Thoracic Organ Transplantation Committee Meeting
Via Telephone and Internet
October 29, 2010

Mark Barr, MD (Chair) ~ Steven Webber, MD (Vice-Chair)

The following is a summary of the Thoracic Organ Transplantation Committee's (Committee) deliberations that occurred on October 29, 2010.

Review and Vote on the Proposed Interim Policy on Outpatient Candidates with Total Artificial Hearts (TAH)

The Committee reviewed proposed policy language that gives outpatient candidates implanted with TAHs 30 days of Status 1A time, and unlimited time as Status 1B. After much discussion, the Committee voted in favor of the following language, its presentation to the Board of Directors in November, 2010, and its distribution for public comment in March, 2011: 18- supported; 0-opposed; and, 1-abstained.

> Status 1A:
> A candidate with a total artificial heart who has been discharged from the listing hospital may be listed as Status 1A for 30 days at any point in time after the discharge.
>
> Status 1B:
> A candidate with a total artificial heart who has been discharged from the listing hospital may be listed as Status 1B at any point in time after the discharge.

The proposed interim policy – a "band-aid" approach – could disadvantage candidates implanted with VADs, and in particular, candidates implanted with right and left VADs. (The proposed policy could give some candidates implanted with TAHs 30 days at Status 1A, in addition to the unlimited 14-day time periods as Status 1A if they are inpatients.) However, outpatient candidates with TAHs represent a new transplant population, a group whose medical urgency the policy may not address adequately. Concerned by the number of institutions stating that the Committee was interpreting current policy rather than stating the policy, the Committee considered requesting the OPTN President to distribute a communiqué to the thoracic community to further clarify existing policy on candidates with TAHs. But, such memos may not be necessary and could suggest that the Committee is further "interpreting" current policy, a common judgment received since September 3, 2010. If the Board of Directors approves the interim policy proposal in November, 2010, UNOS staff will distribute a policy notice immediately following the meeting and again one month after the meeting.

The Committee considered its three options (listed below), and decided to request the Board of Directors to approve the aforementioned interim policy for a temporary time period (option two).

1. Leave the policy as is, i.e., outpatient candidates continue to be assigned Status 1B upon discharge
2. Develop an interim policy for outpatient candidates with TAHs where these patients receive some time as Status 1A
    a. Interim policy would have an expiration date
3. Reconsider medical urgency classifications for all candidates with TAH and VAD
    a. Evaluate policy on VADs (left VAD, right VAD, or both left and right VADs) and determine whether it should continue to classify the medical urgency status similarly for all candidates with VADs

Option one is not reasonable as it does not address the medical urgency of outpatient candidates implanted with TAHs. Further, as written, one can interpret the policy to mean that outpatient candidates with TAHs are Status 2.

The Committee tasked the Heart Subcommittee to pursue option 3 while the interim policy is in effect. The Committee urged UNOS staff to expedite the implementation of the interim policy, and requested the Heart Subcommittee to review data to inform revisions to the mechanical circulatory support device policy. The Committee requested the following data analysis from UNOS:

- Tabulate the list management practice for candidates who receive a mechanical circulatory support device (MCSD) after listing. For example, was the candidate inactivated prior to implant, moved to Status 2, etc. These results are to be stratified by device type (LVAD, RVAD, BiVAD and TAH) and by intended use type (temporary vs. chronic), where possible.

  This tabulation will be based on all adult heart transplant candidates ever waiting between January 2009 and June 2010 for whom a device was reported to have been implanted during the same time frame. The device type and brand will be based on the combination of the Status 1A justification form (criteria (a) or (b) if VAD infection).

- Tabulate the time to transplant for adult heart candidates with an MCSD, stratified by device type.

  Some candidates may have accrued additional time in Status 1A prior to MCSD implantation. This may affect a candidate's priority on a match run so the additional time may have to be accounted for in the analysis.

  This tabulation will be based on all adult heart candidates added to the waiting list between January 2009 and June 2010. To account for other possible waiting list outcomes, a competing risks extension of the Kaplan-Meier method may be used to produce the time to transplant.

The interim policy expires in November, 2011. The Committee plans to circulate a revised mechanical circulatory support device policy for public comment in September, 2011.

(The Committee discussed the potential number of candidates that may become outpatients due to SynCardia's clinical trial: likely to be 30, but may be up to 60.)

Review of Public Comment Proposal Relevant to the Thoracic Committee

Proposal to Establish Qualifications for a Director of Liver Transplant Anesthesia in the OPTN Bylaws (MPSC)

UNOS staff presented an overview of the proposal, and the Committee considered if such a bylaw is necessary for cardiac anesthesiologists. Surgeons perform cardiac transplants with a team that includes cardiac or thoracic anesthesiologists, not general anesthesiologists. It is possible that general anesthesiologists are involved in liver transplantation; hence, the bylaw proposal.

The Committee voted in favor of the proposal: 19-supported; 0-against; and, 0-abstained.

Proposal to Clarify which Transplant Program has Responsibility for Elements of the Living Donation Process and to Reassign Reporting Responsibility for Living Donation from the Recipient Transplant Program to the Transplant Program Performing the Living Donor Nephrectomy or Hepatectomy (Living Donor)

UNOS staff presented an overview of the proposal. The proposal does not address living donor lungs; however, the proposed policy applies to the procurement of a living donor lung. (The number of living donor lung transplants performed in the United States is small.)

One member sought clarification about the living donor organ procurement process and the transport of a living donor organ from one region of United States to another. Policy requires procurement of living donor organs at OPTN member centers and permits the transport of organs, such as for kidney-paired exchange.

Placing responsibility of the living donation process on the recovery center is logical. Thus, the Committee voted in favor of the proposal: 19-supported; 0-against; and, 0-abstained.

Meeting Participants

Mark Barr, MD (Chair)
Steven Webber, MD (Vice-Chair)
Kevin Dushay, MD (Region 1 Representative)
Raymond Benza, MD (Region 2 Representative – by phone)
Dan Meyer, MD (Region 4 Representative)
Nahush Ashok Mokadam, MD (Region 6 Representative)
Ramsey Hachem, MD (Region 8 Representative)
Alan Gass, MD (Region 9 Representative)
Nancy Blumenthal, MSN, CRNP (At Large Member)
Gregory Couper, MD (At Large Member)
Denise Kinder, RN, CPTC (At Large Member)
Maryl Johnson, MD (Ex Officio)
Theodore Liou, MD (At Large Member)
David Nelson, MD (At Large Member)
Isabel Neuringer, MD (At Large Member)
Linda Ohler, MSN, RN, CCTC, FAAN (At Large Member)
Joe Rogers, MD (At Large Member)
Stuart Sweet, MD (At Large Member – Lung Subcommittee Chair)
J. David Vega, MD (At Large Member)
Mark Zucker, MD, JD (At Large Member – Heart Subcommittee Chair)
Ba Lin, MA (Ex Officio – HRSA)
D. Bradley Dyke, MD (Arbor Research)
Susan Murray, ScD (Arbor Research)
Ying Qian, MS (Arbor Research)
Monica Colvin-Adams, MD (SRTR)
Marshall Hertz, MD (SRTR)
Melissa Skeans, PhD (SRTR)
Cynthia Coleman, JD (UNOS)
Leah Edwards, PhD (UNOS)
Vipra Ghimire, MPH, CHES (UNOS)
Lori Gore (UNOS)
Aaron McKoy (UNOS)
Jory Parker (UNOS)
Brian Shepard (UNOS)