

**OPTN/UNOS Thoracic Organ Transplantation Committee Meeting
December 6, 2011
Teleconference and Internet**

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

What follows is a summary of the Thoracic Organ Transplantation Committee's (Committee) discussions that occurred on December 6, 2011.

1. Proposal to Eliminate the Use of an "Alternate" Label when Transporting Organs on Mechanical Preservation Machines and to Require the OPTN Distributed Standardized Label [Sponsored by the Organ Procurement Organization (OPO) Committee]

The Organ Procurement Committee's Vice-Chairman presented the proposed policy concepts. The Committee did not voice concerns or questions about the proposed policy, and voted in favor of it: 15-supported; 0-opposed; and, 0-abstained.

2. Proposal to Change the Term "Consent" to "Authorization" Throughout Policy When Used in Reference to Organ Donation [Sponsored by the Organ Procurement Organization Committee]

The Organ Procurement Committee's Vice-Chairman presented the proposed policy concepts. A summary of the proposed policy change follows.

The proposed modification will change the term "consent" to "authorization" throughout policy when used in reference to deceased organ donation. Currently, OPTN policy uses the term "consent" to describe the act of making an anatomical gift. However, the public associates "consent" with the medico-legal concept of "informed consent" through which physicians must give patients all the information they need to understand the risks, benefits, and costs of a particular medical treatment.

In the context of organ/tissue/eye donation after death, this blending of terms leads to misunderstandings about the act of donation that could hinder our national goal of increasing organ/tissue/eye donation and transplantation. The OPO community has responded to this circumstance by changing the donation terminology from "consent" to "authorization." This change focuses attention on the altruistic act of donation and reinforces the fact that donation after death does not involve medical treatment.

One member queried how the proposed policy change affects donation after cardiac death. The proposed change in terminology only applies to all deceased donation. Thus, a patient consenting to donate his or her organs, prior to death, is participating in an informed consent process. Currently, the term "consent" is used in living and deceased donation. Informed consent can only be given by a living individual. In deceased donation, the donor's family member authorizes (where appropriate and according to the wishes of the decedent) the donation of the decedent's organs. Given this explanation, the Committee voted in favor of the proposed policy change: 17-supported; 0-opposed; and, 0-abstained. (The difference in this voting tally reflects the participation of additional voting members by phone.)

3. Proposal to Modify the Imminent and Eligible (I & E) Neurological Death Data Reporting Definitions [Sponsored by the Organ Procurement Organization Committee]

The Organ Procurement Committee's Vice-Chairman presented the proposed policy concepts. Through clarified definitions, the proposed changes attempt to improve reporting of imminent and eligible deaths. The proposed changes neither not change the deceased donor organ offer process nor transplant program behavior. The Committee voted in favor of the proposed changes: 15-supported; 0-opposed; and, 0-abstained.

4. Proposal to Clarify Requirements for Waiting Time Modification Requests [Sponsored by the Kidney Organ Transplantation Committee]

A summary of the proposed policy change is below:

Current OPTN/UNOS policies for submitting waiting time modification requests are not clear, leading to wasted time for the transplant centers that submit requests, for OPTN Contractor staff who process requests, and for the Committees that review requests. Required documentation is often missing and results in delays for transplant candidates to receive the waiting time that they may be entitled to receive under OPTN policy. With these proposed clarifications, the Committee expects to see fewer submissions of incomplete requests and faster time to implementation of approved requests.

Thoracic transplant programs should not request reinstatement of waiting time accrued for previous thoracic transplants (for their thoracic candidates). The Committee determined that for thoracic candidates, Policy 3.7.13 (see below) applies.

Policy 3.7.13 (Removal of Thoracic Organ Transplant Candidates from Thoracic Organ Waiting Lists When Transplanted or Deceased)

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.

The Committee accepted the other modifications proposed, and voted in favor of a revised policy that references Policy 3.7.13 for thoracic candidates: 17-supported; 0-opposed; and, 0-abstained.

5. Proposal to Clarify and Improve Variance Policies [Sponsored by the Policy Oversight Committee]

The proposed revisions do not change the intent of the variance policies or the existing variances. The Committee did not voice concerns or questions about the proposed variance policy changes and voted in favor of it: 16-supported; 0-opposed; and, 0-abstained.

