UNOS DONATE LIFE
UNITED NETWORK FOR ORGAN SHARING

Since 1984 — sharing organs, sharing data, sharing life.

700 North 4th Street, Richmond, VA 23219
P.O. Box 2484, Richmond, VA 23218
tel: 804-782-4800
fax: 804-782-4817
www.unos.org

IMPORTANT POLICY NOTICE

To: Transplant Professionals

From: Karl J. McCleary, Ph.D., M.P.H
UNOS Director of Policy, Membership and Regional Administration

RE: Summary of actions taken at the OPTN/UNOS Executive Committee Meeting—Dec. 18, 2007

Date: January 18, 2008

The attached document summarizes actions taken by the OPTN/UNOS Executive Committee at its December 18, 2007 meeting. As always, we will continue to inform you of policy and bylaw changes made at OPTN/UNOS Board of Directors meetings. The next board meeting will be held on February 20-21, 2008 and you will receive an update no later than March 25, 2008.

This format allows you to scan the outcome of committee actions and quickly determine what, if anything, is required by you. You can also access the modified policy language by clicking on the link below the summary table.

Thank you for your careful review. If you have any questions about a particular notice within this document, please contact your regional administrator at (804) 782-4800.

Overview of Policy Modifications/Executive Committee Actions and Affected Professionals

Who should be aware of these actions? Please review the **6** notices included on the grid grid below and share with other colleagues as appropriate.

	Policy/Bylaw Change or Executive Committee Action	Directors of Organ Procurement	Lab Directors	Lab Supervisors	OPO Data Coordinators	OPO Executive Directors	OPO Medical Directors	OPO PR/Public Education Staff	OPO Procurement Coordinators	Transplant Administrators	Transplant Coordinators	Transplant Data Coordinators	Transplant Physicians	Transplant PR/Public Education Staff	Transplant Program Directors	Transplant Social Workers	Transplant Surgeons	Page #
Link 1	Modifications to Policy 4.1.1 (Communication of Donor History) detailing requirements for informing potential organ recipients about any known high risk behavior(s) in donors - *Executive Committee*	X			X	X	X	X	X	X	X	X	X	X	X	X	X	3
Link 2	Donor Testing Requirements - *Operations Committee*	X	X	X	X	X	X	X	X	X	X		X	X	X		X	5
Link 3	Modifications to Policies 2.5.5 (Organ Procurement Quality) and 3.5.9.1 (Essential Information for Kidney Offers) clarifying the number of red top tubes of blood required to accompany each organ for ABO verification - *Transplant Coordinators Committee*	X	X	X		X	X		X	X	X		X		X		X	6
Link 4	Modifications to Policy 3.7.6.1 (Candidates 12 and Older) to include PCO_2 in the lung allocation score - *Thoracic Organ Transplantation Committee*									X	X	X	X		X	X	X	7
Link 5	Modifications to Policies 3.7.8 (ABO Typing for Heart Allocation) and 3.7.8.1 (Heart Allocation to Pediatric Candidates Eligible to Accept a Donor Heart of Any Blood Type) clarifying the intent of changes passed in September 2006 - *Pediatric Transplantation Committee*	X	X	X	X	X	X		X	X	X	X	X	X	X	X	X	9
Link 6	Modification to UNOS Bylaws Appendix B, Attachment I, XIII, D (4)(a)(ii)- clarifying the requirements for programs performing living donor liver transplantation - *Membership and Professional Standards Committee*									X			X		X		X	10

Notice of Implementation — Executive Committee- Modifications to Policy 4.1.1 (Communication of Donor History), Detailing Requirements for Informing Potential Organ Recipients about Any Known High Risk Behavior in Donors

Action Required: Review and Respond as Necessary

Effective Date: January 18, 2007

Professional Groups Affected by the change: OPO Executive Directors, Directors of Organ Procurement, OPO Procurement Coordinators, OPO Data Coordinators, OPO Medical Directors, Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians, Transplant Data Coordinators, OPO PR/Public Education staff, Transplant PR/Public Education Staff, Transplant Social Workers

Current Issue/Policy	Proposed Change or Addition	What You Need to Do
Current policy requires the host OPO and transplant centers to communicate about any high risk behavior associated with the donor. The CDC Guidelines for Preventing Transmission of Human Immunodeficiency Virus Through Transplantation of Human Tissue and Organs defines high risk behavior. Current policy, however, does not require that OPOs and transplant centers communicate this information to potential organ recipients. Additionally, while the policy specifically cites the CDC guidelines, the level of knowledge and practice of these specific criteria varies among organ placement personnel.	In December 2007, the Executive Committee approved policy language that requires transplant centers to inform potential organ recipients about any known high risk donor behavior (as defined by CDC Guidelines). Because of potential patient safety issues, the Executive Committee approved this policy prior to public comment. The policy modifications are intended to *clearly* identify the criteria for high risk that the Host OPO must communicate to transplant centers receiving offers. The modifications should also close the communication gap by requiring transplant centers to share any high risk donor information with the potential recipient prior to implantation. Transplant professionals and potential recipients must continue to make case by case shared decisions about whether to accept organs from donors who meet one or more of the CDC high risk criteria. This policy	OPOs must clearly communicate knowledge of any CDC defined high risk behavior(s) to the transplant centers. The accepting transplant program must then share this information with any potential recipient prior to implantation *and* document that consent was received in light of this information. While this policy is **currently in effect**, the Executive Committee is seeking comment and will reconsider policy language during its June 2008 Board of Directors meeting.

	only intends to: • require an informed consent process when an organ donor meets high risk criteria as defined by the CDC • clarify what information must be communicated during the informed consent process • require documentation of the informed consent process.	

