

OPTN/UNOS Thoracic Organ Transplantation Committee
Report to the Board of Directors
November 14-15, 2011
Atlanta, Georgia

Summary

I. Action Items for Board Consideration

- Proposal to Encourage Organ Procurement Organizations (OPOs) to Provide Non-Contrast CT Scan if Requested by Transplant Programs, and to Modify Language in 3.7.12.3 (Essential Information for Lung Offers) and 3.7.12.4 (Desirable Information for Lung Offers) for Currency and Readability. The Board is asked to approve plain language modifications to Policy 3.7.12.3, and the addition of non-contrast computed tomography (CT) scan of the chest to Policy 3.7.12.4. (Item 1, page 3)
- Proposal to Require Updates of Certain Clinical Factors Every 14 Days for Lung Transplant Candidates with Lung Allocation Scores (LAS) of at Least 50, and to Modify Policy 3.7.6.3 (Candidate Variables in UNetSM) for Currency and Readability. The Board is asked to approve plain language modifications to Policy 3.7.6.3, and require transplant programs to update in no more than 14 days, any observed changes in certain clinical values for candidates with LASs of 50 or higher. (Item 2, page 4)
- Proposal to Extend the Interim Policy for Outpatient Adult Heart Transplant Candidates Implanted with Total Artificial Hearts (TAH). The Board is asked to extend for one year the interim policy for outpatient adult candidates implanted with TAHs. (Item 3, page 7)
- Mandating the Blood Titer Value to Report in UNetSM for Candidates Who Are Eligible to Receive Hearts from Donors with any Blood Type. The Board is asked to mandate the entry of the higher titer value when more than one result is provided for a given blood sample. (Item 4, page 10)

II. Other Significant Items

- Revising to the Lung Allocation Score System. The Committee plans to submit revisions to the Lung Allocation Score system for public comment in March, 2012. (Item 5, page 12)
- Review of the Adult Heart Policy. The Committee continues to explore potential policy options for candidates implanted with mechanical circulatory support devices. (Item 6, page 12)
- Revising the Pediatric Heart Policy. The Committee plans to distribute revisions to the pediatric heart policy in March, 2012. (Item 7, page 13)
- Proposal Distributed for Public Comment on September 16, 2011. The Committee proposes that heart transplant programs must record in UNetSM changes to a heart transplant candidate's status or criterion within 24 hours. (Item 8, page 13)

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Mark L. Barr, MD (Chair)
Steven A. Webber, MD (Vice-Chair)

The following is a summary of the Thoracic Organ Transplantation Committee's (Committee) deliberations on June 13 and September 13, 2011.

1. Proposal to Encourage Organ Procurement Organizations (OPOs) to Provide Non-Contrast CT Scan if Requested by Transplant Programs, and to Modify Policies 3.7.12.3 (Essential Information for Lung Offers) and 3.7.12.4 (Desirable Information for Lung Offers) for Currency and Readability

The Committee proposes the addition of non-contrast computed tomography (CT) scan of the chest to Policy 3.7.12.4. The proposed policy encourages an OPO to provide the result of a CT scan if it is requested to do so by a transplant program. The proposed policy does not require a transplant program to request a CT scan.

Deceased donor lungs may have contusions or infiltrates or malignant nodules which may not be visible in a chest X-ray (CXR). In instances where significant clinical suspicion for such abnormalities exists, a non-contrast CT scan of the chest can provide additional information.

The Committee distributed this proposed policy for public comment on March 13, 2011. The Committee discussed comments about this proposal in June and September, 2011. (The briefing paper and the resource impact summary for this proposed policy is **Exhibit A.**) The Committee acknowledged concerns cited in the comments as these were similar to what the Committee discussed in developing the policy. Indeed, the proposal had already addressed some of the comments received. The Committee emphasized that the proposal is making a suggestion to clinicians to use their best judgment in requesting CT scans, and for OPOs to provide CT scans when requested. While higher discard rates have been noted as a possible consequence of this proposal, there is no evidence to support that notion; rather, it is possible that marginal lungs are more likely to be used. Regarding comments about organ offer delays, the Committee opined that in practice, it is likely that CT scans are anticipated only for marginal lung donors. The proposal attempts to address patient safety through further examination of marginal lungs for emphysema or cancerous lesions.

The Committee will monitor the practice of conducting CT scans if there are complaints from transplant programs or OPOs. The Committee believes that the policy promotes the utility of CT scanning when needed. Thus, the Committee voted to present the proposed policy (see below) to the Board of Directors for consideration in November, 2011: 28-supported; 0-opposed; and, 0-abstained.

****RESOLVED, that Policies 3.7.12.3 (Essential Information for Lung Offers) and 3.7.12.4 (Desirable Information for Lung Offers) shall be modified as set forth below, effective upon Member notification:**

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/H₂O/PEEP including PO₂/FiO₂ ratio and preferably 100% FiO₂ 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 3.4.42;
- (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~~
¶
- 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~~
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Non-contrast computed tomography (CT) scan of the chest, if requested by the transplant center.

