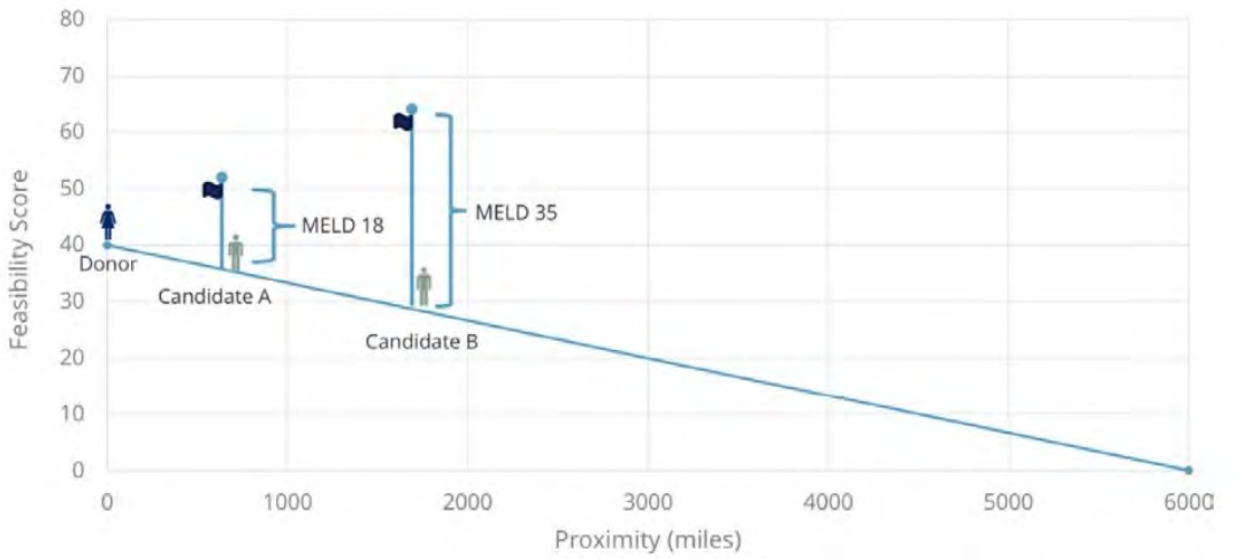
[50] Institute of Medicine, Committee on Non-Heart-Beating Transplantation II. 2000. *Non-heart-beating organ transplantation: practice and protocols*. Washington, DC: National Academy Press.
[51] Egan TM, Kotloff RM. 2005. *Pro/Con debate:* lung allocation should be based on medical urgency and transplant survival and not on waiting time. Chest. 128(1):407-15. *citing* JD Hosenpud, LE Bennett, BM Keck, et al. 1998. *Effect of diagnosis on survival benefit of lung transplantation for end-stage lung disease* Lancet, 351, pp. 24-27
[52] 42 CFR Sec. 121.8(a)(2).
[53] 63 FR 16315 (1998).
[54] OPTN, *Minutes from Meeting of Lung Continuous Distribution Workgroup,* June 18, 2020.
[55] Project Management Institute, *Project Management Book of Knowledge,* 2017.

Travel Efficiency or Cost

The Committee discussed travel efficiency. Members have expressed concern about transporting organs long distances for small differences in medical priority, especially when the candidates are less medically urgent. The farther an organ is transported, the more likely it is to travel by air than ground and the cost of transportation increases.[56] Financial costs are one aspect of overall system efficiency. The Committee received analysis from the SRTR to construct a rating scale related to the relative cost of transporting lungs over distance.[57]

General Proximity Scale

Another concept discussed by the Committee was a generic proximity attribute. This could either replace or be in addition to the above mentioned travel efficiency attribute. As explained below, the Committee discussed and rejected many other potential attributes because they did not feel that there was enough data to make an evidence based decision that justified their inclusion at this time. However, they noted a trend amongst some of the attributes: there was a relationship between efficiency and proximity between the donor and transplant hospital. For example, hospitals are less likely to accept organs that are from further away. Candidate density grows as distance grows which would prioritize candidates closer to the donor hospital. Surgeons are out of the hospital for longer periods of time if they have to procure an organ from further away. For these reasons, the committee decided to include a generalized proximity scale as a proxy for the efficiencies associated with proximity, that are not related to cost. This will be similar to the scale first proposed by Snyder et al.[58]



[56] Gentry SE, Chow EK, Dzebisashvili N, et al. 2016. *The Impact of Redistricting Proposals on Health Care Expenditures for Liver Transplant Candidates and Recipients*. Am J Transplant. 16(2):583-93. Dubay DA, Maclennan PA, Reed RD, et al. 2015. *The impact of proposed changes in liver allocation policy on cold ischemia times and organ transportation costs*. Am J Transplant. 15(2):541-6.

