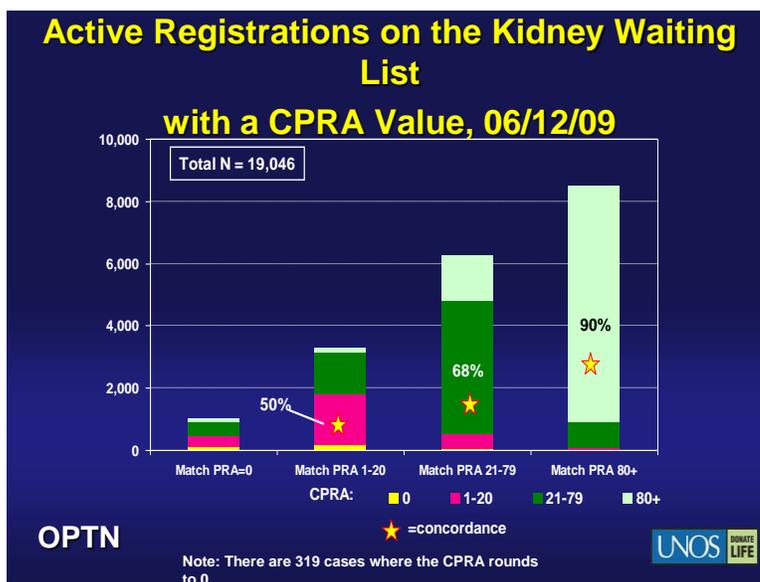
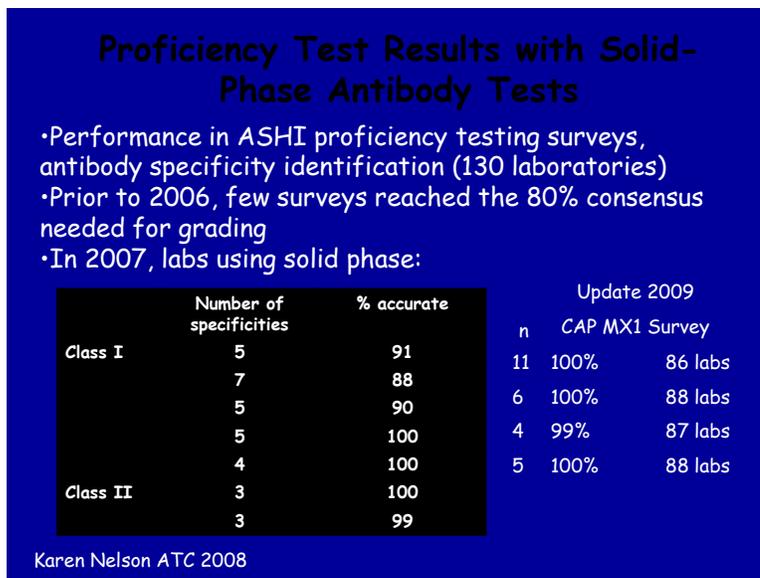


**Thoracic Organ Transplantation Committee Meeting  
September 2, 2010  
Chicago, Illinois  
Mark Barr, MD (Chair) ~ Steven Webber, MD (Vice-Chair)**

The following is a summary of the Thoracic Organ Transplantation Committee's (Committee) deliberations that occurred on September 2, 2010.

**Consider Replacing Panel Reactive Antibody (PRA) with Calculated PRA (CPRA) on the Recipient Histocompatibility Form for Thoracic Recipients**

The immediate past Chair of the OPTN/UNOS Histocompatibility Committee presented a memo (Exhibit A) and the following slides to request that the Thoracic Committee consider the collection of CPRA instead of PRA for thoracic recipients on the recipient histocompatibility form:



Currently, only PRA is collected for thoracic recipients. At its March, 23, 2010 meeting, the Committee reviewed the Tiedi<sup>®</sup> forms, and made final suggestions on data elements for collection for thoracic candidates and recipients. This review occurred as part of the Committee’s review of the following public comment proposal: “Proposed Modifications to Data Elements on the following Tiedi<sup>®</sup> forms: Transplant Candidate Registration (TCR), Transplant Recipient Registration (TRR), Transplant Recipient Follow-up (TRF), Living Donor Registration (LDR), Living Donor Follow-up (LDF), Deceased Donor Registration (DDR), Histocompatibility Form (HF), and approval of a new Explant Pathology Form for Liver Recipients.”

On March 23, 2010, the Committee commented as follows regarding the need to collect PRA on the histocompatibility form:

“In general, the Committee supported the collection of the proposed addition, modification and deletion of the data elements on the DDR form. The Committee strongly urged the collection of PRA at the time of transplant. The Committee would like to analyze PRA to assess its role in waiting list mortality, and also would like this variable to be collected on the waiting list.

UNOS staff commented that it had noted that the Committee sought the addition of PRA to the waiting list. The WaitList<sup>SM</sup> is flexible, and needs to be to accommodate improvements in organ allocation. Changes to WaitList<sup>SM</sup> do not currently require approval by the Office of Management and Budget. The Committee acknowledged this information, and requested again the need for data to pre-populate whenever possible. So, if PRA is collected at the time of transplant, perhaps this information could reverse-populate on the waiting list.”

The OPTN/UNOS Board of Directors did not review the aforementioned public comment proposal in June, 2010, but will review components of it – especially modifications the histocompatibility forms – in the near future.

The Histocompatibility Committee significantly revised the histocompatibility form for recipients. The proposed revisions include both PRA and CPRA data elements:

The image shows a screenshot of a form with six rows of data entry fields. Each row consists of a text label, a text input box, and a dropdown menu labeled 'ST='.

PRA (%) - Most Recent Class I:	<input type="text"/>	ST= <input type="text"/>
PRA (%) - Most Recent Class II:	<input type="text"/>	ST= <input type="text"/>
PRA (%) - Peak Serum Class I:	<input type="text"/>	ST= <input type="text"/>
PRA (%) - Peak Serum Class II:	<input type="text"/>	ST= <input type="text"/>
CPRA (%) - Most Recent	<input type="text"/>	ST= <input type="text"/>
CPRA (%) - Peak	<input type="text"/>	ST= <input type="text"/>

The dropdown menu for the last row is open, showing the following options: Missing, Unknown, N/A, and Not Done.

The Histocompatibility Committee noted that many laboratories are providing data for CPRA, but these data are likely being entered as PRA in the histocompatibility form. As such, the Histocompatibility Committee prefers that these forms only collect CPRA.

The Committee favored the collection of CPRA but discussed whether all laboratories would be able to perform this test. There are a limited number of laboratories that do not provide CPRA, but these

laboratories have the capability to do so. Further, the change proposed by the Histocompatibility Committee would not be in effect, i.e., programmed, for at least a year. In about a year from now, several members of the Committee commented that all laboratories will be performing CPRAs.

The Committee discussed whether the collection of CPRA at the time of transplant would impact unacceptable antigen data entered in the waiting list. Some transplant centers make use of DonorNet<sup>®</sup> to screen donor organs that are medically unsuitable for their candidates. Some transplant centers prefer that screening for organs be a clinical decision not made through DonorNet<sup>®</sup>. Given that there is variation in the entry of candidates' unacceptable antigens, the Committee requested strongly that sensitization data entered on waiting list not be affected by the CPRA collection concept proposed by the Histocompatibility Committee. Indeed, if CPRA is calculated through data entered in the waiting list, it is unlikely that the resulting value would be a true indicator of the candidate's sensitization status. Information on waiting list is for the purposes of accepting the most medically suitable organ for candidates, and not for the purposes of understanding the candidates' CPRA at the time of transplant. The Committee reiterated that it would like to have PRA collected on the waiting list, but that this programming suggestion is an issue separate from the current discussion.

