

**OPTN/UNOS THORACIC ORGAN TRANSPLANTATION COMMITTEE
SUMMARY**

I. Action Items for Board Consideration

- Proposed collection of PaCO₂ in the Lung Allocation algorithm. This proposal would add PaCO₂ to the Lung Allocation Score, using the lower 90% confidence limit for the hazard ratios for current PaCO₂ and change in PaCO₂, for candidates ages 12 and up registered for lung transplantation. This proposal has completed the public comment process and was approved by the Policy Oversight Committee. (Item 1 page 3)

II. Other Significant Issues

- Strategic Planning and Annual Goals. (Item 13, Page 15)

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**Report of the OPTN/UNOS
Thoracic Organ Transplantation Committee
To the Board of Directors
March 23, 2007
St. Louis, Missouri**

**J. David Vega, M.D., Chair
Mary Johnson, M.D., Vice Chair**

The following report presents the OPTN/UNOS Thoracic Organ Transplantation Committee's deliberations and recommendations on matters considered by the Committee during its October 30, 2006, and February 2, 2007, meeting, that had not otherwise been presented to the Board at its December 2006 meeting.

1. Proposed Modification to OPTN/UNOS Policy 3.7.6 (Lung Allocation). The Committee discussed the proposed modification to Policy 3.7.6 (Lung Allocation). This proposal would add PaCO₂ to the Lung Allocation Score using the lower 90% confidence limit for the hazard ratios for current PaCO₂ and a change in PaCO₂ for candidates ages 12 and up registered for lung transplantation. The Executive Summary with Briefing Paper is attached as **Exhibit A**. The proposal was submitted for public comment on August 28, 2006. The Committee reviewed the responses at its October 30, 2006, meeting. As of October 27, 2006, 41 responses were submitted to UNOS regarding this policy proposal. Of these, 22 (53.66%) supported the proposal, 0 (0%) opposed the proposal, and 19 (46.34%) had no opinion. Of the 22 who responded with an opinion, 22 (100.00%) supported the proposal and 0 (0%) opposed the proposal. There were no written comments received that required a Committee response. All eleven regions supported the proposal. The Pediatric Transplantation Committee voted in favor of this proposal (4-0-1). A Pediatric Committee member noted this may prove to be a short-term solution to help a subset of candidates that has not been adequately served within the LAS system, but is seen as a good addition that will benefit children in the long run. The Transplant Coordinators Committee supported the proposed change by a vote of 13-0-0. No other Committee comments were received on this proposal. Due to the specification document not being complete in time for the December 2006 Board meeting, the Committee voted 16 yes, 0, no, 1 abstention to recommend this proposal to the Board in March 2007.

Based on the data analyses that indicate PaCO₂ is a significant predictor of waitlist mortality among lung transplant candidates, the Committee, at its October 30, 2006, meeting, voted 16 yes, 0 no, and 1 abstention to approve and recommend the following resolution for consideration by the Board of Directors:

****RESOLVED, that Policy 3.7.6 (Lung Allocation) shall be modified to include PaCO₂ in the Lung Allocation Score using the lower 90% confidence limits for the hazard ratios associated with the most recent values of PaCO₂ and an increase in PaCO₂ greater than or equal to 15% in the previous six-month period, as described in the modifications to OPTN/UNOS policy 3.7 below, effective pending notice and programming in UNetsm:**

3.7.6 Lung Allocation. Candidates are assigned priority in lung allocation as follows:

3.7.6.1 Candidates Age 12 and Older. Candidates age 12 and older are assigned priority for lung offers based upon Lung Allocation Score, which is calculated using the following measures: (i) waitlist urgency measure (expected number of days lived without a transplant during an additional year on the waitlist), (ii) post-transplant survival measure (expected number of days lived during the first year post-transplant), and (iii) transplant benefit measure (post-transplant survival measure minus waitlist urgency measure). Waitlist urgency measure and post-transplant survival measure (used in the calculation of transplant benefit measure) are developed using Cox proportional hazards models. Factors determined to be important predictors of waitlist mortality and post-transplant survival are listed below in Tables 1 and 2. Table 2 describes the calculation of current PaCO₂ and change in PaCO₂ in the Lung Allocation Score. It is expected that these factors will change over time as new data are available and added to the models. The Thoracic Organ Transplantation Committee will review these data in regular intervals of approximately six months and will propose changes to **Tables 1, and 2 and 3** as appropriate.

Table 1

Factors Used to Predict Risk of Death on the Lung Transplant Waitlist	
1.	Forced vital capacity (FVC)
2.	Pulmonary artery (PA) systolic (Group A, C, D ¹)
3.	O ₂ required at rest (A, C, D ¹)
4.	Age
5.	Body mass index (BMI)
6.	Diabetes
7.	Functional status (New York Heart Association (NYHA) class)
8.	Six-minute walk distance
9.	Continuous mechanical ventilation
10.	Diagnosis
11.	PaCO ₂

¹Group A includes candidates with obstructive lung disease, including without limitation, chronic obstructive pulmonary disease (COPD), alpha-1-antitrypsin deficiency, emphysema, lymphangiomyomatosis, bronchiectasis, and sarcoidosis with mean pulmonary artery (PA) pressure ≤ 30 mmHg.

Group B includes candidates with pulmonary vascular disease, including without limitation, primary pulmonary hypertension (PPH), Eisenmenger's syndrome, and other uncommon pulmonary vascular diseases.

Group C includes, without limitation, candidates with cystic fibrosis (CF) and immunodeficiency disorders such as hypogammaglobulinemia.

