

Thoracic Organ Transplantation Committee Meeting

March 23, 2010

Chicago, Illinois

Maryl R. Johnson, MD – Chair

Mark L. Barr, MD – Vice-Chair

The following is a summary of the Thoracic Organ Transplantation Committee's (Committee) discussions when it met in Chicago, Illinois on March 23, 2010.

Item 1: Proposed Modifications to Data Elements on the following Tiedi[®] 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

The Committee discussed the following public comment proposal: "Proposed Modifications to Data Elements on the following Tiedi[®] 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."

The Committee focused its discussion on data elements proposed for all organ types, as well as thoracic, deceased donor, and histocompatibility data elements. The Committee first reviewed the slides prepared by UNOS staff (Exhibit L) and then reviewed the data elements as outlined in the public comment proposal. After much deliberation – including a philosophical discussion on the collection of data elements for current or future endeavors to improve thoracic organ allocation – the Committee voted in favor of the proposal (20-supported; 0-opposed; and, 0-abstained) provided that its comments be considered or accepted, or both.

One comment the Committee provided applies to data entry in general:

To minimize data entry burden and to make data entry as efficient as possible in the OPTN forms, when there are identical data elements that exist in multiple forms, UNOS should program these forms such that data pre-populate. The programming, however, should allow transplant coordinators to have an opportunity to correct any data if necessary.

Provided below, organized by form type and population, are the Committee's comments on specific data elements:

Data Elements Proposed on the Transplant Candidate Registration (TCR) Form for All Organ Types

For heart and heart-lung candidates, there is no need to collect the following data elements proposed for addition to the TCR:

- Coronary bypass;
- Coronary angioplasty and/or stent;
- Myocardial infarction; and,
- Other cardiac disease.

The Committee commented that for lung candidates, the proposed addition of the four data elements listed above is appropriate.

Definitions need to accompany the proposed addition of “drug-treated systemic hypertension” and “cirrhosis.”

The Committee considered the addition of angina to the TCR for all organ types. The response to this potential data element could be “ischemic” or “not ischemic.”

Separately, the Committee also considered the addition of therapy type as a data element for lung candidates on the lung TCR form. The group concluded that most candidates with pulmonary arterial hypertension typically receive all three types of medication therapies. Therefore, collecting this data element would not further discriminate on which medication might be contributing to higher or lower waiting list mortality. Therefore, the Committee decided to not pursue the collection of this data element.

Data Elements Proposed on the Heart TCR Form

For heart candidates, there is no need to collect the following data elements proposed for addition to the TCR:

- Defibrillator with biventricular pacemaker;
- Biventricular pacemaker;
- BNP; and,
- Pro-BNP.

The Committee proposed the addition of “implantable cardioverter defibrillator (ICD)” on the heart TCR form. UNOS staff commented that “implantable defibrillator” is an existing data element on the heart TCR form, but not on the lung TCR form. The Committee commented that the lung TCR form did not need to include the implantable defibrillator data element.

The Committee commented that there lacks consistent collection of BNP and Pro-BNP across heart transplant centers. As such, the collection of BNP and Pro-BNP could result in an incomplete data set. Some argued that this collection could be mandatory. UNOS staff commented that mandating a test may not be permissible. Thus, the Committee opted to delete the proposed addition of BNP and Pro-BNP on the heart TCR form.

The Committee discussed the proposed addition of LVAD implant date and RVAD implant date, and queried whether the addition of these data elements was redundant. In 2008, the Committee requested the addition of these data elements to the waiting list removal page, and UNOS is in planning the implementation of these variables. The Committee commented that if possible, the data entered in the waiting list pages should pre-populate in the heart TCR page. UNOS staff will evaluate the potential for such data to pre-populate; however, staff cautioned that this effort may need to occur separately from the current waiting list removal project.

The Committee sought clarification on the need to collect “right atrial pressure/central venous pressure.” UNOS staff commented that there are other hemodynamic data elements collected on the Heart TCR, and this proposed collection would complement the list of

variables. The Committee commented that the collection of right atrial pressure/central venous pressure is satisfactory.

The Committee questioned the utility of collecting “systolic blood pressure” and the method proposed: obtaining the value at one point in time. Some members argued that systolic blood pressure value is prognostic of health quality for some candidates. The Committee agreed with this rationale, but again argued that the value could be obtained using a different data collection approach.

Data Elements Proposed on the Lung TCR Form

For lung candidates, there is no need to collect the following data elements proposed for addition to the TCR:

- Defibrillator;
- Defibrillator with biventricular pacemaker; and,
- Biventricular pacemaker.

The Committee determined that the collection of BNP and Pro-BNP is appropriate as these biological variables are prognostic of health, especially for candidates with primary or secondary pulmonary hypertension.

Data Elements Proposed on the Heart-Lung TCR Form

For heart-lung candidates, there is no need to collect the following data elements proposed for addition to the TCR:

- Defibrillator with biventricular pacemaker; and
- Biventricular pacemaker.

The Committee did not approve the proposed addition of either variable on the heart TCR form or the lung TCR form; therefore, their collection on the heart-lung TCR form is not logical. The Committee determined that the collection of BNP and Pro-BNP may be appropriate on the heart-lung TCR form, as it approved the collection of these variables on the lung TCR form. The Committee commented that the collection of variables on this form should correlate with the data elements recommended for collection or deletion on the lung and heart TCR forms.

Data Elements Proposed on the Transplant Recipient Registration (TRR) Form for All Organ Types

For heart, lung, and heart-lung candidates, there is no need to collect the following data element proposed for addition to the TCR: Islet cell recipient.

For heart candidates, there is no need to collect the proposed data elements as these data are collected elsewhere for this population:

- Myocardial infarction;
- Coronary bypass;
- Coronary angioplasty and/or stent; and,
- Other cardiac disease.

The Committee commented again on the need for programming that auto-populates data, where relevant, and enables the transplant coordinator to make modifications as necessary.

Data Elements Proposed on the Heart TRR Form

The Committee emphasized again the need for programming that auto-populates data, where relevant, and enables the transplant coordinator to make modifications as necessary. The Committee made no further comments on the data elements proposed for addition to the heart TRR.

Data Elements Proposed on the Lung TRR Form

In 2009, the Committee initially discussed the collection of the following data elements at both 24-hours post-transplant and 72-hours post transplant:

- Intubated at 24 hours and at 72 hours
- PaO₂ at 24 hours and at 72 hours;
- FiO₂ at 24 hours and at 72 hours;
- ECMO at 24 hours and at 72 hours; and,
- Inhaled NO at 24 hours and at 72 hours.

It is the current opinion of the Committee to collect the above data elements at only 72-hours post-transplant. Data collected at the 72-hour time frame will enable better understanding of a candidate's likelihood to experience primary graft failure.

Data Elements Proposed on the Heart-Lung TRR Form

To be consistent with its recommendation for proposed data elements added to the lung TRR, the Committee requested the collection of the following data elements at only 72-hours post-transplant:

- Intubated at 72 hours
- PaO₂ at 72 hours;
- FiO₂ at 72 hours;
- ECMO at 72 hours; and,
- Inhaled NO at 72 hours.

To Committee also recommended that the following data not be added to the heart-lung TRR: Tricuspid valve annuloplasty. Some members sought and received clarification on the proposed collection of "peripheral vascular disease requiring intervention." The Committee commented on the significance of collecting this data element as vascular disease can contribute to mortality.

Data Elements Proposed on the Transplant Recipient Follow-up (TRF) Form for All Organ Types

The Committee supported the collection of the proposed addition and deletion of the data elements on the TRF form for all organ types.

The Committee discussed the frequency in which centers submit the follow-up forms, as well as mandating testing for transmissible diseases. UNOS staff stated that centers complete a follow-up form each year. However, if a center does not perform this follow-up, it may opt

to respond “not done.” The Committee discussed a policy that states that centers must test recipients of high-risk donors at 3, 6, and 12-month intervals.

The Committee requested that the Ad Hoc Disease Transmission Advisory Committee (DTAC) comment on the proposed data elements for addition. Specifically, the Committee seeks to learn DTAC’s opinion on the time frame for collecting the proposed data elements. Does DTAC wish to mandate the collection of these data elements? Will the deceased donor’s classification of “high-risk” have an impact on the collection of these data elements?

Data Elements Proposed on the Heart TRF

The Committee supported the collection of the proposed modification and deletion of the data elements on the heart TRF form. The Committee commented that the changes appeared to clarify recipients with renal insufficiency.

Data Elements Proposed on the Lung TRF

The Committee supported the collection of the proposed modification and deletion of the data elements on the lung TRF form. The Committee commented that the changes appeared to clarify recipients with renal insufficiency.

Data Elements Proposed on the Heart-Lung TRF

The Committee supported the collection of the proposed modification and deletion of the data elements on the heart-lung TRF form. The Committee commented that the changes appeared to clarify recipients with renal insufficiency.

Data Elements Proposed on the Deceased Donor Registration (DDR) 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 the donor’s terminal value, and queried at what point in time the collection of terminal value occurs. The Committee recommended that the collection of terminal value prior to the donor’s delivery in the operation room.

The Committee also recommended the addition of the following data elements:

- Peak airway pressure to the “ventilator mode” element proposed for addition; and
- Tidal volume to the arterial blood gas section.

