OPTN | UNOS

Public Comment Proposal

Frameworks for Organ Distribution

OPTN/UNOS Ad Hoc Geography Committee

Prepared by: Matthew A. Prentice, MPH
UNOS

Contents

Frameworks for Organ Distribution

Affected Policies: *N/A*
Sponsoring Committee: *Ad Hoc Geography Committee*
Public Comment Period: *August 3, 2018 – October 3, 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 the 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. Additionally, the Board of Directors accepted the Ad Hoc Geography Committee's recommendation to request community feedback on the recommended distribution frameworks, with a goal of identifying a single, preferred distribution framework to be used across organs. This proposal includes three distribution frameworks identified by the Ad Hoc Geography Committee as being in alignment with the adopted principles of geographic distribution and the OPTN Final Rule.

Is the sponsoring Committee requesting specific feedback or input about the proposal?

Yes, the Ad Hoc Geography Committee (hereafter, "the Committee") requests feedback from the community regarding the three distribution frameworks. The goal is to identify a single framework to be used across organs. The community is encouraged to provide their rationale for preferring one specific framework of the three proposed.

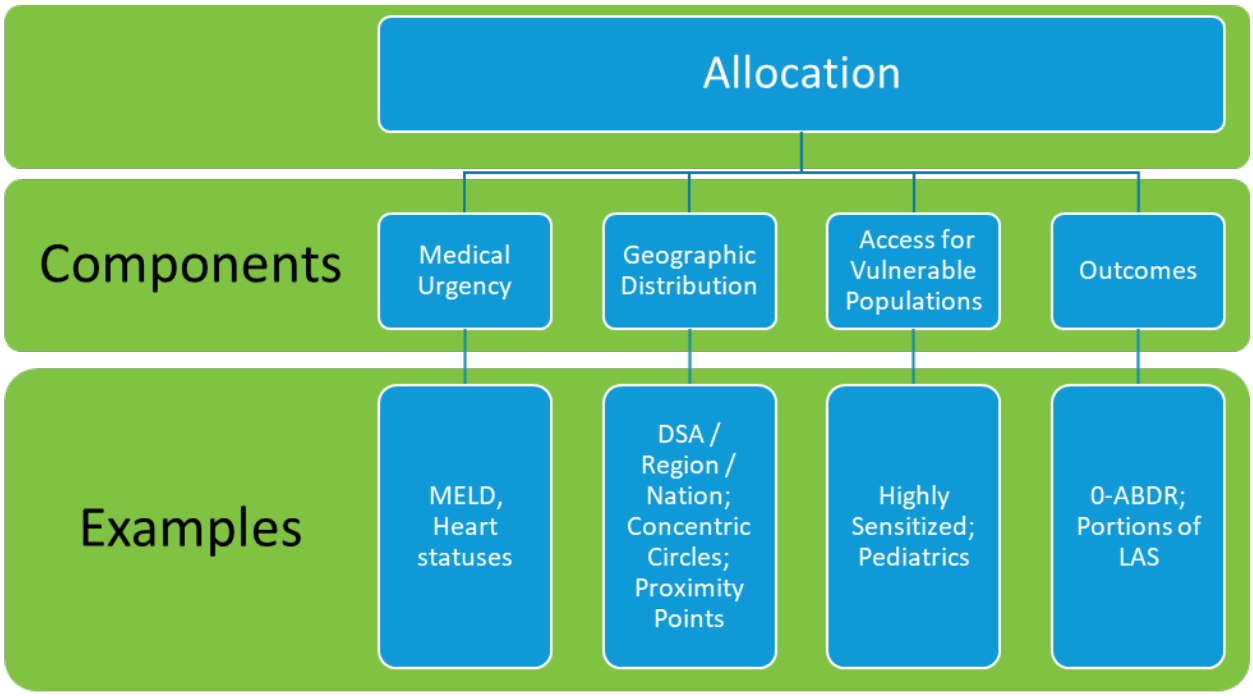
Members are asked to comment on both the immediate and long term budgetary impact of resources that may be required by the distribution frameworks. This information assists the Board in considering the proposal and its impact on the community.