Click Here to View the Modified Policy Language

Notice of Executive Committee Action— Operations Committee—Donor Testing Requirements

Action Required: Review Only

Date: December 18, 2007 *(notice revised January 24, 2008)*

Professional Groups Affected by the change:
OPO Executive Directors, Directors of Organ Procurement, OPO Procurement Coordinators, OPO Data Coordinators, OPO Medical Directors, Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians, Lab Directors, Lab Supervisors, OPO PR/Public Education staff, Transplant PR/Public Education Staff

Current Issue/Policy	Proposed Change or Addition	What You Need to Do
Policy 2.2 states that OPOs must screen donors using FDA licensed Anti HIV I and II screening tests. Policy 4.0 states OPOs must test all potential donors for Human Immune Deficiency Virus (HIV) using a screening test licensed by the U.S. Food and Drug Administration (FDA). Some of the screening test supplies that OPOs currently use may become unavailable. As a result, some OPOs may find themselves out of compliance with current policy requiring them to use FDA licensed screening tests.	In looking for a suitable replacement option, OPOs may encounter a problem with diagnostic versus screening testing and the possibility of discordant results. The FDA has already approved many diagnostic kits, but not specifically for deceased organ donor testing. OPOs may, upon request and approval of the Executive Committee, use diagnostic laboratory testing to screen potential organ donors until the following has occurred: (1) An investigation of current OPO practices can be completed (2) The Disease Transmission Advisory Group can assess the sensitivity and specificity of diagnostic vs. screening tests for potential organ donors (3) The OPTN/UNOS Board of Directors approves the proposed policy modifications.	OPO personnel should review their testing supplies and determine if they will need to find alternate testing kits for donor screening. If so, they should work with their Regional Administrators to prepare a request to utilize diagnostic testing for consideration by the OPTN/UNOS Executive Committee until policy modifications are completed. If you have specific questions regarding the continued availability of your testing supplies, please contact the manufacturer. *There are no policy changes associated with this notice; therefore, there is no Exhibit 2 included for review.*

Notice of Policy Change— Transplant Coordinators Committee – Modifications to Policies 2.5.5 (Organ Procurement Quality) and 3.5.9.1 (Essential Information for Kidney Offers) clarifying the number of red topped tubes of blood required to accompany each organ for ABO verification.

Action Required: Review Only

Effective Date: December 18, 2007

Professional Groups Affected by the change:
OPO Executive Directors, Directors of Organ Procurement, OPO Procurement Coordinators, OPO Medical Directors, Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians, Lab Directors, Lab Supervisors

Current Issue/Policy	Proposed Change or Addition	What You Need to Do
Confusion exists about how many red topped tubes of blood should accompany each organ.	Modifications to Policies 2.5.5 and 3.5.9.1 clarify that one red topped tube is required to accompany each organ.	The OPO should send one red topped tube of blood with each organ to the receiving OPO or transplant center.

Click Here to View the Modified Policy Language

Notice of Policy Change— Thoracic Organ Transplantation Committee - Modification of the PCO_2 Language in Policy 3.7.6.1 (Candidates 12 and Older)

Action Required: Review Only

Effective Date: Implementation Date TBD

Professional Groups Affected by the change:
Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians, Transplant Social Workers, Transplant Data Coordinators

Current Issue/Policy	Proposed Change or Addition	What You Need to Do
Data analyses showed that lung transplant candidates who experience elevations in their current or change in PCO_2 values are more likely to die on the waiting list. Currently in UNet^{SM}, transplant centers may enter candidate values for arterial, venous, or capillary PCO_2 – the entry of these values is optional, not required. These values have not been used to calculate the lung allocation score (LAS).	These current modifications to Policy 3.7.6.1 clarify the Thoracic Committee's intent for including PCO_2 in the lung allocation score. Policy 3.7.6.1 requires transplant centers to report a candidate's venous, capillary, or arterial PCO_2 values for use in the lung allocation score. UNet^{SM} will substitute a PCO_2 value that is missing, expired, or less than 40 mmHg with the normal clinical value of 40 mmHg. Current PCO_2 and a change in PCO_2 that is at least 15% will impact a candidate's lung allocation score. A PCO_2 change of 15% or higher is threshold change. UNet^{SM} will calculate change using the highest and lowest values of PCO_2 if <u>all</u> of the following conditions are met: • the test dates of the highest and lowest values are no more than six months apart; • the test date of the lowest value is earlier than the test date of the highest; and, • the highest value is not expired. The candidate will maintain the	Transplant professionals should familiarize themselves with this refined PCO_2 policy language, and either continue or begin entering PCO_2 values (arterial, venous and/or capillary) for lung transplant candidates in UNet^{SM}. UNOS will notify transplant professionals when it has programmed the policy and an implementation date is available.

	impact from threshold change if the current PCO_2 value is not expired and is at least 15% higher than the lowest value used in the threshold change calculation.	

Click Here to View the Modified Policy Language

To read the complete policy language visit http://optn.transplant.hrsa.gov; select Policy Management > Policies.

Notice of Policy Change- Pediatric Transplantation Committee- Modifications to Policies 3.7.8 (ABO Typing for Heart Allocation) and 3.7.8.1 (Heart Allocation to Pediatric Candidates Eligible to Accept a Donor Heart of Any Blood Type)

Action Required: Review Only

Effective Date: Implementation Date TBD

Professional Groups Affected by the change:
OPO Executive Directors, Directors of Organ Procurement, OPO Procurement Coordinators, OPO Data Coordinators, OPO Medical Directors, Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians, Transplant Social Workers, Transplant Data Coordinators, Lab Directors, Lab Supervisors, Transplant PR/Public Education Staff

Current Issue/Policy	Proposed Change or Addition	What You Need to Do
Original modifications to these policies (extending the age limit from 1 to 2 years for listing pediatric candidates for heart transplant from donors of any blood type that the recipient has not yet formed type-specific antibodies against) were approved by the Board in September 2006. After programming was underway and members were able to see the pending policy changes on-line, several questions arose that were addressed during policy development but not clearly stated in the policy language. The Pediatric Committee approved housekeeping edits suggested by UNOS staff. The edits were then sent to the Executive Committee in December 2007 for expedited review. These language clarifications will allow UNOS IT staff to quickly program and implement the already delayed policy changes.	The approved edits clearly communicate the Committee's intent in a way that will be much easier for members and staff to read and understand without changing the original intent. Implementing this policy will increase the transplant opportunity for eligible pediatric heart candidates and also decrease the potential waste of these small hearts that may be otherwise discarded if they cannot be placed with ABO compatible recipients.	Familiarize yourself with the revised policy language for allocating hearts to pediatric candidates. A System Notice will alert OPOs and Transplant Centers of a final implementation date once it is established.

