

**OPTN/UNOS Thoracic Organ Transplantation Committee**  
**Report to the Board of Directors**  
**June 25-26, 2012**  
**Richmond, VA**

**Summary**

**I. Action Item For Board Consideration**

- The Board is asked to approve changes to Policies 3.7.3 (Adult Candidate Status) and 3.7.4 (Pediatric Candidate Status). The proposed changes include: 1) technical edits to policy; and 2) requirement that heart transplant programs record in UNet<sup>SM</sup> changes to a heart transplant candidate's status or criterion within 24 hours. (Item 1, page 2)

**II. Other Significant Items**

- The Committee plans to submit the following proposals for public comment in September, 2012: 1) changes to the pediatric heart medical urgency criteria for Status 1A and Status 1B; 2) lowering of isohemagglutinin titer level for certain candidates willing to accept ABO-incompatible heart transplants; 3) elevating the allocation priority of candidates willing to receive ABO-incompatible heart offers; and, 4) disallowing registration of candidates in utero on the waiting list. (Item 2, Page 8)
- The Committee will work with the Membership and Professional Standards Committee to remove the heart-lung program requirement from the bylaws. There are currently bylaws for heart-lung transplant programs but not for kidney-pancreas or liver-intestine transplant programs. (Item 3, Page 8)
- The Committee continues to emphasize that it no longer wants thoracic transplant programs to prepare for submission the following waiting time reinstatement requests: adding waiting time accrued for a previous thoracic transplant to a current thoracic transplant waiting time. (Item 4, Page 9)
- The Committee voted to modify a question asked on the waiting list removal page that refers to a heart or heart-lung candidate's mechanical circulatory support device (MCSD) history. The question will be revised so that it is clear that transplant programs should report extracorporeal membrane oxygenation history as well as any other MCSDs implanted prior to the candidate's transplant. In addition, the Committee voted to modify the ECMO cannulation site data collected on the waiting list removal page. (Item 5, Page 11)

**OPTN/UNOS Thoracic Organ Transplantation Committee**  
**Report to the Board of Directors**  
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**Mark L. Barr, M.D. - Chair**

The Thoracic Organ Transplantation Committee (Committee) met by telephone and Internet on December 6, 2011, and May 8, 2011. During both of these meetings, the Committee discussed the policy or bylaw proposals to provide relevant commentary. This commentary is in sponsoring committees' briefing papers, and therefore, not included in this report. The following is the Committee's deliberations that occurred in Chicago, Illinois on March 20, 2012.

**1. Plain Language Modifications to the Adult and Pediatric Heart Allocation Policies, Including the Requirement of Transplant Programs to Report in UNet<sup>SM</sup> a Change in Criterion or Status within Twenty-Four Hours of that Change**

The Committee reviewed comments submitted by the public, OPTN/UNOS regions, and OPTN/UNOS committees to this policy proposal. The public and the OPTN/UNOS regions voted in favor of the policy revisions. Three committees voted in favor of the proposal and the remaining committees did not comment. The Committee voted in favor of the following resolution for submission to the Board of Directors for its review in June 2012: 28-supported; 0-opposed; and, 0-abstained. (See **Exhibit A** for policy brief.)

**\*\*RESOLVED, that Policies 3.7.3 (Adult Candidate Status) and 3.7.4 (Pediatric Candidate Status) shall be modified as set forth below, pending programming in UNet<sup>SM</sup>:**

**3.7.3 Adult Candidate Status.**— ~~Each candidate awaiting heart transplantation is assigned~~receives a status code ~~which corresponds~~ corresponding to ~~how medically urgent it is that the candidate's medical urgency receive~~ afor transplant. ~~Medical urgency is assigned to a heart transplant candidate who is greater than or equal to 18 years of age at the time of listing as follows~~A heart transplant candidate at least 18 years of age at the time of listing receives a status code as follows:

Status Definition

**Status 1A** A candidate listed as Status 1A is admitted to the listing transplant center hospital (with the exception for a 1A(b) candidates) and has at least one of the following devices or therapies in place:

- (a) Mechanical circulatory support for acute hemodynamic decompensation that includes at least one of the following:
  - (i) left and/or right ventricular assist device implanted  
Candidates listed under this criterion, may be listed for 30 days at any point after being implanted as Status 1A once the treating physician determines that they are clinically stable. Admittance to the listing transplant center hospital is not required.
  - (ii) total artificial heart;
  - (iii) intra-aortic balloon pump; or
  - (iv) extracorporeal membrane oxygenator (ECMO).

Qualification for Status 1A under criterion 1A(a)(ii), (iii) or (iv) is valid for 14 days and must be recertified by an attending physician every 14 days from the date of the candidate's initial listing as Status 1A to extend the Status 1A listing.

A candidate with a total artificial heart who has been discharged from the listing hospital may be listed as Status 1A for 30 days at any point in time after the discharge.

- (b) Mechanical circulatory support with objective medical evidence of significant device-related complications, such as thromboembolism, device infection, mechanical failure or life-threatening ventricular arrhythmias. A transplant center can report a complication not listed here. The report of an “other” complication will result in a review by the respective heart regional review board. (Candidate sensitization is not an appropriate device-related complication for qualification as Status 1A under this criterion. The applicability of sensitization to thoracic organ allocation is specified by Policy 3.7.1.1 (Exception for Sensitized Candidates).)

Admittance to the listing center transplant hospital is not required. Qualification for Status 1A under this criterion is valid for 14 days and must be recertified by an attending physician every 14 days from the date of the candidate's initial listing as Status 1A to extend the Status 1A listing.

- (c) Continuous Mechanical ventilation. Qualification for Status 1A under this criterion is valid for 14 days and must be recertified by an attending physician every 14 days from the date of the candidate's initial listing as Status 1A to extend the Status 1A listing.
- (d) Continuous infusion of a single high-dose intravenous inotrope or multiple intravenous inotropes, in addition to continuous hemodynamic monitoring of left ventricular filling pressures.

Qualification for Status 1A under this criterion is valid for 7 days and may be renewed for an additional 7 days for each occurrence of a Status 1A listing under this criterion for the same candidate. The OPTN contractor shall maintain in the heart status justification form in UNet<sup>SM</sup> a list of the specific inotropes and doses approved by the Board of Directors to be compliant with this criterion.

### **Status 1A by -Exception**

A candidate who does not meet ~~criteria~~criterion (a), (b), (c), or (d) may nevertheless be Status 1A upon application by his or her transplant physician. The transplant physician must justify~~and justification~~ to the applicable Regional Review Board ~~that why~~ the candidate is considered, using acceptable medical criteria, to have an urgency and potential for benefit ~~comparable to that of~~as other candidates in Status 1A~~this status as defined above~~. The justification must be for a candidate admitted to his or her listing transplant center hospital and must include a rationale for incorporating the exceptional case as part of Status 1A~~the status criteria~~. The justification must be reviewed and approved by the Regional Review Board. Timing of the review of these cases, whether prospective or retrospective, will be left to the discretion of each Regional Review Board. ~~A report of the decision of the Regional Review Board and the basis for it shall be forwarded for review by the Thoracic Organ~~

~~Transplantation Committee to determine consistency in application among and within Regions and continued appropriateness of the candidate status.~~

A candidate's listing under this exceptional provision is valid for 14 days. Any further extension of the Status 1A listing ~~under this criterion by exception~~ requires prospective review and approval by a majority of the Regional Review Board Members. If Regional Review Board approval is not given, the candidate's transplant physician may list the candidate as Status 1A, subject to automatic referral to the Thoracic Organ Transplantation Committee. A report of the decision of the Regional Review Board and the basis for it shall be forwarded for review by the Thoracic Organ Transplantation ~~Committee and Membership and Professional Standards Committees to determine consistency in application among and within Regions and continued appropriateness of the candidate status criteria.~~ The Thoracic Organ Transplantation Committee may refer the case to the Membership and Professional Standards Committee.

### **Submission of Status 1A Justification Form**

A completed Heart Status 1A Justification Form must be submitted ~~to~~ in UNet<sup>SM</sup> in order to list a candidate as Status 1A, or extend his or her listing as Status 1A in accordance with the criteria listed above. When a candidate's time at Status 1A expires, the candidate will automatically be classified as Status 1B ~~unless the attending physician recertifies the candidate's qualification for a Status 1A criterion. Note: This~~ The automatic downgrade will not require submission of a Status 1B Justification Form. The attending physician must classify the candidate as Status 2 or 7 if the candidate's medical condition does not qualify for Status 1A or Status 1B.

### **Status 1B**

A candidate listed as Status 1B has at least one of the following devices or therapies in place:

- (aa) left and/or right ventricular assist device implanted; or
- (bb) continuous infusion of intravenous inotropes.

A candidate with a total artificial heart who has been discharged from the listing hospital may be listed as Status 1B at any point in time after the discharge.