6. Proposed Revisions to and Reorganization of Policy 6.0 (Transplantation of Non-Resident Aliens), Which Include Changes to the Non-Resident Alien Transplant Audit Trigger Policy and Related Definitions [Sponsored by the Ethics Committee and the Ad Hoc International Relations Committee (AHIRC)]

The Committee members discussed the proposal and expressed diverging thoughts on the proposed review policy. The Chair of the Committee emphasized that the review section of the proposal to

obtain information that will help the AHIRC to better understand the activity of transplant programs using the definitions itemized in the policy and to try to better clarify what is the actual extent of transplant tourism in the US.

The proposed review policy reads:

6.3 Audit and Reporting of Non-US Citizens/Non-US Residents. As a condition of membership, all member transplant centers agree to allow the Ad Hoc International Relations Committee to review and, at its discretion, audit all member transplant center activities pertaining to transplantation of non-US residents/non-US citizens. At member transplant centers where non-US residents/non-US citizens are listed for transplant, the Ad Hoc International Relations Committee shall review the circumstance and justification for listing any non-US resident/non-US citizen traveling to the United States for transplant.

The PowerPoint slide presentation describing this review policy states that the AHIRC's review does not entail an automatic referral to the OPTN/UNOS Membership and Professional Standards Committee (MPSC). This statement, which was intended to alleviate anxiety about the review process during its discussion, created confusion as some members of the Committee considered this statement to be part of the proposed review policy language. The language about MPSC referral is not in the proposed review policy, but the MPSC reviews all policy violations. However, as written, a transplant program cannot violate the proposed review policy by transplanting non-US residents/non-US citizens. The OPTN does not have a policy that forbids medical tourism.

Several members commented favorably about the AHIRC's and Ethics Committee's effort to promote transparency in transplantation, which is a goal of the proposed revisions to Policy 6, but expressed the following comments and questions about the review policy:

- 1) What constitutes the review process? What will be the impact of the proposed review on programs? When would a transplant in a non-US residents/non-US citizen be justified? The proposed review policy should state clearly what constitutes an acceptable an unacceptable transplant among non-US residents/non-US citizens. Some members of the Committee expressed concern about approving the proposed review policy without knowing details about the process and its effect.

The AHIRC's and the OPTN Contractor's process for conducting, managing, and reporting data due to the review of transplants among non-US residents/non-US citizens has not been developed. The AHIRC and the Ethics Committee have begun this discussion, but the plan is not final. (The current audit trigger policy evaluates transplant programs; the proposed review policy evaluates the transplantation of individual patients who are non-US residents/non-US citizens.)

- 2) How will the AHIRC treat the data gathered through the review of deceased donor transplants among non-US residents/non-US citizens?
- 3) Is transplant tourism necessarily unethical? One member commented that it is, but a few other members commented that the proposed review policy may place physicians in an uncomfortable place of having to turn patients away, which might be contrary to the Hippocratic Oath. Patients who seek transplantation in the US do so for various reasons, but most fundamentally because they have end-stage organ failure and need transplants.

However, it was pointed out by one member that other countries specifically point to the OPTN's greater-than-5%-audit trigger in the US as justification for the practice of transplant tourism in their respective countries.

- 4) Shouldn't the rate of deceased donation by undocumented residents be considered when reviewing transplants among non-US residents/non-US citizens? What details can be provided about non-residents who are deceased donors?
 - a. One member expressed concern that the proposed review policy may create a perception of hypocrisy: the US is willing to transplant organs from undocumented deceased donors in US residents, but the US is not willing to transplant non-US residents/non-US citizens who seek this service in the US.
- 5) Why eliminate the current audit trigger when it has served as a useful policy in restricting the number of foreign nationals who receive transplants? One member commented that the current policy has facilitated in restricting foreign organizations, such as embassies, that send many patients to a select hospital for transplant services.
- 6) Pediatric lung transplants performed in foreign nationals are done so, because these patients may not be able to find this same service in their home countries. If accepting such children for transplant is transplant tourism, then how would the proposed review policy affect this reality?

