

**OPTN/UNOS Thoracic Organ Transplantation Committee
Meeting Minutes
June 8, 2017
Conference Call**

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

Introduction

The Thoracic Organ Transplantation Committee met via Citrix GoToTraining teleconference on 06/08/2017 to discuss the following agenda items:

1. Review Board Guidance for Adult Congenital Heart Disease Exception Requests
2. Review Board Guidance for Hypertrophic/Restrictive Cardiomyopathy Exception
3. SRTR Acceptance Model Presentation

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

1. Review Board Guidance for Adult Congenital Heart Disease Exception Requests

The Committee reviewed a final draft of the guidance and voted to send out for public comment in the fall of 2017.

Summary of discussion:

The Committee provided final edits to UNOS staff. They opted to remove a sentence about regions reviewing exception cases from other regions because it speaks to process, and is not included in policy. As part of the new policy changes, an educational module covering review boards and the new policy is planned, so information on review board operations does not need to be included in this document.

Category 1: Single Ventricle Heart Disease

Regarding the phrase "not eligible for exception to a higher status," the language was considered problematic because patients who are not on inotropic support can be eligible for exceptions. The group felt it was important to make clear that patients who have CHD but not requiring inotropic or other support and those with extra-cardiac complications of single-ventricle physiology but not requiring hospital admission should not merit exceptions. The group decided to strike this phrase. Regarding stating that these candidates are generally appropriately categorized as status 4, the original rationale for including the phrase was to reiterate that a patient would be Status 4 unless the stated conditions were met. Some Committee members felt it was redundant to state this and the language was unnecessary; other members felt the phrase should remain. Keeping the phrase addresses the writers' intent in their original wording: to clarify for those with less exposure to the process (like members of regional review boards) that Status 4 is the appropriate category for the majority of patients. The group opted to keep the language but to rephrase and relocate it to another section of the guidance.

Table 1: Recommended Criteria for Status Exceptions

The Vice Chair felt that the title of column 1, "If the candidate meets these criteria," is unclear because it incorrectly suggests that patients need to meet more than one of the criteria.

The Committee agrees to change the wording to "If the candidate meets this criteria..."

There were questions raised regarding the "multiple inotropes" criteria under Status 2. It is thought to be too high of a status to assign a patient solely for being on inotropes. One member

argued that specific doses shouldn't be required because it may invite criticism (e.g., if readers of the document feel the suggested doses are too high or too low). Other members felt that reasonable dosages (e.g. the inotropes and dosages in the approve policy) should be included because not doing so could lead to manipulation of this criteria. The Committee agreed to include the inotropes and dosages from the approved policy.

Category 2: Dual Ventricle Heart Disease

The section on multiple inotropes will be copied to this section, per the change made to the Category 1 exception criteria.

One member felt the language in the first bullet is unclear and could imply a requirement that both ventricles be failing. The actual intention of the language is to communicate that the patient has two-ventricle congenital heart disease with factors that make VAD support risky. This language will be changed to: "Has heart failure with a systemic right ventricle or other risk factors for VAD support, including failing pulmonary ventricle, heterotaxy syndrome, or multiple previous sternotomies." The group also agreed to include Ebstein's.

UNOS staff questioned the definition of "bystander organ injury," wondering if this is an official term. For the benefit of lay readers, the group decided to replace "bystander organ injury" with "non-cardiac end organ injury."

The guidance was unanimously approved (15-yes, 0-no, 0-abstentions) to send out for fall 2017 public comment.

Next steps:

Include specific assignments for specific people (Research will collect ## data as requested, UNOS Staff will determine whether ## is a realistic policy expectation, etc.)

2. Review Board Guidance for Hypertrophic/Restrictive Cardiomyopathy Exception

The Heart Subcommittee Chair provided an update to the Committee. Despite progress within the last two weeks, UNOS staff and Committee leadership were not confident the workgroup would meet the deadlines for fall 2017 public comment. The workgroup will continue work through the summer and to submit for the next public comment cycle.

3. SRTR Acceptance Model Presentation

Representatives from SRTR shared that as part of the SRTR contract with HRSA, they are in the process of developing reports on offer acceptance for all organs. The kidney offer acceptance information is being integrated into the upcoming PSRs next month. SRTR's intent is to preview the lung offer acceptance reports later this summer with potential integration into SRTR PSR's in January of 2018. SRTR sought the Lung Subcommittee's (Subcommittee) input on model structure, particularly risk factors for adjustment, as well as information of interest for public and private reporting.

SRTR began by pulling a list of every donor and candidate risk factor. Clarification was requested on the difference between offer acceptance and organ acceptance. SRTR advised that organ acceptance looks at each organ you are offered in terms of whether or not you eventually accepted and transplanted it. Offer acceptance evaluates each individual offer in terms of whether it was accepted or declined. For SRTR's data collection, only offers up to point of acceptance are being analyzed, so anything after the last acceptance on a match run is not considered.

SRTR asked the Subcommittee for feedback on acceptance variables (e.g., factors a program may use to screen out certain organs in order to increase allocation efficiency). The goal is to get feedback on whether the model is including all variables that are used in lung acceptance

decisions. For instance, there has been recent literature on the effect of donor-recipient gender mismatch on outcomes in liver transplant. The group provided the following responses:

- Missing donor factors:
 - PO2
 - CT scan
 - Chest x-ray
 - Cause of death
 - Bronchoscopy
 - Lung side (left or right), especially if it is a single-lung transplant. This can also be a candidate factor in some cases.
 - EVLP availability
- Donor-candidate interactions:
 - HLA typing
 - Chest x-ray lung sizes are used more frequently than height/weight ratio because they provide more precise information for size matching. The OPTN collects this information only for the donor, but not for the recipient.

SRTR asked whether the Subcommittee had any suggestions for information in terms of program offer acceptance. The Subcommittee provided the following responses:

- High-risk donors
- DCD donors
- CDC high-risk donors
- Hepatitis C might be separated out as a surrogate for donor quality
- Distance (It's known that most programs will go up to Zone B, but it's very rare to go beyond that distance (1,000 nautical miles). It may or may not be helpful to know whether programs will go past Zone B).
- Donor age
- Smoking history
- Would acceptance rate be affected by how sick the patient is and the quality of the donor? E.g., would you accept a marginal-quality donor for a high-LAS patient? OPOs do frequently take high LAS into consideration, so this might be a useful factor to consider.

Next steps

SRTR will preview the model during the Committee's in-person meeting in October.

Upcoming Meeting

- October, 2017