UNOS DONATE LIFE
UNITED NETWORK FOR ORGAN SHARING

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IMPORTANT POLICY NOTICE

To: Transplant Professionals

From: James B. Alcorn
Director, Policy

RE: Summary of actions taken at May 1, 2013, OPTN/UNOS Executive Committee Meeting

Date: May 30, 2013

The attached report summarizes OPTN policy changes approved by the OPTN/UNOS Executive Committee at its May 1, 2013, meeting. This policy notice provides the specific policy language changes and the corresponding implementation dates. When reviewing the language changes, please note that underlined language is new and what will be in effect upon implementation and language that is ~~struck~~ will be deleted upon implementation. The policy language used to denote the changes approved at the May 2013 Executive Committee meeting reflects the most recent version of policy that has been approved, but not necessarily what is currently implemented.

This policy notice, and those reviewing changes from previous Board of Directors meetings, can be found at optn.transplant.hrsa.gov (click on "News," and then select "View all Policy Notices").

For additional information on these policies, you should also review the relevant sections in the Evaluation Plan. The Evaluation Plan reviews specific details regarding how members will be assessed for compliance with OPTN policies and bylaws. It can also be found at optn.transplant.hrsa.gov (click on "Policy Management," and then select "Evaluation Plan").

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

Table of Contents

Clarification of Blood Typing Requirements for Living Donor Transplantation

Sponsoring Committee: Living Donor Committee

Policies Affected: 12.3.1 (ABO Identification) and 12.3.2 (ABO Subtype Identification)

Distributed for Public Comment: No

Effective Date: May 31, 2013

Problem Statement
In February 2013, UNOS hosted a town hall meeting to address questions on recently implemented policies for the consent, medical evaluation, and follow-up of living kidney donors. The most common question did not pertain to the recently approved living kidney donor policies. Instead, the most common question concerned established policy requirements for living donor blood type testing (12.3.1 (ABO Identification) and 12.3.2 (ABO Subtype Identification)). Specifically, transplant programs questioned if the living donor recovery hospital is required to complete two blood type tests in addition to blood type testing that has already been performed by other facilities.

Changes
Policies 12.3.1 and 12.3.2 were clarified to help members understand and meet the policy requirements. Specifically, living donor recovery hospitals are not required personally to complete the two blood type tests required for living donor blood type testing. Instead, while the recovery hospital is responsible for making sure that the two tests are performed accurately, they may rely upon tests performed by somebody else.

Action Required
Recovery hospitals should update their internal procedures to reflect this policy clarification. The living donor's blood type must still be tested twice. To ensure this testing has been done, living donor recovery hospitals may review blood type source documentation from other facilities. The living donor recovery center is not required to perform two separate and additional blood type tests.

Default Bilirubin and PCO_2 Values in the Lung Allocation Score Calculation

Sponsoring Committee: Thoracic Organ Transplantation Committee

Policy Affected: 3.7.6.3 (Reporting Data for Candidates Who Receive Lung Allocation Scores (LAS))

Distributed for Public Comment: No

Effective Date: To be determined, implementation pending programming

Problem Statement

There are inconsistencies in different sections of the policies defining the Lung Allocation Score (LAS) calculation:
• Discrepancy in the default values provided for current bilirubin in the LAS calculation:
  ○ 0.7 mg/dL is listed in Policy 3.7.6.1.4(c) (Use of Normal Clinical Value for Current Bilirubin);
  ○ 1.0 mg/dL is listed in Table 5 (Data Substituted for Missing, Expired, or Below Threshold Actual Values in Calculating the LAS) in Policy 3.7.6.3 (Reporting Data for Candidates Who Receive Lung Allocation Scores (LAS)).
• Discrepancy as to when default values are substituted for bilirubin and PCO_2, respectively:
  ○ Table 5 indicates that UNet℠ substitutes default values for bilirubin and PCO_2 when the current value is missing, expired, or below threshold;
  ○ Default values apply to both current *and* Change Calculation bilirubin values in Policy 3.7.6.1.4(d) (Bilirubin Values Used in the Change Calculations (Group B Only)). Similarly, default values apply to both current *and* Change Calculation PCO_2 values in Policy 3.7.6.1.3(e) (PCO_2 Values Used in the Change Calculations).

Changes
Table 5 in Policy 3.7.6.3 will be edited to list 0.7 mg/dL as the default value for bilirubin. The word "current" will be removed from the bilirubin and PCO_2 descriptions in Table 5 to clarify that the default values apply to the current values *and* the Change Calculations for bilirubin and PCO_2.

Member Actions
No additional member action is required. These policy changes adopted in May 2013 by the Executive Committee address policy language that the Board of Directors approved in November 2012. All of these changes are still awaiting programming, and UNOS will send members a system notice before these policies are implemented.

