OPTN | UNOS

Briefing Paper

Frameworks for Organ Distribution

OPTN/UNOS Ad Hoc Geography Committee

Prepared by: Scott N. Castro, MPP
UNOS Policy Department

Contents

Frameworks for Organ Distribution

Affected Policies:	*N/A*
Sponsoring Committee:	*Ad Hoc Geography Committee*
Public Comment Period:	*August 3, 2018 – October 3, 2018*
Board of Director's Date:	*December 3, 2018 – December 4, 2018*

Executive Summary

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

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

The OPTN Final Rule sets requirements for allocation polices developed by the OPTN, including sound medical judgement, best use of organs, the ability for centers to decide whether to accept an organ offer, to avoid wasting organs, and to promote efficiency.[1] The Final Rule also includes a requirement that policies "shall not be based on the candidate's place of residence or place of listing, except to the extent required" by the other requirements of section 121.8.

Each of the three geographic frameworks proposed by the Committee implement mechanisms to bring OPTN/UNOS organ allocation policy more in line with the Final Rule. By eliminating the use of Donor Service Areas (DSAs) and regions from organ-specific allocation policy, the OPTN can effectively maintain a more equitable and efficient transplant network backed by more evidence-based approaches. This allows the OPTN to bring policies more in line with the OPTN Final Rule.

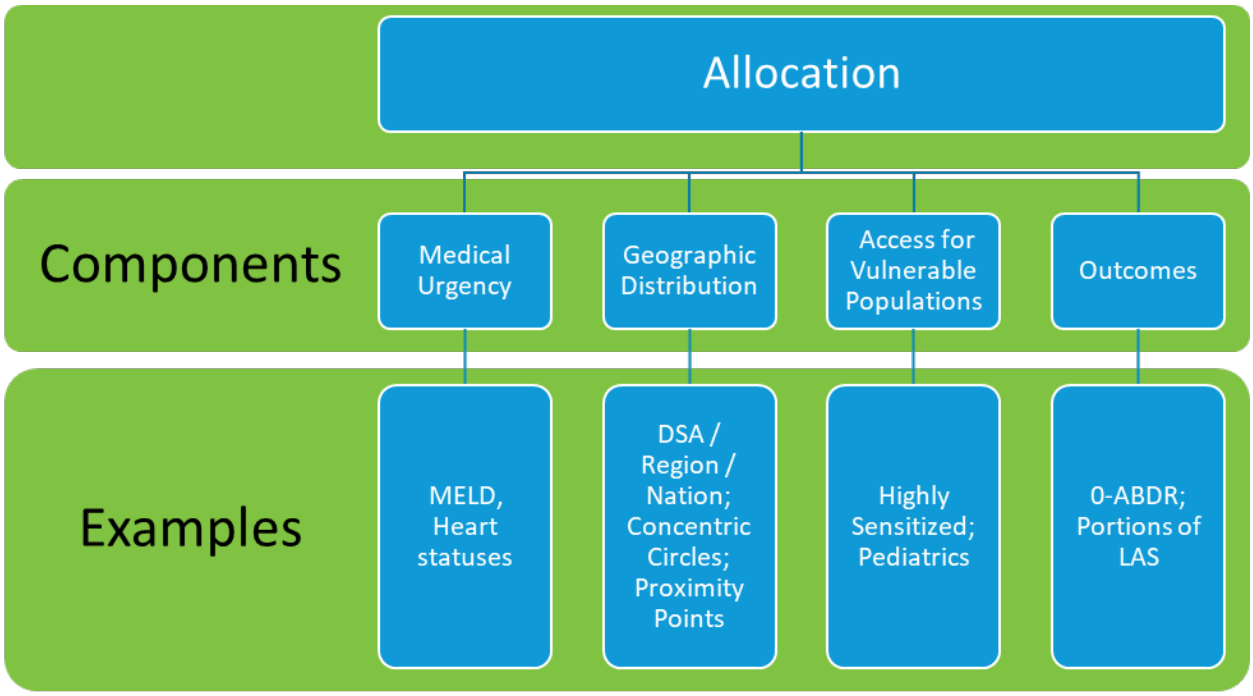
On June 11, 2018, the OPTN/UNOS Board of Directors adopted principles to guide future organ transplant policy relating to geographic aspects of organ distribution that are based on the geographic requirements of the Final Rule. Following the Board meeting, the Geography Committee (hereafter, "the Committee") requested community feedback on three distribution frameworks, with a goal of identifying a single, preferred distribution framework to be used across organs. This proposal recommends one distribution framework identified by the Ad Hoc Geography Committee as being in alignment with the adopted principles of geographic distribution and the OPTN Final Rule.

[1] 42 C.F.R. §121.8(a).

What problem will this proposal address?

Geographic distribution is one of several components in organ allocation policies. Allocation is a combination of multiple factors, including medical urgency, geographic location, access for vulnerable populations, and outcomes. The Committee's charge was to focus only on the frameworks used by the OPTN to determine geographic distribution. **Figure 1** shows the role of geographic distribution among other factors in organ allocation.

Figure 1: The role of geographic distribution among other factors in organ allocation



Organ allocation policies are developed and proposed by individual OPTN Committees. This approach has resulted in different distribution frameworks used in the respective organ-specific policies. **Figure 2** shows the current distribution frameworks with respect to each organ.

Figure 2: Current organ distribution frameworks, including board-approved and pending implementation

Organ-Specific Allocation	Distribution Framework
Kidney	Region, DSA, and National
Pancreas, Kidney-Pancreas, and Islets	Region, DSA, and National
Liver and Liver-Intestine	Region + Circle, DSA, and National
Intestine	Region, DSA, National
Lung	Zone
Hearts	Zone and Zone + DSA
Vascular Composite Allografts	Region and National

The DSA (Donation Service Area) is "the geographic area designated by the Centers for Medicare and Medicaid Services (CMS) that is served by one organ procurement organization (OPO), one or more transplant hospitals, and one or more donor hospitals."[2] As shown in Figure 2, allocation policies for kidneys, livers, intestines, and pancreas incorporate the DSA as a unit of distribution. Similarly, those organ types, along with vascular composite allografts, use OPTN regions as another unit of distribution in allocation policy.[3] Zones are concentric bands that are centered around the donor hospital used for the distribution of thoracic organs.[4]

The Committee identified two prominent issues with the current variation in distribution frameworks among organs, including:

1. Variation in compliance with requirements in the OPTN Final Rule
2. Inefficiencies in programming changes to OPTN allocation policy

1. Variation in compliance with requirements in the OPTN Final Rule

The OPTN Final Rule requires that allocation policies "not be based on the candidate's place of residence or place of listing" except as required by permissible reasons in the Final Rule.[5] These permissible reasons include achieving the best use of organs, avoiding organ wastage, promoting patient access, and promoting the efficient management of organ placement.[6] In the context of the current methods for organ distribution, the different organ systems use different geographic units to achieve these goals. (Ex. a geographic unit nearby the donor hospital can decrease the amount of flying required for organ recovery and thus promotes the efficient management of organ placement.)

The organ systems use different methods for balancing the regulatory requirements and have achieved varying levels of balance amongst those requirements. The Committee acknowledges that from an overall network perspective, there is very little rationale for thoracic organs to be distributed based on a candidate's distance from the donor hospital, while all other organs are based on the candidate's location

[2] OPTN/UNOS *Policy 1: Definitions*, "Donation Service Area (DSA)." https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf#nameddest=Policy_01. Accessed on July 11, 2018.
[3] OPTN/UNOS *Policy 1: Definitions*, "Region." https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf#nameddest=Policy_01. Accessed on July 11, 2018.
[4] OPTN/UNOS *Policy 1: Definitions*, "Zone." https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf#nameddest=Policy_01. Accessed on July 11, 2018.
[5] 42 C.F.R. §121.8(a)(8).
[6] 42 C.F.R. §121.8(a).

within an OPTN Region and DSA.If there is an inherent operational or legal benefit of one approach over the other, then that approach should be consistent among all organ groups; the difference between the organ policies should be based upon clinical differences and not philosophical differences or operational preferences.

