

OPTN/UNOS Thoracic Organ Transplantation Committee
September 12, 2011
Chicago, Illinois

Mark L. Barr, MD (Chair)
Steven A. Webber, MD (Vice-Chair)

The following is a summary of the Thoracic Organ Transplantation Committee's (Committee) discussion on September 13, 2011.

1. Review of Site Audit Data – Heart and Lung Transplant Programs

The Committee reviewed data, prepared by the Department of Evaluation and Quality (DEQ), on heart and lung site survey patterns and trends. The Committee found the presentation useful and requested that DEQ present such data to the group annually. The Committee would like to comment on policies that are reviewed during site audits. The Committee tasked the Heart and Lung Subcommittees to review the current data elements that the DEQ site audit staff use and make recommendations to the Thoracic Committee. It is possible that some of the recommendations may result in changes to policy language.

2. Proposal to Encourage Organ Procurement Organizations (OPO) to Provide Non-Contrast CT Scan if Requested by transplant Programs, and to Modify Language in 3.7.12.3 (Essential Information for Lung Offers) and 3.7.12.4 (Desirable Information for Lung Offers) for Currency and Readability

The Committee proposes the addition of non-contrast computed tomography (CT) scan of the chest to Policy 3.7.12.4. The proposed policy encourages an OPO to provide the result of a CT scan if it is requested to do so by a transplant program. The proposed policy does not require a transplant program to request a CT scan.

Deceased donor lungs may have contusions or infiltrates or malignant nodules which may not be visible in a chest X-ray (CXR). In instances where significant clinical suspicion for such abnormalities exists, a non-contrast CT scan of the chest can provide additional information.

The Committee distributed this proposed policy for public comment in March 13, 2011. The Committee discussed regional comments about this proposal in September. (The Committee had discussed comments from the public and committees in June, 2011.)

The Committee will monitor the proposal through complaints submitted by transplant programs or OPOs. The Committee will evaluate compliance with this policy through complaints from transplant programs and OPOs. Although the OPTN Contractor cannot monitor this policy, the Committee maintained that the policy promotes the utility of CT scanning when needed. The Committee plans to issue guidance to the OPO and lung transplant communities to avert abuse of CT scan requests or denials. Thus, the Committee voted to present its proposed policy – as is – to the OPTN/UNOS Board of Directors for approval in November, 2011: 28-supported; 0-opposed; and, 0-abstained.

3. Proposal to Require Updates of Certain Clinical Factors Every 14 Days for Lung Transplant Candidates with Lung Allocation Scores (LAS) of at Least 50, and to Modify Policy 3.7.6.3 (Candidate Variables in UNetSM) for Currency and Readability

The Committee proposes requiring transplant programs to update in no more than 14 days, any observed changes in clinical values most important to determining a candidate's Lung Allocation Score for high-LAS candidates. For high-LAS candidates, the proposal would require transplant programs to report in UNet^{SM1} any changes in the assisted ventilation, supplemental oxygen (frequency and amount), or PCO₂ clinical variables.

Policy 3.7.6.3.2 (Updating Candidate Variables) requires a transplant program to update its candidates' clinical values in UNetSM every six months. Candidates with high-LAS are likely receiving therapeutic interventions that may improve their health and thus decrease their scores.

Policy 3.7.6.3.1 (Candidate Variables in UNetSM upon Implementation of Lung Allocation Scores Described in Policy 3.7.6) is no longer current, because it applied only to candidates waiting for lung transplants when the OPTN implemented the LAS system in May, 2005. In addition to this modification, other modifications proposed include general edits for readability.

The Committee distributed this proposed policy for public comment in March 13, 2011. The Committee discussed regional comments about this proposal in September. (The Committee had discussed comments from the public and committees in June, 2011.).

The Committee emphasized that the proposed policy is a requirement but one which will affect a small number of candidates. The proposed policy requires updates to a very few number of variables. The proposed policy does not replace the need for transplant programs to appropriately manage their waiting lists. Rather, the proposal ensures that transplant programs are appropriately managing their list of candidates whose scores are 50 and higher so that patients receive deceased donor lung offers based on their true disease severity. Finally, the proposed data updates are similar to but perhaps not as aggressive as the heart policies.

However, the Committee will monitor the proposed policy and make amendments as needed. The Committee voted to present its proposed policy – as is – to the OPTN/UNOS Board of Directors for approval in November, 2011: 28-supported; 0-opposed; and, 0-abstained.