### **Status 1B- by Exception**

A candidate who does not meet the criteria for Status 1B may nevertheless be ~~assigned to such status~~ listed as Status 1B upon application by his or her transplant physician. The transplant physician must and justification justify to the applicable Regional Review Board ~~that why~~ the candidate is considered, using ~~accepted~~ acceptable medical criteria, to have an urgency and potential for benefit ~~comparable to that of~~ as other Status 1B candidates ~~in this status as defined above.~~ The justification must include a rationale for incorporating the exceptional case as part of Status 1B ~~the status criteria.~~ A report of the decision of the Regional Review Board and the basis for it shall be forwarded for review by the Thoracic Organ Transplantation ~~Committee and Membership and Professional Standards Committees to determine consistency in application among and within Regions and continued appropriateness of the candidate status criteria.~~ The Thoracic Organ Transplantation

Committee may refer the case to the Membership and Professional Standards Committee.

**Submission of Status 1B Justification Form**

A completed Heart Status 1B Justification Form must be submitted ~~to~~in UNet<sup>SM</sup> in order to list a candidate as Status 1B.

**Status 2** A candidate who does not meet the criteria for Status 1A or 1B is listed as Status 2.

**Status 7** A candidate listed as Status 7 is considered temporarily unsuitable to receive a thoracic organ transplant.

**Change in Status 1A or 1B Criterion or Eligibility**

If a change in the candidate's medical condition makes the criterion used to justify a candidate's Status 1A or 1B no longer accurate, the transplant program must report the accurate information in UNet<sup>SM</sup> within 24 hours of the change in medical condition.

~~Prior to downgrading any candidates upon expiration of any limited term for any listing category, the OPTN contractor shall notify a responsible member of the relevant transplant team.~~

**3.7.4 Pediatric Candidate Status.** ~~Each candidate awaiting heart transplantation is assigned receives a status code which corresponds~~corresponding to how medically urgent it is that the candidate's medical urgency for receive a transplant. Medical urgency is assigned to a heart transplant candidate who is less than 18 years of age at the time of listing as follows: Pediatric heart transplant candidates who have not received a heart transplant remain on the Waiting List at the time of before their 18<sup>th</sup> birthday without receiving a transplant, shall continue to qualify for medical urgency status based upon the criteria set forth in on Policy 3.7.4. A heart transplant candidate who is less than 18 years of age at the time of listing receives a status code as follows:

Status Definition

**Status 1A** A candidate listed as Status 1A meets at least one of the following criteria:

- (a) Requires assistance with a ventilator;
- (b) Requires assistance with a mechanical assist device (e.g., ECMO);
- (c) Requires assistance with a balloon pump;
- (d) A candidate less than six months old with congenital or acquired heart disease exhibiting reactive pulmonary hypertension at greater than 50% of systemic level. Such a candidate may be treated with prostaglandin E (PGE) to maintain patency of the ductus arteriosus;
- (e) Requires infusion of high dose ~~(e.g., dobutamine > / = 7.5 mcg/kg/min or milrinone > / = .50 mcg/kg/min)~~ or multiple inotropes ~~(e.g., addition of dopamine at > / = 5 mcg/kg/min)~~ (The OPTN contractor shall maintain in the heart status justification form in UNet<sup>SM</sup> a list of the specific inotropes and

doses approved by the Board of Directors to be compliant with this criterion.); or,

- (f) A candidate who does not meet the criteria specified in (a), (b), (c), (d), or (e) may be listed as Status 1A if the candidate has a life expectancy without a heart transplant of less than 14 days, such as due to refractory arrhythmia. Qualification for Status 1A under this criterion is valid for 14 days and may be recertified by an attending physician for one additional 14-day period. Any further extension of the Status 1A listing under this criterion requires a conference with the applicable Regional Review Board. If Regional Review Board approval is not given, the candidate's transplant physician may list the candidate as Status 1A, subject to automatic referral to the Thoracic Organ Transplantation Committee. A report of the decision of the Regional Review Board and the basis for it shall be forwarded for review by the Thoracic Organ Transplantation Committee. The Thoracic Organ Transplantation Committee may refer the case to the Membership and Professional Standards Committee.

Qualification for Status 1A under criteria (a) through (e) is valid for 14 days and must be recertified by an attending physician every 14 days from the date of the candidate's initial listing as Status 1A to extend the Status 1A listing.

#### **Submission of Status 1A Justification Form**

~~For all pediatric candidates listed as Status 1A, a completed Heart Status 1A Justification Form must be received on UNet<sup>SM</sup> in order to list a candidate As as Status 1A, or extend their listing as Status 1A in accordance with the criteria listed above in Policy 3.7.4. Candidates who are listed as Status 1A will automatically revert back to Status 1B after 14 days unless these candidates are re-listed on UNet<sup>SM</sup> as Status 1A by an attending physician within the time frames described in the definitions of status 1A(a)-(e) above~~

A completed Heart Status 1A Justification Form must be submitted in UNet<sup>SM</sup> in order to list a candidate as Status 1A, or extend his or her listing as Status 1A in accordance with the criteria listed above in Policy 3.7.4. When a candidate's time at Status 1A expires, the candidate will automatically be classified as Status 1B. The attending physician must classify the candidate as Status 2 or 7 if the candidate's medical condition does not qualify for Status 1A or Status 1B.

#### **Status 1B**

A candidate listed as Status 1B meets at least one of the following criteria:

- (a) Requires infusion of low dose single inotropes ~~(e.g., dobutamine or dopamine < / =7.5 mcg/kg/min)~~(The OPTN contractor shall maintain in the heart status justification form in UNet<sup>SM</sup> a list of the specific inotropes and doses approved by the Board of Directors to be compliant with this criterion.);
- (b) Less than six months old and does not meet the criteria for Status 1A; or
- (c) Growth failure *i.e.*, ~~+~~less than 5<sup>th</sup> percentile for weight and/or height, or loss of 1.5 standard deviations of expected growth

(height or weight) based on the National Center for Health Statistics for pediatric growth curves.

Note: This criterion defines growth failure as either < 5<sup>th</sup> percentile for weight and/or height, or loss of 1.5 standard deviation score of expected growth (height or weight). The first measure looks at relative growth as of a single point in time. The second alternative accounts for cases in which a substantial loss in growth occurs between two points in time. –Assessment of growth failure using the standard deviation score decrease can be derived by, first, measuring (or using a measure of) the candidate’s growth at two different times, second, calculating the candidate’s growth velocity between these times, and, third, using the growth velocity to calculate the standard deviation score (*i.e.*, (candidate’s growth rate - mean growth rate for age and sex) divided by standard deviation of growth rate for age and sex).

### **Status 1B by Exception**

A candidate who does not meet the criteria for Status 1B may be listed as Status 1B upon application by his transplant physician to the applicable Regional Review Board. The transplant physician must justify why the candidate is considered, using acceptable medical criteria, to have an urgency and potential for benefit as other candidates listed as Status 1B. The justification must include a rationale for incorporating the exceptional case as part of Status 1B. A report of the decision of the Regional Review Board and the basis for it shall be forwarded for review by the Thoracic Organ Transplantation Committees. The Thoracic Organ Transplantation Committee may refer the case to the Membership and Professional Standards Committee.

~~For all pediatric candidates listed as Status 1B, a completed Heart Status 1B Justification Form must be received on UNet<sup>SM</sup> in order to list a candidate as Status 1B. A candidate who does not meet the criteria for Status 1B may nevertheless be assigned to such status upon application by his/her transplant physician(s) and justification to the applicable Regional Review Board that the candidate is considered, using accepted medical criteria, to have an urgency and potential for benefit comparable to that of other candidates in this status as defined above. The justification must include a rationale for incorporating the exceptional case as part of the status criteria. A report of the decision of the Regional Review Board and the basis for it shall be forwarded for review by the Thoracic Organ Transplantation and Membership and Professional Standards Committees to determine consistency in application among and within Regions and continued appropriateness of the candidate status criteria.~~

### **Submission of Status 1B Justification Form**

A completed Heart Status 1B Justification Form must be submitted in UNet<sup>SM</sup> to list a candidate as Status 1B.

### **Status 2**

A candidate who does not meet the criteria for Status 1A or 1B is listed as Status 2.

### **Status 7**

A candidate listed as Status 7 is considered temporarily unsuitable to receive a thoracic organ transplant.

### **Change in Status 1A or 1B Criterion or Eligibility**

If a change in the candidate's medical condition makes the criterion used to justify a candidate's Status 1A or 1B no longer accurate, the transplant program must report the accurate information in UNet<sup>SM</sup> within 24 hours of the change in medical condition.

~~Prior to downgrading any candidates upon expiration of any limited term for any listing category, the OPTN contractor shall notify a responsible member of the relevant transplant team.~~

## **2. Revising the Pediatric Heart Policies**

Dr. Steven Webber, Vice-Chairman of the Committee, provided an update on the activities of the pediatric heart policy working group. This working group includes members of the Heart Subcommittee and Pediatric Transplantation Committee. This working group is:

- Continuing its effort to modify the pediatric heart medical urgency policy
- Discussing to eliminate listing of heart transplant candidates who are *in utero*
- Discussing to modernize the policy on ABO-incompatible heart transplantation to keep pace with current science on the topic
- Revising the eligibility criteria for candidates to receive ABO-incompatible heart transplants
- Revising the priority of ABO-incompatible candidates for pediatric heart allocation

## **3. Remove OPTN and UNOS Bylaws for Heart-Lung Transplant Program**

The Committee reviewed the following recommendations from the OPTN Contractor's Membership Department:

- Dissolve the single OPTN approval requirements for heart-lung transplant program
- Eliminate the heart-lung program status
- Endorse a requirement that any organ or combination of organs can be listed for, allocated to, and transplanted if the transplant hospital has OPTN/UNOS transplant program approval for any transplanted organ

These modifications would not affect any heart, lung, or heart-lung transplant program personnel requirements. An OPTN-approved heart-lung program must be approved as a heart transplant program and a lung transplant program. The heart-lung transplant program designation is the only such designation for combined organ transplant programs. For example, there are no program bylaws for a program that performs a kidney-pancreas transplant.