2. Inefficiencies in programming changes to OPTN allocation policy

The OPTN currently manages algorithmic architecture for all organ allocation. Within each organ-specific allocation, there is complexity based on candidate age, donor characteristics, blood type compatibility, and other factors. The Committee foresees a future algorithmic architecture where a singular distribution framework will increase the efficiency in which the OPTN can program new allocation changes. This will further enhance the OPTN's ability to respond to the ever-changing field of transplantation by developing policy and implementing solutions efficiently.

The Committee acknowledges that clinical and logistical specificity by organ type is critical to organ allocation.[7] There will always be organ-specific parameters in allocation policy. However, a singular framework will allow future policy changes to be uniformly compliant with the OPTN Final Rule and enhance the efficiency of the OPTN in responding to changes in transplantation through a more uniform and efficient approach to developing and implementing policy changes.

Why should you support this proposal?

The goal of this proposal is to receive feedback and build consensus around a singular framework of organ distribution. The consensus built around a singular framework will allow the OPTN and organ specific committees to begin moving towards a framework that ensures compliance with federal law and increases the ability for the OPTN to respond to innovations in the field of transplantation in an efficient and uniform manner across organs.

How was this proposal developed?

The Committee was formed in December 2017 and charged with:

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

The OPTN/UNOS Board of Directors approved the following Principles of Geographic Distribution on June 12, 2018:

> Deceased donor organs are a national resource to be distributed as broadly as feasible. Any geographic constraints pertaining to the principles of organ distribution must be rationally determined and consistently applied.
>
> Geographic distribution may be constrained in order to:
>
> 1. Reduce inherent differences in the ratio of donor supply and demand across the country
> 2. Reduce travel time expected to have a clinically significant effect on ischemic time and organ quality
> 3. Increase organ utilization and prevent organ wastage

[7] Additionally, the OPTN Final Rule requires that "organ allocation policies … shall be specific for each organ type." 42 C.F.R. §121.8(a)(4).

4. Increase efficiencies of donation and transplant system resources[8]

During the development of these principles, the Committee began to analyze frameworks for organ distribution. This effort involved a review of current OPTN policies, previous distribution frameworks developed by researchers in the community, and novel concepts put forth by members of the community and Scientific Registry of Transplant Recipients (SRTR).

The Committee used a survey to begin to focus on distribution frameworks that are in line with the OPTN Final Rule and the principles developed by the Committee. The Committee identified three frameworks for geographic distribution that are consistent with the principles and the Final Rule. The Committee agrees that the OPTN would be best served by adopting a single common framework to be applied to all organ allocation policies. Even within a common framework, each organ would have medically determined factors that apply specifically to that organ. The Committee orginially considered several potential frameworks, including those based primarily on population density as well two individual frameworks (optimized districts and neighborhoods) that would eventually fall under the same "Mahtematically Optimized" framework. After consideration, and based upon their alignment with the OPTN Final Rule, the three frameworks identified by the Committee for public comment were:

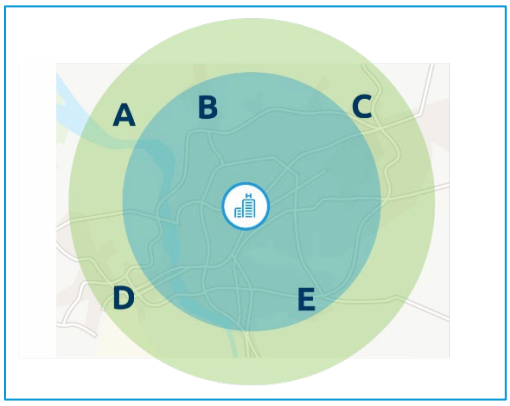
1. Fixed Distance from the Donor Hospital
2. Mathematically Optimized Boundaries
3. Continuous Distribution

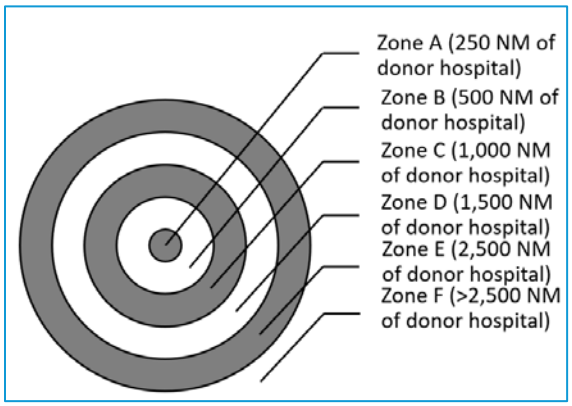
1. Organ Distribution Based on Fixed Distance from the Donor Hospital

This framework utilizes a system of fixed geographic units based on the distance from the donor hospital to the candidate's place of listing. One example of this framework is currently utilized in heart and lung distribution and referred to as "concentric circles" or "zones." The changes to liver distribution being recommended to the Board of Directors in December utilize concentric circles around a donor hospital.

Figure 3 (Left): Representation of Organ Distribution Based on Fixed Distance from the Donor Hospital

Figure 4 (Right): Current Lung Distribution Policy, concentric circles in nautical miles (NM) around the donor hospital





The Committee discussed several advantages of this distribution framework and its alignment with the principles. Distance from a donor hospital is related to multiple interests recognized by the OPTN Final Rule: organ outcomes, system efficiency, and patient access. Committee members have stated that there are improved outcomes for organs with lower cold ischemic time (CIT). [9]CIT increases as the distance

[8] *Geographic Organ Distribution Principles and Models Recommendations Report*, OPTN/UNOS Geography Committee, June 2018, https://optn.transplant.hrsa.gov/media/2506/geography_recommendations_report_201806.pdf (accessed July 5, 2018).

[9] Sampaio, M S, et al. "Impact of Cold Ischemia Time on the Outcomes of Kidneys with Kidney Donor Profile Index ≥85%: Mate

between the donor hospital and transplant hospital increase. A fixed distance circle could decrease CIT and justify some local priority due to the need to "achieve the best use of donated organs."[10]

Furthermore, committee members noted that some transplant surgeons travel to participate in organ procurement efforts.[11] Therefore, organ offers that require additional travel time result in more surgeons away from the hospital and unavailable to perform transplants.

Additionally, organ recoveries that require air travel increase the financial cost of organ placement.[12] A fixed distance circle placed at the point where procurement typically changes from driving to flying could limit the travel time or number of organs flying. This distance could be organ specific (ex. hearts could travel by air at shorter distances due to the impact of CIT). Similarly, this distance could depend upon donor characteristics if they impact transplant outcomes (ex. DCD organs). This increase in cost could justify some local priority due to the need "to promote the efficient management of organ placement."[13]

The size constraints of the circle can also reduce inherent differences in potential donor supply and demand by broadening distribution across multiple DSAs and current regional boundaries. For example, DSAs in the Northeast are relatively small, so a circle that was fixed at 250 nautical miles would span across multiples DSAs and donor hospitals close to the border of a current region would now have increased distribution across that current boundary. This would be consistent with the Final Rule charge that "allocation policies … (5) shall be designed to … promote patient access."[14] However, a fixed distance circle drawn too small could improperly prioritize local organ offers and fail to balance all of the requirements in the OPTN Final Rule. Specifically, by drawing a fixed distance circle without providing a rationale for that distance would work directly in contrast with the clause of the OPTN Final rule that dictates that, to the extent possible, OPTN policies should limit the influence that a candidate's geography has on their likelihood of receiving an organ offer.

