OPTN/UNOS Liver and Intestinal Organ Transplantation Committee
Meeting Minutes
June 13, 2018
Conference Call

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Introduction

The Liver and Intestinal Organ Transplantation Committee met via teleconference on 6/13/2018, to discuss the following agenda items:

1. Distribution Frameworks

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

1. Distribution Frameworks

HRSA seeks OPTN's view on how new policy that was passed is aligned with NOTA and the Final Rule on four points: using Donor Service Areas (DSAs) as units of allocation, using OPTN regions as allocation, using proximity points in relation to DSAs, and using median MELD in DSAs in granting exceptions.

Executive Committee (EC) reviewed the letters and the Liver and Intestinal Organ Transplantation Committee will meet again Friday to give feedback on the four points to the EC. The Policy Oversight Committee will review feedback and send comments to EC. The EC will review the feedback, edit and draft letters and then make a final approval before providing the letter to HRSA.

Summary of discussion:

The Committee's responsibility is to make a recommendation to the Executive Committee by June 13th on how they should respond to the letter. The Chair received this request 3 days ago and came up with a few ideas. This could be done by 1) discussing how the current plant (passed in December 2017) is compliant with final rule and it allocates to the most urgent candidates in a larger area and has components that could be changed or 2) to say that the current plan was selected after a thorough process and represents a compromise that is a stepwise improvement over the previous system, but was not compliant with the final rule.

A third possible option, an option 1.5, could be the current plan, but removing the DSA component by eliminating the threshold of 32. It could continue for the region plus the circle from Status 1 all the way down to 15. Exception patients would have to be put into the system at some point.

One Committee member didn't agree with the wording of either option saying "compliant" or "not compliant" with the final rule. The complaint that is being made in the letter is that the DSA is not logical to distribute organs for multiple reasons. Both options just have to do with the entire allocation plan not being compliant with the final rule. It is difficult to defend the DSA as a unit of distribution based on its size, shape, continuity, the fact they don't take ranges of population or geographic areas into account regarding organ distribution.

The Chair reiterated that the DSA could be taken out of the policy, meaning that there is no threshold after 32 and use the circle and region for the whole thing. The proximity points do not need to be addressed. Also, measuring by the median MELD at transplant in Option 1 is

controversial and shouldn't be the only metric. Perhaps there should be a different approach to measuring access to transplant.

One Committee member suggested that regarding DSAs, no one wants needless excessive travel (which would be inefficient), so that component should still be encouraged. Population and geographic points don't always make sense. Not including DSA was discussed by the Committee before coming up with the proposal. It was a 150-mile circle. One consideration was to use the circle, not the circle, and/or the DSA.

One member suggested the Committee could keep the proposal and endorse it as compliant (as shown on last slide); leave it, but reduce DSA as a functional unit by dropping MELD; or change DSA to a circle or a region. But the Committee would need to be prepared to replace everywhere it says DSA with the word circle or region and define the distance of the circle or region.

The Chair pointed out the liver policy is more complicated than lung and they could recommend to consider one of the previously-modeled solutions with some time to do that. Liver's policy is not just region because they have the biggest circle. Regions have some inequity. She also reminded everyone that at the bottom of page 2 of the letter they sent is not just whether the proposal is consistent with the final rule, but in relation to the revised OPTN policy passed in December.

The Committee members felt the issue is more legal than medical. DSAs are only used because they're expedient. Is using a DSA in a UNOS region in line with the final rule? Is it in line with equitable liver allocation? The answer is no.

Several members worried this was just an attack with the Committee's policy and that they should defend it. They worked on it for a year and it was the best they could do under the circumstances. If they don't defend it as is, the Committee will lose control of the process and of the next policy iterations. One member wanted to make sure that part of the final rule was to keep the number of transplants the same or increase the number. The policy can be defended by saying the wider you go, the more you'll lose organs.

The Committee members then went back and forth regarding DSAs:

One member said circles would have the same problem as DSAs, so the only real solution is a national list, but another disagreed with a national list and thought that DSAs are a legally valid measure consistent with the final rule. Another member suggested using the components of the plan they came up with, keeping the sharing threshold at 32, but not necessarily keeping the DSA. They could work on a population-based model for the future. Another member agreed DSAs are not correct, and they should work on building a system that doesn't rely on that.

The Committee originally liked the 150-mile circle because at least it's based on distance, which is a surrogate of time that it takes. When they first discussed doing 11 regions with a circle, they compared that to the concentric circles and looking at data in terms of how mileage worked and flying. One member suggested 150 miles, no DSA, and share 15, followed by national. However, there may be difficulty using the word "local" because it has specific meaning in terms of policy. Local in the Pacific Northwest is 1,500 miles. Local does not equal DSA.

A member of the committee asked how a high-acuity MELD 35 patient would fit into the 150 miles and if there would be region for those. The Chair said right now it's allocated to the whole region plus 150 miles down to 32, so it could become the region plus the circle all the way down to 15.

This far there was no discussion on NLRB and the median MELD and DSAs in terms of granting exceptions. They could make the median MELD the NLRB score and everyone has the same score for exceptions.

The Committee then discussed the threshold of 32 or 29 before it goes back to the DSA. There is a threshold of going down to 15 to go outside of DSA, beyond your region. This is another area that could be tweaked to help that with the notion of arbitrary borders. Another member felt there could be a medical MELD 40 that goes to 250 miles, so it would advocate if they cross over the river, they have access to that organ. Without median MELD at transplant, there may be places with very high MELD exceptions compared to other places. The Chair said it would just be whatever the median is in the region plus the circle.

A committee member stated that the Committee should acknowledge that the Department of Justice's view that the use of DSA in the Lung Allocation Policy was indefensible because DSAs for distribution are not rational, as there's no logic to the way they're configured. He thought there was no provision to take care of the high-acuity patients in lung, as was put in with liver, so the liver situation is more defensible.

This fall, three models will be proposed by the Geography Committee, so it may go back to the Committee to start over. A committee member asked if the idea is that there would be one allocation system that goes to all organs of that allocation. The Chair said they agreed it would be fixed boundaries or circles, but not that the same-sized circle would be used for everybody. It could be a population circle for one organ and a fixed distance for another organ. Therefore, if a fixed distance is adopted, then all the models would have to fit in that.

Next steps:

The Committee will meet again Friday to finalize comments to EC. If they go with Option 1.5, they will have extra time to finalize the model. The Chair will make a revised draft based on today's comments and will send it and the slides to the Committee members for further feedback at the next meeting.

Upcoming Meeting

- June 15, 2018