

OPTN/UNOS Thoracic Organ Transplantation Committee

SUMMARY

Action Items for Board Consideration

- None

Significant Items (Do Not Require Board Action)

- *Modifications to Policy 3.7.6.1 (PCO₂ Language)*
On December 18, 2007, the OPTN/UNOS Executive Committee approved clarifications to the PCO₂ language in Policy 3.7.6.1. These clarifications detailed the Committee's intent for including current and change in PCO₂ in the lung allocation score. These modifications also enhanced the flow and readability of information in Policy 3.7.6.1. (Item 1, Page 3)
- *Analysis of Variables in the Patient and Graft Survival Models (Center Specific Reports)*
The Committee, through its Heart and Lung Subcommittees, has assessed the covariates in the thoracic patient and graft survival models for their continued inclusion. The Committee has identified new covariates for possible inclusion in these models. The Committee is working with the SRTR to analyze these newly identified variables for inclusion in the models. (Item 2, page 11)
- *Modifications to Pediatric Heart Allocation Sequence and Lung Allocation Sequence*
The Committee is working with the OPTN/UNOS Pediatric Committee to modify the heart allocation sequence for candidates 0-17 years of age, and the lung allocation sequence for candidates 0-11 years of age. (Item 3, page 12)
- *Addition of Bilirubin in the Lung Allocation Score*
At its last meeting (10/2/2007), the Committee voted to include bilirubin in the waitlist model of the lung allocation score. In 2008, the Committee will modify language in Policy 3.7.6.1 to include bilirubin. An increase in bilirubin that is at least 50% higher than the bilirubin value at listing increases a lung candidate's mortality on the waitlist. (Item 4, page 13)
- *Impact of the Lung Allocation Score System (Update)*
The Committee continues to monitor the impact of the lung allocation score system (LAS). Analyses indicate that, overall, the lung allocation score is producing the desired results. (Item 5, page 14)
- *Impact of the Heart Allocation Sequence (Update)*
The Committee continues to monitor the impact of the heart allocation sequence implemented in July, 2006. Analyses indicate that, overall, this sequence is producing the desired results. (Item 9, page 19)
- *Impact of DonorNet[®] on the Quality of Thoracic Organs Offered for Transplant*
At its last meeting (10/2/2007), the Committee reviewed the 6-month data on the efficiency and impact of DonorNet[®]. The Committee decided to develop additional screening criteria to eliminate the unintended consequence of offers of organs judged ultimately to be medically unsuitable for transplant. (Item 16, page 22)

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**Report of the OPTN/UNOS Thoracic Organ Transplantation Committee to the
Board of Directors
February 20-21, 2008
Orlando, Florida**

**J. David Vega, MD, Chair
Maryl R. Johnson, MD, Vice-Chair**

The OPTN/UNOS Thoracic Organ Transplantation Committee (Thoracic Committee) met on May 3, 2007 and October 2, 2007. The following is a summary of the Committee's deliberations:

**1. Modifications to Policy 3.7.6.1 (Candidates Age 12 and Older)
[Inclusion of PCO₂ in the Lung Allocation Score]**

On March 23, 2007, the OPTN/UNOS Board of Directors approved these modifications to Policy 3.7.6.1 to include PCO₂ in the lung allocation score. In the days preceding this Board meeting, the Lung Implementation Subcommittee met by conference call, on March 16, 2007 (Exhibit A), and by email. In these meetings, the Subcommittee discussed the PCO₂ functional specification document, reviewed the impact of PCO₂ on the lung allocation score (LAS), and revised the policy language. On March 16, 2007, the Lung Implementation Subcommittee also requested the SRTR to explore the following question: Are there decreases in waitlist mortality among lung candidates who report PCO₂ change $\geq 15\%$ in one 6-month period, but not in subsequent 6-month periods?

On May 3, 2007, UNOS staff presented to the Committee a summary of the March Subcommittee meetings, and the policy changes approved by the Board in March, 2007. These policy revisions:

- Added title to Table 2;
- Changed PaCO₂ to PCO₂ to allow for the collection of arterial, venous, and capillary blood gases (the central venous blood gas value will be reduced by 6 mmHg to equal an arterial value; capillary blood gas value will equal an arterial value);
- Incorporated the terms "highest" and "lowest" to refer to the two values used in calculating change in PCO₂. The lowest PCO₂ value has to occur temporally before the highest; and,
- Changed least beneficial value from 0 mmHg to the normal clinical value of 40 mmHg. This normal value cannot be used to calculate change in PCO₂.

Programming of PCO₂ will occur alongside the programming of Functional Status (remove existing NYHA class) in the LAS.

The Lung Subcommittee met again on July 19, 2007 to discuss the SRTR analysis of the Subcommittee's data request made on March 16, 2007: whether there are decreases in waitlist mortality among lung candidates reporting PCO₂ change $\geq 15\%$ in one six-month period but not in subsequent 6-month periods (Exhibit B). Dr. Duane Davis, Lung Subcommittee Chair, provided a summary of this meeting at the October 2, 2007 Committee meeting. The Subcommittee couldn't make recommendations based on data on whether to retain LAS impact from change $\geq 15\%$. The Subcommittee, relying on clinical evidence, recommended the retention of change benefit as long as the candidate continued to demonstrate PCO₂ change $\geq 15\%$.

UNOS staff commented that the Subcommittee's recommendations may need to be in the policy language, and that programming efforts ought to follow a change in the policy language. Other implementation questions also existed, and answers to some of these questions may also need to be in the policy language. Several Committee members expressed concerns about programming delays and disagreed with the need for language change. The proposed language change might require a public

comment phase, which could further delay programming. Many in the thoracic community think that programming for PCO₂ is complete. One Committee member suggested that UNOS staff prepare a document that details the relevant implementation concerns. The Lung Subcommittee planned to convene in the days following the Committee meeting to further discuss the PCO₂ policy and potential revisions.

Action Items Resulting from the October 2, 2007 Meeting:

- UNOS staff will organize a Lung Subcommittee meeting to further discuss the PCO₂ policy.
- UNOS staff will prepare a document that outlines the policy implementation concerns.

The Lung Subcommittee met on October 25, 2007 to discuss PCO₂ implementation and policy language concerns (Exhibit C). At this meeting, the Subcommittee decided that the PCO₂ policy language needed further clarification for the purposes of implementation and readability. The Subcommittee also decided to submit the policy changes to the Executive Committee.

Subsequent to the October 25, 2007 meeting, the Subcommittee refined the PCO₂ policy language and submitted these revisions to the Committee for approval. These revisions did not undergo a public comment cycle, because the proposed changes did not change the intent or scope of the policy. Further, the public had scrutinized this policy before its March 23, 2007 approval. The Committee voted in favor of the revisions and in sending the refined policy to the Executive Committee (16-Yes, 0-No, 0-Abstention).

On December 18, 2007, the Executive Committee approved the following proposed modifications to Policy 3.7.6.1 (8-Yes, 0-No, and 0-Absentions):

****RESOLVED, that Policy 3.7.6.1 (Candidates Age 12 and Older) shall be modified as set forth below, effective December 18, 2007:**

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 PCO₂ and change in PCO₂ 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, 2, and 3 as appropriate.

Table 1
Factors Used to Predict Risk of Death on the Lung Transplant Waitlist

Factors Used to Predict Risk of Death on the Lung Transplant Waitlist
1. Forced vital capacity (FVC)
2. Pulmonary artery (PA) systolic (Groups A, C, and D ⁺ – see 3.7.6.1.a)
3. O ₂ required at rest (Groups A, C, and D ⁺ – see 3.7.6.1.a)
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. PCO_2 , (see 3.7.6.1.b)

[†]Group A includes candidates with obstructive lung disease, including without limitation, chronic obstructive pulmonary disease (COPD), alpha 1 antitrypsin deficiency, emphysema, lymphangioliomyomatosis, 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-retransplant).

Table 2
PCO₂ Used in the LAS Calculation

<u>Value of current PCO₂[†]</u>	<u>Value of prior PCO₂[†]</u>	<u>PCO₂ used in LAS calculation[†]</u>	<u>Change in PCO₂ used in LAS calculation[†]</u>
<u>Not missing or expired</u>	<u>Not missing or expired; within 6 months of current PCO₂</u>	<u>Current PCO₂</u>	<u>Change in PCO₂ (i.e., highest – lowest/lowest)²</u>
<u>Not missing or expired</u>	<u>Missing or expired or is not within 6 months prior to current value</u>	<u>Current PCO₂</u>	<u>No Change³</u>
<u>Missing or expired</u>	<u>(any value, expired or not)</u>	<u>Normal Clinical Value (40 mmHg)⁴</u>	<u>No Change³</u>

[†]A center may enter a PCO₂ from an arterial, venous, or capillary blood gas into UNetSM to count towards a candidate's lung allocation score. A center must enter the value into UNetSM exactly as reported by the laboratory. Ideally, the arterial blood gas value will be used to calculate the lung allocation score. If venous and capillary blood gas values are entered, these values will be used to estimate an arterial value as follows: a capillary value will be equal to an arterial value; a venous value will have 6 mmHg subtracted from it to produce an equivalent arterial value.

²Both numbers must be actual, candidate blood gas values, and must be within 6 months of each other. Also, the lowest value must come temporally before the highest. A transplant candidate will receive a benefit from this parameter if the PCO₂ change is greater than or equal to 15% PCO₂

³Change must be calculated using two actual, candidate blood gas values. Therefore, if the equation contains a prior blood gas value that is missing, expired, or outdated, then change cannot be computed. The result is no change.

⁴The default value will be the normal clinical value of 40 mmHg.

Table 232
Factors That Predict Survival After Lung Transplant

<p>Factors That Predict Survival After Lung Transplant</p> <ol style="list-style-type: none"> 1. FVC (Groups B; and D⁺ – see 3.7.6.1.a) 2. PCW pressure \geq 20 (Group D⁺ – see 3.7.6.1.a) 3. Continuous mechanical ventilation 4. Age 5. Serum Creatinine 6. Functional Status (NYHA class) 7. Diagnosis
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NOTE: ~~The amendments to Policy 3.7.6.1 (Candidates Age 12 and Older) shall be implemented pending distribution of appropriate notice & programming in UNetSM, if and as applicable. (Approved at the March 2007 Board of Directors Meeting)~~

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.

