

**OPTN/UNOS Ethics Committee  
Meeting Minutes  
February 21, 2019  
Conference Call**

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**Introduction**

The OPTN/UNOS Ethics Transplantation Committee (the Committee) met via GoTo teleconference on 2/21/2019 to discuss the following agenda items:

1. Public Comment Review: Eliminate the use of DSAs and regions from Kidney-Pancreas Distribution Concept Paper
2. Public Comment Review: Eliminate the use of DSAs in Thoracic Distribution
3. Public Comment Review: Eliminate the Use of Regions in Vascularized Composite Allograft (VCA) Distribution

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

**1. Public Comment Review: Eliminate the use of DSAs and regions from Kidney-Pancreas Distribution Concept Paper**

A presenter from the Kidney Transplantation Committee gave an overview of the KP Concept Paper, followed by discussion by the Committee.

Data summary:

This proposal highlights SRTR modeling of different options for removing DSA and region from kidney and pancreas distribution systems. It gives the community an opportunity to weigh in these options to change kidney and pancreas distribution before a policy proposal is put forward.

Specifically, the concept paper outlines SRTR modeling of the following 5 options:

- Fixed concentric circle framework with a 150 NM small circle and a 300 NM large circle
- Fixed concentric circle framework with a 250 NM small circle and a 500 NM large circle
- Fixed concentric circle framework with a single 500 NM circle
- Hybrid framework with a single 500 NM circle that uses a small number of proximity points inside and outside of the circle
- Hybrid framework with a single 500 NM circle that uses a large number of proximity points inside and outside of the circle

Summary of discussion:

One member asked if there had been any consideration for trial runs, applying a new allocation to one area (like a variance) before evaluating the results and expanding the allocation to the nation as a whole. The presenter explained that in order to accurately evaluate this proposal, more than one Distribution Service Area (DSA) would have to participate, as the objective of the proposal is to evaluate a new allocation system without conventional DSA boundaries. From a logistical point of view, a trial run would be difficult to implement. One member asked if there were considerations about how a broader distribution may require shipping kidneys farther to high cPRA candidates, resulting in greater cold ischemic time. The presenter responded that

there had been strong consideration given to travel time, cold ischemic time and creating a balance with broad distribution.

The presenter noted that the workgroup had evaluated data on travel methods by distance. A member asked about whether there could be issues with increased shipping distance if a certain center did not accept local backups. The presenter explained that expanding geography outside of the traditional DSAs will require new relationships between programs and OPOs in order to have effective communication and eliminate travel inefficiencies. One member asked about fewer transplants being done.

The KP Workgroup did consider the decreased transplant rates and noted that much is due to the weaknesses of modeling due to the fact that acceptance rates currently are heavily influenced by DSA and region and most of the organs offered outside of DSA and region are not high quality and are more likely to be turned down. However the presenter acknowledged that higher travel distances and cold ischemic times could also contribute to a decrease in transplants.

How do different proximity points impact more rural vs urban areas? The proximity points are from the donor hospital to the recipient hospital rather than directly to a patient's personal residence. For many rural areas the difficulty in accessing the transplant system is due to the distance between individual patients and the nearest transplant programs. Currently there is not data regarding that specific distance in order to take it into consideration, rather calculations are based on program location. Current proximity point models do not show any significant differences from the concentric circles models. A lot of thought has been given by the KP workgroup to non-contiguous states and whether proximity points will require places like Hawaii to ship more organs.

The Committee expressed significant concern about the balance between equity (justice) and utility (efficiency) in this project. The Committee considers that equity and utility should be balanced, and this project may overly prioritize equity over utility. It is important to quantify the extent to which utility is reduced compared to the increase in equity, and the populations who are harmed must be more fully identified. The Committee questioned if the overall objective of the project is focused on increasing patient access to transplant or increasing outcome metrics? Ideally, the KP workgroup would like to see an improvement in outcomes while also increasing patient access to transplant by standardizing DSAs and regions with new geographical boundaries, however they recognize that it may not be possible to do so. Balancing this multi-faceted issue is one of the reasons that the workgroup is presenting these models for public comment and to committees.

