

- **Proposal to Require Updates of Certain Clinical Factors Every 14 Days for Lung Transplant Candidates with Lung Allocation Scores (LAS) of at Least Fifty, And to Modify Policy 3.7.6.3 for Currency and Readability**
- **Affected Policies:** 3.7.6.3 (Candidate Variables in UNet<sup>SM</sup>), 3.7.6.3.1 (Candidate Variables in UNet<sup>SM</sup> upon Implementation of Lung Allocation Scores Described in Policy 3.7.6), and 3.7.6.3.2 (Updating Candidate Variables)
- **Thoracic Organ Transplantation Committee**

The Thoracic Committee proposes requiring transplant programs to update in no more than 14 days, any observed changes in clinical values most important to determining a candidate's Lung Allocation Score for candidates whose scores are 50 or higher (high-LAS). For high-LAS candidates, the proposal would require transplant programs to report in UNet<sup>SM</sup> any changes in the assisted ventilatio<sup>n</sup>, supplemental oxygen (frequency and amount), or PCO<sub>2</sub> clinical variables.

Policy 3.7.6.3.2 requires a transplant program to update its candidates' clinical values in UNet<sup>SM</sup> every six months. Candidates with high-LAS are likely receiving therapeutic interventions that may improve their health and thus decrease their scores.

- **Affected Groups**

Transplant Administrators  
Transplant Coordinators  
Transplant Data Coordinators  
Transplant Physicians  
Transplant Surgeons  
Transplant Program Directors  
Lung Transplant Candidates with LAS over 50

- **Number of Potential Candidates Affected**

This proposed policy would affect all high-LAS candidates.

- **Compliance with OPTN Final Rule**

This proposal complies with the following constructs in the OPTN Final Rule:

121.8 Allocation of organs.

(a) Policy development. [...]

(5) Shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement;

(6) Shall be reviewed periodically and revised as appropriate;

## **Proposal to Require Updates of Certain Clinical Factors Every 14 Days for Lung Transplant Candidates with LAS of at Least Fifty, And to Modify Policy 3.7.6.3 for Currency and Readability**

**Affected Policies:** 3.7.6.3 (Candidate Variables in UNet<sup>SM</sup>), 3.7.6.3.1 (Candidate Variables in UNet<sup>SM</sup> upon Implementation of Lung Allocation Scores Described in Policy 3.7.6), and 3.7.6.3.2 (Updating Candidate Variables)

### **Thoracic Organ Transplantation Committee**

#### **Summary of the Proposal:**

The Thoracic Committee proposes requiring transplant programs to update in no more than 14 days, any observed changes in clinical values most important to determining a candidate's Lung Allocation Score for high-LAS candidates. For high-LAS candidates, the proposal would require transplant programs to report in UNet<sup>SM1</sup> any changes in the assisted ventilation, supplemental oxygen (frequency and amount), or PCO<sub>2</sub> clinical variables.

Policy 3.7.6.3.2 requires a transplant program to update its candidates' clinical values in UNet<sup>SM</sup> every six months. Candidates with high-LAS are likely receiving therapeutic interventions that may improve their health and thus decrease their scores.

#### **Background and Significance of the Proposal**

Policy 3.7.6.3.2 requires transplant centers to report in UNet<sup>SM</sup> these changes in clinical values biannually. (An update to data obtained through heart catheterization is an exception to this rule; however, if transplant program repeats a heart catheterization test, it must report the new test result in UNet<sup>SM</sup>.)

High-LAS candidates are a sicker waiting list population whose medical management needs could require therapeutic interventions that affect their scores. Policy's requirement of biannual updates of data that contribute to candidates' LAS may prioritize candidates higher for allocation than their current health would warrant, and especially the high-LAS group. Some of these candidates' medical urgency may lower after therapy; but, without requiring more frequent updates to their record in UNet<sup>SM</sup>, the actual score – higher or lower – is unknown. Thus, some high-LAS candidates may receive transplants due to a high score that does not reflect their current clinical profile.

Listed below are the variables used in the LAS calculation.

#### *Factors Used to Predict Risk of Death on the Lung Transplant Waitlist<sup>2</sup>*

1. Forced vital capacity (FVC)
2. Pulmonary artery (PA) systolic pressure (Groups A, C, and D)
3. O<sub>2</sub> required at rest (Groups A, C, and D)
4. Age

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<sup>1</sup> UNet<sup>SM</sup> 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.

