OPTN/UNOS Thoracic Organ Transplantation Committee
Report to the Board of Directors
June 21-22, 2010
Richmond, Virginia
Summary

I. Action Items For Board Consideration

- *Proposed Programming Changes to the Pediatric Heart Status Justification Form*

  The Board of Directors is asked to modify existing mechanical circulatory support device data elements. (Item 1, page 3)

- *Voluntary Dissolution of the Organ Donor Center of Hawaii's (HIOP) Variance*

  The Board of Directors is asked to grant HIOP's request to dissolve its variance. This variance dissolution would not require programming.
  (Item 2, page 6)

II. Other Significant Items

- *Change in the Heart Review Board Case Evaluation Process and Modifications to the Heart Review Board Guidelines*

  On April 19, 2010, the Executive Committee approved modifications to the Heart Regional Review Board process and related guidelines.
  (Item 3, page 7)

- *Updating the Lung Allocation Score (LAS) System – SRTR's Efforts*

  The Committee continues its effort to update the waiting list and post-transplant models using data collected since 2005. (Item 4, page 8)

- *Modification to Policy 3.7.3 (Adult Candidate Status)*

  The Committee plans to distribute for public comment slight modifications to Policy 3.7.3 that includes the addition of "e" as a label for the Status 1A exception request and exception language in Status 1A(b), which is programmed in UNet^{SM}. (Item 5, page 18)

- *Addition of Human Leukocyte Antigen (HLA) to Policy 3.7.12.1 (Essential Information)*

  The Committee is collaborating with the Operations and Safety, Organ Procurement Organization, and Histocompatibility Committees to determine when this information should be made available to centers. (Item 6, page 19)

- *Effort to Revise Policy 3.7.7 (Allocation of Thoracic Organs to Heart-Lung Candidates)*

  The Committee continues its efforts to revise Policy 3.7.7 to include geography and medical urgency of Status 1B and lung transplant candidates. (Item 7, page 22)

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Maryl R. Johnson, MD, Chair
Mark Barr, MD, Vice-Chair

The Thoracic Organ Transplantation Committee (Committee) met in Chicago, Illinois on November 4, 2009 and March 23, 2010. The following is a summary of the Committee's deliberations:

1. Proposed Programming Changes to the Pediatric Heart Status Justification Form

In the pediatric heart status justification form, there exists only one field that collects information about ventricular assist device (VAD) and extracorporeal membrane oxygenation (ECMO). To collect meaningful data on the two types of mechanical circulatory support devices, the field should be separated into two data elements. On January 29, 2010, the Heart Subcommittee commented that the pediatric and adult heart status justification forms should collect similar data elements. After extensive discussion about the need to prevent, as much as possible, duplication of data collected elsewhere in the Organ Procurement and Transplantation Network's (OPTN) database, the group decided on the following:

- VAD, ECMO, and total artificial heart (TAH) data elements collected on the adult and pediatric heart status justification forms should be the same;
- Right VAD (RVAD) data elements to collect are implant date and device type (or, brand);
- Left VAD (LVAD) data elements to collect are implant date and device type (or, brand);
- ECMO data element to collect is the date of cannulation;
- TAH data elements to collect are implant date and device type (brand); and,
- Device type for the specific mechanical circulatory system should be the same as those listed in the waiting list removal page.

Also, to reduce data entry burden, the Heart Subcommittee requested that UNOS evaluate the cost and programming potential of having mechanical circulatory data, which were entered in the status justification form or another OPTN form, to auto-populate the waiting list removal page.

Therefore, the proposed programming would not only separate collection of VAD data and ECMO data, but would also improve, for the purposes of developing a heart allocation score, the data collected on all mechanical circulatory support devices.

Shown below are five images of the proposed programming.

Figure 1: Image of Proposed Changes to Criterion B on the Pediatric Heart Status Justification Form: Separation of ECMO and VAD Data Elements

The patient must meet one of the following criteria (Check the applicable box): R

- [ ] A.) Requires assistance with a ventilator;
- [x] B.) Requires assistance with a mechanical assist device ;
  - [ ] Extracorporeal Membrane Oxygenation (ECMO)
  - [ ] LVAD
  - [ ] RVAD
  - [ ] Total Artificial Heart
- [ ] C.) Requires assistance with a balloon pump;
- [ ] D.) The patient is less than 6 months old with congenital or acquired heart disease exhibiting reactive pulmonary hypertension at greater than 50% of systemic levels;
- [ ] E.) Requires infusion of a single high-dose intravenous inotrope (e.g., dobutamine greater than or equal to 7.5 mcg/kg/min, or milrinone greater than or equal to .50 mcg/kg/min), or multiple intravenous inotropes (e.g., addition of dopamine at greater than or equal to 5mcg/kg/min);or
- [ ] F.) The patient does not meet any of the criteria specified above, but has a life expectancy without a heart transplant of less than 14 days, such as due to refractory arrhythmia. Qualification for Status 1A under this criterion is valid for 14 days and may be recertified by an attending physician for one additional 14-day period. Any further extension of the Status 1A listing under this criterion requires a conference with the applicable UNOS Regional Review Board.

NOTE: PEDIATRIC PATIENTS LISTED UNDER CRITERIA (A) THROUGH (E) MUST BE RECERTIFIED BY AN ATTENDING PHYSICIAN EVERY 14 DAYS TO CONTINUE THE STATUS 1A LISTING.

To qualify for Status 1A under criterion (F) or with any 14 day extension under criterion (D), (E), or (F), a current/updated clinical narrative must be provided which supports the eligibility of the patient for this status.

Narrative:

(Maximum of 5000 characters) 5000 characters remaining

Figure 2: Image of Proposed ECMO Data Collection *(Note: the "implant date" will change to "cannulation" date.)*

The patient must meet one of the following criteria (Check the applicable box): R

- [ ] A.) Requires assistance with a ventilator;
- [x] B.) Requires assistance with a mechanical assist device;
  - [x] Extracorporeal Membrane Oxygenation (ECMO)
    - Implant Date: R
  - [ ] LVAD
  - [ ] RVAD
  - [ ] Total Artificial Heart

Figure 3: Image of Proposed LVAD Data Collection

The patient must meet one of the following criteria (Check the applicable box): R

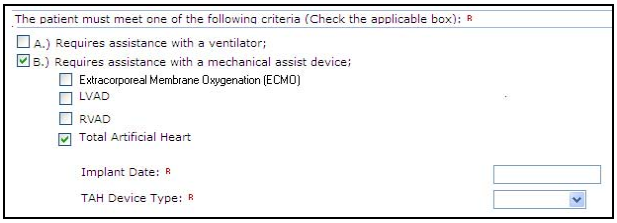
- [ ] A.) Requires assistance with a ventilator;
- [x] B.) Requires assistance with a mechanical assist device;
  - [ ] Extracorporeal Membrane Oxygenation (ECMO)
  - [x] LVAD
    - Device Type: R
    - Implant Date: R
  - [ ] RVAD
  - [ ] Total Artificial Heart

Figure 4: Image of Proposed RVAD Data Collection

The patient must meet one of the following criteria (Check the applicable box): R

- [ ] A.) Requires assistance with a ventilator;
- [x] B.) Requires assistance with a mechanical assist device;
  - [ ] Extracorporeal Membrane Oxygenation (ECMO)
  - [ ] LVAD
  - [x] RVAD
    - Device Type: R
    - Implant Date: R
  - [ ] Total Artificial Heart

Figure 5: Image of Proposed TAH Data Collection



On March 26, 2010, the Heart Subcommittee discussed the proposed changes to the pediatric heart status justification form, as illustrated in the five figures shown above. As shown in Figure 1 above, the proposed programming would allow centers to select all the mechanical circulatory devices that apply for a given candidate. For a candidate that has a RVAD and a LVAD (BiVAD), a center would select the "LVAD" and "RVAD" options, and enter the VAD-specific data requested for each.

The Heart Subcommittee reviewed Figure 1 and queried whether a center could click on criteria A, B, C, D, and E; and, whether the transplant candidate registration (TCR) form duplicated information proposed for collection on this status justification form. UNOS staff stated that the current programming only allows a center to select one criterion (A, B, C, D, E, or F), and that the TCR form did not include these same data elements. Further, the information collected on the TCR and transplant recipient registration (TRR) form capture data on candidates and recipients only at the time of listing and at transplant, respectively; but, the status justification forms collect information during the entire period of time that a candidate is waiting for a transplant.

The Heart Subcommittee commented that a candidate on ECMO would likely also meet criterion A (Requires assistance with a ventilator). Also, in order to improve the pediatric heart allocation system, it may be useful to know how many candidates meet each criterion. If a candidate has a VAD, but is also in need of ventilation (criterion A), then in spite of having a VAD, that candidate may not do well after transplant. If the TCR and TRR do not duplicate data collected on the heart status justification form, the Heart Subcommittee would like to consider allowing a center to select all criteria (A-E) that apply for a candidate.

UNOS staff will evaluate the programming possibility of allowing centers to select each criterion that applies to the candidate. (A center would select Criterion F to apply for an exception; therefore, it would not be logical to include F in the "select all that apply" possible programming.) UNOS staff will also evaluate if this effort could be included with the proposed programming. The Pediatric Organ Transplantation Committee (Pediatric Committee) would also need to review the concept of allowing centers to select all criteria that apply (A, B, C, D, and E).

The Heart Subcommittee commented that in the future, the adult form would also need to allow centers to select multiple criteria. The group emphasized the need for both the pediatric and adult heart status justification forms to be similar.

When the Pediatric Committee met on March 24, 2010, it favored the programming proposed for the pediatric heart status justification form.

