**OPTN/UNOS Liver and Intestinal Organ Transplantation Committee**
**Meeting Minutes**
**June 15, 2018**
**Conference Call**

**Julie Heimbach, M.D., Chair**
**James Trotter, M.D., Vice Chair**

## Introduction

The Liver and Intestinal Organ Transplantation Committee met via teleconference on 6/15/2018 to discuss the following agenda items:

1. Finalize Comments for Executive Committee Review

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

## 1. Finalize Comments for Executive Committee Review

Data summary:

HRSA requested an opinion from the OPTN on whether the following four aspects of the liver allocation policy passed last year are aligned with NOTA and the Final Rule:

1. Using DSAs as units of allocation
2. Using OPTN regions as units of allocation
3. Using proximity points in relations DSAs
4. Using median MELD in DSAs as a basis for exception scores.

The committee discussed this question on the last call and continued the discussion on this call.

The timeline was presented. The Policy Oversight Committee will review the Committee's comments this afternoon and will forward their feedback to the Executive Committee (EC). The EC will meet June 18 to review the draft, with final approval of the letter on June 22.

A map of the Donor Service Areas (DSAs) was presented. The DSAs don't always align with state borders. Information was provided about the population, land area, and population density of each DSA. In general, when population is lower, DSA is larger and when population is higher, DSA is smaller. However, this is not always the case. The average land area is 6,000, as opposed to the almost 200,000 land area for the sparsely populated areas. The DSA is definitely not perfect, but there are some benefits to using DSA for allocation.

Summary of comments since the last meeting was reviewed. There was support for the work that the Committee went through to in regard to the policy of December 2017. It did attempt to balance efficiency and minimizing discards with decreasing disparity based on a candidate's location. There was support for Option 1 (continuing to support the policy that was passed last year), while committing to move forward on refining and improving that policy. There was recognition that DSA/regions are not optimized for organ distribution, but there was some support for efficiency provided by the DSA. Others commented that it's difficult to make a change to a policy not yet implemented and not using the same process that was used to create the policy. The Committee would commit to implementing new ideas once they've seen the initial changes (support for Option 1).

NLRB will also make an impact on organ distribution, which will happen in the same timeframe. It is unclear how the Median MELD at Transplant (MMaT) be determined. The Committee could propose using the region, since the 150-mile circle is based on donor hospital location.

There would be increased logistical issues if changes to sharing are made. There is some data to back up the decision to select out the organs already selected for a different allocation pathway (the MELD 15 threshold). It was reiterated that the committee members need to make sure the views of the liver committee are represented and not their personal views.

A high-level overview of the three potential options was again presented, with the goal of the committee making a recommendation to the EC regarding how to respond to HRSA by Friday:

Option 1: the current plan is and is not compliant with the final rule.

Option 1.5: move forward with current policy, but remove the threshold to minimize role of DSA. In new policy, it would be argued the region is region plus circle, which is different from the region.

Option 2: the current policy would not be recommended because it does not meet the component of the final rule.

Based on the Chair's discussions with the EC and OPTN leaders, feedback was requested from the committee on 8 points. The goal of this call is to provide feedback on the proposed points below:

1. Status 1 and MELD/PELD greater than 32 are allocated initially to region and then to the circle. Any changes to this should be carefully considered and not rushed. This is supported.
2. It is best to move to better models. One would be to change the parameter of the model already selected by making the circle bigger, by lowering the sharing threshold, or joining adjacent DSAs to improve upon the current system. Another would be to move to a new system, such as heard from the Geography Committee, such as circles or borderless system. The goals would be to reduce disparity while considering valid geographic restrictions, like those outlined in the final rule. This is supported.
3. Removing or diminishing use of the DSA in that range/dropping the threshold immediately. There is mixed support for recommending this change.
4. Removing the DSA prioritization for DCD and age 70 or older donors. Those who commented wanted to keep this in place until the System Optimization Group finishes a new policy.
5. Using a different unit than the DSA for the MMaT calculation for the exception patients. This could possibly be done, perhaps using region instead.
6. Removing region from allocation. General agreement that under current proposal region plus circle is a good step.
7. Removing proximity points from the DSA or the circle and the circle. There were mixed opinions on this.
8. When can the Committee replace DSA/region by? A timeframe will depend on whether or not the Committee is trying to modify the system already passed.

