

**OPTN/UNOS Thoracic Organ Transplantation Committee
Report to the Board of Directors
November 12-13, 2014
St. Louis, Missouri**

**Joe Rogers, MD, Chair
Kevin Chan, MD, Vice Chair**

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This report reflects the work of the OPTN/UNOS Thoracic Organ Transplantation Committee between June 22, 2014 and September 23, 2014.

Action Items

1. Heart-Lung Allocation Guidance Document

Public Comment: n/a

For several years, the Committee has worked to clarify *Policy 6.5.E: Allocation of Heart-Lungs* to reduce the vagueness of the policy and to help OPOs consistently allocate heart-lung blocks. With the help of the OPO Committee, the Committee has created a guidance document that can be used by OPOs nationwide. The Committee also plans on distributing a policy proposal, consistent with the guidance document in the near future. On September 18, 2014, the Thoracic Committee voted to recommend the guidance document for consideration by the Board of Directors (17 support, 0 oppose; 0 abstentions).

RESOLVED, that the guidance document entitled *Guidance to Organ Procurement Organizations for Allocation of Heart-Lung Blocks*, as set forth in Exhibit A, is hereby approved, effective November 13, 2014.

2. LAS Policy Modifications

Public Comment: [March 16 – June 25, 2012](#)

Board Approval: [November, 2012](#)

The Board of Directors approved modifications to the Lung Allocation Score (LAS) policy in November, 2012. UNOS IT staff is currently programming the modifications, but has identified elements in the approved policy language that prevent the correct LAS calculation in the areas of the waiting list mortality measure, the post-transplant survival measure, and the threshold change and threshold change maintenance calculations from being calculated correctly. In order to ensure that the LAS calculation is accurate and the implementation of the LAS modifications are not delayed, the Thoracic Committee voted to recommend modifications to the policy language for consideration by the Board of Directors (17 support; 0 oppose; 0 abstentions). The recommended modifications also include edits for clarity and corrections to plain language rewrite transitional errors.

RESOLVED, that additions and modifications to Policies 10.1.C: Priority and Clinical Data Update Schedule for Candidates less than 12 Years Old; 10.1.E: LAS Values and Clinical Data Update Schedule for Candidates at Least 12 Years Old; 10.1.F: The LAS Calculation; 10.1.F.i: Lung Disease Diagnosis Groups; 10.1.F.ii: PCO₂ in the LAS; 10.1.F.iii: Bilirubin in the LAS; 10.1.F.iv: Creatinine in the LAS; 10.2.B.iv: LAS Values and Diagnoses Approved by the LRB; 10.3 Waiting Time; and 10.5: Probability Data Used in the LAS Calculation, as set forth in Exhibit B, are hereby approved, effective pending programming and notice to OPTN membership.

3. LAS of 50 or Higher Clarification

Public Comment: [March 11 – June 10, 2011](#)

Board Approval: [November, 2011](#)

The Board of Directors approved the proposal to require lung transplant programs to report three LAS variables (PCO₂, Assisted Ventilation, and Supplemental Oxygen) every 14 days for lung candidates with an LAS of 50 or higher. Though the policy was implemented on February 1, 2012, the UNOS Department of Evaluation and Quality (DEQ) cannot monitor the policy due to ambiguity in policy language. The Thoracic Committee worked with DEQ to clarify policy language to reflect the original intent of policy and allow effective DEQ monitoring. The Thoracic Committee voted to recommend clarifications to the policy language for consideration by the Board of Directors (17 support; 0 oppose; 0 abstentions).

RESOLVED, the modifications to Policy 10.1.G: Reporting Additional Data for Candidates with an LAS of 50 or Higher, as set forth in Exhibit C, are hereby approved, effective February 1, 2015.

Committee Projects

4. ECMO Data Collection

Public Comment: [September 29 – December 5, 2014](#)

Board Consideration: June, 2015 (Estimated)

In August 2014, the Committee voted to distribute the *Proposal to Collect ECMO Data Upon Waitlist Removal for Lung Candidates* for public comment. The Committee proposes capturing the following data fields related to a lung candidate's ventilator support history while waiting for transplant: 1) device type (ECMO veno-venous, ECMO veno-arterial, invasive mechanical ventilator support); 2) date of cannulation/intubation; 3) data of decannulation/extubation (if applicable); and 4) ambulatory status while on support.

For more information, see the public comment proposal and the Thoracic Committee meeting summary from August 25, 2014.

5. Changes to Heart-Lung Allocation Policy

Public Comment: January, 2015 (Estimated)

Board Consideration: June, 2015 (Estimated)

In addition to recommending the Heart-Lung allocation guidance document, the Thoracic Committee plans to propose a modification to *Policy 6.5.E: Allocation of Heart-Lungs*. The proposed modification would mirror the guidance document, but would be enforceable as policy. The Thoracic Committee believes it is important to urgently address the issue of heart-lung allocation, as OPOs currently do not have clear guidance and therefore heart-lung candidates may not have equitable access to organs depending on their OPO. In the future, the Thoracic Committee plans a larger overhaul to the heart-lung allocation policy to include an LAS threshold, just as there is a Status 1A heart threshold in the policy.

6. Pediatric Lung Allocation Policy Revision

Public Comment: January, 2015 (Estimated)

Board Consideration: June, 2015 (Estimated)

With the recent approval of the Adolescent Classification Exception for Pediatric Candidates, the Lung Subcommittee is now conducting a comprehensive review of pediatric

lung allocation policy to identify any opportunities for improving pediatric access to transplant. The Lung Subcommittee is investigating four potential opportunities for improvement:

1. Matching donors to candidates by physical size, rather than age
2. Broader sharing of child (age 0-11) and adolescent (12-17) donor lungs
3. ABO-incompatible (ABO-i) lung allocation for very young pediatric candidates
4. Use of the LAS in allocation for candidates less than 12 years old

They also plan to review recent Lung Review Board (LRB) exception cases to identify any circumstances that could be addressed by policy rather than the exception process.

Since May 2014, the Lung Subcommittee has considered size matching, broader sharing, and ABO-incompatible transplantation. After reviewing descriptive data, the Lung Subcommittee decided against size matching, believing it had the potential to disadvantage child candidates since child donors are likely to be an acceptable size match for adolescent candidates.

In July, the SRTR presented the results of a Thoracic Simulated Allocation Model (TSAM) of broader sharing of child and adolescent donor lungs. The results showed a modest benefit to adolescent candidates without negatively impacting either child or adult candidates. In August, the Lung Subcommittee requested changes to the modeled allocation sequence to investigate whether a sequence that also benefits child candidates is possible. A final decision regarding broader sharing policy will be made upon review of that data.

Finally, in August the Lung Subcommittee discussed the feasibility of an ABO-i lung allocation policy similar to the one that currently exists for very young heart candidates. The Lung Subcommittee continues to review available literature from the relatively few ABO-i lung transplants performed worldwide. Discussion continues about whether a proposed policy would first have more conservative eligibility criteria while data is collected to confirm the safety of ABO-incompatible lung transplant.

For more information, see the Lung Subcommittee meeting minutes from May 20, 2014, July 17, 2014, and August 21, 2014.

7. Modification of the Adult Heart Allocation System

Public Comment: August, 2015 (Estimated)

Board Consideration: June, 2016 (Estimated)

The Heart Subcommittee continues to develop modifications to the adult heart allocation system, including additional medical urgency tiers, qualifying criteria for each tier, prioritization of sensitized heart candidates, and broader sharing of donor hearts. The Heart Subcommittee is awaiting the results of a Thoracic Simulation Allocation Model (TSAM) of the first draft of these proposed changes. It is likely that the Heart Subcommittee will request additional iterations of the TSAM model based on the results.

For more information, see the Heart Subcommittee meeting minutes from May 27, 2014, July 24, 2014, and August 28, 2014.

8. Allocation of Deceased Donor Lungs that Have Undergone Ex Vivo Lung Perfusion (EVLP)

Public Comment: August, 2015 (Estimated)

Board Consideration: December, 2015 (Estimated)

In August, the Food & Drug Administration (FDA) approved a humanitarian device exemption for EVLP for deceased donor lungs. The Thoracic Committee previously decided not to recommend changes to lung allocation policy despite the introduction of EVLP technology to market, and continues to support this position. Instead, the Thoracic Committee focused on the data elements that may need to be collected in order to monitor the use of EVLP for deceased donor lungs.

A new version of the Deceased Donor Registration form (DDR) will be used beginning in the spring of 2015. The new lung DDR will include fields for left lung machine perfusion and right lung machine perfusion, with an option of selecting yes or no for each. The Thoracic Committee discussed these fields during its September 18, 2014 meeting and recommended a slight modification to the field description to attempt to capture whether the lungs were recovered with the intent to use machine perfusion.

The Thoracic Committee noted that even if EVLP utilization is captured on the DDR, there will be an information gap if the transplant program decides to use EVLP after accepting the lungs. Therefore, the Thoracic Committee may produce additional fields to include on the Transplant Recipient Registration form (TRR) to ensure that the OPTN is capable of capturing all instances of EVLP. Any recommended changes to the TRR will be circulated for public comment once developed.

For more information, see the Thoracic Committee meeting summary from September 18, 2014.

9. Clarify Status of Domino Donors

Public Comment: *January, 2015 (Estimated)*

Board Consideration: *June, 2015 (Estimated)*

The Living Donor Committee is drafting a policy proposal to clarify the living donor status of a domino donor. In the past, domino donor heart transplants have been performed, though none have occurred since 2006. Therefore, the Living Donor Committee sought early feedback from the Thoracic Committee regarding its proposal. The Thoracic Committee approved the concept and policy language proposed by the Living Donor Committee, with suggestions regarding the clarity and intent of the policy language.

For more information, see the **Living Donor Committee's Report to the Board**, and the Thoracic Committee meeting summary from September 18, 2014.

Committee Projects Pending Implementation

10. LAS Modification Implementation

Public Comment: [March 16 – June 25, 2012](#)

Board Approval: [November 12-13, 2012](#)

Projected Implementation: *February 2015 (Estimated)*

The Thoracic Committee and UNOS Staff continue to provide support and subject matter expertise as UNOS IT staff programs the modifications to the LAS. If the Board of Directors approves the proposed modifications to the policy language as set forth in **Exhibit A**, the project is on schedule to be implemented by the end of February 2015. UNOS Staff will provide content webinars and systems training, focusing on the policy changes and changes to UNetSM, respectively.

11. Pediatric Heart Allocation Modification

Public Comment: [March 15 – June 15, 2013](#)

Board Approval: June, 2014

Implementation Date: This project is not scheduled for implementation within the next 12 months.

The Pediatric Heart Allocation Modification changes to the qualifying criteria for the medical urgency statuses, expands the qualifying criteria for ABO-incompatible (ABO-i) heart transplantation, modifies the prioritization of candidates eligible for ABO-i heart transplants, and eliminates the ability to register an *in utero* heart candidate.

Implemented Committee Projects

12. Pediatric Lung Adolescent Classification Exception

Public Comment: [March 14 – June 13, 2014](#)

Board Approval: [June, 2014](#)

Implementation Date: July 1, 2014

The Thoracic Committee continues to monitor the number of pediatric lung candidates requesting an exception to be registered as an adolescent candidate for the purposes of offers from adolescent and adult deceased donors. As of September 8, 2014, 12 candidates received approval for the adolescent classification exception.

Review of Public Comment Proposals

The Committee has reviewed one of the 17 proposals released for public comment from September – December, 2014.