In January, 2012, the UNOS Chrysalis project team made clear its intent to develop an efficient system for listing combined organ transplant candidates. The solution is to eliminate the combined heart-lung program. With this solution, a candidate in need of a heart-lung transplant would be registered for a heart transplant and a lung transplant. These candidates would be eligible to receive deceased donor heart-lung offers if the programs making these registrations are approved by the MPSC. For example, a kidney-pancreas candidate is registered on the kidney transplant program waiting list and the pancreas transplant program waiting list. When registered for both organs, UNet<sup>SM</sup> recognizes that the candidate is need of both organs and if both programs are approved by the MPSC, then the candidate will be able to receive those multiple organ offers. This "bundling" of individual organ program approvals is efficient.

The Committee inquired how such bylaw changes would affect any requirements of the US Centers for Medicare and Medicaid Services (CMS). CMS requires a heart-lung designation for such a program to function. HRSA will notify CMS about these bylaw changes. The bylaw proposal will state clearly the OPTN consequences due to this bylaw change, and that this bylaw change will not affect CMS practices.

The Committee supported sponsoring the bylaw proposal, but with the MPSC as co-sponsor: 28-supported; 0-opposed; and, 0-abstained.

#### **4. Revisions to the Waiting Time Modification Policy (Post Public Comment Draft from the Kidney Organ Transplantation Committee)**

On December 6, 2012, the Committee discussed the proposal to clarify requirements for waiting time modification. A summary of the proposed policy change is below:

Current OPTN/UNOS policies for submitting waiting time modification requests are not clear, leading to wasted time for the transplant centers that submit requests, for OPTN Contractor staff who process requests, and for the Committees that review requests. Required documentation is often missing and results in delays for transplant candidates to receive the waiting time that they may be entitled to receive under OPTN policy. With these proposed clarifications, the Committee expects to see fewer submissions of incomplete requests and faster time to implementation of approved requests.

Thoracic transplant programs should not request reinstatement of waiting time accrued for previous thoracic transplants (for their thoracic candidates). The Committee determined that for thoracic candidates, Policy 3.7.13 (see below) applies.

##### **Policy 3.7.13 (Removal of Thoracic Organ Transplant Candidates from Thoracic Organ Waiting Lists When Transplanted or Deceased)**

If a heart, lung, or heart-lung transplant candidate on the Waiting List has received a transplant from a deceased or living donor, or has died while awaiting a transplant, the listing center, or centers if the candidate is multiple listed, shall immediately remove that candidate from all Thoracic Organ Waiting Lists for that transplanted organ and shall notify the OPTN contractor within 24 hours of the event. If the thoracic organ recipient is again added to a Thoracic Organ Waiting List, waiting time shall begin as of the date and time the candidate is relisted.

The Committee accepted the other modifications proposed, and voted in favor of a revised policy that references Policy 3.7.13 for thoracic candidates: 17-supported; 0-opposed; and, 0-abstained.

In February 2012, the Committee reviewed another request to modify a pediatric heart transplant candidate's waiting time to include time accrued waiting for a previous heart transplant. The Committee members questioned voting on this case as they had voted consistently in the past to follow Policy 3.7.13 (see below), and deny the requests. The candidate's pediatric status generated conflicted voting on the case, such that the Committee voted a second time on the same case.

##### **3.7.13 Removal of Thoracic Organ Transplant Candidates from Thoracic Organ Waiting Lists When Transplanted or Deceased.**

If a heart, lung, or heart-lung transplant candidate on the Waiting List has received a transplant from a deceased or living donor, or has died while awaiting a transplant, the listing center, or centers if the candidate is multiple listed, shall immediately remove that candidate from all Thoracic Organ Waiting Lists for that transplanted organ and shall notify the OPTN contractor within 24 hours of the event. If the thoracic organ recipient is again added to a Thoracic Organ Waiting List, waiting time shall begin as of the date and time the candidate is relisted.

On March 20, 2012, the Committee discussed the case and emphasized that regardless of age, Policy 3.7.13 must apply. To accompany this discussion, the Committee again reviewed the modified policy language on submitting waiting time modification requests for candidates seeking time accrued for their previous transplants. The Kidney Transplantation Committee modified Policy 3.2.1.8 (Waiting Time Modification) and submitted the policy modifications for public comment in September 2011.

The Committee reviewed the modified language in December 2011 and stated that it did not want the thoracic community to submit requests to add waiting time, accrued for a previous thoracic transplant, to the current waiting time of thoracic organ transplant candidates.

The Committee reviewed the language below. Text with double underlines denotes information added to the proposed policy after the public comment cycle.

#### **3.2.1.8.1 Permissible Modifications**

Applications for waiting time modifications that meet *any* of the following qualifications must follow the procedures for expedited modifications of waiting time in Policy 3.2.1.8.3 below.

- An error occurred in modifying, removing, or renewing the candidate's waiting list record and the Transplant Program requests a modified waiting time to include time accrued under the previous registration, in addition to any time lost by the error.
- The candidate was removed from the waiting list for medical reasons, other than receiving a transplant, was subsequently relisted for the same organ with the same diagnosis, and the Transplant Program requests a modified waiting time to only include the time accrued under the previous registration without the time interval when the candidate was removed from the waiting list.
- The candidate is waiting for a heart, liver, or lung, needs a second organ, and the Transplant Program requests a modified waiting time for the second organ that includes the waiting time accrued for the first organ.

Applications to modify a candidate's registration date and all other applications for waiting time modifications must follow the procedures for modifications of waiting time in Policy 3.2.1.8.4 below. Additionally, applications must meet any additional requirements stipulated in the organ-specific allocation policies.

#### **3.2.1.8.2 Application**

To apply for a waiting time modification, a candidate's Transplant Program must submit an application to the OPTN Contractor with *all* of the following information:

1. The requested listing date and documentation showing an intent to register the candidate at the requested listing date.
2. That the candidate met applicable waiting time qualifying criteria in the organ specific policies (Policy 3.0 *et seq.*).
3. A corrective action plan, if the application is due to an error.
4. The name and signature of the candidate's physician or surgeon.
5. Signatures indicating agreement from all kidney transplant programs in the OPO. If a signature cannot be obtained from a transplant program, the submitting program must explain the efforts it made to obtain a signature and include any stated reasons for disagreement with the request.

The Committee, generally dissatisfied with the double-underlined text in Policy 3.2.1.8.1, requested that the Kidney Transplantation Committee further revise the policy language, as described below:

- The phrase "needs a second organ" is vague.
- The policy must read such that it prohibits a thoracic transplant program from submitting requests to modify a candidate's waiting time to include time accrued for a previous thoracic transplant.
- The Kidney Transplantation Committee should identify the "other applications for waiting time modifications."

## **5. Removing a Candidate with a Mechanical Circulatory Support Device History**

UNOS staff presented the three issues that have emerged with the following mechanical circulatory support device data collection question on the waiting list removal page:

#### Mechanical Circulatory Support Device Data:

Has the candidate ever had a mechanical circulatory support device implanted?  Yes  No

- Issue 1: Transplant programs frequently do not report data about extracorporeal membrane oxygenation (ECMO)
- Issue 2: Transplant programs report data about device implanted after transplant  
  
(Policy requires that transplant programs remove candidates within 24 hours of transplant. Some transplant centers interpret current language to include devices implanted after transplant, but before removal from the waiting list.)
- Issue 3: Is the list of ECMO cannulation sites complete in the waiting list removal page?

To address issue 1, the Committee voted in favor (24-supported; 0-opposed; and, 0-abstained) of revising the current question (Has the candidate ever had a mechanical circulatory support device implanted?) to read as follows: Has the candidate ever had a mechanical circulatory support device (i.e., LVAD, RVAD, TAH or ECMO) implanted?

To address issue 2, the Committee voted in favor (24-supported; 0-opposed; and, 0-abstained) of adding the following note to the question, “Has the candidate ever had a mechanical circulatory support device (i.e., LVAD, RVAD, TAH or ECMO) implanted?”:

“NOTE: If the candidate was removed from the waiting list for a transplant, only devices implanted prior to transplant should be reported.”

To address issue 3, the Committee voted in favor (25-supported; 1-opposed; and, 0-abstained) of modifying the existing ECMO cannulation site list to read as follows:

- Chest
- Other (neck, central)

There was discussion about whether these changes required public comment. UNOS staff will advise the Committee at a later date.