2. Proposal to Require Updates of Certain Clinical Factors Every 14 Days for Lung Transplant Candidates with Lung Allocation Scores (LAS) of at Least 50, and to Modify Policy 3.7.6.3 (Candidate Variables in UNetSM) for Currency and Readability

The Committee proposes requiring transplant programs to update at least every 14 days, any observed changes in clinical values most important to determining a candidate's Lung Allocation Score for high-LAS candidates. For a high-LAS candidate, the proposal would require the transplant program to report in UNetSM¹ any change in the candidate's need for assisted

¹ UNetSM is a network of 5 UNOS-developed transplant applications that are interconnected to provide for the candidate waiting list, the organ placement process, data collection, and data security.

ventilation or supplemental oxygen (frequency and amount), as well as a change in the candidate's PCO₂ value if the transplant program performed this blood gas test during the proposed time period.

Policy 3.7.6.3.2 (Updating Candidate Variables) requires a transplant program to update its candidates' clinical values in UNetSM every six months. Candidates with high-LAS are likely receiving therapeutic interventions that may improve their health and thus decrease their scores.

Policy 3.7.6.3.1 (Candidate Variables in UNetSM upon Implementation of Lung Allocation Scores Described in Policy 3.7.6) is no longer current, because it applied only to candidates waiting for lung transplants when the OPTN implemented the LAS system in May, 2005. Therefore this section of policy language is being deleted. In addition to this modification, other modifications proposed include general edits for readability.

The proposal was distributed for public comment on March 13, 2011, and in June and September, the Committee reviewed the responses submitted by the public, the regions, and other OPTN/UNOS committees. (The briefing paper and the resource impact summary for this proposed policy is **Exhibit B**.) The proposal had already addressed some of the comments received. The Committee acknowledged concerns submitted, such as the data entry burden and the selection of the seemingly arbitrary 14-day time period. The proposed policy does not require that transplant programs perform the invasive test to obtain a PCO₂ value for high-LAS candidates. Rather, if the transplant program obtains a PCO₂ value, it must report it in UNetSM no more than 14 days from the date of the test. According to the data reviewed by the Committee, most candidates with high-LAS do not remain so for very long periods of time. Thus for most candidates with high-LAS, transplant programs would need to update the specified variables only once.

The proposed policy will affect a small number of candidates. The proposed policy requires updates to only three variables. The proposed policy does not replace the need for transplant programs to appropriately manage their waiting lists. Rather, the proposal ensures that transplant programs are appropriately managing their list of candidates whose scores are 50 and higher so that patients receive deceased donor lung offers based on their true disease severity. Finally, the proposed data updates are similar to but not as aggressive as the heart policies.

However, the Committee will monitor the proposed policy and make amendments as needed. The Committee voted to present the proposed policy (see below) to the Board of Directors for approval in November, 2011: 28-supported; 0-opposed; and, 0-abstained.

****RESOLVED, that Policies 3.7.6.3 (Candidate Variables in UNetSM), 3.7.6.1 (Candidate Variables in UNetSM upon Implementation of Lung Allocation Scores Described in Policy 3.7.6), and 3.7.6.2 (Updating Candidate Variables) shall be modified as set forth below, effective upon Member notification:**

3.7.6.3 Candidate Variables in UNetSM. Entry into UNetSM 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.



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.



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 UNetSM 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.~~

3.7.6.3.23.7.6.3.1 **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 UNetSM 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.



UNetSM defines a “six -month anniversary date,” which first occurs six months from the date of initial listing, then every six months thereafter. UNetSM will consider a variable to be expired if the variable’s test date is six-months older than the most recent anniversary date.



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 expired~~, 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 UNetSM.

¶

UNetSM will consider ~~A~~ actual values or estimated values for pulmonary pressures ~~will~~ to be valid until the transplant center ~~they are either updated~~ them with ~~a~~ new actual values or ~~a~~ new estimated values ~~is entered~~ pursuant to Policy 3.7.6.4.

¶

A program must update three key variables in UNetSM no more than 14 days after a candidate’s LAS becomes greater than 50: assisted ventilation, supplemental oxygen, and current PCO₂. If a program does not perform a PCO₂ test in that time, then it does not need to update this value in UNetSM. 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.

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

On November 9, 2010, the Board of Directors approved an interim policy, concurrent with public comment, for adult heart transplant candidates implanted with a TAH and discharged from the hospital. These candidates may now be listed as Status 1A for 30 days. When this 30-day time period ends, if these candidates are not eligible to be listed as Status 1A by other existing criteria, then they must be downgraded and may be listed as Status 1B. This interim policy is in effect and is comparable to the Status 1A policy for candidates with ventricular assist devices (VAD).