13. Define Pancreas Graft Failure

The Pancreas Committee presented its proposal to define pancreas graft failure to the Thoracic Committee on September 18. The Pancreas Committee sought feedback on whether a general definition of graft failure is appropriate for all organs, or whether there should be an organ-specific definition defined by each organ-specific committee. The Thoracic Committee determined that the general definition of graft failure is not entirely applicable to the thoracic organs as currently written in policy, and believes that each organ most likely requires a different definition of graft failure. The Thoracic Committee provided this feedback to the Pancreas Committee.

Other Committee Work

14. Regional Review Board Process Changes

The Committee has recently received a relatively large number of appeals of heart regional review board (RRB) decisions. Policy permits transplant programs to appeal Lung Review Board (LRB) and RRB decisions to the Thoracic Committee. This is impractical because the whole Committee cannot meet and respond in a timely manner. This in turn exposes the transplant programs to risk because they may transplant candidates at the requested status without the final answer, but if the result is ultimately a denial of their request the program may be referred to the Membership and Professional Standards Committee (MPSC).

To respond more quickly, the Thoracic Committee agreed that a smaller subcommittee should be formed to vote on these cases, as modeled after the Liver Committee's similar

review. The cases will be decided by majority vote. The members of the Subcommittee will be the chair and vice chair of the Thoracic Committee, the Lung Subcommittee Chair and the Heart Subcommittee Chair. The Committee also determined that it would be prudent to have an odd number of people on the Subcommittee to avoid ties. The “odd” member will be a cardiologist or heart transplant surgeon from the Committee if the case originates at an RRB, and will be a pulmonologist or lung transplant surgeon from the Committee if the case originates from the LRB. This person would be appointed by the Chair of the Thoracic Committee for a one year term.

On August 25, 2014, the Committee voted 18 support; 0 oppose; and 0 abstentions for the creation of this Subcommittee.

The Thoracic Committee [communicated the changes](#) to the transplant community on September 30, 2014.

15. Staged Lung Transplants

The Thoracic Committee discussed the policy implications of an abstract published in April, 2014 entitled, “Is a Priori Staging of Bilateral Lung Transplant the Optimal Surgical Approach for High-risk Patients with Interstitial Lung Disease?”¹ The abstract presents a surgical strategy to provide a double-lung transplant to patients with interstitial lung disease. Rather than performing a double-lung transplant, the candidate would receive a single lung transplant, and a few months later would receive a second, contralateral single lung transplant.

Policy 10.1.E *LAS Values and Clinical Data Update Schedule for Candidates at Least 12 Years Old*, requires transplant programs to update lung candidates’ LAS variables every 6 months. Upon initial registration, the candidate’s data can be up to 6 months old. Therefore, if a candidate undergoes a staged bilateral lung transplant, the candidate’s variables reported for their *second* registration could still be valid even if they were obtained prior to their *first* registration, as long as those variables are not more than 6 months older than the date of the candidate’s *second* registration. OPTN data reveal that there are instances in which transplant programs are reporting variables that pre-date the first transplant for the candidate’s second registration, even when the first graft is not reported to have failed.

After discussion, the Thoracic Committee determined it may be appropriate to prohibit the entry of LAS data that pre-dates a candidate’s previous lung transplant. However, the Committee was hesitant to recommend any policy changes without considering potential unintended consequences on candidates re-registered due to primary graft dysfunction or failure of the first transplant. The Thoracic Committee will also consult with the Ethics Committee regarding potential ethical implications of this surgical practice.

16. Primary Graft Dysfunction

The Membership and Professional Standards Committee (MPSC) sent the Thoracic Committee a letter inquiring whether additional data related to immediate graft dysfunction should be added to the Transplant Recipient Registration form (TRR) or Transplant Recipient Follow-Up form (TRF) for heart recipients. The MPSC specifically asked whether the OPTN should collect data to capture graft function immediately after implantation, and if so, which data elements are needed to define and assess graft dysfunction. Additionally, the MPSC asked whether programs should be required to report immediate graft dysfunction that may or may not result in graft failure. The goal of the data collection would be to

¹ Hartwig, M.G. “Is a Priori Staging of Bilateral Lung transplants the Optimal Surgical Approach for High-Risk Patients with Interstitial Lung Disease?” *Journal of Heart and Lung Transplantation* 33:4 (2014): S30-31. doi: <http://dx.doi.org/10.1016/j.healun.2014.01.111>

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determine whether there are factors that contribute to a potentially higher incidence of primary graft dysfunction (PGD) in transplant programs across the country.

The Thoracic Committee reviewed the current and future data collection fields on the TRR and TRF and determined that they are not adequate to capture PGD because the forms only capture failure or function, with no middle ground for dysfunction with mechanical support. Though the Committee determined that current data collection is inadequate to capture PGD, it did not agree upon a definition of PGD or additional fields that would help identify PGD.

For more information, see the Thoracic Committee meeting summary from September 18, 2014.

Meeting Summaries

The committee held meetings on the following dates:

- August 25, 2014
- September 18, 2014

Meetings summaries for this Committee are available on the OPTN website at: <http://optn.transplant.hrsa.gov/converge/members/committeesDetail.asp?ID=5>.

Guidance to Organ Procurement Organizations for Allocation of Heart-Lung Blocks

Summary and Goals

This document contains specific recommendations for use by Organ Procurement Organizations (OPOs) for allocating heart-lung blocks. The intent of these guidelines is to promote a consistent practice amongst the OPOs throughout the country. This is a continuation of previous efforts to clarify heart-lung allocation policy. This document summarizes the Thoracic Organ Transplantation Committee's recommendations to the OPTN/UNOS Board of Directors.

This resource is not an OPTN policy, so it does not carry the monitoring or enforcement implications of policy. It is not an official guideline for clinical practice, nor is it intended to be clinically prescriptive or to define a standard of care. This is a resource tool intended to provide guidance to OPOs and is for voluntary use by OPTN members.

Background

For several years, Policy 6.5.E. (Allocation of Heart-Lungs) has generated considerable discussion because of its ambiguity in directing OPOs in how to allocate heart-lung blocks. The Thoracic Organ Transplantation Committee (the Committee) agreed upon an interpretation of current policy:

- **Current policy:** "When a heart-lung candidate is allocated a heart, the lung from the same deceased donor must be allocated to the heart-lung candidate."
- **Clarification:** If the OPO generates the heart or heart-lung match run, the heart will be offered in order of the match. If a heart candidate is eligible to receive the heart offer, but also needs a lung, then that candidate shall be allocated the lung from the same donor.
- **Current policy:** "When the heart-lung candidate is allocated a lung, the heart from the same deceased donor may only be allocated to the heart-lung candidate if no suitable Status 1A isolated heart candidates are eligible to receive the heart."
- **Clarification:** If the OPO generates the lung match run, and the next eligible candidate for the lung offer also needs the heart, the candidate will receive the heart-lung block offer unless there is a Status 1A isolated heart candidate in the same geographic zone as the heart-lung candidate.

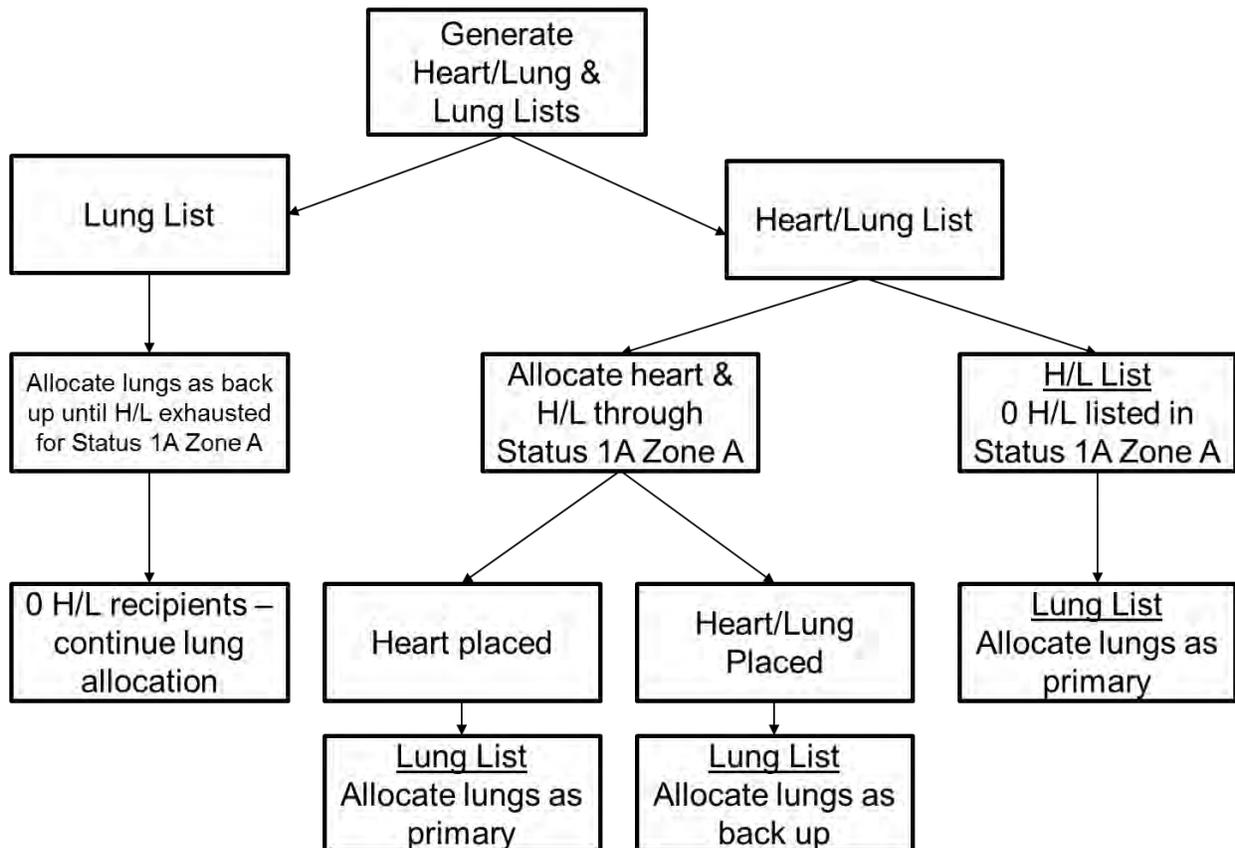
For the purposes of heart-lung allocation, an "isolated" heart candidate is a candidate that is only registered on the deceased donor waiting list for a heart, and is not waiting for a heart-lung block. The candidate may be waiting for another organ besides a lung.

After agreeing upon this interpretation, the Thoracic Committee asked the OPO Committee to determine how to best put the policy clarification into practice. Representatives from various OPOs presented the manner in which their OPO allocates heart-lung blocks and found that each OPO allocates heart-lung blocks differently. The Thoracic and OPO Committees ultimately agreed upon the following allocation process for OPOs upon recovery of a heart-lung block.