In May, 2010, the Committee voted electronically and in favor of the proposed programming: 14-Supported; 1-Opposed; and, 5-Abstained. The resources required for programming the proposed modifications are in **Exhibit A**. Therefore, the Committee asks the Board of Directors to consider the following recommendation:

****RESOLVED, that programming to separate the existing VAD and ECMO data element into separate fields, collect VAD device brand and type, collect VAD implant date, collect ECMO cannulation date, collect TAH device brand and implant date, and enable a center to enter data for all mechanical circulatory devices that were in use, is hereby approved, effective pending programming in UNet^{SM}.**

2. Voluntary Dissolution of Organ Donor Center of Hawaii's Variance

On February 16, 2004, the Board of Directors approved an alternative distribution system requested by the Organ Donor Center of Hawaii (HIOP). This alternative distribution system applied to thoracic organs procured by HIOP from donors located in Hawaii. HIOP requested a modification of the thoracic allocation geographic zones by proposing two new allocation zones: X and Y. HIOP's plan was to: first offer thoracic organs from Hawaii donors locally; and, second, offer thoracic organs to Zone X, which extended the geographic area to include all transplant centers within 2,500 miles of Honolulu. HIOP planned to finally offer thoracic organs to Zone Y, which extended the geographic area to include all transplant centers beyond 2,500 miles of Honolulu.

HIOP argued that the extreme distance from the U.S. mainland made the placement of thoracic organs outside the HIOP local area difficult. At the time of HIOP's request, Zone D was the most distant geographic zone. So, all candidates waiting beyond 1500 miles from the donor hospital would have been in Zone D, which included all candidates waiting in the mainland of United States (mainland). Therefore, all candidates residing in the mainland would appear on the match run, without distinction on their distance from Hawaii, resulting in HIOP having to "bypass" those candidates whose geographic location placed them outside the thoracic range of cold ischemia and travel time. Each candidate "bypass" required HIOP to submit an explanation to the UNOS Policy Compliance (now, Department of Evaluation and Quality (DEQ)). The proposed alternative distribution system enabled match-runs that prioritized candidates who were within the acceptable range of cold ischemic time.

In the meantime, the Committee considered revisions to the geographic allocation criteria to improve thoracic organ allocation. In June 29-30, 2006, the Board of Directors first approved modifications to Policy 3.7.2 (Geographic Sequence of Thoracic Organ Allocation). The Committee revised the nautical miles covered in Zone D and created Zone E. Zone D became the geographic area between 1500 nautical miles and 2500 nautical miles, inclusive, from the donor hospital. Zone E became the geographic area further than 2500 nautical miles from the donor hospital. The Board of Directors approved the final, i.e., post-public comment, version of the policy proposal in December, 2006, and implemented this policy on May 16, 2007.

In 2008, the Committee, as well as other organ-specific committees began reviewing variances (e.g., an alternative distribution system) that had been previously approved by the Board of Directors. UNOS requested the transplant and procurement community to complete a newly developed variance application to aid this tracking effort. That year, HIOP submitted its request to dissolve its alternative distribution system as the revised Policy 3.7.2 met its geographic allocation needs. The Committee voted in favor of the dissolution: 17-Supported; 0-Opposed; 0-Abstained. This dissolution will not require any programming in UNet^{SM}.

The estimated resources required to dissolve the HIOP variance is in **Exhibit B**. The Committee asks the Board of Directors to consider the following recommendation:

****RESOLVED, that the voluntary dissolution of HIOP's variance, is hereby approved, effective June 22, 2010.**

3. Change in the Heart Review Board Case Evaluation Process and Modifications to the Heart Review Board Guidelines

The Committee reviewed a revised memo to the heart regional review boards. The revisions eliminated terms such as "approvals," as only clinicians can approve medical urgency statuses. to the revised memo's title read "Automatic Approval of All Non-Exception Cases." The Committee members voted in favor of the revised memo: 17-supported; 0-opposed; 0-abstained.

The Committee then reviewed the guidelines and requested that the following edits be made:

a) Lay persons need no longer serve on the review boards. In the past, such individuals were uncomfortable making clinical decisions, and therefore, deferred decision making to the physicians or surgeons on the board. Public oversight of regional review board cases is accomplished through Committee review of complicated cases.

   Chair of the heart review board must be with an active heart program, but that Chair need not serve as a regional representative on the Committee. Currently, the regional representatives serve as heart review board chairs. The review board guidelines state that the chair of a heart regional review board must be affiliated with an active heart transplant program. In current practice, some of the heart review board chairs are, pulmonologists or lung surgeons. These chairs often defer to their colleagues who are cardiologists or heart surgeons. As such, tying the regional representation on the Committee with the chairmanship of the heart regional review board may not always result in the selection of a chair that is affiliated with an active heart transplant program, or is neither a cardiologist or a heart surgeon, or all three. The Committee commented that if a regional representative is a cardiologist or a heart surgeon affiliated with an active heart transplant program, then that individual may serve as a heart review board chair. However, if the regional representative is not a heart transplant physician or surgeon affiliated with an active heart transplant program, then the affected heart regional review board needs to select a qualified chair. In the meantime, the regional representative may continue to serve on the Committee.

   The Committee voted in favor the above changes to the heart regional review board guidelines: 17-supported; 0-opposed; 0-abstained.

As part of its electronic discussion of this change in the heart review board process, the Committee recognized that an adult heart status exception – specifically, Status 1A (b), which is about mechanical circulatory devices – that is possible in UNet^{SM} is not in written in policy. As part of its effort to modify Policy 3.7.3 (Adult Candidate Status; see item 5 in this report), UNOS staff will include this exception language so that policy reflects the programming.

On April 19, 2010, the Executive Committee convened by telephone and unanimously approved (8-Yes; 0-No; 0-Abstained) the following two resolutions:

** RESOLVED, that heart justification requests for candidates who meet the heart status criteria set forth in Policies 3.7.3 (Adult Candidate Status) and 3.7.4 (Pediatric Candidate Status), other than candidates seeking an exception, will receive automatic approval, and Regional Heart Review Boards shall only review heart status justification exception requests, effective April 19, 2010.

** RESOLVED, that the modifications to the heart regional review board guidelines set forth in **Exhibit 2** are hereby approved, effective April 19, 2010.

The memo that was distributed to the heart regional review board Chairs on May 17, 2010, and the revised heart review board guidelines are in **Exhibit C**.

4. Update to the Lung Allocation Score (LAS) System and the Lung Subcommittee's Activities

On November 4, 2009, the Scientific Registry of Transplant Recipients (SRTR) presented its ongoing analyses on the waiting list mortality model of the LAS system. This analysis is **Exhibit D**. The Committee was asked if it wanted to vote to update the waiting list model with the new parameters. The Committee decided that the Lung Subcommittee needed to have more detailed discussions on the analysis. The Committee would act according to the Lung Subcommittee's recommendations.

The Lung Subcommittee met on March 2, 2010 to continue discussing the updates to the LAS system. During that meeting, the Committee discussed alternative implementation approaches: 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. (The report of the March 2, 1010 meeting is **Exhibit E**.)

Cost estimates were not yet available at the March 23, 2010 meeting, but it would be available for the Subcommittee to review on March 30, 2010.

On March 23, 2010, the Committee discussed whether an update to the mathematics 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.

It was noted 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

	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
Diagnosis Group (ref=Group A)						
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
Lymphangioleiomyomatosis	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 these data, FVC would not have an impact on candidates' LAS.

The Committee queried about retaining PCO_2, as the hazard ratio decreased in the updated model (from 1.85 to 1.10). The SRTR performed various analyses using PCO_2, and one analysis resulted in

a statistically significant hazard ratio. For now, the SRTR recommended retaining PCO_2 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 mm/Hg)	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' PCO_2 estimates are not from this cohort of patients
PCO_2 (per 10 mmHg) currently implemented with HR = 1.06 (lower 90% confidence limit)
PCO_2 increase ≥15% currently implemented with HR = 1.08 (lower 90% confidence limit)

SRTR

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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-alue
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
Lymphangioleiomyomatosis	0.54	(0.22, 1.30)	0.1684	0.25	(0.04, 1.79	0.1673
Obliterativebronchiolitis (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

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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)	<.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

