

**CONTINUOUS DISTRIBUTION OF LUNGS**  
SUMMER 2020 PRIORITIZATION EXERCISE – COMMUNITY RESULTS

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# CONTINUOUS DISTRIBUTION OF LUNGS

## SUMMER 2020 PRIORITIZATION - COMMUNITY RESULTS

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## Summary

The transplant community participated in an Analytic Hierarchy Process (AHP)<sup>1</sup> exercise regarding the allocation of deceased donor organs from August 1 through October 2, 2020. This report provides background on the project and the results of the exercise. The project received almost 200 participants from across the transplant community. Areas suggested for discussion are highlighted to stimulate the Committee's deliberations. The Committee will then decide on which scenarios for the SRTR to model before the Committee develops a policy proposal for public comment in 2021.

Participants were asked to weigh their preferences between pairs of attributes in terms of how important each should be in prioritizing candidates for lung transplantation. These pairwise comparisons were then aggregated into overall preferences, or relative importance "weights," for the different attributes. The analysis revealed variability in the weights between the different demographic groups. Another way to compare their relative importance is to rank the attributes according to the AHP weights. [Figure 7](#) shows the ranking (1 for most important – 6 for least important) of each attribute by the different demographic groups and the average ranking across all demographic groups. When viewed as rankings, the most important attribute was increasing access for patients under the age of 18 ("pediatric priority") and the least important attribute was improving placement efficiency. Within each pairwise comparison, there is a fair amount of variance within each demographic group. Because of this, many of the comparisons result in moderate preferences or equal balances between attributes.

When compared to the revealed preference analysis (RPA), the community AHP results show a more balanced approach to equity and utility as well as less preference for the role of distance or placement efficiency. For many of the pairwise comparisons, there is variation within each demographic group but there is little variation across the average results for the different demographic groups. This report also contains the comments submitted during the public comment process. They show general support for the project and its methodology while contributing details on specific attributes.

## Project Background

Continuous distribution will be a move from a classification based system to a points based system for organ allocation. Continuous distribution means replacing the current classification approach, which draws hard boundaries between types of patients (blood type 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. One aspect of the project includes prioritizing the different attributes used to allocate organs. This report summarizes the results of the August 2020 community prioritization exercise.

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<sup>1</sup> Saaty, T.L., 1980, 1986 rev. *Multicriteria Decision Making: The Analytic Hierarchy Process*. 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*.

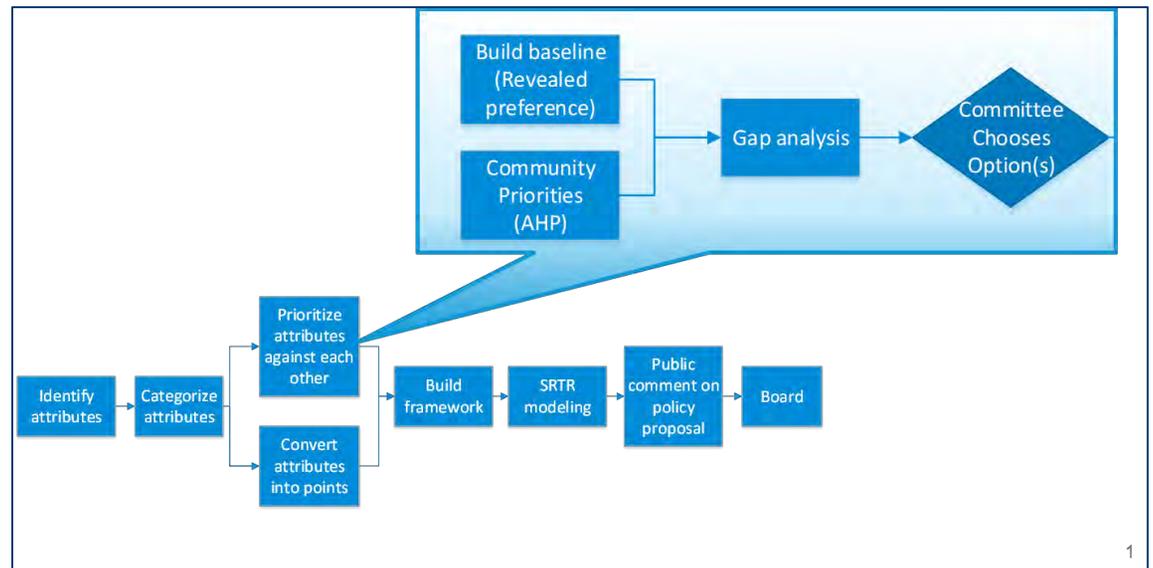
To construct the composite allocation score for lungs, the Committee is currently pursuing two parallel stages: 1) prioritizing attributes against each other (as described in this report) and 2) converting attributes into points. The Committee spent 2019 and much of 2020 selecting and building evidence based rating scales<sup>2</sup> to score candidates for each attribute.

This report focuses on the community’s input to prioritize the attributes against each other. This overall stage contains several complementary approaches. First, the OPTN contracted with an outside research firm, RTI International, to quantify “baseline” value judgements inherent in current lung allocation by approximating this policy by a points based system (otherwise known as a revealed preference analysis). To begin, the OPTN is building a baseline of the current allocation policies in points.<sup>3</sup> 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. 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.

Next, the OPTN collected information from the transplant community on how the attributes should be prioritized relative to each other in a reimagined lung allocation policy.<sup>4</sup> To perform the “gap analysis,” the Committee will compare these two analyses, along with their own priorities and the requirements in NOTA and the OPTN Final Rule. From here, the Committee will select a set of priorities to model and build into the composite allocation score.

Figure 1: Project Plan



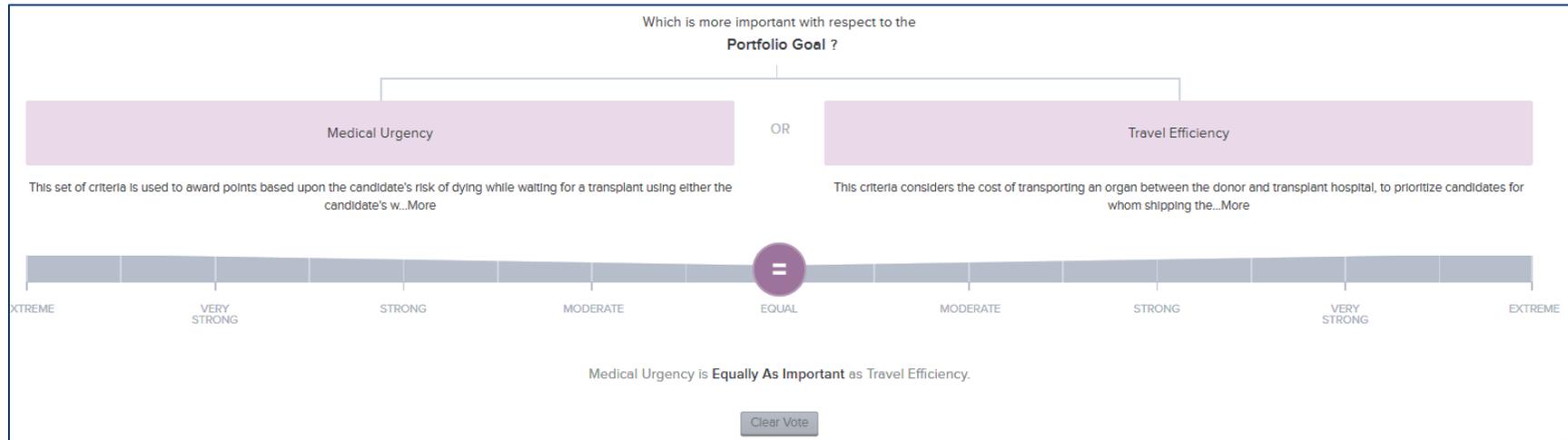
<sup>2</sup> Rating scales are used to score candidates on clinical data for each attribute. Each ranges from 0-1 points.

<sup>3</sup> 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. Mark, T. L., & Swait, J., 2004. *Using stated preference and revealed preference modeling to evaluate prescribing decisions*. Health economics.

<sup>4</sup> 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*.

In an AHP exercise, participants provide their personal value judgments for each pairwise comparisons of attributes in the project hierarchy. (See [Figure 2.](#)) Participants used the Decision Lens online tool for this exercise.<sup>5</sup> Attribute comparisons are rated from 1 (equal importance) to 9 (extremely important).

Figure 2: Sample Pairwise Comparison



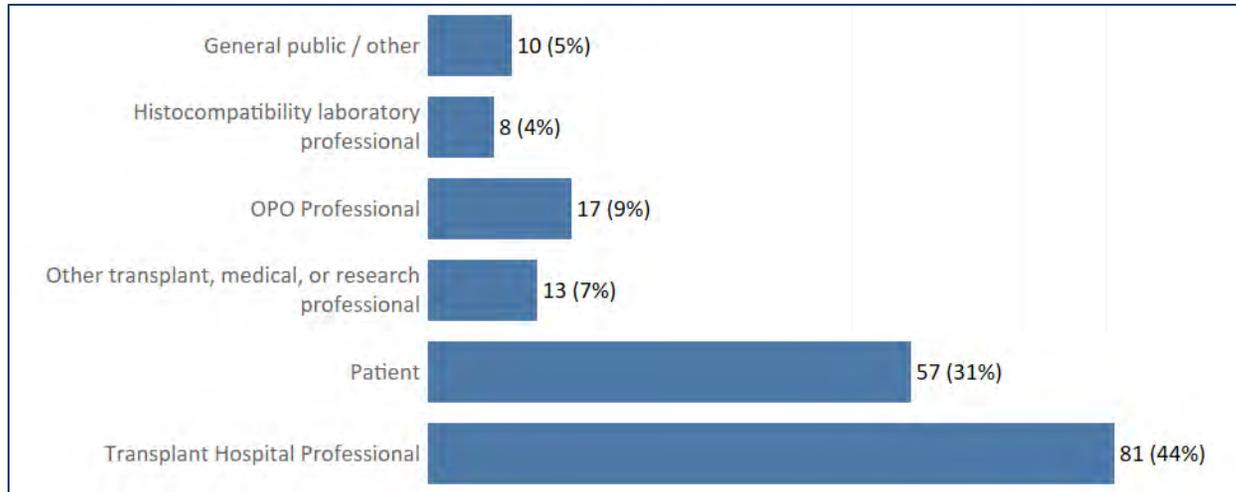
## Participation

The AHP exercise was available on the OPTN website, and presented at 11 regional meetings and nine OPTN committee<sup>6</sup> meetings. The exercise was available for participation from August 31, 2019 to October 1, 2020. 196 individuals submitted responses to the AHP exercise. When signing up for the exercise, participants were asked for their relationship to transplant. The two most frequent participant groups were transplant hospital professionals (44%) and patients (31%). This patient representation is larger than the typical patient participation in public comment proposals and is a result of the outreach performed to patient populations. Excluding individuals who came back to complete their results in multiple sessions, the average participant spent eight (8) minutes completing the exercise.

<sup>5</sup> <https://www.decisionlens.com/>

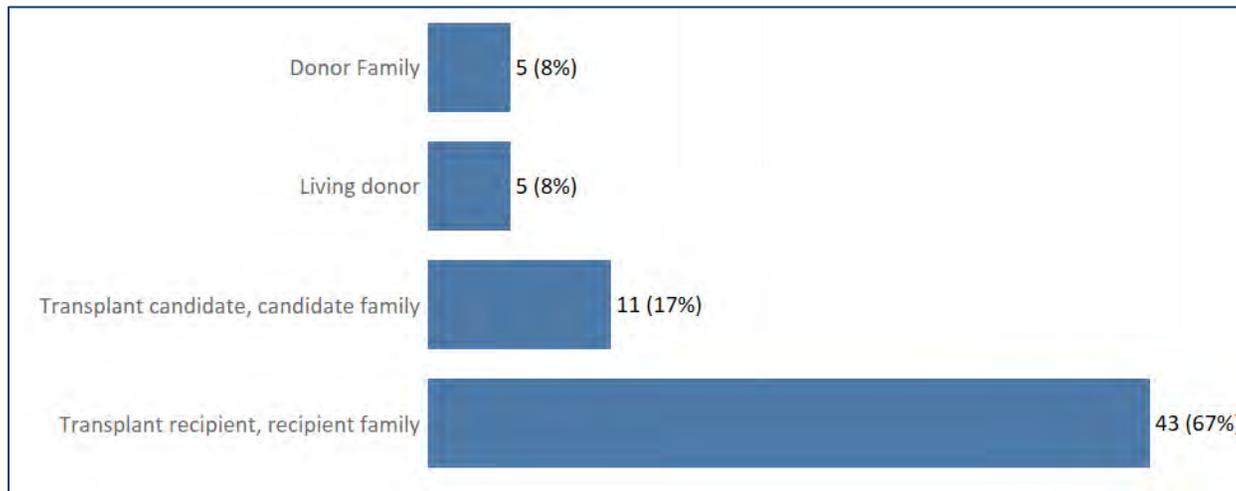
<sup>6</sup> OPO, Kidney, MAC, Pancreas, Pediatrics, Ethics, OSC, PAC, and DAC

Figure 3: Participation



The next chart shows the participation of the different patient populations. Within the patient populations, the majority of the participants were either transplant recipients or recipient family members.

Figure 4: Patient Participation

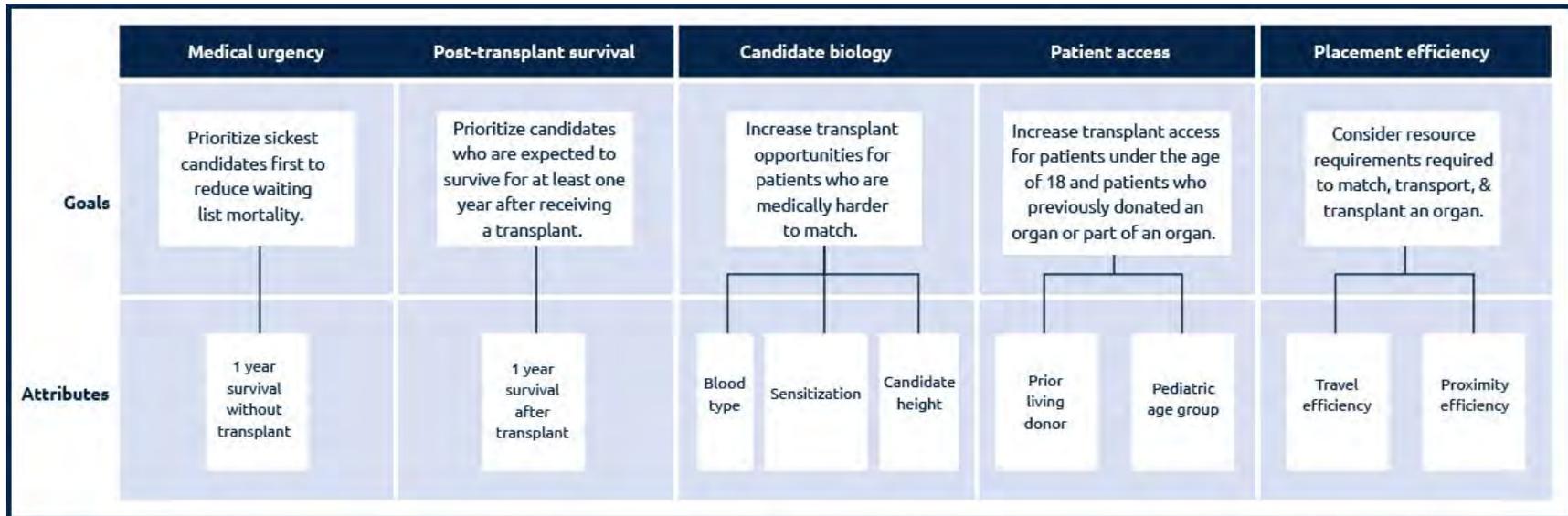


## AHP Hierarchy for Allocating Deceased Donor Lungs

In 2019, the Committee identified and discussed the attributes to include in the composite allocation score. In selecting the attributes, attention was given to the goal for each attribute and how these aligned with the requirements in NOTA and the OPTN Final Rule. The hierarchy of the composite score shows goals and attributes. The goals relate to the OPTN’s goals for developing equitable allocation policies as defined by the OPTN Final Rule and are broad enough to be used 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.

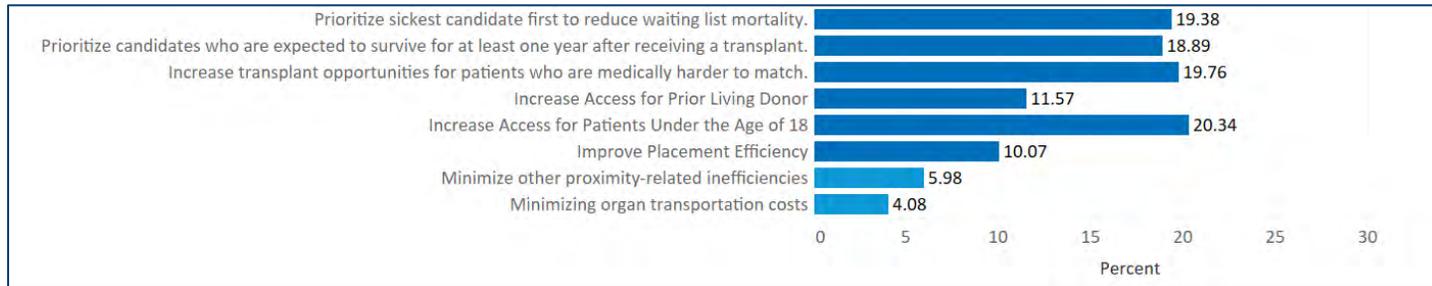
In the AHP exercise, participants were asked to weight pairs of goals or attributes. Where multiple attributes could be empirically weighed on a common scale, clinical data was used for that purpose. (For example, we can use clinical data to measure the likelihood of transplant based upon a candidate’s blood type, CPRA, or height.) The AHP exercise therefore included: medical urgency, post-transplant survival, candidate biology, prior living donors, pediatric age group, and placement efficiency. Within placement efficiency, participants were asked to compare travel efficiency with proximity efficiency.

Figure 5: Hierarchy of Attributes

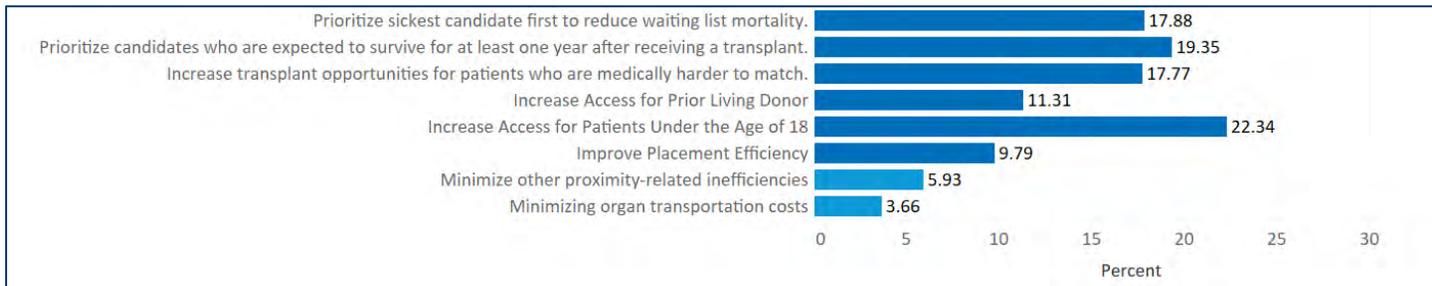


## Overall Ratings

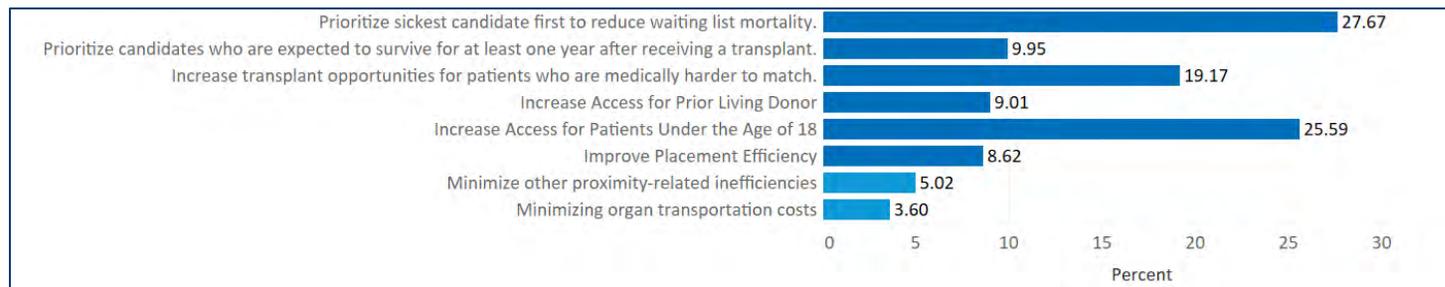
Below are the overall ratings from the community AHP exercise. The first chart shows the overall, unweighted ratings. Because transplant hospital professionals participated in greater volume than other demographic groups, this view skews toward their preferences. In viewing these overall ratings, it is important that the Lung Committee remember that this is not a public opinion survey and they should consider the comments alongside the ratings.



