

**OPTN/UNOS Ad Hoc Geography Committee  
Meeting Minutes  
March 26-27, 2018  
Chicago, IL**

**Kevin O'Connor, MS, PA, Chair**

**Introduction**

The OPTN/UNOS Ad Hoc Geography Committee met in Chicago, Illinois on 03/26/2018 and 03/27/2018 to discuss the following agenda items:

1. Committee Efforts – Recap & Legal Issue Primer
2. Overview of Distribution Models Identified by Committee
3. In-Depth Models & Principles Alignment Discussion

The following is a summary of the Committee's discussions.

**1. Committee Efforts – Recap & Legal Issue Primer**

Summary of discussion:

The Committee Chair "the Chair" reviewed the principles identified by the Committee. It was reiterated that the Committee was focused on organ distribution and the geographic units of organ allocation. The principles build upon the overarching principle to share organs as broadly as possible with respect to several constraints related to avoiding organ wastage, financial and logistical consideration, and access to transplant by any specific patient population. It was reiterated that any geographic constraints must be rationally and consistently applied to minimize the effect of geography. The current principles identified by the Committee include:

1. Deceased donor organs should be considered a national resource to be distributed as broadly as possible consistent with the Final Rule.
2. Organ distribution policy should aim to reduce inherent differences in potential donor supply and demand (as continually assessed) across the country.
3. The potential impact on organ system resource utilization should be taken into account in organ distribution.
4. Travel time expected to have a clinically significant effect on cold ischemic time and organ quality should be taken into account in organ distribution.
5. Organ distribution should aim to reduce travel of organs for patients with similar allocation priority.

The Chair reiterated that the group would continue to discuss these principles and possible modification during the in-person meeting and future conference calls. A member of the Committee provided a brief overview on the legal perspective of the committee's efforts. It was stated that it was important to note that geography cannot be an influence on a candidate's access to transplant unless justified by the other parts of the Final Rule. The idea of a policy being "rationally determined" was presented to the Committee. A committee member asked for clarification about whether a court could disagree with a decision, but not overturn policy as long as it was rationally determined. A committee member agreed and restated that a government agency would be focused on the specific rational that supports a policy or rule, but the actual rule does not need to be perfect. A committee member asked if a policy could be consistent with the Final Rule but not defensible from a legal perspective. An example was provided that a distribution policy could be aligned with the principles of the Final Rule, but not be rationally determined or consistent. It was stated that when the Committee reviews distribution models, the Committee needs to be able to articulate how the distribution model is in line with the framework and how it was rationally determined and could be consistently applied.

The Committee discussed the example of the Donor Service Area (DSA) and its ability to be legally defensible. There was discussion that the vulnerabilities of the DSA could have been brought to a legal proceeding at any time and this concern highlights the work of this Committee. A committee member identified that the current DSA boundaries do vary based on population size, with geographically larger DSAs predominantly existing in areas of sparse population. The case was made that any static constraint could be viewed as arbitrary because it would affect different areas disproportionately. Additional conversation highlighted that the inconsistencies with the use of the DSA are potentially greater than any geographic measure (for example a 250 mile circle). Committee members stated that with the distribution models currently under review by the Committee, any specific model could be in line with the Final Rule and defensible depending on the constraints included. The Committee discussed and agreed that one of the most important aspects of the committee' work, and future efforts to change organ distribution, is the process that led to a policy more than the actual policy.

The group discussed the role of consensus in developing organ distribution policies. It was identified that in prior efforts, the process to reach consensus resulted in policies that are likely less impactful and less in line with the Final Rule, but represented the consensus of the community as a whole. The group agreed there are benefits and vulnerabilities to the current process for consensus, but it highlights the importance of a body like this Committee to identify overarching principles that can be above any specific organ perspective. It was reiterated by several committee members the role of leadership in identifying difficult decisions that benefit the network as a whole.

## **2. Overview of Distribution Models Identified by Committee**

### Summary of Discussion

The Committee began reviewing the different distribution models that were identified by the Committee as warranting additional discussion. The "Hybrid Approach" utilized by the recent board approve liver distribution policy was presented to the Committee. The Committee discussed the rationale for some of the details of the proposal. It was stated that this approach allowed for subsequent changes based on the effect of the change on the disparity in access to transplant. Committee members discussed vulnerabilities in the model including the use of the DSA with regards to proximity points and maintaining regional and DSA boundaries.

The Committee reviewed the concept of concentric circles. It was presented that the details of concentric circles in thoracic allocation were developed through consensus in the community and include the use of the DSA. However, the legal challenge to lung allocation removed the DSA as a unit of allocation, it remains in heart allocation policy. It was stated that the distance parameters of the thoracic allocation policies have some resemblance to ischemic time and method of travel, however they can be considered fairly arbitrary. Committee members highlighted the concern with concentric circles being the sharp boundaries that separate candidates, for example a candidate 499 and 501 miles away from the donor hospital are in separate distribution zones.