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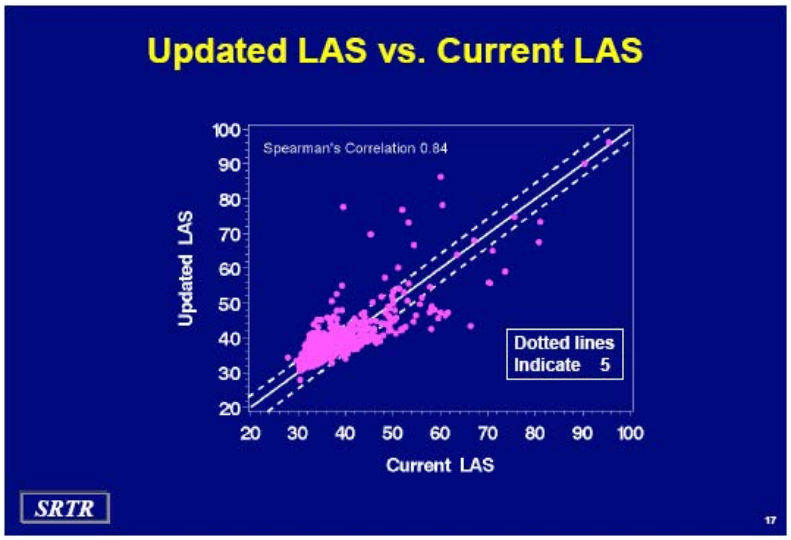
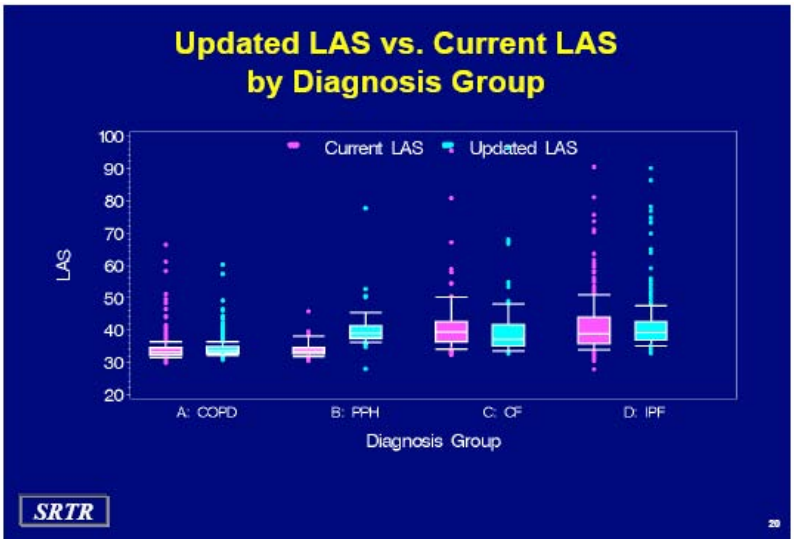
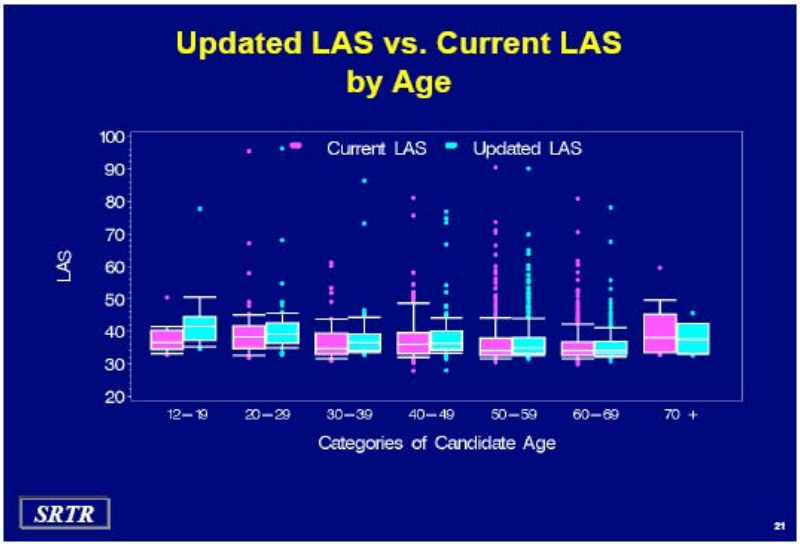
As shown in the slide below, the SRTR commented that there is satisfactory correlation between the current LAS and the LAS with the updated hazard ratios. However, the impact of a few factors appears to be different in the updated model, resulting in different LAS for some candidates using the current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



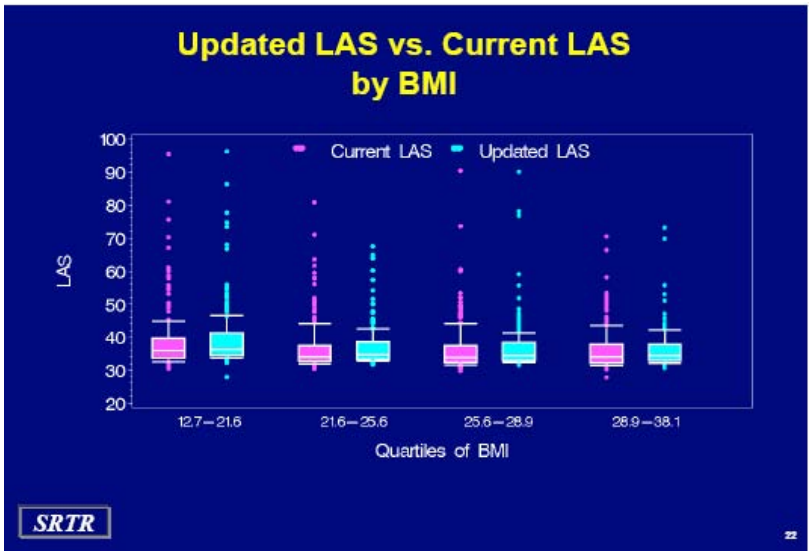
As shown in the slide below, the updated LAS system increases the scores for candidates in diagnosis Group B. This group has an improved post-transplant outcomes in recent years compared to the earlier era used for the current LAS calculation.

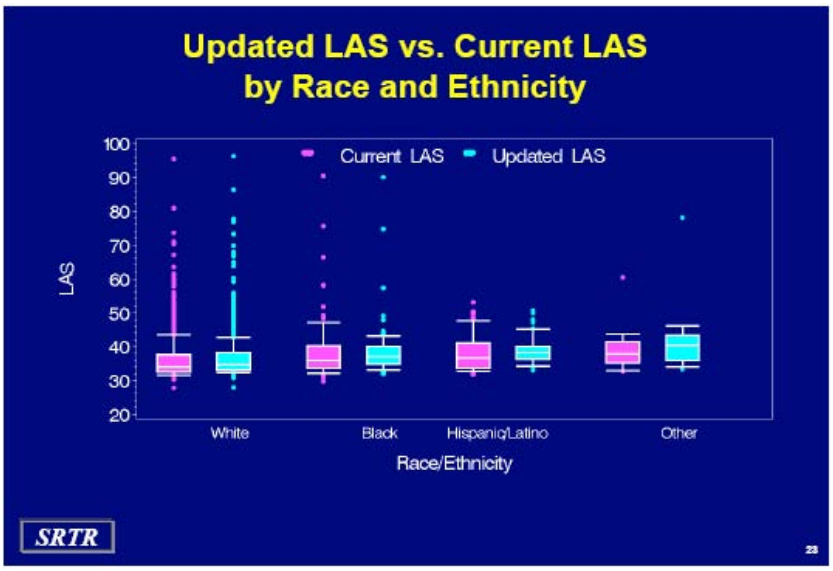


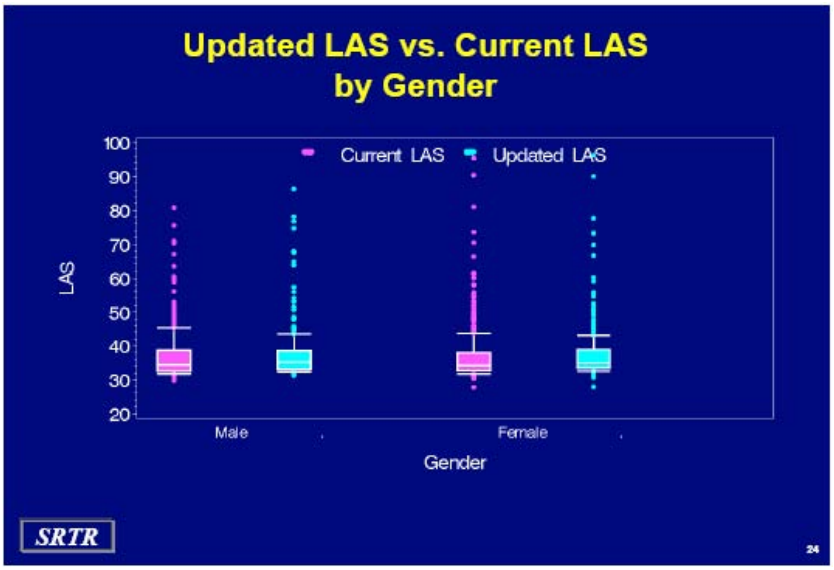
As shown in the slide below, in the updated LAS system, younger candidates appear to have higher lung allocation scores than older candidates. Candidates who are 70 years of age and older appear to receive slightly lower lung allocation scores in the updated LAS system.



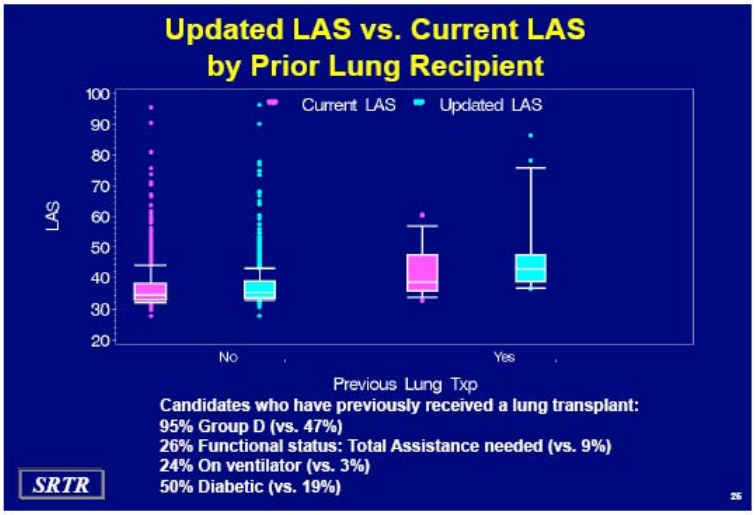
As shown in the three slides below, the updated LAS system appears similar to the current LAS system for the following variables: body mass index (BMI), race and ethnicity, and gender.


Updated LAS vs. Current LAS
by BMI
Current LAS
Updated LAS
LAS
100
90
80
70
60
50
40
30
20
12.7–21.6
21.6–25.6
25.6–28.9
28.9–38.1
Quartiles of BMI
SRTR
22


Updated LAS vs. Current LAS
by Race and Ethnicity
Current LAS
Updated LAS
LAS
100
90
80
70
60
50
40
30
20
White
Black
Hispanic/Latino
Other
Race/Ethnicity
SRTR
23



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.

The Lung Subcommittee met on March 30, 2010, and April 27, 2010. The summary of its discussions on the LAS update, as well as other lung transplantation topics, are in **Exhibit F**. The Lung Subcommittee will next meet on May 25, 2010.

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 are 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.