[57] SRTR, Feb. 28, 2020. *LU2020_01: Data Request from the Continuous Distribution Workgroup of the OPTN Thoracic Committee*.

[58] Snyder et al, Figure 1.

Other Attributes Considered

The Committee discussed multiple potential attributes related to placement efficiency, including:

- Reduce the time between match run and final offer acceptance
- Candidate and hospital density
- Aura placement
- Reduce surgeon unavailability and donor hospital delays by encouraging more local recovery
- Use of OPTN tools that add to placement system efficiency

Reduce the time between match run and final offer acceptance

The likelihood of acceptance is another aspect of placement efficiency. The concept is that if an OPO can place an organ quicker, then the placement system is more efficient. There are different approaches to design this attribute:

> ***National acceptance practices*:** The OPTN collects information on acceptance practices. These could be analyzed to discover national acceptance patterns. These patterns could then be used to prioritize offers that are more likely to be accepted. The SRTR acceptance model used for simulating allocation policies provide some examples that could be included here.[59]
>
> ***Member specific acceptance practices*:** The OPTN collects information regarding member specific acceptance practices. These could be analyzed to determine member specific acceptance patterns. These patterns could then be used to prioritize members that are more likely to accept donor lungs matching certain criteria. An example of the use of past acceptances to determine future offer priority is in policy is Policy 11.6 *Facilitated Pancreas Allocation*.
>
> ***Candidate specific criteria*:** Another theory is that a candidate with a low LAS might be more willing to accept a less than ideal lung offer because they understand their LAS will not be high enough to prioritize them for ideal lung offers. Transplant hospitals would have to indicate this through some sort of screening criteria.

After discussion, the Committee declined at this time to include the likelihood of acceptance as an attribute in the composite allocation score. The Committee's discussion focused on two concerns. First, committee members expressed concern that the OPTN does not collect enough information to accurately predict the likelihood of acceptance. This is because acceptance patterns can differ between and within transplant hospitals, some accepting physicians consider clinical information that is not reported to the OPTN in a structured format, acceptance patterns can change over time, and we would not want to reinforce poor acceptance practices. Second, some committee members expressed concern about the OPTN limiting offers and physician's clinical decision making abilities. Additionally, lungs are typically offered and accepted within the first few offers which is different than organs such as kidney and livers; therefore, therefore, this approach might not amount to significant improvements in efficiency.[60]

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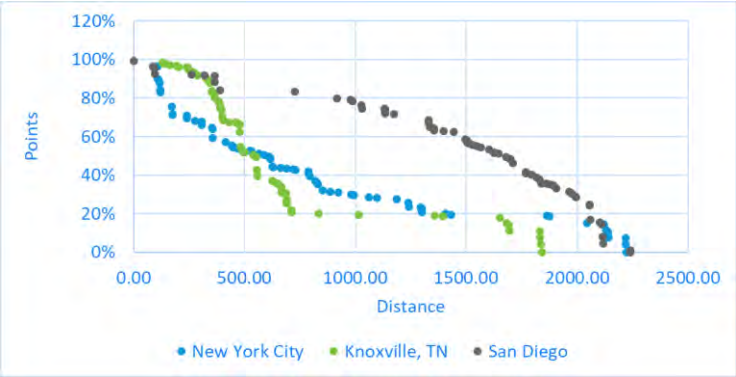
[59] https://www.srtr.org/reports-tools/offer-acceptance/

[60] Lehman, Rebecca. Jan. 16, 2019. *Monitoring of the Lung Allocation Change, 1 Year Report. Removal of DSA as a Unit of Allocation,* Figure 21. Available at https://optn.transplant.hrsa.gov/media/2815/20190116_thoracic_committee_report_lung.pdf.

