

OPTN/UNOS Liver and Intestinal Organ Transplantation Committee
Meeting Minutes
November 15, 2018
Conference Call

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Introduction

The Liver and Intestinal Organ Transplantation (Liver) Committee met via teleconference on 11/15/18 to discuss the following agenda items:

1. Intestine Bylaws Update
2. Exception Cap Discussion
3. Region 8 Variance Questions

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

1. Intestine Bylaws Update

UNOS staff provided an update on the implementation of the new intestinal transplantation program requirements.

Summary of discussion:

In 2015, the Liver Committee created membership requirements for intestinal transplantation programs. Prior to these requirements, the only requirement for a hospital to have an intestinal transplantation program was to also have a liver program. UNOS has been implementing the new requirements over the past year, and the programs that have been able to meet the requirements will go to the Membership and Professional Standards Committee (MPSC) on November 20, 2018 for approval. At the time this occurs, the Bylaws will go into effect and any new programs will need to meet the updated requirements.

Prior to the meeting, UNOS staff provided the Liver Committee with a memo updating them on the status of the implementation process. Forty intestinal transplantation programs had a status of "active, approval not required" before the new membership requirements were implemented. Fifteen of these programs submitted opt-out forms, saying they would not be applying for an intestinal transplantation program. Programs that do not submit an application or do not meet the requirements will be withdrawn at the time that the Bylaws go into effect. These programs will have the opportunity to re-submit an application at any time, however. Twenty-four programs have performed at least one transplant in the last five years, and 16 are likely to be granted full or conditional approval at the MPSC meeting.

One of the Liver Committee members asked if there have been any issues with medical directors being able to observe isolated small bowel procedures, which is one of the requirements. Another committee member noted that experienced medical directors are being forced to observe organ procurement procedures, which is logistically difficult. UNOS staff noted that the required procedure observations are additional work. However, under the new Bylaws, programs can have conditional surgeons and physicians, who have three years to get full approval. Some programs did not perform enough transplants to satisfy the new requirements, but the programs that do the majority of intestinal transplants will be approved. The chair summarized the committee's feedback by stating that the requirement for medical directors to observe an isolated small bowel procedure is difficult and potentially unnecessary. The committee suggested that the procedure observation requirement be for any intestinal organ as

opposed to a specific organ and the procurement procedure observation requirement be for any procurement. A committee member asked for more details on the conditional approval status and reiterated his/her difficulty in observing an isolated small bowel procedure.

Next steps:

The committee asked UNOS staff to share the committee's thoughts to the MPSC and report back to the committee.

2. Exception Cap Discussion

The committee discussed the Model for End-Stage Liver Disease (MELD) or Pediatric End-Stage Liver Disease (PELD) cap for exception candidates in the allocation policy titled "Liver and Intestine Distribution Using Distance from Donor Hospital" that is going to the OPTN/UNOS Board of Directors on December 3, 2018.

Summary of Discussion:

In the new proposed allocation policy, the committee decided on an exception score cap at MELD/PELD 28. The chair of the committee stated that she thought this cap was an oversight in the proposed policy. In the National Liver Review Board (NLRB) policy, exception scores are based on the Median MELD at Transplant (MMaT) within 250 nautical miles (nm) of the liver transplant program. Status 1 transplants, transplants from donors over 500 nm away from the recipient, transplants from living donors, and transplants from donors after cardiac death (DCD) are excluded from the MMaT calculation.

The chair presented data showing that some DSAs have a MMaT higher than 31. In the soon-to-be implemented NLRB policy, all standard adult exceptions are set at MMaT minus three, except for oxalosis and Hepatic Artery Thrombosis (HAT). This means that in areas where MMaT is greater than 31, standard exception scores will be above the MELD/PELD 28 cap. These areas would need to have the standard exceptions be MMaT minus four or five instead of three.

Additionally, the MELD/PELD cap for oxalosis patients is MMaT. However, if these patients are in an area where the MMaT is above MELD/PELD 28, then their exception score would be capped at MELD/PELD 28, which will make it difficult to access liver-kidney donors which are allocated at 250 nm at the MELD/PELD 29 threshold. There are only about 30 of these patients each year.

The chair summarized the issue by saying that the NLRB policy set the standard exception score at MMaT minus three and the exception score for oxalosis patients at MMaT. However, the new distribution policy set the exception score cap at MELD/PELD 28. For oxalosis patients, if they are listed in an area with a MMaT higher than 28, they will not be able to have their exception score set at MMaT and they could lose access to livers. Additionally, some areas have a MMaT at MELD/PELD 31 or higher, so the MMaT minus three would be above the cap at MELD/PELD 28. Standard exception patients in these areas would not be able to have their MELD/PELD score set at MMaT minus three.

The chair stated that the committee could remove the exception cap or they could move the cap to MELD/PELD 34. Modelling predicts that MELD scores will decrease with the implementation of the NLRB so this problem will get better with time. Another option is to set the standard cap at MMaT minus three.