Click Here to View the Modified Policy Language

Notice of Bylaw Modification — Membership and Professional Standards Committee— UNOS Bylaws Appendix B, Attachment I, XIII, D (4)(a)(ii) – clarifies the requirements programs performing living donor liver transplantation.

Action Required: Review Only

Effective Date: December 18, 2007

Professional Groups Affected by the change: Transplant Administrators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians

Current Issue/Policy	Proposed Change or Addition	What You Need to Do
There was a typo (omission of a comma) in the live donor liver program membership criteria. The omission of the comma opens up possible misinterpretation of the Bylaw.	This Bylaw change clarifies that the 20 hepatic resections must be performed within the past 5 years, and of those 20, at least 7 must be live donor procedures. Without the comma the time period over which the 20 hepatic resections need to have occurred was not clear.	No action required

To view the affected bylaw language, please turn to **Exhibit 6**.

Notice of Implementation — Executive Committee- Modifications to Policy 4.1.1 (Communication of Donor History), Detailing Requirements for Informing Potential Organ Recipients about Any Known High Risk Behavior in Donors

Affected Policy/Bylaw Language:

4.0 ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS), HUMAN PITUITARY DERIVED GROWTH HORMONE (HPDGH), AND REPORTING OF POTENTIAL RECIPIENT DISEASES OR MEDICAL CONDITIONS, INCLUDING MALIGNANCIES, OF DONOR ORIGIN

4.1 SCREENING POTENTIAL ORGAN DONORS FOR HIV. All potential donors are to be tested by use of a screening test licensed by the U.S. Food and Drug Administration (FDA) for Human Immune Deficiency Virus (HIV). If the potential donor's pre-transfusion test for HIV is negative and blood for subsequent transfusions has been tested and found to be negative for HIV, retesting the potential donor for HIV is not necessary. If no pre-transfusion sample of the potential donor's blood is available, the Host OPO (as defined in Policy 2.1) must provide, to the recipient transplant center the screening test results and a complete history of all transfusions received by the donor during the ten (10) day period immediately prior to removal of the organ. Organs from donors with a positive screening test are not suitable for transplantation unless subsequent confirmation testing indicates that the original tests' results were falsely positive for HIV. If additional tests related to HIV are performed, the results of all tests must be communicated immediately to the Organ Center and all institutions receiving organs from the donor. Exceptions for cases in which the testing cannot be completed prior to transplant are provided in paragraph 4.1.3 below.

4.1.1 **Communication of Donor History**. The Host OPO will obtain a history on each potential donor in an attempt to determine whether the potential donor is in a "high risk" group, as defined by the Centers for Disease Control and Prevention (CDC). If the donor meets the criteria below,[1] the Host OPO must communicate this information regarding donor history to all institutions receiving organs from the donor.

Behavior/History Criteria

i) Men who have had sex with another man in the preceding 5 years.

ii) Persons who report nonmedical intravenous, intramuscular, or subcutaneous injection of drugs in the preceding 5 years.

iii) Persons with hemophilia or related clotting disorders who have received human derived clotting factor concentrates.

[1] Rogers MF, Simonds RJ, Lawton KE, et al. Guidelines for Preventing Transmission of Human Immunodeficiency Virus Through Transplantation of Human Tissue and Organs. CDC MMWR Recommendations and Reports. 1994;May 20/ 43(RR-8):1-17. http://www.cdc.gov/mmwr/preview/mmwrhtml/00031670.htm

iv) Men and women who have engaged in sex in exchange for money or drugs in the preceding 5 years.

v) Persons who have had sex in the preceding 12 months with any person described in terms i-iv above or with a person known or suspected to have HIV infection.

vi) Persons who have been exposed in the preceding 12 months to known or suspected HIV-infected blood through percutaneous inoculation or through contact with an open wound, nonintact skin, or mucous membrane.

vii) Inmates of correctional systems (This exclusion is to address issues such as difficulties with informed consent and increased prevalence of HIV in this population).

Pediatric Donor Criteria

viii) Children meeting any of the criteria listed above for adults.

ix) Children born to mothers with HIV infection or mothers who meet the behavioral or laboratory criteria for adult donors (regardless of their HIV status) unless they are greater than 18 months of age, have not been breast fed within the last 12 months and the child's antibody tests, physical examination, and review of medical records do not indicate evidence of HIV infection.

x) Children less than or equal to 18 months of age who are born to mothers with or at risk for HIV infection or who have been breast fed within the past 12 months.

Laboratory and Other Medical Criteria

xi) Persons who cannot be tested for HIV infection because of refusal, inadequate blood samples (e.g., hemodilution that could result in false-negative tests), or another other reasons.

xii) Persons with a repeatedly reactive screening assay for HIV-1 or HIV-2 antibody regardless of the results of supplemental assays.

xiii) Persons whose history, physical examination, or medical records reveal other evidence of HIV infection or high-risk behavior, such as a diagnosis of AIDS, unexplained weight loss, night sweats, blue or purple spots on the skin or mucous membranes typical of Kaposi's sarcoma, unexplained lymphadenopathy lasting greater than 1 month, unexplained temperature greater than 100.5 F (38.6 C) for greater than10 days, unexplained persistent cough and shortness of breath, opportunistic infections, unexplained persistent diarrhea, male to male sexual contact, sexually transmitted diseases, or needle tracks or other signs of parenteral drug abuse.