Some members stated that in the long run, they did support "candidate specific criteria." However, this is likely too complex of an idea to pursue in the first iteration of continuous distribution, and there may not be enough data in UNet to support it for some time.

Candidate and Hospital Density

Another aspect of efficiency concerns the number of hospitals involved in the match at any given time. It takes less time for an OPO and transplant hospital to discuss the offer of one organ to five candidates at the same hospital than it does for an OPO to have similar conversation with five different hospitals. An efficient system would limit the number of hospitals with whom an OPO needs to interact at any given time.



While some members have expressed interest in this as an attribute, the Committee declined to include this as an attribute. Concerns were raised that this could advantage candidates registered at a transplant hospital close proximity to other transplant hospitals (typically large urban areas). Concerns were also raised whether it would be better to model this using donor density which then raised questions concerning the use of actual vs. potential donors and whether this attribute was more focused on equity or efficiency. Ultimately, the Committee believed this is worth further research and possible inclusion in a future iteration of continuous distribution, but were not ready to include candidate density at this time.

Aura placement

Another concept discussed by the Committee was a composite score aura. The concept is also based upon the notion it is more efficient to make 10 offers to 10 candidates at one hospitals than 10 offers to 10 candidates at 10 different hospitals. In this situation, a center would be permitted to accept the organ for any candidate whose composite score fell within the prescribed "aura".

The Committee saw this concept as ripe for abuse by transplant candidates with "magnet candidates" and did not endorse this approach. Furthermore, this approach strayed from the OPTN's long held approach that organs are allocated to candidates and not transplant programs.

Hypothetical match run under CD

Aura (cushion) = 0.2

Composite allocation score	Candidate	Center
5.45	1	A
5.40	2	B
5.35	3	A
5.33	4	A
5.30	5	B
3.90	6	A
3.50	7	B
3.25	8	C
3.00	9	C
2.96	10	A

Center A would be allowed to consider the organ for candidates #1, 3 & 4

If Center B became primary, it would be allowed to consider the organ for candidates #2 & 5

Reduce surgeon unavailability and donor hospital delays by encouraging more local recovery

Another aspect of efficiency concerns who recovers the organs. In most thoracic procurements, a recovery team travels from the accepting transplant hospital to the donor location then back to the transplant hospital. Other countries have found that it is more efficient for a recovery team closer to the

donor location to procure the organs then ship the organs to the transplant hospital.[61] Bonus points could be given to candidates willing to accept a locally recovered organ. This could happen in a couple different ways and would require monitoring to combat late turndowns and reallocations after the organ is transported.

While some members expressed interest in this as an attribute, the Committee declined to include this as an attribute. Concerns were raised concerned the availability of local procurement teams for lung transplantation. This attribute would be more meaningful if there already existed a broad system of local, lung procurement teams; right now, it is too dispersed to be meaningful for all transplant programs. Concerns were also raised that a member could indicate that they were willing to accept the organ from a local procurement team but change their mind once they had accepted the offer. There is also a lack of data regarding the level of efficiency gained by a local procurement team in the United States.[62] Ultimately, the Committee believed this is worth further research and possible inclusion in a future iteration of continuous distribution, but were not ready to include this attribute now. It is worth noting that the Policy Oversight Committee currently has a workgroup that is exploring how to increase the use of and efficiency of local procurement teams.

Use of OPTN tools that add to placement system efficiency

Another way in which to consider placement management efficiency is the "use of screening tools." The theory is that screening tools are similar to unacceptable antigens. If a member submits unacceptable antigens, it makes it harder for the candidate to receive a matching offer but makes the system more efficient. In exchange, sensitized candidates receive priority through CPRA points. Similarly, if a candidate has strict screening criteria, it will make it harder for the candidate to receive a matching offer and makes the placement system more efficient. For this, they could be awarded points. While the OPTN encourages members to use reasonable screening criteria, this approach could be concerning if it encouraged members to use screening criteria to not accept marginal donor organs. Additionally, the OPTN would likely need to improve the granularity and available options for screening tools available to members before this could be implemented. For these reasons, the Committee generally did not favor the addition of this attribute.