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.

Table 3
Example Illustrating the LAS Calculation

<u>Parts of the Score Equation</u>	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

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.

a. Lung Disease Diagnosis Groups

The following are some of the diagnoses included in groups A, B, C, and D.

(i) Group A

Includes candidates with obstructive lung disease, including without limitation, chronic obstructive pulmonary disease (COPD), alpha-1-antitrypsin deficiency, emphysema, lymphangioleiomyomatosis, bronchiectasis, and sarcoidosis with mean pulmonary artery (PA) pressure \leq 30 mmHg

(ii) Group B

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

(iii) Group C

Includes, without limitation, candidates with cystic fibrosis (CF) and immunodeficiency disorders such as hypogammaglobulinemia

(iv) 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-retransplant)

b. PCO₂ in the Lung Allocation Score

UNetSM will use two measures of PCO₂ in a candidate's lung allocation score calculation: current PCO₂, and change in PCO₂. There are two types of PCO₂ change calculations: "threshold change" and "threshold change maintenance." The following explanations (i-vi) and illustrations (Figures 1-3) detail how UNetSM uses PCO₂ in the lung allocation score.

(i) Use of Arterial, Venous, or Capillary PCO₂ Values

In UNetSM, a center may enter a PCO₂ value from an arterial, venous, or capillary blood gas test. UNetSM will convert a venous or capillary value to estimate an arterial value as follows:

- a capillary value will equal an arterial value; and,
- UNetSM will subtract 6 mmHg from a venous value to equal an arterial value.

In the lung allocation score calculation, UNetSM will use the PCO₂ value with the most recent test date, regardless of the blood gas type. Exception: if an arterial value and either a venous or capillary value have the same test date, UNetSM will use the arterial value in the lung allocation score calculation.

(ii) Definition of Current PCO₂

Current PCO₂ is the PCO₂ value with the most recent test date entered in UNetSM.

(iii) Expiration of Current PCO₂ Value

UNetSM will evaluate a current PCO₂ value as expired according to Policy

3.7.6.3.2.

(iv) Use of Normal Clinical Value for Current PCO₂

The normal clinical value of PCO₂ is 40 mmHg. UNetSM will substitute this normal clinical value in the lung allocation score calculation when the value of current PCO₂ is less than 40 mmHg, missing, or expired.

(v) PCO₂ Values Used in the Change Calculations

There are two types of PCO₂ change calculations: threshold change and threshold change maintenance.

The threshold change calculation evaluates whether the PCO₂ change is 15% or higher. In this calculation, UNetSM will use highest and lowest values of PCO₂. The test date of the lowest value must be earlier than the test date of the highest value. Test dates of these highest and lowest values cannot be more than 6 months apart. If necessary, UNetSM will use an expired lowest value, but not an expired highest value. If a value is less than 40 mmHg, UNetSM will substitute the normal clinical value of 40 mmHg before calculating change. The equation for threshold change is [(highest PCO₂ – lowest PCO₂)/lowest PCO₂]

The threshold change maintenance calculation occurs *after* the candidate receives the impact from threshold change in the lung allocation score. This maintenance calculation determines the candidate's eligibility for retaining the impact from threshold change in the lung allocation score. To maintain the impact from threshold change in the lung allocation score, the current PCO₂ value must be at least 15% higher than the lowest value used in the threshold change calculation. The equation for threshold change maintenance is [(current PCO₂ – lowest PCO₂)/lowest PCO₂].

UNetSM will perform the threshold change maintenance calculation either when the current PCO₂ value expires (Policy 3.7.6.3.2) or a new current PCO₂ value is entered. For this calculation, the lowest and highest values that were used in the threshold change calculation can be expired. The current PCO₂ value can be the highest one that was used in the threshold change calculation. If a current PCO₂ value expires, the candidate's lung allocation score will lose the impact from threshold change. The reason for this loss is that when a current PCO₂ value expires, UNetSM will substitute that expired value with the normal clinical value of 40 mmHg. This normal value, therefore, cannot be 15% *higher* than the lowest value in the threshold change calculation.

If a center enters a new current PCO₂ value for a candidate who has lost the impact from threshold change, UNetSM will perform the threshold change maintenance calculation. If the new current PCO₂ value is at least 15% higher than the lowest value used in the threshold change calculation, UNetSM will *reapply* the impact from threshold change to the candidate's lung allocation score.

(vi) Impact of PCO₂ Threshold Change in the Lung Allocation Score

A change in PCO₂ that is 15% or higher, or threshold change, will impact a candidate's lung allocation score. The candidate will not lose the lung allocation score impact from threshold change provided that the current PCO₂ is at least 15% higher than the lowest value used in the threshold change calculation.

Figure 1
Use of Current PCO₂ in the Lung Allocation Score

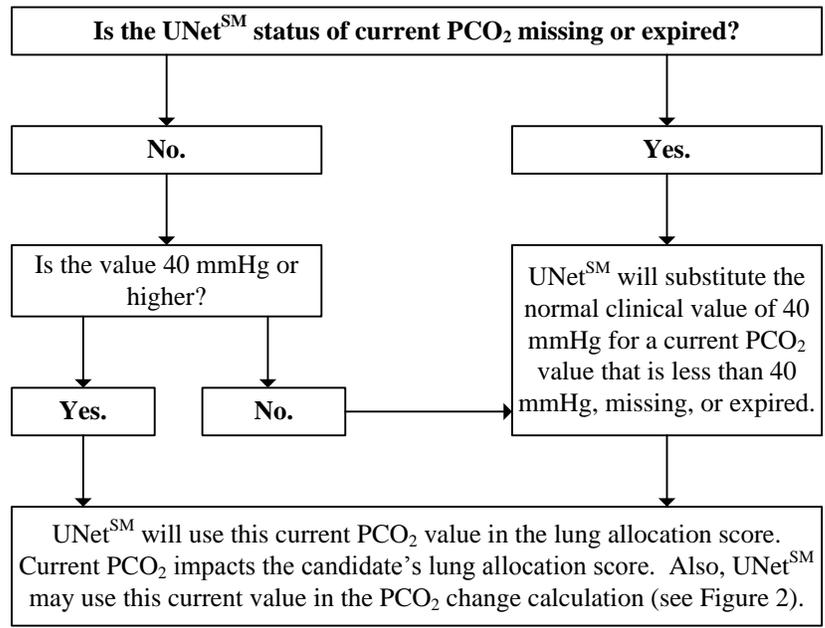


Figure 2
PCO₂ Threshold Change Calculation

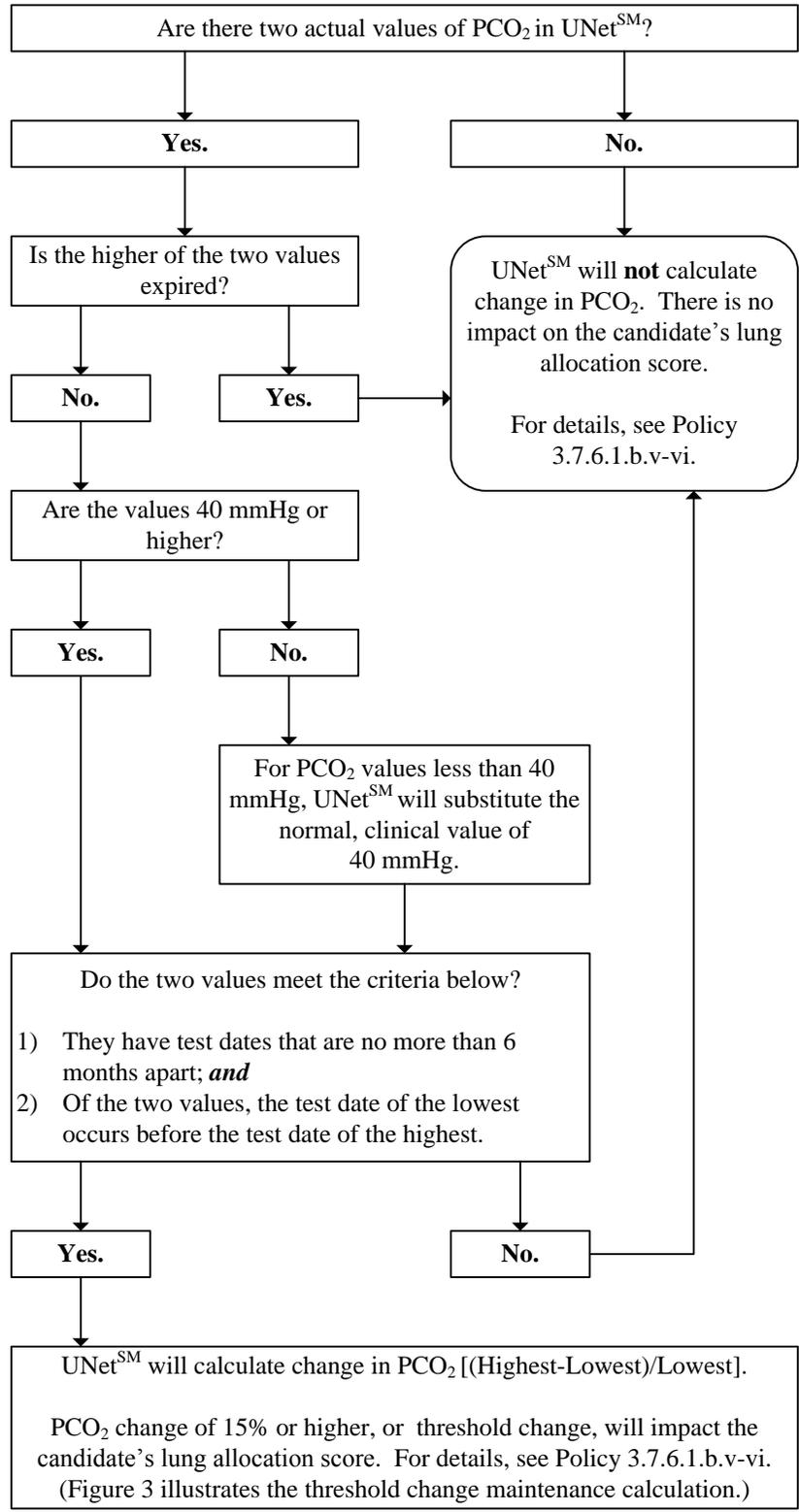
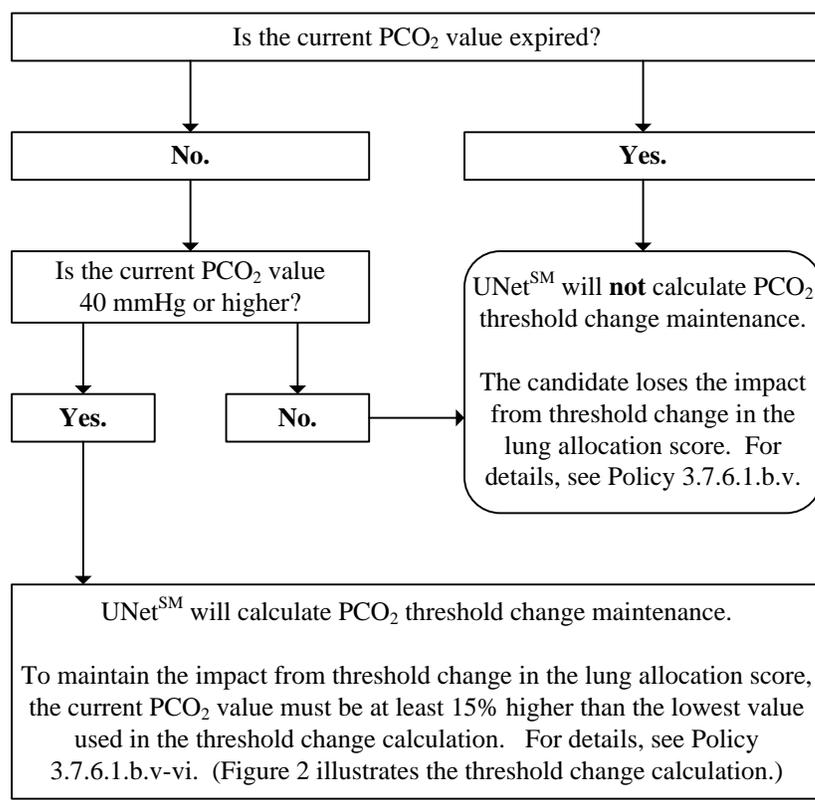