If the transplant center receives information from the Host OPO that the donor meets any of the above criteria, the transplant center must inform the potential recipient prior

to implantation. The transplant center shall maintain documentation of the potential recipient's informed consent to receive an organ from the donor who meets any of the above criteria. In the event that the potential recipient is not able to provide informed consent, the legal next of kin, designated healthcare representative, or appropriate surrogate may provide consent on this matter.

Notice of Policy Change— Transplant Coordinators Committee – Modifications to Policies 2.5.5 (Organ Procurement Quality) and 3.5.9.1 (Essential Information for Kidney Offers) clarifying the number of red topped tubes of blood required to accompany each organ for ABO verification.

Affected Policy/Bylaw Language:

2.5.5 Each OPO, with their respective histocompatibility laboratories, will establish minimum written requirements for tissue typing material required to generate match runs for local or regional placement of all organs. Organ procurement organizations will establish minimum requirements for tissue typing material required for local disposition of livers, hearts and lungs. In view of the frequent need for regional shipment of pancreas and kidney allografts, however, sufficient specimens for several crossmatches are required. Minimal typing material to be obtained for EACH kidney and pancreas will include the following:

- One 7 to 10ml. clot (red topped) tube for ABO verification, plus
- 2 ACD (Yellow top) tubes
- 3 to 5 lymph nodes
- One 2 X 4 cm. wedge of spleen in culture medium, if available.

3.5.9.1 Essential Information for Kidney Offers. The Host OPO must provide the following information to the potential recipient center with each kidney offer:

(i) Donor name and Donor I.D. number, age, sex, and race;

(ii) Date of admission for the current hospitalization;

(iii) Diagnosis;

(iv) Blood type;

(v) HLAA, B, Bw4, Bw6, and DR antigens;

(vi) Current history of abdominal injuries and operations;

(vii) Pertinent past medical or social history;

(viii) Current history of average blood pressure, hypotensive episodes, average urine output, and oliguria;

(ix) Final urinalysis;

(x) Final BUN and creatinine;

(xi) Indications of sepsis;

(xii) Assurance that final blood and urine cultures are pending;

(xiii) Pre- or post-transfusion serologies as indicated in 2.2.7.1 (pre-transfusion preferred);

(xiv) Current medication and transfusion history;

(xv) Recovery blood pressure and urine output information;

(xvi) Recovery medications;

(xvii) Type of recovery procedure (e.g., en bloc); flush solution and method (e.g., in situ); and flush storage solution;

(xviii) Description of typing material available, including, as a minimum for each kidney:

- One 7 to 10ml. clot (red topped) tube <u>for ABO verification</u>, plus
- 2 ACD (yellow top) tubes
- 3 to 5 lymph nodes
- One 2 X 4 cm wedge of spleen in culture medium, if available

(xix) Warm ischemia time and organ flush characteristics; and

(xx) Anatomical description, including number of blood vessels, ureters, and approximate length of each, injuries to or abnormalities of the blood vessels, ureter(s) or kidney.

Notice of Policy Change— Thoracic Organ Transplantation Committee - Modification of the PCO_2 Language in Policy 3.7.6.1 (Candidates 12 and Older)

Affected Policy/Bylaw Language:

3.7.6.1 **Candidates Age 12 and Older**. Candidates age 12 and older are assigned priority for lung offers based upon Lung Allocation Score, which is calculated using the following measures: (i) waitlist urgency measure (expected number of days lived without a transplant during an additional year on the waitlist), (ii) post-transplant survival measure (expected number of days lived during the first year post-transplant), and (iii) transplant benefit measure (post-transplant survival measure minus waitlist urgency measure). Waitlist urgency measure and post-transplant survival measure (used in the calculation of transplant benefit measure) are developed using Cox proportional hazards models. Factors determined to be important predictors of waitlist mortality and post-transplant survival are listed below in Tables 1 and ~~23~~2. ~~Table 2 describes the calculation of current PCO_2 and change in PCO_2 in the Lung Allocation Score.~~ It is expected that these factors will change over time as new data are available and added to the models. The Thoracic Organ Transplantation Committee will review these data in regular intervals of approximately six months and will propose changes to Tables 1~~, and 2,~~ and ~~3~~2 as appropriate.

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

~~**Factors Used to Predict Risk of Death on the Lung Transplant Waitlist**~~	
1.	Forced vital capacity (FVC)
2.	Pulmonary artery (PA) systolic (Groups A, C, and D~~[1]~~ – see 3.7.6.1.a)
3.	O_2 required at rest (Groups A, C, and D~~[1]~~ – see 3.7.6.1.a)
4.	Age
5.	Body mass index (BMI)
6.	Diabetes
7.	Functional status ~~(New York Heart Association (NYHA) class)~~
8.	Six-minute walk distance
9.	Continuous mechanical ventilation
10.	Diagnosis
11.	PCO_2 (see 3.7.6.1.b)

~~[1]Group A includes candidates with obstructive lung disease, including without limitation, chronic obstructive pulmonary disease (COPD), alpha-1-antitrypsin deficiency, emphysema, lymphangioleiomyomatosis, bronchiectasis, and sarcoidosis with mean pulmonary artery (PA) pressure ≤ 30 mmHg.~~

~~Group B includes candidates with pulmonary vascular disease, including without limitation, primary pulmonary hypertension (PPH), Eisenmenger's syndrome, and other uncommon pulmonary vascular diseases.~~

~~Group C includes, without limitation, candidates with cystic fibrosis (CF) and immunodeficiency disorders such as hypogammaglobulinemia.~~

~~Group D includes candidates with restrictive lung diseases, including without limitation, idiopathic pulmonary fibrosis (IPF), pulmonary fibrosis (other causes), sarcoidosis with mean PA pressure > 30 mmHg, and obliterative bronchiolitis (non-retransplant).~~