The Committee commented that hospitals do not routinely perform heart biopsies on donors, and such, this data element should be deleted.

Upon a query from a member, the Committee commented that the following data elements were recommended for addition to the DDR form proactively: liver machine perfusion, heart machine perfusion, and left/right lung machine perfusion. These perfusions would be performed ex-vivo and are proposed for addition in the event that sections of a heart, lung, or liver undergo perfusion, and the remaining sections do not.

Data Elements Proposed on the Histocompatibility (HF) 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 WaitListSM is flexible, and needs to be to accommodate improvements in organ allocation. Changes to WaitListSM 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.

Item 2: Proposal to Require Collection of Human Leukocyte Antigen (HLA) on Deceased Donor Thoracic Organs

The discussed its proposal to add HLA to Policy 3.7.12.1 (Essential Information). Policy 3.7.12.1 currently requires that an OPO provides the following data with each deceased donor 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.*

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.

During its meeting, the Committee discussed the proposal with the Chair of the Organ Procurement Organization (OPO) Committee, Jeffrey P. Orlowski, MS, CPTC. (UNOS staff had invited both Mr. Orlowski and the Vice-Chair of the OPO Committee, Ms. Lori E. Brigham, MBA, to participate in the meeting by phone; however, on the day of the meeting, only Mr. Orlowski could participate.)

The Committee explained to the OPO Committee's Chair its intent to add HLA to Policy 3.7.12.1: knowledge of deceased donor HLA would enable programs to screen thoracic organ offers for unacceptable donor antigens, enable sensitized thoracic candidates to receive suitable organ offers, and promote the practice of virtual cross-matching. The Committee asserted that current laboratory technology allowed for HLA typing of thoracic donors. The Committee sought commentary from the OPO Committee's leadership on: 1) when OPOs could provide HLA typing for thoracic donors, i.e., at the time of the organ offer or before performing a match-run; 2) the specificity of HLA typing the OPOs could provide for thoracic organ donors; and, 3) the operational issues the OPOs would encounter with such a policy.

Prior to the meeting, both the OPO Committee's leadership and the Thoracic Committee reviewed a draft of the HLA policy proposal prepared by UNOS staff.

During the meeting, the OPO leadership cautioned that obtaining HLA typing for thoracic donors before performing a match-run, as indicated in the draft policy proposal, could be burdensome operationally to some OPOs. The group discussed that there is indeed only anecdotal knowledge of which OPOs could or could not provide HLA data readily for thoracic donors. However, OPOs do provide HLA typing at the time of a kidney match-run. (The OPO Committee Chair suggested that this kidney practice may be changing.) The Thoracic Committee recollected comments from the leadership of the Histocompatibility Committee's Vice-Chair, who attended the July, 2009 meeting: it is entirely feasible for histocompatibility laboratories to perform HLA typing tests, and provide the results.

One Thoracic Committee member informed the group of having conducted an informal telephone survey of 15 OPOs to understand how quickly these organizations could test for and provide HLA typing for thoracic donors. Most of the organizations responded that they received HLA typing information within 6-8 hours. Nevertheless, as this member commented, it is necessary for the Committee to understand logistical issues that exist for OPOs that do not receive HLA typing information in the 6-8 hour time frame, i.e., when the time frame is longer.

The group also discussed if blood or lymph nodes was the more appropriate sample to submit for receiving accurate typing of deceased donor HLA; and, the impact of a hemodiluted blood sample on accurate HLA typing.

The OPO Committee leadership supported the concept of typing thoracic donors' HLA, but suggested that the Thoracic Committee collaborate with the OPO Committee to first understand the availability of HLA typing information for thoracic organ donors. (The OPO Committee meets next on April 20, 2010.) The Thoracic Committee should conduct this formative research before making a policy recommendation. The Thoracic Committee should also identify how readily the proposed policy could be applied by OPOs. Finally, the OPO Committee Chair recommended that the Thoracic Committee engage the Histocompatibility community or Committee, or both, in this discussion.

Mr. Orłowski commented that should such a survey result in the fact that a majority of OPOs are able to provide HLA typing on thoracic donors and in a short time frame, then it is the OPO Committee's and community's responsibility to provide operational guidance to those organizations in the minority who may need assistance to improve their HLA typing time frame. The Committee agreed that a survey could provide necessary information about OPO operational practices regarding thoracic HLA typing.

The group also discussed that the OPO community reacted initially to the need to perform nucleic acid testing (NAT) with concern, but over time, became accepting of this requirement. The Thoracic Committee countered that an OPO's performance of NAT does not impact organ allocation, whereas the performance of HLA typing does. The Committee's focus is to improve organ allocation to sensitized thoracic candidates, and this is best accomplished by the addition of HLA to Policy 3.7.12.1. Many transplant centers already perform virtual cross-matching to identify medically suitable donor organs for their candidates.

The Thoracic Committee thanked Mr. Orłowski for participating in the meeting. After Mr. Orłowski's departure, the Thoracic Committee continued its discussion of the proposal.

Knowing that there are sensitized candidates who could benefit from the addition of HLA to Policy 3.7.12.1, what is the right action for the Committee to take? The Committee should do its best to abide by the needs of the sensitized patient. Literature supports the identification of candidates' unacceptable antigens, performed through virtual cross-matching, or through prospective or retrospective cross-matching. Thus, Committee considered proceeding with its intent to change Policy 3.7.12.1.

Some members of the Committee argued for building consensus on the proposed policy change before distributing it for public comment. This approach would increase the likelihood of the proposal's acceptability to the OPO community. Others argued that the Committee need not "sell" its idea of adding HLA typing to Policy 3.7.12.1. Rather, given the time that exists between this meeting and the next public comment cycle, the Committee could collaborate with the OPO, Histocompatibility, and Operations and Safety Committees to conduct the survey discussed earlier, i.e., build the consensus without losing sight of doing right by the sensitized candidate. The Committee could apply the survey results to further develop the proposal.

Regarding OPOs that might experience operational difficulties with the addition of HLA to Policy 3.7.12.1, the Committee pondered also surveying histocompatibility laboratories. The intent of surveying this group would be to understand whether the operational difficulties in HLA typing reside in fact in laboratories affiliated with said OPOs.

The group also discussed that it is possible that the operational issues faced by some OPOs have to do with historical or cultural practices that exist locally in a donation service area.

The Committee also commented that the policy language does not clearly state when OPOs should provide HLA typing information to transplant centers. While the proposal states that OPOs may not be able to conduct a match-run without having deceased donor HLA typing, the policy does not. Further, the Committee members opined that it was not their intent for HLA typing information to be ready before a match-run. Rather, the Committee members commented that they could be comfortable with the receipt of HLA typing from OPOs when they offer thoracic organs for transplant. UNOS staff commented that it sought this clarity on when exactly the OPO would be expected to provide deceased donor thoracic HLA typing.

One member proposed the following policy alternative: require HLA typing only if the OPO will offer a thoracic organ outside of its local unit. Another member countered that if in the future, the Committee were to eliminate "local" as a geographic factor in allocation, then the proposed alternative would require revisions. Further, given that there is technology to type HLA and that the Committee has learned that laboratories can perform this test – as well as several OPOs already perform this test for thoracic donors – the Committee should maintain its original proposal.

The Committee also recommended that the proposal language should focus on unacceptable antigens and virtual cross-matching. The proposal currently mentions virtual cross-matching, but provides more statements about prospective cross-matching.

The Committee requested that a few of its members be present at the April 20, 2010 OPO Committee meeting as the proposal would be discussed, and possibly, the results of the survey mentioned earlier.

Regarding the survey, the Committee requested that UNOS staff develop a working group representing the following Committees: Thoracic, OPO, Operations and Safety, and Histocompatibility. This working group will draft and distribute the aforementioned survey to the OPO and histocompatibility communities, and prepare a final draft of the proposal for review by the Thoracic Committee. Specifically, the survey will include the following content:

- 1) An introduction that educates the Committee's intent for collecting HLA from thoracic donors, the significance of unacceptable donor antigens to sensitized thoracic candidates, and the evidence for their proposal; and

- 2) Questions listed below.
 - a. How much time does your laboratory require to provide deceased thoracic donor HLA typing?
 - b. How much time does your OPO currently need to collect blood or tissue sample for HLA typing of thoracic donors?
 - c. What operational impact would your OPO experience if the Board of Directors approves the addition of HLA to 3.7.12.1?
 - i. If the impact is potentially unfavorable, how can the OPO community assist your organization in complying with the policy and your organizational needs?
 - d. Which sample provides accurate typing of deceased donor HLA: blood or lymph nodes?
 - e. What impact does a hemodiluted sample have on the accuracy of HLA typing?
 - f. When a sample is hemodiluted, what tests can a laboratory apply to determine the accuracy of HLA typing?
 - g. How often does HLA mistyping occur for a thoracic donor?
 - i. What is the magnitude of the impact of this mistyping?

Item 3: Center #07056B (Case Review)

On March 23, 2010, the Committee reviewed a heart Status 1A-exception request made by a transplant program for a heart-lung candidate. The respective heart regional review board denied the status justification request. Relevant background information is below:

A transplant center had requested an extension of its candidate's Status 1A-exception. (This candidate needed a heart and a lung.) The respective review board denied the request. The center appealed to the review board. Before the review board could meet to discuss the case again, the center transplanted the candidate. The regional review board requested that the Committee review the case, because the board questioned the candidate's medical urgency. The regional review board requests that the Committee review the lung allocation score system for efficacy.