Ethical Analysis

All of the attributes outlined above align with ethical principles of equity or utility. These principles have been expressed consistently in NOTA, the 1986 Taskforce on Transplantation, and the OPTN Ethical Principles in the Allocation of Human Organs.[63] While these documents express a need to consider and balance both equity and utility, they do not call for an exact 50/50 balance between these two ethical principles.

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[61] Natl. Health. Services. 2019. *Annual Report on the National Organ Retrieval Service*, available at https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/17072/annual-report-on-the-national-organ-retrieval-service-201819.pdf. Matesanz R, Miranda B, Felipe C.. 1994. *Organ procurement in Spain: impact of transplant coordination*. Clin Transplant. 8(3 Pt 1):281-286.

[62] While there is evidence about the efficiency of local recovery teams in the United Kingdom and Spain, those are national systems that are not the same as the dispersed procurement system in the United States.

[63] 42 USC Sec. 273, National Organ Transplant Act. U.S. Dept. of Health & Human Services. 1986. *Organ Transplanttion: Issues and Recommendations: Report of the Task Force on Organ Donation*. OPTN. 2015. *Ethical Principles in the Allocation of Human Organs*. Note: Equity is sometimes referred to as justice in these sources.

Continuous distribution serves as a vehicle to *not* to reargue well settled principles and requirements but rather to explore how the OPTN meets these requirements. Several years ago, Veatch and Ross foresaw the values of a composite allocation score as a method to balance our ethical goals.

> There is another strategy for integrating utility and justice that more plausibly would give them equal weight. We could standardize measures of expected medical benefit to that the candidate would the most expected benefit would get a full or maximum number of points for medical benefit. Then all the other candidates would be assigned lesser points in proportion to their expected medical benefit from the particular organ being allocated. Finally, we could standardize measures of medical need… with the most needy person receiving a maximum number of "justice points" and others who are less needy receiving lesser numbers of points in proportion. … The points of each type would then need to be allocated based on empirical evidence of how various factors are related to their target.[64]

Key features of allocation are not clinical decisions but rather are values laden questions. At its simplest level, we seek to balance equity and utility in the system. Many of the most essential and controversial allocation policy decisions are those that are values laden questions. For example, "the real issue in the debate over a local or national allocation are moral. … [D]eciding whether to trade off efficiency to make the allocation more fair is fundamentally not a technical medical questions. It is a question of the relative moral priority of efficiency and equity."[65]

Organ allocation requires the balancing of multiple goals. The field of operations research provides many tools for evaluating what are known as multi-criteria decisions. Because patients are just as capable of making values laden judgments and are ultimately impacted by these decisions,[66] the OPTN sought an approach that will allow patients to participate in this process. After much discussion and analysis, the Committee settled on a hybrid approach of different multi-criteria decision making (MCDM) methodologies to develop this project. Community feedback is most useful on the values laden decisions therefore the Committee is utilizing an Analytical Hierarchy Process (AHP) for its strengths in collecting feedback from a broad and diverse community. This has shown great promise for solving complex ethical problems[67] and including patients in clinical decision making. [68]

Policy Development Approach

As described in the August 2018 concept paper, the development of the composite allocation score requires the Committee to both 1) prioritize attributes against each other and 2) assign points to candidates within each attribute. The process to assign points within an attribute uses clinical and operational data to construct a ratings scale for each attribute. More information about each attribute is included above.

The approach to prioritize or weigh the attributes against each other is depicted in **Figure 11**. We can not use solely clinical or operational information to choose the relative weights of these attributes, as

