OPTN/UNOS Executive Committee
Meeting Minutes
January 25, 2019
Teleconference

Sue Dunn, Chair
Maryl Johnson, Vice Chair

Introduction

The Executive Committee met via teleconference on 01/25/2019 to discuss the following agenda items:

1. Emergency Proposal to Amend MELD Exception Score Transition in NLRB Implementation
2. Executive Committee Discussion and Vote

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

1. Emergency Proposal to Amend MELD Exception Score Transition in NLRB Implementation

The Chair welcomed the Committee to this emergency meeting being held based on timing of the implementation of National Liver Review Board (NLRB) policy. The Committee is being asked to consider an emergent change to the transition plan the Board approved in December and which is set to go into effect on 01/31/2019.

The Committee must consider:

- Overall impact to patients
- Transparency of the deliberative process
- Risk to the organization
- Faith in the national transplant system from community and public at large

Proposal to Amend MELD Exception Score Transition in NLRB Implementation

Data summary

The Chair of the Liver & Intestinal Organ Transplantation Committee presented the proposal.

In June 2017, the NLRB policy was approved, in which patients who cannot be allocated with a MELD score, are given an exception score on a national level, or a fixed score just below the median score required to access transplant for the area of distribution. At that time, the primary area of distribution for liver was DSA, so that policy was not implemented. In December 2017, a liver distribution policy was approved involving the region plus extra 150 nm circle from the donor hospital, but which led to a lawsuit in May 2018.

In May 2018, a new liver distribution policy was developed and approved in December 2018. However, the NLRB scoring system based on Median MELD at Transplant (MMaT) -3 for most patients for DSA had to be changed to no longer be based on DSA. The solution was a 150 nm circle around the transplant hospital for the purposes of calculating the local score required for a patient to be expected to get a transplant. The NLRB is a complex proposal with many moving parts and program differences, and the distribution policy is also very different from what was done in the past. The LIVER COMMITTEE felt it would be helpful for the NLRB scoring system

to be in place so that the new distribution policy would be using those scores, rather than the old scores.

When they looked at the 250 nm circles center by center, they found that there are multiple centers within the same DSA with some having different MMaTs. This occurs in four DSAs. This will be an issue during the transition period when allocation is still done by DSA and circle-based MMaT. There will be a conflict because patients being allocated within the same area will have a different fixed score that will not change. Therefore, for exception patients in the affected DSAs, all the livers will go to the transplant program with the higher score only.

A 250 nm circle around the transplant hospital includes programs not within the DSA, but in neighboring regions possibly with lower scores. This would cause the program's score to be lowered relative to the other programs in the DSA not within the 250 nm circle of programs outside the DSA.

The Liver Committee considered five different options as solutions to the problem.

- Option 1 is to use the DSA for calculating the MMaT minus some amount (usually -3).
- Option 2 is to manually adjust for the affected four DSAs so that they all have the same MMaT, allowing the circle-based model for NLRB to start as planned and considering the interest of the patient.
- Option 3 would be to delay the NLRB until the distribution policy is implemented.
- Option 4 is to make no changes, allowing for a specific cohort of patients to have a fixed score below others in the same area of distribution.
- Option 5 is to go to the national MMaT during the transition period, but there are differences between programs throughout the country.

The Liver Committee ultimately voted unanimously to recommend Option 1, the continued use of MMaT in the DSA during the transition period (January 31st to April 30th) until the circle-based allocation is implemented.

Summary of discussion

One Committee member asked if the issue is one that could not have been predicted by the Liver Committee due to not seeing the data. She agreed that it could not have been predicted.

Another member asked how the NLRB transition plan might have been written differently if all the data were available. It does not make sense to use two different systems, so MMaT -3 for distribution would be used, which is the way it was always written. The main justification for NLRB was a national system to prevent regional differences when sharing outside of the region. Then in order to account for score differences in different regions, a new scoring system was developed.

When going to the new allocation, there will still be an overlap of transplant hospitals and different donor hospitals so one member brought up the concern that the same issues will continue in the new system. It was clarified that every circle in the new system will be a different area. In a DSA, the only way to get a liver on a system that is allocating only within the DSA, is based on the score. The reason one would get a liver under the new system is because someone at the other program is in a different circle. The circle changes every time, so a program in the DSA with a different score will not matter because allocation will be by circle and not DSA.

For example, the Liver Committee Chair is 75 miles from the University of Minnesota, whose score is different from her score because her 250 nm circle would be around Chicago. Chicago

patients have a lower score than Minnesota patients. Therefore, for all patients including NLRB, livers from Chicago will go to her patients, livers from Indiana will go to Chicago, and patients in Rochester will go to the University of Minnesota, but she can still get livers from Illinois, but University of Minnesota cannot. Under the DSA system, the only offers the Liver Chair's candidates would see would be from the DSA because if there is a patient with a higher score that will never be lower than the other patients, then the other patients will never be offered a liver. The Executive Committee Vice Chair reiterated that some of the problems currently being discussed will not go away until after some time when the MMaTs are uniform across different centers. Under the new system, it's hard to predict what patients in bigger cities have donors available.

Another concern was the issue of eliminating DSA and region from allocation. For clarification, the DSA would still exist, just not be used in allocation. This issue would only be a problem until the new allocation system is implemented.

The Executive Committee Chair directed Committee members to the mini brief, which includes a graphic of the centers around the donor hospital compared to circles around the transplant hospital.

