

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 Executive Committee meeting— October 23, 2009

Date: November 23, 2009

The attached report summarizes policy changes the Executive Committee approved during its October 2009 meeting.

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. If you are interested in reviewing policy changes from previous board meetings, go to www.unos.org and click on Newsroom and then select “View all Policy Notices.” We have archived all policy notices from the March 2007 board meeting and forward.

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 and Affected Professionals

Who should be aware of these actions? Please review the **3** notices included on the grid below and share with other colleagues as appropriate.

Policy Change (Sponsoring Committee)		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 #
1	Modifications to Requirements for Mandatory HTLV-1/2 Testing for All Potential Deceased Donors (Ad Hoc Disease Transmission Advisory Committee)	X	X	X	X	X	X	X	X	X	X		X	X	X	X	X	3
2	Add Factors "Current Bilirubin" and "Change in Bilirubin" to the Lung Allocation Score (LAS) (Thoracic Organ Transplantation Committee)									X	X	X	X		X	X	X	5
3	Modifications to Renal Acceptance Criteria Policy (Executive Committee)	X			X	X	X		X	X	X		X		X		X	6

Title of Policy Change: Modifications to Requirements for Mandatory HTLV-1/2 Testing for All Potential Deceased Donors

Sponsoring Committee: Ad Hoc Disease Transmission Advisory

Policy Affected: 2.2.3.1 (For All Potential Donors)

Action Required: Review Only

Effective Date: November 23, 2009

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, Lab Directors, Lab Supervisors, OPO Public Relations or Public Education staff, Transplant Public Relations or Public Education Staff

Problem Statement	Changes	What You Need to Do
<p>Current policy requires OPOs to screen all potential deceased donors for anti-HTLV-1/2 antibodies. Most OPOs currently use a specific enzyme immunoassay (EIA) test system. This system will no longer be manufactured effective 12/31/2009.</p> <p>The only remaining FDA-licensed testing system is designed to test a large number of samples in a high-volume setting. This may not meet the time constraints and logistics associated with prospective testing for organ donation.</p>	<p>Policy will no longer require HTLV-1/2 screening for potential deceased donors.*</p> <p>*Note- The Executive Committee executed this policy change on October 23, 2009, after reviewing a public comment proposal and the responses from the OPTN/UNOS committees, its eleven regions, and the general public . Available data suggest very low prevalence of HTLV-1 in the donor population (approximately 0.03%), considerable discard of organs due to false positive results using screening tests, and favorable short-term follow-up of recipients of HTLV-1/2 screen positive organs in the U.S.</p>	<p>OPOs may choose to continue HTLV-1/2 screening at their discretion (as is done at some OPOs for Chagas, West Nile Virus and other diseases). Until programming related to this policy change is completed, OPOs must still enter positive, negative, or not done in the HTLV-1/2 donor screening results field in order to generate a match run for organ placement.</p> <p>Transplant centers should be prepared to discuss HTLV as part of their standard pre-transplant informed consent process. In addition, centers should consider notifying candidates regarding the elimination of HTLV screening requirements, as candidates have previously had the option to automatically opt out of offers for HTLV-1/2 positive organs. Until UNOS completes the programming related to this change, candidates listed as not</p>

		<p>willing to accept HTLV-1/2 positive organs will still receive offers for donor organs where testing has not been done and for organs that are HTLV-1/2 screen negative by OPOs which choose to continue this testing.</p> <p>You may review the following article to learn more about HTLV:</p> <p>Kaul DR, Taranto SE, et al. Donor Screening for Human T-cell Lymphotropic Virus 1/2: Changing Paradigms for Changing Test Capacity. <i>AJT</i>. 2009; 9: epub ahead of print. PMID: 19839982.</p>
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Title of Policy Change: Add Factors “Current Bilirubin” and “Change in Bilirubin” to the Lung Allocation Score (LAS)

Sponsoring Committee: Thoracic Organ Transplantation

Policy Affected: 3.7.6.1.c (Candidates Age 12 and Older; Bilirubin in the Lung Allocation Score)

Action Required: Review Only

Effective Date: Upon Implementation (no earlier than 2011)

Professional Groups Affected by the Change:

Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians, Transplant Social Workers, and Transplant Data Coordinators