Instructions for Heart-Lung Block Allocation:

1. Generate both a combined heart-lung match run and a lung match run simultaneously
2. Using the combined heart-lung match run:
 - a. Within the donation service area (DSA), offer the heart to all status 1A heart candidates
 - i. If the status 1A heart candidate only needs a heart, the heart should be offered to that candidate
 1. The lung(s) will be offered from the lung match run
 - ii. If the status 1A heart candidate is also registered for a lung, the heart-lung block should be offered to that candidate
3. Using the lung-alone match run:
 - a. If there are no status 1A isolated heart candidates or heart-lung candidates, or if all status 1A isolated heart candidates and status 1A heart-lung candidates decline within the same DSA, then the lungs may be offered from the lung match run to isolated lung candidates and lung-heart candidates within the DSA
 - i. If the lungs are accepted within the DSA for an isolated lung candidate, the heart should then be allocated using the heart-lung match run
4. Repeat steps 2 and 3 for each successive geographic zone until the organs are allocated

The instructions above are depicted graphically below:



Title: Modifications to Approved Lung Allocation Policy

Name(s) of the Sponsoring Committee(s): Thoracic Organ Transplantation Committee

Summary and Goals of the Proposal:

The goal of this proposal is to request approval of modifications to previously-approved policy language regarding the Lung Allocation Score (LAS). In February 2015, UNOS will implement a modified LAS policy, based on Board-approved modifications from June 2009¹, October 2009,² November 2009³, November 2012⁴, May 2013⁵, and April 2014⁶. During the programming process, UNOS staff has identified areas in which the policy can be improved, clarified, or changed to ensure the LAS is calculated properly. The Thoracic Committee seeks approval from the Board of Directors on these issues prior to the February 2015 implementation of the LAS modification.

Background and Significance of the Proposal:

The LAS modification scheduled for implementation in February 2015 is an amalgamation of a number of Board-approved LAS policy language and programming modifications over the last few years. UNOS staff, working to implement these approved modifications, have identified instances in which the policy language either is unclear, thus leading to programming questions and calculation errors. The changes identified by UNOS staff, and recommended by the Thoracic Committee, fall into three categories:

1. Non-substantive clarifications
2. Substantive changes
3. Policy rewrite transition errors

The Committee reviewed the policy in depth and is confident that the recommend changes match the original intent of the policy, and are necessary to ensure a smooth implementation of the LAS modification.

Proposed Solution

Issue	Proposed Solution	Solution Type
The organization of Table 10-1: Values Substituted for Missing or Expired Actual Values in Calculating the LAS may lead to multiple interpretations.	Reorganize Table 10-1 by adding a column and changing the column titles	Non-substantive clarification

¹ June 22-23, 2009 Board of Directors Meeting Policy Notice:

<http://optn.transplant.hrsa.gov/SharedContentDocuments/2009JulyPolicyNotice.pdf>

² October 23, 2009 Executive Committee Meeting Policy Notice:

http://optn.transplant.hrsa.gov/SharedContentDocuments/091023_Exec_Comm_Policy_Notice.pdf

³ November 16-17, 2009 Board of Directors Meeting Executive Summary:

http://optn.transplant.hrsa.gov/converge/SharedContentDocuments/Executive_Summary1109.pdf

⁴ November 12, 2012 Board of Directors Meeting Policy Notice: http://optn.transplant.hrsa.gov/ContentDocuments/2012-12_Policy_Notice.pdf

⁵ May 1, 2013 Executive Committee Meeting Policy Notice: http://optn.transplant.hrsa.gov/ContentDocuments/Policy_Notice_05-2013.pdf

⁶ April 9, 2014 Executive Committee Meeting Policy Notice: http://optn.transplant.hrsa.gov/ContentDocuments/Policy_Notice_04-10-2014.pdf

Issue	Proposed Solution	Solution Type
When the value “continuous mechanical ventilation” (CMV) is programmed, transplant programs will have the option of selecting CMV “while hospitalized” or CMV without a qualifier. The default value will only apply if the candidate is hospitalized, but the description in Table 10-1 does not explicitly explain this.	Add “while hospitalized” to the description of CMV in the substituted value column of Table 10-1.	Non-substantive clarification
The coefficient for oxygen needed to maintain minimum oxygen saturation at rest, in both Table 10-3: Waiting List Mortality Calculation: Covariates and their Coefficients, and Table 10-4: Post-Transplant Survival Calculation: Covariates and Their Coefficients, is missing the multiplier that is necessary to make the calculation operable.	Add “*O ₂ ” to this covariate in Tables 10-3 and 10-4.	Substantive change
The description of the coefficient for creatinine increase of at least 150% in Table 10-4: Post-Transplant Survival Calculation: Covariates and Their Coefficients is misleading as written.	Remove “or creatinine decreases” from the description of the coefficient for creatinine increase of less than 150%.	Non-substantive clarification
The description of the coefficient for functional status in Table 10-4: Post-Transplant Survival Calculation: Covariates and Their Coefficients uses incorrect phrasing for “activities of daily living.”	Change “or” to “of” for the phrase “activities of daily living.”	Policy rewrite transition error
The coefficient for six-minute-walk-distance in Table 10-4: Post-Transplant Survival Calculation: Covariates and Their Coefficients is not clear because it is not spelled out.	Change “6mw” to “six-minute-walk-distance” for clarity.	Non-substantive clarification
The diagnosis for BAC is misspelled in Diagnosis Group D	Change the spelling to bronchioloalveolar carcinoma (BAC)	Non-substantive clarification
The diagnosis Pulmonary lymphangiectasia (PL) is missing from the lists of diagnoses in Diagnosis Group D. It was added as a result of the “other diagnosis” project approved in November 2009.	Add Pulmonary lymphangiectasia (PL) to the list of Group D diagnoses.	Non-substantive clarification

Issue	Proposed Solution	Solution Type
<p>During the plain language rewrite, the term for the threshold change calculation was replaced with “increase in...” for PCO₂, bilirubin and creatinine. Describing the calculation as a threshold change is more accurate than describing it as an “increase,” because the values for PCO₂, creatinine and bilirubin could increase but the calculation would still not apply unless the threshold was met.</p>	<p>Change the title of the calculation back to “threshold change.”</p>	<p>Policy rewrite transition error</p>
<p>The definition of Current PCO₂ is missing the time component. Current PCO₂ was programmed in 2010, and uses most recent date only; if there are multiple tests from the same date, it will choose an arterial test over a venous or capillary test. Current bilirubin and current serum creatinine, on the other hand, use the value with the most recent date and time.</p>	<p>Add “and time” to the definition of current PCO₂ so that it is consistent with the definitions for current bilirubin and current serum creatinine, and delete the section of policy that indicates arterial values should be chosen over other test types if the dates are the same.</p>	<p>Substantive change</p>
<p>The description of Current Bilirubin, which states that a current bilirubin value of at least 1.0 mg/dL will impact a candidate’s LAS, is mathematically incorrect. The current bilirubin value must be greater than 1.0 mg/dL to impact the LAS.</p>	<p>Change the description from “at least 1.0 mg/dL” to “greater than 1.0 mg/dL.”</p>	<p>Substantive change</p>

Issue	Proposed Solution	Solution Type
<p>For both serum creatinine and bilirubin, the least beneficial values provided in Table 10-1: Values Substituted for Missing or Expired Actual Values in Calculating are both less than 1. However, in the threshold change calculation for both bilirubin and serum creatinine, the high value must be at least 1. Threshold change maintenance is awarded if the high value for serum creatinine is 150% greater than low value used in the threshold change calculation (and 50% greater than the low value used in the threshold change calculation for bilirubin). If 0.1 is the low value used in the threshold change calculation for serum creatinine, the high value used in the threshold change could be 150% higher than 0.1 but still not be 1 – which is the requirement for the threshold change calculation. The same holds true for bilirubin; if 0.7 is the low value used in the threshold change calculation, the high value used in the threshold change could be 50% higher than 0.7 but still not be 1.</p>	<p>In the description of the threshold change maintenance calculation in both the bilirubin and serum creatinine sections, modify the description to require the current bilirubin and current serum creatinine values to be at least 1.0 mg/dL, in addition to meeting the respective percentage increase to maintain the impact of the threshold change calculation.</p>	<p>Substantive change</p>
<p>The section title for 10.2.B.iv: LAS Values and Diagnoses Approved by the LRB is misleading, because the section only discusses diagnoses approved by the LRB.</p>	<p>Remove “Values and” from the section title.</p>	<p>Policy rewrite transition error</p>
<p>Policy 10.3: Waiting Time does not correctly describe the waiting time policies for lung candidates less than 12 years old. These candidates do accrue waiting time while inactive.</p>	<p>Add the waiting time accrual policy for candidates less than 12 years old in this section.</p>	<p>Policy rewrite transition error</p>
<p>The values in the Table 10-8: Baseline Waiting List Survival (SWL(t)) Probability and Table 10-9: Baseline Post-Transplant Survival (STX(t)) Probability are only rounded to the sixth digit. The LAS calculation uses these values to the tenth digit.</p>	<p>Include the values to the tenth digit in Tables 10-8 and 10-9.</p>	<p>Non-substantive clarification</p>

Additional Data Collection:

This proposal does not require additional data collection beyond what is already described in previous policy notices.

Expected Implementation Plan:

UNOS staff recommends implementing these policy modifications concurrently with the LAS modification effort, which is currently underway and scheduled to be released in February 2015.

Communication Activities			
Type of Communication	Audience(s)	Deliver Method(s)	Timeframe
UNet SM System Notice upon implementation of the LAS Modification	All UNet SM users	Email notification, UNet SM notice	30 days before implementation and again upon implementation
Article on OPTN, UNOS and Transplant Pro	Members	Website article	Upon implementation

Compliance Monitoring:

During on-site surveys, the Department of Evaluation and Quality (DEQ) staff reviews and verifies the clinical covariates entered into UNetSM and utilized to calculate the LAS with the actual medical record documentation. Staff also verifies all information submitted to the Lung Review Board with the actual medical record documentation.

DEQ staff will also investigate any reports of noncompliance.

Policy or Bylaw Proposal:

RESOLVED, that additions and modifications to Policies 10.1.C: Priority and Clinical Data Update Schedule for Candidates less than 12 Years Old; 10.1.E: LAS Values and Clinical Data Update Schedule for Candidates at Least 12 Years Old; 10.1.F: The LAS Calculation; 10.1.F.i: Lung Disease Diagnosis Groups; 10.1.F.ii: PCO2 in the LAS; 10.1.F.iii: Bilirubin in the LAS; 10.1.F.iv: Creatinine in the LAS; 10.2.B.iv: LAS Values and Diagnoses Approved by the LRB; 10.3 Waiting Time; and 10.5: Probability Data Used in the LAS Calculation, as set forth below, are hereby approved, effective pending programming and notice to OPTN membership.

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

10.1.C Priority and Clinical Data Update Schedule for Candidates Less than 12 Years Old

A transplant program may update the reported clinical data to justify a candidate's priority at any time. When a candidate meets the requirements for priority 1 the candidate will remain at priority 1 for six months from the date first registered as priority 1 on the lung transplant waiting list.

To remain as priority 1, the transplant program must then update the required clinical data, except data that requires a heart catheterization, every six months following the first six months as a priority 1 candidate. The updates must occur in each six month period following the initial six

months at priority 1 to remain at priority 1. The transplant program may determine the frequency of performing the heart catheterization.

If the data used to justify the priority 1 criteria are more than 6 months old at the 6-month anniversary date, other than data requiring a heart catheterization, the candidate will automatically be assigned priority 2.

Lung candidates registered on the waiting list at inactive status are subject to these same requirements for updating clinical data.

10.1.E LAS Values and Clinical Data Update Schedule for Candidates at Least 12 Years Old

When registering a candidate who is at least 12 years old for a lung transplant, or when registering a candidate with an approved adolescent classification exception according to *Policy 10.2.B: Lung Candidates with Exceptional Cases*, transplant programs must report to the OPTN Contractor clinical data corresponding with the covariates shown in *Table 10-3: Waiting List Mortality Calculation: Covariates and Their Coefficients* and *Table 10-4: Post-Transplant Survival Calculation, Covariates, and Their Coefficients*.