On January 29, 2010, the Heart Subcommittee discussed this case. After some discussion on the case, the Subcommittee decided to uphold the decision of the review board. The Subcommittee recognized the need to improve policy on the joint allocation of heart and lung, and requested that the UNOS staff convey to the center that the Committee is undertaking the effort to develop a better multi-organ allocation policy. The Subcommittee recommended that the Committee not place any penalty or sanctions on the center. The Subcommittee commented that this case highlights, again, the problem with Policy 3.7.7 (Allocation of Thoracic Organs to Heart-Lung Candidates).

On March 23, 2010, the Committee discussed whether the center was justified in requesting a Status 1A-exception for its candidate. Was the candidate really in need of a heart based on the clinical information submitted? Also, should a center consider requesting a Status 1A-exception for a candidate who needs a heart and a lung? Should the Committee sanction this precedent that centers may apply for a Status 1A-exception request for candidates who need a heart and lung, especially, as one member commented, if the clinical information submitted indicate that the candidate would not be otherwise eligible to be listed as a Status 1A? The center believed that its candidate was sick enough that a request for Status 1A-exception was justified.

The center had argued previously that in its donation service area, an offer for a lung did not also bring an offer for a heart. The Committee commented that Policy 3.7.7 does state, as shown below, that as long as there is a Status 1A heart candidate eligible to receive a heart offer, the offer for a lung will not include a heart to a candidate who needs a heart and lung.

3.7.7 Allocation of Thoracic Organs to Heart-Lung Candidates. 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.

One member argued that the Committee should not take any action against the center. Another member queried about the appeal process: what happens to a candidate's status during an appeal, i.e., does the Status 1A remain as requested or does it become Status 1B? UNOS staff commented the status likely stays as requested, but that this fact would need to be verified. A member cited the following section of Policy 3.7.3 (Adult Candidate Status):

[...] A candidate who does not meet the criteria for Status 1A 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 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 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. 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. [...]

A member commented that the center did appear to follow policy. Another member queried if all heart review boards should perform prospective reviews of Status 1A-exception requests. Another question posed was whether the Committee should forward this case to the MPSC. What message, if any, should the Committee convey to the center?

One member identified following three areas for the Committee would need to address:

- 1) The center followed policy;
- 2) The language in Policy 3.7.7 is vague, and until revisions to it are made, the Committee needs to determine whether or not to uphold the decision of the regional review board; and,
- 3) The Committee needs to guide regional review boards on how to address such requests in the future.

Upon query by UNOS staff, the Committee decided that the Heart Subcommittee did not need to further review this case – the Committee would decide.

The Committee commented that centers should only apply for a Status 1A-exception if the candidate meets the relevant criteria listed, and not because the candidate needs a heart and a lung. With respect to this case, the Committee determined the following:

- The center did not violate Policy 3.7.3;

- It is unclear if the candidate met the Status 1A-exception criterion;
- UNOS staff should send a letter to the center stating that the Committee will monitor the center's exception request activities and may choose to act in the future, i.e., inform the MPSC if a pattern of submitting such requests emerge.

The Committee voted in favor on the above actions: 22-Supported; 1-Opposed; 2-Abstained.

Item4: Case #22145D

On March 23, 2010, the Committee reviewed a heart Status 1A-exception request made by a transplant program for a heart candidate. The respective heart regional review board denied the status justification request. Relevant background information is below:

A center had requested Status 1A-exception for its candidate. The respective regional review board denied the request. When the center was informed of the decision, the center had already transplanted the patient. Instead of appealing the decision to the review board, the center opted to have the Committee review the case.

At its January 29, 2010 meeting, the Heart Subcommittee determined that the center must submit a narrative explaining the reasons for appealing the case. The case documentation submitted to the review board must be accompanied by a separate narrative – the appeal – for the Thoracic Committee. This narrative was missing. UNOS staff commented that the center had been asked if it wanted to provide additional information, but that the center had responded that the information submitted to the review board was sufficient.

The Subcommittee could not determine whether the candidate's Status 1A-exception was justified based on the information presented. The Subcommittee is willing to review the case again, but only with additional narrative. If the center does not provide such a narrative, the Subcommittee will recommend to the Committee to uphold the review board's decision and to involve the MPSC. UNOS staff will contact the center and request the additional narrative.

Upon request, center #22145D provided the following narrative on why it considered its candidate was justified to receive a Status 1A-exception.

“The patient was a 57 year old male with non ischemic cardiomyopathy and coronary disease that was out of proportion to the degree of ventricular dysfunction whose initial presentation was related to congestive heart failure. He had previously undergone stenting in 1998 and 2002. He developed problems with symptomatic ventricular arrhythmias and underwent ICD implantation in 2002. In 2008 he developed problems with sustained ventricular tachycardia with multiple AICD therapies both antitachycardia pacing and cardioversions despite amiodarone, mexilitine and quinidine. The patient also was receiving carvedilol and lisinopril for the treatment of worsening ventricular function. He underwent attempted RV and LV VT ablation both epicardially and endocardially on 9/08, 10/08 and 01/09. He continued to have potentially lethal arrhythmias despite optimized medical therapy and therefore on 6/29/09 he underwent HeartMate II implantation as an attempt to decompress the left ventricle and reduce the frequency of his arrhythmias. This was unsuccessful and he continued to receive ICD shocks with the LVAD implanted. We applied for a 1Ae exemption on 10/8/09 and he was transplanted on 10/14/09. We received the decision that our request for 1Ae exemption was denied several hours after the transplant. The patient's arrhythmias

precluded the implantation of a pulmonary artery catheter for long term management and also the use of inotropes.”

Upon receiving the narrative above, the Chair of the Heart Subcommittee requested the following additional information from the center:

Question 1: Had the thirty days of 1A time for VAD been used?

- Response from the center: the 30 days of 1A time had been used.

Question 2: What was the actual frequency of ICD shocks after LVAD and before transplant?

- Response from the center: the patient had been cardioverted at least a half dozen times once he was stable post HeartMate II implantation and was receiving intravenous antiarrhythmics.

On February 26, 2010, the Heart Subcommittee reviewed the case again, and commented that such detail should have been provided initially by the center. However, the center transplanted the candidate before it received the Review Board’s decision. Hence, the Subcommittee determined that based on the additional clinical information provided, it would not take an action against the center.

On March 23, 2010, the Committee reviewed the case and the decision of the Heart Subcommittee. The Committee commented that this center had not provided sufficient information initially. Specifically, the center did not detail the number of malignant arrhythmias the candidate had been experiencing. This information would have enabled the Heart Subcommittee to arrive at its decision sooner. The Committee voted in favor (25-supported; 0-opposed; 0-abstained) of upholding the Heart Subcommittee’s decision. The Committee requested UNOS staff to inform the center that in the future, the center must provide a separate narrative detailing the decision to list a candidate as Status 1A.

Item 5: Thoracic Procurement Complaint Letter

On March 23, 2010, the Committee discussed a complaint made by physicians in one center against a visiting heart recovery surgeon. Specifically, the complaint addressed two areas: 1) the surgical technique used by the visiting surgeon jeopardized the two lungs and liver still left to be procured, because the surgeon did not appropriately or proficiently divide the shared tissues; and 2) the non-collaborative behavior of the visiting surgeon in the operating room.

The Committee commented on the importance of the surgeons, while in the operating room, to discuss the procedure about to take place and especially how the division of shared tissue will occur. It appears that this type of discussion may not have occurred. Further, when such conversations occur, they need to occur before placing cross clamps.

The Committee commented that the behavior of the visiting heart recovery surgeon, based on the letter submitted, was egregious. While some surgeons on the Committee commented that they had not encountered such behavior while traveling to procure thoracic organs, others commented this type of behavior does occur. One member commented that the response should include related education of surgeons.

The Committee queried if the OPO had directly responded to UNOS regarding the letter. UNOS staff had not received any responses from the OPO affiliated with the heart recovery surgeon.

UNOS staff also reported that the center that made the complaint had distributed copies of the letter to MPSC staff. UNOS staff submitted a copy of the complaint letter to DEQ. Though DEQ will send a letter acknowledging receipt of the complaint, UNOS staff queried about the role of UNOS and the Committee in resolving this issue. How should UNOS respond to these types of complaints?

The Committee commented that only one side of the story had been told thus far, and in order to act, statements from all parties must be heard. The Committee could collect information from the visiting surgeon or affiliated center, and the OPO. Or, the MPSC could be the OPTN/UNOS body to investigate this complaint.

Some members queried if the visiting surgeon violated any policies or bylaws. There are no bylaws or policies that address specific individuals. The American Society for Transplant Surgeons (ASTS) has published a document, "Recommendations For Standards for Individuals Procuring Deceased Donor Organs for Transplantation," the intent of which is to: "...establish criteria by which transplant centers and...OPOs...can provide the highest quality organs possible from every donor with consistency, safety and professionalism." One member argued that this ASTS document does not apply in this case, as all recovering surgeons were attending physicians, i.e., neither residents nor fellows.