Frequent Updates to Lung Transplant WaitList^{SM} Variables for Candidates with High Scores

On November 4, 2009, a Committee member queried if a center should update a candidate's record more frequently than every six months if this individual's lung allocation score is high, e.g., 80 or 90. Should this update be required and should it be every two weeks once a candidate exceeds a certain lung allocation score? Per Policy 3.7.6.3.2 (Updating Candidate Variables), a center may update a candidate's record at anytime, but must update certain waiting list variables at least every six months. The group queried whether there were data to suggest that centers were deliberately not updating candidate records, especially when candidates' lung allocation scores were very high. Centers would not be violating any policy by not updating more than once every six months. It was noted that the frequency with which a lung transplant candidate's waiting list record is updated should be similar to the update frequency for a heart transplant candidate justification form. Requiring centers to update certain candidates' records more frequently would necessitate a policy change. In general, the group favored this policy change approach.

Such a policy change could be costly, especially in the area of testing the effectiveness of an automated solution. The Committee inquired about these costs, and decided that the Lung Subcommittee should deliberate on this topic further. The Committee also queried whether the UNOS auditors could assist in the implementation of this policy, i.e., enable a non-computer based solution.

The Committee requested that the Lung Subcommittee determine which variables would need to be updated, and what lung allocation score would dictate the beginning of the frequent update process.

On March 23, 2010, 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 UNOS staff 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 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.

Age Matching – Lungs from Donors Less than 35 Years of Age (Similar to Kidney Policy)

In the past few years, the Committee has discussed how best to improve allocation of young donor lungs. Does the lung allocation score system advantage certain populations over others? Are young donor lungs best offered, medically, to younger candidates? In other words, should there be age matching in lung allocation? On November 4, 2009, the Committee reviewed the following kidney allocation policy:

3.5 ALLOCATION OF DECEASED KIDNEYS. […]

3.5.11.5 Pediatric Kidney Transplant Candidates. Kidney transplant candidates who are less than 11 years old shall be assigned four additional points for allocation of kidneys from donors with whom the candidate shares a zero antigen mismatch. Candidates who are 11 years old or older but less than 18 years old will be assigned three additional points for allocation of kidneys from donors with whom the candidate shares a zero antigen mismatch. These points shall be assigned when the candidate is registered on the Waiting List and retained until the candidate reaches 18 years of age.

3.5.11.5.1 Pediatric Kidney Transplant Candidates Priority for Kidneys from Donors Aged less than 35 Years. Kidneys from donors aged less than 35 years that are not shared mandatorily for 0 HLA mismatching, for renal/non-renal organ allocation, or locally for prior living organ donors pursuant to Policy 3.5.11.6 (Donation Status) shall be offered first for transplant candidates who are less than 18 years of age at listing irrespective of the number of points assigned to the candidate relative to candidates 18 years old and older, with the exception of candidates assigned 4 points for PRA levels of 80% or greater under Policy 3.5.11.3 (Panel Reactive Antibody) who otherwise rank higher than all other listed candidates based upon total points assigned under policy. When multiple pediatric transplant candidates are eligible for organ offers under this policy, organs shall be allocated for these candidates in descending point sequence with the candidate having the highest number of points receiving the highest priority. For purposes of assigning allocation priority among pediatric candidates for kidneys from donors aged less than 35 years under this Policy 3.5.11.5.1, one additional point shall be assigned for candidates who are less than 11 years old; only in the case of candidates who are zero antigen mismatched with Donation after Cardiac Death donor kidneys allocated regionally or nationally, four

> (rather than one) additional points shall be assigned for candidates who are less than 11 years old and three additional points shall be assigned for candidates who are 11 years old or older but less than 18 years old. The priority assigned for pediatric candidates under this policy does not supercede obligations to share kidneys as a result of a zero antigen mismatch pursuant to Policies 3.5.3 (Sharing of Zero Antigen Mismatched Kidneys) and 3.5.4 (Sharing of Zero Antigen Mismatched Kidneys to Combined Kidney-Pancreas Candidates). […]

Representatives from the Health Resources and Services Administration (HRSA) were asked if this age discussion could be had; HRSA replied that the variable could be discussed. Further, the policy that includes age already exists. The policy cited above was created jointly by the Pediatric Committee and the Kidney Transplantation Committee. The Committee requested that the Lung Subcommittee further discuss this topic.

Thoracic Simulated Allocation Model (TSAM) Analysis of Broader Geographic Sharing for Lung

On November 4, 2009, the SRTR presented its analyses on the impact of broader geographic sharing on lung allocation. This analysis is **Exhibit G**. The Committee determined that the Lung Subcommittee needed to have more detailed discussions on the analysis. The Committee would act according to the Lung Subcommittee's recommendations.

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

On March 23, 2010, 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"[1] 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. The estimated cost for creating this tool would be $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 Executive Committee prioritize the programming of the bilirubin policy.

It was asked 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.

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

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.

5. Modification to Policy 3.7.3 (Adult Candidate Status)

On November 4, 2009, the Committee reviewed a case that involved an adult candidate in need of a heart and a lung. The candidate's center had contacted UNOS to inquire whether this individual could receive a Status 1A-exception classification. The center could not complete the exception form in UNet^{SM}, because the candidate was not hospitalized. In UNet^{SM}, a center cannot request a Status 1A-exception for a candidate if this individual is not in the hospital. So, the center asked how best to approach this case as the center believed that the candidate was quite ill and eligible to receive the Status 1A-exception classification.

UNOS staff suggested that the center ask its regional review board to conduct a prospective review of this request for Status 1A-exception. So, the center submitted its request, and the regional review board opined that the candidate could receive the Status 1A-exception classification. Once this review board decision was rendered, UNOS staff informed the center of the judgment. UNOS staff also requested that the center not act until the Committee voted on the case. (The case review and the Committee meeting's occurred within a few days of each other.)

On November 4, the Committee reviewed the Status 1A-exception policy language and the case documentation. Some members commented that the presentation of the policy language describing criteria for Status 1A-exeption was confusing. It was possible for the review board in question, as well as any review board, to read that language – especially as it is presented in policy – and determine that an exception to the policy could be allowed, i.e., hospitalization may not be a requisite. Some members considered the possibility that there are candidates who qualify for Status 1A-exception, but can be outpatients.

Other members argued that a non-hospitalized medically urgent candidate could not be a Status 1A-exception. Historically, hospitalization was a requirement for many of the Status 1A criteria; hence, the current UNet^{SM} programming.

The presentation of the Status 1A-exception language is an administrative error, and should be updated to match its programming in UNet^{SM}. Further, there ought to exist the letter "e" to indicate the exception language. The group argued that the presentation of the language was at issue, especially since it allowed for conflicting understanding of what criteria could justify a Status 1A-exception.

Some members commented that the center did what it was asked to do by UNOS staff. The regional review board approved the case, and if the Committee had not met in a time that so closely followed that review, the case would stand approved. In the latter event, the Committee may not have received an opportunity to review the case.

Since the candidate is in need of a heart and lung, the Committee argued that the center could also request higher LAS from the Lung Review Board.

After much discussion, the Committee voted (15-supported; 2-opposed; 1-abstained) to do the following:

a) Deny the Status 1A-exception for the candidate, i.e., not uphold the regional review board's decision;
b) Suggest to the center that it may wish to submit a higher lung allocation score request to the lung review board; and,
c) Revise the presentation of the Status 1A-exception language so that it is clear that hospitalization is a requirement.

6. Addition of Human Leukocyte Antigen (HLA) to Policy 3.7.12.1 (Essential Information [for Thoracic Offers])

The proposal to add HLA to Policy 3.7.12.1 was scheduled for public comment distribution during the March, 2010 public comment cycle. On November 4, 2009, the Committee re-affirmed the need to submit the proposal for public comment. A draft of the proposal will be circulated to the Committee for review and approval.

On March 23, 2010, the Committee continued its discussion to add HLA to Policy 3.7.12.1 (Essential Information). UNOS staff did not distribute the proposal for public comment as there emerged questions about the policy language. (The Committee's meeting packet had included a draft of the policy proposal, which had been reviewed and edited by a few of the Committee members.)

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 Committee (OPO Committee). 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 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 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 Committee recollected comments from the leadership of the OPTN/UNOS Histocompatibility Committee's (Histocompatibility Committee) 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 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. 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 Committee should conduct this formative research before making a policy recommendation. The Committee should also identify how readily the proposed policy could be applied by OPOs. Finally, the OPO Committee Chair recommended that the Committee engage the Histocompatibility community or Committee, or both, in this discussion.

It was noted 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 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.

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 Committee members 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 (Operations and Safety Committee) 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 Committee 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 Committee 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 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?

Subsequent to its March 23, 2010 meeting, the Committee sought input from the Operations and Safety, OPO, and Histocompatibility Committees on the survey questions. The Committee anticipates distributing the survey to the OPO and Histocompatibility communities in June, 2010.

7. Effort to Revise Policy 3.7.7 (Allocation of Thoracic Organs to Heart-Lung Candidates)

At its November 4, 2009 meeting, the Committee reviewed a memo submitted on October 15, 2009 by the Membership and Professional Standards Committee (MPSC) on the subject of improving multi-organ allocation policies in general and the joint allocation of heart and lung, in particular. Presented below is an excerpt from the memo:

During its review of member complaints, the Membership and Professional Standards Committee often receives notice that certain allocation policies are unclear or confusing. At its July meeting, the MPSC reviewed the allocation of a liver and intestine. A center complained that an OPO rescinded a liver-only offer to allocate the liver with the intestine to a recipient using the intestine match run. During its review, the MPSC discussed the policies on multi-organ allocations. Multi-organ allocation policies may need review and clarification to ensure that organs are being allocated according to committee intent.

Heart and Lung allocation currently is discussed in Policy 3.7:

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.

The policy may not provide enough specific guidance for allocation of combined hearts and lungs, and may cause confusion. The MPSC requests that the Liver and Intestinal Organ Transplantation Committee and the Thoracic Organ Transplantation Committee review multi-organ allocation policies to attempt to resolve ambiguous organ allocation requirements.