The members supported quantifying accurately the type of foreign patient that receives a transplant in the US due to deceased donation. These data will help in understanding transplant program behavior with respect to the transplantation of non-US residents/non-US citizens. Not all members, however, were supportive of the proposed review, especially without details about the application of the review. These members were concerned that the policy revisions were not strictly about data collection.

The Committee also discussed the proposed definitions of residency and non-residency.

6.1.1 Non-US Citizen/US Resident – A person who is not a citizen of the United States, who is present in the United States, and for whom the United States is the primary place of residence.

6.1.2 Non-US Citizen/Non-US Resident – A person who is not a citizen of the United States and for whom the United States is not the primary place of residence.

Who decides whether the US is a primary place of residence for the candidate? If it continues to be self-reported, then this self-declaration of residency could be exploited by some candidates. The AHIRC and the Ethics Committee did not want to delve into immigration.

A few members commented on what they had heard at their regional discussions:

- 1) Suggestion to eliminate the term “justification” and “audit.”
- 2) Leave the current audit trigger policy alone.

The Committee did not vote on the policy, but some of the members expressed interest in discussing the proposal further at its face-to-face meeting in March, 2012. One member, however, opposed the review policy changes as written. The Committee requested UNOS staff to inquire if the public comment deadline could be extended.

Thoracic Organ Transplantation Committee	December 6, 2011 Meeting Via Teleconference and Internet	
Name	Position	Attendance
Mark L. Barr, MD	Chair	By phone
Steven A. Webber, MD	Vice-Chair	By phone
Tajinder P. Singh, MD	Region 1 Representative	By phone
Raymond L. Benza, MD	Region 2 Representative	By phone
Leonardo Seoane, MD	Region 3 Representative	By phone
Dan M. Meyer, MD	Region 4 Representative	By phone
Craig H. Selzman, MD	Region 5 Representative	
Nahush Ashok Mokadam, MD	Region 6 Representative	
Sangeeta M. Borade, MD	Region 7 Representative	By phone
Joseph C. Cleveland, Jr., MD	Region 8 Representative	By phone ³
Alan L. Gass, MD	Region 9 Representative	By phone
David Bradley S. Dyke, MD	Region 10 Representative	
Timothy P. Whelan, MD	Region 11 Representative	
Luis Angel, MD	At Large Member/Lung Review Board Chair	
Nancy P. Blumenthal, MSN, CRNP	At Large Member	By phone
Kevin Chan, MD	At Large Member	By phone
Ladora Dils, RN, CPTC	At Large Member	
Kevin M. Dushay, MD	At Large Member	By phone
Maryl R. Johnson, MD	At Large Member	
Theodore G. Liou, MD	At Large Member	By phone
William T. Mahle, MD	At Large Member	
Brigette J. Marciniak-Bednar, RN, BSN, CCTC	At Large Member	
Kenneth R. McCurry, MD	At Large Member	
David P. Nelson, MD	At Large Member	
Damian Neuberger, PhD	At Large Member	By phone
Joseph G. Rogers, MD	At Large Member	By phone
Stuart C. Sweet, MD, PhD	At Large Member	By phone
J. David Vega, MD	At Large Member	By phone
Mark J. Zucker, MD	At Large Member	By phone
Ba Lin, MS, MPH	<i>Ex Officio</i> – HRSA	By phone
Monica Lin, PhD	<i>Ex Officio</i> – HRSA	By phone
Richard E. Pietroski, MS, CPTC	Guest (Vice-Chair of the OPO Committee)	By phone
Monica M. Colvin-Adams, MD	SRTR Liaison	By phone
Marshall Hertz, MD	SRTR Liaison	By phone
Brooke Heubner, MD	SRTR Liaison	By phone
Melissa Skeans, MS	SRTR Liaison	By phone
Maryam Valapour, MD	SRTR Liaison	By phone
Leah Edwards, PhD	UNOS Staff	By phone
Robert Hunter	UNOS Staff	By phone
Vipra Ghimire	UNOS Staff	By phone
Elizabeth Miller	UNOS Staff	By phone
Pamela Saunders-Moore	UNOS Staff	By phone
Jory Parker	UNOS Staff	By phone
Ciara Samana	UNOS Staff	By phone