OPTN/UNOS Liver and Intestinal Organ Transplantation Committee
Meeting Minutes
September 4, 2018
Conference Call

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Introduction

The Liver and Intestinal Organ Transplantation Committee met via teleconference on 09/04/2018 to discuss the following agenda items:

1. Introduction
2. MMaT cohorts
3. Cap on Exception Scores
4. Other NLRB Subcommittee Recommendations
5. Hawaii Variance
6. Region 9 Variance
7. Proposed Region 8 Variance
8. Exceptions Scores Relative to MMaT
9. Pediatric Exceptions for Metabolic Disease

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

1. Introduction

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

a. Modeling report will be back from SRTR the last week of September

b. Following regular public comment, there will be a special public comment specifically about the new liver policy on October 8th through November 1st.

c. 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.

d. Board of Directors Meeting will be December 3rd.

2. MMaT Cohorts

The NLRB met to review the number of centers and transplanted patients that would be included in the circle sizes considered for each age group and made the following recommendations to the full committee.

- For patients with MELD scores (12 years old and older), the median MELD at transplant would be based on all MELD scores within a 250nm circle, excluding organs allocated from outside the largest circle (either 500 or 600nm, dependent on the model chosen), living donors and DCD donors.
- For patients with PELD scores (under 12 years old), the median PELD at transplant would be calculated based on all the PELD scores in the nation, excluding organs allocated from outside the largest circle (either 500 or 600nm, dependent on the model chosen), living donors and DCD donors.

<u>Summary of discussion:</u>

The committee agreed with the recommendation of the subcommittee. There was discussion about the choice of 250nm instead of 150nm. The subcommittee recommended 250 based on the fact that the resulting median score for each hospital is similar, but a score based on 250nm circles is expected to be slightly more stable than a smaller circle.

When circles of 500nm were considered, the resulting scores were very close to the national median. This was avoided because the goal of using a median MELD basis at this time is to adjust for candidates who would otherwise have limited access to transplantation because they are in an area with a high median MELD at transplant.

Committee members agreed with the subcommittee's recommendation.

3. Cap on Exception Scores

The NLRB subcommittee recommended capping exception scores for standard exceptions at 32 in the acuity circles model and 31 or 34 in the laddered circles model (depending on whether the MELD threshold of 32 or 35 was chosen).

Summary of discussion:

The committee supported the recommendation of the subcommittee.

4. Other NLRB Subcommittee Recommendations

Further recommendations of the subcommittee are summarized in a document that was circulated prior to the committee meeting (Appendix I). There were no questions or comments about the recommendations on the call. Committee members were encouraged to read over the recommendations and send any questions or comments to the chair or the liaison.

5. Hawaii Variance

There is an existing variance that permits allocation of blood type O donors simultaneously to blood type compatible and identical liver candidates within the DSA. In removing DSA from policy, how should this policy be addressed?

Summary of discussion:

The committee supported keeping the spirit of the variance and changing it so that it referenced either the state or the 500/600nm circle instead of the DSA. There was discussion about whether the variance should also apply to Puerto Rico, since it is also geographically isolated. However, since Hawaii is significantly farther away, the committee chose to proceed with keeping this variance for Hawaii alone at this time.

6. Region 9 Variance

Region 9 has a variance that uses the region as the first unit of allocation instead of the DSA. In removing DSA from policy, how should this policy be addressed?

Summary of discussion:

The committee supported ending this variance since DSA and region will no longer be used in allocation.

7. Proposed Region 8 Variance

Region 8 has requested a new variance that would allow livers recovered and transplanted in the region to be split, and the remaining segment or lobe to be used for another patient at the splitting hospital or an affiliated hospital. It would be limited for a period of 2-3 years as a demonstration project to try to increase the number of transplants. Region 8 fully supports this

variance and would like to see it included in the proposal going out for public comment in October.