The concepts of optimized districts and neighborhoods were presented to the Committee. These concepts involve developing distribution units based on some metric, for example supply and demand for liver transplant and optimizing geographic units to accomplish a goal with the metric. It was stated that the flexibility of the districts or neighborhoods allows for optimization to any constraint that may be identified. Committee members agreed on the benefits of mathematical optimization but identified the use of DSAs in both of the prior districts and neighborhoods models used during liver discussions. It was stated that the DSA was not a necessary unit to create either districts or neighborhoods. There was additional discussion that both districts and neighborhoods have a static boundary that separates candidates, the committee discussed the benefits and concerns with static boundaries and agreed that static boundaries were not necessarily ideal, but permissible if they were rationally determined,

aligned with the Final Rule and in agreement with the final principles identified by this Committee. The Committee reviewed the model of population based circles. This model is similar to concentric circles but utilizes the population dynamics of the area in the sizing of the distribution circle. Committee members stated that population dynamics do not incorporate ischemic time into the sizing of the distribution unit. It was stated that ischemic time is a primary constraint to any distribution unit and the Committee discussed that other constraints (supply/demand, ischemic time) could potentially be a component of this distribution model.

The concept of distribution without boundaries was presented to the Committee. This concept utilizes a *medical priority score* and a *Proximity Score* to create an *Allocation Priority Score* to distribute organs without absolute geographic boundaries. The Committee discussed that a benefit to this model is that there are no “cliffs” to distribution, for example the boundary between a 250 mile zone and a 500 mile zone in heart distribution. It was stated that this concept would result in a much *smoother* “distribution curve”. Other benefits of this concept were discussed by the Committee. These include the ability to adjust the scoring to be organ specific and donor-specific, the potential ease in making future adjustments, and the overarching benefit that the necessary decision making required to identify the parameters of the allocation priority score would create a distribution framework that is rationally determined. Committee members identified a few concerns with this concept. These include the fact that distance from a donor may influence a candidate to list at a transplant hospital that is closest to larger donor hospitals. Additionally, because this is a novel concept, committee members the difficulty in building consensus around the different parameters necessary to develop an allocation priority score. It was noted that there are differing opinions on the ischemic time for different donor and recipient characteristics.

### **3. In-Depth Models & Principles Alignment Discussion**

The Committee began the second day with a recap of yesterday’s discussion. The Committee discussed that following yesterday’s conversation, it appears that a few of the distribution frameworks appear to be in greater alignment with the Committee’s principles of organ distribution. The Committee also agreed that the initial work product of the Committee would be a recommendation to the Board of Directors that includes the Committee’s principles of organ distribution and recommendations for distribution models. The Committee discussed the process that will result in getting the proposed distribution principles and recommendations to drive work by the OPTN committees to address their organ-specific distribution policies. It was emphasized the importance of communicating these ideas and recommendations to the community and the importance of engaging the community’s feedback in future efforts. There was discussion on a potential *gap-analysis* to prioritize future efforts to address areas of current policy. It was stated that these comments would be revisited by the Committee and potentially discussed in the recommendations report to the Board of Directors.

The Committee discussed the challenges in building consensus in the community on any specific direction for organ distribution policies. The representatives of the organ-specific committees stated the challenges in working towards a solution and noted that many of the recent changes to organ allocation (kidney, heart, liver) were notably lesser in their final effect than the initial proposals discussed by the Committee. It was agreed by the Committee that the effort to build consensus on large changes to organ distribution is challenging and highlights the importance of over-arching principles and frameworks that direct future policy development.

The Committee discussed whether the need for future distribution policies to be “nimble” to change, that is easily modifiable, should be a part of the Committee’s principles and recommendations to the Board of Directors. The Committee agreed that the ability to be easily modifiable is certainly a benefit with the future evolution of transplantation, the primary goal is to identify principles and distribution models that are in alignment with the Final Rule and can be rationally determined. The topic of the DSA and its role in distribution was discussed. The Committee agreed that the DSA as a function of an OPO’s recovery territory and its relation to

its CMS designation is not an item of discussion for this group. However, the use of the DSA to classify candidates in organ distribution policies was a focus of this group.

The Committee revisited the principles identified by the Committee. There was discussion on whether the principles should be ranked by importance. It was agreed that there wasn't a need for the Committee to rank the principles, however, each organ specific community would likely find some to be more impactful than others. For example, ischemic time has more impact on thoracic organ distribution compared to kidney distribution. It was stated that the principles could use some editing to remove ambiguity. It was agreed that committee leadership and UNOS staff would incorporate the Committee's feedback to edit the principles and present them to the Committee during their April conference call.