Another member queried about the role of the relevant OPO leadership in resolving such issues. While one member commented that the OPO leadership could take action against the visiting surgeon by not allowing that individual to perform recoveries in the future, another member argued that OPOs would be placed in a challenging position if they were to apply such sanctions. OPOs do not, and, in general, are not qualified to judge surgical skills. But, the OPO affiliated with the heart surgeon under discussion could address the alleged non-collaborative behavior with this individual. An OPO should not be sending recovery physicians who create the type of problems under discussion currently.

One member commented that perhaps hospitals have the role of oversight, and another opined that such recovery behaviors should not be tolerated. The Committee agreed that this type of behavior should not be tolerated.

The MPSC can make the transplant center accountable for an individual's behavior. The MPSC has already been notified of this procurement case and it is likely to be the suitable body to perform the related investigation. The Committee commented that it would not be logical for two OPTN/UNOS bodies to pursue this investigation. Therefore, the Committee voted in favor (25-supported; 0-opposed; 0-abstained) of requesting the MPSC to investigate this procurement case, including the collection of statements from the visiting surgeon or center, and the affiliated OPO.

Item 6: Emergency Explant and Re-Listing

The Committee discussed the following memo from the OPTN/UNOS Ad Hoc Disease Transmission Advisory Committee (DTAC).

The *Ad Hoc* Disease Transmission Advisory Committee (DTAC) has reviewed a small number of cases reported to the Patient Safety System where unexpected malignancy was found during donor autopsy. These findings have warranted emergency explant and/or re-listing of recipients in some instances. While the DTAC recognizes that this is an infrequent occurrence, it hopes that recipients involved in this situation have the opportunity to receive another opportunity for transplant as soon as possible and appropriate when considering the severity of illness in others on the waiting list. Several Committee members questioned whether there were appropriate mechanisms in place to appropriate review these situations in a timely fashion and prioritize the recipient for re-transplantation if appropriate. In some instances, the timely re-transplantation may reduce the risk that the malignancy causes an adverse event.

As a result, the DTAC would like to take this opportunity to request that the Thoracic Organ Transplantation Committee review any existing organ specific policy language or Regional Review Board protocols that pertain to the unexpected need for re-transplant in an effort to determine whether this scenario is adequately addressed.

The Committee queried whether a policy for such a specific episode is needed, especially when both the heart and lung policies allow transplant centers to request exceptions for their candidates. Further, once UNOS implements the pediatric lung policy, centers can apply to the Lung Review Board for Priority 1 exceptions for these candidates (See Policy 3.7.6.2 – Candidates Age 0-11).

In cases like the one described by DTAC, the organ would be considered high-risk. Therefore, the decision of whether or not to accept and transplant such organs, as well as the decision to medically manage this candidate post-transplant, belongs to the candidate's clinical team. This team could, as written in the current heart and lung policies (3.7.3 – Adult Candidate Status; 3.7.4 – Pediatric Candidate Status; and, 3.6.1 – Candidates 12 and Older), request a Status 1A heart exception or a higher lung allocation score to the appropriate review board. The Committee voted in favor of its decision, and requested UNOS staff to convey this decision to DTAC.

Item 7: Heart-Lung Allocation (Possible Policy Alternatives)

UNOS Staff presented several policy concepts that could comprise the revised Policy 3.7.7.

UNOS staff asked the following questions to the Committee:

- 1) Should the heart-lung list be eliminated? Should there be only a heart transplant waiting list, and a lung transplant waiting list? Currently, there are three lists: heart, lung, and heart-lung. A candidate in need of a heart and lung would be on all three lists.
- 2) Should the revised Policy 3.7.7 account for heart candidates who are Status 1B? The Committee had previously discussed that some Status 1B candidates are quite ill.
- 3) Should the policy include language about a lung allocation score equivalent to Status 1A or 1B, or both?
- 4) Should the policy be for both adults and children?
- 5) Should the policy account for geography, and if so, how?

The Committee favored the elimination of the heart-lung list to create simplicity in the match-run process. (The number of candidates who await both hearts and lungs are small (less than 100).) The Committee also considered the development of a joint heart-lung allocation algorithm. OPOs need guidance so that there is consistency on how they allocate hearts and lungs to candidates who need both. Currently, OPOs allocate hearts and lungs to these patients by making more use of the heart match-run than the lung match-run. However, this allocation is a manual process. The policy language does not state what consideration an OPO should give to geography in this allocation process. So, a candidate in need of both

a heart and a lung may wait longer for a transplant than a candidate who only needs a heart or only needs a lung.

The Committee reviewed waiting list mortality for lung candidates by LAS grouping and for heart candidates by Status 1A. These results suggested that a heart Status 1A candidate might have similar waiting list mortality to a lung transplant candidate with a lung allocation score of 50 or higher. But, the Committee requested additional information for waiting list mortality on the other heart statuses to examine them in context of waiting list mortality within LAS groups.

The Committee considered geographic characteristics to include in the policy. The group opined that very few heart-lung offers are being made beyond Zone A, but this is information that UNOS staff could research.

One member commented that a candidate with a lung allocation score of 60 should be able to get the heart offer if that organ was also needed. Another member argued that the heart match-run should continue to be favored as post-transplant survival needs to be considered.

One member recommended that the eventual joint heart-lung allocation policy should be simple, due in part to the small number of candidates who need both organs. This member proposed the following policy concept: when a thoracic match-run prioritizes the heart-lung candidate as the first individual to receive a thoracic organ, the OPO should also offer the other thoracic organ to that candidate. Another member commented that this concept is similar to what was done historically, and queried why this process was abandoned.

Another member proposed the addition of points to the LAS to candidates depending on their heart medical urgency status.

In the interest of time, the Committee ceased its discussion of this joint allocation policy at the March, 2010 meeting. The Committee requested that the Heart and Lung Subcommittees continue this discussion at their meetings.

Upon the adjournment of the meeting, however, several Committee members gathered by a flip chart to outline heart-lung allocation policy alternatives. This informal discussion resulted in the following concepts, which the Heart and Lung Subcommittees will discuss further in the near future.

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 heart-lung (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.

Item 8: ABO Incompatible Policy – Revisited (Consider Allocation Priority for Candidates Who Can Receive an Organ from a Donor with Any Blood Type)

The Committee’s meeting packet included three articles,¹ which concluded that the heart allocation system in the United States needs to reconsider the placement of ABO-incompatible candidates in the allocation sequence. The current placement of ABO-incompatible candidates – at the end of the sequence – does not appear to have an impact on the waiting list mortality. When this placement was decided, the heart community was not certain of the long-term outcomes for ABO-incompatible candidates. Now, however, there are analyses using OPTN data and the outcomes of the Canadian heart allocation system that recommend a change to this allocation sequence placement is important. In general, these data show that ABO-incompatible infant transplants appear to have identical outcomes to ABO-compatible transplants. Therefore, the heart transplant community may wish to consider discarding the concept of allocating thoracic organs based on blood type compatibility.

Changes to the heart allocation sequence would require a public comment proposal. UNOS is currently implementing Policies 3.7.8 (ABO Typing for Heart Allocation) and 3.7.8.1 (Heart Allocation to Pediatric Candidates Less Than 2 Years of Age Willing Eligible to Accept a Donor Heart of Any Blood Type). Adding the modification of the heart allocation algorithm to change the placement of ABO-incompatible candidates would delay significantly the current implementation effort.

The Committee commented that the ABO-incompatible candidate placement discussion should be part of the ongoing effort to evaluate the pediatric heart criteria for medical currency.

¹ Everitt, M.D., Donaldson, A.E., Casper, T.C., Stehlik, J., Hawkins, J.A., Tani, L.Y., Renlund, D.G., Kouretas, P.C., Kaza, A.K., Bullock, E.A., Cardon, M., & Kfoury, A.G. (2009). Effect of ABO-Incompatible Listing on Infant Heart Transplant Waitlist Outcomes: Analysis of the United Network for Organ Sharing (UNOS) Database. *Journal of Heart and Lung Transplantation*, 28, 1254–60.

W., L.J. (2009). Lost in Regulation: Why do U.S. Policies for for ABO-incompatible Transplantation for Infants Lag Behind? *Journal of Heart and Lung Transplantation*, 28, 1246–48.

Almond, C.S.D, Thiagarajan, R.R., Piercey, G.E., Gauvreau, K., Blume, E.D., Bastardi, H.J., Fynn-Thompson, F., & Singh, T.P. Waiting List Mortality Among Children Listed for Heart Transplantation in the United States. (2009). *Circulation*, 119, 717-727

Item 9: Standardizing ABO Verification at Donor Hospitals

The Committee discussed the development of a form to standardize ABO verifications performed at donor hospitals. The need to develop this form was identified by a Committee member, and the details of the issue are presented below:

“CMS² requires that surgeons verify the ABO of donor and recipient with source documents at the donor hospital prior to procuring any organ. Each transplant center has developed its own tools for verifying the ABO but actually having source documents with the surgeons is not always feasible.

