

**OPTN/UNOS Ad Hoc International Relations  
Committee Meeting**

**January 8, 2008  
Teleconference and Live Meeting**

***INTERIM REPORT***

**Andreas Tzakis, MD – Chair  
Gloria Bohrer – Vice Chair**

The OPTN/UNOS Ad Hoc International Relations Committee met on January 8, 2008. The following is a summary of the Committee's discussions.

**1. Clarification to Policy 6.2.5 (Community Participation)**

The Ad Hoc International Relations Committee continued its discussion about modifying Policy 6.2.5 to better clarify the intent of this policy. UNOS staff presented to the Committee a first draft of the revised policy language (shown below). These revisions accommodated the information discussed about the policy on August/September, 2008.

**6.2.5 Community Participation.** Each member center that lists non-resident aliens on its Waiting List should establish and implement a protocol for having dialogues about its candidate acceptance criteria with its community. The purpose of this dialogue is two-fold: 1) to make transparent to the local community the center's criteria for accepting candidates who are non-resident aliens, and to provide information about the OPTN organ allocation policies; and 2) to enable community review of the center's candidate acceptance criteria. This dialogue should, in part, convey that there isn't a separate set of policies for allocating organs to non-resident aliens, i.e., the current organ allocation policies apply equally to all persons, regardless of their US citizenship status (see Policy 6.2.1). The center should also have a plan for responding to community feedback on its candidate acceptance criteria. A center may relay to the OPTN contractor any community feedback on the national organ allocation policies. The center may choose the frequency of and medium for the community dialogue, as well as the logistics for implementing this dialogue. [Need to add a minimum frequency for conveying this information.]

UNOS staff recommended the use of the word "protocol" over "mechanism," partly for clarity and partly to maintain consistency in the terminology used to describe this type of information. UNOS staff suggested retaining the term "should," and encouraged language that would allow the Ad Hoc International Relations Committee to evaluate transplant centers' adherence to the policy. The Committee expressed concern about its role in evaluating the policy. One Committee member suggested that perhaps the Board of the center's organ procurement organization could be the body that evaluates the protocol. Another Committee member countered that this approach wouldn't enable UNOS to understand how the community interprets this policy. If transplant centers submitted their protocols to the Committee, the opportunity would then exist for developing a best practice guideline. The HRSA representative commented that terminologies such as "resource documents" and "guidelines" have various meanings in the transplant community and could be seen as prescriptive (i.e., potentially unfavorable).

The Committee suggested including examples in policy on how a transplant center could implement these dialogues with its community. One Committee member suggested that transplant centers could partner with organ procurement organizations (OPO) to implement this communication effort. UNOS staff suggested that this and other such examples would be useful to the community, but that these examples can rest in the evaluation plan that accompanies each policy. These evaluation plans are

available to the public, and provide guidance to the transplant community on how UNOS evaluates adherence to its policies.

UNOS staff commented that it would revise the draft policy language above to be less restrictive about the type of feedback that the center could submit to UNOS. The Committee suggested that UNOS staff develop one or two alternatives of the above draft language, and in particular, provide more than one approach for evaluating this policy. The Committee will discuss this policy again at its next meeting.

*Action*

- UNOS staff will edit the draft revisions to Policy 6.2.5 based on the discussion above.

**2. Streamline the Importation of an Organ From Another Country Through Focused Activity on the Following Issues: Legitimacy of the Foreign Organization Offering the Organ; Testing/Safety of the Foreign Organ Being Offered; Rules of Distribution of Organs Between Countries; and, Consider Developing an Exception to Policy 6.3**

The Ad Hoc International Relations Committee continued its review of organ import policies to strengthen language on ensuring organ safety, and ensuring the legitimacy of foreign organizations making organ offers.

The Committee queried about measures used internationally to recognize organ procurement organizations. If there is such an international registry of organ procurement organizations, then a foreign OPO registered with this body would gain legitimacy in the US for the purposes of importing organs. The Committee discussed that the World Health Organization may be a source for understanding the legitimacy of these foreign laboratories or OPOs.

