

Thoracic Organ Transplantation Committee Meeting
June 7, 2010
Teleconference and Live Meeting
Maryl Johnson, MD (Chair) ~ Mark Barr, MD (Vice-Chair)

Review of Proposals Distributed for Public Comment on March 19, 2010

The Thoracic Committee discussed the following proposals, which were presented by the liaisons of the sponsoring committees:

1. Ad Hoc Disease Transmission Advisory Committee (DTAC) - Proposal to Modify OPO and Transplant Center Requirements for Screening, Communicating and Reporting All Potential or Confirmed Donor-Related Disease and Malignancy Transmission Events
2. Proposal to Update HLA Equivalences Tables Affected/Proposed Policy (Histocompatibility Committee)
3. Proposal to Require that Deceased Donor HLA Typing be Performed by DNA Methods and Identify Additional Antigens for Kidney, Kidney-pancreas, Pancreas, and Pancreas Islet Offers (Histocompatibility Committee)
4. Proposal to Require a Use of a Standardized, Internal Label that is Distributed by the OPTN and that Transplant Centers Notify the Recovering OPO when they Repackage an Organ (Organ Procurement Organization (OPO) Committee)

The Committee's deliberations on the aforementioned proposals follow.

Proposal to Modify OPO and Transplant Center Requirements for Screening, Communicating and Reporting All Potential or Confirmed Donor-Related Disease and Malignancy Transmission Events (Ad Hoc Disease Transmission Advisory Committee)

The Thoracic Committee discussed the proposal on June 7, 2010, and voted in its favor: 16-Supported; 0-Opposed; and, 0-Abstained.

Proposal to Update HLA Equivalences Tables Affected/Proposed Policy (Histocompatibility Committee)

The Thoracic Committee discussed the proposal on June 7, 2010, and voted in its favor: 16-Supported; 0-Opposed; and, 0-Abstained.

Proposal to Require that Deceased Donor HLA Typing be Performed by DNA Methods and Identify Additional Antigens for Kidney, Kidney-pancreas, Pancreas, and Pancreas Islet Offers (Histocompatibility Committee)

The Thoracic Committee discussed the proposal on June 7, 2010, and voted in its favor: 18-Supported; 0-Opposed; and, 0-Abstained. The Committee also opined the following:

- HLA typing should be performed on donors, regardless of the organs offered; and,
- The HLA typing proposed for collection will be part of the Thoracic Committee's proposal to require HLA type information on all donor hearts and lungs.

The Thoracic Committee leadership had been interested in including thoracic organs in this proposal; however, since provision of HLA type is not required currently for thoracic donors, this proposal does not address thoracic organs. The Committee queried whether laboratories that

don't currently perform DNA testing for HLA type would be given a grace period in which to become compliant with the policy if the Board of Directors approve it.

Proposal to Require a Use of a Standardized, Internal Label that is Distributed by the OPTN and that Transplant Centers Notify the Recovering OPO when they Repackage an Organ (Organ Procurement Organization (OPO) Committee)

The Thoracic Committee discussed this proposal on July 7, 2010, and voted in its favor: 18-Supported; 0-Opposed; and, 0-Abstained.

The Thoracic Committee queried how the new labeling system would improve accuracy of collecting the appropriate information on the labels. The Committee recognized that the intent of the proposal was to generate consistency in the labels used during organ procurement. The Committee commented that the proposal did not appear to make clear the relationship between the development of new labels and the underlying problem: transcription errors that occur during organ procurement.

The Committee queried whether the use of barcodes had been considered as the barcodes could prevent errors in documentation of donor IDs, etc. The Committee learned that the use of barcodes had been investigated but was not pursued due to the large resources required.

The Committee requested that the OPO Committee discuss how to prevent transcription errors, i.e., improve the organ container labeling process. For the purposes improving patient safety, perhaps the OPO Committee could re-assess the potential for barcodes or printing of relevant identification numbers.

Total Artificial Heart

The Thoracic Committee discussed the current adult heart medical urgency policy on total artificial hearts in light of the recent discharge of a heart transplant patient with a total artificial heart. This patient left to await a heart transplant at home due to the recent development of a portable home driver by the SynCardia Systems Inc. The Committee discussed how the current policy addresses such a candidate's waiting list urgency, and what the future policy should be for such candidates.

The Committee opined that historically, candidates with total artificial hearts did not fare as well as candidates with ventricular assist devices (VAD). However, candidates with total artificial hearts are faring better in the current time period and perhaps arguably more so than candidates with left and right VADS. The Committee commented that no data exist to continue to support the policy that allows candidates with total artificial hearts to be classified at Status 1A for more than one 14-day periods. (The candidate discharged with the portable home driver had been in the hospital for about a period of two years, and during that entire time, per policy, the candidate was classified as Status 1A.)

The Committee reviewed the following table to determine what interim guidance to provide to the thoracic community on classifying the medical urgency status of candidates with total artificial hearts who are discharged from the hospital.

Policy for an Adult Heart Candidate with a Total Artificial Heart (TAH)

Possible Clinical Scenarios	Current Eligible Status	Number of Days Candidate Can Remain at Status	Comments
Candidate has a TAH and is hospitalized	Status 1A	14 days, but can be extended indefinitely	
Candidate has a TAH with complications (may or may not be in the hospital)	Status 1A	14 days, but can be extended indefinitely	
Candidate has a TAH and is at home with a portable home driver	Center would need to apply for a Status 1B exception	No time limit for Status 1B	
Other scenarios?			