- We have been using DonorNet source ABO for our verification of recipient ABO since this must be verified by two licensed professionals prior to listing a candidate.
- Many transplant centers are having to develop a corrective action plan on this CMS requirement since they are failing to consistently obtain the required signatures or failing to use source documents at the donor hospital.
- Our thoracic surgeons are often flying out at night from home and do not have forms for verifying ABO with them nor do they have source documents other than that found in DonorNet. This is especially true for centers such as [HOSPITAL X] where the surgeon often flies out without an assistant. Occasionally there is a PA or an OPO coordinator with the surgeon. But the assistant is not consistent and therefore would not be focused on our policy requirement.
- I have discussed this with other transplant administrators and have found this to be a problem at more than our facility. One center has developed a process where the surgeon (upon arrival at the donor hospital) calls the transplant coordinator on call at home to verify the ABO of the recipient. Documents are signed the next day. While this is an okay idea, I think there may be a better way to ensure this patient safety requirement is addressed.
- ***I would like to suggest that there be a standardized ABO document that is part of every donor packet at the donor hospital. This document would be signed by two licensed professionals as part of the donor checks done with the OPO, verifying both donor and recipient ABO prior to removing the donor heart. I am willing to work with colleagues to develop this standardized form.***

During the meeting, this member elaborated that verifying the ABO at donor hospitals is more of an issue when the organ recovery team is visiting from another center, as the forms that collect the same information can vary in format from one center to another.

The Committee commented favorably on the development of the ABO verification form. The Committee expressed interest in working with the OPTN/UNOS Transplant Administrators, Operations and Safety, and the OPO Committees to develop this form. Including this form as part of the DonorNet[®] system may be too costly and the implementation date could be too far in the future. Since DonorNet[®] allows for uploads of documents with “.pdf” file extensions, the Committee could develop a “.pdf” document and post it to UNetSM. This document could be created such that it could be completed electronically and remain part the donor’s electronic files.

UNOS staff will collaborate with the staff of the aforementioned Committees to develop this standardized ABO verification form.

Item 10: Update on the Lung Subcommittee’s Activities

² CMS is the acronym for the Centers for Medicare and Medicaid Services.

On March 23, 2010, the Committee learned that the Lung Subcommittee met on March 2, 2010 to continue discussing the updates to the LAS system. During that meeting, UNOS staff queried the Committee on which implementation approach to plan: 1) an update to the coefficients of the existing LAS factors; or, an update to the coefficients that also includes the addition of factors to the waiting list or post-transplant models, or both. The Subcommittee requested a cost analysis for pursuing the two implementation approaches.

UNOS staff did not have cost estimates available for the March 23, 2010 Committee meeting, but it would, as planned, have it for the Subcommittee to review on March 30, 2010.

On March 23, 2010, the Committee discussed whether an update to the mathematics, essentially, of the LAS system would need to be distributed for public comment. The group commented that Policy 3.7.6.1 (Candidates Age 12 and Older) includes the following language, which could imply that the coefficient update would not require a public comment proposal:

[...] “It is expected that these factors will change over time as new data are available and added to the models. The Thoracic Organ Transplantation Committee will review these data in regular intervals of approximately six months and will propose changes to Tables 1 and 2 as appropriate.” [...]

Tables 1 and 2 referenced in the quotation above list the factors that are in the LAS waiting list and post transplant models.

UNOS staff stated that such mathematical changes could impact candidate ranking for lung allocation. For this ranking reason, the Committee should consider submitting this for public comment. The Committee commented that that neither the factors in the models nor the intent of the policy would change due to an update to the coefficients alone. Therefore, the Committee argued that a public comment proposal may not be necessary.

The Committee then reviewed the new hazard ratios, reflecting the updated coefficients, as presented in the slides shown below.

**Bottom Line:
Waitlist Model Update - Diagnoses**

Diagnosis Group (ref=Group A)	Current Model (Cohort: 11/1/00-10/31/03*)			Updated Model (Cohort: 9/1/06-9/30/08)		
	HR	95% CI	p-value	HR	95% CI	p-value
Group B (IPAH + others)	10.77	(7.08, 16.37)	<0.0001	7.82	(3.12, 19.58)	<0.0001
Group C (CF)	2.57	(1.76, 3.74)	<0.0001	1.22	(0.47, 3.11)	0.6837
Group D (IPF + others)	2.71	(1.27, 5.77)	0.0097	2.98	(0.60, 14.66)	0.1797
Diagnosis						
Bronchiectasis	1.17	(0.70, 1.95)	0.5448	1.96	(0.75, 5.12)	0.1691
Eisenmenger	0.53	(0.28, 1.03)	0.0617	0.00†	(0.00, 0.00)	N/A
Lymphangioliomyomatosis	0.82	(0.34, 2.01)	0.6656	0.58	(0.09, 3.61)	0.5565
Obliterativebronchiolitis (non-retxp)	0.77	(0.39, 1.53)	0.4593	1.29	(0.19, 8.88)	0.7931
Pulmonary Fibrosis other	0.77	(0.55, 1.07)	0.1180	1.10	(0.53, 2.29)	0.8055
Sarcoidosis w/ PA mean >30 mm/Hg	0.49	(0.34, 0.72)	0.0003	0.66	(0.36, 1.21)	0.1767
Sarcoidosis w/ PA mean ≤30 mm/Hg	1.58	(0.87, 2.85)	0.1308	1.64	(0.60, 4.46)	0.3311

† Will use current coefficients since not enough data to estimate based on new cohort (Thoracic Committee discussion 3/27/09)

SRTR

In the slide shown above, the SRTR reported that until better waiting list data are available for candidates with Eisenmenger as their diagnosis, this group should continue to receive the hazard ratio that currently exists in the waiting list model. The Committee agreed.

In presenting the slide below, the SRTR commented that the population of candidates since the implementation of the LAS system in 2005 differs from the group that were waiting for lung transplants prior to the LAS. Prior to the LAS implementation, the candidates received transplants based on waiting time, and not necessarily based on the severity of their disease. As a result, the current candidate population has increases in its hazard ratios for variables that relate to physiologic reserve.

**Bottom Line:
Waitlist Model Update - Physiologic Reserve**

	Current Model (Cohort: 11/1/00-10/31/03*)			Updated Model (Cohort: 9/1/06-9/30/08)		
	HR	95% CI	p-value	HR	95% CI	p-value
Physiologic Reserve						
Age Groups A,B,C (per 10 yrs)	1.16	(1.06, 1.28)	0.0020	1.04	(0.84, 1.29)	0.7040
Age Group D (per 10 yrs)	1.24	(1.12, 1.36)	<0.0001	1.08	(0.92, 1.27)	0.3315
BMI (kg/m ²)	0.95	(0.94, 0.96)	<0.0001	0.94	(0.90, 0.98)	0.0019
Diabetes	1.17	(0.97, 1.42)	0.1045	1.66	(1.20, 2.30)	0.0021
Some assistance needed (ref=no assistance)	1.20	(1.04, 1.39)	0.0135	1.63	(1.04, 2.54)	0.0327
Total assistance needed (ref=no assistance)	1.12	(0.65, 1.94)	0.6817	1.57	(0.90, 2.73)	0.1089
Six-min walk distance: < 150 feet	1.39	(1.10, 1.77)	0.0066	1.84	(1.11, 3.05)	0.0184

SRTR

In presenting the slide below, the SRTR stated that the forced vital capacity (FVC) factor appears to be much less important in the current candidate population than it was prior to 2005. Based on the data in the slide below, FVC would not have an impact on candidates' LAS.

The Committee queried about retaining PCO₂, as the hazard ratio decreased in the updated model (from 1.85 to 1.10). The SRTR performed various analyses using PCO₂, and one analysis resulted in a statistically significant hazard ratio. For now, the SRTR recommended retaining PCO₂ in the model, and the Committee agreed.

**Bottom Line:
Waitlist Model Update - Severity**

	Current Model (Cohort: 11/1/00-10/31/03*)			Updated Model (Cohort: 9/1/06-9/30/08)		
	HR	95% CI	p-value	HR	95% CI	p-value
Severity						
FVC (% predicted, per 10% points)	0.82	(0.79, 0.86)	<0.0001	0.98	(0.89, 1.07)	0.6347
O2 at rest Groups A, D (L/min)	1.21	(1.16, 1.25)	<0.0001	1.13	(1.10, 1.16)	<0.0001
O2 at rest Group B (L/min)	1.04	(0.94, 1.15)	0.4135	1.06	(0.97, 1.16)	0.1855
O2 at rest Group C (L/min)	1.13	(1.08, 1.19)	<0.0001	1.20	(1.16, 1.25)	<0.0001
PA systolic Groups A, C, D (per 10 mmHg)	1.17	(1.12, 1.23)	<0.0001	1.09	(0.99, 1.21)	0.0906
PCO ₂ (per 10 mmHg) *	1.18	(1.03, 1.35)	0.0120	1.14	(1.04, 1.26)	0.0064
PCO ₂ increase of ≥15%*	1.85	(0.98, 3.40)	0.0520	1.10	(0.61, 1.99)	0.7467
Continuous Mechanical Ventilation	3.37	(2.02, 5.60)	<0.0001	5.50	(2.68, 11.29)	<0.0001

*Current Model' PCO₂ estimates are not from this cohort of patients
 PCO₂ (per 10 mmHg) currently implemented with HR = 1.06 (lower 90% confidence limit)
 PCO₂ increase ≥15% currently implemented with HR = 1.08 (lower 90% confidence limit)

SRTR

The Committee discussed the updated hazard ratios for the post-transplant model. The Committee reviewed the updated hazard ratios for diagnosis group, physiologic reserve, and severity of disease. The SRTR recommended the use of 1.0 as the hazard ratio for FVC and pulmonary capillary wedge (PCW) pressure.