#### 6. Memorandum from the Policy Oversight Committee (POC): Input on Multi-Organ Allocation Policies

The Committee discussed the following memorandum from the POC, which the Chair of the POC and a member of the Committee, Dr. Stuart Sweet, presented to the group:

The Policy Oversight Committee has been charged with addressing multi-organ allocation policies. Following several meetings held in 2011, the committee is considering policy modifications that would incorporate minimum listing criteria for each organ in circumstances where a patient is being listed for a multi-organ transplant. In addition, the committee is considering expanding beyond the local DSA the zone where multiple organ recipients will take priority. As we continue working on this project, we have identified four main areas for which the committee would benefit from other committees input: Minimum listing criteria, policy ambiguities, ethical principles, and logistical issues.

The POC is seeking your input and would like for your committee to address the following questions:

- 1) For those committees with minimum listing criteria: Do you think the minimum listing criteria issues are resolved for your organ and if so, what are the important principles that were used to get there?
- 2) Are there organ combinations for which minimum listing criteria do not exist but should?
- 3) In order to minimize unnecessary multi-organ transplants, are there adjustments needed to the allocation system that will ensure a candidate who does not receive multiple organs (due to failure to meet minimal listing criteria) could get appropriate priority if subsequent to the transplant of the primary organ he/she develops failure of the second organ?
- 4) Are there logistical issues regarding waiting list management surrounding multi-organ listing and transplant that need to be addressed?
- 5) Are there procurement issues that could be addressed in this process?
- 6) If the concept of lifesaving organ is removed, are there key ethical principles your committee feels should be included in a framework for allocating the second organ based on a balance between equity and utility.

The Committee commented that:

- There are no minimum listing criteria for candidates in need of joint heart-lung transplants;
- There is no need to develop minimum listing criteria for candidates in need of joint heart-lung transplants;
- The transplant community should reconsider the practice of offering deceased donor kidneys to candidates in need of joint heart-kidney, lung-kidney, and liver-kidney transplants; and,
- Its effort to develop a joint heart-lung allocation policy, a draft concept of which is below, addresses the POC's concerns of equity.

*Proposed Policy Constructs for Candidates in Need of a Heart and Lung (Draft)*

“Heart-centric”

Status 1A

- If an OPO offers a heart to a Status 1A heart candidate who also needs a lung transplant, then the OPO will offer both the heart and lung to that candidate unless there is a single or double lung candidate with a lung allocation score greater than 55 (or greater than the actual LAS of the HL candidate if the HL candidate has a LAS value greater than 55) in the local unit or in Zone A.

Status 1B

- If an OPO offers a heart to a Status 1B heart candidate who also needs a lung transplant, then the OPO will offer both the heart and lung to that candidate unless there is a single or double lung candidate with a lung allocation score greater than 45 (or greater than the actual LAS of the HL candidate if the HL candidate has a LAS value greater than 45) in the local unit or in Zone A.

Status 2

- If an OPO offers a heart to a Status 2 heart candidate who also needs a lung transplant, then the OPO will offer both the heart and lung to that candidate unless there is a single or double lung candidate with a lung allocation score greater than 35 (or greater than the actual LAS of the HL candidate if the HL candidate has a LAS value greater than 35) in the local unit or in Zone A.

“Lung-centric”

If the HL candidate has a LAS score greater than 45 and is a Status 2 heart by criteria, the transplant center has the option to list that candidate as a heart Status 1B-exception.

The Committee will submit the above joint heart-lung allocation concept to the POC for its consideration. Finally, the Committee plans to revive its efforts to improve the joint heart-lung allocation policy.

**7. Memorandum from the Membership and Professional Standards Committee (MPSC): Outcomes Review for Congenital Heart Patients**

The Committee discussed the following memorandum from the MPSC:

The Membership and Professional Standards Committee's (MPSC) associated Performance Analysis and Improvement Subcommittee (PAIS) conducts routine reviews of all transplant program performance by monitoring program outcomes and activity levels. The PAIS specifically monitors one-year graft and patient survival rates.

The PAIS evaluates pediatric and adult transplants separately because the factors influencing pediatric graft and patient survival may be different for children than for adults. We are specifically asking for your committee's input regarding how the PAIS should evaluate the adult (>17 years of age) recipients of heart transplants performed at pediatric centers; these adults receive their transplants at these centers, we surmise, because they have congenital heart disease and are long standing patients in these programs and of these physicians.

Because the volume of transplants in these situations is so low, it is often difficult to determine if a clinical issue exists in these facilities. During its meeting in July 2011, the PAIS discussed whether congenital heart patients >17 years of age at pediatric centers should be included in the pediatric program review/outcomes model, rather than evaluating them separately as adults in a separate adult program at that facility as is the current practice. Without the ability to rely on a statistical model, the PAIS is seeking additional guidance and/or discussion regarding the performance of these heart transplant programs.

On behalf of the MPSC, we are requesting that the Thoracic Organ Transplantation Committee discuss the statistical one-year post-transplant outcome analysis of congenital heart transplant recipients >17 years of age during its next meeting, and provide the MPSC with a summary of the final outcome of the discussions. Thank you for your consideration.

The Committee determined that an equitable solution is for the MPSC to associate, in general, outcomes of a transplant recipient with the transplant program that performed the transplant. So, an adult recipient of a heart transplant that was performed at a pediatric transplant program would be evaluated as part of the overall number of transplants performed by that pediatric heart transplant program. A pediatric recipient of a heart transplant that was performed at an adult heart transplant program would be evaluated as part of the overall number of transplants performed by that adult heart transplant program. The Committee requested UNOS staff to provide this commentary and memorandum to the OPTN/UNOS Pediatric Organ Transplantation Committee (Pediatric Committee).

**8. Memorandum from the Pediatric Transplantation Committee: Inactive Priority 1 Lung Candidates Accruing Waiting Time**

The Committee discussed the following memorandum from the Pediatric Committee:

The Pediatric Transplantation Committee (the Committee) requests input from the Thoracic Organ Transplantation Committee on possible policy and programming changes regarding inactive, Priority 1 lung candidates' accrual of waiting time. Pediatric lung candidates accrue Priority 1 waiting time while they are inactive if the candidate was listed as Priority 1 at the time they were inactivated. UNOS staff was concerned about the appropriateness of this waiting time accrual, and asked the Committee to consider if the current programming aligns with the Committee's original intent. UNOS staff provided the Committee with the policy language that

was originally approved at the June 2008 Board of Directors' meeting (enclosed), and reminded it how the current policy language evolved from what was approved in June 2008 to simplify the programming effort while retaining the original intent. One specific change eliminated tallying multiple periods of time at the most urgent status. Instead, as indicated in current policy language, it was agreed that for allocation purposes, "UNet<sup>SM</sup> will only consider the most recent time spent as Priority 1, i.e., UNet<sup>SM</sup> will not tally the time waiting during multiple Priority 1 periods."

The Committee discussed this issue during its September 2011 meeting. During its discussion, the Committee focused on the appropriateness of urgent lung candidates accruing waiting time while listed as inactive. An example repeatedly cited was an urgent candidate that had an infection that would need to be treated prior to transplant. The Committee agreed that inactivating such candidates to treat their temporary condition did not mitigate their urgent need for a lung transplant, and thus their waiting time should not reset. Accordingly, it would be appropriate for these Priority 1 candidates to continue accruing waiting time while temporarily inactive. The Committee did not believe that these inactive Priority 1 candidates should accrue Priority 1 waiting time indefinitely, and suggested a 30-day timeframe (similar to inactive intestinal organ candidates, Policy 3.11.6 (Waiting Time for Intestinal Organ Transplant Candidates in an Inactive Status)).

In response to this suggestion, UNOS staff pointed out that candidates accruing Priority 1 waiting time while inactive seemed to be in conflict with policy 3.7.9 (Time Waiting for Thoracic Organ Candidates), which states:

"Waiting time will not be accrued by candidates awaiting a thoracic organ transplant while they are registered on the Waiting List as inactive, except as specified in Policy 3.7.9.3 (Waiting Time Accrual for Lung Candidates Less than 12 Years of Age)."

The Committee was reminded that the reference to Policy 3.7.9.3 was added when the pediatric lung policy language approved in June 2008 was later modified to simplify the programming effort. This exception was included to accommodate calculating "total waiting time" (which considers the candidate's entire time on the waitlist- active and inactive) to prioritize Priority 2 potential transplant recipients and serve as a tiebreaker for Priority 1 potential transplant recipients. Acknowledging this, the Committee's discussion focused on Policy 3.7.9 and why inactive time could not be accrued for thoracic organs. Again, Committee members cited situations where a lung candidate would be temporarily unsuitable for transplant but still urgently in need.

Committee members commented that instead of inactivating these candidates that are temporarily unsuitable for transplant, organ offers could be refused for them citing refusal code 801 (Candidate ill, unavailable, refused, or temporarily unsuitable). This would prevent a candidate from losing previously accrued Priority 1 time if the programming were modified so that a Priority 1 lung candidate's Priority 1 waiting time would reset upon being inactivated. Other Committee members responded that their transplant programs will always inactivate candidates that are temporarily unsuitable for transplant due to concerns about future audits, specifically to avoid any questions about refusing organ offers for active candidates. Based on this discussion, the Committee recognized that if UNet<sup>SM</sup> programming is modified so that a Priority 1 lung candidate's Priority 1 waiting time would reset upon being inactivated, then the waiting time accrual for these pediatric Priority 1 lung candidates has the potential to vary depending on what transplant hospital is listing the candidate.