The Committee voted in favor of the Histocompatibility Committee's recommendation to transition from collecting PRA to collecting only CPRA on the recipient histocompatibility form: 22-supported; 0-opposed; 0-abstained. The Committee suggested that histocompatibility laboratories enter the data.

### **Review and Vote on Committee-Sponsored Public Comment Proposals**

The Committee discussed the final policy language in the following two public comment proposals: 1) Proposal to Require Collection of Human Leukocyte Antigen (HLA) Type for Thoracic Organs, and 2) Proposal to Clarify Adult Heart Status 1A Exception Language to Enable Consistent Interpretation of Policy and Reflect Current Programming in UNet<sup>SM</sup>.

#### *Proposal to Require Collection of Human Leukocyte Antigen (HLA) Type for Thoracic Organs*

The Committee reviewed the following policy language and the monitoring plan. The Committee commented that the provision of HLA information would occur through telephone conversations, and policy compliance would require both the transplant center and the OPO to document request for and provision of HLA typing. The Committee emphasized the manual implementation solution of this policy, and that modifications to the DonorNet<sup>®</sup> application were not a part of this policy proposal. One member commented that not all OPOs may be documenting telephone conversations with the transplant center; and, such conversations are places where the request for and provision of HLA typing would be conveyed. The Committee commented that such documentation should be standard practice. The Committee voted in favor of the following policy language and for submitting it for public comment: 22-supported; 0-opposed; and, 0-abstained.

The Committee also voted in favor of the following programming request: modification to DonorNet<sup>®</sup> to include "HLA unavailable" as a refusal code for transplant centers to select for declining an organ offer: 22-supported; 0-opposed; and, 0-abstained.

In general, the Committee discussed the need to modify DonorNet<sup>®</sup> to enable secure communication of requests for and provision of HLA typing. The Committee also sought the addition of "HLA type is pending" as a data element in the process for submitting a "provisional yes" in DonorNet<sup>®</sup>. The Committee requested that the OPO Committee and the Operations and

Safety Committee consider this addition. Changes to DonorNet<sup>®</sup> are possible during the time period when UNOS makes efforts to redesign the waiting list system.

The Committee also discussed whether the phrase “if the donor hospital has the facilities” should follow the requirement for an echocardiogram (see item xi below). Shouldn’t hospitals offering thoracic organs for transplant have the capability to perform an echocardiogram? Unfortunately, small hospitals may not be able to perform echocardiograms. But, this type of language is one which the Heart Subcommittee may to consider modifying.

**“3.7.12.1 Essential Information for Thoracic Offers.** The Host OPO or donor center must provide the following donor information to the recipient center with each thoracic organ offer:

- (i) The cause of brain death;
- (ii) The details of any documented cardiac arrest or hypotensive episodes;
- (iii) Vital signs including blood pressure, heart rate and temperature;
- (iv) Cardiopulmonary, social, and drug activity histories;
- (v) Pre- or post-transfusion serologies as indicated in 2.2.7.1 (pre-transfusion preferred);
- (vi) Accurate height, weight, age and sex;
- (vii) ABO type;
- (viii) Interpreted electrocardiogram and chest radiograph;
- (ix) History of treatment in hospital including vasopressors and hydration;
- (x) Arterial blood gas results and ventilator settings; ~~and~~
- (xi) Echocardiogram, if the donor hospital has the facilities-; and,
- (xii) Human leukocyte antigen (HLA) type if requested by the transplant center.

If a transplant center requires donor HLA type prior to submitting a final organ acceptance, it must communicate this request to the OPO; the transplant center must document this request. If a transplant center requests donor HLA type prior to submitting a final organ acceptance, the OPO must provide the following, identified splits before the organ’s final acceptance: HLA-A, HLA-B, HLA-Bw4, HLA-Bw6, HLA-Cw, HLA-DR, and HLA-DQ antigens. The transplant center may request HLA-DP type, but the OPO need only provide it if its affiliated laboratory performs related testing. The OPO must document provision of HLA type to the requesting transplant center.

The thoracic organ procurement team must have the opportunity to speak directly with responsible ICU personnel or the on-site donor coordinator in order to obtain current first-hand information about the donor physiology.”

*Proposal to Clarify Adult Heart Status 1A Exception Language to Enable Consistent Interpretation of Policy and Reflect Current Programming in UNet<sup>SM</sup>*

The Committee reviewed the following policy language and commented that to assist clinicians in readily identifying inotrope medications that qualify per policy for single high-dose versus in combination, UNOS staff should make such a list available publicly. This list will be added to the briefing paper should this public comment proposal proceed to the Board of Directors for approval in June, 2011. The Committee also suggested that a list of inotropes be made available on the web site. (The proposed policy deletes the examples of inotropes that qualify per policy

for single, high-dose. UNOS staff commented that to list all eligible inotropes in policy would mean changes to policy if a new inotrope medicine were to become available.)

The Committee also supported the concept that entries of an “other” mechanical circulatory support device should continue to be reviewed by the heart regional review boards (RRB). As of April 19, 2010, the RRB only reviews heart status exception cases, and the entry of an “other” is treated as an exception case.

The Committee voted in favor of the following policy language and its submission for public comment: 22-supported; 0-opposed; and, 0-abstained.

**“3.7.3 Adult Candidate Status.** Each candidate awaiting heart transplantation is assigned a status code which corresponds to how medically urgent it is that the candidate receive a 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:

Status Definition

1A A candidate listed as Status 1A is admitted to the listing transplant center hospital (with the exception for 1A (a)(i), and 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.

- (b) Mechanical circulatory support with objective medical evidence of significant device-related complications, such as thromboembolism, device infection, mechanical failure ~~and/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 (~~e.g., dobutamine  $\geq$  7.5 mcg/kg/min, or milrinone  $\geq$  .50 mcg/kg/min~~), 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-Exception**

A candidate who does not meet ~~the criteria (a), (b), (c), or (d) for Status 1A~~ may nevertheless be ~~assigned to such~~ classified as status 1A upon application by his/ or her transplant physician(s) and justification to the applicable Regional Review Board that the candidate is considered, using acceptable 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 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 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 ~~to~~ for review by the Thoracic Organ Transplantation Committee to determine consistency in application among and within Regions and continued appropriateness of the candidate status criteria. A candidate's listing under this exceptional provision is valid for 14 days.

Any further extension of the Status 1A listing under this criterion 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.

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

~~For all adult candidates listed as Status 1A, a~~ completed Heart Status 1A Justification Form must be ~~received by~~ submitted to ~~on~~ UNet<sup>SM</sup> in order to list a candidate as Status 1A, or extend ~~their~~ his or her listing as Status 1A in accordance with the criteria listed above ~~in Policy 3.7.3. Candidates listed as Status 1A will automatically revert back to Status 1B unless they are re-listed on UNet<sup>SM</sup> by an attending physician within the time frames described in the definitions of status 1A(a)-(d) 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 automatic status downgrade will not require submission of a Status 1B Justification Form.

- 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.