Summary of discussion:

There was discussion about whether it was appropriate to have a variance based on a region when allocation is moving away from the use of DSAs and regions. Some members expressed concerns about how it would be difficult to explain, while others suggested that it would be good to have a variance like this included in order to show that a variance for a specific area can still exist within this new approach to distribution.

One member asked if it should be an open variance, and allow any hospital in the nation to participate. Several committee members stated that while they would support this variance in an area that wanted it, they would not want it in their region.

Members were concerned with making sure that the remaining segments would be offered to status 1A and 1B patients as well as higher MELD/PELD patients (above thresholds in the low 30's) before they would be allowed to be retained at the splitting hospital.

Members discussed the idea that this variance may encourage splitting, with some members thinking that other hospitals would want the remaining segments, and others suggesting that it might encourage splitting instead of cutting livers down to fit in some situations.

The committee stated that there would need to be clearly defined outcome measures, including measures of whether the splits are tri-segments or right/left.

Overall, the committee was supportive, with some reservations, and wants to proceed to request approval to proceed with this project from the policy oversight committee. The committee agreed that there were still some details to work out if it is approved.

8. Exceptions Scores Relative to MMaT

The committee reviewed the scores as proposed in last year's NLRB policy change. The NLRB subcommittee recommended keeping the score relative to MMaT the same (-3 in most cases). The one exception was a recommendation that pediatric patients with an exception based on HCC auto-approval criteria receive a set score of 40.

Summary of discussion:

The committee was supportive of the subcommittee's recommendations.

9. Pediatric Exceptions for Metabolic Disease

The NLRB subcommittee suggested that it may not be necessary to assign a MELD/PELD exception score for 30 days and then a score of Status 1B to pediatric patients with metabolic disease, but instead allow them to be listed at 1B initially. The committee reviewed the numbers of patients transplanted at each status with a metabolic disease exception, and the numbers were small (60 or fewer total per year), with approximately 78% transplanted at 1B.

Summary of discussion:

One of the committee members who is very familiar with these patients was concerned that there are very different kinds of candidates with metabolic disease diagnoses. Some are very sick and very fragile, and would absolutely be appropriate to be 1B immediately. Others are not as fragile and probably should only ever receive a MELD/PELD exception. The conversation was tabled for consideration on a subcommittee call in greater depth.

Next steps:

Subcommittee will consider this question and report back a recommendation to the full committee on its next call.

Upcoming Meetings

- September 18, 2018
- September 25, 2018
- September 27, 2018

Appendix I

NLRB Subcommittee Recommendations

10. Define MMaT Cohorts

The subcommittee considered four options for what age group cohort to use to calculate median MELD at transplant (MMaT) for the different ages of candidates, grouped into children under 12, 12-17 year olds, and adults. Due to the small numbers in each population, the subcommittee recommends that:

- all candidates with a MELD score (12 and older) have MMaT based on all MELD scores in a 250nm circle,
- the basis for the median score at transplant in reference to candidates under 12 be the median PELD score in the nation
- Both calculations exclude organs allocated from outside the largest circle (either 500 or 600nm, dependent on the model chosen), living donors and DCD donors.

11. Adjusting exception scores

The subcommittee recommended that all exceptions automatically adjust relative to MMaT when MMaT is recalculated

12. Cap

The subcommittee recommended capping exception scores at 32 in the acuity circles model, and 31 or 34 in the laddered circles model (depending on which version is chosen).

13. MELD Transition Language

There is a clause in Policy 9.1.D that was placed in policy to explain how candidates would be handled in a prior transition. It is no longer applicable, and policy would be clearer if it was removed.

The subcommittee members recommended removal of this language.

14. Times

Time periods are currently written in terms of days or months or hours. It is recommended that they be changed to all give times in terms of days.

The subcommittee members recommended that timelines be listed as days.

15. MELD Transition Language

There is a clause in Policy 9.1.D that was placed in policy to explain how candidates would be handled in a prior transition. It is no longer applicable, and policy would be clearer if it was removed.

The subcommittee members recommend removal of this language.