Considering all this, the Committee's discussion concluded with a general sentiment that it was appropriate for Priority 1 lung candidates to accrue Priority 1 waiting time while inactive; however, waiting time while inactive should be limited to 30 days. The Committee is particularly interested in the Thoracic Organ Transplantation Committee's input on this matter. Specifically:

Would the Thoracic Organ Transplantation Committee support policy modifications (and the associated programming) that would allow Priority 1 lung candidates to accrue “Priority 1 waiting time” while listed as inactive, up to 30 days?

If not, and considering policy 3.7.9.3 and a candidate whose most recent active prioritization was Priority 1, is it reasonable to consider time during a subsequent inactivation status as part of their “most recent time spent as Priority 1,” as UNet<sup>SM</sup> is currently programmed?

If this is not a reasonable interpretation of the current policy, and considering the situation outlined above where lung candidates’ Priority 1 waiting time could be dependent upon a transplant center’s approach to waitlist management, does the potential variability of Priority 1 waiting time accrual justify policy modifications to facilitate more consistent Priority 1 waiting time accrual (and to more clearly reflecting the current programming)?

The Committee recommended the Pediatric Transplantation Committee consider modifying the pediatric lung policy and its programming so that: 1) Priority 1 candidates are able to retain their previously accrued Priority 1 waiting time while they are active as Priority 1; and 2) Priority 1 candidates cannot accrue Priority 1 waiting time while inactive.

## **9. Letter from the American Society for Histocompatibility and Immunogenetics (ASHI): DP Typing**

The Committee discussed a letter from ASHI requesting mandatory HLA-DP typing for all deceased donor organs offered for transplant. (An excerpted image of the letter is below.) ASHI requested the Committee and the Histocompatibility Committee require DP typing for all deceased donor organs recovered for transplant, but allow some time for all histocompatibility laboratories to comply with such requirement. Current policy for providing HLA-typing for all thoracic organ offers, if requested by the transplant program receiving the organ offer, does not mandate DP-typing for thoracic organs offered. Policy requires DP typing of a thoracic organ offered, if requested by the transplant program, but only if the organ procurement organization (OPO) offering the thoracic organ can provide this typing. If the OPO cannot provide it, because its affiliated histocompatibility laboratory lacks technology for performing the DP-typing test, then the OPO does not need to provide this requested information.

The Committee appreciates ASHI’s request, and will work with the Histocompatibility Committee to comply with this request when all histocompatibility laboratories can perform DP typing.

Most laboratories do not perform routine DP typing on deceased donors, only doing so if the patient has DP antibodies. Additionally, there were laboratories that offered only cytotoxic HLA-typing until just recently, when the mandate to convert to molecular methods was published. These laboratories have struggled to gain the competency and proficiency to be accredited in this area. They would be further disadvantaged by having to develop the intermediate to high resolution capabilities necessary to type for DP with the current reagents. Limited personnel, time for validation and training, as well as enrolling in and participating in proficiency testing, would make this a lengthy and costly process for these laboratories. The disadvantage to those laboratories already offering DP typing for their OPO is that additional time and personnel have to be provided to perform it upon request. This will place stress on personnel to return to the laboratory to do additional typing and will negatively impact allocation by delaying it another 2-4 hours.

Since DP antibodies are being found with increased frequency and have a more documented history of affecting graft survival than do those for C locus, which is already typed for, it is suggested that UNOS consider requiring all deceased donors to be DP typed by the OPO HLA laboratories in the future, rather than having a piecemeal approach. In making DP typing universal, you might then consider a longer implementation period (perhaps a year) before the proposal goes into effect, in order to allow all laboratories to comply to the requirement. This proposed approach would properly address the concerns described above. Once DP typing for organ allocation is operational, the last hurdle is supplying that information to UNOS. The lack of entry screens to specifically list DP antigens can be obviated by simply uploading the laboratory’s final typing report when the donor is registered, until such time that they may be entered into the UNOS system.

## 10. Update on the Activities of the Heart Subcommittee

Dr. Mark J. Zucker, who is the Chair of the Heart Subcommittee, provided an overview of the activities of the Heart Subcommittee. The Heart Subcommittee continues to:

- *Discuss improvements to the current adult medical urgency statuses*

Current adult heart medical urgency policy no longer appears to address the clinical heterogeneity and disease severity of candidates implanted with mechanical circulatory support devices, or candidates without such device implants but who are in dire need for transplants.

Current policy does not accommodate the post-transplant outcome of adult heart transplant recipients.

- *Revise the device-related infection and complication section in the adult heart policy*

Revisions to this section of policy may result in fairer distinctions between Status 1A listings of adult candidates who have dire device-related infections or complications and those whose infections or complications are not as severe.

During its February, 2012 meeting, the Heart Subcommittee recommended the extension of the interim policy for outpatient candidates implanted with total artificial hearts (TAH) until December 1, 2013. The Committee argued that the interim policy should be a 'permanent' policy until the development of a new adult heart policy. To make the interim policy permanent, the Committee inquired if it needed to distribute this policy intent for public comment. UNOS staff will inquire and provide guidance to the Committee at a later date.

The Committee, in the meantime, will continue its effort to revise criterion b, which is part of the Status 1A medical urgency criteria for adult heart transplant candidates. Adult heart transplant candidates with device related infections or complications have poorer waiting list outcomes than candidates who are listed as Status 1A by other criteria (but, with the exception of those requiring continuous mechanical ventilation).

Dr. Joe Rogers, a member of the Heart Subcommittee, read a draft of the proposed criterion b modifications to the Committee. Dr. Rogers and a few members from the Heart Subcommittee have worked on adding the following topics to criterion b in an effort to better identify those candidates with severe device-related infections or complications that should be listed as Status 1A:

- Aortic insufficiency
- Hemolysis
- Pump thrombosis
- Pump-related local or systemic infection
- Device malfunction
- Mucosal bleeding
- Right heart failure
- Ventricular tachycardia

To be listed as Status 1A for a condition listed above, the adult heart transplant candidate will need to meet certain criteria, which this small working group continues to make final. When the criterion b modification is in its final draft version, Dr. Rogers will present it to the Heart Subcommittee in June 2012.

UNOS staff presented the following data analysis: *Adult Heart Status 1A Candidates Criteria and Outcomes*. These data were requested by the Heart Subcommittee at its February 2012 meeting. The

Committee requested that the Heart Subcommittee discuss these data in detail at the next Heart Subcommittee meeting.

Finally, the Committee discussed again the possibility of developing a heart allocation score. Several Committee members supported an effort to begin this development right away, and others commented about the length of time required to develop such a score. UNOS staff encouraged the Committee to develop a heart allocation score, as it will more likely address the national diversity in practices to treat candidates awaiting heart transplants and address the post-transplant benefit. Discussions of the Heart Subcommittee thus far have focused on the varying hospital practices in treating candidates with device implants. These discussions have clearly conveyed the frustrations of thoracic clinicians on the Committee about the current adult heart medical urgency policy. Conversations about modifying the existing policy language have been informative, but have not yielded a new medical urgency policy. A new medical urgency policy, however, may not be the policy path to take as it would continue the therapy-based approach in identifying candidates who are in dire need for heart transplants. A therapy-based approach focuses on the individual patient and not the group, which is contrary to public health policy.

## **11. Activities of the Lung Subcommittee**

Dr. Stuart Sweet, Chair of the Lung Subcommittee, provided an update on the activities of the Lung Subcommittee, which include:

- Distribution of the proposal to revise the Lung Allocation Score system for public comment (March 16, 2012)
- Discussions to evaluate the nature and quality of cases submitted to and reviewed by, respectively, the Lung Review Board
- Discussions of ex vivo lung perfusion
- Discussion of the feasibility of ABO-incompatible lung transplantation among infants and small children
- Discussions to improve policy on joint heart and lung allocation

## **12. Review an LAS Exception Case: Lung Review Board Did Not Act in the Time Allotted**

The Committee reviewed a case for which the Lung Review Board (LRB) did not reach a majority decision. The candidate received a transplant based on the requested Lung Allocation Score. Therefore, pursuant to Policy 3.7.6.4 (Lung Candidates with Exceptional Cases), the candidate received the Lung Allocation Scores requested and the Committee deliberated on the case.

[...]If the Lung Review Board has not completed its review of an initial request or an appeal within seven (7) calendar days of receiving it, then the candidate will receive the requested Lung Allocation Score, diagnosis, or estimated value, and the request or appeal will be forwarded to the Thoracic Organ Transplantation Committee for further review.[...]

The Committee reviewed the case but did not vote on it. Policy does not require the Committee to vote on the case. The Committee commented that a case deliberation is moot, because the candidate received a transplant.