Group D includes candidates with restrictive lung diseases, including without limitation, idiopathic pulmonary fibrosis (IPF), pulmonary fibrosis (other causes), sarcoidosis with mean PA pressure > 30 mmHg, and obliterative bronchiolitis (non-re-transplant).

Table 2

<u>Value of current PaCO₂</u>	<u>Value of prior PaCO₂</u>	<u>PaCO₂ used in LAS calculation</u>	<u>Change in PaCO₂ used in LAS calculation</u>
<u>Not missing or expired</u>	<u>Not missing or expired; within 6 months of current PaCO₂</u>	<u>Current PaCO₂</u>	<u>Change in PaCO₂ (i.e., (current – prior)/prior)</u>
<u>Not missing or expired</u>	<u>Missing or expired or not available within 6 months prior to current value</u>	<u>Current PaCO₂</u>	<u>Least beneficial value (0% change)</u>
<u>Missing or expired</u>	<u>(any value, expired or not)</u>	<u>Least beneficial value (0 mm Hg)</u>	<u>Least beneficial value (0% change)</u>

Table 23

Factors That Predict Survival After Lung Transplant
<ol style="list-style-type: none">1. FVC (Group B, D¹)2. PCW pressure \geq 20 (Group D¹)3. Continuous mechanical ventilation4. Age5. Serum Creatinine6. Functional Status (NYHA class)7. Diagnosis

The calculations define the difference between transplant benefit and waitlist urgency: Raw Allocation Score = Transplant Benefit Measure – Waitlist Urgency Measure.

Raw allocation scores range from –730 days up to +365 days, and are normalized to a continuous scale from 0 – 100 to determine Lung Allocation Scores. The higher the score, the higher the priority for receiving lung offers. Lung Allocation Scores are calculated to sufficient decimal places to avoid assigning the same score to multiple candidates.

	Candidate X	Candidate Y
a. Post-transplant survival (days)	286.3	262.9
b. Waitlist survival (days)	101.1	69.2
c. Transplant benefit (a-b)	185.2	193.7
d. Raw allocation score (c-b)	84.1	124.5
e. Lung Allocation Score	74.3	78.0

As an example, assume that a donor lung is available, and both Candidate X and Candidate Y are on the Waiting List. Taking into account all diagnostic and prognostic factors, Candidate X is expected to live 101.1 days during the following year without transplant. Also using available predictive factors, Candidate X is expected to live 286.3 days during the following year if transplanted today. On the other hand, Candidate Y is expected to live 69.2 days during the following year on the waitlist and 262.9 days post-transplant during the following year if transplanted today. Computationally, the proposed system would prioritize candidates based on the difference between each candidate's transplant benefit measure and the waitlist urgency as measured by the expected days of life lived during the next year.

In the example here, Candidate X's raw allocation score would be 84.1 and Candidate Y's raw allocation score would be 124.5.

Similar to the mathematical conversion of temperature from Fahrenheit to Centigrade, once the raw score is computed, it will be normalized to a continuous scale from 0-100 for easier interpretation by candidates and caregivers (see formula above). A higher score on this scale indicates a higher priority for a lung offer. Conversely, a lower score on this scale indicates a lower priority for organ offers. Therefore, in the example above, Candidate X's raw allocation score of 84.1 normalizes to a Lung Allocation Score of 74.3. Candidate Y's raw score of 124.5 normalizes to a Lung Allocation Score of 78.0. As in the example of raw allocation scores, Candidate Y has a higher Lung Allocation Score and will therefore receive a higher priority for a lung offer than Candidate X.

****No further changes to Policy 3.7.6****

Once sufficient data are available through UNetsm, the hazard ratios for the most recent value of PaCO₂ and an increase in PaCO₂ greater than 15% in a six month period will be updated, and the corresponding hazard ratios will be incorporated into the algorithm consistent with Policy 3.7.6.1 (Candidates Age 12 and Older) for the other factors used to calculate the LAS. Transplant centers will be required to update patients' data variables in the UNetsm system on a periodic basis. Because the algorithm needs to be flexible to reflect changes in patients' conditions, variables may be updated at any time. This aspect of the lung allocation algorithm is intended to reflect sudden changes in the severity of patients' illnesses. However, it will be mandatory that centers update their patients' variables in the UNetsm system at least every six months from the date of listing. Due to the serial change being

expressed within six month intervals, the current PaCO₂ value cannot be more than six months old, and the initial value used to calculate change cannot be more than six months older than the current PaCO₂ value. For example, compared to patients who are relatively stable with respect to PaCO₂, higher waitlist hazards will be seen in candidates who have a 15% increase in PaCO₂ at any point within the previous six months, whether this takes three months to occur or six. These higher hazards generally lead to improved ranks using the LAS algorithm. If a patient with a higher value of PaCO₂ stabilizes over the next six months, their hazard relating to change will revert back to no change, but the hazard relating to their current elevated PaCO₂ will remain elevated. If the data variables are not updated, a default least beneficial value will be inserted in place of the expired values. For PaCO₂ where no previous value has been entered, the least beneficial value will be 0 mmHg and no change in PaCO₂. Where there is already a previous PaCO₂ value entered, the least beneficial value for the change in PaCO₂ will be no change in PaCO₂.

