

The Thoracic Organ Transplantation Committee met on October 2, 2007 in Chicago, Illinois. The following is a brief summary of the Thoracic Committee's deliberations. This report presents the discussions by the order in which the Committee discussed each topic. The Thoracic Committee will next meet on March 10, 2008.

1) **Bylaw Modification Issued for Public Comment (September 28, 2007 to December 21, 2007)**

The Thoracic Committee reviewed the following bylaw change proposal submitted for public comment by the Membership and Professional Standards Committee (MPSC):

Proposed Modification to the OPTN Bylaws, Appendix B, *Transplant Hospitals*; Section B. *Survival Rates*; and Section C *"Inactive Membership Status"*; and Attachment I, Section II, *"Inactive Program Status"*; and to the UNOS Bylaws, Attachment I, Section II *"Inactive Program Status"* and Attachment II, Section XIII, C, (10) *"Survival Rates"* (Membership and Professional Standards Committee).

A regional representative commented that at his regional meeting, there were concerns regarding which state would have legal jurisdiction over the "summary" referenced in the following sentence of the proposed language: *"A Member who participates in a discussion with the MPSC is entitled to a summary of the discussion."* Another Committee member commented that states have differing laws about medical peer review.

UNOS staff explained that these informal discussions benefit the OPTN member. A Committee member stated that these discussions provide much needed information. The Committee voted to support this proposal (15-Yes, 0-No, 1-Abstention), but would like to know which state statute has jurisdiction over the summary referenced above. The Committee would also like to know who reviews the document.

Actions

- UNOS staff will research which state has legal jurisdiction over the summary of the discussion, and communicate this information to the Committee.
- UNOS staff will forward the Committee's discussion and vote to the MPSC liaison.

2) **Alpha-1: Impact of Lung Allocation Score System (LAS) on Alpha-1 waitlist candidates**

Guests representing the interests of lung candidates with Alpha-1 attended the Thoracic Committee meeting. These representatives were Ken Irvine (Alpha-1 Foundation), Bettina Irvine (Alpha-1 Association), and Dr. James Stocks (University of Texas in Tyler; Alpha-1 Foundation's Medical and Scientific Advisory Committee; and, Assistant medical director for AlphaNet). Ken and Bettina Irvine, and Dr. Stocks attended the meeting to express concerns about the decline in the number of Alpha-1 candidates receiving lung transplants since the implementation of LAS.

Bettina Irvine, a double-lung transplant recipient, commented that Alpha-1 patients appear to have very low lung allocation scores, and so, are not receiving transplants sooner. She also cited an example of an Alpha-1 candidate who had a high priority for transplant before the LAS, and a low priority for transplant after the LAS.

Dr. Stocks commented that the survival of Alpha-1 candidates on the waitlist is worse after the LAS than it was before. He acknowledged that while this trend might change with new data, the current trend does pose a concern for now. He suggested that one possibility for the current trend may be that Alpha-1 candidates are grouped unfairly, especially with respect to etiologic and physiologic

similarities with other diseases in the group (for example, sarcoidosis). Alpha-1 candidates are classified currently within diagnosis Group A. Dr. Stocks suggested grouping Alpha-1 candidates separately. He commented that while there has been an increase in the number of lung transplants overall, there has been a decrease in the number of transplants among Alpha-1 candidates.

UNOS staff presented data on the impact of the LAS on Alpha-1 candidates. Since the LAS, there has been a decrease in the deaths on the waiting list among candidates in diagnosis Group A. Candidates with sarcoidosis have the highest death rate in this group. In the year prior to the LAS, Alpha-1 recipients comprised 5% of the total number of transplants and in the year after, they comprised 3% of the total. The median lung allocation score among candidates in Group A was 32.1 (active waitlist registrations) and 33.3 (transplants). Among Alpha-1 candidates, the median lung allocation score was 32 (active waitlist registrations) and 33.2 (transplants).

Dr. Stocks requested that the Committee assess whether the Alpha-1 candidates are advantaged or disadvantaged by the LAS. He also expressed concerns that the methodology employed in the LAS, and some of the tools used to constitute that score, may not be providing an accurate picture of the Alpha-1 candidate's physiology. He cited the FEV₁ (% predicted) measure as being inappropriate for deciding transplant eligibility. He suggested that there may be better assessment tools for pulmonary function and physiology, especially with respect to Alpha-1 candidates. The population-based studies may not be appropriate for determining transplant eligibility. A Committee member responded that FEV₁ was one of many variables associated with waitlist mortality, and that this association was statistically significant. This member also stated that LAS models include pulmonary artery pressures, and these values can alter a candidate's score.

The Committee responded that it continues to review the impact of the LAS at each meeting. The waitlist and post-transplant models that comprise the LAS are dynamic, not static. The Committee uses an evidence-based approach for changing the lung allocation score system. The Committee requested examination of serial clinical and physiological data, collected since the LAS, for the current appropriateness of classifying Alpha-1 candidates in Group A.

Action

- The SRTR will examine whether Alpha-1 candidates should remain in diagnosis Group A classification, according to disease progression, waiting list mortality, and post-transplant mortality.