Bottom Line:
Post-Transplant Model Update - Diagnoses

	Current Coefficients (Cohort: 11/1/00-10/31/03) IC=0.59			Updated Coefficients (Cohort: 5/4/05-9/30/08) IC=0.60		
	HR	95% CI	p-value	HR	95% CI	p-value
Diagnosis Group: (Ref=Group A)						
Group B (iPAH + others)	1.86	(0.94, 3.70)	0.0747	1.66	(1.12, 2.47)	0.0118
Group C (CF)	1.01	(0.74, 1.38)	0.9571	1.30	(0.94, 1.79)	0.1129
Group D (IPF + others)	1.51	(1.002, 2.28)	0.0488	1.31	(1.11, 1.55)	0.0014
Minor Diagnoses:						
Bronchiectasis	1.06	(0.63, 1.78)	0.8329	1.27	(0.74, 2.18)	0.3894
*Eisenmenger	1.48	(0.69, 3.18)	0.3115	3.01	(0.41, 22.91)	0.2797
Lymphangiomyomatosis	0.54	(0.22, 1.30)	0.1684	0.25	(0.04, 1.79)	0.1673
Obstructive bronchiolitis (non re-txp)	0.64	(0.26, 1.57)	0.3324	0.32	(0.08, 1.28)	0.1065
Pulmonary Fibrosis other	1.19	(0.80, 1.77)	0.3976	0.99	(0.72, 1.38)	0.9952
Sarcoidosis w/ PA mean > 30	0.88	(0.48, 1.64)	0.6962	0.97	(0.60, 1.56)	0.9070
Sarcoidosis w/ PA mean <= 30	0.98	(0.44, 2.21)	0.9681	0.80	(0.38, 1.70)	0.5620

SRTR

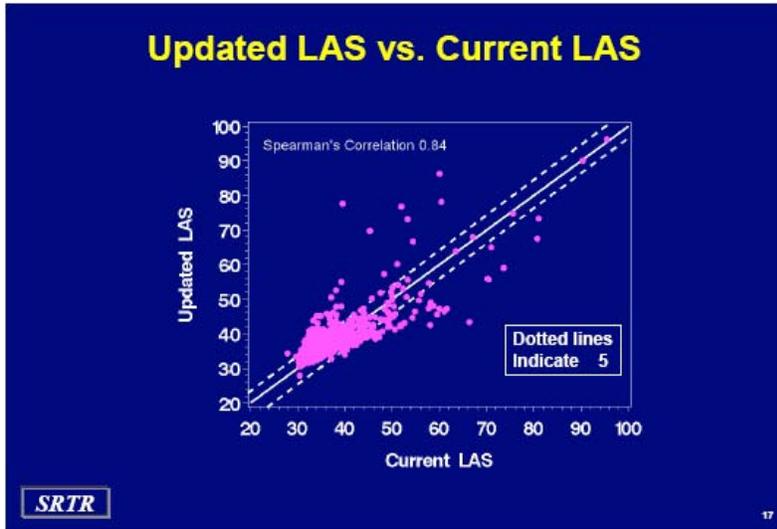
Bottom Line:
Post-Txp Model Update - Physiologic Reserve & Severity

	Current Coefficients (Cohort: 11/1/00-10/31/03*) IC=0.59			Updated Coefficients (Cohort: 5/4/05-9/30/08) IC=0.60		
	HR	95% CI	p-value	HR	95% CI	p-value
Physiological Reserve						
Age (yrs)	1.004	(0.995, 1.01)	0.4102	1.02	(1.01, 1.02)	<0.0001
*No assistance or some assistance (ref=total assistance)	0.61	(0.52, 0.73)	<0.0001			
No assistance (ref=some or total assistance)				0.72	(0.56, 0.92)	0.001
Severity						
Creatinine (mg/dL)	1.06	(1.004, 1.23)	0.0364	1.21	(1.11, 1.34)	<0.0001
FVC Groups B and D (% Predicted, per 1%)	0.997	(0.99, 1.005)	0.4726	1.00**	(-, -)	N/A
PCW Mean >= 20 Group D (mm/Hg)	1.03	(0.57, 1.86)	0.9123	1.00**	(-, -)	N/A
Continuous Mechanical Ventilation	1.37	(0.85, 2.21)	0.1999	2.50	(1.98, 3.16)	<0.0001

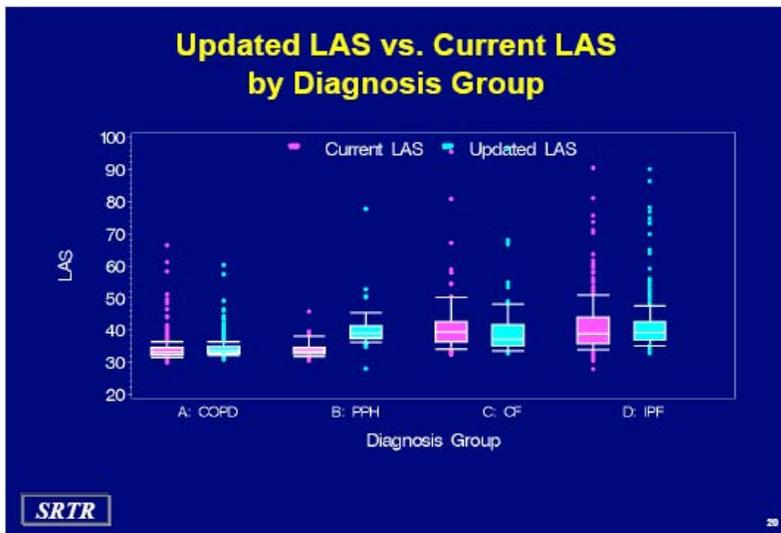
* Effects of some and total assistance were similar enough to be combined in the updated model
Some Assistance (vs. None) HR = 1.40, p = 0.01
Total Assistance (vs. None) HR = 1.42, p = 0.03
** HR=1.01, p=0.81 for FVC for Dgn Groups B, D; HR=0.90, p=0.37 for PCW mean >=20 mm/Hg, Group D. SRTR suggests implementing HR=1.00 for both.

SRTR

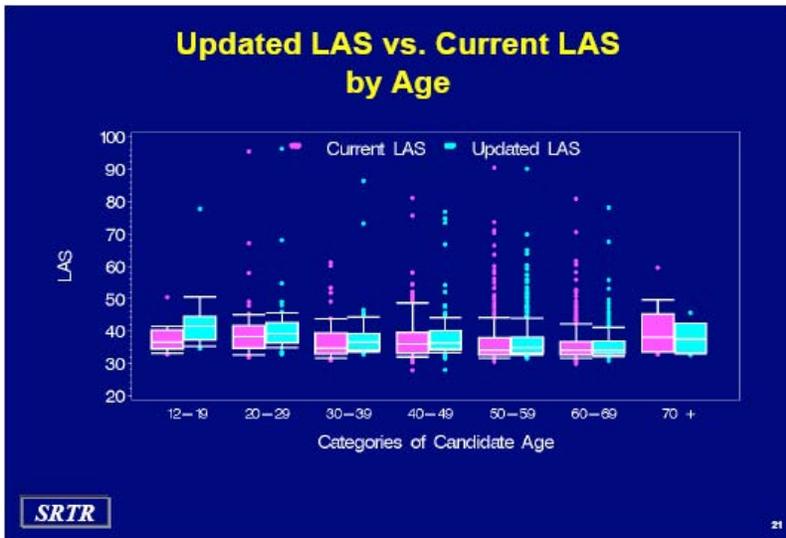
As shown in the slide below, the SRTR commented that there is satisfactory correlation between the current LAS and the LAS with the updated hazard ratios. However, the impact of a few factors appears to be different in the updated model, resulting in different LAS for some candidates using the current formulation compared with the updated formulation. So, some candidates would experience an increase and some a decrease in their lung allocation scores.



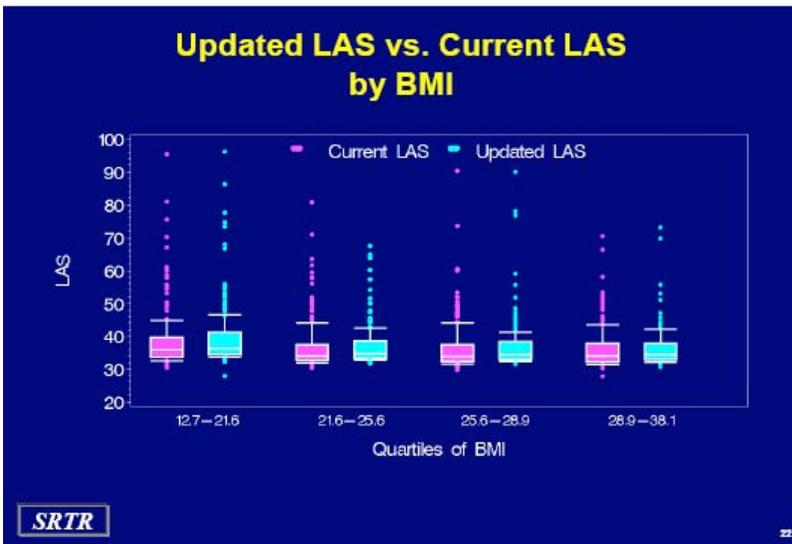
As shown in the slide below, the updated LAS system increases the scores for candidates in diagnosis Group B. This group has an improved post-transplant outcomes in recent years compared to the earlier era used for the current LAS calculation.