2. Update on the Progress of the HHS Program Goals. The Committee members were updated on the progress towards meeting the donor-related HHS Program Goals. Currently, the only goal set for 2006 that is projected to be met is the number of non-DCD donors. The following data were felt to be especially important for the recovery of thoracic organs:

A portion of the increase in the number of deceased donors in recent years can be attributed to an increasing number of donors with some less-than-ideal characteristics. Some examples of these characteristics for deceased non-DCD donors include:

- In 2002, 31% of donors were 50 years or older; during the first 8 months of 2006, 36% were 50+ years old.
- In 2002, 2% of deceased donors had a body mass index (BMI) of 40 or higher. During the first 8 months of 2006, 4% of the donors had a BMI of 40 or higher.
- In 2002, 25% of deceased donors were reported to have a history of hypertension; in the first 8 months of 2006, 32% had a prior history of hypertension.

It was noted that these donor characteristics will likely have a negative impact on the number thoracic organs transplanted per donor.

3. Executive Summary of the Minutes from June and December 2006 Board of Directors Meeting. The Committee was informed that at its June 29-30, 2006 meeting the Board of Directors approved modifications to the heart justification form, and the discontinuation of the Alternative Allocation Systems for lungs in Florida and Region 9. The modifications to Policy 3.7.2 (Geographic Sequence of Thoracic Organ Allocation) to modify Zone D and create Zone E was also approved by the Board, concurrent with public comment.

The Committee was also informed that at the December 13-14, 2006, Board meeting the Board approved a new six-month follow-up form for thoracic organs and approved “final” (post public comment) modifications to policy 3.7.2 (Geographic Sequence of Thoracic Organs) which will create a new Zone E for thoracic organ allocation. Zone E is defined as greater than 2500 miles from the donor hospital.

4. Proposed Modifications to Policy 3.1 (Organ Distribution Definitions). At its February 2, 2007, meeting, the Committee reviewed this proposal from the Operations Committee. The aim of the proposed policy modifications is to improve patient safety by requiring verification of UNOS Donor ID number of all organs prior to transplant. The following points were made during the discussion:

- Concern was expressed that there have been transcription errors involving the UNOS Donor ID numbers and that these kinds of errors can cause problems when verifying the ID number in the operating room prior to transplantation of the organ.
- It was noted that some OPOs and transplant programs use the UNOS Donor ID on labels for all their donor related material and the point was made that the ID number was used very consistently as a check to ensure that the correct organ was transplanted into the correct patient.

A motion was made to support the policy change as written, and the proposal was approved by the Committee by a vote of 15 for, 0 against and 0 abstentions.

5. Proposed Modifications to Data Elements in UNetSM Transplant Recipient Follow-up (TRF). At its February 2, 2007, meeting, the Committee reviewed this proposal from the Policy Oversight Committee. The proposal would significantly reduce the number of data elements that transplant centers will be required to submit on the Transplant Recipient Follow-up (TRF) form after 5 years post-transplant.

A motion was made to support the proposal as written. The proposal was approved by the Committee by a vote of 15 for, 0 against and 0 abstentions.

6. OPTN Data Analysis. At its October 30, 2006, and February 2, 2007, meetings the Committee was provided a description of the results of data analysis by UNOS Research staff.

Lung Allocation Score Summary Statistics

When waiting list mortality was assessed, the median LAS for patients removed for death was 46.5, whereas the LAS for patients removed for transplant was 42.0. When looking at median LAS for removal for death by diagnosis groups, Groups A and B had median LAS scores of 34.9 and 34.7, respectively, whereas Groups C and D had median LAS scores of 48.5 and 62.9, respectively. These data reflected the concerns that the LAS score of patients in Group B is not reflecting their progression of disease. A question was raised concerning the data quoted in a recent New York Times article about the LAS, where it was suggested that one year survival was 56% for patients with an LAS of 44.4 and higher.. It was stated that it is policy not to produce data until a certain period of time following the period of implementation and at the time the article was published there would have been a very limited number of patients with one year follow-up data. At the February 2, 2007, Committee meeting, data was provided that showed that there was not a significant difference in patient survival at 8 months post transplant, pre and post implementation of the LAS.

Lung Waiting List Removals Pre- and Post- LAS

In looking for changes in patterns of removal reasons, a large number of patients improved, and transplant was no longer needed from 3.1% to 8.1%). An increase in the number of patients lost to follow-up was also noted (17.6% to 49.7%).

Waiting List and Transplant Tabulations: On-Going Monitoring of the Heart Allocation Policy Modification on July 12, 2006

Limited information is available at this time. The distribution of status, number of adult patients active on the waitlist, and size of the waitlist are similar pre-and post-implementation. A shift of transplants occurring from local to Zone A was seen. The data suggest that there are more status 1B patients being transplanted and fewer status 2 patients being transplanted.

At its February 2, 2007, meeting, the Committee reviewed further OPTN data analysis attached as **Exhibit B** regarding:

- *General Waiting List and Transplant Statistics*
- *Ongoing Monitoring of Heart the Allocation System*
- *Waiting List Mortality and Transplant Rates in Heart-Lung Candidates*
- *Use of Adult Heart Status IA(D)*
- *Impact of LAS Components on Waiting List Mortality*
- *Impact of ABO Matching on Post-Transplant Survival in Deceased Donor Lung Transplants*- The Committee did not see any need to change the current policy, which allows ABO identical patients to come before ABO compatible patient at this time.
- *Characteristics of Lung Waiting List Candidates at the Time of Death*
- *Tabulation of Fields Recently Added to the Lung Waiting List*- These fields are completed voluntarily by the members. Data submission rates for the optional elements recently added to the lung waiting list as of September 13, 2006, vary considerably by element and across diagnosis groupings. There are relatively few candidates younger than 12 who were added or had 6-month updates within the time period of this analysis so results are summarized primarily for candidates 12 years and older.

