**OPTN/UNOS Thoracic Organ Transplantation Committee Meeting**

**June 13, 2011**
**Mark L. Barr, MD (Chair)**
**Steven A. Webber, MD (Vice-Chair)**

The following is a summary of the Thoracic Organ Transplantation Committee's (Committee) deliberations that occurred by telephone and Internet on June 13, 2011.

**Discuss comments received on Discuss Comments Received, as of June 10, 2011, on the 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 and 3.7.12.4 for Currency and Readability**

The Committee discussed comments received thus far. The proposal had already addressed some of the comments received. The Committee will review the remaining regional votes and comments by email, because these votes and comments were not available for the meeting. If these latter votes and comments warrant a re-review of the policy, the Committee will convene by phone to do so.

The Committee emphasized that the proposal is making a suggestion to clinicians to use their best judgment in requesting CT scans, and for OPOs to provide CT scans when requested. There is no evidence to support the notion that the discard rate for lungs will increase; rather, it is possible that marginal lungs are more likely to be used.

Regarding comments about organ offer delays, the Committee opined that in practice, it is likely that CT scans are anticipated for marginal lung donors. Thus, the delays may not occur. The proposal attempts to address patient safety through further examination of marginal lungs for emphysema or cancerous legions.

Placement of the proposed language is in the thoracic section of OPTN policy, and the decision to move to another section will occur with the OPTN policy rewrite effort.

Finally, the cost of requesting CT scans will not burden potential recipients, because transplant centers will absorb the fee for the request.

So, contingent upon the nature of the comments that have yet to be submitted, the Committee voted in favor of sending the proposed CT scan policy to the Board in November, 2011: 15-supported; 0-opposed; 0-abstained.

**Discuss Comments Received, as of June 10, 2011, on the 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 for Currency and Readability**

The Committee discussed comments received thus far. The proposal had already addressed some of the comments received, but the Committee requested that the briefing paper include additional data on the reason for selecting 50 as the threshold score 14 as the number of days.

The Committee will review the remaining regional votes and comments by email. If these latter votes and comments warrant a re-review of the policy, the Committee will convene by phone to do.

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.

So, contingent upon the nature of the comments that will be submitted in the near future, the Committee voted in favor of sending the proposed LAS frequency policy to the Board in November, 2011: 15-supported; 0-opposed; and, 0-abstained.

**Discuss Comments Received, as of June 10, 2011, on the Proposal to Allow Outpatient Adult Heart Transplant Candidates Implanted with Total Artificial Hearts (TAH) Thirty Days of Status 1A Time**

The Committee discussed comments received thus far, and commented that the feedback received were similar to the feedback provided by programs while the TAH policy was being discussed.

The Committee will review the remaining regional votes and comments by email. If these latter votes and comments warrant a re-review of the policy, the Committee will convene by phone to do so. However, a change in the Committee's opinion is not likely, because the comments submitted are similar to those it received while developing 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 MCSD policy. 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.

The Committee agreed with comments stating that the interim policy favors outpatient TAH candidates over candidates with ventricular assist devices (VAD). Responding to comments about the need for the clinical trial to be successful, the Committee opined that the interim policy was not developed to support a clinical trial; rather, the interim policy addresses the medical need of a new group of thoracic candidates. Unlike outpatient candidates implanted with TAHs, candidates implanted with experimental VADs continue to receive the same number of days at Status 1A as those implanted with VADs approved by the US Food and Drug Administration. The Committee, therefore, is consistent in developing policies independent of clinical trials. Moreover, the OPTN does not have a responsibility to support a clinical trial.

So, contingent upon the nature of the comments that will be submitted in the near future, the Committee voted in favor of asking the OPTN/UNOS Board of Directors to extend the TAH policy for one more year; and, it will do so in November, 2011: 15-supported; 0-opposed; and, 0-abstained.

In the interim, the Committee, through its Heart Subcommittee, will continue to discuss how best to modify Policy 3.7.3 in its entirety. The Committee anticipates presenting a new MCSD policy to the Board of Directors in November, 2012.

**Policy Proposals that the Thoracic Committee will distribute for public comment in September, 2011**

The Committee voted in favor of distributing the following two proposals for public comment during the September, 2011 cycle: 15-supported; 0-opposed; and, 0-abstained.

1) Revisions to the Lung Allocation Score (LAS) system
2) Modification to Policies 3.7.3 and 3.7.4 (Pediatric Candidate Status)

Regarding the second proposal, the Committee requested that the OPTN/UNOS Organ Procurement Organization (OPO) Committee consider whether policy should address the time difference between a match run and an organ offer. If an OPO performs a heart match run in the morning but offers the heart later in the afternoon, it is possible that potential recipients on that match run are no longer at the status as listed; and, likewise, it is possible that new potential recipients could be eligible to receive the heart offered but do not appear on the match run prepared.

The OPTN/UNOS Policy Oversight Committee will review the proposals, followed by the OPTN/UNOS Executive Committee.

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

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 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.
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> Policy 3.2.1.8:
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> […]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 (provided below) is applicable and voted to not reinstate the candidate's time spent waiting for his previous thoracic transplant: 15-supported; 0-opposed; 0-abstained.

**Alert the Thoracic Community that the Committee is Aware of Inappropriate Applications of Policy 3.7.3 criterion (b)**

Policy 3.7.3 criterion (b) – see below – does not specify what constitutes an infection. Nevertheless, learning through the Heart Subcommittee that there are transplant programs who are not judiciously applying Policy 3.7.3 criterion (b), the Committee charged the Heart Subcommittee to develop a memorandum that advises programs to apply Policy 3.7.3 criterion (b) only for non-superficial infections. The Committee requested that this memorandum be sent to the thoracic transplant community as well as to the OPTN/UNOS Membership and Professional Standards Committee.

Committee members who participated:

Mark Barr
Steve Webber
Brigette Bednar
Sangeeta Bhorade
Nancy Blumenthal
Greg Couper
Kevin Dushay
Alan Gass
Maryl Johnson
Denise Kinder
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