<sup>2</sup> In 2009, the Board approved the addition of current and increase in bilirubin to the waiting list model of the LAS. These factors are not yet part of the LAS calculation in UNet<sup>SM</sup>.

5. Body mass index (BMI)
6. Diabetes
7. Functional Status
8. Six-minute walk distance
9. Continuous mechanical ventilation
10. Diagnosis
11. PCO<sub>2</sub> (current and change in PCO<sub>2</sub>)

*Factors that Predict Survival after Lung Transplant*

1. FVC (in Groups B and D only)
2. PCW pressure  $\geq$  20 (in Group D only)
3. Continuous mechanical ventilation
4. Age
5. Serum creatinine
6. Functional status
7. Diagnosis

Of the waiting list variables, the following are those most likely to contribute to high-LAS:

- Assisted ventilation (BiPAP; CPAP; continuous mechanical; intermittent mechanical; or, no assisted ventilation needed);
- Frequency of supplemental oxygen (at rest; at night; with exercise only; or, not needed);
- Amount of supplemental oxygen;
- Six-minute walk distance;
- Functional status (Performs activities of daily living with NO assistance; performs activities of daily living with SOME assistance; or, performs activities of daily living with TOTAL assistance);
- PCO<sub>2</sub>; and,
- Percent predicted FVC.

In discussing this unintended consequence of the LAS system, the Thoracic Committee considered several options for modifying Policy 3.7.6.3.1: leave Policy 3.7.6.3.1 as is; require programs to record in UNet<sup>SM</sup> any change in the aforementioned variables that are most likely to contribute to high-LAS every 72 hours; require programs to record in UNet<sup>SM</sup> any change in the aforementioned variables that are most likely to contribute to high-LAS every 14 days; and, require programs to record in UNet<sup>SM</sup> any change in the aforementioned variables that are most likely to contribute to high-LAS every month. Leaving the policy as is would continue to allow this unintended consequence of the LAS system to occur.

While more frequent updates would yield more accurate data of the candidate's medical condition, the 72-hour time period might be too burdensome for data entry to the transplant programs. The one month time period might be too long to wait for an update for high-LAS candidates. The 14-day time period is comparable to the recertification requirements in the adult and pediatric heart policies,<sup>3</sup> and may be a more reasonable time period for updating changes to significant variables. Many high-LAS candidates are inpatients and managed actively by transplant coordinators and other clinicians; therefore, the data proposed for collection should be readily available in the patient's medical record.

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<sup>3</sup> Policy 3.7.3 (Adult Candidate Status); Policy 3.7.4 (Pediatric Candidate Status)

Requiring frequent updates on all seven variables listed above will create data entry burden for transplant programs. In order to capture changes in health of high-LAS candidates, but doing so without creating unnecessary data entry burden to transplant programs, the Thoracic Committee selected the following four variables as most likely to indicate disease severity for high-LAS candidates: assisted ventilation, frequency of supplemental oxygen, amount of supplemental oxygen, and PCO<sub>2</sub>. While transplant programs can assess the need for assisted ventilation and supplemental oxygen without performing invasive tests, determining if there is a change in a candidate's PCO<sub>2</sub> level, however, requires the performance of a blood test. The proposed policy does not require that transplant programs perform this invasive test to obtain a PCO<sub>2</sub> value for high-LAS candidates; only that if the transplant program obtains a PCO<sub>2</sub> value, it must report it in UNet<sup>SM</sup> no more than 14 days from the date of the test.

The review of language in Policy 3.7.6.3.2 resulted in a review of language in Policy 3.7.6.3 (Candidate Variables in UNet<sup>SM</sup>). Policy 3.7.6.3.1 (Candidate Variables in UNet<sup>SM</sup> 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. In addition to this modification, other modifications proposed include general edits for readability.

In January, 2011, the Thoracic Committee reviewed the proposed policy modifications and voted in favor of it: 19-supported; 2-opposed; and, 0-abstained. If the OPTN/UNOS Board of Directors approves the proposed policy, transplant programs must assess and report in UNet<sup>SM</sup> the candidate's need for assisted ventilation, the amount of supplemental oxygen the candidate requires at rest, the frequency of supplemental oxygen, and the candidate's current PCO<sub>2</sub> value. The transplant program must perform this first report no more than 14 days from the date when the candidate's score became 50.<sup>4</sup> While the candidate's score remains 50 or higher, the transplant program must continue to evaluate and report changes in the four clinical variables no less frequently than 14 days from each previous assessment.