4. Proposal to Allow Outpatient Adult Heart Transplant Candidates Implanted with Total Artificial Hearts (TAH) Thirty Days of Status 1A Time

On November 9, 2010, the Board of Directors approved an interim policy, concurrent with public comment, for adult heart transplant candidates implanted with a TAH and discharged from the hospital. These candidates may now be listed as Status 1A for 30 days. When this 30-day time period ends, if these candidates are not eligible to be listed as Status 1A by other existing criteria, then they must be downgraded and may be listed as Status 1B. This interim policy is in effect and is comparable to the Status 1A policy for candidates with ventricular assist devices (VAD).

Recent availability of a portable driver has allowed some candidates with TAHs to await heart transplantation as outpatients. Prior to the availability of this portable driver, all candidates with TAHs remained inpatients. Policy allows all inpatient TAH candidates to be classified as Status

¹ UNetSM is a network of five UNOS-developed transplant applications that are interconnected to provide for the candidate waiting list, the organ placement process, data collection, and data security.

1A for 14 day periods; however, policy previously prevented outpatient candidates implanted with TAHs be listed as Status 1A unless they qualified for Status 1A by criterion (b).² There are no data to suggest that the medical urgency of an inpatient candidate with a TAH implant is different from an outpatient candidate with a TAH implant. Therefore, the Committee proposes to temporarily provide this outpatient candidate some time at Status 1A while it gathers evidence for developing a long-term policy on outpatient candidates implanted with TAHs. This interim policy will expire on December 1, 2011.

The Committee distributed this proposed policy for public comment in March 13, 2011. The Committee discussed regional comments about this proposal in September. (The Committee had discussed comments from the public and committees in June, 2011.).

Since receiving the policy's approval-concurrent-with-public-comment in November 10, 2010, the Committee has examined data, the literature, and sought other expert advice on revising the policy for candidates implanted with mechanical circulatory support devices. The policy today does not reflect the disease severity of the heterogeneous candidates implanted with such devices. The Committee acknowledges concerns cited in the comments to the interim policy on outpatient candidates implanted with TAHs, as these were similar to what the Committee discussed in developing the policy. At this time, however, the Committee neither has the quantitative data nor clinical rationale for changing the interim policy. The Committee debated whether the renewal time period should be two years, but decided on the one year, because by November, 2012, it expects to have a revised policy for candidates implanted with mechanical circulatory support devices. If necessary, the Committee could request another renewal in November, 2012. Requesting the Board to revoke its decision of November, 2010, requires more evidence, and so far, there is none to indicate that the interim policy is ineffective.

As it promised to the OPTN/UNOS Board of directors on November 10, 2010, the Committee has been engaged in philosophical and praxis conversations that will result in revisions that the heart transplant community is likely to accept as policy. Thus, at this time, the Committee voted to extend the proposed policy for one year to enable the completion of these complicated conversations and to present a revised Policy 3.7.3 to the Board of Directors: 28-supported; 0-opposed; and, 0-abstained.

5. Revising the Adult Heart Policy

The Committee, primarily through its Heart Subcommittee, has been mired in deliberations to revise the policy for candidates implanted with mechanical circulatory support devices. Although the impetus for the conversation was developing the interim policy for outpatient candidates implanted with total artificial hearts, the goal now is to: a) revise the entire policy that addresses the medical urgency of adult heart candidates (Policy 3.7.3 – Adult Candidate Status); b) address the disease severity of candidates implanted with mechanical circulatory support devices (MCSD); and, c) specify MCSD-related infections or complications that warrant the 1A status.

The Committee has reviewed several proposals to revise the policy in its entirety, and anticipates submitting a policy proposal for public comment in 2012. When the Heart Subcommittee meets next, it will continue to discuss the following concept proposed at the September meeting:

² Status 1A, criterion (b): “Mechanical circulatory support with objective medical evidence of significant device-related complications such as thromboembolism, device infection, mechanical failure and/or life-threatening ventricular arrhythmias [...]”