The data reported at the time of the candidate's registration on the lung transplant waiting list must be six months old or less from the date of the candidate's registration date. The transplant program must maintain source documentation for all laboratory values reported in the candidate's medical chart.

Except as noted in *Policy 10.1.G: Reporting Additional Data for Candidates with an LAS of 50 or Higher*, transplant programs must report to the OPTN Contractor LAS covariate clinical data for every covariate in *Table 10-3* and *Table 10-4* for each candidate at least once in every six month period after the date of the candidate's initial registration or the LRB's approval of an adolescent classification exception. The first six-month period begins six months from the date of the candidate's initial registration, or, in the case of adolescent classification exceptions, six months from the date of LRB approval, with a new six-month period occurring every six months thereafter.

A covariate's value expires if the covariate's test date is six-months older than the most recent six-month anniversary date. The LAS system considers actual values and approved estimated values for pulmonary pressures to be valid until the transplant program updates them with new actual values or new approved estimated values as described in *Policy 10.2.B.iii: Estimated Values Approved by the LRB*.

Transplant programs may report a medically reasonable estimated value if a test needed to obtain an actual value for a variable covariate cannot be performed due to the candidate's medical condition. Before entering estimated values, programs must receive approval from the LRB, which will determine whether the estimated values are appropriate according to *Policy 10.2.B.iii: Estimated Values Approved by the LRB*. Approved estimated values remain valid until an updated actual value is reported for the covariate, or until the transplant program reports a new, approved estimated value is reported.

LAS covariate data obtained by heart catheterization does not need to be reported to the OPTN Contractor every six months. For LAS covariate data that requires a heart catheterization, the transplant program may determine the frequency of updating the data. However, if a transplant program performs a heart catheterization test on the candidate during the six month interval, then it must report the data to the OPTN Contractor.

If values for certain covariates are missing, expired, or below the threshold as defined by *Table 10-1*, then the LAS calculation will substitute normal or least beneficial values to calculate the

candidate's LAS. A normal value is one that a healthy individual is likely to exhibit. A least beneficial value is one that will calculate the lowest LAS for a candidate. *Table 10-1* lists the normal and least beneficial values that will be substituted.

Table 10-1: Values Substituted for Missing or Expired Actual Values in Calculating the LAS

If this covariate's value is missing, expired, or below the threshold value:	<u>Is</u>	Then the LAS calculation will use this substituted value:
Bilirubin	<u>Missing, expired, or less than 0.7 mg/dL</u>	0.7 mg/dL if the actual value is missing, expired, or less than 0.7 mg/dL
Body mass index (BMI)	<u>Missing or expired</u>	100 kg/m ² if the actual value is missing or expired
Cardiac index	<u>Missing</u>	3.0 L/min/m ² if the actual value is missing
Central venous pressure (CVP)	<u>Missing or less than 5 mm Hg</u>	5 mm Hg if the actual value is missing or less than 5 mm Hg
Continuous mechanical ventilation	<u>Missing or expired</u>	No mechanical ventilation in the waiting list model if the actual value is missing or expired Continuous mechanical ventilation <u>while hospitalized</u> in the post-transplant survival measure if the actual value is missing or expired
Creatinine: serum	<u>Missing or expired</u>	0.1 mg/dL in the waiting list model if the actual value is missing or expired 40 mg/dL in the post-transplant survival measure for candidates at least 18 years old if the actual value is missing or expired 0 mg/dL in the post-transplant survival measure for candidates less than 18 years old if the actual value is missing or expired
Diabetes	<u>Missing or expired</u>	No diabetes if the actual value is missing or expired
Forced vital capacity (FVC)	<u>Missing or expired</u>	150% for Diagnosis Group D if the actual value is missing or expired, according to Policy 10.1.F.i: Lung Disease Diagnosis Groups

If this covariate's value is missing, expired, or below the threshold value:	Is	Then the LAS calculation will use this substituted value:
Functional status	<u>Missing or expired</u>	No assistance needed in the waiting list model-if the actual value is missing or expired Some or total assistance needed in the post-transplant survival measure-if the actual value is missing or expired
Oxygen needed at rest	<u>Missing or expired</u>	No supplemental oxygen needed in the waiting list model-if the actual value is missing or expired 26.33 L/min in the post-transplant survival measure if the actual value is missing or expired
PCO ₂	<u>Missing, expired, or less than 40 mm Hg</u>	40 mm Hg if the actual value is missing, expired, or if less than 40 mm Hg
Pulmonary artery (PA) systolic pressure	<u>Missing or less than 20 mm Hg</u>	20 mm Hg if the actual value is missing or less than 20 mm Hg
Six-minute-walk distance	<u>Missing or expired</u>	4,000 feet in the waiting list urgency measure-if the actual value is missing or expired 0 feet in the post-transplant survival measure if the actual value is missing or expired

10.1.F. The LAS Calculation

The LAS calculation uses *all* of the following measures:

- Waiting List Urgency Measure, which is the expected number of days a candidate will live without a transplant during an additional year on the waiting list.
- Post-transplant Survival Measure, which is the expected number of days a candidate will live during the first year post-transplant.
- Transplant Benefit Measure, which is the difference between the Post-transplant Survival Measure and the Waiting List Urgency Measure.
- Raw Allocation Score, which is the difference between Transplant Benefit Measure and Waiting List Urgency Measure.

To determine a candidate's LAS, the Raw Allocation Score is normalized to a continuous scale of zero to 100.

The equation for the LAS calculation is:

$$LAS = \frac{100 * [PTAUC - 2 * WLAUC + 730]}{1095}$$

Table 10-2: LAS Calculation Values

Where...	Includes...
$PTAUC = \sum_{k=0}^{364} S_{TX}(k)$	<p>PTAUC = the area under the post-transplant survival probability curve during the first post-transplant year.</p> <p>β_i = the coefficient for characteristic i from the waiting list measure, according to <i>Table 10-3: Waiting List Mortality Calculation: Covariates and their Coefficients</i>.</p>
$S_{TX}(t) = S_{TX,0}(t) e^{\alpha_1 Y_1 + \alpha_2 Y_2 + \dots + \alpha_q Y_q}$	<p>$S_{TX}(t)$ = the expected post-transplant survival probability at time t for an individual candidate.</p> <p>Y_i = the value of the j^{th} characteristic for an individual candidate</p> <p>α_j = the coefficient for characteristic j from the post-transplant survival measure, according to <i>Table 10-4: Post-Transplant Survival Calculation, Covariates, and Their Coefficients</i>.</p>
$WLAUC = \sum_{k=0}^{364} S_{WL}(k)$	<p>WLAUC = the area under the waiting list survival probability curve during the next year.</p>
$S_{WL}(t) = S_{WL,0}(t) e^{\beta_1 X_1 + \beta_2 X_2 + \dots + \beta_p X_p}$	<p>$S_{WL,0}(t)$ = the baseline waiting list survival probability at time t, according to <i>Table 10-5: Baseline Waiting List Survival (SWL(t)) Probability</i>.</p> <p>$S_{TX,0}(t)$ = the baseline post-transplant survival probability at time t, according to <i>Table 10-6: Baseline Post-Transplant Survival (S_{TX}(t)) Probability</i>.</p> <p>$S_{WL}(t)$ = the expected waiting list survival probability at time t for an individual candidate</p> <p>X_i = the value of the i^{th} characteristic for an individual candidate.</p>

Table 10-3 provides the covariates and their coefficients for the waiting list mortality calculation. See Policy 10.1.F.i: Lung Disease Diagnosis Groups for specific information on each diagnosis group.

Table 10-3: Waiting List Mortality Calculation: Covariates and their Coefficients

For this covariate:	The following coefficient is used in the LAS calculation:
1. Age (year)	$0.0083990318885565 * \text{age}$
2. Bilirubin (mg/dL)	$0.0431682188302477 * (\text{bilirubin} - 1)$ if bilirubin is more than 1.0 mg/dL 0 when bilirubin is 1.0 mg/dL or less
3. Bilirubin increase of at least 50%	1.4144058906830200 for Diagnosis Group B 0 for Diagnosis Groups A, C, and D
4. Body mass index (BMI) (kg/m^2)	$0.1261444133358100 * (20 - \text{BMI})$ for BMI less than $20 \text{ kg}/\text{m}^2$ 0 if BMI is at least $20 \text{ kg}/\text{m}^2$
5. Cardiac index prior to any exercise	0.5435368888028200 if the cardiac index is less than $2 \text{ L}/\text{min}/\text{m}^2$ 0 if the cardiac index is at least $2 \text{ L}/\text{min}/\text{m}^2$
6. Central venous pressure (CVP) (mm Hg) at rest, prior to any exercise	$0.0173841981251578 * (\text{CVP} - 7)$ for CVP greater than 7 mm Hg (Diagnosis Group B only) 0 if less than or equal to 7 mm Hg for Diagnosis Group B 0 for candidates in Diagnosis Groups A, C, and D
7. Ventilation status if candidate is hospitalized	1.6771121096052300 if continuous mechanical ventilation needed 0 if no continuous mechanical ventilation needed
8. Creatinine (serum) (mg/dL)	$0.5034346761960600 * \text{creatinine}$ if candidate is at least 18 years old 0 if candidate is less than 18 years old
9. Diabetes	0.4680254026735700 if diabetic 0 if not diabetic
10. Diagnosis Group A	0
11. Diagnosis Group B	1.5774243292137200
12. Diagnosis Group C	1.2313926484343600
13. Diagnosis Group D	0.6259577164157700
14. Detailed diagnosis: Bronchiectasis (Diagnosis Group A only)	0.6680518055684700
15. Detailed diagnosis: Eisenmenger's syndrome (Diagnosis Group B only)	-0.6278657824830000

For this covariate:	The following coefficient is used in the LAS calculation:
16. Detailed diagnosis: Lymphangiomyomatosis (Diagnosis Group A only)	-0.3162937838984600
17. Detailed Diagnosis: Obliterative bronchiolitis (not-retransplant) (Diagnosis Group D only)	0.4453284411081100
18. Detailed Diagnosis: Pulmonary fibrosis, not idiopathic (Diagnosis Group D only)	-0.2091170018125500
19. Detailed Diagnosis: Sarcoidosis with PA mean pressure greater than 30 mm Hg (Diagnosis Group D only)	-0.4577749354638600
20. Detailed Diagnosis: Sarcoidosis with PA mean pressure of 30 mm Hg or less (Diagnosis Group A only)	0.9330846239906700
21. Forced vital capacity (FVC)	<p>0.1829476350587400*(80 – FVC)/10 if FVC is less than 80% for Diagnosis Group D</p> <p>0 if FVC is greater than or equal to 80% for Diagnosis Group D</p> <p>0 for candidates in Diagnosis Groups A, B, and C</p>
22. Functional Status	<p>-0.4471034284458400 if no assistance needed with activities of daily living</p> <p>0 if some or total assistance needed with activities of daily living</p>
23. Oxygen needed to maintain adequate oxygen saturation (88% or greater) at rest (L/min)	<p>0.0213187586203456*O₂ for Diagnosis Group B</p> <p>0.1188479817592500*O₂ for Diagnosis Groups A, C, and D</p>
24. PCO ₂ (mm Hg): current	0.1104609835819100*PCO ₂ /10 if PCO ₂ is at least 40 mm Hg
25. PCO ₂ increase of at least 15%	<p>0.2331149280428300 if PCO₂ increase is at least 15%</p> <p>0 if PCO₂ increase is less than 15%</p>
26. Pulmonary artery (PA) systolic pressure (10 mm Hg) at rest, prior to any exercise	<p>0.4155116686114300*(PA systolic – 40)/10 for Diagnosis Group A if the PA systolic pressure is greater than 40 mm Hg</p> <p>0 for Diagnosis Group A if the PA systolic pressure is 40 mm Hg or less</p> <p>0.0462410402627318*PA systolic/10 for Diagnosis Groups B, C, and D</p>

For this covariate:	The following coefficient is used in the LAS calculation:
27. Six-minute-walk distance (feet) obtained while the candidate is receiving supplemental oxygen required to maintain an oxygen saturation of 88% or greater at rest. Increase in supplemental oxygen during this test is at the discretion of the center performing the test.	-0.0844896372724000*Six-minute-walk distance/100

Table 10-4 lists the covariates and corresponding coefficients in the waiting list and post-transplant survival measures. See Policy 10.1.F.i: Lung Disease Diagnosis Groups for specific information on each diagnosis group.