~~**Table 2**~~
~~**PCO_2 Used in the LAS Calculation**~~

~~Value of current PCO_2[1]~~	~~Value of prior PCO_2[1]~~	~~PCO_2 used in LAS calculation[1]~~	~~Change in PCO_2 used in LAS calculation[1]~~
~~Not missing or expired~~	~~Not missing or expired; within 6 months of current PCO_2~~	~~Current PCO_2~~	~~Change in PCO_2 (i.e., highest – lowest/lowest)[2]~~
~~Not missing or expired~~	~~Missing or expired or is not within 6 months prior to current value~~	~~Current PCO_2~~	~~No Change[3]~~
~~Missing or expired~~	~~(any value, expired or not)~~	~~Normal Clinical Value (40 mmHg)[4]~~	~~No Change[3]~~

~~[1]A center may enter a PCO_2 from an arterial, venous, or capillary blood gas into UNet℠ to count towards a candidate's lung allocation score. A center must enter the value into UNet℠ exactly as reported by the laboratory. Ideally, the arterial blood gas value will be used to calculate the lung allocation score. If venous and capillary blood gas values are entered, these values will be used to estimate an arterial value as follows: a capillary value will be equal to an arterial value; a venous value will have 6 mmHg subtracted from it to produce an equivalent arterial value.~~

~~[2]Both numbers must be actual, candidate blood gas values, and must be within 6 months of each other. Also, the lowest value must come temporally before the highest. A transplant candidate will receive a benefit from this parameter if the PCO_2 change is greater than or equal to 15%.PCO_2~~

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

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

Table ~~23~~32
Factors That Predict Survival After Lung Transplant

~~**Factors That Predict Survival After Lung Transplant**~~	
1.	FVC (Groups B~~,~~ and D[1] – see 3.7.6.1.a)
2.	PCW pressure ≥ 20 (Group D[1] – see 3.7.6.1.a)
3.	Continuous mechanical ventilation
4.	Age
5.	Serum Creatinine
6.	Functional Status ~~(NYHA class)~~
7.	Diagnosis

~~***NOTE:*** ***The amendments to Policy 3.7.6.1 (Candidates Age 12 and Older) shall be implemented pending distribution of appropriate notice & programming in UNet℠, if and as applicable. (Approved at the March 2007 Board of Directors Meeting)***~~

The calculations define the difference between transplant benefit and waitlist urgency: Raw Allocation Score = Transplant Benefit Measure – Waitlist Urgency Measure.

Raw allocation scores range from –730 days up to +365 days, and are normalized to a continuous scale from 0 – 100 to determine Lung Allocation Scores. The higher the score, the higher the priority for receiving lung offers. Lung Allocation Scores are calculated to sufficient decimal places to avoid assigning the same score to multiple candidates.

As an example, assume that a donor lung is available, and both Candidate X and Candidate Y are on the Waiting List. Taking into account all diagnostic and prognostic factors, Candidate X is expected to live 101.1 days during the following year without transplant. Also using available predictive factors, Candidate X is expected to live 286.3 days during the following year if transplanted today. On the other hand, Candidate Y is expected to live 69.2 days during the following year on the waitlist and 262.9 days post-transplant during the following year if transplanted today. Computationally, the proposed system would prioritize candidates based on the difference between each candidate's transplant benefit measure and the waitlist urgency as measured by the expected days of life lived during the next year.

Table 3
Example Illustrating the LAS Calculation

Parts of the Score Equation	Candidate X	Candidate Y
a. Post-transplant survival (days)	286.3	262.9
b. Waitlist survival (days)	101.1	69.2
c. Transplant benefit (a-b)	185.2	193.7
d. Raw allocation score (c-b)	84.1	124.5
e. **Lung Allocation Score**	**74.3**	**78.0**

In the example here, Candidate X's raw allocation score would be 84.1 and Candidate Y's raw allocation score would be 124.5.

Similar to the mathematical conversion of temperature from Fahrenheit to Centigrade, once the raw score is computed, it will be normalized to a continuous scale from 0-100 for easier interpretation by candidates and caregivers (see formula above). A higher score on this scale indicates a higher priority for a lung offer. Conversely, a lower score on this scale indicates a lower priority for organ offers. Therefore, in the example above, Candidate X's raw allocation score of 84.1 normalizes to a Lung Allocation Score of 74.3. Candidate Y's raw score of 124.5 normalizes to a Lung Allocation Score of 78.0. As in the example of raw allocation scores, Candidate Y has a higher Lung Allocation Score and will therefore receive a higher priority for a lung offer than Candidate X.

a. Lung Disease Diagnosis Groups
The following are some of the diagnoses included in groups A, B, C, and D.

(i) *Group A*
Includes candidates with obstructive lung disease, including without limitation, chronic obstructive pulmonary disease (COPD), alpha-1-

antitrypsin deficiency, emphysema, lymphangioleiomyomatosis, bronchiectasis, and sarcoidosis with mean pulmonary artery (PA) pressure ≤ 30 mmHg

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

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

(iv) *Group D*
Includes candidates with restrictive lung diseases, including without limitation, idiopathic pulmonary fibrosis (IPF), pulmonary fibrosis (other causes), sarcoidosis with mean PA pressure > 30 mmHg, and obliterative bronchiolitis (non-retransplant)

b. PCO_2 in the Lung Allocation Score

UNet^{SM} will use two measures of PCO_2 in a candidate's lung allocation score calculation: current PCO_2, and change in PCO_2. There are two types of PCO_2 change calculations: "threshold change" and "threshold change maintenance." The following explanations (i-vi) and illustrations (Figures 1-3) detail how UNet^{SM} uses PCO_2 in the lung allocation score.

(i) *Use of Arterial, Venous, or Capillary PCO_2 Values*
In UNet^{SM}, a center may enter a PCO_2 value from an arterial, venous, or capillary blood gas test. UNet^{SM} will convert a venous or capillary value to estimate an arterial value as follows:

- a capillary value will equal an arterial value; and,
- UNet^{SM} will subtract 6 mmHg from a venous value to equal an arterial value.

