OPTN/UNOS Liver and Intestinal Organ Transplantation Committee
Meeting Minutes
July 31, 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 07/31/2018 to discuss the following agenda items:

1. Introduction
2. Exception Scoring
3. Other Significant Items
4. Review Metrics for SRTR Modeling Request

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

1. Introduction

Data summary:

The overall goal is to make a policy that is compliant with the final rule, specifically about the geography issue. The timeline was presented:

- Modeling request is finalized to SRTR, which is the two different circle models.
- Since new policy does not have DSA, exception scoring must be changed.
- Following regular public comment, there will be a special public comment specifically about the new liver policy on October 8th through November 1st.
- Face-to-face meeting will be on November 2nd with a vote to move the new policy out of the Liver Committee and to the Board of Directors for consideration.
- Board of Directors Meeting will be December 3rd.

2. Exception Scoring

Data summary:

The ideal would be a national Median MELD at Transplant (MMaT) as a solution to the need for exception. However, until similar equilibrium is reached, this would advantage exception patients in the lower MELD areas because they would be national, and disadvantage those in the higher MELD areas. Fixed score (which was previously set at -3 from MMaT) in a high MELD area would be a problem.

One option would be to go back to the MELD elevator, but would cause concern for MELD inflation and disadvantages to the non-exception patients. These concerns might be handled by a lower cap (currently 34), but there would still be the problem of the high and low MELD areas, where some areas wait 20 months and others only 8 months.

There needs to be a solution for the interim until the new policy is in place in the future. Possible solutions are:

- National MMaT with a safety net elevator. A patient that has not been transplanted after a certain period at the exception score, would move to elevator until transplantation.
- MMaT over a smaller area. This would function similarly to using DSA or region. There was concern that an allocation circle might encompass two different areas with different MMaTs, but people are accessing transplants at different times (even if scores are the same, waiting times are different). Therefore, the circle could be enlarged around the transplant hospital for purposes of calculation of MMaT, not allocation.
- MELD elevator with a cap.
- Open to any further new ideas.

A map with the 250- and 500-NM radius circles throughout the country was presented, with the dots representing transplant centers. The idea is that the scores of all transplant centers within a circle would contribute to the MMaT calculation.

MMaT calculation ranges calculated by DSA, region, and transplant center were presented. The ranges of MMaT centered at a transplant center that include all transplant centers within a certain distance do level out a bit from MMaT.

Further data presented included graphs of the distribution of MMaT for each transplant center, rather than the 58 DSAs. The Committee was given time to look over the graphs. There are 143 different transplant centers. When looking at MMaT by transplant centers within 150 NM, many are still close to 28, which is the MMaT for the nation. A graph for 250 NM was also shown. The data excluded national shares and Status 1s, as well as living donors, but included donors over 70. Data including living donors or DCDs do show a similar trend and will be provided to the Committee.

Summary of discussion:

One Committee member asked if a circle around a transplant center would mean assigning a median MELD for each transplant center that would be used for a specific patient with that condition who is coming up on the list. The Chair clarified that would be the case, and in addition would be recalculated every 6 months. The challenge would be for smaller-volume centers.

One Committee member asked if the median MELD minus some number for exceptions would be seen. The Chair stated that the old policy for National Liver Review Board (NLRB) was MMaT -3 for the area of distribution, but the Committee could choose a different number. The focus was on trying to reduce MELD inflation. Therefore, if median MELD ever went down, median MELD -3 would get lower over time and drive it down.

Another Committee member pointed out with the overlap in circles, that if one was in the center that was going to have the median MELD and maybe in an area that had to use more exceptions or didn't use exceptions, it has the median MELD for the same condition 3 points higher than the other. This model would not eliminate a situation such as this. The Chair agreed, but stated this situation would not be very common since it is tight together. Depending on the model chosen, which circle the offer is being allocated in, and where the exceptions are capped, there could be a circle where two patients have the same condition, but different scores. However, this is not so different from two patients with different waiting times for HCC. Over time the median would become more and more similar and the problem would go away.

One Committee member brought up that the elevator is just a surrogate for waiting time and should not be put back in. The Chair stated that it would only be used as a safety net to the possible national MMaT because there areas patients would not have access to transplant because their median MELD in the area they are allocated was higher than the national.

Another Committee member recognized that one principle in this modeling was trying to have some recognition of policy by the public, so agreed with the use of median MELD, rather than an elevator. The Committee should try to be as true to the current NLRB proposal as possible. The smaller circle of 250-NM is probably more true to the idea of median MELD for a local area. Another member thought the 500-NM would make more sense since everything would be changed in the new model.