Figure 3
PCO₂ Threshold Change Maintenance Calculation



NOTE: The amendments to Policy 3.7.6.1 (Candidates Age 12 and Older) shall be implemented pending distribution of appropriate notice & programming in UNetSM, if and as applicable. (Approved initially at the March, 2007 Board of Directors meeting, and further refinements to the language approved at the December 18, 2007 Executive Committee meeting)

2. Analysis of Variables in the Patient and Graft Survival Models (Center Specific Reports)

On May 3, 2007, the Committee discussed a request from the OPTN/UNOS Membership and Professional Standards Committee (MPSC) to review the recipient, donor, and transplant characteristics used in the models that produce center-specific expected outcomes. The Committee was asked to review the models for medical currency and effectiveness. The Committee received a listing of these variables for review.

The SRTR commented that the clinical and statistical relevance of these models needs to be accurate. MPSC reviews these outcome data in three ways to evaluate a program: 1) ratio of observed to expected deaths has to be greater than 1.5; 2) the absolute number of excess deaths observed over expected deaths has to be 3 or more; 3) difference between observed and expected has to be statistically significant. If a program meets all three criteria, then the MPSC “flags” it for further review. Many managed care companies use these outcome data published by the SRTR on its website for determining centers of excellence.

The SRTR staff suggested that the Committee discuss why each variable is included in the model (clinical relevance, statistical relevance, reasonableness of inclusion), and determine if new variables are needed. The SRTR will provide guidance during this discussion and present statistical as well historical information for variables included or not included in the two models (if the suggested new variable was

reviewed previously or not, reasons for exclusion if reviewed previously, etc.). The SRTR commented that the recent updates to the lung and heart models might make this process somewhat easier.

The Committee decided to deliberate further on this topic in the Lung and Heart Subcommittees. To enhance this discussion, the Committee requested data elements from the OPTN and the SRTR for the Subcommittees to review.

The joint meeting of the Heart and Lung Subcommittees occurred on September 20, 2007 (Exhibit D). On October 2, 2007, Dr. Maryl Johnson, Chair of the Heart Subcommittee, updated the Committee on the deliberations of the Heart and Lung Subcommittees. On September 20, 2007, the Subcommittees reviewed variables in the OPTN deceased donor registration form, as well as variables currently used in the center-specific reports. The Subcommittees identified several new variables for analysis by The SRTR. These new variables included xyz. The results of this analysis may mean future inclusion of these variables in the models. The Subcommittees planned to convene again, separately, to determine which heart and lung variables to retain in the models, discard from the models, and add to the models.

One Committee member expressed concerns about the use of small numbers for evaluating centers, and inquired about using a longer time period in the survival models. If a one-year period was necessary, then perhaps this one year analysis could incorporate all cohorts of patients, and not just the one or two year cohorts used currently. Another Committee member commented that while this longer period may be useful to the recipient or the public (to better assess a transplant center's performance over time), this longer period may not be useful to the MPSC.

Action Item Resulting from the October 2, 2007 Meeting:

- UNOS Staff will organize meetings of the Heart and Lung Subcommittees to continue discussing variables that either are in or could be in the center-specific reports.

The Lung and Heart Subcommittees met on December 6, 2007 and December 7, 2007, respectively. Exhibit E is the Lung Subcommittee summary, and Exhibit F is the Heart Subcommittee summary.

3. Modifications to the Pediatric Heart Allocation Sequence and Lung Allocation Sequence (Charge to the Pediatric Committee to Eliminate Deaths on the Pediatric Waiting List)

On October 2, 2007, the Chair of the Pediatric Transplantation Committee, presented the Pediatric Committee's proposal for meeting the immediate past-President's charge to eliminate deaths on the pediatric waiting list. The Pediatric Committee proposed changes to the allocation of hearts from donors 0-10 years of age, and the allocation of lungs from donors 0-11 years of age. (Currently, donor hearts from this age group follow the adult heart allocation sequence (3.7.10).) The Pediatric Committee Chair presented the following data to the Committee:

- 28-62% of hearts and of 69-98% of lungs, from pediatric donors 0-11 years of age, were not transplanted.
- More than 50% of the time, the refusal reason given was donor age/quality or donor size/weight.
- Significant numbers of candidates remained on the waitlist when the match-run was not exhausted.
- 38-68% of heart, and up to 67% of lung candidates were removed from the waiting list, because of death/too sick.
- Very few 0-11 year old donor hearts/lungs are transplanted into adults.
- A significant number of 6-11 year old donor hearts/lungs are transplanted into adolescents.

Upon extensive data analysis, the Heart/Lung Working Group of the Pediatric Committee recommended the following allocation changes that enable geographic sharing of pediatric hearts and lungs.

Proposed Heart Allocation Sequence for Hearts from Donors 0-10 Years of Age

1. Local Status 1A Pediatric candidates
2. Zone A (including local) Status 1A Pediatric candidates
3. Local Status 1A Adult candidates
4. Local Status 1B Pediatric candidates
5. Zone A (including local) Status 1B Pediatric candidates
6. Local Status 1B Adult candidates
7. Zone A Status 1A Adult candidates
8. Zone A Status 1B Adult candidates

Proposed Lung Allocation Sequence for Lungs from Donors 0-11 Years of Age

1. Local, Zone A and Zone B 0-11 by urgency stratification and ABO
2. Local and Zone A 12-17 by LAS and ABO
3. Local adults by LAS and ABO
4. Zone A 0-11 by waiting time and ABO
5. Zone A 12-17 by LAS and ABO
6. Zone A adults by LAS and ABO
7. Zone B 0-11 by waiting time and ABO
8. Zone B 12-17 by LAS and ABO
9. Zone B adults by LAS and ABO

The Pediatric Committee expressed interest in co-sponsoring the above proposals with the Thoracic Committee. These proposals did not appear to impact the allocation to other age groups. The Thoracic Committee supported the Pediatric Committee's proposals and agreed to cosponsor them. The Pediatric Committee planned to draft the final policy language. A joint Pediatric-Thoracic Subcommittee will review the final draft of the revised policy language.

Action Item Resulting from the October 2, 2007 Meeting:

- UNOS staff will coordinate the development of this joint subcommittee with the liaison of the Pediatric Committee. This meeting will occur sometime before the end of this year.

On January 10, 2008, members of the Heart Subcommittee, Lung Subcommittee, and the Pediatric Committee's Heart and Lung Working Group met to continue discussing revisions to the pediatric heart and lung allocation sequences. At this meeting, the members of the Heart and Lung Subcommittees voted in favor of the pediatric proposals, and in co-sponsoring these proposals with the Pediatric Committee (Exhibit G). The Heart and Lung Subcommittees requested UNOS staff to forward the allocation and co-sponsorship proposals to the Thoracic Committee for approval. Subsequent to the January 10, 2008 meeting, the Committee voted in favor of the proposals (10-Yes, 0-No, 0-Abstention), and in co-sponsoring it with the Pediatric Committee. On February 8, 2008, the Pediatric Committee will distribute the two pediatric proposals for public comment.

4. Inclusion of Bilirubin and Creatinine in the Lung Allocation Score

On May 3, 2007, the Committee continued its discussion of including bilirubin and creatinine in the lung allocation score. The SRTR staff reported that an increase in bilirubin of at least 50% from the value at listing, observed in the 6-month post listing period, is associated with an increased mortality risk for diagnosis Group B (primarily candidates with PPH). Likewise, an increase in creatinine that is 30% or greater from the listing value, observed in the 6-month post listing period, is associated with an increased mortality risk for lung candidates. Bilirubin is the first data element examined since the implementation of LAS that shows any benefit in the LAS for the PH patient population. (Currently, UNetSM allows for the collection of creatinine, not bilirubin.)

The Committee advised the SRTR to continue its analysis on bilirubin and creatinine, and suggested that the Lung Subcommittee convene to begin discussing the potential for adding these two variables to the lung allocation score.

