OPTN/UNOS Thoracic Organ Transplantation Committee Meeting **March 10, 2008 ◆ Chicago, Illinois**	***INTERIM REPORT*** **J. David Vega, MD – Chair** **Maryl R. Johnson, MD – Vice Chair**

The OPTN/UNOS Thoracic Organ Transplantation Committee met on March 10, 2008 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 18, 2008.

1. Policy 3.7.7: Allocation of Thoracic Organs to Heart-Lung Candidates

The Committee continued its discussion of Policy 3.7.7. Based on community feedback, the Committee seeks to clarify the current policy language to improve organ allocation to candidates who require both heart and lung transplants. The current policy is understood and applied by the community as such: the heart match run and lung match run are performed separately. While the current practice is not a policy violation, what ought to occur, however, is the parallel performance of the heart and lung match runs. To resolve this practice, the Committee proposed the development of a status for joint heart/lung transplant candidates, and suggested the development of an allocation sequence. The Committee also reviewed data on waitlist and post-transplant mortality provided by the OPTN. The Committee will discuss this policy, as well as the sequence and status proposals with the OPTN/UNOS Organ Procurement Organization (OPO) Committee. These discussions will occur before the Committee convenes in July, 2008.

2. Lung Waiting Time Modification Case

The Committee reviewed a waiting time modification case for a lung candidate. The Committee approved the additional waiting time requested for this candidate: 17-Supported; 0-Opposed; 1-Abstention.

3. Review Public Comment Proposals

The Committee reviewed ten public comment proposals. The Committee's votes and comments are presented below. UNOS staff will communicate the Committee's comments and votes to the sponsoring Committees.

a) Kidney Transplantation Committee - Proposal to Limit Mandatory Sharing of Zero Antigen Mismatch Kidneys to Children and Sensitized Adult Candidates

The Committee reviewed the proposal, but did not comment or vote.

b) Pancreas Transplantation Committee - Proposal to Allow an Additional Method for Waiting Time Reinstatement for Pancreas Recipients

The Committee reviewed the proposal, but did not comment or vote.

c) Living Donor Committee - Proposal to Change the OPTN/UNOS Bylaws to Require Written Notification (or Disclosures) to Living Donors from the Recipient Transplant Programs

The Committee did not support this proposal: 18-Opposed; 0-Support; 0-Abstention. The Committee supported the concept, but did not support the timing of the information delivery. The information should be delivered to the living donor once his/her candidacy for donation is established.

d) *Membership and Professional Standards Committee (MPSC) - Proposal to the OPTN and UNOS Bylaws: Restoration of Membership Privileges Following an Adverse Action*

The Committee supported this proposal: 17-Supported; 0-Opposed; 1-Abstention.

e) *Membership and Professional Standards Committee (MPSC) - Proposal to Change the Elector System for Histocompatibility Lab Members and Medical/Scientific Members*

The Committee supported this proposal: 14-Supported; 0-Opposed; 4-Abstention. The Committee inquired whether this bylaw change would impact future Committee membership.

f) *Operations Committee - Proposal to Change Organ Time Limits to Organ Offer Limits for Zero Antigen Mismatched Kidneys, Pancreata, and Kidney/Pancreas Combinations*

The Committee reviewed the proposal, but did not comment or vote.

g) *OPTN/UNOS Executive Committee - Proposal to Require Transplant Centers to Inform Potential Recipients about Known High Risk Donor Behavior*

The Committee did not support this proposal: 17-Opposed; 0-Support; 1-Abstention. Instead, the Committee suggested the development of a reference document for the transplant community to use in communicating high risk status of donors to transplant recipients. The Committee raised questions about the current hemodilution language in the policy and the need to clarify this language. There were concerns that guidelines in the policy language are not as stringent as some published by other organizations. The Committee raised questions about the precise classification of a high-risk donor, in light of the fact that there are very few donors who pose no health risks to candidates. The Committee raised questions about what specific information about the donor's high-risk status should be conveyed to the recipient.

h) *Pediatric and Liver and Intestinal Organ Transplantation Committees - Proposal to Change How 0-10 Year-Old Donor Livers and Combined Liver-Intestines are Allocated .*

The Committee reviewed the proposal, but did not comment or vote.

i) *Pediatric and Thoracic Organ Transplantation Committee - Proposal to Change Allocation of Pediatric Lungs and Allow Creation of Stratified Allocation System for 0-11 year-old Candidates*

The Committee reviewed the proposal, but did not make any further comments or vote.

j) *Pediatric and Thoracic Organ Transplantation Committee - Proposal to Allocate Pediatric Donor Hearts More Broadly*

The Committee reviewed the proposal, but did make any further comments or vote.