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

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**

~~For all adult candidates listed as Status 1B, a~~ completed Heart Status 1B Justification Form must be ~~received~~ submitted ~~on~~ to UNet<sup>SM</sup> in order to list a candidate ~~within one working day of a candidate's listing as Status 1B."~~

### **Donor Organ Recovery Site: Hospital or Operation Room (OR) Suite**

Policy 3.7.2 (Geographic Sequence of Thoracic Organ Allocation) defines the starting point for concentric circles as the donor hospital. There are a few OPOs that have operation rooms in their own facilities. These OPOs may choose to transport the donor from the donor hospital to their OR suite for organ recovery. The OPOs may do this transport to avoid waiting for operation rooms at the donor hospital. OPOs have reported many advantages to locating an OR suite within the OPO, so the number of donors recovered in these circumstances is anticipated to increase.

The OPTN has become aware of situations where the donor organs are physically recovered in an OR suite located at the OPO rather than at the hospital where the referral was reported. Anecdotally, there is

at least one case where the referral hospital and the OPO's recovery suite were several hundred miles apart.

The current data collection system captures only the donor hospital. In the situation just described we believe that the referral hospital is being reported as the donor hospital. The OPO itself is not a value in the drop-down list for the donor hospital, so it can not currently be reported as a donor hospital.

If the zones should reflect the distance between the transplant center and the location where the organs are physically recovered, the current system may not always be reflecting this distance.

The Committee discussed the following options and questions:

1. Leave the policy as is, because the donor's eligibility for donation was determined at the donor hospital. Policy 3.7.2 states that the donor hospital is the center of the zone but does not state specifically that the donor hospital is the location of organ recovery. So, zones will continue to be based on referral hospital. It is thought that currently the referral hospital is also the recovery site for the majority of donors.
2. Change the policy language to reflect that the center of the concentric circles would be the location where the donor's organs were recovered. This solution would require programming, possibly extensive. If the recovery site should be reported as well, in the cases where the referral hospital and recovery site are different, this will require minimal programming.
3. Is it relevant to consider where the donor was recovered if the recovery occurred within the same donation service area?
4. Is a definition for "donor hospital" necessary?
5. If an OPO recovers thoracic organs at its operation room, would it be accurate to state the starting point of the concentric circle as "donor hospital?"

The Committee queried how many such OR suites exist, and whether the distance the organ travels impacts ischemic time. What is the ground transportation time from the donor hospital versus the ground transportation time to the OPO's OR suite? The Committee opined that match runs, with respect to geography, should be performed based on the location of the donor hospital, not the OR suite. The Committee considered conducting a survey to better understand which organs are being recovered at OR suites, how many OR suites there are, and what the potential number of OR suites may be in the near future. The Committee sought the collection of the following data elements in DonorNet<sup>®</sup>: whether the donor was recovered at the donor hospital or at an OPO OR Suite recovery. (Currently, match runs are performed based on the location of the donor hospital.) The Committee also sought whether moving a donor to an OPO OR suite affects the conversion rate. How many donors are recovered at the donor hospital if the donor family does not approve the recovery at an OPO's OR suite? For now, the Committee opted to leave language in Policy 3.7.2 as is. The Committee will continue this discussion in the future when the following data are available:

- Tabulate the number of OPOs that have OR suites on-site
- For the OPOs with recovery facilities
  - Tabulate the number of donors and organs that were recovered within these on-site ORs.
  - Provide further detail regarding the distance traveled between the donor hospital and the on-site ORs.
  - Provide further information regarding the circumstances where the donor might be recovered at the OPO (For example, is this standard practice or is it only occurring in certain circumstances?)
- Assess, if possible, whether there is any impact of this practice on donor conversion.

### **OPTN Data Analysis: Heart Allocation System**

The Committee reviewed slides prepared by UNOS staff on the impact of the heart allocation system (see Exhibit B). The following is a summary of the waiting list analysis:

- There has been an increase in the number of active waiting list registrations and urgent waiting list registrations; and
- Waiting list mortality in Status 1A and Status 1B appears to have decreased.

The following is a summary of the transplant analysis:

- The number of transplants has remained essentially flat over the past 3 years;
- The distribution of status at transplant has changed: increase in Status 1A and decrease in Status 2; and,
- There is no significant change in post-transplant survival within 2 years for adults or pediatrics, overall or by status at transplant.

The Committee commented that the waiting list mortality appears to have decreased significantly for Status 1A and Status 1B. The Committee commented that improvements in ventricular assist devices may have contributed to the waiting list mortality, the change in policy implemented in 2006, and better medical management of heart waiting list candidates. The Committee commented that candidates in Status 2 are not adversely affected by the change in policy.

### **OPTN Data Analysis: Lung Allocation Score (LAS) System**

The Committee reviewed slides prepared by UNOS staff on the impact of the LAS system (see Exhibit C). The following is a summary of the waiting list analysis:

- The total number of waiting list candidates is substantially lower than prior to the implementation of LAS;
- The number of active candidates who are at least 12 years of age has increased during the most recent two years;
- The distribution of LAS at listing has shifted towards higher scores in the years since implementation; and,
- The waiting list mortality is lower overall in the post-policy era compared to the pre-policy ears; this same pattern was seen within all diagnosis groups.

The following is a summary of the post-transplant analysis:

- The percentage of lungs transplanted has increased from pre- to post-LAS;
- There was a huge increase in the number of transplants from pre-LAS to post-LAS; there was also a large increase in transplants during the most recent complete year;
- There has been a substantial shift in the distribution of diagnosis from pre-LAS (>50% group A) to post-LAS (>50% group D); and,
- Post-transplant survival is comparable pre- and post-LAS, overall and by diagnosis grouping.

The Committee noted an increase in waiting list mortality for candidates in the highest LAS grouping (60+) during the most recent era reported. There did not appear to be a concomitant increase for other

LAS groupings. The Committee felt that this warranted further investigation. [NOTE: This information is to be provided for discussion at the next Lung Subcommittee meeting.]

- Provide the distribution of LAS for re-transplant candidates and recipients; assess whether there is a higher percentage of re-transplant candidates with a high (e.g., 60+) LAS compared to the candidates waiting for a primary transplant.
- Examine other factors that possibly could have had an impact on the increase seen in waiting list mortality for candidates in the highest LAS group.

The SRTR queried about the death rate among end-stage lung failure patients. The Committee queried where such data could be obtained.

### **LAS Update (SRTR Analysis)**

Per the Committee's request, the SRTR provided an analysis (Exhibit D) of a future LAS system that made use of 3 years in the post-transplant survival model but retained the one year in the waiting list mortality model.

The SRTR's study method and population used is presented in the following two slides:

**Revising LAS Models: Methods**

- The waitlist component of the 1-year and 3-year versions of the LAS from each model was the same (censoring at 1 year).
- The post-transplant component was calculated as the area under the curve for the 1-year versions and as the area under the curve divided by three for the 3-year versions.
  - Dividing the 3-year version by three scales the post-transplant survival down to the same level as in the 1-year version. In other words, the post-transplant component has the same range in all the calculations (0-365 days).
- One-year conditional survival curves at transplant, 1 year post-txp, and 2 years post-txp might give estimates of years of life saved on a more similar scale to the current estimate.