[1] 42 C.F.R. §121.8(a)

What problem will this proposal address?

Geographic distribution is one of several components in OPTN 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



Historically, organ allocation policies have been 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. The liver allocation policy adopted by the Board in December 2017 uses an out-of-region proximity circle to expand distribution. This does not exist in the other policies that utilize OPTN Region and DSAs.[7] If there is an inherent benefit of one approach over the other, then that approach should be consistent among all organ groups.

2. Inefficiencies in programming changes to OPTN allocation policy

The OPTN currently maintains programming 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 programming 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.[8] 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] *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).
[8] 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[9]

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).

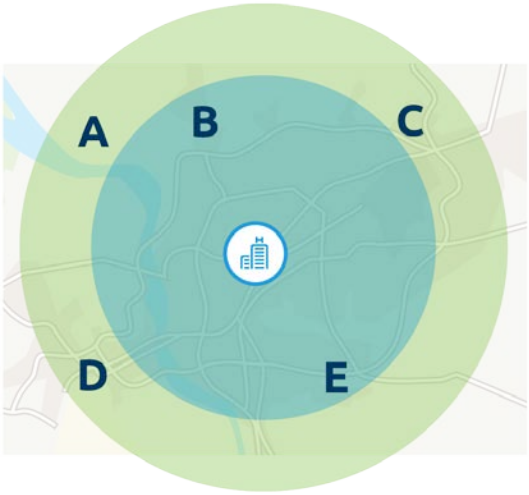
The Committee used a survey to begin to focus on distribution frameworks that are in line with the OPTN Final Rule and the principles developed by the Committee. The Committee identified three frameworks for geographic distribution that are consistent with the principles and the Final Rule. The Committee recommends further discussion by the Board and by the community on the merits of the three frameworks, but 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 three frameworks identified by the Committee are:

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

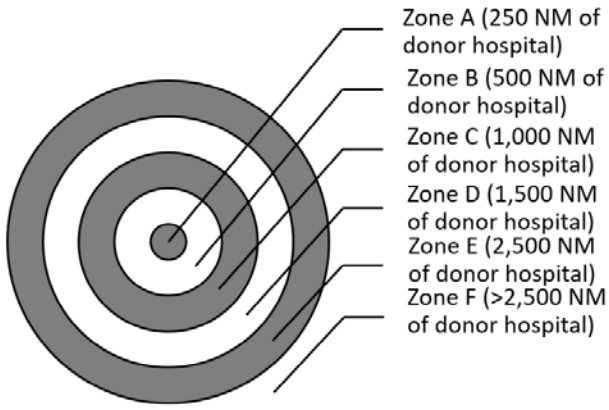
This framework utilizes a system of fixed geographic units based on the distance from the donor hospital to the candidate's place of listing. One example of this framework is currently utilized in heart and lung distribution and referred to as concentric circles or zones. The changes to liver distribution approved by the Board of Directors in December 2017 partially utilizes a similar concept to add a proximity circle around a donor hospital, however the changes to liver distribution still maintain the regional boundaries and the proximity circle expands the geographic unit of allocation outside of the region.

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



[9] *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).

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



The Committee discussed several advantages of this distribution model 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). CIT increases as the distance 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. 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. 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."[11]

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. This would be consistent with the Final Rule charge that "allocation policies … (5) shall be designed to … promote patient access."[12] 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.

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.

A disadvantage of this distribution model 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. 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.