The Committee reemphasized its interest in examining the trends in the LRB practices and trends in the lung transplant community's case submissions. The Committee stated again the need to modify the process for establishing a quorum for case votes. The Committee recommended again the need to add several alternate members to the LRB, including an LRB vice-chair.

UNOS staff informed the Committee that there exists an internal effort to create uniformity in review board practices across the organ types that have them.

### **13. Addressing Candidates on Extracorporeal Membrane Oxygenation (ECMO)**

A Committee member requested the Committee discuss how the Lung Allocation Score (LAS) System should accommodate candidates placed on ECMO. The LAS system neither includes ECMO as a covariate in the waiting list or post-transplant survival models nor does it capture data in UNet<sup>SM</sup>. A candidate placed on ECMO is likely to have a high LAS. However, the LAS system does not reflect this candidate's true lung function. Some transplant programs may identify candidates placed on ECMO as needing continuous mechanical ventilation.

The number of candidates being placed on ECMO is increasing. Therefore, the Committee plans to develop a mechanism for a transplant program to request a higher LAS, through the Lung Review Board, for a candidate placed on ECMO. It is likely that once this mechanism is in place, lung transplant clinicians will receive guidance similar to that for pulmonary hypertension candidates on submitting exception requests for candidates placed on ECMO.

The Lung Subcommittee will further discuss this topic at its next meeting.

### **14. Program Specific Reports (PSR): Report of the February, 2012 Consensus Conference**

Dr. Maryam Valapour with the SRTR presented the results of the PSR Consensus Conference. This consensus conference focused on answering the following questions:

1. What is the SRTR's mandate?
2. Who uses PSRs and why?
3. Are there unintended consequences?
4. What can we learn from others?
5. What statistical methods should we use?
6. How should we adjust for risk?
7. What outcomes should we use?
8. What data should we collect?

Various groups evaluate data in the PSRs: CMS, MPSC, private insurance companies, transplant programs, transplant candidates, and the public. The MPSC initiates evaluations of transplant programs when their observed outcome rates are lower than their expected rates.

PSRs provide improvement opportunities for transplant programs, but several Committee members continued to be concerned by the use of these data for payment purposes by insurance companies; however, such use is likely not going to cease.

The SRTR plans to install a formal process by which organ-specific committees evaluate the covariates comprising the various statistical models that generate PSRs. The SRTR's Scientific and Technical Advisory Committee's task is to improve the PSRs based on recommendations provided at the February, 2012 consensus conference.

### **15. Activities of the Policy Oversight Committee**

Dr. Stuart Sweet, Chair of the Policy Oversight Committee (POC), provided an update on the activities of the POC, which include:

- Multi-organ allocation project
- Review of projects proposed by the OPTN committees
- Review of public comment proposals
- Make recommendations to the Executive Committee about projects and proposal

## 16. Responses to Public Comment Proposals

The Committee reviewed and provided responses to several public comment proposals on December 6, 2011, March 20, 2012, and May 8, 2012. The Committees responses are presented below in the chronology discussed.

*Proposal to Eliminate the Use of an “Alternate” Label when Transporting Organs on Mechanical Preservation Machines and to Require the OPTN Distributed Standardized Label [Sponsored by the Organ Procurement Organization (OPO) Committee]*

On December 6, 2011, the Organ Procurement Organization Committee’s Vice-Chairman presented the proposed policy concepts. The Committee did not voice concerns or questions about the proposed policy, and voted in favor of it: 15-supported; 0-opposed; and, 0-abstained.

*Proposal to Change the Term “Consent” to “Authorization” Throughout Policy When Used in Reference to Organ Donation [Sponsored by the Organ Procurement Organization Committee]*

On December 6, 2011, the Organ Procurement Organization Committee’s Vice-Chairman presented the proposed policy concepts. A summary of the proposed policy change follows.

The proposed modification will change the term "consent" to "authorization" throughout policy when used in reference to deceased organ donation. Currently, OPTN policy uses the term “consent” to describe the act of making an anatomical gift. However, the public associates “consent” with the medico-legal concept of “informed consent” through which physicians must give patients all the information they need to understand the risks, benefits, and costs of a particular medical treatment.

In the context of organ/tissue/eye donation after death, this blending of terms leads to misunderstandings about the act of donation that could hinder our national goal of increasing organ/tissue/eye donation and transplantation. The OPO community has responded to this circumstance by changing the donation terminology from “consent” to “authorization.” This change focuses attention on the altruistic act of donation and reinforces the fact that donation after death does not involve medical treatment.

One member queried how the proposed policy change affects donation after cardiac death. The proposed change in terminology only applies to all deceased donation. Thus, a patient consenting to donate his or her organs, prior to death, is participating in an informed consent process. Currently, the term “consent” is used in living and deceased donation. Informed consent can only be given by a living individual. In deceased donation, the donor’s family member authorizes (where appropriate and according to the wishes of the decedent) the donation of the decedent’s organs. Given this explanation, the Committee voted in favor of the proposed policy change: 17-supported; 0-opposed; and, 0-abstained. (The difference in this voting tally reflects the participation of additional voting members by phone.)

*Proposal to Modify the Imminent and Eligible (I & E) Neurological Death Data Reporting Definitions [Sponsored by the Organ Procurement Organization Committee]*

On May 8, 2012, the Organ Procurement Organization Committee’s Vice-Chairman presented the proposed policy concepts. Through clarified definitions, the proposed changes attempt to improve reporting of imminent and eligible deaths. The proposed changes neither not change the deceased donor organ offer process nor transplant program behavior. The Committee voted in favor of the proposed changes: 15-supported; 0-opposed; and, 0-abstained.

On December 6, 2011, the Committee discussed the proposal to clarify and improve the variance policies. The proposed policy revisions do not change the intent of the variance policies or the existing variances. The Committee did not voice concerns or questions about the proposed variance policy changes and voted in favor of it: 16-supported; 0-opposed; and, 0-abstained.

*Proposed Revisions to and Reorganization of Policy 6.0 (Transplantation of Non-Resident Aliens), Which Include Changes to the Non-Resident Alien Transplant Audit Trigger Policy and Related Definitions [Sponsored by the Ethics Committee and the Ad Hoc International Relations Committee (AHIRC)]*

On December 6, 2011, the Committee members discussed the proposal and expressed diverging thoughts on the proposed review policy. The Chair of the Committee emphasized that the review section of the proposal to obtain information that will help the AHIRC to better understand the activity of transplant programs using the definitions itemized in the policy and to try to better clarify what is the actual extent of transplant tourism in the US.

The proposed review policy reads:

**6.3 Audit and Reporting of Non-US Citizens/Non-US Residents.** As a condition of membership, all member transplant centers agree to allow the Ad Hoc International Relations Committee to review and, at its discretion, audit all member transplant center activities pertaining to transplantation of non-US residents/non-US citizens. At member transplant centers where non-US residents/non-US citizens are listed for transplant, the Ad Hoc International Relations Committee shall review the circumstance and justification for listing any non-US resident/non-US citizen traveling to the United States for transplant.

The PowerPoint slide presentation describing this review policy states that the AHIRC's review does not entail an automatic referral to the OPTN/UNOS Membership and Professional Standards Committee (MPSC). This statement, which was intended to alleviate anxiety about the review process during its discussion, created confusion as some members of the Committee considered this statement to be part of the proposed review policy language. The language about MPSC referral is not in the proposed review policy, but the MPSC reviews all policy violations. However, as written, a transplant program cannot violate the proposed review policy by transplanting non-US residents/non-US citizens. The OPTN does not have a policy that forbids medical tourism.

Several members commented favorably about the AHIRC's and Ethics Committee's effort to promote transparency in transplantation, which is a goal of the proposed revisions to Policy 6, but expressed the following comments and questions about the review policy:

- 1) What constitutes the review process? What will be the impact of the proposed review on programs? When would a transplant in a non-US residents/non-US citizen be justified? The proposed review policy should state clearly what constitutes an acceptable an unacceptable transplant among non-US residents/non-US citizens. Some members of the Committee expressed concern about approving the proposed review policy without knowing details about the process and its effect.

The AHIRC's and the OPTN Contractor's process for conducting, managing, and reporting data due to the review of transplants among non-US residents/non-US citizens has not been developed. The AHIRC and the Ethics Committee have begun this discussion, but the plan is not final.(The current audit trigger policy evaluates transplant programs; the proposed review policy evaluates the transplantation of individual patients who are non-US residents/non-US citizens.)

- 2) How will the AHIRC treat the data gathered through the review of deceased donor transplants among non-US residents/non-US citizens?
- 3) Is transplant tourism necessarily unethical? One member commented that it is, but a few other members commented that the proposed review policy may place physicians in an uncomfortable place of having to turn patients away, which might be contrary to the Hippocratic Oath. Patients who seek transplantation in the US do so for various reasons, but most fundamentally because they have end-stage organ failure and need transplants.

However, it was pointed out by one member that other countries specifically point to the OPTN's greater-than-5%-audit trigger in the US as justification for the practice of transplant tourism in their respective countries.