This next view shows the six general demographic groups equally weighted.



Finally, this is an updated view of the Lung Committee's results.

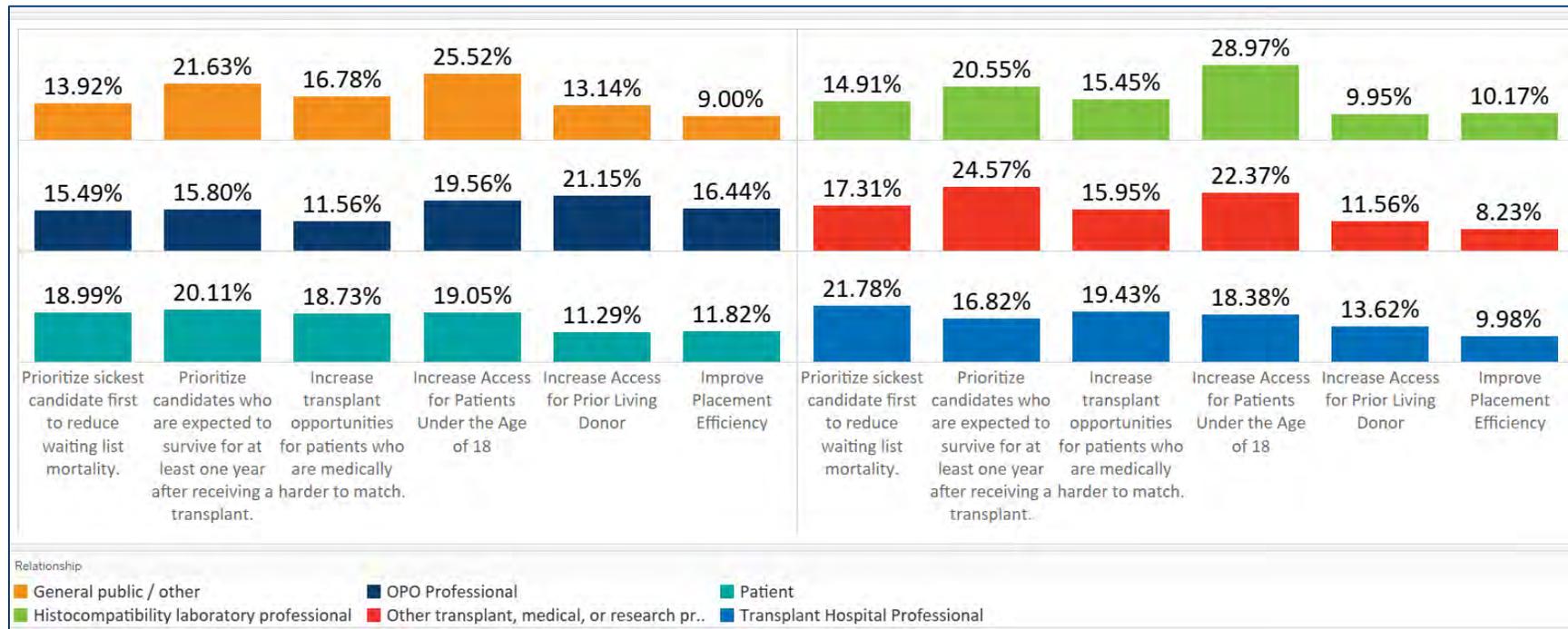


Figure

## Priorities by Demographic Groups

Participants were asked to express their preference between each pair of attributes, in terms of which attribute should have more influence (and to what degree) on lung candidate prioritization on the match run. These preferences were then aggregated into overall preferences, or relative importance weights, for each attribute. [Figure 6](#) shows the overall priorities by the six demographic groups. **Note the variability in the priorities between the different demographic groups.**

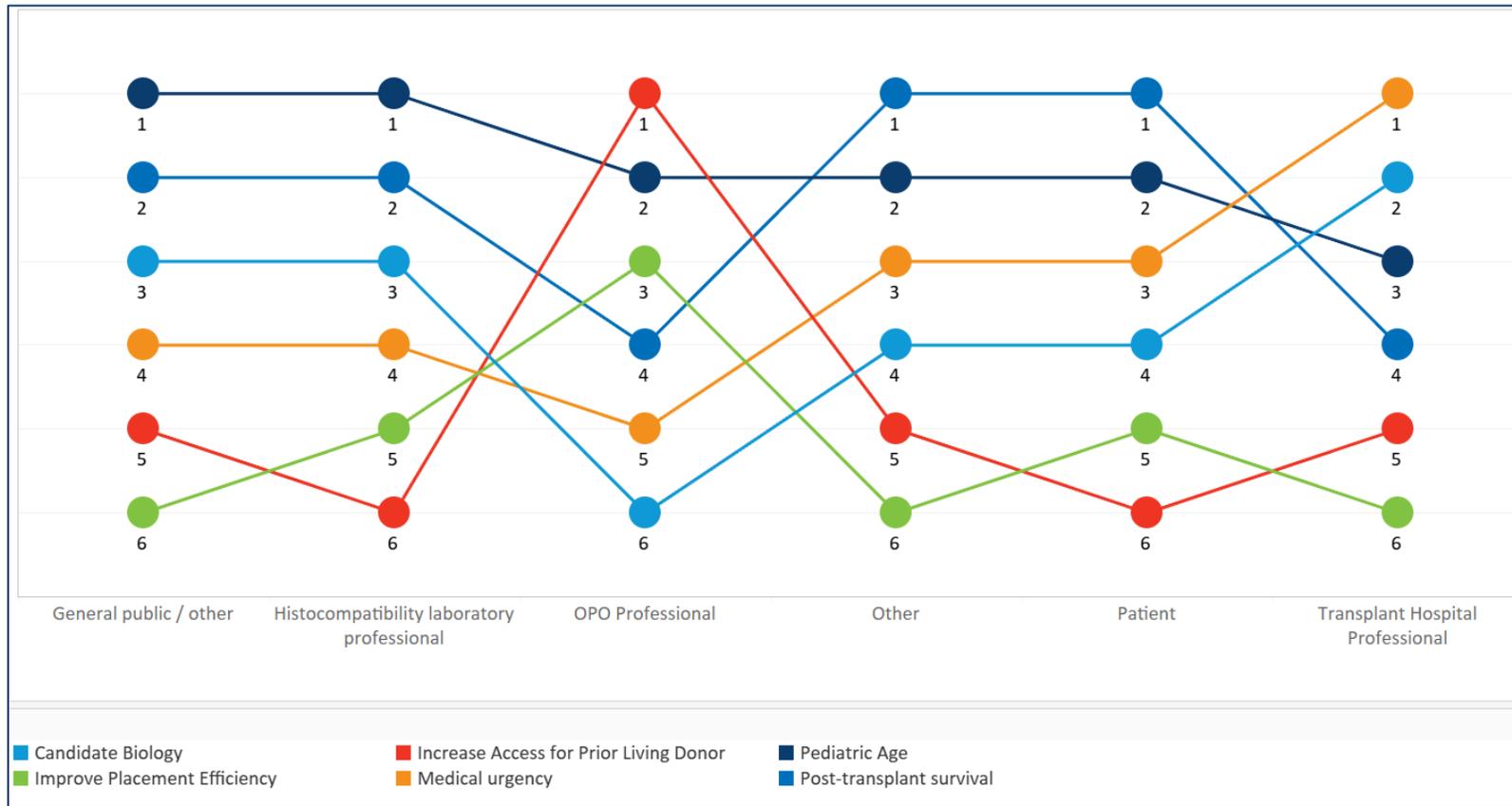
Figure 6: Overall Priorities by Demographic Group



Another way to view these weights are by looking at the rankings of the attributes. [Figure 7](#) shows the ranking (1 for most important – 6 for least important) of each attribute by the different demographic groups and the average ranking across all demographic groups. **When viewed as rankings, the most important attribute was increasing access for patients under the age of 18 and the least important attribute was improving placement efficiency.** There are some notable trends and outliers in these rankings. Pediatric age is consistently in the top half while placement efficiency is typically near the bottom. OPO professionals are different than most demographic groups; they rated access for prior living donors as most important while all other groups ranked that attribute as last or second to last. OPO professionals also rated placement

efficiency as more important than all other demographic groups. There was a wide variation in the ranking for medical urgency; transplant hospital professionals were the only group to rank that attribute first.

Figure 7: Ranking of Attributes



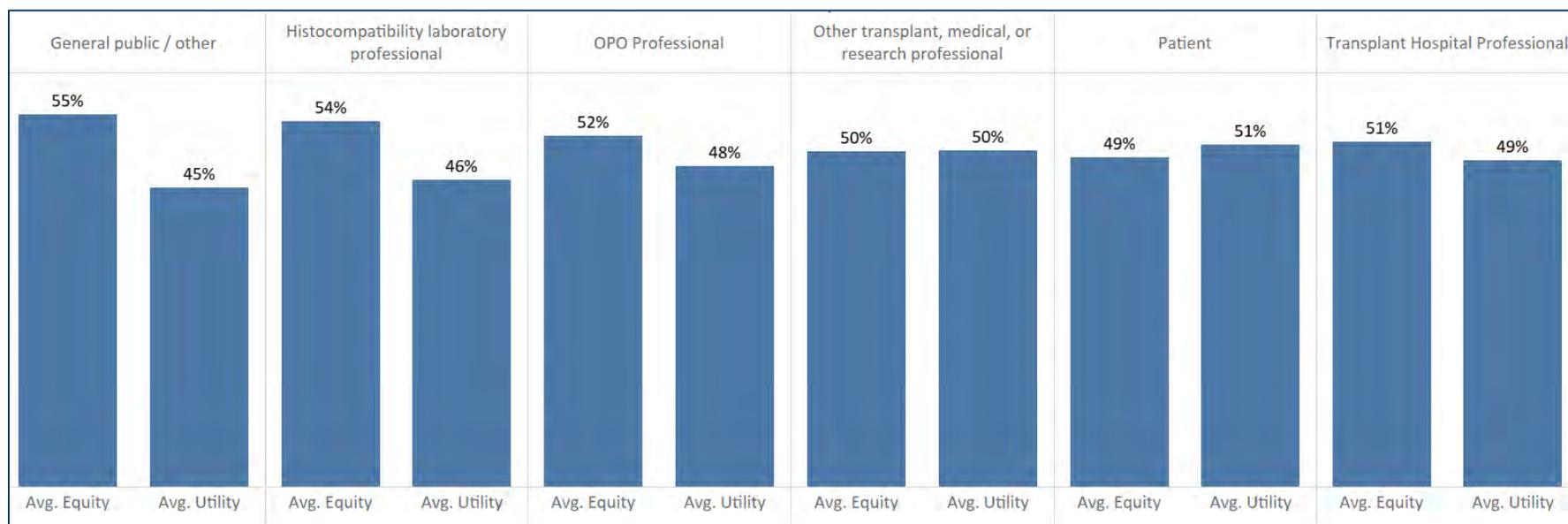
The next table shows the average ranking of the attributes across the six demographic groups. It reinforces the trends mentioned above: pediatric age was consistently ranked as important while prior living donors and improving placement efficiency were consistently ranked less important.

## Ethical Principles

The hierarchy of attributes can be split into ethical principles of equity and utility. These principles have been expressed in NOTA, the 1986 Taskforce on Transplantation, and the OPTN Ethical Principles in the Allocation of Human Organs. While these documents express a desire to consider and balance both equity and utility, they do not call for an exact 50/50 balance between these two ethical principles.

Each of the attributes can be grouped into these equitable principles. Figure 8 reveals relative importance weights that reflect an approximately equal balance between utility across all demographic groups. The general public had the largest variation between equity and utility (10%) while other transplant, medical, or research professionals had the closest balance with 0% difference. For reference, the Lung Committee balanced these 54% equity and 46% utility.

Figure 8: Ethical Balance



## Lung Allocation Score Balance

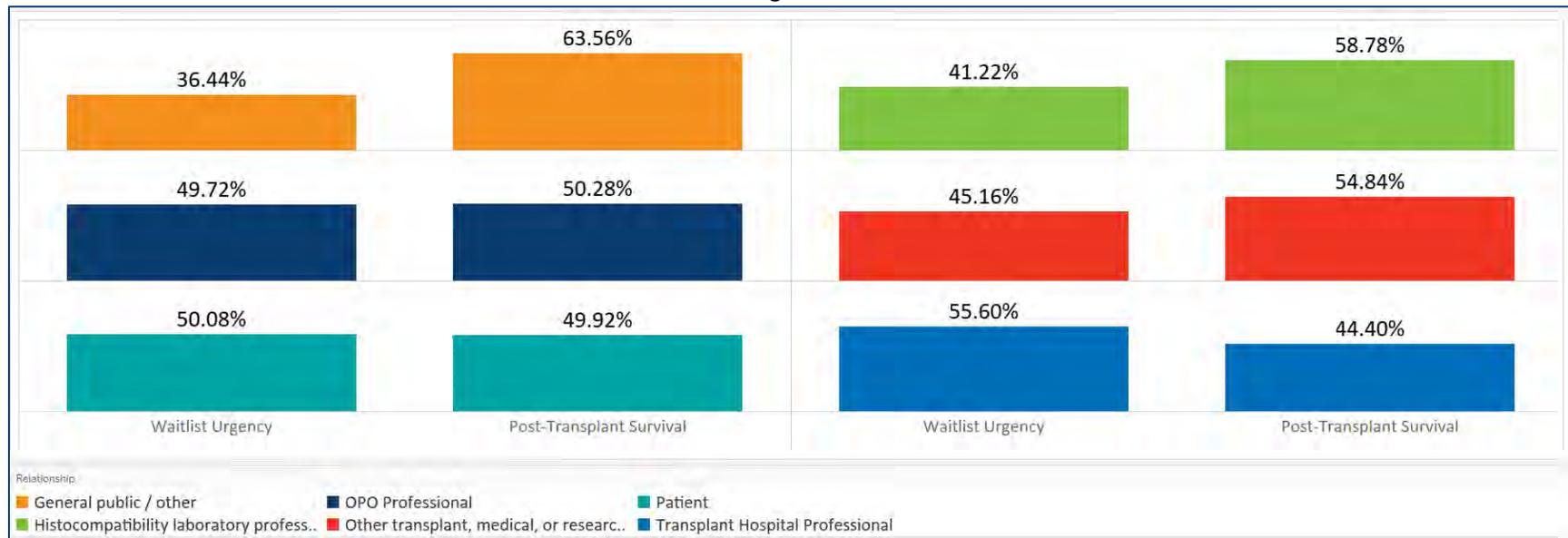
The lung allocation score (LAS) is used to prioritize waiting list candidates based on a combination of waitlist urgency and post-transplant survival. In this context, waitlist urgency (WLAUC) is defined as what is expected to happen to a candidate, given the candidate's characteristics, in the next year if the patient doesn't receive a transplant. Post-transplant (PTAUC) survival is defined as what is expected to happen to a

candidate, given his or her characteristics, in the first year after a transplant if he or she does receive the transplant.<sup>7</sup> LAS is currently balanced as follows: two parts waitlist urgency (67% of LAS) versus one part post-transplant survival (33% of LAS).<sup>8</sup> As part of the AHP exercise, participants weighted the two components in the current LAS score. **As can be seen in the next figure, all demographic groups weighted post-transplant survival higher than in the current system.** The most dramatic change occurred in the general public which weighted waitlist urgency 36% and post-transplant survival 64%: a nearly opposite reflection of the current calculation. Transplant hospital professionals stayed closest to the current system with 56% waitlist urgency and 44% post-transplant survival.

$$LAS = \frac{100 * [PTAUC - 2 * WLAUC + 730]}{1095}$$

Figure 9: Balance of LAS Components

figure



<sup>7</sup> OPTN, "A Guide to Calculating the Lung Allocation Score". Available at: [https://unos.org/wp-content/uploads/unos/Lung\\_Calculation.pdf](https://unos.org/wp-content/uploads/unos/Lung_Calculation.pdf).

<sup>8</sup> OPTN Policy 10.1.F *The LAS Calculation*.

## Comparison to Current System

It is helpful to put the community AHP results in context of other analyses conducted for the continuous distribution of lungs policy development project. This includes comparing against the revealed preference analysis, the Lung Committee AHP results, NOTA, and the OPTN Final Rule.

Table 1: Compare Ranks and Ratings

Candidate Attribute	Importance Rank	Relative Contribution Weight (%)	Importance Rank	Relative Contribution Weight (%)	Importance Rank	Relative Contribution Weight (%)
	Current Policy <sup>9</sup>		Lung Committee AHP		Community AHP <sup>10</sup>	
Medical Priority • Waitlist urgency is 2/3 of current LAS	2	7%	1	27%	3	18%
Medical Priority • Post transplant survival is 1/3 of current LAS	5	3%	4	10%	2	19%
Candidate Age	4	4%	2	26%	1	22%
Proximity/Placement Efficiency	1	81% <sup>11</sup>	6	9%	6	10%
Candidate Biology <sup>12</sup>	3	5%	3	10%	4	18%
Prior Living Donors	n/a	n/a	5	9%	5	11%

<sup>9</sup> Relative contribution weights inherent in current policy were approximated through a revealed preference analysis of adult donor lung match run data. Weights were nearly identical for pediatric donor allocation (but with children prioritized ahead of adults instead of adults ahead of children).

<sup>10</sup> For this table, the community AHP represents the AHP results equally rated by demographic group. See [Overall Ratings](#) on page 8 for more information.

<sup>11</sup> The revealed preference analysis found that proximity has a substantial role in prioritizing lung patients. The relative contribution weight of 81% is a result of comparing a candidate 0 miles away from the donor hospital with one 4,415 nautical miles away, a distance that might be considered infeasible under current practice. When using less extreme distances, the relative importance weight for proximity was still greater than other factors but was far less than 81%.