Recent availability of a portable driver has allowed some candidates with TAHs to await heart transplantation as outpatients. Prior to the availability of this portable driver, all candidates with

TAHs remained inpatients. Policy allows all inpatient TAH candidates to be classified as Status 1A indefinitely while hospitalized, with the qualification being recertified every 14 day periods. However, policy previously prevented outpatient candidates implanted with TAHs be listed as Status 1A unless they qualified for Status 1A due to device-related complication (i.e., criterion (b).²) There are no data to suggest that the medical urgency of an inpatient candidate with a TAH implant is different from an outpatient candidate with a TAH implant. Therefore, the Committee proposes to temporarily provide this outpatient candidate population some time at Status 1A while it gathers evidence for developing a long-term policy on outpatient candidates implanted with TAHs. This interim policy will expire on December 1, 2011.

The Committee distributed the interim policy for public comment on March 13, 2011, and reviewed the comments submitted in June and September, 2011. (The briefing paper and the resource impact summary for this proposed policy is **Exhibit C.**) Commentaries received were similar to the feedback provided by programs while the TAH policy was being discussed. The Committee agreed with comments stating that the interim policy favors outpatient TAH candidates over candidates with ventricular assist devices (VAD). Responding to comments about the need for the clinical trial to be successful, the Committee opined that the interim policy was not developed to support a clinical trial; rather, the interim policy addresses the medical need of a new group of heart transplant candidates.

Since receiving the policy's interim approval last November, the Committee has examined data, the literature, and sought other expert advice on revising the policy for candidates implanted with mechanical circulatory support devices. The policy today does not reflect the disease severity of the heterogeneous candidate population implanted with such devices. The Committee acknowledges concerns cited in the comments to the interim policy on outpatient candidates implanted with TAHs, as these were similar to what the Committee discussed in developing the policy. At this time, however, the Committee neither has the quantitative data nor clinical rationale for changing the interim policy. The Committee expects to have a revised policy for candidates implanted with mechanical circulatory support devices by November 2012.

As it promised to the Board of directors on November 10, 2010, the Committee has been engaged in philosophical and praxis-related conversations that will result in revisions that the heart transplant community is likely to accept as policy. At this time, the Committee proposes to extend the proposed policy for one year to enable the completion of these complicated conversations and to present a revised Policy 3.7.3 to the Board of Directors: 28-supported; 0-opposed; and, 0-abstained.

****RESOLVED, that the interim policy for outpatient adult candidates implanted with total artificial hearts be extended for one year, effective upon Member notification:**

3.7.3 Adult Candidate Status. Each candidate awaiting heart transplantation is assigned a status code which corresponds to how medically urgent it is that the candidate receive a transplant. Medical urgency is assigned to a heart transplant candidate who is greater than or equal to 18 years of age at the time of listing as follows:

² Status 1A, criterion (b): "Mechanical circulatory support with objective medical evidence of significant device-related complications such as thromboembolism, device infection, mechanical failure and/or life-threatening ventricular arrhythmias [...]"

Status Definition

1A A candidate listed as Status 1A is admitted to the listing transplant center hospital (with the exception for 1A(b) candidates) and has at least one of the following devices or therapies in place:

- (a) Mechanical circulatory support for acute hemodynamic decompensation that includes at least one of the following:
 - (i) left and/or right ventricular assist device implanted
Candidates listed under this criterion, may be listed for 30 days at any point after being implanted as Status 1A once the treating physician determines that they are clinically stable. Admittance to the listing transplant center hospital is not required.
 - (ii) total artificial heart;
 - (iii) intra-aortic balloon pump; or
 - (iv) extracorporeal membrane oxygenator (ECMO).

Qualification for Status 1A under criterion 1A(a)(ii), (iii) or (iv) is valid for 14 days and must be recertified by an attending physician every 14 days from the date of the candidate's initial listing as Status 1A to extend the Status 1A listing.

[A candidate with a total artificial heart who has been discharged from the listing hospital may be listed as Status 1A for 30 days at any point in time after the discharge.]

NOTE: The above language (in brackets) will expire on December 1, ~~2011~~2012.

[...]

1B A candidate listed as Status 1B has at least one of the following devices or therapies in place:

- (aa) left and/or right ventricular assist device implanted; or
- (bb) continuous infusion of intravenous inotropes.

[A candidate with a total artificial heart who has been discharged from the listing hospital may be listed as Status 1B at any point in time after the discharge.]

NOTE: The above language (in brackets) will expire on December 1, ~~2011~~2012.

