

**OPTN Liver and Intestinal Organ Transplantation Committee
Meeting Minutes
March 21, 2019
Conference Call**

**Julie Heimbach, MD, Chair
James Trotter, MD, Vice Chair**

Introduction

The OPTN Liver and Intestinal Organ Transplantation Committee (hereafter, “the Committee”) met via teleconference on 03/21/2019 to discuss the following agenda items:

1. National Liver Review Board (hereafter, “NLRB”) Transition

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

1. NLRB Transition

The OPTN Executive Committee sponsored a public comment proposal titled, “MELD Exception Scores during NLRB Transition.” This proposal intended to address the issues raised during the transition period between the implementation of the NLRB and the Acuity Circles distribution model (hereafter, “AC”). The Committee sponsored both the NLRB and AC policies and has been highly engaged in the OPTN Executive Committee’s current public comment proposal. As such, the Committee met to discuss the NLRB transition plan and provide a recommendation to the OPTN Executive Committee on a path forward.

Summary of discussion:

The NLRB Subcommittee met earlier to create a recommendation for the full Committee on how to handle the transition period between NLRB and AC implementation.

The Chair noted that there are two other subcommittees working on different aspects of AC policy.

The Chair presented data on the public comment feedback on the proposal thus far. Many of the comments, especially the comments in opposition, were related to the general NLRB, not specifically the transition period. Four different amendments were proposed at regional meetings. Two regions supported using a national median model for end-stage liver disease (MELD) at transplant (MMaT) once the NLRB is implemented. One region supported a return to the December 2017 Committee proposal. And one region suggested that all non-standard exception forms be reviewed during the transition period. The NLRB Subcommittee determined that it is not operationally possible to review all non-standard exception forms during the transition period. A Committee member from this region noted that the important point is that there are approximately one thousand non-standard exception patients that should be reviewed prior to implementation of AC. A Committee member noted that the MMaT across the nation is already starting to equalize, which makes using a national MMaT more appropriate.

The American Society of Transplantation (AST) was opposed to the proposal as written. Instead, they proposed to either delay AC implementation so there is a three month transition period between NLRB and AC or to reset all exception scores to MMaT-3 for the 250 nautical mile (NM) circle around the transplant hospital at the time that AC is implemented.

Other regions supported using a 500NM circle in the ongoing NLRB. The Chair noted the general suggestion to use a larger geographic area than the 250 NM circle to calculate MMaT.

This could be an early change that the Committee proposes to make to the NLRB system after implementation.

Themes in public comment related to the transition period were:

- Concerns about not having a lot of time between decision and implementation with an April 2 NLRB implementation date
- Preference for either a 3 month transition or simultaneous implementation
- Recommendation to use MMaT for the transplant hospital
- Recommendation for the exact MMaTs by donation service area (DSA)
- Recommendations to convert scores or have NLRB review all scores before Acuity Circles take effect

Themes in public comment related to the ongoing NLRB were:

- Concerns about the MMaT system in general (needs modeling, impact on certain communities, should exclude exception scores)
- Preference for 500NM circles (instead of 250NM)
- Preference for national MMaT
- Recommendation to include nourishment in MELD calculation

The Chair noted that if the NLRB and AC are not implemented at the same time, it will be impossible to rank candidates' base on time at score or higher. The Chair outlined a scenario where Candidate A is granted an exception before Candidate B and after implementation of both NLRB and AC, they end up at the same score. However, because of the transition period, Candidate B has more time at score or higher and is therefore listed higher than Candidate A. This advantage would last beyond the transition period and it is not what the Committee intended when they passed the original NLRB proposal. This issue would occur even if scores were converted upon AC implementation. If both AC and NLRB are implemented at the same time, then this issue will not occur. The Committee had previously opposed implementing the two systems simultaneously only because it would mean having two changes going live at the same time.

The Committee initially suggested a three month transition period because it would allow for all exception candidates to cycle through the NLRB at least once. If NLRB is implemented April 2, 2019 and AC is implemented April 30, 2019, then candidates will not be ranked appropriately due to the situation described above. Also, candidates' scores will be changed more than once which could be confusing. There would also be less time for communication if NLRB were to be implemented on April 2, 2019.

The NLRB Subcommittee recommended implementing both AC and NLRB at the same time so that candidates can be properly ranked by time at score or higher. The NLRB Subcommittee also recommended systematically converting scores upon implementation of the two systems.

The NLRB Subcommittee recommended converting candidates according to the plan outlined below:

- Conversion of adult exceptions
 - Convert standard and "looks like standard" to MMaT-3, except primary hyperoxaluria which will get MMaT
 - Convert non-standard exceptions from MELD 22-39 to MMaT-3
 - Do not convert non-standard scores of MELD 40 or MELD less than 22. Candidate score would remain what it was prior to implementation.