The Committee has been engaged in discussions on how best to improve the policy language so that the OPOs and other members of the transplant community understand clearly:

1) Which match-run (heart, lung, or heart-lung) to use in initiating the search for a candidate in need of a heart and lung;
2) When to switch to another thoracic match-run; and,
3) How best to address geography in the allocation of heart and lung to candidates who need both.

In 2009, the Committee engaged the OPO Committee in this discussion to help guide revisions to Policy 3.7.7. The goal of these discussions is to modify Policy 3.7.7 to clearly state the three items listed above, as well as other concepts that may result from these deliberations.

In discussing the October, 2009 memo from the MPSC, the Committee determined that there ought to exist guiding principles for multi-organ allocation, in general. The Committee opined that the MPSC, the Board of Directors, or the OPTN Contractor could develop these principles which organ-specific committees could then use to improve policies on the joint allocation of multiple organs. The Committee commented that the following principles could serve as some of the proposed guiding principles:

1) Prioritize candidates in a given match-run;
2) Prioritize candidates by geography; and,
3) Provide specific guidance on managing parallel match-runs so that organs that should be offered to candidates in need of a single organ do not get offered to candidates in need of multiple organs.

The Committee requested that the MPSC, the Board or Directors, or UNOS develop such principles that could guide development of policies on the joint allocation of multiple organs. In the meantime, the Committee planned to continue its effort to revise Policy 3.7.7.

While there is the need to change policy, the Committee ought to provide guidance on how to interpret Policy 3.7.7. This interpretive document should be distributed as soon as possible to the thoracic community. This member commented that a failure to register a candidate in need of a heart and lung on the heart waiting list, the lung transplant waiting list, and the joint heart-lung waiting list can result, and in one case did result, in the candidate waiting longer than needed for a heart and lung. The Committee expressed interest in providing such guidance on listing as well as on which match-run to consider when allocating multiple thoracic organs to a candidate. The Committee considered simplifying the multi-organ registration process. Instead of three lists, would it be simpler for the community to have one list to register candidates in need of multiple thoracic organs? Couldn't UNet^{SM} generate a report that states which candidates match on both lists?

The Committee charged the working group of OPO and Thoracic Committee representatives to develop a policy proposal on the joint allocation of heart and lung. The Committee would like to review this proposal at its March 23, 2010 meeting.

On March 23, 2010, UNOS Staff presented several policy concepts that could comprise the revised Policy 3.7.7.

The following questions were posed 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 (fewer 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 then 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.

The Committee raised the following issues:

- A candidate with a lung allocation score of 60 should be able to get the heart offer if that organ was also needed;
- The heart match-run should continue to be favored as post-transplant survival needs to be considered;
- The eventual joint heart-lung allocation policy should be simple, due in part to the small number of candidates who need both organs;
- Similar to what was done historically, 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; and,
- Lung candidates should receive additional LAS points, depending on their heart medical urgency status.

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

Upon the adjournment of the meeting, however, several Committee members outlined heart-lung allocation policy alternatives. This informal discussion resulted in the following concepts, which the Heart and Lung Subcommittees will discuss further.

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

<u>"Heart-centric"</u>

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.

<u>"Lung-centric"</u>

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.

8. Evaluating the Medical Currency of Policy 3.7.4 (Pediatric Candidate Status)

On November 4, 2009, the Committee learned of a pediatric heart case where the candidate was listed as a Status 1A and was at home on inotropes, which were administered intravenously. The Committee discussed the intent of the pediatric heart Status 1A criteria and whether hospitalization of candidates should be required as a further criterion for this medical urgency status. (Currently, the pediatric heart policy does not require hospitalization of Status 1A candidates.) The Committee reviewed OPTN data, which show that: like their adult counterpart, pediatric Status 1A candidates have much higher waiting list mortality rates than pediatric Status 1B or 2 candidates; and, among the pediatric Status 1A candidates, younger pediatric Status 1A candidates have the highest waiting list mortality rate.

The Vice-Chair of the Pediatric Committee, a pediatric thoracic surgeon and who was invited to participate in the discussion of this topic, queried whether hospitalization of candidates would influence waiting list mortality or improve transplant outcome. Is hospitalization really the issue? Some pediatric candidates who are hospitalized, and who are on ECMO device, do not do well either while waiting for a heart or after transplant. Of interest is to learn the impact of duration on ECMO on waiting list mortality and post-transplant survival. Currently, the duration of time on ECMO cannot be calculated using OPTN data. However, enabling knowledge of this duration is a proposed programming effort on the pediatric heart status justification form, and the Board of Directors will review this effort at its meeting in June, 2010.

In general, the Committee discussed how best to improve pediatric heart medical urgency criteria. If any candidate can be listed as a Status 1A, then the pediatric heart allocation policy has in fact become based on waiting time. Thus, this medical urgency system can be perceived as unfair, i.e., everyone is medically urgent and the various policy criteria are not adequately delineating those candidates who are in dire medical need of transplants from those who may not have as dire need medically.

The issue of hospitalization should not be ignored as it poses concerns in classifying the medical urgency of adult heart transplant candidates. For example, there are adult Status 1A candidates who have LVADs and who are at home awaiting transplants. At the same time, there are adults with failed allografts and in the intensive care units. Which population has a more medically urgent need for a transplant? Hospitalization as a criterion for medical urgency status needs further examination. The group concurred.

The Committee refocused its discussion on the pediatric heart allocation policy and how best to improve it. The Committee discussed its efforts on developing a heart allocation score (HAS), a system that would take into account waiting list mortality and post-transplant survival as measures for allocating deceased donor hearts. The Committee commented that there is still much time left before such a system can be developed. For example, the Committee awaits collection of various data elements on VAD and other mechanical circulatory support devices at the time candidates are removed from the waiting list.

The Committee discussed the potential assistance that the Pediatric Heart Transplant Study (PHTS) group could offer in improving the pediatric heart policy. As written on its web site[2], "The…PHTS…is a not-for-profit organization dedicated to the advancement of the science and treatment of children during listing for and following heart transplantation." For example, the PHTS collects data on ECMO duration. So, the PHTS could help the Thoracic and Pediatric Committees understand the impact of ECMO duration on candidate waiting list mortality and post-transplant survival. (Clinical observations indicate that duration on ECMO appears to have an impact on port-transplant outcome.)

The patients that enter the PHTS do so at the time of their addition to the transplant waiting list; so, the PHTS population is a subset of the population of pediatric candidates awaiting heart transplants. As such, there is potential to make direct use of data analyses provided by the PHTS. A Committee member who is also a part of the PHTS offered to present some of the OPTN data at the next PHTS meeting (November, 2009). During this PHTS meeting, the member offered to interact with the PHTS leadership to assess interest in working with the OPTN to evaluate the pediatric heart medical urgency policy. The Committee, commenting on the merit of such a presentation and conversation, requested that UNOS staff provide this member the data necessary to initiate this collaboration with the PHTS.

Given that the HAS could take some years to develop, the Committee decided on the following path forward to evaluate the currency of the pediatric heart medical urgency criteria:

1) The aforementioned member will assess the potential to collaborate with the PHTS; and
2) Should the PHTS agree to work with the OPTN, then UNOS staff should plan a conference call with representatives from the PHTS to begin the data sharing and policy improvement discussions.

The conference call with the PHTS representatives would also include members of the Heart Subcommittee and the Thoracic Working Group of the Pediatric Committee.

This conference call occurred on February 26, 2010. The report of this meeting is in **Exhibit H**.

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

The Committee's March 23, 2010 meeting packet included three articles,[3] which concluded that the heart allocation system in the United States needs to reconsider the placement of ABO-incompatible

[2] http://www.uab.edu/ctsresearch/phts/

[3] 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*

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. 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.

10. Analysis of the Heart Allocation System (OPTN Analysis)

On November 4, 2009, the Committee discussed the impact of the heart allocation system. There has been an increase in the number of active waiting list registrations and urgent waiting list registrations. The waiting list mortality in Status 1A and Status 1B appears to have decreased. The number of transplants has remained essentially flat over the past three years. The distribution of status at transplant has changed: increase in the number of Status 1A candidates and decrease in the number of Status 2 candidates. There is no significant change in post-transplant survival within one year. (Heart allocation slides prepared by UNOS are in **Exhibit I**.)

11. Analysis of Lung Allocation Score System (OPTN Analysis)

On November 4, 2009, UNOS staff presented slides updating the Committee on the impact of the LAS system.

The following is a summary of the impact on the waiting list:

- Since the implementation of LAS there has been a major decline in the total number of candidates on the waiting list;
- The number of active candidates who are at least 12 years of age has increased during the most recent year; and,
- The distribution of LAS at listing has shifted towards higher scores every year since the implementation of this system.

The following is a summary of the impact on transplant and transplant survival:

- The percentage of lungs transplanted has increased from the pre-LAS era to the post-LAS era;
- There was a large increase in the number of transplants from the pre-LAS era to the post-LAS era, but since then, this number has remained relatively stable;
- There has been a substantial shift in the distribution of diagnosis groups from the pre-LAS era (>50% group A) to the post-LAS era (>50% group D); and,

- Post-transplant survival is comparable in the pre- and post-LAS eras, overall and by diagnosis grouping.

The Committee commented that in the future, it would like to further classify LAS by medical urgency, i.e., understand the meaning of a given score.

(Lung allocation slides prepared by UNOS are in **Exhibit J**.)

12. 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, the Committee was asked about its role and the role of UNOS and 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 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.

Hospitals have the role of oversight and 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.

13. Thoracic Case Reviews

Case 1

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.

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.

Case 2

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.

14. Waiting List and Post-Transplant Mortality among Candidates or Recipients Who Have LVAD, or with LVADs and RVAD (OPTN Analysis); Role of INTERMACS in Assisting the Committee Develop the Heart Allocation Score System

Over the past few years, the Committee has discussed the impact of VAD on candidate waitlist mortality, and recipient post-transplant survival. These discussions have resulted in the proposal to collect mechanical circulatory support data elements on the candidate waiting list removal page. The Board of Directors approved the programming proposal in November, 2008. UNOS is planning the implementation of these data elements.