3) Heart Review Board Case

The Committee reviewed a case denied by the Heart Regional Review Board. A patient's transplant center had submitted an exception requesting an upgrade from Status 2 to Status 1B. The exception request did not include sufficient information for the case evaluation, and so, the Review Board denied the request. Before all Review Board members could submit their votes, the center transplanted the candidate as a Status 1B. The center, when presented with the opportunity to either appeal to the review board or present their case to the Thoracic Committee, opted to submit this case to the Committee.

The Committee discussed the details of the case as well as the broader data collection concerns with Status 1B exception requests. The center did not provide sufficient information on the patient. For example, a patient could be hypotensive for many reasons. The center's transplant of this candidate, while an exception request was open and subsequently denied, was its first.

The data requirements to justify Status 1B upgrades aren't as thorough as those for Status 1A upgrades. The Committee discussed creating a form for a Status 1B exception that is similar to the one for Status 1A exception. The Committee also discussed developing a resource document that would outline clinical data useful in evaluating Status 1B exception cases. The Regional Review Board members would use this document to assess the information provided by the center. If necessary, the Review Board would ask for additional information, as suggested in this document.

The Committee decided to develop this resource document as well as listing criteria for inclusion in the Status 1B exception form.

The Committee did not take any adverse action against the transplant center (19-Yes, 0-No, 0-Abstention). The Status 1B exception form has neither served as an adequate guide to centers submitting this request, nor has it served as a tool for Regional Review Board members to use when evaluating these exceptions.

Actions

- UNOS staff will communicate the Committee's decision on the case to the transplant center.
- UNOS staff will convene the Heart Subcommittee to develop listing criteria for the Status 1B exception form. The Heart Subcommittee will also outline information that will better help Review Board members to evaluate Status 1B exception requests.

4) Impact of DonorNet[®] on Organ Offer and Acceptance Rates

Dr. Marlon Levy, Chair of the Electronic Organ Placement Working Group (EOPWG, a sub-group of the Operations Committee) presented data on the impact of DonorNet[®] on organ offers and placements. (UNOS implemented DonorNet[®] 2007 on April 30, 2007). Dr. Levy reported that since its implementation, DonorNet[®] has increased the volume of organ offers made and received.

Results from a questionnaire sent to transplant centers in July-August, 2007 show that 30% (n=45) of the transplant centers are changing who screens organ offers. In these cases, the non-decision makers are the first to review organ offers. Dr. Levy stated that this is a negative change as the intent is to have the decision-maker review the offers.

Between May 1, 2007 and September 5, 2007, there were 8,753 electronic offers from heart matches and 10,340 from heart-lung matches. The median time a center took to initially respond to an electronic offer, from either match, was approximately 17 minutes. There were 20,370 electronic lung offers, and the median time a center took to initially respond to an electronic lung offer was 16.9 minutes.

The median acceptance time for all thoracic offers was about an hour. Between May 1, 2007 and September 5, 2007, there were 268 acceptances from heart matches and 378 acceptances from heart-lung matches. The median acceptance time was approximately 55 minutes from either match. There were 596 lungs accepted with the median acceptance time of 53 minutes. A Committee member requested data on the average amount of time lapse between organ acceptance and transplant. It is this member's observation that this time is the same or longer than before DonorNet[®], and this poses concerns about the changing donor physiology.

DonorNet[®] allows for an increased possibility to exhaust the match-run. In the era just *before* DonorNet[®] (1/1/07 – 4/30/07), there were 581 heart matches run and 36 (6.2%) exhausted the list. In this same era, there were 1133 lung matches run with 69 (6.1%) exhausting the list. There for 845 heart/lung matches run and 56 of these (6.6%) exhausted the list. In the era *after* DonorNet[®], there were 735 heart matches run and 99 (13.5%) exhausted the list. There were 1229 lung matches with 163 (13.3%) exhausting the list. There were 813 heart/lung matches run and 112 (13.8%) exhausted the match list. Dr. Levy emphasized that a key concern of HRSA is that match runs do not skip recipients. DonorNet[®] minimizes this skipping and is helping to meet this objective.

Overall, the number of organs transplanted before and after DonorNet[®] was fairly close. However, any increases or decreases were not necessarily attributable to DonorNet[®] only as there were many other events also occurring in the same time period.

The Committee expressed concerns about the number and quality of organ offers received. The Committee cited instances of electronic notifications sent for organs the Committee considered unsuitable for thoracic transplantation. Dr. Levy replied that OPOs are under pressure to increase

their organ recovery and placement rates. The resolution is in strengthening screening criteria. Another Committee member noted the need for tiered acceptance in DonorNet[®], and that it would have been preferable to have tiered acceptance in place prior to the implementation of DonorNet[®]. Dr. Levy commented that DonorNet[®] will incorporate additional screening over the next several months.