Additionally, the use of fixed distance circles can minimize travel of organs for patients with similar allocation priority by ordering candidates within a zone by organ-specific measures of medical urgency. For example, lung distribution candidates are ordered within a zone by their lung allocation score (LAS). Similar stratification can be achieved in other organs by their medical urgency score (MELD score for liver distribution) or by waiting time. For kidneys, variables such as Estimated Post-Transplant Longevity (EPTS) and Kidney Donor Profile Index (KDPI) scores can be used to stratify candidates within each of the fixed distance circles.

A disadvantage of this distribution framework is the inherent "cliffs" between each concentric circle. For example, within a policy that employs 500 mile circles, a candidate with an LAS of 50 at a transplant program 499 miles away from the donor hospital and another candidate with an LAS of 50 501 miles away from the donor hospital are treated differently, although in terms medical urgency they are identical and in terms of geographic proximity they are very similar. Candidates with a high medical urgency listed just over the fixed distance circle border from a donor hospital (255nm away with a 250nm circle) would be affected negatively based on their geography. Such a disadvantage is required to be limited to the extent possible based on the OPTN Final Rule. Those differences are smaller in circle models that assign some number of proximity points to each circle than in circle models that offer to all candidates within one circle before offering to the subsequent circle.

Any proposal to incorporate circles into allocation policies should clearly define the relationship between the selection of the circle sizes and the Principles of Geography and the OPTN Final Rule. For example, the sizes of the circles could be based upon the distance when recovery typically changes from driving to flying because this impacts costs and the overall efficiency of the system. Alternatively, the size of a circle

Kidney Analysis - a Retrospective Study." *Transplant International*, vol. 17, 31 July 2018, pp. 729–738. *PubMed.gov*, www.ncbi.nlm.nih.gov/pubmed/29368361.

[10] 42 CFR 121.8(a)(2).

[11] Dubay, D. A, et al. "The Impact of Proposed Changes in Liver Allocation Policy on Cold Ischemia Times and Organ Transportation Costs." American Journal of Transplantation, vol. 15, 15 Feb. 2015, pp. 541–546. Wiley Online Library, onlinelibrary.wiley.com/doi/full/10.1111/ajt.12981.

[12] Sommer Gentry, "Fixed Population vs. Fixed Radius" (PowerPoint presentation, OPTN/UNOS Geography Committee, March 26 2018).

[13] 42 CFR 121.8(a)(5).

[14] Ibid.

could be based upon the time when hospitals are typically unwilling to accept organ offers due to cold ischemic time because this impacts organ discard rates and organ utilization.

2. Mathematically optimized boundaries

The use of mathematical optimization in organ distribution has been discussed previously with the development of the changes to liver distribution.[15] In this framework, one or more objectives (minimize effect of geography, pre-transplant deaths, etc.) and possible constraints (amount of travel, supply and demand, etc.) are used to create the optimal distribution system. The Committee was presented with several models that utilize this approach including *Optimized Districts*, *Optimized Neighborhoods*, and *Population Density Bubbles*. The specifics of each model vary, however the goal of each is the same: to create an optimal geographic distribution area based on pre-determined metrics and constraints.

Figure 5: Example of Population Density Bubbles depicting the difference between a fixed radius circle (400 miles) and a fixed population circle (at least 50,000,000 population) around a transplant center[16]

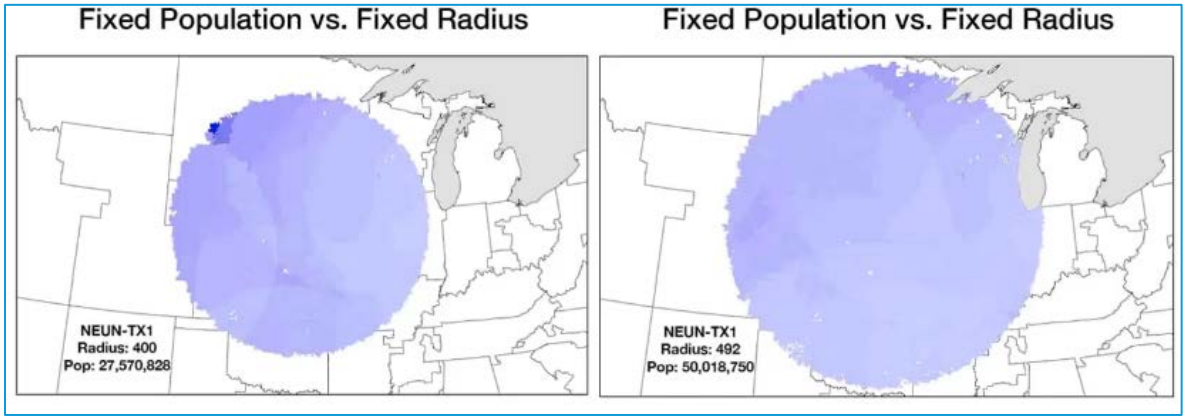
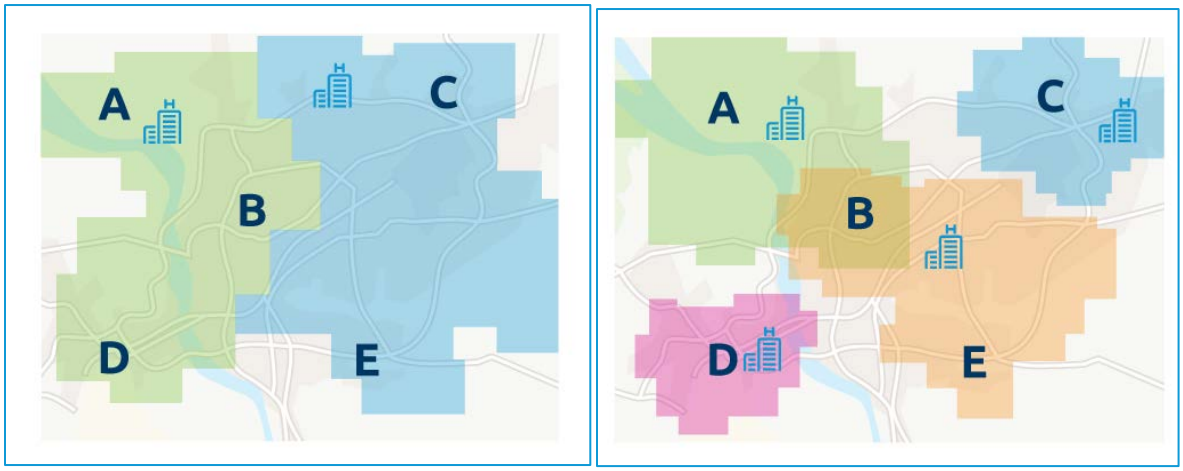


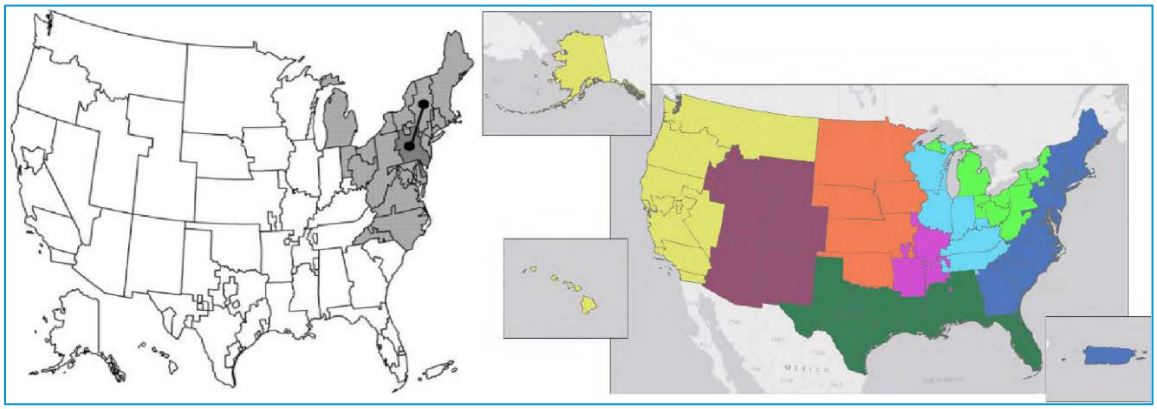
Figure 6 (Left): Representation of Organ Distribution Based on Optimized Districts

Figure 7 (Right): Representation of Organ Distribution Based on Optimized Neighborhoods



[15] *Redesigning Liver Distribution*, OPTN/UNOS Liver and Intestinal Organ Transplantation Committee, December 2017, https://optn.transplant.hrsa.gov/media/1913/liver_redesigning_liver_distribution_20160815.pdf (accessed October 31, 2018).
[16] Sommer Gentry, "Fixed Population vs. Fixed Radius" (PowerPoint presentation, OPTN/UNOS Geography Committee, March 26 2018).