4. DonorNet®

The Committee continued its discussion on the quality of organs offered via DonorNet®. The Committee will work with the OPO Committee to develop performance criteria regarding the number of organs transplanted verses the number of organs offered. The Committee considered limiting the number of offers that can be indicated as a "provisional yes." The Committee is interested in exploring the following questions at its next meeting:

- What are the clinical characteristics of organs that are unlikely to be accepted anywhere?
- Can organ turn-down criteria be developed? What are the patterns of organ refusal?
- How many offers are made before an acceptance is received?

The Committee discussed the outcome of a meeting between representatives of the Thoracic Committee and representatives of the Kidney, Liver/Intestine, Pancreas, Operations, and the OPO Committees. This group had met on February 22, 2008, and determined that the development of additional organ-specific screening criteria were necessary.

5. Thoracic Policy Re-Write Project

In the next several months, UNOS staff will re-write the thoracic policies based on feedback from the OPTN/UNOS Policy Oversight Committee and the Thoracic Committee. The goal of this re-write effort is to create language that is reader-friendly and that clearly states the policy's intent (goal).

6. Report of the Heart and Lung Subcommittees

The Chairs of the Heart and Lung Subcommittees presented the groups' activities. The Lung Subcommittee continues to develop the characteristics of the policy that will add change in bilirubin to the lung allocation score. The Lung Subcommittee met on February 5, 2008 and March 10, 2008. The bilirubin policy will resemble the policy to add PCO_2 to the lung allocation score. UNOS staff will draft the language, and submit the policy for public comment in June, 2008.

The Heart Subcommittee met on March 9, 2008 to discuss the impact of the heart allocation sequence that was implemented on July, 2006. Some of the members of the former Heart Allocation Task Force participated in the Heart Subcommittee meeting. OPTN data show that heart waitlist mortality has decreased since the implementation in 2006. The Committee will continue to monitor the impact of this heart allocation sequence.

The Heart and Lung Subcommittees met together on March 9, 2008 to continue discussing the covariates that are included in the thoracic patient and graft survival models. In 2007, the Subcommittees assessed the covariates in the 12 thoracic patient and graft survival models for their continued inclusion. The Subcommittees recommended over 28 covariates for inclusion in the models, and 3 covariates for deletion from the models. The SRTR presented its initial analyses of these covariates: some were statistically significant, others were not. This analytical process will continue, and the SRTR will develop models independent of the Committee. On March 9, a discussion ensued about the use of donor variables in the center-specific reports. A discussion also ensued about the role of the Committee in periodically reviewing the center-specific reports. UNOS staff will communicate the Committee's activities to the OPTN/UNOS Membership and Professional

Standards Committee. UNOS staff will also inquire about the Committee's role in evaluating the center-specific reports.

7. Organ Offers with Unacceptable Antigens

The Committee discussed a memo from a fellow Committee member who requested that the Committee (and the OPTN/UNOS Histocompatibility Committee) consider policy modifications that prevent recipient centers from receiving offers organs that have unacceptable antigens. The Committee decided that one solution is to add "HLA" to Policy 3.7.12.1 (Essential Information), and that this eventual policy requirement would be implemented in DonorNet®.

8. MPSC Memo: Questions about Language in Policy 3.7.3 (Adult Candidate Status)

The OPTN/UNOS Membership and Professional Standards Committee submitted a memo to the Committee with the following queries:

1. *After a candidate qualifies for Status 1A, must the candidate continue to meet the qualification criterion each day for Status 1A in order to retain that status? Or, after a candidate qualifies for Status 1A, does the candidate remain as Status 1A for the maximum number of days the qualification may remain valid as defined in policy, even if the candidate's medical condition changes?*
2. *After a patient qualifies for Status 1A, and the patient's status changes such that he/she no longer qualifies for Status 1A, or qualifies for Status 1A under a different qualification criterion, what is required of the transplant center regarding documenting the change in medical condition in UNet℠?*

The Committee discussed the memo and commented that the policy language, especially with the use of the word "continuous" is clear. Regarding question 1 above, the candidate should be considered a Status 1A only if the requisites outlined in policy are met. Regarding question 2, the Committee expects that the transplant center will update a candidate's clinical status within 24 hours of the change. The Committee will send a memo to the OPTN/UNOS Membership and Professional Standards Committee that documents the Committee's intent. The Committee will also explore policy modifications during the policy re-rewrite effort.