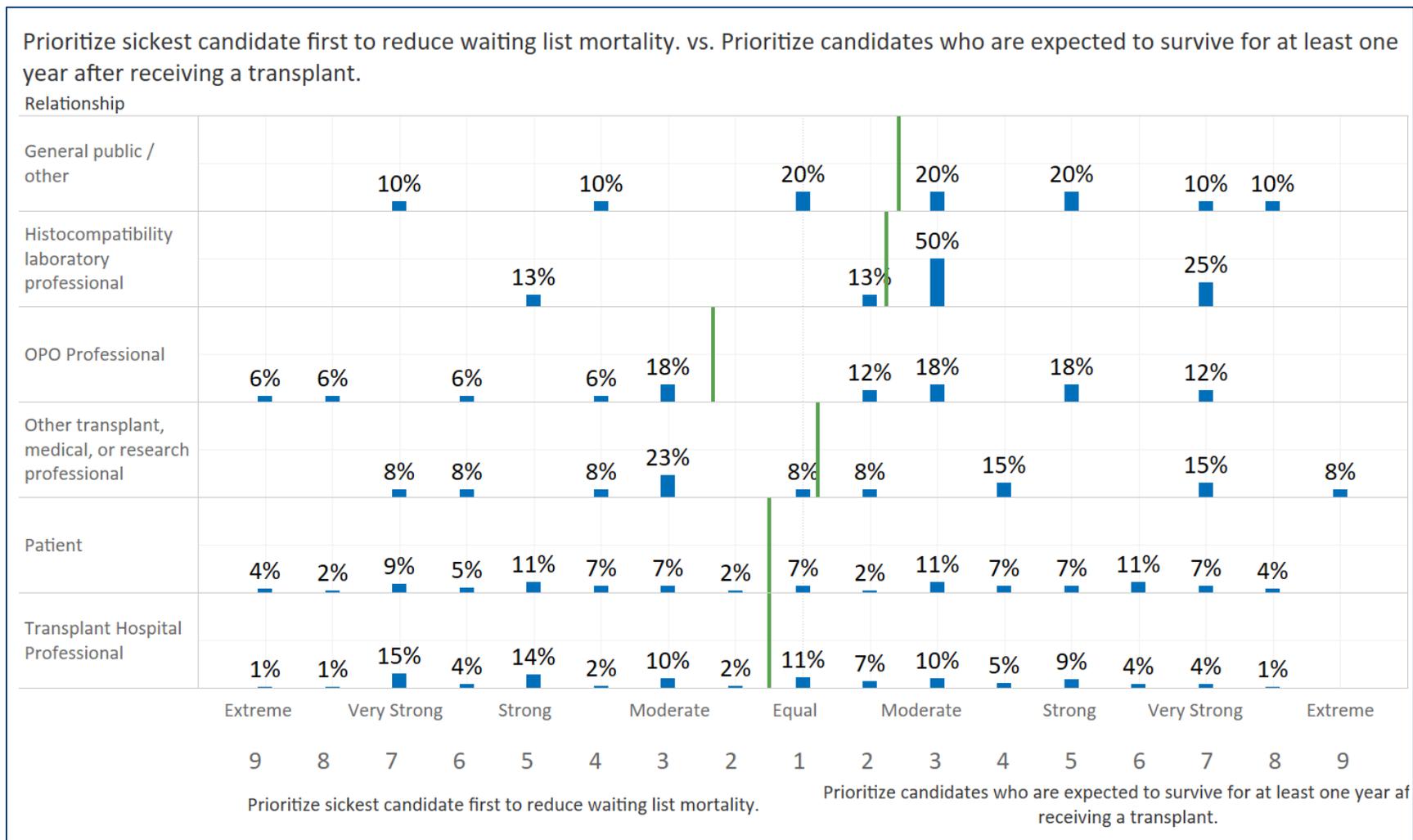
<sup>12</sup> In the RPA, this only included the difference between identical and compatible blood types. In the AHP exercise, this included likelihood of transplant by blood type, CPRA, and height.

## Specific Pairwise Comparisons

In reviewing the specific pairwise comparisons, we looked for agreement amongst voters (do voters agree which of the two attributes is most important) and alignment in their scores (do voters place similar levels of importance on the preferred attribute). We also look for any outliers to the overall group. When the Committee discusses these results, they should pay attention to areas where there is low alignment, low agreement, or outliers. **For many of the pairwise comparisons, there is variation within each demographic group but there is little variation across the average results for the different demographic groups.**

## Medical urgency vs Post-transplant survival

There was wide variation in the results of this pairwise comparison: patients and transplant hospital professionals both recorded some extreme values for both attributes. The result was that the average ratings were only moderately leaning toward either attribute. Histocompatibility professionals has the most consistent results, which indicate a moderate preference for post-transplant survival.



Comments:

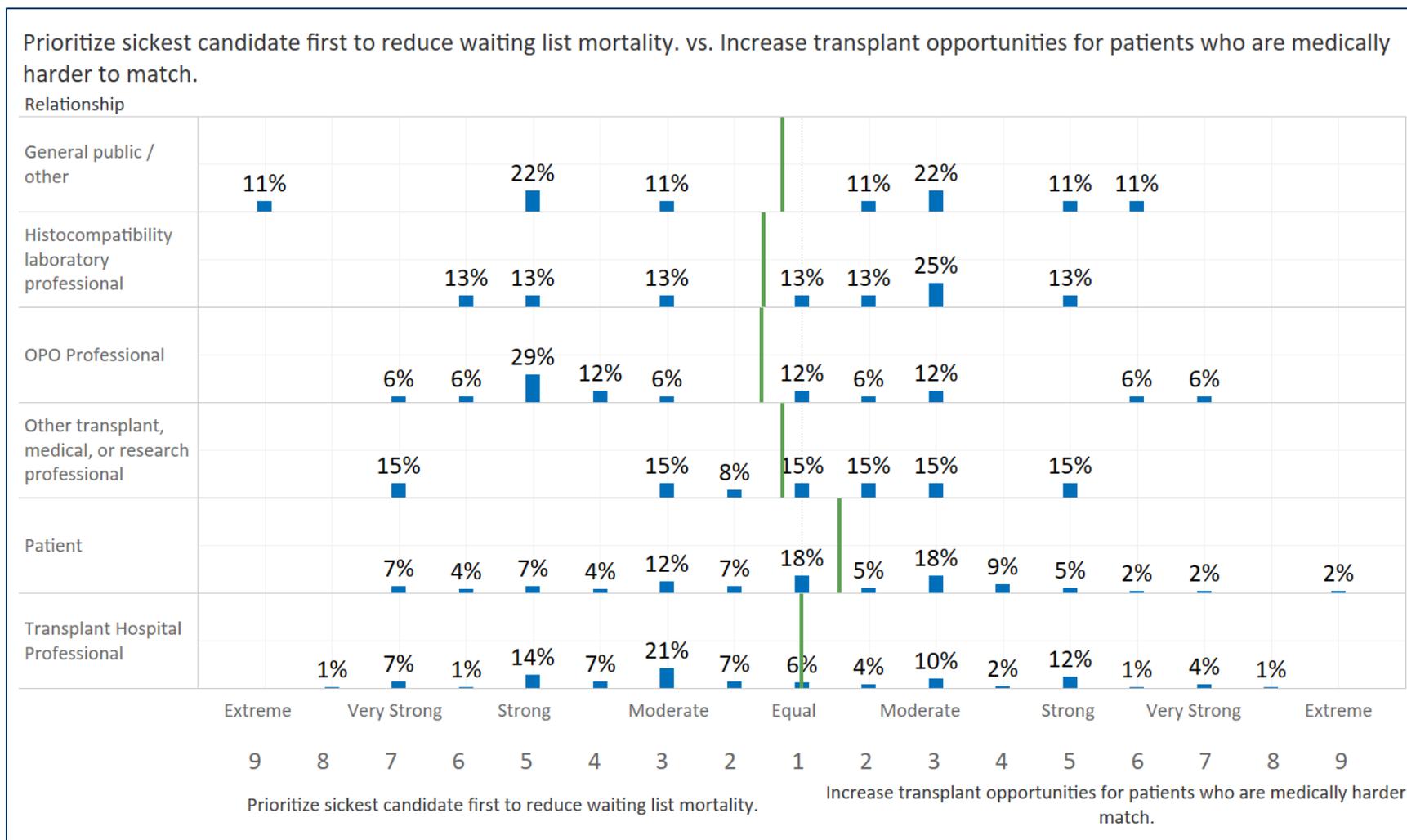
Value	Judgement	Comment
<b>Prioritize sickest candidate first to reduce waiting list mortality.</b>		
3	Moderate	My vote would be different for longer-term outcomes.
		Recipient mortality on the list is important to a degree; however, always transplanting the sickest patient first is not the best use of a scarce resource. The theory of course is that the less acute patients have longer to wait but given that we know (a) there are not enough organs to go around at this point and (b) those less acute patients tend to have better long term outcomes, creating a system where you have to be very acute to get transplanted means people will have more difficult (and expensive) pre-transplant courses with worse outcomes after transplant. Some acuity weight is appropriate but should not be too out of balance.
		Survivability is important but if that measure is equal then the sickest candidate should have priority.
		this shouldn't be framed as an either-or, as the critical value to prioritize is survival benefit, the difference between post-transplant survival and waitlist survival.
5	Strong	The Lung Transplant candidate will be in the condition were they need a transplant. But there can be a situation where the health of transplant candidate can become worst. There will be changes that do not follow a typical pattern of lung disease. There need to be a way to handle the special needs requirement
6	Very Strong	Prioritizing the sickest is an easier task that is empiric (as opposed to prioritizing based on predictable survival, which cannot clearly account for unknown outcome variables such as surgical infection risk)
7	Very Strong	Ensuring access in short periods of time with improve outcomes for these patients.
		I believe that sickest patients should be prioritize to the compatible donor. Post transplant survival is also an equally important metric but its dependent on many variables.
9	Extreme	Priority should be for the sickest. I don't exactly understand the priority to survive the 1st year. If this is prioritized, the younger, healthier candidates would be prioritized, meaning the lowest LAS, COPD patients. If greatest likelihood to survive 1 year was th priority, and I was listed, I would have the highest score. Perhaps another way to think about it may be the candidate that is not going to die in the first year, meaning some of the sickest patients may also have factors that are going to make them more likely to die, and they should lose a few points.

Value	Judgement	Comment
<b>Prioritize candidates who are expected to survive for at least one year after receiving a transplant.</b>		
2	Moderate	With the limited availability of organs, the system needs to be good stewards of the gifts to best ensure successful outcomes - its a delicate balance as stopping mortality is also so very important
3	Moderate	I think 1-year survival is not long enough. In a comparison between longer survival (3-5 years) and sickness, i would lean more heavily to long-term outcomes
		If expected survival can be reliably predicted, it is more important than degree of sickness, to prevent listing too sick patients. It is only moderately more important to prevent bias towards specific diagnosis.
		Unless CMS discontinues evaluating Trx Ctr performance on survival rates - survival rates must be taken into account. The sicker candidates have more than likely a lower survival rate
		While I see the point of reducing waitlist mortality, my view is backed by the notion that organs are scarce and by weighting survival as moderately more important, we are trying to get the most from the organs that are donated.
4	Strong	While it is very bad for a patient to die on the waitlist, it is arguably even worse for a patient to receive a deceased lung transplant and die within a year of transplant (given the financial and other costs of such a transplant) if there is one or more potential transplantees who would live longer than a year who could have received it instead.
5	Strong	the current allocation system prioritizes older white men with limited life expectancy because of the group D priority and 2 fold weight of waitlist urgency
		This is difficult since a lot of emergent medical decisions are based on triage. Since organs aren't available for all patients, it seems the best utility is to improve life years after transplant, perhaps changing transplant center behaviors and listing practices for transplant candidates not likely to survive greater than one year. Otherwise, a perpetual cycle could occur where previously healthy candidates had to wait until severely sick, and die within a year of transplant, instead of receiving the organ in a healthier, stronger state.
		Waste of a lung if transplanted w very low chance of survival

Value	Judgement	Comment
6	Very Strong	As a lung transplant recipient, I feel it is important for numerous reasons, to be in the best health possible when receiving a lung transplant. Where it is a fine balance between too healthy and not sick enough, ultimately if the transplant is not going to extend ones life, what is that point. And to extend that life, you need to be healthy enough to be set up for success. For many post transplant is not an easy road. And lastly, coming from a patient population (Cystic Fibrosis) where you may be very ill but according to current scoring standards would be rated "comparitively" low score, you may not get a transplant because your "too healthy". CF patients have high rate of long term survival. It should not be assumed that these two criteris are synonymous. Just cause you are the sickest candidate you therefore with have the best outcome. Maybe one should also review what defines "the sickest candidate".
7	Very Strong	I strongly believe that a candidate that would have a good chance of a longer life post transplant should hold higher president. Especially if there are no other underlying issues.
		<p>This seems like a false choice to me - one year survival should not be the goal of lung transplant. For the purposes of utility (getting the most out of the transplant) and justice (fair innings rule), longer term post-transplant survival should be prioritized. The 70+ year old patients will almost always have a higher risk of death without transplant, which the current LAS system accentuates by weighting WL death x 2, and I don't think that's the best way to prioritize lung allocation. I think medical urgency is important, of course! We need to prevent people from dying acutely. Finding ways to optimize post-transplant survival (2-year or 3-year survival would be better than 1-year!), and thus the utility of the organs, while still helping those who have an acutely increased risk of dying should be the goal.</p> <p>If the entire LAS cannot be revised at the same time as the start of continuous distribution, please consider adding age to the allocation algorithm in a way that makes sense.</p>

## Medical urgency vs Candidate biology

There was wide variation in the results of this pairwise comparison: patients and transplant hospital professionals both recorded some extreme values for both attributes. The result was that the average ratings were equal or moderately leaning toward one attribute.

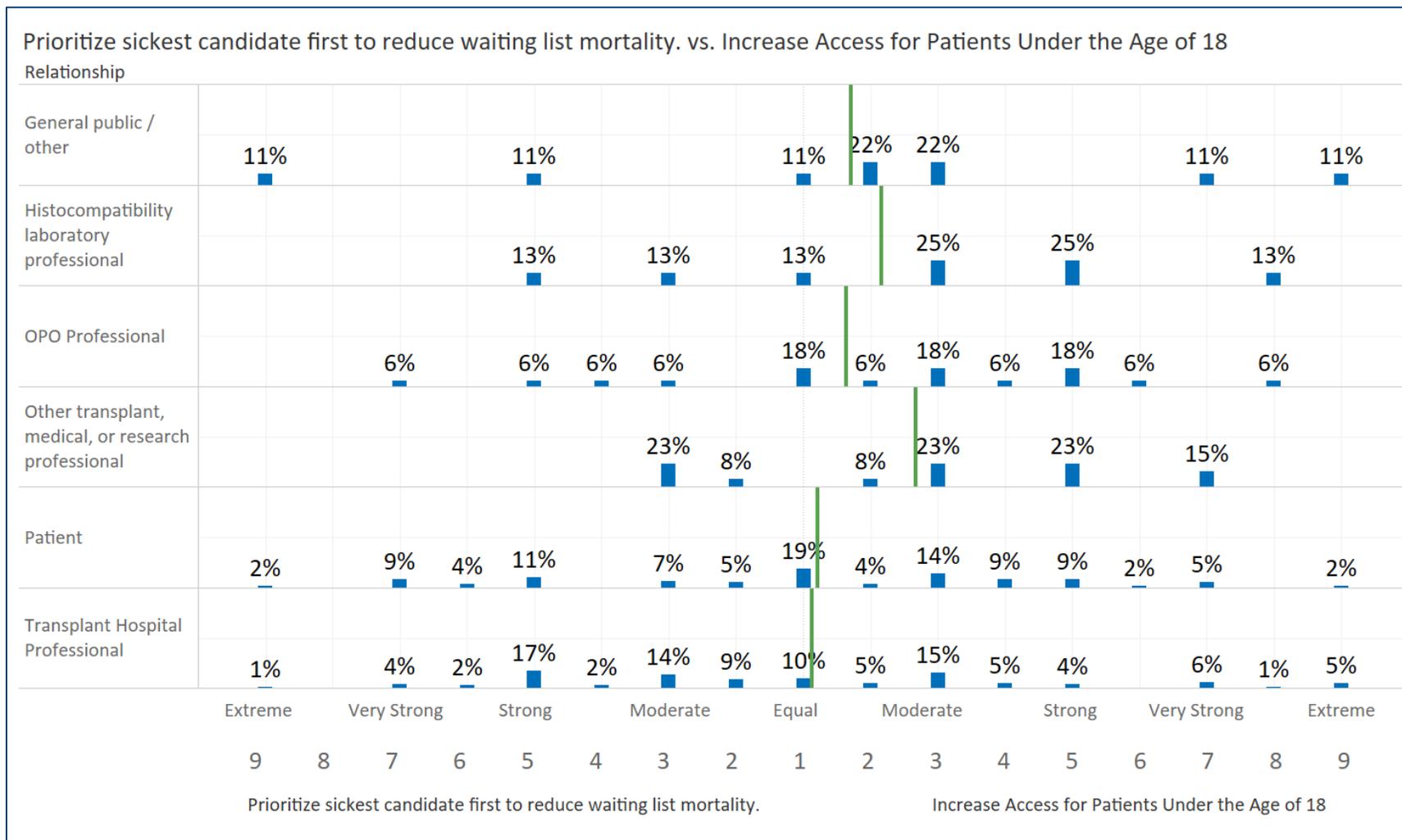


Comments:

Value	Judgement	Comment
<b>Prioritize sickest candidate first to reduce waiting list mortality.</b>		
6	Very Strong	Organ allocation policy has already created numerous roadblocks for OPO staff, especially while trying to allocate organs for smaller or larger sized donors. The waitlist criteria for transplant candidates is not closely monitored, requiring OPO staff to navigate through numerous transplant candidates with significant height and weight differences. Giving increased priority to patients with size and ABO matching complications will allow transplant teams to be more "selective" of offers, similar to how AB blood group donors are evaluated, instead of using the offers received. It will instead turn into, "I can wait for a better one."
<b>Increase transplant opportunities for patients who are medically harder to match.</b>		
3	Moderate	if a pt is medically harder to match, it'd be more important to transplant them as they may never get another match
		My impression of this Goal was that there was a person that had an exact match which can not be easily found. The sickest candidate was not an exact match.
		Some (maybe most) patients that are medically harder to match are harder to match due to reasons beyond their control and/or subject to inequitable health disparities, and so reducing the inequality of chance of transplant with others who are medically easier to match improves equity.
		To optimize the utility of the organs and justice, it makes sense to give priority (within reason) to people who are medically harder to match. Wait-time might be considered here, perhaps triggering priority after a certain amount of time waiting with one of the listed specific factors.
4	Strong	Oftentimes the sickest patients are the ones with the high PRA and abnormal HLA. Their wait times are worse due to the HLA and they have worse long term complications as well.
		The opportunities for patients who are medically harder to match should be leveraged. I am a candidate with O+ blood and I would have no problem with priority given to a harder to match patient.
5	Strong	There is likely to be overlap here; those without good opportunity and health security will be sicker by nature.
7	Very Strong	Difficult to match patients should, IMO, always have strong priority as they may have very limited opportunities to be transplanted and shouldn't be bypassed for an acute but stable patient, or someone who can wait longer and will be easier to match.
		short stature women with PRAs face significant disparity in access to organs

### Medical urgency vs Increase Access for Patients Under the Age of 18

There was wide variation in the results of this pairwise comparison. Four of the demographic groups had a moderate preference for increasing access for patients under the age of 18 while two demographic groups rated them equally.



