OPTN/UNOS Thoracic Committee
Meeting Minutes
December 28, 2017
Teleconference

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

Introduction

The Thoracic Committee met via Citrix GoToTraining teleconference on December 28, 2017 to discuss the following agenda items:

1. Required Policy Changes: Heart Lung Policy and Sensitized Patients
2. Required Policy Changes: Sensitized Patients
3. Final Vote on Policy Changes' Language

The following is a summary of the Thoracic Committee's discussions:

1. Required Policy Changes: Heart-Lung Policy

Summary of discussion:

Following discussions resulting from the month's meetings, the Thoracic Committee voted on approving changes to heart-lung policy.

As a review of previous discussions and the need for heart-lung policy changes:

> Heart-lung transplant policy needs to be reviewed and changed in order to align it with the Executive Committee's emergency change to 250 nautical miles. Currently, heart-lung sharing is dependent on DSA. When a heart-lung candidate is allocated a heart, the lung from the same deceased donor must be allocated to the heart-lung candidate. When the heart-lung candidate is allocated a lung, the heart from the same deceased donor may only be allocated to the heart-lung candidate if no suitable Status 1A isolated heart candidates are eligible to receive the heart. A heart-lung guidance document was released previously to aid in the execution of heart-lung policy under the DSA system.
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> Having reviewed the changes that would be necessary to update the Heart-Lung Guidance, it was recommended that the document be pulled given the complications for such updating. In addition to the guidance document, the heart-lung policy must be reviewed and altered.

The recommended changes to the heart-lung policy are as follows: *if a heart potential transplant recipient (PTR) requires a lung, the OPO must offer the lung from the same deceased donor to the heart PTR according to Policy 6.6.D. If a lung PTR in allocation classification 1 through 12 according to Policy 10.4.C requires a heart, the OPO cannot allocate the heart from the same deceased donor to that lung PTR until after the heart has been offered to all heart and heart-lung PTRs in allocation classifications 1 through 4 according to Policy 6.6.D.* This proposed policy language arose from discussions during the December 21, 2017 Thoracic Committee meeting.

For pediatric donor lungs, the major issue is that allocation goes through Zones A, B, and C. Respectively, this is 250, 500, and 1,000 nautical miles. This creates geographic inconsistencies with the new policy. In order to create consistencies, the recommended changes to heart-lung policy for pediatric donors is as follows: *if a heart potential transplant recipient (PTR) requires a lung, the OPO must offer the lung from the same deceased donor to*

the heart PTR according to Policy 6.6.E. If a lung PTR in allocation classification 1 through 10 according to Policy 10.4.D requires a heart, the OPO cannot allocate the heart from the same deceased donor to that lung PTR until after the heart has been offered to all heart and heart-lung PTRs in allocation classifications 1 through 12 according to Policy 6.6.E.

One Committee member voiced a concern about the policy language. With the policy language reading that the lungs must follow heart, there is some concern about a scenario in which a primary heart placement followed by lung placement would cause issue if the heart candidate backs out during the heart-lung process. The OPO would have to rescind the primary lung offer or the OPO would have to break the policy that requires the lungs to follow the heart. This could slow down allocation. Other Committee members agreed with this concern, stating that OPOs would be in their means to continue with the process given the expediency needed for heart-lung patients. In the end, Committee members agreed that it would be difficult to include any additional language for such a scenario, and that Committee members would need to work with OPOs as such situations occur. In the future, it will be necessary to revisit this topic as changes are made over the course of 2018.

2. Required Policy Changes: Sensitized Patients

Summary of discussion:

Current policy for sensitized patients includes the following: *lungs may be allocated to sensitized candidates within a DSA out of the sequence required by the match run if (1) the candidate's transplant surgeon or physician determines that the candidate's antibodies would react adversely to certain human leukocyte antigens (HLA); (2) all lung transplant programs and the OPO within the DSA agree to allocate the lung from a compatible deceased donor to the sensitized candidate because the results of a crossmatch between the blood serum of the candidate and the cells of the lung donor are negative; and (3) the candidate's transplant program, all lung transplant programs, and the OPO within a DSA agree upon the level of sensitization at which a candidate qualifies for the sensitization exception*. In addition, sensitization alone does not qualify a candidate for an exception described in *Policy 10.2.B*.

DSA is included in the current policy language. With the emergency change to 250 nautical miles, the sensitized patient policy is at odds given the use of DSA in the policy. Three options exist for altering this policy to match the emergency changes:

- *Strike the policy completely*. The advantage of this option is that the policy is rarely, if ever, used according to UNOS staff and Committee members. A potential disadvantage is that completely eliminating this pathway may disadvantage a candidate in the future.
- *Require all programs and OPOs in any area in which a candidate in Zone A to agree*. Advantages include that this would be similar to current structures, it would provide a pathway for sensitized candidates to gain more access, and it is equitable as it allows anyone who would be skipped to agree. Disadvantages include logistical difficulties and that it may not provide much benefit if what sensitized candidates need is access to a broader range of geographic donors (the current policy change may already result in that effect).
- *Permit candidates to apply to the LRB to be deemed a sensitized candidate, thus permitting the OPO to offer to the candidate out of the sequence.* Advantages include centralizing the process through the national board and this is also a fairly simple solution. Disadvantages include the potential for variability in approvals; not providing much benefit if what sensitized candidates need is access to a broader range of geographic donors (the current policy change may already end with that effect); and creating a spike in requests.

Most Committee members agreed that option two is far too complicated. As such, discussion turned to options one and three. Committee members also voiced that they believe a pathway should be included in policy for these candidates. While option three may have some flaws, it allows sensitized patients to have a pathway rather than just simply eliminating pathways. While it may not need to be utilized, it may still be worthwhile to have a pathway. Committee members also stated that, if option three is selected, guidelines would need to be written to give direction to the LRB. However, other Committee members believed that striking the policy may be an appropriate action as even option three may be complicated. The Committee ultimately decided to strike the policy altogether but to work on a better solution for sensitized candidates while optimizing the lung allocation policy prior to expiration of the emergency policy enacted on November 24, 2017.

3. Final Vote on Policy Changes' Language

The Thoracic Committee voted to send out the emergency changes proposed by the Executive Committee and the subsequent policy language changes to heart-lung candidates, both adult and pediatric, and to sensitized candidate policy (13 yes, 0 no, 0 abstentions). As such, the proposal will be included in the upcoming spring 2018 public comment cycle.

Upcoming Meeting and Next Steps

- January 16, 2018 – TSAM Results Review
- Public Comment between January 22, 2018 and March 23, 2018
- Regional Meetings begin February 1, 2018 through March 21, 2018

Attendance

- **Committee Members**
- **HRSA Representatives**
- **SRTR Staff**
- **OPTN/UNOS Staff**
    - Liz Robbins
- **Other Attendees**