**SRTR**

4

## LAS Calculation: Population and Models

- Patient Population for LAS Comparison: Lung candidates aged  $\geq 12$  active on the waitlist on January 1, 2009 who have complete data.
- Calculated two versions of the LAS for each patient in the LAS comparison population:
  - Step 1 Revised Model – 1-year version
  - Step 1 Revised Model – 3-year version

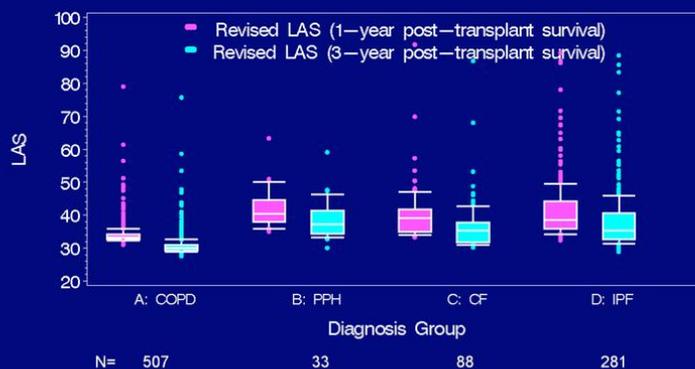
SRTR

5

The SRTR reported that the primary difference in the use of a one-year post-transplant survival term versus a three-year post-transplant survival term is that the hazard ratios decrease for the diagnosis groups.

In the figure below, the SRTR discussed the ranking between each diagnosis group. This ranking is similar whether one year is used or three years is used in the post-transplant survival model.

## 1-year vs. 3-year Revised LAS by Diagnosis

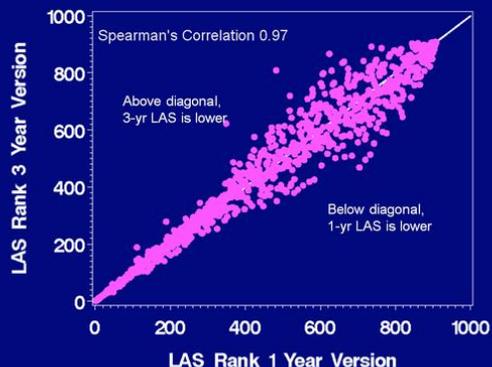


SRTR

10

Overall, as shown in the scatter plot below, the lung allocation scores appear to be similar whether the one-year survival term is used or three-year survival term is used in the post-transplant model.

## Patient Rank Comparison: 1- vs. 3-Year Version of LAS (Revised Model)

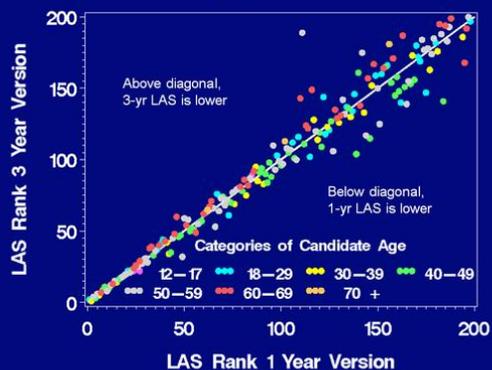


SRTR

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The figure below suggests that the use of the three-year term for post-transplant survival could reduce the lung allocation scores for older candidates.

## Rank Comparison for Top 200 Patients by Age Group (Revised Model)



SRTR

13

The Committee commented that using current data to predict what the LAS system would appear with the use of the three-year post-transplant survival term is likely ineffective. With the exception for age, the other variables in the LAS system do not appear to be affected by the use of a three-year survival term in the post-transplant outcome model. The index of concordance for the LAS using the one-year survival term is 0.63, and the index of concordance using the three-year survival term is 0.61.

The Committee requested the following analysis:

To compare the existing revised LAS models and the 3-year adjusted LAS models:

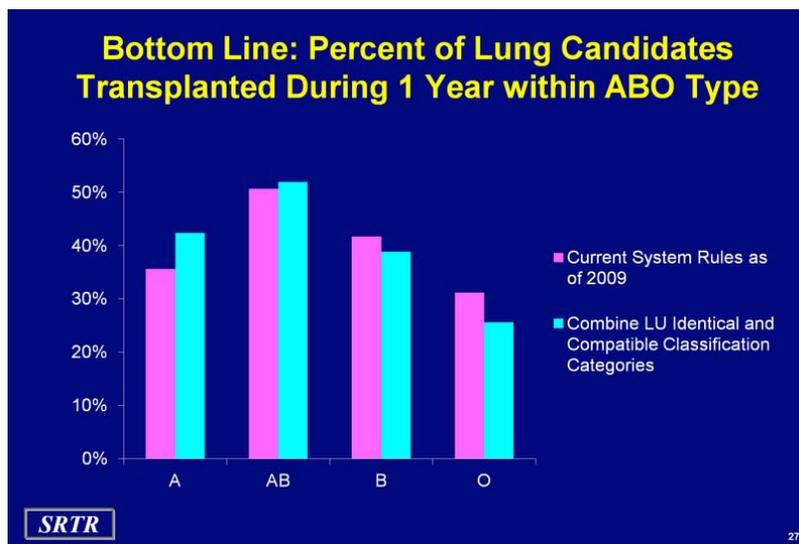
- Report the index of concordance for each diagnosis grouping for the updated and revised models.
- Provide scatter plots for the highest ranking candidates: comparing their ranking for the three methods (updated LAS, revised LAS, 3-year adjusted LAS).

To validate the Committee’s decision not to incorporate re-transplant as a separate diagnosis in the updated LAS, for the same cohorts used in the update LAS analyses, provide:

- Demographics of re-transplant candidates and recipients, compared to primary candidates and recipients
- Inter-transplant interval for re-transplants
- Waiting list outcomes of candidates listed for re-transplant compare to outcomes by diagnosis grouping of candidates listed for primary transplant
- Post-transplant outcomes for recipient of re-transplants compared to post-transplant outcomes by diagnosis grouping for primary transplant recipients

### Impact of ABO on Lung Allocation (SRTR Analysis)

The SRTR presented its thoracic-simulated-allocation-model of a system for lung allocation that combined blood group identicalness and compatibility (Exhibit E). The SRTR compared this proposed model with the existing lung allocation system, which prioritizes lung allocation based on blood group compatibility and identicalness. The following slide illustrates the impact of combining ABO-identical and ABO-compatible in one category for allocating deceased donor lungs.



In the current system, candidates with blood type AB are more likely to receive transplants during a year, whereas candidates with blood type O are least likely to receive transplants within a year. The thoracic simulated allocation model, which combines blood-group identicalness and compatibility, appears to worsen this disparity. Given this potential outcome, the Committee decided not to pursue further discussion on this topic.

### Heart Subcommittee: Update on Activities

The Chair of the Heart Subcommittee provided the following summary to the Committee discussions related to updating the medical urgency policy on candidates with total artificial hearts, joint allocation of hearts and lungs, and efforts to improve the pediatric heart allocation policy. A brief summary on the discussions for each topic are presented below.