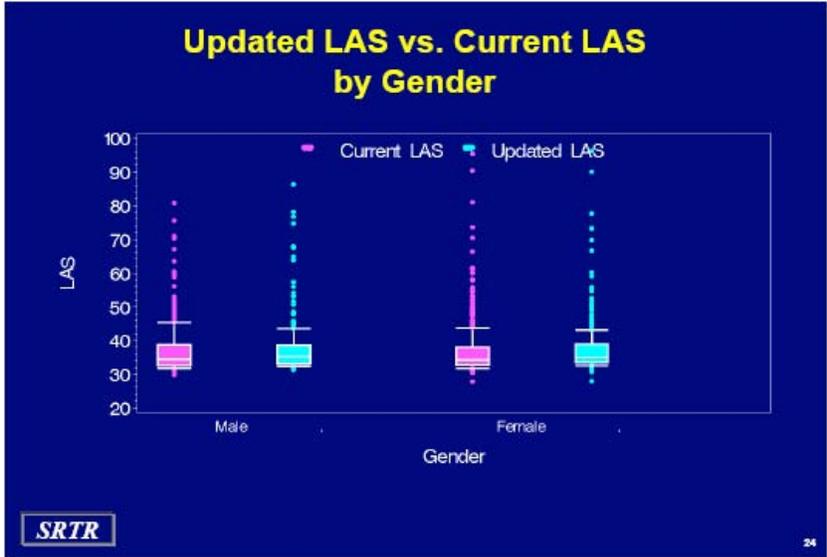
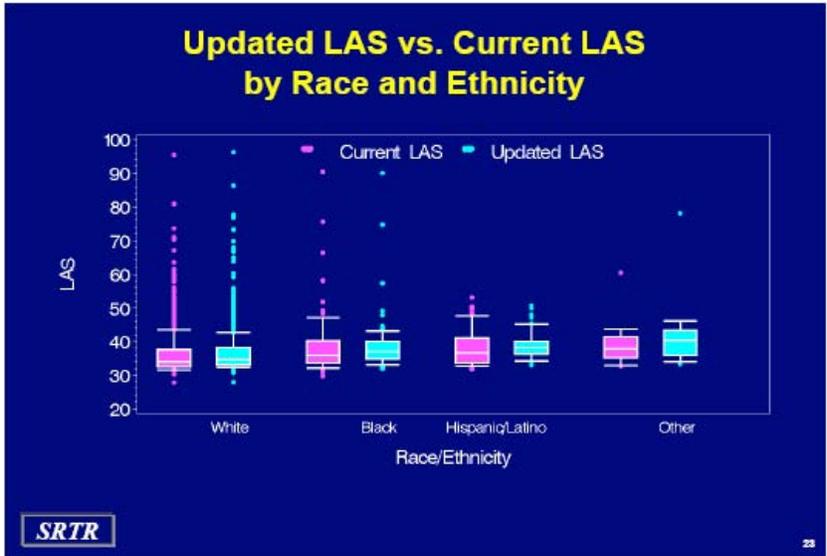


As shown in the slide below, in the updated LAS system, younger candidates appear to have higher lung allocation scores than older candidates. Candidates who are 70 years of age and older appear to receive slightly lower lung allocation scores in the updated LAS system.

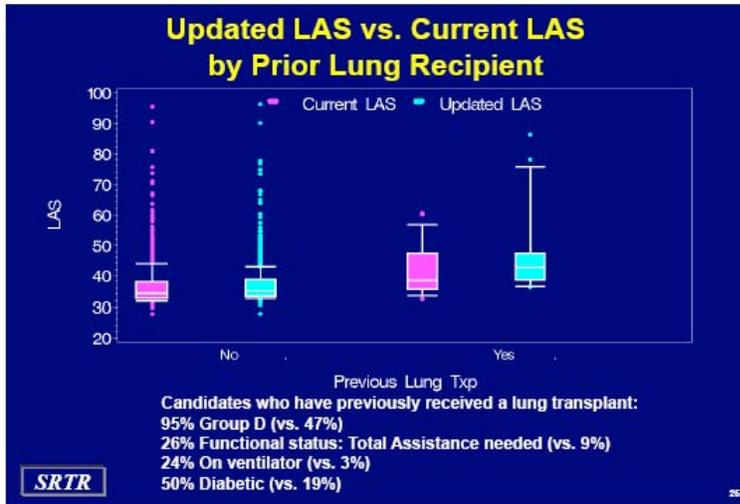


As shown in the three slides below, the updated LAS system appears similar to the current LAS system for the following variables: body mass index (BMI), race and ethnicity, and gender.





The Committee discussed the “prior lung recipient” factor, which is not in the current LAS system. As shown in the slide below, candidates with prior lung transplants have higher lung allocation scores in the updated LAS system. The Lung Subcommittee will discuss the possible inclusion of this new variable at its next meeting.



The Committee voted in favor (25-supported; 0-opposed; 0-abstained) of updating the existing waiting list and post transplant models using the new hazard ratios. The Committee considered asking the Executive Committee if updates to the coefficients alone will require a public comment proposal.

The Committee charged the Lung Subcommittee to continue discussing possible additions of variables to the waiting list and post-transplant models.

Item 11: Using 3-Year Survival (Instead of 1 Year) in the LAS

Currently, the waiting list model estimates the number of days a candidate can live in the next year without a transplant; and, the post-transplant model estimates the number of days a recipient is likely to survive in the year following a transplant. On March 23, 2010, the Committee commented that it would like the SRTR to consider the possibility of changing the number of days in the post-transplant model from 365 to 1095, i.e., from one year to three years.

There is sufficient post-transplant follow-up data to analyze the likelihood for a recipient to survive three years following a transplant. The SRTR commented that an adjustment of the estimated three-year survival might be needed to maintain the relative priority of waiting list urgency in the LAS calculation.

The Committee requested that the resulting analysis include box and whisker plots and index of concordance. UNOS staff requested if the SRTR could also provide LAS ranking, as the average LAS may be lower in a three year period.

The SRTR will prepare the analysis, and in addition to the averaging method described above, it will consider other approaches to the three-year calibration.

The Lung Subcommittee will review this analysis at its next meeting.

Item 12: Adding Items to the LAS or Additional Specific Guidelines to the Lung Review Board Regarding Additional Points for Pulmonary Hypertension Patients

The Committee discussed guidance to provide to the Lung Review Board on the most appropriate lung allocation score to grant to candidates with pulmonary hypertension (Group B).

The Committee commented that the delay in programming “current” and “change in bilirubin”³ in the LAS system warrants an interim solution to correlate Group B’s lung allocation score with its severity of disease. The Committee discussed the development of a bilirubin calculator. UNOS staff commented that the cost for creating this tool could be around \$98,000. The Committee was surprised to learn of this cost, but in 2009, UNOS had calculated this price as this tool was considered as an alternative to implementing the bilirubin policy in full.

The Committee commented that historically, during the development of the LAS system, there existed a calculator created using Microsoft Excel. Couldn’t such a calculator be developed? Would this type of calculator have a lower cost? UNOS staff will explore the development of a calculator using Microsoft Excel.

UNOS staff commented that in lieu of developing an interim measure, the Committee could request that the OPTN/UNOS Executive Committee prioritize the programming of the bilirubin policy.

One member queried if candidates with pulmonary hypertension should receive additional points in their LAS. The Lung Subcommittee will discuss this possibility, as well as addition of variables to the LAS system that address waiting list mortality of Group B candidates.

Item 13: Impact of Identical versus Compatible ABO-Matching in Lung Transplantation (OPTN Data Analysis)

The Committee reviewed a presentation prepared by UNOS Research staff. UNOS staff commented that there appears to be no statistically significant difference between identical and compatible ABO-matching in the LAS system; and, the rationale for using ABO-matching as a characteristic in lung allocation does not appear to be based on survival data.

The Committee queried if the thoracic simulated allocation model (TSAM) could inform on the impact of lung allocation without prioritizing ABO-matching. The SRTR will perform this analysis.

New Item: Frequent Updates to Variables in the Lung Transplant WaitListSM Page

The Committee again discussed the need for centers to update more frequently, such as two weeks, lung transplant waiting list records of candidates with high lung allocation scores. To achieve this goal requires a change in policy. As programming this update requirement would likely be costly, the Committee considered if DEQ staff members could monitor these updates during site visits. However, this administrative effort in monitoring such updates would likely be time intensive and expensive.

UNOS staff will explore costs for various approaches to implementing this proposed policy.

As of the time of the March meeting, 3% of the total lung transplant candidate population had lung allocation scores over 60. About 10% of the lung transplant candidates had scores of 45 or higher.

The Lung Subcommittee will further discuss this proposed policy change, including the specific variables that would require updates.

³ In 2009, the Board of Directors approved the inclusion of current and change in bilirubin to the waiting list model in the LAS.

