Report of the OPTN/UNOS Thoracic Organ Transplantation Committee Meeting
Via Telephone and Internet
January 24, 2011
Mark Barr, MD (Chair
Steven Webber, MD (Vice-Chair)

The following is a summary of the Thoracic Organ Transplantation Committee's (Committee) deliberations that occurred on January 24, 2011.

Item 1: Proposal to Encourage Organ Procurement Organizations (OPO) to Provide Computed Tomography (CT) Scans if Requested by Transplant Programs, And to Modify Language in Policy 3.7.12.3 for Currency and Readability

The Committee discussed the following proposed modifications to Policies 3.7.12.3 (Essential Information for Lung Offers) and 3.7.12.4 (Desirable Information for Lung Offers), and voted in favor of the changes and its distribution for public comment: 12-supported; 0-opposed; and, 0-abstained. The Committee members who did not participate in this January 24 meeting voted electronically on the policy modification. Thus, the final vote on the proposed policy modification is: 22-supported; 1-opposed; 0-abstained.

Policy Modification Proposed:

3.7.12.3 **Essential Information for Lung Offers**. In addition to the essential information specified above for a thoracic organ offer, the Host OPO~~ or donor center~~ shall provide the following specific information with each lung offer:

(i) Arterial blood gases on 5 cm/$H_2$0/PEEP including PO_2/FiO_2 ratio and preferably 100% FiO_2 within 2 hours prior to the offer;

(ii) Bronchoscopy results. Bronchoscopy of a lung donor is recognized as an important element of donor evaluation~~., and should be arranged by the Host OPO or donor center. If the Host OPO or donor center lacks the personnel and/or technical capabilities to comply, the bronchoscopy responsibility will be that of the recipient center. The inability of the Host OPO or donor center to perform a bronchoscopy must be documented.~~ The Host OPO must document if it is unable to provide bronchoscopy results. Confirmatory bronchoscopy may be performed by the lung retrieval team provided unreasonable delays are avoided. A lung transplant program may not insist upon performing its own bronchoscopy before being subject to the 60 minute response time limit as specified in Policy 3.4.~~1~~2;

(iii) Chest radiograph interpreted by a radiologist or qualified physician within 3 hours prior to the offer;

(iv) Sputum gram stain with a description of the sputum character; and,

(v) Smoking history.

3.7.12.4 **Desirable Information for Lung Offers**. With each lung offer, the Host OPO~~ or donor center~~ is encouraged to provide the ~~recipient center~~ transplant center with the following information:

- Mycology smear; ~~and~~
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- 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~~.~~; and,
  ¶
- Non-contrast computed tomography (CT) scan of the chest, if requested by the transplant center.

The modifications included the deletion of "donor center" from Policies 3.7.12.3 and 3.7.12.4, readability edits and correct policy number reference in Policy 3.7.12.3.ii, and the addition of CT scan in Policy 3.7.12.4. During the aforementioned electronic voting period, the CT scan language changed slightly to include "non-contrast" prior to CT scan and "of the chest" following the word "scan." Historically, "Host OPO" and "Donor Center" were used synonymously. For policy compliance purposes, the UNOS Department of Evaluation and Quality holds the Host OPO responsible for providing deceased donor data, not the donor center. Policy 3.1.6 defines a Host OPO as follows:

> The Host OPO is the OPO which, having identified a potential organ donor, assumes responsibility for donor management and organ allocation.

Item 2: Proposal to Require Updates of Certain Clinical Factors Every 14 Days for Lung Transplant Candidates whose Lung Allocation Scores (LAS) Are at Least Fifty (Affected policies: 3.7.6.3.1 (Candidate Variables in UNet^{SM} upon Implementation of Lung Allocation Scores Described in Policy 3.7.6) and 3.7.6.3.2 (Updating Candidate Variables))

The Committee sought simpler language on the 14-day update concept. Subsequent to the January 24 meeting, the Committee reviewed the final 14-day update language and voted electronically in favor of it and other changes to Policy 3.7.6.3.1 and 3.7.3.6.2: 19-supported; 2-opposed; and, 0-abstained. (During the meeting, the Committee approved the 14-day update concept.)