For candidates 12 years and older newly added to the waiting list between September 13, 2006, and December 15, 2006, greater than 70% had FEV1 reported. But FEV1 was much less frequently provided for group B candidates somewhat less frequently provided for group C candidates. Only about 25% of the candidates had post-bronchodilator FEV1. Hemoglobin and hematocrit were provided on more than 80% of newly added candidates; these rates were fairly similar across diagnosis groupings. The blood gas type was provided on approximately 65% of the candidates across all diagnosis groups. For those candidates with blood gas type reported, the blood gas fields (pH, PaCO₂, PaO₂) were almost universally reported.

When PA systolic was reported, greater than 95% of candidates across diagnosis groups had PA diastolic reported. Cardiac output was reported somewhat less frequently, with cardiac index and CVP reported even less so with about 55-65% of candidates in each diagnosis group having CVP reported.

The data submission rates for 6-month updates were much lower than for the newly added candidates. For example, FEV1 was provided on greater than 70% of the newly added candidates but only about 25% of the 6-month updates. Any ABG information was available on less than 15% of updates.

Thus it may be possible to utilize these recently added optional elements, with varying degrees of completeness, in examining possible modifications to the LAS for candidates at the time they are listed. In contrast the level of completeness for 6-month updates is substantially lower, so this information does not currently appear to be useful in examining longitudinal changes. But these elements are of relatively recent vintage so it is possible that the patterns of data submission may change in the future.

7. SRTR Data Analysis: Continued Development of Heart Waiting List Mortality and Post-Transplant Survival Models. At its October 30, 2006, meeting, representatives from the SRTR gave the Committee an update on their work on the heart waiting list mortality and post-transplant survival models. The issue of dependent censoring on the waitlist mortality model was explained. Due to the sickest patient being removed for transplant, their waitlist outcomes are not represented due to their removal from the list. To correct for this, patients remaining on the waitlist with similar characteristics carry the weight of those removed, with

the additional weight capped at 20. Upon weighting the significant factors ($p < 0.10$) were assessed. The Committee recommended delving further into the cardiomyopathy variable to look for any significance with chemotherapy-induced cardiomyopathy due to the presence of a significant signal with previous malignancy. In the post-transplant survival model not much change was seen from previous reports. It was decided to leave out donor-related variables at this time and readdress them in the future. Issues with waitlist analysis with VAD patients were addressed. It was questioned whether the SRTR could obtain data from the INTERMACS registry. It was noted that the INTERMACS data is more focused on destination therapy as opposed to bridge-to-transplant patients. It was suggested to capture patient status is changed when VADs are used. At a future meeting the Committee will look at the results when the data is entered into TSAM to see how the outcomes would change with a modification to the policy.

At the February 2, 2007, Committee meeting, the SRTR presented the analysis comparing the relative ordering of heart candidates using the existing 3-tiered status system and a survival benefit system. In summary, ranking patients based on survival benefit at listing results in differences in the relative ordering of patients compared to the current 3-tiered status system. Although the rankings of Status 1A and 1B patients tend to be higher than those of Status 2 patients, there is considerable overlap in the rankings by status. Some Status 2 patients would be ranked higher than some 1A and 1B patients and some 1B patients would be ranked higher than some 1A patients. In addition, VAD patients would tend to be ranked lower than non-VAD patients because their waitlist survival is better than that of the non-VAD patients.

At its February 2, 2007, meeting, the Committee reviewed further SRTR data analysis summarized in **Exhibit C** regarding:

- *Impact of Serially Obtained Creatinine and Bilirubin on the Waiting List Mortality Component of the LAS-* In an ongoing effort to refine the LAS, the Committee expressed interest in utilizing existing data to examine the impact of creatinine and bilirubin on waiting list mortality. These fields were collected in the retrospective data project so are available on a large cohort of patients that were used in the development of the LAS. They may prove useful in refining the waiting list mortality component of the LAS, particularly group B candidates.

Decreases in bilirubin from listing to 6-months post-listing of at least 40% or increases of at least 100% are significant predictors of waitlist mortality. These results may be counter-intuitive as one would expect that decreasing bilirubin would reflect better cardiac function. The large amount of missing serial change data (40%) may have influenced these results. Increase in creatinine from listing to 6-months post-listing of at least 30%, as well as follow-up creatinine, was associated with significantly higher risk of waitlist mortality. Other LAS factors were consistent in terms of the hazard ratios, though not all factors maintained statistical significance. The SRTR will do further analysis on this for the next meeting.

- *Prior Malignancy as a Risk Factor for Heart Candidate Mortality-* Results of the heart waiting list mortality models in ongoing development for a revised heart allocation system were reviewed at the Heart Subcommittee meeting. Although prior malignancy was present in less than 4% of the cohort, it was associated with a 44% higher risk of mortality on the waiting list. It was speculated that one possible explanation for this is the increased risk associated with a diagnosis of chemotherapy induced cardiomyopathy.

Another suggestion was that prior malignancies may be more common in older candidates so that prior malignancy was perhaps a surrogate for older age.

The effect for prior malignancy does not appear to be a surrogate for either chemotherapy-induced dilated cardiomyopathy or older candidate age.