- 4) Shouldn't the rate of deceased donation by undocumented residents be considered when reviewing transplants among non-US residents/non-US citizens? What details can be provided about non-residents who are deceased donors?
  - a. One member expressed concern that the proposed review policy may create a perception of hypocrisy: the US is willing to transplant organs from undocumented deceased donors in US residents, but the US is not willing to transplant non-US residents/non-US citizens who seek this service in the US.
- 5) Why eliminate the current audit trigger when it has served as a useful policy in restricting the number of foreign nationals who receive transplants? One member commented that the current policy has facilitated in restricting foreign organizations, such as embassies, that send many patients to a select hospital for transplant services.
- 6) Pediatric lung transplants performed in foreign nationals are done so, because these patients may not be able to find this same service in their home countries. If accepting such children for transplant is transplant tourism, then how would the proposed review policy affect this reality?

The members supported quantifying accurately the type of foreign patient that receives a transplant in the US due to deceased donation. These data will help in understanding transplant program behavior with respect to the transplantation of non-US residents/non-US citizens. Not all members, however, were supportive of the proposed review, especially without details about the application of the review. These members were concerned that the policy revisions were not strictly about data collection.

The Committee also discussed the proposed definitions of residency and non-residency.

**6.1.1 Non-US Citizen/US Resident** – A person who is not a citizen of the United States, who is present in the United States, and for whom the United States is the primary place of residence.

**6.1.2 Non-US Citizen/Non-US Resident** – A person who is not a citizen of the United States and for whom the United States is not the primary place of residence.

Who decides whether the US is a primary place of residence for the candidate? If it continues to be self-reported, then this self-declaration of residency could be exploited by some candidates. The AHIRC and the Ethics Committee did not want to delve into immigration.

A few members commented on what they had heard at their regional discussions:

- Suggestion to eliminate the term “justification” and “audit.”
- Leave the current audit trigger policy alone.

The Committee did not vote on the policy, but some of the members expressed interest in discussing the proposal further at its face-to-face meeting in March, 2012. One member, however, opposed the review policy changes as written. The Committee requested UNOS staff to inquire if the public comment deadline could be extended.

*OPTN Bylaws Substantive Rewrite of Appendix A: Application and Hearing Procedures for Members and Designated Transplant Programs*

On March 20, 2012, the Committee approved the proposed bylaw revisions (28-supported; 0-opposed; 0-abstained), but requested that the proposed bylaw modification be accompanied with a diagram, as part of the evaluation plan, to display the various processes. In general, the Committee commented that the document is long and whenever possible, UNOS staff should make such documents as concise as possible.

*Proposal to Require Reporting of Unexpected Potential and Proven Disease Transmission Involving Living Organ Donors (Living Donor Committee)*

On May 8, 2012, the Committee reviewed a policy proposal sponsored by the Living Donor Committee. Below is the proposal's summary:

Under this proposal, existing policy would be modified to require members to report to the OPTN Contractor any unexpected potential or proven living donor-derived disease transmission, including infections or malignancies. Current OPTN/UNOS policy requires specific infectious disease testing for all deceased organ donors. It also requires that any unexpected potential or proven disease transmission, including infections and malignancies, discovered after donation be reported to the OPTN Contractor. Although rare, unexpected potential or proven disease transmissions involving a living donor have occurred. The types of events reported to date include small renal cell carcinomas (RCC) found in the living donor during recovery and malignancies and viral infections identified in the recipient or the donor after donation. This policy change is being proposed to help improve the reporting of disease transmissions involving living donors.

The Committee voted in favor of the proposal: 13-supported; 0-opposed; and, 0-abstained.

*Proposal to Require Extra Vessel(s) Disposition to be Reported to the OPTN within Five Days of Transplant or Disposal (Operations and Safety Committee (OSC))*

On May 8, 2012, the Committee reviewed a policy proposal sponsored by the OSC. Below is the proposal's summary:

The Operations and Safety Committee is proposing policy language within section 5.10.2 (Vessel Storage) to require transplant centers to report the disposition of extra vessels to the OPTN within five days of transplant or disposal. This proposal will enhance patient safety and recipient outcomes in cases where extra vessels are transplanted by providing timely information on the disposition of extra vessels that could be part of an investigation by the OPTN/UNOS ad hoc Disease Transmission Advisory Committee's (DTAC) review of a potential disease transmission event. It is expected that this proposal can reduce the risk of disease transmission when the donor of the extra vessel is potentially at risk for transmitting disease a primary or secondary recipient.

The Committee voted in favor of the proposal: 11-supported; 0-opposed; and, 2-abstained.

The Committee requested details on cases resulting in the 17 extra vessels described in Table 2 below. The Committee members queried if congenital heart transplant programs recover extra vessels. The pediatric cardiologists participating in the meeting commented that their programs did not recover extra vessels. The Committee also queried if the 17 vessels recovered were done

for storage and future use. Were the 17 vessels recovered really ‘extra vessels,’ as defined in policy, or were they recovered for anastomoses but reported incorrectly as extra vessels to the OPTN Contractor?

**Table 2. Transplants from 1/2011 – 11/2011 Vessel Usage Reported at Waitlist Removal or by Fax**

<i>Transplanted organ</i>	WERE EXTRA VESSELS USED IN THE TRANSPLANT PROCEDURE:						Total (ALL)
	Unknown		No		Yes		
	N	%	N	%	N	%	N
<b>Thoracic</b>	427	11.1	3,413	88.5	17	0.4	<b>3,857</b>
<b>Intestine</b>	5	4.0	44	35.5	75	60.5	<b>124</b>
<b>Kidney</b>	1,630	10.6	13,709	88.9	74	0.5	<b>15,413</b>
<b>Pancreas/KP</b>	170	16.9	410	40.7	428	42.5	<b>1,008</b>
<b>Liver</b>	872	14.9	4,547	77.9	421	7.2	<b>5,840</b>
<b>Total (ALL)</b>	<b>3,104</b>	<b>11.8</b>	<b>22,123</b>	<b>84.3</b>	<b>1,015</b>	<b>3.9</b>	<b>26,242</b>

*Proposal to Document All Locally Assigned Unique Identifiers in the Donor Record (OPO Committee)*

On May 8, 2012, the Committee reviewed a policy proposal sponsored by the OPO Committee. Below is the proposal’s summary:

This proposal will require OPOs and living donor recovery centers to document all unique identifiers used to label any tissue typing specimen in the donor record. This will allow transplant centers to validate the unique identifier information.

The Committee voted in favor of the proposal: 14-supported; 0-opposed; and, 0-abstained. How often does this lack of documentation occur? Where would the documentation reside? UNOS staff commented that the documentation of a unique identifier would be in the donor’s medical record, as well as in DonorNet®.

*Proposal to Update and Clarify Language in the DCD Model Elements (OPO Committee)*

On May 8, 2012, the Committee reviewed a policy proposal sponsored by the OPO Committee. Below is the proposal’s summary:

The proposed changes to the Donation after Cardiac Death (DCD) Model Elements will clarify and update language for the donation and transplantation community. These Model Elements do not change any current level of oversight by the donor hospital to ensure that appropriate practices are following for a patients end of life care, and that hospital approved practitioners follow hospital palliative care policies and guidelines involving the withdrawal of life sustaining medical treatment/support. These Model Elements identify specific requirements that OPOs and transplant centers must include in their DCD policies. As such, the name Model Elements has been changed to "Requirements." DCD is redefined as Donation after Circulatory Death (DCD) in order to accurately reflect the definition of death determined by cardio-pulmonary criteria. The committees also added the following language that mirrors the Centers for Medicare & Medicaid Services (CMS) requirements: 1) OPOs and transplant centers must establish protocols that define the roles and responsibilities of the OPO and the transplant center for all activities associated with the DCD donor and 2) OPOs must have a written agreement with Medicare and Medicaid participating hospitals and critical access hospitals in its service area that describes the responsibilities of both the OPO

and hospital concerning DCD. Additionally, other policies that have the terms "Donation after Cardiac Death" will be modified for consistency. These proposed changes will help provide a common understanding of DCD protocols for the transplant community and the public. Note: This proposal was distributed for public comment during the March 11, 2011 to June 10, 2011 period. Prior to the Nov. 14-15, 2011 Board of Directors meeting, several letters were submitted to the OPTN contractor requesting that the public comment period be reopened to allow the requesting organizations to provide comments. The Executive Committee directed the OPO Committee to review the comments outlined in the letters, revise the proposal if necessary, and resubmit the proposal for public comment during the spring 2012 cycle.

The Committee voted in favor of the proposal: 14-supported; 0-opposed; and, 0-abstained.

*Proposal to Update Data Release Policies (Policy Oversight Committee)*

On May 8, 2012, the Committee reviewed a policy proposal sponsored by the OPO Committee. Below is the proposal's summary:

The proposed revisions to the OPTN Data Release Policies will combine Policy 9 and Policy 10 into a single policy (Policy 9-Release of Data). The proposed changes will: 1) Allow the OPTN Contractor to release more data than is currently released. 2) Provide an appeals process if the OPTN denies a data request. 3) Set requirements for the release of confidential information. 4) Allow the OPTN contractor to release non-confidential data by institution to any requester. 5) Eliminate the list of data elements that can be released in special circumstances out of policy to allow for greater flexibility in data release. 6) The process for release of person-identified data will not change. During the evaluation of the policies as part of the Plain Language Rewrite Project, it was noted that the data release policies contained outdated elements that required substantive changes. The proposed revisions align these policies with current practice and present the information in a simpler format.