New Item: ECMO Use as a Bridge to Transplant

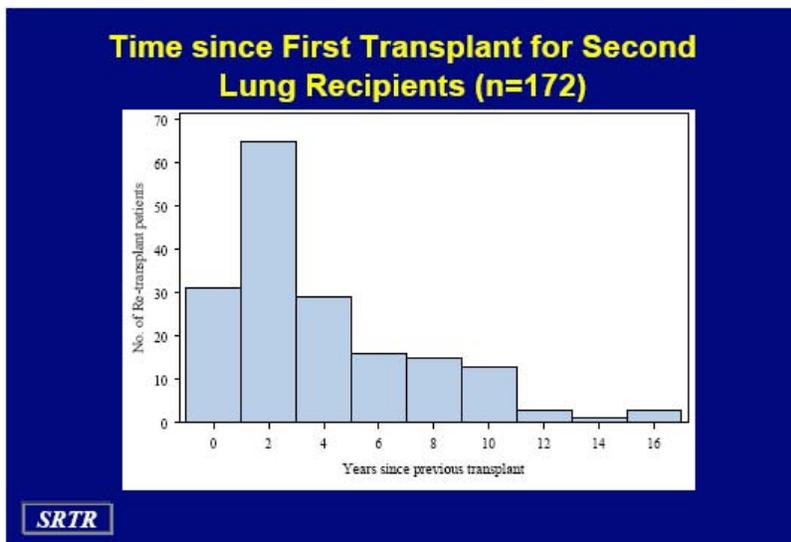
On March 23, 2010, the Committee discussed that currently, when a candidate is placed on ECMO, this individual's LAS decreases. This decrease is illogical as the candidate's health has worsened.

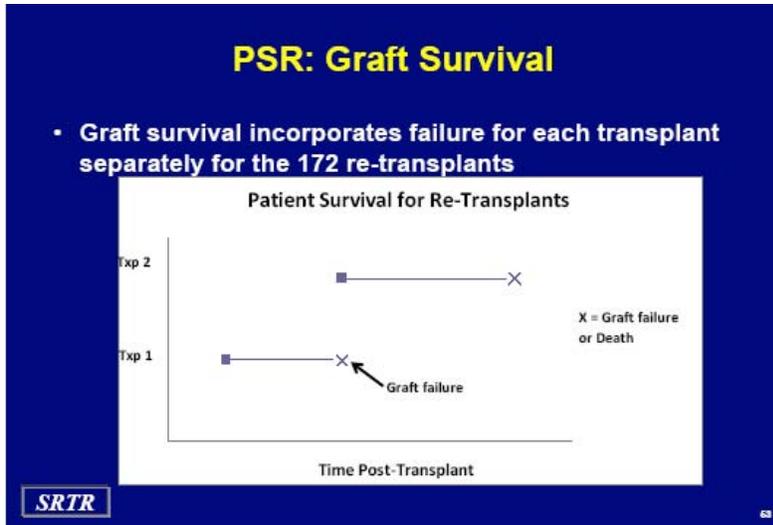
The Committee queried if ECMO should be part of the new factors considered for inclusion in the revised LAS system (see item 4 in this report). If so, then this inclusion would require a policy change. The Committee voted in favor (25-supported; 0-opposed; and, 0-abstained) of this proposed policy change, and requested that the Lung Subcommittee further discuss this topic at its future meetings.

Item 14: Inclusion of the Following Factor in the Patient Survival Model of the Program Specific Report (PSR): Recipients with Re-transplants (Heart or Lung) Who Die

The Committee requested that the SRTR include in the PSR's graft survival model those recipients who die after receiving a lung re-transplant. Further, Committee commented that this variable concept should be used for in organ-specific PSRs.

The SRTR commented that the inclusion of this variable is on its agenda, and presented the following two slides for the Committee's review.





The Committee requested updates from the SRTR on its efforts to include this variable in the lung graft survival model.

Item 15: Update on the Heart Subcommittee's Activities

The Chair of the Heart Subcommittee provided an update of this group's activities. Since the Committee's November, 2009 meeting, the Heart Subcommittee met on January 29, 2010 and February 26, 2010. The Subcommittee reviewed two heart cases, which the Committee discussed and voted on in this meeting. During its February meeting, the Subcommittee met with the Thoracic Working Group of the Pediatric Committee, and representatives from the Pediatric Heart Transplant Study (PHTS) group to evaluate the medical currency of Policy 3.7.4 (Pediatric Candidate Status).

The Subcommittee has been reviewing the proposed changes to the pediatric heart status justification form. The intent of these programming changes (not policy) are twofold: 1) separate ECMO and ventricular assist device data element; and 2) create similarity in the data collected in the adult and pediatric heart status justification forms.

Item 16: OPTN Data Analysis: Post-Transplant Mortality for Recipients with an LVAD, or an LVAD and RVAD

On March 23, 2010, the Committee continued its discussion on allowing adult heart candidates with LVADs and RVADs to remain indefinitely as a Status 1A, even if these candidates did not have device related complications. Policy 3.7.3.a.i allows candidates with a single VAD or BiVAD to be eligible as Status 1A for 30 days. The Committee had queried whether candidates with a BiVAD were more likely to develop complications than candidates with an LVAD.

The Committee evaluated previously differences in waiting list mortality for candidates with a BiVAD versus just a LVAD. During this March meeting, the Committee evaluated post-transplant survival rates of candidates with a BiVAD and candidates with LVADs by medical urgency status.

When all medical urgency statuses were combined, there was a statistically significant difference between the survival rates within the first 18 months for candidates with LVADs only versus those with a BiVAD. But, the survival rates for LVAD alone versus those for no VAD were not statistically different. These same conclusions held when the cohort was limited to those recipients who were Status 1B at the time of

transplant. For candidates who were Status 1A at the time of transplant, there was no statistically significant difference between the survival rates of candidates who had LVADs versus candidates who had a BiVAD. This same conclusion was observed for the survival rates for recipients who had LVADs versus those who did not have any VADs.

Item 17: Tracking Scheduled Operation Room (OR) Time versus Actual Arrival Time

The Committee continued its discussion on the need to monitor the time OPOs schedule for organ recovery versus the actual arrival time the deceased donor is brought to the OR for procurement.

One member commented that at his center, liver transplant clinicians are also concerned about delays in the scheduled versus actual arrival time of deceased donors in the operating room. This member stated that a center could lose up to \$200,000 due to these OR delays.

UNOS staff commented that this issue was discussed by the working group consisting of members from the Thoracic and OPO Committees. At this group's January 25, 2010 meeting (Exhibit M), the group considered developing a survey to understand the reasons for the delays.

The Committee commented that while knowing the reasons for the delays is important, it may be difficult to arrive at the causes without first collecting data to track the scheduled versus actual time of arrival in the OR. The Committee considered the addition of fields in DonorNet[®] (scheduled OR time, arrival time at OR).

Subsequent to the meeting, UNOS staff queried the MPSC staff if it was possible to collect these data as part of the OPO Performance Metrics effort. MPSC staff commented that the Committee could request the MPSC to consider tracking an OPO's scheduled versus actual time of arrival in the OR.

Thoracic Organ Transplantation Committee	March 23, 2010 Chicago, Illinois	
Name	Position	Attendance
Maryl R. Johnson, MD	Chair	X
Mark L. Barr, MD	Vice-Chair	X
Kevin Dushay, MD	Regional Rep. (1)	X
Raymond L. Benza, MD	Regional Rep. (2)	X
Mark Rolfe, MD	Regional Rep. (3)	By phone
Luis Angel, MD	Regional Rep. (4)	By phone
John Chin, MD	Regional Rep. (5)	X
Howard Song, MD	Regional Rep. (6)	
Robert Love, MD	Regional Rep. (7)	X
Ramsey R. Hachem, MD	Regional Rep. (8)	X
Sean P. Pinney, MD	Regional Rep. (9)	X
LaDora Dils, RN, CPTC	Regional Rep. (10)	X
Isabel P. Neuringer, MD	Regional Rep. (11)	X
Kevin Chan	At Large; Lung Review Board Chair	X
Gregory S. Couper, MD	At Large	X
R. Duane Davis, MD	At Large	X
William Fiser, Jr., MD	At Large	X
Herbert Heili	At Large	
Denise Kinder, RN, CPTC	At Large	X
Dan M. Meyer, MD	At Large	X
David P. Nelson, MD	At Large	X
Linda Ohler, MSN, RN, CCTC	At Large	X
Genevieve Reilly, NP	At Large	X
Stuart Sweet, MD, PhD	At Large	X
Steven A. Webber, MD	At Large	X
J. David Vega, MD	At Large	X
Mark Zucker, MD	At Large	X
Amy Shorin-Silverstein, JD	BOD - Liaison	
Ba Lin	Ex Officio – HRSA	By phone
Monica Lin, PhD	Ex Officio – HRSA	X
Bernie Kozlovsky, MD	Ex Officio - HRSA	X
Jeffrey P. Orlowski, MS, CPTC	Guest (Chair of the OPO Committee)	By phone
Brad Dyke, MD	SRTR Liaison	X
Susan Murray, ScD	SRTR Liaison	X
Tempie Shearon	SRTR Liaison	X
Ying Qian	SRTR Liaison	X
Franki Chabalewski	OPO Committee's Support Staff	X
Leah Edwards PhD	Support Staff	X
Vipra Ghimire, MPH, CHES	Committee Liaison	X
Jory Parker	Support Staff	By Phone