On November 4, the Committee discussed analysis of data it had requested at its previous meeting in July, 2009. For adult heart candidates who have LVADs and RVADs, i.e., BiVAD, or for adult heart candidates with LVADs only, the Committee sought the following information:

- Waiting list mortality for candidates who have LVADs *and* RVADs;
- Waiting list mortality for candidates who have LVADs;

- Post-transplant survival for recipients who had LVADs *and* RVADs;
- Post-transplant survival for recipients who only had LVADs;
- Clinical information about candidates who had LVADs *and* RVADs; and,
- Clinical information about candidates who had LVADs.

This OPTN data analysis indicates that a candidate who had both a LVAD and RVAD was 2.5 times more likely to die while waiting for a heart than a candidate who only had a LVAD. This mortality rate is close to the mortality rate observed among patients enrolled in the Interagency Registry for Mechanically Assisted Circulatory Support study (INTERMACS)[4]. The clinical characteristics of candidates who had a BiVAD versus those with only a LVAD were different. Candidates with a BiVAD were more likely to be younger, less likely to have coronary heart disease, were more likely to be female, and less likely to have diabetes.

The Committee commented that the waiting list mortality appears to be lower than observed clinically. Historically, clinical observations suggest that the waiting list mortality among candidates with VADs is 25% to 30%. The Committee reviewed a data report by INTERMACS, and opined that the OPTN data collection efforts are not gathering enough clinical information about heart transplant candidates who receive VADs and die before receiving a transplant.

Candidates with a BiVAD prior to transplant had lower post-transplant survival rates than candidates who only had a left ventricular assist device. Recipients who once had a BiVAD at the time of transplant were more likely to have had cardiomyopathy, less likely to have coronary artery disease, had a higher rate of dialysis use, and higher rate of treated graft rejection. Candidates who only had LVADs had a higher rate of stroke than candidates with a BiVAD.

Prior to the Committee's meeting, the Chair and Dr. James Kirklin, the Principal Investigator of INTERMACS, discussed data sharing between INTERMACS and the OPTN. The INTERMACS project collects a vast amount of data on recipients of LVADs and BiVADs. Due to the nature of its patient informed consent criteria as well as its contract with the National Institutes of Health, INTERMACS cannot share patient-identified data with the OPTN. The Chair informed the Committee of this fact, and that this fact is not negotiable until the INTERMACS' contract is under negotiation. This negotiation period is some years away. Therefore, the Chair and Dr. Kirklin determined that the best approach could be for the Committee to pose research questions to INTERMACS, and use the results to understand the waiting list mortality of candidates who have VADs and who die before transplantation. (Dr. Kirklin's schedule prevented him from participating in the meeting as planned.) The Committee charged the Heart Subcommittee to develop these research questions and present it to the Committee for review.

To better understand the clinical characteristics of candidates with VADs, the Committee also requested the following data analysis from the OPTN Contractor: stratify post-transplant survival rates by heart medical urgency status.

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.

[4] http://www.intermacs.org/

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 versues 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.

15. LVAD and RVAD Brands to Add or Delete in UNet[SM]

On November 4, 2009, UNOS staff presented the following brand names of left ventricular assist devices (LVAD) to retain, modify, delete, or add.

Existing – Retain As Is	Existing – Modify	Existing – Delete	Possible Additions
• Biomedicus • Heartmate II • Heartmate XVE • Heartsaver VAD • Jarvik 2000 • Medos • MicroMed DeBakey • Thoratec IVAD • Toyobo	• Abiomed BVS – 5000 • Cardiac Assist Tandem Heart (formerly Pittsburgh AB180)	• Arrow Lionheart • Berlin Heart (only brand) • HeartMate IP • HeartMate VE • Novacor PC • Novacor PCq • Thoratec (only brand)	• Abiomed AB5000 • Berlin Heart EXCOR • Evaheart • Heartware HVAD • Impella Recover 2.5 • Impella Recover 5.0 • Levitronix Centrimag • Maquet Jostra Rotaflow • MicroMed DeBakey – Child • Terumo DuraHeart • Thoratec PVAD • Ventacor VentrAssist • Worldheart Levacor

The Committee commented that these same modifications should apply to RVAD brands. UNOS staff commented that there would be an "other" field to capture a newly developed brand. UNOS will periodically request the Committee for guidance on updating this list.

The Committee also reviewed the following modifications of total artificial heart brands.

Existing – Retain As Is	Existing – Modify	Existing – Delete	Possible Additions
AbioCor	SynCardia Cardiowest		

The Committee voted in favor of the modifications to brands of ventricular assist devices and total artificial hearts: 17-supported; 0-opposed; and, 0-abstained.

16. Update on the Heart Subcommittee's Activities

On March 23, 2010, the Committee learned of the Heart Subcommittee's activities. The Heart Subcommittee met on January 29, 2010 and February 26, 2010. The Heart Subcommittee reviewed two heart cases, which the Committee discussed and voted on in this meeting. During its Feburary meeting, the Heart Subcommittee met with the Thoracic Working Group of the Pediatric Committee, and representatives from the PHTS group to evaluate the medical currency of Policy 3.7.4 (Pediatric Candidate Status).

The Heart 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.

The Heart Subcommittee met again on March 26, 2010 and April 30, 2010. The reports of the Heart Subcommittee's January 29, 2010, March 26, 2010, and April 30, 2010 meetings are **Exhibit K**. The Heart Subcommittee will next meet on May 28, 2010.

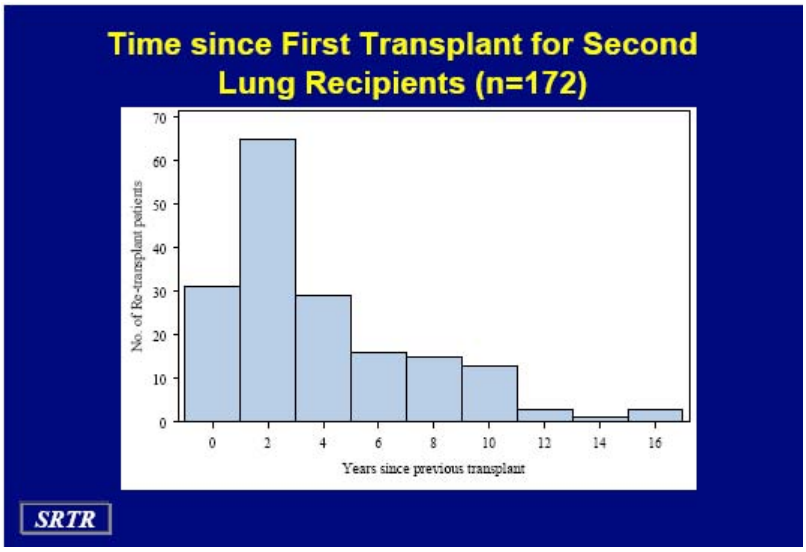
17. Heart Program-Specific Reports (PSRs)

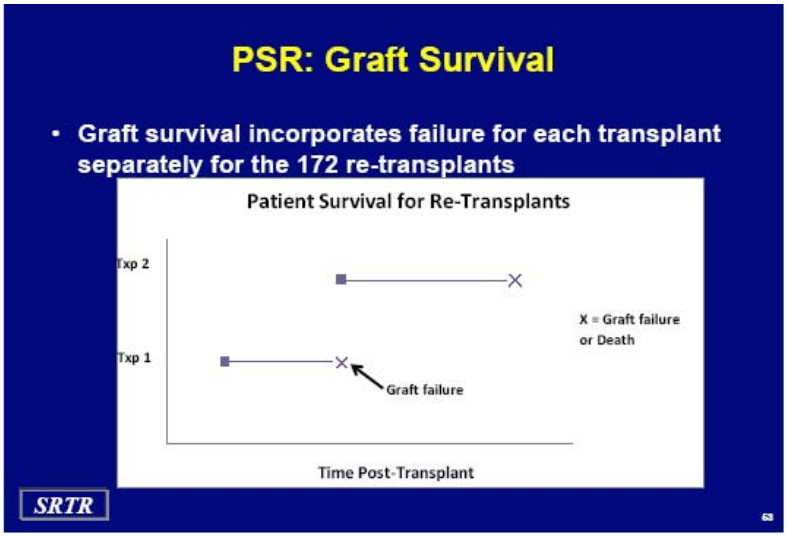
On November 4, 2009, the SRTR reported that its priority, as established by the Committee in 2009, is to analyze the waiting list and post-transplant survival models of the lung allocation score. Therefore, once this heart PSR analysis is ready in the future, the Heart Subcommittee will discuss it.

18. Inclusion of the Following Factor in the Patient Survival Model of the Program Specific Report (PSR): Recipients with Thoracic Re-transplants Who Die

On March 23, 2010, 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.

19. Pediatric Lung Outcome Review (MPSC Memo)

On November 4, 2009, the Committee discussed the following memo from the MPSC:

> As you are aware, the Membership and Professional Standards Committee (MPSC) and the Pediatric Transplantation Committee established a joint work group to review the age classification for pediatric recipients in the lung outcome review analysis conducted by the SRTR. This work group recommended that the age classification for pediatric recipients be modified from the current definition of 0-11 to 0-17 years of age for both the graft and patient survival models.
>
> During the July 2009 MPSC meeting, the Committee discussed this recommendation and considered feedback from the SRTR regarding the impact of this change. The MPSC recognizes that changing the age definition as described will result in fewer programs being analyzed by the statistical model and that there still will not be a pediatric lung survival model. However, the MSPC recommended proceeding with the change in age classification and confirming that the Thoracic and Pediatric Transplantation Committees are aware and supportive of this modification. Additionally, the MPSC recommended that the public data available on the SRTR website, www.ustransplant.org, be modified to be consistent with the analyses used by the MPSC but recognized that this decision could not be made by the OPTN or its Committees. The SRTR has requested feedback from all impacted committees prior to implementing this age definition change on the public website in order to minimize the need for additional changes at a later date.
>
> Because the Committee would like to implement this change as soon as possible, please let us know if the Thoracic Transplantation Committee has any concerns regarding the proposal.