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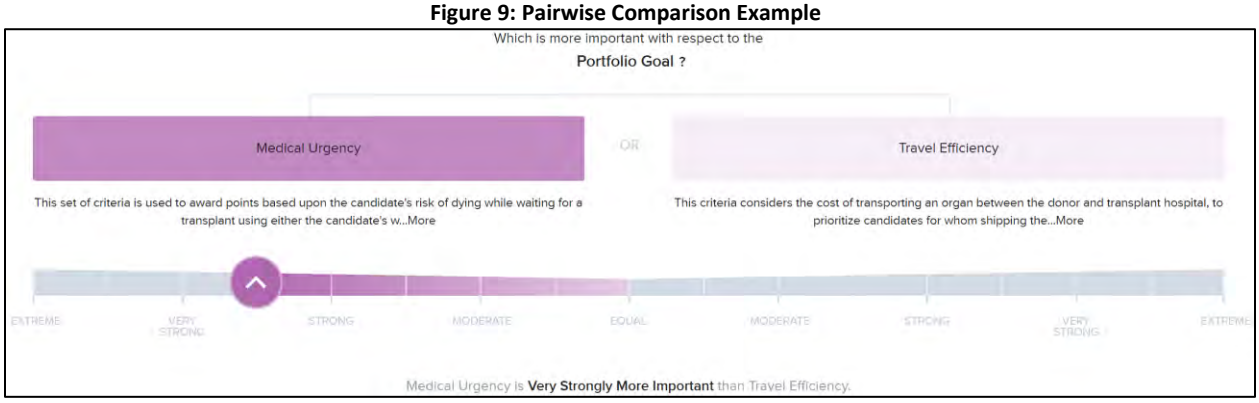
[64] Veatch & Ross, *Transplantation Ethics*, p. 302.
[65] Veatch & Ross, *Transplantation Ethics*, pp 377-378
[66] Veatch & Ross, *Transplantation Ethics*, pp 271-282.
[67] Millet, Ido. 1998 *Ethical Decision Making Using the Analytic Hierarchy Process*. Journal of Business Ethics. 17(11):1197-1204.
[68] Dolan, James. 2010. *Multi-criteria decision support: A primer on the use of multiple criteria decision making methods to promote evidence-based, patient-centered healthcare*.

these decisions also require making value judgments and ensuring compliance with laws and regulations. For this reason, it will benefit from a different analytical approach.

To begin, the OPTN is building a baseline of the current allocation policies in points.[69] The OPTN has years worth of prior decisions (in the form of match run data) that can be analyzed to estimate the community's priorities in how to allocate organs.[70] This is helpful for three reasons: 1) it shows the capability to allocate organs equitably and efficiently using a points based approach; 2) it provides a baseline to compare future iterations of a composite allocation score; and 3) it provides a potential backup policy in case the community is deadlocked about moving forward with the more ambitious composite allocation score.

We then are collecting feedback from the community regarding the community's priorities.[71] The Committee seeks input from a diverse cross-section of the transplant community. The prioritization exercise will show each participant a pair of attributes that will be used to prioritize candidates. (For example **Figure 9** shows medical urgency and travel efficiency.) Participants will then be asked 1) which attribute is more important and *how much* more important is that attribute. Participants are also encouraged to leave comments to explain their rationale as this information is very helpful to the Committee.

Figure 9: Pairwise Comparison Example

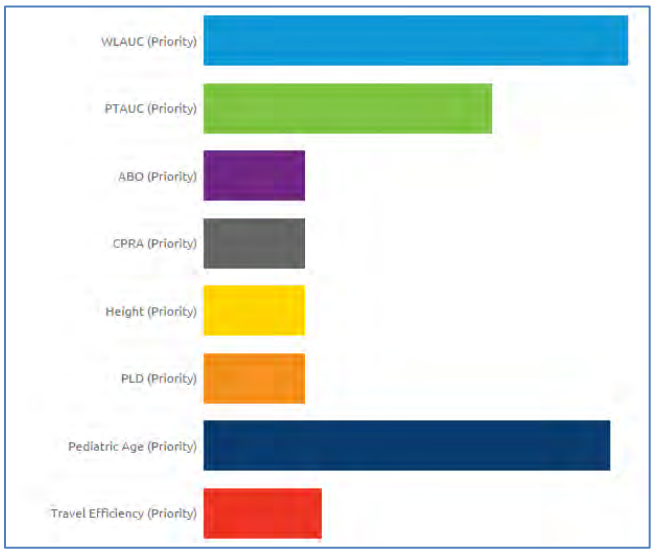


[69] The OPTN is using what is referred to as a revealed preference analysis, which is a cousin to discrete choice ("stated preferences") experiments. *See generally* Howard, Kirsten. et. al. 2016. *Preferences for Policy Options for Deceased Organ Donations for Transplantation: A Discrete Choice Experiment.* Transplantation.

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

[71] This is also referred to as an Analytic Hierarchy Process (AHP). *See generally*, Lin, Carol and Harris, Shannon 2013. *A Unified Framework for the Prioritization of Organ Transplant Patients: Analytic Hierarchy Process, Sensitivity, and Multifactor Robustness Study*. Journal of Multi-Criteria Decision Analysis.