One Committee member commented that OPOs should be accountable for making inappropriate organ offers. A Committee member suggested that transplant centers document those OPOs making these medically unsuitable organ offers. The Committee could then discuss this information at the next meeting, or at a joint Subcommittee meeting of the Thoracic and OPO Committees. Before acting on this suggestion, the Committee decided to review additional data on DonorNet[®]. The Committee requested the following: whether it was possible to identify thoracic organs for which offers were made but were considered not transplantable; and, possible patterns of behavior in offering thoracic organs that are not transplantable. One Committee member suggested the use of regional forums for educating OPOs about potentially unsuitable offers.

A Committee member requested the average number of offers associated with a refusal of an organ. This average number can serve as a guide to OPOs for identifying medically unsuitable organs

A Committee member commented that the large number of organ offers will force people other than the surgeon to receive calls about organ offers. This member also commented that DonorNet[®] has shifted the financial burden from the OPO to the transplant center. Though it is early in the DonorNet[®] experience, several Committee members commented that there does not appear to be demonstrable benefit of DonorNet[®] with regards to increased number of organs transplanted. But, there does seem to be an increased burden on the transplant centers. A few Committee members remarked that an electronic placement system was inevitable and necessary, but that this system still needs improvement.

The Thoracic Committee will discuss additional screening criteria and approaches to minimizing the number of medically inappropriate organ offers. The Committee requested its regional representatives to attend their regional meetings and discuss the impact of DonorNet[®] with their colleagues. The members should present reports of unsuitable organ offers at the next Thoracic meeting. The Committee will analyze this information, and consider forwarding the information to the Operations Committee, the OPO Committee, or the MPSC.

Actions

- UNOS staff will communicate the Committee's discussion to the EOPWG.
- The Regional Representatives will present data on the impact of DonorNet[®].
- If medically inappropriate offers can be identified, UNOS staff will tabulate rates at which such offers are made overall and by OPO.
- UNOS staff will examine the average number of offers associated with organs that are never accepted.

5) LAS Update: Post-Transplant Survival Benefit for Transplant Recipients, Stratified by LAS at Time of Transplant

UNOS staff presented data on the predicted survival benefit of lung candidates at the time of transplant. The analysis included all deceased donor lung and heart-lung transplants performed between May 4, 2005, and June 30, 2007. Patients with lung allocation scores less than 35 (N=1261) did not have positive predicted survival benefits in the one year following transplant. All patients with scores of 50 or higher had positive survival benefits (N=430), i.e., they would live more days with a transplant than without. An increase in the lung allocation score at the time of transplant results in positive survival benefits in the one year following transplant.

A Committee member queried whether it was now appropriate to remove geographic boundaries in lung allocation, and establish a score threshold, such as 35, for assigning zonal and transplant

priority. Another Committee member commented that the current lung allocation score system does not respond to progression of disease equally across all diagnostic groups. A threshold of 35 would benefit candidates in Group D, but not those with pulmonary hypertension. The ability for a candidate to receive a higher score when his/her disease progresses is more likely to happen if the candidate is in Group D or C, but not Group B or A.

The SRTR staff commented on its abstract submitted to the International Society for Heart and Lung Transplantation (ISHLT; 2008 Annual Meeting). The abstract presents results of a thoracic simulated allocation model (TSAM) for lung allocation that removes "local" for all candidates and for candidates with scores higher than 40. The SRTR performed this analysis by region. One Committee member suggested performing this analysis by diagnosis group and age. A Committee member requested The SRTR to present this abstract at the next Thoracic Committee meeting.

UNOS staff presented an update on the effects of the LAS. In recent months, there has been a decline in the number of candidates on the lung transplant waiting list. While there has been a significant decrease in the number of candidates in the lung transplant waitlist since the implementation of the LAS, the more recent decline may suggest decreases in the number of inactive candidates. Since the LAS, the number of active lung and heart/lung registrations has been relatively constant. The transplant center lung transplant waiting list volume has also been relatively constant. Group A still represents the largest diagnosis grouping on the waitlist, followed by Group D. The median lung allocation score on the waiting list for all groups combined remains around 34. The transplanted population has higher scores than the waitlist population.

Since the LAS, there has been a decrease in death rates on the lung transplant waitlist overall, and for all diagnosis groups except B. There may be a slight increase in waiting list mortality among lung candidates in the second year after LAS compared with the first year after LAS, but further data accrual are necessary to make definitive conclusions.

Recently, the Lung Review Board has primarily received cases seeking increases in the score. Exception requests for candidates in Group C are typically for increases in hemodynamic values, whereas for Group B, the requests are for score increases.

Group A candidates comprise 34.2% of the recipients in the most recent post-LAS transplant population, a decrease from 52.1% in the pre-LAS era. Group D candidates comprise 46.5% of the recipients in the most recent post-LAS transplant population, an increase from 28.1% in the pre-LAS era. In the waitlist, there hasn't been a significant change in representation of the diagnosis groups.

There are no significant differences across diagnosis groups in post-transplant survival at 9 months after transplant in the pre-LAS and post-LAS populations.

The Committee requested lung allocation score analysis by age (>50 years of age) and match run position. The Committee also requested data on waitlist deaths by initial lung allocation score (i.e., listing score).