The Committee continued their discussion of the distribution frameworks from the previous day. The topic of the use of the DSA in organ distribution was discussed by the Committee. A few committee members stated that the DSA didn't necessarily have to be removed from organ distribution, but its place in policy needs to be rationally determined. The use of the DSA in the "Hybrid Approach", was discussed. It was stated that the Hybrid Approach introduced broader distribution to the most medically urgent candidates, and used the DSA as a surrogate for candidates in local proximity to the donor. However, there was agreement that the variation in size of the DSAs makes it questionable as a unit of local proximity around a donor. There was additional discussion that the continual use of the DSA as a unit of geography is difficult may serve OPO and transplant center relationships, but reduced access to organs outside of a DSA does not serve patients. The committee discussed the topic of costs when discussing the role of the DSA in organ distribution. The Committee noted many examples where distributing outside of the DSA would reduce costs in areas where there are candidates within close proximity of the donor but in another DSA.

Several committee members discussed the difficulty in approaching changes to organ distribution policies, when they have just underwent years to develop new allocation policies, including changes to kidney, heart, and liver. There was discussion that the work of this committee needs to be communicated to the community in a manner that demonstrates the legal ramifications, impact on patients, and the larger transplant community.

The Committee revisited the optimized districts and neighborhoods frameworks that were discussed on the previous day. Several committee members reiterated the benefit of these solutions was the ability to apply constraints based on the concerns the Committee has identified during their work (travel time, cost, and logistics). The committee discussed the relationship between arbitrary DSA boundaries, and boundaries that would be present in any of the optimized distribution frameworks. The concerns with static boundaries separating patients was reiterated, however, committee members discussed that if the boundaries were rationally developed and created a distribution system that increased equity in access to transplant, then they would be defensible.

Concentric circles as a framework was discussed in detail by the Committee. It was stated that distance from a donor is a rational construct that can be tied to constraints for ischemic time. The Committee revisited the concept of circles based on population density. It was noted that although this seems like a rational way to construct a distribution unit, population size is not necessarily a proxy for donor availability. In terms of addressing inequities, the committee discussed that distance circles, or population-based circles, needed to be large.

The distribution without boundaries framework was discussed by the Committee. Several committee members stated that this concept is most equitable on an individual basis, in the sense that a candidate's medical urgency and distance to a donor influences their access to the donor. There would not be a situation where a static boundary separates a candidate within close proximity of donor, but in a different zone, district, etc. Several committee members stated that there is a specific concern with this concept in that it prioritizes candidates listed at

transplant programs near high volume donor hospitals, thus it could prioritize metropolitan transplant programs and disadvantage rural or geographically isolated programs. It was stated that this framework could be tuned to address this. This framework was also highlighted for its ability to be tweaked based on donor characteristics. Committee members highlighted the potential difficulties in explaining this system to the community and to their respective patients. However, it was noted that it is likely no more difficult than explaining the purpose of regions, DSAs, zones, etc. and how they impact a patient's access to a donor.

Several committee members expressed their intent to move forward and identify specific distribution frameworks to move forward for future discussion. Committee members noted the importance of future work by committees to dive into the details of these different frameworks for different organs. It was stated that the majority of modeling and analyses were geared towards liver distribution and several of the discussed frameworks had not been applied to other organs. The Committee emphasized the benefits of three distribution frameworks:

- 1) Organ distribution based on fixed distance from the donor hospital
- 2) Organ distribution based on mathematical optimized boundaries
- 3) Organ distribution without geographic boundaries

The Committee identified that any distribution framework would ideally lead to increases in equitable organ distribution, however the focus of this Committee was to identify distribution frameworks that could go forward to be used by committees and stakeholders in future changes to organ distribution.

The Committee discussed the principles that have been identified by the group. The specific principle of "organ distribution should aim to reduce travel of organs for patients with similar allocation priority" was examined. Several committee members stated that this was important to alleviate costs, and avoid delays in allocation by offering organs to distant centers that are likely not to accept. However, other committee members stated that the system should not constrain access for a patient, and individual transplant program behavior will dictate whether a program accepts a distant offer when they can anticipate a closer offer in the future.

The Committee highlighted the importance of having a principle that was tied to the efficient management of the network, as this is a consideration in the Final Rule. It was stated that the principle "the potential impact on organ system resource utilization should be taken into account in organ distribution" could be reworded to be specific about efficiency. There were questions about what resource was being discussed in this principle. It was noted that UNOS staff and leadership would edit based on the Committee's comments and the Committee will revisit the principles on their April conference call.

### **Upcoming Meetings**

- April 13<sup>th</sup>, 2018 Teleconference