In the lung allocation score calculation, UNet^{SM} will use the PCO_2 value with the most recent test date, regardless of the blood gas type. Exception: if an arterial value and either a venous or capillary value have the same test date, UNet^{SM} will use the arterial value in the lung allocation score calculation.

(ii) *Definition of Current PCO_2*
Current PCO_2 is the PCO_2 value with the most recent test date entered in UNet^{SM}.

(iii) *Expiration of Current PCO_2 Value*
UNet^{SM} will evaluate a current PCO_2 value as expired according to Policy 3.7.6.3.2.

(iv) *Use of Normal Clinical Value for Current PCO_2*
The normal clinical value of PCO_2 is 40 mmHg. UNet^{SM} will substitute this normal clinical value in the lung allocation score calculation when

the value of current PCO_2 is less than 40 mmHg, missing, or expired.

(v) *PCO_2 Values Used in the Change Calculations*
There are two types of PCO_2 change calculations: threshold change and threshold change maintenance.

The threshold change calculation evaluates whether the PCO_2 change is 15% or higher. In this calculation, UNet^{SM} will use highest and lowest values of PCO_2. The test date of the lowest value must be earlier than the test date of the highest value. Test dates of these highest and lowest values cannot be more than 6 months apart. If necessary, UNet^{SM} will use an expired lowest value, but not an expired highest value. If a value is less than 40 mmHg, UNet^{SM} will substitute the normal clinical value of 40 mmHg before calculating change. The equation for threshold change is **[(highest PCO_2 – lowest PCO_2)/lowest PCO_2]**

The threshold change maintenance calculation occurs *after* the candidate receives the impact from threshold change in the lung allocation score. This maintenance calculation determines the candidate's eligibility for retaining the impact from threshold change in the lung allocation score. To maintain the impact from threshold change in the lung allocation score, the current PCO_2 value must be at least 15% higher than the lowest value used in the threshold change calculation. The equation for threshold change maintenance is **[(current PCO_2 – lowest PCO_2)/lowest PCO_2].**

UNet^{SM} will perform the threshold change maintenance calculation either when the current PCO_2 value expires (Policy 3.7.6.3.2) or a new current PCO_2 value is entered. For this calculation, the lowest and highest values that were used in the threshold change calculation can be expired. The current PCO_2 value can be the highest one that was used in the threshold change calculation. If a current PCO_2 value expires, the candidate's lung allocation score will lose the impact from threshold change. The reason for this loss is that when a current PCO_2 value expires, UNet^{SM} will substitute that expired value with the normal clinical value of 40 mmHg. This normal value, therefore, cannot be 15% *higher* than the lowest value in the threshold change calculation.

If a center enters a new current PCO_2 value for a candidate who has lost the impact from threshold change, UNet^{SM} will perform the threshold change maintenance calculation. If the new current PCO_2 value is at least 15% higher than the lowest value used in the threshold change calculation, UNet^{SM} will *reapply* the impact from threshold change to the candidate's lung allocation score.

(vi) *Impact of PCO_2 Threshold Change in the Lung Allocation Score*
A change in PCO_2 that is 15% or higher, or threshold change, will impact a candidate's lung allocation score. The candidate will not lose the lung allocation score impact from threshold change provided that the current PCO_2 is at least 15% higher than the lowest value used in the threshold change calculation.