Actions

- The SRTR will provide results of a TSAM that removes local for all candidates as well as for candidates with scores greater than 40. The SRTR will perform this analysis by region, age, and diagnosis group.
- The SRTR will share their ISHLT abstract with the Committee at the next meeting.
- UNOS staff will examine the LAS distribution for candidates 50 years of age or older.
- UNOS staff will analyze waitlist mortality by lung allocation score.

6) Time to Transplant Stratified by ABO (OPTN)

At its May 3, 2007 meeting, the Committee reviewed lung transplant survival rates stratified by ABO match level and distance. The Committee wanted to know if one blood group was likely to receive

transplants sooner than another group. UNOS staff reported that non-O blood groups had similar probabilities for receiving a transplant (about 70% after 1 year of waiting). The O blood group population had a slightly lower probability for receiving a transplant (64% after 1 year of waiting).

Action

- None.

7) Update from Lung Implementation Subcommittee

a) *PCO₂ in the Lung Allocation Score*

Dr. Duane Davis, the Lung Subcommittee chair, updated the Committee on the Subcommittee's activities. The Subcommittee met on July 19, 2007 to discuss whether there are decreases in waitlist mortality among lung candidates reporting PCO₂ change $\geq 15\%$ in one six-month period but not in subsequent 6-month periods. Due to the small dataset, the Subcommittee couldn't make recommendations based on data on whether to retain LAS impact from change $\geq 15\%$. The Subcommittee instead relied on clinical evidence, and recommended the retention of change benefit as long as the candidate continued to demonstrate PCO₂ change $\geq 15\%$.

UNOS staff commented that the Subcommittee's recommendations may need to be in policy, and that programming efforts ought to follow a change in the policy language. There are also other implementation questions, and answers to some of these questions may also need to be in the policy language. Several Committee members expressed concerns about programming delays and disagreed with the need for language change. The proposed language change might require a public comment phase, which could further delay programming. Many in the thoracic community think that programming for PCO₂ is complete. One Committee member suggested that UNOS staff prepare a document that details the relevant implementation concerns. The Lung Subcommittee will convene in the days following the Thoracic Committee meeting to further discuss the PCO₂ policy and potential revisions.

Actions

- UNOS staff will organize a Lung Subcommittee meeting to further discuss the PCO₂ policy.
- UNOS staff will prepare a document that outlines the policy implementation concerns.

b) *Inclusion of Bilirubin and Creatinine in the Lung Allocation Score*

Dr. Davis presented the Subcommittee's deliberations on the inclusion of bilirubin and creatinine in the lung allocation score. Change in bilirubin and change in creatinine are associated with waitlist mortality, but not post-transplant survival. These markers may help predict waitlist mortality for candidates with pulmonary hypertension. There are limited but statistically significant data that support the inclusion of bilirubin in the LAS. Clinical observations also support this inclusion.

Dr. Reda Girgis with the Reveal Registry joined the Committee via conference call. Dr. Girgis reported that the Registry is very new, and doesn't have adequate data regarding bilirubin as a marker for candidates with pulmonary hypertension. Increases in bilirubin, he reported, are predictive of poor health outcomes, such as right heart failure. The Committee requested data on bilirubin from the Reveal Registry as they become available. In the future, Dr. Girgis will share relevant Registry data with the Thoracic Committee for possible inclusion in the lung allocation score.

The Committee voted in favor of including bilirubin and change in bilirubin in the lung allocation score (20-Yes, 0-No, 0-Abstentions).

The Committee next discussed the inclusion of creatinine and change in creatinine in the lung allocation score. Creatinine is in the lung post-transplant model but not the waitlist model. The SRTR presented data on the interaction of glomerular filtration rate (GFR) and age, as requested

by the Subcommittee. The interactions between GFR and age, like the interaction with creatinine and age, were not statistically significant. One Committee member expressed concerns about continually adding variables to the models without making use of data collected since the LAS.

The Committee decided not to include creatinine in the LAS at this time. The Committee will reconsider this variable when more data become available.

Actions

- UNOS staff will prepare the policy language to include bilirubin and change in bilirubin in the lung allocation score. The Committee will review this draft language at its next meeting.
- UNOS staff will continue communications and collaborations with Dr. Girgis and the Reveal Registry.

8) Variation in Placement of Single and Double Lungs (OPTN Analysis)

At its May 3, 2007 meeting, the Thoracic Committee requested information on the impact of LAS on the placement of single versus double lungs. The percentage of non-DCD donors from whom at least one lung was transplanted increased from 13.8% in the first year after LAS to 15.7% in the second year after LAS. A majority of this increase is in the donor group who had both lungs recovered and transplanted (10.9% in the first year, 12.6% in the second year). When only one lung was transplanted, the other lung was not recovered in 75.9% of the cases (n=228). Also when only one lung was transplanted, the other lung was recovered for transplant but not transplanted in 15.4% of the cases (n=228). The primary reasons for this non-transplant include poor organ function and medically unsuitable organ (upon evaluation in the operating room).

The Committee had previously asked the following question: when one lung is placed, how often is the other lung either not placed or is discarded? UNOS staff reported that in cases where one lung is placed, data do not clearly demonstrate difficulty in placing the other lung. But as this information is not explicitly collected, this question is difficult to address directly.