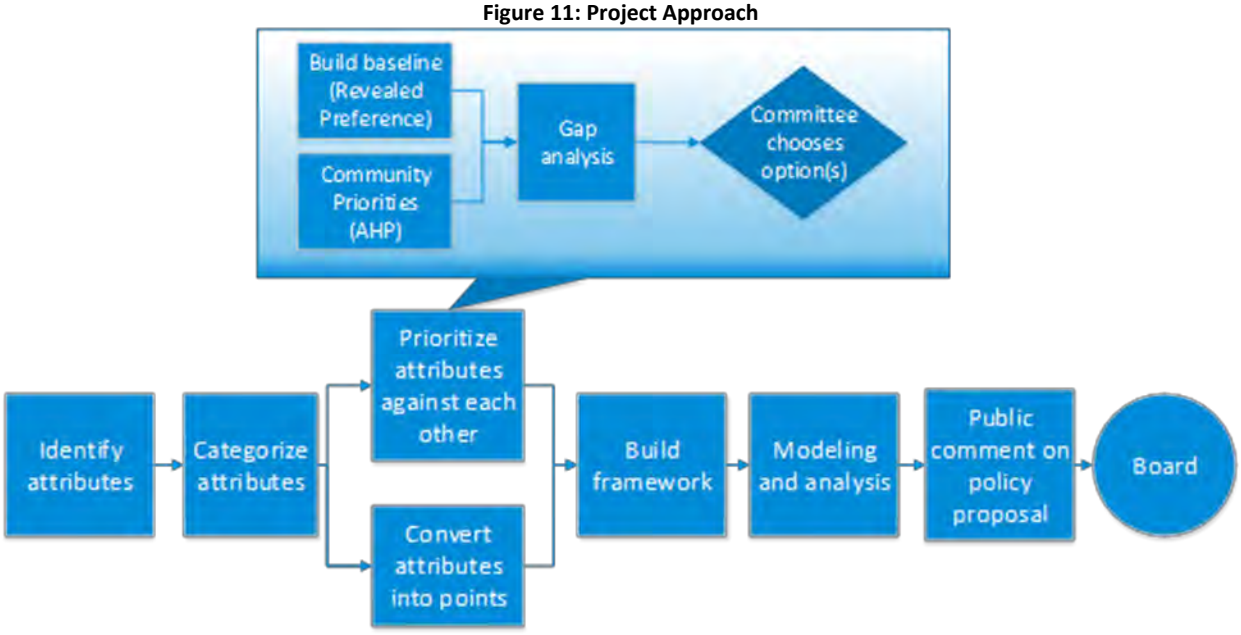
Figure 10: Hypothetical Attribute Weights



At the conclusion of the exercise, participants will be able to see their personal priorities for these attributes. (For example, see **Figure 10**.) The Committee will then review the overall priorities by specific attributes or demographics in order to better understand the community's preferences. If you wish to participate in the exercise to prioritize the attributes, please click here.

The Committee will then perform a gap analysis before choosing alternatives for SRTR modeling. This begins by building a baseline of the current policies in a points based fashion.[72] The Committee will review and discuss the differences between the baseline of current policies and the community's expressed priorities, along with a comparison against the OPTN's obligations in NOTA and the OPTN Final Rule, to develop a modeling request for the SRTR. The Committee will look for agreement across all of those resources and explore the reasoning for minority or different opinion. After reviewing those results and refining the relative weights of the attributes in the composite allocation score, the Committee will submit a modeling request to the SRTR. The Committee will *not* be bound to the majority perspective of the prioritization exercise; for the Committee *must* put forward a proposal that meets our statutory and regulatory requirements. The Committee will review the results of that modeling prior to releasing a policy proposal for public comment.

Figure 11: Project Approach



[72] This is referred to as "revealed preference" in **Figure 11**. For more information, *see* Swait, J. 2004. *Using stated preference and revealed preference modeling to evaluate prescribing decisions* Health Economics 13:563-573 https://doi: 10.1002/hec.845.