The Committee voted in favor of the proposal: 14-supported; 0-opposed; and, 0-abstained.

<b>Thoracic Organ Transplantation Committee</b>	<b>December 6, 2011 Meeting Via Teleconference and Internet</b>	
<b>Name</b>	<b>Position</b>	<b>Attendance</b>
Mark L. Barr, MD	Chair	By phone
Steven A. Webber, MD	Vice-Chair	By phone
Tajinder P. Singh, MD	Region 1 Representative	By phone
Raymond L. Benza, MD	Region 2 Representative	By phone
Leonardo Seoane, MD	Region 3 Representative	By phone
Dan M. Meyer, MD	Region 4 Representative	By phone
Craig H. Selzman, MD	Region 5 Representative	
Nahush Ashok Mokadam, MD	Region 6 Representative	
Sangeeta M. Bhorade, MD	Region 7 Representative	By phone
Joseph C. Cleveland, Jr., MD	Region 8 Representative	By phone
Alan L. Gass, MD	Region 9 Representative	By phone
David Bradley S. Dyke, MD	Region 10 Representative	
Timothy P. Whelan, MD	Region 11 Representative	
Luis Angel, MD	At Large Member/Lung Review Board Chair	
Nancy P. Blumenthal, MSN, CRNP	At Large Member	By phone
Kevin Chan, MD	At Large Member	By phone
Ladora Dils, RN, CPTC	At Large Member	
Kevin M. Dushay, MD	At Large Member	By phone
Maryl R. Johnson, MD	At Large Member	
Theodore G. Liou, MD	At Large Member	By phone
William T. Mahle, MD	At Large Member	
Brigette J. Marciniak-Bednar, RN, BSN, CCTC	At Large Member	
Kenneth R. McCurry, MD	At Large Member	
David P. Nelson, MD	At Large Member	
Damian Neuberger, PhD	At Large Member	By phone
Joseph G. Rogers, MD	At Large Member	By phone
Stuart C. Sweet, MD, PhD	At Large Member	By phone
J. David Vega, MD	At Large Member	By phone
Mark J. Zucker, MD	At Large Member	By phone
Ba Lin, MS, MPH	<i>Ex Officio</i> – HRSA	By phone
Monica Lin, PhD	<i>Ex Officio</i> – HRSA	By phone
Richard E. Pietroski, MS, CPTC	Guest (Vice-Chair, OPO Committee)	By phone
Monica M. Colvin-Adams, MD	SRTR Liaison	By phone
Marshall Hertz, MD	SRTR Liaison	By phone
Brooke Heubner, MD	SRTR Liaison	By phone
Melissa Skeans, MS	SRTR Liaison	By phone
Maryam Valapour, MD	SRTR Liaison	By phone
Leah Edwards, PhD	UNOS Staff	By phone
Robert Hunter	UNOS Staff	By phone
Vipra Ghimire	UNOS Staff	By phone
Elizabeth Miller	UNOS Staff	By phone
Pamela Saunders-Moore	UNOS Staff	By phone
Jory Parker	UNOS Staff	By phone
Ciara Samana	UNOS Staff	By phone

<b>Thoracic Organ Transplantation Committee</b>	<b>March 20, 2012 Meeting Chicago, Illinois</b>	
<b>Name</b>	<b>Position</b>	<b>Attendance</b>
Mark L. Barr, MD	Chair	Present
Steven A. Webber, MD	Vice-Chair	Present
Tajinder P. Singh, MD	Region 1 Representative	Present
Raymond L. Benza, MD	Region 2 Representative	
Leonardo Seoane, MD	Region 3 Representative	By phone
Dan M. Meyer, MD	Region 4 Representative	By phone
Craig H. Selzman, MD	Region 5 Representative	Present
Nahush Ashok Mokadam, MD	Region 6 Representative	Present
Sangeeta M. Bhorade, MD	Region 7 Representative	Present
Joseph C. Cleveland, Jr., MD	Region 8 Representative	Present
Alan L. Gass, MD	Region 9 Representative	By phone
David Bradley S. Dyke, MD	Region 10 Representative	Present
Timothy P. Whelan, MD	Region 11 Representative	Present
Luis Angel, MD	At Large Member/Lung Review Board Chair	Present
Nancy P. Blumenthal, MSN, CRNP	At Large Member	Present
Kevin Chan, MD	At Large Member	Present
Ladora Dils, RN, CPTC	At Large Member	Present
Kevin M. Dushay, MD	At Large Member	Present
Maryl R. Johnson, MD	At Large Member	Present
Theodore G. Liou, MD	At Large Member	Present
William T. Mahle, MD	At Large Member	Present
Brigette J. Marciniak-Bednar, RN, BSN, CCTC	At Large Member	Present
Kenneth R. McCurry, MD	At Large Member	By phone
David P. Nelson, MD	At Large Member	Present
Damian Neuberger, PhD	At Large Member	Present
Joseph G. Rogers, MD	At Large Member	Present
Stuart C. Sweet, MD, PhD	At Large Member	Present
J. David Vega, MD	At Large Member	Present
Mark J. Zucker, MD	At Large Member	Present
Ba Lin, MS, MPH	<i>Ex Officio</i> – HRSA	By phone
Monica Lin, PhD	<i>Ex Officio</i> – HRSA	Present
Monica M. Colvin-Adams, MD	SRTR Liaison	Present
Marshall Hertz, MD	SRTR Liaison	
Brooke Heubner, MD	SRTR Liaison	By phone
Melissa Skeans, MS	SRTR Liaison	Present
Jon Snyder, PhD	SRTR Liaison	By phone
Maryam Valapour, MD	SRTR Liaison	Present
Leah Edwards, PhD	UNOS Staff	Present
James Alcorn, JD	UNOS Staff	Present
Ronald Brown	UNOS Staff	Present
Vipra Ghimire	UNOS Staff	Present
Leigh Kades	UNOS Staff	By phone
Cliff McClenney	UNOS Staff	By phone
Aaron McKoy	UNOS Staff	By phone
Elizabeth Miller	UNOS Staff	By phone
Heather Neil	UNOS Staff	By phone
Jory Parker	UNOS Staff	By phone
Anne Paschke	UNOS Staff	By phone
Sharon Shepherd	UNOS Staff	By phone

<b>Thoracic Organ Transplantation Committee</b>	<b>May 8, 2012 Meeting Via Teleconference and Internet</b>	
<b>Name</b>	<b>Position</b>	<b>Attendance</b>
Mark L. Barr, MD	Chair	By phone
Steven A. Webber, MD	Vice-Chair	By phone
Tajinder P. Singh, MD	Region 1 Representative	By phone
Raymond L. Benza, MD	Region 2 Representative	
Leonardo Seoane, MD	Region 3 Representative	
Dan M. Meyer, MD	Region 4 Representative	
Craig H. Selzman, MD	Region 5 Representative	
Nahush Ashok Mokadam, MD	Region 6 Representative	By phone
Sangeeta M. Borhade, MD	Region 7 Representative	
Joseph C. Cleveland, Jr., MD	Region 8 Representative	By phone
Alan L. Gass, MD	Region 9 Representative	By phone
David Bradley S. Dyke, MD	Region 10 Representative	By phone
Timothy P. Whelan, MD	Region 11 Representative	
Luis Angel, MD	At Large Member/Lung Review Board Chair	
Nancy P. Blumenthal, MSN, CRNP	At Large Member	By phone
Kevin Chan, MD	At Large Member	By phone
Ladora Dils, RN, CPTC	At Large Member	
Kevin M. Dushay, MD	At Large Member	By phone
Maryl R. Johnson, MD	At Large Member	By phone
Theodore G. Liou, MD	At Large Member	
William T. Mahle, MD	At Large Member	
Brigette J. Marciniak-Bednar, RN, BSN, CCTC	At Large Member	By phone
Kenneth R. McCurry, MD	At Large Member	By phone
David P. Nelson, MD	At Large Member	By phone
Damian Neuberger, PhD	At Large Member	By phone
Joseph G. Rogers, MD	At Large Member	By phone
Stuart C. Sweet, MD, PhD	At Large Member	By phone
J. David Vega, MD	At Large Member	
Mark J. Zucker, MD	At Large Member	By phone
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Marshall Hertz, MD	SRTR Liaison	
Brooke Heubner, MD	SRTR Liaison	
Melissa Skeans, MS	SRTR Liaison	By phone
Maryam Valapour, MD	SRTR Liaison	By phone
Lee Bolton	UNOS Staff	By phone
Leah Edwards, PhD	UNOS Staff	By phone
Vipra Ghimire	UNOS Staff	By phone
Robert Hunter	UNOS Staff	By phone
Elizabeth Robbins	UNOS Staff	By phone
Kimberly Taylor	UNOS Staff	By phone
Elizabeth Miller	UNOS Staff	By phone
Jory Parker	UNOS Staff	By phone
Anne Paschke	UNOS Staff	By phone