The Lung Subcommittee convened on September 20, 2007. Dr. Duane Davis, Lung Subcommittee Chair, presented the Subcommittee's deliberations at the October 2, 2007 Committee meeting (Exhibit H). Change in bilirubin and change in creatinine are associated with waitlist mortality, but not post-transplant survival. These markers may help predict waitlist mortality for candidates with pulmonary hypertension. There are limited but statistically significant data that support the inclusion of bilirubin in the LAS. Clinical observations also support this inclusion.

Dr. Reda Girgis, affiliated with the Reveal Registry, joined the Committee via conference call. Dr. Girgis reported that the Registry is very new, and doesn't have adequate data regarding bilirubin as a marker for candidates with pulmonary hypertension. Increases in bilirubin, he reported, are predictive of poor health outcomes, such as right heart failure. The Committee requested data on bilirubin from the Reveal Registry as they become available. In the future, Dr. Girgis will share relevant Registry data with the Committee for possible inclusion in the lung allocation score.

The Committee voted in favor of including bilirubin and change in bilirubin in the lung allocation score (20-Yes, 0-No, 0-Abstentions).

The Committee next discussed the inclusion of creatinine and change in creatinine in the lung allocation score. Creatinine is in the lung post-transplant model but not the waitlist model. The SRTR presented data on the interaction of glomerular filtration rate (GFR) and age, as requested by the Subcommittee. The interactions between GFR and age, like the interaction with creatinine and age, were not statistically significant. One Committee member expressed concerns about continually adding variables to the models without making use of data collected since the LAS.

The Committee decided to not include creatinine in the LAS. The Committee will reconsider this variable when more data become available.

Action Items Resulting from the October 2, 2007 Meeting:

- UNOS staff will prepare the policy language to include bilirubin and change in bilirubin in the lung allocation score. The Committee will review this draft language at its next meeting.
- UNOS staff will continue communications and collaborations with Dr. Girgis and the Reveal Registry.

5. Update: Lung Allocation Score

On May 3, 2007, UNOS staff provided an update on the current LAS results. UNOS staff reported that some issues were raised at the 2007 ISHLT Annual Meeting about the impact of the lung allocation system. Both OPTN and SRTR staff reported that the observed survival rates are similar to the predicted rates underlying the LAS calculation. The Committee suggested providing the community survival statistics (one year survival for waitlist and post-transplant) when presenting candidate lung allocation scores.

On October 2, 2007, UNOS staff presented data on the predicted survival benefit of lung candidates at the time of transplant. The analysis included all deceased donor lung and heart-lung transplants performed between May 4, 2005, and June 30, 2007. Patients with lung allocation scores less than 35 (N=1261) did not have positive predicted survival benefits in the one year following transplant. All patients with scores of 50 or higher had positive survival benefits (N=430), i.e., they would live more days with a transplant than without. An increase in the lung allocation score at the time of transplant results in positive survival benefits in the one year following transplant.

A Committee member queried whether it was now appropriate to remove geographic boundaries in lung allocation, and establish a score threshold, such as 35, for assigning zonal and transplant priority. Another Committee member commented that the current lung allocation score system does not respond to

progression of disease equally across all diagnostic groups. A threshold of 35 would benefit candidates in Group D, but not those with pulmonary hypertension. The ability for a candidate to receive a higher score when his/her disease progresses is more likely to happen if the candidate is in Group D or C, but not Group B or A.

The SRTR staff commented on its abstract submitted to the International Society for Heart and Lung Transplantation (ISHLT; 2008 Annual Meeting). The abstract presents results of a thoracic simulated allocation model (TSAM) for lung allocation that removes “local” for all candidates and for candidates with scores higher than 40. The SRTR performed this analysis by region. One Committee member suggested performing this analysis by diagnosis group and age. A Committee member requested The SRTR to present this abstract at the next Committee meeting.

The Committee next discussed the overall impact of the LAS (Exhibit I). UNOS staff commented that in recent months, there has been a decline in the number of candidates on the lung transplant waiting list. While there has been a significant decrease in the number of candidates in the lung transplant waitlist since the implementation of the LAS, the more recent decline may suggest decreases in the number of inactive candidates. Since the LAS, the number of active lung and heart/lung registrations has been relatively constant. The transplant center lung transplant waiting list volume has also been relatively constant. Group A still represents the largest diagnosis group on the waitlist, followed by Group D. The median lung allocation score on the waiting list for all groups combined remains around 34. The transplanted population has higher scores than the waitlist population.

Since the LAS, there has been a decrease in death rates on the lung transplant waitlist overall, and for all diagnosis groups except B. There may be a slight increase in waiting list mortality among lung candidates in the second year after LAS compared with the first year after LAS, but further data accrual are necessary to make definitive conclusions.

Recently, the Lung Review Board has primarily received cases seeking increases in the score. Exception requests for candidates in Group C are typically for increases in hemodynamic values, whereas for Group B, the requests are for score increases.

Group A candidates comprise 34.2% of the recipients in the most recent post-LAS transplant population, a decrease from 52.1% in the pre-LAS era. Group D candidates comprise 46.5% of the recipients in the most recent post-LAS transplant population, an increase from 28.1% in the pre-LAS era. In the waitlist, there hasn't been a significant change in representation of the diagnosis groups.

There are no significant differences across diagnosis groups in post-transplant survival at 9 months after transplant in the pre-LAS and post-LAS populations.

The Committee requested lung allocation score analysis by age (>50 years of age) and match run position. The Committee also requested data on waitlist deaths by initial lung allocation score (i.e., listing score).

Action Items Resulting from the October 2, 2007 Meeting:

- The SRTR will provide results of a TSAM that removes local for all candidates as well as for candidates with scores greater than 40. The SRTR will perform this analysis by region, age, and diagnosis group.
- The SRTR will share their ISHLT abstract with the Committee at the next meeting.
- UNOS staff will examine the LAS distribution for candidates 50 years of age or older.
- UNOS staff will analyze waitlist mortality by lung allocation score.

Time to Transplant Stratified by ABO (Lung Allocation)

On May 3, 2007, UNOS staff presented an analysis of survival in ABO identical and ABO compatible transplants by diagnosis group and geography. When looking at both diagnosis groups and geography,

Groups C and D exhibited significant differences between the identical versus compatible ABOs for one-year survival. Currently, OPTN allocates according to ABO identical first and then compatible. Results of this analysis suggest that this allocation can continue, and UNOS will continue to monitor these data.

On October 2, 2007, the Committee reviewed lung transplant survival rates stratified by ABO match level and distance. The Committee wanted to know if one blood group was likely to receive transplants sooner than another group. UNOS staff reported that non-O blood groups had similar probabilities for receiving a transplant (about 70% after 1 year of waiting). The O blood group population had a slightly lower probability for receiving a transplant (64% after 1 year of waiting).

6. Variation in Placement of and Utilization of Single Versus Double Lungs

On May 3, 2007, a Committee member described a case in one region where both lungs of an 18-year old donor were offered: the right lung was transplanted in a 73-year old recipient, and the left was discarded because a suitable single recipient for a left lung was not identified. The Committee discussed the various ways to appropriately allocate single lungs versus double lungs, and the significance to place on age – outside of pediatric allocation.

UNOS staff provided data on distribution of donor age and recipient age in the allocation of lungs. Prior to the LAS, lungs from 18-34 year old donors were transplanted in recipients 65 years of age or greater about 7% of the time. Since the LAS, this percentage is about 11. Also, there has been a slight increase in the transplantation of lungs from 35-49 year old donors in recipients 65 years of age or older. There has been a decline in the transplantation of lungs from 11-17 year old donors in recipients 65 years of age or older. There has been an increase in the number of candidates who are older than 65; but, the increase in the number of donor lungs transplanted in recipients 65 years of age or older is statistically significant, and larger than expected given the candidate pool.

The transplantation of young donor lungs in much older recipients might be a result of the LAS. Currently, the LAS only takes into consideration the survival benefit for one year after transplant. Age is not a factor in the LAS. The LAS is new and can be improved to minimize unintended consequences.

The issue of lung utilization impacts allocation policy, and proposals to improve utilization of lungs would necessitate changes in policy. The Committee members suggested the following as possible ways to improve single and double lung utilization.

- Ensure placement of both organs before placing single lungs transplants.
- Consider age in lung allocation, and giving priority to younger recipients. The developing KARS model might serve as a resource.
- Expedite placement of the second lung when a donor can offer both lungs. The split liver policy model might serve as a resource.
Evaluate donor variables in allocation with respect to how they might interact with recipient variables.
- Consider each lung as an organ. So, when placing both as a unit, reference policies that guide placement of double organs.
- Consider having two patient populations: one awaiting double lung, and one awaiting single lung. This stratification would be donor-driven, i.e., if a donor can offer both lungs, then these lungs would be offered to a candidate awaiting a double lung transplant.

The consensus of the Committee is that the LAS works, and furthermore, this allocation system has decreased the chances for discarding lungs.

The Committee wanted to examine whether there had been changes in single versus double lung placement as a result of the LAS allocation system. The Committee requested data regarding single vs.

double lung placement. The Committee also requested further data on the LAS scores of and demographic data for single and double lung recipients.

On October 2, 2007, UNOS staff reported that the percentage of non-DCD donors from whom at least one lung was transplanted increased from 13.8% in the first year after LAS to 15.7% in the second year after LAS. A majority of this increase is in the donor group who had both lungs recovered and transplanted (10.9% in the first year, 12.6% in the second year). When only one lung was transplanted, the other lung was not recovered in 75.9% of the cases (n=228). Also, when only one lung was transplanted, the other lung was recovered for transplant, but not transplanted, in 15.4% of the cases (n=228). The primary reasons for this non-transplant include poor organ function and medically unsuitable organ (upon evaluation in the operating room).

The Committee had previously asked the following question: when one lung is placed, how often is the other lung either not placed or is discarded? UNOS staff reported that in cases where one lung is placed, data do not clearly demonstrate difficulty in placing the other lung. But as this information is not explicitly collected, this question is difficult to address directly.