4. Proposal to Mandate the Blood Titer Value to Report in UNetSM for Candidates Who Are Eligible to Receive Hearts from Donors with any Blood Type

Some laboratories perform more than one test on a given blood sample, which may yield differing Anti-A or Anti-B isohemagglutinin titer values for a given blood sample. (These different hemagglutination tests primarily identify IgM or IgG isohemagglutinins, commonly known as room temperature titers and anti-human globulin titers.) Neither Policy 3.7.8 (ABO Typing for Heart Allocation) nor its programming allow for the entry of more than one Anti-A or Anti-B isohemagglutinin titer value. (Policy and its programming do allow for the entry of Anti-A and Anti-B isohemagglutinin titer values.) While many laboratories provide only one type of titer value to a transplant program, those that provide more than one type of Anti-A or Anti-B isohemagglutinin titer value for a given blood sample results in the transplant program having to decide which value to enter in UNetSM. In the latter scenario, the higher Anti-A or Anti-B titer value provided by the laboratory is likely the better predictor of an adverse graft outcome. Policy 3.7.8 supports this decision, because it identifies patients with high titer antibody and precludes their eligibility for an ABO-independent heart transplant. Thus, the Committee and the Pediatric Committee (Committees) contend that there would be consensus in the community about the proposed requirement to enter the higher Anti-A or Anti-B titer value when a laboratory provides more than one for a given blood sample, and therefore, view the proposed requirement as a clarification to Policy 3.7.8. (The briefing paper and the resource impact summary for this proposed policy is **Exhibit D**.)

In 2006, the Board of Directors approved modifications to the ABO-independent heart transplant policy. The OPTN Contractor implemented these policy modifications on November 22, 2011. Soon after policy implementation, the Committees received an inquiry about which type of titer to enter in UNetSM: IgG or IgM. The Committees discussed whether policy should address the type of titer to enter, or the entry of the higher Anti-A or Anti-B titer value when a laboratory provides more than one result for a given blood sample. The Committees chose the latter option for the reasons cited in the summary section above. In October, 2011, the Committees voted in favor of the following resolution (Thoracic Organ Transplantation Committee (23-supported; 0-opposed; and 1-abstained); Pediatric Organ Transplantation Committee (19-supported; 0-opposed; and 2-abstained)):

****RESOLVED, that Policy 3.7.8 (ABO Typing for Heart Allocation) and 3.7.8.1 (Heart Allocation to Pediatric Candidates Eligible to Accept a Donor Heart of Any Blood Type) shall be modified as set forth below, effective upon Member notification:**

3.7.8 ABO Typing for Heart Allocation. Within each heart status category, hearts will be allocated to patients according to the following ABO matching requirements:

- (i) Blood type O donor hearts shall only be allocated to blood type O or blood type B patients;
- (ii) Blood type A donor hearts shall only be allocated to blood type A or blood type AB patients;
- (iii) Blood type B donor hearts shall only be allocated to blood type B or blood type AB patients;

- (iv) Blood type AB donor hearts shall only be allocated to blood type AB patients.
- (v) If there is no patient available who meets these matching requirements, donor hearts shall be allocated first to patients who have a blood type that is compatible with the donor's blood type.
- (vi) Following allocation for all born transplant candidates who have blood types that are compatible with donors, hearts will be allocated locally first and then within zones in the sequence described in 3.7.10, by heart status category to born Status 1A or 1B pediatric heart candidates who are eligible to receive a heart from any blood type donor. Allocation to *in utero* candidates eligible for any blood type donors is initiated after all eligible born candidates have received offers.

A center may specify on the waiting list that a candidate is eligible to accept a heart from any blood type donor if one of the following conditions is met:

- (i) Candidate is *in utero*;
- (ii) Candidate is less than 1 year of age, and ~~meets all of the following:~~
 - a. ~~Is Listed~~ listed at Status 1A or 1B, and
 - b. ~~Has Current~~ current isohemagglutinin titer information for A and/or B blood type antigens reported in UNetSM.
- (iii) Candidate is greater than or equal to 1 year of age, and ~~meets all of the following:~~
 - a. Is listed prior to age 2;
 - b. Is listed at Status 1A or 1B;
 - c. ~~Is~~ Has current isohemagglutinin titer level(s) less than or equal to 1:4 for A and/or B blood type antigens reported in UNetSM; and,
 - d. ~~Is~~ Has *not* received treatments within the prior 30 days that may have reduced his or her titer values to 1:4 or less.

3.7.8.1 Heart Allocation to Pediatric Candidates Eligible to Accept a Donor Heart of Any Blood Type. A center may specify on the waiting list that a candidate is eligible to accept a heart from any blood type donor if the eligibility requirements set forth in Policy 3.7.8 are met.

Anti-A and/or Anti-B titers value must be reported in UNetSM:

- (i) At time of listing (except for *in utero* candidates);
- (ii) Every 30 days after listing (**all** eligible born candidates);
- (iii) At transplant; and,
- (iv) In the event of graft loss or death within one year after transplant (for all candidates transplanted with other than blood type identical or compatible donor hearts).

The transplant program must enter the highest titer value if a laboratory provides more than one Anti-A or Anti-B isohemagglutinin titer value for a given blood sample.

Listing and transplant outcomes for candidates determined to be eligible under this policy will be monitored on a quarterly basis by a subcommittee of the Pediatric Transplantation Committee, including at least two non-Committee members with analytical and/or other professional expertise in this area of medicine, and reported to the Pediatric Committee. Transplant programs that list candidates for receipt of donor hearts of any blood type shall be required to provide information requested for review by the subcommittee, including, for example, autopsy reports.

