

The OPTN/UNOS Thoracic Organ Transplantation Committee met on March 27, 2009 in Chicago, Illinois. The following is a report of the Thoracic Committee's deliberations. The report is presented by agenda item and the order in which each item was discussed. The Thoracic Committee will next meet on July 14, 2009.

Cases for Review

1. *Justification for Heart Status 1B Declined by the Heart Review Board*

The Committee reviewed a heart Status 1B justification case that the respective Heart Regional Review Board had voted against three times. The Heart Regional Review Board had determined that the candidate did not meet the respective Status 1B criteria. However, the center transplanted the candidate before receiving the first set of votes from the Review Board. Per Policy 3.7.3 (Adult Candidate Status), the Thoracic Committee reviewed this case. The Committee concurred with the decision of the Heart Review Board, but decided not to submit the case to the Membership and Professional Standards Committee (MPSC). With this case serving as the exception, the respective center had not transplanted Status 1A or Status 1B heart candidates without first receiving status-designation approval from its Heart Review Board. As such, the Committee decided to not send this case to the MPSC for its review.

2. *Query Regarding Policy 3.7.1.1 (Exception for Sensitized Candidates)*

The Committee discussed the following request from a center regarding a highly sensitized heart candidate:

“We are requesting a variance of donor allocation procedures in order to identify a suitable donor for this patient given the special circumstances outlined in detail below. Specifically, we seek to broaden the donor pool for this patient by providing him priority status to all potential donors which are both local or from Zone A, B or C (e.g., within a 1,500 mile radius of the donor hospital).”

Policy 3.7.1.1 permits the center to do as requested. (Of note, the patient received a locally procured heart shortly after UNOS received this query.) Per policy, when a center seeks to prioritize a highly sensitized candidate for a suitable donor, the center seeks permission from its local organ procurement organization (OPO) as well as all transplant centers served by that OPO. Typically, such a prioritization request is contained within a center's donation service area. The center that queried UNOS, however, sought to prioritize its candidate in other donation service areas (DSA), as well as its own.

The question before the Committee was whether to add the restriction of “local” in the policy language, or to leave the language as currently written: prioritization not restricted to local DSAs. The Committee decided that it did not want to prohibit centers willing to seek such a national prioritization if circumstances warranted it. As such, the Committee decided to leave the language in Policy 3.7.1.1 as currently written. The Committee did discuss the potential for incorporating sensitization in thoracic organ allocation, and sought data for its next meeting.

Heart and Lung Allocation

3. *Policy 3.7.7 (Allocation of Thoracic Organs to Heart-Lung Candidates)*

The Committee continued its discussion of issues posed by the existing language in Policy 3.7.7. OPOs seek concrete guidance from the Committee on how best to allocate hearts and lungs to candidates who need both. Currently, most OPOs allocate allocation hearts and lungs to heart-lung candidates using the heart allocation sequence. As written, the policy tends to favor those heart-lung candidates who are Status 1A, and does not explicitly consider lung candidates who are very sick but whose heart statuses are neither 1A nor 1B. Further, this policy language needs to consider the geographic allocation variable. The Committee has considered several policy alternatives in its previous meetings. The Committee decided to work with the OPO Committee to revise the policy language.

4. *Data Elements that Require Approval from the Federal Office of Management and Budget*

In early 2009, the Heart and Lung Subcommittees met together and separately to discuss data elements in OPTN data collection forms that require approval from the federal Office of Management and Budget (OMB). The Subcommittees reported their discussions and recommendations to the Committee. The Committee reviewed recommendations and suggested some additional data elements. The Committee continues to discuss these data elements and will do through its Subcommittees. The Committee will vote on these recommendations and submit them to the Policy Oversight Committee in early May, 2009.

5. *Alternative Listing Practices*

The Committee reviewed correspondences between the OPTN President and Duke University Medical Center. Duke inquired about developing an alternative list, much like the one that exists at UCLA. Duke received recommendation to submit an alternative allocation system application. The Committee discussed the content of the letter and considered the following possibilities: 1) evaluating the UCLA variance for its applicability in the national allocation system; 2) developing a Committee-Sponsored Alternative Allocation System to pilot alternative listing practices in several centers; and 3) developing policy that enables better utilization of deceased donor hearts and lungs. The Committee proposed alternative 2 as a means for collecting the requisite data in the event that the UCLA variance (alternative 1) does not yield sufficient evidence to consider (or not consider) incorporating the alternative list concept as part of the national system. The Committee will continue to discuss this topic at its next meeting.

6. *Impact of Donor Profile Index (DPI) on Heart and Lung Recipient Mortality*

The Committee reviewed additional analyses prepared by the SRTR regarding the development of the heart and lung donor profile indexes.

Heart Allocation

7. *Pediatric Status 1A Heart Listing Practices*

The Thoracic Committee discussed the content of a memorandum from the MPSC. The MPSC requested the Thoracic Committee (as well as the Pediatric Committee) to consider pediatric heart Status 1A criteria (Policy 3.7.4 – Pediatric Candidate Status). Specifically, the MPSC queried whether the intentional omission of a hospitalization requirement for pediatric Status 1A candidates is still medically appropriate. As the Pediatric Committee had met the day before and had discussed this memo, the Committee sought information on the Pediatric Committee's answer to this question. The Pediatric Committee decided that current policy did not need to be changed, i.e., there was no need to add a statement regarding hospitalization (required or not). Upon some vigorous debate, the Thoracic Committee, however, determined otherwise. The Committee learned that in current practice, though candidates may meet the Status 1A criteria, if these candidates do not require hospitalization, it is common practice for centers to reclassify these candidates as Status 1B. A Committee member who is a pediatric transplant professional commented that the community assumes that UNOS policies imply a lower medical urgency status if the candidate does not require hospitalization. Given the differing opinions of the two Committees, the Thoracic Committee sought the following resolution: collaborate with the Pediatric Committee, as well as members of the Pediatric Heart Study Group, to review the pediatric heart policies for their medical currency.