One Committee member commented that there are international standards for laboratories. If a foreign laboratory is in compliance with these international standards, then UNOS could assume that organs tested at this laboratory are safe. As a precaution, the US OPO importing the organ could perform additional lab tests, related to organ safety, using its own laboratories.

UNOS staff stated that Policies 6.4.2 and 6.4.2.1 could incorporate the information discussed above as well as ways to prevent donor-related disease transmission. UNOS staff also commented that the body of policies categorized under 6.0 could improve in readability through reorganization of information.

The Committee discussed that the “rules of distribution” are well-defined in Policy 6.4.2.1.

The Committee emphasized the need to strengthen these policies, and that strengthening these policies will vastly improve the organ exchange process. The Committee Chair stated that in his conversations with Dr. Frank Delmonico, Dr. Delmonico supported the Committee’s efforts to strengthen these policies. The Committee encouraged UNOS staff to revise language in the policies under 6.0 to meet the Committee’s goals: ensure organ safety, and ensure legitimacy of the foreign organization offering the organ. The Committee also encouraged revisions that would improve the readability of these policies. The Committee intends to submit these policy revisions for public comment in the June, 2008 feedback cycle.

*Actions*

- UNOS staff will revise select language in the organ exchange policies to better meet the goals of the Committee, and circulate it to members for feedback.
- UNOS staff will research if there is an international organization that recognizes all OPOs.

**3. Policy 6.3 and the MPSC**

UNOS staff updated the Committee that the Membership and Professional Standards Committee (MPSC) is not requesting the Ad Hoc International Relations Committee to share the transplant center data outlined in Policy 6.3. Reviewing these data remains the responsibility of the Ad Hoc International Relations Committee, and not the MPSC. The Committee acknowledged this request, and did not discuss the topic further.

**4. Tracking Americans Going Overseas for Transplant**

UNOS staff stated that the OPTN President, Dr. Tim Pruett, recommends that the Committee continue to discuss approaches for tracking Americans who travel overseas for transplants. UNOS staff suggested adding a removal code such as “transplantation in another country” to Waitlist. One Committee member also suggested developing a follow-up form to collect information about patients who return to the US after receiving a transplant overseas, and who receive follow-up medical care at OPTN member centers. UNOS staff commented that the OPTN currently tracks candidates transplanted in the US, not overseas. Therefore, developing this form would mean tracking patients transplanted overseas. The HRSA representative advised that this form would not capture those recipients who receive transplants overseas and visit medical professionals who are not in the OPTN system (i.e., private nephrologists, etc.).

The Committee discussed the removal code addition at the August/September meeting, but had not voted to advance this project. The Committee supported the development of this data field during this call (3-Yes, 0-No, 0-Abstentions). At its next meeting, the Committee will discuss the follow-up form for capturing information about candidates transplanted overseas, and medically followed by OPTN member centers.

*Actions*

- UNOS staff will develop a proposal for adding a removal code regarding overseas transplant.
- UNOS staff will research the development of the follow-up form.

**5. Review of Programs with Greater Than 5% Non-Resident Alien Transplants: 2005-2006**

As indicated in Policy 6.3 (Audit), the Ad Hoc International Relations Committee reviewed the annual rates of non-resident alien transplants performed in 2005 and 2006. Policy 6.3 is excerpted below.

*As a condition of membership, all member transplant centers agree to allow the Ad Hoc International Relations Committee to review and audit, at its discretion, all center activities pertaining to transplantation of non-resident aliens. The Committee will review the activities of each member transplant center where non-resident alien recipients constitute more than 5% of recipients of any particular type of deceased organ. At centers where non-resident alien transplant recipients constitute more than 5% of recipients of any particular organ type, circumstances underlying the transplants for non-resident aliens will be reviewed by the Committee. Special consideration will be given to programs served by OPOs with non-resident alien organ donors.*

UNOS staff presented an analysis of all deceased donor transplants performed between January 1, 2005 and December 31, 2006. (All analyses reflected OPTN data collected as of August 3, 2007.) This analysis presented data as agreed upon by the Committee in its previous meetings. The analysis counted each recipient only once within each transplant program and calendar year. The analysis reported multi-organ transplants within each organ type, but reported separately the following transplants: intestine alone, and intestine with other organs. In this analysis, there were 871 programs that performed non-resident alien transplants at a rate higher than 5%. The analysis presented those programs that transplanted deceased-donor organs in non-resident aliens at an annual rate greater than 5%. (The OPTN Transplant Candidate Registration (TCR) form collects citizenship information about each recipient.) UNOS staff identified those programs that exceeded the 5% rate by performing more than one non-resident alien transplant (i.e., more than 1 organ).