One Committee member commented that even in the absence of data, to maintain good public relations, the Committee should consider matching lungs of donors 12-19 years of age with recipients 12-19 years of age. The Committee will consider revising the lung allocation, but requested that the SRTR prepare an analysis using TSAM comparing the current allocation system (12-17 years) and the following age groups: 12-19, 12-21, 12-23, and 12-25. The Committee would like to see these results by candidate age and diagnosis groups.

Action

- The SRTR will provide TSAM results using the current allocation system and the following age groups: 12-19, 12-21, 12-23, and 12-25. This analysis will present data by age and diagnosis group.

9) Report of the Joint Heart and Lung Subcommittees

Dr. Maryl Johnson, Chair of the Heart Subcommittee, updated the Committee on the review of heart and lung variables used in the patient and graft survival models. The joint meeting of the Heart and Lung Subcommittees occurred on September 20, 2007. At this meeting, the Subcommittees reviewed variables in the OPTN deceased donor registration form, as well as variables currently used in the center-specific reports. The Subcommittees identified several new variables for analysis by The SRTR. The results of this analysis may mean future incorporation of these variables in the models. The Subcommittees will convene again separately to determine heart and lung variables to retain in the models, discard from the models, and new variables to add to the models.

One Committee member expressed concerns about the use of small numbers for evaluating centers, and inquired about the use of a longer time period in the survival models. If a one-year period was necessary, then perhaps this one year analysis could incorporate all cohorts of patients, and not just

the one or two year cohorts used currently. Another Committee member commented that while this longer period may be useful to the recipient or the public (to better assess a transplant center's performance over time), this longer period may not be useful to the MPSC.

Action

- UNOS Staff will organize meetings of the Heart and Lung Subcommittees to continue discussing variables that either are in or could be in the center-specific reports.

10) Development of a Donor Risk Index for Heart, and a Donor Risk Index for Lung

The SRTR presented their analysis of variables for use in the heart donor risk index and lung donor risk index. Some of the variables they analyzed were cause of death, pre-recovery T4, and age (categorical). The Committee recommended adjusting for OPO when analyzing variables. (This OPO impact will only be used in the developing models, not in the final DRI.) The Committee suggested combining T3/T4 for analysis. The SRTR performed univariate modeling on donor age (categorical). Donors in the higher age groups have a higher hazard. The Committee recommended using the following age groups in future analyses: 18-30, 30-40, 40-50, 50-60, and 60+. The Committee suggested that the SRTR analyze ischemic time, and assess the interactions between ischemic time and recipient age. In an interaction between donor and recipient size (height, weight), body surface area (BSA) was statistically significant (univariate model). This interaction was not significant in the multivariate model. A Committee member requested analysis of cocaine use. The SRTR analyzed cocaine use (drug abuse variable) and it was not statistically significant.

Action

- The SRTR will perform additional donor risk index analyses with the following parameters: narrower donor age groupings (30-40, 40-50, 50-60, and 60+); T3/T4 in one category; OPO; cold ischemia time; and the interaction of ischemia time and age.

11) Dr. Sue McDiarmid's Charge to the Pediatric Committee

Dr. Stuart Sweet, Chair of the Pediatric Committee, presented the Pediatric Committee's proposal for meeting the immediate past-President's charge to eliminate deaths on the pediatric waiting list. The Pediatric Committee proposes changes to the allocation of hearts and lungs from donors 0-11 years of age. (Currently, donor hearts from this age group follow the adult heart allocation sequence (3.7.10).) Dr. Sweet presented the following data to the Committee:

- 28-62% of hearts and of 69-98% of lungs, from pediatric donors 0-11 years of age, were not transplanted.
- More than 50% of the time, the refusal reason given was donor age/quality or donor size/weight.
- Significant numbers of candidates remained on the waitlist when the match-run was not exhausted.
- 38-68% of heart, and up to 67% of lung candidates were removed from the waiting list, because of death/too sick.
- Very few 0-11 year old donor hearts/lungs are transplanted into adults.
- A significant number of 6-11 year old donor hearts/lungs are transplanted into adolescents.

Upon extensive data analysis, the results of which Dr. Sweet presented to the Committee, the Heart/Lung Working Group of the Pediatric Committee recommended the following allocation changes that also incorporate geographic sharing.

Proposed Heart Allocation Sequence for Hearts from Donors 0-10 Years of Age

1. Local Status 1A Pediatric candidates
2. Zone A (including local) Status 1A Pediatric candidates
3. Local Status 1A Adult candidates

4. Local Status 1B Pediatric candidates
5. Zone A (including local) Status 1B Pediatric candidates
6. Local Status 1B Adult candidates
7. Zone A Status 1A Adult candidates
8. Zone A Status 1B Adult candidates

Proposed Lung Allocation Sequence for Lungs from Donors 0-11 Years of Age

1. Local, Zone A and Zone B 0-11 by urgency stratification and ABO
2. Local and Zone A 12-17 by LAS and ABO
3. Local adults by LAS and ABO
4. Zone A 0-11 by waiting time and ABO
5. Zone A 12-17 by LAS and ABO
6. Zone A adults by LAS and ABO
7. Zone B 0-11 by waiting time and ABO
8. Zone B 12-17 by LAS and ABO
9. Zone B adults by LAS and ABO

The Pediatric Committee would like to co-sponsor the above proposals with the Thoracic Committee. These proposals do not appear to impact the allocation to other age groups. The Thoracic Committee supported the Pediatric Committee's proposals and agreed to cosponsor them. The Pediatric Committee will draft the final policy language. A joint Pediatric-Thoracic Subcommittee will review the final draft of the revised policy language.