Summary of discussion:

Dr. Chapman asked if the implementation of the plan passed could be sped up under the premise that the changes will be made and assessed looking at potential unintended consequences, cost impact, and transportation impact. The Chair stated the initial plan was to

implement the NLRB and the new policy in October. Due to difficulty with education NLRB was moved to December. One staff member stated it would involve 8 large IT projects, so on the implementation side, October would be the soonest possible.

One Committee member suggested obtaining data about the impact moving to larger circle based distribution has had on lung candidates. Leadership has not seen increase in discards. There was a little different shape to the geography with a 250-mile circle. Most earlier logistical issues have settled out. The data will can be distributed to the Committee. For the lung, the federal judge and the DOJ lawyers felt the DSAs and the regions were not compliant with the final rule, but there was no official ruling from the judge on this.

The Chair pointed out that in the new policy the most important difference in liver and lung is that the liver is first allocated to the most urgent patients over a more broad area than either the region or the DSA.

The Committee discussed the 9 discussion items one by one:

1. Committee unanimously agreed with item 1.
2. Committee agreed with item 2. A member requests tracking of costs and travel specifically in this process. For his center there's been a dramatic increase in travel and cost due to changes to lung allocation. Another member suggests defining the word "disparity," as it has caused contention the past 2 years. The Chair understands disparity as access to transplant for patients on the waitlist. It could be changed to variability in access to transplant. This will be discussed in the future.
3. Item 3 would change the threshold and change the current policy, reducing the role of the DSA. The Committee understands more changes need to come, but huge unintended consequences could occur. Although the DSA could be eliminated altogether, going back to DSA plus circle, the Committee needs to respect the process and not lose credibility with the members. There was agreement with this view, but a committee member had concerns with going down to 15. For the large percentage of really marginal organs, to tell the OPO community that they have to through the region one by one, that could cripple their work with organ use consequences.

Another member advocated for sharing down to 15. UNOS staff members supported replacing DSA with a better proxy for local to the donor, rather than just eliminating. Prioritizing candidates does have positive effects on waitlist mortality. Moving from a share 32 concept to a share 15 is a larger conversation and not necessarily what is being requested right now. It's just trying to explain the use of the geographic units in allocation. The question is whether or not the DSA needs to be the unit when one comes out of that classification down to MELD 15. The Chair reiterated the Committee doesn’t have a shape of 75 miles or 85 miles. They could continue with the policy or deemphasize the DSA in the policy to avoid going to court.

One member added that the Committee's done a diligent job of process, public comment, and discussion. The committee was hesitant to abandon that process without any idea of what might happen in court.

The commitment to continue to move has to be faster than what was demonstrated in the past. The current policy stated that the Committee would continuously monitor the process and make appropriate changes as needed. If a date is added, then the Committee would have to come up with something whether it's relevant or not. The chair agreed they don't need to come up with a date, but definitely a timeline.

One Committee member asked how long the policies have to be in place to start generating data for analysis. The Chair stated they already know what MMaT is supposed to be for every

OPO, so the Committee can figure out what could be done and what the impact would be. This could be done as soon as the NLRB agenda items get done. One Committee member suggested something could have something based on the modeling prepared 6 months after implementation.

One UNOS staff member stated if there is DSA in the policy 6 or 12 or 18 months from now, there is a potential that a judge will rule against them in the future. The longer that potential exists, the higher likelihood that potential is realized. If the Committee decides to look at 6 months and then start a process without some kind of commitment that the next process won't be 5 years, then outside intervention likelihood is high. Ultimately it should be decided through review and community input, so time needs to be left to do that. This does not need to be finalized at this meeting.

One member felt a judge wouldn't care about community feedback, but it should be emphasized that the community are practitioners who take care of patients and deal with the organs. The Committee was in agreement that they would want to prepare the strongest argument to defend their proposal, but they wouldn’t want to take a stand that makes them feel good about it while the policy gets changed by a judge.

The Chair summarized that the Committee supports the process, but there remains concern about eliminating the process and going with something that wasn't developed in a consensus way. They want to retain control of the process. They were in agreement that there are ways to change the current system that are significant and that could be done in the fall. That could be part of the presentation to the EC, that the policy has strengths to it. There are things that could be done to improve upon the policy, as in Option 1.5, but Option 1.5 does not have broad support from the Committee.

A timeline commitment will be important in reducing the Committee's risk. The Committee needs some data back from the new policy that validates the modeling.

Next steps:

The Committee's timeline would include summer. They could try to make the three changes to the model now so that the modeling is available as quickly as possible. The Chair will finalize the comments with the help of Dr. Trotter and keep the Committee updated.

**Upcoming Meeting**

- June 21, 2018