Figure 8: Example of Optimized Neighborhoods[17] and Optimized Districts[18]



The use of metrics and constraints to select the geographic distribution area reduces the concern for arbitrarily defined geographic borders of distribution. There is flexibility to allow organ-specific variation details due to variation in ischemic time and donor characteristics. As long as the input constraints are consistent with the Geographic Principles and the Final Rule, mathematically optimized units of distribution are ethically and legally defensible. Concern for system resources and efficient operation of the OPTN can be addressed by constraining the extent of organ travel and number of programs within any given geographical unit.

Hypothetically, most concerns for travel and logistics with this approach could be addressed in the optimization. However, optimized units have not been well-received by the community in the past.[19] Many versions of this framework still retain fixed borders that create the possibility of two similarly situated candidates on either side of the border receiving different levels of access to organs. Additionally, optimized distribution frameworks that utilize existing DSAs as a building block are fundamentally flawed given the variation in DSA characteristics (size, population density, etc.) throughout the country.

3. Continuous Distribution

The framework of organ distribution without geographic boundaries incorporates proximity of candidates to a donor through an algorithm designed to account for the principles above (e.g. outcomes, discards, efficiency), rather than their location inside or outside a boundary.[20][21] The concept initially reviewed by the Committee proposed that candidates' *Allocation Priority Score* would be made up of a *Medical Priority Score* plus a *Proximity Score*. By using this kind of calculation, there would not be absolute geographic boundaries, and candidates would be ranked on a match run based on a combination of their clinical characteristics and proximity to a donor.

[17] Sanjay Mehrotra, PhD,Vikram Kilambi, PhD,Kevin Bui, MS,Richard Gilroy, MD, Sophoclis P. Alexopoulos, MD, David S. Goldberg, MD, MSCE, Daniela P. Ladner, MD, MPH, and Goran B. Klintmalm, MD, PhD; A Concentric Neighborhood Solution to Disparity in Liver Access That Contains Current UNOS Districts; Transplantation, February 2018, Volume 102, Number 2.
[18] *Redesigning Liver Distribution*, OPTN/UNOS Liver and Intestinal Organ Transplantation Committee, December 2017, https://optn.transplant.hrsa.gov/media/1913/liver_redesigning_liver_distribution_20160815.pdf (accessed July 5, 2018).
[19] "Redesigning Liver Distribution," OPTN, updated December, 2016, https://optn.transplant.hrsa.gov/governance/public-comment/redesigning-liver-distribution/. This page contains the comment received during the public comment period.
[20] Snyder, John, "Systems without Geographic Boundaries" (PowerPoint presentation, OPTN/UNOS Geography Committee, March 26, 2018).
[21] Snyder, John. "Organ Distribution without Geographic Boundaries: A Possible Framework for Organ Allocation." American Journal of Transplantation, 18 Sept. 2018, pp. 2635–2640, www.srtr.org/media/1350/snyder-jj_organ-distribution-without-geographic-boundaries_2018-ajt.pdf. SRTR.org.

Figure 9: Example of Continuous Distribution

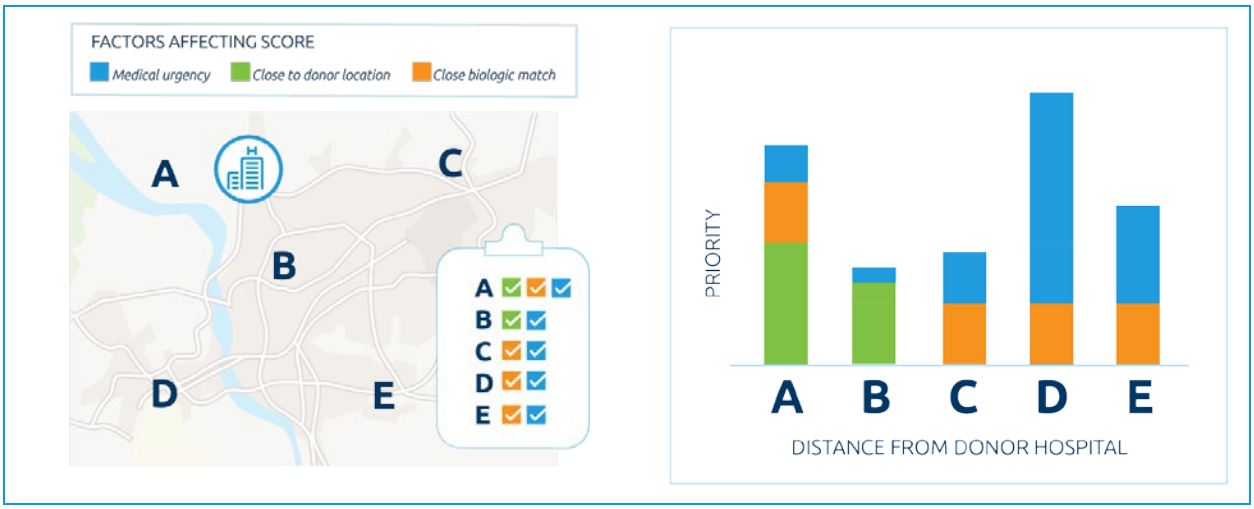
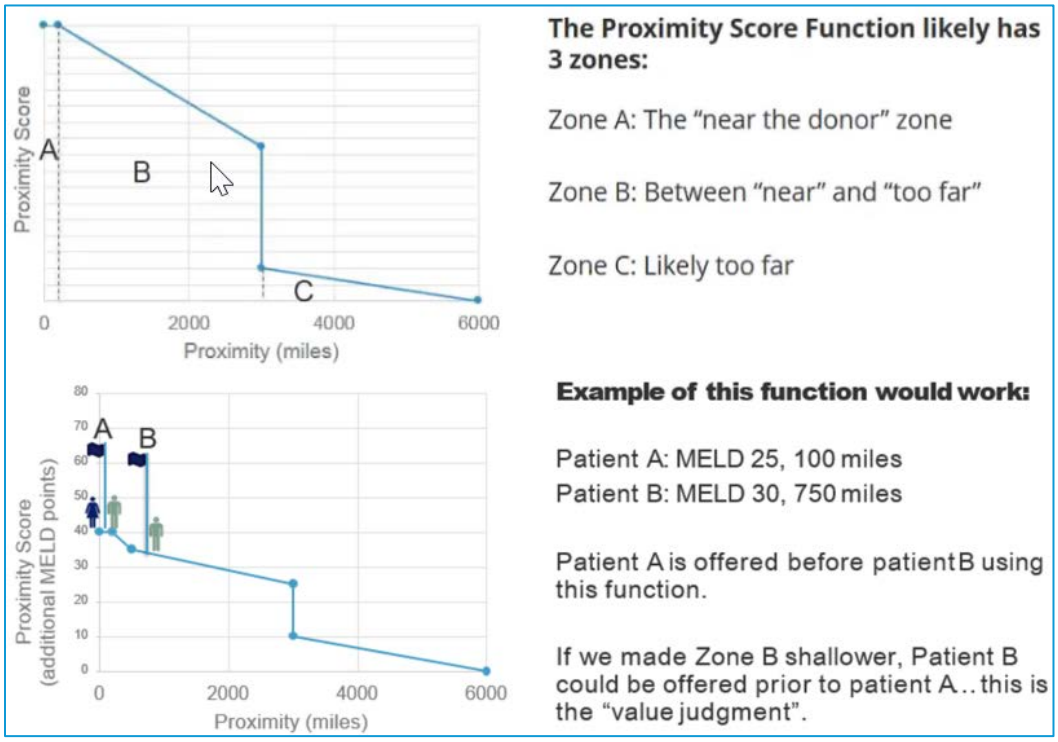


Figure 10: Depiction of the proximity score under the concept of distribution without boundaries



The Committee discussed several advantages of this distribution framework and its alignment with the principles. This framework contains all of the benefits described in the fixed distance framework above.