5. Revising the Lung Allocation Score (LAS) System

In developing and implementing the LAS, the Committee intended – and the policy reflects – that the system be dynamic so that it could address the changing candidate and recipient population. Since the LAS' implementation, the Committee added PCO₂ and bilirubin to the LAS. The Committee is currently developing a proposal to revise the LAS system; updating the baseline survival rates, parameter estimates, and modifying the variables included in the waiting list and post-transplant survival models.

Recognizing that the implementation of the revised LAS system would require around 6000 person hours to automate, and that the OPTN Contractor has not yet implemented the bilirubin policy for reasons that include person-hours required (over 6000), the Committee considered the following options for making changes to the LAS system:

- Update the LAS system:
 - i) Only change the baseline survival rates and parameter estimates for the existing variables in the LAS
- Revise the LAS system:
 - i) Add new variables to the waiting list and post-transplant models;
 - ii) Change the baseline survival rates; and,
 - iii) Change the parameter estimates for all variables in the waiting list and post-transplant models.

The Committee selected to revise the LAS system to better address the waiting list mortality, and plans to distribute the proposal for public comment in March, 2012.

6. Review of the Adult Heart Policy

The Committee, primarily through its Heart Subcommittee, has been working to revise the policy for candidates implanted with mechanical circulatory support devices. Although the impetus for the conversation was developing the interim policy for outpatient candidates implanted with total artificial hearts, the proposed policy has three goals: a) revise the entire policy that addresses the medical urgency of adult heart candidates (Policy 3.7.3 – Adult Candidate Status); b) address the disease severity of candidates implanted with mechanical circulatory support devices (MCSD); and, c) specify MCSD-related infections or complications that warrant the 1A status.

The Committee has reviewed several proposals to revise the policy in its entirety, and anticipates submitting a policy proposal for public comment in 2012.

7. Revising the Pediatric Heart Policy

The Committee's Heart Subcommittee, the Pediatric Committee's Thoracic Working Group, and representatives from the Pediatric Heart Transplant Study (PHTS) continue to discuss revisions to the current pediatric heart medical urgency policy (3.7.4 – Pediatric Candidate Status).

Currently, a majority of pediatric heart candidates are listed as Status 1A at the time of their transplants, resulting in waiting time being the primary criterion for receiving deceased donor heart offers. Waiting time is an indicator of access to transplantation services, not disease severity. Current policy enables a candidate to be listed as Status 1A if she or he has an MCS/D implanted. However, the status justification form does not enable entry of the specific type of MCS/D. Literature and clinical experience suggest that many candidates placed on extracorporeal membrane oxygenation (ECMO) fare worse post-transplant.

Therefore, the group opted to change policy rather than leave it as is. The group considered expanding the number of statuses. Due to the potentially high cost and time required for programming an additional tier (or two), the group opted to retain the existing statuses but with changes in status criteria. Thus, this working group has spent close to two years reviewing OPTN data on waiting list mortality by status and criteria, as well as post-transplant outcomes by status and criteria. More recently, this working group reviewed data analyses from the PHTS on ECMO-related pre- and post-transplant outcome data for pediatric candidates listed on ECMO.

In addition to reviewing quantitative data, the working group reviewed the current criteria and opined on which criterion should continue to be part of the Status 1A and 1B criteria and why.

The OPTN and PHTS data indicated that candidates who were placed on ECMO at listing were less likely to survive to transplant than candidates who were not placed on ECMO at listing. Candidates who were on ECMO for more than 7 days while waiting for a heart transplant were less likely to survive to transplant. Candidates who were on ECMO at the time of transplant had lower survival rates after transplant than candidates who were not on ECMO at the time of transplant, and this was especially true for candidates who were less than one year of age. Also, candidates on ECMO at the time of transplant and who have high creatinine values (1.0 to 4.2) have a lower post-transplant survival. Finally, diagnosis is also a factor in determining poorer waiting list and post transplant survival outcomes for candidates placed on ECMO (see two images below). Candidates diagnosed with a congenital disease or cardiomyopathy and placed on ECMO during listing are less likely to survive to transplant. However, candidates diagnosed with myocarditis who were on ECMO at the time of transplant have a lower post-transplant survival rate than candidates diagnosed with cardiomyopathy or a congenital disease and were on ECMO at the time of transplant.

The working group continues to consider qualitative and quantitative data and apply the evidence in revising the current status criteria as shown in the table below. The Thoracic and Pediatric Committees anticipate submitting a revised pediatric heart policy for public comment in March, 2012.

