OPTN/UNOS Liver and Intestinal Organ Transplantation Committee Meeting Minutes July 10, 2018 Conference Call

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Introduction

The Liver and Intestinal Organ Transplantation Committee met via teleconference on 7/10/2018 to discuss the following agenda items:

- 1. Choosing a Circle Concept to Model
- 2. Option 1
- 3. Option 2

1. Choosing a Circle Concept to Model

Data summary:

The committee considered three frameworks for allocation using concentric circles with the goal of choosing which framework to request that the SRTR model.

Option 1 Key Points

An acuity circle concept, this system would adjust to population density. Livers would be allocated in circles of 150, 250 and 500nm (or 150, 300 and 600nm), in bands of 3 MELD points, and in sparse areas it would go to the larger circles, while in densely populated areas it would start with the smaller circles. The range is similar to the proximity points.

Option 2 Key Points

This would be simply replacing DSA with a 150nm circle and region with a 500nm circle around the donor hospital. It would be a big circle for 1As and 1Bs and a big circle of 500 nautical miles down to MELD 32-40 (32 is what was passed before). To go to 35 would be less sharing than is done under the revised policy of December 17. For candidates with MELD of 15-31, back to the 150 circle, and then 500 for the circle with MELD 15-31. The 32 threshold remains, but it doesn't consider population density.

Option 3 Key Points

250nm circle for MELD down to 32, then smaller 150nm circle, and then to national offers.

All Options

There is the option with these concepts to continue to treat DCD and over 70 year old donors differently to account for less tolerance of ischemic time in these organs. It would also be possible to introduce the concept of pediatric donors going only to children all the way through the national system without going to adults, except for 1As. Awarding exception points is a complex question that will be answered in the future.

Summary of discussion:

Members of the committee were concerned that it would be difficult to choose a concept without being able to compare the actual impact of both through modeling results. They asked the SRTR if it would be possible to request 2 models. The committee members expressed a preference for having more data in the form of modeling results for two versions even if it meant

that there was less time to discuss, since the discussion would be more informed. The SRTR explained that even if they had 3 more weeks to complete the modeling request, it would not be possible to model two different concepts in that time frame. Committee members also expressed a desire for a way to measure the changes to costs of procurement and transplants in the modeling so that they could attempt to avoid a change that would create too much inefficiency or decrease the number of transplants.

The members discussed the proposed models and the options for medium circle sizes of either 250 or 300 and large circle sizes of either 500 or 600nm.

A member suggested that rather than clumps of 3, it would be easier to argue a 36 MELD and a 37 MELD may not be different in terms of degree illness. She recommended 29-34 and then 15 to 28. It would be the same circle, but wider tiers.

A member asked about donor hospitals compared to procurement centers. The Chair said the previous policy, which was discussed as well, defined donor hospital as the hospital where the donor originated. Oftentimes the recovery center is in a bigger city. When the donor is removed from originating hospital, if the donor travels 300 miles to get to the recovery center, it could advantage the center that's next door. The decision to have it around the donor hospital was based on perceived fairness.

Another member pointed out CMS has already ruled that the donor location is the recovery center. CMS as part of the agency background has already made that ruling. The Chair said there are also other areas of UNOS policy where there is discordance.

Committee members discussed including larger circles as well, but decided that there was not enough difference in the efficiency of recovering a liver from 800nm away and one that is 1,500nm away because in either case, it is a significant flight. In both cases, a more desirable liver can handle the cold ischemic time. The committee members agreed that it was appropriate to group the national offers together once the 500 or 600nm threshold was passed. Currently, 95% of livers are transplanted within 598nm of the donor hospital, so the committee felt comfortable with a large circle around that size in order to avoid wasting organs or inefficient placement.

2. Option 1

For Option 1, a member commented that because of the smaller number of transplant centers that take care of children and the smaller population in general, when considering pediatrics the Committee recommends that they be included in this planning, and that probably the wider circles will be most relevant for allocation to children. In this model the Committee would recommend 1) the wider circles would be pertinent mostly to pediatric recipients and that 2) pediatric donors that are most commonly used for children, the 500 circle will be more relevant. Because of the smaller numbers of pediatric candidates, there was less need for the smaller circles.

For every group of MELD scores, it would go out to progressively larger circles before dropping down to the next lowest group of MELD scores. A member felt this would function differently from the system everyone is used to. It would mean the allocation system is different. The benefit theoretically would be that in the dense area one would not need to travel as much because there would always be candidates of the various MELD levels in the circle.

A member felt Option 1 would be closer to a two-district model with some local priority for the smaller circles. Many times there won't be a Status 1 or MELD 40 in the local circle, but there may be in half the U.S. The large number of centers and donors would lead to logistical issues. Another member pointed out that 600 nautical miles would be the longest the organ would

travel. All centers in the 1,200 nautical miles would be at play, but only when there's nobody in the 150-mile circle. The distinction between the radius and the diameter of the circle was important to the discussion of how the circle sizes are tied to efficient travel.

The concept of the acuity circle is that it prioritizes the most efficient placement (closer to the donor) among the candidates with similar need, and when there is need defined by high MELD, the liver is able to travel further earlier.

3. Option 2

Option 2 would use the current policy, except places that said "region" would be replaced by 400 or 500 nautical miles, and places that said "DSA" would be replaced by 150. The liver would be shared in the larger circle first in status A1 and AB as currently done, but in the same larger circle one would go down to a certain threshold, which was proposed to be 32 because of the policy passed in December 2017. Then it would go to the 150-mile radius around donor hospital for patients with 15-32. Then it would go to national status (1A, 1B) and then national patients with at least a MELD of 15. Then it would go back to 150 for MELD under 15. The size of the largest circle needs to have patients in it.

A member stated that whether it's 250 or 500 miles of MELD 35-40, the highest acuity patients would attract a larger circle so they can get transplanted. If there are no patients in highest need, it goes down to 150 miles or MELD of 15. Then it goes to a 250-mile circle and then 400 or 500. All components of the final rule need to be taken into account, including underserved populations. Another member pointed out that Option 2 would have to model cities versus rural areas. Very sick patients are more likely to be in cities, so cities may take up the donors before they get out to the 250 or 500 circle. A liver may not reach someone with a MELD of 37-39 in a rural area. One Committee member expressed concern over the fact that someone with a MELD of 16 would get a liver within 150 miles prior to someone with a MELD of 31. There needs to be efficiency in organ utilization with marginal organs so an optimal organ won't go to a 16 in somebody 150 miles away. All aspects need to be looked at.

One Committee member asked if there was a role to ask the Scientific Registry of Transplant Recipients just to make an educated guess about how the two models would work. The Chair will reach out to the SRTR for feedback.

A poll was held to see which of the two options the Committee would want to model. The results were 11 Option 1; 1 Option 2; 1 Unsure.

One Committee member felt there would be a lot of support to have two plans that are in many ways similar: circles, different sizes, and a little different algorithm on how they're implemented.

Next steps:

Group leadership will figure out what the next step is. The modeling request should be finalized to SRTR by 7/13/18. The Chair will be available phone or email if Committee members have further comments.

Summary of discussion:

The acuity circle model will be 500 miles for the region and 150 for the Donor Service Area (DSA). This would require the 500-mile circle to hit someone with a MELD of 37-40. Still there may be no candidate in that circle because oftentimes there is no high-MELD candidate in the region. Only if there was no candidate in either of those circles would it go to the bigger circle. This is all around the donor hospitals to the edge of the circle.