Figure 1
Use of Current PCO_2 in the Lung Allocation Score

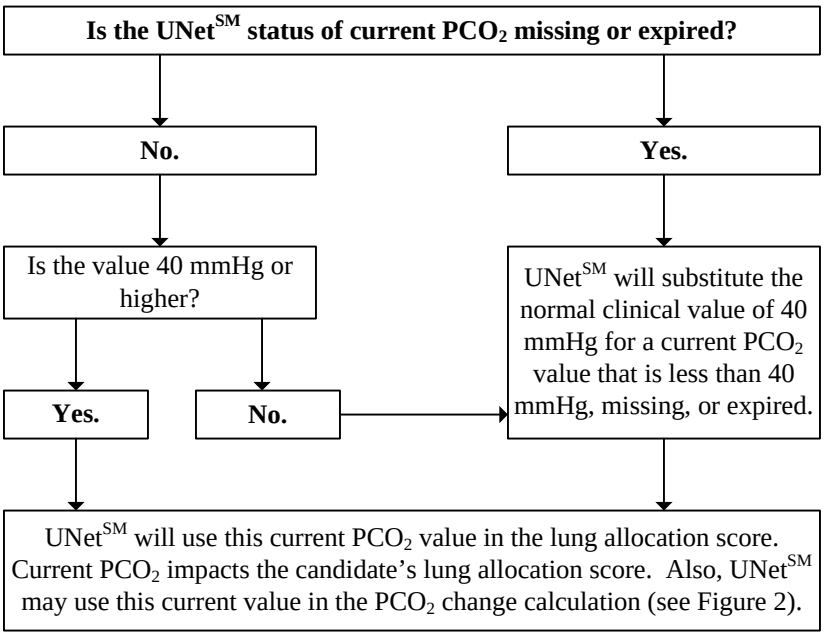


Figure 2
PCO_2 Threshold Change Calculation

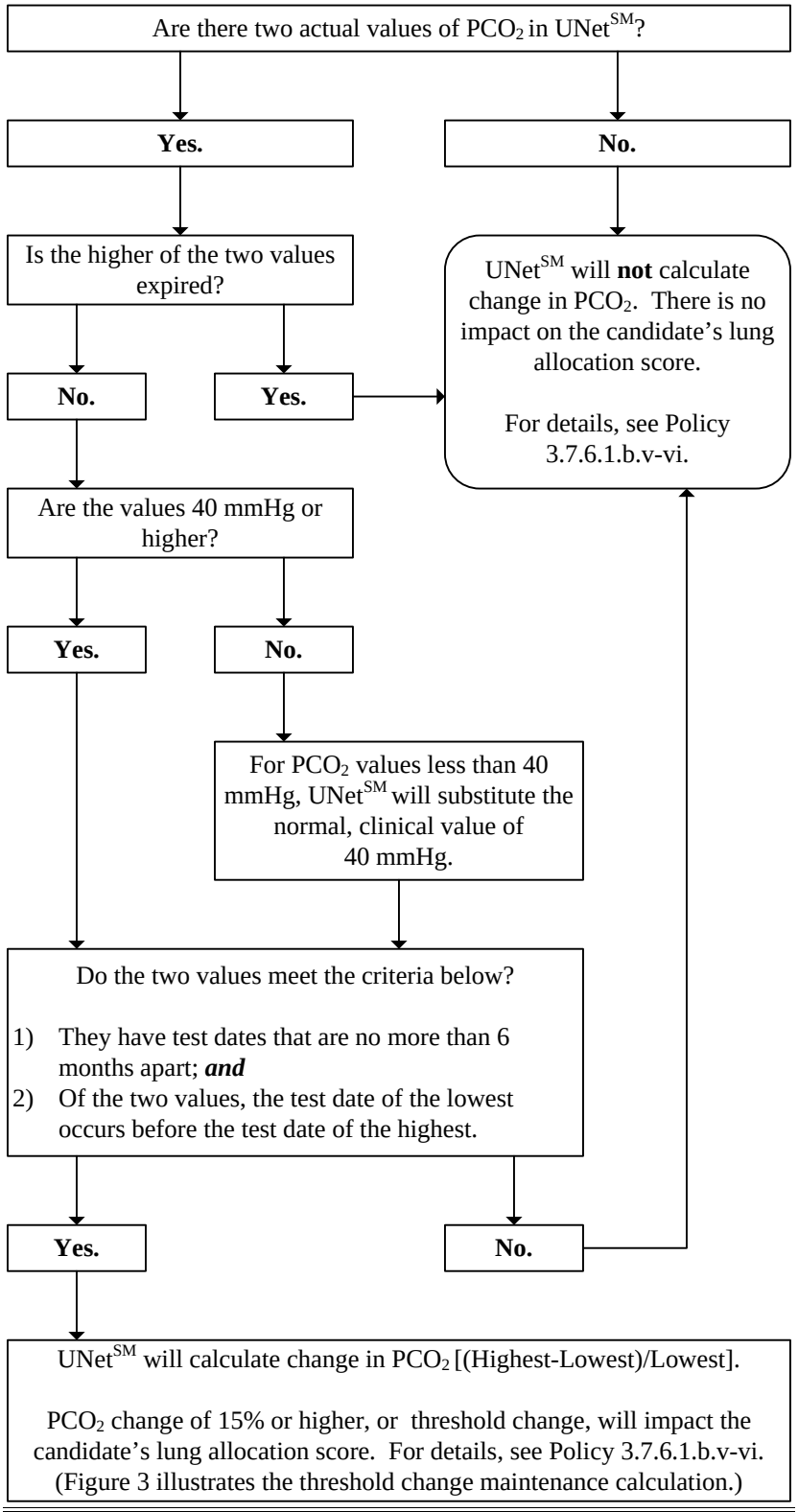
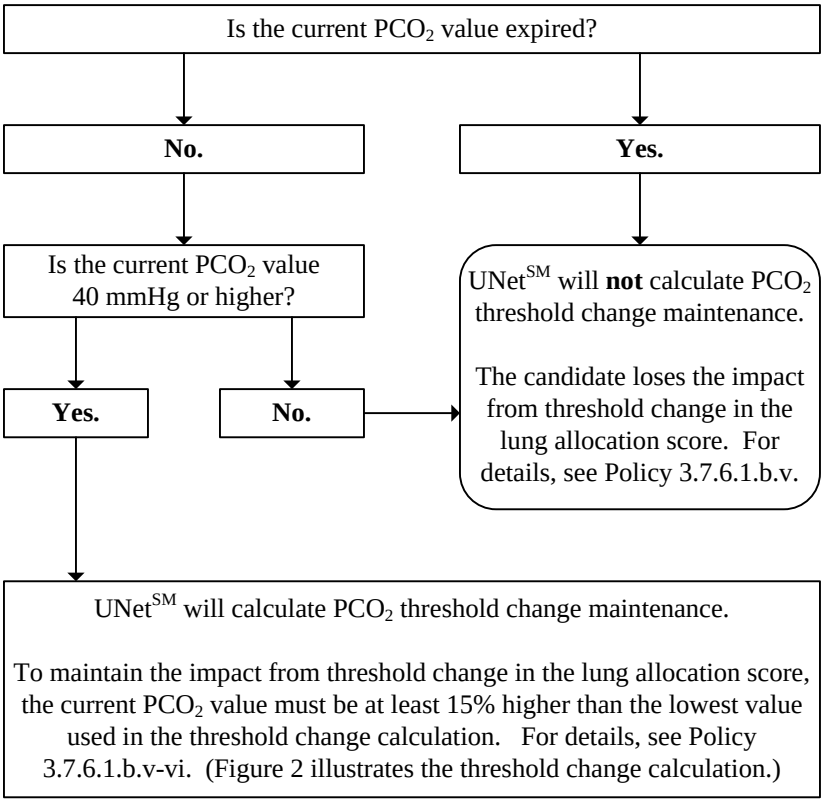


Figure 3
PCO_2 Threshold Change Maintenance Calculation



NOTE: ***The amendments to Policy 3.7.6.1 (Candidates Age 12 and Older) shall be implemented pending distribution of appropriate notice & programming in UNet^{SM}, if and as applicable. (Approved at the March 2007 Board of Directors Meeting)***

Notice of Policy Change- Pediatric Transplantation Committee- Modifications to Policies 3.7.8 (ABO Typing for Heart Allocation) and 3.7.8.1 (Heart Allocation to Pediatric Candidates Eligible to Accept a Donor Heart of Any Blood Type)

Affected Policy/Bylaw Language:

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

(i) Blood type O donor hearts shall only be allocated to blood type O or blood type B patients;

(ii) Blood type A donor hearts shall only be allocated to blood type A or blood type AB patients;

(iii) Blood type B donor hearts shall only be allocated to blood type B or blood type AB patients;

(iv) Blood type AB donor hearts shall only be allocated to blood type AB patients.