One Committee member commented that even in the absence of data, to maintain good public relations, the Committee should consider matching lungs of donors 12-19 years of age with candidates 12-19 years of age. The Committee will consider revising the lung allocation, but requested that the SRTR prepare an analysis using TSAM comparing the current allocation system (12-17 years) and the following age groups: 12-19, 12-21, 12-23, and 12-25. The Committee would like to see these results by candidate age and diagnosis groups.

Action Item Resulting from the October 2, 2007 Meeting:

- The SRTR will provide TSAM results using the current allocation system and the following age groups: 12-19, 12-21, 12-23, and 12-25. This analysis will present data by age and diagnosis group.

7. Suggested addition to Policy 3.7.12.3 (Essential Information for Lung Offers)

On October 2, 2007, the Committee reviewed suggestions from a community member for updating Policy 3.7.12.3 to include the following standards for chest x-rays as well as measurements that can be made from chest x-rays:

- supine versus upright versus 45 degrees upright versus other
- x-ray taken at full inspiration on standard vent settings (5 peep versus whatever the settings on which the patient is being managed)
- Standardize measurements (What is being measured?)
 - Length: from underside of first rib to top of diaphragm, to mid diaphragm, to base of diaphragm
 - Trans-thoracic measurement (Taken where? At tip, mid, or base of aortic notch, and at widest part of thorax or top, mid, base of diaphragm?)

One Committee member inquired how often x-rays appear in DonorNet[®]. Another Committee member commented that height, age, and gender are more important than the chest x-ray measurements. Chest x-ray measurements are variable and can be difficult to interpret. Several Committee members commented that they do not use these measurements for making decisions. Given that some members in the community do use these data, the information listed above could appear in UNetSM as guidelines for measurement. The Committee decided not to incorporate these measurement suggestions in Policy 3.7.12.3. The current language in Policy 3.7.12.4 (Desirable Information for Lung Offers) is clear and sufficient (see below). Under this policy, the physician/surgeon may request chest x-ray measurement information.

Policy 3.7.12.4(ii): Measurement of chest circumference in inches or centimeters at the level of the nipples and x-ray measurement vertically from the apex of the chest to the apex of the diaphragm and transverse at the level of the diaphragm, if requested.

Action Items Resulting from the October 2, 2007 Meeting:

- UNOS staff will communicate the Committee's decision to the member.
- UNOS staff will incorporate these guidelines in the help section of UNetSM.
- UNOS staff will research how often x-rays are uploaded to DonorNet[®].

8. Alpha-1: Impact of Lung Allocation Score System (LAS) on Alpha-1 waitlist candidates

On October 2, 2007, guests representing the interests of lung candidates with Alpha-1 attended the Committee meeting. These representatives were Ken Irvine (Alpha-1 Foundation), Bettina Irvine (Alpha-1 Association), and Dr. James Stocks (University of Texas in Tyler; Alpha-1 Foundation's Medical and Scientific Advisory Committee; and, Assistant Medical Director for AlphaNet). Ken and Bettina Irvine, and Dr. Stocks attended the meeting to express concerns about the decline in the number of Alpha-1 candidates receiving lung transplants since the implementation of LAS.

Bettina Irvine, a double-lung transplant recipient, commented that Alpha-1 patients appear to have very low lung allocation scores, and so, are not receiving transplants sooner. She also cited an example of an Alpha-1 candidate who had a high priority for transplant before the LAS, and a low priority for transplant after the LAS.

Dr. Stocks commented that the survival of Alpha-1 candidates on the waitlist is worse after the LAS than it was before. He acknowledged that while this trend might change with new data, the current trend does pose a concern for now. He suggested that one possibility for the current trend may be that Alpha-1 candidates are grouped unfairly, especially with respect to etiologic and physiologic similarities with other diseases in the group (for example, sarcoidosis). Alpha-1 candidates are classified currently within diagnosis Group A. Dr. Stocks suggested grouping Alpha-1 candidates separately. He commented that while there has been an increase in the number of lung transplants overall, there has been a decrease in the number of transplants among Alpha-1 candidates.

UNOS staff presented data on the impact of the LAS on Alpha-1 candidates. Since the LAS, there has been a decrease in the deaths on the waiting list among candidates in diagnosis Group A. Candidates with sarcoidosis have the highest death rate in this group. In the year prior to the LAS, Alpha-1 recipients comprised 5% of the total number of transplants and in the year after, they comprised 3% of the total. The median lung allocation score among candidates in Group A was 32.1 (active waitlist registrations) and 33.3 (transplants). Among Alpha-1 candidates, the median lung allocation score was 32 (active waitlist registrations) and 33.2 (transplants).

Dr. Stocks requested that the Committee assess whether the Alpha-1 candidates are advantaged or disadvantaged by the LAS. He also expressed concerns that the methodology employed in the LAS, and some of the tools used to constitute that score, may not be providing an accurate picture of the Alpha-1 candidate's physiology. He cited the FEV₁ (% predicted) measure as being inappropriate for deciding transplant eligibility. He suggested that there may be better assessment tools for pulmonary function and physiology, especially with respect to Alpha-1 candidates. The population-based studies may not be appropriate for determining transplant eligibility. A Committee member responded that FEV₁ was one of many variables associated with waitlist mortality, and that this association was statistically significant. This member also stated that LAS models include pulmonary artery pressures, and these values can alter a candidate's score.

The Committee responded that it continues to review the impact of the LAS at each meeting. The waitlist and post-transplant models that comprise the LAS are dynamic, not static. The Committee uses an evidence-based approach for changing the lung allocation score system. The Committee requested

examination of serial clinical and physiological data, collected since the LAS, for the current appropriateness of classifying Alpha-1 candidates in Group A.

Action Item Resulting from the October 2, 2007 Meeting:

- The SRTR will examine whether Alpha-1 candidates should remain in diagnosis Group A classification, according to disease progression, waiting list mortality, and post-transplant mortality.

9. Update on the Heart Allocation Sequence

On October 2, 2007, UNOS staff updated the Committee on the effects of the heart allocation sequence implemented on July 12, 2006 [Exhibit J]. There haven't been any major changes in the waiting list regarding the total number of candidates, total number of active candidates, distribution of status, distribution of age group, distribution of region, and center volume. Overall, there has been a decline in the deaths on the waitlist for all age groups (0-17, 0-10, 11-17, and 18+ years). There has been a decrease in waiting list mortality among Status 1A and Status 1B candidates. A Committee member requested analysis of deaths on the waiting list by region.

There appears to have been a slight increase in the total number of status justifications submitted since the implementation of the new heart allocation sequence. The Regional Review Board decisions were similar in the time before and after the implementation. The number of exception cases among adult candidates increased from 157 (7/5/05-7/11/06) to 193 (7/12/06-7/11/07). The number of exception cases among pediatric candidates increased from 22 (7/5/05-7/11/06) to 63 (7/12/06-7/11/07).

There aren't any major changes in organ utilization since the implementation of the new allocation sequence. One Committee member suggested analyzing heart utilization data that excludes DCD and older donors.

The number of transplants since July 12, 2006 is very similar to the numbers in the previous era. There were 2224 transplants before implementation (7/5/05-7/11/06) and 2205 in the era after implementation (7/12/06-7/11/07).

The distribution of candidate status at transplant has changed. There has been an increase in the number of transplants in recipients who were Status 1A or Status 1B, but a decrease in transplants of Status 2 recipients. Status 1A recipients comprise 47.1% of the transplants in the first year after implementation. For all recipient groups, the number of Status 2 recipients transplanted prior to implementation was 555 (25.0%), and the number in the era after implementation was 339 (15.4%).

Although the number of transplants in the two eras is similar, there are major differences among regions. The regional percent change in the number of transplants in the two eras ranges from -22% to +22%. The decrease may reflect the characteristics of candidates on the list, and not necessarily an adverse effect of the new allocation sequence. The Committee requested that the numbers used in calculating percent changes be provided in the regional analysis, in addition to percentage change.

In a vast majority of donation service areas (DSAs), the total number of transplants performed in the two eras is similar. A Committee member questioned this occurrence given the regional variations. UNOS staff replied that a small change in several DSAs within the same region could result in a relatively large change in the results summarized by region.

A Committee member inquired about the status of the Heart Sequence Task Force. The Chair commented that the work of the Task Force is also the work of the Committee. Many of the Committee members on the Task Force are members of the Committee. The Committee will monitor this new heart allocation sequence in the same way it monitors the lung allocation score system. As such, the need for the Task Force may be unnecessary. UNOS staff commented that the OPTN President would need to approve this

dissolution of the Task Force. Members of the Task Force who are not members of the Committee may be able to participate in discussions on the impact of the new heart allocation sequence. The Committee member commented that there were outstanding data requests from the last Task Force meeting, and inquired about their status. UNOS staff will prepare these data analyses for presentation at the next Committee meeting.

Action Items Resulting from the October 2, 2007 Meeting:

- UNOS staff will draft a letter to the OPTN President on the Committee's position on the existence of the Task Force.
- UNOS staff will share the outstanding data request of the Task Force with the Committee, and present the analysis at the next Committee meeting.
- UNOS staff will provide another update on the impact of the new heart allocation sequence at the next meeting. This update will include the following: raw numbers for percent changes in the heart transplants performed by region; heart utilization data that does not include DCD donors or older donors; and, deaths per 100 patient-years on the waiting list by region.

10. Use of LVADS in Heart Waiting List Candidates

On May 3, 2007, UNOS staff presented a summary regarding heart waiting list candidates who could have had a ventricular assist device (VAD) implanted without this VAD being reported. The most common scenario discussed was waiting list candidates receiving a VAD who may become inactivated at the time of VAD implantation; in these cases, the VAD would not necessarily be reported to the OPTN. Since VAD usage plays a crucial role in the assessment of waiting list mortality, a lack of information regarding VAD status in these patients has a major impact on this analysis that contributes to the development of the heart allocation score. UNOS will provide listings of these candidates to their centers and request further information regarding VAD implantation.