- *Revising to the policy on the joint-allocation on heart and lungs*

- The Lung Subcommittee has been evaluating lung allocation scores that are equivalent to each heart medical urgency status
- The Lung Subcommittee will work with the Heart Subcommittee to determine the following:
  - How best to include geography in the revised policy?
  - Should the policy for pediatric candidates be different from that for adults?
  - What is the guidance to provide in policy for the OPOs?
  - What solution – automated or manual – should be pursued?
- *Improving the pediatric heart allocation policy*
  - The Heart Subcommittee continues to meet with the representatives of the Pediatric Committee and representatives from the Pediatric Heart Transplant Study (PHTS) to improve the pediatric heart allocation system.
  - The working group will review additional OPTN data in the next few weeks, as well as Dr. Chris Almond’s paper (once its cleared by HRSA) to determine what evidence there exist in the data and literature on reclassifying the pediatric heart allocation system.
  - The group queried if other systems internationally offered guidance, and Dr. Anne Dipchand provided to the group the Canadian system for consideration.
  - The group will reconvene in the next few months to discuss: inferences that can be made from the OPTN data and the article.
  - In the meantime, the group has requested extracorporeal membrane oxygenation (ECMO) and ventricular assist device (VAD) outcome data from the PHTS. The PHTS is willing to help in this effort, and if requested, it could begin data analysis in November.
- *Revising the policy on candidates with total artificial hearts who are no longer inpatients*
  - The Heart Subcommittee has been discussing how best to modify the total artificial heart policy to account for a recent change in technology – the development of a portable driver that allows a candidate with a total artificial heart to be outpatient. Policy as well as past and current clinical sentiments indicate that candidates with total artificial hearts should not be treated differently in policy than candidates with VADs.
  - The Heart Subcommittee presented a letter to the Thoracic Committee for its review and approval. Policy dictates candidates who are discharged from the hospital should be Status 1B.
  - The Heart Subcommittee will work with UNOS staff to prepare a revised total artificial heart policy proposal for review and approval by the Committee: outpatient candidates with total artificial hearts receive 30 days of total Status 1A time (no re-certifications).

The letter to the thoracic community (see below) also stated that outpatient candidates with total artificial hearts did not qualify for Status 1A by any criterion or by exception. The Committee re-emphasized that the letter reiterates policy. The Committee suggested edits to the letter (see struck language in the letter cited below), and voted in favor of the revised letter’s distribution to the thoracic community: 22-supported; 0-opposed; and, 0-abstained.

“An adult heart transplant candidate with a total artificial heart (TAH) implant qualifies for Status 1A if this individual is hospitalized while waiting for a deceased donor heart. A transplant center may list a candidate with a TAH implant at Status 1A for 14 days, which can be extended in 14-day periods if the treating physician certifies to UNOS that the candidate still has a TAH and is hospitalized.

If a transplant center discharges a candidate with a TAH implant from the hospital to await a deceased donor heart at home, then the candidate qualifies for neither Status 1A nor 1A

exception. ~~Although not stated explicitly in current policy, the Thoracic Organ Transplantation Committee interprets Policy 3.7.3 and current UNOS processes to require that a candidate with a TAH that is discharged home should be downgraded to Status 1B immediately. A candidate with a TAH implant and experiencing complications or infections due to the device qualifies for Status 1A, regardless of hospitalization status (see Policy 3.7.3 – Status 1A, criterion b). If you have questions about the UNOS process on changing a candidate’s heart status, please contact Mr. Aaron McKoy at [mckoyar@unos.org](mailto:mckoyar@unos.org) or 804-782-6575 (extension # 6575).~~

~~This interpretation of current Policy is not intended to penalize a candidate with TAH and discharged home on the portable driver.~~

Due to change in technology in managing transplant candidates with total artificial hearts, the Thoracic Organ Transplantation Committee is working on revising Policy 3.7.3 (Adult Candidate Status) to more specifically address the appropriate medical urgency status of a candidate with a TAH implant and awaiting a donor heart at home.

To read Policy 3.7.3 in its entirety, please visit the web site linked below and click on the document with the title, “Organ Distribution: Allocation of Thoracic Organs:”

<http://optn.transplant.hrsa.gov/policiesAndBylaws/policies.asp>

If you have questions for the Thoracic Organ Transplantation Committee, please contact Ms. Vipra Ghimire at [ghimirev@unos.org](mailto:ghimirev@unos.org) or 804-782-4071.”

The revised policy will be similar in text to the policy on ventricular assist devices. The Committee noted that like the VAD policy, the experimental nature of the portable driver should not be addressed in the revised total artificial heart policy.

The Committee also discussed that the 30-day of Status 1A time for candidates with VADs may need to be reassessed. At its next meeting, the Heart Subcommittee will initiate discussion on the VAD policy and whether 30 days of Status 1A time is adequate or needs to be reconsidered. A policy based on medical urgency should remain that, and not become one allowing the majority of adult heart transplant candidates to be classified as Status 1A. When the latter occurs, the policy in effect would become one that prioritizes candidates for allocation by waiting time.

The Vice Chair of the Committee provided an update on the effort to improve the pediatric heart policy. The joint working group includes members of the Heart Subcommittee, representatives from the Pediatric Committee, and PHTS representatives. This group will continue to meet over the next few months to determine revisions to policy.

### **Lung Subcommittee: Update on Activities**

The Chair of the Lung Subcommittee provided the following summary to the Committee:

- Ongoing discussion of the SRTR’s analysis on updating the existing LAS model, as well as revising the updated model with new variables to create a more sensitive LAS system for lung transplant candidates
  - On March 23, 2010, the Committee approved the updated LAS system.
  - During its August 24, 2010 teleconference meeting, the Lung Subcommittee voted in favor of submitting for public comment the revised LAS system – one which includes

new variables as well as updated parameter estimates – in the March, 2011 public comment cycle.

- The Subcommittee and the Committee need to determine the future intervals at which the LAS will be updated. The cost of updating just the parameter estimates versus revising the system will likely guide the discussion.
- In the post-Chrysalis era, and after the revised LAS has been implemented, what is the likelihood for updating just the parameter estimates on a more frequent basis? What will be the cost?
- Does the Thoracic Committee vote in favor of submitting for public comment the following proposed revisions to the LAS system?
  - Addition of the following variables to the waiting list model: serum creatinine, FVC for Groups B and D, PCW for Diagnosis Group D
  - Addition of the following variables to the post-transplant model: age with a spline at 45 (currently, age is a continuous variable), serum and change in creatinine greater than or equal to 150%; Six Minute Walk (per 100 ft) <1200, cardiac index less than 2, oxygen at rest (different hazard ratio for Group B, C, and D than for Group A)
  - Modifications to the baseline and survival estimates accordingly.
- Discussion of how best to classify ECMO in its absence from the lung allocation score
  - Currently, the lung allocation system does not accommodate the waiting list urgency of candidates on ECMO.
  - Currently, members are advised that ECMO is “equivalent” to continuous mechanical ventilation; however, this advice is a work-around as ECMO is not included as a data element in the lung transplant waiting list page. As a result, this work-around may not accurately reflect the lung allocation score of the individual placed on ECMO.
  - The Lung Subcommittee has discussed whether the lung review board (LRB) could assist in classifying the waiting list urgency of lung transplant candidates on ECMO.
  - The Lung Subcommittee also discussed adding ECMO as a data element to the lung transplant waiting list pages in UNet<sup>SM</sup>.
  - The Lung Subcommittee continues to discuss the best path forward. Should the LRB be requested to accept a certain lung allocation score for candidates on ECMO the way they do for candidates with pulmonary hypertension, i.e., provide members a range from which to request a higher lung allocation score for candidates on ECMO? If so, what would be that recommended score or range of scores? Or, should ECMO be added to the lung transplant waiting list page and contribute to a candidate’s lung allocation score?
- Discussion of revising the policy on the joint-allocation on heart and lungs
  - The Lung Subcommittee has been evaluating lung allocation scores that are equivalent to each heart medical urgency status.
  - The Lung Subcommittee will work with the Heart Subcommittee to determine answers to the following questions:
    - How best to include geography in the revised policy?
    - Should the policy for pediatric candidates be different from that for adults?
    - What is the guidance to provide in policy for the OPOs?
    - What solution – automated or manual – should be pursued?