Problem Statement	Changes	What You Need to Do
<p>Although the death rate has declined among lung transplant candidates who are at least 12 years of age since UNOS implemented the LAS in 2005, there continue to be waiting list deaths in this group. Further, the death rate in the diagnosis Group B¹ population (see footnote) appears to have increased slightly. This lung waitlist mortality rate prompted the thoracic community to enhance the ability of the LAS to better predict waitlist urgency and reduce deaths on the waiting list for lung transplant candidates.</p>	<p>This policy adds two factors to the LAS to better predict a lung transplant candidate’s waiting list urgency:</p> <ol style="list-style-type: none"> 1) Current bilirubin that is at least 1.0 mg/dL for all diagnosis groups 2) Change (increase) in bilirubin of at least 50% for a candidate in diagnosis Group B only when: <ul style="list-style-type: none"> • the increase occurs during a six-month period; and • the higher bilirubin value is at least 1.0 mg/dL . 	<p>Transplant professionals should become familiar with the bilirubin policy language.</p> <p>The Executive Committee recommended that UNOS implement this policy using the automated solution proposed by the Thoracic Committee. Once developed, UNOS will inform transplant professionals of the implementation schedule.</p> <p>Note: This is the second notice about adding current and change in bilirubin to the LAS. The first policy notice informed you that the Board of Directors approved the policy concept but asked the Executive Committee to create an implementation plan².</p>

¹ Diagnoses currently included in Group B: congenital malformation; crest - pulmonary hypertension; eisenmenger's syn: atrial septal defect; eisenmenger's syn: multi congenital anomalies; eisenmenger's syn: other specify; eisenmenger's syn: pda; eisenmenger's syn: vsd; portopulmonary hypertension; primary pulmonary hypertension; pulmonary telengectasia - pulmonary hypertension; pulmonary thromboembolic disease; pulmonary vascular disease; pulmonary veno-occlusive disease; pulmonic stenosis; right hypoplastic lung; scleroderma - pulmonary hypertension; secondary pulmonary hypertension; and, thromboembolic pulmonary hypertension.

² <http://optn.transplant.hrsa.gov/news/newsDetail.asp?id=1277>

Title of Policy Change: Modifications to Renal Acceptance Criteria Policy

Sponsoring Committee: Executive

Policy Affected: 3.3.3 (Renal Acceptance Criteria)

Action Required: Review Only

Effective Date: December 23, 2010

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,

Problem Statement	Changes	What You Need to Do
<p>In current policy, responsibilities of the transplant centers and the Organ Center are unclear in terms of applying renal acceptance criteria to non local organ offers. After UNOS implemented DonorNet® in 2007, a proposal allowed OPOs to use the renal acceptance criteria filter for non-local kidney offers made through DonorNet®. Analyzing DonorNet’s effects, it is now evident that practice patterns, member preferences, and the resources required do not support automating the renal acceptance criteria functionality for OPOs.</p>	<p>We have clarified the policy to reflect the current OPO practice. The policy now clearly indicates that only the Organ Center will be responsible for applying a transplant center’s minimal acceptance renal criteria when offering kidneys to those centers from non-local OPOs.</p>	<p>Kidney transplant programs should review their minimum renal acceptance criteria. These programs should make adjustments if necessary to reflect the characteristics of kidneys that the program is most likely to accept as import offers from nonlocal OPOs.*</p> <p><i>*Note: these criteria do not apply to zero-antigen mismatch offers.</i></p>

Affected Policy Language:

2.2.3 The Host OPO must perform the following pertinent FDA licensed, approved, or cleared serological screening tests and provide this information to the OPO or transplant center. In the event that such screening tests are not commercially available prior to transplant, then a FDA approved diagnostic test is permissible to assess the donor. The Host OPO must document in the donor record circumstances when such information is not available. In all cases, the transplant center will make the clinical decision whether to accept or reject the organ based on the available data or identify the need for additional information. The Host OPO may be requested to provide additional information if possible in addition to the information required on all donors. Required tests should include:

2.2.3.1 For all potential donors:

- ABO typing with sub-typing for ABO-A donors;
- FDA licensed Anti-HIV I, II;
- CBC;
- Electrolytes;
- Hepatitis screen serological testing; including HBsAg, HBcAb, and Anti-HCV;
- VDRL or RPR;
- ~~Anti-HTLV I/II;~~
- Anti-CMV;
- EBV serological testing;
- Blood and urine cultures;
- Urinalysis within 24 hours prior to cross clamp;
- Arterial blood gases;
- Chest x-ray; and
- Serum Glucose.

Additional Organ Specific information is required as follows:

[...]

To read the complete policy language visit www.unos.org or optn.transplant.hrsa.gov. From the UNOS Web site, select Resources from the main menu, then select policies. From the OPTN Web site, select Policies from the main menu.

Affected Policy 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 2. 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 as appropriate.