One member wondered how many transplants would occur during the 3 months of the transition period since it seems like it would be a very small number. The number of patients affected today would be 184 patients. All those affected would have to have their scores adjusted, but not all would be transplanted. A manual adjustment of the scores so that median is the same for the DSA for those small numbers was an option discussed by the Liver Committee, although the question they had was whether to adjust upwards to match the highest or downwards to match the lowest. They decided not to recommend this option due the possibility of the community perceiving the adjustments as devious and just trying to make changes to things.

The Executive Committee Chair asked if the Liver Committee discussed the 2018 HRSA directive to the OPTN to eliminate the DSA in allocation and the risk of going counter to that directive during the transition period. The Liver Committee did not feel that was a concern, given that DSA would still be the unit of distribution during the transition period and therefore it would not be inconsistent.

One Committee member understood the transition period was not just in case the policy was complicated or allowed for adjustments to be made, but that actually the community and Committee had concerns that all the candidates in a broader sharing system need to go through the National Liver Review Board and have more consistent scores. Therefore, simply delaying implementation of NLRB would be contrary to the expectation of the community.

The Liver Committee worked with IT on the scenario of rolling out NLRB and the new policy together so everyone gets a score at the same time, but it did not seem to be a workable solution. Therefore, they agreed that every time a score has to be renewed (which is every 3 months) or new scores given under the new system, then everyone would hit the NLRB at least once and would have a new score of MMaT -3. Again, manually adjusting the scores up or down will likely cause some concern. Going to the national MMaT will likely overly advantage some exception patients and overly disadvantage some others.

One concern was over possibly giving an advantage to people currently on the list during the transition period and perhaps new patients added should not get such equivalent scoring/elevation above those who have been waiting because that might dilute people who feel the DSA is against protocol. However, this would not seem to be a risk while allocation is done on the DSA. With the circle-based model, there will be slightly different exception scores, so some advantages and some disadvantages, but at least some chance to get an offer.

Another question was whether the Liver Committee considered the relative chance of getting an offer at different MELD levels. For clarification, the issue at hand pertains to the exception patients only, so it is possible some areas will have no exception patients transplanted. However, nationally about 35% of patients are done with an exception score. In any given transplant, a high MELD patient will be transplanted first and the organ will only go to the exception patient if there is no regional patient with a MELD above 35. If program A has no exception patients, then program B or C can get an offer. As long as there is even one exception patient, then the other patients will not be able to be transplanted during the transition period.

One suggestion was to adjust the six programs, which would be the smallest number to do an adjustment to make every program within each DSA have the same MELD scores. This seems fair from an access standpoint.

Given the fact that the solution is for a temporary problem, one Committee member suggested deferring to the expertise of the Liver Committee is probably best. In the case of manually adjusting scores, the concern is that people come up with all kind of stories and filling in the blanks as they will. During discussion at this meeting today, nothing was uncovered that the Liver Committee previously missed. Therefore, she felt the Executive Committee should support the Liver Committee and the recommendation they unanimously voted on. Six other Committee members voiced their agreement with supporting the recommendation.

Another member agreed with supporting the Liver Committee, but felt they should be careful with how they present the solution to the transplant community. Her criticism was not of the Liver Committee, but of how data is obtained. For example, in December they wanted data on a threshold of 29, and it was rejected. A request for center-identified data is something that was not done in the past. UNOS staff clarified that center-level data could be supplied to the committees instead of center-identified data, and that is what happened in this situation. This is because Committees should not be making decisions about impacts on individual members, but should be setting national policy.

The Executive Committee Chair agreed with the comments, but was still concerned about their HRSA directive to eliminate DSA in allocation policy. However, the risk will be minimized as long as they have considered all the factors and concerns about process and transparency in the system and because the transition period is temporary. The Liver Committee Chair does feel that if they had the data on this issue sooner, they would have still recommended the same solution. Therefore, this issue remains in the realm of allowing clarification of an existing policy without additional public comment.

The Executive Committee Chair asked if HRSA had any comments to share. A HRSA staff person encouraged the Committee members to consider all risks in any decision and has been consistent in deferring to the OPTN's clinical expertise. They want to be sure the OPTN is following the appropriate process and considering transparency for the community. This policy change would be reordering the allocation of livers from what the Board approved and would be doing so without the opportunity for public comment. HRSA reiterated that this is critical to consider.

The Committee Chair asked whether HRSA thought it would be better to delay implementation since the option of having a system in which patients could not have access to transplant is unacceptable. HRSA agreed that taking no action is far from ideal but will defer to the OPTN on exactly what action is taken. The HRSA staff person reiterated that considering patient access, safety as well as transparency in the process and public faith in the system.

The UNOS General Counsel also spoke to offer that OPTN Bylaws do provide that public comment can appropriately be waived where it's a proposal only to clarify or correct existing policy rather than changing the intent of the policy. The Liver Committee Chair had noted that this decision would have been made if center-specific data had been available at the time. She also noted that the original proposal from June 2017 included this system to include the area of distribution (not the transplant hospital).

The Executive Committee Chair thanked HRSA for their comments and reiterated that it is clear that this was the Liver Committee's intent from the beginning.

2. Executive Committee Discussion and Vote

Summary of discussion

The Executive Committee Chair asked for a motion and a motion was made for the Executive Committee to approve the proposed change to NLRB implementation policy.

A roll call vote was taken and the results were as follows: 11 approve; 0 no; 0 abstained.

Next steps

UNOS staff will talk with the communications team about vehicles for reaching out to people to make them aware of the change, which was the concern mentioned during the roll call vote. This is an adjustment of the implementation phase so that the implementation of the NLRB matches the geography of the allocation system as the allocation system is changing and so that there are no separate geographies. The NLRB scoring process will begin, but NLRB geography will begin the same time the geography changes in distribution occur.