While this project will finish with a new method for allocating organs, it also represents new approaches for developing organ allocation policies. The policy development approaches have proceeded deliberately so that they can be replicated with other organ systems. For example, the discussions about how to award points to remove disadvantages based in candidate biology can be replicated for other organ systems or other biological disadvantages. The specific clinical outcomes from the lung project will not be binding upon other organs, but the methods will provide a structure to convert other organ systems to continuous distribution. In this way, this project will create efficiencies in future policy development efforts.

The Policy Oversight Committee discussed and agreed upon a sequencing for all of the organ systems to convert to continuous distribution. While lung continues their work, the OPTN has started work to convert kidney and pancreas. Liver and intestine will follow next. And last will be heart and VCA.

Figure 12: Sequence of Organs

NOTA and Final Rule Analysis

Organ allocation policies are governed by NOTA and the OPTN Final Rule.[73] These laws set requirements for allocation polices developed by the OPTN, including: sound medical judgement, best use of organs, avoiding wasting organs, promoting patient access to transplant, avoiding futile transplants, and promoting the efficiency of the organ placement system. The Final Rule also stipulates that allocation policies "shall not be based on the candidate's place of residence or place of listing, except to the extent required" by the other requirements of Section 121.8 of the Final Rule. Finally, the Final Rule includes a performance goal for allocation policies of "Distributing organs over as broad a geographic area as feasible under paragraphs (a)(1)-(5) of this section, and in order of decreasing medical urgency."

A critical objective of the Final Rule is to achieve the most equitable and medically effective use of donated human organs.[74] Towards that goal, the Final Rule directs the OPTN to overcome, as much as possible, arbitrary geographic barriers that restrict the allocation of organs to patients with the greatest medical urgency.[75] The proposed concept will allow a much more transparent nexus between any

[73] 42 U.S.C. Sec. 273 and 42 C.F.R. Sec. 121.8.
[74] 64 Fed. Reg. 56,650, October 20, 1999.
[75] 64 Fed. Reg. 56,651, October 20, 1999.

adopted policy and the legal requirements in the OPTN Final Rule. For example, the current system cannot easily express how each attribute aligns with the Final Rule or how important each factor is compared to one another. Whereas, continuous distribution's structure keeps these issues front and center. These requirements include the allocation policies:

- **Be based on sound medical judgment:** The construction of the individual ratings scales will be based on objective clinical and operations evidence. Because each attribute will have its own ratings scale, it will be easier to update the ratings scales 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 best uses of a donated organ is that it is transplanted according to medical urgency; therefore one of the attributes will concern each candidate's waitlist mortality. Additionally, this clause of the OPTN Final Rule will be considered as the Committee prioritizes the weight of that attribute. Finally, 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:** At this time, the proposed composite allocation score does not contain any attributes specifically designed to avoid wasting organs. The Committee has discussed attributes, such as the likelihood of organ offer acceptance, that would also have a positive effect on this Final Rule requirement. Additionally, 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 included several attributes in the proposed composite allocation score specifically to address this clause. This includes the three attributes under the goal of candidate biology (highly sensitized, candidate blood type, and candidate height) and the two attributes under patient access (candidate age and prior living donors). The inclusion of these attributes will increase access to transplantation for these patients.
- **Be designed to…promote the efficient management of organ placement:** The Committee will consider travel costs and proximity between the donor and transplant hospitals as indicators of the efficient management of organ placement. Travel costs have a more direct impact on the efficiency of the organ placement system than the current geographic zones. Furthermore, the Committee will weigh this attribute only as much as necessary so that organs are distributed as broadly as feasible. The committee is continuing to discuss other attributes related to placement efficiency and requests feedback on other potential attributes related to the efficient management of organ placement.
- **Not be based on the candidate's place of residence or place of listing, except to the extent required [by the aforementioned criteria]:** The requirement to distribute over a broad geographic area reflects professional consensus that organs are a national resource meant to be allocated based on patients' medical need.[76] Specifically, the 1986 Task Force stated that: "The principle that donated cadaveric organs are a national resource implies that, in principle, and to the extent technically and practically achievable, any citizen or resident of the United States in need of a transplant should be considered as a potential recipient of each retrieved organ on a

[76] 42 C.F.R. §121.8(b)(3)

basis equal to that of a patient who lives in the area where the organs or tissues are retrieved. Organs and tissues ought to be distributed on the basis of objective priority criteria, and not on the basis of accidents of geography."[77] The Institute of Medicine made this same conclusion in 1999[78] and so did the American Medical Association in 2012.[79] The two attributes related to efficiency are the only attributes related to the candidate's place of registration. The Committee will weight these attributes only as much as is necessary.