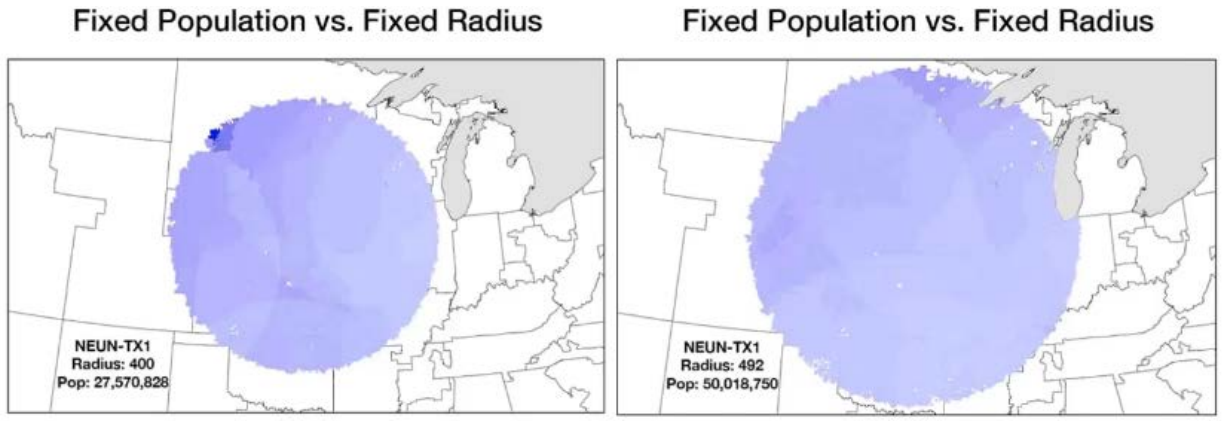
[10] 42 CFR 121.8(a)(2).
[11] 42 CFR 121.8(a)(5).
[12] Ibid.

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 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. In this model, 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[13]