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

1. Forced vital capacity (FVC)
2. Pulmonary artery (PA) systolic pressure (Groups A, C, and D – see 3.7.6.1.a)
3. O₂ required at rest (Groups A, C, and D – see 3.7.6.1.a)
4. Age
5. Body mass index (BMI)
6. Diabetes
7. Functional status
8. Six-minute walk distance
9. Continuous mechanical ventilation
10. Diagnosis
11. PCO₂ (see 3.7.6.1.b)
12. Bilirubin (current bilirubin – all gGroups; change in bilirubin – Group B; see 3.7.6.1.c)

[No further changes are proposed to this section of Policy 3.7.6.1.]

a. Lung Disease Diagnosis Groups

[No changes are proposed to this section of Policy 3.7.6.1.]

b. PCO₂ in the Lung Allocation Score

[No changes are proposed to this section of Policy 3.7.6.1.]

c. Bilirubin in the Lung Allocation Score

UNetSM will use two measures of total bilirubin in a candidate's lung allocation score calculation: current bilirubin (for all candidates), and change in bilirubin (for Group B only). There are two types of bilirubin change calculations: "threshold change" and "threshold change maintenance." This section of Policy 3.7.6.1 explains how UNetSM uses bilirubin in the lung allocation score.

(i) Definition of Current Bilirubin

Current bilirubin is the total bilirubin value with the most recent test date and time entered in UNetSM. UNetSM will include in the lung allocation score calculation a current bilirubin value that is at least 1.0 mg/dL.

(ii) Expiration of Current Bilirubin Value

UNetSM will evaluate a current bilirubin value as expired according to Policy 3.7.6.3.2.

(iii) Use of Normal Clinical Value for Current Bilirubin

The normal clinical value of current bilirubin is 0.7 mg/dL. UNetSM will substitute this normal clinical value in the lung allocation score calculation when the value of current bilirubin is less than 0.7 mg/dL, missing, or expired.

(iv) Bilirubin Values Used in the Change Calculations (Group B Only)

There are two types of bilirubin change calculations: threshold change and threshold change maintenance.

The threshold change calculation evaluates whether the bilirubin change is 50% or higher. In this calculation, UNetSM will use highest and lowest values of bilirubin. The test date of the lowest value must be earlier than the test date of the highest value. The highest value must be at least 1.0 mg/dL. Test dates of these highest and lowest values cannot be more than 6 months apart. If necessary, UNetSM will use an expired lowest value, but not an expired highest value. If a value is less than 0.7 mg/dL, UNetSM will substitute the normal clinical value of 0.7 mg/dL before calculating change. The equation for threshold change is $[(\text{highest bilirubin} - \text{lowest bilirubin})/\text{lowest bilirubin}]$.

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 bilirubin value must be at least 50% higher than the lowest value used in the threshold change calculation. The equation for threshold change maintenance is $[(\text{current bilirubin} - \text{lowest bilirubin})/\text{lowest bilirubin}]$.

UNetSM will perform the threshold change maintenance calculation either when the current bilirubin value expires (Policy 3.7.6.3.2) or a new current bilirubin value is entered. For this calculation, the lowest and highest values that were used in the threshold change calculation can be expired. The current bilirubin value can be the highest one that was used in the threshold change calculation. If a current bilirubin 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 bilirubin value expires, UNetSM will substitute that expired value with the normal clinical value of 0.7 mg/dL. This normal value, therefore, cannot be 50% higher than the lowest value in the threshold change calculation.

If a center enters a new current bilirubin value for a candidate who has lost the impact from threshold change, UNetSM 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 threshold change calculation, UNetSM will *reapply* the impact from threshold change to the candidate's lung allocation score.

(v) *Impact of Bilirubin Threshold Change in the Lung Allocation Score (Group B only)*

A change in bilirubin that is 50% 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 bilirubin is at least 50% higher than the lowest value used in the threshold change calculation.

To read the complete policy language visit www.optn.transplant.hrsa.gov. From the OPTN Web site, select Policies from the main menu.

Affected Policy Language:

3.3.3 Renal Acceptance Criteria. All renal transplant programs must submit their minimum renal acceptance criteria annually through UNetSM. ~~defining which import deceased donor kidneys will be offered to the program from nonlocal OPOs. The renal transplant program will not subsequently be offered import deceased kidneys that fail to meet the program's acceptance criteria.~~ These criteria define which import deceased donor kidneys will be offered by the Organ Center to programs from nonlocal OPOs. When asked to place organs, the Organ Center will only offer deceased donor kidneys that meet these criteria. The renal acceptance criteria will not apply to import zero antigen mismatched kidney offers.

To read the complete policy language visit www.unos.org or optn.transplant.hrsa.gov. From the UNOS Web site, select Resources from the main menu, then select policies. From the OPTN Web site, select Policies from the main menu.