Table10-4: Post-Transplant Survival Calculation: Covariates and Their Coefficients

For this variable:	The following is used in the LAS calculation:
1. Age (years)	0.0246579831271869*(age-45) if candidate is greater than 45 years old 0 if candidate is 45 years old or younger
2. Creatinine (serum) at transplant (mg/dL)	0.0895569900508900*creatinine if candidate is at least 18 years old 0 if candidate is less than 18 years old
3. Creatinine increase of at least 150%	0.7708616024698100 if increase in creatinine is at least 150%, and when the higher value determining this increase is at least 1 mg/dL 0 if increase in creatinine of 150% if the higher value determining this increase is less than 1 mg/dL 0 if increase in creatinine less than 150% or creatinine decreases
4. Cardiac index (L/min/m ²) at rest, prior to any exercise	0.3499381679822400 if less than 2 L/min/m ² 0 if at least 2 L/min/m ²
5. Ventilation status if candidate is hospitalized	0.6094478988424900 if continuous mechanical ventilation needed 0 if no continuous mechanical ventilation needed
6. Diagnosis Group A	0
7. Diagnosis Group B	0.6115547319209300
8. Diagnosis Group C	0.3627014422464200
9. Diagnosis Group D	0.4641392063023200

For this variable:	The following is used in the LAS calculation:
10. Detailed diagnosis: Bronchiectasis (Diagnosis Group A only)	0.1889100379099400
11. Detailed diagnosis: Eisenmenger's syndrome (Diagnosis Group B only)	0.9146727886744700
12. Detailed diagnosis: Lymphangiomyomatosis (Diagnosis Group A only)	-1.5194416206749400
13. Detailed diagnosis: Obliterative bronchiolitis (not-retransplant, Diagnosis Group D only)	-1.2050508750702600
14. Detailed diagnosis: Pulmonary fibrosis, not idiopathic (Diagnosis Group D only)	-0.0723596761367600
15. Detailed diagnosis: Sarcoidosis with PA mean pressure greater than 30 mm Hg (Diagnosis Group D only)	-0.0437880049066331
16. Detailed diagnosis: Sarcoidosis with PA mean pressure of 30 mm Hg or less (Diagnosis Group A only)	-0.1389363636019300
17. Oxygen needed to maintain adequate oxygen saturation (88% or greater) at rest (L/min)	0.0747978926517300*O ₂ for Diagnosis Group A 0.0164276945879309*O ₂ for Diagnosis Groups B, C, and D
18. Functional Status	-0.1900086366785100 if no assistance needed with activities of daily living 0 if some or total assistance needed with activities of daily living
19. Six-minute-walk-distance (feet) obtained while candidate is receiving supplemental oxygen required to maintain an oxygen saturation of 88% or greater at rest. Increase in supplemental oxygen during this test is at the discretion of the center performing the test.	0.0004594953809594*(1200-Six-minute-walk distance 6mw) 0 if six-minute-distance-walked is at least 1,200 feet

See Policy 10.5: Probability Data Used in the LAS Calculation for Tables 10-8 and 10-9 that provide data used in the LAS calculation.

10.1.F.i Lung Disease Diagnosis Groups

The LAS calculation uses diagnosis Groups A, B, C, and D as listed below.

Group A

A candidate is in Group A if the candidate has any of the following diagnoses:

- Allergic bronchopulmonary aspergillosis
- Alpha-1 antitrypsin deficiency

- Bronchiectasis
- Bronchopulmonary dysplasia
- Chronic obstructive pulmonary disease/emphysema
- Ehlers-Danlos syndrome
- Granulomatous lung disease
- Inhalation burns/trauma
- Kartagener's syndrome
- Lymphangiomyomatosis
- Obstructive lung disease
- Primary ciliary dyskinesia;
- Sarcoidosis with mean pulmonary artery pressure of 30 mm Hg or less
- Tuberous sclerosis
- Wegener's granuloma – bronchiectasis

Group B

A candidate is in Group B if the candidate has any of the following diagnoses:

- Congenital malformation
- CREST – pulmonary hypertension
- Eisenmenger's syndrome: atrial septal defect (ASD)
- Eisenmenger's syndrome: multi-congenital anomalies
- Eisenmenger's syndrome: other specify
- Eisenmenger's syndrome: patent ductus arteriosus (PDA)
- Eisenmenger's syndrome: ventricular septal defect (VSD)
- Portopulmonary hypertension
- Primary pulmonary hypertension/pulmonary arterial hypertension
- Pulmonary capillary hemangiomatosis
- Pulmonary telangiectasia – pulmonary hypertension
- Pulmonary thromboembolic disease
- Pulmonary vascular disease
- Pulmonary veno-occlusive disease
- Pulmonic stenosis
- Right hypoplastic lung
- Scleroderma – pulmonary hypertension
- Secondary pulmonary hypertension
- Thromboembolic pulmonary hypertension

Group C

A candidate is in Group C if the candidate has *any* of the following diagnoses:

- Common variable immune deficiency
- Cystic fibrosis
- Fibrocavitary lung disease
- Hypogammaglobulinemia
- Schwachman-Diamond syndrome

Group D

A candidate is in Group D if the candidate has *any* of the following diagnoses:

- ABCA3 transporter mutation

- Alveolar proteinosis
- Amyloidosis
- Acute respiratory distress syndrome or pneumonia
- Bronchioloalveolar carcinoma (BAC)
- Carcinoid tumorlets
- Chronic pneumonitis of infancy
- Constrictive bronchiolitis
- CREST – Restrictive
- Eosinophilic granuloma
- Fibrosing Mediastinitis
- Graft versus host disease (GVHD)
- Hermansky Pudlak syndrome
- Hypersensitivity pneumonitis
- Idiopathic interstitial pneumonia, with at least one or more of the following disease entities:
 - Acute interstitial pneumonia
 - Cryptogenic organizing pneumonia/Bronchiolitis obliterans with organizing pneumonia (BOOP)
 - Desquamative interstitial pneumonia
 - Idiopathic pulmonary fibrosis (IPF)
 - Nonspecific interstitial pneumonia
 - Lymphocytic interstitial pneumonia (LIP)
 - Respiratory bronchiolitis-associated interstitial lung disease
- Idiopathic pulmonary hemosiderosis
- Lung retransplant or graft failure: acute rejection
- Lung retransplant or graft failure: non-specific
- Lung retransplant or graft failure: obliterative bronchiolitis-obstructive
- Lung retransplant or graft failure: obliterative bronchiolitis-restrictive
- Lung retransplant or graft failure: obstructive
- Lung retransplant or graft failure: other specify
- Lung retransplant or graft failure: primary graft failure
- Lung retransplant or graft failure: restrictive
- Lupus
- Mixed connective tissue disease
- Obliterative bronchiolitis: non-retransplant
- Occupational lung disease: other specify
- Paraneoplastic pemphigus associated Castleman's disease
- Polymyositis
- Pulmonary fibrosis: other specify cause
- Pulmonary hyalinizing granuloma
- Pulmonary lymphangiectasia (PL)
- Pulmonary telangiectasia – restrictive
- Rheumatoid disease
- Sarcoidosis with mean pulmonary artery pressure higher than 30 mm Hg
- Scleroderma – restrictive
- Secondary pulmonary fibrosis: (specify cause)
- Silicosis
- Sjogren's syndrome
- Surfactant protein B mutation
- Surfactant protein C mutation

- Teratoma
- Wegener's granuloma – restrictive

10.1.F.ii PCO₂ in the LAS

The LAS calculation uses two measures of PCO₂:

1. Current PCO₂
2. Increase in PCO₂ Threshold Change

Current PCO₂

Current PCO₂ is the PCO₂ value reported to the OPTN Contractor with the most recent test date and time. A program may report a PCO₂ value from an arterial, venous, or capillary blood gas test. All blood gas values will be converted to an arterial value as follows:

- A capillary value will equal an arterial value.
- A venous value minus 6 mmHg equals an arterial value.

The LAS calculation uses the PCO₂ value with the most recent test date. If an arterial value and either a venous value, or an arterial value and a capillary value, have the same test date, the LAS calculation will use the arterial value.

Increase in PCO₂ Threshold Change Calculations

There are two increase in PCO₂ threshold change calculations:

- The Increase in PCO₂ Threshold Change Calculation
- The Threshold Change Maintenance Calculation

The Increase in PCO₂ Threshold Change Calculation

An increase in PCO₂ that is at least 15% will impact a candidate's LAS. If a value is less than 40 mmHg, the system will substitute the normal clinical value of 40 mmHg before calculating change. The increase in PCO₂ threshold change calculation uses the highest and lowest values of PCO₂ as follows:

- The test date and time of the lowest value reported to the OPTN Contractor used in the PCO₂ threshold change calculation must be earlier than the test date and time of the highest value used in the PCO₂ threshold change calculation.
- Test dates of these highest and lowest values cannot be more than six months apart.
- The increase in PCO₂ threshold change calculation will can use an expired lowest value, but cannot use an expired highest value.

If a current PCO₂ value expires according to *Policy 10.1.E: LAS Values and Clinical Data Update Schedule for Candidates at Least 12 Years Old*, the candidate's LAS will lose the impact from the increase in PCO₂ threshold change calculation. The equation for the increase in PCO₂ threshold change calculation is:

$$\frac{\text{Highest PCO}_2 - \text{Lowest PCO}_2}{\text{Lowest PCO}_2}$$

The Threshold Change Maintenance Calculation

When a 15% or greater increase in PCO₂ threshold change calculation impacts a candidate's LAS, the LAS threshold change maintenance calculation assesses

whether to maintain that impact. To maintain the impact of the PCO₂ increase, the candidate's current PCO₂ value must be at least 15% higher than the lowest value used in the increase-in-PCO₂ threshold change calculation. The equation for this threshold change maintenance calculation is:

$$\frac{\text{Current PCO}_2 - \text{Lowest PCO}_2}{\text{Lowest PCO}_2}$$

The threshold change maintenance calculation occurs either when the current PCO₂ value expires, according to *Policy 10.1.E: LAS Values and Clinical Data Update Schedule for Candidates at Least 12 Years Old*, or a new current PCO₂ value is entered reported to the OPTN Contractor. For this calculation, the lowest and highest values that were used in the increase-in-PCO₂ threshold change calculation can be expired. The current PCO₂ value can be the highest one that was used in the increase-in-PCO₂ threshold change calculation. If a current PCO₂ value expires, the candidate's LAS will no longer be affected by the increase-in-PCO₂ threshold change.

If a transplant hospital reports a new current PCO₂ value for a candidate who has lost the impact from the increase-in-PCO₂ threshold change calculation, the LAS will perform the threshold change maintenance calculation. If the new current PCO₂ value is at least 15% higher than the lowest value used in the increase-in-PCO₂ threshold change calculation, the candidate's LAS will again be affected by the increase-in-PCO₂ threshold change calculation.