The Lung Subcommittee will further consider the use of the three-year term in the post-transplant model of the LAS. The Lung Subcommittee will continue to meet in the next few months, develop a draft of the public comment proposal on revisions to the LAS system, and present it to the Committee for review and

approval. While the initial drafts of the proposal document will be reviewed electronically and during Lung Subcommittee conference calls, the Committee will need to meet by phone and prior to its March, 2011 meeting to formally discuss and vote on the proposal's distribution for public comment. (The first public comment cycle in 2011 begins in March, and before the Committee's face-to-face meeting.)

The Lung Subcommittee will discuss the addition of ECMO and related data collection, and how best to collect such data in an era of limited resources and consideration for data entry burden placed on transplant centers.

### **Heart-Lung Allocation Policy: Update on Discussions and Activities to Date**

The Committee has been making efforts to improve Policy 3.7.7 (Allocation of Thoracic Organs to Heart-Lung Candidates). The following is the current policy language:

“When the candidate is eligible to receive a heart in accordance with Policy 3.7, or an approved variance to this policy, the lung shall be allocated to the heart-lung candidate from the same donor. When the candidate is eligible to receive a lung in accordance with Policy 3.7, or an approved variance to this policy, the heart shall be allocated to the heart-lung candidate from the same donor if no suitable Status 1A isolated heart candidates are eligible to receive the heart. Heart-lung candidates shall use the ABO matching requirements described in Policy 3.7.8 when they are included in the heart match run results. Heart-lung candidates shall use the ABO matching requirements described in policy 3.7.8.2 when they are included in the lung match run results.”

As written, Policy 3.7.7:

- Does not address geography, and as its applied for heart candidates and lung candidates;
- Does not address blood group identicalness and compatibility (lung allocation does not address blood group incompatibility whereas heart allocation does);
- Does not provide OPOs guidance on running matches for candidates who need hearts and lungs – which thoracic match run to start with and when to switch;
- Does not address appear to reduce the high waiting list mortality for adult and pediatric candidates who need hearts and lungs; and,
- Does not provide guidance to transplant programs on listing heart-lung candidates in the heart list, lung list, and heart-lung list.

The Committee re-emphasized its interest in resolving problems with the policy as outlined above. The Chair of the Committee apprised the group of the following constructs being considered by the Lung Subcommittee and Heart Subcommittee:

#### “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 requested that UNOS staff educate OPOs to perform heart-lung match runs whenever a donor offers a heart and a lung. OPOs may not be uniformly performing heart-lung matches, as the policy states that if there is a suitable Status 1A candidate, then the OPO must be offered to that candidate. Some OPOs may understand the policy to mean that if there is a suitable Status 1A candidate nationally, then the OPO must offer the heart to that candidate. The Committee opined that such an interpretation allows for the potential of heart-lung candidates never receiving offers. The policy is vague on geographic sharing of heart-lung blocs. One member commented that effort to educate OPOs may need to be a mandate.

The Committee also requested that UNOS staff educate transplant programs to list a candidate in need of a heart and lung on the heart transplant waiting list, the lung transplant waiting list, and the heart-lung transplant waiting list.

Policy revisions will be based on statistical data, but efforts to revise current Policy 3.7.7 are not complete. Based on OPTN data analysis performed earlier this year, the Committee opined that Zone A may be the greatest distance for a heart-lung bloc to travel for transplant in a candidate in need of both. In which geographic zone does transplantation of the majority of heart-lung blocs occur? UNOS staff will research this information.

One possible solution to address the geographic problem with the current policy is to use the geographic allocation sequence for the organ that appears first on the match run, i.e., use the geographic sequence in lung allocation if the lung match is run or use the heart geographic sequence if the heart match is run.

Should the final policy distinguish allocation for pediatric heart-lung candidates from allocation for adult heart-lung candidates?

Historically, the Committee had requested guidance from the OPTN/UNOS Membership and Professional Standards Committee for principles that should guide multi-organ allocation. The Committee has not received such guidance, which would be useful in helping the Committee resolve problems with this heart-lung allocation policy.

The Committee once again commented on the need to eliminate the heart-lung waiting list. The existence of three lists poses operational issues for an OPO coordinator performing the match run. The Committee

also commented that transplant centers must list a heart-lung candidate on the heart transplant waiting list, the lung transplant waiting list, and the heart-lung waiting list.

As shown in the two figures below, the Committee opined that the high waiting list mortality of as adult and pediatric heart-lung candidates – compared with the mortality rates of heart-alone candidates and lung-alone candidates – warrants revisions to the current policy to better serve these candidates.

Figure 3. Probability of death on the waiting list

Figure 3A. Adult registrations

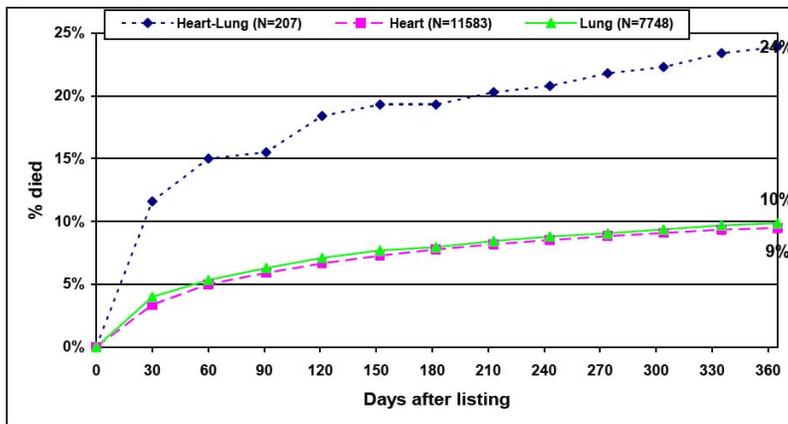
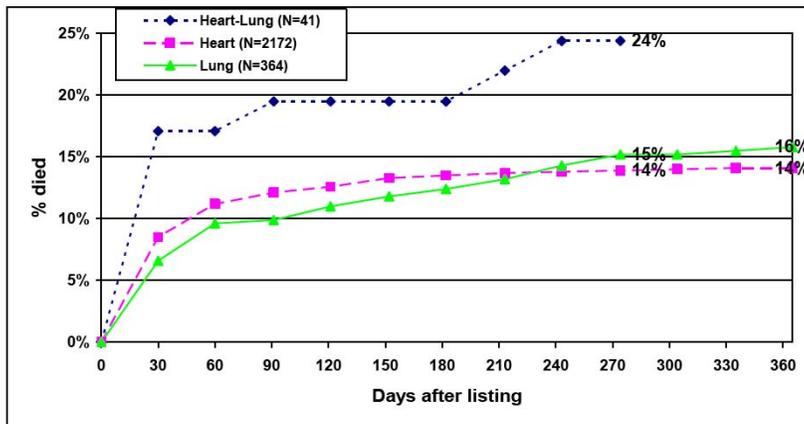


Figure 3B. Pediatric registrations



The Committee discussed that Policy 3.7.7 is not consistent with Policy 3.7.10 (Sequence of Adult Heart Allocation). Does 3.7.10 “trump” Policy 3.7.7? But, the “suitable Status 1A” language in Policy 3.7.7 poses compliance with Policy 3.7.10 which only addresses the allocation of hearts from adult donors. To follow 3.7.10 would mean addressing allocation of heart-lung blocs to Status 1B and Status 2 candidates, who are not addressed in Policy 3.7.7. What geographic boundary does the “suitable Status 1A” candidate referenced in Policy 3.7.7 have: local, within a specific zone, or national?