Policy for an Adult Heart Candidate with a Left Ventricular Assist Device (LVAD), Right Ventricular Assist Device (RVAD), or Both (BiVAD)

Possible Clinical Scenarios	Eligible Status	Number of Days Candidate Can Remain at Status	Comments
Candidate has LVAD, RVAD, or BiVAD (may or may not be in the hospital)	Status 1A	30 days (no extension)	
	or Status 1B	or No time limit	
Candidate has LVAD, RVAD, or BiVAD; and, has complications (may or may not be in the hospital)	Status 1A	14 days, but can be extended indefinitely	

As shown in the table above, UNOS staff advised that current interpretation of policy would suggest that transplant programs need to apply for a Status 1B-exception for candidates with total artificial hearts and discharged home (to await a transplant) on a portable driver.

The Committee commented that the future policy on total artificial hearts should classify candidates with this device as candidates with VADs, i.e., receipt of one-time 30-day Status 1A status. Currently, candidates with VADs – experimental or non-experimental – qualify for this 30-day time at Status 1A. These candidates may be at Status 1A if they experience device complications. Otherwise, these candidates are classified as Status 1B. The Committee opined that the development of experimental VADs has not lead to changes in policy. Similarly, the Committee does not wish to treat differently this experimental portable driver for total artificial hearts. So, the future policy should mimic the current VAD policy.

The Committee also commented that the policy on total artificial hearts was written at a time when these patients could not be discharged from the hospital.

The Committee discussed the potential role of the heart regional review boards (RRB). Could the RRB be requested currently to evaluate requests for one 30-day period of Status 1A time for candidates with total artificial hearts and discharged on portable home drivers? While the RRB could be asked to evaluate such requests, but, were the RRB to grant such a request, the transplant center would not be able to complete the heart Status 1A-exception form in UNetSM. Per current policy implementation, this form is programmed in UNetSM to not allow for submission of Status 1A-exception forms for candidates who are not inpatients. So, the RRB granting the 30-day Status 1A time to a candidate with a total artificial heart and on a portable driver would in essence be suggesting that the transplant program answer “yes” to hospitalization when in fact the candidate would have been an outpatient. The Committee considered this interim policy implementation method to be unsatisfactory.

The Committee advised UNOS staff to develop a letter that guides the thoracic community on how the current policy guides the classification of the medical urgency of candidates with total artificial hearts and discharged with portable home drivers. The Committee requested that UNOS staff begin developing the public comment proposal to modify the total artificial heart policy as described above.

The Committee expressed concern about the marketing of the portable home driver in relation to the heart policy. The marketing suggests that even candidates discharged with portable home drivers can receive unlimited time at Status 1A.

The Committee opined that this policy change is urgent. Would it be possible for the Executive Committee to approve the policy change concurrent with public comment? UNOS staff will explore this path. If this path is not satisfactory, UNOS staff will prepare the public comment proposal for the Committee’s review.

Update on the Activities of the Heart and Lung Subcommittee Meeting

Due to the lack of meeting time, the Thoracic Committee did not discuss activities of the Heart and Lung Subcommittee.

General Comments

The Thoracic Committee learned that the Chrysalis project will begin in earnest in early 2011. With the start of Chrysalis, all programming projects that impact the WaitListSM pages will be halted for 18 months. However, the Thoracic Committee commented that it does not wish to stop working on policy

improvements and propose projects for the Board of Directors' approval. The Thoracic Committee will yield to the Board of Directors regarding the prioritization of programming projects.

Thoracic Committee Members Who Participated in the June 7, 2010 Meeting

1. Maryl R. Johnson, MD (Chair)
2. Mark L. Barr, MD (Vice-Chair)
3. Kevin Dushay, MD (Region 1 Representative)
4. Raymond Benza, MD (Region 2 Representative)
5. Mark Rolfe, MD, FCCP (Region 3 Representative)
6. Luis Angel, MD (Region 4 Representative)
7. John Chin, MD (Region 5 Representative)
8. Ramsey Hachem, MD (Region 7 Representative)
9. Sean Pinney, MD (Region 9 Representative)
10. Isabel Neuringer, MD (Region 11 Representative)
11. R. Duane Davis, MD (At Large Member)
12. William P. Fiser, MD (At Large Member)
13. Dan Meyer, MD (At Large Member)
14. Linda Ohler, MSN, RN, CCTC, FAAN (At Large Member)
15. Stuart Sweet, MD, PhD (At Large Member)
16. J. David Vega, MD (At Large Member)
17. Steven Webber, MD (At Large Member)
18. Mark J. Zucker, MD (At Large Member)
19. Bernard Kozlovsky, MD (HRSA Representative – Ex Officio)
20. Monica Lin, PhD (HRSA Representative – Ex Officio)
21. Ba Lin (HRSA Representative – Ex Officio)

SRTR Staff Participating

1. Kate Meyer, MS
2. Susan Murray, ScD
3. Ying Qian, MS

UNOS Staff Participating

1. Shandie Covington
2. Franki Chabalewski
3. Leah Edwards
4. Vipra Ghimire
5. Lori Gore
6. Aaron McKoy