Additionally, this framework can eliminate any concern over fixed geographic boundaries separating candidates and donors. This distribution framework is theoretically similar to the idea of concentric circles and zones, except the fixed "cliff" that separates candidates in their respective zones would be a much more smooth transition, rather than an absolute boundary based on distance.

This framework could be uniform across the organs and the medical priority and proximity scores could be specific to the clinical characteristics and ischemic considerations of each organ. This would require significant discussion by the organ-specific stakeholders to identify the medical and geographic thresholds to prioritize candidates.

Furthermore, the Committee has considered the possibility that other variables could be accounted for to calculate a score for each candidate, besides proximity. Such variables include wait time, medical urgency, and biologic match. Points could also be added and weighted accordingly for vulnerable populations, or to offset variable supply and demand across the country.

Alternatives Considered

The Committee reviewed several other distribution frameworks in their process to identify these final three. The review of other distribution frameworks focused on alignment with the Final Rule, and with the Committee's principles of geographic distribution. The Committee discussed the use of OPTN region and DSA and overwhelmingly stated that these geographic boundaries were not designed for the purposes of organ distribution and were an imperfect substitute for geographic proximity. The concept of a single national list was discussed and identified as a framework that is not in alignment due to the lack of efficiency in allocation, potential impact on discards, and the logistical concerns of a national list absent of any further constraints.

One of the biggest concerns that committee members heard outside of public comment is the significance of their recommendation and confusion as to why the committee was selecting a single framework.

Members noted that if the Board adopts a *preferred* framework, the Executive Committee and Policy Oversight Committee (POC) would develop a timeline for transition to a unified framework, which would take place over time as allocation policies are continuously revised and improved.

The Executive Committee and POC regularly discuss the approval and prioritization of committee projects. Allocation and distribution-related projects would take priority in the context of all other requests for committee projects. Transitioning all organ distribution to a common framework constitutes a long-term efficiency project; it will not be work undertaken in response to a current legal or clinical risk. Therefore, there is flexibility in how the organ-specific committees implement the selected framework.

Furthermore, the Committee stated that a single OPTN distribution framework is necessary for long-term efficiency benefits. The current system uses multiple frameworks for distribution, and this complicates cross-organ analysis. A single framework will make it easier to explain the system to the public, which can increase trust in the system. It can also facilitate analysis of the system by UNOS, SRTR, and other researchers. Use of a single framework should shorten the time necessary to identify issues in the allocation systems and to develop solutions for those issues. A single framework will also facilitate faster IT programming and solution implementation.

Finally, the Committee recognizes that the adoption of a single framework across all organ types has the potential to make cross-organ allocation more streamlined and efficient. For example, currently, many kidneys and pancreas are allocated together when a donation is received. Each of these organs currently has their own system of allocation, which means there are different processes by which they can be allocated. With a single framework approach, these organs will have far fewer differences.

How well does this proposal address the problem statement?

The Committee believes the frameworks included in this proposal balance the requirements of the OPTN Final Rule, and are in alignment with the Principles of Geographic Distribution approved by the Board of Directors in June 2018.

Figure 11: Framework Advantages and Disadvantages

Framework	Advantages	Disadvantages
Fixed distance	• Used in thoracic distribution. • Has been modeled. • Can address organ outcomes, system efficiency, and geographic disparities in access. • Can be organ specific. • Potentially easiest for general public to understand.	• "Cliffs" can separate similarly situated patients with minor geographic differences.
Mathematically optimized boundaries	• Has been modeled and published. • Can address organ outcomes, system efficiency, and geographic disparities in access. • Can be organ specific.	• Has not been used in organ distribution. • "Cliffs" can separate similarly situated patients with minor geographic differences.
Continuous Distribution	• "Cliffs" need not separate similarly situated patients with minor geographic differences. • Can address organ outcomes, system efficiency, and geographic disparities in access. • Can be organ specific. • Potentially most flexible framework.	• Has not been modeled or used in organ distribution.

The distribution frameworks included in this proposal represent the consensus of an ad hoc committee of transplant surgeons, physicians, OPO leadership, a donor family member, and a transplant recipient. The Committee consists of members of the OPTN/UNOS Board of Directors, representatives from AST and ASTS, and the leadership of the OPTN organ-specific committees, OPO Committee, Transplant Administrators Committee (TAC) and Ethics Committee.

Which populations are impacted by this proposal?

This proposal and subsequent changes to organ distribution will affect every member of the transplant community.

How does this proposal impact the OPTN Strategic Plan?

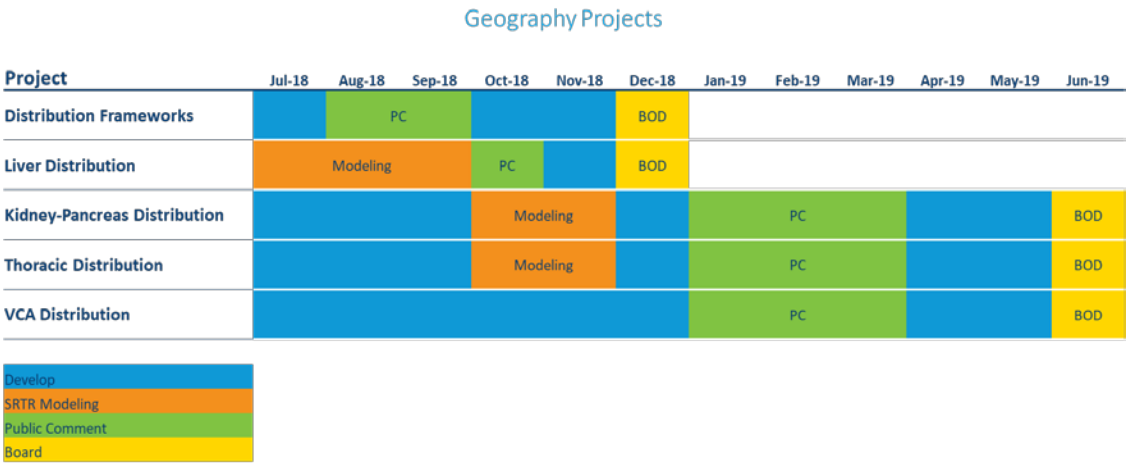
1. *Increase the number of transplants:* There is no impact to this goal.
2. *Improve equity in access to transplants:* There is no immediate impact to this goal. Changing to a uniform framework for distribution need not change the level of distribution in the system. It is possible, and even likely, that the development of organ specific policy proposals to align with a uniform framework will result in improvements in equity in access to transplantation.
3. *Improve waitlisted patient, living donor, and transplant recipient outcomes:* There is no impact to this goal.
4. *Promote living donor and transplant recipient safety:* There is no impact to this goal.
5. *Promote the efficient management of the OPTN:* Once a single distribution framework is chosen, the cost and time to program future distribution changes will decrease. This is because there will not be as many programmatic variance across each of the organs, which will save staff time and resources that would otherwise be dedicated to accounting for these differences in distribution frameworks.

How will the OPTN implement this proposal?

Once the Board adopts a preferred distribution framework, all future distribution proposals will be evaluated against that framework. The fiscal impact of the proposal among all departments is small. This will include outreach and education to members after the Board meeting.