Normal PCO₂ Value

The normal clinical PCO₂ value is 40mmHg. If a current PCO₂ value is below 40 mmHg, or if the current PCO₂ value is missing or expired, the LAS calculation will use the normal clinical PCO₂ value.

10.1.F.iii Bilirubin in the ~~Lung Allocation Score~~ LAS

The LAS calculation uses two measures of total bilirubin:

- Current bilirubin (for all candidates)
- ~~Increase-in-b~~ Bilirubin Threshold Change (for diagnosis Group B only)

Current Bilirubin

Current bilirubin is the total bilirubin value with the most recent test date and time reported to the OPTN Contractor. A current bilirubin value greater than ~~of at least~~ 1.0 mg/dL will impact candidate's LAS.

~~Increase-in~~ Bilirubin Threshold Change (Diagnosis Group B Only)

There are two ~~increase-in~~ Bilirubin threshold change calculations:

- ~~Increase-in-Bilirubin~~ Threshold Change Calculation
- Threshold Change Maintenance Calculation

~~Increase-in-Bilirubin~~ Threshold Change Calculation

For candidates in diagnosis Group B, an ~~increase-in-bilirubin~~ that is at least 50% impacts the candidate's LAS. The ~~increase-in-bilirubin~~ threshold change calculation uses the highest and lowest values of bilirubin as follows:-

- The test date and time of the lowest bilirubin value reported to the OPTN Contractor used in the ~~increase-in-bilirubin~~ threshold change calculation must

be earlier than the test date and time of the highest bilirubin value reported used in the bilirubin threshold change calculation.

- The highest value must be at least 1.0 mg/dL.
- Test dates of these highest and lowest values cannot be more than six 6 months apart.
- The ~~increase-in-bilirubin~~ threshold calculation ~~can~~ will use an expired lowest value, but cannot use an expired highest value.
- If a value is less than 0.7 mg/dL, the ~~increase-in-bilirubin~~ threshold change calculation will use the normal clinical value of 0.7 mg/dL.

The equation for this ~~increase-in-bilirubin~~ threshold change calculation is:

$$\frac{\text{Highest Bilirubin} - \text{Lowest Bilirubin}}{\text{Lowest Bilirubin}}$$

Threshold Change Maintenance Calculation

When a 50% or greater increase in bilirubin impacts a candidate's LAS, the LAS threshold change maintenance calculation assesses whether to maintain that impact. To maintain the impact of the bilirubin increase, the candidate's current bilirubin value must be at least 1.0 mg/dL and at least 50% higher than the lowest value used in the ~~increase-in-bilirubin~~ threshold change calculation. The equation for the threshold change maintenance calculation is:

$$\frac{\text{Current Bilirubin} - \text{Lowest Bilirubin}}{\text{Lowest Bilirubin}}$$

The ~~increase-~~ threshold change maintenance calculation occurs either when the current bilirubin value expires, according to *Policy 10.1.E: LAS Values and Clinical Data Update Schedule for Candidates at Least 12 Years Old*, or a new current bilirubin value is entered. For this calculation, the lowest and highest values that were used in the ~~increase-in-bilirubin~~ threshold change calculation can be expired. The current bilirubin value can be the highest one that was used in the ~~increase-in-bilirubin~~ threshold change calculation. If a current bilirubin value expires, the candidate's LAS will no longer be affected by the ~~increase-in~~ bilirubin threshold change.

If a transplant hospital reports a new current bilirubin value for a candidate who has lost the impact from the ~~increase-in-bilirubin~~ threshold change calculation, the LAS will perform the threshold change maintenance calculation. If the new current bilirubin value is at least 50% higher than the lowest value used in the ~~increase-in-bilirubin~~ threshold change calculation, the candidate's LAS will again be affected by the ~~increase-in-bilirubin~~ threshold change calculation.

Normal Bilirubin Value

The normal clinical current bilirubin value is 0.7 mg/dL. If a current bilirubin value is below 0.7 mg/dL, or if the current bilirubin value is missing or expired, the LAS calculation will use the normal clinical current bilirubin value.

10.1.F.iv. Creatinine in the LAS

The LAS calculation uses two measures of creatinine:

1. Current creatinine (only for candidates who are at least 18 years old)
2. ~~Increase in e~~ Creatinine Threshold Change (for all candidates)

Current Creatinine

Current creatinine is the serum creatinine value with the most recent test date and time reported to the OPTN Contractor for candidates who are at least 18 years old.

~~Increase in Creatinine~~ Threshold Change Calculations

There are two ~~Increase in Creatinine~~ threshold change calculations:

1. ~~Increase in Creatinine~~ Threshold Change Calculation
2. Threshold Change Maintenance Calculation

~~The Increase in Creatinine~~ Threshold Change Calculation

An increase in creatinine that is at least 150% will impact a candidate's LAS. The ~~increase in creatinine~~ threshold change calculation uses the highest and lowest values of creatinine as follows:

- ~~For this variable to impact a candidate's LAS,~~ The test date and time of the lowest creatinine value reported to the OPTN Contractor used in the ~~increase in creatinine~~ threshold change calculation must be earlier than the test date and time of the highest creatinine value used in the ~~increase in creatinine~~ threshold change calculation.
- The highest value must be at least 1.0 mg/dL.
- Test dates of these highest and lowest values cannot be more than ~~6~~six months apart.
- The ~~increase in creatinine~~ threshold change calculation ~~will~~can use an expired lowest value, but ~~cannot~~ use an expired highest value.

The equation for this ~~increase in creatinine~~ threshold change calculation is:

$$\frac{\text{Highest Creatinine} - \text{Lowest Creatinine}}{\text{Lowest Creatinine}}$$

~~The Threshold Change~~ Maintenance Calculation

When an ~~increase in creatinine~~ threshold change calculation impacts a candidate's LAS, the threshold change maintenance calculation assesses whether to maintain that impact. To maintain the impact of the increase in creatinine, the candidate's current creatinine value must be at least 1.0 mg/dL and at least 150% higher than the lowest value used in the ~~increase in creatinine~~ threshold change calculation. The equation for the threshold change maintenance calculation is:

$$\frac{\text{Current Creatinine} - \text{Lowest Creatinine}}{\text{Lowest Creatinine}}$$

If the current creatinine value expires or a new creatinine value is entered, then the ~~increase~~ threshold change maintenance calculation will occur.

~~10.2.B.iv LAS Values and Diagnoses~~ Approved by the LRB

A diagnosis that has been approved by the LRB or the Thoracic Organ Transplantation Committee is valid indefinitely, or until an adjustment is requested and, if necessary, approved by the LRB.

10.3 Waiting Time

Waiting time for lung candidates begins when the candidate is registered on the waiting list. Candidates at least 12 years old awaiting a lung transplant on the waiting list at inactive status will not accrue any waiting time while at inactive status. Lung candidates less than 12 years old accrue waiting time when registered at inactive status.

When waiting time is used for lung allocation, a candidate will receive a preference over other candidates who have accumulated less waiting time within the same priority or LAS.

10.5 Probability Data Used in the LAS Calculation

Table 10-8: Baseline Waiting List Survival (SWL(t)) Probability Where t=Time in Days

t	SWL(t)	t	SWL(t)	t	SWL(t)	t	SWL(t)	t	SWL(t)
0	1.0000000000	49	0.9966437334	98	0.9931596573	147	0.9905400510	196	0.9872991723
1	0.9999907157	50	0.9965433845	99	0.9930980163	148	0.9905400510	197	0.9872626749
2	0.9999254055	51	0.9965175429	100	0.9930607383	149	0.9905400510	198	0.9871552755
3	0.9998674170	52	0.9963972737	101	0.9930052489	150	0.9905400510	199	0.9871220338
4	0.9997455435	53	0.9963972737	102	0.9930052489	151	0.9905400510	200	0.9865302072
5	0.9995975343	54	0.9963631304	103	0.9929378277	152	0.9903840245	201	0.9865302072
6	0.9994989961	55	0.9963053385	104	0.9929378277	153	0.9903328361	202	0.9864801346
7	0.9993713802	56	0.9961914895	105	0.9928829296	154	0.9903328361	203	0.9859628001
8	0.9993046242	57	0.9961189511	106	0.9928829296	155	0.9903328361	204	0.9859256159
9	0.9992177050	58	0.9959421227	107	0.9928506946	156	0.9902446847	205	0.9859256159
10	0.9990851999	59	0.9959421227	108	0.9927619069	157	0.9902446847	206	0.9858198690
11	0.9989901794	60	0.9959092500	109	0.9927244496	158	0.9902446847	207	0.9858198690
12	0.9988873318	61	0.9959092500	110	0.9926433860	159	0.9901449203	208	0.9857415923
13	0.9988160788	62	0.9958731922	111	0.9926433860	160	0.9896887318	209	0.9857415923
14	0.9987295863	63	0.9958457969	112	0.9925624932	161	0.9896887318	210	0.9857415923
15	0.9986602768	64	0.9958457969	113	0.9920885646	162	0.9896520090	211	0.9857075131
16	0.9985875403	65	0.9956136053	114	0.9920640055	163	0.9895745634	212	0.9857075131
17	0.9984554393	66	0.9955529860	115	0.9920400127	164	0.9895745634	213	0.9855411680
18	0.9983616851	67	0.9955529860	116	0.9919966080	165	0.9889025189	214	0.9855411680
19	0.9982588046	68	0.9955529860	117	0.9919660469	166	0.9888730124	215	0.9855411680
20	0.9982200289	69	0.9955000986	118	0.9919399263	167	0.9888730124	216	0.9854501485
21	0.9980677506	70	0.9954789372	119	0.9919399263	168	0.9887838841	217	0.9854501485
22	0.9980357372	71	0.9953493820	120	0.9919399263	169	0.9887222824	218	0.9854501485
23	0.9979724590	72	0.9952934145	121	0.9915144847	170	0.9886945957	219	0.9853304718
24	0.9978684291	73	0.9951363273	122	0.9915144847	171	0.9886945957	220	0.9852652088
25	0.9977699910	74	0.9949654223	123	0.9915144847	172	0.9886945957	221	0.9852652088
26	0.9977420222	75	0.9948209678	124	0.9915144847	173	0.9886549235	222	0.9852652088
27	0.9976665328	76	0.9947736691	125	0.9914883902	174	0.9886549235	223	0.9852652088
28	0.9976255053	77	0.9947021905	126	0.9914618560	175	0.9886549235	224	0.9852652088
29	0.9975404117	78	0.9947021905	127	0.9913925084	176	0.9886246774	225	0.9846212073
30	0.9974725579	79	0.9946337898	128	0.9913069760	177	0.9885475245	226	0.9845486667
31	0.9973914097	80	0.9945649862	129	0.9913069760	178	0.9885475245	227	0.9845486667
32	0.9973268946	81	0.9945465023	130	0.9912697831	179	0.9885475245	228	0.9845486667
33	0.9972974521	82	0.9944645092	131	0.9912361687	180	0.9880619575	229	0.9845486667
34	0.9972743143	83	0.9944645092	132	0.9912361687	181	0.9880619575	230	0.9844886959
35	0.9972419197	84	0.9942969766	133	0.9910529687	182	0.9880619575	231	0.9844886959
36	0.9972419197	85	0.9942969766	134	0.9910121623	183	0.9880212199	232	0.9843962284
37	0.9971814314	86	0.9942969766	135	0.9910121623	184	0.9879335450	233	0.9843236173
38	0.9971367830	87	0.9942969766	136	0.9909776544	185	0.9878851712	234	0.9842799561
39	0.9971209292	88	0.9941805902	137	0.9909776544	186	0.9878851712	235	0.9840794709
40	0.9971209292	89	0.9940771789	138	0.9909776544	187	0.9878851712	236	0.9840794709
41	0.9970189115	90	0.9940345018	139	0.9909355857	188	0.9878851712	237	0.9840145629
42	0.9969461979	91	0.9940082090	140	0.9909011142	189	0.9878560942	238	0.9840145629
43	0.9969159237	92	0.9938663826	141	0.9909011142	190	0.9878560942	239	0.9840145629
44	0.9968488001	93	0.9938313146	142	0.9908111395	191	0.9878560942	240	0.9840145629
45	0.9968488001	94	0.9938070978	143	0.9907387924	192	0.9878560942	241	0.9838347625
46	0.9968199961	95	0.9937145919	144	0.9905945464	193	0.9878560942	242	0.9838347625

