

**OPTN/UNOS Ad Hoc Geography Committee
Meeting Minutes
September 25, 2018
Conference Call**

**Kevin J. O'Connor, Chair
Peter Goldin, Liaison**

Introduction

The Ad Hoc Geography Committee met via teleconference on 09/25/2018 to discuss the following agenda items:

1. Introduction and Announcement
2. Update on Regional Meetings
3. Public Comment
4. Committee Updates
5. Moving Forward in 2018

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

1. Introduction and Announcements

All meeting attendees were acknowledged. The Chair thanked the departing UNOS liaison for his service to the Geography Committee. A new policy analyst will be assigned to the Geography Committee moving forward.

2. Update on Regional Meetings

Data summary:

Leadership has been attending regional meetings and will have visited all regions by the end of this week. Regions have voted on the geography frameworks as proposed. Regions 1, 2, 5 and 8 support continuous distribution. Region 4 is split between all three frameworks. Region 6 had 22 votes for continuous distribution, but with 31 abstentions. Region 3 had majority vote for a fourth framework that they chose to add. Region 11 supported each organ-specific committee to support its own framework, and Region 3 supported this idea as well.

The fourth "framework" from a group at Vanderbilt and Emory is a state-based distribution which is actually a liver distribution policy proposal. Distribution would be based on the state in which the liver originates and then a halo of any and all states adjacent to any part of the border of the donor state being the first distribution zone for patients with a MELD of 35 or higher in this proposal. Then it would go to MELD 20-34 within the state, and then out for national sharing. They claim they modeled this along with the fixed distance model with Scientific Registry of Transplant Recipients (SRTR). Their conclusion is that it reduced the overall extremes of the changes anticipated in the fixed distance model, especially in regions 3, 6, 8, 10 and 11. It would be predicted to increase access in regions 1, 2, 4, 5, 7 and 9. They also claim a reduced number of discards, decreased air travel, and the most positive impact on length of waitlist for liver. They assert that national fixes to local problems hurt rural and minority patients, and worsens their survival and access to care.

There were themes to the comments provided by the regions. For the continuous distribution model, many were concerned that it would be too difficult to explain to patients. For fixed distance model, there was concern over population density variation across the country and about areas on the coast. One region felt the size of the circles should be similar or larger than

current circles allocation policy. The least amount of feedback was for the mathematically optimized model, but one comment was that it would be difficult to get consensus on supply and demand measures.

Additional themes of feedback were cost and availability of aircraft with increased air travel. Some felt each organ would need its own geography framework and that a uniform framework across all organs would not be realistic. There was concern that the Liver Committee proposal using fixed distance circles will not align with the geography framework approved by the Board of Directors and will need to be reconsidered in the future. Some felt the additional frameworks that were brought up by the regions should be considered. Others were concerned about considerations for the underserved populations.

Generally the regions acknowledge that the system does need to change, but they have had a hard time choosing because they need greater detail on each framework. There was concern over the makeup of the Geography Committee, that perhaps there was not representation from experts who are opposed to broader sharing. Another concern voiced was that perhaps it is outside the scope of the Geography Committee for them to be sponsoring public comment. Committee Leadership has been addressing all these concerns at the regional meetings.

Summary of discussion:

The Final Rule requirement is that distribution should not be based on candidate's place of residence or listing except to the extent required to avoid compromising outcomes, wasting organs, etc.. Use of DSA was found non-compliant with the Final Rule through litigation because DSAs are non-uniform, arbitrary and capricious distribution zones. They are neither rationally determined nor consistently applied. The state-based framework seems to work along the same lines, being based on place of listing, so it would be difficult to defend it as compliant with the Final Rule. With a federal system of allocation, distribution needs consistent units to meet the requirement that place of listing is used only for things like the potential to avoid wastage. When looking at the fourth framework, for example, Maine has a halo of one state, New Hampshire, and neither state has a liver program.

Unless there is a constitutional challenge to the Secretary of Health and Human Services' authority to regulate organ allocation, National Organ Transplant ACT (NOTA) and the Final Rule are predicated on that responsibility. States have rights to regulate other components of the delivery or payment of healthcare, but this is not relevant to the legal question of whether state-based organ distribution would be legally compliant.

From the standpoint of the Liver Committee, this fourth framework is no more compliant with the Final Rule than the liver policy that was passed last year that they were forced to replace.

3. Public Comment

Data summary:

Several hundred comments regarding the three frameworks have been received thus far, mainly from the transplant hospitals. The continuous distribution model appears to be the overwhelming favorite. There is a bit of support for mathematical optimization and small support for fixed distance. Again, there was comment of no support for all three models and the desire for them to be able to come up with their own model of distribution.

Summary of discussion:

It is anticipated there will be an increase in the public comment over the next week as the period for public comment comes to a close. History shows that the majority of comments from individuals will come in the last 72 hours.

