OPTN/UNOS Liver and Intestinal Organ Transplantation Committee
Meeting Minutes
July 19, 2018
Conference Call

Julie Heimbach, M.D., Chair
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Introduction

The Liver and Intestinal Organ Transplantation Committee met via teleconference on 7/19/2018 to discuss the following agenda items:

1. Welcome and Announcements
2. Review Modeling Request
3. Exception Scoring Discussion

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

1. Welcome and Announcements

Data summary:

A lawsuit has been filed. There was no change in the Executive Committee's (EC) request of the Board, which was to revise the Liver Allocation Policy to reduce disparity and remove DSA and region from the policy. The lawsuit contends that the issue is that the current policy and the policy passed in 2017 are non-compliant with the final rule. The EC has asked the Liver Committee to eliminate those policies and develop a new one that would be compliant with the final rule. They feel that using the DSA for allocation places too much emphasis on geography without tying it to a basis that is supported by the final rule, so geography may not be a consideration except how it is related to the four or five points listed in the final rule and the principals of organ allocation passed by the board last year.

2. Review Modeling Request

Data summary:

The Chair presented the Board directive that the Committee received in June. The Committee was asked to provide input to EC, who was asked by HRSA to provide their input. The feedback provided by the Committee to the EC defended the policy passed in 2017, which was a compromise that had components that were compliant because of use of a circle plus a region. The Committee presented a timeline with steps for policy monitoring and modifications to be made over time. The EC responded with an expedited timeline.

The Geography Committee is working simultaneous to the Liver Committee with three different frameworks. If they happen to select a framework that is not the one the Liver Committee is working on, the Committee may have to make further changes to liver allocation in the future.

The Timeline was presented. The modeling request was finalized after input from several people. Dr. Shah did a lot to work through the second model with feedback from others. The modeling will come back for the Committee to review on a conference call. One model will be chosen to go out for special comment October 8 through November 1, 2018. Then based on public comment review and the Committee's view at the face-to-face meeting November 2nd, it may go to the Board for consideration on December 2nd.

Variables have been modeled for each of the frameworks:

1) Model 1. Acuity circles with two different sizes. For livers from non-DCD donors and donors at least age 70, it will go to a different scheme that mirrors as best it could the scheme that was passed in the fall, which had it going to the DSA first. Essentially after the Status 1s to the DSA, the 150-nautical mile circle would be the closest thing there is to the DSA. There will be many hospitals where the 150-nautical mile circle does not encompass any listed transplant patients at any centers. Then it would go to 250 or 300 and then 500 or 600 nautical miles, followed by national.
   With pediatrics, it could be modeled in the same way it is now. Children would have the same sort of circles. Feedback stated that it would be valuable to have a bigger circle from the start. UNOS staff and SRTR agreed. Also, pediatric donors will be modeled going through all children in the country before coming back to any adults, except for Status 1.
2) Model 2. This is the second circle model, currently called "the ladder" because it goes up and down. It starts with the big circle around the donor hospital 500 nautical miles and then goes to 250 nautical miles for two different thresholds. The variable that was changed in this model was either a variable of MELD 35 or a threshold of MELD 32 for that circle of 250 nautical miles around the donor hospital. Then it goes to 150 around the donor hospital for a group of patients at MELD 15 to either 34 or 31. Then it goes back up again, same group (MELD 15 to 34 or 31) for 250 nautical miles and then 500 nautical miles. There was consideration for having different circle sizes depending on how many donor hospitals fell within the circle, but that was not something that could be modeled with LSAM on an expedited timeline, so the modeling request was adjusted. The model keeps the DCD donors and the age of 70 in the circle over 150 nautical miles, as the old policy did. There is the possibility this will be less sharing in some areas of the country than is done now with share 35. In some areas of the country actually more than this is being shared. The policy would be easy to defend, but the Committee would just have to monitor its performance. The fact that it is not following DSA and region, it might be effective in reducing disparity in ways they're not envisioning.

Summary of discussion:

There were concerns expressed about the speed required to make this change, and discussion about the reasoning behind the change. This particular lawsuit is comprised of people from several different states who feel they are disadvantaged by the current liver distribution policies. First, they claim DSA and regions are not compliant with several laws. Second, they are asking the Committee not to implement the new liver policy, but a zone-based liver distribution policy. The EC has charged the Liver Committee with putting forth a proposal for special public comment to the Board. The Committee wants the transplant community and the OPTN to set the direction for the distribution policy and therefore needs to move forward the putting forth the best proposal possible that the Board can adopt and can be implemented quickly. There was concern that if the Committee was unable to reach a recommendation, a federal judge may ultimately order a change without considering the liver transplant community’s input.

One Committee member stated the lawsuit claims are about a national system. While there may be benefit to one area versus another area of the country, despite the fact it's originating from a law firm in New York, a federal court has jurisdiction. Therefore, the Committee should focus on how these changes would impact the national distribution system and whether they're consistent with federal regulations that govern the national system. There were concerns expressed that the expedited timeline puts the process at risk for being unsuccessful or have serious unintended consequences.

There was discussion about Model 1 staying closer to the December 2017 compromise agreement, and speculation that it might be more acceptable to the community.

Going to circles will be a big change for liver allocation. There was some discussion about whether it would be wiser to send two models out for public comment instead of just one, in case there is widespread opposition to the model that is put out.

The Chair reminded the Committee that the goal is to improve disparity, which was also the goal when they first started the process back in 2012.

The Committee discussed whether it would be possible to allocate livers nationally, without using any smaller units of distribution at all. The difficulty in doing this would be the logistics related to that which would create inefficiencies and potentially increase the number of organs discarded.

Next steps:

Additional questions can be forwarded to the Chair.

3. Exception Scoring Discussion

Data summary:

For the modeling request, HCC exception scores will be capped at 34 as they are today. Well over 50% of exceptions are HCC. For remaining ones, the current scoring will be used, where the patient goes up every 3 months and it's not going to be capped. This will allow for cleaner comparisons to prior models and the current system.

Summary of discussion:

There was discussion about whether the modeling should only use lab scores above a certain threshold, like what was passed last December, or whether it makes sense to cap extension scores instead. There has not yet been time for the Committee to discuss how MMaT will change, or where a cap would be set. Further, past modeling has not looked at changes to the exception scoring in conjunction with changes to allocation, so it will be easier to compare if allocation changes are modeled without changes to exception scores.

There was also discussion about what are to use for calculation of MMaT. Region was considered as a way to transition to another unit such as state, 300nm circles, national, or other areas. Moving to national MMaT basis was considered problematic because it would not affect patients the same way, since MMaT and supply and demand ratios vary so much depending on location. The Committee agreed that it would be important to figure out how it would work to have the unit for MMaT different than the unit for allocation, so that similar patients in the same allocation unit may have different scores. It would be important that exception patients aren't disadvantaged or advantaged at transplant programs in higher- or lower-MELD areas.

Next steps:

The Committee will start to develop what it would look like around the country to go to a national MMaT and whether to keep the elevator with a cap. Leadership will get feedback on what is an acceptable geographic unit, such as squares or states. A summary of different options will be put together for the next meeting.