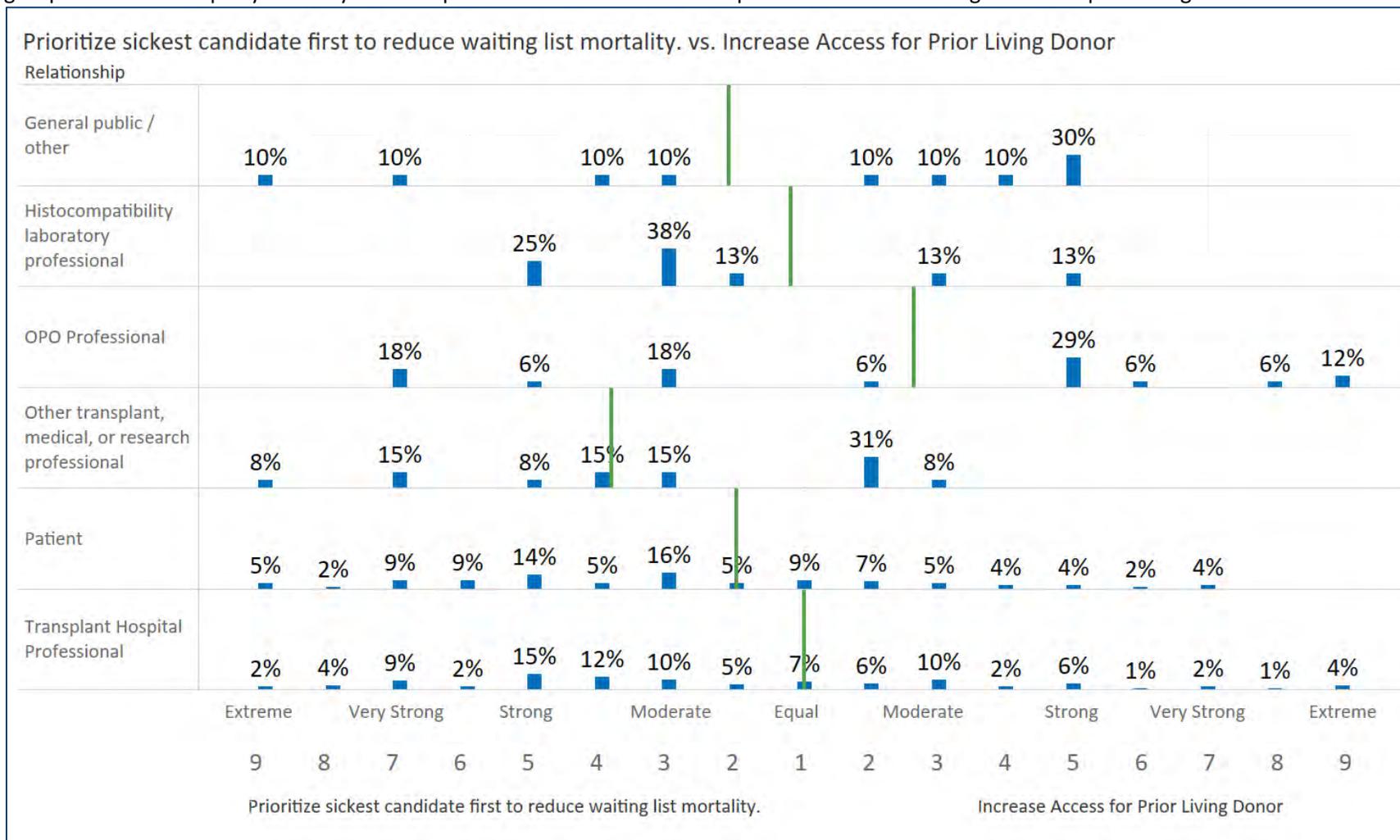
**Comments:**

Value	Judgement	Comment
<b>Prioritize sickest candidate first to reduce waiting list mortality.</b>		
2	Moderate	Based on the limited knowledge, I would see the sickest person to get the transplant. The under 18 person was able to survive until the next organ is available.
3	Moderate	I would think donor/recipient size match will still help prioritize those under 18 that are size limited. but don't necessarily believe that an adult sized 18 y/o should get more priority than the same acuity or sicker patient who's 19, 20 or 40 yrs old
		When age correlates with better expected medical outcome, I strongly support such prioritization, but do not support such prioritization when it applies the arguably arbitrary cutoff of the age of 18.
Equal		
1	Equal	Patients under 18 sometimes have a better survival rate - and if performance is based on survival rate regardless of other extenuating circumstances - these are about equal then
		With no other background on the situation for a patient under 18 I see this as equal.
<b>Increase Access for Patients Under the Age of 18</b>		
2	Moderate	For me this ties into survival benefit (patients in this <18 age group do not do as well), but also the fair innings rule (they have not had a fair number of years in their lives). Very difficult, but I lean towards prioritizing the patients <18 all other things being equal.
		It should not be a simple age-under 18- more should be considered. Overall health, overall outcome, compliance, etc. Just because young, should not be assumed greater chance of survival but would say in theory younger would greatly benefit from early intervention like a transplant.
3	Moderate	This option follows the similar goal of life years after transplant (LYAT). Changes must require pediatric transplant centers are careful to closely and accurately list their candidates only to receive offers from donors that are legitimate donor candidates. Examples of what shouldn't happen is a transplant center listing acceptance criteria for a 6 year old candidate, willing to receive an intestine offer from a donor as old as 55 years, up to 300 pounds, and as far away as 9999 nautical miles. That is inappropriate use of the allocation system, unless the center has transplanted a similar donor and recipient combination beforehand.

Value	Judgement	Comment
5	Strong	<p>Again, as with the first two questions, it is easy to rush to transplant the sickest patient first (equity?) when the best decision for utility is to transplant a less-acute patient that has priority for other reasons. This is certainly true in pediatrics. Transplanting a high acuity adult with a lifetime of complications/sequelae from their underlying disease may save a life in the short term but a pediatric patient has potentially many more years of life and productivity; these patients are also often difficult to match. I do believe that there should be two tiers of Peds patients...0-12 y/o (true kids) and 13-18 (often physically very similar to adults) to emphasize getting small, difficult to match patients transplanted and hopefully head off any developmental issues.</p>
		<p>If goal is to move toward improving outcomes, you would want to give lungs to those with the best chance of recovery.</p>

### Medical urgency vs Increase Access for Prior Living Donor

There was wide variation in the results of this pairwise comparison. One group (other transplant, medical, and research professionals) had a strong preference for prioritizing the sickest candidate, while three groups has a moderate preference for prioritizing the sickest candidate. Two groups rated them equally and only the OPO professionals had a moderate preference for increasing access for prior living donors.



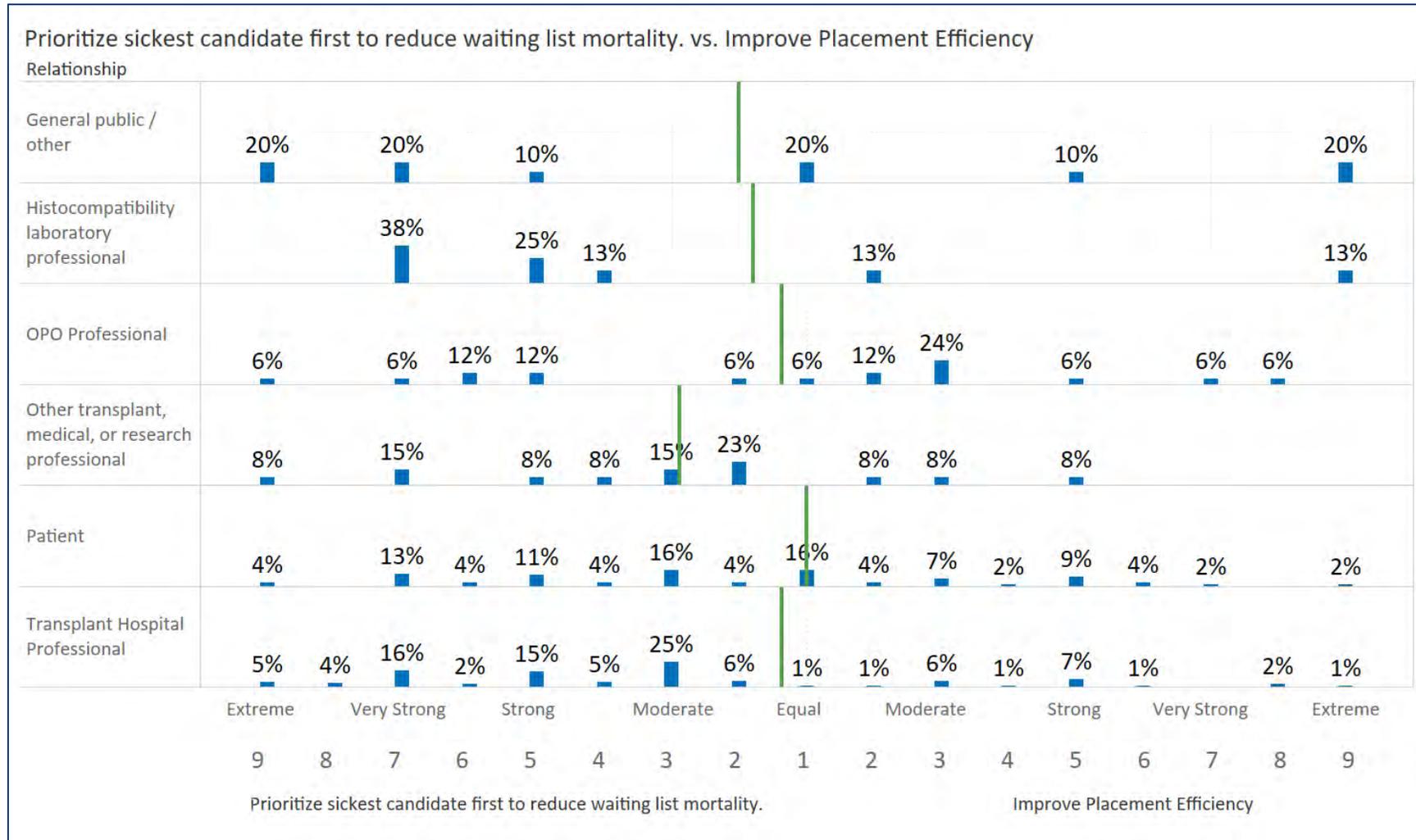
**Comments:**

Value	Judgement	Comment
<b>Prioritize sickest candidate first to reduce waiting list mortality.</b>		
2	Moderate	I believe that previously donated organ person should be honored for their donation. But I am sure they would want a sick person to survive knowing they will get a transplant.
		There is no scientific reason to allow a prior living donor additional access. There would be no way to know the circumstance of the prior organ donation and therefore feel it could be a trick to include.
		While a person should be rewarded for their altruistic act, we should still try to get the sickest patient transplanted.
3	Moderate	In this scenario, those that are sickest should be prioritized over prior living who may not be very sick yet.
4	Strong	Altruism is not conditioned on future bargains. If I had to choose between someone who is sick and someone who was a prior candidate, I would almost always choose the sickest patient.
		I appreciate the desire to favor people who have been altruistic, but I don't think donating an organ should "buy" you more points/priority if you go on to needing an organ in the future.
5	Strong	I can understand how it makes sense in kidney/liver if you develop end-stage organ failure after donation but not sure about how this would be prioritized in lung. It is interesting in that it promotes overall organ sharing but not directly related to the donation.
6	Very Strong	I've never heard of "extra credit" for a patient who has previously donated an organ before. I have always been willing to make an organ donation purely for humanitarian reasons and wouldn't expect to be moved up a waiting list if I subsequently needed a transplant myself.
7	Very Strong	Altruistic if a potential recipient has been a donor previously, but I am not sure it should garner them more points in this new distribution model
<b>Equal</b>		
1	Equal	Increasing access to prior donors for subsequent transplant seems capricious. Why not increase access for all registered donors? Why not those who donate to non-profits in donor advocacy? Seems a slippery road to coercion.

Value	Judgement	Comment
<b>Increase Access for Prior Living Donor</b>		
2	Moderate	if its for an organ that the pt donated, then they should be prioritized but if its for a different one, maybe not so much
		Reciprocity and appropriate incentives to promote much-needed voluntary donation justify some priority for prior living donors. This priority can be outweighed, in some circumstances, if the prior full or part organ donation adversely affect expected medical outcome of a transplant to a significant extent.
3	Moderate	All other criteria being equal I would be comfortable with a prior living donor having increased access.
		The pool of prior living donors (of any organ) who need and qualify for a lung transplant should be small and the community has already determined that this group of candidates deserve additional priority but not "top of the list" for kidney but would be listed by MELD alone for liver. So a slight prioritization sends a positive message to the LD community with out significantly compromising access for other candidates.
5	Strong	I believe that there needs to be a priority given to those who are former living donors. They selflessly stepped in to help someone else through living organ donation and the system should then, in turn, step in to help them.
8	Extreme	Prior donation assists the waiting list and should definitely be considered in score if the patient later needs a transplant. The worst case scenario is that everyone becomes a living donor, hopefully reducing the number of people on the overall waiting list, decreasing waitlist mortality and increasing life years after transplant.
9	Extreme	Anyone who has previously been a living donor deserves the highest consideration.
		Anyone who has voluntarily added an organ to the pool who subsequently needs a transplant should always have priority. They have previously allowed a candidate of the waiting list by their selfless act and should have priority in all circumstances.

### Medical urgency vs Improve Placement Efficiency

There was wide variation in the results of this pairwise comparison. The average results for the different demographic groups ranged from equal priority for the two attributes to moderate preference for medical urgency.



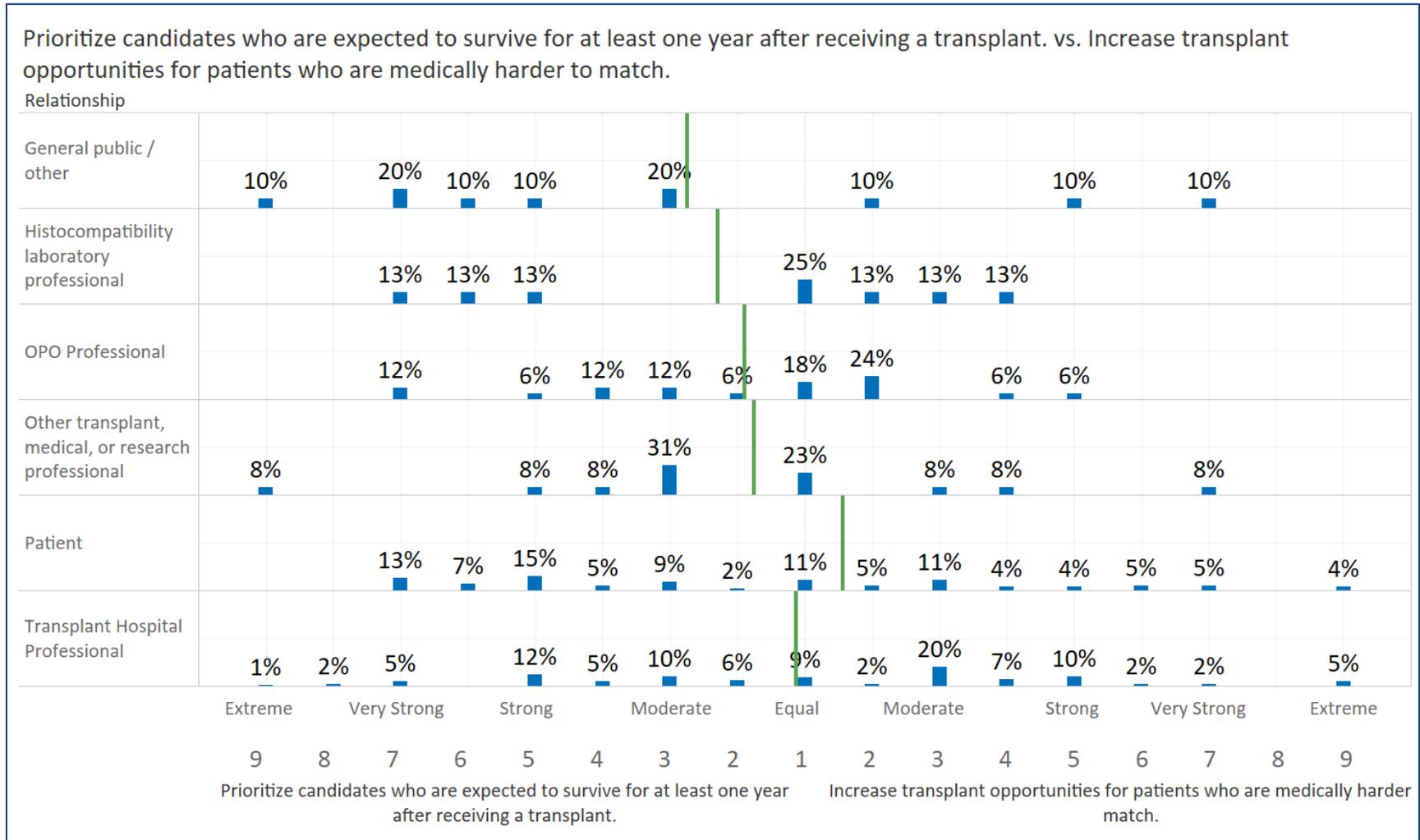
**Comments:**

Value	Judgement	Comment
<b>Prioritize sickest candidate first to reduce waiting list mortality.</b>		
3	Moderate	Given the scarcity and value of a successful lung transplant as well as the disvalue of waitlist mortality, the cost of resources required to identify a suitable recipient willing to accept the organ and transport the organ for transplantation are often significantly outweighed by the need to reduce waitlist mortality.
		While improving efficiency is should always be an important goal, saving lives should be our main objective. Therefore, reducing waitlist mortality is moderately more important than placement efficiency.
4	Strong	Particularly with the increasing use of normothermic, ex vivo preservation of lungs, distance and time to transport should continue to become less of a factor with respect to placement efficiency
8	Extreme	I think the sickest patients should be prioritized up to a certain point. Once a threshold is reached, I think proximity should play a greater factor, not exactly directly inverse relationship.
<b>Improve Placement Efficiency</b>		
2	Moderate	So I would understand that based improvement of getting organs for transplant that there would soon be an organ for the sickest, but the attributes are the best for the identified recipient
3	Moderate	I think you want to try to maximize the potential for a good outcome, so in that regard efficiency matters more.
		Improved efficiency should prevent organ discard from logistical purposes, donor family time constraints, or limited/non-existent working relationships between OPOs and transplant programs.
		While patient acuity is important, a balance with efficiency of placement, tilted slight to efficiency, is important. The U.S. by far discards more organs than any other nation; in fact, we discard more organs than most nations transplant. While not all of this is a logistics/efficiency issue, it is a significant factor based upon personal practice. Also based upon personal practice, increasing DCD and older donors make list driven by acuity over all other things an unworkable solution.
		With lungs, transportation is a huge issue and prioritizing by the sickest may incur additional costs in transport of teams and then organ function after transport due to potential delays. Until lungs can be transported on a pump this is probably not feasible.
5	Strong	I feel location to a facility should NOT be a key factor in the decision of the organ allocation, People needing a transplant make it work. If I live close to the hospital but other other factors would place me lower, it should not

Value	Judgement	Comment
		matter where I live in relation. People take on much financial hardships moving to have a greater risk of a transplant. This could be considered financial discrimination.
		If the viability of the lung in this case diminishes to meet the needs of the sickest candidate then efficiency should take priority.
		Inefficiency is common in organ allocation. Adding additional administrative work will further strain smaller less efficient OPOs and potentially lead to higher risk in organ transplant if these inefficiencies increase

### Post-transplant survival vs Candidate biology

There was wide variation in the results of this pairwise comparison. Four demographic groups had a moderate preference for prioritizing candidates who are expected to survive for at least one year after transplant, while one group rated the attributes equally, and the remaining group had a moderate preference for increasing transplant opportunities for patients who are medically harder to match.



**Comments:**

Value	Judgement	Comment
<b>Prioritize candidates who are expected to survive for at least one year after receiving a transplant.</b>		
3	Moderate	Again, I find one-year survival to be a false choice. No one undergoes lung transplant for 1-year benefit. I am rating this choice as if the survival question considers longer-term survival (2-year or 3-year).
		In my opinion, stewardship of the gift requires we be seeking to maximize long-term benefit from the organs donated by donors/donor families. I would therefore give a moderate edge to survival versus difficulty in matching.
		Unless CMS discontinues evaluating Trx Ctr performance on survival rates - survival rates must be taken into account. The sicker candidates have more than likely a lower survival rate
5	Strong	Survival rate post transplant should play an important role. However harder to match patients opportunities should also be considered.
		Transplanted organs are a scarce resource and all efforts should be made to prevent/minimize futile transplants or poor survival recipients
6	Very Strong	If I understand correctly those with harder matches of blood type etc. are also going to have a harder time surviving if you open up this criteria. I would stick to the science of who does best long time. There should be opportunity for these patients but in a balanced fashion.
<b>Increase transplant opportunities for patients who are medically harder to match.</b>		
2	Moderate	So in this case the individual is an exact match where the other person is not an exact match
3	Moderate	Assuming the candidate with a 1 year+ survival expectation is not significantly harder to match the medically harder to match candidate should receive the lung.
5	Strong	As long as they reasonable predicted outcome
		Important to improve access to the disadvantaged gps who may have a longer time on the waitlist and possibly higher mortality while on the waitlist
		My vote would be different for longer-term outcomes.