Committees will need to justify any distribution model that does not move toward the preferred distribution framework. Depending upon available resources and priorities, the Policy Oversight and Executive Committees will prioritize requests to transition from the current distribution models to the preferred distribution framework.

Figure 12: Timeline of Current Geographic Allocation Projects



The broad purpose for a consistent framework is long term, efficiency as opposed to addressing an imminent, legal risk. Therefore, the OPTN does not need to switch all of the organ systems to a consistent framework rapidly. Through separate projects, the OPTN is working to rapidly convert each of the organs systems to one of the three frameworks in this proposal. This work is a necessary short-term step towards transitioning to a unified Continuous Distribution framework for organ allocation. Furthermore, the work protects the OPTN from further litigation because of the use of DSAs and regions throughout current allocation policy while modeling and data gathering can be performed in service of the long-term goal of a Continuous Distribution framework. Figure 12 (above) illustrates the timeline that evidence gathering, public comment, and board consideration of each of the current organ-specific geographic allocation projects are projected to occur.

The OPTN frequently makes changes to allocation policies. As we review data and make future changes, we will have a guidepost that all the committees can work toward. For example, if the first iteration of a Continuous Distribution framework weighs proximity too heavily in relation to other factors such as medical urgency, the policy and variable weights can be adjusted to produce a better outcome. The Policy Oversight Committee and Executive Committee will review and prioritize these efforts.

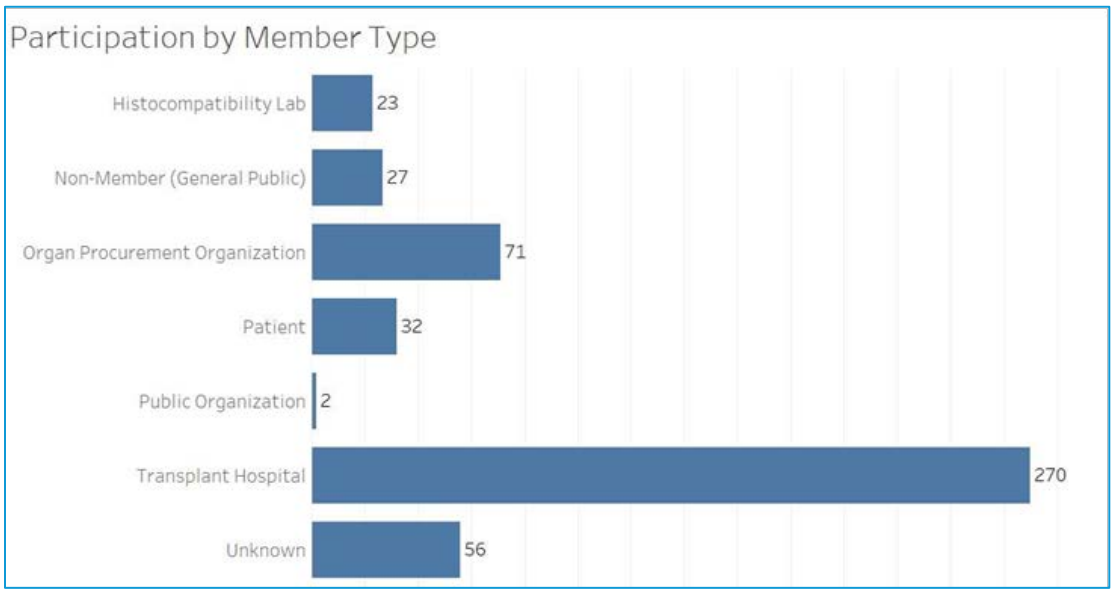
How will members implement this proposal?

There is no fiscal impact or change to member requirements associated with this proposal. As a result, members do not need to take any action at this time. The details regarding member impact will be included in the analysis of any future, specific changes to the organ allocation systems.

Public Comment Feedback and Deliberations

The public comment period for consideration of the three proposed geographic organ distribution frameworks began on August 3, 2018 and concluded on October 3, 2018. During the 30-day period, 481 members (both individuals and organizations) and 27 non-members provided quantitative and qualitative feedback on preferences between the three proposed frameworks. The following graphic represents participation in the public comment period by member type:

Figure 13: Public Comment Participation by Member Type



All member types, as well as non-members, actively participated in the public comment process. Transplant hospitals account for approximately 56 percent of the total public comment feedback received. Fifty-six responses appear as an “unknown” member type due to individuals selecting the “Other” option when identifying their member type or failing to identify a member type.

The committee sought feedback from the transplant community on which of the three frameworks they preferred as well as the rationale for their support. The following questions appeared on the public comment page. Question 1 asked about their preferred geographic distribution framework. Question 2 included a blank field for users to enter a text narrative describing the rationale for their preference.

1. Of the three distribution frameworks, the one I most support is:
    a. Fixed
    b. Mathematically Optimized
    c. Continuous
2. Please provide your rationale for preferring one specific framework of the three proposed

Public comments are available to view on the OPTN website here: OPTN Organ Distribution Public Comment.

Public Comment Feedback

Figure 14: Regional Feedback*

Region	Support	Poll Results
1	Unanimous for Continuous Distribution	0 Fixed Distance 0 Mathematically Optimized **15 Continuous Distribution**
2	Strong Support for Continuous Distribution	4 Fixed Distance 5 Mathematically Optimized **25 Continuous Distribution**
3	Support for State-Based Allocation	0 Fixed Distance 0 Mathematically Optimized 4 Continuous Distribution **28 State-Based**
4	Support for Continuous Distribution	8 Fixed Distance 6 Mathematically Optimized **15 Continuous Distribution**
5	Strong Support for Continuous Distribution	3 Fixed Distance 3 Mathematically Optimized **30 Continuous Distribution**
6	Majority Abstain	0 Fixed Distance 0 Mathematically Optimized 22 Continuous Distribution' **31 Abstain**
7	Majority Abstain	3 Fixed Distance 0 Mathematically Optimized 4 Continuous Distribution **19 Abstain**
8	Support for Continuous Distribution	0 Fixed Distance 0 Mathematically Optimized **19 Continuous Distribution** 7 Abstain
9	Mixed Support	9 Fixed Distance 3 Mathematically Optimized **10 Continuous Distribution**
10	Mixed Support	0 Fixed Distance 0 Mathematically Optimized 11 Continuous Distribution **13 Abstain** 4 Fixed Distance 2 Mathematically Optimized **16 Continuous Distribution**
11	Elected to Let Each Committee Choose Its Own Framework	3 Fixed Distance 0 Mathematically Optimized 3 Continuous Distribution **19 Allow Committees To Choose Their Own Frameworks**