Affected Policy Language:

12.3.1 ABO Identification. The member ~~transplant~~ recovery hospital must ensure that ABOType~~e~~ing~~,~~ of each living donor~~s~~ is performed on two separate occasions prior to the donation. Two separate occasions are defined as two ABO samples taken at different times, and sent to the same or different laboratories.

12.3.2 ABO Subtype Identification. The member ~~transplant~~ recovery hospital subtyping a living donor whose initial subtype test indicates the donor to be non-A1 (negative for A1) or non-A1B (negative for A1B), must ~~complete~~ ensure a second determination test is performed prior to donation to assess the accuracy of the result. Blood samples for subtype testing must be taken on two separate occasions, defined as two samples taken at different times and sent to the same or different laboratories. Samples tested must not be taken after a blood transfusion. When the initial and second determination subtypings are the same result, the result can be used to determine transplant compatibility with the intended recipient or any other potential recipient (e.g., in a paired exchange program or allocation of non-directed donor). If the results do not indicate the same subtype, the donor must be allocated based on the primary blood type, A or AB.

To read the complete policy language visit optn.transplant.hrsa.gov or www.unos.org. From the OPTN website, select the "Policy Management" tab, then select "Policies." From the UNOS website, select "Policies" from the "I am looking for:" box in the upper left hand corner.

Affected Policy Language:

3.7.6.3 Reporting Data for Candidates Who Receive Lung Allocation Scores (LAS)

When registering a candidate who is at least 12 years of age for lung transplantation, transplant programs must report to the OPTN Contractor clinical data corresponding to the covariates shown in Tables 1 and 2 in Policy 3.7.6.1.1. Data reported upon registering the candidate must be no more than six months older than the registration date. The transplant program must maintain source documentation for the reported data in the candidate's chart.

Except as noted in Policy 3.7.6.3.1, transplant programs must report to the OPTN Contractor each element of a candidate's clinical data at every six-month anniversary date. A six-month anniversary date first occurs six months after the date of initial registration, then every six months after. A covariate's value expires if the covariate's test date is six-months older than the most recent six-month anniversary date. Actual values or estimated values for pulmonary pressures are valid until the transplant program submits new actual values or new estimated values to the OPTN Contractor according to Policy 3.7.6.4.

Transplant programs may determine how often to update clinical data that must be obtained through heart catheterization. However, if a transplant program performs a heart catheterization on the candidate during any six month interval, then it must report the relevant results to the OPTN Contractor. The transplant program must maintain source documentation of all heart catheterization test results in the candidate's chart.

If values for certain covariates are missing, expired, or below a threshold as defined by Table 5, 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 5 lists the normal and least beneficial values that will be substituted.

Table 5
Data Substituted for Missing, Expired, or Below Threshold Actual Values in Calculating the LAS

If this covariate's value is missing, expired, or below the threshold value:	**Then the LAS calculation will use this substituted value:**
Bilirubin~~: current~~	~~1.0~~ 0.7 mg/dL if the actual value is missing, expired, or less than ~~1.0~~ 0.7 mg/dL
Body mass index (BMI)	100 kg/m^2 if the actual value is missing or expired
Cardiac index	3.0 L/min/m^2 if the actual value is missing
Central venous pressure (CVP)	5 mm Hg if the actual value is missing or less than 5 mm Hg
Continuous mechanical ventilation	No mechanical ventilation in the waiting list model if the actual value is missing or expired Continuous mechanical ventilation in the post-transplant model if the actual value is missing or expired
Creatinine: serum	0.1 mg/dL in the waiting list model if the actual value is missing or expired 40 mg/dL in the post-transplant model for candidates at least 18 years of age if the actual value is missing or expired 0 mg/dL in the post-transplant model for candidates less than 18 years of age if the actual value is missing or expired
Diabetes	No diabetes if the actual value is missing or expired
Forced vital capacity (FVC)	150% for Group D if the actual value is missing or expired, according to Policy 3.7.6.1.2(d)
Functional status	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 model if the actual value is missing or expired
Oxygen needed at rest	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 model if the actual value is missing or expired
PCO_2~~: current~~	40 mm Hg if the actual value is missing, expired, or less than 40 mm Hg
Pulmonary artery (PA) systolic pressure	20 mm Hg if the actual value is missing or less than 20 mm Hg
Six minute walk distance	4000 feet in the waiting list urgency model if the actual value is missing or expired 0 feet in the post-transplant survival model if the actual value is missing or expired

Programs are permitted to enter a medically reasonable estimated value if a test needed to obtain an actual value for a variable cannot be performed due to the medical condition of a candidate. Before entering such estimated values, programs must receive approval from the Lung Review Board, which will determine whether the estimated values are appropriate. Estimated values will remain valid until those values are either updated with an actual value, or a new estimated value is entered according to Policy 3.7.6.4.

To read the complete policy language visit optn.transplant.hrsa.gov or www.unos.org. From the OPTN website, select the "Policy Management" tab, then select "Policies." From the UNOS website, select "Policies" from the "I am looking for:" box in the upper left hand corner.