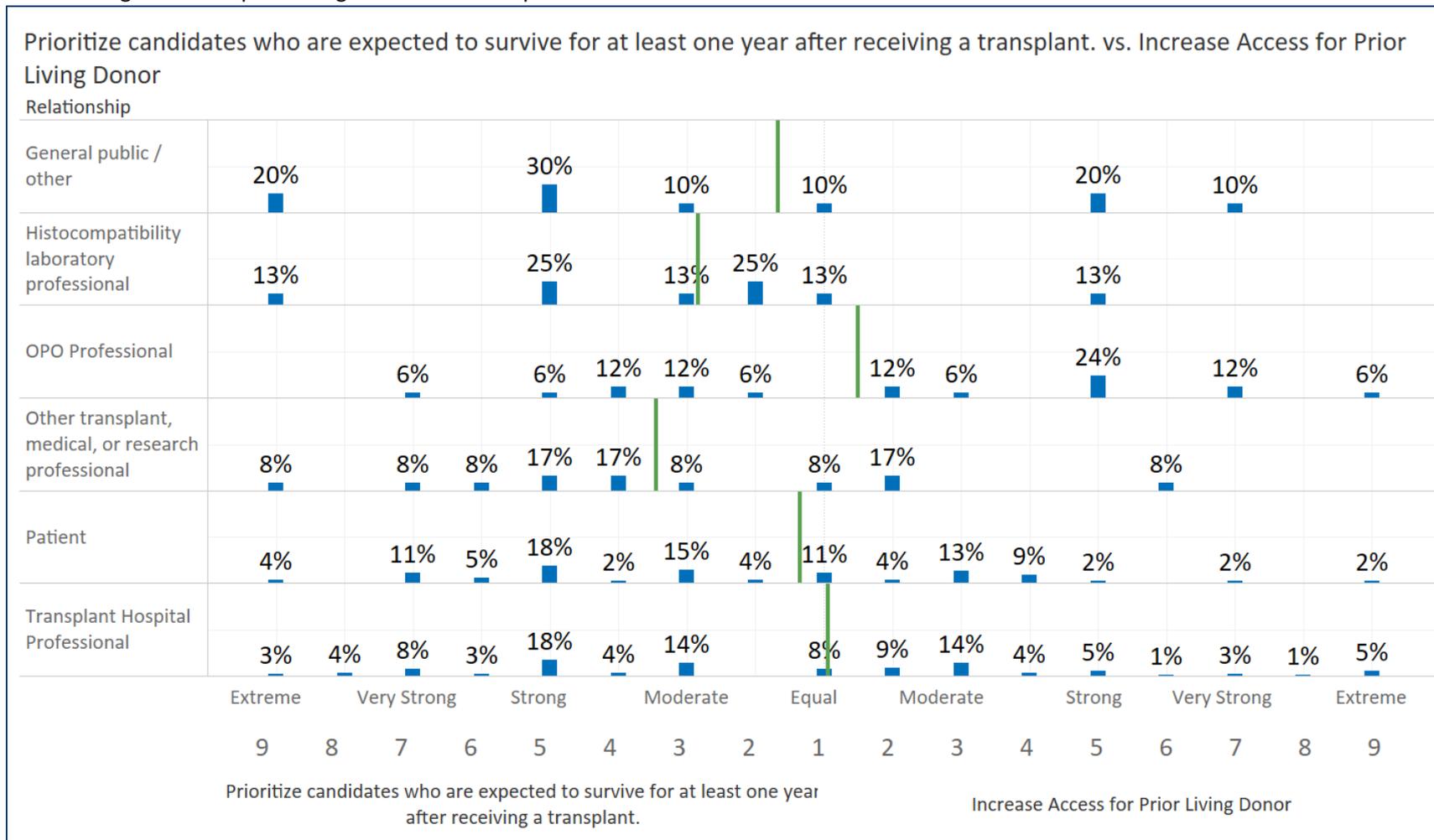


Comments:

Value	Judgement	Comment
<b>Prioritize candidates who are expected to survive for at least one year after receiving a transplant.</b>		
6	Very Strong	Young age is important (fair innings rule), but survival benefit is the more important value you for me. Again, I am treating this as longer term (2- or 3- year) survival.
7	Very Strong	It is much more important to prioritize candidates who are expected to survive for at least a year after receiving a transplant than to increase access for patients under the age of 18. For example, it would be much more important to give a 19 year old two further expected years of life than a 17 year old 9 further expected months of life. The eighteen year age boundary is arguably arbitrary. However if a potential candidate is young, and their medical prospects for survival are good, then the priorities align in favor of them.
		This option should hopefully include pediatric transplant candidates if the data suggests pediatric transplant survival rates are better than older adults.
<b>Equal</b>		
1	Equal	So I am not sure if age is a determinate. The idea is that an under 18 person has so much to gain of having a transplant. I am not sure how to determine this over the other person who has a developed a life especially of others depend on them. Difficult to determine who receives
		While CMS considers survival rate much more important than other factors, I cant help but feel under 18 also has a higher survival rate and should have an equal chance
		With no other information on the patient under age 18 this is equal in my mind.
<b>Increase Access for Patients Under the Age of 18</b>		
2	Moderate	I think there is strong overlap here with respect to the goal; the young theoretically should have a better chance of surviving a year-post transplant (all other things being equal).
3	Moderate	These are about equal in my opinion. As a rule, peds patients who get transplanted have the largest LYFT potential of anyone on the list...if they are prioritized slightly over the one year survival metric, I believe that's okay as they will as an aggregate group have many more years of life in theory.

### Post-transplant survival vs. Increase Access for Prior Living Donor

Four groups either had strong or moderate preference for prioritizing post-transplant survival. While two groups rated that equal in importance to increasing access for prior living donor is more important.

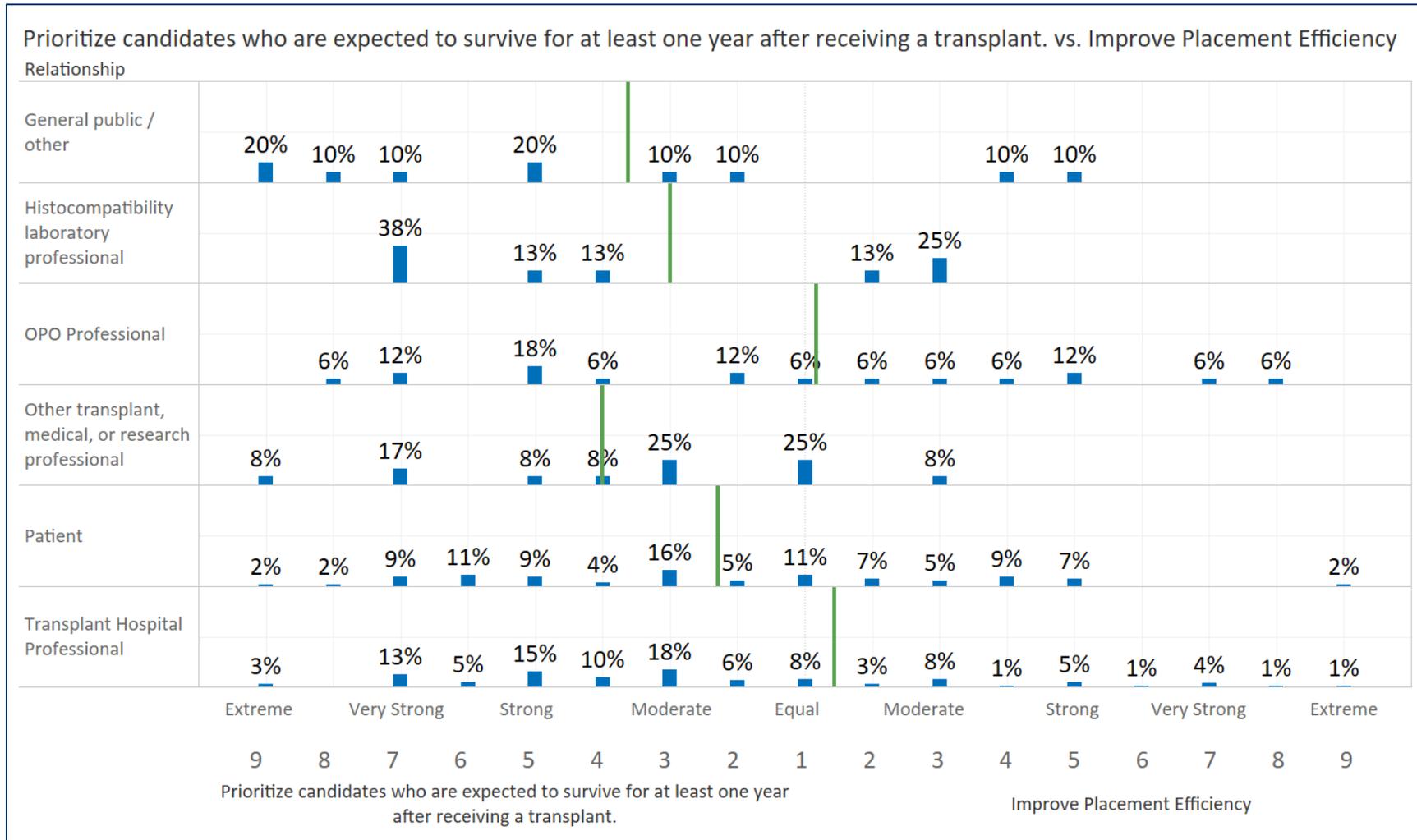


**Comments:**

Value	Judgement	Comment
<b>Prioritize candidates who are expected to survive for at least one year after receiving a transplant.</b>		
3	Moderate	Unless CMS discontinues evaluating Trx Ctr performance on survival rates - survival rates must be taken into account. The sicker candidates have more than likely a lower survival rate
4	Strong	All other things being equal, a prior living donor whose expected length of survival is less than a year should be of less priority that a non-donor whose expected length of survival is more than a year.
		I appreciate the desire to favor people who have been altruistic, but I don't think donating an organ should "buy" you more points/priority if you go on to needing an organ in the future.
7	Very Strong	Not all donors will have the opportunity to donate previous, it would seem a little unfair.
<b>Equal</b>		
1	Equal	Both recipients are equal is my belief
<b>Increase Access for Prior Living Donor</b>		
3	Moderate	Ethically those who have donated an organ previously should be given a priority
4	Strong	Access for a prior living donor should be scored.
		only if its for the same organ that was previously donated
7	Very Strong	Again, any living donor who's added an organ to the pool should have ultimate priority. One hundred deceased donor organs transplanted is 100. If a living donor added one to the pool and then needs one, there are still 100 other people transplanted so prioritizing them does not take away from the pool. We need to incentivize LD in every way possible to grow the pool of available organs...most won't need a transplant (in fact, nearly none will). If ten LD's add organs to 100 deceased organs, and one of the LDs gets a priority transplant, 109 other people will have been transplanted as opposed to only 100 if the LD's don't donate. LD's are additive, even if they get priority for a later transplant and additive grows the pool of organs.

### Post-transplant survival vs. Placement Efficiency

Four groups had either strong or moderate priority for post-transplant survival while two groups had equal to moderate priority for placement efficiency.

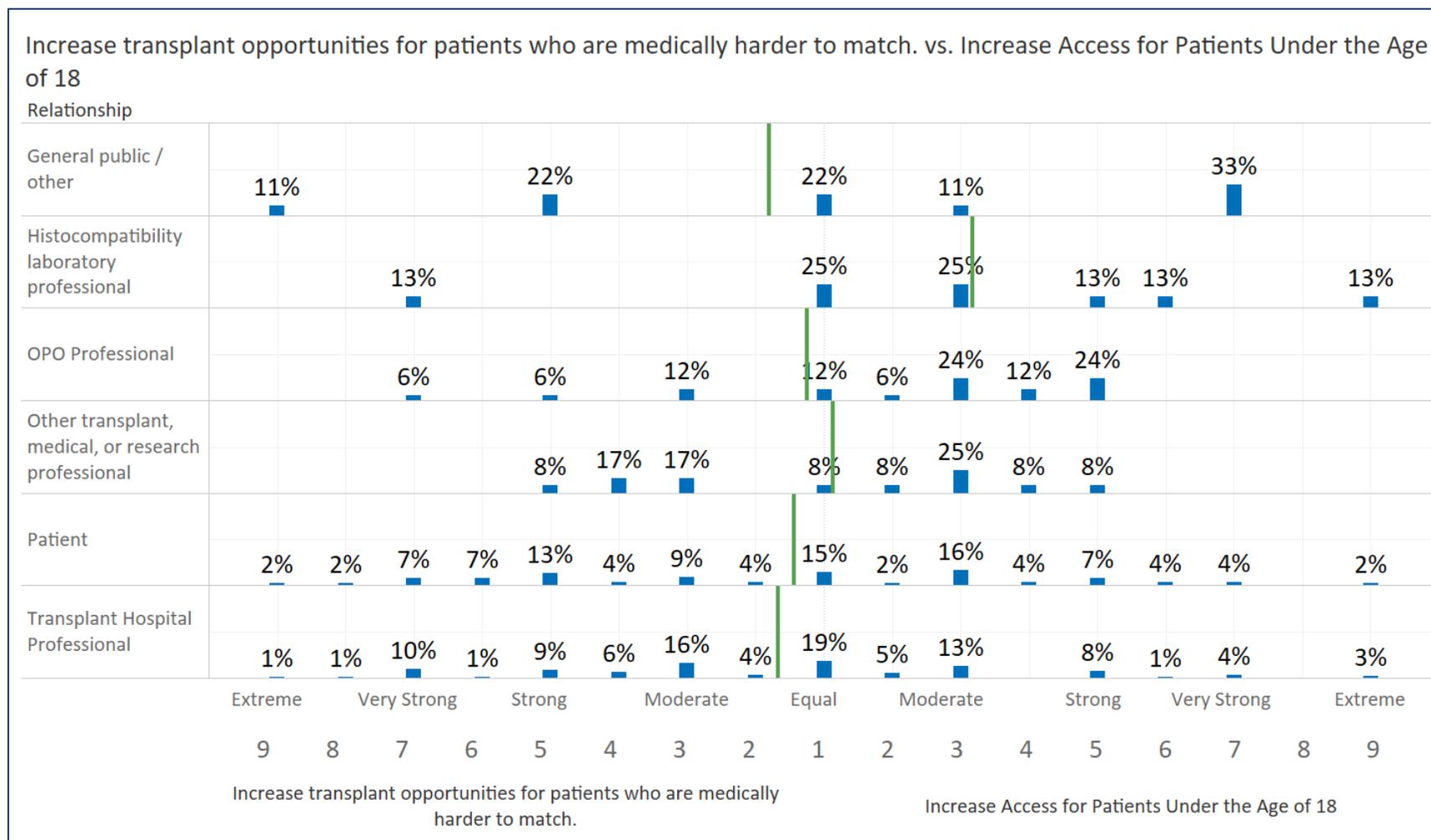


**Comments:**

Value	Judgement	Comment
<b>Prioritize candidates who are expected to survive for at least one year after receiving a transplant.</b>		
5	Strong	Survival trumps placement efficiency. However, efficient placement generally leads to more transplants, less discards, shorter cold times, and all of those contribute to better outcomes which is "effective" and effective is a close relative of efficient.
<b>Improve Placement Efficiency</b>		
2	Moderate	my impression is that through improved placement that more individuals can overall receive organ transplants
3	Moderate	I would assume there is a correlative relationship between improving efficiency and survival outcomes.
		Inefficiency's in placement would result in organ/resource wastage
		With lungs, transportation is a huge issue and prioritizing by the sickest may incur additional costs in transport of teams and then organ function after transport due to potential delays. Until lungs can be transported on a pump this is probably not feasible.
4	Strong	My vote may be different for longer-term outcomes.
		Placement efficiency should be ranked higher especially if it menas the lung remains more viable.

## Candidate biology vs Increase Access for Patients Under the Age of 18

Five groups rated these attributes equally while one group preferred increasing access for patients under the age of 18.

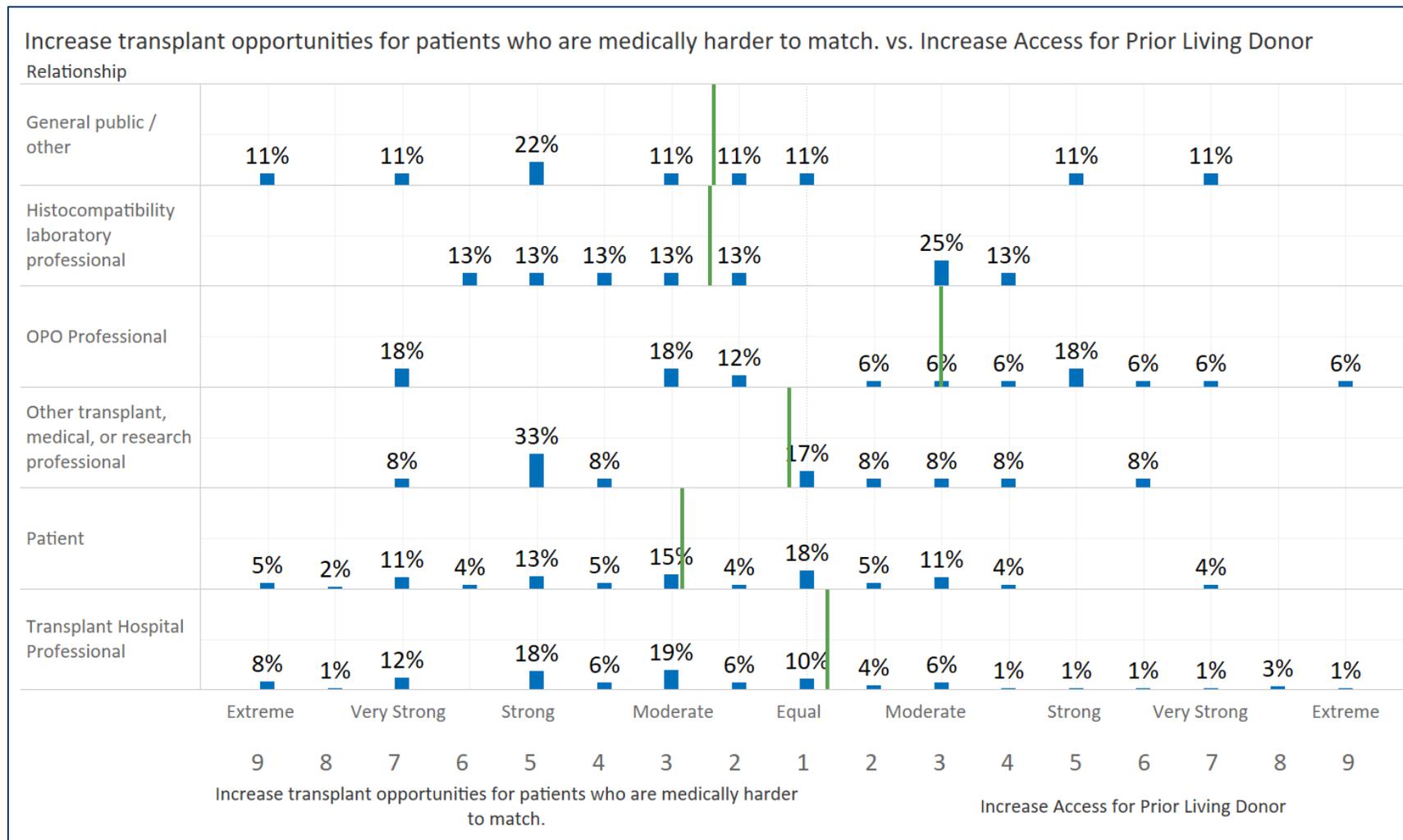


**Comments:**

Value	Judgement	Comment
<b>Increase transplant opportunities for patients who are medically harder to match.</b>		
2	Moderate	The hard to match person should get the organ as the under 18 person will be getting an available organ and possibly a better matched organ
4	Strong	Medically harder to match patients should receive consideration ahead of candidates able to accept donor lungs from a broader pool.
5	Strong	Though not presented as such, increasing placement for harder to match candidates could also include minors.
6	Very Strong	I think this criteria could benefit both goals.
<b>Equal</b>		
1	Equal	Children must be accounted for.
		Equal IMO.
<b>Increase Access for Patients Under the Age of 18</b>		
3	Moderate	Those that are medically harder to match may in fact have a lower survival rate due to the length of time they may have been listed However those under 18 may have a better survival rate which is important in Trx Ctr performance measures

### Candidate biology vs Increase Access for Prior Living Donor

Three groups had a moderate preference to increase transplant opportunities for patients who are medically harder to match. Two groups rated the attributes equally and one group (OPO professionals) expressed a moderate preference for increasing access for prior living donors.