<u>t</u>	<u>S_{wl}(t)</u>	<u>t</u>	<u>S_{wl}(t)</u>	<u>t</u>	<u>S_{wl}(t)</u>	<u>t</u>	<u>S_{wl}(t)</u>	<u>t</u>	<u>S_{wl}(t)</u>
<u>47</u>	<u>0.9967799694</u>	<u>96</u>	<u>0.9933077154</u>	<u>145</u>	<u>0.9905945464</u>	<u>194</u>	<u>0.9876077782</u>	<u>243</u>	<u>0.9837917116</u>
<u>48</u>	<u>0.9967313053</u>	<u>97</u>	<u>0.9932199214</u>	<u>146</u>	<u>0.9905400510</u>	<u>195</u>	<u>0.9873585581</u>	<u>244</u>	<u>0.9837534417</u>

Table 10-8: Baseline Waiting List Survival (S_{wl}(t)) Probability Where t=Time in Days (Continued)

<u>t</u>	<u>S_{wl}(t)</u>								
<u>245</u>	<u>0.9837534417</u>	<u>269</u>	<u>0.9829597020</u>	<u>293</u>	<u>0.9818267812</u>	<u>317</u>	<u>0.9802178676</u>	<u>341</u>	<u>0.9785965606</u>
<u>246</u>	<u>0.9837534417</u>	<u>270</u>	<u>0.9829597020</u>	<u>294</u>	<u>0.9818267812</u>	<u>318</u>	<u>0.9801289145</u>	<u>342</u>	<u>0.9785965606</u>
<u>247</u>	<u>0.9836972199</u>	<u>271</u>	<u>0.9827972342</u>	<u>295</u>	<u>0.9815730256</u>	<u>319</u>	<u>0.9801289145</u>	<u>343</u>	<u>0.9783012252</u>
<u>248</u>	<u>0.9836363251</u>	<u>272</u>	<u>0.9827972342</u>	<u>296</u>	<u>0.9813194319</u>	<u>320</u>	<u>0.9800157994</u>	<u>344</u>	<u>0.9782502701</u>
<u>249</u>	<u>0.9836363251</u>	<u>273</u>	<u>0.9827972342</u>	<u>297</u>	<u>0.9807747475</u>	<u>321</u>	<u>0.9800157994</u>	<u>345</u>	<u>0.9782502701</u>
<u>250</u>	<u>0.9836363251</u>	<u>274</u>	<u>0.9827972342</u>	<u>298</u>	<u>0.9807747475</u>	<u>322</u>	<u>0.9800157994</u>	<u>346</u>	<u>0.9782502701</u>
<u>251</u>	<u>0.9836363251</u>	<u>275</u>	<u>0.9827004206</u>	<u>299</u>	<u>0.9805186284</u>	<u>323</u>	<u>0.9797725024</u>	<u>347</u>	<u>0.9781167565</u>
<u>252</u>	<u>0.9832432776</u>	<u>276</u>	<u>0.9826027019</u>	<u>300</u>	<u>0.9803970706</u>	<u>324</u>	<u>0.9797725024</u>	<u>348</u>	<u>0.9780370471</u>
<u>253</u>	<u>0.9832432776</u>	<u>277</u>	<u>0.9826027019</u>	<u>301</u>	<u>0.9803970706</u>	<u>325</u>	<u>0.9796706377</u>	<u>349</u>	<u>0.9780370471</u>
<u>254</u>	<u>0.9832432776</u>	<u>278</u>	<u>0.9825107450</u>	<u>302</u>	<u>0.9803970706</u>	<u>326</u>	<u>0.9796706377</u>	<u>350</u>	<u>0.9780370471</u>
<u>255</u>	<u>0.9830967678</u>	<u>279</u>	<u>0.9824570403</u>	<u>303</u>	<u>0.9803970706</u>	<u>327</u>	<u>0.9791639481</u>	<u>351</u>	<u>0.9780370471</u>
<u>256</u>	<u>0.9830967678</u>	<u>280</u>	<u>0.9824570403</u>	<u>304</u>	<u>0.9803970706</u>	<u>328</u>	<u>0.9791639481</u>	<u>352</u>	<u>0.9779370209</u>
<u>257</u>	<u>0.9830967678</u>	<u>281</u>	<u>0.9824570403</u>	<u>305</u>	<u>0.9803970706</u>	<u>329</u>	<u>0.9791639481</u>	<u>353</u>	<u>0.9779370209</u>
<u>258</u>	<u>0.9830967678</u>	<u>282</u>	<u>0.9824128485</u>	<u>306</u>	<u>0.9803970706</u>	<u>330</u>	<u>0.9791639481</u>	<u>354</u>	<u>0.9779370209</u>
<u>259</u>	<u>0.9830967678</u>	<u>283</u>	<u>0.9823232942</u>	<u>307</u>	<u>0.9803390799</u>	<u>331</u>	<u>0.9791001516</u>	<u>355</u>	<u>0.9778553245</u>
<u>260</u>	<u>0.9830967678</u>	<u>284</u>	<u>0.9823232942</u>	<u>308</u>	<u>0.9803390799</u>	<u>332</u>	<u>0.9791001516</u>	<u>356</u>	<u>0.9778553245</u>
<u>261</u>	<u>0.9830967678</u>	<u>285</u>	<u>0.9823232942</u>	<u>309</u>	<u>0.9803390799</u>	<u>333</u>	<u>0.9789346942</u>	<u>357</u>	<u>0.9778553245</u>
<u>262</u>	<u>0.9830516708</u>	<u>286</u>	<u>0.9823232942</u>	<u>310</u>	<u>0.9803390799</u>	<u>334</u>	<u>0.9789346942</u>	<u>358</u>	<u>0.9777099092</u>
<u>263</u>	<u>0.9830516708</u>	<u>287</u>	<u>0.9823232942</u>	<u>311</u>	<u>0.9803390799</u>	<u>335</u>	<u>0.9788174060</u>	<u>359</u>	<u>0.9777099092</u>
<u>264</u>	<u>0.9830516708</u>	<u>288</u>	<u>0.9823232942</u>	<u>312</u>	<u>0.9803390799</u>	<u>336</u>	<u>0.9788174060</u>	<u>360</u>	<u>0.9768812539</u>
<u>265</u>	<u>0.9830516708</u>	<u>289</u>	<u>0.9823232942</u>	<u>313</u>	<u>0.9803390799</u>	<u>337</u>	<u>0.9788174060</u>	<u>361</u>	<u>0.9768812539</u>
<u>266</u>	<u>0.9830516708</u>	<u>290</u>	<u>0.9823232942</u>	<u>314</u>	<u>0.9803390799</u>	<u>338</u>	<u>0.9788174060</u>	<u>362</u>	<u>0.9768812539</u>
<u>267</u>	<u>0.9830516708</u>	<u>291</u>	<u>0.9819156574</u>	<u>315</u>	<u>0.9802178676</u>	<u>339</u>	<u>0.9788174060</u>	<u>363</u>	<u>0.9767085255</u>
<u>268</u>	<u>0.9829597020</u>	<u>292</u>	<u>0.9818779459</u>	<u>316</u>	<u>0.9802178676</u>	<u>340</u>	<u>0.9788174060</u>	<u>364</u>	<u>0.9767085255</u>

Table 10-9: Baseline Post-Transplant Survival ($S_{TX}(t)$) Probability Where t =Time in Days

t	$S_{TX}(t)$								
0	1.0000000000	48	0.9818819454	97	0.9724145650	146	0.9651646731	195	0.9585852831
0	0.9989463518	49	0.9813940581	98	0.9724145650	147	0.9650179741	196	0.9585852831
1	0.9975582572	50	0.9811149797	99	0.9721278916	148	0.9650179741	197	0.9585106153
2	0.9968950221	51	0.9808357071	100	0.9719843820	149	0.9647244778	198	0.9583612369
3	0.9963635815	52	0.9804163818	101	0.9717688365	150	0.9646510762	199	0.9580621750
4	0.9954983869	53	0.9802065044	102	0.9716969486	151	0.9645042403	200	0.9580621750
5	0.9951651492	54	0.9801365116	103	0.9715531365	152	0.9643573707	201	0.9579873451
6	0.9945645668	55	0.9799264755	104	0.9713373330	153	0.9640634927	202	0.9579873451
7	0.9941636334	56	0.9796462096	105	0.9712653813	154	0.9638429283	203	0.9579125074
8	0.9939630137	57	0.9794358024	106	0.9711934225	155	0.9636958085	204	0.9577628083
9	0.9933601591	58	0.9790847785	107	0.9711214419	156	0.9634750547	205	0.9576130592
10	0.9931589002	59	0.9788739877	108	0.9710494372	157	0.9633278327	206	0.9575381540
11	0.9924871748	60	0.9787334069	109	0.9709774209	158	0.9631069028	207	0.9573882873
12	0.9923526429	61	0.9784520623	110	0.9707613132	159	0.9627384081	208	0.9573133332
13	0.9919487360	62	0.9783816832	111	0.9706892585	160	0.9625171483	209	0.9572383663
14	0.9916792045	63	0.9781704820	112	0.9706171946	161	0.9624433701	210	0.9571633895
15	0.9912068471	64	0.9781000588	113	0.9705451162	162	0.9622957853	211	0.9571633895
16	0.9905308509	65	0.9779591798	114	0.9704730247	163	0.9620743353	212	0.9569383725
17	0.9902600814	66	0.9778182436	115	0.9703288079	164	0.9619266457	213	0.9568633391
18	0.9899212765	67	0.9778182436	116	0.9699680182	165	0.9617049921	214	0.9567883006
19	0.9895819543	68	0.9775361418	117	0.9698236079	166	0.9616310727	215	0.9567132550
20	0.9895140131	69	0.9772537901	118	0.9696791597	167	0.9615571395	216	0.9566381918
21	0.9889017936	70	0.9770418835	119	0.9696069224	168	0.9614831983	217	0.9564880147
22	0.9882201168	71	0.9769712231	120	0.9693901236	169	0.9614831983	218	0.9562625865
23	0.9878104319	72	0.9769005466	121	0.9691008601	170	0.9614092449	219	0.9562625865
24	0.9874685977	73	0.9767590709	122	0.9689561390	171	0.9611132339	220	0.9561873965
25	0.9872633504	74	0.9765466782	123	0.9686665562	172	0.9611132339	221	0.9561121949
26	0.9870579950	75	0.9764758630	124	0.9685941382	173	0.9610391867	222	0.9560369867
27	0.9865784176	76	0.9761925132	125	0.9683767411	174	0.9609651281	223	0.9558865533
28	0.9863040866	77	0.9759089522	126	0.9681590825	175	0.9608910582	224	0.9557360679
29	0.9860295071	78	0.9757670435	127	0.9680864781	176	0.9607428635	225	0.9557360679
30	0.9859608276	79	0.9756250284	128	0.9678684348	177	0.9605945954	226	0.9557360679
31	0.9857547158	80	0.9754829371	129	0.9677956729	178	0.9604462255	227	0.9556608016
32	0.9854796626	81	0.9754829371	130	0.9675043666	179	0.9604462255	228	0.9556608016
33	0.9851355094	82	0.9754829371	131	0.9673585766	180	0.9603719931	229	0.9555102388
34	0.9849288641	83	0.9749850268	132	0.9671398110	181	0.9602977341	230	0.9555102388
35	0.9845152420	84	0.9749850268	133	0.9671398110	182	0.9601491697	231	0.9552089409
36	0.9844462708	85	0.9747001806	134	0.9669939177	183	0.9600748710	232	0.9552089409
37	0.9841701925	86	0.9747001806	135	0.9667019115	184	0.9598519074	233	0.9551335669
38	0.9838247337	87	0.9744152006	136	0.9664827327	185	0.9597775675	234	0.9549827718
39	0.9834789109	88	0.9739873157	137	0.9664827327	186	0.9597032090	235	0.9548319320
40	0.9832019349	89	0.9738445742	138	0.9664096522	187	0.9596288106	236	0.9546810412
41	0.9830633211	90	0.9736303735	139	0.9662634193	188	0.9595543795	237	0.9545300840
42	0.9828552725	91	0.9734160812	140	0.9661902639	189	0.9594799325	238	0.9544545732
43	0.9827164882	92	0.9734160812	141	0.9661902639	190	0.9592564778	239	0.9542279182
44	0.9825775890	93	0.9732016972	142	0.9659707159	191	0.9591074222	240	0.9542279182
45	0.9822995280	94	0.9730587142	143	0.9657510525	192	0.9590328768	241	0.9540767061
46	0.9821604041	95	0.9729156920	144	0.9656778054	193	0.9590328768	242	0.9540767061
47	0.9819515885	96	0.9726294362	145	0.9653113457	194	0.9587345577	243	0.9539254009