One member commented that while the Final Rule does have mandates applicable to geography, it also requires the best use of organs. The member worries that we are sacrificing utility just for the sake of removing current artificial borders. Another member asked if there should be some ethical consideration given regarding the donor rather than just recipients? Donors donate with the intention of saving lives but if transplant counts go down then more organs are likely discarded and therefore it might be disrespectful to donors.

One member asked if the benefits that African Americans saw from the implementation of KAS would be negatively affected by this system. The presenter explained that the data currently showed relatively more transplants for African Americans. An OPTN/UNOS staff member involved with the KP workgroup provided some clarification regarding African American and the "relative" nature of the improvement. African American transplant counts still went down according to the same pattern of other populations, the difference for the former is that the rate of decrease was less significant and therefore the "relative" number of transplants improved.

This metric is also subject to the same limitations as the rest of the KPSAM and could potentially improve as acceptance behavior adapts to new geographic boundaries.

Next steps:

The takeaways from the Ethics Committee's comments on the KP Concept Paper will be summarized and posted on the OPTN public comment site.

**2. Public Comment Review: Eliminate the use of DSAs in Thoracic Distribution**

An OPTN/UNOS staff member gave an overview of the current thoracic public proposal, followed by discussion by the Committee.

Data summary:

The OPTN/UNOS Thoracic Organ Transplantation Committee proposes replacing DSA with a 250 nautical mile (NM) circle from the donor hospital. The goal of this change is to make heart allocation policy more consistent with the Final Rule and provide more equity in access to transplantation regardless of a candidate's place of listing. In addition, this proposal realigns the first units of distribution for heart and lung allocation, addresses the limited utility of the exception for sensitized heart candidates, and finally, resolves several clerical issues that arise as a consequence of removing DSA as a unit of distribution from heart allocation policy.

Summary of discussion:

The Committee discussed how the distances modeled by the Thoracic Committee differed in terms of recipient outcomes. While there was some support for a smaller 150 NM circle, the modeling did not show a significant difference between 150 NM and 250 NM in terms of outcomes, which was a key factor in the Thoracic Committee's decision to replace DSA with 250 NM. Besides questioning the outcomes of the different options considered, the Ethics Committee members did not express significant concern with the proposal. In a poll issued during the call, a majority of Ethics Committee members indicated support for the proposal.

Next steps:

The takeaways from the Ethics Committee's comments on the Thoracic Public Proposal will be summarized and posted on the OPTN public comment site.

**3. Public Comment Review: Eliminate the Use of Regions in Vascularized Composite Allograft (VCA) Distribution**

A UNOS/OPTN staff member gave an overview of the public comment proposal of the VCA Committee, followed by discussion by the Committee.

Data Summary:

This proposal would replace region in VCA allocation with a 750 nautical mile (NM) circle around a donor hospital. This proposal is consistent with Goal Two of the OPTN Strategic Plan to increase equity in access to transplant. This project aims to implement rational units for geographic distribution that are more consistent with the requirements of the Final Rule.

Summary of Discussion:

One member asked whether additional criteria such as hard to match skin tones or pediatric sized limbs have been taken into account when determining the new allocation system. The VCA Committee did consider these criteria but found that the low volume of VCA transplants made analysis difficult. Committee members questioned whether it was premature to change policy without sufficient data. The presenter iterated the need to abide by the Final Rule and assured the Committee that the VCA Committee is using all the evidence currently available. A

majority of the Ethics Committee abstained from a vote on the VCA proposal because of concerns about lack of sufficient data.

Next steps:

The takeaways from the Ethics Committee's comments on the VCA Public Proposal will be summarized and posted on the OPTN public comment site.

**Upcoming Meetings**

- March 20 (teleconference)
- April 8 (Chicago)