16. Downgrading & Recertification

Currently, when a candidate is downgraded from a status 1A or status 1B to a MELD of 25 or greater (regardless of whether or not the candidate's lab score is current or has expired), the system accounts for a grace period of 7 days to benefit sickest patients by allowing an

additional 7 days for center to enter candidate's labs before the system downgrades the candidate any further.

When MELD was originally implemented in 2002, the Liver Committee discussed this situation and decided to allow the candidate to remain at the 25 or greater MELD for another week.

The subcommittee members recommended that this operational rule be removed and candidates be downgraded on the schedule as spelled out in policy.

17. Review of 1A and 1B Applications

Policy language states that the committee will review all status 1A and 1B applications.

The subcommittee members stated this was not intentional and should be changed to reflect that only those that do not meet standard criteria need to be reviewed by the liver committee.

18. Timing of Extension Submission

Extension that are submitted within 3 days of the deadline are not given the score while they await review by the review board. Extension submitted before that cutoff are given the score while they await the review board decision. Treating these differently increases programming complexity.

There was discussion about the possibility of a hospital waiting until the last moment to submit an extension application when they do not expect the extension to be granted in order to ensure that the candidate keeps the exception score for longer. However, it was agreed that this was less likely to present a problem with extensions than appeals because they are more likely to be granted, and the longest a candidate could keep the exception would be 7 days (while the NLRB votes).

The subcommittee members recommended eliminating the difference and giving all candidates the score on extension until the review board reaches a decision.

19. HCC in Pediatrics

It is unclear in existing policy language whether pediatric patients with HCC automatically get an exception score of 40 or go to the NLRB for consideration.

The subcommittee recommended that pediatric patients with HCC should receive a score of 40, but that the Milan criteria used for adults would exclude pediatric patients who should also receive the exception. The idea of creating separate criteria for pediatric candidates was considered. After considering the small numbers of these patients, the subcommittee recommended that pediatric candidates who meet Milan criteria be automatically assigned a 40, and otherwise go to the NLRB, with the recommendation that a score of 40 should be considered.

20. CCA

The language is unclear whether a candidate must have at least one or only one of the criteria listed.

The subcommittee members recommended that it should read "at least one".

21. FAP

On initial application, candidates can qualify by being on the heart waiting list or having an ejection fracture <40%. At time of extension, ejection fraction is required. Extension criteria includes no mention of a heart registration as an option to meet criteria like the initial criteria does. There is a question about whether or not a candidate could continue to qualify based on the heart listing.

The subcommittee members recommended that a candidate should be able to continue to qualify based on being listed for a heart on extension.

22. HAT for Pediatrics

Pediatric candidates qualify for status 1A as long as they have HAT within 14 days. The requirements for a HAT MELD exception also require that the candidate have HAT within 14 days. There is a question about whether a pediatric candidate needs to retain the option of a standard MELD exception for HAT.

The subcommittee recommended that there is no need for an option to auto-approve pediatric candidates for a HAT score of 40, and those candidates should be applying for status 1A instead.

23. Primary Hyperoxaluria

The subcommittee recommended that candidate should be required to continue to be registered for a combined liver-kidney on extension as well as on initial request.

24. Sorting for MELD/PELD <6

The subcommittee recommended that all candidates should be sorted in the same way, and the different sorting rules for low MELD/PELD should be removed.

25. Recertification Schedule

The recertification schedule is less frequent for pediatric candidates and is based on current age rather than age at listing. Most other reference to age in liver policies reference age at listing.

The subcommittee understood that there was a reasoning behind drawing labs less frequently on small children, and recommended keeping the different recertification schedule. Since the difference is based on the age and size of the candidate when the labs are drawn, it makes sense to keep based on current age rather than age at listing. The subcommittee considered treating adolescents differently, but decided that there was not enough reason to make that change, which would create an additional burden on hospitals and patients.

26. Portopulmonary Hypertension

Post-treatment and following intervention are synonymous. Other questions about this diagnosis were referred to an expert and his answers will be reported back.