- **Consider whether to adopt transition procedures:** A points-based framework will facilitate the use of transition procedures for existing candidates. For example, we will be able to compare the policy proposal with the results of the revealed preference analysis to determine who is impacted and if there is a need for transition procedures. This would allow members and patients time to prepare for these changes.

Conclusion

This project serves as an opportunity to redefine how the OPTN allocates organs and addresses long standing inequities and inefficiencies in the system. It also represents an opportunity to rethink how the OPTN and the transplant community develops organ allocation policies. This paper explains the work that the Lung Committee has performed to date and how it will move forward to a policy proposal. It also demonstrates a framework that can be replicated for other organs while continuing to tailor it for the specific clinical needs of that organ.

Community Feedback

- Is there anything else that the OPTN can do to better help you understand how this proposal is being developed?
- Do you agree with the Committee's recommended attributes?
- Are there any additional attributes related to placement efficiency that you can recommend?
- If you wish to participate in the AHP exercise to prioritize the attributes, please click here. This will bring you to a registration form. After you register your email address, you will receive an email from admin@decisionlens.com with instructions regarding the prioritization exercise. If you do not have internet access and wish to participate in the prioritization exercise, please call 1-844-395-4428.

[77] U.S. Dept. of Health & Human Services, Public Health Service, Health Resources and Services Administration, Office of Organ Transplantation, 1987. *Organ Transplantation: Issues and Recommendations: Report of the Task Force on Organ Transplantation*. Rockville, MD., p. 91, 1987, quoting Hunsicker, LG

[78] National Academies Press. 1999. *Organ Procurement and Transplantation*.

[79] American Medical Association. 2012. *Opinion 2.16 – Organ Transplantation Guidelines*. AMA Journal of Ethics 14(3) pp. 204-214, available at *https://journalofethics.ama-assn.org/article/ama-code-medical-ethics-opinions-organ-transplantation/2012-03*.

Appendix: Glossary of Terms:

The following terms are used throughout the concept paper.

Attribute

Attributes are criteria we use to classify then sort and prioritize candidates. For example, in lung allocation, our criteria include medical urgency, travel mode, ischemic time, blood type compatibility, and others.

Classification-based framework

A classification-based framework groups similar candidates into classifications or groupings. We then sort candidates within those classifications. A candidate will only appear in the classification that is most beneficial to them. This is the framework currently used to allocate organs.

Cliff

Cliffs are an illustrative term to describe hard boundaries in the attributes used to prioritize candidates. For example, the zones used in concentric circles have hard boundaries at specific distances. Continuous distribution and the move to a points-based framework aim to smooth these hard boundaries.

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. This introduces a hard boundary in how candidates are prioritized. Thoracic organs were the first organs to be allocated using concentric circles.

Continuous Distribution

Continuous distribution was the phrase used in the 2018 Snyder article and by the Ad Hoc Geography Committee to describe a new framework for organ distribution. It utilizes points to prioritize candidates for organ transplant.

Distance

The distance between the donor hospital and transplant hospital is either the straight line or travel distance. Straight line distance is the current method for calculating distance and represents the shortest two points. Travel distance is the most likely distance that the organ would travel between two points. For example, a straight line distance would be the shortest distance between hospitals on either side of a body of water; whereas, the travel distance would be the distance that somebody might drive on the roads and bridges around the body of water.

Framework

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

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.

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. For example, if all else is equal, should a candidate with an LAS 80 receive twice as much priority as a candidate with an LAS 40? 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.

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 or DCE) that asks the decision maker to state their preferences in an experiment.

Stated Preference

A stated preference analysis asks participants to state their preferences in a pairwise comparison. AHP and DCE are examples of stated preference analysis.

Weight

Weights are the relative importance or priority of each attribute toward our overall goal of organ allocation. For example, should waitlist mortality be more or less important than post-transplant outcomes? Combined with the ratings scale and each candidate's information, this results in an overall composite score for prioritizing candidates.