UNOS staff encrypted the center identifiers, and the Committee discussed these data without knowledge of the centers' names.

Of the 871 programs analyzed, 45 (5%) programs transplanted non-resident aliens at a rate of 5% or higher during 2005 or 2006. 14 (1.6%) of these 45 programs transplanted at least two non-resident alien recipients in one calendar year to exceed the 5% rate. Of these 14, there were 6 programs (<1%) that exceeded the 5% rate by transplanting more than one non-resident alien recipient in 2005 *and* 2006. Those six programs included four kidney programs, one intestine with other organ program, and one pancreas program.

As in previous Committee meetings, the Committee decided not to send letters to programs that exceeded 5% as a result of one transplant. The Committee sought a pattern in programs exceeding the 5% rate. The Committee decided to send letters to, or audit, only those transplant programs that exceeded the 5% rate in 2005 *and* 2006. Therefore, the Committee voted (3-Yes, 0-No, 0-Abstentions) to send audit letters to 6 of the 14 transplant programs. The letters will be sent to 4 kidney programs, 1 pancreas program, and 1 multi-organ and intestine program. In each letter, the Committee will request the transplant program to explain the circumstances for its >5% non-resident alien transplant rate. The Committee queried if the programs receiving letters this year had exceeded the 5% rate in previous years. UNOS staff will provide this information at the next Committee meeting.

Although all center codes were encrypted, the Chair of the Committee excused himself from reviewing one set of data that resembled his center's data. The Chair did not vote on the decision to send any letters to this center. So, in this case, the voting was 2-Yes, 0-No, and 0-abstentions for sending letters to two programs at this center (pancreas, and multi-organ intestine).

The Committee also discussed the intent of Policy 6.3, and how to identify violations of this policy. UNOS staff commented that violations of Policy 6.3 only occur when the transplant centers does not respond to the Committee's request for an explanation about the >5% transplant rate. Exceeding the 5% rate, however, is not a violation of policy. Also, Policy 6.5 uses the phrase "persistent violations." UNOS staff commented that "persistent" may be too vague to clearly identify a center that has violated the policy, and requested that the Committee consider clarifying this phrase.

The Committee requested that UNOS staff share this discussion with the other members not on the call. The Committee asked these members to comment whether they support or oppose the votes.

### *Actions*

- UNOS staff will provide historical information for each program that is receiving a letter.
- UNOS staff will prepare the letters for distribution.
- UNOS staff will share this discussion with the rest of the Committee.

**6. Board Meeting Committee Report**

UNOS staff commented that the Ad Hoc International Relations Committee will report to the Board of Directors on February 21, 2008. Dr. Tzakis will present the Committee’s current activities. The presentation content will consist of the salient topics contained in the Committee meeting reports. The report will not contain any items that require Board action.

*Actions*

- UNOS staff will prepare the Committee’s presentation to the Board, and circulate it to the members.

Ad Hoc International Relations Committee	<b>January 8, 2008 Teleconference and Live Meeting</b>	
Name	Position	Attendance
Andreas G. Tzakis, MD, PhD	Chair	By phone
Gloria Garcia Bohrer	Vice Chair	By phone
Victor Ankoma-Sey, MD	At Large	
David R Grant, MD	At Large	
Marian A. O’Rourke, RN, CCTC	At Large	
Myron E. Schwartz, MD	At Large	
Tatiana Alvarez, RN, BSN, CCTC	At Large	By phone
Bernard Kozlovsky, MD, MS	Ex Officio – HRSA	By phone
Diane Steffick	SRTR Liaison	By phone
Vipra Ghimire, MPH, CHES	Committee Liaison	By phone
Sarah Taranto	Support Staff	By phone
Stacey Burson	Support Staff	By phone
Catherine Monstello	Support Staff	By phone