One recommendation was that the Policy 3.7.7 be modified to state that OPOs offer hearts through Zone A. Perhaps this modification could be considered a clarification, as it would enable OPOs to offer heart-lung blocs to candidates who need both. This Committee considered whether this clarification would require approval by the Board of Directors.

UNOS staff cautioned that heart-lung blocs transplanted through heart-lung matches would not be recorded as transplants in UNet<sup>SM</sup>, and therefore difficult to track. Further, not all transplant centers are listing heart-lung candidates in all three lists. The Committee will continue discussion on this topic at its future meetings as well in its subcommittees. The Committee requested that UNOS staff organize a conference call with the Committee's leadership to discuss the path forward.

### **Requiring Transplant Centers to Update More Frequently Records of Candidates with High Allocation Scores**

Transplant programs have to recertify heart transplant candidates' medical urgency more often than when lung transplant programs have to update laboratory values and test results of candidates who receive lung allocation scores. Policy states that lung transplant programs update their candidates' waiting list record once every six months (with the exception of data obtained through heart catheterization). At its March 23, 2010 meeting, the Committee requested that UNOS staff prepare a public comment proposal that requests that transplant programs update certain LAS-related values every two weeks.

During this September meeting, the Committee opined that transplant programs must update every two weeks the waiting list records of candidates with lung allocation scores of 50. The Committee commented that transplant programs need only update a minimum number of data elements, which are oxygen requirement and ventilator requirement. Procedures that are invasive would not be part of this proposed update policy.

The lung allocation score uses age as a variable, and as a result, a candidate's lung allocation score changes from one day to the next – even without updates to laboratory values. Therefore, the computer programming hours required to implement this policy will be high. The Committee commented that it would be satisfied with a manual solution as long as the solution can be audited. UNOS staff commented that a manual solution would likely require auditing efforts from the UNOS Department of Evaluation and Quality. The Committee commented that due to the number of hours required for programming, the Board of Directors may not look favorably upon an automated solution for this policy change.

The Committee also considered a policy solution similar to the heart medical urgency policy where candidates must be listed at a lower status within 24 hours if they no longer meet Status 1A criteria. However, the two-week update time frame may be more sensible for lung transplant candidates with scores over 50, as these candidates' clinical condition varies in a given 24-hour time period. So, updating a lung transplant candidate's record every 24 hours may be too burdensome on transplant programs.

Transplant programs caring for patients with lung allocation scores above 50 would likely understand being asked to update their candidates' records more frequently.

The OPTN will provide the following data analysis for the Committee to review:

Examine the distribution of ventilator usage, oxygen usage, functional status and other non-invasive tests in candidates with a lung allocation score >50. For comparison purposes provide the same distributions for candidates with lower LAS values.

This information will be provided for lung candidates 12 years and older who have been added to the waiting list between 5/4/05 and 5/3/10. Where appropriate, the results will be stratified by yearly eras based on the LAS start date (e.g., 5/4/05-5/3/06).

The Lung Subcommittee will continue to discuss this topic at its future conference calls, including whether the proposed frequent update policy would apply to scores 50 or higher obtained through an exception request to the Lung Review Board.

### **Develop an Interim Measure for Better Identifying the Medical Urgency of Candidates with Pulmonary Hypertension**

The Committee continued its discussion on the need for an interim measure to address the waiting list urgency of candidates with pulmonary hypertension. The Committee had previously discussed the development a calculator that includes current and change in bilirubin, factors approved by the Board of Directors for inclusion in the LAS. These factors have not yet been programmed in UNet<sup>SM</sup>. A transplant center could submit the score generated from the calculator as an exception request to the Lung Review Board.

In addition to current and change in bilirubin, are there other variables that could be analyzed for their impact on the waiting list mortality of candidates with pulmonary hypertension? The Reveal Registry could be a source to learn which other variables to assess. Also, the SRTR's modeling of a revised LAS system indicates that the revisions benefit candidates with pulmonary hypertension.

The Committee requested that UNOS staff develop a simple, cost-effective calculator that includes current and change in bilirubin. This calculator would be provided to lung transplant programs to assist them in determining their candidates' score that includes current and change in bilirubin. The calculator could remain as simple as what is posted to the OPTN website, as shown below.

DOB:

Height:  ft  in  cm

Weight:  lbs  kg

Lung Diagnosis:

Code:

Functional Status:

Diabetes:

Assisted Ventilation:

Requires supplemental O<sub>2</sub>:

Amount:  L/min  %

Percent Predicted FVC:  %

Pulmonary Artery Systolic Pressure:  mm Hg

Mean Pulmonary Artery Pressure:  mm Hg

Pulmonary Capillary Wedge Mean:  mm Hg

Current PCO<sub>2</sub>:  mm Hg

Highest PCO<sub>2</sub>:  mm Hg

Lowest PCO<sub>2</sub>:  mm Hg

Change in PCO<sub>2</sub>:  %

Six minute walk distance:  feet

Serum Creatinine:  mg/dl

→ LAS Score

**Adding Computerized Tomography (CT) Scan to Policy 3.7.12.4 (Desirable Information for Lung Donors)**

The Committee had previously requested that CT Scan be added to Policy 3.7.12.4 and that UNOS staff prepare the related public comment proposal. During this meeting, UNOS staff sought clarity on the problem that the proposed policy would solve.

CT scans of donor lungs would inform physicians on the following: whether the offered lung or lungs have a contusion or experienced lack of oxygenation. The CT scan could also help identify, in some cases, whether there are cancerous nodules present in the donor lungs.

At a previous Lung Subcommittee meeting, the members had suggested that CT scans could be requested from OPOs for lung donors who are at least 45 years of age and who have a smoking history of 20-25 pack-years. However, there are different schools of thought the donor age cut point as well as on the number of smoking pack-year history. Some transplant centers would accept lungs from a donor with a 20-25 pack year history without a CT scan, but would request CT scans on lungs from donors with

smoking history of 30 pack-years or higher. Some transplant centers request CT scans for reasons other than smoking, and not necessarily due to malignancy.

Regardless of the reasons for requesting a CT scan, the Committee commented that physicians evaluating whether to accept a lung offer or not should be able to request tests, the results of which would guide their decision-making.

The Committee also discussed sections in Policy 3.7.12 (Minimum Information for Thoracic Organ Offers) that delineate essential (required) information from desirable information. If a piece of information aids in making decisions about accepting lung offers, should such information be desirable or required? Some hospitals in the nation may not be able to perform certain tests due to lack of staff or equipment. But, language for the echocardiogram requirement in Policy 3.7.12.1 (Essential Information) accommodates a hospital that may not be able to perform this test. Perhaps information that are desirable, because hospitals may not be able to provide such test results, should be part of the requirements section in Policy 3.7.12 and should include language that accommodate hospitals that may not have facilities to perform such tests.