Action

- UNOS staff will coordinate the development of this joint subcommittee with the liaison of the Pediatric Committee. This meeting will occur sometime before the end of this year.

12) Alternatives to distant organ retrieval

The Lake Michigan tragedy earlier this year underscores the need for alternate organ retrieval methods.

There are collaborations among physicians/surgeons at two separate, distant institutions for the purposes of retrieving hearts and lungs. These collaborations, however, are not nearly widespread enough to reduce the need for travel by local teams to recover organs. The OPO community could provide insight on how to make these collaborations more systemic. One Committee member stated that the Collaborative identifies surrogate recovery as a best practice.

The Committee discussed alternative methods for distant organ retrieval. One option could be to hire foreign-trained physicians/surgeons who are not Board-certified in the US. These physicians/surgeons cannot practice medicine in the US, but are very capable of recovering organs. There is such a practice in the west coast, and it works. Perhaps institutionalizing this practice nationally is an option, especially through grants from HRSA. Dr. Helen Li will relay this request to HRSA.

One Committee member noted that building trust nationally among physicians/surgeons in competitive programs is the key to having alternative distant retrieval methods work.

Another Committee member inquired about objective data that could better assert the need for this collaboration. Data on the economics of organ retrieval (sending local team to the recovery location, organ recovery numbers using the current approach) might sway the community into embracing alternative approaches. One Committee member inquired about the possibility of reducing the number of people who travel for organ recoveries. Several members commented that people who tend to go in these trips are the ones who probably should go. Allowing medical students to go, for example, could help recruit new professionals into the field.

At the last Thoracic Committee meeting, the Committee stated that only trained physicians and surgeons should recover organs. Several Committee members commented that other health care professionals, with proper training, can recover organs and do so using good medical judgment. These members stated that the use of trained non-physicians and surgeons may be another option. Committee members may bring their ideas for distant organ retrieval to the next meeting.

Action

- None.

13) Clarifying the Heart Justification Form

The Committee received a request from a Review Board member to clarify data fields in the following section of the heart justification form. The reason for this request is that in some cases, the hemodynamic data are not as current or complete.

Physiologic

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

Vital Signs Date ^R	<input type="text"/>	Date of Hemodynamics ^R	<input type="text"/>
Resting Heart Rate ^R	<input type="text"/> bpm	Mean Arterial Pressure (MAP) ^R	<input type="text"/> mmHg
Heart Rhythm ^R	<input type="text"/>	Systolic Blood Pressure (SBP) ^R	<input type="text"/> mmHg
Were the hemodynamic values obtained while the patient was on inotropes/vasodilators? ^R	<input type="radio"/> YES <input type="radio"/> NO	Diastolic Blood Pressure (DBP) ^R	<input type="text"/> mmHg
Does the patient have a pulmonary artery catheter? ^R	<input type="radio"/> YES <input type="radio"/> NO		

The location of the "Date of Hemodynamics" field, shown above, may be confusing. Since this date does not have to be current, there have been instances where the Review Board requested this information from the center. Further, the location of this field is above the vital sign data fields. Adding to the confusion is the question shown below that appears in the same column as vital sign data.

Were the hemodynamic values obtained while the patient was on inotropes/vasodilators? YES NO

A Committee member proposed that reorganizing fields in this section would make the data collection requirements clearer and more logical in flow. UNOS staff commented that programming these changes would be simple. The committee agreed that UNOS staff should program these layout changes.

Action

- UNOS staff will make these changes to the form, and communicate the decision to the community member.

14) Suggested addition to Policy 3.7.12.3 (Essential Information for Lung Offers)

The Committee reviewed the suggestions from a community member for updating Policy 3.7.12.3 to include the following standards for chest x-rays as well as measurements that can be made from chest x-rays:

- supine versus upright versus 45 degrees upright versus other
- x-ray taken at full inspiration on standard vent settings (5 peep versus whatever the settings on which the patient is being managed)
- Standardize measurements (What is being measured?)
 - Length: from underside of first rib to top of diaphragm, to mid diaphragm, to base of diaphragm
 - Trans-thoracic measurement (Taken where? At tip, mid, or base of aortic notch, and at widest part of thorax or top, mid, base of diaphragm?)