Status 1A

- a) *Mechanical circulatory support for acute hemodynamic decompensation that includes at least one of the following devices or therapies in place:*
- i. LVAD
(Candidates listed under this criterion may be listed for 30 days at any point after being implanted at Status 1A once the treating physician determines that they are clinically stable. Admittance to the listing transplant center hospital is not required.)
 - ii. *TAH or dischargeable BiVAD*
(Candidates listed under this criterion will remain 1A indefinitely while hospitalized (for any reason) – initial hospitalization, not return -- and may be listed for an additional 30 days after discharge after which their status will revert to 1B – see criteria 1A(b))
 - iii. *iii) IABP; (14 days – renewable)*
 - iv. *iv) ECMO; (14 days – renewable)*
 - v. *v) RVAD; (14 days – renewable)*
 - vi. *vi) LVAD requiring RVAD support (inpatient) or multiple high-dose inotropes at doses currently defined in 1A(d) or with PA catheter (beyond first 7 days) (14 days – renewable)*
- b) *Defined complication*
- i. *VAD with defined complication (will be indefinite so long as complication remains active) (may be audited)*
 - ii. *TAH with defined complication (will be indefinite so long as complication remains active) (may be audited)*
- c) *Continuous mechanical ventilation (14 days – renewable)*
- d) *Inotropes – single, high dose or multiple inotropes at currently identified doses; inpatient (or with PA catheter with or without inotropes) (14 days – renewable)*
- e) *By Exception (14 days – renewable x 1 then RRB conference call)*

All inpatients except as noted. At the completion of each 14 day time period, if the physician does not act to make the candidate a Status 1A, then the candidate's Status becomes 1B. The physician must list the candidate at a status that matches the candidate's clinical condition.

The Committee discussed whether the focus in revising Policy 3.7.3 should be based on treatments candidates receive or based on other characteristics, such as hospitalization or clinical characteristics that make one candidate differ from another. If the Committee were to proceed with the concept outlined above, should another term be used in lieu of “discharge?” Should the 30-days of Status 1A time for VAD patients remain or should the number of days increase? How many VAD patients receive transplants after having received 30 days at Status 1A?

6. Proposal to Mandate the Blood Titer Value to Report in UNetSM for Candidates Who Are Eligible to Receive Hearts from Donors with any Blood Type

Some laboratories perform more than one test on a given blood sample, which may yield differing Anti-A or Anti-B isohemagglutinin titer values for a given blood sample. (These different hemagglutination tests primarily identify IgM or IgG isohemagglutinins, commonly known as room temperature titers and anti-human globulin titers.) Neither Policy 3.7.8 (ABO Typing for Heart Allocation) nor its programming allow for the entry of more than one Anti-A or Anti-B isohemagglutinin titer value. (Policy and its programming do allow for the entry of Anti-A and Anti-B isohemagglutinin titer values.) While many laboratories provide only one type of titer value to a transplant program, those that provide more than one type of Anti-A or Anti-B isohemagglutinin titer value for a given blood sample results in the transplant program having to decide which value to enter in UNetSM. In the latter scenario, the higher Anti-A or Anti-B titer value provided by the laboratory is likely the better predictor of an adverse graft outcome. Policy 3.7.8 supports this decision, because it identifies patients with high titer antibody and precludes their eligibility for an ABO-independent heart transplant. Thus, the Committee, as well as the Pediatric Committee, contends that there would be consensus in the community about the proposed requirement to enter the higher Anti-A or Anti-B titer value when a laboratory provides more than one for a given blood sample, and therefore, view the proposed requirement as a clarification to Policy 3.7.8.

The Committee reviewed a draft of this proposed policy and suggested edits. UNOS staff made these edits and submitted them to the Committee and the Pediatric Committee for a vote in October, 2011.

7. Allocation of Deceased Donor Heart and Lungs, off the Deceased Donor Lung Match Run, to Candidates Who Need Both Thoracic Organs Offers

For several years, the Committee has made efforts to revise Policy 3.7.7 (Allocation of Thoracic Organs to Heart-Lung Candidates). Specifically, the Committee has attempted to develop a mandate on how OPOs must allocate off the lung match run a heart and a lung to a candidate who needs both. This document is in development. The OPTN/UNOS Policy Oversight Committee (POC) is developing principles regarding multi-organ allocation in general, and using the heart-lung allocation as a case study. Once the Committee receives specific recommendations from the POC, it will resume its effort to refine the mandate.

8. Breaking a Tie When Two Heart-Lung Candidates Are Eligible to Receive a Heart-Lung Bloc in the Same Geographic Zone

At a given point in time, there is a possibility that two heart-lung candidates, who are in the same geographic area, could be eligible to receive that same set of organs, through a heart or heart-lung match run and a lung match run. In other words, after the OPO has offered the heart to all isolated Status 1A heart candidates in the geographic area and been refused, it is possible that the highest ranking heart-lung candidate on the heart-lung match and the highest ranking heart-lung candidate on the lung match are different candidates. While this scenario is rare and has likely not occurred, Policy 3.7.7 (Allocation of Thoracic Organs to Heart-Lung Candidates) needs to address this scenario. The Committee decided that in such a scenario, the candidate's Lung Allocation Score (LAS) could be used to break the tie. This project is currently on hold for the same reason as that cited in item 15.