#### *Intended Consequence*

The proposed policy modification will result in a more appropriate prioritization of all candidates that receive LAS, and especially high-LAS candidates.

#### *Unintended Consequence*

The proposed policy modification will create a data entry burden for transplant centers managing high-LAS candidates. Further, the manual monitoring of candidates' records could prove burdensome to the transplant programs. The Thoracic Committee will evaluate the impact of this proposed policy.

#### **Supporting Evidence:**

There is a strong relationship between a candidate's diagnosis group and whether her or his LAS was at least 50 (see Table 1). However, once a candidate's diagnosis is entered in UNet<sup>SM</sup>, it does not need to change (unless there is an error); so, transplant programs do not need to change this variable's value.

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<sup>4</sup> The LAS system makes use of age to the day in its waiting list and post-transplant models. As a result, time alone could result in a lung allocation score of 50 or higher.

Anecdotal evidence suggests that the distance walked during six minutes and percent predicted FVC do not contribute as strongly to a score being 50 or higher – unlike assisted ventilation and supplemental oxygen (frequency and amount). Anecdotal evidence also suggests that changes in a candidate’s PCO<sub>2</sub> level is a significant clinical indicator of disease progression. A candidate’s functional status contributes to high-LAS, but this physical ability is likely captured through the candidate’s need for assisted ventilation and supplemental oxygen.

Diagnosis Group	Total Registrations (N)	Ever Had LAS >50	
		N	%
All Groups	9635	2464	25.6
A	3271	148	4.5
B	441	39	8.8
C	1239	329	26.6
D	4684	1948	41.6

Table 1: Lung Registrations with High LAS (Waiting List Additions 5/4/2005 to 5/3/2010) [OPTN Data as of October 1, 2010]

As shown in Figure 1, the median number of days that candidates with high-LAS waited for transplants was 18, and this was true across all diagnosis groups. Thus, the data suggest that at least half of the candidates would need to have one or more of the three aforementioned variables updated at least once while they are in the high-LAS category. However, the data also suggest that the majority of high-LAS candidates will not require a second update.

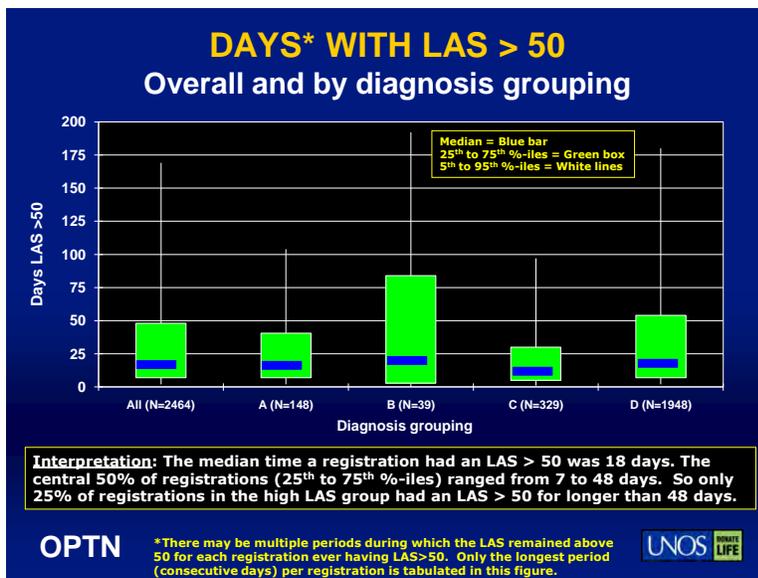


Figure 1: Days with LAS Greater than 50 (Overall and by Diagnosis Grouping) [OPTN Data as of October 1, 2010]

**Expected Impact on Living Donors or Living Donation:**

This section is not applicable to this policy proposal.

### **Expected Impact on Specific Patient Populations:**

This proposed policy could affect all candidates with high-LAS, and especially those whose health improves enough that their scores become less than 50. If the candidates' condition warrants them to remain in the high-LAS category, then this proposed policy will not affect this group of patients.