11. Heart Survival Benefit Analysis

On May 3, 2007, the SRTR updated the Committee on the development of a heart survival benefit model. The post-transplant model has thus far met the Committee's approval, and the primary work is now on the waitlist model. Specifically, the SRTR is researching the best method for incorporating candidates with VAD into the model. Status 1A candidates without a VAD tend to be ranked higher than 1B candidates, who in turn are ranked higher than Status 2 candidates. Candidates who had received a VAD and were waitlisted for the first time (despite having a VAD) tend to have poor waitlist mortality compared to their within-status counterparts. Candidates who are placed on the waitlist and start off without a VAD, and sometime during this wait receive a VAD, do very well compared to their similar-status counterparts. The Committee discussed these results, and requested the SRTR to analyze these data by specific type VAD, because different types of devices – and the clinical reasons associated with their implant – might be contributing to this waitlist mortality observation. The Committee strongly encouraged UNOS staff to explore the possibility of obtaining VAD data from the INTERMACS database for further analyses of the impact of VAD usage on mortality. This database contains much more detailed information on VAD implantation than the OPTN collects and may be useful for future analyses. But due to the recent nature of this database, it cannot be incorporated into the cohort that is being used in the current analysis. UNOS staff will contact INTERMACS to discuss the possibility of data sharing.

12. Clarifying the Heart Justification Form

On October 2, 2007, the Committee discussed a request from a Review Board member to clarify data fields in the following section of the heart justification form. The reason for this request is that in some cases, the hemodynamic data are not as current or complete.

Physiologic

All physiological data entered below should have been obtained within the last 24 hours.

Vital Signs Date ^R	<input type="text"/>	Date of Hemodynamics ^R	<input type="text"/>
Resting Heart Rate ^R	<input type="text"/> bpm	Mean Arterial Pressure (MAP) ^R	<input type="text"/> mmHg
Heart Rhythm ^R	<input type="text"/>	Systolic Blood Pressure (SBP) ^R	<input type="text"/> mmHg
Were the hemodynamic values obtained while the patient was on inotropes/vasodilators? ^R	<input type="radio"/> YES <input type="radio"/> NO	Diastolic Blood Pressure (DBP) ^R	<input type="text"/> mmHg
Does the patient have a pulmonary artery catheter? ^R	<input type="radio"/> YES <input type="radio"/> NO		

The location of the “Date of Hemodynamics” field, shown above, may be confusing. Since this date does not have to be current, there have been instances where the Review Board requested this information from the center. Further, the location of this field is above the vital sign data fields. Adding to the confusion is the question shown below that appears in the same column as vital sign data.

Were the hemodynamic values obtained while the patient was on inotropes/vasodilators? YES NO

A Committee member proposed that reorganizing fields in this section would make the data collection requirements clearer and more logical in flow. UNOS staff commented that programming these changes would be simple. The Committee decided that UNOS staff should program these layout changes.

Action Item Resulting from the October 2, 2007 Meeting:

- UNOS staff will make these changes to the form, and communicate the decision to the community member.

13. Heart Review Board Case

On October 2, 2007, the Committee reviewed a case denied by the Heart Regional Review Board. A patient’s transplant center had submitted an exception requesting an upgrade from Status 2 to Status 1B. The exception request did not include sufficient information for the case evaluation, and so, the Review Board denied the request. Before all Review Board members could submit their votes, the center transplanted the candidate as a Status 1B. The center, when presented with the opportunity to either appeal to the review board or present their case to the Committee, opted to submit this case to the Committee.

The Committee discussed the details of the case as well as the broader data collection concerns with Status 1B exception requests. The center did not provide sufficient information on the patient. For

example, a patient could be hypotensive for many reasons. The center's transplant of this candidate, while an exception request was open and subsequently denied, was its first.

The data requirements to justify Status 1B upgrades aren't as thorough as those for Status 1A upgrades. The Committee discussed creating a form for a Status 1B exception that is similar to the one for Status 1A exception. The Committee also discussed developing a resource document that would outline clinical data useful in evaluating Status 1B exception cases. The Regional Review Board members would use this document to assess the information provided by the center. If necessary, the Review Board would ask for additional information, as suggested in this document. The Committee decided to develop this resource document as well as listing criteria for inclusion in the Status 1B exception form.

The Committee did not take any adverse action against the transplant center (19-Yes, 0-No, 0-Abstention). The Status 1B exception form has neither served as an adequate guide to centers submitting this request, nor has it served as a tool for Regional Review Board members to use when evaluating these exceptions.

Action Items Resulting from the October 2, 2007 Meeting:

- UNOS staff will communicate the Committee's decision on the case to the transplant center.
- UNOS staff will convene the Heart Subcommittee to develop listing criteria for the Status 1B exception form. The Heart Subcommittee will also outline information that will better help Review Board members to evaluate Status 1B exception requests.

14. Listing Candidates Who Cannot Tolerate Inotropes

On May 3, 2007, a Committee member requested that the Committee provide the Heart Regional Review Board a standard set of guidelines to evaluate status exceptions submitted for candidates diagnosed with complex congenital heart disease, restrictive cardiomyopathy, or hypertrophic cardiomyopathy. These groups of candidates are frequently listed as Status 2 rather than Status 1A or Status 1B because they often can't tolerate inotropic therapy. Elevating their status to 1B-exception is not controversial, but upgrading these patients to Status 1A via the exception process is. Therefore, standard guidelines from the Committee on how to evaluate these exceptions would make the resulting decisions more consistent. The Committee requested data from the OPTN to understand the variations in regional review board responses to these exception requests.

15. Update on Regional Cross-Matching for Hearts

On May 3, 2007, a Committee member provided an update on his efforts at working with the HLA community to arrive at a hybrid method for performing cross-matches (using both virtual cross-matching and regional cross-matching). This Committee member reported that there is very little agreement among the HLA directors about virtual cross-matching. The next step is to convene a Subcommittee with representatives from the Thoracic, OPO, and HLA Committees to further discuss this issue in detail.

16. Impact of DonorNet[®] on Organ Offer and Acceptance Rates

On October 2, 2007, Dr. Marlon Levy, Chair of the Electronic Organ Placement Working Group (EOPWG, a sub-group of the OPTN/UNOS Operations Committee) presented data on the impact of DonorNet[®] on organ offers and placements. (UNOS implemented DonorNet[®] 2007 on April 30, 2007). Dr. Levy reported that since its implementation, DonorNet[®] has increased the volume of organ offers made and received.

Results from a questionnaire sent to transplant centers in July-August, 2007 show that 30% (n=45) of the transplant centers are changing who screens organ offers. In these cases, the non-decision makers are the first to review organ offers. Dr. Levy stated that this is a negative change as the intent is to have the decision-maker review the offers.

Between May 1, 2007 and September 5, 2007, there were 8,753 electronic offers from heart matches and 10,340 from heart-lung matches. The median time a center took to initially respond to an electronic offer, from either match, was approximately 17 minutes. There were 20,370 electronic lung offers, and the median time a center took to initially respond to an electronic lung offer was 16.9 minutes.

The median acceptance time for all thoracic offers was about an hour. Between May 1, 2007 and September 5, 2007, there were 268 acceptances from heart matches and 378 acceptances from heart-lung matches. The median acceptance time was approximately 55 minutes from either match. There were 596 lungs accepted with the median acceptance time of 53 minutes. A Committee member requested data on the average amount of time lapse between organ acceptance and transplant. It is this member's observation that this time is the same or longer than before DonorNet[®], and this poses concerns about the changing donor physiology.

DonorNet[®] allows for an increased possibility to exhaust the match-run. In the era just *before* DonorNet[®] (1/1/07 – 4/30/07), there were 581 heart matches run and 36 (6.2%) exhausted the list. In this same era, there were 1133 lung matches run with 69 (6.1%) exhausting the list. There were 845 heart/lung matches run and 56 of these (6.6%) exhausted the list. In the era *after* DonorNet[®], there were 735 heart matches run and 99 (13.5%) exhausted the list. There were 1229 lung matches with 163 (13.3%) exhausting the list. There were 813 heart/lung matches run and 112 (13.8%) exhausted the match list. Dr. Levy emphasized that a key concern of HRSA is that match runs do not skip recipients. DonorNet[®] minimizes this skipping and is helping to meet this objective.

Overall, the number of organs transplanted before and after DonorNet[®] was fairly close. However, any increases or decreases were not necessarily attributable to DonorNet[®] only as there were many other events also occurring in the same time period.

The Committee expressed concerns about the number and quality of organ offers received. The Committee cited instances of electronic notifications sent for organs the Committee considered unsuitable for thoracic transplantation. Dr. Levy replied that OPOs are under pressure to increase their organ recovery and placement rates. The resolution is in strengthening screening criteria. Another Committee member noted the need for tiered acceptance in DonorNet[®], and that it would have been preferable to have tiered acceptance in place prior to the implementation of DonorNet[®]. Dr. Levy commented that DonorNet[®] will incorporate additional screening over the next several months.

One Committee member commented that OPOs should be accountable for making inappropriate organ offers. A Committee member suggested that transplant centers document those OPOs making these medically unsuitable organ offers. The Committee could then discuss this information at the next meeting, or at a joint Subcommittee meeting of the Thoracic and OPO Committees. Before acting on this suggestion, the Committee decided to review additional data on DonorNet[®]. The Committee requested the following: whether it was possible to identify thoracic organs for which offers were made but were considered not transplantable; and, possible patterns of behavior in offering thoracic organs that are not transplantable. One Committee member suggested the use of regional forums for educating OPOs about potentially unsuitable offers.

A Committee member requested the average number of offers associated with a refusal of an organ. This average number can serve as a guide to OPOs for identifying medically unsuitable organs

A Committee member commented that the large number of organ offers will force people other than the surgeon to receive calls about organ offers. This member also commented that DonorNet[®] has shifted the financial burden from the OPO to the transplant center. Though it is early in the DonorNet[®] experience, several Committee members commented that there does not appear to be demonstrable benefit of DonorNet[®] with regards to increased number of organs transplanted. But, there does seem to be an

increased burden on the transplant centers. A few Committee members remarked that an electronic placement system was inevitable and necessary, but that this system still needs improvement.

The Committee will discuss additional screening criteria and approaches to minimizing the number of medically inappropriate organ offers. The Committee requested its regional representatives to attend their regional meetings and discuss the impact of DonorNet[®] with their colleagues. The members should present reports of unsuitable organ offers at the next Committee meeting. The Committee will analyze this information, and consider forwarding the information to the Operations Committee, the OPO Committee, or the MPSC.