The Committee's intentions with the 14-day update concept are as follows:

- The transplant program will assess and report any observed change in the following four variables: assisted ventilation; frequency of supplemental oxygen; the amount of supplemental oxygen; and, PCO_2 value (if the test was performed in the 14-day time period).
- The first 14-day cycle begins when the candidate's score first becomes 50.
- The subsequent 14-day cycles – if the candidate's score remains 50 or higher – are based on the date of each previous assessment.
- Identify candidates with high LAS but whose health improves such that their scores become less than 50.
- If the candidate's score becomes less than 50, then the transplant program must report candidate data every six months in UNet^{SM}, pursuant to Policy 3.7.6.3.

In general, the Committee expects that lung transplant programs are updating their candidates' variables in UNet^{SM} whenever there is change – not just in the six months or the proposed 14-day time periods. Citing the heart policy's interpretation that a program must lower a candidate's status within 24 hours of the candidate no longer meeting the given criterion, the Committee recommended that similar language be included in Policy 3.7.6.3. Placing this in policy might create too much data entry burden for lung transplant programs; in addition, such language is not part of the heart policy. The Committee will consider this modification to the heart policy in 2011.

Modifications to the aforementioned policies were the deletion of Policy 3.7.6.3.1 (Candidate Variables in UNet^{SM} upon Implementation of Lung Allocation Scores Described in Policy 3.7.6.), because it is no longer current; clarification that the result of a repeated a heart catheterization test must be reported in UNet^{SM}; edits to the language on the six-month anniversary concept for readability; and, general edits. The final, proposed policy language is presented below:

Policy Modification Proposed:

3.7.6.3 Candidate Variables in UNet^{SM}. Entry into UNet^{SM} of candidate clinical data corresponding to the variables shown in Tables 1 and 2 ~~above~~ in Policy 3.7.6.1~~, as they may be amended from time to time,~~ is required when listing a candidate for lung transplantation. Diagnosis, birth date (used to calculate age), height~~,~~ and weight (used to calculate BMI) must be entered for a candidate to be added to the waitlist. Candidates will receive a Lung Allocation Score of zero~~,~~ if the Functional Status class or assisted ventilation variable is missing a value at any time.

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If values for pulmonary artery systolic pressure, pulmonary capillary wedge pressure, or pulmonary artery mean pressure are missing, then a default value will be assigned that represents a normal clinical value for these missing pulmonary pressure variables. ~~(~~A default value of 20 mm~~/~~ Hg will be assigned for missing pulmonary artery systolic pressure, a default value of 5 mm~~/~~ Hg will be assigned for missing pulmonary capillary wedge pressure, and a default value of 15 mm~~/~~ Hg will be assigned for missing pulmonary artery mean pressure.~~)~~ The default values for pulmonary pressures will also be used in the calculation of Lung Allocation Scores for those candidates whose actual values are provided, but are lower than the default value. If any other candidate variables are missing, then a default value, which will be the value that results in the lowest contribution to the Lung Allocation Score for that variable field ("Least Beneficial Value"), will be selected for the candidate.

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Programs are permitted to enter a value deemed medically reasonable in the event a test needed to obtain an actual value for a variable cannot be performed due to the medical condition of a specific candidate. Prior to entering such estimated values, programs must request review and approval from the Lung Review Board to determine whether the estimated values are appropriate~~ and whether further action is warranted~~. Estimated values will remain valid until those values are either updated with an actual value or a new estimated value is entered pursuant to ~~the procedures set forth in~~ Policy 3.7.6.4.