- *Examination of VAD as a Risk Factor for Heart Candidate Mortality-* Results of a waiting list mortality model for candidates with a VAD implanted were reviewed at the by the Committee. The analysis presented did not incorporate the impact of device malfunction/complication. (Status 1A criteria b). In summary, a time-dependent indicator of Status 1A(b) was not a statistically significant predictor of waitlist mortality amongst the VAD population. A number of issues were raised regarding the censoring of VAD patients from the waitlist and how this can affect the data analysis. It was noted that most VAD patients are made inactive on the waitlist for 30 days and that approximately 30% of the patients with VADs die before they get transplanted. The concern was raised that candidates who receive a VAD and become inactive, and never get reactivated and die get counted as a waitlist death, but the death does not get attributed to the VAD group in this analysis.
 - *Lung Allocation Score-* During the implementation phase of the Lung Allocation Score, the Committee expressed interest in reviewing updated parameter estimates and baseline survival on an ongoing basis. The results of this request will be utilized by the Thoracic Committee to determine whether the impact is considered substantial enough to warrant modifications to the LAS calculation. In summary, there are very few substantive differences between the estimates that are currently being used and the estimates from the updated cohort. It should not be surprising that a few differences do exist since the rules change in May 2005 resulted in patients being selectively removed from the list due to disease progression as indicated through serial data collection. The IPF population (Diagnosis Group D) is one factor that may be changing as we have moved from a waiting time-based system to one based on disease progression, transplant-benefit, and medical urgency. However, the SRTR does not recommend that changes to the system be made at this time based on these data. It is preferable to refine the model based on a post-policy change cohort that provides sufficient follow-up to estimate the effects under the new system.
8. IT Status Update. At its October 30, 2006, meeting, UNOS IT staff gave the Committee an overview of the issues and workload, contributing factors to the problems being faced, and plans to fulfill the needs of the department while continuing their service to the Committees.

At its October 30, 2006, meeting, the Committee discussed the implementation of the approved proposals that would allow transplant centers to ability to indicate whether it would accept Hepatitis B and/or C positive thoracic organs for its patients. The Committee was informed that in implementing these proposals in UNetsm the patients would show up on the match list if the transplant center did not enter any information in the acceptance field. The Committee concurred with the programming of these proposals, and asked that a data analysis be performed, in approximately six months, that describes how many thoracic patients on the waitlist are listed to accept hepatitis B and/or C positive organs.

9. Review of the Thoracic Six-Month Follow-Up Form. At its October 30, 2006, meeting, the Committee was presented with a sample 6-month follow-up form for its review. Upon review of the form, the Committee requested the following changes be made: auto-populate the state of residence by utilizing the zip code, titer data fields only generating for the

necessary candidates; clinical information only appears if patient status indicated is “living” or “re-transplanted” or “dead” with a cause of death indicated as something other than graft failure. The Committee voted 14 yes, 3 no, 1 abstention to approve the form with the noted changes. The Committee will send this information to the Membership and Professional Standards Committee for its determination that the proposal is ready for Board approval.

10. OPTN Data Reduction Project Update. At its October 30, 2006, meeting, UNOS staff gave the Committee an update on the data reduction project. Recommendations made by the Committee at its meetings to review the recommended deletions were reviewed by the Policy Oversight Committee and stakeholders. Separate efforts are being made to reduce the data collected for follow-up past five years. The Committee was asked to look at the items and justify those that are recommended for retention with one of the five principles of data collection. The Committee recommended the following items for retention for post-five year follow-up for the reasons of future allocation policy development and patient care:

- Heart function: coronary artery disease
- Lung Function: bronchiolitis obliterans grade
- Renal dysfunction with creatinine greater than 2.5, chronic dialysis, and renal transplant since thoracic transplant

11. Report from the Heart Allocation Subcommittee. The following describes the presentation of issues by the heart subcommittee to the full Committee:

Housing and Maintenance of Status 1A Patients at Alternative Facilities

At the May 10, 2006, Committee meeting, representatives from the University of Pennsylvania Health System and Presbyterian Medical Center requested that the Committee approve a local variance so that Status 1A patients could be listed at an affiliated hospital and not at the transplant hospital. The Committee denied the request for a variance, but charged the Heart Subcommittee with evaluating the possibility of allowing other facilities affiliated with the transplant center the opportunity to house Status 1A patients using the University of Pennsylvania’s request as an example. Currently, Status 1A patients must be housed at the transplant center unless admitted to a VA facility, or listed as 1A under criterion b. It was noted that the nature of center affiliations to other facilities are not all based on similar grounds, and relationships can be terminated without much notice. It was also noted that defining allowable circumstances or methodologies would be difficult. The subcommittee felt it needed to be consistent with its decisions regarding the housing and maintenance of Status 1A patients and would recommend that Status 1A patients, with the exception of those in the VA system and those listed under criterion b, would be required to be housed in the transplant center.

Heart-Lung Allocation Questions

Since implementation of the modification of the heart allocation sequence, several inquiries concerning the allocation of thoracic organs for heart-lung candidates have come up. The questions stemmed from the statement in Policy 3.7.7, “When the candidate is eligible to receive a lung in accordance with Policy 3.7, or an approved variance to this policy, the heart shall be allocated to the heart-lung candidate from the same donor if no suitable Status 1A isolated heart candidates are eligible to receive the heart.” OPOs questioned when they could allocate lungs on the lung list when heart-lung patients appear as Status 1A further on the heart list outside of the local area (Zone A, Zone B, Zone C, or Zone D). Data were requested regarding the status and LAS of heart-lung patients listed for transplant and whether those transplanted were allocated based on their heart status or LAS. Clarification in the policy language will be drafted to indicate the heart shall be allocated to the heart-lung

candidate from the same donor if no suitable Status 1A isolated heart candidates are eligible to receive the heart *within any individual geographic area of allocation* and presented to the full committee in October.

At the full Committee meeting, data presented showed a majority of heart-lung patients were being allocated to from the heart match run list. It was decided to have a joint heart and lung subcommittee meeting to discuss this further.