Action Items Resulting from the October 2, 2007 Meeting:

- UNOS staff will communicate the Committee's discussion to the EOPWG.
- The Regional Representatives will present data on the impact of DonorNet[®].
- If medically inappropriate offers can be identified, UNOS staff will tabulate rates at which such offers are made overall and by OPO.
- UNOS staff will examine the average number of offers associated with organs that are never accepted.

17. Tiered Acceptance: Results from the DSA Task Force

On May 3, 2007, UNOS staff provided an update on the Tiered Acceptance project. The intent of this project is to streamline the allocation process by developing approaches to screening that will eliminate inappropriate match runs for a given candidate. Staff detailed the screening approaches taken by the organ-specific groups. The Liver Workgroup favored a center profile approach (the center would specify three donor groups: ideal, good, and willing to accept, and then indicate the appropriate profile for each candidate). The Kidney/Pancreas Workgroup preferred a multiple variable approach. The Thoracic Workgroup preferred to use individual, stand-alone criteria to screen matches, and just expand the current list of stand-alone screening criteria. The Committee requested the addition of the following variables to the screening list: DCD, donor HTLV, donor echocardiogram (heart candidates), donor smoking history, and donor height (heart candidates only, already exists for lung candidates). The Committee voted in favor (16-Yes, 0-No, 0-Abstentions) of the Thoracic Workgroup's decision, and decided not to use center profiles.

18. Development of a Donor Profile Index for Heart, and a Donor Profile Index for Lung

On May 3, 2007, the Committee discussed the charge from Dr. Sue McDiarmid, OPTN/UNOS President, to develop a definition for an expanded criteria donor (ECD) for heart and lung. The Committee decided that at this time, it would not develop a formal definition of an ECD for heart and lung. Gaining consensus on such a definition will be difficult to obtain from the thoracic community, and is not anticipated to improve organ utilization. A Committee member noted that this issue was discussed by the Pulmonary Council of the International Society for Heart and Lung Transplantation (ISHLT) and they reached a similar conclusion: a dichotomous definition of ECD for heart or lung donors would not be beneficial. The Committee, instead, supported the development of a more continuous measure for heart and lung donors such as the donor profile index (DPI) developed for liver donors. The Committee requested the OPTN and the SRTR to begin data analyses for a heart DRI and lung DPI.

On October 2, 2007, the SRTR presented their analysis of variables for use in the heart DPI and lung DPI. Some of the variables they analyzed were cause of death, pre-recovery T4, and age (categorical). The Committee recommended adjusting for OPO when analyzing variables. (This OPO impact will only be used in the developing models, not in the final DRI.) The Committee suggested combining T3/T4 for analysis. The SRTR performed univariate modeling on donor age (categorical). Donors in the higher age groups have a higher hazard. The Committee recommended using the following age groups in future analyses: 18-30, 30-40, 40-50, 50-60, and 60+. The Committee suggested that the SRTR analyze

ischemic time, and assess the interactions between ischemic time and recipient age. In an interaction between donor and recipient size (height, weight), body surface area (BSA) was statistically significant (univariate model). This interaction was not significant in the multivariate model. A Committee member requested analysis of cocaine use. The SRTR analyzed cocaine use (drug abuse variable) and it was not statistically significant.

Action Item Resulting from the October 2, 2007 Meeting:

- The SRTR will perform additional DPI analyses with the following parameters: narrower donor age groupings (30-40, 40-50, 50-60, and 60+); T3/T4 in one category; OPO; cold ischemia time; and the interaction of ischemia time and age.

19. Joint Allocation of Heart and Lung

On October 2, 2007, the Committee discussed a community member's query regarding the impact of the new heart allocation sequence on the joint allocation of heart and lung. The practice of joint allocation has been that the lung always follows the heart, but the heart doesn't always follow the lung. One Committee member inquired how thoroughly the heart match-run needed to be exhausted before following the lung allocation sequence.

There were 31 heart/lung transplants performed during 2006. In the first half of 2007, there were 19 heart/lung transplants performed.

The Committee discussed the current language in Policy 3.7.7 (Allocation of Thoracic Organs to Heart-Lung Candidates). A Committee member commented that the policy language is not clear. The language does not provide a clear guidance for allocating heart and lung together. References to Status 1A may need further clarification with respect to geographic allocation.

One Committee member suggested introducing a time factor that would enable upgrades of heart/lung candidates to Status 1A. For example, a heart/lung candidate who isn't a Status 1A could be classified as such after waiting for 1 year. The concern with the heart/lung transplant group is that candidates who are not Status 1A may never qualify to become 1A with the current criteria. Further, when these candidates receive lung offers, they may not have priority for the heart. This member suggested altering policy to improve these candidates' likelihood for receiving transplants.

Another Committee member commented that waiting time for joint heart/lung candidates can be quite long. Status 2 candidates face significant health challenges during their wait. This member commented that the waiting time option may not be the answer, but suggested setting lung allocation score thresholds.

The Committee discussed the following sentence 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."

One Committee member suggested adding the word "local" between "suitable" and "Status" in the sentence above. The Committee discussed whether this addition would resolve the policy confusion. The addition of the word "local" may still not align well with the current heart allocation sequence, and therefore, may not be enough of a clarification.

A Committee member suggested pursuing the addition of "local" in the policy language. This language change would restore practice to the way it was before zonal sharing, and may resolve the ambiguity in the policy created by zonal sharing. The Committee could then pursue a more thorough analysis of the policy for other language changes. Another Committee member suggested modeling this policy with the use of the word "local." This model should incorporate data collected in the past year and assess the

impact of the new heart allocation sequence on candidates awaiting joint heart and lung transplants. UNOS staff cautioned that this modeling may not be as easy given the behavior factor inherent in this policy – the OPO has to exhaust one match run before starting another. UNOS staff will check with The SRTR about the feasibility of developing this model.

One Committee member requested data on the deaths on the waiting list, by status, among heart/lung candidates. Another Committee member requested that this analysis include lung allocation scores. A Committee member requested data on the heart/lung transplants by age group. The Committee decided that more discussion of this policy language is necessary, and will include this item as its first on the next meeting agenda.

Action Items Resulting from the October 2, 2007 Meeting:

- UNOS staff will analyze waiting list mortality for heart-lung candidates.
- UNOS staff will analyze heart medical urgency status and LAS for heart-lung candidates.
- The SRTR will model heart/lung allocation with “local” in the policy language.

20. Distant Organ Retrieval Alternative and Certifying Non-Physicians/Surgeons to Recover Organs

On May 3, 2007, the Committee discussed a letter from Dr. Joshua Sonett (New York-Presbyterian) requesting that the Committee consider a surgical certification for highly skilled physician assistants to recover organs. The Committee discussed this issue of certifying non-physicians and non-surgeons to recover organs, and expressed tremendous concerns related to liability issues. The Committee questioned the qualifications of these non-physicians and non-surgeons to assess thoracic donor organs for disease. The Committee voted (16-Yes, 0-No, 0-Abstentions) to oppose the suggestion put forth by Dr. Sonett, and will reply to him as follows: heart and lung procurement should be performed by appropriately trained transplant physicians and surgeons.

On October 2, 2007, the Committee discussed that the Lake Michigan tragedy earlier that year underscored the need for alternate organ retrieval methods.

There are collaborations among physicians/surgeons at two separate, distant institutions for the purposes of retrieving hearts and lungs. These collaborations, however, are not nearly widespread enough to reduce the need for travel by local teams to recover organs. The OPO community could provide insight on how to make these collaborations more systemic. One Committee member stated that the Collaborative identifies surrogate recovery as a best practice.

The Committee discussed alternative methods for distant organ retrieval. One option could be to hire foreign-trained physicians/surgeons who are not Board-certified in the US. These physicians/surgeons cannot practice medicine in the US, but are very capable of recovering organs. There is such a practice in the west coast, and it works. Perhaps institutionalizing this practice nationally is an option, especially through grants from HRSA. Dr. Helen Li will relay this request to HRSA.

One Committee member noted that building trust nationally among physicians/surgeons in competitive programs is the key to having alternative distant retrieval methods work.

Another Committee member inquired about objective data that could better assert the need for this collaboration. Data on the economics of organ retrieval (sending local team to the recovery location, organ recovery numbers using the current approach) might sway the community into embracing alternative approaches. One Committee member inquired about the possibility of reducing the number of people who travel for organ recoveries. Several members commented that people who tend to go in these trips are the ones who probably should go. Allowing medical students to go, for example, could help recruit new professionals into the field.

At the May 3, 2007 meeting, the Committee had stated that only trained physicians and surgeons should recover organs. Several Committee members commented that other health care professionals, with proper training, can recover organs and do so using good medical judgment. These members stated that the use of trained non-physicians and surgeons may be another option. Committee members may bring their ideas for distant organ retrieval to the next meeting.

21. Stand-Alone Thoracic Transplant Programs

On May 3, 2007, the Committee continued to discuss the issue of stand-alone thoracic programs and their need in the community. The Committee had last discussed the issue of stand-alone programs at its February, 2007 meeting. At that February meeting, the Committee requested application materials, bylaws, and other relevant supporting materials be made available for review at this May meeting. As such, the Committee members received all relevant materials, including a list of all programs (stand-alone, etc.) in their meeting packet.

A Committee member cautioned that the Membership and Professional Standards Committee (MPSC) will likely receive more of these applications, particularly for stand-alone pediatric programs. This member also stated that given the breadth of infrastructure needed for lung transplantation, it may be useful for centers to have in place a heart or kidney program. Also, given the current enforcement by the Centers for Medicare and Medicaid Services (CMS), UNOS/MPSC should consider elevating its program application standards.

Staff commented that the OPTN, for reasons that include antitrust, sets only those minimum standards needed to provide quality care. Standards higher than this minimum may be seen as exclusionary and could generate antitrust concerns. Staff also reported that there are several stand-alone adult heart transplant programs, and one lung transplant program. Further, stand-alone programs are not “flagged” at a higher rate than those programs that exist with other organ programs. Staff suggested that the Committee review the application materials, consider improvements, recommend new application elements if necessary, and explain how these suggestions could be applied to programs. The results of this review could then be forwarded as recommendations to the MPSC. The Committee members supported this review plan.