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

Figure 6: Representation of Organ Distribution Based on Optimized Districts

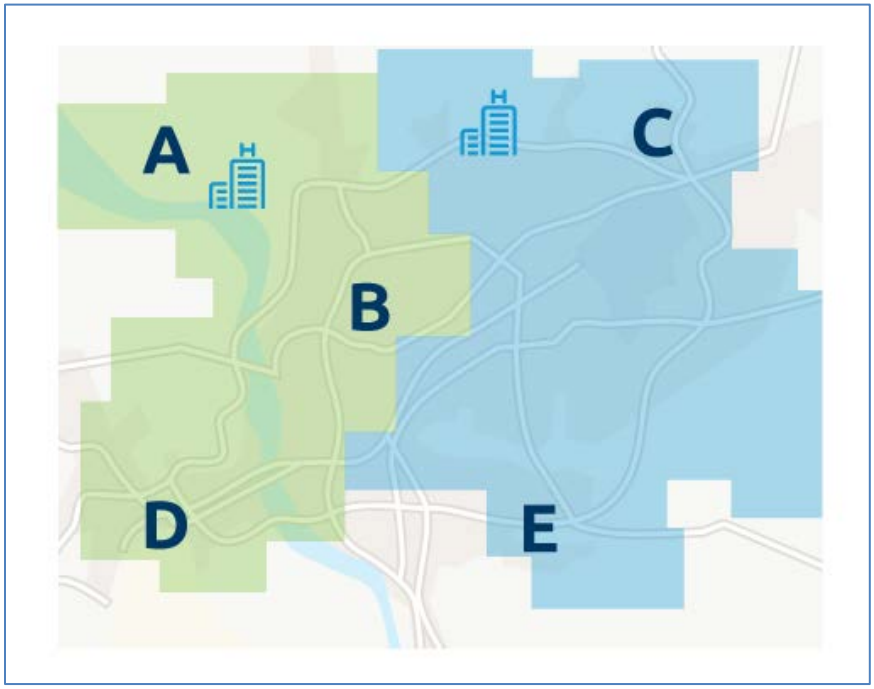


Figure 7: Representation of Organ Distribution Based on Optimized Neighborhoods

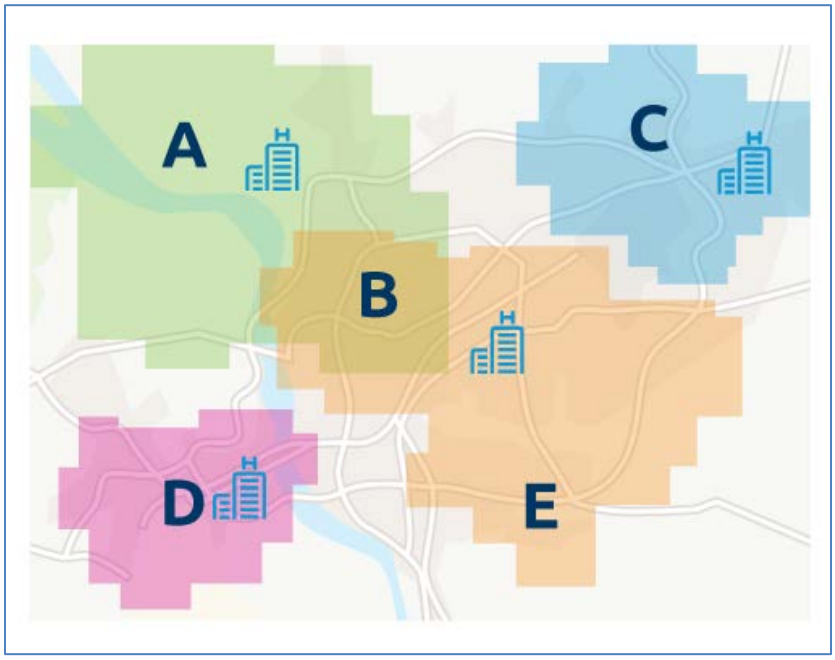
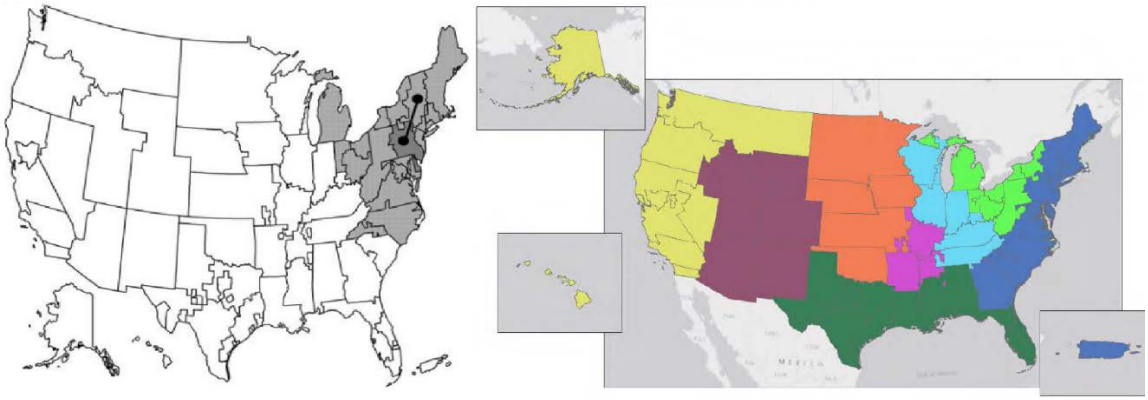


Figure 8: Example of Optimized Neighborhoods[14] and Optimized Districts[15]



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.[16] Many versions of this model 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 models 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 model 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.[17] The concept 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.

[14] 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.
[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 July 5, 2018).
[16] "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.
[17] Jon Snyder, "Systems without Geographic Boundaries" (PowerPoint presentation, OPTN/UNOS Geography Committee, March 26, 2018).