8. *Review of Heart Allocation Data Requested on November 21, 2008*

The Committee reviewed data analyses requested at the previous Committee meeting.

9. *Heart Subcommittee's Programming and Review Board Decisions*

Currently, UNetSM truncates inotrope dosages to one number to the right of the decimal point. The center may enter more numbers, but UNetSM will drop off the all numbers after the first one following the decimal point. UNetSM does not round any numbers. This UNetSM programming poses data matching issues during UNOS audits. Therefore, to enable matching of numbers that are reported in UNetSM and what exist in patient records at centers, the Committee voted to allow centers to be able to enter up to three numbers after the decimal point.

The Committee voted to add Epinephrine ≥ 0.02 mcg/kg/min as a new single, high-dose inotrope. The Committee voted that only the following are acceptable combinations of inotropes: dobutamine (≥ 7.5 mcg/kg/min); milrinone (≥ 0.5 mcg/kg/min); dopamine (≥ 7.5 mcg/kg/min); Epinephrine (≥ 0.02 mcg/kg/min); or Norepinephrine. All of these medication names already exist in UNetSM. UNetSM should not consider the following drugs as inotropes: Phenylephrine; Vasopressin; IV Nitroglycerin; Nesiritide; and Nitroprusside. (It is important to note that though the programming did not match policy, the UNOS Heart Review Board staff review each justification form to ensure that cases that reference inotropes indeed cite the correct inotrope medications.)

The Committee also discussed the possibility of nationalizing the Heart Review Board. As part of this discussion, the Committee voted in favor of allowing the Heart Review Board staff to approve all non-exception heart status justifications. The Committee also continued its discussion of drafting guidelines for reviewing exception cases. The Committee charged the Heart Subcommittee to discuss this issue further.

Lung Allocation Score (LAS) System

10. Analysis of Lung Allocation Score Requested on November 21, 2008

The Committee reviewed LAS data, including analyses requested at the November, 2008 meeting.

11. Update of Baseline Survival Estimates and Parameter Estimates Used in Calculating the LAS

The Committee reviewed the SRTR's initial analysis of the LAS system using data collected since 2005 (LAS implementation). The Committee inquired about the methodology and the study population. The Committee requested the following analyses for the Lung Subcommittee to review prior to the July, 2009 meeting:

Revisions to existing analyses:

- Retain age as a risk factor but delete interaction of age with diagnosis grouping.
- Examine the impact of both current information as well as the change (delta). In order of priority, assess the impact of FEV1, FVC, oxygen use, creatinine, weight and BMI. Additionally examine the impact of current and change in CVP.
- Consider analysis that re-enters each candidate into the analysis with a new time 0 every time an LAS factor (other than age) is modified.

Presentation of Results:

- In addition to presenting hazard ratios, provide results in terms of LAS and rank ordering.
- Provide box-and-whisker plots of LAS by various characteristics (both demographics and clinical characteristics) to ensure that there are no unintended consequences of revised models.

12. Availability of Six-Minute Walk Distance and CVP for Lung Waiting List Candidates 12 Years and Older

The OPTN analyzed these data as part of its collaboration with the Reveal Registry. In the Reveal Registry's analysis presented to the Committee in July, 2008, the following two variables were found to have an impact on the waiting list mortality of lung transplant candidates with pulmonary hypertension: "Six-Minute Walk Distance" and "Mean Right Atrial Pressure >15 ." Representatives from the OPTN, SRTR, and the Reveal Registry met thrice since the July, 2008 Committee meeting. There appears to be enough OPTN data that the SRTR can use to analyze the impact of six-minute walk and CVP on lung transplant waiting list mortality.

13. Impact of Right Heart Catheterization (RHC) Fields on Waiting List Mortality and Post-Transplant Survival Component of LAS

This analysis also relates to the SRTR's and OPTN's collaboration with the Reveal Registry (see item 11 above). The SRTR will begin this analysis once the analysis described in item 10 (see above) is complete.

14. TSAM Analyses for Lung Allocation (II) – Geography

The Committee continued to discuss the impact of eliminating geography from the allocation algorithm. The Committee reviewed data analysis prepared by the SRTR. The Committee requested further information regarding the underlying acceptance rate model. The Committee asked that TSAM be updated with new models for acceptance and waitlist mortality.

15. Lung Subcommittee's Programming Decisions that Require Committee Review and Vote

The Committee voted in favor of the Lung Subcommittee's programming recommendation:

- Adding an "other" field to the list of diagnoses in the waitlist screen for candidates less than 12 years of age
- Retaining "other/specify" as a re-transplant diagnosis item
- Adding the following re-transplant diagnosis codes: Re-Tx/GF Obliterative Bronchiolitis-Restrictive, and Lung Re-TX/FG Obliterative Bronchiolitis-Obstructive

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16. OPTN Data Analysis

Due to meeting time constraints, the Committee decided to discuss this analysis at its next meeting.

Program Specific Reports

17. Prior Donor Cardiac Arrest in Pediatric Heart Transplant Outcomes

Due to meeting time constraints, the Committee did not fully discuss this issue. The Committee will discuss this issue at its next meeting.