9. Qualifications for 1A Exceptions and 1B Exceptions

The Heart Subcommittee will meet before the next Committee meeting to discuss the development of these guidelines. UNOS staff will convene the Heart Subcommittee to develop listing criteria for the Status 1A and 1B exception forms. The Heart Subcommittee will also develop language that will enable Review Board members to consistently evaluate Status 1A and Status 1B exception requests.

10. Lung Allocation Score: Updates and Analyses

a) *SRTR Analysis (TSAM that removes local for all candidates as well as for candidates with scores greater than 40 (Analysis by region, age, and diagnosis group))*

The SRTR presented its analysis to the Committee. The SRTR commented that partial or complete removal of local geography reduces total deaths across most regions, age groups and

LAS diagnosis groups. The Committee will continue to discuss this topic and explore additional data at its next meeting.

b) *OPTN Analysis(LAS distribution for candidates 50 years of age or older; waitlist Mortality by Lung Allocation Score)*

The Committee discussed the OPTN data analysis. In the first year after the implementation of the LAS, approximately 12% of the transplants were performed in recipients with a lung allocation score of 50 or higher. In the most recent era, approximately 20% of transplants were performed in this group.

c) *SRTR Analysis (TSAM results using the current allocation system and the following age groups: 12-19, 12-21, 12-23, and 12-25 (Analysis by age and diagnosis group))*

The Committee is interested in pursuing policy that will enable broader geographic sharing of lungs. The Committee discussed the SRTR analysis, and inquired about how the TSAM makes use of acceptance rates. The Committee requested the following additional data for future discussion:

- Can TSAM be adjusted so that it is not based on the number of times an organ is refused? What is the discard rate of organs? Has the discard rate gone up by 15%? What are the criteria for discard within TSAM?
- How is TSAM handling these different age groups in terms of the acceptance model?
- What are the post-transplant survival predictions based on donor age and recipient age?

The Committee will continue this discussion at its next meeting.

d) *SRTR Analysis (whether Alpha-1 candidates should remain in diagnosis Group A classification, according to disease progression, waiting list mortality, and post-transplant mortality)*

The Committee discussed the SRTR analysis. The SRTR reported that there was no significant difference in post-transplant outcomes for Alpha-1 recipients than other Group A patients. Data do not indicate that Alpha-1 candidates should be placed in a different diagnosis group. The SRTR will present additional data as they become available.

Mr. Ken Irvine, with the Alpha-1 Foundation, participated in the meeting. He commented that he will present these data at an Alpha-1 conference, and that the Alpha-1 Foundation may be pursuing this topic further in the future.

11. MPSC Memo: Documentation of "Not Diabetic" for Lung Transplant Waitlist Candidates

The OPTN/UNOS Membership and Professional Standards Committee submitted a memo to the Committee stating the following issue:

Transplant centers enter into UNetSM values for several variables that go into the calculation of the Lung Allocation Score (LAS). One of the variables is diabetes status. Site surveyors currently cite transplant centers if they select "Not diabetic" as the diabetes status and do not maintain medical record documentation to support that selection. At its November 2007 meeting, the Membership and Professional Standards Committee discussed the requirement to document a

UNetSM entry of "not diabetic" during its review of lung program site survey results, expressing concern that requiring documentation of a condition that does not exist in a patient is not standard medical practice. The purpose of this memo is to request clarification from the Thoracic Committee on this issue.

If there is no suspicion that a candidate is diabetic, the Committee stated that it does not expect transplant centers to document that a candidate is not diabetic in the candidate's medical record.

12. Consider 3-5 Year Survival Time in Post-Transplant Model of the LAS (Community Member Request)

The Committee will consider incorporating the 3-5 year survival time in the post-transplant model of the lung allocation score when sufficient data, collected since the implementation of the LAS, are available.

13. Donor Profile Index

The Committee reviewed the SRTR analysis pertaining to the development of a donor profile index for heart and for lung. The Committee will continue to discuss this topic. The Committee requested the following additional analyses from the SRTR for discussion on July 18, 2008.

- Examine the impact of ischemia time on the heart DPI, modeling both as a continuous risk factor and as a categorical factor;
- Examine the impact of donor inotropic support on the heart DPI; and,
- Provide details in subsequent reports regarding any interactions that were considered.

14. Consider the Inclusion of PRA in the LAS

The Committee discussed a request from a community member who asked that the Committee provide guidance on how the Lung Review Board should consider sensitization in the allocation of lungs. The Committee discussed this issue, and will discuss the following at its next meeting:

- Are there data available to support the use of sensitization in the LAS? (data with respect to time to transplant, waitlist mortality, and post-transplant outcome, stratified by listed PRA)
- Are these candidates being disadvantaged in terms of wait-time?