8. Proposal Distributed for Public Comment on September 16, 2011

The OPTN contractor's Evaluation Plan³ requires that heart transplant programs record in UNetSM changes to a heart transplant candidate's status or criterion within 24 hours, but this requirement

³ http://optn.transplant.hrsa.gov/content/policiesAndBylaws/evaluation_plan.asp

is not written in Policies 3.7.3 (Adult Candidate Status) and 3.7.4 (Pediatric Candidate Status). The two policies state that the OPTN contractor will notify “a responsible member of the transplant team” prior to downgrading a candidate’s Status. The OPTN Contractor does provide notification of impending downgrades in UNetSM but does not notify provide additional notification to transplant program personnel. (Clinicians may view a candidate’s status at any time in UNetSM.) The proposed modifications include the 24-hour requirement, removal of the notification clause, and edits for plain language. For consistency, the modifications also include language about potential referral of pediatric heart status exception case decisions to the Committee.

The Committee will evaluate the comments on this proposed policy in the first quarter of 2012.

9. Update on the Heart Allocation System

On September 13, 2011, the Committee reviewed OPTN data on the status of the heart allocation system (**Exhibit E**).

Summary of the waiting list outcomes:

- There has been an increase in the number of active waiting list registrations and urgent waiting list registrations
- Waiting list mortality in Status 1A and Status 1B appears to have decreased

Summary of the post-transplant outcomes:

- The number of transplants remained essentially flat for 3 years and then experienced an increase in the most recent complete year.
- The distribution of status at transplant has changed: increase in Status 1A and decrease in Status 2.
- There was a borderline significant decline in post-transplant survival for adult status 2 recipients (p=0.08).
- There was a borderline significant increase in post-transplant survival for pediatric recipients, all statuses combined (p=0.098).

The Committee will next review these data in September, 2012.

10. Update on the Lung Allocation Systems

On September 13, 2011, the Committee reviewed OPTN data on the status of the heart allocation system (**Exhibit F**).

Summary of the waiting list outcomes:

- The total number of waiting list candidates is substantially lower than prior to the implementation of LAS.

- The number of active candidates 12+ years has increased during the most recent two years.
- The distribution of LAS at listing has shifted towards higher scores in the years since implementation.
- The waiting list mortality is lower overall in the post-policy era compared to the pre-policy era.

Summary of the post-transplant outcomes:

- The percentage of lungs transplanted has increased from pre- to post-LAS.
- There was a huge increase in the number of transplants from pre-LAS to post-LAS. There was also a large increase in transplants during the most recent complete year.
- There has been a substantial shift in the distribution of diagnosis from pre-LAS (>50% group A) to post-LAS (>50% group D).
- Post-transplant survival is comparable pre- and post-LAS, overall and by diagnosis grouping.

The Committee will next review these data in September, 2012.

11. Request to Reinstate Waiting Time Accrued While Waiting for a Previous Heart Transplant

On June 13, the Committee reviewed a case submitted by a transplant program that requested that time a patient accrued while waiting for a previous heart transplant be applied to the patient's current time waiting for another heart transplant. The Committee reviewed another such case in August, 2011.

The Committee reviewed Policies 3.2.1.8 (Waiting Time Modification) and 3.7.14 (Removal of Thoracic Organ Transplant Candidates from Thoracic Organ Waiting Lists When Transplanted or Deceased).

Policy 3.7.14:

If a heart, lung, or heart-lung transplant candidate on the Waiting List has received a transplant from a deceased or living donor, or has died while awaiting a transplant, the listing center, or centers if the candidate is multiple listed, shall immediately remove that candidate from all Thoracic Organ Waiting Lists for that transplanted organ and shall notify the OPTN contractor within 24 hours of the event. If the thoracic organ recipient is again added to a Thoracic Organ Waiting List, waiting time shall begin as of the date and time the candidate is relisted.

Policy 3.2.1.8:

[...]All other requests for waiting time reinstatement that are not specified under Policy 3.2.3.2 (Waiting Time Reinstatement for Kidney Recipients), or other policies which

describe permissible waiting time adjustments, shall be first approved by unanimous agreement among the hospitals (with transplant programs for the applicable organ) within the local area in which the candidate is listed, and then submitted to the appropriate organ-specific committees and Board of Directors for review with appropriate supporting documentation. Notwithstanding the above, however, upon demonstration to the appropriate organ-specific committee that unanimous agreement among the relevant parties cannot be obtained despite efforts to do so, such a request may be submitted with appropriate supporting documentation, including without limitation, reasons provided by the dissenting party(ies) for any disagreement, for consideration despite the lack of unanimous approval.[...]

The Committee voted to not reinstate a candidate’s time spent waiting for a previous thoracic transplant.

12. List of Life-Support Options in Tiedi® Forms: Is the list of options current?

OPTN life support data may be used for program-specific performance analyses and policy development. In reviewing forms that require approval from the federal Office of Management and Budget (OMB), the Transplant Administrators Committee requested that organ-specific committees review life support for completeness and accuracy. On September 13, UNOS staff presented data considered as life support, and sought the following responses from the Committee regarding data collection categorized as life support:

Mechanism	Organ	Age group	Questions
IV inotropes	Heart-lung and lung	Adult	Add back to form?
Pacemaker/defibrillator	All organs	All ages	Add separately? Add combined?
Plasmapheresis/dialysis	All organs	All ages	Don’t add? Consider as life support for analysis purposes?
Oxygen	All organs	All ages	Don’t add? Consider as life support for analysis purposes?
BiPAP/CPAP	Heart-lung and lung	All ages	Add separately? Add combined?