One Committee member inquired how often x-rays appear in DonorNet[®]. Another Committee member commented that height, age, and gender are more important than the chest x-ray measurements. Chest x-ray measurements are variable and can be difficult to interpret. Several Committee members commented that they do not use these measurements for making decisions. Given that some members in the community do use these data, the information listed above could appear in UNetSM as guidelines for measurement. The Committee decided not to incorporate these measurement suggestions in Policy 3.7.12.3. The current language in Policy 3.7.12.4 (Desirable Information for Lung Offers) is clear and sufficient (see below). Under this policy, the physician/surgeon may request chest x-ray measurement information.

Policy 3.7.12.4.ii: Measurement of chest circumference in inches or centimeters at the level of the nipples and x-ray measurement vertically from the apex of the chest to the apex of the diaphragm and transverse at the level of the diaphragm, if requested.

Actions

- UNOS staff will communicate the Committee's decision to the member.
- UNOS staff will incorporate these guidelines in the help section of UNetSM.
- UNOS staff will research how often x-rays are uploaded to DonorNet[®].

15) Update on the Heart Allocation Sequence

UNOS staff updated the Committee on the effects of the heart allocation sequence implemented in July 12, 2006. There haven't been any major changes in the waiting list regarding the total number of candidates, total number of active candidates, distribution of status, distribution of age group, distribution of region, and center volume. Overall, there has been a decline in the deaths on the waitlist for all age groups (0-17, 0-10, 11-17, and 18+ years). There has been a decrease in waiting list mortality among Status 1A and Status 1B candidates. A Committee member requested analysis of deaths on the waiting list by region.

There appears to have been a slight increase in the total number of status justifications submitted since the implementation of the new heart allocation sequence. The Regional Review Board decisions were similar in the time before and after the implementation. The number of exception cases among adult candidates increased from 157 (7/5/05-7/11/06) to 193 (7/12/06-7/11/07). The number of exception cases among pediatric candidates increased from 22 (7/5/05-7/11/06) to 63 (7/12/06-7/11/07).

There aren't any major changes in organ utilization since the implementation of the new allocation sequence. One Committee member suggested analyzing heart utilization data that excludes DCD and older donors.

The number of transplants since July 12, 2006 is very similar to the numbers in the previous era. There were 2224 transplants before implementation (7/5/05-7/11/06) and 2205 in the era after implementation (7/12/06-7/11/07).

The distribution of candidate status at transplant has changed. There has been an increase in the number of transplants in recipients who were Status 1A or Status 1B, but a decrease in transplants of Status 2 recipients. Status 1A recipients comprise 47.1% of the transplants in the first year after implementation. For all recipient groups, the number of Status 2 recipients transplanted prior to implementation was 555 (25.0%), and the number in the era after implementation was 339 (15.4%).

Although the number of transplants in the two eras is similar, there are major differences among regions. The regional percent change in the number of transplants in the two eras ranges from -22% to +22%. The decrease may reflect the characteristics of candidates on the list, and not necessarily an adverse effect of the new allocation sequence. The Committee requested that the numbers used in calculating percent changes be provided in the regional analysis, in addition to percentage change.

In a vast majority of donation service areas (DSAs), the total number of transplants performed in the two eras is similar. A Committee member questioned this occurrence given the regional variations. UNOS staff replied that a small change in several DSAs within the same region could result in a relatively large change in the results summarized by region

A Committee member inquired about the status of the Heart Sequence Task Force. The Chair commented that the work of the Task Force is also the work of the Committee. Many of the Committee members on the Task Force are members of the Thoracic Committee. The Thoracic Committee will monitor this new heart allocation sequence in the same way it monitors the lung allocation score system. As such, the need for the Task Force may be unnecessary. UNOS staff commented that the OPTN President would need to approve this dissolution of the Task Force. Members of the Task Force who are not members of the Committee may be able to participate in discussions on the impact of the new heart allocation sequence. The Committee member commented that there were outstanding data requests from the last Task Force meeting, and inquired about their status. UNOS staff will prepare these data analyses for presentation at the next committee meeting.

Actions

- UNOS staff will draft a letter to the OPTN President on the Committee's position on the existence of the Task Force.
- UNOS staff will share the outstanding data request of the Task Force with the Committee, and present the analysis at the next Committee meeting.
- UNOS staff will provide another update on the impact of the new heart allocation sequence at the next meeting. This update will include the following: raw numbers for percent changes in the heart transplants performed by region; heart utilization data that does not include DCD donors or older donors; and, deaths per 100 patient-years on the waiting list by region.

16) Joint Allocation of Heart and Lung

A community member had queried the Committee regarding the impact of the new heart allocation sequence on the joint allocation of heart and lung. The practice of joint allocation has been that the lung always follows the heart, but the heart doesn't always follow the lung. One Committee member inquired how thoroughly the heart match-run needed to be exhausted before following the lung allocation sequence.

There were 31 heart/lung transplants performed during 2006. In the first half of 2007, there were 19 heart/lung transplants performed.

The Committee discussed the current language in Policy 3.7.7 (Allocation of Thoracic Organs to Heart-Lung Candidates). A Committee member commented that the policy language is not clear. The language does not provide a clear guidance for allocating heart and lung together. References to Status 1A may need further clarification with respect to geographic allocation.