- Conversion of adolescent exceptions
 - Convert standard and “looks like standard” to MMaT, except primary hyperoxaluria which will get MMaT+3 and hepatocellular carcinoma (HCC) which will get MELD 40
 - Convert non-standard exceptions from MELD 22-39 to MMaT
 - Do not convert non-standard scores of MELD 40 or MELD less than 22. Candidate score would remain what it was prior to implementation.

- Conversion of pediatric exceptions
 - Convert standard and “looks like standard” to median pediatric end-stage liver disease (PELD) at transplant (MPaT) except primary hyperoxaluria, which will get MPaT+3
 - Convert all non-standard exceptions to MPaT

A Committee member asked what “looks like standard” means. The Chair stated that these are exception forms that fit into the standard criteria but were not categorized as such in the system.

The NLRB Subcommittee felt that candidates with non-standard scores from MELD 22-39 were likely assigned a score in this range because they were similar to standard exception candidates. This is why the Subcommittee recommended converting them to the same score as standard and “looks like standard.” These candidates would still have the option to ask the NLRB for a different score.

On the other hand, the NLRB Subcommittee felt non-standard candidates with a MELD less than 22 should not be converted because the regional review boards (RRBs) likely felt that these candidates did not need the same priority as standard exception candidates. The Chair clarified that candidates with the same MELD score would still be ranked by time at score or higher. If two candidates have the same MELD and time at score or higher, then the tiebreaker would be time with an exception.

A Committee member asked if time with an exception score below MELD 22 would count as part of this tiebreaker. UNOS staff stated that it would count. The Committee member felt that this should be changed so that time with an exception only accrues when the score is 22 or higher. The Chair stated that the use of this tiebreaker will not happen often.

The Chair asked how candidates with an exception score for HCC in the early stages of the MELD elevator will be converted into the new system. UNOS staff stated that these candidates would use their lab MELD score. The Chair asked if it would be possible to rank these candidates according to their time with an exception instead of by their MELD. UNOS staff and the Chair agreed to discuss this issue at a later time.

The Chair asked if there are any PELD scores that should not be converted. For example, scores of MELD 40 will not be converted because RRBs granted this exception score so that the candidate would get higher priority. Many PELD candidates are granted exception scores higher than PELD 40 so that they also get priority. Therefore, the Chair wanted to know if scores higher than PELD 40 should be converted to MPaT or left where they are. A Committee member noted that many of these pediatric candidates are granted Status 1B so he or she did not think there was a certain PELD threshold above which scores should not be converted. Another Committee member noted that the MPaT for the nation is lower than it should be because Status 1B candidates are not included in the calculation. Very few pediatric candidates are transplanted at their calculated PELD score, so it is important to rank the exception candidates correctly in relation to other exception candidates.

A Committee member noted that PELD scores vary across the country. Another Committee member suggested that PELD 40 be the threshold for conversion. The Committee member stated that RRBs typically grant exception scores higher than PELD 40 only for very sick candidates. Therefore, candidates with an exception above PELD 40 should not be converted and should keep their RRB-assigned score. A Committee member noted that there are not many candidates with a PELD higher than 40. The Committee member agreed that candidates with a PELD greater than 40 should not be converted and should keep their RRB-assigned score. UNOS staff stated that, on any given day, there were 41 non-standard PELD exceptions higher than 40. UNOS staff asked if there was any concern about converting PELD scores that are particularly low to MPaT. The Chair stated that this is not a concern. The Committee agreed that candidates with an exception score of PELD 40 or higher should not be converted.

The NLRB Subcommittee also recommended that programs submit all exception forms prior to the seven day period before implementation. However, the RRBs will still try to approve any forms that come in during this timeframe. If the RRB cannot get to a pending form before implementation, non-standard forms will be routed to the NLRB for review and standard forms will be withdrawn and the program will re-submit so that the form can be automatically approved. UNOS staff stated that it would be possible to route standard forms to the NLRB with a requested score that aligns with NLRB policy. The forms would need to be reviewed by the NLRB but this would prevent programs needing to withdraw and resubmit forms, which could lead to a candidate being downgraded. Programs could still withdraw and resubmit under this scenario.

A formal vote was taken: Do you support the transition and conversion plan as discussed. Results were as follows: 8 (100%) Yes; 0 (0%) No; 0 Abstain

UNOS staff reminded the Committee that public comment closes on March 22, 2019. UNOS staff will send any additional public comments to the Committee for consideration.

Next steps:

The Committee's recommendations will be presented to the Executive Committee during their next meeting.

Upcoming Meeting

- April 8, 2019 – Chicago, Illinois