9. Ex Vivo Lung Perfusion (EVLP)

The Committee has recently begun its discussion of EVLP, a new technology that allows lungs that may otherwise be discarded to undergo perfusion for the purposes of transplantation, i.e., improve the clinical quality of the lung. EVLP is in the clinical trial phase, but many Committee members anticipate that the US Food and Drug Administration (FDA) will approve this perfusion technology in early 2012.

Today, only transplant centers that participate in the EVLP clinical trial may accept a lung but they may do so only for “research.” However, On September 13, 2011, the Committee discussed a letter it received from a community member who asked if this organ could then be allocated using a separate match run. The Committee is uncomfortable granting this request, but it recognizes that EVLP may change the volume of deceased donor lungs that may become available for transplantation. The Committee is also aware that once the device that performs EVLP receives approval from the FDA, it is possible that OPOs may purchase this device.

The Committee will continue to discuss this topic.

10. List of list of life-support options in the Tiedi forms: Is the list of options current?

OPTN life support data may be used for program-specific performance analyses and policy development. In reviewing forms that require approval from the federal Office of Management and Budget (OMB), the Transplant Administrators Committee requested that organ-specific committees review life support for completeness and accuracy. On September 13, UNOS staff presented data considered as life support, and sought the following responses from the Committee regarding data collection categorized as life support:

Mechanism	Organ	Age group	Questions
IV inotropes	Heart-lung and lung	Adult	Add back to form?
Pacemaker/defibrillator	All organs	All ages	Add separately? Add combined?
Plasmapheresis/dialysis	All organs	All ages	Don't add? Consider as life support for analysis purposes?
Oxygen	All organs	All ages	Don't add? Consider as life support for analysis purposes?
BiPAP/CPAP	Heart-lung and lung	All ages	Add separately? Add combined?

The Committee also considered if there were other types of life support currently being used but not captured on the form or in the table above. The Committee opined that it would not consider mechanisms such mechanisms as life support, with the exception of ECMO. The Committee tasked the Heart and Lung Subcommittees to assist UNOS staff in identifying data elements that appropriately should be labeled life support.

11. Request to Reinstate Waiting Time Accrued While Waiting for a Previous Heart Transplant

On June 13, the Committee reviewed a case submitted by a transplant program that requested that time a patient accrued while waiting for a previous heart transplant be applied to the patient's current time waiting for another heart transplant. The Committee reviewed another such case in August, 2011.

The Committee reviewed Policies 3.2.1.8 (Waiting Time Modification) and 3.7.14 (Removal of Thoracic Organ Transplant Candidates from Thoracic Organ Waiting Lists When Transplanted or Deceased). Policy 3.7.14 prevents reinstatement of waiting time in such a case but Policy 3.2.1.8 overrides 3.7.14 (see below).

Policy 3.7.14:

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

Policy 3.2.1.8:

[...]All other requests for waiting time reinstatement that are not specified under Policy 3.2.3.2 (Waiting Time Reinstatement for Kidney Recipients), or other policies which describe permissible waiting time adjustments, shall be first approved by unanimous agreement among the hospitals (with transplant programs for the applicable organ) within the local area in which the candidate is listed, and then submitted to the appropriate organ-specific committees and Board of Directors for review with appropriate supporting documentation. Notwithstanding the above, however, upon demonstration to the appropriate organ-specific committee that unanimous agreement among the relevant parties cannot be obtained despite efforts to do so, such a request may be submitted with appropriate supporting documentation, including without limitation, reasons provided by the dissenting party(ies) for any disagreement, for consideration despite the lack of unanimous approval.[...]

The Committee determined that for thoracic candidates, Policy 3.7.14 is applicable and voted to not reinstate a candidate's time spent waiting for a previous thoracic transplant. Later in 2011, the Committee will review a public comment proposal that revises the language in Policy 3.2.1.8, and suggest these modifications.

12. Revising the Lung Allocation Score (LAS) System

In developing and implementing the LAS, the Committee intended – and wrote into policy as such – that the system be dynamic so that it could address the changing candidate and recipient population. Since the LAS' implementation, the Committee added PCO₂ and bilirubin to the LAS. The Committee now submits this proposal to revise the LAS system in its entirety, i.e., update the baseline survival rates, parameter estimates, and modify the variables included in the waiting list and post-transplant survival models.