Other committee members shared that this situation was not an oversight but was actually the intent of the policy. Exception patients have historically had a higher transplant rate so they thought exception candidates should have their scores capped at 28, one MELD point below the

250 nm distribution circle for candidates with MELD/PELD scores of 29 or higher in the proposed distribution policy, so they intentionally do not have access to the 250 nm circle.

The chair of the committee presented data showing that the transplant rates for Hepatocellular Carcinoma (HCC) and non-HCC candidates are becoming more even. Transplant rate is not a perfect metric however.

The chair also shared data from a paper that compared the incidence of wait list dropout for HCC patients in short, medium, and long waitlist areas. The incidence is the lowest in short wait list areas. Survival probability also varies across the different waitlist lengths.¹

The chair presented four options to the committee. Option one would be to remove the cap altogether. The second option would be to change the exception cap to MELD/PELD 34. The third option would be to have an exception cap at MMaT minus three for standard exceptions except for oxalosis and HAT candidates. And the fourth option would be to exclude oxalosis patients from the cap requirement.

A committee member suggested changing the sharing threshold from MELD/PELD 29 to MELD/PELD 32 as a solution. However, the chair said that this is not an option because the sharing threshold is already part of the policy that was presented to the Board Policy Group and Executive Committee. This could be changed at the Board meeting, but it cannot be changed by the Liver Committee at this time. A committee member stated that the biggest problem is that patients with the same condition will have different exception scores. This is true regardless of the exception cap issue.

Another committee member suggested changing the standard exception score to MMaT minus six. The chair stated that this change would be substantial enough to be an amendment at the Board meeting. A committee member asked if it would be possible to first execute a match run for non-exception candidates with MELD/PELD 29 and above that are within 250 nm of the donor hospital and then, if that list is exhausted, execute a match run including the MMaT minus three exception candidates with no cap. The chair said that this is not possible.

A committee member stated that the original intent of the policy was to ensure the proper priority for lab MELD/PELD candidates. Additionally, the committee noted that the cap only affects a few areas of the country and the issue is not widespread. The affected areas are primarily Region 5 and Region 8. However, another committee member stated that this is not the case because distribution goes out to 500 nm.

A committee member asked if HCC exception patients would get transplanted more quickly in the areas of the country where the cap would have an effect. The chair stated that they will not be transplanted before other candidates because they are in a high MELD area. A committee member asked for data on the number and/or percent of exception patients listed at the transplant centers in each of the affected regions.

A committee member asked if MMaT across the country could get higher by the time that the new allocation policy is implemented. The committee member was concerned that MMaT will increase by the time that the new allocation policy goes into effect. The chair noted that exception candidates will cycle through the NLRB within the first three months after its implementation so the MMaT should not increase. Another committee member stated that a floating MELD cap would alleviate this concern. However, a floating cap at MMaT minus three

¹ Mehta et al., "Increasing Liver Transplantation Wait-List Dropout for Hepatocellular Carcinoma With Widening Geographical Disparities: Implications for Organ Allocation." *Liver Transplantation* 24, no. 10 (October 2018): 1346-1356 <https://doi.org/10.1002/lt.25317>

would have exception patients in high MMaT regions above the MELD/PELD 29 sharing threshold.

The chair reminded the committee that they will be monitoring the effects of the NLRB so if anything unexpected is happening, they can seek to delay the implementation of the new allocation policy. A committee member stated that the percentage of transplants that were for exception patients in Region 5 was about 20% in some donation service areas (DSAs) up to 38% in other DSAs. This data is from the old allocation system that relied on regions and DSAs.

A committee member suggested delaying implementation of the new allocation policy until at least six months after the NLRB goes live to allow for two cycles of the exception patients. The chair stated that the idea of more time for implementation of the allocation policy may be helpful based on when NLRB is implemented.

A committee member noted that there is not much difference between removing the cap and having a floating cap at MMaT minus three. The committee member suggested allowing candidates to have an exception score above the set cap if MMaT in their region is well above the cap. The chair stated that this idea is vague and does not have the necessary justification. The chair reiterated that the issue being discussed only affects Region 5, Region 8, and oxalosis patients.

The NLRB is targeted to go live early in the first quarter of 2019. There is no set date for implementation of the new allocation policy.

A formal vote was taken regarding: do you want to remove the cap completely?

Results were as follows: 9 Yes (64%); 5 No (36%); 0 Abstain

Ultimately, the committee approved removing the cap because doing so provides better access for all liver candidates on the waitlist, rather than prioritizing non-exception candidates. Because this option was approved, the other solutions were not considered.

Next Steps:

The exception cap at MELD/PELD 28 will be removed from the proposed new distribution policy.

3. Region 8 Variance Questions

The committee did not have time to discuss the Region 8 variance. The chair will send the slides and revised proposal to the committee for review.

Upcoming Meeting

- December 7, 2018