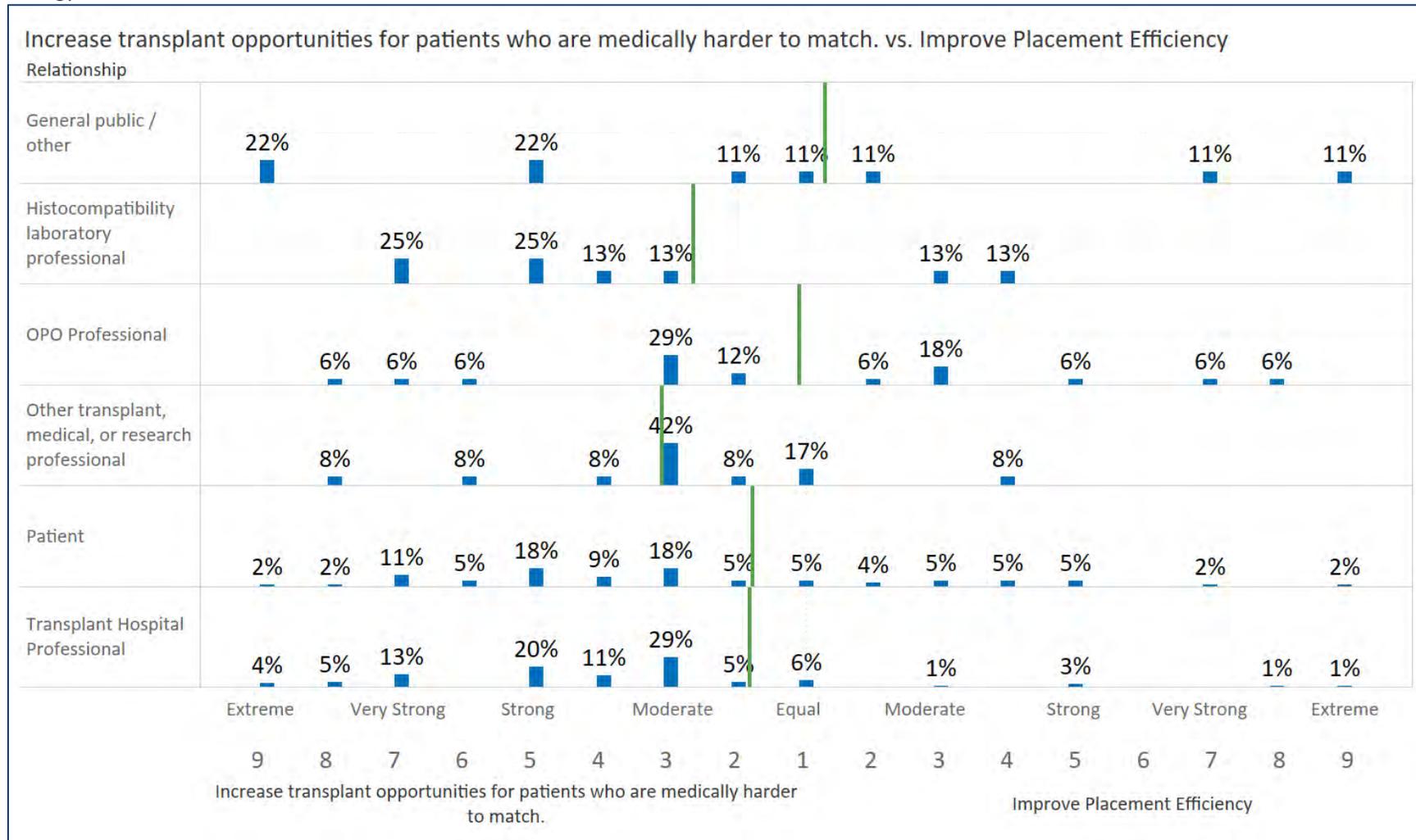


**Comments:**

Value	Judgement	Comment
<b>Increase transplant opportunities for patients who are medically harder to match.</b>		
2	Moderate	The hard to match person should receive the organ where the prior living donor person will have a better chance to get an organ soon based on improved distribution.
3	Moderate	The prior living donors should be better positioned to receive additional offers
4	Strong	Medically harder to match patients should receive consideration ahead of candidates able to accept donor lungs from a broader pool.
5	Strong	I appreciate the desire to favor people who have been altruistic, but I don't think donating an organ should "buy" you more points/priority if you go on to needing an organ in the future.
6	Very Strong	You could be listed for transplant and be a donor at the same time. Not all organ donors will have the opportunity to be a donor. It would seem like your being penalized.
<b>Equal</b>		
1	Equal	The relative prioritization depends on the underlying reasons why the patients are medically harder to match (e.g. social, racial, health inequities), so is hard to judge in general.
<b>Increase Access for Prior Living Donor</b>		
7	Very Strong	As previously stated, LD adds organs to the pool, increasing everyone's chance to get transplanted. The occasional LD who goes to the head of the list because they need an organ will not numerically disadvantage the system when all the LDs who don't need a transplant are considered. We need to incentivize LD above all else!

### Candidate biology vs Improve Placement Efficiency

There was wide variation in the results of this pairwise comparison: the general public, patients, and transplant hospital professionals all recorded some extreme values for both attributes. The result was that the average ratings were equal or moderately leaning toward candidate biology.

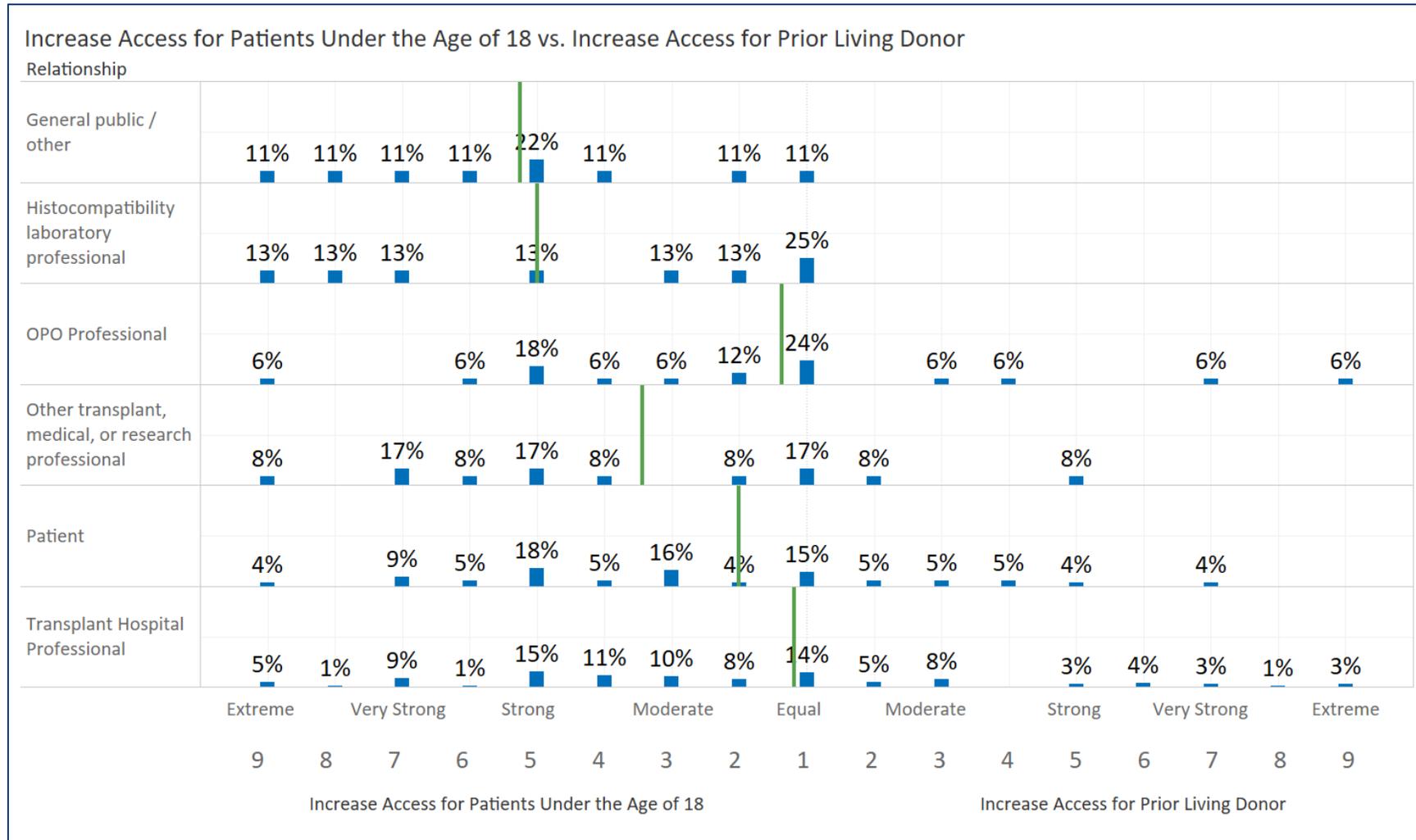


**Comments:**

Value	Judgement	Comment
<b>Increase transplant opportunities for patients who are medically harder to match.</b>		
2	Moderate	so I understand in this situation, the exact match for those who are difficult to match, where the available resources is of minor differences. To better understand is whether the organ is at risk of not being used. I did not see that here. So this is what is meant, but was not discussed. More info is needed. My concern is that there are organs not used because of limited resources, this info would change my answer
3	Moderate	I feel our current system puts extreme value on prioritizing patients who are medically hard to match, often sacrificing efficiency. I think medically matching should have priority but not as much as current system.
		It is worth losing some efficiency to find a rare match for a person with one of these specific factors
		Medically difficult patients are somewhat but not completely more important than efficiency in my opinion. A reasonable level of effort expended on placement to get harder to transplant patients transplanted is acceptable. we just need to make sure that doesn't lead to broad inefficiency and waste of organs, which helps no one.
<b>Equal</b>		
1	Equal	The exception is if the viability of the lung becomes less viable before reaching a medically harder to match patient then efficiency should be selected.
<b>Improve Placement Efficiency</b>		
3	Moderate	With lungs, transportation is a huge issue and prioritizing by the sickest may incur additional costs in transport of teams and then organ function after transport due to potential delays. Until lungs can be transported on a pump this is probably not feasible.

### Increase Access for Patients Under the Age of 18 vs Increase Access for Prior Living Donor

A majority of participants and all demographic groups agreed that increasing access for patients under the age of 18 was equal to or more important than increasing access for prior living donors. The general public and histocompatibility professionals felt this most strongly.

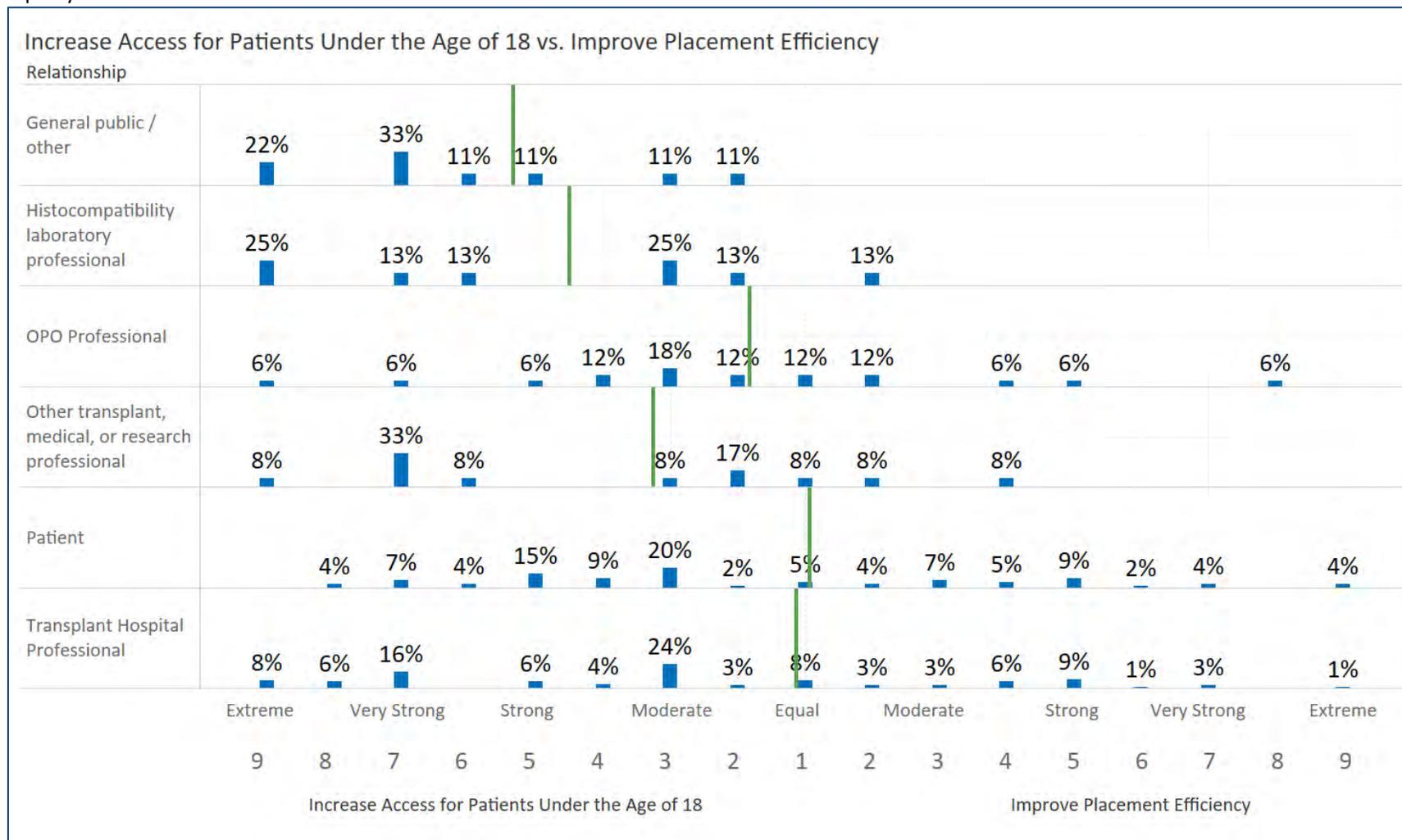


**Comments:**

Value	Judgement	Comment
<b>Increase Access for Patients Under the Age of 18</b>		
4	Strong	Pretty straightforward for me. Age over altruism.
5	Strong	I appreciate the desire to favor people who have been altruistic, but I don't think donating an organ should "buy" you more points/priority if you go on to needing an organ in the future.
<b>Increase Access for Prior Living Donor</b>		
2	Moderate	So age does not make it a priority, but being generous does mean they are to be recognized.
4	Strong	The prior living donor if all other factors are equal.
7	Very Strong	LD's should always have priority as they have added to the supply, as a total group, way more organs than will occasionally be needed for one who needs a transplant.

### Increase Access for Patients Under the Age of 18 vs. Improve Placement Efficiency

There was agreement among all demographic groups that placement efficiency was not more important than increasing access to patients under the age of 18. The general public felt this was of very strong importance while patients and transplant hospital professionals weighed them equally.

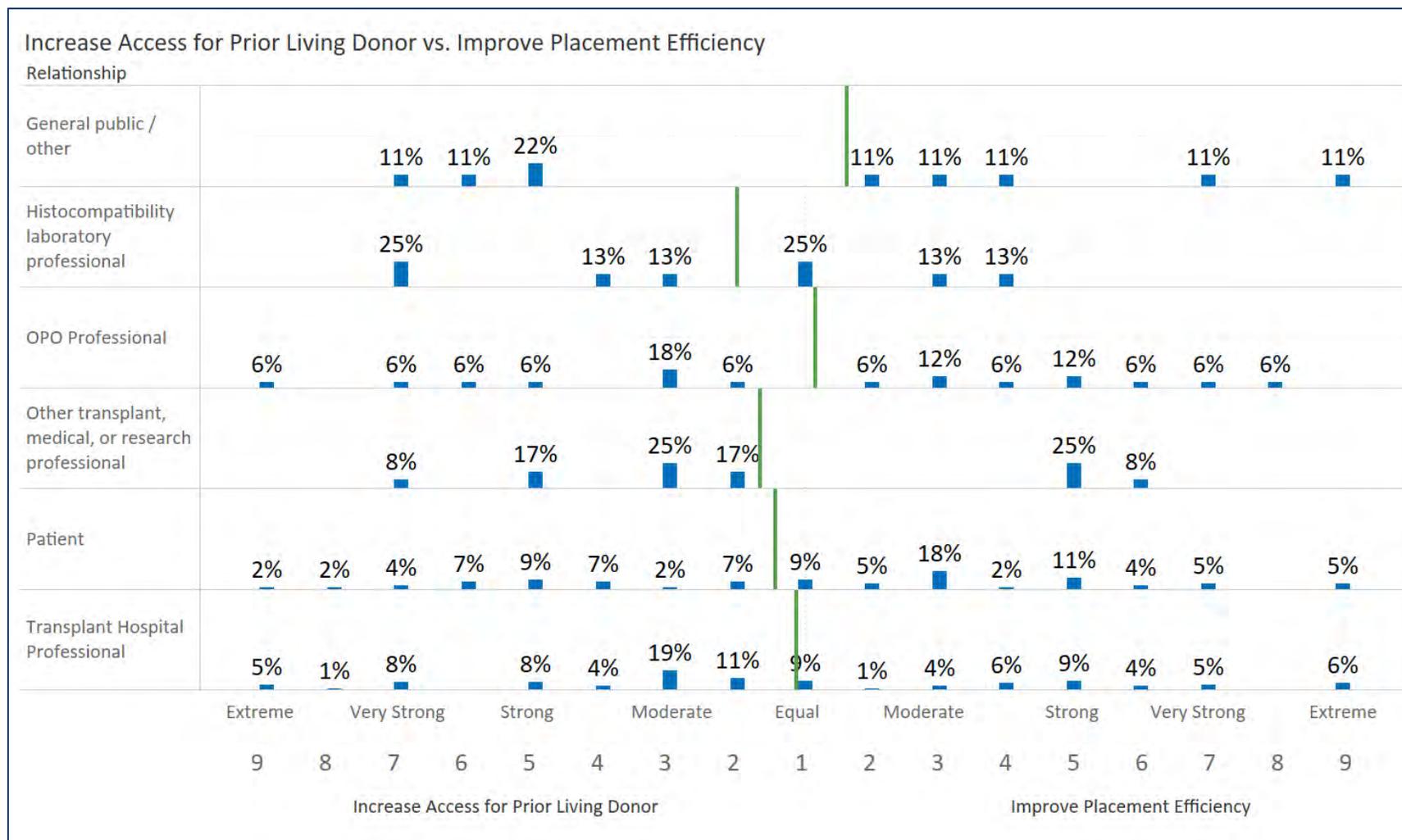


**Comments:**

Value	Judgement	Comment
<b>Increase Access for Patients Under the Age of 18</b>		
3	Moderate	As with difficult to match patients, peds are an area where a moderate and carefully considered level of additional process (somewhat less efficient) is acceptable. Again, have to be careful to assure we don't create inefficiency to the level it causes organ wastage.
<b>Improve Placement Efficiency</b>		
2	Moderate	my understanding that through efficient placement would be mean more get organ transplants
4	Strong	Placement efficiency should receive consideration ahead of candidates able to accept donor lungs from a broader pool.

### Increase Access for Prior Living Donor vs. Improve Placement Efficiency

There was wide variety in the responses to this pairwise comparison with all demographic groups resulting in equal or moderately leaning toward one or the other attribute.



**Comments:**

Value	Judgement	Comment
<b>Increase Access for Prior Living Donor</b>		
7	Very Strong	LD's take priority; they've added to the pool and helped get more people transplanted!
<b>Equal</b>		
1	Equal	The exception is if the viability of the lung becomes less viable before reaching a prior living donor then efficiency should be selected.
<b>Improve Placement Efficiency</b>		
2	Moderate	More efficient placement would mean the prior living donor would be getting an organ soon
6	Very Strong	I appreciate the desire to favor people who have been altruistic, but I don't think donating an organ should "buy" you more points/priority if you go on to needing an organ in the future.



**Comments:**

Value	Judgement	Comment
<b>Equal</b>		
1	Equal	I guess cost should be considered, but it should be about getting the organ to the recipient quickest.
		This equation/evaluation factor does not seem to consider the patient need.
<b>Minimizing organ transportation costs</b>		
2	Moderate	There is, as best as I can see, no inherent difference relevant to prioritization between organ transportation costs and non-transportation costs. However use of a linear scale of distance, while easy to obtain, is a very imprecise measure of those non-transportation costs. The organ transportation cost measure is somewhat less imprecise because it takes into account method of transport, so it should be given some priority (however only when such costs are relevantly similar/close-to-each-other - otherwise such priority should be outweighed by the magnitude of the difference in costs)

## Appendix A: Comparison Matrixes

Table 2 shows the aggregate results for each of the pairwise comparisons by demographic group. Items less than one are shaded red and indicate that the column header is the preferred attribute. Items greater than one are shaded blue and indicate that the row header is the preferred attribute in the pairwise comparison. For example, many of the values underneath “Improve Placement Efficiency” are blue which indicates the row header is the preferred attribute in those situations.