~~**3.7.6.3.1 Candidate Variables in UNet^{SM} upon Implementation of Lung Allocation Scores Described in Policy 3.7.6**. Candidates registered on the Lung Waiting List at the time of implementation of the Lung Allocation Score described in Policy 3.7.6 with no or incomplete clinical data will receive the Least Beneficial Value or the default pulmonary pressure value for each incomplete variable or a Lung Allocation Score of zero, as described in Policy 3.7.6 above.~~

~~**3.7.6.3.2**~~**3.7.6.3.1** **Updating Candidate Variables.** Programs may update their candidates' clinical data at any time they believe a change in candidate medical condition warrants such modification. Programs must update each element of a candidate's clinical data in UNet^{SM} every six months, except those data obtainable only by heart catheterization. Also, as described further below, programs must

update three clinical variables more frequently than six months for candidates with LAS of 50 or higher.

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UNet^{SM} defines a "six -month anniversary date," which first occurs six months from the date of initial listing, then every six months thereafter. UNet^{SM} will consider a variable to be expired if the variable's test date is six -months older than the most recent anniversary date.

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~~Programs must update every candidate variable, except those candidate variables that are obtainable only by heart catheterization, for each candidate at least once every six months beginning on the date of initial listing on the lung waitlist. If at any time, more than six months have elapsed since the last six-month "anniversary" date of the candidate's initial listing, without an update, then the variable will be considered expired. (For example, if a candidate was first registered on the waitlist on January 1, 2005, and the most recent six-month "anniversary" is January 1, 2006, then any variables older than July 1, 2005, will be considered expired.)~~

If the test dates of the Functional Status or assisted ventilation variable ~~is~~ expire~~d~~, then the candidate's ~~will receive a~~ Lung Allocation Score will be ~~of~~ zero. If any other candidate variable expires~~,~~ - excluding pulmonary artery systolic pressure, pulmonary capillary wedge pressure, or pulmonary artery mean pressure~~, is expired,~~ - then the candidate will receive the Least Beneficial Value for that variable. The transplant center determines the frequency of updating those candidate variables that are required to be obtained by heart catheterization (pulmonary artery pressures and pulmonary capillary wedge pressure) ~~will be left to the discretion of the transplant center~~. If a transplant center repeats a heart catheterization test, it must report the results in UNet^{SM}.

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UNet^{SM} will consider ~~A~~actual values or estimated values for pulmonary pressures ~~will~~ to be valid until the transplant center ~~they are either~~ update~~d~~s them with ~~a~~ new actual values or ~~a~~ new estimated values ~~is entered~~ pursuant to Policy 3.7.6.4.

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A program must update three key variables in UNet^{SM} no more than 14 days after a candidate's LAS becomes greater than 50: assisted ventilation, supplemental oxygen, and current PCO_2. If a program does not perform a PCO_2 test in that time, then it does not need to update this value in UNet^{SM}. While the candidate's score remains 50 or higher, a program must continue to assess and report any observed change in the three clinical variables no less frequently than 14 days from the date of the previous assessment.

The UNOS Department of Evaluation and Quality (DEQ) will monitor through site audits compliance to the proposed 14-day update policy written above. In addition to DEQ's manual monitoring of patient records, transplant programs will need to develop their own system for identifying candidates with LAS of 50 or higher. (This policy is not being programmed in UNet^{SM}. It is possible that in the future, this

policy will be programmed.) If the OPTN/UNOS Board of Directors approves this proposed policy, UNOS will provide guidance to transplant programs on manually tracking candidates' scores.

Item 3: Proposal to Revise the LAS System

Analyses for a revised LAS system could not consider the impact of current and increase in bilirubin. Although the Board of Directors approved the inclusion of current and increase in bilirubin in the waiting list model of the LAS, UNOS has not yet implemented the collection of serial bilirubin in the waiting list pages. Thus, current and increase in serial bilirubin could not be included as factors in the analysis to revise the LAS system.