The Heart and Lung Subcommittees will discuss which information is desirable and which information is essential, and potential edits to Policy 3.7.12.

The Lung Subcommittee will discuss in detail the components of the proposed CT scan policy and in which section of 3.7.12 the language should be placed.

### **Include as a Factor in the Patient Survival Model of the Program Specific Report (PSR) “Patients Who Are Re-Transplanted”**

In its review of the SRTR’s analyses on how best to update the LAS models, the Lung Subcommittee has discussed the impact of including re-transplant as a variable. In these analyses, the lung transplant score appears to be high for patients who are re-transplanted. Related to this discussion, but with the focus on the SRTR’s program specific reports, the Committee discussed why the PSR’s patient survival model does not include re-transplanted patients but the PSR’s graft survival model does. The SRTR commented that the reason, in part, is due to the statistical complexity involved in including this variable in the patient survival model. The Committee discussed whether this lack of inclusion is affecting an insurance company’s perception of a transplant center’s performance. The Committee requested that future patient survival models convey more clearly information about re-transplants performed by transplant centers. The number of lung re-transplants is small, but this number appears to be increasing since the implementation of the LAS. To understand the patient population in need or receipt of a re-transplant, the Committee requested the following analysis from the SRTR:

To validate the Committee’s decision not to incorporate re-transplant as a separate diagnosis in the updated LAS, for the same cohorts used in the updated LAS analyses, provide:

- Demographics of re-transplant candidates and recipients, compared to primary candidates and recipients;
- Inter-transplant interval for re-transplants;
- Waiting list outcomes of candidates listed for re-transplant compare to outcomes by diagnosis grouping of candidates listed for primary transplant; and,
- Post-transplant outcomes for recipient of re-transplants compared to post-transplant outcomes by diagnosis grouping for primary transplant recipients.

## **OPO's Actual Time of Arrival Time in the Operating Room versus Its Scheduled Time of Arrival**

The Committee continued its discussion on understanding the national scope of delays on the part of OPOs regarding their scheduled time to the operating room and the actual time of arrival for organ recovery. The Committee will submit a memo to the OPO Committee requesting that these two variables be part of the OPO Performance Metric.

## **Update on Committee-Sponsored Programming Projects**

UNOS will program the following Committee-sponsored policy modifications in 2010:

- Policies 3.7.6.2 (Candidates Age 0-11) and 3.7.11.1 (Sequence of Pediatric Donor Lung Allocation)
  - Lung transplant candidates less than 12 years of age will receive medical urgency classification of Priority 1 or 2.
  - Lung offers from young pediatric donors will be extended to a combined group of local, Zone A and Zone B young pediatric candidates, and then to a combined group of local and Zone A adolescents before local offers are made to adults.
- Policies 3.7.8 (ABO Typing for Heart Allocation), 3.7.8.1 (Heart Allocation to Pediatric Candidates Eligible to Accept a Donor Heart of Any Blood Type), and 3.7.10.1 (Sequence of Pediatric Heart Allocation)
  - The policy extends the age from 1 to 2 years for listing pediatric heart candidates who can receive hearts from donors whose blood type is incompatible with the candidate's. The policy specifies which born candidate is eligible to be listed to receive an ABO-incompatible organ. The policy also requires collection of titer values. Born candidates must be listed as Status 1A or 1B. Candidates who are at least one year old must have titer levels of 1:4 or less and not due to treatment received in the previous 30 days. All titer values must be updated every 30 days.
  - Hearts recovered from pediatric donors will be allocated to all born pediatric candidates before candidates in utero. Hearts from pediatric donors will be offered to candidates in utero in the combined Local and Zone A geographic area. Further, this allocation prioritizes heart offers for candidates in utero by blood group compatibility in the following order: 1) ABO-identical; 2) ABO-compatible; and, 3) ABO-incompatible. This same blood group compatibility prioritization will apply when pediatric hearts are offered to candidates in utero in Zones B through E. Offers to candidates in utero in these geographic areas will occur after offers to candidates in utero in the local and Zone A area.

UNOS will program the following Committee-sponsored programming projects in 2010:

- Modify the adult and pediatric heart Status 1A justification form to delineate medications which are inotropes from those which are vasopressors;
- Modify the heart and heart-lung waiting list removal page to include data elements related to mechanical circulatory support devices, i.e., ventricular assist device, total artificial heart, and extracorporeal membrane oxygenation;
- Modify the lung diagnosis drop down list in the lung transplant waiting list as follows:
  - Inactivate "Lung Re-TX/GF Obliterative Bronchiolitis" from the existing list of diagnosis codes.

- Add the following re-transplant diagnosis codes to the existing list of diagnosis codes: lung Re-Tx/GF Obliterative Bronchiolitis-Restrictive and Lung Re-Tx/GF Obliterative Bronchiolitis-Obstructive.
- Add usual interstitial pneumonitis (UIP) to the item “idiopathic pulmonary fibrosis (IPF)” in the drop down list.
- Change the lung disease diagnosis group for “Constrictive Bronchiolitis (no-retx)” from Group A to Group D.

## **Committee Members Who Participated**

Mark Barr, MD (Chair)  
Steven Webber, MD (Vice-Chair)  
Kevin Dushay, MD (Region 1 Representative)  
Raymond Benza, MD (Region 2 Representative – by phone)  
Dan Meyer, MD (Region 4 Representative)  
Craig Selzman, MD (Region 5 Representative)  
Nahush Ashok Mokadam, MD (Region 6 Representative)  
Sangeeta Bhorade, MD (Region 7 Representative)  
Ramsey Hachem, MD (Region 8 Representative)  
Alan Gass, MD (Region 9 Representative)  
Ladora Dils, MD (Region 10 Representative)  
Nancy Blumenthal, MSN, CRNP (At Large Member)  
Kevin Chan, MD (At Large Member; Lung Review Board Chair)  
Gregory Couper, MD (At Large Member)  
Theodore Liou, MD (At Large Member)  
Brigitte Marciniak-Bednar, RN, BSN, CCTC (At Large Member)  
Kenneth McCurry, MD (At Large Member)  
Mandeep Mehra, MD (At Large Member – by phone)  
Stuart Sweet, MD (At Large Member – Lung Subcommittee Chair)  
J. David Vega, MD (At Large Member)  
Mark Zucker, MD, JD (At Large Member – Heart Subcommittee Chair)  
Maryl Johnson, MD (Ex Officio)  
Monica Lin, PhD (Ex Officio – HRSA)  
Ba Lin, MA (Ex Officio – HRSA)  
Mike Cecka, PhD (Ex Officio, Histocompatibility Committee – guest who participated by phone)  
D. Bradley Dyke, MD (SRTR)  
Susan Murray, ScD (SRTR)  
Ying Qian, MS (SRTR)  
Wida Cherikh, PhD (UNOS – by phone)  
Leah Edwards, PhD (UNOS)  
Vipra Ghimire, MPH, CHES (UNOS)  
Brian Shepard (UNOS)  
Lori Gore (UNOS – by phone)  
Cliff McClenney (UNOS – by phone)  
Anna Kucheryavaya (UNOS – by phone)  
Aaron McKoy (UNOS – by phone)  
Jory Parker (UNOS – by phone)