The group discussed whether the age classification should change from 0-11 to 0-17 years of age in the patient and graft survival models. The Pediatric Committee initially raised this question, and is in favor of the change. The Committee supported the pediatric age change for program specific reports: (17-supported; 0-opposed; 0-abstained).

20. Proposal to Improve the Variance Appeal Process (Policy Oversight Committee)

On November 4, 2009, the Committee voted in support of the proposal (18-supported; 0-opposed; and 0-abstained) provided that the following comment is addressed in the final policy language:

The following proposed policy language appears in Policies 3.7.6.a., and variations of it appear in Policies 3.7.8.3.a., and 3.4.9.6.a:

> To express its intent to appeal a committee's decision on an alternative organ distribution or allocation system, the participating Member must do so in writing and within 30 days, inclusive, of the committee's communication of its decision. The participating Member must appeal a committee's decision *before* the Policy Oversight Committee (POC) reviews this recommendation.

The language cited above, as well as its variations, state that members have 30 days to appeal a Committee's decision on a variance. This 30-day time period begins on the date when the Committee notifies the member of the decision. Were the POC to meet during that 30-day time period granted to the member, then the member would have less than 30 days to prepare an appeal to a decision. To prevent such an occurrence, the Committee requests that the POC consider modifying policy so that the POC can only review an appeal in the post 30-day time frame.

21. 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

On March 23, 2010, 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 hemondynamic 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
- PaO_2 at 24 hours and at 72 hours;
- FiO_2 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
- PaO_2 at 72 hours;
- FiO_2 at 72 hours;
- ECMO at 72 hours; and,
- Inhaled NO at 72 hours.

The 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.

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.

The Committee sought the addition of PRA to the waiting list. The WaitList^{SM} is flexible, and needs to be to accommodate improvements in organ allocation. Changes to WaitList^{SM} 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.

22. Emergency Explant and Re-Listing

On March 23, 2010, the Committee discussed the following memo from the 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.

23. Definition of Local for OPOs without Heart Transplant Programs

At its November 4, 2009 meeting, the Committee discussed the following subject raised by a community member:

> "Currently, there exists a heart transplant center (Center X) that transplants a large number of candidates from a donation service area (DSA) that does not serve Center X. Can Center X collaborate/partner with the organ procurement organization (OPO) that does not serve the center, but one that is part of the DSA where Center X's many candidates reside? This partnership could enable these candidates to be considered as "local" in geography to Center X and its OPO."

The Committee determined that such a collaboration or partnership is a variance of the national thoracic allocation system (Policy 3.7 – Allocation of Thoracic Organs). The Committee has been discussing the need for broader geographic allocation of thoracic organs. As such, the Committee recommended that the variance application observe the following section of the OPTN Final Rule:

> […]§ 121.8 […] "(b) Allocation performance goals. […] (3) Distributing organs over as broad a geographic area as feasible under paragraphs (a)(1)-(5) of this section, and in order of decreasing medical urgency;[…]"

The Committee requested that UNOS staff convey this information to the community member, and that this communication include the variance application documents. UNOS staff conveyed this decision to the community member.

24. Standardizing ABO Verification at Donor Hospitals

On March 23, 2010, 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:

> "CMS[5] 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

[5] CMS is the acronym for the Centers for Medicare and Medicaid Services.

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 <u>standardized</u> 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 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 UNet℠. 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.

25. Tracking OPO Scheduled Operation Room (OR) Time versus Actual Arrival Time

A Committee member expressed concern about delays between the times scheduled for a procurement of a deceased donor's organ versus the start of the procurement. It appears that some OPOs are not able to stay on schedule, and at times, these deviations are routine. The transplant center bears the cost in the event of such delays (e.g., human resources, aviation resources, etc.) Several Committee members commented that they have experienced such delays. The Committee discussed the development of a scorecard to track, and ultimately prevent, such delays. The Committee suggested that the existing working group of OPO and Thoracic Committee members further assess the prevalence of these delays, and explore solutions.

On March 23, 2010, 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 its January 25, 2010 meeting (**Exhibit M**), the representatives from the Thoracic and OPO Committees 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.

26. Provisional "Yes" and the Time to "Placed Designation" Status

On November 4, 2009, a Committee member made an observation that as a result of DonorNet®, there were more provisional "yes" statuses, i.e., more centers stating that they might accept a given organ if it were offered to them. The member queried if the increase in these provisional "yes" entries was a result of new technology alone, or if there were other reasons. When does a provisional "yes" in DonorNet® become a final yes or no? At what point does the transplant center know that the provisional "yes" is a true yes or no? Sometimes, centers are not prepared to travel to recover organs when they are not alerted in advance that their provisional "yes" to an organ offer has changed to a final "yes." In the latter cases, centers have assumed that they were not the final recipients of the organ offer, when in fact, they were. OPOs have 30 days to formally close an organ offer. However, what can be done to improve the communication process in that interim time period? The Committee determined that the joint working group of the OPO and Thoracic Committee, as well as the Operations and Safety Committee should consider this topic further.

27. SoftMD and DonorNet®

On November 4, 2009, a Committee member raised this topic for informational purposes. The Committee discussed SoftMD and its utility in electronically reviewing donor related documents (x-rays, etc.). SoftMD cannot be part of DonorNet®. The company is based in California, and as of November, there were 32 OPOs in the United States testing the utility of this software.

28. Addition of "Other" Field to Lung Diagnosis Data Elements

On November 4, 2009, the Committee discussed briefly the following thoracic programming agenda item that the Board of Directors will review on November 16-17, 2009:

For a lung transplant candidate who is less than 12 years of age, a center cannot enter a diagnosis that is not already programmed in UNet℠. There is no "other" category where the center can enter this diagnosis. (There is an "other" category for lung candidates who receive lung allocation scores ($\geq$12). When an "other" diagnosis is entered, the center submits an exception request to the lung review board.)

On February 25, 2009, UNOS staff discussed with the Lung Subcommittee the addition of an "other" field to enter a lung disease diagnosis that is not listed in UNet℠. This discussion was prompted by a center contacting UNOS staff to inquire how to enter a diagnosis not already listed in UNet℠. These contacts have not occurred too frequently, thus laying open the possibility that either the diagnoses listed in UNet℠ are complete or that diagnoses that most closely match are being selected. To encourage accuracy in the diagnoses entered, the Lung Subcommittee recommended allowing centers to enter a diagnosis that is not in UNet℠. The Committee discussed and supported this recommendation at its March 27, 2009 meeting.

The Lung Subcommittee discussed this topic again on September 29, 2009. UNOS Staff posed programming questions related to the addition of the "other" field, and queried the Lung Subcommittee's interest in the following alternatives to adding the "other" field. These alternatives were:

1) Add more lung diagnosis codes (rather than adding a new "Other Diagnosis" field); or
2) Allow all candidates less than 12 years old to submit an LAS Exception for a "Other Diagnosis"

The Lung Subcommittee maintained its support of adding the "other" text field. After this text field has been added to UNet[SM], the Subcommittee commented that it would consider adding to the quantitative diagnosis list those diseases that are frequently entered in the text field.

In November, 2009, the Board of Directors approved the following resolution:

> **RESOLVED, that programming to add the lung diagnosis data element "other" for candidates who are less than 12 years of age, as set forth in **Exhibit A**[6], is hereby approved, effective pending programming in UNet[SM].

The above is the justification provided to the Board of Directors in a report from the Committee.

The Committee reviewed the estimated cost for adding this "other" field: $92,648. The Committee commented that the cost for programming one data element appeared high, but that the programming did need to occur. It is important to collect the correct diagnosis of a pediatric lung candidate as this diagnosis will later be used to determine the candidate's lung allocation score.

On November 16-17, 2009, the Board of Directors approved the programming changes.

29. Reorganization of Hemodynamic Data on the Adult Status 1A Heart Justification Form

On October 2, 2007, the Committee received a request from a Heart Regional Review Board member to clarify data fields in the heart justification form. The reason for this request is that in some cases, the hemodynamic data are not current or complete. In addition, for some Status 1A justification requests, the location of the "Date of Hemodynamics" field is also confusing.

A Committee member proposed that reorganizing fields in this section would make the data collection requirements clearer and more logical in flow. The Committee agreed.

On October 13, 2009, the Heart Subcommittee met to further discuss the presentation of hemodynamic data elements in the Status 1A(d) and Status 1A-exception (Status 1A(e)) forms. The Heart Subcommittee made further recommendations for the Thoracic Committee to discuss at its November 4, 2009 meeting. These recommendations were:

- The physiologic data elements should be organized vertically on the 1A(e) form;
- The "ejection fraction" data element needs to be part of the group of data elements that begin with "Date of Most Recent Echocardiogram" on the Status 1A(e) form;
- Hemodynamic data need to be included in both the Status 1A(d) and Status 1A(e) forms;
- The hemodynamic data need to be "current for Status 1A(d)," whereas the vital signs data need to be current as of the last 24 hours; and,
- A visual separator should be placed on the Status 1A(e) form, and this separation (such as a line) should be placed between the data obtained from a pulmonary artery catheter and the data obtained from an echocardiogram.