The revised LAS system was scheduled for distribution in the March, 2011 public comment cycle. However, a distribution in March, 2011 or September, 2011 – the difference between a Board of Directors' meeting in November, 2011 and June, 2011 – is not significant from the perspective of placing the revised LAS model in the queue for programming. The Executive Committee will schedule projects for programming based on their priority, not based on the order the project was approved by the Board of Directors. So, waiting to distribute the revised LAS for public comment in November, 2011 will allow the OPTN and the SRTR to answer lingering questions about addressing current and increase in bilirubin in the revised LAS system.

While there is a difference in time between the cohorts used in the development and revision of the LAS system, perhaps further analytical modeling could guide whether this time difference is significant. This analysis could make use of the retrospective data project's cohort. A comparison of the revised LAS model (without bilirubin) with a revised LAS model that includes bilirubin data (as well as other data proposed for inclusion during recent discussion) could inform whether current and increase in bilirubin remain significant predictors of waiting list mortality – especially for candidates with pulmonary hypertension. In other words, would the inclusion of current and increase in bilirubin in the revised LAS model enhance the model's ability to predict a candidate's waiting list mortality?

The Lung Subcommittee's next meeting is on February 22, 2011, and on this date, the Lung Subcommittee will review the analysis described above as well as the relationship between bilirubin and the new factors proposed for inclusion in the revised LAS system.

Item 4: Guidance on Listing Candidates Who Need Heart-Lung Transplants and Removing from WaitList^{SM} Recipients of Heart-Lung Transplants

The Committee reviewed a memo (see below) that provides guidance to thoracic clinicians on listing heart-lung candidates on the waiting list, and correctly removing heart-lung candidates from the waiting list. On January 11, 2011, the Lung Subcommittee approved the memo, and on January 21, 2011, the Heart Subcommittee approved the memo. The Committee approved this missive's distribution to thoracic clinicians by UNOS staff: 15-supported; 0-opposed; and, 0-abstained. (UNOS staff distributed the memo on January 27, 2011.)

MEMORANDUM [DRAFT]

To: Thoracic Transplant Clinicians

From: Mark L. Barr, MD
Chair, Thoracic Organ Transplantation Committee

Re: Guidance on Listing Candidates Who Need Heart-Lung Transplants and Removing from WaitList[SM] Recipients of Heart-Lung Transplants

Date: January ##, 2011

The Thoracic Organ Transplantation Committee offers the following guidance to thoracic transplant programs for listing a heart-lung candidate and removing a heart-lung recipient from the waiting list. While this recommended listing practice is not required by policy, the practice suggested here will **allow a heart-lung candidate to appear on a heart, lung, or heart-lung match run, ensuring that the individual is visible to the organ procurement organization placing organs for transplant**.

To list a candidate for a heart-lung transplant, the transplant program should register that candidate on the heart, lung, and heart-lung transplant waiting lists in UNet[SM]. This registration practice will require that the transplant center maintain information entered on each list. Unfortunately, this registration practice will likely generate isolated heart or lung offers that transplant programs may not want to receive or consider for their heart-lung candidates. However, the suggested listing practice for heart-lung candidates will make certain that a heart-lung candidate appears in the heart, lung, and heart-lung match run.

A transplant program may register a heart-lung candidate on the heart, lung, and heart-lung lists with the fee for only one registration.

To remove a recipient from the waiting list due to a heart-lung transplant, the transplant program must perform both of the following actions:

1) The candidate should be removed from the heart-lung waiting list with a removal code of "transplant." Per Policy 3.7.14 (Removal of Thoracic Organ Transplant Candidates from Thoracic Organ Waiting Lists When Transplanted or Deceased), the transplant program must remove the candidate within 24 hours of the transplant.

2) The heart and lung registrations should be removed with a removal code of "other," and the reason as "received a heart-lung transplant." Per Policy 3.7.14, the transplant program must remove the candidate within 24 hours of the transplant.

Please click on the link below to read the policy on heart-lung allocation – Policy 3.7.7 (Allocation of Thoracic Organs to Heart-Lung Candidates) – and other thoracic policies:

http://optn.transplant.hrsa.gov/PoliciesandBylaws2/policies/pdfs/policy_9.pdf

If you have questions, please contact your regional administrator at 804-782-4800. Thank you.