Recognizing that the implementation of the revised LAS system would require around 6000 person hours to automate, and that the OPTN Contractor has not yet implemented the bilirubin policy for reasons that include person-hours required (over 6000), the Committee considered the following options for making changes to the LAS system:

- Update the LAS system:
 - i) Only change the baseline survival rates and parameter estimates for the existing variables in the LAS
- Revise the LAS system:
 - i) Add new variables to the waiting list and post-transplant models;
 - ii) Change the baseline survival rates; and,
 - iii) Change the parameter estimates for all variables in the waiting list and post-transplant models.

The Committee selected to revise the LAS system to better address the waiting list mortality, and plans to distribute the proposal for public comment in March, 2012.

13. Revising the Pediatric Heart Policy

The Heart Subcommittee, Thoracic Working Group of the Pediatric Committee and representatives from the Pediatric Heart Transplant Study (PHTS) continue to revise the current pediatric heart medical urgency policy (3.7.4 – Pediatric Candidate Status). This working group anticipates distributing these revisions for public comment in March, 2012.

14. Update on the Heart Allocation System

On September 13, 2011, the Committee reviewed OPTN data on the status of the heart allocation system.

Summary of the waiting list outcomes:

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

Summary of the post-transplant outcomes:

- The number of transplants remained essentially flat 3 years and then experienced an increase in the most recent complete year.
- The distribution of status at transplant has changed: increase in Status 1A and decrease in Status 2.
- There was a borderline significant decline in post-transplant survival for adult status 2 recipients (p=0.08).
- There was a borderline significant increase in post-transplant survival for pediatric recipients, all statuses combined (p=0.098).

The Committee will next review these data in September, 2012.

15. Update on the Lung Allocation Systems

On September 13, 2011, the Committee reviewed OPTN data on the status of the heart allocation system.

Summary of the waiting list outcomes:

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

Summary of the post-transplant outcomes:

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

The Committee will next review these data in September, 2012.

Thoracic Organ Transplantation Committee	September 13, 2011 Chicago, Illinois	
Name	Position	Attendance
Mark L. Barr, MD	Chair	X
Steven A. Webber, MD	Vice-Chair	X
Tajinder P. Singh, MD	Region 1 Representative	X
Raymond L. Benza, MD	Region 2 Representative	X
Leonardo Seoane, MD	Region 3 Representative	By phone
Dan M. Meyer, MD	Region 4 Representative	X
Craig H. Selzman, MD	Region 5 Representative	X
Nahush Ashok Mokadam, MD	Region 6 Representative	X
Sangeeta M. Borade, MD	Region 7 Representative	X
Joseph C. Cleveland, Jr., MD	Region 8 Representative	X
Alan L. Gass, MD	Region 9 Representative	X
David Bradley S. Dyke, MD	Region 10 Representative	X
Timothy P. Whelan, MD	Region 11 Representative	X
Luis Angel, MD	At Large Member/Lung Review Board Chair	X
Nancy P. Blumenthal, MSN, CRNP	At Large Member	X
Kevin Chan, MD	At Large Member	X
Ladora Dils, RN, CPTC	At Large Member	X
Kevin M. Dushay, MD	At Large Member	X
Maryl R. Johnson, MD	At Large Member	X
Theodore G. Liou, MD	At Large Member	X
William T. Mahle, MD	At Large Member	X
Brigette J. Marciniak-Bednar, RN, BSN, CCTC	At Large Member	
Kenneth R. McCurry, MD	At Large Member	X
David P. Nelson, MD	At Large Member	X
Damian Neuberger, PhD	At Large Member	X
Joseph G. Rogers, MD	At Large Member	X
Stuart C. Sweet, MD, PhD	At Large Member	X
J. David Vega, MD	At Large Member	X
Mark J. Zucker, MD	At Large Member	X
Ba Lin, MS, MPH	<i>Ex Officio</i> – HRSA	By phone
Monica Lin, PhD	<i>Ex Officio</i> – HRSA	X
Monica M. Colvin-Adams, MD	SRTR Liaison	X
Marshall Hertz, MD	SRTR Liaison	
Bertram Kasiske, MD	SRTR Liaison	
Melissa Skeans, MS	SRTR Liaison	X
Jon Snyder, PhD, MS	SRTR Liaison	
Maryam Valapour, MD	SRTR Liaison	X
Tyrone Brown	UNOS Staff	By phone
Leah Edwards, PhD	UNOS Staff	X
Rich Endert	UNOS Staff	X
Vipra Ghimire, MPH	UNOS Staff	X
Lee Goodman	UNOS Staff	X
Elizabeth Miller	UNOS Staff	By phone
Jory Parker	UNOS Staff	By phone
Amy Putnam	UNOS Staff	By phone
Brian Shepard	UNOS Staff	X
Chad Waller	UNOS Staff	By phone