Figure 9: Example of Continuous Distribution

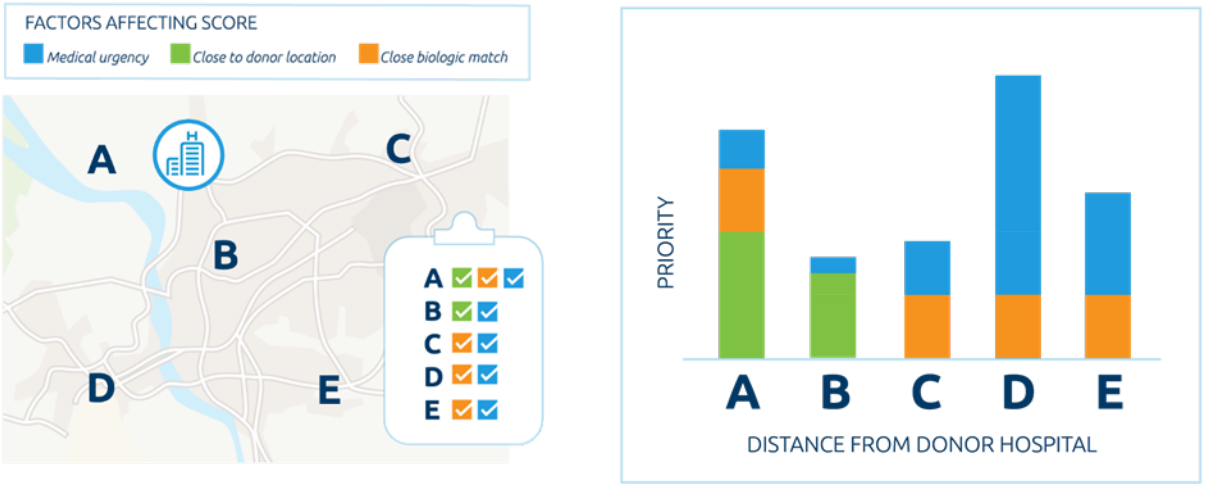
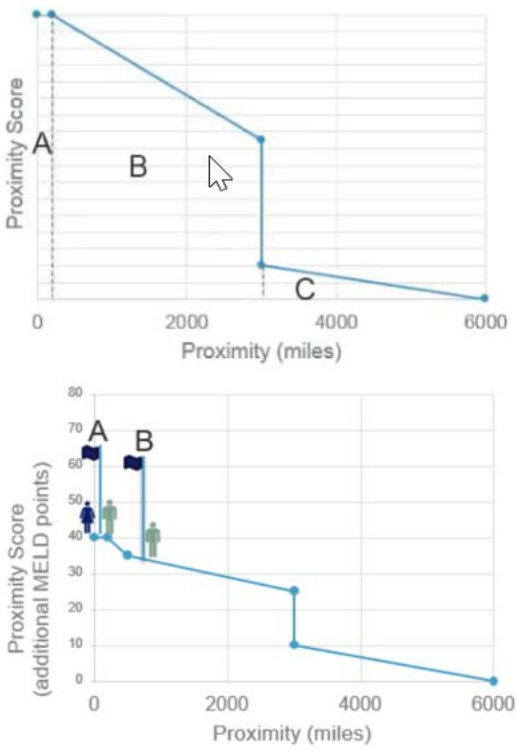


Figure 10: Depiction of the proximity score under the concept of distribution without boundaries



The Proximity Score Function likely has 3 zones:

Zone A: The "near the donor" zone

Zone B: Between "near" and "too far"

Zone C: Likely too far

Example of this function would work:

Patient A: MELD 25, 100 miles
Patient B: MELD 30, 750 miles

Patient A is offered before patient B using this function.

If we made Zone B shallower, Patient B could be offered prior to patient A.. this is the "value judgment".

The Committee discussed several advantages of this distribution model and its alignment with the principles. This model contains all of the benefits described in the fixed distance framework above. Additionally, this model can eliminate any concern over fixed geographic boundaries separating candidates and donors. This distribution model 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 model 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.

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.

How well does this proposal address the problem statement?

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.

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.

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 model.	• Has not been modeled or used in organ distribution.

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 model is chosen, the cost and time to program future distribution changes will decrease.

How will the OPTN implement this proposal?

Once the Board adopts a preferred distribution model, all future distribution proposals will be evaluated against that model. Committees will need to justify any distribution model that does not move toward the preferred distribution model. 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 model.

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 all 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.

The OPTN frequently makes changes to the allocation policies. As we review data and make future changes, we'll have a guidepost that all the committees can work toward. For example, if cliffs are bad, the committees can all take a similar approach to smoothing out cliffs. Which framework is preferred will impact the order and speed by which the OPTN can change the existing systems. For example, if circles are preferred, than heart and lung distribution is largely there. If mathematically optimized boundaries or continuous distribution are preferred, that's a different situation. In either situation, the Policy Oversight Committee and Executive Committee will review and prioritize these efforts.

How will members implement this proposal?

As this proposal does not change any member requirements, members will not need to do anything to implement this proposal. The details regarding member impact will be included in the analysis of any future, specific changes to the organ allocation systems.