The Committee also considered if there were other types of life support currently being used but not captured on the form or in the table above. The Committee opined that it would not consider such mechanisms as life support, with the exception of ECMO. The Committee tasked the Heart and Lung Subcommittees to assist UNOS staff in identifying data elements that appropriately should be labeled life support.

13. Review of Site Audit Data – Heart and Lung Transplant Programs

The Committee reviewed data, prepared by the Department of Evaluation and Quality (DEQ), on heart and lung site survey patterns and trends (**Exhibit G**). The Committee found the presentation useful and requested that DEQ present such data to the group annually. The Committee would like to comment on policies that are reviewed during site audits. The Committee tasked the Heart and Lung Subcommittees to review the current data elements that the

DEQ site audit staff use and make recommendations to the Thoracic Committee. It is possible that some of the recommendations may result in changes to policy language.

14. Notify the Thoracic Community that the Committee is Aware of Inappropriate Applications of Policy 3.7.3 criterion (b)

Policy 3.7.3 criterion (b) – see below – does not specify what constitutes a device-related infection. Nevertheless, learning through the Heart Subcommittee that the application of Policy 3.7.3 criterion (b) is not being applied consistently nationally, the Committee charged the Heart Subcommittee to develop a memorandum that advises programs to apply Policy 3.7.3 criterion (b) only for non-superficial infections. The Committee requested that this memorandum be sent to the thoracic transplant community as well as to the Membership and Professional Standards Committee.

“Mechanical circulatory support with objective medical evidence of significant device-related complications such as thromboembolism, device infection, mechanical failure or life-threatening ventricular arrhythmias. A transplant center can report a complication not listed here. The report of an “other” complication will result in a review by the respective heart regional review board. (Candidate sensitization is not an appropriate device-related complication for qualification as Status 1A under this criterion. The applicability of sensitization to thoracic organ allocation is specified by Policy 3.7.1.1 (Exception for Sensitized Candidates).) Admittance to the listing center transplant hospital is not required. Qualification for Status 1A under this criterion is valid for 14 days and must be recertified by an attending physician every 14 days from the date of the candidate's initial listing as Status 1A to extend the Status 1A listing.”

15. Allocation of Deceased Donor Heart and Lungs, off the Deceased Donor Lung Match Run, to Candidates Who Need Both Thoracic Organs Offers

For several years, the Committee has made efforts to revise Policy 3.7.7 (Allocation of Thoracic Organs to Heart-Lung Candidates). Specifically, the Committee has attempted to develop a policy on how OPOs must allocate off the lung match run a heart and a lung to a candidate who needs both. This document is in development. The Policy Oversight Committee (POC) is developing principles regarding multi-organ allocation in general, and using the heart-lung allocation as a case study. Once the Committee receives specific recommendations from the POC, it will resume its effort to refine the policy.

16. Breaking a Tie When Two Heart-Lung Candidates Are Eligible to Receive a Heart-Lung Bloc in the Same Geographic Zone

At a given point in time, there is a possibility that two heart-lung candidates, who are in the same geographic area, could be eligible to receive that same set of organs, through a heart or heart-lung match run and a lung match run. In other words, after the OPO has offered the heart to all isolated Status 1A heart candidates in the geographic area and been refused, it is possible that the highest ranking heart-lung candidate on the heart-lung match and the highest ranking heart-lung candidate on the lung match are different candidates. While this scenario is rare and has likely not occurred, Policy 3.7.7 (Allocation of Thoracic Organs to Heart-Lung Candidates) needs to address this scenario. The Committee recommends that in such a scenario, the candidate's Lung Allocation Score could be used to break the tie. This project is currently on hold for the same reason as that cited in item 15.

17. Ex Vivo Lung Perfusion (EVLP)

The Committee has recently begun its discussion of EVLP, a new technology that allows lungs that may otherwise be discarded to be transplanted through an improvement in the clinical quality of the lung. EVLP is in the clinical trial phase, but many Committee members anticipate that the US Food and Drug Administration (FDA) will approve this perfusion technology in early 2012.