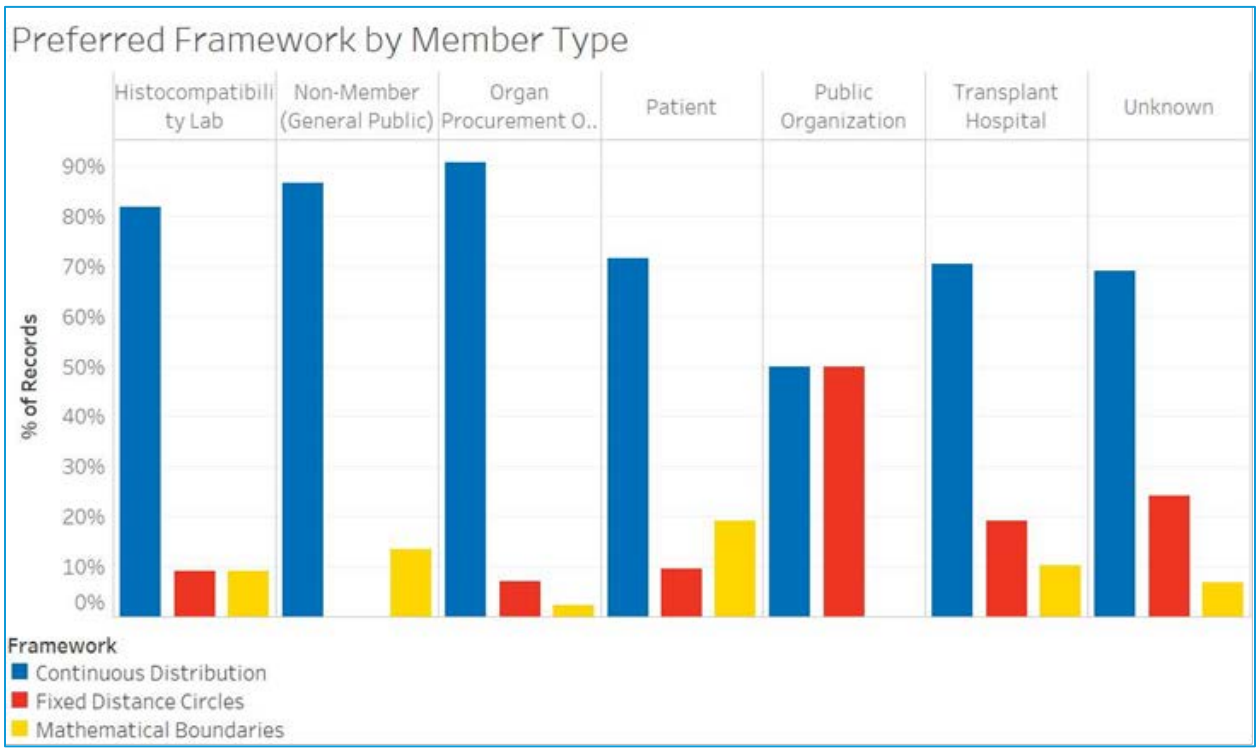
The public comment proposal was presented to each of the eleven regions during their respective regional meetings between August and October. Members were polled on their preference between the three frameworks. The table above represents polling numbers from across the eleven regions.

Multiple regions immediately recognize the need to replace Donor Service Area (DSA) and Region from OPTN organ allocation policy. Region 11 states that when replacing DSA and Region, the OPTN should carefully consider all aspects of the Final Rule, including reducing inequalities among candidates across varying socioeconomic statuses.

Support for the Committee to adopt a framework of continuous distribution is present in a majority of the eleven regions. Each region provides valuable critical feedback for each of the three frameworks. Region 10 conducted two polls: one with an option to abstain and one with no such option.

Continuous distribution is the preferred proposed framework for organ allocation across each of the member types, though public organizations prefer the fixed distance framework and continuous distribution frameworks equally. Mathematically optimized districts polled second in only one region (Region 2); however, the framework is the second-most preferred framework by both patients as well as members of the public (non-members). The fixed distance framework is the second-most preferred framework among transplant hospitals and OPOs. The graphic below illustrates the breakdown of framework preference by member type.

Figure 15: Public Comment Analysis by Member Type



Below is a summary of the key themes of narrative feedback received on the OPTN/UNOS Public Comment regarding each of the three proposed frameworks.

Fixed Distance

Consistency
Several comments from transplant hospitals cite the utilization of a Fixed Distance framework in thoracic organ allocation as an advantage for the framework in order to promote consistency across organ types. One comment specifically cites logistic similarities with thoracic organs and share 35 livers as well as high KDPI kidneys.

Efficiency

Individuals that prefer the Fixed Distance framework note that it promotes broader distribution while also promoting efficiency concerning organ transportation.
One comment states that the broadening of organ sharing practices could increase the average organ donor case times, which has a major impact on donor families. It should be noted that none of the three frameworks require broader or narrower distribution. The organ-specific committees have discretion to set fixed distances based on consensus and evidence-based practices that emphasize equity while considering efficiency.

Conversely, several comments from transplant hospitals cite biologic differences across organs as a reason that fixed distances should not be consistent across organs and instead be variable. For example, a very large circle could shift liver allocation towards centers with larger numbers of high-MELD candidates while simultaneously disadvantaging kidney allocation programs that currently share more locally and have short wait times. Again, none of the three frameworks require broader or narrower distribution. The organ-specific committees have discretion to set fixed distances based on consensus and evidence-based practices that emphasize equity while considering efficiency.

Differences in Geography
A few comments critical of the Fixed Distance framework note that the framework places far too much priority on geography and does not optimize cold times for organs that are able to travel much further without any increase in hazard rate. However, organ-specific committees could choose to implement different fixed distance circle sizes by candidate or donor type, such as a Donor after Cardiac Death (DCD) or pediatric donor / candidate.

Differences in population density is a commonly expressed concern within the Fixed Distance framework between transplant hospitals, OPOs, and patients. Several comments state that even larger, 500 nautical mile concentric circles would encompass extremely small donor pools in the Northwest, West, and Southwest regions when compared to population dense regions such as the Northeast. This is important because it represents a key weakness of the Fixed Distance framework in that it lacks flexibility to account for differences in population density and supply and demand in different regions across the country. Wider circles could help account for this weakness; however, it could create inefficiencies in terms of travel method. For example, if a 750 nautical mile circle were implemented as the first circle, more organs could be flying upwards of 600 miles for a candidate that may only have a slightly longer wait time than a candidate within driving distance. Furthermore, the framework would not recognize regional differences in recipient selection.

Several comments express concerns that a Fixed Distance framework would disadvantage transplant programs on the coasts because bodies of water would represent large portions of those concentric circles. Specifically, Region 3 and participants in the Southeast are critical that the Fixed Distance framework did not account for Puerto Rico and the unique geography of the Florida panhandle. Region 10 and participants in the Midwest outline similar concerns regarding the geography of the state of Michigan. Region 1 notes that the boundaries inherent in the Fixed Distance framework reinforce an outlook of local ownership of organs, which directly contrasts with the principle of distribution that states that organs are a national resource to share as broadly as is feasible. The Committee considered these arguments and articulated that geography dedicated to water within a fixed concentric circle does not substantially affect the supply or demand for organs because there are neither donors nor candidates occupying that space. Furthermore, donor hospitals on the coasts see far denser population centers than those in the middle regions of the country that are landlocked.

Participants also note concerns that the Fixed Distance framework is not flexible enough to account for variable population densities across the country as well as regional inconsistencies in organ supply and demand.

Mathematically Optimized

Metric-Driven

Comments from several member types note that a Mathematically Optimized framework is preferred over a Fixed Distance framework because of the ability to customize based on non-discriminatory data that remove bias from the equation in organ allocation. Conversely, some comments note that the ability to customize the metrics within the algorithm prove that the framework is not free from bias.

Boundaries
Region 8 notes that this framework, similar to the fixed distance framework, would likely not account for differences in organ supply and demand across the country. The Committee noted that this criticism could be addressed, as exampled in Gentry's presentation, "Fixed Population vs. Fixed Radius."[22] Other comments note that this framework is not free of boundaries that could separate candidates from organ offers who live just miles apart.

Knowledge Translation
A few comments from transplant hospitals state that this framework could prove difficult to explain to the public and practitioners alike while still not addressing compatibility or adequately balancing in cold time.

Continuous Distribution

Continuous Distribution garners the most support from across the regional meetings, and both members and non-members outline the strengths and weaknesses of the proposed framework.

Compliance
One of the major narrative themes from commenters that preferred the Continuous Distribution framework is its compliance with the Final Rule and its representation of the Board-approved principles of geographic distribution. Participants favoring broader distribution and national distribution believe that the Continuous Distribution framework most effectively adheres to the principle that organs are a national resource to distribute as broadly as feasible. Individuals note that kidneys possess much longer cold ischemic times and should not be bound by a fixed distance, but instead distributed to the sickest individual regardless of geography. Like the Fixed Distance and Mathematically Optimized Frameworks, the Continuous Distribution Framework does not dictate that distribution should be broader or more localized. The framework allows for organ-specific committees to make value judgements regarding the weight of geographic proximity in relation to other variables. Additionally, comments favoring the framework note that the weight given to proximity in the form of points could consider efficiency.