There was question as to why Region 6's vote consisted mainly of abstentions. Region 6 has an unusual system in place for voting where some centers have more than one vote, so there is some disproportionate representation from some programs with more votes based on the size of the program. In addition, a thought leader in the community advocated for abstaining rather than voting on any of the three frameworks.

4. Committee Updates

Data summary:

Liver Update

The Liver Committee sent two different proposals in response to the lawsuit, which the full Committee will review today with SRTR. A public comment will start 10/8/2018, there will be a national webinar 10/9/2018, and then each region will give feedback and vote for one proposal. Then one policy proposal will be presented to the Board at their December meeting.

Thoracic Update

The thoracic Committee submitted their request for modeling to SRTR looking at various options for replacing DSA in a few areas of the policy dealing the allocation sequence, but not to change the actual allocation sequence itself. Analysis of other areas of policy relevant to heart where DSA might need to be replaced is ongoing, but this will depend on the distance chosen to replace DSA since heart-lung allocation is based on the sequence order.

They also discussed exceptions to heart allocation with ability to request approval to bypass candidates for an earlier allocation due to high sensitization. Lung previously recommended a similar policy for lung be eliminated. Instead, the Board approved an alternative in which a center could ask all centers above their candidate for permission to bypass at time of allocation, which the Committee felt was not realistically feasible. Thoracic is voting to strike the policy.

Kidney-Pancreas Work Group Update

The KP Work Group came up with important considerations for modeling, which should arrive around mid-November. One model includes fixed concentric circles (150/300 NM and 250/500 NM) with feedback from Geography Committee. SRTR indicated an additional variation referred to as the hybrid model, which was supported by the KP Work Group as variation that could be implemented as they move towards continuous distribution.

The hybrid would be 500 NM with a steep line, shallow line, or single circle. Outside of 500 NM is national allocation. For shallow/shallow linear variation 1 point would be awarded to candidate at donor hospital and 0 points to candidate 500 NM from donor hospital. Then 2 points at 501 NM, 0 at 2500 NM. Steep/steep linear variation would award 2 points to a candidate at donor hospital and 0 points to candidate 500 NM from donor hospital. Then 4 points to 501 NM, 0 at 2500 NM. Local and regional were combined into the 500 NM circle and national is outside of that. In model 1, there would be no proximity points, but a single 500 NM circle. Everything outside 500 NM is national. In model 2, there would be a single 500 NM circle with the shallow proximity points. In model 3, there would be a single 500 NM circle with steep proximity points.

Several metrics for SRTR modeling were discussed and they narrowed it down to 9 metrics based on what is available in SRTR at this time, including things like transplant rates and waiting list mortality rates.

Ops and Safety Update

Ops and Safety Committee is trying to get an assessment as to availability of airplanes and pilots. They plan to conduct interviews with every OPO and transplant centers in those DSAs where the OPOs don't handle transportation issues. So far 40 entities have been contacted.

They want to find out things like who is coordinating travel, how often they could not find a plane or only found a pilot, had to switch out flight teams due to time restrictions. The survey results once fully compiled will hopefully help guide decisions which ultimately need to be made by the organ-specific committees regarding the distance between flying and driving.

Summary of discussion:

It was noted by several committee members that this type of survey information is of minimal value since it is anecdotal and/or opinion vs. factual information.

One Committee member asked how the KP Work Group data collection might be used and how it would be helpful. Some believe that if the new allocation systems results in more flying, it will potentially increase cost, delay OR times, or the policies will not be initiated due to lack of planes or pilots. Because the analysis is not available yet, things may not dramatically change for the worse. Systems adapt in response to rule changes, so there should be caution in how the data is interpreted.

Another Committee member agreed and cautioned the Work Group to look at the denominator to the questions being asked that would be important in actually finding out the reasons for situations with the planes and pilots. The interviews are being conducted one-on-one, rather than an emailed survey, so as to ascertain the most relevant information as possible. The O&S committee wants to get an assessment on what the feeling was from different regions because they are very diverse. No pre-judgments will be made.

5. Moving Forward in 2018

Liver special public comment will start 10/8/2018 with final proposal to the Board for consideration in December 2018. Policies and bylaws removing DSA and region will be brought to the board in December 2018 for liver and in June 2019 for the rest of the organs. Heart, K-P and VCA proposals will be brought to the board for consideration in December 2018 and go out for public comment in Spring 2019.

The final decisions on frameworks proposal will be brought to the Board December 2018 as well. The big picture of why the Geography Committee was asked to put out the public comment proposal is really about long-term efficiency and compliance with the Final Rule for all organ allocation policies.

Upcoming Meetings

- October 23, 2018, 2 p.m. EST
- November 27, 2018, 2 p.m. EST
- December 18, 2018, 2 p.m. EST