Waiting Time Modifications

The Committee reviewed the following cases for waiting time modifications and accepted the recommendations of the heart subcommittee:

- A patient's status was changed from Status 2 to inactive. Upon reactivating the patient as a Status 2, the patient was not activated on the waiting list. The Heart Subcommittee felt this request for time lost was acceptable but would like more detail on measures the center would take to prevent this from happening in the future.
- A patient was listed as Status 1A (b) but was not in the hospital as required by Policy 3.7.3 (the change in listing requirements had not yet been implemented). The center was asking to relinquish its time as Status 1A and convert it to Status 1B. The Heart Subcommittee supported the request but felt the request to downgrade time was not necessary.
- A patient was upgraded to Status 1A(d), but five days later the Milrinone dose was decreased no longer making the patient eligible for 1A status. The center was requesting the 1A time to be converted to 1B time. The subcommittee maintained its feelings that the downgrading of time did not need to come to the Committee.
- A patient received a heart transplant as a Status 2. While in the operating room "his perioperative course was complicated by right ventricular failure, and a right ventricular assist device was placed. It was decided to re-list the patient." Instead of removing the patient and re-listing, the center upgraded the patient's status to 1A. The following day the center realized the error and removed and re-listed the patient. The center was requesting Status 1A time for the time lost from the upgrade of status to re-listing. The subcommittee felt this request was acceptable but questioned whether it was an issue at this point since so much time had passed since the incident.
- A patient was listed as a Status 1A(a) after VAD placement. The patient remained a 1A for 30 days and was then downgraded to Status 1B. Later in the month the center discovered the patient's acceptance criteria was entered incorrectly as minimum donor weight "172 kg" instead of "172 lbs." It was discovered the patient was excluded from 255 match runs. The center requested to re-list the candidate as a Status 1A for an additional 30 days and convert the initial 1A time to 1B time. The regional heart review board was provided a summary of the events and the center's request. The chair agreed with the upgrade to Status 1A and the conversion of the previous 1A time to 1B time. The center was notified of the chair's decision and was instructed to submit a waiting time modification request for the time conversion. The patient was upgraded to a Status 1A(e) and the review board approved the listing. The Heart Subcommittee it was not necessary to get involved in this case and deferred to the Regional Review Board that handled the case.
- A patient was listed as a Status 1A(d). The Swan-Ganz catheter was removed two days later, but the patient remained listed as a Status 1A. The center was requesting a downgrade of time for the days in error. The Heart Subcommittee remained firm on its stance that downgrades of time did not need to be presented to the committee.

A motion to approve the recommendations of the Heart Subcommittee to no longer review wait time modifications involving a downgrade of status time was approved 13

yes, 0 no, 0 abstentions. A motion to approve the actions of the Heart Subcommittee along with having the heart and Lung Subcommittees work further on the issue of heart-lung allocation and the recommendations for the wait time modifications was approved 13 yes, 0 no, 0 abstentions.

12. Report from the Lung Allocation Subcommittee. *OPTN/UNOS Membership and Professional Standards Committee Consideration of Pediatric Lung Listings for Candidates Under 12 Years Old:*

On May 10, 2006, the Committee reviewed a request from the MPSC regarding the listing practices of lung candidates under the age of 12 years old. The MPSC had received a complaint from an OPO that a pediatric lung transplant program was frequently refusing lung offers for candidates due to the patient not being available. At the October 26th meeting, it was stated that discussions with the MPSC resulted in two possible solutions: 1- adjust the policy such that candidates under the age of 12 years old accrue waiting time as Status 7, or 2- the affected centers provide the OPOs in their Zone A with a list of candidates who are ready for transplant. It was decided that, due to the number of candidates involved, the subcommittee was in support of changing the policy for those candidates to accrue waiting time as Status 7. It was felt that this change could improve the efficiency of OPOs placing organs, while at the same time reflecting the inefficiency of the allocation process by allowing patients not ready for transplantation to compete with patients who are. It was decided that this matter would be taken to the Pediatric Transplantation Committee as a proposal and then return to the Committee for support.

ABO Identical versus Compatible in the LAS

A question was raised regarding the appropriateness of allocating lungs to identical blood types over compatible blood types with a higher LAS. Concerns were raised that candidates with blood type O would be disadvantaged if this change were to take place. A request was made that data be obtained to assess the effect this type of change in allocation could make.

Addition of Right Atrial Pressure as an Additional Lung Field

While working on the Additional Lung Fields project a question arose whether right atrial pressure should be collected. It was noted that if CVP was being collected as a surrogate for RAP, it is already collected on a voluntary basis. It was questioned what data points were already being collected on a voluntary basis. It was opined that with RAP being one of the items on the list of proposed variables to be collected for PPH patients then the committee should look at collecting not only RAP, but all values obtainable with right heart catheterization. It was stated that the right heart catheterization would not be required every year but at least once; if a center would like to use those values to manipulate its patient's score, it would be able to update the values voluntarily.

At the full Committee meeting it was reported that the submission rate of the optional fields being collected was higher than expected: pre-bronchodilator FeV¹ was collected 73.2%, hemoglobin 85.8%, hematocrit 85.3%, cardiac output 90.6%, PA diastolic 97.6%, CVP 56.5%, and ABG information 62.1%-65.3%. Due to the importance of the data it was proposed to amend the PaCO₂ proposal to collect PaCO₂ at time of listing and at six month intervals. The Committee voted 15 yes, 0 no, 0 abstentions to this proposal. Another proposal was made to collect right heart catheterization data. The Committee voted 15 yes, 0 no, 0 abstentions to the following proposal: right heart catheterization data (cardiac index, PA systolic and diastolic pressures, CVP or RAP) shall be collected at time of listing and may be updated at time of subsequent catheterization.