Table 2: Comparison Matrix

General public / other					
	Post-transplant Survival	Candidate Biology	Increase Access for Patients Under the Age of 18	Increase Access for Prior Living Donor	Improve Placement Efficiency
Medical Urgency	0.543	1.025	0.647	0.871	1.476
Post-transplant Survival		2.104	0.624	1.675	2.839
Candidate Biology			0.845	1.863	1.470
Increase Access for Patients Under the Age of 18				4.389	5.551
Increase Access for Prior Living Donor					0.960

Histocompatibility laboratory professional					
	Post-transplant Survival	Candidate Biology	Increase Access for Patients Under the Age of 18	Increase Access for Prior Living Donor	Improve Placement Efficiency
Medical Urgency	0.398	1.000	0.550	1.755	2.570
Post-transplant Survival		1.311	0.659	2.196	2.102
Candidate Biology			0.481	1.454	2.432
Increase Access for Patients Under the Age of 18				3.330	3.637
Increase Access for Prior Living Donor					1.627

OPO Professional					
	Post-transplant Survival	Candidate Biology	Increase Access for Patients Under the Age of 18	Increase Access for Prior Living Donor	Improve Placement Efficiency
Medical Urgency	0.856	1.701	0.623	0.692	1.013
Post-transplant Survival		1.374	0.500	0.711	1.204
Candidate Biology			0.605	0.818	1.198
Increase Access for Patients Under the Age of 18				1.428	1.487
Increase Access for Prior Living Donor					0.901

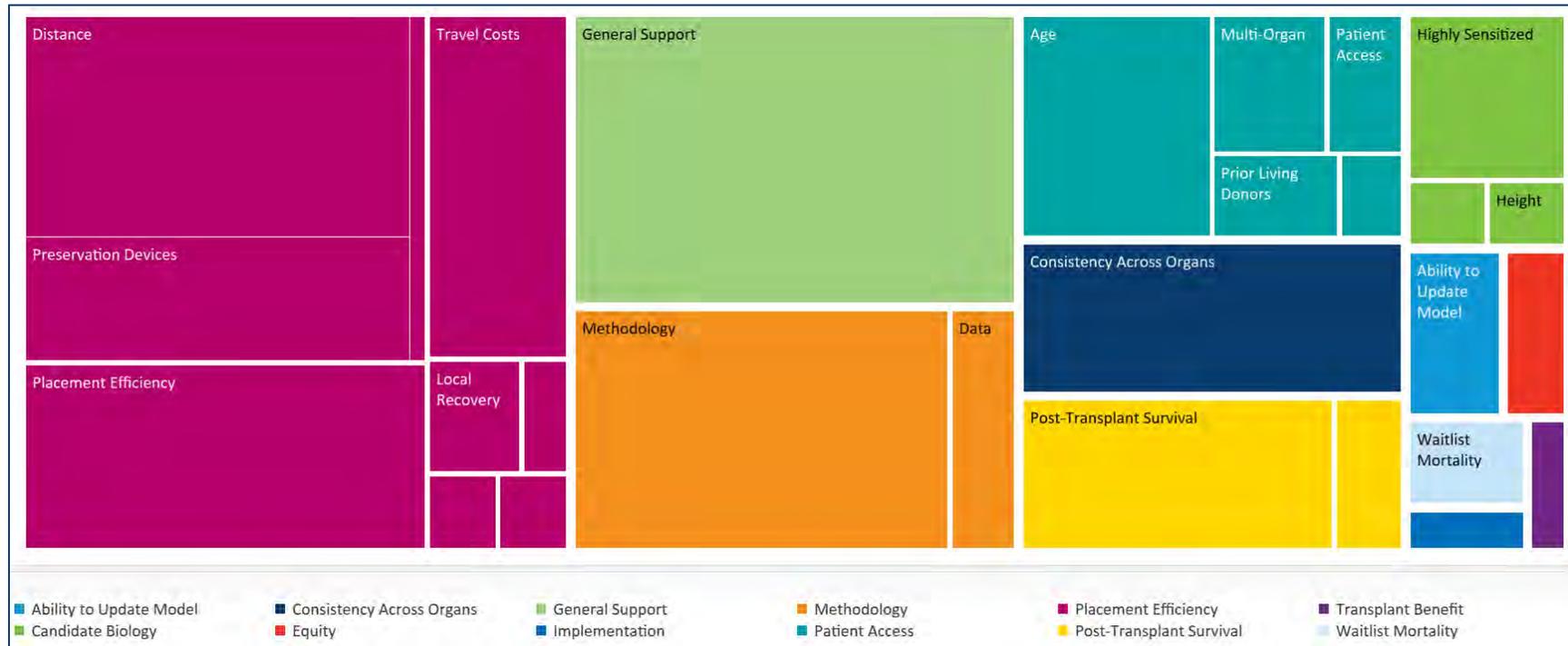
Other transplant, medical, or research professional					
	Post-transplant Survival	Candidate Biology	Increase Access for Patients Under the Age of 18	Increase Access for Prior Living Donor	Improve Placement Efficiency
Medical Urgency	0.916	0.998	0.511	1.967	2.152
Post-transplant Survival		1.487	1.541	2.272	2.560
Candidate Biology			0.967	1.492	2.312
Increase Access for Patients Under the Age of 18				2.475	2.759
Increase Access for Prior Living Donor					1.309

Patient	Post-transplant Survival	Candidate Biology	Increase Access for Patients Under the Age of 18	Increase Access for Prior Living Donor	Improve Placement Efficiency
Medical Urgency	0.998	1.005	0.943	1.993	1.502
Post-transplant Survival		1.284	1.067	1.644	1.602
Candidate Biology			1.214	1.862	2.055
Increase Access for Patients Under the Age of 18				1.868	1.440
Increase Access for Prior Living Donor					0.875

Transplant Hospital Professional	Post-transplant Survival	Candidate Biology	Increase Access for Patients Under the Age of 18	Increase Access for Prior Living Donor	Improve Placement Efficiency
Medical Urgency	1.290	1.361	1.089	1.543	2.339
Post-transplant Survival		0.902	0.928	1.293	1.929
Candidate Biology			1.296	2.201	3.206
Increase Access for Patients Under the Age of 18				1.717	1.973
Increase Access for Prior Living Donor					1.175



This next figure shows the relative frequency that each topic appeared.



Next, you can see the themes organized by member type associated with the public comment participant.

	Member Type = Unassigned <sup>14</sup>	Member Type = Non-Member (General Public)	Member Type = Patient	Member Type = Transplant Hospital	Member Type = Stakeholder Organization	Member Type = Organ Procurement Organization
<b>Ability to Update Model</b>	Yes	No	No	No	Yes	No
<b>Candidate Biology</b>	No	No	No	Yes	No	No
<b>Height</b>	No	No	No	No	Yes	No
<b>Highly Sensitized</b>	Yes	No	Yes	No	Yes	No
<b>Consistency Across Organs</b>	Yes	No	No	No	Yes	No
<b>Equity</b>	Yes	No	No	No	No	No
<b>General Support</b>	Yes	No	Yes	Yes	Yes	Yes
<b>Implementation</b>	Yes	No	No	No	No	No
<b>Methodology</b>	Yes	No	No	No	Yes	No
<b>Data</b>	Yes	No	No	No	No	No
<b>Patient Access</b>	Yes	No	No	No	No	No
<b>Age</b>	Yes	No	No	No	Yes	No
<b>Multi-Organ</b>	Yes	No	No	No	Yes	No
<b>Prior Living Donors</b>	Yes	No	No	No	No	No
<b>Waiting Time</b>	Yes	No	No	No	No	No

<sup>14</sup> This column represents comments submitted at regional meetings that are not associated with any specific speaker.

	Member Type = Unassigned <sup>14</sup>	Member Type = Non-Member (General Public)	Member Type = Patient	Member Type = Transplant Hospital	Member Type = Stakeholder Organization	Member Type = Organ Procurement Organization
<b>Placement Efficiency</b>	Yes	No	No	Yes	Yes	No
<b>Aura Placement</b>	No	No	No	Yes	No	No
<b>Distance</b>	Yes	No	No	No	Yes	No
<b>Hard boundaries</b>	No	No	Yes	No	No	No
<b>Preservation Devices</b>	Yes	No	No	No	Yes	Yes
<b>Likelihood of Acceptance</b>	Yes	No	No	No	No	No
<b>Local Recovery</b>	Yes	No	No	No	No	Yes
<b>Marginal Organs</b>	Yes	No	No	No	No	No
<b>Travel Costs</b>	Yes	No	No	No	Yes	No
<b>Post-Transplant Survival</b>	Yes	No	No	No	Yes	No
<b>Ischemic Time</b>	No	No	No	No	Yes	No
<b>Transplant Benefit</b>	Yes	No	No	No	No	No
<b>Waitlist Mortality</b>	Yes	No	No	Yes	No	No

Below are the relevant excerpts organized by theme.<sup>15</sup>

Theme	Number Of Coding References
<b>Ability to Update Model</b>  Careful deliberation with community involvement on how to appropriately weight this factor fairly and ensuring future ability to revisit frequently as perfusion technologies evolve, is requested by some of our COP members.  Continuous distribution will also provide future flexibility by allowing the OPTN to be more nimble in its ability to adjust and change the relative rating of attributes over time as conditions for organ distribution evolve.  it will be important that the attributes are regularly evaluated and are able to be adjusted as technology and procurement practices advance.	<b>3</b>
<b>Candidate Biology</b>  On the other hand, size matching and age matching attributes should be reconsidered. They are the only way any donor factor is considered in this composite allocation score and would be an important step towards making a successful match.	<b>1</b>
<b>Candidate Biology\Height</b>  In particular, we are pleased to see that UNOS has included sensitization and candidate height as attributes for candidate biology in order to address certain patient access challenges.	<b>1</b>
<b>Candidate Biology\Highly Sensitized</b>  ASHI/NCAC is pleased to see that there is consideration for incorporating a cPRA sliding scale as one component of a composite allocation score for lung allocation. ASHI/NCAC is willing to provide any needed expertise in addition to that of the OPTN/UNOS Histocompatibility Committee to address this issue.given the uncertainties of what agents might be targeted for testing.  In particular, we are pleased to see that UNOS has included sensitization and candidate height as attributes for candidate biology in order to address certain patient access challenges.	<b>5</b>

<sup>15</sup> All of the comments in their original form are available at: <https://optn.transplant.hrsa.gov/governance/public-comment/update-on-the-continuous-distribution-of-organs-project/>.

Theme	Number Of Coding References
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Regarding PRA or sensitization status are you only considering points for cPRA or have more granularity regarding points by loci like DQ

The Committee is concerned that sensitized transplant candidates, especially lung candidates, may need unique considerations per candidate beyond what a weighted score or extra points may offer. As the workgroup considers incorporating CPRA into allocation, please ensure the Histocompatibility Committee has the opportunity for timely and frequent input.

The current allocation exceptions for highly sensitized patients aren't sufficient, and incorporating CPRA would help ensure access.

**Consistency Across Organs**

**11**

This is important in not just Lung, but all solid organ transplant in my opinion.

The Pediatric Transplantation Committee (the Committee) thanks the Lung Transplantation Committee for their Update on the Continuous Distribution of Organs Project and the opportunity to provide feedback. The Committee encourages consistency in the pediatric designation in allocation and feels strongly that this should be reflected in all future continuous distribution efforts.

The Continuous Distribution of Organs Project (Lung) has created a paper outlining the development of a composite allocation score that will be applied broadly to allocation across the organ systems.

The Committee expressed concern that other organ groups have put more emphasis on access to transplant or decreasing waitlist mortalities than post-transplant survival.

One member stated that the Policy Oversight Committee is helping to orchestrate Continuous Distribution and the work of the lung committee will inform the other organ-specific committees.

The Committee also appreciates that the work undertaken by the Lung Transplantation Committee may serve as a model for the efforts for the kidney allocation system.

Consistency in approach should be an aim among different organ allocation schemes (not all same, but at least consistent)

Another attendee commented that the idea that lung continuous allocation will serve as "the model" for other organ allocation is extremely disturbing. The idea that a few lung physicians have any understanding of the needs of organ recipients was clearly shown to be erroneous given the discussion during the meeting.

A member encouraged the rest of the region to take the AHP prioritization exercise, since this framework will be expanded to other organs in the future.

Theme	Number Of Coding References
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In addition, another attendee commented that it appears this distribution model will eventually make it to the other solid organs, the committee should ensure all aspects of ethics be taken into consideration.

Lastly, one attendee noted that this is excellent work by the Lung Committee and the process should be replicated as all organs move to a Continuous Distribution model.

<b>Equity</b>	<b>2</b>
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Allocation of organs should be approached with value or equity at the forefront, but with preservation of a center's ability to make final decisions about a recipient's transplant.

This system provides for a more equitable allocation of organs

<b>General Support</b>	<b>24</b>
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The American Society of Transplant Surgeons (ASTS) supports the concept of continuous distribution of organs with the following concerns. We appreciate the complexity of the task, the efforts of the OPTN Lung Transplantation Committee and the diligence of the process they are following. We do reserve judgement until the final proposal is reached as further details emerge and will solidify the final intended actions.

The American Society of Transplantation supports the Continuous Distribution of Organs Concept which uses 5 components in a Composite Allocation Score to overcome long-standing problems of accidents of geography created by arbitrary geographic borders. We acknowledge and appreciate the timely actions taken by UNOS to address evolving issues and needs within the transplant and donation community related to the Continuous Distribution Project.

The Committee is overall supportive of the work in progress to create an organ allocation system based on continuous distribution.

The Kidney Transplantation Committee (the Committee) thanks the Lung Transplantation Committee for the opportunity to provide feedback on the Update on the Continuous Distribution of Organs Project. The Committee supports the current approach of the project and looks forward to hearing the feedback regarding how the community prioritizes attributes that is received from the prioritization exercise.

The Operations and Safety Committee thanks the OPTN Lung Transplantation Committee for their efforts in developing this public comment proposal for the Update on the Continuous Distribution of Organs Project.

**Theme****Number Of Coding References**

We strongly support and encourage members of the ASTS, and other transplant professionals, to participate in the "exercise to prioritize the attributes." Broad participation in this will likely result in a more balanced final proposal. ASTS suggests the OPTN make the document/video more widely available understanding that weighting each of these parameters will be very important as will be voting by as many vested parties in the proposed Analytical Hierarchical Project (AHP). We look forward to the continued development of the proposal and strongly support the stated intent for periodic re-evaluation and changes in the future.

The OPTN Minority Affairs Committee (MAC) thanks the OPTN Lung Transplantation Committee for their efforts in developing this request for feedback and the opportunity to comment. The MAC commends the OPTN Lung Transplantation Committee for leading the charge to operationalize the continuous distribution framework.

The Patient Affairs Committee (PAC) appreciates the opportunity to provide feedback on this project. Overall, the PAC continues to support this project and the work to include the patient community.

Yes, as proposed

The OPTN Ethics Committee thanks the Lung Transplantation Committee for presenting its update on Continuous Distribution. The Committee supports this proposal overall and encourages broad outreach when collecting input to capture many viewpoints, including those of the general public.

Support the OPTN lung committee's work on this continuous distribution of organs project

The American Society for Histocompatibility (ASHI) and its National Clinical Affairs Committee (NCAC) is supportive of ongoing efforts to revise organ allocation based on a continuous distribution model to eliminate inequities introduced by donor service area and region.

One commenter noted that the Lung Committee should be lauded for leading this OPTN initiative for all organ transplants as our transplant system migrates from a local defined matching and allocation system to a more national and continuous distribution strategy to improve fairness, equity, efficiency, and cost-effectiveness in the spirit of NOTA and the Final Rule.

An attendee agreed that this is an important concept to develop. They are pleased that the lung committee is taking the lead on this and stated this should be expanded to all organs.

Several comments were made in general support of the project.

Another commenter agreed that this is really impressive work by the Lung Committee and it is a very thoughtful and cogent approach to difficult and sometimes conflicting allocation factors.

Theme	Number Of Coding References
<p>AOPO appreciates the opportunity to comment on the update to the concept document for implementation of continuous distribution for lung allocation and continues to support this framework as an effective way to incorporate and balance multiple medical and efficiency-based factors in a manner that is patient-focused.</p>	
<p>Carolina Donor Services supports the continuous distribution framework to eliminate hard boundaries and balance medical need with system efficiency.</p>	
<p>An attendee expressed support for the concept but concerned about execution. For example, equitable access to care and placement efficiency are vital but simpler concepts likely to prevail.</p>	
<p>Laudable concept. The various weights attributed to the goals that form the composite allocation score will be critically important and debate over this will likely be contentious</p>	
<p>Laudable concept. The various weights attributed to the goals that form the composite allocation score will be critically important and debate over this will likely be contentious</p>	
<p>LifeGift supports the continuous distribution concept and its framework of the 5 goals in order as written in the proposal material. It reduces the impact of accidents of geography and is generalizable to all organs.</p>	
<p>Members stated the committee is doing an excellent job presenting the material and the work will serve as a good template for other organ types.</p>	
<p>Fully support the concept.</p>	
<p><b>Implementation</b></p>	<p><b>1</b></p>
<p>After implementation, it will be very important for the committee to develop extensive education for patients, families, donor families, and the general public to help explain this new distribution model.</p>	
<p><b>Methodology</b></p>	<p><b>17</b></p>
<p>While the members appreciate the efforts made to help explain the project to lay audiences, they do suggest continuing to make this project even more understandable (adding a glossary, providing more context to visuals, etc.). The committee suggested sharing the raw data from the AHP exercise, as well as providing a real life application of the results to the community.</p>	

Theme	Number Of Coding References
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While the MAC finds the project innovative, they encourage that the weighing of different attributes limit subjectivity to avoid unintended consequences on vulnerable populations.

We found the document to be extremely helpful in understanding the process and steps involved in determining the goals and attributes which are being considered for the Composite Allocation Score. The discussion on why or why not specific attributes were being used was transparent, not difficult to follow the reasoning and based on prior literature.

The proposal fails to adequately explain the process that will be used to calculate cost (somewhat euphemistically referred to as travel efficiency) and proximity efficiency.

The Priority exercise was helpful to understand this process. The AST encourages all lung transplant professionals to complete this survey.

The Committee suggests providing more transparency in how the criteria are weighted and how consensus is reached among the various members of the transplant community. The Ethics Committee looks forward to providing ethical analysis as this project progresses.

The committee should work with the Minority Affairs committee to make sure there is no bias.

Several attendees supported the committee work and valued the opportunity to participate in the prioritization exercise.

Members felt it was important to include more explanation around the attributes that were discussed but not included.

One attendee was encouraged that the OPTN Ethics Committee was involved in the project and supported having an Ethics Committee member serve on the Lung Committee during the development of the CD score.

Many members commended the committee on its work and expressed interest in completing the prioritization exercise.

Ensuring vulnerable populations (lower socioeconomic status, African American ethnicities, pediatrics, previous living donors, etc.) are able to provide significant comments will be important. Therefore, this committee should get input from Minority Affairs committee, Living Donor committee, Pediatric committees, etc. ? Another attendee commented that the committee needs to work on defining the process for consensus from the community with varied preferences for weightage of the five attributes. It will be important to know how the differing weights will be adjudicated. ? An attendee expressed that the public comment involves input from professionals, transplant staff, patients who are on committees, and some educated participants. There is no input from the true population of patients who are ill, and their level of education is not adequate to understand the attributes. The process is for all patients and the language needs to be simplified for their input.

ASTS believes the OPTN can do better with helping the public understand how this proposal is being developed. The given algorithm is not that easy to understand. In general, the ASTS agrees with the recommended attributes to align the process with other organs and how they are considered.

Theme	Number Of Coding References
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AOPO appreciates the ability to participate in the exercise to inform the relative weight of different medical and efficiency attributes and views the ultimate goal of this work as ensuring fair distribution of available organs and increasing transplantation to the patients most in need.

A member encouraged the rest of the region to take the AHP prioritization exercise, since this framework will be expanded to other organs in the future.

Continuous Distribution Has the Potential to Improve Patient Access: We are supportive of UNOS's aim to move to a continuous distribution framework for organ allocation, and we believe the strength of this model lies in its flexibility. With the shift to continuous distribution, UNOS has the opportunity to improve upon accommodations for individuals who are medically harder to match or have other special considerations with bearing on access. The challenge with this model will be successfully identifying appropriate factors and their weights for inclusion in the final allocation system. We feel the categories of attributes identified by UNOS included the most recent update to the continuous distribution project are appropriate. In particular, we are pleased to see that UNOS has included sensitization and candidate height as attributes for candidate biology in order to address certain patient access challenges.