Thoracic Organ Transplantation Committee	June 13, 2011 Teleconference and Live Meeting	
Name	Position	Attendance
Mark L. Barr, MD	Chair	By phone
Steven Webber, MD	Vice-Chair	By phone
Maryl R. Johnson, MD	<i>Ex officio</i>	By phone
Kevin Dushay, MD	Region 1 Representative	By phone
Raymond Benza, MD	Region 2 Representative	
Leonardo Seoane, MD	Region 3 Representative	
Dan Meyer, MD	Region 4 Representative	By phone
Craig Selzman, MD	Region 5 Representative	
Nahush Ashok Mokadam, MD	Region 6 Representative	
Sangeeta Borhade, MD	Region 7 Representative	By phone
Ramsey Hachem, MD	Region 8 Representative	
Alan Gass, MD	Region 9 Representative	By phone
Ladora Dils, RN, CPTC	Region 10 Representative	
Isabel Neuringer, MD	Region 11 Representative	
Nancy Blumenthal, MSN, CRNP	At Large Member	By phone
Kevin Chan, MD	At Large Member/Lung Review Board Chair	
Gregory Couper, MD	At Large Member	By phone
Herbert Heili	At Large Member	
Denise Kinder, RN, CPTC	At Large Member	By phone
Theodore Liou, MD	At Large Member	
Brigitte Marciniak-Bednar, RN, BSN, CCTC	At Large Member	By phone
Kenneth McCurry, MD	At Large Member	By phone
David Nelson, MD	At Large Member	
Linda Ohler, MSN, RN, CCTC, FAAN	At Large Member	By phone
Joseph Rogers, MD	At Large Member	
Stuart Sweet, MD, PhD	At Large Member	By phone
J. David Vega, MD	At Large Member	By phone
Mark J. Zucker, MD	At Large Member	By phone
Monica Lin, PhD	<i>Ex Officio</i> – HRSA	By phone
Ba Lin, MS, MPH	<i>Ex Officio</i> – HRSA	By phone
Monica M. Colvin-Adams, MD	SRTR Liaison	
Marshall Hertz, MD	SRTR Liaison	
Brooke Heubner	SRTR Liaison	By phone
Bertram Kasiske, MD	SRTR Liaison	
Melissa Skeans, MS	SRTR Liaison	By phone
Jon Snyder, PhD, MS	SRTR Liaison	
Maryam Valapour, MD	SRTR Liaison	By phone
Tyrone Brown	UNOS Staff	By phone
Leah Edwards, PhD	UNOS Staff	By phone
Vipra Ghimire, MPH	UNOS Staff	By phone
Jory Parker	UNOS Staff	By phone
Ciara Samana	UNOS Staff	By phone
Brian Shepard	UNOS Staff	

Thoracic Organ Transplantation Committee	September 13, 2011 Chicago, Illinois	
Name	Position	Attendance
Mark L. Barr, MD	Chair	X
Steven A. Webber, MD	Vice-Chair	X
Tajinder P. Singh, MD	Region 1 Representative	X
Raymond L. Benza, MD	Region 2 Representative	X
Leonardo Seoane, MD	Region 3 Representative	By phone
Dan M. Meyer, MD	Region 4 Representative	X
Craig H. Selzman, MD	Region 5 Representative	X
Nahush Ashok Mokadam, MD	Region 6 Representative	X
Sangeeta M. Borade, MD	Region 7 Representative	X
Joseph C. Cleveland, Jr., MD	Region 8 Representative	X
Alan L. Gass, MD	Region 9 Representative	X
David Bradley S. Dyke, MD	Region 10 Representative	X
Timothy P. Whelan, MD	Region 11 Representative	X
Luis Angel, MD	At Large Member/Lung Review Board Chair	X
Nancy P. Blumenthal, MSN, CRNP	At Large Member	X
Kevin Chan, MD	At Large Member	X
Ladora Dils, RN, CPTC	At Large Member	X
Kevin M. Dushay, MD	At Large Member	X
Maryl R. Johnson, MD	At Large Member	X
Theodore G. Liou, MD	At Large Member	X
William T. Mahle, MD	At Large Member	X
Brigette J. Marciniak-Bednar, RN, BSN, CCTC	At Large Member	
Kenneth R. McCurry, MD	At Large Member	X
David P. Nelson, MD	At Large Member	X
Damian Neuberger, PhD	At Large Member	X
Joseph G. Rogers, MD	At Large Member	X
Stuart C. Sweet, MD, PhD	At Large Member	X
J. David Vega, MD	At Large Member	X
Mark J. Zucker, MD	At Large Member	X
Ba Lin, MS, MPH	<i>Ex Officio</i> – HRSA	By phone
Monica Lin, PhD	<i>Ex Officio</i> – HRSA	X
Monica M. Colvin-Adams, MD	SRTR Liaison	X
Marshall Hertz, MD	SRTR Liaison	
Bertram Kasiske, MD	SRTR Liaison	
Melissa Skeans, MS	SRTR Liaison	X
Jon Snyder, PhD, MS	SRTR Liaison	
Maryam Valapour, MD	SRTR Liaison	X
Tyrone Brown	UNOS Staff	By phone
Leah Edwards, PhD	UNOS Staff	X
Rich Endert	UNOS Staff	X
Vipra Ghimire, MPH	UNOS Staff	X
Lee Goodman	UNOS Staff	X
Elizabeth Miller	UNOS Staff	By phone
Jory Parker	UNOS Staff	By phone
Amy Putnam	UNOS Staff	By phone
Brian Shepard	UNOS Staff	X
Chad Waller	UNOS Staff	By phone