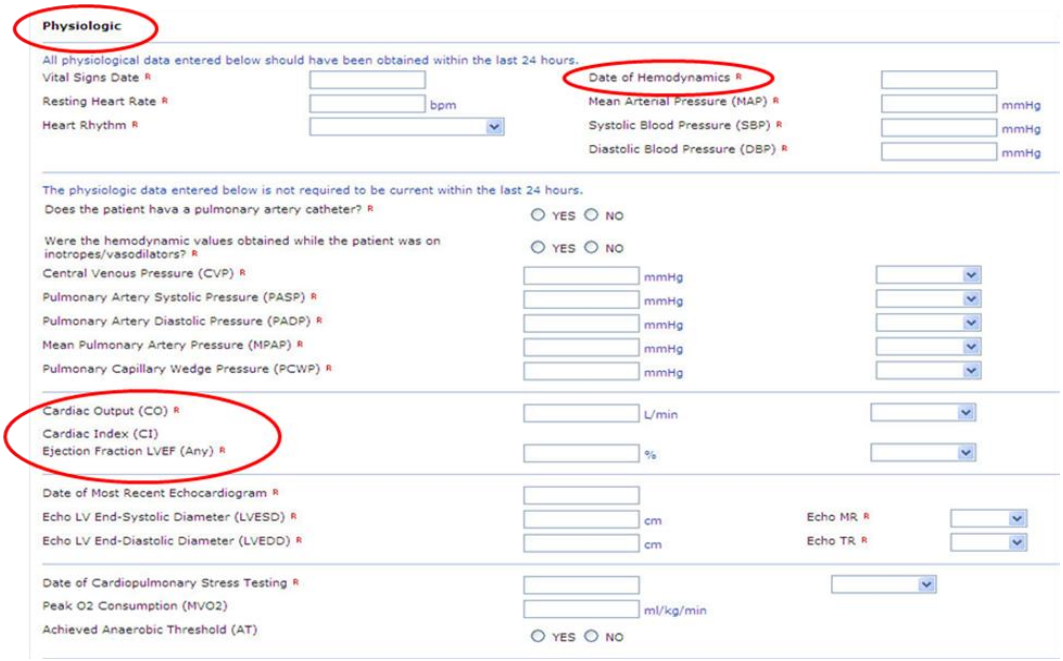
[6] This exhibit is not part of this report.

On November 4, 2009, UNOS staff presented modified screen captures of the Status 1A(d) and Status 1A(e) forms to the Committee. The Committee determined that changes to the Status 1A(d) form is not necessary as the layout of the hemodynamic data is satisfactory. The Committee recommended that the date of vital signs should be moved on the Status 1A(e) form, and that the vital sign data need to be current within the last 24 hours.

The Committee commented that it is possible to have the same hemodynamic data entered repeatedly, and so, the hemodynamic data could be over four months old at the time the Status 1A(e) form is reviewed by the regional review board. Hemodynamic data that are not current are not useful in assessing Status 1A(e) forms by regional review boards.

The following images illustrate the current presentation of hemodynamic data on the Status 1A(e) form and the proposed layout of the hemodynamic data on the Status 1A(e) form:

Current Status 1A-Exception Form



Modified Status 1A(e) Form

Physiologic

All physiological data entered below should have been obtained within the last 24 hours.

Vital Signs Date *
Resting Heart Rate * bpm
Heart Rhythm *
Mean Arterial Pressure (MAP) * mmHg
Systolic Blood Pressure (SBP) * mmHg
Diastolic Blood Pressure (DBP) * mmHg

Reorganized layout of data in this section – vertical versus horizontal presentation. Date of hemodynamics moved to the section below.

The physiologic data entered below is not required to be current within the last 24 hours.

Does the patient hava a pulmonary artery catheter? * YES NO
Date of Hemodynamics *

Date of hemodynamics is here.

Were the hemodynamic values obtained while the patient was on inotropes/vasodilators? * YES NO
Central Venous Pressure (CVP) * mmHg
Pulmonary Artery Systolic Pressure (PASP) * mmHg
Pulmonary Artery Diastolic Pressure (PADP) * mmHg
Mean Pulmonary Artery Pressure (MPAP) * mmHg
Pulmonary Capillary Wedge Pressure (PCWP) * mmHg
Cardiac Output (CO) * L/min
Cardiac Index (CI)

CO and CI are here.

Date of Most Recent Echocardiogram *
Ejection Fraction LVEF (Any) * %
Echo LV End-Systolic Diameter (LVESD) * cm Echo MR *
Echo LV End-Diastolic Diameter (LVEDD) * cm Echo TR *

Ejection Fraction is here.

Date of Cardiopulmonary Stress Testing *
Peak O2 Consumption (MVO2) ml/kg/min
Achieved Anaerobic Threshold (AT) YES NO

The Committee voted in favor of the modifications to the presentation of hemodynamic data on the Status 1A(e) form, because these changes solve the problem of not knowing the date of hemodynamics: (18-supported; 0-opposed; and, 0-abstained). The Committee discussed the estimated cost of the modification: $27,804.

On November 16-17, 2009, the Board of Directors approved the programming changes.

30. Implementation of Current and Change in Bilirubin in the Lung Allocation Score (LAS)

At its meeting on June 22-23, 2009, the Board of Directors discussed the Committee's proposal to add current and change in bilirubin to the LAS. After considerable discussion and several amendments to the resolution regarding the implementation of the policy modification, upon motion duly made and seconded, by a vote of 28 for, 2 against, and 2 abstentions, the Board of Directors approved the following:

RESOLVED, that Policy 3.7.6.1 (Candidates Age 12 and Older) shall be modified as set forth below, effective pending programming and notice to the membership:

- Approve the policy in concept but defer adding it to the LAS;
- Refer this proposal to the Executive Committee for a definitive implementation plan, which would include working with staff to determine an appropriate solution, which may include:
    - Adding an LAS calculator to UNet^{SM} for the purpose of providing guidance for the Lung Review Board;
    - Performing a cost analysis of serial bilirubin collections via UNet^{SM}; and
    - Development of an education plan for centers on the process to be used to award additional priority to eligible candidates.

Though the Board of Directors approved the policy proposal in concept, it expressed concerns about the proposed cost of implementing it using an automated solution: $363,233.

At its meeting on July 14, 2009, the Committee expressed concern about the Board of Directors' deliberations on policy implementation, and discussed how it should move forward with policy development in the future. The Committee decided to submit this query to the Executive Committee. In October, 2009, the Committee voted electronically and in favor of submitting policy implementation questions (see **Exhibit A**[7]) to the Executive Committee: 23-Support; 0-Oppose; 0-Abstain. (The Committee has a total of 27 voting members. Four members did not submit a vote.)

The Chair reported that the Executive Committee, during its call on October 23, 2009, approved the Committee-supported implementation plan for the addition of current and change in bilirubin to the LAS. The Executive Committee were given several alternatives (including cost) for implementing the policy (see **Exhibit A**), however, none of the options except the one originally proposed by the Committee would program the policy in one effort and would cost the least. Though the cost of implementing the policy in full is $363,233, the cost of implementing the policy in parts, as described in Appendix B[8], would result in an overall implementation cost higher than $363,233. Further, the cost of implementing the policy administratively would need to be tracked prospectively. It is likely that the cost of implementing this alternative would be much higher than $363,233.

On October 23, 2009, due to lack of enough time, the Executive Committee was not able to consider all questions posed by the Thoracic Committee. UNOS staff will inquire to its leadership when the Executive Committee or the Board of Directors could consider the remaining questions.

On November 4, 2009, the Committee asked about the timetable for implementing this policy. It is possible that the implementation of bilirubin in the LAS would need to follow the completion of the Chrysalis project (includes the redesign of the waiting list system). Otherwise, programming of current and change in bilirubin may need to occur twice: prior to the completion of Chrysalis and post-Chrysalis.

31. General Business

Beginning in 2010, the Lung and Heart Subcommittees will meet monthly and at a specified time. The Heart Subcommittee will meet the last Friday of each month. The Lung Subcommittee will meet the last Tuesday of each month. Both meetings will occur in the afternoon.

UNOS staff requested the Committee if it could present general heart and lung analyses once a year. The Committee agreed to this request.

[7] This exhibit is not part of this report.
[8] This exhibit is not part of this report.

Thoracic Organ Transplantation Committee	November 4, 2009 Chicago, Illinois	
Name	**Position**	**Attendance**
Maryl R. Johnson, MD	Chair	X
Mark L. Barr, MD	Vice-Chair	X
Kevin Dushay, MD	Regional Rep. (1)	
Raymond L. Benza, MD	Regional Rep. (2)	X
Mark Rolfe, MD	Regional Rep. (3)	By phone
Luis Angel, MD	Regional Rep. (4)	
John Chin, MD	Regional Rep. (5)	X
Howard Song, MD	Regional Rep. (6)	
Robert Love, MD	Regional Rep. (7)	
Ramsey R. Hachem, MD	Regional Rep. (8)	X
Sean P. Pinney, MD	Regional Rep. (9)	X
LaDora Dils, RN, CPTC	Regional Rep. (10)	
Isabel P. Neuringer, MD	Regional Rep. (11)	
Kevin Chan	At Large; Lung Review Board Chair	
Gregory S. Couper, MD	At Large	X
R. Duane Davis, MD	At Large	X (and, by phone in the afternoon)
William Fiser, Jr., MD	At Large	By phone
Herbert Heili	At Large	
Denise Kinder, RN, CPTC	At Large	
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	By phone
Monica Lin, PhD	Ex Officio – HRSA	X
Bernie Kozlovsky, MD	Ex Officio - HRSA	X
David Campbell, MD	Guest (Vice-Chair of the Pediatric Committee)	By phone
Brad Dyke, MD	SRTR Liaison	X
Kate Meyer	SRTR Liaison	X
Susan Murray, ScD	SRTR Liaison	X
Ying Qian	SRTR Liaison	X
Leah Edwards PhD	Support Staff	X
Vipra Ghimire, MPH, CHES	Committee Liaison	X
Lee Goodman	Support Staff	X
Aaron McKoy	Support Staff	By phone
Jory Parker	Support Staff	By Phone
Chad Waller	Support Staff	By phone

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