### **Adherence to the OPTN Contract and the Final Rule:**

Frequent reports of specific data in UNet<sup>SM</sup> for a candidate with high-LAS will enable accurate prioritization – based on timely information of the candidate's disease progression – of that candidate for organ allocation. The following constructs in the OPTN Contract and the Final Rule support the proposed policy's goal described above.

#### *OPTN Contract*

[...]

Task 2 addresses the development, implementation, monitoring, and enforcement of policies. The intent of this task "...is to minimize the burden of end-stage organ failure on transplant candidates; maximize the benefit of transplantation for recipients; and increase the number of viable organs for transplantation." [...]

#### *OPTN Final Rule*

[...]

"121.8 Allocation of organs.

(a) Policy development. [...]

(5) Shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement;

(6) Shall be reviewed periodically and revised as appropriate;"

[...]

### **Plan for Evaluating the Proposal:**

Through a review of analyses of site audits performed by the Department of Evaluation and Quality (DEQ), the Thoracic Committee will assess the unintended consequences of this proposed policy. Questions that the Thoracic Committee will ask during this evaluation process are:

- 1) What is the impact of this proposed policy in the management of candidates with LAS of 50 or higher?
- 2) On average, how many iterations of the 14-day update need to be made?

### **Additional Data Collection:**

Transplant programs must assess and report in UNet<sup>SM</sup> any changes to the following four clinical variables in no more than the 14 days following their candidates' LAS becoming 50: assisted ventilation, frequency of supplemental oxygen, amount of supplemental oxygen required, and PCO<sub>2</sub>.

The proposed policy will require transplant programs to monitor their candidates' scores, i.e., the proposed policy's implementation will not create automatic high-LAS triggers in UNet<sup>SM</sup> for any

candidate. If the Board approves this proposed policy, UNOS will distribute a memo (guidance document) to the lung transplant community on how to generate custom reports in UNet<sup>SM</sup> to facilitate identification and monitoring of high-LAS candidates.

**Expected Implementation Plan:**

If the Board approves the proposed policy, UNOS will implement it 60 days after the approval. The proposed policy does not require programming in UNet<sup>SM</sup>.

**Communication and Education Plans:**

Communication Activities			
Type of Communication	Audiences	Deliver Method	Timeframe
Policy Notice	<ul style="list-style-type: none"> <li>• Transplant Administrators</li> <li>• Transplant Coordinators</li> <li>• Transplant Data Coordinators</li> <li>• Transplant Physicians</li> <li>• Transplant Surgeons</li> <li>• Transplant Program Directors</li> </ul>	E-mail	30 days after the Board meeting

Educational Activity			
Activity	Audiences	Deliver Method	Timeframe and Frequency
Guidance Document	<ul style="list-style-type: none"> <li>• Transplant Administrators</li> <li>• Transplant Coordinators</li> <li>• Transplant Data Coordinators</li> <li>• Transplant Physicians</li> <li>• Transplant Surgeons</li> <li>• Transplant Program Directors</li> </ul>	E-mail	30 days after the Board meeting

**Monitoring and Evaluation:**

For high-LAS candidates, lung transplant programs must record and maintain documentation that they assessed the four variables in question in the time period stated in policy; and, the DEQ audit staff will review this documentation while on-site. (Note: This policy modification does not change the process of the Lung Review Board.)

## Policy Proposal:

**3.7.6.3 Candidate Variables in UNet<sup>SM</sup>.** Entry into UNet<sup>SM</sup> 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 mmHg will be assigned for missing pulmonary artery systolic pressure, a default value of 5 mmHg will be assigned for missing pulmonary capillary wedge pressure, and a default value of 15 mmHg 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 UNet<sup>SM</sup> 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 UNet<sup>SM</sup> 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.

### ¶

UNet<sup>SM</sup> defines a “six-month anniversary date,” which first occurs six months from the date of initial listing, then every six months thereafter. UNet<sup>SM</sup> 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 UNet<sup>SM</sup>.

¶

UNet<sup>SM</sup> 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 UNet<sup>SM</sup> no more than 14 days after a candidate’s LAS becomes greater than 50: assisted ventilation, supplemental oxygen, and current PCO<sub>2</sub>. If a program does not perform a PCO<sub>2</sub> test in that time, then it does not need to update this value in UNet<sup>SM</sup>. 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.

*There are no further changes to Policy 3.7.6.3.*