Request for Clarification on the Six Minute Walk

A work order was submitted for clarification on whether a patient should be on room air or supplemental oxygen at the time of the six minute walk test. The subcommittee viewed the guidelines published in the AJRCCM from the ACS- if patients are on chronic oxygen therapy oxygen should be given at their standard rate or as directed by a physician or protocol. It was opined that candidates should be on the rate of oxygen therapy entered in the LAS at time of listing.

13. Strategic Planning and Annual Goals- The Committee was notified of a conference call that took place August 16, 2006, between David Vega, M.D. and OPTN/UNOS President, Sue McDiarmid, M.D., to consider issues recommended for discussion in the Committee this year. The Committee discussed the following items:

- ***Consider the Status 2 definition– is there a range of severity of disease that predicts mortality on the list that should be used to better prioritize allocation in this status?***
- ***Why do Status 2 patients die on the list?***

The Committee has requested data analyses which could provide an insight into both of these questions. The Committee will be reviewing data analyses and modeling results at its' February 2, 2007 meeting. The Committee has expressed an interest in determining if there are differences in waitlist mortality for Status 2 patients with ischemic cardiomyopathy versus idiopathic cardiomyopathy, or adult congenital heart disease which would lead to a greater risk of waitlist mortality.

- ***Does the increased use of LVADs and other assist devices need to be adjusted for in allocation policy?***

The Committee believes that the work that the SRTR is currently doing to construct a heart benefit model will answer this question in a comprehensive systems approach. The Committee will be reviewing additional work and analysis from the SRTR regarding its progress in constructing a heart benefit model at its February 2, 2007, meeting.

- ***What is the definition of the ECD heart or lung and how should it be allocated?***

The Committee discussion made it clear that there is extensive diversity of practice for the defining both Standard Criteria Donor (SCD) hearts and lungs and Extended Criteria Donor (ECD) organs. The question was raised regarding the purpose of defining an ECD organ. If the primary purpose for defining ECD donors is to facilitate the utilization of thoracic organs, then the Committee felt it would be better to focus its efforts on streamlining the thoracic organ offer and acceptance process. The Committee will be monitoring the effectiveness of the upcoming changes to the waitlist and match run screen which will include the minimum acceptable donor age maximum acceptable donor age, maximum miles the organ recovery team will travel, minimum acceptable donor weight, maximum acceptable donor weight and the acceptance of hepatitis B and C organs. One committee member noted the Pulmonary Task Force of the International Society for Heart and Lung Transplantation (ISHLT) was not able to decide on ECD lung criteria due to wide variation in program practice.

- *DCD for lung- consider developing ‘best practices guidelines’.*

The Committee noted that the experience in performing lung transplants from DCD donors is very limited. The committee estimated that approximately 40 DCD lung transplant have been performed to date and that only a handful of programs have used DCD donor lungs. The general consensus was that additional experience by more lung programs is necessary before it would be useful to develop “best practice” guidelines.

14. Heart Sequence Task Force Update. At the June, 2006, Board of Directors meeting, a Task Force was created to monitor the modifications to Policy 3.7.10 (Sequence of Adult Heart Allocation). The task force was charged with monitoring the impact the change potentially would have due to concerns voiced in the transplant community. On August 16, 2006, the group met to discuss what data elements would be necessary to monitor the change in heart allocation. Another meeting was scheduled for November 29, 2006, to look at the first set of data. The Task Force met on November 29, 2006, and reviewed the data analysis’s that it had requested. **Exhibit D** provides a summary of the Task Force discussion.
15. Local versus Non-Local Cross-Matching. Dr. Lee Ann Baxter-Lowe, Director, Immunogenetics and Transplantation Laboratory, University of California, San Francisco and Region 5 Representative, Histocompatibility Committee, spoke to the Committee regarding differential and non-uniform availability for local versus non-local thoracic organ crossmatching. Currently, there are cases in which centers are offered a thoracic organ from outside of their local OPO, but are told by the non-local OPO they will not wait for a crossmatch of any type or method (even in cases in which the recipient’s sera was sent to one of the non-local HLA labs). On the other hand, some OPOs (for example, CTDN) have made a concerted effort to create a system to allow non-local programs to send sera in advance to an HLA lab within that OPO (in this case, UCSF), where regional and local sera trays are set up on a monthly basis, thus allowing for prospective T-cell crossmatching for all of those thoracic recipients (local and non-local) appearing on the match run within the compatible ABO donor types. This practice allows non-local centers to benefit from the crossmatches being completed prior to organ offers. A reasonable approach to the issues involved in crossmatching non-local recipients with potential donors is needed, both regionally and nationally. A Joint Subcommittee will be formed with members of the Histocompatibility, OPO, and Thoracic Committees to discuss this matter further. Mark Barr, M.D. and R. Duane Davis, M.D. will participate as representatives from the Thoracic Committee.
16. Referral from MPSC – Metric to Monitor Activity. A request was made from the MPSC to discuss whether it is necessary to develop a formal metric for the review of transplant centers with an excessive delay between internal approval of transplant candidate listing and activation on the waitlist. The Committee felt it was not necessary at this time but would continue to monitor the situation if it arises.
17. Proposal to Update LAS. UNOS staff presented a proposal to the Committee to formalize the process and expectation of reviewing the parameter estimates of the lung allocation score at six-month intervals. This proposal would create a standing data request for updated parameter estimates every six months. The Committee voted 18 yes, 0 no, 0 abstentions to approve this proposal.
18. Lung Donor Protocol. Luis Angel, M.D. presented a protocol regarding lung donors that was recently published in the American Journal of Respiratory and Critical Care Medicine. During the protocol period the number of lung donors increased from 38 in the pre-protocol

period to 98. The Committee voiced their support for the protocol and Dr. Angel's efforts and recommended that he present his work to the OPO Committee.