Propose that the "best" model agreed to by majority of the community move forward prior to modeling regional/center impact since that is where the push back comes from.

<b>Methodology\Data</b>	<b>3</b>
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This attendee also asked that all data presented to the committee be readily available to the public.

Modeling will bolster community confidence

The Committee inquired about the data being used to weigh attributes and if it has been a straight forward process. There is clinical data for some attributes, which should be direct, but there is no data when measuring the importance between attributes.

<b>Patient Access</b>	<b>2</b>
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The committee was asked to carefully review the impact of these changes on the financial viability of small programs and programs in less populous areas and, if possible, to consider how patient's insurance access/options disadvantages some populations, particularly the Medicaid populations as part of this framework.

Two attendees commented that the committee needs to consider socioeconomic disparities and access to healthcare.

Theme	Number Of Coding References
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<b>Patient Access\Age</b>	<b>8</b>
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The Society of Pediatric Liver Transplantation (SPLIT) urges strong consideration of unequivocally prioritizing pediatric age recipients as they cross 4 of the 5 attributes. In the UNOS white paper, Ethical Principles of Pediatric Organ Allocation, published as a joint effort of the Ethics and Pediatrics Committees, there are well-established ethical reasons for prioritizing children. We urge all of the members of our pediatric community to give feedback on this via the online tool and exercise presented with this proposal

We have reservations about the current proposal's approach to the pediatric patient - drawing a line at 18-years old is biologically arbitrary and binary - as such it is at odds with the overall move towards continuous variables.

we do also want to ensure that young pediatric candidates are not disadvantaged (see comments below).

The Pediatric Transplantation Committee (the Committee) thanks the Lung Transplantation Committee for their Update on the Continuous Distribution of Organs Project and the opportunity to provide feedback. The Committee encourages consistency in the pediatric designation in allocation and feels strongly that this should be reflected in all future continuous distribution efforts.

A member provided feedback that they are concerned about candidates under the age of 12 and competition with older pediatrics and also that further segmentation of pediatric candidates is not scientific and that the committee should clearly articulate their intent to ensure patients under 12 are not disadvantaged.

Another attendee noted that it makes sense to include pediatrics in the patient access attribute, but it is unclear why priority is given to prior living donors.

An attendee commented that pediatric status should be given a higher weight due to conditions such as a child's failure to thrive while waiting.

At the direction of the HHS secretary in response to a court challenge several years ago, the most recent change to the pediatric donor sequence in the lung allocation policy prioritized access for pediatric lung candidates under 12 to adolescent donor organs (including priority over other adolescents within 1000 nm of the donor) while protecting priority for under 12 candidates to access under 12 donor organs. In the proposed continuous distribution framework, candidates under 12 will lose both sets of priorities. Although the proposal outlines steps intended to mitigate these changes (assigning pediatric lung candidates under 12 medical urgency and post-transplant survival scores based on historical cohorts, giving pediatric candidates as a group additional points and giving smaller patients additional points based on the proportion of donors with suitably sized organs), it remains to be seen whether modeling will verify that these changes will not negatively impact access to transplant and waiting list outcomes for children under 12. Because the numbers will likely be too small to reach statistical significance, gathering sufficient evidence to make a change post implementation may be challenging. To ensure that this project continues to move forward in a timely manner, we recommend that the committee consider including in their modeling requests alternate constructs that protect access for this small but vulnerable patient population.

Theme	Number Of Coding References
<p data-bbox="178 292 525 332"><b>Patient Access\Multi-Organ</b></p> <p data-bbox="178 349 1906 422">Has the committee given any consideration for how allocation would be affected when lung is involved with a multi-organ situation; i.e. heart-lung, where heart 'pulls' lung, and can potentially pull from a high LAS recipient or lung-liver where there isn't a very clear path?</p> <p data-bbox="178 438 1906 617">UNOS should further consider adding multi-organ transplant as an attribute under the candidate biology category in order to improve access to needed donor organs for this vulnerable patient population. The present allocation system has failed to adequately address the needs of this population, and UNOS should take this opportunity to improve access to multi-organ transplants. We are aware that UNOS is working on a project to look at the needs of multi-organ transplant candidates at this time, and we look forward to seeing this work reflected in future iterations of the continuous distribution project.</p> <p data-bbox="178 633 1906 706">We agree with the committee's recommended attributes but are concerned about the failure to account for multi-organ transplants within the proposal. Clearly, patients with the need for a multi-organ transplant are currently disadvantaged and will remain so in the proposal as it stands.</p>	<p data-bbox="1470 292 1512 332"><b>3</b></p>
<p data-bbox="178 779 609 820"><b>Patient Access\Prior Living Donors</b></p> <p data-bbox="178 828 1906 868">A member commented that including some type of priority for all previous living donors would be a great way to encourage living donation.</p> <p data-bbox="178 885 1906 958">Another attendee noted that it makes sense to include pediatrics in the patient access attribute, but it is unclear why priority is given to prior living donors.</p>	<p data-bbox="1470 779 1512 820"><b>2</b></p>
<p data-bbox="178 1023 546 1063"><b>Patient Access\Waiting Time</b></p> <p data-bbox="178 1071 1906 1144">One attendee noted that waiting time should probably be listed amongst the main attributes, even if not strongly weighted, to set the precedent for other organs.</p>	<p data-bbox="1470 1023 1512 1063"><b>1</b></p>
<p data-bbox="178 1218 441 1258"><b>Placement Efficiency</b></p> <p data-bbox="178 1266 1906 1339">There is concern that this will dramatically increase the complexity and time of allocation, which has already become long with the prior changes.</p> <p data-bbox="178 1356 703 1396">Seems guidelines will enhance distribution.</p>	<p data-bbox="1470 1218 1533 1258"><b>14</b></p>

Theme	Number Of Coding References
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Priority should be on the patient and not the ease of OPO placement

Placement efficiency should have the least bearing on a person's prioritization for a given donor organ.

Placement efficiency attributes should be deprioritized as it could disadvantage certain centers unnecessarily.

Lung placement was also mentioned as a consideration since OPOs vary in how much time they will invest in lung donor management and consider having OPOs review successful lung placement and why lungs are not placed.

Of the composite elements, placement efficiency seems to be the least important and should be given the least weight.

As described currently, the fifth goal, Placement Efficiency, is of particular importance to the Society's Recovery and Preservation Community of Practice.

AOPO also would like to highlight the importance of the OPTN continuing its work through the identified strategic policy priority to develop and implement policies, process and systemwide tools designed to improve the efficiency of the matching process. This work towards a more efficient system is crucial in order to support the full value of any allocation framework by facilitating maximum utilization of transplantable organs.

A comment was made that surgeon availability and travel time are key factors that could be really important and may be difficult to track. One member made a comment that this could increase cost and complexity.

Of the composite elements, placement efficiency seems to be the least important and should be given the least weight.

I reiterate comments regarding placement efficacy. Time is LIFE and the longer the allocation process takes, the more viable organs are buried. This needs to be a priority in the points system

I have concern with this continuing to negatively impact the ability of OPO's to get lungs placed efficiently and drive up expenses and fees

In addition, another attendee agreed that distance and travel include cost concerns, but air travel is a transplant team safety concern, especially in unpredictable and inclement weather. The financial proxy considerations does not consider these safety concerns.

**Placement Efficiency\Aura Placement**

**1**

The aura concept seems extremely problematic, and the committee's apparent lack of favor at this time for the aura approach to allocation is noteworthy and correct. As the committee has noted, the aura approach is in violation of a long held paradigm of placing organs with candidates, not with programs, and the committee should be lauded for discarding the aura approach

Theme	Number Of Coding References
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**Placement Efficiency\Distance**

**6**

With increasing use of OCS systems, should distance be less a priority? If an individual center does not have OCS, they can still decline.

We support the dissolution of hard boundaries in the current classification system and agree with the proposed attributes that make up the composite allocation score.

They agreed that this project makes the most sense to balance travel times with addressing geographic disparities.

It is also concerning that, unless distance is heavily weighted, this will further exacerbate the socioeconomic disparities that worried us for the acuity circle model. Please recall, our region previously strongly opposed this kind of broadened sharing on those grounds.

Additionally, in situations where initially declined organs are sent to regional perfusion centers for repair or rescue treatment, the distance starting point for the subsequent allocation of the organ after treatment should be from that perfusion center's location. This is important to accurately calculate where the organ will be traveling from and also to limit disincentives for utilizing regional perfusion centers as a key strategy for increasing the availability of transplantable organs.

Doing away with miles puts responsibility on transplant centers to calculate cold ischemic time. ? Transplant outcomes need to be considered. Taking away distance could negatively affect cold ischemic times and transplant outcomes

**Placement Efficiency\Distance\Hard boundaries**

**1**

Coming from a lung recipient family, this is a step toward a welcome change to removing hard geographic boundaries from lung allocation, and this will be especially beneficial for highly sensitized patients.

**Placement Efficiency\Distance\Preservation Devices**

**9**

We urge the OPTN to continue to evaluate and collect data regarding tools that add placement efficiencies to include preservation devices and the local recovery of organs.

Will the committee give any consideration for the use of lung perfusion devices to negate some of the efficiency and distance concerns?

With increasing use of OCS systems, should distance be less a priority? If an individual center does not have OCS, they can still decline.

Two attendees encouraged the committee to consider how perfusion devices will effect distance, cost, cold ischemic time and patient survival.

**Theme****Number Of Coding References**

Ex vivo lung perfusion and onsite organ recovery centers were mentioned as factors that should be considered in the model.

It will be important to consider the increasing presence of new preservation devices and modalities in the fifth goal. These devices allow for longer preservation times if the organ is transported on device and thus distance attribute points assignments will need to be modified for this welcomed advancement in organ preservation.

For example, as perfusion and other ex vivo devices provide for viability over longer time periods between recovery and transplantation (as is already happening with lungs), the continuous distribution framework can adjust for the relative weight of time/distance in those case-specific circumstances as part of the overall composite score.

Another attendee commented that the committee should consider adding machine perfusion to one of the attributes, as it is becoming more commonplace.

TransMedics, Inc. (TMDX) is writing in response to the request for feedback on the OPTN Lung Transplantation Committee's Update on the Continuous Distribution of Organs Project. TMDX is the developer of the Organ Care System (OCS?) which is the only portable extracorporeal warm perfusion and assessment technology for thoracic donor organs for transplantation. The OCS? Lung is the only FDA approved device for both standard and expanded criteria DBD and DCD donor lungs for transplantation. To-Date, more than 500 lung transplants have been successfully performed utilizing the OCS? Lung technology. TMDX demonstrated that OCS? Lung technology plays a substantial role in eliminating the discussion around cold ischemic storage as TMDX recovered lungs in Hawaii and transplanted these lungs successfully in North Carolina and Arizona, with a preservation time of 22 and 11 hours respectively. Given the capabilities of the OCS? Lung technology, we support the Committee's intent to eliminate the historic geographic ?hard? boundaries and allow for broader distribution of organs. We agree with the Committee's decision to eliminate ischemic times as a specific factor in determining lung allocation. However, our rationale differs from the Committee's concerning predicting travel-related ischemic time and ?because transplant programs do not accept organs when ischemia time is

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expected to be problematic. (p. 8). The Committee is basing this conclusion on the assumption that cold preservation of lungs on ice (and its inherent ischemic time limitations) will continue to be used almost exclusively as the method of preservation. We strongly believe that portable extracorporeal perfusion is well underway to replace cold ischemic storage as the new standard of care for lung preservation and this should be an important consideration in developing the updated allocation schemes. In the discussion of the "Efficient Management of Organ Placement" (p 16), the Committee noted there was a "relationship between efficiency and proximity between the donor and transplant hospital. . . hospitals are less likely to accept organs that are from further away . . . [as] surgeons are out of the hospital for longer periods of time if they have to procure an organ from further away." These statements are reasonable if one assumes that the current system of procurement remains in place, i.e. transplant surgeons travel from the transplant center to the donor hospital to observe and procure the donor lungs. Within the current confines of cold ischemic storage, once the aorta is cross clamped, the transplanting surgeon has no ability to assess the lung functions, perform diagnostic bronchoscopy or initiate therapeutic or recruitment maneuvers to improve lung function. Essentially the transplant surgeon is flying blind. With OCS Lung, the transplant surgeon gains the ability to perform recruitment maneuvers, continuously assess organ function during transport and initiate diagnostic and therapeutic interventions all the way through the time the lungs are ready for reimplantation into the recipient. These new OCS Lung clinical capabilities open the door for potential new models to make thoracic organ retrieval more efficient and maximize donor lung utilization for transplantation. TransMedics has initiated a new national program in collaboration with major OPOs and transplant programs that would transform the way thoracic organ retrieval would work. This new model is later described below. In a related area, (p18-19) the Committee declines to consider local recovery of lungs as an attribute to include in developing allocation priority, noting that "This attribute would be more meaningful if there already existed a broad system of local lung procurement teams" The Committee notes this issue is "worth further research and possible inclusion in a future iteration of continuous distribution." We strongly urge the Committee to reconsider this conclusion. TransMedics is currently creating a national network of highly qualified thoracic transplant and surgical recovery experts to enable recovery of donor lungs. TransMedics will be using this network of qualified surgical experts to procure lungs allocated and accepted by not only their own transplant program, but also transplant programs around the country. In addition, TransMedics has established collaboration with major OPOs and invested in creating a national network of regional OCS Lung perfusion management expertise at or near these OPO DSAs. Using this new approach and leveraging this national network, should maximize donor lungs utilization for transplantation from both standard and extended criteria DBD and DCD donors without taxing the resources of the transplant program with the lung retrieval and OCS Lung management process. We strongly believe that this could be the next frontier for thoracic organ retrieval and assessment. In summary, we applaud the work of the Committee but are concerned that its conclusions are being based on the current, imperfect system of organ procurement and preservation using ischemic cold storage. The Committee makes reference to considering factors beyond ischemic cold storage in future iterations which we believe may be a missed opportunity given that the OCS Lung System is the only FDA approved platform for all types of donor lung preservation and assessment in the U.S. Along with the TransMedics growing national network of OCS Lung perfusion and management expertise, a model already exists to address the Committee's concerns. We kindly ask the committee to seriously consider the potential significant positive impact of the OCS Lung technology and the national model being established by TransMedics for thoracic organ retrieval and OCS perfusion management in this revision of lung allocation. Organ allocation protocols change very slowly and the next iteration is likely to be five to seven years away. The OCS Lung technology is an FDA approved product that is increasing the pool of available donors, streamlining the allocation process and replacing cold storage. We are grateful for the opportunity to provide input to the Committee's

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Theme	Number Of Coding References
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deliberations. We would very much welcome the opportunity to discuss our national model with the Thoracic Organ Committee and would be delighted to provide any assistance as the policy development process moves forward. Best regards, Waleed Hassanein, MD President & CEO

<b>Placement Efficiency\Likelihood of Acceptance</b>	<b>1</b>
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It was recommended that the match run should take into account a transplant center's acceptance history; OPO perspective is important for the prioritization exercise and understanding placement efforts will be critical as all of the organ specific committees work on continuous distribution.

<b>Placement Efficiency\Local Recovery</b>	<b>2</b>
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The recent increase in local recovery in response to COVID was mentioned as a change and that if the practice continues, it could increase efficiency.

We urge the OPTN to continue to evaluate and collect data regarding tools that add placement efficiencies to include preservation devices and the local recovery of organs.

<b>Placement Efficiency\Marginal Organs</b>	<b>1</b>
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One attendee suggested emphasizing placement efficiency for DCD and marginal BD lungs. They added that offering these organs to every patient on the wait list is not a good use of resources and results in lost opportunities.

<b>Placement Efficiency\Travel Costs</b>	<b>9</b>
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We believe, as it currently stands, that the placement efficiency attribute is the weakest of the five and recommend it be given the least weight in the composite score. It is the most easily influenced by outside parameters (especially with the pandemic transport freeze in effect) and would prioritize largest cities over others.

Support that you are looking at cost of flights in both direct flight cost and time.

Theme	Number Of Coding References
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One stated that the committee should consider looking at cost/efficiency consideration and proximity to major airports (less relevant for more highly time sensitive organs like lung). They added that they would not recommend using this as a factor for kidney allocation it would discriminate against smaller market transplant centers.

One member commented that this should have a significant impact on diminishing unnecessary travel.

The Committee supports the discussion around travel efficiency attributes. It was suggested to consider the complexity of travel as a way to analyze the failure aspect of placement efficiency. Additionally, the Committee suggested reviewing other organs? travel efficiencies.

Another member stated that looking at travel efficiency and cost is important and should be done consistently when organ allocation is changed.

Another attendee commented that they support the idea to encourage less geography as a factor guiding allocation. However, the pressures to consider expenses needs to be taken into consideration. As organs are traveling farther distances, the cost of transplants is rapidly rising.

A member addressed placement efficiency and stated that placement efficiency isn?t just about the cost of transporting an organ, which others reiterated.

Hard to justify prioritizing proximity, travel costs in lung while the cost / travel / recovery / efficiency concerns were not acknowledged during liver allocation changes. Liver is a much more common transplant with much greater overall costs and impact.

**Post-Transplant Survival**

**9**

UNOS Must Revise the Benefit Component: One-year survival rate alone does not accurately reflect how beneficial a transplant is for any given patient. It is unlikely that people undergo lung transplantation with the aim of only surviving for one year. Instead, we should be using endpoints that are more reflective of transplant success and patient wishes. It is critical that the inputs used in the continuous distribution algorithm are as

appropriately reflective as possible in measuring the factors they are designed to assess. We therefore urge UNOS to move away from use of one-year survival to either three- or five-year survival at this time. We recognize that using long-term survival measures in place of one-year survival introduces more uncertainty in the model given that predictability of survival decreases the further out a patient is from the time of transplant. UNOS should therefore consider whether incorporating age as a predictor for transplant outcomes can be used as a proxy for long-term survival. The data demonstrating that post-transplant survival decreases with older age is compelling. Providing a similar benefit score to individuals where long-term survival is likely similar based on age may provide a more reliable measure for the benefit an individual is likely to receive from a transplant. This measure could be used in concert with other measures of survival. Long-term Survival Should Be Given the Most Weight in a Composite Score: Finally, in terms of weighting different categories of attributes based on importance, we believe long-term post-transplant survival is of highest importance in determining allocation of donor organs. As stated above, we believe that long-term post-transplant survival is a stronger measure for transplant benefit compared with one-year survival and urge UNOS to pursue this change in conjunction with the move to continuous distribution. Long-term survival additionally supports the goal of ensuring fair innings for transplant candidates. Following long-term survival, candidate biology and patient access should be considered given the importance of improving access for otherwise difficult-to-match patients.

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Some members said that using one year post transplant survival as a metric is not particularly useful and suggested the committee consider a longer time period.

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Significant consideration should be given not just to one year survival, but also longer term survival

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One member is in favor of including the anticipated duration of graft survival.

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It was also noted that the issue of people at higher risk for graft failure may be disadvantaged by that one-year post-transplant survival metric.

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Another commenter stated that as the work continues across all organs, patient predicted outcomes should be part of the allocation system.

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A couple members felt that using more than just one year post transplant survival as part of the score would be a good idea.

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I think COVID should be a separate category and outcomes tracked carefully

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Another member commented that post-transplant survival is a goal that is hard to measure, and if it is used to determine who receives an organ offer, it would be a dramatic shift from current policy.

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### Post-Transplant Survival\Ischemic Time

2

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It is and will be increasingly important to allow for flexibility of the nautical mileage attribute as a proxy for ischemic time as more preservation devices are being used to extend preservation time and thus distance, if the organ is going to be transported on device.

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Theme	Number Of Coding References
<p>We additionally appreciate that UNOS has ruled out the use of ischemic time as an attribute for placement efficiency. While we believe it is reasonable to include a placement efficiency score as a component of the model, ischemic time is not a valuable measure for efficiency of organ placement.</p>	
<p><b>Transplant Benefit</b></p> <p>Would recommend Transplant Benefit be used as a metric on the Comprehensive Allocation Score</p>	<p><b>1</b></p>
<p><b>Waitlist Mortality</b></p> <p>What is the current death rate on the waitlist by specific lung disease?</p> <p>Would give more weight to patient acuity and equal to the remainder.</p>	<p><b>2</b></p>