Region 4, which polled overwhelmingly in support of the Continuous Distribution framework, states that the framework was the most flexible of the three proposed and offers the most legally defensible principles. Region 1 also comments favorably on the ability to defend the Continuous Distribution framework from future litigation, adding that it also offers the most patient-centric approach.

Flexibility
Several comments reference the balance that the Continuous Distribution framework provides between medical urgency, compatibility, and geography. These comments are present across almost all member types. Many individuals note that the framework allows the flexibility to weigh these variables differently based on organ type and furthermore provides the OPTN and UNOS the ability to adjust these values based on post-implementation feedback. For example, as one comment noted, if a programed Continuous Distribution framework results an unintended result (e.g. decrease in pediatric rate of transplant), the OPTN could adjust the model coefficients accordingly.

Some regions express preferences regarding the allocation of points within the continuous distribution framework. Specifically, Region 4 put forward the possibility of including donor quality as a metric within the greater framework. Many regions express the need to prioritize pediatric patients. Region 9 cites medical urgency as a concern within the framework, as medical urgency is not a current consideration within the Kidney Allocation System (KAS).

[22] Sommer Gentry, "Fixed Population vs. Fixed Radius" (PowerPoint presentation, OPTN/UNOS Geography Committee, March 26 2018).

The Committee recognizes the flexibility allowed for within the Continuous Distribution framework to customize the parameters based on the needs of the specific biologic characteristics and transplant logistics of each organ. The framework allows the community to have the most nuanced conversation about how a transplant network can and should operate in order to be the most equitable while maintaining efficiency.

OPOs also note that the Fixed Distance and Mathematically Optimized frameworks are essentially two variation of the Continuous Distribution framework with geography weighted differently. These comments solidify the work that is currently being done in organ specific committees concerning allocation. Though the committees will not be able to implement a pure Continuous Distribution framework in the short term, the framework does represent just a variation of either the Fixed Distance or the Mathematically Optimized frameworks.

Equity
Members and non-members alike associate the Continuous Distribution framework with the ability to provide patient equity across the system regardless of geography. Patients note that the fact that medical urgency and biologic match could outweigh proximity and provide them with greater opportunity to receive organs from increased distances.

Patients and patient advocates identify the continuous distribution framework as the option that would provide the most confidence to the community that discriminating factors are less prevalent in order to offer the organ to the sickest patient regardless of geography.

Efficiency and Wastage
Efficiency as well as increase in travel and the associated costs are some of the biggest weaknesses of the Continuous Distribution framework based on public comment feedback. Several critical comments state that increased travel could inflate the cost of organ transplantation for centers who could in turn pass costs onto patients in order to stay fiscally sound. This is a concern shared by OPOs and patients alike.

Organ wastage is another concern associated with increased travel. Numerous comments mention an increased risk for organ wastage when incorporating the complex logistics of organ transportation on a more frequent basis. Though kidneys on average possess longer cold ischemic times without increases in hazard rate, some believe the goal should still be to limit the risks associated with longer cold ischemic times. Again, none of the three frameworks require broader or narrower distribution. The organ-specific committees have discretion to set fixed distances based on consensus and evidence-based practices that emphasize equity while considering efficiency.

Transformation
Some participants believe that this is the most transformative frameworks, and thus has the most unknowns and potential for unintended consequences. Subsequently, several believe that thorough modeling is necessary before implementing the continuous distribution framework. It is worth noting that no framework, in any organ specific committee, would be implemented without thorough modeling. Each organ specific committee will consider the numerous value judgements that would need to be made to construct their own Continuous Distribution framework based on the clinical, biologic, and logistic factors. These variables could be modeled during the evidence-gathering phase of each of the individual projects in their respective committees and help inform every conclusion regarding the weight of each variable.

Region 8, which polled favorably in support of Continuous Distribution, notes the difficulty in recommending any of the three frameworks without modeling and understanding the specific characteristics and effects on transplantation across each organ type.

<u>Additional Feedback Themes</u>

Socioeconomic Factors

Numerous comments reference the need to consider socioeconomic factors when deciding on a new framework for organ allocation. More specifically, some participants believe that a fixed distance framework could disadvantage poorer rural communities separated from population centers and transplant hospitals. On the other hand, some comments noted that a Continuous Distribution framework could take organs further away from minority communities in urban areas in favor of non-minorities in surrounding counties and states. The OPTN/UNOS Minority Affair Committee has composed a checklist of vulnerable populations that would need to be considered in the modeling and deliberative process within any committee seeking to implement a new framework for organ allocation. This checklist was reviewed, considered, and referenced in each of the organ-specific committees during the evidence gathering process.

OPO Performance
Several comments from public organizations and transplant hospitals state that none of the three frameworks effectively account for OPO performance. Participants note that every OPO operates differently and some are much more aggressive at pursuing organs for transplantation than others. Patients note that placement in a fixed concentric circle containing a less-aggressive OPO could disadvantage them. A number of comments state that an OPO performance metric would be valuable in framework construction.

Priority of Pediatric Patients
Comments from transplant hospitals, patients, public organizations, and others express the need to prioritize pediatric patients regardless of framework. Many of the same comments cite preference for the Continuous Distribution framework due to its ability to customize allocated points based on variables and state that pediatric patients should receive more points than older candidates with similar medical characteristics.

State-Based Allocation Proposal
At the Region 3 meeting in Atlanta, Georgia on August 24, 2018; Dr. Raymond Lynch conducted a presentation on a method of geographic allocation that differs from the frameworks considered in public comment. This “State-Based” method prioritizes candidates in the same state as the donor hospital followed by candidates in immediately surrounding states before moving to national distribution. Members polled at the meeting favored the framework as an alternative to the three frameworks presented by the Committee.

The Committee heard from Dr. Raymond Lynch of the Emory University School of Medicine on his proposal for a state-based system of organ allocation during their October 23, 2018 meeting. The Committee was critical of the proposal’s non-alignment with the OPTN Final Rule. Furthermore, members were critical of whether the method is legally defensible. Members of the Committee posited whether there was any difference between the state-based approach and a less-customizable variant of the districts / neighborhoods approach. Finally, committee members noted inherent variability in state size and the number of programs per state that could cause significant advantages and disadvantages based solely on geography.

The Committee does not believe that the framework allows flexibility or gives ample room for nuanced conversation about each of the variables that needs to be considered in allocation. Furthermore, the state-based allocation framework does not align with the OPTN Final rule as closely as the Continuous Distribution framework (or the Fixed Distance and Mathematically Optimized Frameworks) because it relies too heavily on geography and borders without providing an evidence-based justification for those borders. With a Fixed Distance framework, at least the borders of each circle could be tied to a variable that increases equity or efficiency, such as when organ transportation switches from driving to flying.

Vote
Following the public comment analysis and discussion, the Committee voted 87 percent (14 of 16 votes) in favor of moving forward to present Continuous Distribution as the preferred framework for adoption at the December Board meeting. 13 percent (2 of 16 votes) voted in favor of a Fixed Distance framework. There were no votes for the Mathematical Optimization framework. There were no abstentions.

RESOLUTION 1

WHEREAS, that the Board of Directors, in order to promote efficiency, understanding, and clear communication, has determined that it is beneficial to have a single framework for allocation policy development; and

WHEREAS, that within that framework, individual policy committees would retain the flexibility to make customizations appropriate to the clinical differences among organs; and

WHEREAS, that the Ad Hoc Geography Committee recommends the Continuous Distribution allocation framework for its ability to appropriately integrate cold ischemic time, system costs, and candidates' medical urgency; Now, therefore be it

RESOLVED, that the Board of Directors adopts the Continuous Distribution allocation framework as best suited for future OPTN organ allocation policies; and

FURTHER RESOLVED, that the Board directs the organ-specific committees to move toward the Continuous Distribution allocation framework as they consider future amendments and improvements to their respective allocation policies.