Table 10-9: Baseline Post-Transplant Survival ($S_{TX}(t)$) Probability Where t =Time in Days (Continued)

t	$S_{TX}(t)$								
244	0.9538497172	269	0.9511902217	293	0.9485888127	317	0.9463585089	341	0.9437285938
245	0.9538497172	270	0.9509612738	294	0.9483586281	318	0.9463585089	342	0.9436509982
246	0.9537740199	271	0.9506558210	295	0.9482818803	319	0.9462042511	343	0.9435733917
247	0.9537740199	272	0.9505794198	296	0.9481283428	320	0.9462042511	344	0.9434181618
248	0.9536983112	273	0.9504265693	297	0.9480515582	321	0.9461270863	345	0.9433405390
249	0.9536225901	274	0.9502736813	298	0.9479747621	322	0.9460499065	346	0.9431075841
250	0.9533952367	275	0.9501207590	299	0.9478210865	323	0.9460499065	347	0.9430298440
251	0.9533193886	276	0.9501207590	300	0.9476673351	324	0.9458955253	348	0.9430298440
252	0.9530158831	277	0.9498147874	301	0.9476673351	325	0.9458183199	349	0.9429520371
253	0.9530158831	278	0.9496617253	302	0.9473596856	326	0.9455866228	350	0.9427185272
254	0.9527122194	279	0.9496617253	303	0.9473596856	327	0.9454321012	351	0.9427185272
255	0.9527122194	280	0.9495851653	304	0.9473596856	328	0.9454321012	352	0.9427185272
256	0.9527122194	281	0.9495851653	305	0.9473596856	329	0.9453548209	353	0.9426406582
257	0.9524843651	282	0.9494319939	306	0.9472827362	330	0.9452775175	354	0.9424848995
258	0.9524083896	283	0.9493553886	307	0.9472827362	331	0.9451228653	355	0.9424848995
259	0.9523323977	284	0.9492787721	308	0.9472057776	332	0.9451228653	356	0.9421732641
260	0.9522563886	285	0.9492787721	309	0.9471288083	333	0.9449681796	357	0.9420173651
261	0.9521803676	286	0.9492021461	310	0.9469748345	334	0.9448908227	358	0.9417833903
262	0.9521043365	287	0.9492021461	311	0.9468208245	335	0.9447360580	359	0.9417053586
263	0.9518761834	288	0.9491255112	312	0.9468208245	336	0.9445812189	360	0.9416273052
264	0.9518000820	289	0.9490488687	313	0.9468208245	337	0.9445037758	361	0.9415492338
265	0.9516477499	290	0.9488955575	314	0.9467438071	338	0.9441938892	362	0.9415492338
266	0.9516477499	291	0.9488188902	315	0.9465897325	339	0.9440388525	363	0.9413148953
267	0.9515715365	292	0.9488188902	316	0.9464356005	340	0.9439613054	364	0.9413148953
268	0.9514952979								

Clarification to Policy 10.1.G: Reporting Additional Data for Candidates with an LAS of 50 or Higher

Name(s) of the Sponsoring Committee(s): Thoracic Organ Transplantation Committee

Summary and Goals of the Proposal:

The goal of this proposal is to clarify the data reporting requirements for lung candidates with a lung allocation score (LAS) of 50 or higher. Adopting clarifications to this policy will ensure that transplant programs understand the requirements in this policy, and will also permit the OPTN/UNOS Department of Evaluation and Quality (DEQ) to monitor compliance with the policy.

Background and Significance of the Proposal:

In November 2011, the Board of Directors adopted the Thoracic Committee's proposal "Requiring Updates of Certain Clinical Factors Every 14 Days for Lung Transplant Candidates with Lung Allocation Scores of at Least 50¹." The policy requires transplant programs to report values for assisted ventilation, supplemental oxygen, and current PCO₂ every 14 days from the date a candidate's LAS becomes 50 or higher. Because current PCO₂ is obtained by an invasive test, transplant programs must only report current PCO₂ values if they performed the test within the respective 14 day period. The policy became effective on February 1, 2012.

In March 2014, DEQ outlined its difficulties monitoring the policy due to the way it is written. They questioned whether programs need to assess and report new data every 14 days regardless of a change in the variables, or assess and only report observed changes every 14 days; if no changes are found upon assessment, must the transplant programs report new values?

The Lung Subcommittee addressed these questions during its May 20, 2014 teleconference. The Subcommittee agreed upon policy clarifications and recommended these clarifications to the full Thoracic Committee. The Thoracic Committee clarified the policy language further to ensure the intent of the policy is clearly communicated, and voted on September 18, 2014 to recommend the policy clarifications, detailed below, to be approved by the Board of Directors. (17 support; 0 oppose; 0 abstentions).

Proposed Solution

The Thoracic Committee worked closely with DEQ to develop clarifying policy language. One complexity created by the current policy language is the interpretation of "any observed changes." Policy currently states that every 14 days after the candidate's LAS becomes 50 or higher, the transplant program must "assess and report any observed changes" in the variables. It is therefore unclear, if there are no changes, whether the transplant program must report any data. On the other hand, if there are numerous changes within the 14 day period, it is unclear whether the transplant program must report every observed change within each 14 day period.

¹ Shepard, Brian. "Summary of Actions Taken at the OPTN/UNOS Board of Directors Meeting – November 14-15, 2011." http://optn.transplant.hrsa.gov/SharedContentDocuments/2011-11_Policy_Notice.pdf. Accessed on October 2, 2014.

The Thoracic Committee agreed that this policy was modeled after the six-month data reporting requirement for other LAS variables, and the Status 1A heart reporting requirements for heart candidates (in which a candidate’s registration must be recertified every 14 days). In both of these policies, the transplant programs are not responsible for providing an entire retrospective history of the candidate’s clinical data over the reporting period, rather, the transplant program provides a snapshot of the candidate’s condition on the day the program reports the candidate’s values. For this reason, the Thoracic Committee confirmed that even if there is no observed change, the transplant program must assess and report these variables every 14 days once a lung transplant candidate’s LAS becomes 50 or higher, but the transplant program is not required to provide information about every observed change in these variables over the course of each 14 day reporting period.

DEQ also noted that, by specifying a transplant program must report “three key variables” to the OPTN Contractor every 14 days, DEQ could not monitor all of the values associated with assisted ventilation, supplemental oxygen, and current PCO₂. For example, when transplant programs report values for supplemental oxygen in UNetSM, there are fields for frequency and for amount. Likewise, for current PCO₂, there is a field to also capture the test used to obtain the value (venous, capillary or arterial). These additional fields mean there are more than “three key variables” that are intended to be captured with this policy.

The Thoracic Committee asserted its intent was to capture not just the “three key variables,” but also all the fields associated with those variables. The easiest way to clarify this confusion is to remove the word “three” before “key variables” in policy.

The Thoracic Committee and DEQ are confident that the clarified policy language will ensure that the policy can be monitored as intended by the Thoracic Committee.

Additional Data Collection:

This proposal does not require additional data collection beyond what is already described in previous policy notices.

Expected Implementation Plan:

The policy is already implemented, but communication regarding the policy clarification will be provided to the transplant community.

Communication Activities			
Type of Communication	Audience(s)	Deliver Method(s)	Timeframe
Article on OPTN and other sites	Members	Website articles	Upon implementation
Policy Notice	Transplant Community	Electronic – Included in the monthly Transplant Pro e-newsletter sent on the 3 rd Thursday of each month	December 2014 (or 30 days after board approves the change)

Compliance Monitoring:

During on-site surveys, the Department of Evaluation and Quality (DEQ) staff reviews and verifies the clinical covariates entered into UNetSM and utilized to calculate the LAS with the actual medical record documentation. Staff also verifies all information submitted to the Lung Review Board with the actual medical record documentation.

DEQ staff will also investigate any reports of noncompliance.

Policy or Bylaw Proposal:

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

1 At a meeting of the OPTN/UNOS Board of Directors convened on November 12th and
2 November 13th in St. Louis, Missouri, the following resolution is offered.

3
4 *A resolution to clarify the reporting requirements for lung candidates with an LAS of 50 or
5 higher.*

6
7 Sponsoring Committee: Thoracic Organ Transplantation Committee

8
9 **RESOLVED, the modifications to Policy 10.1.G: Reporting Additional Data for Candidates
10 with an LAS of 50 or Higher, as set forth below, are hereby approved, effective February
11 1, 2015.**

12
13
14 **10.1.G Reporting Additional Data for Candidates with an LAS of 50 or
15 Higher**

16 Within 14 days of the date a candidate's LAS becomes 50 or higher, A the candidate's transplant
17 program must assess and report data for three key variables to the OPTN Contractor the
18 following variables no more than 14 days after a candidate's LAS becomes 50 or higher:

- 19
20 1. Assisted ventilation
21 2. Supplemental oxygen
22 3. Current PCO₂

23
24 ~~The transplant program is only required to report an updated PCO₂ value if the test was~~
25 ~~performed within those 14 days. While the candidate's LAS score remains 50 or higher, the~~
26 ~~transplant program must continue to assess and report any observed changes in the three clinical~~
27 ~~key variables assisted ventilation and supplemental oxygen data every 14 days. The transplant~~
28 ~~program is only required to report updated PCO₂ data if the assessment was performed during~~
29 ~~the previous 14 day interval.~~

30
31 The transplant program must maintain documentation of each assessment in the candidate's
32 medical chart.

33 #