The Committee will review the program application materials provided to them in the meeting packet and present suggestions for improvement at the next meeting. To facilitate this next discussion, the Committee requested that the MPSC staff provide sample, average responses, that applying programs provide, to questions about ancillary services. The Committee would like to understand how applying programs are describing their environment and the ancillary services.

22. Review of Public Comment Proposals

On May 3, 2007, the Committee discussed the following seven public comment proposals distributed in March, 2007.

Proposed Modifications to Data Elements for Pediatric Candidates and Recipients on UNetSM Transplant Candidate Registration (TCR), Transplant Recipient Registration (TRR) and Transplant Recipient Follow-up (TRF) Forms (Pediatric Transplantation Committee)

The Committee supported this proposal: 16-Yes, 0-No, 0-Abstentions.

Proposed Modifications to OPTN/UNOS Policy 7.1.5 “Reporting Definitions” and OPTN/UNOS Policy 7.3.2 “Submission of Organ-Specific Transplant Recipient Registration Forms and Submission of Living Donor Registration Forms” (Living Donor Committee)

The Committee supported this proposal: 16-Yes, 0-No, 0-Abstentions.

Proposed Modification to OPTN/UNOS Policy 7.3.3 “Submission of Living Donor Death and Organ Failure Data” (Living Donor Committee)

The Committee supported this proposal: 16-Yes, 0-No, 0-Abstentions.

Proposed Modifications to the UNetSM Living Donor Registration (LDR) and Living Donor Follow-Up (LDF) Forms (Living Donor Committee)

The Committee supported this proposal: 16-Yes, 0-No, 0-Abstentions.

Proposed Modifications to Data Elements on UNETSM Deceased Donor Registration (DDR) Form (Organ Availability Committee)

The Committee made a statement of “no comment”: 16-Yes, 0-No, 0-Abstentions.

Proposed Imminent Neurological and Eligible Death Definition Data Elements (OPO Committee)

The Committee made a statement of “no comment”: 16-Yes, 0-No, 0-Abstentions.

Proposed Modifications to OPTN and UNOS Bylaws, Appendix A2-1, Section 2.06A, (b), (3) “Probation,” (4) “Member Not in Good Standing,” (5) “Suspension of Member Privileges,” (6) “Termination of Membership or Designated Transplant Program Status,” (7) “Action Specified in OPTN Final Rule.” (Patient Affairs Committee)

The Committee supported this proposal: 16-Yes, 0-No, 0-Abstentions.

On October 2, 2007, the Committee reviewed the following bylaw change proposal submitted for public comment by the OPTN/UNOS Membership and Professional Standards Committee (MPSC):

Proposed Modification to the OPTN Bylaws, Appendix B, Transplant Hospitals; Section B. Survival Rates; and Section C “Inactive Membership Status”; and Attachment I, Section II, “Inactive Program Status”; and to the UNOS Bylaws, Attachment I, Section II “Inactive Program Status” and Attachment II, Section XIII, C, (10) “Survival Rates” (Membership and Professional Standards Committee).

A regional representative commented that at his regional meeting, there were concerns regarding which state would have legal jurisdiction over the “summary” referenced in the following sentence of the proposed language: “A Member who participates in a discussion with the MPSC is entitled to a summary of the discussion.” Another Committee member commented that states have differing laws about medical peer review.

UNOS staff explained that these informal discussions benefit the OPTN member. A Committee member stated that these discussions provide much needed information. The Committee voted to support this proposal (15-Yes, 0-No, 1-Abstention), but would like to know which state statute has jurisdiction over the summary referenced above. The Committee also wanted to know who reviews the document.

Action Items Resulting from the October 2, 2007 Meeting:

- UNOS staff will research which state has legal jurisdiction over the summary of the discussion, and communicate this information to the Committee.
- UNOS staff will forward the Committee’s discussion and vote to the MPSC liaison.

23. Thoracic Variances: Updates and New Activity

On May 3, 2007, UNOS staff informed the Committee that in an effort to better comply with the variance section of the OPTN Final Rule, UNOS will begin ensuring that all existing and future alternative allocation systems will follow a research design. UNOS will be developing a template for this research design and will present it to the Committee at a later date.

24. Committee Annual Goals (2007-2008)

On October 2, 2007, UNOS staff stated that the Board of Directors, at its September, 2007 meeting, approved the annual goals of all Committees. These goals are associated with the strategic plan.

Action Item Resulting from the October 2, 2007 Meeting:

- The Committee will continue making efforts to accomplish its annual goals.

25. Meeting the HHS Program Goals

On May 3, 2007, UNOS staff updated the Committee on the efforts of OPTN to achieve the HHS Program Goals. The goals presented aim to increase the number of donors, organs transplanted, and organs transplanted per donor. Overall, the OPTN projections for 2006 were fairly close to the achieved numbers/rates. During 2006, the actual number of deceased donor organs transplanted (24,416) was about 5% below the goal of 25,651. The OPTN reported 7375 non-DCD deceased donors for 2006, surpassing the goal of 6920. OPTN reported 647 DCD donors, a number lower than the goal of 793. The rate for organs transplanted per non-DCD donor in 2006 was 2.11, a rate lower than the goal of 2.33.

26. Electronic Meeting Packet

On May 3, 2007, the Committee voted in favor (16-Yes, 0-No, 0-Abstentions) of having future meeting packets distributed to members in an electronic format.

Thoracic Organ Transplantation Committee	May 3, 2007 Chicago, Illinois	
Name	Position	Attendance
J. David Vega, MD	Chair	X
Maryl Johnson, MD	Vice Chair	By phone
Gregory Couper MD	Regional Rep.	X
Alberto Pochettino, MD	Regional Rep.	
Cliff Van Meter, Jr, MD	Regional Rep.	
David Nelson, MD	Regional Rep.	X
Mark Barr, MD	Regional Rep.	X
Michael Mulligan, MD	Regional Rep.	By phone
William Cotts, MD	Regional Rep.	X
Wade Fischer, MD	Regional Rep.	
Jonathan Chen, MD	Regional Rep.	By phone
Gosta Pettersson, MD	Regional Rep.	X
Vacant (Region 11)	Regional Rep.	
Diane Brockmeier, RN, BSN,MA	At Large	By phone
David Campbell, MD	At Large	X
R. Duane Davis, MD	At Large	
James Gleason	At Large	X
Jennifer Prinz, RN	At Large	X
Keith Stevens, BSN,RN	At Large	X
Stuart Sweet, MD, PhD	At Large	X
Thomas Threlkeld, PA, CPTC	At Large	By phone
Claude Young	At Large	
Paul Oldam, BSS	BOD - Liaison	X
Edward Garrity, Jr, MD, MBA	Ex Officio	
Monica Lin, PhD	Ex Officio – HRSA	X
Helen Li, MD, MPH, PhD	Ex Officio - HRSA	By phone
Robert Merion, MD	SRTR Liaison	X
Jeff Moore, MS	SRTR Liaison	X
Susan Murray, ScD	SRTR Liaison	X
Katherine Pearson	SRTR Liaison	
Tempie Shearon	SRTR Liaison	
Vipra Ghimire, MPH, CHES	Committee Liaison	X
Doug Heiney	Committee Liaison	X
Donna Whelan	Support Staff	X
Leah Edwards, PhD	Support Staff	X
Ciara Gould, MSPH	Support Staff	X
Stacey Burson	Support Staff	By phone
Catherine Monstello	Support Staff	By phone
Aaron McKoy	Support Staff	By phone

Thoracic Organ Transplantation Committee		October 2, 2007 Chicago, Illinois	
Name	Position	Attendance	
J. David Vega, MD	Chair	X	
Maryl R. Johnson, MD	Vice Chair	X	
David DeNofrio, MD	Regional Rep. (1)	X	
Kenneth R. McCurry, MD	Regional Rep. (2)	X	
Cliff H. Van Meter, Jr., MD	Regional Rep. (3)		
David P. Nelson, MD	Regional Rep. (4)	X	
Mark L. Barr, MD	Regional Rep. (5)	X	
Michael S. Mulligan, MD	Regional Rep. (6)	X	
William G. Cotts, MD	Regional Rep. (7)	X	
A. Michael Borkon, MD	Regional Rep. (8)	X	
Jonathan Chen MD	Regional Rep. (9)	X	
Kevin M. Chan, MD	Regional Rep. (10)	X	
Isabel P. Neuringer, MD	Regional Rep. (11)	X	
Bruce W. Brooks	At Large	X	
Gregory S. Couper, MD	At Large	X	
R. Duane Davis, MD	At Large	X	
Edward Garrity, Jr., MD, MBA	At Large	X	
Herbert Heili	At Large	X	
Diane Lynn Kasper, RN, CCTC	At Large	By phone	
Denise Kinder, RN, CPTC	At Large	X	
Jennifer Prinz, RN	At Large	By phone	
Keith Stevens, BSN,RN	At Large	X	
Stuart Sweet, MD, PhD	At Large	X	
Paul Oldam, BSS	BOD - Liaison	X	
Amy Shorin-Silverstein, JD	BOD - Liaison	X	
Reda Girgis, MD	Guest	By phone	
Ken Irvine	Guest	X	
Bettina Irvine	Guest	X	
James Stocks, MD	Guest	X	
Marlon Levy, MD	Guest	By phone	
Monica Lin, PhD	Ex Officio – HRSA	By phone	
Helen Li, MD, MPH, PhD	Ex Officio – HRSA	X	
Brad Dyke, MD	SRTR Liaison	X	
Robert M. Merion, MD	SRTR Liaison		
Jeff Moore MS	SRTR Liaison	X	
Susan Murray, ScD	SRTR Liaison	X	
Tiffani Pace	SRTR Liaison		
Katherine Pearson	SRTR Liaison		
Tempie Shearon	SRTR Liaison		
Stacey Burson	Support Staff	X	
Leah Edwards, PhD	Support Staff	X	
Vipra Ghimire, MPH, CHES	Committee Liaison	X	
Karl McCleary, MPH, PhD	Support Staff	X	
Donna Whelan	Support Staff	X	
Aaron McKoy	Support Staff	By phone	
Catherine Monstello	Support Staff	By phone	
Nell Aronoff	Support Staff	By phone	
Shandie Covington	Support Staff	By phone	