(v) If there is no patient available who meets these matching requirements, donor hearts shall be allocated first to patients who have a blood type that is compatible with the donor's blood type.

(vi) Following allocation for all born transplant candidates who have blood types that are compatible with donors, hearts will be allocated locally first and then within zones in the sequence described in 3.7.10, by heart status category to born Status 1A or 1B pediatric heart candidates who are eligible to receive a heart from any blood type donor. Allocation to *in utero* candidates eligible for any blood type donors is initiated after all eligible born candidates have received offers.

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

(i) Candidate is *in utero*;

(ii) Candidate is less than 1 year of age, and meets all of the following:

a. Listed at Status 1A or 1B, and
b. Current isohemagglutinin titer information for A and/or B blood type antigens reported in UNet^{SM}.

(iii) Candidate is greater than or equal to 1 year of age, and meets all of the following:
a. Listed prior to age 2;
b. Listed at Status 1A or 1B;
c. Current isohemagglutinin titer level(s) less than or equal to 1:4 for A and/or B blood type antigens reported in UNet^{SM}; and

d. Has not received treatments (such as plasmapheresis or transfusions) within the prior 30 days that could potentially alter spontaneously produced titer values.

~~Following allocation for all born transplant candidates who have blood types that are compatible with donors, hearts will be allocated locally first and then within zones in the sequence described in Policy 3.7.10, by heart status category to Status 1 pediatric heart candidates less than one year up to less than two years of age at time of listing identified as being compatible with **any** eligible to receive a heart from **any** blood type donor. (typically based on having Eligibility is defined as age ≤ 6 months 1 year old or recipient candidate isohemagglutinin titers less than or equal to 1:4 for A and/or B blood type antigens) for infants >6 months old > 1 year old who have a blood type that is incompatible with the donor's blood type if the candidate is been listed with the blood type "Z" designation as willing to accept a heart from a donor of any blood type. The isohemagglutinin titer used for recipient selection shall best reflect the recipient's candidate's responsiveness to spontaneous production of blood group antigens independent of modifiers, such as plasmapheresis or transfusions, within 30 days. When isohemagglutinin titers in recipientscandidates >6 months old >1 year old cannot be accurately determined due to modifiers received within 30 days that could potentially manipulate titer values, then status Z listing the candidate shall not be designated as eligible to accept donor hearts of any blood type under this policy used. Following allocation for born pediatric candidates who are eligible to accept donor hearts of any blood type "Z" incompatible pediatric heart candidates, less than one year of age, hearts will be allocated, locally first and then within zones in the sequence described in Policy 3.7.10, to patients listed *in utero.*~~

3.7.8.1 Heart Allocation to Pediatric Candidates ~~Less Than 2 Years of Age Willing~~ Eligible to Accept a Donor Heart of Any Blood Type. A center may specify on the waiting list that a candidate is eligible to accept a heart from any blood type donor if the eligibility requirements set forth in Policy 3.7.8 are met.

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

(i) At time of listing (except for *in utero* candidates);

(ii) Every 30 days after listing (**all** eligible born candidates);

(iii) At transplant; and

(iv) In the event of graft loss or death within one year after transplant (for all candidates transplanted with other than blood type identical or compatible donor hearts.

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

~~For pediatric candidates less than two years of age at time of listing who meet the eligibility requirements set forth in Policy 3.7.8, including *in utero* candidates for whom blood type is unknown, centers may specify on the Waiting List those candidates who will accept a heart from a donor of any blood type,. the blood type "Z" designation may be added as a suffix to the actual blood type (e.g., "AZ") of a pediatric patient less than one year up to less than two years of age, or used alone if actual blood type is not known for *in utero* candidates. Patients older than two years of age may be listed with the type "Z" designation suffix upon an application by his/her transplant physician(s) providing justification to the applicable Regional Review Board. Timing of the review of these cases shall be prospective. Anti-A and anti-B titers shall must be reported at the times of listing, (except for *in utero* candidates), monthly after listing (all eligible candidates), at transplant and in the event of graft loss or death within one year after transplant (for candidates transplanted with other than blood type identical or compatible donor hearts). Listing and transplant outcomes for status Z candidates determined to be eligible under this policy will be monitored on a quarterly basis by a subcommittee of the Pediatric Transplantation Committee, including at least two non-Committee members with analytical and/or other professional expertise in this area of medicine, and reported to the Pediatric Committee. Transplant programs that list candidates with the blood type Z designation for receipt of donor hearts of any blood type shall be required to provide information requested for review by the subcommittee, including, for example, autopsy reports.~~

[No further Changes to Policy 3.7.8]

Notice of Bylaw Modification — Membership and Professional Standards Committee— UNOS Bylaws Appendix B, Attachment I, XIII, D (4)(a)(ii) – clarifies the requirements programs performing living donor liver transplantation.

Affected Policy/Bylaw Language:

(4) Liver Transplant Programs that Perform Living Donor Liver Transplants.

a. Personnel and Resources: Liver transplant programs that perform living donor liver transplants must demonstrate the following:

(i) That the center meets the qualifications of a liver transplant program as set forth above; and

(ii) That the center has on site no fewer than two surgeons who qualify as liver transplant surgeons under UNOS Bylaws Appendix B, Attachment I, and who have demonstrated experience as the primary surgeon or first assistant in20 major hepatic resectional surgeries (to include living donor operations, splits, reductions, resections, etc.), 7 of which must have been live donor procedures, within the prior 5-year period. These cases must be documented. Documentation should include the date of the surgery, medical records identification and/or UNOS identification number, and the role of the surgeon in the operative procedure. It is recognized that in the case of pediatric living donor transplantation, the live organ donation may occur at a center that is distinct from the approved transplant center;

[No further changes to the Bylaw.]