OPTN/UNOS Thoracic Organ Transplantation Committee
Meeting Minutes
April 26, 2018
Conference Call

Kevin Chan, MD, Chair
Ryan Davies, MD, Vice Chair

Introduction

The Thoracic Organ Transplantation Committee (Committee) met via Citrix GoToTraining teleconference on 04/26/2018 to discuss the following agenda items:

1. Modifications to the Distribution of Deceased Donor Lungs: Clarifications to the proposed lung sensitized candidate policy
2. Revisions to the Heart Review Board Operational Guidelines

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

1. Modifications to the Distribution of Deceased Donor Lungs: Clarifications to the proposed lung sensitized candidate policy

The Committee voted on clarifications to the proposed sensitized candidate policy being recommended to the OPTN/UNOS Board of Directors in June 2018.

Summary of discussion:

During the April 19, 2018 meeting, the Committee considered several policy options for sensitized candidates. The option they opted for required UNOS staff to draft policy language in an expedited manner, thus precluding additional UNOS staff the opportunity to review the language prior to the Committee voting on the language. The Committee reviewed minor language clarifications to the policy, which included changes to ensure consistency across policy language and adherence to policy language conventions.

The Committee voted unanimously to approve the language clarifications (11-yes, 0-no, 0-abstain).

Next steps:

These changes will be incorporated into the language version sent to the OPTN/UNOS Board of Directors in June.

2. Revisions to the Heart Review Board Operational Guidelines

The Committee reviewed revised review board operational guidelines that will be implemented when the Board-approved adult heart allocation policy changes go into effect fall of 2018.

Summary of discussion:

During the April 19, 2018 meeting, the Committee did not have sufficient time to discuss and vote on the revised heart review board operational guidelines. They were previously discussed during the March 22, 2018 Heart Subcommittee meeting, where there was some confusion

regarding what operational guidelines were and how much detail they should contain.[1] In addition, there was controversy around the Committee's previous decision to have regions review cases from other regions to mitigate perceive bias in decision-making on the review boards, and the implications that broader sharing would have for higher urgency statuses.[2]

Those favoring removal of this provision felt that there were varying, unique nuances and intricacies of the patient populations, disease prevalence and waiting times in each respective region that only members from the same regions would understand. They stated they felt it was premature to make this change prior to the adult heart allocation policy changes being implemented, because it introduced a potential confounding factor and generally, there is a high level of uncertainty around what exception landscape will look like under new system (volume, type, etc.) In addition, new policy criteria is more stringent and objective, which should reduce some of the ambiguity and subjectivity that plagues current policy. Further, this operational change was proposed before the decision to create guidance for conditions in Status 4 was conceived. The guidance should help standardize decision-making for requests for those candidates with those conditions, where the qualifying criteria is less specific. The Committee noted that no changes were made to the heart review board system post-pediatric heart allocation policy changes in July, 2016, which included broader sharing for pediatric status 1A and 1B candidates. They cited concern over the complexity of executing this operation due to staff having to manage the heart review board system manually. They pointed out that the scope of the problem is unknown; it may be that the original problem-perceived bias within regional review boards-is no longer an issue once the policy changes are implemented and the guidance for review boards is utilized. This faction felt that any changes to the heart review board system, including consideration of a national review board, should be postponed until the Committee is able to monitor the changes of the new policy. Or, it may be that they begin exploring a national review board system, beginning with a pediatric board, as data is available and pediatric policy was not impacted by the changes to adult policy.

Those opposed to extracting the provision for regions to review cases from other regions felt that reviewers reviewing cases from other regions might be more objective due to the regional variability in the evaluation and approval of exception requests. They felt that unique patient populations, disease prevalence and waiting time shouldn't necessarily matter, because policy states "Transplant physician believes, using acceptable medical criteria, that a heart candidate has an urgency and potential for benefit comparable to that of other candidates at the requested status." Further, members who favored keeping the provision felt that this was a necessary change in light of broader sharing for higher urgency statuses.

The Committee considered metrics around the review board processes that could be incorporated into the adult heart allocation policy monitoring plan. The group acknowledged there may be a spike in exception requests around implementation as the community becomes accustomed to the new policies. They suggested collecting the following metrics around exceptions:

- Volume stratified by region
- Status stratified by region (i.e. status 1 exception, status 2 exception, etc.)

[1] United Network for Organ Sharing. *Heart Review Board Operational Guideline Crosswalk*, Reference differences between 2010, 2016 and 2018 heart review board guidelines.
[2] Thoracic Organ Transplantation Committee. *Proposal to Modify the Adult Heart Allocation System,* 2016, Board Briefing Paper, https://optn.transplant.hrsa.gov/media/2006/thoracic_brief_201612.pdf.

One member asked if it was possible to monitor exceptions in more real-time. UNOS staff explained that because exception information is captured in narrative form, that may be challenging. It may require significant staff resources.

The Committee approved the other revisions to the review board operational guidelines. Ultimately, the Committee voted to endorse the guidelines, excluding the provision to have regions review cases from other regions (8-yes, 3-no, 0-abstain).

Next steps:

The revised heart review board guidelines will be sent to the Board for consideration in June 2018. If approved, they will be implemented with the adult heart allocation policy changes in the fall of 2018.

Upcoming Meeting

- October 4, 2018