Item 5: Proposal to Allow Outpatient Adult Heart Transplant Candidates Implanted with Total Artificial Hearts (TAH) Thirty Days of Status 1A Time

On December 16, 2010, the OPTN/UNOS Executive Committee set the expiration date of the interim policy on outpatient candidates implanted with TAH. The resolution on which the Executive Committee voted follows:

> "RESOLVED, that the changes adopted by the Board of Directors to Policy 3.7.3 on November 9, 2010, shall expire on December 1, 2011."

A formal expiration date is necessary for two reasons: 1) the Board discussed the concept at its meeting in November, 2010 – when the interim policy received approval – yet the resolution for the interim policy did not include an expiration date; and 2) when the Board approves a policy without a benefit of public comment, an expiration date will serve as a reminder that the Board needs to act on the policy – maintain, amend, or delete – after the public comment cycle. So, on December 1, unless the Board renews the interim policy or approves a new proposed policy on candidates with mechanical circulatory support devices, the interim policy will expire (all candidates implanted with TAH must be inpatients to be Status 1A).

The Committee also provided editorial suggestions to the interim policy proposal on outpatient candidates implanted with TAH.

Item 6: Provide Feedback on the Proposed Model for Assessing the Effectiveness of Individual OPOs in Key Measures of Organ Recovery and Utilization (Sponsored by the Membership and Professional Standards Committee (MPSC))

UNOS staff presented the bylaw proposal to the Committee. This proposal is the result of a joint effort between the MPSC and the OPO Committee.

The model assigns each OPO an "N" of 1, and not by the type of organ the OPO recovers; so, the N is 58 in the model. (All OPOs have the capability of recovering all organs.) The proposed bylaw includes an organ-specific model, which assesses a given OPO's ability to recover and transplant an organ type. An OPO could be performing well in the overall model, but not as well in one or more of the organ specific models.

Currently, only the Centers for Medicare and Medicaid Services (CMS) audit an OPO's performance. The proposed bylaw would allow UNOS to audit an OPO's performance. The Committee queried whether the proposed model and the one used by the CMS are in fact the same, and whether the proposed model, if approved by the Board, would create additional work burden for UNOS staff. (The Board directed the development of the proposal under discussion. The proposed model has received favorable feedback from the OPO community.) However, neither the proposed OPO model nor the one applied by the CMS address the relationship between OPO performance and transplant outcome. Perhaps it is in the purview of the OPTN to consider this transplant outcome factor.

The Committee approved proposed model: 15-supported; 0-opposed; and, 0-abstained.

Item 7: Update and Clarification of Language in the Model Elements for Controlled Donation after Cardiac Death (DCD) Recovery Protocols (Attachment III to Appendix B of the OPTN Bylaws)

The OPO Committee asked the Thoracic Committee for the following feedback:

- Please provide any general comments about the changes.
- Please comment on what impact the change in terminology from DCD to DCDD might have on OPTN members and the general public. Are there any unintended consequences that may result from this change?
- Please comment on what impact the following changes in terminology will have: Withdrawal of life sustaining "measures" to Withdrawal of life sustaining "Medical Treatment/Support," and the addition of "disease" included in the suitable candidate evaluation section.

The Committee recommended that the OPO Committee include in the proposal that the agreement that exists between the OPO and the hospital should detail the methodology that will be used during the declaration of death process. It is important to have this information be available to clinicians as they are making the pronouncement.

Committee Members Who Participated

Mark Barr (Chair)
Brigette Bednar
Ray Benza
Sangeeta Bhorade
Nancy Blumenthal
Dorrie Dils
Kevin Dushay
Maryl Johnson
Mandeep Mehra
Ken McCurry
Nahush Mokadam
Linda Ohler
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Amy Putnam
Brian Shepard