OPTN/UNOS Policy Oversight Committee
Meeting Minutes
October 23, 2018
Conference Call

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Introduction

The Policy Oversight Committee (POC) met via teleconference on 10/23/2018 to discuss the following agenda items:

1. Review and Vote on Recommendation for New Committee Project
2. Liver Public Comment Update and Next Steps
3. Other Significant Items

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

1. Review and Vote on Recommendation for New Committee Project

Summary of Discussion:

The proposed new project, Modify HOPE Act Variance to Include Other Organs, received unanimous affirmative votes in the pre-meeting survey. Members provided comments on the project, and these comments, which were generally positive, were reviewed by the Vice Chair of the Ad Hoc Disease Transmission Advisory Committee (DTAC). There were questions about the balance of the IT effort versus how much the project would expand the donor pool. However, these organs would otherwise not be used, so the POC expressed that the IT effort is worthwhile. The DTAC Vice Chair agreed to include feedback from other stakeholders as well.

The POC unanimously agreed that the project fell under the first strategic goal of increasing the number of transplants. This strategic goal is currently under its allocation target, therefore the POC is supportive of considering new projects that align with this goal.

A formal vote was taken regarding: Does the POC vote to recommend to the Executive Committee that the new project be approved (Modify HOPE Act Variance to Include Other Organs)?

Results were as follows: 14 (100%) yes; 0 (0%) no; 0 (0%) abstained.

Next steps:

The project will move forward for consideration by the Executive Committee.

2. Liver Public Comment Update and Next Steps

Summary of Discussion:

The Vice Chair of the Liver and Intestinal Organ Transplantation (Liver) Committee presented on the proposal titled, "Liver and Intestine Distribution Using Distance from Donor Hospital" that is out for special public comment (October 8 – November 1, 2018).

The proposal contains two potential allocation models that would eliminate use of Donation Service Areas (DSAs) and regions for organ allocation. The first is referred to as Broader-2-Circles (B2C) with a threshold of Model for End Stage Liver Disease (MELD)/Pediatric End Stage Liver Disease (PELD) 32. In this model, allocation starts with Status 1A and 1B candidates within 500 nautical miles (nm) of the donor hospital, followed by candidates with a

MELD/PELD score of 32 or higher within 250 nm of the donor hospital. Then livers would be offered to candidates with a MELD/PELD of 15-31, first within 150nm, then within 250nm, then within 500nm.

The National Liver Review Board (NLRB) is proposed to remain as approved in December 2017 by the OPTN/UNOS Board of Directors (BOD). Because the December 2017 proposal used Median Meld at Transplant (MMaT) within the DSA, the Liver Committee is proposing to change MMaT to be based on a 250 nm circle around the transplant hospital.

The Liver Committee is asking for the community's feedback through public comment on several questions. These include:

1.) What is your opinion of this proposal of B2C sharing at 32 threshold? Do you prefer one of the other models, such as the acuity based model?
2.) What is your opinion of the MELD/PELD sharing threshold? Is 32 appropriate, or would you prefer 29? Or 35?
3.) What is your opinion of the fixed-distance circles? Are they the right size?
4.) Do you support expanding *Policy 9.11.B: Closed Variance for Allocation of Blood Type O Deceased Donor Livers in Hawaii* to apply to Puerto Rice as well?

Currently, distribution within the region is done at MELD/PELD 35, but the current proposal would start distribution at MELD/PELD 32. There has been some discussion about moving it further to 29. As the MELD/PELD threshold is moved down, the number of patients eligible for broader distribution would increase. There are about 130 candidates currently on the waiting list with MELD 35 or higher, roughly 200 with MELD 32 or higher, and approximately 500 with MELD 29 or higher.

The Liver Committee Vice Chair presented data on public comments that had been submitted as of 10/22/2018. Most responses came from transplant hospitals, with a high number of comments coming from Texas, especially Houston. There have been 266 comments thus far and the Committee has been able to review all comments submitted to date.

The Liver Committee Vice Chair discussed public comment themes that have been identified by UNOS staff. One theme is that the circles could include coastal areas and national borders. Many comments from Houston are about a large part of their circle being over water, meaning that area of allocation would be wasted since there are no candidates or donors. The Committee response to this concern is that coastal cities are so large that the impact of having part of the circle over water is mitigated by population density.

Some commenters express concern about making the areas smaller than current DSAs, which could lessen broader sharing. There have also been requests for more population-based modeling to better address population density, which varies across the country. The Liver Committee acknowledges that this modeling would be useful but under the circumstances there is not time to complete additional modeling. All organ-specific Committees will continue to evaluate the impact of revised policies and take additional actions as indicated, including more refined and extensive modeling.

Some comments support the Acuity Circle model and put the most weight on lower mortality and less variance between areas.

Other public comments express a desire to move more aggressively to Acuity Circles over larger areas (300 and 600 nm) to expand broader sharing. The rationale is that since changes are being proposed, they should be as impactful as possible.

Other public comments express concern that with wider sharing of organs, marginal organs (e.g. organs from persons over age 70) would not maintain their quality as they travel farther

distances, which might increase discards. However, other commenters do not think the discard rate will be increased.

Additional public comments express concern about the B2C model adequately meeting the requirements set forth in the Final Rule.

Some public comments prefer a sharing threshold of MELD/PELD 29 because it appears to be an inflection point on the mortality curve and this would give access to more patients within 250 nautical miles. However, not all commenters agree that this inflection point is an obvious data threshold.

Some public commenters think the solution should be as close to the continuous distribution model as possible. However, others believe the changes should be minimal and should just satisfy the Final Rule and answer *Cruz et al v. U.S. Dept. of Health and Human Services, (S.D.N.Y 18-CV-06371)* by removing DSA and Region.

There was some support for changes to pediatric allocation and a desire to move more cautiously because the process is moving more quickly than desired.

Public comment will end on 11/01/2018. On 11/02/2018, the Liver Committee will meet in-person in Chicago, IL. At that time, they will make a policy recommendation. The final decision will be made at the OPTN/UNOS BOD Meeting on 12/03/2018 in Dallas, TX. Implementation will begin in the first quarter of 2019. The NLRB will still be rolled out in January 2019 because changes are expected to be minimal. Implementation of the new policy will start in the second quarter of 2019.

One POC member asked whether the Liver Committee would have enough time to go through all public comments since they need to make a recommendation the day following the conclusion of public comment. The Committee continues to review public comments as they come in, instead of waiting to review them all at the end of the cycle to help mitigate this concern. This expedited timeline is based on multiple considerations including the Human Resources and Services Administration (HRSA) and the impending lawsuit which has a stay that expires after the BOD Meeting. While the timeline is expedited, it is necessary to meet external directives and circumstances.

Next steps:

The proposal will be considered and finalized by the Liver Committee on 11/1. The OPTN/UNOS BOD will vote on 12/3.

3. Other Significant Items

No other significant items were discussed.

Upcoming Meeting

- December 11, 2018 (tentative)