One Committee member suggested introducing a time factor that would enable upgrades of heart/lung candidates to Status 1A. For example, a heart/lung candidate who isn't a Status 1A could be classified as such after waiting for 1 year. The concern with the heart/lung transplant group is that candidates who are not Status 1A may never qualify to become 1A with the current criteria. Further, when these candidates receive lung offers, they may not have priority for the heart. This member suggested altering policy to improve these candidates' likelihood for receiving transplants.

Another Committee member commented that waiting time for joint heart/lung candidates can be quite long. Status 2 candidates face significant health challenges during their wait. This member commented that the waiting time option may not be the answer, but suggested setting lung allocation score thresholds.

The Committee discussed the following sentence in Policy 3.7.7:

"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."

One Committee member suggested adding the word "local" between "suitable" and "Status" in the sentence above. The Committee discussed whether this addition would resolve the policy confusion. The addition of the word "local" may still not align well with the current heart allocation sequence, and therefore, may not be enough of a clarification.

A Committee member suggested pursuing the addition of "local" in the policy language. This language change would restore practice to the way it was before zonal sharing, and may resolve the ambiguity in the policy created by zonal sharing. The Committee could then pursue a more thorough analysis of the policy for other language changes. Another Committee member suggested modeling this policy with the use of the word "local." This model should incorporate data collected in the past year and assess the impact of the new heart allocation sequence on candidates awaiting joint heart and lung transplants. UNOS staff cautioned that this modeling may not be as easy given the behavior factor inherent in this policy – the OPO has to exhaust one match run before starting another. UNOS staff will check with The SRTR about the feasibility of developing this model.

One Committee member requested data on the deaths on the waiting list, by status, among heart/lung candidates. Another Committee member requested that this analysis include lung allocation scores. A Committee member requested data on the heart/lung transplants by age group. The Committee decided that more discussion of this policy language is necessary, and will include this item as its first on the next meeting agenda.

Actions

- UNOS staff will analyze waiting list mortality for heart-lung candidates.
- UNOS staff will analyze heart medical urgency status and LAS for heart-lung candidates.
- The SRTR will model heart/lung allocation with "local" in the policy language.

17) 2007-2008 Committee Annual Goals

UNOS staff stated that the Board of Directors, at its September, 2007 meeting, approved the annual goals of all committees. These goals are associated with the strategic plan.

Action

- The Thoracic Committee will continue making efforts to accomplish its annual goals.

Thoracic Organ Transplantation Committee	October 2, 2007 Chicago, Illinois	
Name	Position	Attendance
J. David Vega, MD	Chair	X
Maryl R. Johnson, MD	Vice Chair	X
David DeNofrio, MD	Regional Rep. (1)	X
Kenneth R. McCurry, MD	Regional Rep. (2)	X
Cliff H. Van Meter, Jr., MD	Regional Rep. (3)	
David P. Nelson, MD	Regional Rep. (4)	X
Mark L. Barr, MD	Regional Rep. (5)	X
Michael S. Mulligan, MD	Regional Rep. (6)	X
William G. Cotts, MD	Regional Rep. (7)	X
A. Michael Borkon, MD	Regional Rep. (8)	X
Jonathan Chen MD	Regional Rep. (9)	X
Kevin M. Chan, MD	Regional Rep. (10)	X
Isabel P. Neuringer, MD	Regional Rep. (11)	X
Bruce W. Brooks	At Large	X
Gregory S. Couper, MD	At Large	X
R. Duane Davis, MD	At Large	X
Edward Garrity, Jr., MD, MBA	At Large	X
Herbert Heili	At Large	X
Diane Lynn Kasper, RN, CCTC	At Large	By phone
Denise Kinder, RN, CPTC	At Large	X
Jennifer Prinz, RN	At Large	By phone
Keith Stevens, BSN,RN	At Large	X
Stuart Sweet, MD, PhD	At Large	X
Paul Oldam, BSS	BOD - Liaison	X
Amy Shorin-Silverstein, JD	BOD - Liaison	X
Reda Girgis, MD	Guest	By phone
Ken Irvine	Guest	X
Bettina Irvine	Guest	X
James Stocks, MD	Guest	X
Marlon Levy, MD	Guest	By phone
Monica Lin, PhD	Ex Officio – HRSA	By phone
Helen Li, MD, MPH, PhD	Ex Officio - HRSA	X
Brad Dyke, MD	SRTR Liaison	X
Robert M. Merion, M	SRTR Liaison	
Jeff Moore MS	SRTR Liaison	X
Susan Murray, ScD	SRTR Liaison	X
Tiffani Pace	SRTR Liaison	
Katherine Pearson	SRTR Liaison	
Tempie Shearon	SRTR Liaison	
Stacey Burson	Support Staff	X
Leah Edwards PhD	Support Staff	X
Vipra Ghimire, MPH, CHES	Committee Liaison	X
Karl McCleary, MPH, PhD	Support Staff	X
Donna Whelan	Support Staff	X
Aaron McKoy	Support Staff	By phone
Catherine Monstello	Support Staff	By phone
Nell Aronoff	Support Staff	By phone
Shandie Covington	Support Staff	By phone