19. Heart Catheterization on Donors. A Committee member questioned if angiograms are part of the standard acquisition fee for all heart donors or whether they are charged an additional fee at the time of catheterization. Discussion among Committee members revealed a varying degree of practice around the country. It was noted that some OPOs take in to account the previous year's activity and budget to create an average cost for the fee. It was also noted that not all hospitals have the capabilities to perform the catheterization procedure, but Policy 3.7.12.2 (Desirable Information for Heart Donors) provides situations where it is deemed appropriate to request a heart catheterization.
20. Review of Thoracic Waiting-Time Modification Request. A patient was listed as a Status 1A(b) heart patient with a VAD infection but was not admitted to the hospital. This occurred prior to the implementation of the policy change on July 12, 2006. The Committee recommended no action to be taken but a reminder be sent to the center that policy changes are not in effect until implementation.
21. Lung Allocation Score Modification Request. A request for an estimated score was denied and overridden. The Committee felt no action was necessary.
22. Stand Alone Thoracic Transplant Programs. A Committee member raised an issue regarding whether a stand alone heart or lung transplant program should be approved when there is no other approved transplant program in the hospital. There was concern that these programs may not have sufficient ancillary services available in order to ensure good quality patient care. The Committee agreed that it should review the existing membership requirements for thoracic transplant programs. The Committee will determine if there are recommendations for improvements to the thoracic organ transplant program requirements that could be made to the Membership and Professional Standards Committee.
23. Heart Regional Review Board Case Review– At its February 2, 2007, meeting, the Committee reviewed two cases referred to it from the Heart Regional Review Boards and issued decisions in both cases.

Case #1 involved a center that requested Status 1A exceptional case for a heart candidate. The candidate had been diagnosed with idiopathic dilated myopathy. The center contended that the candidate could not receive a mechanical assist device due to heparin-induced thrombocytopenia positive testing. The candidate had considerable clinical deterioration within the past 4 months with increasing right heart pressures and symptomology, despite maximal medical therapy. The initial Status 1A listing was denied by review board. The center chose to maintain the Status 1A listing through the appeals process. The center requested a conference call to continue its appeal of the case and the review board affirmed the denial. The Committee reviewed the information on the case. By a vote of 15 for, 0 against, and 0 abstentions, the Committee found that the listing was not inappropriate, and that the center should be notified of its decision and its opinion on the listing.

Case #2 involved a center that requested a Status 1B initial listing for a heart candidate. The patient had end-stage restrictive cardiomyopathy and had been recently hospitalized with class IV decompensated heart failure. The center assessed the patients' risk of mortality within the next 6 months as extremely high. The Status 1B initial listing was denied by the review board. The candidate received a transplant at Status 1B two days before the review board initial denial of the case. The center appealed the decision and the review board affirmed the denial of the case. The center requested a conference call to continue its appeal

of the case and the review board affirmed the denial. The Committee reviewed the information on the case. By a vote of 15 for, 0 against, and 0 abstentions, the Committee found that the listing was appropriate and that no further action was necessary.

Thoracic Transplantation Committee

	Format (select)	In Person	Teleconference/ LiveMeeting
	Date (mm/dd/yyyy)	10/30/2006	02/02/2007
Name	Position		
J. David Vega MD	Chair	X	X
Maryl Johnson MD	Vice Chair	X	X
Gregory Couper MD	Region 1 Representative	X	
Alberto Pochettino MD	Region 2 Representative	X	
Cliff Van Meter Jr, MD	Region 3 Representative	X (via phone)	
David Nelson MD	Region 4 Representative	X	X
Mark Barr MD	Region 5 Representative	X	X
Michael Mulligan MD	Region 6 Representative	X (via phone)	X
William Cotts MD	Region 7 Representative	X	X
Wade Fischer MD	Region 8 Representative	X	
Jonathan Chen MD	Region 9 Representative	X	X
Gosta Pettersson MD	Region 10 Representative	X	X
Aaron Milstone, MD	Region 11 Representative	Position open, no representation 10/06	
Diane Brockmeier RN, BSN,MA	At Large	X	
David Campbell MD	At Large	X	X
R. Duane Davis MD	At Large	X	X
James Gleason	At Large	X	X
Jennifer Prinz RN	At Large	X (via phone)	X
Keith Stevens BSN,RN	At Large	X	X
Stuart Sweet M.D.	At Large	X	X
Thomas Threlkeld PA, CPTC	At Large		
Claude Young	At Large		
Paul Oldham	At Large	X	X
Edward Garrity Jr, MD, MBA	Ex. Officio	X	X
Michael Dreis PharmD, MPH	Ex Officio	X (via phone)	
Monica Lin Ph.D.	Ex Officio	X (via phone)	X
UNOS Staff Attending			
Douglas Heiney, BBA	Director, Department of Membership and Allocation Policy	X	X
Amy Bogard	Policy Analyst	X	
Leah B. Edwards, PhD	Director, Department of Research	X	X
Courtney Bland	Business Systems Analyst	X	X
Berkeley Keck, RN, MPH	Assistant Executive Director. Department of IT	X	X
Donna Whelan	Development Applications Engineer III/Team Lead	X	X
SRTR Staff Attending			

Susan Murray, ScD		X	X
Jeff Moore, MS		X	X
Tempie Shearon			X