

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

**May 20, 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 May 20, 2008. The following is a summary of the Committee's deliberations.

1. Review of Programs that Transplanted More than 5% Non-Resident Aliens

As indicated in Policy 6.3 (Audit), the Ad Hoc International Relations Committee reviewed the annual rates of non-resident alien transplants performed in 2007. 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, 2007 and December 31, 2007. (All analyses reflected OPTN data collected as of April 18, 2008. The analysis counted each recipient only once within each transplant program and calendar year. The analysis reported multi-organ transplants within each organ type received, but reported separately the following transplants: intestine alone, and intestine with other organs. When counting intestine-alone and intestine with other organs as separate programs, there were a total of 941 programs during the 2007 calendar year. Citizenship information about each recipient was obtained through the OPTN Transplant Candidate Registration (TCR) form. The analysis identified 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 center's name. The analysis presented those programs that transplanted deceased-donor organs in non-resident aliens at an annual rate greater than 5%.

Of the 941 programs analyzed, 40 (4%) programs transplanted non-resident aliens at a rate of 5% or higher during 2007. 22 (2.3%) of these 40 programs performed transplants in at least two or more non-resident alien recipients during 2007, resulting in a non-resident alien transplant rate of 5% or higher. Of these 22, there were 3 programs that exceeded the 5% rate by transplanting more than one non-resident alien recipient in 2006 and 2007. (Historically, the Committee opted to send letters to only those centers that exceeded the 5% rate in two consecutive years.) Those 3 programs included one multi-organ intestine program and 2 kidney programs.

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. Therefore, the Committee voted to send audit letters to 3 of the 22 transplant programs. Two programs received the following vote: 3-Yes; 0-No; 0-Abstention. 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, for the third program, the voting was 2-Yes, 0-No, and 1-Abstention for sending a letter to one program at this center (multi-organ intestine). In each letter, the Committee will request the transplant program to explain the circumstances for its >5% non-resident alien transplant rate.

The Committee also decided to send a "reminder" letter to 7 programs. These 7 programs all had non-resident alien transplant rates of greater than 5%. However, these 7 programs did not exceed the 5% transplant rate in the previous calendar year (2006). The reminder letter will detail the language in Policy 6.3 and indicate that the program exceeded the 5% rate in 2007. The intent of the letter will be to inform these programs about Policy 6.3, and will not audit the program.

Actions

- UNOS staff will prepare the letters for distribution to the centers.

2. Policy 6.3 Audit Letters (2006-2007 Calendar Years)

UNOS staff reported that the audit letters to programs that exceeded the 5% non-resident alien transplant rate in 2005 and 2006 will be distributed in the few days following this meeting.

Actions

- UNOS staff will distribute the audit letters to the centers.

3. AHIRC Public Comment Proposals

The Committee discussed the public comment proposals it anticipated distributing on June 30, 2008. During this discussion, the scope of the revisions to Policy 6.2.5 changed. Thus far, the revisions to this policy addressed responsibilities of the transplant center. During the meeting on May 20, the Committee decided to place the responsibility for reviewing and developing the communication protocols on the organ procurement organization (OPO). UNOS staff responded that the OPO community may be more likely to accept the proposed language revisions if the corresponding proposal was co-sponsored with the OPO Committee. The Committee agreed to co-sponsor the proposal with the OPO Committee. The Committee postponed the distribution of revisions to Policy 6.2.5 until the OPO Committee has an opportunity to comment on the proposal.

UNOS staff reported that a draft of the public comment proposal to revise language in Policy 6.4.2 and 6.4.3 will be distributed to the Committee for comment in the days following this meeting. The Committee agreed to review the proposal and vote on it by email.

Actions

- UNOS staff will communicate with liaison of the OPO Committee about the proposed revisions to Policy 6.2.5.
- UNOS staff will distribute a draft of the public comment proposal (streamline the importation of organs to the United States) to the Committee by email.

4. Transplant Tourism

The Committee continued its discussion about adding a removal code in WaitlistSM to collect information about organ transplant candidates who are removed from the waiting list, because they will receive or have received transplants in another country. UNOS staff reported that the sub-question, "In what country will or did the transplant occur," will have a quantitative data entry field.

The field will be drop-down in nature, and will list all countries. The user can select the relevant country. This drop-down list will prevent users from entering variations of the same country name. The Committee supported this programming suggestion.

Proposed Removal Code:
Transplant in another Country

Proposed Sub-Questions if Transplant Center selects the above Removal Code:
In what country will or did the transplant occur? [Text Field; Capture “Unknown”]
Will the patient be followed at your transplant program? [Yes, No, or Don’t Know]

Action Items:

- UNOS staff will begin programming this waitlist removal and its sub-questions.

5. Re-write of Policy 6.0 (Transplantation of Non-Resident Aliens)

UNOS staff reported that it will present to the Committee a draft of the revised Policy 6.0 at its next meeting.

Action Item:

- UNOS staff will draft revisions to Policy 6.0.

Ad Hoc International Relations Committee	May 20, 2008 Teleconference and Live Meeting	
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	By phone
Marian A. O’Rourke, RN, CCTC	At Large	
Myron E. Schwartz, MD	At Large	
Tatiana Alvarez, RN, BSN, CCTC	At Large	
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
David Clark	Support Staff	By phone