One Committee member asked if there could be a minimum number of centers or transplants in circle. One suggestion was a 250-NM circle that includes more than 3 centers and if not, then go out to whatever distance it takes to get more than 3 centers. The Chair clarified that the current task at hand is to fix median MELD and not to allocate at this time. Allocation would be a different circle, which would be around the donor hospital. This is different than the circle around the transplant centers when talking about exception patients. This would be a step in coming to the national similar scores, but going right to the national MMaT would overly advantage the low-MELD at transplant areas, creating a need to address the disadvantaged high-MELD patients.

Outliers were discussed. When looking at the map of the circles, there were at least two or three centers where there would be only one transplant center within a 250-mile radius. Outliers seem to be Portland, Seattle, Salt Lake City, and Denver. From the map it looks like there is a cluster of programs with a median MELD of about 34 for the 500 circle and 36 for the 250 circle. One program on both models has a median MELD of 17. In one model there is a low MELD next to a high MELD. The data presented showed ordering based on MMaT in DSA. Puerto Rico was low when based on DSA and still low when centered around transplant centers.

One Committee member asked if it would be possible to calculate the MMaT for the allocation circle on a dynamic basis. One important point is the allocation circle will change based on which hospital it is, meaning people in disparate areas could have dramatically different median MELDs. The 250 miles with no elevator may work, but if using national MMaT, there must be an elevator due to tremendous differences in exceptions for HCC in different places.

Another Committee member suggested a model which would involve choosing basic centers to normalize the process and therefore eliminate the need to recalculate every time. For instance, there could be three different transplant centers in the mix for an allocation circle that otherwise would not have been together; take all three of those centers and pick the highest one. Basically, there would be two different groups, and there would be different median MELDs in different groups. Pick one group and use it as a reference point for the whole circle. It could be that the MMaT of the closest center to the donor hospital would rule. The suggested model caused some confusion. The Vice Chair agreed that this would be a dynamic way to handle exceptions based on matching those with the allocation, but this would not be feasible. It cannot be done in real time. The Chair stated that standard MELD exceptions are set by policy and are all median MELD -3 for adults. The previous guidance was written in reference to the standard. The majority of exceptions would be the same, but some would be different.

Next steps:

Staff will distribute the data and graphs requested, including those presented today, to the Committee members for further consideration. Any further objections or ideas to the ultimate goal of MMaT should be sent to the Chair.

3. Other Significant Items

Data summary:

The Committee received a response from the Secretary of the HHS regarding the critical comment related to liver distribution. The letter will be distributed to the Committee members. The Secretary has taken an official position that the use of DSA and region in organ distribution, specifically liver distribution, is not consistent with the requirements under NOTA and OPTN Final Rule. This is the premise of critical comment and the litigation that is before the Committee.

The Secretary also laid out a timeline in line with the Liver Committee timeline, namely getting the modeling request (already done), have public comment, and then the decision being made at the December 2018 Board of Directors meeting. The letter also included comments related to the NLRB and liver distribution that were already passed by the Board of Directors.

Summary of discussion:

One Committee member asked if there are any comments about the amendment to NOTA that was in process. It was clarified that there is currently competing legislation to amend NOTA regarding organ allocation. But since it takes time to change laws, all the committees will move forward to be in compliance with current laws.

One Committee member commented that the Committee needs to make decisions about organ distribution right now, but there's a bigger conversation going on about this. The issue is not necessarily the how that is important, as it is the who gets to make the decision. It is important that the transplant community of volunteers and experts be allowed to work together through the committee and the Board to make these decisions in the future without interference by legislature or HRSA and HHS.

4. Review Metrics for SRTR Modeling Request

Data summary:

Priority metrics for SRTR were presented, which are actually ones that have been used before. SRTR will provide data, but not as detailed as reports received in the past due to the expedited timeline. Importantly, additional subgroups for SRTR metrics are DSA, urban/city, insurance status, and community risk score (CCRS).

Summary of discussion:

The Vice Chair asked if discard rates could be requested from SRTR. The Chair stated that transplant count was more of a focus in the past, rather than discard rates. Another staff member recognized the model used by Liver Simulated Allocation Model (LSAM) for discard use is simple. Once a certain number of offers or data exceptions is reached, it is discarded, so there is not much data about predicting discard rates under changing circumstances. Therefore, rates that are a better measure of what is likely to change in the system, rather than LSAM creation of discard rate, will be provided.